

# **QUALITY SYSTEM MANUAL**

**LOGIC Devices Incorporated**  
**Sunnyvale, CA**  
[www.logicdevices.com](http://www.logicdevices.com)

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B.Volz: President & CEO

## **QUALITY POLICY STATEMENT**

The Quality Policy has been approved by Bill Volz, President and CEO

LOGIC Devices is committed to its goals of providing:

- Quality products
- In a timely manner
- At competitive prices
- While ensuring continual improvement
- And compliance to applicable regulations

LOGIC Devices is committed to respecting the interests of the stakeholders involved in its business relationships:

- Its customers
- Its suppliers
- Its investors
- Its employees
- And the communities in which it operates

<b>Sec. #</b>	<b>Title</b>	<b>Page #</b>
	Quality Policy Statement	2
1.0	Introduction	4
2.0	Scope	5
3.0	Exclusions	5
4.0	Quality Management System Requirements	5
4.1	General Requirements	5
4.2	Documentation Requirements	6
5.0	Management Responsibility	7
5.1	Management Commitment	7
5.2	Customer Focus	7
5.3	Quality Policy	7
5.4	Planning	8
5.5	Responsibility, Authority and Communication	8
5.6	Management Review	9
6.0	Resource Provision	9
6.1	Provision of Resources	9
6.2	Human Resources	10
6.3	Infrastructure	10
6.4	Work Environment	10
7.0	Product Realization	11
7.1	Planning of Product Realization	11
7.2	Customer Related Processes	11
7.3	Design and Development	12
7.4	Purchasing	13
7.5	Product and Service Provision	14
7.6	Control of Monitoring and Measuring Equipment	15
8.0	Measurement, Analysis and Improvement	15
8.1	General	15
8.2	Monitoring and Measurement	16
8.3	Control of Non-Conforming Product	17
8.4	Analysis of Data	18
8.5	Improvement	18
Appendix 1	Process Interaction	20
Appendix 2	Organization Chart	21
Appendix 3	Correlation of MIL-PRF-38535 to Quality System Manual	22
Appendix 4	Reconciliation of ISO Clauses to LDI's Procedures and Documents	23
	Revision History	25

## **1.0 Introduction**

LOGIC Devices Incorporated (hereafter referred to as LDI) develops and markets high-speed digital integrated circuits that perform high density storage and signal/image processing functions. Our products enable SD and HD video display, transport, editing, composition, and special effects. We also provide solutions for digital filtering in wireless base stations, image enhancement in medical diagnostic scanning and imaging equipment, and guidance and target recognition capabilities in smart-weapons systems.

LDI is a supplier focused on providing integrated circuits with the highest quality, density, performance, and support. We support world leaders in the networking, personal computer, telecommunications, data communication, and testing equipment markets. Superior product design, manufacturing, quality, and a drive for innovation, are cornerstones of our corporate philosophy.

### **Technology**

Our solutions offer greater computation rates, lower cost, and lower power consumption than alternative approaches. Using our experience in high-speed data path and embedded memory development, with a structured custom design methodology, our chip solutions involve highly optimized, integrated, and dedicated high-speed computation functions. We work closely with customers to define the features and performance required to meet demanding requirements. LDI is continuing to increase its activities in related complementary core technologies with algorithm and mixed signal efforts, while relying on standard advanced lithography semiconductor process technology provided by wafer foundry sources.

### **Customers**

LDI products are used by a large number of industrial customers. Broadcast equipment manufacturers include: Snell and Wilcox, Quantel, and Phillips in Europe; Ikegami, Hitachi, and Sony in Japan; and Pinnacle in the United States. Medical diagnostic imaging manufacturers include: Vingmed (GE) in Europe; Acuson and HP in the United States; and Hitachi Medico in Japan. Military customers include Lockheed Martin Loral on programs, such as the Tomahawk Cruise Missile and the Lantirn; and communications customers include SDX (Lucent) in Europe and Teradyne (test equipment) and (DSC) Alcatel in the United States.

Other customers include Ikegami, Hitachi, Sony, Phillips, Wilcox, Quantel, and Pinnacle.

### **Management Principles**

#### **Management at LDI adheres to the eight management principles of ISO9000:**

##### **1. Customer Focus**

LDI depends on its customers and relies on their inputs for future and current product and service needs.

##### **2. Leadership**

Management establishes the direction and purpose of the organization by setting objectives and providing the guidance to achieve its goals.

### 3. Involvement of People

People are the foundation by which LDI is able to meet its customer needs. Management supports the staff with ample communication and training to meet business needs.

### 4. Process Approach

LDI uses a business management system with processes that interconnect to form a system to achieve the stakeholder needs.

### 5. System Approach to Management

Management has a system whereby individual processes are integrated to provide a structure to meet objectives and to encourage continual improvement.

### 6. Continual Improvement

Continual improvement in product realization and the supporting processes required to meet the stakeholder needs is a foundation of management.

### 7. Factual Approach to Decision Making

Statistical methods are used in making decisions. The analysis of data to demonstrate efficiency and effectiveness is used to review the business management system.

### 8. Mutually Beneficial Supplier Relationship

As a design facility where outsourcing is a key to success, LDI works closely with suppliers to ensure that customer needs are of primary consideration.

## **2.0 Scope**

LDI's headquarters, located at 1375 Geneva Drive, Sunnyvale, California, includes design of integrated circuits, outsourcing of wafer fabrication and assembly processes, and testing of product at the headquarters and at outsourced suppliers. All of the processes required to meet the Management System are guided by ISO 9001:2008 and MIL-PRF-38535.

## **3.0 Exclusions (ISO Cl. 4.2.2.a)**

None

## **4.0 Quality Management System Requirements**

### **4.1 General Requirements (ISO Cl. 4.1)**

LDI has established and documented a quality management system (QMS) in compliance with ISO 9001:2008, which is implemented and includes a mechanism for continual improvement of the system (e.g. through Management Review quality objectives and corrective and preventive actions). The quality system at LDI meets applicable regulatory requirements, such as MIL-STD-883.

