

# **Engel Diversified Industries**

## **Quality Manual**

## **QUALITY POLICY**

Engel Diversified Industries strives to provide our customers with first class quality products on-time. In an effort to accomplish this EDi maintains a Quality Management System based upon customer satisfaction, continuous improvement, and a commitment to comply with all applicable requirements. These activities are sustained by EDi's Mission and Value Statements.

## **INTRODUCTION**

This manual defines the quality system and related processes used by EDi to manage its business and to achieve a world class quality level in our products and/or services. In addition, the Quality Manual sets the framework for EDi operations as well as continual improvement activities.

The quality system complies with the International Standard ISO 9001:2008

The quality system manual is divided into five sections modeled on the sectional organization of the ISO 9001 standard. Sections are further subdivided into several subsections representing main quality system processes and elements. Each subsection starts with a general policy statement expressing the commitment to implement basic requirements and principles for the pertinent quality system process or element.

The purpose of this manual is to define the quality system and describe the interaction between the processes of the system, to define authorities and responsibilities of the management personnel involved in the system, and to include procedural policies for the implementation of all processes comprising the quality system.

Another purpose of this manual is to present the quality system to our customers and other external interested parties, and to inform them what specific controls are implemented at Engel Diversified Industries.

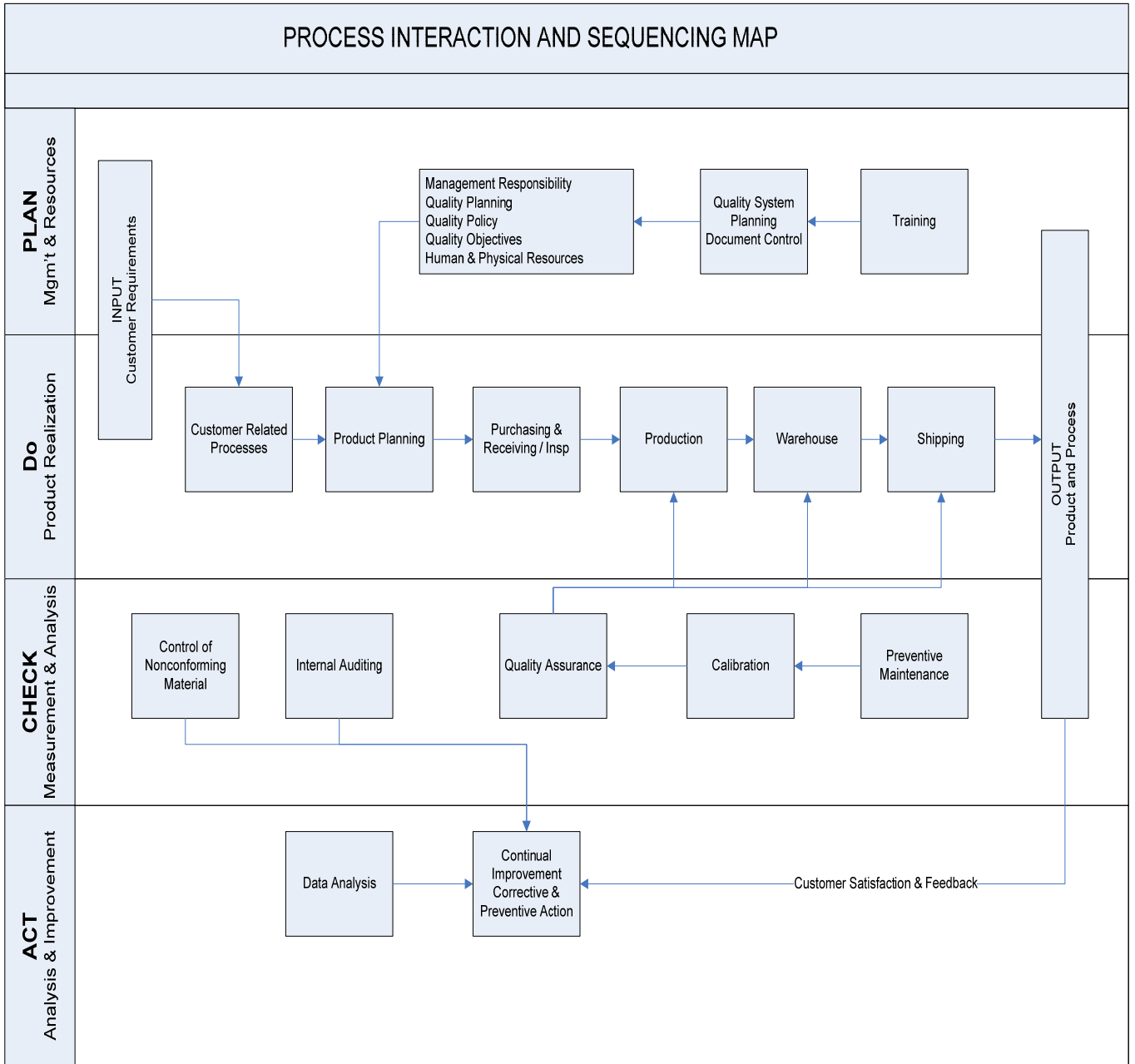
## **SCOPE**

EDi is a contract manufacturer of ferrous and non-ferrous stampings, deep drawing, metal fabrication, tube forming/fabrication and welding assembly.

## **EXCLUSIONS**

Because of the nature of our business we do not do design, and as such Engel Diversified Industries has identified the following quality system exclusions which are not part of our registrations scope: 7.3 Design and Development, and portions of 7.5.1 and 7.5.2 relating to Service Provisions.

## PROCESS INTERACTION AND SEQUENCING MAP



## SECTION 2 - QUALITY MANAGEMENT SYSTEM

### SECTION 4.1

#### Process approach

- 1.1 The quality management system is designed as a system of interrelated processes. The process approach is applied to the auditing of the system.
- 1.2 Quality system documentation defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

#### 2 Resources and information

- 2.1 Management Representative is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the top management. Top management is responsible for ensuring the availability of necessary resources and information. Quality Manual Section 6.1, Provision of Resources, explains in more detail how resource requirements are identified and satisfied.

