Engel Diversified Industries, Inc.

Quality Manual

1 Introduction

Engel Diversified Industries Inc. (EDi) has developed and implemented a Quality Management System (QMS) which uses the International Standard Organization (ISO) 9001:2015 standard as a framework that allows our organization to document and improve our practices to meet and/or exceed the expectations of our customers, stakeholders and Interested Parties.

This Quality Manual describes the Quality Management System and defines authorities, inter-relationships, and responsibilities of personnel operating within the management system. The manual also provides references to procedures and activities that comprise our Quality Management System.

The manual is used to familiarize customers and other external organizations or individuals with the controls that have been implemented and to assure them that the integrity of our Quality Management System is maintained and is focused on customer satisfaction and continual improvement.

Our management system meets the requirements of ISO 9001:2015 and uses the Plan, Do, Check, and Act approach to process planning. Our QMS addresses and supports our strategies for the supply of temporary, contract and permanent personnel.

This manual is divided into ten sections modeled on the sectional organization of the ISO 9001 standard. Sections are further subdivided into several subsections representing the main quality system processes and elements.

2 References

In addition to ISO 9001:2015 we also make references to customer expectations and specifications appropriate to our products and market.

3 Definitions

This document does not introduce any new definitions but relies on the following:

- Definitions typically referred to by our customers, stakeholders and market.
- Terms typically used in standards and regulations as they relate to our QMS or products.
- Standard business terminology.
- Terms and vocabulary commonly used in quality practices.

4 Context of the Organization

4.1 Context of the Organization

Engel Diversified Industries Inc. is committed to defining our position within the marketplace and understanding how relevant factors arising from legal, technological, competitive, market, cultural, social and economic environments impact our organization.

Engel Diversified Industries Inc. identifies, analyzes, monitors and reviews factors that may affect our ability to satisfy our customers and stakeholders, as well as factors that may adversely affect the stability of our process or our management system's integrity.

To ensure our QMS is aligned with our strategy, an extensive evaluation of internal and external context can be found in the form of maintained document QF-00135 Context of the Organization in conjunction with input of information as identified on maintained document QF-00134 EDi SWOT (Strengths, Weaknesses, Opportunities, and Threats) Analysis.

Although we acknowledge that the ISO 9001:2015 standard does not require organizational context to be maintained as documented information, we maintain and retain the information to easily monitor, retrieve, review, analyze, and update information when applicable.

4.2 Interested Parties

Engel Diversified Industries Inc. recognizes that we have a unique set of Interested Parties whose expectations change and develop over time. Only a limited set of their respective needs and expectations are applicable to our operations or our Quality Management System. Evaluation of needs and expectations can be found in the form of maintained document QF-00136 Interested Parties.

To ensure that our products and processes continue to meet all relevant requirements, we identify and assess the potential impact of any relevant needs and expectations that may be elicited from Interested Parties.

Where appropriate, to ensure that our processes are aligned to deliver the requirements of our Interested Parties, we may convert relevant needs and expectations into requirements which become inputs to our QMS and to our products and services.

4.3 Scope of the Quality Management System (QMS)

The scope of the Quality Management System is the manufacture, inspection, shipping, and support services of ferrous and non-ferrous metal stampings, deep drawing, fabrication, and welding assembly. The design and development requirements of ISO 9001:2015 are not applicable because the organization does not perform any design of its products or services. All product requirements and specifications are received from customers. In addition, the validation and revalidation requirements relating to the processes for production and service provision are not applicable because the organization tests and measures all products prior to release to the customer.

The scope of the Quality Management System is developed and is relevant when taking into consideration the organization and its context, as well as Interested Parties relevant to the business.

The QP-004 Quality Manual is the top-level document defining the overall management system. This manual also describes the quality system processes, their sequence, and interrelation.

4.4 Quality Management System and its Processes

4.4.1 Processes with Inputs and Expected Outputs Approach

The Quality Management System is designed as a system of interrelated processes with inputs and expected outputs for the processes (see Process Interaction and Sequencing Map on Page 6). The processes with inputs and expected outputs approach is also applied to the auditing of the system.

Quality system documentation defines criteria and methods needed to ensure that the operation and control of the quality system's processes with inputs and outputs expected are effective. This typically includes assignment of responsibilities and allocation of resources for inputs to the process, instructions on how to perform or operate the process, and definition of methods for monitoring and/or measuring the effectiveness of the expected outputs.

Resources and Information

The Management Team, which is also considered the steering committee of the organization, consists of the President, Vice President of Finance/Human Resources Manager, Vice President of Sales, Quality Manager, Production Manager and Maintenance Manager. This group is responsible for determining resources and information requirements necessary to support the operation and monitoring of quality system processes and for communicating these requirements to all interested parties. The Management Team is also responsible for ensuring the availability of necessary resources and information. Sections 7.1.1 General and 7.1.2 People of the Quality Manual explain in greater detail how resource requirements are identified and satisfied.

Monitoring and Measurement

Performance of management system processes are systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.

Performance of quality system processes are monitored through performance to quality objectives (see Section 6.2), and internal quality audits (see Section 9.2)

Quality system processes are reviewed and analyzed via the Management Review of the quality system (see Section 9.3 and Management Review Meeting Minutes).

Continual Improvement

Quality Management System processes are regularly reviewed by the Management Team 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, corrective actions, and risk mitigation actions.

Quality Management System processes address risks and opportunities. Section 6.1 provides greater detail of the processes necessary.

Quality Management System changes, when identified as necessary, are evaluated thoroughly to ensure they achieve their intended results.

Section 10 of the Quality Manual defines how the Quality Management System itself ensures its own compliance and continual improvement.

Outsourced Processes

When processes that affect product conformity are outsourced, 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
- Monitoring of supplier quality performance
- Requirements for process control, inspection, testing, and other retained documented information demonstrating product conformity
- Containment and verification of the supplied product (used only as a temporary measure in conjunction with vendor returns, non-conformances, and/or corrective actions)
- Customer requirements of specific vendor use

Quality Manual Section 8.4 defines the purchasing control system.

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

4.4.2 Documentation

Quality System Documentation

Quality system documentation comprises the following types of documents:

- QP-004 Quality Manual, which includes a documented quality policy and process interaction and sequencing
- Quality Procedures
- Process Work Instructions
- Quality Forms
- Statements of quality objectives as outlined in metrics included in Management Review and Operations Review presentations
- Reference manuals, standards and other technical references
- Customer engineering documents
- Production control plans

Purpose, scope, and responsibility for controlling several types of documents are defined within this Quality Manual (see Sections 7.5, 7.5.1, 7.5.2, and 7.5.3 for greater detail).