For implementation of the system, the following topics are documented and referenced in Appendix 1 of this manual:

- a. Determination of the processes needed for this QMS,
- b. Sequence and interaction of these processes, and
- c. Availability of information for operation and monitoring of these processes.

Criteria and methods for effective operation and control of QMS processes are established through process descriptions for each key process. A process description also indicates appropriate monitoring methods. Section 8.1 of this manual describes general methods to monitor, measure, where applicable, and analyze QMS processes. The system also describes necessary controls and workmanship required by MIL-PRF-38535 and MIL-STD-883.

Outsourcing of processes: Outsourced processes include fabrication of prototype and production parts. The purchasing procedure controls the suppliers of these services by qualifying and evaluating (at least annually) these suppliers (QP-1011). The Purchasing Management may undertake periodic on-site supplier audits, depending upon the number of nonconformances and late deliveries by the suppliers.

## **4.2 Documentation Requirements**

### **4.2.1 General (ISO Cl. 4.2.1)**

QMS documentation includes:

- a. Quality Policy and Quality Objectives
- b. Documents required by ISO 9001:2008
- c. Quality Manual
- d. Documents required by the organization for effective operation and control of the processes, such as work instructions
- e. Applicable external documents
- f. Internal documents listed in the Master List/Distribution Matrix (FM-1001)
- g. Records required for the QMS

### **4.2.2 Quality Manual (ISO Cl. 4.2.2)**

LDI has a Quality Manual that is managed by the Management Representative for quality. It describes the scope of the QMS. This manual contains no exclusions as defined in Clause 1.2 (Application) ISO 9001: 2008.

### **4.2.3 Control of Documents (ISO Cl 4.2.3)**

QP-1001 describes the method for:

- a. Approving documents for adequacy prior to release;
- b. Reviewing, updating and reapproving the documents;
- c. Identifying the current revision status and revision history of the documents;
- d. Issuing documents and ensuring availability of the relevant version of applicable documents at point of use;
- e. Ensuring that the documents are legible, identifiable and easily retrievable;

- f. Preventing unintentional use of obsolete documents and identifying such documents if retained for historical purposes; and
- g. Identifying and controlling distribution of external documents as determined by the organization. Such documents include, but are not limited to, the following:
  - \* ISO 9001:2008 (Quality Management Systems – Requirements),
  - \* ANSI/ISO/ASQC Q100-11-1 (Guidelines for Auditing Quality Systems),
  - \* ISO 9000:2008 (Quality Management Systems – Fundamentals & Vocabulary),
  - \* MIL-STD-883 (Test Methods and Procedures for Microelectronics),
  - \* MIL-PRF-38535 (General Specification for Integrated Circuits (Microcircuits) Manufacturing),
  - \* ANSI/NCSL Z540 (Calibration Systems Requirements), and
  - \* JESD22 (Test Methods and Procedures for Solid State Devices Used in Transportation/Automotive Applications)

#### **4.2.4 Control of Quality Records (ISO Cl 4.2.4)**

LDI establishes and controls legible records to provide evidence of conformity to QMS requirements and of the effective operation of the system. Procedure QP-1002 describes the method of identification, storage, retrieval, protection, retention and disposition of records.

## **5.0 Management Responsibility**

### **5.1 Management Commitment (ISO Cl. 5.1)**

Management's statement of commitment is in the Quality Policy. Top management actively participates in the development and improvement of the QMS through the following:

- a. Communication regarding the importance of meeting customer and/or regulatory requirements,
- b. Communication of the Quality Policy and Quality Objectives to all employees,
- c. Management reviews, and
- d. Availability of necessary resources.

### **5.2 Customer Focus (ISO Cl. 5.2)**

LDI determines customer needs and expectations through customer-related processes (Ref. section 7.2.1) and customer feedback (Ref. section 7.2.3).

LDI ensures customer requirements are met as indicated through inspection records. One of the agenda items for management reviews is the analysis of customer feedback to evaluate how customer needs and expectations can be converted to organizational objectives that are aimed towards continual improvement and enhancing customer satisfaction (Ref. QP-1018).

### **5.3 Quality Policy (ISO Cl. 5.3)**

Top Management ensures that the quality policy:

- a. Is appropriate to the purpose of the organization;
- b. Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS; and
- c. Provides a framework for establishing and reviewing quality objectives.

The Quality Policy is communicated and made understood to all the employees. The policy is reviewed for its continuing suitability during management reviews.

## **5.4 Planning (ISO Cl. 5.4)**

### **5.4.1 Quality Objectives (ISO Cl 5.4.1)**

Top management ensures that quality objectives are established at all relevant levels and functions. The objectives include those needed to meet requirements for the product, and are measurable and consistent with the Quality Policy. Quality objectives are defined and monitored through separate documents that will be attached to each Management Review Record maintained in Document Control and stored on the shared server “ISO” on the network ‘Server’.

### **5.4.2 Quality Planning (ISO Cl 5.4.2)**

Through the Management Representative, top management ensures that quality planning is carried out and includes a plan to achieve quality objectives. LDI plans its quality QMS processes through Appendix 1 and process descriptions resulting from that appendix.

When changes to the QMS are planned and implemented, integrity of the system is maintained through modification of relevant processes, related documentation and training.

## **5.5 Responsibility, Authority and Communication (ISO Cl. 5.5)**

### **5.5.1 Responsibility and Authority (ISO Cl. 5.5.1)**

Top management ensures responsibilities and authorities are defined and communicated through the Organization Chart (Appendix 2) and one-to-one correspondence or internal meetings. The chart includes all those functions that contribute directly to the quality of the product or services of LDI.

NOTE: Responsibilities and authorities of other key personnel are given in the respective procedures and/or work instructions.