#### 3 Monitoring and measurement

- 3.1 Performance of quality system processes is systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.
- 3.2 Performance of quality system processes is monitored through Performance to quality objectives (refer to Quality Manual section 5.4.1), and internal quality audits (refer to Quality Manual Section 8.2). The overall performance of the quality system is monitored by measuring customer satisfaction (refer to Quality Manual Section 8.2).
- 3.3 Quality system processes are reviewed and analyzed by the Management Review of the quality system (refer to Quality Manual Section 5.6 and **Management Review** minutes).

#### 4 Continual improvement

- 4.1 Quality management system processes are regularly reviewed by the top management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through management projects for achieving quality objectives and through corrective and preventive actions.
- 4.2 Quality Manual Section 8.5 defines how the quality management system itself ensures its own compliance and continual improvement.

## 5 Outsourced processes

5.1 When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate:

- Evaluation and/or pre-qualification of suppliers;
- Assessment of supplier realization processes and quality system;
- Monitoring of supplier quality performance;
- Requirements for process control, inspection, testing or other records demonstrating product conformity; and
- Containment and verification of the supplied product (used only as a temporary measure in conjunction with supplier corrective actions).
- Source has been recommended by the customer (mandatory)

Quality Manual Section 7.4 defines the purchasing control system.

5.2 Ensuring control over outsourced processes does not absolve Engel Diversified Industries of the responsibility of conformity to all customer requirements.

## SECTION 4.2 – DOCUMENTATION AND RECORDS

### 1 Quality system documentation

1.1 Quality system documentation comprises the following types of documents:

- Quality Assurance Manual (QAM), (including a documented quality policy and procedures);
- Statements of quality objectives as outlined in Metrics included in Management Review and Operations Review Presentations;
- Process and other work instructions;
- Reference manuals, standards and other technical references;
- Customer engineering documents; and
- Production and control plans.

Purpose, scope, and responsibility for controlling various types of documents are defined within this Quality Assurance Manual.

### 2 Quality manual (QP-004)

2.1 The top level document defining the overall quality management system is the Quality Assurance Manual. It includes:

- The scope of the quality system, including details of and justification for any exclusions (refer to Page 2);
- Procedures as required by ISO 9001
- Description of quality system processes, their sequence, and interrelation.

### **3 Control of Documents** (QP-005, WI-001)

3.1 EDI documents are controlled through the following activities:

- Documents are reviewed for adequacy and electronically approved prior to issue and recorded in Q-Pulse. In the case of previously "Active" documents or forms there may not be an approver listed.
- Reviewing documents and updating them as necessary and ensuring re-approval of documents is the responsibility of the document owner who receives requested changes verbally, via e-mail, or Q-Pulse. Documents will be reviewed for continuing adequacy during the internal/process audits cycle.
- Ensuring that changes are identified via Q-Pulse and the current revision status of documents are identified by date, revision level and revision date in the header or footer, of each document,
- Ensuring that relevant versions of applicable documents are available at points of use, management provides access for employees to controlled documents and users are typically advised of changes verbally, via e-mail, or Q-Pulse.
- Ensuring that documents remain legible and readily identifiable via title and revision date,
- Ensuring that documents of external origin (excluding prints) are listed in the document master list on Q-Pulse.
- In order to prevent the unintended use of obsolete documents, printed obsolete documents are stamped "Obsolete" and archived appropriately, either in Q-Pulse or the legacy hard copy router files.
- The Quality Manual shall be updated when Procedures, Work Instructions, or Quality Forms are created, made obsolete, or whenever associated document numbers are changed.

### **4 Engineering Specifications** (WI-003)

4.1 Customer engineering specifications and changes are reviewed in a timely manner

4.2 Engineering reviews print changes and gathers old revision customer prints. If they are to be maintained, one copy is stamped "Obsolete" and placed in the legacy hard copy router files. Any archived copies of scanned (electronic prints) are retained in files & drawers clearly labeled as "Reference Only".

4.3 The implementation date for EDI is the date of revised documentation has been provided by the customer, unless otherwise noted.

### **5 Control of quality records** (QP-003)

5.1 Quality records are established and maintained to provide evidence that:

- Process designs satisfy design input requirements,
- Materials, components, and production processes meet specified requirements,
- Finished products conform to specifications, and

- The quality system is implemented in compliance with planned arrangements and the ISO 9001 standard, and that it is effective.

Quality records also include traceability information, where required.

- 5.2 Records will remain legible and shall be stored in a manner that prevents damage or loss.
- 5.3 Retention periods for quality records are determined on the basis of customer requirements, warranty periods, useful life of product, legal obligations, etc.

## **SECTION 5.1 – MANAGEMENT COMMITMENT**

### **1 Top management**

- 1.1 For the purpose of administrating the quality management system, top management includes the President and direct reports

### **2 Customer requirements** *(QP-002)*

- 2.1 Top management is committed to communicate the importance of meeting customer as well as regulatory and legal requirements. Management Representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of Management Representative is stipulated in this manual in Section 5.5, Organization and Communication.

### **3 Quality policy and quality objectives** *(Management Review Presentations)*

- 3.1 Top management defines the purpose and objectives for the quality management system. They are documented and communicated in the form of a written quality policy and collection of quality objectives as outlined in Dashboard Metrics presentations as a part of Management Review and Operations Review cycles. Processes for establishing and implementing the quality policy are defined in this quality manual in Section 5.3.

### **4 Management Reviews** *(QF-003 / QP-0017)*

- 4.1 Top management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates current status and performance of the quality system and initiates actions for further improvement of the system. The process for conducting Management Reviews is defined in Section 5.6 of this manual.

### **5 Resources**

- 5.1 Top management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. Section 6.1 of this manual defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

### **6 Process efficiency**

- 6.1 Top management reviews the effectiveness and efficiency of product realization processes and other support processes. This is done through informal communication, production meetings, and management review meetings.

