Engel Diversified Industries

Quality Manual

1. **Introduction**

Engel Diversified Industries Inc. 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 manual describes the quality management system, defines authorities, inter-relationships and responsibilities of personnel operating within the management system. The manual also provides references to procedures and activities that also 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 seven 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. 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.

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:

1. Definitions typically referred to by our customers, stakeholders and market.
2. Terms typically used in standards and regulations as they relate to our QMS or products.
3. Standard business terminology.
4. 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.

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 initial evaluation of internal and external context can be found in the form of maintained documents QF-00135 (Context of the Organization) in conjunction with input of information as identified on maintained document QF-00134 S.W.O.T. (Strengths, Weaknesses, Opportunities and Threats).

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 Relevant 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 the 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.

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 Quality Manual(QP-004) 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

1. **Processes with Inputs and Expected Outputs Approach**

1.1 The quality management system is designed as a system of interrelated processes with inputs and expected outputs for the process. (See Page 7 for Process and Sequencing Map Diagram)
The processes with inputs and expected outputs approach is also 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 the quality systems processes with inputs and outputs expected are effective. This typically includes assignment of responsibilities and allocation of resources for input 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.

2. **Resources and information**

2.1 The Top Management Team that is also considered the steering committee of the organization consisting of the President, HR Controller, VP 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 relevant interested parties. The Management Team is also responsible for ensuring the availability of necessary resources and information. Quality Manual sections 7.1.1 and 7.1.2 general provision of resources and people provision of resources respectively, explain in greater detail how resource requirements are identified and satisfied.

3. **Monitoring and measurement**

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

3.2 Performance of quality system processes are monitored through performance to quality objectives (refer to Quality Manual section 6.2), and internal quality audits (refer to Quality Manual section 9.2)

3.3 Quality system processes are reviewed and analyzed via the Management Review of the quality system (refer to Quality Manual section 9.3 and Management Review meeting minutes).

4. **Continual improvement**

4.1 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.

4.2 Quality management system processes address risks and opportunities. Section 6.1 of this manual provides greater detail of the processes necessary.

4.3 Quality management system changes when identified as necessary, are evaluated thoroughly to ensure they achieve their intended results.

4.3 Quality Manual section 10 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, 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 records 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.

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

4.4.2 Documentation

1. Quality system documentation

1.1 Quality system documentation comprises the following types of documents:

- Quality Manual *(QP-004)* including a documented quality policy, 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