### **5.5.2 Management Representative (ISO Cl. 5.5.2)**

Top management appointed the Quality Manager as the Management Representative. The Management Representative has the authority and responsibility to:

- a. Ensure that processes of the QMS are established and maintained;
- b. Report to top management on the performance of this QMS and any needs for improvement;
- c. Ensure promotion of awareness of customer requirements throughout the organization;
- d. Liaise with external agencies, including the certifying body on matters related to this QMS;
- e. Plan and organize internal and external audits, follow-up on corrective/preventive actions resulting from the audits and maintaining records; and

- f. Plan and organize management review meetings and prepare minutes of the meetings.

The Management Representative may oversee requirements related to regulations applicable to LDI's products and services.

### **5.5.3 Internal Communication (ISO Cl. 5.5.3)**

Flow of information and instructions related to the effective implementation of the QMS is in line with the organization chart and process descriptions.

Any employee may communicate ideas and/or suggestions for QMS improvement to top management directly or through the Management Representative. The Management Representative reviews employee feedback and takes necessary action. If the feedback or suggestion is aimed at improving the QMS or any process, it may be discussed during management reviews so that actions can be taken to implement the suggested improvement options.

## **5.6 Management Review (ISO Cl. 5.6)**

### **5.6.1 General (ISO Cl. 5.6.1)**

LDI conducts management reviews at least twice a year and after each complete internal audit. Inputs to such reviews are in accordance with the management review agenda (FM-1004) to ensure its continuing suitability, adequacy and effectiveness in satisfying the requirements of the QMS.

### **5.6.2 Review Input (ISO Cl. 5.6.2)**

Information for discussion will include, but not be limited to:

- a. Audit results,
- b. Customer feedback,
- c. Status of corrective and preventive actions,
- d. Process performance and product conformity,
- e. Changes that could affect the QMS,
- f. Recommendations for improvement, and
- g. Review of last management meeting

### **5.6.3 Review Output (ISO Cl. 5.6.3)**

Management review outputs shall include:

- a. Evaluating improvement options;
- b. Making necessary changes to the QMS, quality policy and quality objectives; and
- c. Ensuring the provision of adequate resources.

## **6.0 Resource Provision**

### **6.1 Provision of Resources (ISO Cl. 6.1)**

LDI ensures provision of necessary resources to implement, maintain and continually improve its QMS, and to address customer satisfaction. Through management reviews, the organization

determines additional resources needed to implement and improve this QMS and its processes and to enhance customer satisfaction by meeting customer requirements.

## **6.2 Human Resources (ISO Cl. 6.2)**

### **6.2.1 Competence of Personnel (ISO Cl. 6.2.1)**

Employee competence is based on education, training, skill and experience and performance reviews (Ref. QP-1003). Minimum competence for personnel at different levels is based on job descriptions.

### **6.2.2 Competence, Training and Awareness (ISO Cl. 6.2.2)**

To ensure employees' competence to perform respective tasks, LDI takes the following actions:

- a. Identifies competence needs of personnel performing activities that affect conformity to product requirements;
- b. Where applicable, providing training or other actions to achieve the necessary competence. Relevant employees receive training for any additions or changes to LDI's processes. Training is tracked with FM-1002;
- c. Evaluates effectiveness of training or actions taken to ensure competence;
- d. Makes employees aware of the relevance and importance of their activities and contributions to achieving quality objectives; and
- e. Maintains appropriate records of education, experience, training, and skills.

## **6.3 Infrastructure (ISO Cl. 6.3)**

Current infrastructure is adequate for the present activities to achieve product conformity. However, management review includes discussion and determination of actions to provide additional infrastructural requirements, such as:

- a. Workspace and associated facilities,
- b. Equipment, hardware and software, and
- c. Supporting services (such as transportation, communication or information systems).

## **6.4 Work Environment (ISO Cl. 6.4)**

Management review includes discussion of human and physical factors pertaining to the work environment required to achieve conformity of the products.

LDI has defined and developed the work environment needed to achieve conformity to product requirements. Manufacturing processes are verified and implemented in a controlled manner. The established system ensures that all quality requirements are carried out as stipulated by the customer and LDI's internal workmanship criteria. Areas for handling, storage and packaging of products are clean, safe, and organized to ensure that they do not adversely affect quality or personnel performance.

Procedures exist (Ref. FM-1001) for Process Control; Electrostatic Discharge (ESD) Control; Facility and Environmental Control, (Ref. Electrical Test Work Instructions); Product ID and

Traceability; Procedure for Warehouse; Work Instructions for Receiving and Storage of Incoming Products; Packaging and Shipping.

## **7.0 Product Realization**

### **7.1 Planning of Product Realization (ISO Cl. 7.1)**

The QMS includes processes to ensure product realization per customer needs. The flowchart in Appendix 1 illustrates these product realization processes and how they interrelate. The planning for product realization includes determining the following:

- a. Customer requirements,
- b. Quality objectives and requirements of the product,
- c. Product-specific resource provisions,
- d. Documents necessary to carry out a process,
- e. Process documentation to transfer customer requirements to purchasing (Ref. section 7.4) and production specifications (Ref. section 7.5),
- f. Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance, and
- g. Records to evaluate that the product realization processes and final deliverables meet the customer and quality requirements.

### **7.2 Customer Related Processes (ISO Cl. 7.2)**

#### **7.2.1 Determination of Customer Requirements (ISO Cl. 7.2.1)**

LDI uses its order process procedure (QP-1009) to determined product requirements, such:

- a. Customer requirements that include specification, quantity, delivery and other information or amendments, if any,
- b. Requirements not specified by the customer, but necessary for the intended use of the product (e.g. packaging and/or transportation requirements),
- c. Regulatory or legal requirements applicable to the product, if any, and
- d. Post-delivery requirements, such as engineering support for application issues and logistic follow-up for returned products.

