Esterline Interface Technologies

Quality Manual

Advanced Input Devices

Approvals

Revision AL Released Date: October 16, 2013

Originated by: _____ Date: _____

Director of Quality _____ Date: _____

Approved by:

President _____ Date: _____

VP Operations _____ Date: _____

VP Med/Mil/Ind _____ Date: _____

VP Gaming _____ Date: _____

VP HR _____ Date: _____

VP Finance _____ Date: _____

Revision Page

Revision #	Description	Date	Originator
A-Z	Revision history is preserved on revision Z	11/23/2009	Randy Nell
AA	Update to reflect title change for VP of Operations	04/21/2006	Randy Nell
AB	Update to reflect organization change	04/23/2007	Randy Nell
AC	Update per PAR7409	07/01/2008	Randy Nell
AD	Update to compliance to ISO 9001:2008, organization change	06/26/2009	Randy Nell
AE	Update Appendix B, Index of Operational Procedures per CAR 8375	12/31/2009	Randy Nell
AF	Update to comply with ISO 13485:2003	09/09/2010	Randy Nell
AG	Update to reflect the excluded clauses of ISO 13485:2003	09/21/2010	Randy Nell
AH	Update Section 4 and Appendix B	10/21/2011	Randy Nell
AJ	Update to org. chart to reflect “Management Representative”, organization and title changes	01/31/2012	Randy Nell
AK	Update Section 3 to add Order Fulfillment, Section 4 and Update Section 5; added paragraph 5	08/23/2012	Randy Nell
AL	Updated Appendix C: Cross Reference Table Updated section 3 Update Add reference to ISO 13485:2003/NS-EN ISO 13485:2012 Update Section 4 sub section 3.2 risk management Update Section 2 sub section 1 documentation	09/18/2013	Mike Hughes

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INTRODUCTION

Esterline Advanced Input Systems developed and implemented a quality management system to better satisfy the needs of its customers and to improve management of the company. The quality system complies with the international standards ISO 9001:2008 and ISO 13485:2003/NS-EN ISO 13485:2012. It covers the design and production of custom control panels and input devices. Excluded clauses from ISO 13485 are 7.5.1.2.2 installation, 7.5.2.2, sterile devices and active Implantable Devices, and 7.5.3.2.2 Particular requirement for active Implantable and Implantable medical device

The manual is divided into 20 sections with a cross-reference matrix to the ISO 13485 elements corresponding to quality system requirement standard. Each section starts with a general policy statement expressing the commitment to implement the basic principles of the quality system element that is the subject of the section. The general policy statement is followed by more specific procedural policies outlining how the general policy should be carried out and referencing the relevant operational procedures.

The purpose of this manual is to define and describe the quality system, to define the authorities and responsibilities of the management personnel affected by the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present our quality system to our customers and to inform them what specific controls are implemented to assure product and process quality.

QUALITY POLICY

Esterline Advanced Input Systems is committed to customer satisfaction by meeting quality and delivery expectations through continual improvement of the quality objectives.

Our quality objectives are to:

- Improve quality performance based on warranty returns.
- Improve delivery performance based on promise dates to the customers.
- Improve Customer Satisfaction based on Customer Feedback

PRESIDENT:

_____

Dennis Staver

This policy insures we maintain the effectiveness of our quality system and comply with customer and product requirements. It has been formulated and approved by the executive staff of Esterline Advanced Input Systems. The policy is explained and discussed at orientation training given to all existing and new employees. The policy is also posted throughout the company.

SECTION 1. MANAGEMENT RESPONSIBILITY

General Policy

The executive management is ultimately authorized and responsible for establishing, implementing, and maintaining the quality system. Specific responsibilities comprise: formulating the quality policy, identifying quality objectives, defining the organizational structure, assigning authorities and responsibilities, appointing the management representative, periodically reviewing the quality system, and identifying and making available the resources and personnel necessary to maintain the system and achieve quality objectives. Management communicates the importance of the quality objectives through the publication of quality metrics throughout the organization. These metrics are used as management tools to measure the continual improvement of the quality system and quality objectives.

Procedural Policies

1. Management Representative

    1.1. Esterline Advanced Input Systems appoints as the Management Representative the Director of Quality. The Director has the authority and responsibility to ensure that the quality management system is maintained and that the system complies with the requirements of the ISO 9001:2008 and ISO 13485:2003/NS-EN ISO 13485:2012 standards.

2. Organization

    2.1. Interrelation of personnel who manage, perform, and verify work affecting quality is defined in the organizational chart enclosed at the end of this section.

    2.2. The Esterline Advanced Input Systems organization comprises the following departments:

Business Development Unit headed by the VP of Business Development which includes the following functions:
- Engineering
- Sales and Marketing
- Business Development - Medical
- Business Development – Military and Industrial

Business Development Unit headed by the VP of Gaming which includes the following functions:
- Engineering
- Sales and Marketing
- Business Development - Gaming

Operations department headed by the VP of Operations which includes the following functions:
- Manufacturing
- Receiving, Stores, Shipping, and Production Control
- Facilities
- Manufacturing Engineering
- Purchasing and Material Planning
- Order Fulfillment
- Quality Management System

Procurement Quality
Quality Engineering
Offshore Operations
Offshore Material Purchasing
Service

Human Resources department headed by the VP of HR

Finance department headed by the VP of Finance which includes
Export Compliance
Information Technology

The President and the department heads constitute the executive management.

3. Responsibilities

3.1. Executive Staff

Formulates the quality policy and quality objectives.
Initiates and supervises the Quality Management System.
Provides resources necessary to maintain the system.

3.2. Business Development Units

Provides regional sales support and staff
Establishes functional specifications of products and associated services (product briefs).
Provides customer liaison and service.
Handles customer complaints.
Carries out contract and order reviews.
Prepares product specifications from product briefs or customer-specified requirements.
Designs products.
Initiates design reviews.
Verifies and tests the designs.
Documents design outputs.
Collects field reliability data.
Assigns action items where improvement is needed to meet the quality policy and quality objectives.

3.3. Marketing

Conducts market research and analysis to establish the desired quality characteristics of products.
Advertises and promotes company's products emphasizing their quality aspects.

3.4. Engineering

Provides Technical Staff engineering expertise
Designs products.
Manages R&D and Technology Projects
Provides PCB Design Services
Provides Graphic Design Services
Responsible for Component Engineering
Maintains Test Engineer Lab facilities
Maintains Model Shop facilities
Maintains CAD Tools
Coordinates document control activities.

3.5. Operations

Manufacturing
Receiving, Stores, Shipping, and Production Control
Facilities
Manufacturing Engineering
Purchasing and Material Planning
Order Fulfillment
Quality Management System
Procurement Quality
Quality Engineering
Offshore Operations
Offshore Material Purchasing
Service

3.5.1 Manufacturing

Determines production personnel and equipment requirements.
Controls and monitors processes.
Defines workmanship standards.
Maintains production equipment.
Administrates storage areas.
Performs production engineering.
Prepares and maintains production plans.
Performs inspection & testing in accordance with the Quality plans.
Prepares quality plans
Maintains inspection and test records.