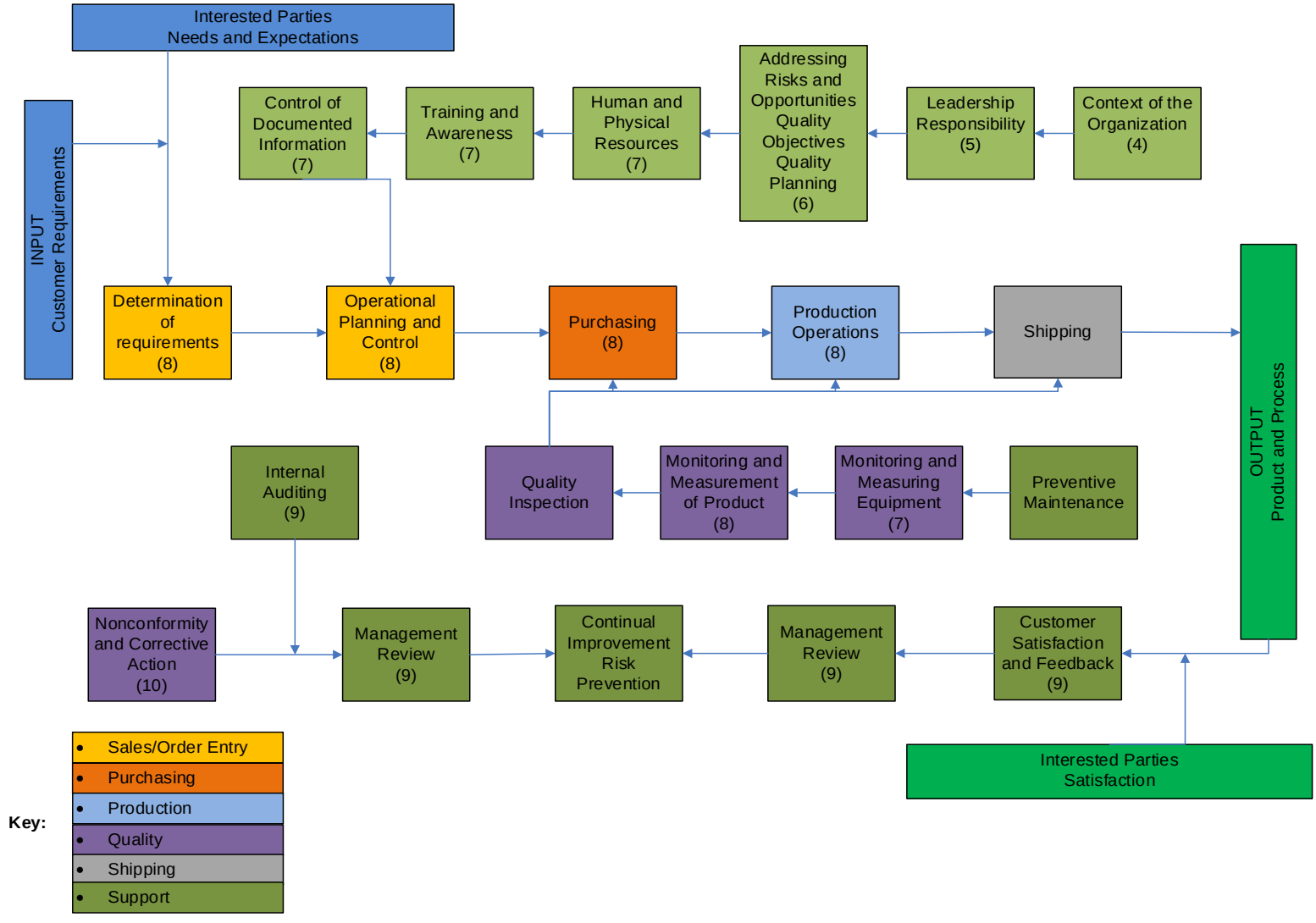
QP-004 Quality Manual

The top-level document defining the overall Quality Management System is the Quality Manual. It includes:

- The scope of the quality system, including details and justification for any clauses that are not applicable to the organization.

- Procedures as required by ISO 9001:2015
- Descriptions of quality system processes, their sequences, and interrelationships (see Process Interaction and Sequencing Map)

Process Interaction and Sequencing Map



5 Leadership

5.1 Leadership and Commitment

5.1.1 Management Team

The Management Team, as identified in QF-0098 Organizational Charts, consisting of the President and direct reports, is accountable and responsible for the overall effectiveness of

the Quality Management System with the common goal of satisfying our Interested Parties needs and expectations.

Quality Policy and Quality Objectives (Management Review Presentations)

The Management Team defines the purpose and objectives of the Quality Management System. They are documented and communicated in the form of a written quality policy, as well as in a collection of quality objectives outlined in Dashboard Metrics presentations as a part of the Management Review and Operations Review cycles.

The Management Team ensures that the quality policy, quality objectives and the overall integration of the Quality Management System are compatible with the context and strategic direction of the organization. Processes for establishing and implementing the quality policy are defined in Section 5.2. Processes for establishing quality objectives and achieving them are defined in Section 6.2.

Quality Management System (Strategic Planning)

The Management Team ensures the integration of the Quality Management System requirements with the organization's business processes through the evaluation of maintained documents on an annual basis to ensure their relevance. The information found in maintained documents QF-00134 SWOT Analysis, QF-00135 Context of the Organization, and QF-00136 Interested Parties is utilized as input during the strategic planning process to ensure the integration of the Quality Management System with process outputs, namely the organization's strategic goals.

Management Review

Reference: QP-0017 Management Meetings
QF-003 Quarterly Management Review Meeting Minute Template

The Management Team periodically reviews the Quality Management System to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates the current status and performance of the quality system and initiates actions for further improvement of the system. The process of conducting Management Reviews is defined in Section 9.3 of this manual.

Communication

Reference: QP-0013 Monthly Operations Meeting Minute Agenda

The Management Team uses a variety of platforms of communication including, but not limited to, informal communications, Monthly Operations Meetings, yearly training, general training, Quarterly Management Review Meetings and review of Dashboard Metrics as a part of Monthly Operations and Quarterly Management Review Meetings to communicate and promote the following:

- The importance of effective quality management and conforming to Quality Management System requirements.
- The use and value of a process approach and risk-based thinking (see also Section 6.1 and QF-00134 SWOT Analysis for greater detail)
- Improvements driven by various aspects of the Quality Management System

Resources

The Management Team provides the resources necessary to establish, implement and improve the Quality Management System. Section 7.1 defines the processes for identifying resource requirements and allocating resources for specific activities and projects.

Leadership Process Support

One or more members of the Management Team engage, direct, and/or support their respective reporting staff's contributions to the effectiveness of the Quality Management System. This is achieved through day-to-day verbal feedback, work direction, formal and informal training, Monthly Operations Meetings, and extensive use of message boards. This interaction occurs on a daily, weekly, monthly, quarterly, and annual basis, as applicable.

Management Team members support all other relevant management roles as applicable to their respective areas of responsibility. The Management Team may hold management meetings to discuss and support various areas of the business as appropriate.

5.1.2 Customer Focus

Determining Customer Requirements

Reference: QP-002 Contract Review

The Management Team is committed to communicating the importance of meeting customer as well as statutory and regulatory requirements. The team is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. The responsibility of the Management Team is stipulated in Section 5.3 Organizational Roles, Responsibilities, and Authorities.

Customer requirements are determined and verified through the process of order review. This process is defined in Section 8.2 Determination of Requirements for Products and Services.

Meeting Customer Requirements

Reference: QP-002 Contract Review

Nearly all processes and elements of the quality system are designed and implemented specifically to ensure that customer requirements are met. This is achieved consistently by starting with the provision of required training, adequate infrastructure, and a suitable work environment (see Section 7 Support for greater detail). Next, follows planning and implementation of reliable and effective product realization processes (see Section 8 Operation for greater detail). Lastly, activities related to product and process monitoring and verification are explained in greater detail in Section 9 Performance evaluation.

Consistently meeting customer requirements is monitored and/or verified by a variety of methods defined in Section 9.1 Monitoring, Measurement, Analysis, and Evaluation. Results of these verification activities are recorded to provide evidence of product conformity as defined in Section 7.5 Documented Information.

Risks and opportunities that may affect conformity of products or services are addressed through QF-00136 SWOT Analysis, which is reviewed and updated, if necessary, during the strategic planning process and through risk mitigation actions, as defined in Section 6.1 Actions to Address Risks and Opportunities.