#### **7.2.2 Review of Product Requirements (ISO Cl. 7.2.2)**

LDI reviews and maintains records of these reviews at appropriate stages per Procedure QP-1009 (e.g. prior to order confirmation) to ensure identification of product requirements, confirmation of customer requirements prior to order confirmation, resolution of discrepancies in order requirements from those previously expressed, and the assessment of LDI's ability to meet the requirements. This includes reviewing the customer request for quote, customer purchase order, and any change order after confirmation of the initial purchase order. Accepted changes to any documentation are communicated to relevant employees.

#### **7.2.3 Customer Communication (ISO Cl. 7.2.3)**

Arrangements established for communication with the customer include:

- a. Product information (Ref. QP-1009 and QP-1018),
- b. Inquiries, orders and amendments (Ref. QP-1009),
- c. Customer feedback (Ref. QP-1018), and
- d. Customer complaints (Ref. QP-1018).

Depending upon complaints or customer feedback, the QMS includes procedures to initiate corrective and preventive action (Ref. QP-1005) to ensure customer satisfaction and continual improvement.

### **7.3 Design and Development (ISO Cl. 7.3)**

#### **7.3.1 Design and Development Planning (ISO Cl. 7.3.1)**

LDI plans and controls the design and development of products through the corresponding procedure (Ref. QP-1015) and documents referenced in this procedure. This procedure provides information for design and development planning, communication links and responsibilities involved. Planning output is updated, as appropriate, as the design and development progresses.

Specific requirements for design and development planning include the following information:

- a. The design and development stages,
- b. The review, verification and validation that are appropriate to each design and development stage, and
- c. The responsibilities and authorities for design and development.

#### **7.3.2 Design and Development Inputs (ISO Cl. 7.3.2)**

Procedure QP-1015 includes the determination and recording of inputs related to product requirements, including:

- a. Functional and performance requirements,
- b. Applicable statutory or regulatory requirements,
- c. Information from previous and/or similar designs, where applicable, and
- d. Other requirements essential to design and development.

The inputs are reviewed for adequacy and requirements shall be complete, unambiguous and not in conflict with each other, per Procedure QP-1015.

#### **7.3.3 Design and Development Outputs (ISO Cl. 7.3.3)**

The outputs of design and development, such as the prototype of the design, are in a form suitable for verification against the design and development inputs and are approved prior to release. Engineering management ensures that design and development outputs:

- a. Meet the input requirements for design and development,
- b. Provide appropriate information for purchasing, production and service provision,

- c. Contain or reference product acceptance criteria, and
- d. Specify the characteristics of the product that are essential for its safe and proper use.

#### **7.3.4 Design and Development Review (ISO Cl. 7.3.4)**

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements to evaluate the ability of the results to meet requirements and to identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stages being reviewed. Records of the results of the reviews and necessary actions are maintained per Procedure QP-1015.

#### **7.3.5 Design and Development Verification (ISO Cl. 7.3.5)**

Verifications are performed in accordance with planned arrangements to ensure that the design and development outputs meet the design and development input requirements. Records of the results of the verification and any necessary actions are maintained per Procedure QP-1015.

#### **7.3.6 Design and Development Validation (ISO Cl. 7.3.6)**

Design and development validation are performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting requirements for the specified application or intended use, where known. Wherever it is possible, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained per Procedure QP-1015.

#### **7.3.7 Control of Design and Development Changes (ISO Cl. 7.3.7)**

Any changes to design and development are reviewed, verified and validated, as appropriate, and approved before implementation. The reviews of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained per Procedure QP-1015.

### **7.4 Purchasing (ISO Cl. 7.4)**

#### **7.4.1 Purchasing Control (ISO Cl. 7.4.1)**

QP-1011 describes the methodology for controlling the purchasing process to ensure a supplier's product/service conforms to the purchase requirements, including qualification and continuing evaluation of suppliers. These qualifications, evaluations and any follow-up based on the evaluations are maintained.

#### **7.4.2 Purchasing Information (ISO Cl. 7.4.2)**

LDI evaluates its suppliers based on criteria listed in Appendix 1 of Procedure QP-1011. Purchasing reviews a purchase requisition for adequacy of specification, quantity, inspection and delivery requirements prior to releasing a purchase order. Quality assurance reviews purchase orders for similar requirements, where applicable.

### **7.4.3 Verification of Purchased Product (ISO Cl. 7.4.3)**

Receiving and receiving inspection processes describe the necessary requirements for verification of purchased product to ensure that purchased product meets purchase requirements (Ref. QP-1006 for Warehouse and WI-1011 for QC Receiving Inspection). In cases where LDI intends to perform verification at the supplier's premises, purchasing management communicates with the supplier about verification arrangements and the method of product release prior to any inspections.

## **7.5 Product and Service Provision (ISO Cl. 7.5)**

### **7.5.1 Control of Production and Service Provision (ISO Cl. 7.5.1)**

LDI has the following controls to address the product and service operations needed for the manufacturing process:

- a. Quality plans or process descriptions to properly determine the product requirements,
- b. Work instructions and proper qualification of personnel performing the duties (Ref. WI-XXXX documents), including documentation of process changes and training of the personnel,
- c. Evaluation of equipment for suitability to provide the product and services,
- d. Monitoring and measurement process implementation, and
- e. Product release, delivery and post-delivery process implementation per agreements with customers.

### **7.5.2 Validation of Processes for Production and Service Provision (ISO Cl. 7.5.2)**

All production processes are validated through monitoring and measuring. LDI strives to minimize the possibility of a finished product failing while in use by the end user. In certain cases, where it may not be possible to test or verify all possible functions of a complex semiconductor device under all possible environmental and mechanical conditions, LDI may elect to take extra process steps (including electrical and environmental testing) to validate expected field performance.

### **7.5.3 Identification and Traceability (ISO Cl. 7.5.3)**

All materials, parts, components and subassemblies incorporated into the product and/or service offered by LDI to its customers shall be identified by suitable means and maintained throughout product realization (Ref. WI-1007). Unique identification includes a lot number, a part number and a supplier product ID, when applicable.