3.5.2 Purchasing

Selects qualified suppliers and subcontractors.
Prepares and approves purchasing documents.

3.5.3 Order Fulfillment

Processes customer orders and plans supply requirements to fulfill customer orders.

3.5.4 Service Department

Provides warranty repair, non-warranty repair, and product upgrade services.

3.6 Quality

Establishes and maintains the quality management system.
Verifies quality and quantity (catalog items only) of received goods.
Carries out supplier quality surveys and audits.
Monitors and assesses supplier performance.
Performs incoming inspections and testing in accordance with the quality plans.
Maintains incoming inspection and test records.
Manages nonconforming material
Maintains and calibrates inspection, measuring and test equipment.
Audits implementation of the quality management system.
Manages the corrective actions and preventive actions system (CAPA).
Schedules and conducts quality system reviews, identifying areas of improvement.
Performs supplier audits, receiving inspection and first article inspection
Manages nonconforming material.

3.7 Human Resources

Defines personnel qualification requirements.
Implements measures to motivate personnel.
Facilitates training.

3.8 Offshore Operations

Selects qualified suppliers and subcontractors.
Offshore Commodity Management

3.9 Information Technology

Provides the company with basic IT infrastructure including but not limited to the following:
Personal computers and appropriate software
A LAN for information and data storage
Communication systems in the form of e-mail and PBX
Backup and archiving of digital quality records

3.10 Finance

Provides Export Compliance
Establishes and maintains ITAR/EAR export affected projects and programs.
Provides Information Technology

4. Management Review

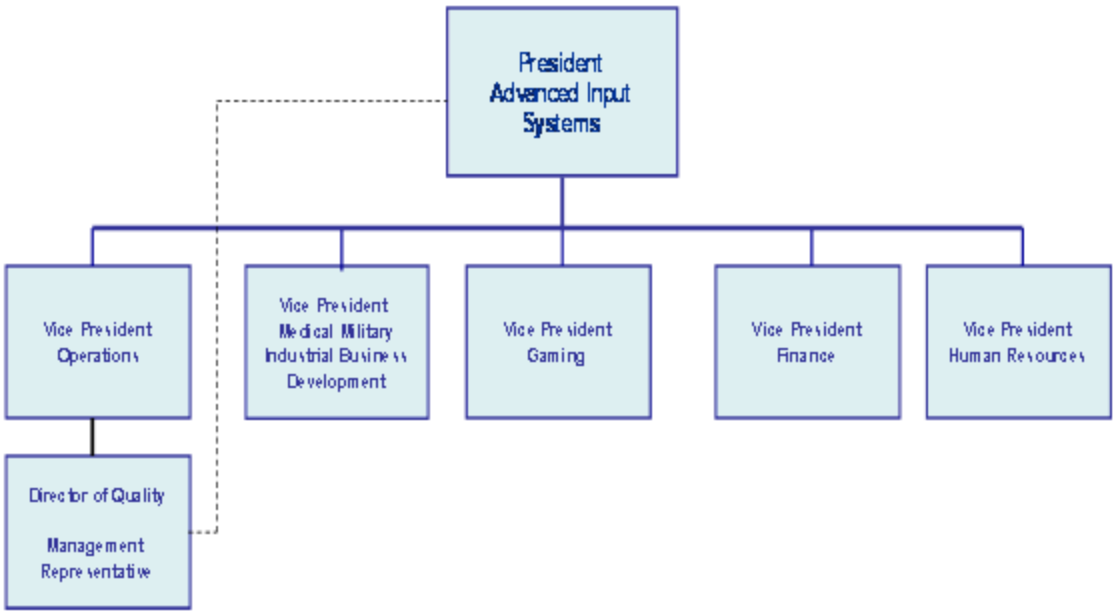
4.1 The company's executive management reviews the quality system and plan at least semi-annually with the intent on conducting them on a quarterly basis. The purpose of the review is to assess the effectiveness of the quality system, review the quality policy and quality objectives to assure continuing suitability, verify compliance with regulatory and statutory requirements, to assign and implement actions to achieve planned results and continual improvement of the quality system. The input and output elements of the management review are defined, including any new or revised regulatory requirements.

The Director of Quality is responsible and authorized for scheduling and conducting the reviews. Conclusions of the reviews are recorded. Detailed rules for scheduling, conducting, and recording the reviews are provided in Procedure P01_01, Management Review.

5. Internal Communications

5.1 Management communicates information throughout the company regarding the company's quality policy, quality objectives, performance improvement metrics, and compliance with regulatory and statutory requirements. There are performance metrics posted throughout the company on bulletin boards. These metrics are supportive of the quality objectives in that they have direct or indirect relationships to the continual improvement of product and process quality, on-time delivery, and customer satisfaction.

Advanced Input Systems
Senior Management



SECTION 2. QUALITY SYSTEM

General Policy

Esterline Advanced Input Systems maintains a documented quality management system designed and implemented to fulfill ISO 13485 requirements. This system creates a framework for clearly defining the control of materials, processes, and verification activities, thus providing our customers with confidence that the design, manufacture, and servicing of Esterline Advanced Input Systems products are performed in a well defined and controlled environment.

Procedural Policies

1. Documentation

1.1. The scope of the quality system is defined in the following documents including one complete set of last obsoleted:

Quality manual
Operational procedures
Work instructions, process procedures and internal standards
Applicable national and international standards
Product drawings, bills of materials, specifications
Production and quality plans

1.2. These documents collectively define a quality system that complies with ISO 13485. Operational procedures P05_01, Quality System Documentation, P05_02, Engineering Document Control, and P05_03, Manufacturing Document Control, explain the purpose and the methods for controlling these documents.

1.3. Esterline Advanced Input Systems has defined a description of the interaction between the processes of the quality system. The detailed flow diagram is described in Appendix A.

1.4. Esterline Advanced Input Systems' Quality System documentation extends throughout all aspects of the organization. The documentation is structured into levels, as described below:

Level 1

Documentation is contained within the Quality Manual and includes the company's quality policy and objectives. Level 1 documentation is approved by the executive management. Additional approvals may be obtained as deemed necessary.

Level 2

Documentation is contained within the Policies and Procedures manual and includes departmental policies and procedures. Level 2 documentation is approved by at least the department manager. Additional approvals may be obtained as deemed necessary.

Level 3

Documentation is kept accessible within the appropriate work areas and contains specific work instructions for inspection, distribution, assembly and test. Level 3 documentation is approved by the appropriate Engineering or Management functions.

Level 4

Documentation includes forms used in the organization.