Customer Satisfaction

Focusing on customer requirements and meeting these requirements results in enhanced customer satisfaction. In fact, the level of customer satisfaction is used as a metric/measure of the effectiveness of the QMS.

Specific methods for determining customer satisfaction are defined in Section 9 Performance Evaluation. Information is reported and used as described in Section 9.3 Management Review.

5.2 Policy

Quality Policy

The Quality Policy is established by the Management Team and is approved by all of the team members. Any changes to the policy must be reviewed and approved by all of the Management Team members.

To ensure that our Quality Policy is aligned with our context and supports our strategic direction, we have created maintained documented information form QF-00138 Mission, Values, and Quality Policy. The purpose of this document is to provide the framework for setting quality objectives, to ensure the satisfaction of applicable requirements, and communicate our commitment to continual improvement of the QMS. The use of the Quality Policy in setting quality objectives is addressed in Section 6 Planning.

Although we acknowledge that the ISO 9001:2015 standard does not require the company's mission, values, and Quality Policy to be maintained as documented information, we maintain and retain this information to easily monitor, retrieve, review, analyze, and update information when appropriate.

Communication

The Quality Policy is posted throughout the company and its role is explained/discussed during general training of employees.

The Quality Policy is also communicated to customers, suppliers and all other Interested Parties. For this purpose, it is displayed in the reception area, printed on reference cards given to employees during general training, and is readily available upon inquiry by any Interested Party via the maintained document form QF-00138 Mission, Values, and Quality Policy.

Review
Reference: Quarterly Management Review Presentations
QF-003 Quarterly Management Meeting Minutes

The QF-00138 Mission, Values, and Quality Policy is periodically reviewed within the framework of the Quarterly Management Reviews of the quality system and/or can be reviewed during the strategic planning process as defined in Section 5.1.1.

At a minimum, the review is performed annually to ensure the policy's continual relevance and suitability while taking into consideration the context and strategic direction of the business.

5.3 Organizational Roles, Responsibilities, and Authorities

Management Responsibilities

The Quality Manager has the responsibility and authority to:

- Ensure that the Quality Management System conforms to the ISO 9001:2015 standard. This is achieved by using the ISO 9001:2015 standard as a model for establishing our management system.
- Ensure that the processes with inputs deliver the expected outputs. This is achieved through evaluation of performance data of each process against the objectives set for it and directing actions, if necessary, to achieve the stated objectives. This is also achieved through internal audits, using inputs and expected outputs methodology, and the review of any opportunity for improvement actions and/or findings where corrective actions are put in place to correct detected issues.
- Ensure that customer focus and awareness are maintained throughout the organization. This is achieved in a variety of ways, such as:
    - The review and analysis of customer feedback at Quarterly Management Review Meetings and Monthly Operations Meetings, which can result in actions that turn in to requirements
    - Through the customer complaint and/or returns system, which results in effective corrective actions
    - Through general improvement projects to enhance customer satisfaction
- Coordinate communication with internal and external Interested Parties on matters relating to the quality system and ISO 9001:2015 registration.
- Direct quality activities, including internal process audits of the system.
- Ensure that the integrity of the quality system is maintained when changes to the system are planned and implemented. This is achieved by taking in to consideration, and evaluating thoroughly, any affects a change may have on the QMS. Contemplated changes typically go through an approval process and/or a test run, as applicable, to determine how the QMS would be impacted by the change.

The President has the responsibility and authority to:

- Report on the performance of the quality system, including opportunities for improvement. This is accomplished via Quarterly Management Review presentations for Management Team to bring them up-to-date on the performance of the QMS.
- Direct any projects identified as necessary during the QMS performance reporting process.

Organizational Responsibility and Authority

The Management Team assigns the responsibilities of departments, groups, and functions within the company as defined in QF-0098 Organizational Charts.

Responsibilities and authorities for specific processes and activities of the Quality Management System are outlined in this manual, Quality Procedures and Work Instructions.

Roles, responsibilities and authorities are further defined in position profiles for each position within the company. Section 7 Support provides greater detail of specific responsibilities.

Irrespective of their other responsibilities, all departments and functions in the company are responsible for implementing, maintaining and improving the quality system.

Responsibility for Quality Product and Processes

All EDi employees are responsible for ensuring product quality. Quality and management have the authority to stop production to correct and direct containment activities of nonconforming product.

In the absence of the Quality Manager, the responsibility to direct Quality activities can be assumed by the President, Production Manager, QC Technician, or Production Supervisor.

All EDi employees are responsible for promptly reporting detection of product and/or process nonconformities to the Quality Department.

6 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 Risk and Opportunity Management

Analysis of information contained in QF-00135 Context of the Organization, QF-00134 SWOT Analysis, and QF-00136 Interested Parties, which is explained in further detail in Section 4, is taken into consideration when planning the management system. Information from these three documents is used as inputs by the Management Team to apply a risk-based approach with the following expected outputs:

- Assurance that the Quality Management System consistently achieves its intended results
- Enhance the desirable effects of the quality system
- Prevent and/or reduce the undesirable effects of the quality system
- Achieve continual improvement of the quality system

This is achieved by evaluation of risks and opportunities by the Management Team, in both a formal and informal manner, at least annually during the review of information as part of the strategic planning process. Typically, the information is evaluated for severity or importance on a more regular basis and actions are communicated throughout the year

via management meetings, Quarterly Management Review Meetings, and Monthly Operations Meetings.

Another input to risk analysis is the Corrective Action system. Corrective actions are defined in greater detail in Section 10.2 Nonconformity and Corrective Action. This process includes the identification of nonconforming product and/or processes through various means with the involvement of various Interested Parties and their requirements, for example:

- Internal Audit findings and/or opportunities for improvement
- Customer complaints or returns
- Internal inspection findings
- Supplier incoming inspections

The risks and opportunities analysis takes into consideration all aspects of the Quality Management System, addressing inputs of risk and expected outputs as necessary, for example:

- Section 4.1 Context of the Organization – Input
- Section 4.2 Interested Parties – Input (Expectations)
- Section 4.4 QMS and its Processes – Input & Output
- Section 5 Leadership - Output
- Section 5.1.2 Customer Focus – Output
- Section 9.3 Management Review – Input & Output
- Section 10.2 Nonconformity and Corrective Action – Periodic Input (Corrective Actions)

6.1.2 Integrating Actions to Address Risks and Opportunities into the QMS

Quarterly Management Review and Monthly Operations Meetings are utilized as a platform to analyze, evaluate, and communicate identified risks and opportunities. During these meetings discussions cover, in addition to other topics, corrective action effectiveness, risks facing the organization, and opportunities for improvement.

The Management Team also uses the Quarterly Management Review Meeting platform to promote risk-based thinking, ensure that the organization maintains its focus on customer satisfaction, and plan and initiate the conversion of risks and/or opportunities into requirements of the QMS based on information analysis.

Actions to address risks and opportunities that are planned and incorporated into the QMS include, but are by no means limited, to the following examples:

Risks:

- Additional controls implemented by updating Quality Procedures and/or Work Instructions. This may include testing ahead of a permanent change to ensure that the effects on the QMS are as intended, with permanent change following after approval by appropriate personnel.
- Calibration of measurement equipment to ensure accurate judgement. If deemed necessary, measurement equipment can be calibrated at more frequent intervals to ensure effectiveness.
- Effective corrective action controls implemented through updates to operation control plans.

- Updates to the Context of the Organization, Interested Parties, or SWAT Analysis documents, which are changed through the approval process only after being thoroughly reviewed and analyzed by appropriate personnel.