LDI's inspection and test status identification system identifies and controls material to prevent unintended use, consumption or dispatch before it has passed or been exposed to the prescribed tests and inspections specified in the manufacturing lot traveler. This includes receiving, and incoming and final product inspection.

The unique lot traveler and associated documentation on the inspection and test status is controlled and maintained.

Product identification and traceability is described in detail through procedures related to various product realization stages that include receiving and receiving inspection, storage and preservation, Quality Control (inspection and testing), shipping and purchasing.

#### **7.5.4 Customer Property (ISO Cl.7.5.4)**

Products received for repair/rework from the customers are considered customer property. Such products are identified based on product type, such as part # and RMA# (Ref. QP-1014). LDI protects customer property by following adequate handling and storage procedures. In case of damage, deterioration or unfit for use product, management ensures subsequent action is taken in alliance with the customer. Any intellectual properties in the form of drawings or documents provided to LDI by customers are handled through the procedure for Document Control (Ref. QP-1001).

#### **7.5.5 Preservation of Product (ISO Cl. 7.5.5)**

LDI has procedures for processes such as receiving, storing, assembling, packaging and shipping that address requirements for product preservation during internal processing. The requirements include product identification, handling, packaging, storage, preservation and delivery, as applicable. In addition, ESD compliance is ensured per corresponding work instructions (Ref. WI-1009).

### **7.6 Control of Monitoring and Measuring Equipment (ISO Cl. 7.6)**

Procedure QP-1017 describes the responsibility for and method of monitoring and measuring equipment, including, but not limited to:

- a. A list of monitoring and measuring equipment requiring control and records related to their calibration;
- b. A calibration schedule (also maintained when equipment is outsourced);
- c. Relevant information about the equipment, including identification and the reference standard (national/international) or the basis used for calibration/verification in absence of any existing standard;
- d. Periodic maintenance schedule and safeguards against adjustments that could invalidate a calibration (Such equipment will be properly handled by authorized employees only to prevent damage/deterioration);
- e. A method for taking appropriate action if any effected, delivered product is found to be nonconforming due to the lack of an equipment calibration/maintenance (Ref. QP-1005); and
- f. A record of the calibrations and verifications.

## **8.0 Measurement, Analysis and Improvement**

### **8.1 General (ISO Cl. 8.1)**

The following methods were developed to plan and implement the processes, such as monitoring, measurement, analysis and improvement:

<b>Requirement:</b>	<b>Processes:</b>		
	<i>Monitoring &amp; Measurement</i>	<i>Analysis</i>	<i>Improvement</i>
Conformity of product with respect to the customer requirement(s)	Inspections and/or customer complaints	Inspection records and nonconformance reports (if any)	<ol style="list-style-type: none"> <li>1. Analysis of customer complaint,</li> <li>2. Corrective and preventive action to reduce customer complaints, and</li> <li>3. Feasibility of adapting improved technology and/or hiring expertise</li> </ol>
Conformity of QMS to ISO 9001:2008 standard	Internal audit of QMS	Internal audit reports and completion of corrective and preventive action	<ol style="list-style-type: none"> <li>1. Identification of root cause for nonconformance,</li> <li>2. Prompt corrective and preventive action, and</li> <li>3. Conducting regular audits and management reviews</li> </ol>
Effectiveness and continual improvement of QMS	Internal audits and management reviews	Management review records	<ol style="list-style-type: none"> <li>1. Ensuring employees/contractors understand their role in the QMS,</li> <li>2. Setting objectives to improve the quality of products and effectively implement the QMS, and</li> <li>3. Reviewing objective fulfillment and the planned arrangement of the QMS</li> </ol>

## 8.2 Monitoring and Measurement (ISO Cl. 8.2)

### 8.2.1 Customer Satisfaction (ISO Cl. 8.2.1)

To demonstrate the fulfillment of customer requirements and customer satisfaction, LDI maintains:

- a. Inspection records,
- b. Customer relations management system, and
- c. Customer complaint log.

LDI handles customer complaints on a case-by-case basis. The operations manager or in certain severe cases, top management, evaluates corrective actions to be taken to ensure customer satisfaction (Ref. FM-1006). Management reviews include discussion of the outcome of these processes to determine and implement actions required for improvement (Ref. management review meeting minutes).

### **8.2.2 Internal Audits (ISO Cl. 8.2.2)**

Procedure QP-1012 for Internal Audits ensures that the QMS conforms to planned arrangements (quality plan and resulting process descriptions/procedures) and requirements of the Standard ISO 9001:2008, and that the QMS is effectively implemented and maintained:

This procedure describes requirements for audit programs, audit intervals/frequency (defined as annual through QP-1012), responsibilities and authorities to conduct audit and report results, as well as the method of undertaking follow-up activities.

### **8.2.3 Monitoring and Measurement of Processes (ISO Cl. 8.2.3)**

Processes related to QMS implementation at LDI are monitored through internal audits and periodic management reviews to demonstrate the ability of the processes to achieve planned arrangements, including the monitoring and measurement of quality objectives. Measurement includes processes related to the established quality objectives and advancement towards goals indicates improvement in the processes.

When a process is identified as not implemented per planned arrangements, a Corrective Action Form (FM-1006) may be initiated depending upon the severity of the deviation. Any correction and/or corrective action taken is commensurate with the identified nonconformance.

The management reviews include examining the results of the monitoring and measurement of the QMS processes to assess the level of achievement of planned results and determining necessary corrective actions.

### **8.2.4 Monitoring and Measurement of Product (ISO Cl. 8.2.4)**

LDI monitors and measures the required characteristics of the product to verify that product requirements are met. This is carried out at appropriate stages of the manufacturing processes in accordance with the product quality requirements. Receiving, in-process and final inspection are carried out per Procedure QP-1007.