2. Quality System Implementation

2.1. All personnel who manage, perform, and verify work affecting quality are authorized and responsible for implementing the quality system. The Director of Quality is responsible for coordinating, monitoring, and auditing the system.
2.2. Implementation of the quality system is assessed regularly by way of Internal and external audits and management reviews.

3. Quality Planning

3.1. SOP's (Standard Operating Procedures) are developed and published for each area, which define the specific steps within the process. Consideration is given to process controls and equipment, design compatibility, and inspection and testing.
3.2. Quality planning is performed by senior management through the review of key quality metrics, setting targets, and reviewing progress towards goals. Minutes of these reviews are recorded and published.

SECTION 3. CONTRACT REVIEW

General Policy

All contracts and orders are reviewed to assess if customer's requirements are adequately defined and are well understood, and if the company has the capacity to meet the contractual requirements. A thorough review of all contracts and orders allow the company to enhance customer satisfaction.

Procedural Policies

1. Responsibility

    1.1. The Customer Service Representatives are responsible and authorized for receiving and processing all Purchase Orders. Contracts for products are reviewed by the Sales, Engineering, and Manufacturing functions prior to committing to contracts.

2. Contract Review

    2.1. Contracts are reviewed by the appropriate functions to verify that the customer's requirements are adequately defined and documented, and have been well understood; and that the company has the capacity to meet the contract requirements. If applicable, a Sales Order Review milestone meeting may be called to review/authorize the project to proceed.

    2.2. All contracts are reviewed to determine any delivery and post-delivery requirements, requirements necessary for use, statutory and regulatory requirements, and any additional requirements determined by Esterline Advanced Input Systems.

3. Amendment to Contract

    3.1. Change orders are received and reviewed by the same functions that are responsible for the review of initial purchase orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements.

4. Order Fulfillment

    4.1 Customer purchase orders are entered as customer orders, they are scheduled and acknowledged back to the customer. Job orders are released by master scheduling to the manufacturing floor to be assembled. When job order delivery will impact customer order delivery, delays are communicated to customer service when delivery is impacted to the customer.

5. Customer Communication

    5.1. Sales, Manufacturing Engineering, Design, and Service provide communications with the customer regarding product or project status, order status, change orders, customer complaint feedback, adverse events, and advisory notices.

6. Records

6.1. All contracts/purchase orders are recorded. For recurring production orders, a copy of the quote, customer purchase order, and Esterline Advanced Input Systems sales order constitutes a record of the contract review. More details regarding establishment and maintenance of contract review records are provided in procedure P03_01. Procedure P16_01, Quality Records, stipulates the storage location and retention period for the contract review records.

SECTION 4. DESIGN CONTROL

General Policy

The design process is planned. Design activities are identified, responsibilities for carrying them out are assigned, and organizational interfaces are defined and controlled. The design input is formally documented and reviewed. The design is verified and, when applicable, validated to ascertain that it meets the design input requirements. The design output is documented and checked before it is released for production. Design changes are controlled.

Procedural Policies

1. General

    1.1. Esterline Advanced Input Systems designs products to customer specifications. The design team within the Business Unit is authorized and responsible for design and development review. At each stage, any uncovered problems have appropriate actions proposed. The quality management system for design is defined in Procedure P04_01, Design Control and P04_06, NPI Management Review. All design review and design change records are retained.

2. Design Input

    2.1. The design input is provided to the Business Unit by Sales via customer supplied specifications. Applicable information may be derived from previous similar designs. If applicable, a Sales Order Review milestone meeting may be called to review/authorize the project to proceed.

3. Design Planning

    3.1. Project Management is responsible for the planning of design projects, including assignment of design activities and control of organizational and technical interfaces.

    3.2. Risk management is addressed in accordance with product, procedural, contractual, or regulatory requirements per P04_07.

4. Design Verification and Validation

    4.1. As a minimum, every design is verified by holding and recording design reviews and undertaking qualification tests and demonstrations or prototypes as applicable. Design verification activities are described in Procedure P04_01.

    4.2. Design validation is performed to ensure product conforms to customer needs. Design validation activities are described in Procedure P04_01.

5. Design Output

    5.1. Design output is documented on two levels: Primary output consists of documents defining the designed product, verifying design-input requirements have been met, while the secondary output supports the design with calculations, analysis, etc. Design output documents define all acceptance criteria, special procurement requirements, production needs, or servicing provisions, and any applicable safety or other critical characteristics.

Design output documents are checked and approved before they are released for production. Establishment, verification, and release of design output are governed by Procedure P04_01.

6. Design Changes

6.1. Design changes are initiated using Engineering Change (EC) forms, as documented in Procedure P04_02. EC's may be initiated by Marketing, Sales, Operations, Quality Assurance, Technology, or the Business Unit. The EC provides design input for changing the design. Design changes assess the effect of work in process and delivered product. Planning, design, and design verification/validation activities follow the same rules as apply to original designs, as documented in Procedure P04_01.

6.2. Deviations to product designs are generated using a Deviation form, as documented in Procedure P04_03. A deviation is a temporary and intentional change to the design of the product. Deviations may be initiated by any employee but will be approved by design engineering, manufacturing engineering, program manager, and materials prior to implementation. A deviation has a defined purge date.

SECTION 5. DOCUMENT AND DATA CONTROL

General Policy

The purpose and scope of quality system documents and data are defined. All documents and data are reviewed and approved prior to issue. The quality manual and operational procedures are issued by the Quality Assurance department. Product drawings and specifications are issued by the Business Units. Other documents and data are issued directly by the departments to which they pertain. Appropriate documents and data are available at locations where they are used. Obsolete documents and data are removed from points of use. Central Services is responsible for coordinating & enforcing the document and data control-related activities.

Procedural Policies

1. Quality System Documentation

    1.1. Esterline Advanced Input Systems quality system documentation comprises the following types of documents:
    - Quality manual
    - Operational procedures
    - Work instructions and process procedures
    - Standards and other reference material
    - Product drawings and specifications
    - Production and quality plans
    - External origin documents

    1.2. The purpose, scope, and responsibility and authority for controlling quality system documents are defined in Procedure P05_01, Quality System Documentation, P05_02, Engineering Document Control, P05_03, Manufacturing Document Control, and P05_04, Export Compliance.

2. Document Approval and Issue

    2.1. Documents and data and document changes may be initiated by anyone in the organization, but may only be issued by an authorized department. The authorized departments and the rules governing issue of documents are defined in procedures P05_01, Quality System Documentation, P05_02, Engineering Document Control, and P05_03, Manufacturing Document Control. All documents and data are reviewed and approved prior to issue. All distributed documents are reviewed to ensure they remain legible and identifiable.

3. Document Placement

    3.1. Documents and data are distributed to personnel and locations where they are used. When appropriate and relevant, documents display a distribution list. Engineering document placement is regulated by Procedure P05_02.

4. Document Changes

    4.1. Document and data changes are reviewed and authorized by the same function that issued the original document and data. Revised portions of documents are distributed with a change brief. Obsolete documents and data are removed. Each controlling department maintains a master list specifying the latest issues and revisions of its documents and data.