## SECTION 5.2 – CUSTOMER FOCUS

### 1 Determining customer requirements (QP-002)

- 1.1 Customer requirements are determined and verified through the process of order review. This process is defined in this manual in Section 7.2, Customer-related Processes.

### 2 Meeting customer requirements (QP-002)

- 2.1 Nearly all processes and elements of the quality system are designed and implemented specifically to ensure that customer requirements are met. This starts with provision of required training, and adequate infrastructure and suitable work environment (Section 6, Resource Management). Next follows planning and implementation of reliable and effective product realization processes (Section 7, Product Realization), and finally, activities related to product and process monitoring and verification (Section 8, Measurement, Analysis and Improvement).
- 2.2 Meeting of customer requirements is monitored and/or verified by variety of methods defined in Section 8.2, Monitoring and Measurement. Results of these verification activities are recorded to provide evidence of product conformity, as defined in Section 4.2, Documentation and Records.

### 3 Customer satisfaction (QP-002)

- 3.1 Focusing on customer requirements and on meeting these requirements should result in enhancing customer satisfaction. In fact, the level of customer satisfaction is used as a measure of the effectiveness of the whole quality system.
- 3.2 Specific methods for determining customer satisfaction are defined in quality manual Section 8.2. This valuable information is reported and used as described in Section 5.6, Management Review.

## SECTION 5.3 - QUALITY POLICY

### 1 Authority

- 1.1 Quality policy is established by the top management and is approved by the President. Any changes to the policy must be likewise approved by the President.

### 2 Role of the policy

- 2.1 The main role of the quality policy is to communicate the company's commitments and aspirations with regard to quality, and to define principal objectives for the quality management system.
- 2.2 The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of quality policy in setting quality objectives is addressed in this manual in Section 5.4, Quality Planning.

### 3 Communication

- 3.1 The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.

3.2 The quality policy is also communicated to customers, consumers, suppliers, and other interested parties. For this purpose, it is displayed in the reception area and posted on the company's internet site.

#### **4 Review** (*Management Review Presentations / QF-003*)

4.1 The quality policy is periodically reviewed within the framework of Management Reviews of the quality system. This is to ensure its continual relevance and suitability.

## **SECTION 5.4 – QUALITY SYSTEM PLANNING**

### **1 Quality objectives**

1.1 Quality objectives are established throughout the organization to address customer satisfaction, deploy the quality policy, and meet requirements for products and processes. Another purpose for quality objectives is to provide direction and define priorities for continual improvement.

1.2 Quality objectives are defined and documented as represented in Dashboard Metrics presentations as a part of the Management Review and Operations Reviews processes. Key objectives are published as separate, removable presentations, to facilitate distribution, communication and review.

1.3 Quality objectives are measurable and are achievable within a defined time period.

1.4 Quality objectives are defined, reviewed and updated by the top executive management during the Management Reviews of the quality system.

### **2 Quality system planning**

2.1 Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

- To achieve the quality policy;
- To ensure and demonstrate our ability to consistently provide product that meets customer and regulatory requirements;
- To ensure high level of customer satisfaction;
- To facilitate continual improvement, emphasizing defect prevention and reduction of variation and waste; and
- To comply with requirements of ISO 9001

2.1 The output of quality system planning is documented in this quality manual, in associated operational work instructions, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

2.2 Changes to the quality system ensure integrity is maintained and are planned within the framework of Management Reviews. These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational change; or to improve the effectiveness and efficiency of the quality system.

### **3 Product realization and planning**

3.1 Planning of product realization and planning are addressed in this manual in Sections 7.1.

## SECTION 5.5 – ORGANIZATION AND COMMUNICATION

### 1 Responsibility and authority

- 1.1 Departments, groups and functions within the company, and their interrelations, are defined in this Quality Manual.
- 1.2 Responsibilities and authorities for specific processes and activities of the quality management system are defined in the quality manual and operational work instructions directly where these processes and activities are documented.
- 1.3 Irrespective of their other specific responsibilities, all departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.

### 2 Responsibility for quality

- 2.1 Quality Assurance has the responsibility for ensuring product quality, and the authority to stop production to correct quality problems.
- 2.2 When the leader of Quality Assurance is absent, the responsibility and authority for ensuring product quality can be assumed by the President, Production Manager, QC Inspector/Technician, or a Supervisor, so that operations across shifts are staffed with personnel responsible for maintaining product quality.
- 2.3 All instances of product and/or process nonconformity are promptly reported to Quality Assurance.

### 3 Management representative

- 3.1 Management Representative has the authority and responsibility to:
  - Ensure that the quality management system is implemented, maintained and continually improved;
  - Promote awareness of customer requirements throughout the organization;
  - Report to the top management on the performance of the quality system, including opportunities for improvement; and
  - Coordinate communication with external parties on matters relating to the quality system and ISO 9001 registration.

### 4 Customer Representative

- 4.1 The Management Representative has the responsibility and authority to ensure that customer requirements are addressed. To fulfill this responsibility, the leader of Quality Assurance participates in such activities as product quality planning, development reviews, selection of special characteristics, setting of quality objectives, and related training, corrective and preventive actions.

### 5 Internal communication

- 5.1 Internal communication regarding the quality system flows two ways:
  - The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

- The President communicates information and data regarding customer needs and expectations, customer satisfaction, quality performance, the effectiveness of the quality system, and opportunities for improvement.
- 5.2 The information is communicated through instructions, drawings, specifications, quality records, reports, etc.; and through training, on-the-job instruction, and meetings.
- 5.3 Management Review meetings have a special role in ensuring proper communication between the top management and the organization. The meeting provides the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate policies, objectives, and directives to change and/or improve the quality system.
- 5.4 Management Representative has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the top management.

## **SECTION 5.6 – MANAGEMENT REVIEW**

### **1 General** (*QF-003/QP-0017*)

1.1 The purpose of Management Reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives; and
- Identify opportunities for improvement of the quality system, processes and products.