Inspection records provide evidence of conformity with the acceptance criteria. This includes personnel that are authorized to release final product for delivery to the customer (initial on each lot report). The release of product does not proceed until all the required processes are satisfactorily completed, unless otherwise approved by management and, where applicable, by the customer.

## **8.3 Control of Nonconforming Product (ISO Cl. 8.3)**

Procedure QP-1004 exists to document the:

- a. Identification and control of nonconforming product;
- b. Responsibility and authority for controls;
- c. Methods of initiating and completing corrective actions;
- d. Acceptance under concession by relevant authority of the customer, when applicable;

- e. Preclusion of a product's original intended application;
- f. Method of recording the nature of the nonconformity and subsequent actions taken;
- g. Reverification of the corrected product for conformity to the requirements (e.g. rework or repair);
- h. Review of the customer's complaints for nonconformity detected after delivery; and
- i. Corrective and/or preventive action taken appropriate to the effect or potential effect of the nonconformity.

#### **8.4 Analysis of Data (ISO Cl. 8.4)**

LDI determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources. Management reviews include significant aspects of such data.

The analysis of data provides information relating to:

- a. Customer satisfaction,
- b. Conformity to product requirements,
- c. Characteristics and trends of processes and products,
- d. Opportunities for preventive action, and
- e. Suppliers

#### **8.5 Improvement (ISO Cl. 8.5)**

##### **8.5.1 Continual Improvement (ISO Cl. 8.5.1)**

LDI ensures continual improvement of the QMS by the use of:

- a. The quality policy,
- b. Quality objectives,
- c. Audit results,
- d. Analyses of data,
- e. Corrective and preventive actions, and
- f. Management reviews.

##### **8.5.2 Corrective Actions (ISO Cl. 8.5.2)**

Procedure QP-1005 documents processes to ensure that appropriate corrective actions are taken to eliminate the causes of nonconformity. The procedure defines the requirements for the following:

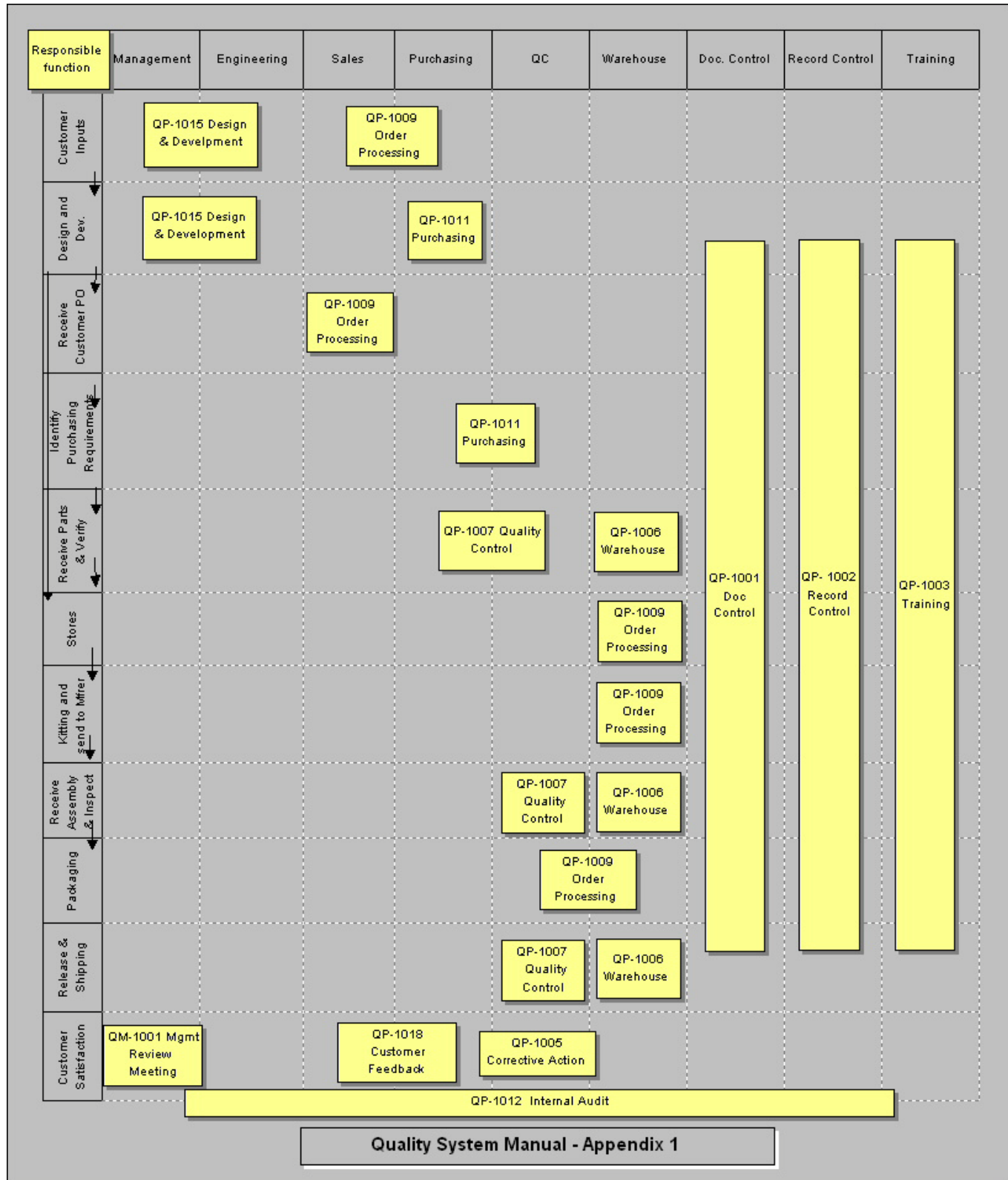
- a. Reviewing nonconformities, including customer complaints;
- b. Determining the cause of nonconformities;
- c. Evaluating the need for action to prevent recurrence;
- d. Determining and implementing action needed;
- e. Recording the results of action taken; and
- f. Reviewing the effectiveness of the corrective action taken.