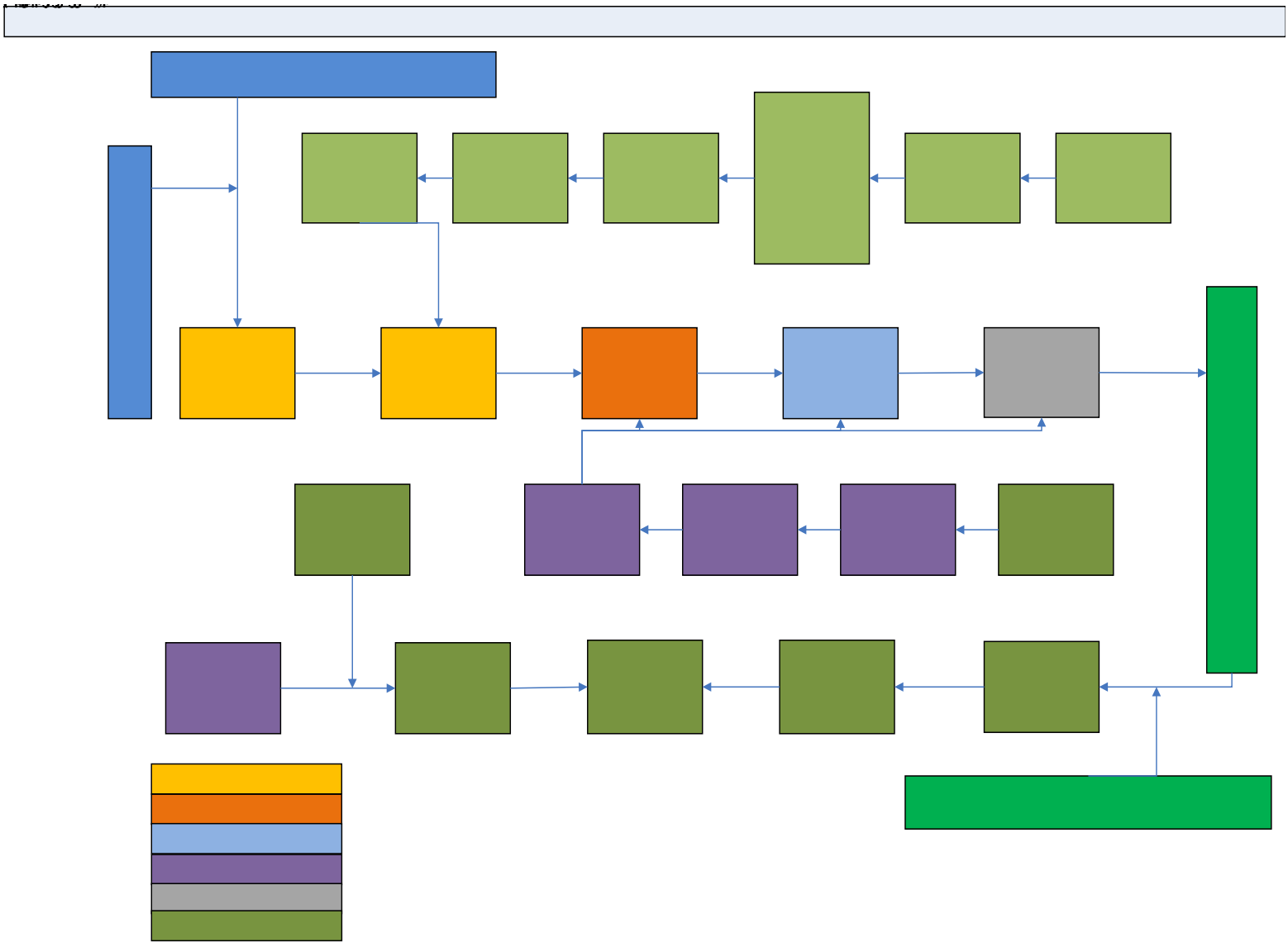
Purpose, scope, and responsibility for controlling several types of documents are defined within this Quality Manual (QP-004). See sections 7.5, 7.5.1, 7.5.2 and 7.5.3 for greater detail.

2. **Quality Manual *(QP-004)***

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

- The scope of the quality system, including details of and justification for any areas as not applicable.
- Procedures as required by ISO 9001:2015.
- Description of quality system processes, their sequence, and interrelation (see page 7)

Process Interaction and Sequencing Map



5. Leadership

5.1 Leadership and Commitment

1. Top management

1.1 Top management as identified in QF-0098 (Organizational Charts) consisting of the president and direct reports are accountable and responsible for the overall effectiveness of the quality management system with a common goal of satisfying our relevant interested parties needs and expectations.

2. Quality policy and quality objectives (Management Review Presentations)

2.1 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; as well as a collection of quality objectives as outlined in Dashboard Metrics presentations as a part of Management Review and Operations Review cycles.

2.2 Top management 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 this quality manual in Section 5.2. Processes for establishing quality objectives and achieving them are defined in this manual in Section 6.2.

3. Quality Management System (Strategic Planning)

3.1 Top management ensures the integration of the quality management system requirements into the business processes through evaluation of maintained documents on a yearly basis in ensuring their relevance. This evaluation of information found on maintained documents QF-00134 SWOT Analysis, QF-00135 Context of the Organization and QF-00136 Interested Parties is used at the time of strategic planning to ensure the integration of the quality management system into business processes as inputs with outputs of strategic goals.

4. Management Review *(QP-0017) Management Meetings/(QF-003) Quarterly Management Meeting Minutes*

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 of conducting Management Reviews is defined in Section 9.3 of this manual.

5. Communication

5.1 Top management uses a variety of platforms of communication including but, not limited to; informal communications, production operations meetings, yearly training, general training, management reviews and review of dashboard metrics as a part of

production operations and management review meetings to communicate and promote the following:

- The importance of effective quality management and conforming to the quality management system requirements.
- The use and value of a process approach and risk-based thinking. See also Section 6.1 and S.W.O.T Analysis (QF-00134) for greater detail.
- Improvements driven by various aspects of the quality management system.

6. Resources

6.1 Top management provides the resources necessary to establish, implement and improve the quality management system. Section 7.1 of this manual defines the processes for identifying resource requirements and allocation of resources for specific activities and projects.