    4.2. Obsolete documents and data are retained and suitably identified.

5. Documentation Audits

5.1 Periodically, audits are conducted of each document island and of the top level electronic files and ensure they match the master index and original released file cabinet. The document islands will also be audited to verify external origin documents are distributed and they match the master index.

6. Export Compliance

6.1. Export Compliance processes are managed by the authorized Empowered Official. All exports are coordinated through the Empowered Official and the appropriate government agencies.

SECTION 6. PURCHASING

General Policy

Esterline Advanced Input Systems assesses it suppliers and procures only from those that can meet or exceed the quality requirements of the company. Quality performances of suppliers and subcontractors are continuously monitored. Purchasing documents clearly and completely describes ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release.

Procedural Policies

1. Responsibility

    1.1. Assessment and quality performance monitoring of suppliers are the responsibility of Purchasing and Quality Assurance.

2. Assessment and Monitoring

    2.1. Quality capabilities and references of suppliers are assessed before ordering materials, components, and services. Quality performance of all suppliers is continuously monitored. The system for assessing and monitoring suppliers is defined in Procedures P06_03, Supplier Qualification Process, P06_07, Supplier Quality Reporting and Monitoring, and P06_08, Supplier Quality Communications Procedure.

3. Purchasing Data

    3.1. Purchasing documents are prepared by the Purchasing Department. These documents adequately describe the products to be ordered. They include precise identification of the products, reference applicable standards, and quality requirements. Purchasing and Quality Assurance are authorized and responsible for the suppliers adhering to these documents.

    3.2. Rules applicable to preparation, review, and approval of purchasing documents are provided in Procedure P06_02, Purchasing.

4. Customer Verification of Purchased Product

    4.1. Our customers are normally given the right to verify for themselves that the purchased products conform to specified requirements, either at our site or the supplier's facilities. Customer verification does not absolve us from the responsibility to deliver a quality product. Procedure P06_02 contains further instructions regarding customer verification of purchased products.

5. Esterline Advanced Input Systems Verification of Purchased Product

    5.1. As needed, Esterline Advanced Input Systems may perform source inspection at our supplier's premises. When source inspection is to be performed, the arrangements and methods of verification are documented to the supplier.

SECTION 7. CUSTOMER SUPPLIED PROPERTY

General Policy

Customer supplied property is handled in the same manner as other products purchased for incorporation into the supplies. When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures. Loss, damage, or unsuitability of a customer's property is recorded and reported to the customer.

Procedural Policies

1. Responsibility

    1.1. The Purchasing department is authorized and responsible for coordinating with the customer the reception of customer supplied property.

2. Receiving

    2.1. Customer supplied property is received, inspected, and tested in the same manner as other purchased products. Procedure P07_01, Customer Supplied Property, contains further instructions in this regard, and references appropriate procedures governing the receiving and inspecting of customer supplied property.

3. Marking, Storage, and Handling

    3.1. Marking, storage, handling, and preservation of customer supplied property also follow the same procedures that apply generally to purchased products.

4. Special Requirements

    4.1. When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures.

5. Loss or Damage

    5.1. The customers are contacted in the event of loss, damage, deterioration, or unsuitability of their property.

SECTION 8. PRODUCT IDENTIFICATION AND TRACEABILITY

General Policy

Materials, components, subassemblies, and products are identified by a part number correlated to corresponding drawings, specifications, and other technical documents. Finished products are uniquely identified by serial numbers. When traceability is specified by a customer, the unique identification of the customer product is documented.

Procedural Policies

1. Responsibility

    1.1. Each Business Unit is authorized and responsible for assigning part numbers and for maintaining the pertinent documentation and records.

    1.2. Receiving and Production are responsible and authorized for marking/labeling purchased products and manufactured parts/subassemblies and finished products with their required product identification labeling. All personnel handling products are responsible for maintaining the identification.

2. Material, Part, and Product Identification

    2.1. All purchased and in-house manufactured materials and parts are identified with the company's internal part numbers assigned by the Engineering department. The part numbers provide for correlation between a part and its technical documentation.

    2.2. Finished products are labeled with a unique serial number and/or lot code to allow for traceability of product configurations.

    2.3. Assignment, marking, and maintenance of product identification are regulated by Procedure P08_01, Product Identification and Traceability.

3. Records

    3.1. The Business Units and/or Central Services maintain the part number lists and associated technical documentation. The part number of a product is the key to correlation with its technical documentation.

SECTION 9. PROCESS CONTROL

General Policy

Production and individual operations are planned and documented. Personnel performing complex or critical operations are provided with work instructions and, when applicable, workmanship criteria. Special processes are controlled and are carried out in accordance with written procedures. Production and process equipment is checked and maintained to ensure continuing process capability. Production areas are regularly cleaned to provide a suitable production and working environment.

Procedural Policies

1. Production Process

    1.1. The general production process is specified on a routing prepared by the Manufacturing Engineering department.

    1.2. The routing may list all production work centers and the sequence of work necessary to manufacture and verify products. Procedure P09_01, Process Control, instructs in establishment and use of the routing.

    1.3. A specific build of a product is defined on a factory work order. The factory work order identifies the quantity, configuration, and due date for the specific order.

2. Work Instructions

    2.1. For complex and/or important production operations, production personnel are provided with work instructions. Work instructions are established by the responsible Manufacturing Engineer and are reviewed by the Production Manager. The criteria for evaluating when work instructions are needed, and the rules for issuing and controlling them, are stipulated in Procedure P09_01, Process Control.

3. Process Control and Monitoring

    3.1. Production processes are controlled by written process procedures, process operator training and/or qualification, process equipment qualification, or continuous process monitoring and statistical analysis.

    3.2. The Manufacturing Engineer is responsible and authorized for selecting appropriate process control methods for particular processes. Simple and verifiable processes are not formally controlled.

    3.3. Special processes (results cannot be verifiable) are always controlled using one or more methods listed in 3.1. The Manufacturing Engineer department identifies and qualifies special processes. The relevant activities are regulated by Procedure P09_01.

4. Production Equipment and Environment

    4.1. Production equipment and its supporting software and machines are regularly maintained following the schedules and recommendations provided by their manufacturers, or as specified by Manufacturing Engineering. Performance and accuracy of the equipment is continuously monitored. Maintenance records are created and available.

    4.2. Suitable production environment is ensured by proper maintenance of buildings and HVAC equipment, and by regular cleaning of the production areas.

SECTION 10. INSPECTION AND TESTING

General Policy

Inspection and testing are conducted when purchased materials and components are received, at significant stages of production, and prior to dispatch of finished products. The objective of inspections and testing is to verify product conformance with specified requirements. Materials, components, subassemblies, and finished products are prevented from use, assembly, and dispatch until the required inspections are completed. Records of inspections are established and maintained as evidence that products comply with stated requirements.