##### **8.5.3 Preventive Actions (ISO Cl. 8.5.3)**

Procedure QP-1005 documents processes to ensure that appropriate preventive actions are taken to affect the potential problems. The procedure includes:

- a. Determining potential non-conformities and their causes;
- b. Evaluating the need for action to prevent occurrences of nonconformities;
- c. Determining and implementing action taken;
- d. Recording of results of action taken; and
- e. Reviewing the effectiveness of the preventive action taken.

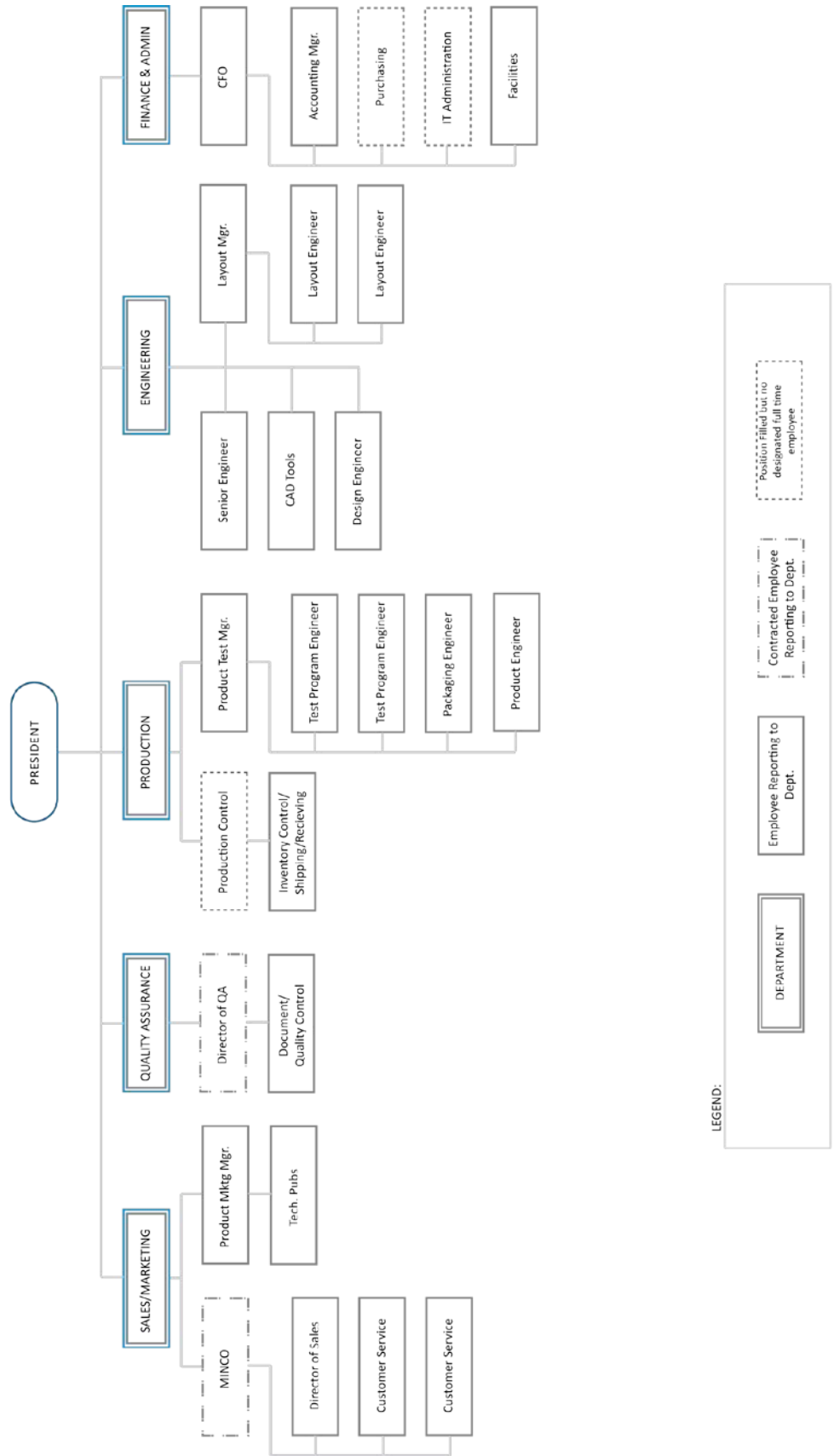
# Appendix 1: Process Interaction



# Appendix 2: Organization Chart



## Organization Chart



**Appendix 3: Correlation of MIL-PRF-38535 to Quality System Manual**

MIL SPEC #	Topic	Ref. Quality System Manual #
	<b>In house documentation covering these areas (See A.4.8.1.3)</b>	
A 4.8.1.1.1	Conversion of customer requirements into manufacturer's internal instructions	7.1, 7.2
A .4.8.1.1.2	Personnel training and testing	6.2
A.4.8.1.1.3	Inspection of incoming materials and utilities and of work in-process	7.4.3,8.2.4
A.4.8.1.1.4	Quality-control operations	8.2.3,8.2.4.8.4
A.4.8.1.1.5	Quality Assurance operations	4.2,7.0,8.0
A.4.8.1.1.6	Design, processing, manufacturing equipment, and materials instruction	7.3,6.3,7.5.4,7.5.5
A.4.8.1.1.7	Cleanliness and atmosphere control in work areas	6.4
A.4.8.1.1.8	Design, material, and process change control	4.2.3, 5.4.2, 7.5.1
A.4.8.1.1.9	Tool, gauge, and test equipment maintenance, and calibration	6.3, 7.6
A.4.8.1.1.10	Failure and defect analysis and feedback	8.2.1, 8.4
A.4.8.1.1.11	Corrective action and evaluation	8.5.2
A.4.8.1.1.12	Incoming, in-process, and out-going inventory control	7.5.1
A.4.8.1.1.13	Schematics	4.2.3
A.4.8.1.1.14	ESD handling control program	6.4
	<b>In-house records covering these areas (A.4.8.1.2)</b>	
A.4.8.1.2.1	Personnel training and testing	6.2.
A.4.8.1.2.2	Inspection operations	8.2.4
A.4.8.1.2.3	Failure and defect report analysis	8.4
A.4.8.1.2.4	Initial documentation and subsequent changes in design, materials, or processing	4.2.3, 5.4.2, 7.5.1
A.4.8.1.2.5	Equipment calibrations	7.6
A.4.8.1.2.6	Process utility and material controls	7.5.1
A.4.8.1.2.7	Product lot identification	7.5.3
A.4.8.1.2.8	Product traceability	7.5.3
A.4.9.3.6	Self-audit report	8.2.2
	<b>A program plan covering these areas (see A.4.8.1.3)</b>	Quality Records Matrix (4.2.4)
A.4.8.1.3.1	Functional block organization chart	5.5.1
A.4.8.1.3.2	Examples of manufacturing flowchart	7.5.1
A.4.8.1.3.3	Proprietary documents identification	4.2.3
A.4.8.1.3.4	Examples of design, material, equipment, visual standard, and process instructions	7.5.1
A.4.8.1.3.5	Examples of records	4.2.4
A.4.8.1.1.8 and as required in A.3.4.2	Examples of design, material, and process change control documents	4.2.3
A.4.8.1.1.10	Examples of failure and defect analysis and feedback documents	8.4
A.4.8.1.1.11	Examples of corrective actions and evaluations documents	8.5.2
A.4.8.1.3.6	Manufacturer's internal instructions for internal visual inspection	8.2.4
A.4.8.1.3.7	Examples of test travelers	7.5.1
A.4.8.1.3.8	Examples of design and construction baselines	7.3
A.4.9.1	Manufacturer's self-audit	8.2.2

**Appendix 4: Reconciliation of ISO Clauses to LDI's Procedures and Documents:**

<b>ISO 9001:2008 Section</b>	<b>LDI Document #</b>	<b>LDI Document Title</b>
