

Section 1 - General

1.1 Approvals



**QUALITY MANAGEMENT  
SYSTEM MANUAL**

**TSI Incorporated  
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Shoreview, MN 55126**

***This Document Approved by TSI Incorporated Executive Management  
October 15, 2008***

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## 1.4 Revision History

REVISION HISTORY			
DATE	REV	ECO #	DESCRIPTION OF CHANGE
6/21/04	L	500000010332	Para 1.2: Added Table of Figures. Para 2.2: Fig 1; Clarified ATEX Authorized Persons in Org Chart. Para 4.1: Updated Figure 2, Interaction of Processes. Para 5.5: Clarified ATEX Authorized Persons. Para 5.6: Clarified ATEX Management Review input and retention period of Management Review Reports and Minutes.
1/24/05	M	500000011124	ATEX Significant Changes? Yes Para 2.2: Added TSI Operating Principles Para 2.2: Fig 1; Organization change and clarified ISO 10012 responsibilities in Org Chart. Para 2.3: Added European Sales and Service Operations to Scope Para 4.1: Updated Figure 2, Interaction of Processes. Para 7.1 Added reference to procedure 9020514: New Product Opportunity Realization Para 7.5 Added reference to procedures; 9020608: Unrepairable Service Equipment and 9020611: End of Product Service Life Appendix A; Updated Appendix to current list of procedures. Added procedures; 9020514: New Product Opportunity Realization, 9020608: Unrepairable Service Equipment and 9020611: End of Product Service Life
4/1/05	N	500000011398	ATEX Significant Changes? Yes Para 2.3: Clarified facility and scope application. No change to certification scope. Para 5.5 & 5.6 : Changed "Office of the President" to "Office of the President (Executive Vice Presidents)"
10/1/05	O	500000011863	ATEX Significant Changes? Yes Para 2.2: Revised Corporate Profile Para 2.3: Updated TSI Facilities and QMS Scope information. Added Fig 2, Registration Certificate. Para 5.6: Added "Customer and other external audits" Para 7.4: Changed reference from Document Control to Document Management Systems (DMS). Para 7.6: Removed "recall". Added Reference to DKD, UKAS and SWEDAC Para 8.5: Added "actions from management reviews"
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9/25/06	Q	N/A	ATEX Significant Changes? Yes Para 1.1: Added TSI France Inc. Para 2.2: Added Bangalore, India to Int'l Service and Support locations and Tekran Instruments Corporation to subsidiary list. Para 2.2: Fig 1; Updated Organization Chart Para 2.3: Updated TSI Facilities and QMS Scope information. Para 3.4: Updated ISO 9001:2000 Exclusions. Para 4.1: Fig 2, Updated Interaction of Processes. Para 5.5 & 5.6 : Changed "The Office of the President (Executive Vice Presidents) . . ." to "The President, Executive Vice Presidents . . ." Para 8.3: Added statement regarding issuance of "Stop Shipment Notifications" Appendix: Added new procedure: 9020669 Stop Shipment Notification
3/20/07	R	N/A	ATEX Significant Changes? Yes Title Changes/Updated Org. Chart
2/27/08	S	N/A	ATEX Significant Changes? Yes Title & Department Name Changes (7.3 & 7.4) Updated Org. Chart
10/10/08	T	N/A	ATEX Significant Changes? No Removed TSI GmbH from Scope

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## Section 2 - Introduction And Scope

### 2.1 Introduction

The TSI Quality Management System Manual describes our organization's unique and specific conformance to the requirements to *ISO 9001:2000, Quality Management Systems - Requirements*. Each section represents our organization's vision of quality as seen through the requirements of the standard, needs of our customers and our internally defined quality goals and objectives.

TSI Incorporated also complies with *EN 13980:2002: Potentially Explosive Atmospheres – Application of Quality Systems* to support products on EC type-examination certificates. These elements are certified by a notified body.

### 2.2 TSI Corporate Profile

#### Global Reach

TSI Incorporated is an international company that designs and manufactures precision instruments used to measure flow, particulate, and other key parameters in environments the world over. A leader in measurement technology, TSI® serves the needs of industry, governments, research institutions and universities, with applications ranging from pure research to primary manufacturing. TSI customers are found in industry, government, universities and military establishments worldwide.

TSI instruments can be found almost anywhere. From mountaintops to submarines to desert battlefields. They help people identify and solve measurement problems. Some of our instruments have flown in the space shuttle and one even went to Mars to measure the velocity and direction of Martian winds! TSI instruments play a role in designing or modifying production processes or testing procedures, then help verify the problem has been resolved or the process improved. From helping scientists build a better heart valve to monitoring the safety of the air in your child's classroom—TSI instruments are in demand in every major industry, in every corner of the world.

Our customers have the ongoing assurance that every TSI instrument is backed by over 40 years of technical expertise and outstanding quality that began in 1961 in the basement of one of our founders. These founders, a group of University of Minnesota engineering students, were on a mission to solve the problem of making accurate flow measurements in turbulent combustion. This small gathering served as the springboard of what today has become TSI, an international leader in state-of-the-art measurement systems and technologies.

#### International Service and Support

TSI has over 450 dedicated employees working in facilities in North America, Europe and Asia. Our corporate sales and service offices (St. Paul, Minnesota, USA; Aachen, Germany; Marseille, France; High Wycombe, United Kingdom; Bangalore, India; and Beijing, China) all provide regional customer support that is readily accessible by telephone and email.

TSI employees are committed to serving customers on many levels from conducting training sessions to providing product demonstrations to serving on standard committees relating to product usage. TSI researchers have more than 50 patents in the fields of particle and flow measurement technology. In addition, the company holds more than 25 technology licenses from leading researchers and developers throughout the world.

#### Our Products

TSI instruments have made their mark throughout the world. Our unique product line includes over 200 major instruments with a full complement of accessories. They can be classified into a variety of product families:

Atmospheric Monitoring – Instruments used to obtain climate, visibility and air quality measurements.

Automated Filter Testing – Automated Filter Testers that set the standard in the filter industry for determining the efficiency of media and filter assemblies.

Biomedical Test Equipment – Ventilator testers that measure air, oxygen, and nitrous oxide flow in institutional and home-care, field service, laboratory and production applications.

Chemical Characterization – Instruments that analyze chemical composition and/or molecular weight of a material in research applications ranging from engine exhaust analysis to pharmaceutical studies to chemical/biological detection.

Combustion Gas Analyzers – A complete line of combustion gas analyzers, from single gas monitors to full-featured emissions analyzers, used for combustion system maintenance, compliance monitoring, engine research and monitoring, combustion research and industrial emission sampling.