7. Leadership Process Support

7.1 At least one or more of the top management team members engages, directs, and/or supports their respective reporting staff contributions to the effectiveness of the quality management system. This is achieved through day to day verbal feedback, work direction, training both formal and informal, Operations review meetings, and through the use of message boards. This interaction occurs on a daily, weekly, monthly, quarterly and yearly basis, as applicable.

7.2 Top management supports all other relevant management roles as part of the Top management team for their respective areas of responsibility. Top management may hold management meetings to discuss and support various areas of the business as applicable.

5.2 Customer Focus

1. Determining customer requirements *(QP-002) Contract Review*

1.1 Top management is committed to communicate the importance of meeting customer as well as statutory and regulatory requirements. The management 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 this manual in Section 5.3, Organizational roles, responsibilities and authorities.

1.2 Customer requirements are determined and verified through the process of order review. This process is defined in this manual in Section 8.2 Determination of requirements for products and services.

2. Meeting customer requirements *(QP-002) Contract Review*

2.1 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 suitable work environment. See Section 7 (Support) of this manual for greater detail. Next, follows planning and implementation of reliable and effective product realization processes. See Section 8 (Operation) of this manual for greater detail. Lastly, activities related to product and process monitoring and verification are explained in greater detail in Section 9 (Performance evaluation) of this manual.

2.3 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).

2.4 Risks and opportunities that may affect conformity of products or services are addressed through the initial S.W.O.T Analysis (QF-00136) which is reviewed at minimum at the time of strategic planning for update and through risk mitigation actions as defined in Section 6.1 (Actions to address risks and opportunities) of this manual.

3. Customer Satisfaction

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

3.2 Specific methods for determining customer satisfaction are defined in Section 9 (Performance evaluation) of this manual. Information is reported and used as described in Section 9.3 (Management Review) of this manual.

5.3 Policy

1. Quality Policy

1.1 The Quality policy is established by the top management team and is approved by all of the team members. Any changes to the policy must be reviewed and likewise approved by all of the management team members.

1.2 To ensure 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 satisfy applicable requirements and as a commitment statement to continual improvement of the QMS. The use of the quality policy in setting quality objectives is addressed in Section 6 (Planning) of this manual.

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

2. Communication

2.1 The quality policy is posted throughout the company and its role is explained/discussed at the general training provided to employees.

2.2 The quality policy is also communicated to customers, suppliers and all other relevant interested parties. For this purpose, it is displayed in the reception area, reference cards are given to employees at general training and is readily available upon inquiry by any relevant interested party via the maintained document form QF-00138.

3. Review *(Management Review Presentations/ QF-003 Quarterly Management Meeting Minutes)*

3.1 The Mission, Values and Quality Policy (QF-00138) is periodically reviewed within the framework of the management reviews of the quality system and/or can be reviewed at the time of strategic planning as defined in Section 5.1.3 of this manual.

3.2 At minimum the review is performed on a yearly basis. This is to ensure the policies continual relevance and suitability while taking into consideration the context and strategic direction of the business.

5.4 Organizational roles, responsibilities and authorities

1. Management Responsibilities

1.1 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 expected outputs as intended. 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 objectives. This is also achieved through internal audits using inputs and expected outputs methods and review/actions of any opportunity for improvement and/or findings where a corrective action is put in place as applicable to correct detected issues.
- Ensure customer focus and awareness is maintained throughout the organization. This is achieved in a variety of ways such as customer feedback reviewed and analyzed at management review and operations meetings which may create actions that turn in to requirements as a result, through the customer complaint and/or returns system with effective corrective actions as a result, and through general improvement projects to enhance the satisfaction of the customer.
- 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 to the QMS. Changes are typically put through an approval process and/or a test run is considered ahead of change to validate how the QMS could be affected by the change as applicable.

1.2 The President has the responsibility and authority to:
- Report on the performance of the quality system including opportunities for improvement. This is accomplished via Management Review presentations where top management is in attendance and informed of the performance.
- Direct any projects that may be needed when identified through the reporting of performance.

2. Organizational responsibility and authority

2.1 Top management assigns responsibility of departments, groups and functions within the company as defined in *(QF-0098) Organizational Charts*.

2.2 Responsibilities and authorities for specific processes and activities of the quality management system are outlined in this manual, within operating quality procedures and operational work instructions.

2.3 Roles, responsibilities and authorities within each entity are further defined through position profiles for each position within the company. Section 7 (Support) of this manual provides greater detail of the specific responsibilities within each entity.