Procedural Policies

1. Receiving Inspection

    1.1. All purchased products are subject to either a one- or a two-stage receiving inspection. First all products are inspected visually by the receiving clerk, and then designated products and products that have been custom manufactured to Esterline Advanced Input Systems requirements are subject to a more detailed and technical QA inspection. Nonconforming products are segregated and are prevented from use in production. Whenever urgency dictates, product can be released to production with proper identification as described in Procedure P13_01, Control of Nonconforming Product. Procedure P10_01, Receiving Inspection, sets forward detailed rules for performing and recording receiving inspections. Procedure P10_08, Custom Color Management Procedure, defines the process for generating and obtaining approval for custom color products.

    1.2. First Article Inspections are performed to verify that piece parts and tooling manufactured by internal and external suppliers meet specifications and engineering drawing requirements. Procedure P10_04, First Article Inspection, describes the process for this type of inspection.

2. Final Inspection

    2.1. All finished product lots are subject to the final inspection. Final inspection may be 100% or on a sampling basis. Only those products that pass the final inspection are admitted to the finished products store or shipping. Performing and recording the final inspection is regulated by Procedure P10_03, Final Inspection.

3. Inspection Equipment and Procedures

    3.1. Carrying out the inspections, the inspectors or production personnel use appropriate and calibrated measuring and testing equipment.

    3.2. For complex inspection operations, inspectors are provided with inspection procedures and/or checklists as part of the standard process of documentation.

4. Inspection and Test Records

    4.1. All types of inspections are concluded with establishment of an inspection record. Inspection and test records show clearly whether the products have passed or failed according to the defined criteria. Rules for establishing these records are described in procedures P10_01, P10_03, and P10_04. Filing and maintenance of inspection records are regulated by Procedure P16_01, Quality Records.

SECTION 11. INSPECTION, MEASURING AND TEST EQUIPMENT

General Policy

Accuracy of the required measurements is known and appropriate equipment is selected to perform the measurements. All measuring and test equipment used for verification of products is calibrated using calibration standards traceable to the national standard. Calibration records are maintained. The calibration status of measuring equipment is identified with calibration stickers. The equipment is well maintained and its placement and use are controlled.

Procedural Policies

1. Scope

    1.1. All measuring and test equipment, comparative references (such as gauges and templates), used for verification of products and for controlling of critical production processes are regularly calibrated and/or verified. Critical production processes will be identified by either Manufacturing Engineering or Quality Engineering.

    1.2. Equipment used for purposes other than verification of products or control of critical production processes is exempted from the requirement for calibration. Such equipment is labeled with stickers warning that it is not calibrated.

2. Measurement Identification

    2.1. Measurements and the required accuracy are identified on drawings by the Engineering department. Manufacturing Engineering, Quality Engineering, and Test Engineering are responsible and authorized for selecting suitable equipment to perform the measurements.

3. Calibration and Maintenance

    3.1. The Calibration Lab is responsible and authorized for calibrating and maintaining the measuring and test equipment. All active equipment is entered on a controlled list, indicating the calibration status and the locations where the equipment is placed.

    3.2. Measuring equipment is calibrated using written instructions, ensuring environmental conditions are suitable. Only calibration instruments and standards having known relationship to nationally recognized standards are used for calibrating the measuring and test equipment.

    3.3. Calibration is recorded in a calibration database and the calibrated equipment is labeled with a calibration sticker.

    3.4 Equipment found and verified to be out of calibration is assessed and the validity of previous results is documented.

    3.5 Proper handling, preservation, and storage of measuring equipment are maintained.

    3.6 Calibration personnel take the appropriate and necessary steps to prevent any unauthorized adjustments.

    3.7 All calibration-related activities are regulated by Procedure P11_01, Inspection, Measuring, and Test Equipment.

4. Production Test

4.1. Test software is validated before it is used for verification of products. Software is re-validated or re-certified whenever there is a change of conditions for which it was initially validated.

4.2. Production test equipment is calibrated and maintained as described in Procedure P11_02, Production Test Controls.

SECTION 12. INSPECTION AND TEST STATUS

General Policy

Inspection and Test status of a product is identified to assure that only product that has passed inspection or test is used, installed, or dispatched. Authority responsible for the release of conforming product is defined.

Procedural Policies

1. Responsibility

   1.1. QA inspectors and other personnel authorized to carry out inspections and testing are responsible for documenting the results of the inspection or test. All personnel handling products are responsible for maintaining the identification.

2. Inspection Status

   2.1. A product's inspection status is maintained throughout the processes. The appropriate inspection status of product and release authority is defined in Procedure P12_01, Inspection Status.

3. Test Status

   3.1. A products test status is maintained throughout the processes. The appropriate test status of product and release authority is defined in Procedure P12_03, Production Test Status.

SECTION 13. CONTROL OF NONCONFORMING PRODUCT

General Policy

Nonconforming product is identified, documented, evaluated, and prevented from being used or shipped. Responsibility and authority for disposition of nonconforming product is defined and, when required, the customer is contacted for concession. Repaired or reworked product is reinspected.

Procedural Policies

1. Identification and Documentation

   1.1. Esterline Advanced Input Systems identifies and documents nonconforming products using a nonconformity report form. The nonconformity reports are an invaluable tool in tracking performance and trends that give indication where and when a corrective action is required.

   1.2. The use of the form and its processing are explained in Procedure P13_01, Control of Nonconforming Product.

   1.3. To prevent nonconforming products from being used or shipped, they are rejected and are segregated with a copy of the nonconformity report.

2. Nonconformity Review and Disposition

   2.1. Manufacturing Managers and Manufacturing Engineers may make the disposition decision for a nonconforming product when it is obvious that the product must be scrapped or regraded, or if it can be repaired by a simple process without affecting its quality. In all other cases, it is the Manufacturing Engineer together with the Quality Engineer and, when required, the Business Unit representative that make the disposition decision.

   2.2. The disposition decision may be:

   Accept, product is conforming,
   Rework or repair,
   Use-as-is,
   Scrap
   Return To Vendor
   Sort

   2.3. When required, the customer is contacted for acceptance by concession of a nonconforming product.

   2.4. If nonconforming product is detected after delivery or usage, appropriate actions are taken to address the issue. Amongst the options are P13_01, Control of Nonconforming Product, P13_02, QA Ship/Hold Release, and P14_01, Control of Internal Corrective Action.

   2.5. Detailed rules for nonconformity review, for making the disposition decision, and for recording these activities are provided in Procedure P13_01, Control of nonconforming Product.

3. Reinspection

   3.1. Repaired or reworked products are reinspected in accordance with procedures P10_01 or P10_03, as applicable.

4. Product Build/Ship Hold

4.1. Esterline Advanced Input Systems identifies and documents products and shipments that have been deemed not fit for customer use. The use of the form F13_02 is explained in Procedure P13_02, Product Build/Ship Hold.