Critical Environments Monitors/Controllers – Monitors and controllers that help control the room environment to ensure the safety and comfort of personnel working in laboratories, hospital isolation rooms and other hazardous environments.

Exposure Monitoring – Instruments that measure airborne dust and aerosol mass concentrations along with ones that measure or monitor gas concentrations in industrial settings.

Flow Measurement Instruments – A group of systems that accurately capture flow velocity data from a broad range of measurement situations—from simple to turbulent flows, flames, combustion and a range of other applications.

Indoor Air Quality – Instruments designed to measure accurately and reliably a variety of parameters important in monitoring and maintaining occupant thermal comfort while helping to assure healthy indoor environments; measurements include temperature, humidity, outdoor air calculations, carbon dioxide, carbon monoxide and airborne particles.

Mass Flowmeters – Flowmeters designed for a multitude of gas flow measurement applications from measuring gas flows in laboratories to manufacturing settings.

NBC Protection – Aerosol measurement products that help protect military and civilian personnel from nuclear, biological, or chemical (NBC) threats.

Particle Research Instruments – Instruments for sizing, counting, generating and dispersing aerosol particles for applications in air filter testing, atmospheric aerosol measurement, biological aerosol detection, particle characterization and engine emission studies.

Phase Doppler Particle Analysis (PDPA) – Systems that provide global flow velocity and particle size data on sprays, with applications related to medical inhalers, fuel injectors, spray nozzles and others.

Respirator Fit Testing – Instruments and software to perform quantitative respirator fit testing for commercial and military respirators.

Ventilation Test Instruments – Instruments that measure parameters important in monitoring and maintaining indoor environments, including static pressure, gauge pressure, differential pressure, velocity, volume, temperature and humidity.

TSI has three wholly owned subsidiaries:

- Environmental Systems Corporation (ESC) (Knoxville, Tennessee USA), a leading supplier of products and services for outdoor environmental monitoring,
- DICKEY-john<sup>®</sup> Corporation (Auburn, Illinois USA), a manufacturer of specialized instrumentation used in public works and agriculture, and
- Tekran Instruments Corporation (Toronto, Canada), development of ultra-trace mercury measurement instrumentation.

Our facilities total more than 425,000 square feet of space devoted to product development, manufacturing, and customer support.

### **TSI Vision Statement**

The TSI Vision Statement provides the foundation for future evolution of the company. Our ability to achieve this vision is dependent upon excellence in customer satisfaction to our valued customers for their measurement needs.

***Our Vision***

***TSI is a world-class provider of innovative solutions to our customers' measurement needs.***

### **TSI Mission Statement**

In order to achieve our vision, TSI has established a mission based on excellence in applications of our technology to focus on customers' environments with high quality products and service to ensure their measurement needs are met.

#### ***Our Mission***

*Our mission is to continuously develop new products by applying technology to solve measurement problems in a variety of environments. Our products improve the health, safety and productivity of individuals, businesses, research organizations and government agencies worldwide.*

*We aggressively pursue our mission by continually developing and managing a portfolio of both technology and products, taking measured business risks, providing comprehensive customer support, and fostering an environment of innovation, creativity and hard work.*

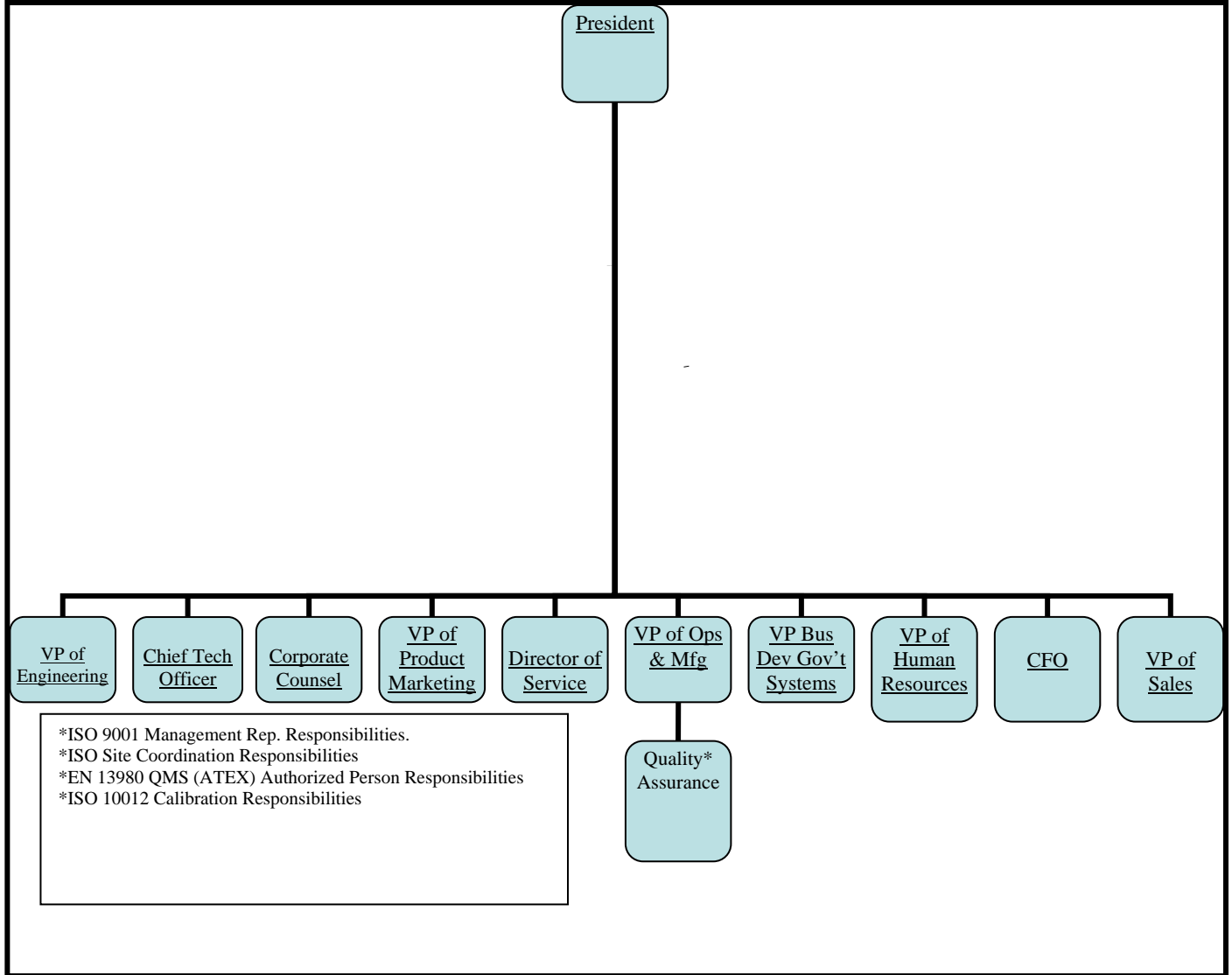
### **TSI Operating Principles**

In order to achieve our vision, TSI has established a mission based on excellence in applications of our technology to focus on customers' environments with high quality products and service to ensure their measurement needs are met.