Opportunities:

- Acquiring new manufacturing capabilities, i.e. equipment or software
- Exploring new technology
- Expanding to new geographical markets, industries, or types of customers
- Updates to the Context of the Organization, Interested Parties, or SWOT Analysis documents.

All actions are analyzed to ensure that they are proportionate to their potential impact on the conformity of products and services provided by EDi.

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 Quality Objectives

Quality objectives are established across the organization to address Interested Party satisfaction, deploy the Quality Policy, and meet requirements for products, services, and processes. Another purpose of the quality objectives is to provide direction and define priorities for continual improvement.

Quality objectives are defined and documented in Dashboard Metrics presentations as a part of the Quarterly Management Review Meetings and Monthly Operations Meetings. Certain objectives are published as separate, removable presentations, to facilitate distribution, communication and review.

Quality objectives are intended to:

- Be consistent with EDi's Mission, Values, and Quality Policy
- Ensure that objectives are measurable and achievable
- Ensure and demonstrate the ability to consistently provide product that meets customer and regulatory requirements
- Ensure a high level of customer confidence and satisfaction

Quality objectives are defined, reviewed and updated by the Management Team during their quarterly reviews of the quality system and are updated at least annually.

6.2.2 Quality Planning

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.

Planning to achieve the quality objectives is documented and communicated in the Quarterly Management Review Meetings, Monthly Operations Meetings, and Dashboard Metrics presentations, which define:

- A brief scope of the plan to achieve objectives
- Resources required to achieve the objectives
- Responsible parties
- Due dates for when the objectives will be achieved

- Evaluation of the results, typically performed on a quarterly or annual basis, and adjusted, if necessary, with new goals

The output of quality system planning is documented in this manual, in associated Work Instructions, and in other referenced documents. These documents identify and define the elements and processes of the quality system.

6.3 Planning of Changes that May Affect the QMS

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

Changes to the quality system will be reviewed, taking into account the following:

- The purpose of the change and its potential consequences
- The availability of resources to perform the change
- The allocation or reallocation of responsibilities and authority necessitated by the change

7 Support

7.1 Resources

7.1.1 General

Resources required for implementation and improvement of the quality system, and for addressing Interested Party satisfaction, may include people, suppliers, information, infrastructure, work environment, and/or financial resources.

The Management Team is responsible for determining resource requirements for the implementation and improvement of the system.

The Management Team is responsible for determining resource requirements for addressing Interested Party satisfaction. This is typically based on input from the team members that are responsible for activities relevant to particular aspects of Interested Party satisfaction.

The Management Team has responsibility and authority for the provision of resources.

Allocation of resources for specific activities are integrated with the process of defining and initiating the activity. This may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

Allocation of resources may be documented by Work Instructions, meeting minutes, memoranda, or as retained invoices/quotes/estimates/etc.

7.1.2 People

The Management Team determines and provides the people needed for the QMS and effective operation of its processes.

7.1.3 Infrastructure

The Management Team is responsible for the planning of production facilities and equipment. These activities are integrated with the development and validation of manufacturing processes.

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

New and existing manufacturing equipment is proactively maintained through the implementation and sustainment of WI-009 Preventive Maintenance Program. Maintenance staff, augmented by external contractors as needed, perform these activities.

Manufacturing capabilities and effectiveness are assessed in Management Team meetings, Quarterly Management Review Meetings and Monthly Operations Meetings.

Support services and maintenance of facilities are performed, by way of example but not limited to:

- Transportation services are typically purchased from parcel delivery, courier, trucking, or other transportation companies or consolidators. This may include customer specific transportation companies as required.
- Various telephone providers, internet service providers, and IT staff and external IT providers supply communication services.
- Maintenance staff and external contractors perform maintenance of buildings and facilities. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and general cleaning. Major repairs to buildings and other such facilities are contracted as needed.

The Management Team 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, or field returns. QP-0015 Emergency Planning, Response, and Recovery Plan provides greater detail.

Contingency plans consider the types of emergencies that could disrupt or stop production. Recovery plans and other mitigating actions consider those types of emergencies that can be reasonably identified and could cause significant disruption to delivery schedules.

Contingency plans may be reviewed and updated in response to plant and/or contract changes, i.e. changes in volume.

7.1.4 Environment for the Operation of Processes

Reference: QP-0012 EDi Employee Manual
QP-0013 AWAIR Policy
QP-0014 EDi Right to Know Manual

Human Factors - Human Resources and department 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.

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

Personnel Safety – Potential risks to employees are considered in the development of manufacturing processes. Safety requirements are defined in the process design activity, when applicable, and in compliance with OSHA and/or other workplace requirements.

In day-to-day operations, personnel safety is managed with the help of the AWAIR (A Workplace Accident and Injury Reduction), LOTO (Lock Out Tag Out) and RTK (Right-to-Know) safety programs. These programs, administered by the Management team, Safety Committee, Right-to-Know coordinator, and Human Resources, are independent of the Quality Management System.

Cleanliness of Premises – 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 workstations.

Safety Committee members, Management Team members and other applicable personnel assess the state of order, cleanliness, and repair through first-person review as necessary.

7.1.5 Monitoring and Measuring Resources

Reference: QP-008 Control of Monitoring and Measuring Devices
WI-0032 Calibration Process
QF-0056 Calibration Data Sheet Template

Identification of measurements to be performed, equipment to be used for evaluation, and tolerances of the measured characteristics are documented in control plans (see QF-005 Operation Sheet) and/or in product drawings.

The Quality Manager or Quality designee is responsible for appropriately evaluating and selecting measuring and monitoring devices and equipment to obtain measurement results.

The Quality Manager or Quality designee is responsible for the system used to calibrate and maintain measuring and monitoring equipment. Calibration may be subcontracted, but the Quality department retains certifications of external calibration results. All active measuring and monitoring devices and equipment are inventoried on a controlled list located within the Enterprise Software.

Only calibrated instruments and reference standards having identifiable traceability to N.I.S.T. (National Institute of Standards and Technology) are used to verify devises or calibrate measuring and testing equipment. If a gauge is found to be out of tolerance, it is removed from service and/or restricted in its use. Gauges taken out of service or identified as restricted use are labeled as such, reviewed by the Quality Manager (including, at a minimum, a risk analysis), and de-activated or updated within the Enterprise Software, as applicable.

All equipment used for internal calibration with standards traceable to N.I.S.T. are protected, safeguarded, and locked in protective cabinets to prevent damage. These standards are only used for calibration purposes.

Each piece of equipment, whether externally or internally calibrated, is labeled with a Cal ID Number, Calibration Test Date, Next Calibration Due Date, and "Cal By" reference. Calibration schedules are maintained within the Enterprise Software for each piece of equipment in the calibration system.

Internal inspection and calibration methods are spelled out in maintained document WI-0032 Calibration Process. Internal calibration results are recorded on retained document QF-0056 Calibration Data Sheet Template.

Quality Department personnel are competent in the specific inspections and calibrations they are authorized to perform.

If there is ever a question of calibration regarding a piece of measurement equipment or any suspected damage to a device, verification of the device and/or calibration of the measurement equipment shall be performed prior to use.

7.1.6 Organizational Knowledge

Engel Diversified Industries, Inc. realizes that organizational knowledge is a valuable resource that supports our quality management activities and ensures continual product and service conformity. There is a strong link between organizational knowledge and the competency of our people, the latter being employees' ability to apply knowledge to their work.