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

3. Responsibility for quality product and processes

3.1 All EDi staff have responsibility to ensure product quality. Quality and management have the authority to stop production to correct and direct containment activities of non-conforming product.

3.2 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.

3.3 All EDi staff have the responsibility to promptly report to the Quality department or delegate when a product and/or process non-conformity is detected.

6. Planning

6.1 Actions to address risks and opportunities

1. **Risk and opportunity management**

1.1 Analysis of information found on *(QF-00135) Context of the Organization*, *(QF-00134) SWOT Analysis* and *(QF-00136) Interested* Parties explained in further detail within Section 4 of this manual are taken into consideration when planning the management system. The information on these three documents is used by top management to apply a risk-based approach as inputs with the expected outputs of:

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

1.2 This is achieved by rating the risks and opportunities by top management in both a formal and informal manner, at minimum, upon review of the information on a yearly basis at the time of strategic planning. Typically, the information is rated for severity or importance on a more regular basis and actions are communicated throughout the year via top management meetings, management reviews and operations review meetings.

1.3 Another input to the risk analysis is the Corrective Action system. Corrective actions are defined in greater detail in Section 10.2 Nonconformity and corrective action of this manual. This process includes identification of nonconforming product and/or processes through various sources of relevant interested parties and their requirements, by example:

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

1.4 The risk and opportunities analysis takes in to consideration the following which, may take inputs of risk and expected outputs as necessary, by example:

- Section 4.1, Context of the Organization – Input
- Section 4.2, Interested Parties Expectations – Input
- Section 4.4, QMS and its processes – Input/output
- Section 5, Leadership - Output
- Section 5.4, Customer Focus – Output
- Section 9.3.2, Management review – Input/output
- Section 10.2.1, Corrective actions – Periodic Input

2. Integrating actions to address risk and opportunities into the QMS

2.1 Management and operations review meetings are used as a platform to analyze, evaluate and communicate risks and opportunities as identified. Included in these meetings are corrective action effectiveness, addressing risks of the organization and, opportunities for improvement.

2.2 Top management also uses the management review meeting platform to promote risk-based thinking, ensure customer focus is maintained, and may plan and initiate turning risks and/or opportunities into requirements of the QMS based on the information analysis.

2.3 Actions to address risks and opportunities that are planned and implemented into the QMS by example but, not limited to are:

Risk:

- Additional controls through update of procedures and/or process work instructions. This may include testing to ensure the effects to the QMS are as intended to ensure effectiveness and, takes place ahead of permanent change, then permanent change with approvals from 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 through various updates to operation control plans.
- Updates to context, interested parties or SWOT analysis documents also, changed through the approval process to be thoroughly reviewed and analyzed by appropriate personnel.

Opportunities:

- Purchasing new capabilities of manufacture IE: Equipment or Software.
- Exploring new technology.
- Expanding to new markets or new customers.
- Updates to context, interested parties or SWOT analysis documents.

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

6.2 Quality objectives and planning to achieve them

1. **Quality objectives**

1.1 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 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 Review processes. Certain objectives are published as separate, removable presentations, to facilitate distribution, communication and review.

1.3 Quality objectives are intended to achieve goals of the following:

- Consistency 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.
- To ensure a high level of customer confidence and satisfaction.

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

2. **Quality 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.

2.2 Planning to achieve the quality objectives are documented and communicated in the management review and operation review Dashboard Metrics presentations which define:

- A brief scope of the plan to achieve objectives.
- Resources required to achieve the objectives.
- Responsible parties.
- A due date of when the objectives will be achieved.
- Evaluation of the results, typically, performed on a quarterly or yearly basis and adjusted if necessary with new goals.

2.3 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 the elements and processes of the quality system.

3. **Planning of changes that may affect the QMS**

3.1 Changes to the quality system ensure integrity is maintained and is planned for 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.

3.2 Changes to the quality system will be reviewed and take into account the following:

- The purpose of the change and their potential consequences.
- The availability of resources to perform the change.
- The allocation or reallocation of responsibilities and authority as necessary.

7. Support

7.1 Resources

1. General

1.1 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 financial resources.

1.2 Top management is responsible for determining resource requirements for the implementation and improvement of the system.

1.3 Top management is responsible for determining resource requirements for addressing interested party satisfaction. This is typically based on input from other management personnel within the group that are responsible for activities relevant to particular aspects of relevant interested party satisfaction.