#### ***Operating Principles***

- *We understand that the successful introduction of new products is the single greatest predictor of TSI's future value.*
- *We understand that successful product development results from knowing our markets and our customers' needs.*
- *We continually leverage our technologies across various applications and markets.*
- *We strive to reduce the time from identification of market opportunities to the introduction and shipment of new products.*
- *We seek growth opportunities regardless of the presence of competition, the size of the market, or the source of the technology.*
- *We will expand our presence internationally.*
- *We encourage and support taking thoughtful business risks.*
- *We continuously improve the effectiveness and efficiency of our business processes.*
- *We are performance driven and are accountable for our results.*
- *We attract, develop and retain talented employees.*
- *We motivate and reward our employees for their initiative and performance—their accomplishments are vital to our success.*

The following is a basic organizational chart. (Figure 1).



**2.3 Scope**

The following facilities are certified to *ISO 9001:2000, Quality Management Systems - Requirements*. The scope of the certifications is applicable to:

<b>TSI Facility</b>	<b>ISO 9001:2000 Certification Scope</b>
<b>TSI Incorporated</b> 500 Cardigan Road, Shoreview, MN 55126-3996 U.S.A.	<i>Design, Manufacture, Sales and Service of Measurement Instrumentation and Accessories for Occupational and Environmental Comfort, Health, Safety, Industrial Hygiene and Building Services Applications.</i>
<b>TSI Instruments Ltd.</b> Lancaster Road Cressex Business Park High Wycombe, Buckinghamshire HP12 3QP United Kingdom	<i>The provision of design, manufacture, sales, distribution, service and calibration of air measuring test equipment.</i>

*Note: TSI Instruments operates an independent certified ISO 9001:2000 Quality Management System*

The registration certificates for the facilities may be found at the following Web Address:

<http://www.tsi.com/corporate/quality/index.aspx>

**2.4 Exclusions**

TSI Incorporated does not exclude any ISO 9001:2000 elements.

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**Section 3 - Definitions****3.1 Accountability:**

- When people at TSI can count on one another and support each other by keeping our work obligations and commitments.

**3.2 ATEX (French – ATmospheres EXplosibles):**

- The European Parliament and the Council of the European Union Directive 94/9/EC, on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres. Directive 94/9/EC is known as the ATEX directive. Quality System Requirements are specified in EN 13980: Potentially Explosive Atmospheres – Application of Quality Systems.

**3.3 Contract Or Accepted Order:**

- Agreed requirements between a supplier and customer transmitted by any means.

**3.4 Product:**

- Result of activities or processes.
- A product may include service, hardware, process material, software, or a combination thereof.
- A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

**3.5 Quality:**

- "A Quality Product or Service is One Viewed as Such by the Customer."
- The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.
- Degree to which a set of inherent characteristics fulfills requirements.

**3.6 Quality System:**

- The organizational structure, responsibilities, procedures, processes, and resources needed for implementing quality management.

**3.7 Tender:**

- Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

TSI defines other definitions to help facilitate a common understanding of the meaning of various definition and acronym terminologies. (*Procedure 9020371: Definitions and Acronyms*)

## Section 4 - Quality Management System

### 4.1 General Requirements

The TSI Incorporated Quality Management System is based upon ISO 9001:2000 and EN 13980:2002. (*Manual 9000055: Quality Management System Manual*)

All processes that affect the Quality Management System are identified, documented, maintained and controlled. These controls include:

- identification of the sequence and interaction of the processes (See Figure 2),
- criteria and methods required to ensure effective operation and control,
- ensuring compliance of products with the type described per EC type-examination certificates,
- identification and availability of resources and information necessary to support the operation and monitoring of the processes, and
- methods to measure, monitor and analyze these processes and implementation of action necessary to achieve planned results and continual improvement.

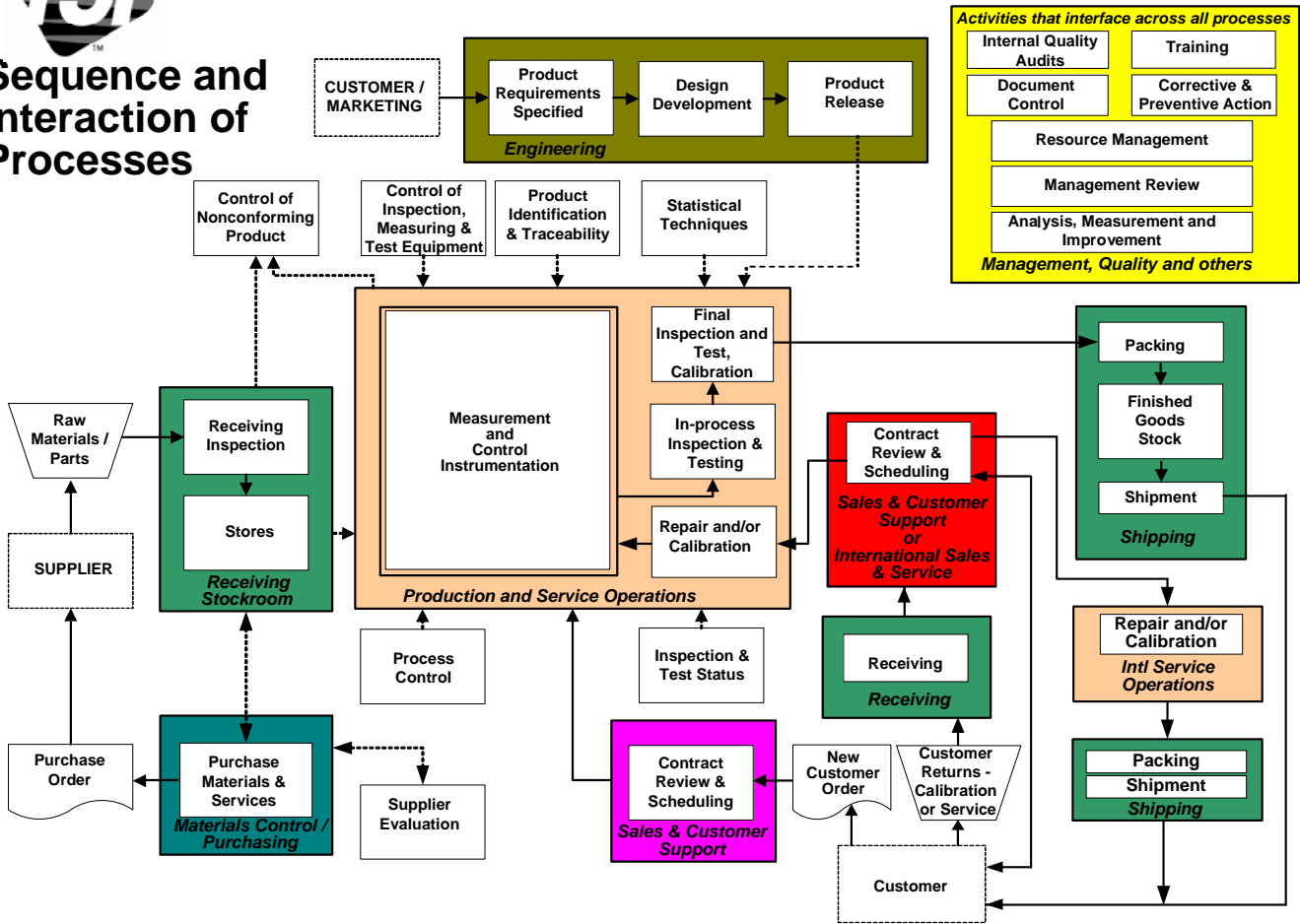
Where applicable, the procedures that define the processes and controls are referenced in this manual. Please see Appendix for a complete cross-reference between ISO 9001:2000 and applicable TSI Quality Management System Documents.