4.1 Quality management system 4.2 Documentation requirements 4.2.2. Quality manual 4.2.3 Control of documents 4.2.4 Control of records	QM-1001  QM-1001 QP-1001 QP-1002	Quality Manual  Quality Manual Control of Documents Control of Records
5.1 Management commitment 5.2 Customer focus 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority and commitment 5.6 Management review	QM-1001 QM-1001, QP-1020 QM-1001 QM-1001 QM-1001 QM-1001	Quality Manual Quality Manual Quality Manual Quality Manual Quality Manual Quality Manual
6.1 Provision of resources 6.2 Human resources 6.2.1 General 6.2.2 Competence, training and awareness 6.3 Infrastructure 6.4 Work environment	QM-1001  QM-1001 QP-1003 QM-1001 WI-xxxx	Quality Manual  Quality Manual Training Procedure Quality Manual Various Work Instructions
7.0 Product realization 7.1 Planning of product realization 7.2 Customer related processes 7.2.1 Determination of requirements 7.2.2 Review of requirements 7.2.3 Customer communication 7.3 Design and development 7.3.1 Design and development planning 7.3.2 Design and development inputs 7.3.3 Design and development outputs 7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation  7.3.7 Control of D&D changes	QM-1001/QP-1009 QP-1015  QP-1009 QP-1009 QP-1009/QP-1018  QP-1015 QP-1015 QP-1015 QP-1015 QP-1015 QP-1015 QP-1015/QP-1021  QP-1001	Quality Manual/Order Process Control Design & Development  Order Process Control Order Process Control Order Process Control/Customer Feedback  Design and Development Design and Development Design and Development Design and Development Design and Development Design and Development/Process and Product Qualification Control of Documents

Appendix 4 continued on next page.

**Appendix 4:** (continued)

ISO 9001:2008 Section	LDI Document #	LDI Document Title
7.4 Purchasing 7.4.1 Purchasing process 7.4.2 Purchasing information 7.4.3 Verification of purchases 7.5 Production provision 7.5.1 Control of production provision  7.5.2. Validation of processes 7.5.3 Identification and traceability 7.5.4 Customer property 7.5.5 Preservation of product  7.6 Control of Monitoring and Measuring Equipment	QP-1011 QP-1011 QP-1007  QP-1009/WI-####  QP-1009 QP-1006/WI-1007 QM-1001 QP-1009/WI-1012  QM-1001/ QP-1005/QP-1017	Purchasing Purchasing Quality Control Receiving Inspection  Order Process Control/Various Work Instructions Order Process Control Warehouse/Product ID and Traceability Quality Manual Order Process Control/Receiving and Storage of Incoming Material Quality Manual/Corrective and Preventive Action/Calibration
8.0 Measurement, analysis and improvement 8.1 General 8.2 Monitoring and measurement 8.2.1 Customer satisfaction 8.2.2 Internal Audit 8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of products 8.3 Control of nonconforming product 8.4 Analysis of data 8.5 Improvement 8.5.1 Continual improvement 8.5.2 Corrective action  8.4.3 Preventive action	WI-1021 QM-1001  QP-1018 QP-1012 QM-1001 QM-1001 QP-1004/QP-1014 QP-1007  QM-1001 QM-1001/QP-1005  QM-1001/QP-1005	Statistical Methods Quality Manual  Customer Feedback and Analysis Internal Audit Quality Manual Quality Manual Control of Nonconforming Product/RMA Quality Control  Quality Manual Quality Manual/Corrective and Preventive Action Quality Manual/Corrective and Preventive Action

<b>Revision</b>	<b>Description of Change</b>	<b>Date</b>	<b>ECO Originator</b>
E	Annual update – editorial changes only	03/20/10	Richard Aria