4.2. All actions required to release product for shipment are identified on the Product Build/Ship Hold form.

4.3. After all actions are completed, the Hold/Release form is routed for approval and Quality Assurance distributes Release notice via E-Mail.

SECTION 14. CORRECTIVE AND PREVENTIVE ACTION

General Policy

Causes of product and quality system nonconformities are investigated and corrective actions are implemented to prevent their recurrence. Processes, work operations, quality records, service reports, and customer complaints are analyzed to detect any sources of potential quality problems in order to initiate preventive actions. Controls are applied to ensure that corrective and preventive actions are implemented and that they are effective.

Procedural Policies

1. Corrective Action

1.1 Initiation of Corrective Actions

Anyone in the company may initiate a corrective action request. Quality Assurance assigns the responsibility to define and implement the corrective action.

Corrective actions may be initiated as the result of:

- Identification of product nonconformity,
- Problems with a process or operation,
- Noncompliance's observed during audits,
- Customer complaints,
- Nonconforming deliveries from suppliers or subcontractors, and
- Other occurrences of nonconforming conditions.
- Notification by regulatory agencies.

An investigation occurs to determine the root cause of the nonconforming condition. The results are verified as effectively implemented and recorded.

Procedures P14_01, Control of Corrective and Preventive Actions, and P14_05, Control of Supplier Corrective Action provides a complete list of the relevant nonconforming conditions, and describes in detail the rules that apply to initiating a corrective action request.

1.2 Follow Up

Audit corrective action plans are followed up by Internal Auditors to determine if the action has been implemented and if it is effective prior to closing.

1.3 Customer Complaints

The Business Units are responsible and authorized for receiving and processing customer complaints, advisory notices, and adverse events notifications.

Every received complaint, advisory note, and adverse events notification is evaluated and, when relevant, is communicated to the functions concerned. Quality Assurance and/or Customer Service decide how to

respond to the customer and, when appropriate, request corrective or preventive actions to be implemented within the organization.

2. Preventive Action

2.1 Initiation of Preventive Actions

Anyone in the company may initiate a preventive action request. Quality Assurance assigns the responsibility and authority to define and implement the preventive action.

Preventive actions may be initiated as the result from processes and work operations which affect:

- product quality
- concessions
- audit results
- quality records
- service reports
- customer complaints
- other potential occurrences of nonconforming conditions

2.2 Follow-up

An investigation occurs to determine the root cause of the potential nonconforming condition. The results are verified and may be recorded.

Relevant information on preventive actions taken is submitted for management review.

Procedure P14_01, Control of Corrective and Preventive Actions, describes in detail the rules that apply to initiating a preventive action request.

SECTION 15. HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

General Policy

Methods and means of handling that prevent product damage and deterioration is provided. Receipt and dispatch to and from storage areas are controlled. The condition of stored products is assessed regularly. Packaging is specified and controlled. Products are protected prior to and during delivery.

Procedural Policies

1. Handling and Preservation

    1.1. The Stockroom Manager is responsible and authorized for product handling and preservation; in particular, ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and that operators are trained in use of the equipment, and that products are adequately protected during production, storage, and delivery.

    1.2. Procedure P15_01, Material Handling General, describes in detail the implementation of these policies. Procedure P15_06, ESD Control Policy, describes the practice for the prevention of damage to product due to electrical overstress and electrostatic discharge.

2. Storage

    2.1. The stockrooms and storage areas, and their operation, is the responsibility of Materials management. Only products that are properly identified and that have passed the mandatory inspections are authorized to enter and leave the stockrooms. On a periodic basis the stockrooms are cleaned up and are inspected to assess the condition of stock. Procedure P15_04, Receiving Product, describes the methods of material transfers from Receiving to stock. Procedure P15_05, Stockroom Material Request Process, provides inventory transaction steps for inventory movement.

    2.2. Procedure P15_02, Storage, governs the operation of stockrooms and storage areas, and the assessments of stock.

3. Packaging and Delivery

    3.1. Packaging is specified by the Business Unit. The specifications are communicated to the shipping personnel in the form of drawings and work instructions. Packaging is designed for the intended means of delivery.

    3.2. After the final inspection, products are protected and stored in adequate conditions to prevent damage and deterioration. If delivery is specified, it is subcontracted only to prequalified shippers.

    3.3. The activities of packaging and delivery are governed by Procedure P15_03, Packaging and Delivery.

SECTION 16. QUALITY RECORDS

General Policy

Quality records demonstrate achievement of the required quality and effective operation of the quality system. The records are identified, indexed, and stored in a suitable environment to minimize deterioration. Records are normally stored by the department that is responsible and authorized for their establishment. Retention periods for quality records are defined.

Procedural Policies

1. General

    1.1. Quality records provide the evidence that product designs meet their design input requirements, that finished products conform to the design output requirements, and that the quality system is operated in accordance with documented procedures and that it is effective.

2. Establishment of Records

    2.1. Records are usually established by the personnel directly involved with the task, operation, or activity whose results need to be recorded.

    2.2. Records identify the product, person, or event to which they pertain and provide the relevant facts and data.

    2.3. Specific record formats are usually prescribed by the procedures that call for their establishment. These can be forms, reports, minutes of meetings, sign-offs or stamps placed on other documents, and so forth. Records can also be established and maintained in electronic media (computer files or databases).

    2.4. Quality records must be legible and stored and retained to prevent damage or deterioration.

3. Indexing and Storage

    3.1. Records are indexed and grouped to facilitate their retrieval. Binders, drawers, cabinets, etc., containing records are clearly labeled with identification of their content.

    3.2. The activities of identification, collection, indexing, filing, storage, maintenance and disposition of quality records are governed by Procedure P16_01, Quality Records.

4. Storage Location and Retention Periods

    4.1. Records are usually stored and maintained by the same department that initially established the record. Procedure P16_01, Quality Records, stipulates the storage locations for all types of records required by the quality system.

    4.2. Retention period for records is determined by the department that establishes and maintains the records. The retention period is determined on the bases of contractual obligations, warranty periods, useful life of products, legal considerations, etc. Procedure P16_01, Quality Records, stipulates the retention periods for all types of records required by the quality system.

SECTION 17. INTERNAL QUALITY AUDITS

General Policy

Comprehensive, planned, and documented quality audits are carried out at least twice a year. Audits are scheduled on the basis of the status and importance of the activity. The audits are conducted by personnel independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and a corrective action is requested.

Procedural Policies

1. Planning and Scheduling

    1.1. The QA department establishes the internal audit plan and schedule in accordance with Procedure P17_01, Internal Quality Audits. Every activity and area is audited at least semi-annually. Selected activities may be audited more frequently, depending on their importance and quality performance history.

    1.2. Export Compliance audits are conducted at least annually or as requested by Esterline. They are conducted in accordance with P17_04.