When processes that affect product conformity are subcontracted, appropriate controls are implemented to ensure that company requirements are met. (*Procedure 9020181: Purchase Orders*)

The TSI Quality Policy and Quality Objectives are documented and reviewed for adequacy at Management Review Meetings to ensure planned results and improvements are being made. (*Procedure 9020178: Management Review*)



**Sequence and Interaction of Processes**



**Figure 1: Sequence and Interaction of Processes**

## 4.2 Documentation Requirements

The TSI Quality Management System has been defined on five levels.

- Tier 0 is the regulatory and industry requirements and standards under which TSI operates.
- Tier 1 is the TSI Quality Management System Manual (this document). This Manual documents the company policies and provides the relationship of the TSI Quality Management System to the requirements of ISO 9001:2000.
- Tier 2 is the quality system standard operating procedures (SOPs) that detail the activities necessary to achieve the objectives of the Quality Management System.
- Tier 3 of documentation is work instructions that may be issued as required.
- Tier 4 is various records and forms used in the system that may be issued as required.

The depth and detail required for the documentation is determined by Management and is dependent upon the complexity and interaction of the processes and the skills and training needed by personnel performing the activity. (*Procedure 9020220: Quality System*)

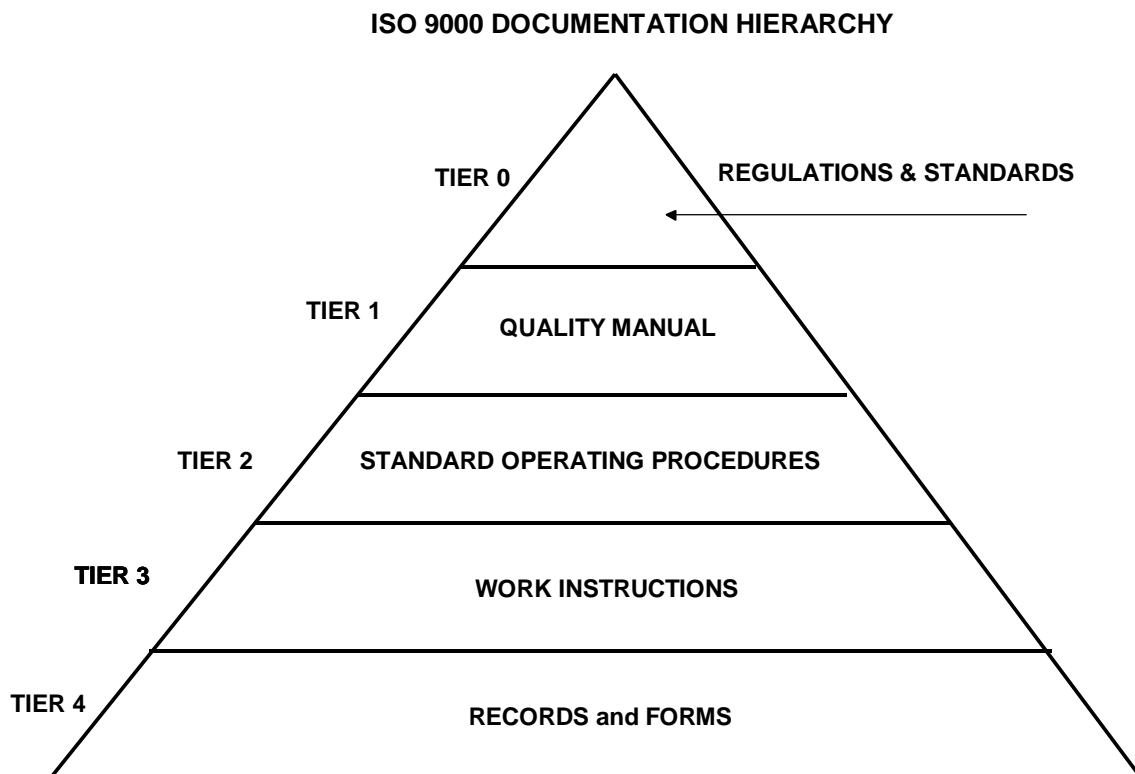


Figure 2: ISO 9001 Documentation Hierarchy

The Sr. Quality Systems Specialist is responsible for maintaining documents relevant to TSI's ISO 9001:2000 Quality Management System. The Sr. Quality Systems Specialist reviews changes and improvements to documents with affected management personnel. TSI Managers and supervisors are responsible for making sure that documented procedures are effectively implemented in all areas that affect product quality.