To ensure that organizational knowledge is retained and transferred, it is recorded as documented information, and embedded in our processes, products and services. Examples of organizational knowledge include:

- Documented information regarding a process, product or service
- Previous specifications and Work Instructions
- The experience of skilled people and their processes and operations
- Knowledge of technologies and infrastructure relevant to our organization

Internal sources of organizational knowledge also include our intellectual property, knowledge gained from experience and coaching, lessons learned from failures and successes, the capturing and sharing of undocumented knowledge and experience, and the results of improvements in processes, products and services.

External sources of organizational knowledge often include standards used by customers, research papers and publications, or other knowledge gathered from customers or other Interested Parties.

Engel Diversified Industries, Inc. continually seeks out and reviews various types of knowledge from both internal and external sources, such as:

- Lessons learned from nonconformities, corrective actions, and results of improvements
- Gathering knowledge from customers, suppliers, and partners, and benchmarking against competitors
- Capturing knowledge existing within the organization through mentoring/succession planning
- Sharing knowledge with Interested Parties to ensure sustainability of the organization
- Knowledge from third-party training, conferences, trade shows, networking seminars, or other external events

7.2 Competence

Reference: QP-0016 Training Operating Procedure

General

The Management Team is responsible for identifying company-wide training and awareness needs, such as general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

The Management Team is responsible for identifying competency requirements and training needs, and for establishing position profiles. On-the-production-floor training is primarily focused on increasing the level of skills relating to operating equipment and processes, conducting inspections, and Quality Management System assessments.

In addition, training needs are often identified in response to corrective actions or risk mitigation action requests, as nonconformities may be caused by inadequate training.

Documents identifying training and awareness needs and the provision of training are retained. Training effectiveness is judged as a by-product of corrective action and risk mitigation reporting, audit results, and customer satisfaction/retention.

Training Programs

EDi provides or supports the following categories of company-wide and departmental training programs:

- General orientation
- Safety training, A Workplace Accident and Injury Reduction (AWAIR) program, Lock Out Tag Out (LOTO) program, and Right-to-Know (RTK) program
- Use of company-wide systems
- Manufacturing process operator training (on-the-job)
- QC Technician inspection, and lab training
- External training and self-study

7.3 Awareness

Reference: QP-0016 Training Operating Procedure

Employee Awareness, Motivation and Empowerment

Awareness, motivation and empowerment programs include:

- Quality Policy and Quality Management System awareness training
- AWAIR, LOTO, and RTK awareness training
- Customer quality-related issues and consequences of non-conformances
- Quick Win recognition to motivate employees to achieve continual improvement
- Quality objectives to promote innovation, quality, and increased skills in the use of company equipment

Internal process audits are utilized as a measure of how knowledgeable employees are regarding specific aspects of the QMS, their respective area(s) of expertise, and/or their impact on the quality system.

Effectiveness of Training and Awareness

Ultimately, EDi judges training and awareness effectiveness through the measure of continued business, returned goods, customer and Interested Parties satisfaction, and on-time delivery. When more specific evaluation of effectiveness of training and awareness is warranted, it can be evaluated using the following:

- Follow-up performance evaluation of trained employees
- Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities

Training and Awareness Retained Documents

Training and awareness program retained documents are established. EDi retains as-hired qualification documents and documents of training provided during employment.

Administration retains a training summary within the Enterprise Software to augment support for progress in completion of Position Profiles and as a tool for supervisors/managers to track training needs. Other retained training documents may include certificates of training filed by employee separate from personnel files.

7.4 Communication

External Communication

The Quality Manager and the Management Team coordinate external communications regarding the Quality Management System to relevant external parties. These communications may include, but are not limited to, company website postings, email or phone communications, or meetings with customers and other Interested Parties.

External communications regarding the Quality Management System are reviewed at minimum by the Quality Manager and typically reviewed by other Management Team members for the following:

- What will be communicated
- When communication will occur

- Whom to communicate to
- How to communicate
- Who will communicate

Internal Communication

Internal communications regarding the QMS flows in multiple ways, for example:

- 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 Quality Manager and Management Team, representing the Interested Parties including the customer, communicate information and data regarding Interested Parties needs and expectations, customer satisfaction, quality performance, effectiveness of the quality system, and opportunities for improvement.

The information is communicated through instructions both verbal and written, drawings, specifications, retained quality documents, records, reports, as well as through training, on-the-job instruction, and meetings.

Quarterly Management Review meetings have a special role in ensuring proper communication between the Management Team and the organization. This meeting provides the platform for the organization to report on the status of quality-related issues and activities, and for the Management Team to formulate policies, objectives, and directives to change and/or improve the quality system.

The Quality Manager has the overall responsibility for ensuring that all pertinent documents, reports, and records are distributed to appropriate departments and functional areas, and that information and data regarding quality performance and the effectiveness of the quality system are reported to the Management Team.

7.5 Documented Information

7.5.1 General

Although EDi acknowledges that the ISO 9001:2015 standard does not require documentation to be maintained or retained as documented information, the company maintains and retains documented information to easily monitor, retrieve, review, analyze, update, and ensure the most current relevant information is available and in use throughout the organization.

The Management Team determines the documentation necessary for the effectiveness of the Quality Management System and ensures the implementation of all documentation required by the international standard.

Maintained documents include the following by example:

- Quality Procedures
- Work Instructions
- Production and Control Plans
- Quality Forms
- Externally controlled documents, such as customers' controlled paint specifications

Retained documents include the following by example:

- Information recorded in Quality Form Templates

7.5.2 Creating and Updating Maintained Documented Information

New documents are submitted as drafts through the Microsoft Office system and placed in a pending approval location on the F: drive of the network for review by appropriate personnel.

Documents are reviewed for adequacy and electronically approved prior to being issued and recorded in the enterprise software and through retained electronic communications via Microsoft Office. In the case of older, but still current, legacy documents or forms, there may not be an approver list.

Reviewing, updating, and ensuring re-approval of documents is the responsibility of various supervisors/managers, who receive requested changes verbally, via e-mail, or other documented means. Documents can also be reviewed for continued adequacy during internal process audits.

Changes are outlined via the enterprise software and the current revision status is identified by release date and revision level in the header or footer of each document.

7.5.3 Control of Documented Information

Control of Maintained Documented Information
Reference: QP-005 Document Control

Relevant versions of applicable documents are available at points of use, management provides access for employees to maintained and retained documents, and users are advised of changes verbally or via e-mail.

Documents remain legible and readily identifiable via title and revision date blocks.

Documents of external origin may be transformed into EDi documents as requirements or standards. However, most external documents (excluding prints) are listed on the F: drive within a controlled customer documentation location on the network. Typically, the externally controlled document will have a date received attached to identify the most current document. If a new or newly revised customer document (excluding prints) is received, the old document is deleted and replaced with the new document labelled with the date received. Previous customer documents may not have a date received if it is not known.

To prevent the unintentional use of obsolete documents, printed obsolete documents are destroyed and replaced, and obsolete electronic documents are watermarked “obsolete” password protected, and retained for revision history purposes.

Control of Retained Documented Information
Reference: QP-003 Control of Records

Quality retained documents are established and retained to provide evidence that/of:

- Process designs satisfy design input requirements
- Materials, components and production processes meet specified requirements
- Finished products conform to specifications
- The quality system is implemented in compliance with planned arrangements and the ISO 9001:2015 standard, and that it is effective
- Traceability of materials or product, or statistical process control records, where required

Retained documents will remain legible and shall be stored in a manner that prevents damage or loss.

Retention periods of retained documents are determined on the basis of customer requirements, warranty periods, useful life of product, legal obligations, etc.

8 Operations

8.1 Operational Planning and Control

Quality and Product Realization Planning
Reference: QP-004 Quality Manual

Quality planning activities are multi-disciplinary, and are therefore defined in many different places in the quality system documentation.