1.2 Management Reviews are chaired by the President based upon an agenda developed by the Management Representative and are typically attended by representatives of Human Resources, Other Management, and Quality Assurance..

1.3 Management Reviews are conducted quarterly at minimum. More frequent reviews may be scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from the top management.

### **2 Management system performance** (*QF-003/ QP-0017*))

2.1 The scope of the review includes the requirements of the quality system and its performance trends.

2.2 Management Review includes the monitoring of progress toward achieving quality objectives and setting of new objectives.

### **3 Review input** (*QF-003 / QP-0017*)

3.1 Input into the Management Reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Follow-up actions from last Management Review,
- Status, schedule and results of audits,
- Process performance and product conformity data,
- Status of preventive and corrective actions,

- Changes that could affect the quality system,
- Customer satisfaction including feedback and complaints,
- Recommendations for improvement, and
- Quality objectives and quality policy.

#### **4 Review output** (*QF-003 / QP-0017*)

- 4.1 Management Reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.
- 4.2 Results of Management Reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

### **SECTION 6.1 – PROVISION OF RESOURCES**

#### **1 General**

- 1.1 Resources required for implementation and improvement of the quality system, and for addressing customer satisfaction, may include people, suppliers, information, infrastructure, work environment, and financial resources.

#### **2 Determination of resource requirements**

- 2.1 Management Representative and other management personnel involved in the quality system are responsible for determining resource requirements for the implementation and improvement of the system.
- 2.2 The President is responsible for determining resource requirements for addressing customer satisfaction. This is based on input from other management personnel responsible for activities relevant to particular aspects of customer satisfaction.

#### **3 Provision of resources**

- 3.1 Top management has the responsibility and authority for provision of resources.
- 3.2 Allocation of resources for particular activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.
- 3.3 Allocation of resources may be documented in the Quality Assurance Manual, operational work instructions, minutes of meetings, memoranda, or any other form.

### **SECTION 6.2 – COMPETENCE, AWARENESS AND TRAINING**

#### **1 General** (*QP-0016*)

- 1.1 Records identifying training and awareness needs, the provision of training, and the evaluation of the effectiveness of training are maintained.

## **2 Identification of training and awareness needs (QP-0016)**

- 2.1 Top Management is responsible for identifying training and awareness needs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.
- 2.2 Top Management is responsible for identifying competency requirements and training needs, and for establishing job descriptions. On the shop floor training is primarily focused on increasing the level of skills in operating equipment and processes conducting inspections, and Quality Management System assessments.
- 2.3 In addition, training needs are often identified in response to corrective or preventive action requests (CA/PAs), as nonconformities may be caused by inadequate training.

## **3 Training programs (QP-0016)**

- 3.1 EDi provides, or supports, the following categories of company-wide and departmental training programs:
  - General orientation,
  - Safety training, AWAIR and Right to Know
  - Use of company-wide systems,
  - Manufacturing process operator training (on-the-job),
  - QC inspector and lab training,
  - External training and Self-study.

## **4 Employee awareness, motivation and empowerment (QP-0016)**

- 4.1 Awareness, motivation and empowerment programs include:
  - Quality system awareness training
  - AWAIR & Right to Know training
  - Customer quality-related issues and consequences of non-conformances
  - Employee recognition to motivate employees to achieve continual improvement.
  - Quality objectives promote innovation, quality and increased skills in the use of company equipment.
- 4.2 Internal audits are utilized as a measure of how knowledgeable employees are of quality objectives applicable to their area and how they can impact those objectives.

## **5 Effectiveness of training (QP-0016)**

- 5.1 Ultimately, EDi judges training effectiveness as a measure of continued business, returned goods, customer satisfactions, on-time delivery, etc. When more specific evaluation of effectiveness of training is warranted, it can be evaluated using the following approaches:
  - Follow-up performance evaluation of trained employees.
  - Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities.

## **6 Training records (QP-0016)**

- 6.1 Training and awareness programs records are established. EDi maintains as-hired qualification records and records of training provided during employment.

6.2 Administration maintains a Training Status Matrix to augment support for progress in completion of Position Profiles and as a tool for Supervisors / Managers to track training needs

## **SECTION 6.3 – INFRASTRUCTURE**

### **1 Plant, facility and equipment planning (WI-009)**

1.1 The President and Maintenance Manager are responsible for planning of production facilities and equipment. These activities are integrated with the development and validation of the manufacturing processes.

1.2 The effectiveness of existing production operations focuses on such issues as equipment reliability, material travel, handling, use of floor space and so forth.

1.3 Manufacturing capabilities and effectiveness are assessed in Production Meetings/Management Review.

### **2 Supporting services and maintenance of facilities (QP-0016)**

2.1 Supporting services include transportation, communication services:

- Transportation services are usually purchased from parcel delivery and courier services, and from trucking or other transportation companies or consolidators.
- Communication Services are provided by various telephone, wireless, and internet access companies. Top Management and the President is responsible for administrating and coordinating these contracts.

2.2 Maintenance of buildings and facilities is performed by internal employees and external contractors. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning. Repairs of buildings and other such facilities are contracted as needed.

2.3 Maintenance of manufacturing equipment is carried out by the Maintenance staff, augmented by external contractors when needed.

### **3 Contingency plans (QP-0015)**

3.1 The President is responsible for preparing contingency plans to satisfy customer requirements in the event of an emergency, such as utility interruptions, labor shortages, key equipment failure, and field returns (see Emergency Planning, Response & Recovery Manual).

3.2 Contingency plans consider:

- Types of emergencies that could disrupt or stop production,
- Recovery plans and other mitigating actions for those types of emergencies that are reasonably likely to occur and could cause significant disruption to delivery schedule.