TSI's quality system will ensure that ATEX controlled product conforms to the type described in the EC type-examination certificate. All the elements, requirements and provisions adopted by the company will be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation permits a consistent interpretation of quality programs, plans, manuals and records. (*Procedure 9020220: Quality System*)

The TSI Quality Management System documents are controlled. (*Procedures: 9020174: Document and Data Control and 9020186: Engineering Change*)

The document and data control procedure defines the controls that ensure:

- documents are approved for adequacy prior to issue,
- documents are reviewed and updated as necessary and re-approved,
- changes and the current revision status of documents are identified,
- relevant versions of applicable documents are available at points of use,
- documents remain legible and readily identifiable,
- documents of external origin are identified and their distribution controlled, and
- unintended use of obsolete documents is prevented and that suitable identification is applied to them if they are retained for any purpose.

TSI maintains records to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. (*Procedure 9020166: Quality Records*)

Records are legible, readily identifiable and retrievable. The quality records procedure defines the controls needed to identify, store, protect, retrieve and dispose of quality records. It also states retention times for quality records.

## Section 5 - Management Responsibility

### 5.1 Management Commitment

The Management at TSI Incorporated is committed to manufacturing products of the highest quality that completely satisfy customer expectations. TSI Management supports all efforts to comply with and improve the Quality Management System as required by ISO 9001:2000. (*Procedure 9020179: Management Responsibility*)

The company's management has established a quality policy and the quality management system by which our company performs its operations to ensure customer satisfaction. The quality policy and effectiveness of the quality management system are evaluated at least quarterly during Management Review Meetings, where key quality measurements are analyzed against their established objectives and suggestions for improvement of the system are considered. Further quality planning is also conducted during Management Review Meetings to ensure the continuing availability of the resources necessary to meet the expectations of our customers.

### 5.2 Customer Focus

TSI commitment to customer focus is demonstrated in the Vision, Mission and Quality Policy where statements regarding meeting or exceeding customers' needs and expectations, supplying high quality products, and providing superior support are found in all three documents.

During the product realization process, TSI ensures that customer needs and expectations are determined, converted into requirements, and fulfilled with the aim of enhancing customer satisfaction.

### 5.3 Quality Policy

TSI management has established the following quality policy, ensuring that it provides a framework for establishing and reviewing quality objectives.

#### *Our Quality Policy*

*TSI's policy is to meet or exceed our customers' needs and expectations through continual improvement of our processes, products and services.*

TSI management ensures that the quality policy is communicated and understood by all employees and that the policy is implemented throughout the company. TSI's Quality Policy is communicated to employees through the New Employee Orientation Program, the TSI Quality Management System Manual, the TSI Quality Management System Reference Guide and posters located throughout the facility. The Quality Policy is

reviewed for continued suitability at Management Review Meetings.

#### 5.4 Planning

Quality objectives have been established that are derived from the Quality Policy. These objectives have been established to continually improve the quality management system as a whole as well as key management processes, extending to processes involved with meeting customer and product requirements. (*Procedure 9020365: Quality Objectives*)

Quality objectives are measurable, so that they can be analyzed during Management Reviews to determine the degree to which they are met.

As part of the regular maintenance and improvement of the TSI quality management system, major changes to the system are reviewed during Management Review Meetings. This review ensures the requirements of the quality system and impact on the quality objectives have been addressed prior to the implementation. No new process is implemented without first considering the actions that must be taken to ensure that the company remains in compliance with the system as it is documented. Items evaluated and planned actions are documented in the Management Review Meeting minutes.

#### 5.5 Responsibility, Authority and Communication

The President, VP of Operations, and the Sr. Quality Systems Specialist have overall responsibility for ensuring the implementation and maintenance of ISO 9001:2000 requirements for TSI. Vice Presidents, Directors and Functional Managers have overall responsibility for quality within their respective areas. Each is responsible for defining the organizational structure and employee responsibilities. The Sr. Quality Systems Specialist has the responsibility and authority to develop and maintain procedures and work instructions to ensure compliance with the ISO 9001:2000 Quality System. (*Procedure 9020179: Management Responsibility*) Approval authority for procedural performance of requirements of the quality system and product dispositions is controlled by TSI. (*Procedure 9020471: Authorized Signatories*)

Corporate Operating Policies (COP's) contain quality policies and objectives written by TSI Management. These policies provide an operating foundation for all TSI functional units. Those applicable to ISO 9001:2000 are referenced in this manual, standard operating procedures, or work instructions.

Managers and/or Supervisors are responsible for communicating to employees the policies and procedures that affect them as well as ensuring compliance. Employees may obtain copies of these documents from masters stored on the local area network.

All employees are responsible for the quality of their output. All individuals whose work affects the quality of product have the authority within their area of responsibility to:

- initiate action to prevent the occurrence of any non-conformities relating to product, process, or the quality system,

- identify and report or record product, process or service quality problems,
- initiate, recommend or provide corrective and preventive solutions through designated channels,
- verify the implementation of solutions, and
- control the further processing, delivery or use of non-conforming product until the problem or unsatisfactory condition has been corrected.

Where appropriate, employees who perform verification of the achievement of quality are independent of the work performed.

TSI top management has appointed an ISO Management Representative. Irrespective of other duties, the Management Representative has the main responsibility and authority for establishing, implementing, and maintaining the quality management system (QMS) and ensuring that it continues to be compliant with the requirements of ISO 9001:2000.

The Management Representative is responsible for:

- Communicating the Quality Policy and reporting on the QMS to outside parties,
- Scheduling internal audits and appointing the audit team, (*Procedure 9020172: Internal Quality Audits*)
- Evaluating the effectiveness of the QMS,
- Reporting the effectiveness of the QMS to executive management,
- Communicating the effectiveness of the QMS to employees,
- Make suggestions to improve the system, and
- Scheduling, coordinating the agenda, and recording minutes of Management Review meetings.

TSI management has given responsibility and authority as authorized persons to the Engineering Manager for technical requirements, and the Sr. Quality Systems Specialist for the quality management system, to ensure compliance with EN 13980:2002. (*Procedure 9020220: Quality Management System*)

## 5.6 Management Review

The TSI Quality Management System is systematically reviewed at defined intervals by management to ensure its continuing suitability, adequacy, effectiveness and improvement in satisfying ISO 9001:2000, the TSI Quality Policy and TSI Quality Objectives. (*Procedure 9020178: Management Review*)

Inputs for Management Review include, but are not limited to:

- TSI Quality Objectives performance,
- Internal Audit results,
- Customer feedback,
- Customer complaints,
- Customer and other external audits,
- Product Support/Service data,

- Process and product performance,
- Corrective/Preventive Actions,
- Actions raised from previous Management Reviews,
- Changes that could affect the Quality Management System,
- Recommendations for improvement,
- Overall effectiveness of the quality management system with respect to products intended for use in potentially explosive atmospheres, and
- Suitability, adequacy, improvements and effectiveness of the Quality Management System in meeting ISO 9001 and EN 13980.