1.4 Top management has the responsibility and authority for provision of resources.

1.5 Allocation of resources for specific activities are 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.

1.6 Allocation of resources may be documented by operational work instructions, minutes of meetings, memoranda, or as a product retained invoices/quotes/estimates/etc.

2. People - General

2.1 Top management determines and provides the people needed for its QMS and effective operation of its processes.

3. Infrastructure

3.1 Top management is responsible for planning of production facilities and equipment. These activities are integrated with the development and validation of the manufacturing processes.

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

3.3 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.

3.4 Manufacturing capabilities and effectiveness are assessed in Top Management, Management Review and Operations Meetings.

3.5 Supporting services and maintenance of facilities are performed by example but, are 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, internet service providers, and internal and external IT providers of service provide communication Services.
- Internal employees 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 of buildings and other such facilities may be contracted as needed.

3.6 Top management 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. (QP-0015) Emergency Planning, Response & Recovery Procedure provides greater detail.

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

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

4. Environment for the operation of processes *(QP-0012) EDi Employee Manual, (QP-0013) AWAIR Policy, and (QP-0014) EDi Right To Know Manual*

4.1 Human factors - 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.

4.2 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, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

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

In day-to-day operations, personnel safety is managed with the help of the A.W.A.I.R (A Workplace Accident and Injury Reduction program), L.O.T.O (Lock Out Tag Out program) and R.T.K (Right To Know program) safety programs. These programs are independent from the quality management system. The management team, safety committee, right to know coordinator and human resources administrate it.

4.4 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.

5. Monitoring and measuring resources *(QP-008) Control of Monitoring and Measuring Devices, (WI-0032) Calibration Process, and (QF-0056) Calibration Data Sheet Template*

5.1 Identification of measurements to be performed, equipment to use for evaluation, and tolerance of the measured characteristics are documented in Control Plans (Operation Sheets) and/or in product drawings.

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

5.3 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 in a controlled list located within the Enterprise Software.

5.4 Only calibrated instruments and reference standards having an identifiable traceability to N.I.S.T. (National Institute of Standards and Technology) are used to perform verifications of and/or for calibrating to measuring and test 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 is labeled as such, reviewed by the Quality Manager at minimum for risk analysis, and de-activated or updated within the Enterprise Software as applicable.

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

5.6 Externally and internally calibrated equipment is labeled with the 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.

5.7 Internal inspection and calibration methods are documented within maintained document work instruction (WI-0032) Calibration Process. Internal calibration result records are documented on retained document (QF-0056) Calibration Data Sheet Template.

5.8 Quality department personnel are competent in specific inspections and calibrations, which they are authorized to perform.

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

6. Organizational Knowledge

6.1 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 competence of our people, the latter being peoples' ability to apply knowledge to their work.

6.2 To ensure the Organizational knowledge is retained and transferred, Organizational knowledge is recorded in documented information, and is 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.

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

6.4 Sources of external knowledge often include other standards used by customers; research papers and publications; or other knowledge gathered from customers, stakeholders or other external parties. Engel Diversified Industries Inc. determines and reviews internal and external sources of knowledge such as:

- Lessons learned from non-conformities, corrective actions and results of improvement.
- Gathering knowledge from customers, suppliers and partners, and benchmarking against competitors.
- Capturing knowledge existing within the organization by example, through mentoring/succession planning.
- Sharing knowledge with relevant interested parties to ensure sustainability of the organization.
- Knowledge from conferences, attending trade fairs, networking seminars, or other external events.

7.2 Competence *(QP-0016) Training Operating Procedure*

1. **General**

1.1 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.

1.2 Top management 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 in operating equipment and processes conducting inspections, and Quality management system assessments.

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

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

2. **Training programs**

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

- General orientation.

- Safety training, (A.W.A.I.R.) A Workplace Accident and Injury Reduction program, (L.O.T.O.) Lock Out Tag Out program, and (R.T.K.) Right To Know 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 *(QP-0016) Training Operating Procedure*

1. **Employee awareness, motivation and empowerment**

1.1 Awareness, motivation and empowerment programs include:
- Quality Policy and quality 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 promote innovation, quality and increased skills in the use of company equipment.

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

2. **Effectiveness of training and awareness**

2.1 Ultimately, EDi judges training and awareness effectiveness as a measure of continues business, returned goods, customer and relevant 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.

3. **Training and Awareness records**

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

3.2 Administration maintains 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 training records may include certificates of training located within the employee file.