3.3 Contingency plans may be reviewed and updated in response to plant and/or contract (volume) changes.

## **SECTION 6.4 – WORK ENVIRONMENT**

## **1 Human factors** (QP-0013)

1.1 Human Resources and departmental managers are responsible for ensuring suitable conditions in the workplace. Relevant workplace policies are implemented mainly through training and awareness programs and, where necessary, disciplinary actions.

## **2 Physical factors** (QP-0013)

2.1 Production and Quality Assurance are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

## **3 Personnel safety** (QP-0013)

- 3.1 Potential risks to employees are considered in development of manufacturing processes. Where applicable, safety requirements are defined in the process design activity.
- 3.2 In day-to-day operations personnel safety is managed with the help of the AWAIR, LOTO and Right to Know Safety Programs. The programs are independent from the quality management system. It is administrated by The President, Safety Committee, Right to Know Coordinator and Human Resources.

## **4 Cleanliness of premises** (QP-0013)

- 4.1 Facilities are maintained in a state of order, cleanliness and repair. Process operators are responsible for maintaining order at and around process equipment and their work stations.
- 4.2 The state of order, cleanliness and repair are assessed through first-person review by Safety Committee members, Management Team members and others.

# **SECTION 7.1 – PLANNING OF PRODUCT REALIZATION**

## **1 Quality and product realization planning** (QP-004)

- 1.1 Quality planning activities are multi-disciplinary, and are therefore defined in many different sections of the quality system documentation.
- 1.2 Development of realization processes is organized and documented in the Quality Manual.
- 1.3 A multi-disciplinary Team is responsible for managing and coordinating quality planning and manufacturing process development activities, and for developing control plans. Core members of the team are representatives from the President, Production, Sales and Quality Assurance.
- 1.4 Customer requirements and references to its technical specifications are included in product realization and quality planning, typically being documented in Product Routers.
- 1.5 The output of quality planning is documented in control plans (Routers). Control plans define or reference product and process acceptance criteria; monitoring, verification and control activities and methods; and reaction plans to be implemented when acceptance criteria are not met.

## **2 Acceptance criteria** (WI-002 / QF-0057 / QF-0069 / QF-0044)

2.1 Acceptance criteria for products are defined in the customer drawings, and other applicable specifications and regulations.

2.2 Acceptance criteria for products and processes are summarized and referenced in the control plans.

### **3 Confidentiality**

3.1 EDi recognizes the importance of confidentiality with regard to customer-contracted products under development, and will strive to ensure confidentiality of the development, testing and related product information.

### **4 Change control (WI-003)**

4.1 Product design changes made by the customer are controlled through the review, distribution and implementation of the changed engineering documents.

4.2 Manufacturing process design changes are controlled by Engineering. Customers are notified for approval of any process changes that result in a limitation in meeting customer requirements.

4.3 Product and process changes are verified and/or validated as appropriate, and are evaluated, where required with respect to their impact on Production Part Approval Process (PPAP) submission. All relevant submission items are updated as necessary. Where required by the customer, additional verification/identification requirements, such as those required for new product introduction, are met.

## **SECTION 7.2 – CUSTOMER-RELATED PROCESSES**

### **1 Product requirements and order review (QP-002)**

1.1 Product requirements are determined and reviewed with regard to requirements specified by the customer; other relevant product requirements not specified by the customer, and the company's capacity and capability to meet all applicable requirements. The record of this review can include QF-001 when needed.

1.2 Where applicable, the manufacturing feasibility of the proposed products is investigated and confirmed by a multidisciplinary team. The team investigates whether the company will be able to meet requirements for product quality, delivery schedule, and capital equipment and tool cost.

1.3 Any incomplete or conflicting requirements are resolved with the customer before acceptance of the order.

### **2 Amendments to orders (QP-002)**

2.1 Amendments to orders (changes to delivery dates, quantity, etc.) are received and reviewed by the same functions that are responsible for the review of the initial orders. Amendments are communicated to necessary functions within the organization that may be affected by the customer amendment request.

### **3 Product Information**

3.1 Management Representative is responsible for developing the content and format for company's brochures, catalogs, internet site, and other promotional and product information material.

### **4 Inquiries and order handling (QP-002)**

4.1 The office staff is responsible for receiving customer inquiries and orders.

4.2 Handling of order amendments is controlled to the same extent as the handling of initial orders. Amendments are reviewed to verify that the new or modified requirements can be met, and a confirmation of acceptance is sent back to the customer.

## **5 Customer feedback and complaints**

5.1 Activities related to receiving, logging and processing customer feedback and complaints are documented under Section 8.5.3, Corrective and Preventive Actions.

## **SECTION 7.4 – PURCHASING**

### **1 Supplier evaluation (WI-0011)**

1.1 As warranted, new suppliers are evaluated with regard to their capabilities. Purchasing and/or Quality Assurance establishes the criteria for selection of suppliers, and conduct supplier evaluation when needed. The criteria to be monitored include 1) Acceptable on-time delivery from the purchase order date. 2) Verification of market price of product and quality of product. 3) All requirements of the purchase order are met including material certification papers as needed. 4) Verification of delivered materials by Quality Control, physical and visual properties. Existing suppliers with acceptable performance history may be exempted from evaluation and re-evaluation, and regarded as APPROVED as a result of on-going performance. Records of the initial and subsequent supplier surveys are maintained.

### **2 Supplier quality performance monitoring (WI-0011)**

2.1 Quality performance of suppliers is monitored. Suppliers showing inadequate performance may be asked to implement corrective actions. If the requested corrective actions are not implemented and there is no improvement, EDi can discontinue use of the supplier. Records of corrective actions, supplier monitoring and re-evaluations are maintained in Q-Pulse, or other formats.

### **3 Purchasing information (WI-0011 / QF-0019)**

3.1 Purchasing documents are prepared by office personnel. The documents clearly and completely describe ordered products, including precise product identification and quality requirements.

### **4 Verification of purchased product (QF-0066, QF-0067)**

4.1 Purchased products are verified by receiving inspector. This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all requested certificates and quality records are available. Designated products are further inspected or tested by Quality Assurance.