Actions raised from Management Review meetings include, but are not limited to:

- improvement of the Quality Management System and its processes, including processes with respect to products intended for use in potentially explosive atmospheres,
- improvement of processes and products related to ensuring achievement customer requirements, and
- resource needs of the organization.

Evidence of the efficiency and effectiveness of quality system may include, but is not limited to:

- TSI Quality Objectives
- Audit reports
- Corrective and preventive actions
- Customer feedback and complaints
- Material review reports
- Records documenting continuous improvement initiatives

Information for the review is monitored on a monthly basis. Findings, conclusions, recommendations and agreed actions from the review are prepared and distributed by the ISO Management Representative.

The President, VP of Operations and the Sr. Quality Systems Specialist are responsible for ensuring that recommendations from the meeting are implemented and effective.

Reports and minutes from Management Review Meetings are retained on file for a minimum of 10 years after date of last ATEX product manufacture.

**Section 6 - Resource Management****6.1 Provision of Resources**

Resources are identified and provided, where needed, to implement, maintain and improve the processes of the Quality Management System and to enhance customer satisfaction. (*Procedure 9020366: Resources, Infrastructure and Work Environment*)

**6.2 Human Resources**

Where relevant, personnel are selected and their competency determined and evaluated based on education, training, skills, experience or pre-employment testing. All personnel who perform activities which affect quality have their training needs identified either at the beginning of their employment or at appraisals which are normally held once a year. On the job training is provided as required prior to performing work and the effectiveness of the training evaluated before the training records are signed off as complete. (*Procedure 9020177: Training*)

Employees attending internal or external training courses will have the details logged on their individual training and personnel file wherever possible. The effectiveness of training courses is assessed by use of course evaluation forms or Audits.

TSI management identifies resource requirements and provides adequate resources and training for management, performance of work and verification activities (including internal quality audits). Job descriptions for all personnel are available in the Human Resources department. Training records are maintained by Human Resources, Quality Assurance or by the respective manager/supervisor.

**6.3 Infrastructure**

Facilities needed to achieve conformity of product are identified, provided and maintained. This includes buildings, workspace, associated facilities, environmental conditions, equipment (hardware and software) and supporting services. These considerations are reviewed during Management Review Meetings.

**6.4 Work Environment**

The human and physical factors of the work environment needed to achieve conformity of product are identified and managed. Consideration of such factors includes health and safety conditions, work methods, handling methods, and ambient working conditions. These considerations are also reviewed during Management Review Meetings.

## Section 7 - Product Realization

### 7.1 Planning of Product Realization

The planning for product realization is accomplished by implementing quality standards during product design, development, contract review, purchasing, production, inspection, test, shipment and servicing in accordance with established procedures and work instructions. (*Procedure 9020367: Product Realization Planning*)

These activities include the following to achieve the required level of product quality:

- product specification, design, development, verification and validation plans,
- selection and classification of component parts and qualified vendors,
- development of manufacturing procedures and work instructions,
- product testing and acceptance criteria at various points in the production process, including those which contain a subjective element,
- identification, control, and calibration of process and test equipment,
- review/acceptance criteria for customer orders, tender submittals and contracts,
- establishment of product identification and traceability,
- identification of handling, storage, packaging and shipping requirements,
- assignment and training of qualified personnel, and
- identification and preparation of quality records.

### 7.2 Customer-related Processes

All customer tenders, purchase orders or contracts are reviewed and records maintained to ensure that:

- product requirements are defined and documented,
- differences between the contract or purchase order requirements and those in the tender are resolved, and
- TSI has the capability to meet the contract or accepted order requirements.

Products are sold through a Sales Order process. Under this system, products have predefined specifications and standard TSI Sales Order terms apply. Purchase Orders and Sales Orders serve as records for contract review. Procedures have been established that detail guidelines for handling standard sales as well as requirements that vary from defined specifications. Additionally, this procedure covers amendments to contracts. (*Procedure 9020173: Contract Review*)

Purchase orders or contracts are also reviewed and records maintained for products returned for repair or servicing. (*Procedure 9020425: Contract Review & Special Requirements*)

### 7.3 Design and Development Planning

Procedures have been established to control the product development process and to ensure that specified requirements are met. (*Procedure 9020562: Design Development Plan*)

The product development process planning ensures that the project is well defined at the beginning the project. The plans detail all the important design tasks and assigns tasks to qualified individuals. The development team members assigned to a project are selected based on skills and availability. The business aspects of the project are outlined in the Business Case. The detailed elements of the project are listed in the Project Plan, along with a projected schedule and project milestones. The Design/Development Plan is revised as needed, to reflect the current status of the project.

The specific elements of a design/development project are quantified in the requirement documents. At a minimum, these documents consist of a mechanical, electrical, sensor, industrial design and firmware/software specifications. The engineering specifications are quantitative in nature; they provide specific and exact detail about the project: how much, how big, how accurate, how sensitive, etc.

The progress of the design/development project is captured in a variety of documents, collectively kept on the SharePoint project site. Project team members contribute to this collective of information, depending upon their functional responsibility.

At appropriate stages in the design/development project, design reviews are conducted as defined in the Design Development Plan *Procedure 9020562*.

Gate reviews are conducted to review continued project viability. This review evaluates project progress, customer need changes, market conditions, product justification, product definition, and cost structure to determine if the initial assumptions defined in the business plan or subsequent iterations are still valid.

At appropriate stages in the design/development project, the project team may conduct design verification exercises or tests. Verification is centered on demonstrating or proving the concept/principle/model/theory that is at the core of the project. Verification takes place after the initial output of a design/development project. It is focused on substantiating the principle of the design.

Design validation follows successful verification. Through a series of tests, design validation examines the design output, as embodied in a prototype, model or finished product, and compares it to the design input, as embodied in the engineering specifications. User testing, if used, simulates as closely as possible the actual use by a customer.

The software or firmware provided as products, used in products, or used in product manufacturing is validated and controlled. (*Procedure 9020358: Software/Firmware Release*)

## 7.4 Purchasing

TSI's purchasing processes are defined and controlled. Supply Chain Management makes efforts to obtain on time, high-quality parts by ensuring the required technical requirements are defined in purchasing documents provided to suppliers. (*Procedure 9020181: Purchase Orders*)

A supplier performance system tracks nonconforming parts received from each vendor. Quality Assurance uses this data to evaluate suppliers and provides feedback to them.