2. Audit Team and Preparation for Audit

    2.1. Only personnel independent of the audited activities are assigned to conduct the internal audits.

    2.2. Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists. Selection of auditors and preparation for the audit are explained in Procedure P17_01, Internal Quality Audits.

3. Conducting the Audit

    3.1. Conducting the audit, auditors seek objective evidence whether the audited activities comply with the requirements of the documented quality system. The evidence is collected by observing the activities, interviewing personnel, and examining quality records.

    3.2. Nonconforming conditions are documented and recorded. A model of the form and instructions on how to use it are provided in Procedure P17_01.

    3.3. Audits are conducted in a way that minimizes disruption of the audited activities.

4. Corrective Action and Follow-up

    4.1. When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to propose and implement a corrective action. Implementation and effectiveness of the action is verified by a follow-up audit.

SECTION 18. RESOURCE MANAGEMENT

General Policy

The company provides the appropriate resources to implement and maintain the quality management system in order to continually improve its effectiveness and its ability to enhance customer satisfaction. The company identifies training needs of all personnel and provides the required training. Personnel assigned to perform specific tasks are qualified on the basis of appropriate education, training, skills, or experience. Records of personnel qualifications and training are maintained.

Procedural Policies

1. Training Needs

    1.1. All employees are assessed at least annually by their supervisors or managers to determine if their qualifications are adequate and if they need to be supplemented by additional training.

    1.2. Occurrences of product nonconformities and problems with operations and processes may provide data for determining employee training needs.

2. Training Program

    2.1. Esterline Advanced Input Systems provides employee orientation training to all new employees. The training includes explanations of how the quality system works and how the employee should use and maintain the system.

    2.2. Training in skills and knowledge required to perform specific tasks is provided to employees directly by their departments. The training, skills, and knowledge, along with the employee's experience, improve the employee's competence.

    2.3. There is also an educational reimbursement program for employees who upgrade their qualifications by external education or training.

    2.4. Procedure P18_01, Training, describes in detail the training programs provided by Esterline Advanced Input Systems, including national or regional training needs.

    2.5. The Training Steering Committee evaluates the effectiveness of the training program.

3. Training Records

    3.1. Records of all internal and external training provided to employees are maintained.

SECTION 19. SERVICING

General Policy

Returned products are repaired and/or upgraded as an extenuation of production repair and the process is defined in Procedure P19_01, Product Repair and Upgrade.

Procedural Policies

1. Returned Material Process

1.1. The customer contacts the Service Coordinator and provides sufficient information to determine the initial status of the returned material. The Service Coordinator will then issue a return authorization and product is processed upon receipt.

1.2. Upon receipt, paperwork and product is verified as accurate. Discrepancies will be reported to the Service Coordinator for resolution. Customer requested corrective action, if required, will be generated at this time.

1.3. Service technicians will verify reported problem and determine repair needs. The status as to in-warranty, out of warranty, upgrade, lot rejection, or prototype is determined. The technicians also consult with appropriate personnel to assist with accurate response for corrective action request.

1.4. The Service Department will perform or coordinate repairs on returned materials and will communicate schedule and charge detail to the customer.

1.5. The Service Department will process or coordinate shipment of material for return to customer.

1.6. Quality records are generated and retained per P16_01, Quality Records.

SECTION 20. ANALYSIS OF DATA

General Policy

Where and when appropriate, data is collected and analyzed to demonstrate the effectiveness of the quality management system and to evaluate where continual improvement can be accomplished. Statistical techniques are employed to verify customer satisfaction, product conformity, delivery performance, and supplier performance.

Procedural Policies

1. Customer Satisfaction

   1.1. Customers are selected periodically and queried to determine their perceived satisfaction as to whether Esterline Advanced Input Systems has met the customers' expectations.

   1.2. The results of the periodic queries are compiled and published. The Strategic Business Manager will develop action plans as required. The customer satisfaction results are reviewed periodically. Procedure P20_02, Customer Satisfaction Survey, defines the process for obtaining and monitoring information related to customer perception as to whether customer requirements have been met.

2. Product Conformity

   2.1. Product conformity is measured throughout production using defect data collection methodologies and statistical techniques. Product returned for warranty repair is monitored and measured.

   2.2. Action items are generated and assigned to the appropriate personnel to take appropriate measures to prevent the recurrence of defects discovered during production. Corrective and Preventive Actions may be generated due to existing or potential product deficiencies.

3. Quality System Process Conformity

   3.1. Process characteristics are monitored throughout the company using metrics. These metrics are used as management tools to measure continual improvement of the quality system.

   3.2. Actions may be taken as appropriate address undesirable characteristics or trends. Corrective and Preventive Actions may be generated due to existing or potential issues.

4. Delivery

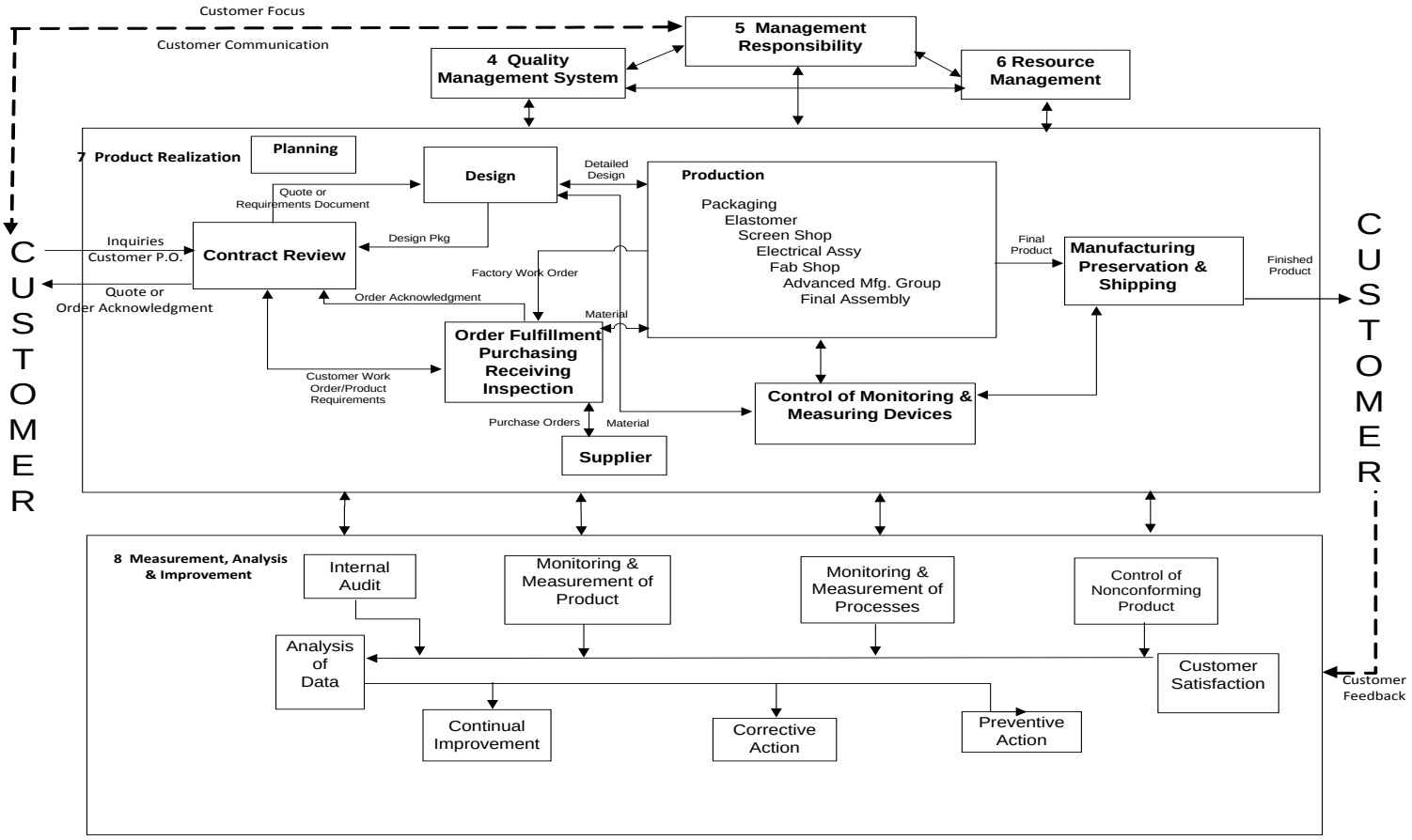
   4.1. Delivery performance is measured and published. Appropriate actions are assigned when necessary.