4.2 Quality Assurance inspection or testing may not be necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history.

4.3 Quality Assurance is responsible for selecting appropriate methods for purchased product verification and acceptance, and for performing receiving and Quality Assurance inspections.

## SECTION 7.5 – PRODUCTION OPERATIONS

### **1 Production control** (*WI-002*)

- 1.1 Production processes are controlled through variety of approaches, activities and techniques. The system is designed to control the information, material and human (operator) input into the process; the technology, tools and equipment used; the implementation of process performance and product characteristics monitoring and measurement; and the release of the finished product.
- 1.2 Production runs are initiated and controlled via the customer purchase order. The purchase order documents and communicates the production schedule and plan.
- 1.3 The Production Work Order:
  - Provides a platform for recording completion of production and verification operations and their results, and for recording material and process traceability data; and
  - Provides product identification and inspection status identification during production.

### **2 Control plans** (*WI-002/ QF-005 / Print Specifications*)

- 2.1 Control plans define or reference controls used for the manufacturing process control, methods used for monitoring special characteristics, and reaction plans for responding to process instability.

### **3 Work instructions**

- 3.1 Work instructions are established for operators of processes that impact product quality. Work instructions include job set-up instructions, process instructions, control plans, rework instructions (as applicable), inspection and test instructions and calibration instructions, and so forth.

### **4 Verification of job setups**

- 4.1 Whenever processing equipment or machines are reset (for example, maintenance, repair, product change, etc.) the set-up is verified before the production is resumed.

### **5 Preventive and predictive maintenance** (*WI-009*)

- 5.1 Predictive and preventive maintenance plans are developed as needed for process equipment. The system includes availability of replacement parts, and maintenance objectives. Perishable tooling is monitored by the operator and is changed as required.

### **6 Management of production tooling**

- 6.1 Production tooling is managed by a system which includes tooling storage, maintenance, recovery and repair facilities; and tool set-up work instructions; tooling design and design modification records (by date); and tool status (production, repair, disposal, etc.) identification as designated by location within the shop and/or tags.

### **7 Production scheduling**

- 7.1 Production scheduling is order-driven, i.e., production runs are scheduled to meet current customer orders and Kanban requirements.

## **8 Service agreement with customer**

8.1 EDi does not currently have any service agreements with its customers.

## **9 Validation of production processes**

9.1 Production processes are validated and revamped following changes by conducting further production runs.

## **10 Product identification and traceability (QF-0062 / QF-0017 / QF-0078)**

10.1 Products are identified throughout all stages of production, to include purchased materials and components, customer-owned products, parts and subassemblies during production, and the finished products.

10.2 Inspection and test status of products is identified to prevent nonconforming product, or product with unknown inspection status, to be used or dispatched. The identification may be in the form of reference stickers or work in process tags, work orders, colored tags, or placement of products in designated locations, such as quarantines (for nonconforming product) or staging areas (for further processing of conforming product).

10.3 Traceability of materials, operators, etc. is maintained and recorded when required via labels or notations on the work order.

## **11 Customer property**

11.1 Customer property, to include products, tooling, equipment, returnable packaging, and intellectual property, is normally identified, verified, stored, used, and controlled in the same manner as company-owned products of the same type or category, unless there are other specific requirements.

11.2 Where no other method exists to track, Customer-owned tooling and equipment are marked by the part number and listing on the customer owned tooling list so that the ownership of each item can be determined.

## **12 Product preservation, packaging and shipping (QF-005)**

12.1 Products are protected and preserved during all stages of production, to include purchased materials and components, customer-owned products, and parts during production.

12.2 Packaging, labeling and shipping of final products are controlled and may include written specifications for packaging materials, methods and processes and labeling specifications. On-time delivery is monitored via the FabriTrak software system.

## **13 Storage and inventory**

13.1 Purchased materials and components, in-process parts and finished products are stored in production staging areas. In order to detect deterioration, the condition of over-runs is evaluated prior to shipment to the customer and raw material prior to use.

13.2 Obsolete product is treated as nonconforming. Minimum buys of raw material are planned to optimize inventory turn-over.

# **SECTION 7.6 – MEASURING AND MONITORING EQUIPMENT**

## **1 Measurement identification and selection of equipment (QP-008)**

- 1.1 Identification of measurements to be made and the tolerance of the measured characteristics are documented in Control Plans and/or in product drawings and specifications.
- 1.2 Quality Assurance is responsible for evaluating and selecting monitoring and measuring devices and equipment.

## **2 Equipment calibration and maintenance (QP-008)**

- 2.1 Quality Assurance is responsible for calibrating and maintaining measuring and monitoring equipment. Calibration may be subcontracted, but the technical control is retained by the Quality Assurance Manager. All active measuring and monitoring devices and equipment are inventoried in a controlled list located in Q-Pulse
- 2.2 Only calibration instruments and standards having known relationship to the national standards are used for calibrating measuring and test equipment. If a gage is found to be out of tolerance, an "Out Of Calibration" label will be placed on the item and documented in Q-Pulse..
- 2.3 Calibration is recorded in a calibration certificate or database and the calibrated equipment is labeled with a calibration sticker, or by serial number.

## **3 Internal (QF-0056)**

- 3.1 Internal inspecting and calibration records include equipment and methods used for performing the listed tests and calibrations. Records of calibration will be maintained.
- 3.2 Inspecting and calibration methods are documented in work instructions (WI-006). Quality Assurance personnel are competent in specific inspections and calibrations which they are authorized to perform.

# **SECTION 8.1 – PLANNING OF MONITORING AND MEASUREMENT**

## **1 Monitoring and measurement planning (QF-0057 / QF-0043 / QF-0044 / QF-005 / QF-0074)**

- 1.1 Measurement and monitoring activities to verify products and manufacturing processes are planned in the course of process design and development of manufacturing processes. Appropriate statistical tools for evaluating and monitoring manufacturing processes are defined in control plans.
- 1.2 The effectiveness of the quality system is monitored by internal audits, measuring quality performance and customer satisfaction in production meetings and management review meetings. Results of these activities are reported to the top management and are used to identify opportunities for improvement.