Supply Chain Management and Quality Assurance representatives may visit suppliers to evaluate their capability and capacity to meet TSI needs. TSI has a supplier approval process for subcontractor assessment and the creation of an Approved Suppliers List (ASL). (*Procedure 9020182: Supplier Selection & Approval*)

The supplier approval process utilizes several systems to gather supplier information including:

- Supplier Surveys
- Supplier Performance Reports
- Supplier Nonconforming Material Reviews
- Supplier On-site Audits
- Supplier 1<sup>st</sup> Article Reports

Suppliers are required to provide data on all drawing notes and characteristics when parts are produced for the first time or when drawing changes are made. Supplier 1<sup>st</sup> articles are used to validate the drawing and the supplier's processes to meet drawing requirements. (*Procedure 9020466: Supplier 1<sup>st</sup> Article*)

All suppliers are evaluated periodically for their ability to deliver quality products on a timely basis. Suppliers that cannot meet contractual requirements for quality and delivery may be removed from the Approved Suppliers List (ASL). (*Procedure 9020370: Supplier Control and Corrective Action*)

Fabricated or purchased materials require a drawing, manufacturer's part number, inventory description, or engineering specification sheet. TSI's document management system (DMS) maintains current and archive specification sheets and drawings. Changes to these production documents are made through the Engineering department. TSI's purchase order specifies the basic terms and conditions of purchase. Supply Chain Management staff reviews the specifics of purchase orders (PO) before sending them out and notes any additional requirements (such as quality system requirements).

Applicable inspection and testing of purchased product is planned and carried out in a controlled manner in order to verify that specified product requirements are met. TSI maintains an inspection system and assigns responsibilities for performing and recording the receiving inspection data on materials, components and other products from suppliers for incorporation into finished goods. (*Procedure 9020205: Receiving Inspection*)

When necessary or contractually required TSI will verify purchased product at the

subcontractor's premises, and will specify verification arrangements and the method of product release in the purchasing documents. TSI will facilitate arrangements whereby the notified body may audit aspects of the suppliers operations that affect the type of protection in accordance with ATEX product requirements.

### 7.5 Production and Service Provision

TSI plans and carries out production and service activities under controlled conditions. (*Procedures 9020367: Product Realization Planning and 9020180: Process Control*)

These activities include, as applicable or necessary:

- availability of information that describes product characteristics,
- availability of work instructions, inspection & test instructions,
- use of suitable equipment,
- availability and use of monitoring and measuring devices,
- implementing monitoring and measuring, and
- implementing release, delivery and service activities.

TSI validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results. (*Procedure 9020345: Manufacturing Process Validation*)

The planning and implementation for these processes include, as applicable:

- defined criteria for review and approval of the process,
- approval of equipment and qualification of personnel,
- use of specific methods and procedures,
- requirements for records, and
- revalidation.

Where appropriate, TSI identifies products by suitable means throughout product realization. Where traceability is a requirement, TSI controls and records the unique identification of the product. (*Procedure 9020203: Product ID and Traceability*)

TSI performs necessary inspections and tests and identifies the product status with respect to monitoring and measuring requirements. (*Procedures 9020202: Inspection and Test and 9020204: Inspection and Test Status*)

TSI preserves the conformity of products during internal processing through delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection, including product parts. (*Procedure 9020206: Handling, Storage, Packaging, Preservation and Delivery*)

Product returned to TSI for servicing or recalibration is controlled. Customer

requirements are determined and products are processed through servicing according to the same established test and calibration procedures used for new product acceptance and calibration. (*Procedures 9020368: Product Returns & Servicing and 9020611: End of Product Service Life*)

## 7.6 Control of Monitoring and Measuring Devices

Production, measuring, and test equipment and associated software (including software used to test products) are controlled. This control includes verifying the production and test fixtures and tooling prior to use, or at regularly scheduled intervals. All measuring and test equipment used in product acceptance is selected to ensure it is capable of making the specified measurements. Instrument calibrations are traceable to nationally recognized reference standards of the respective country.

- United States: calibrations are traceable to the National Institute of Standards and Technology (NIST).
- Germany: calibrations are traceable to the German Calibration Institute (DKD)
- United Kingdom: calibrations are traceable to the United Kingdom Accreditation Service (UKAS) and/or the German Calibration Institute (DKD).

Where no standards exist, the basis used for calibration or verification is recorded. Damaged production equipment or fixtures and out-of-calibration instruments will not be used for production.

TSI maintains a calibration system that ensures conformance to requirements. This system complies with ISO 9001:2000 and ISO 10012; *Quality Assurance Requirements for Measuring Equipment. Procedure 9020047: Inspection, Measurement and Test Equipment*)

**Section 8 - Measurement, Analysis And Improvement****8.1 General**

TSI plans and implements the monitoring, measurement, analysis and improvement processes needed to:

- demonstrate conformity of the product,
- ensure conformity of the Quality Management System, and
- continually improve the effectiveness of the Quality Management System

TSI determines applicable methods, including statistical techniques, and the extent of their use. (*Procedure 9020369: Measurement, Analysis and Improvement*)

**8.2 Monitoring and Measurement**

TSI monitors information relating to customer perception of whether customer requirements have been met. A Customer Feedback form is used to document input from customers, internal and external, about issues and problems that have a negative impact on quality. Feedback from an external customer is of particular importance. Quality problems and complaints should be resolved as quickly as possible to the complete satisfaction of the customer. Customer Feedback records are reviewed monthly by a Quality Review Team. (*Procedure 9020208: Customer Feedback*)

Internal audits are performed at planned intervals to ensure that the Quality Management System conforms to the planned requirements of ISO 9001:2000, TSI's documented requirements, and is effectively implemented and maintained. (*Procedure 9020172: Internal Quality Audits*)

TSI's audit program is planned and takes into consideration the status and importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. The audit program also addresses the effectiveness of the quality system in accordance with EN 13980 to ensure that applicable products conform to EC type-examination certificates. Auditors are selected and audits are conducted to ensure objectivity and impartiality in the audit process. Auditors do not audit their own work.

The audit procedure provides additional information on the responsibilities for planning and conducting audits, reporting results and maintaining records.

Managers in areas being audited ensure that actions are taken in a timely manner to eliminate detected nonconformances and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

TSI applies suitable methods for monitoring and, where applicable, measurement of QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When these planned results are not achieved, correction and corrective action is

taken, as appropriate, to ensure conformity of the product.

TSI monitors and measures characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accord with planned arrangements.

Evidence of conformance with acceptance criteria is maintained. Records indicate the person(s) authorizing release of the product. (*Procedure 9020471: Authorized Signatories*)

Product release and service delivery does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by relevant authority and, where applicable, the customer.