Development of realization processes is organized and documented in the Quality Manual.

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 include the President and representatives from Quality, Production, and Sales.

Customer and Interested Party requirements and references to technical specifications are included in product realization and quality planning, typically documented in individual product Operation Folders.

The output of quality and production planning is documented in control plans (Operations Folders – stored electronically in the enterprise software). Control plans define product and process acceptance criteria, monitoring, verification and control activities, and methods. Reaction plans, for when acceptance criteria are not met, are defined and implemented via control of nonconforming product and/or inspection criteria methods.

Acceptance Criteria
Reference: WI-002 Standard Production Order Process Flow
QF-0057 First Article Inspection Report Template
QF-0066 Receiving Quality Control Report
QF-0044 Characteristic Data Collection Report

Acceptance criteria for products and services are defined in customer drawings and other applicable specifications and regulations.

Acceptance criteria for products and processes are summarized and defined in control plans.

8.2 Customer-Related Processes

Product Requirements and Order Review
Reference: QP-002 Contract Review

Product requirements are determined and reviewed with regard to requirements specified by the customer, other relevant product requirements not specified by the customer but implied, and the company's capacity and capability to meet all applicable requirements. The retained documentation of this review will include Form QF-001 Sales Order Confirmation for Standard Production Orders when needed.

Where applicable, manufacturing feasibility of a proposed product 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, as well as capital equipment and tool cost, as applicable.

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

Amendments to Orders
Reference: QP-002 Contract Review

Amendments to orders (changes to delivery dates, quantity, price, 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 requests.

Confidentiality
Reference: QP-005 Document Control

EDi recognizes the importance of confidentiality with regard to customer-contracted products under development and strives to ensure confidentiality of the development, testing, and related product information via confidentiality agreements and protection of customers' intellectual property shared with EDi.

Change Control

Reference: WI-003 Customer Specification Revision Change Process

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

Manufacturing process design changes are controlled by Quality and Engineering. Customers and other Interested Parties are notified for approval of any process changes that result in a limitation in meeting customer requirements.

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. When required by the customer, additional verification/identification requirements, such as those required for a new product introduction, are met.

8.3 Design Provisions

The design and development requirements of ISO 9001:2015 are not applicable because the organization does not perform any design of its products or services. All product requirements and specifications are received from customers.

EDi does provide engineering design assistance, however, the final design and implementation released are, ultimately, decided by the customer.

8.4 Control of Externally Provided Processes, Products and Services

General

Purchasing decides which suppliers of products and services are used from the active supplier list within the enterprise software. If a new supplier of products and/or services is selected, the new supplier is evaluated prior to placement of a purchase order.

Supplier Evaluation

Reference: WI-0011 Supplier Evaluation and Re-Evaluation Process

As warranted, new suppliers are evaluated with regard to their capabilities. Quality, Purchasing, and/or customers may establish the criteria for selection of suppliers and conduct supplier evaluations when needed. The criteria to be monitored include:

- Acceptable on-time delivery from the purchase order date
- Verification of market price and quality of products and/or services
- All requirements of the purchase order are met, including any required certifications
- Verification by quality control that materials received meet requirements for physical performance and visual properties

Existing suppliers with acceptable performance histories may be exempted from evaluation and re-evaluation, and regarded as approved as a result of on-going performance. Initial and subsequent supplier surveys are retained as documented information.

Quality determines the type and extent of controls of externally provided processes, products, and services. Controls may include:

- Verification of purchased products by receiving inspection personnel
  Reference: QP-0022 Shipping and Receiving
  QF-0066 Receiving Quality Control Report
- Verification of product identity, quantity, visual inspection requirements and, where applicable, verification that requested certificates and quality documents are available
- Further inspection and testing by the Quality
- 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 the supplier has a satisfactory quality performance history.

Quality performance of suppliers is monitored. Suppliers showing inadequate performance may be asked for the following:

- Vendor warning sent with request for correction of nonconformity
- Vendor return material authorization request
- Request for corrective action(s)
- Request for formal review of supplier scorecard
- Quality audit at supplier location

Suppliers that are non-responsive or do not improve their performance in response to the requested actions may be discontinued as an active supplier or, if they pose minimal risk to EDi, put on probation for a period of time. Documentation of corrective actions, supplier monitoring, quality audits, supplier scorecards, vendor returns, and re-evaluations is retained in the enterprise software or other formats.

Supplier Information

Purchasing documents are prepared by Purchasing. These documents clearly and completely describe ordered processes, products, and/or services when applicable. This includes precise product identification and quality requirements.

8.5 Production and Service

8.5.1 Control of Production and Services

Reference: WI-002 Standard Production Order Process Flow

Production and service processes are controlled through a variety of approaches, activities, and techniques. The system is designed to control the information, material, and human inputs to the process, the technology, tools, and equipment used, the implementation of process performance and product characteristics monitoring and measurement, and the release of finished products and services.

Production runs are initiated and controlled via the customer purchase order and/or contract. The purchase order/contract documents and communicates the production schedule and plan.

The production job packet, which includes a printed copy of the operations folder:

- Provides a platform for retaining documentation of completed production and verification operations and their results, as well as material and process traceability data.
- Provides product identification, inspection data, and status throughout the production process.

Control plans define controls used for manufacturing process control, methods for monitoring special characteristics critical to quality for either individual process control or final customer specification critical characteristics, and reaction plans for responding to process instability.

Work Instructions are established for operators of processes that impact product quality. Work Instructions include, but are not limited to, job set-up instructions, process instructions, control plans, production jobs, rework instructions (as applicable), inspection and test instructions, and calibration instructions.

At initial setup or when there is a change to equipment that may affect form, fit, or function of the product, a first piece inspection is verified and documented to conformance specifications before production begins/resumes.

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

Production tooling is individually identified and managed by a system which includes retained documentation regarding storage location, maintenance, and repair. Documentation regarding tool set-up instructions, tooling designs, and design modifications is also retained. Tool identification is achieved through the use of designated locations within the shop and/or through the use of tool ID tags or markings stamped directly into the tools.

Production scheduling is order-driven. Production is scheduled to meet current customer orders and Kanban requirements.

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

8.5.2 Identification and Traceability

Reference: QF-0062 Raw Material Inventory Tag
QF-0017 Sheet Metal Form
QF-0078 WIP Tag

Product is identified throughout all stages of production, including purchased materials and components, customer owned products, parts and subassemblies during, and finished products.

Inspection and test status of products are identified to prevent nonconforming product, or product with unknown inspection status, to be used or dispatched. Identification may be in the form of reference stickers or work-in-process (WIP) tags, jobs, colored tags, or placement of products in designated locations, such as containment quarantines for

nonconforming product or staging areas for conforming product requiring further processing.

Traceability of materials, operators, etc. are retained as documented information, when required, via labels or notations on the job and/or product. This documented information can also be retained within the enterprise software for easy retrieval after the job is completed.

8.5.3 Customer or External Provider Property

Customer and/or externally provided property may include such material as finished/in-process goods, tooling, equipment, returnable packaging, or intellectual property. Customer and/or externally provided property is identified, verified, stored, used, and controlled in the same manner as company-owned property of the same type and category, unless there are other specific requirements.

Where no other method exists to track them, customer and/or externally provided tooling and equipment are identified by the part number and listing on the customer/externally provided tooling list so that the ownership of each item can be determined.

8.5.4 Preservation

Reference: QF-005 Operation Sheet Template

Products are protected and preserved during all stages of production, including purchased materials and components, customer and/or externally owned products, and parts.