## **2 Statistical techniques and concepts**

- 2.1 Quality Control is familiar with basic statistical concepts, such as variation, stability, process capability, and over-adjustment. Where applicable, explanations and discussions of these concepts are included in the process operator training.

# **SECTION 8.2 – MONITORING AND MEASUREMENT**

## **1 Customer Satisfaction (QP-0017)**

1.1 Information and data related to customer satisfaction are acquired from quality performance data and from customer feedback and complaints, to include:

- Customer disruptions and returns,
- Delivery schedule performance,
- Customer notifications,
- Other customer complaints and feedback.

## **2 Internal Audits (QP-0018)**

2.1 EDi conducts internal system assessments based upon the annual schedule to determine whether the quality management system:

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization
- Is effectively implemented and maintained.

2.2 The assessment schedule covers all processes and shifts and is developed based upon process flow. Assessments are scheduled Quality based upon the importance and status of processes. A schedule listing the processes and applicable ISO clauses is utilized as an input in planning the scope for a particular assessment. The scope or boundaries of each assessment and the objective is planned by Quality, or designee for each assessment.

2.3 Quality or designee plans and compiles the criteria to be used for each assessment. This may include the quality manual, the ISO 9001 standard, Quality Operating Procedure, process Work Instructions, or other criteria. When required, Quality will review the audit criteria with the designated assessors who develop and record audit specific checklists on the checklist form. This is done on an ongoing basis. The checklists are reviewed by Quality or Auditor prior to completion of the assessment to ensure adequate coverage of the assessment scope and criteria.

2.4 Trained internal assessors conduct the internal assessments, recording objective evidence on the checklists. Quality may accompany the assessors on the audit. Once the assessment is completed, Quality or Auditor reviews the completed checklists, ensuring adequate coverage of the planned objective and scope. The assessment team works with Quality or designee to confirm and document CA/PA's from the assessment. CA/PA's are documented in Q-Pulse.

2.5 In "Systems" audits Quality works to ready the assessors for a formal or informal closing meeting as needed. During a closing meeting an assessor or Quality may cover the following agenda items: thanks to the owner of the process, attendance, confirmation of the objective and scope, areas of good practice, nonconformities identified, general trends, opportunities for improvement, questions and the agreed upon time for responses. Internal assessors read the nonconformities they have documented in Q-Pulse during the closing meeting.

2.6 The lead assessor shall develop an assessment summary report and distribute this report with the CA/PA's forms assigned to the appropriate personnel. Checklists with notes and CA/PA's provide the records for each assessment and are maintained in Q-Pulse by the assessor or by Quality. Checklists and auditor notes shall be retained.

- 2.7 Follow-up activities are taken and recorded per Q-Pulse. Follow-up / verification of corrective actions will take place per the timetable within Q-Pulse or at a minimum, during the next scheduled audit of the area the corrective action was written against.
- 2.8 Management responsible for the area being audited shall ensure that actions are taken to correct nonconformities without undue delay.
- 2.9 Auditors shall not audit their own work and shall be selected to ensure impartiality.

### **3 Monitoring and measurement of processes** (QP-0018)

- 3.1 Quality management system processes are monitored by variety of approaches and techniques, as appropriate for a particular process and its importance. These include:
- Conducting internal audits of the quality system;
  - Monitoring trends in corrective and preventive action requests;
  - Analyzing product conformity and other quality performance data and trends;
  - Measuring and monitoring customer satisfaction;
- 3.2 When a quality management system process does not conform to requirements, corrective and/or preventive actions are implemented.
- 3.3 Manufacturing processes are measured and monitored at various stages of their development and operation, to include:
- Validation of new processes, usually in the form of initial production runs;
  - Validation of job set-ups via first article inspection;
  - Ongoing process monitoring during production (via in process inspections)
- 3.4 Manufacturing processes are controlled through implementation of control plans, to include adherence to the specified measurement techniques, sampling plans, acceptance criteria, and reaction plans when acceptance criteria are not met. Process capability or performance is maintained as specified by the customer part approval process requirements.
- 3.5 When manufacturing process acceptance criteria are not met, a reaction plan is initiated, to include containment of product and inspection as appropriate. The plan also includes corrective actions to assure that the process becomes stable and capable.
- 3.6 Where required by the customer, important process events such as a tool change or machine repair are recorded.

### **4 Monitoring and measurement of product** (QF-0057 / QF-0069 / QF-0044 / QF-005 / QF-0074)

- 4.1 Product monitoring and measurement may be applied to purchased product, to in-process product, and to final product. The monitoring and measurement may take the form of:
- Inspections of purchased products;
  - In-process inspections,
  - Visual inspections
  - Final inspection and packaging and/or dock (product) audits, and
- 4.2 Inspection and testing program for a product is defined in control plans. The plans identify (or reference) inspection prints, acceptance criteria, and reaction plans.

- 4.3 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products.
- 4.4 All products that have had the final inspection completed will have a product acceptance label affixed to their container (typically a "green tag").

## **SECTION 8.3 – CONTROL OF NONCONFORMING PRODUCT**

### **1 Identification and documentation**

- 1.1 EDi ensures that product which does not conform to requirements is identified via "Quality Hold" tags and controlled to prevent its unintended use or delivery. Customer Supplied material that is found to be defective will have a CA/PA generated and the appropriate steps will be completed to ensure it is not used.
- 1.2 In the event EDi ships nonconforming product, the Customer will be promptly notified.
- 1.3 When the nonconforming product is caused by EDi, management looks for trends and implements appropriate actions to prevent recurrence.
- 1.4 The Quality Assurance Department is responsible for the disposition of nonconforming products which may include scrap, reworking, re-labeling or authorizing use or release.
- 1.5 Records of nonconformities and subsequent actions are maintained in Q-Pulse.
- 1.6 When EDi receives non-conforming parts for re-work or replacement they are first received and appropriately labeled as nonconforming. Complaints will be logged in Q-Pulse to begin processing the material accordingly.
- 1.7 Quality Assurance will inspect the parts and determine whether they are accepted or rejected. If any parts are not within print spec, a "QC Hold" label is placed on all non-conforming parts and Quality Assurance or the Production Manager will then dictate whether the parts are to be re-worked, replaced, or scrapped. Actions are logged in Q-Pulse.
- 1.8 After parts have been re-worked (utilizing the drawings and work orders as a work instruction) or replaced, Quality Assurance will conduct the final inspection and the parts will be shipped to the customer. Results of inspections will be maintained.