### 8.3 Control of Nonconforming Product

Procedures are established and maintained to prevent the inadvertent use of non-conforming material or product. Parts or materials that are defective and/or out of specifications are handled by the Material Review system. This system provides a standard method for reporting, evaluating, and correcting problems or discrepancies. The overall goal is to prevent problems from reoccurring or similar discrepancies from occurring. (*Procedures 9020472: Material Purge and 9020185: Control of Non-Conforming Material (Material Review)*).

TSI will not allow concessions for product on EC type-examination certificates.

When a discrepancy is detected, the potential costs TSI might incur are considered. Discrepancies are reported on a material review. A bar-coded Material Review label accompanies the material to the material review staging room.

Material not meeting specification requires a decision to determine if the material is fit for its intended use. Affected areas evaluate the discrepancy to determine the appropriate corrective action. This information is reviewed and reported to cognizant personnel. Cooperation of all departments involved is necessary for effective and efficient operation of this system. (*Procedures 9020423: Material Deviation Request*).

A Stop Shipment Notification will be issued when circumstances are discovered and investigated which indicates the quality of TSI Incorporated products or the systems controlling and assuring integrity of product quality is compromised. (*Procedure 9020669 Stop Shipment Notification*)

Product shipped to customers that is found to be subsequently non-conforming is subject to product recall. (*Procedure 9020506: Product Recall*). Appropriate actions regarding product with EC type-examination certificates include notification and liaison with the notified body and notification of affected customers.

## 8.4 Analysis of Data

TSI identifies where statistical techniques may be applied to control products and processes. During a design/development project, the project manager is responsible for the identification and implementation of statistical techniques. After a product is in production, the cognizant engineer and manufacturing engineer are responsible for the use and integration of statistical techniques. (*Procedures 9020167: Statistical Techniques and 9020444: Measurement Uncertainty Analysis*)

TSI utilizes statistical techniques to verify acceptability of product characteristics, process capabilities, quality system data reporting and analysis, where appropriate. Statistical and data analysis techniques used by TSI may include, but are not limited to:

- product design,
- reliability predication/specification,
- process control/process capability studies,
- quality level determination/inspection plans,
- data analysis/performance assessment/defect analysis,
- servicing reports,
- customer concerns/complaints, and
- data analysis and reporting.

## 8.5 Improvement

TSI continually strives to improve the effectiveness of the Quality Management System through the use of:

- quality policy and quality objectives,
- actions from management reviews,
- analysis of internal audit reports,
- analysis of corrective/preventive actions,
- analysis of material reviews (nonconforming material),
- analysis of product and process data, and
- customer feedback and complaints.

TSI takes corrective action to eliminate the causes of existing nonconformances in order to prevent recurrence, and takes preventive action to eliminate the causes of potential nonconformances in order to prevent occurrence. (*Procedure 9020201: Corrective and Preventive Action*)

Corrective and Preventive actions are appropriate to the effects of the nonconformities or problems encountered. Proposed corrective and preventive actions are reviewed and concurred with by a Quality Review Team.

Personnel independent from those performing root cause analysis and implementing corrective/preventive actions conduct corrective/preventive effectiveness evaluations.

For corrective actions, the procedure defines the requirements for:

- reviewing nonconformities, including customer complaints,
- determining the causes of nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
- determining and implementing action needed,
- recording the results of the action taken, and
- reviewing the corrective action taken.

For preventive actions, the procedure defines the requirements for:

- determining potential nonconformances and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,
- determining and implementing action needed,
- recording the results of the actions taken, and
- reviewing the preventive action taken.

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**Appendix A – ISO 9001:2000 / QMS Documents Cross Reference****4.0 QUALITY MANAGEMENT SYSTEM****4.1 General Requirements**

9000055	Quality Management Systems Manual
9020220	Quality Management System
9020371	Definitions and Acronyms

**4.2 Documentation Requirements**

9020166	Quality Records
9020174	Document and Data Control
9020186	Engineering Change

**5.0 MANAGEMENT RESPONSIBILITY****5.1 Management Commitment**

9020179	Management Responsibility
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**5.2 Customer Focus (See 5.1)****5.3 Quality Policy (See 5.1)****5.4 Planning**

9020365	TSI Quality Objectives
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**5.5 Responsibility, Authority and Communication**

9020471	Authorized Signatories
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**5.6 Management Review**

9020178	Management Review
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**6.0 RESOURCE MANAGEMENT****6.1 Provision of Resources**

9020366	Resources, Infrastructure and Work Environment
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**6.2 Human Resources**

9020177	Training
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**6.3 Infrastructure (See 6.1)****6.4 Work Environment (See 6.1)****7.0 PRODUCT REALIZATION****7.1 Planning of Product Realization**

9020367	Product Realization Planning
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**7.2 Customer-related Processes**

9020173	Contract Review
9020425	Product Returns and Servicing Contract Review

**7.3 Design and Development Planning**

9020562	Design/Development Planning
9020358	Software/Firmware Release

**7.4 Purchasing**

9020181	Purchase Orders
9020182	Supplier Selection & Approval
9020205	Receiving Inspection
9020370	Supplier Control and Corrective Action
9020466	Supplier 1st Article

**7.5 Production and Service Provision**

9020180	Process Control
9020202	Inspection and Test
9020203	Product ID and Traceability
9020204	Inspection and Test Status
9020206	Handling, Storage, Packaging, Preservation and Delivery
9020345	Manufacturing Process Validation
9020368	Product Returns and Servicing
9020611	End of Product Service Life

**7.6 Control of Monitoring and Measuring Devices**

9020047	Inspection, Measurement and Test Equipment
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**8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT****8.1 General**

9020369	Measurement, Analysis and Improvement
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**8.2 Monitoring and Measurement**

9020172	Internal Quality Audits
9020208	Customer Feedback

**8.3 Control of Nonconforming Product**

9020185	Control of Non-Conforming Product (Material Review)
9020423	Material Deviation Request
9020472	Material Purge
9020669	Stop Shipment Notification
9020506	Product Recall

**8.4 Analysis of Data**

9020167	Statistical Techniques
9020444	Measurement Uncertainty Analysis

**8.5 Improvement**

9020201	Corrective and Preventive Action
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**Controlled Documents of External Origin (Standards)**

ISO 9001:2000	Quality Management Systems - Requirements.
EN 13980:2002	Potentially Explosive Atmospheres – Application of Quality Systems
ISO 10012:2003	Measurement Management Systems — Requirements for Measurement Processes and Measuring Equipment