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

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

Obsolete product is treated as nonconforming. The purchasing of raw material is planned to optimize inventory turn-over.

8.5.5 Post-Delivery Activities

Reference: QP-002 Contract Review

Engel Diversified Industries Inc. reviews contracts periodically to ensure that our customer related processes are effectively meeting our customers' needs. Reviews may, by way of example, take the form of process checklists, e-mails, meeting minutes, or journal entries. Post-delivery activities include, where appropriate:

- Review of any complaints
- Review of services provided
- Amendments/variations to the contract, as required by the customer
- Planned improvements
- Review of any other issues raised by the customer or various internal departments

8.5.6 Control of Changes

Reference: WI-003 Customer Specification Revision Change Process

Changes to design and development requirements are identified and recorded. Any changes are reviewed, verified, validated, and approved. The review of design development changes includes evaluating the effects of those changes upon stock parts in inventory. All results relating to the review of changes are retained as documented information.

8.6 Release of Products and Services

Reference: QF-0057 First Article Inspection Report Template
QF-0044 Characteristic Data Collection Report
QF-005 Operation Sheet Template
QF-0074 Inspection Report Template

The Quality Manager has overall responsibility for planning and implementing the inspection and test activities necessary to verify that product and service requirements are met at appropriate stages of the product realization process.

Product monitoring and measurement may be applied to purchased product, to in-process product, and/or to final product. This monitoring and measurement may take the form of:

- Inspection of incoming purchased product
- In-process inspections
- Visual inspections
- Final inspection, packaging, and/or dock audits

Inspection and testing programs for product are defined in control plans. The plans identify inspection prints, acceptance criteria, and reaction plans.

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 testing have the authority to release products.

All products that have passed final inspection will have product acceptance labels (typically a “green tag”) affixed to their containers.

8.7 Control of Nonconforming Outputs

Identification and Documentation

Reference: QP-0021 Control of Nonconforming Product

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 is treated in the same manner, except that the customer is notified for determination of disposition of the material.

Nonconforming product returned by a customer or received from a supplier is received in the enterprise software, identified as nonconforming with a Quality Hold Tag, and placed in the Quality Hold Designated Area until disposition is determined. Returns and complaints are logged into the enterprise software and appropriate actions are taken.

In the event that EDi discovers that it has shipped nonconforming product, the customer will be notified immediately to perform containment and/or disposition evaluation activities.

Quality personnel ensure proper containment, evaluation, validation, and obtainment of disposition, whether from within or external to the organization. The Quality Manager, with input from other Management Team members, is responsible for the disposition of nonconforming products, which may include reworking, relabeling, scrapping, or authorizing their use or release.

Documented information regarding nonconformities and subsequent actions is retained in the enterprise software and, for rework jobs, also printed for use by production personnel, as applicable. Management reviews nonconformities, looking for trends, and implements appropriate actions to prevent recurrence.

Product that has been reworked or replaced will have, at a minimum, a final inspection by quality personnel prior to release with results retained as documented information, and only then will it be released for shipment to the customer or placed in stock, as applicable.

Whenever product or manufacturing processes differ from those currently approved, the customer will be sent a deviation request. Deviations, associated communications, and other information regarding the deviation are retained as documented information.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

Reference: QF-0057 First Article Inspection Report Template
QF-0043 Operation Control Record of Activity
QF-0044 Characteristic Data Collection Report
QF-005 Operation Sheet Template
QF-0074 Inspection Report Template

Measurement and monitoring activities to verify product and manufacturing processes (including improvement activities) are planned during the course of tool design and the development of the manufacturing processes utilized. Appropriate analytical/statistical tools for evaluating and monitoring manufacturing processes are defined in control plans (Operation Folders).

The effectiveness of the quality system is monitored through internal audits and by measuring quality performance and customer satisfaction in Monthly Operations Meetings and Quarterly Management Review Meetings. Results of these activities are reported to the Management Team for use in identifying opportunities for improvement.

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

Monitoring and measurement of processes are accomplished through a variety of approaches and techniques, as appropriate for any given process and its associated risks. These include:

- Internal process audits of the quality system (see QP-0018 Internal Audit)
- Monitoring trends in corrective action and/or risk mitigation action requests
- Analyzing product conformity and other quality performance data and trends
- Measuring and monitoring customer satisfaction

When a Quality Management System process does not conform to requirements or desired outputs, corrective actions and/or risk mitigation actions are implemented.

Manufacturing processes are measured and monitored at various stages of development and operation, including:

- Validation of new processes, usually in the form of initial production runs
- Validation of job set-ups through first piece inspections
- Ongoing process monitoring during production through in-process inspections

Manufacturing processes are controlled through implementation of control plans (Operations Folders), including adherence to 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 customer part approval process requirements.

When manufacturing process acceptance criteria are not met, a reaction plan is initiated for containment of product and inspection, as appropriate. The plan also includes corrections and/or corrective actions to assure that the process becomes stable and capable.

Where required by the customer or other Interested Parties, data on important process events, such as tool changes or machine repairs, is retained as documented information.

9.1.2 Customer Satisfaction

Reference: QP-0017 Management Meetings

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

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

9.1.3 Analysis of Data

Reference: QP-0017 Management Meetings

Data retained as documented information relating to quality is compiled and analyzed as needed to determine trends in the performance and effectiveness of the quality system and to identify risks and opportunities for improvement.

The Quality Manager or designee is responsible for coordinating these activities and for reporting conclusions and trends to the Management Team. The complied data and trends are reported to the Management Team and are evaluated within the framework of

Quarterly Management Review Meetings and Monthly Operations Meetings of the quality system.

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

- Risk management
- Customer and other Interested Parties' satisfaction
- Conformity of product and process requirements
- Characteristics and trends of products and processes
- Supplier quality performance

Identified trends in quality and operational performance are utilized for:

- Developing solutions to eliminate and/or mitigate customer and other Interested Parties' problems
- Developing solutions to address risks and opportunities
- Monitoring customer and other Interested Parties' changes in satisfaction, and their correlation, for use in status reviews, decision making, and long-term strategic planning
- An information system for reporting product related information/requirements arising from customer usage, i.e. inadequately communicated aesthetic requirements
- Monitoring progress towards achieving quality objectives and effectiveness of continual improvement activities

9.2 Internal Audit

Reference: QP-0018 Internal Audit
QF-00117 Management Meetings

EDi conducts internal system and process audits to determine whether the quality system is:

- Effectively achieving its expected outputs
- Effectively implemented and maintained
- Conforming to the planned arrangements (see Section 8.1), to the requirements of the ISO 9001:2015 International Standard, and to the Quality Management System requirements established by the organization

The process audit schedule covers the scope of the organization's systems and processes, and is developed based upon process flow. Process audits are scheduled based upon the importance and status of processes. A schedule listing, at a minimum, the processes and applicable Quality Procedures, Work Instructions, and Quality Forms is utilized as an input for planning the scope of a particular audit assessment. The scope or boundary of each process audit and its objective(s) are planned by the Quality Manager or designee.

A lead auditor and an assistant auditor plan and compile the criteria to be used for each process audit. This may include the Quality Manual, the ISO 9001 standard, Quality Procedures, Work Instructions, or other criteria. When required, the lead auditor will review the audit criteria with the designated auditors, who develop and record audit specific checklists and/or other criteria.