   4.2. When required, statistical techniques are employed in determining sample sizes for the receiving and in-process inspections. Personnel performing the inspections are provided with charts, tables, and other instructions in the use of the relevant statistical techniques. Procedure P20_01, Statistical Techniques, governs the application of statistical techniques to inspection sampling.

5. Supplier Performance

   5.1 Supplier performance for quality and delivery is periodically reviewed and appropriate actions are assigned to improve an individual supplier's performance.

APPENDIX A. PROCESS INTERACTION FLOW DIAGRAM



APPENDIX B. CROSS REFERENCE TABLE

ISO 9001:1994 elements and ISO 13485 sections

ISO 9001:1994	ISO 13485:2003
1. Scope	1
2. Normative reference	2
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4.1 Management responsibility (title only)	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization (title only)	
4.1.2.1 Responsibility and authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management representative	5.5.2
4.1.3 Management review	5.6.1 + 8.5.1
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4.2.2 Quality system procedures	4.2.1
4.2.3 Quality Planning	5.4.2 + 7.1
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4.4.9 Design changes	7.3.7
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ISO 9001:1994	ISO 13485:2003
4.6.4.1 Supplier verification at sub-contractors 4.6.4.2 Customer verification of sub-contracted product	
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4.11 Control of inspection, measuring and test equipment (title only) 4.11.1 General 4.11.2 Control procedure	 7.6 7.6
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4.13 Control of nonconforming product (title only) 4.13.1 General 4.13.2 Review and disposition of nonconforming product	 8.3 8.3
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4.15 Handling, storage, packaging, preservation & delivery (title only) 4.15.1 General 4.15.2 Handling 4.15.3 Storage 4.15.4 Packaging 4.15.5 Preservation 4.15.6 Delivery	 6.4 7.5.5 7.5.5 7.5.5 7.5.5 7.5.1 7.5.5
4.16 Control of quality records	4.2.4
4.17 Internal quality audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
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4.20 Statistical techniques (title only) 4.20.1 Identification of need 4.20.2 Procedures	 8.1 + 8.2.3 + 8.2.4 + 8.4 8.1 + 8.2.3 + 8.2.4 + 8.4

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4 QUALITY MANAGEMENT SYSTEM		
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	P05_03	Manufacturing Document Control
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	P05_07	**Technical Assistance Agreement (TAA) Procedure**
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7.2.1 Determination of requirements	P03_01	Contract Review for Custom Product related to the product

ISO 13485 ELEMENT	PROCEDURE	TITLE
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7.2.3 Customer communication	P03_01	Contract Review for Custom Product
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	P04_05	Design for the Environment
7.3.6 Design and development validation	P04_01	Design Control
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	P04_02	Engineering Change Control Policy
	P04_03	Deviation Polity and Procedure
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	P04_05	Design for the Environment
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7.4 Purchasing		
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	P06_03	Supplier Qualification Process
	P06_04	Procurement Ethics & Conflict of Interest
	P06_05	Delegation of Authority
	P06_07	Supplier Quality Reporting and Monitoring
	P06_08	Supplier Quality Communication Procedure
7.4.2 Purchasing information	P06_02	Purchasing
	P06_10	Country of Origin Guidelines
	P06_11	Obsolete Part Process
7.4.3 Verification of purchased product	P06_02	Purchasing
	P06_09	Supplier First Article Requirements
	P06_12	Receipt of Damaged Product into AIS
	P06_13	Material Transaction Policy
	P10_01	Receiving Inspection
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7.5.1 Control of production and service	P09_01	Process Control

	P15_03	Packaging and Delivery
	P19_01	Product Repair & Upgrade
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	P19_01	Product Repair and Upgrade
7.5.3 Identification and traceability	P08_01	Product Identification and Traceability
	P10_03	Final Inspection
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	P12_03	Production Test Status

ISO 13485 ELEMENT	PROCEDURE	TITLE
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7.5.5 Preservation of product	P15_01	Material Handling General
	P15_02	Storage Areas
	P15_03	Packaging and Delivery
	P15_04	Receiving Product
	P15_05	Stockroom Material Request Process
	P15_06	ESD Control Policy
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8.2.1 Customer satisfaction	P20_02	Customer Satisfaction Survey
8.2.2 Internal Audit	P17_01	Internal Quality Audits
	P17_04	Export Compliance Auditing
	P17_02	Product Audits
	P14_01	Control of Internal Corrective Action
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	P17_01	Internal Quality Audits
	P20_01	Statistical Techniques
8.2.4 Monitoring and measurement of product	P10_01	Receiving Inspection
	P10_03	Final Inspection
	P10_04	First Article Review
	P10_06	Skip Lot Sampling Program
	P10_08	Custom Color Mgmt. Procedure
	P20_01	Statistical Techniques
	P20_03	Foreign Object Debris (FOD) Prevention
8.3 Control of nonconforming product	P13_01	Control of Nonconforming Product
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	P14_01	Control of Internal Corrective Action
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	P09_01	Process Control
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	P14_06	Failure Reporting, Analysis and Corrective Action System
	P16_01	Quality Records
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	P14_05	Control of Supplier Corrective Action
	P14_06	Failure Reporting, Analysis and Corrective
8.5.3 Preventive action	P14_01	Control of Internal Corrective Action