### **2 Customer Waiver (QF-0053)**

- 2.1 Whenever product or manufacturing process is different from that which is currently approved, the customer will be asked for a deviation. Products shipped on a deviation are specifically identified on/or in each shipping container. Deviations are quality records and shall be retained.

## **SECTION 8.4 – ANALYSIS OF DATA**

### **1 General (QP-0017)**

- 1.1 Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance and effectiveness of the quality system, and to identify opportunities for improvement.
- 1.2 Quality Assurance is responsible for coordinating these activities, and for reporting conclusions and trends to the top management. The collected data and trends are reported to top management, and are evaluated within the framework of Management Reviews of the quality system.

## **2 Scope**

2.1 The collecting and analysis of data focuses on providing information relating to:

- Customer satisfaction,
- Conformity to product and manufacturing process requirements,
- Characteristics and trends of products and processes, and
- Supplier quality performance.

## **3 Analysis and use of data**

3.1 Trends in quality and operational performance are used for:

- Development of solutions to customer-related problems;
- Determination of customer satisfaction trends and correlation for status reviews, decision making, and longer-term planning; and as
- An information system for reporting product information arising from usage.
- The data are compared with progress toward achieving quality objectives.

# **SECTION 8.5 – CONTINUAL IMPROVEMENT**

## **1 Continual Improvement (QF-0079)**

- 1.1 EDi deploys continual improvement philosophy throughout the organization. The quality system itself is designed to incorporate processes, activities, and systems necessary to identify opportunities for improvement and to implement improvement projects. Management Representative is responsible for coordinating and monitoring the continual improvement effort.
- 1.2 Opportunities for improvement are identified from:
  - Analysis and evaluation of data regarding product conformity, manufacturing process performance, customer satisfaction, effectiveness of the quality system, and other such quality performance indicators via management reviews and production meetings;
  - Internal assessments of the quality management system,
  - Employee suggestions for improving their processes and work environment; routinely through the “Quick Win” submission process.
  - Immediate need to address specific problems and new or changing requirements.
- 1.3 Improvement opportunities which are prioritized for implementation may be defined either as quality objectives or as preventive actions. In the first case, continual

improvement activities are initiated and implemented to achieve the quality objectives. In the second case, they are recorded and processed through the preventive action log.

## **2 Customer feedback and complaints**

- 2.1 Customer feedback and complaints are received by Quality Assurance and Sales. All such communication is logged. Verbal complaints are also recorded and logged.
- 2.2 Quality Assurance evaluates and classifies customer feedback and complaints, and forwards them to relevant functions. Quality Assurance and the function responsible for the complaint decide how to respond to the customer and, when applicable, what needs to be done to correct the problem for the customer.

## **3 Corrective and preventive action (QP-0020)**

- 3.1 EDi takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. Inputs to the process include but are not limited to internal audits, recurring customer issues, and top management discretion.
- 3.2 Q-Pulse includes data fields for description of issue, short term or interim action taken, corrective actions, root cause analysis, long term / prevention steps and controls taken, including error proofing, evidence of effectiveness and approvers comments. Time periods for responses are based upon severity, and are defined in Q-Pulse. Time periods are specified by the owner of the complaint and include timing for implementing the short term or interim actions, and timing for implementing completion of long term / prevention steps control taken. The complaint owner reviews all corrective / preventive actions for completeness prior to completion.
- 3.3 Quality or designee determines the assignee for corrective / preventive actions. Assignees are responsible to ensure actions are taken without delay to eliminate issues and their causes. The complaint owner monitors response timeliness, using Q-Pulse as a monitoring tool. The complaint owner approves or rejects all completed corrective actions. Upon approval the complaint owner also records what has been verified to close the issue.
- 3.4 Corrective / preventive actions are an input to the management review process.
- 3.5 EDi analyzes parts rejected by the customer's manufacturing plants. EDi minimizes the cycle time of this process. Records of these analyses are kept. EDi performs analysis and initiates corrective actions to prevent recurrence as required.
- 3.6 EDi determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.
- 3.7 Routine preventive actions include but are not limited to new process design, preventive maintenance, internal audits, management reviews and employee suggestions. Ideas are discussed at Management Review meetings including the need for actions and records of results of actions taken. Top management determines the need for action, the root causes of potential problems, ensures implementation of needed actions and reviews records of completed actions.

Revision History		
Rev. Level	Brief Description of Change	Release Date
1	New Document	6/13/08
2	Removed the statement in QM that "The above process constitutes EDI's documented procedure for Control of Records". Don created a quality procedure (qp-003) which defines the requirements listed in this N/C.	10/10/08
3	Added to section 2.7: Audit findings will be changed to a "Pending" status while awaiting verification. Verification of corrective actions will take place, at a minimum, during the next scheduled systems audit of the area the corrective action was written against.  Updated QM with new references to procedures and work instructions, including forms which we use to manage our various processes.	12/10/08
4	1-Removed the statement in QM that "The above process constitutes EDI's documented procedure for Control of Documents.  2-Variou changes to verbiage to reflect consistency with updated procedures	2/18/09
5	Added text to section 7.5.4, 11.2	03/01/10
6	Restated references to Quality Manager, corrected referenced documents (QP, WI, and QF numbers), reviewed (minimal changes) entire document for accuracy and clarity.	2/21/11