Externally educated and trained audit assessors and/or in-house trained audit assessors conduct the internal process or system audits, recording objective evidence. The Quality Manager and/or other Management Team members may accompany the audit assessors

during the audit process. Once the audit assessment is completed, the Quality Manager and/or the audit team review the completed audit summary, ensuring adequate coverage of the planned objective(s) and scope. The audit assessment team works with the Quality Manager or designee to confirm and document corrective actions and/or risk mitigation actions from the audit assessment. Corrective actions or risk mitigation actions are retained as documented information in the enterprise software.

Audits may include formal or informal closing meetings, as appropriate. If conducted, a meeting agenda could include, for example: a thank you to the owner of the process, attendance, confirmation of the objective(s) and scope, areas of good practice, identified nonconformities, general trends, risk mitigation and opportunities for improvement activities, and questions and agreed upon timeframe for responses. Internal auditors may read the nonconformities during the closing meeting.

The lead and assistant auditors shall develop an assessment summary report to be retained in the enterprise software upon completion. This includes any corrective actions and/or risk mitigation actions assigned to appropriate personnel. The completed QF-00117 Audit Reporting Template, summary, and actions, stored within the enterprise software, provide the retained documented information for each audit assessment.

Follow up activities are completed and retained as documented information in the enterprise software, typically in the form of a corrective action or risk mitigation action. Follow-up and verification of effectiveness activities take place per the timetable established during the audit or during the next scheduled audit of the system or process against which the action was written.

Management responsible for the area being audited shall ensure that actions are taken to correct nonconformities without undue delay. This action may have a timetable that is adjusted depending on the scope and magnitude of the action.

Auditors shall not audit their own work as much as possible and shall be selected to ensure impartiality.

9.3 Management Review

Reference: QP-0017 Management Meetings
QF-003 Quarterly Management Meeting Minute Template

The purpose of management review is to:

- Evaluate the suitability, adequacy, and effectiveness of the quality system
- Consider changes to the Quality Management System, Quality Policy, and quality objectives
- Identify and communicate risks and opportunities for improvement of the quality system, processes, and products
- Direct other projects, as necessary, to achieve organizational goals

Management Review Meetings are chaired by the President or designee based upon agenda developed by the Management Team and are typically attended by representatives as defined in QF-0098 Organizational Charts document.

Management Review Meetings are conducted on a quarterly basis at a minimum. More frequent reviews may be scheduled during periods when organizational and/or product

change or other circumstances require increased attention and input from the Management Team.

The scope of the review includes requirements of the quality system and its performance trend data.

Management review includes the monitoring of progress toward achieving quality objectives and setting new objectives and goals.

Input into the Quarterly Management Review Meeting agenda consists of information and data related to the quality performance of the organization. At a minimum, this includes:

- Follow-up actions from the last Quarterly Management Review Meeting and/or Monthly Operations Meeting
- Review of operational topics and resource needs
- Review of risks and opportunities, as well as the status of actions to address them
- Changes that could affect the Quality Management System
- Recommendations for improvement
- Status, schedule, and results of audits, both internal and external
- Status of corrective actions
- Process performance and conformity data
- Customer satisfaction, including feedback, complaints, and customer scorecard data
- On-time delivery performance data
- QMS goals and objectives and Quality Policy

Management Reviews Meetings are concluded with actions related to improvement of the organization and/or Quality Management System, as well as improvement of processes and products to better meet customer and other Interested Parties' requirements. The review also identifies resources needed to implement these actions.

Results of management reviews are retained as documented information in the form of meeting minutes and copies of presentation materials, both of which are stored on the company F: drive.

10 Improvement

10.1 General

Reference: QF-0079 Quick Win

EDi deploys a continual improvement philosophy throughout the organization. The quality system itself is designed to incorporate processes, activities, and systems necessary to identify risks and opportunities for improvement and to implement improvement projects. The Management Team is responsible for coordinating and monitoring the continual improvement effort.

10.2 Nonconformity and Corrective Action

Reference: QP-0020 Corrective Action

EDi takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrections and 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 returns or complaints, and Management discretion.

Enterprise software entries include data fields for description of issue, short-term or interim action taken, correction of issue, root cause analysis, and corrective actions to address occurrence and detection, as well as evidence of effectiveness and approver comments, as warranted. Time periods for responses are based upon severity and scope of corrective actions taken. Time periods are specified and monitored by the Quality Manager and include the timing for implementation of corrections or short-term actions, as well as a timeline for implementation of long-term corrective actions, when required. The Quality Manager reviews all corrections and corrective actions for completeness prior to closure.

The Quality Manager determines the assignee for corrective action. Assignees are responsible for ensuring that actions are taken to eliminate the root cause of nonconformity and address occurrence and/or detection as necessary. The corrective action assignee monitors response timeliness, using the enterprise software as a monitoring tool. The Quality Manager approves or rejects all completed corrective actions. Upon approval, verification of implementation of the corrective action is retained as documented information within the enterprise software.

The Quality Manager validates the effectiveness of corrective actions taken on major nonconformities and monitors corrective actions taken on minor nonconformities.

Corrective actions are an input to the management review process of the Quarterly Management Review/Monthly Operations Meetings.

EDi analyzes parts rejected by customers' manufacturing facilities and, where appropriate, retains as documented information the analysis results. EDi performs analysis and initiates containment of product, correction of issue, and/or corrective actions, as required. The determination of actions taken is dependent upon the magnitude of the issue. EDi may choose to accept the consequences in cases where the nonconformity appears to be an anomaly, such as one part returned for a scuff.

10.3 Continual Improvement

Opportunities for improvement can be identified through:

- Analysis and evaluation of data regarding product conformity, manufacturing process performance, customer and other Interested Parties' satisfaction, effectiveness of the quality system, and other quality performance indicators identified in Quarterly Management Review/Monthly Operations Meetings
- Internal and external audits of the Quality Management System
- Employee suggestions for improving processes and work environment by way of the Quick Win submission and implementation process or verbal communications
- Immediate need to address risks and opportunities, as well as new or changing requirements
- Customer or other Interested Party feedback or complaints
- Risk mitigation projects

Improvement opportunities which are prioritized for implementation may be defined either as quality objectives or as risk mitigation action projects. In the case of quality objectives, continual improvement activities are initiated and implemented to achieve the quality objectives. In the case of risk mitigation action projects, they may be a result of

corrective actions identifying other similar processes or products that may require similar corrective actions and are typically retained as documented information within the corrective action system of the enterprise software.

Risk mitigation actions are proportional to the company's exposure and include, but are not limited to, the following:

- New process design
- Preventive maintenance
- Implementation of opportunities for improvement resulting from internal process audits
- Initiation of projects identified through Management Reviews
- Implementation of employee suggestions, i.e. Quick Wins

Items are discussed at Quarterly Management Review/Monthly Operations Meetings, including the need for actions and retained documented information regarding results of actions taken. The Management Team or any combination of the team determines the need for action, reviews root cause analysis of potential problems that may arise, ensures the implementation of needed actions, and reviews the retained documented information regarding 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-Various 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.	02/21/11
7	Updates and amendments were made throughout the Quality Manual to clarify and more properly reflect current policies and practices.	01/27/12
8	Revised references to Fabritrack and The Enterprise Software. Amended procedures to reflect changes resulting from changes to enterprise software. Removed/added/corrected references to affiliated Procedures, Work Instructions, and Forms.	07/07/15
9	Revised to remove reference to Q-Pulse add reference to the Enterprise Software. Update reference to the word router replaced with operations folder and reference to the word work order replaced with job. This ensures accuracy to current nomenclature definitions of the enterprise software.	05/20/16
10	Various additions and reorganization updates to the 9001:2015 ISO Standard.	02/19/18
11	Revised various additions and reorganization updates to the 9001:2015 ISO Standard for improved clarity and readability.	06/18/18