7.4 Communication

1. **External communication**

1.1 The quality manager and top management team coordinates external communication regarding the quality management system to relevant external parties. These

communications may include but are not limited to the company website, via email or phone communications or meetings with customers and other relevant interested parties.

1.2 External communications regarding the quality management system are reviewed at minimum by the quality manager and typically reviewed by other top management team members for the following:

- What will be communicated
- When to communicate
- With whom to communicate
- How to communicate
- Who will communicate

2. **Internal communication**

2.1 Internal communication regarding the QMS flows in multiple ways, by 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 relevant interested parties including the customer, communicates information and data regarding interested parties needs and expectations, customer satisfaction, quality performance, effectiveness of the quality system, and opportunities for improvement.

2.2 The information is communicated through instructions both verbal and written, drawings, specifications, quality records, reports, etc.; and through training, on-the-job instruction, and meetings.

2.3 Management Review meetings have a special role in ensuring proper communication between 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 team to formulate policies, objectives, and directives to change and/or improve the quality system.

2.4 The Quality Manager 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 team.

7.5 Documented information

1. General

1.1 Although we acknowledge that the ISO 9001:2015 standard does not require documentation to be maintained or retained as documented information, we maintain and retain documented information to easily monitor, retrieve, review, analyze, update and ensure the most current relevant information is available and in use throughout the organization.

1.2 Top management determines the documentation necessary for the effectiveness of the quality management system and ensures the implementation of all documentation required by the international standard.

1.3 Maintained documents include the following by example:

- Quality Procedures
- Work Instructions
- Production and Control Plans
- Quality Forms
- Externally controlled documents

1.4 Retained documents include the following by example:

- Quality form template recorded information

2. Creating and Updating Maintained documented information

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

2.2 Documents are reviewed for adequacy and electronically approved prior to issue and recorded in the enterprise software and through retained electronic communications via MS Office. In the case of previously "Active" documents or forms there may not be an approver list.

2.3 Reviewing, updating, and ensuring re-approval of documents is the responsibility of varying member of the operations team receiving requested changes verbally, via e-mail, or other documented means. Documents can also be reviewed for continued adequacy during the internal process audit process.

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

3. Control of Maintained documented information *(QP-005) Document Control*

3.1 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.

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

3.3 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 date received and document. Previous customer documents may not have a date received as unknown.

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

4. Control of Retained documented information *(QP-003) Control of Records*

4.1 Quality retained documents are established and retained to provide evidence of:

- Process designs satisfy design input requirements.
- Materials, components and production processes meet specified requirements.
- Finished product conforms 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.

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

4.3 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

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

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, Quality, Production and Sales.

1.4 Customer and relevant interested parties requirements and references to its technical specifications are included in product realization and quality planning, typically being documented in individual product operation folders.

1.5 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 when acceptance criteria are not met, are defined and implemented via control of nonconforming product and/or inspection criteria methods.

2. **Acceptance Criteria *(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***

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

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

8.2 Customer-related processes

1. **Product requirements and order review *(QP-002) Contract Review***

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, but implied, and the company's capacity and capability to meet all applicable requirements. The record of this review can include form (QF-001) Sales Order Confirmation for Standard Production Orders, when needed.

1.2 Where applicable, the manufacturing feasibility of the proposed products are 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 as applicable.

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

2. Amendments to orders *(QP-002) Contract Review*

2.1 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 request.

3. **Confidentiality *(QP-005) Document Control***

3.1 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 properties shared with EDi.

4. **Change Control *(WI-003) Customer Specification Revision Change Process***

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 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.

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.

8.3 Design provisions

1.1 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.

1.2 EDi does provide engineering design assistance however, ultimately, the final design and implementations are decided by the customer for release.

8.4 Control of externally provided processes, products and services

1. **General**

1.1 Purchasing agents decide which suppliers of products and services are used from the active supplier list within the enterprise software. If a new supplier of products and services is selected, the new supplier is evaluated prior to placing a purchase order.

2. **Supplier evaluation *(WI-0011) Supplier Evaluation and Re-Evaluation Process***

2.1 As warranted, new suppliers are evaluated with regard to their capabilities. Quality, Purchasing Agents, and/or customers may establish the criteria for selection of suppliers, and conduct supplier evaluation 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 services.
- All requirements of the purchase order are met including certifications as required.
- Verification of delivered materials by quality control, physical performance, and visual properties.

2.2 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. Retained documents of the initial and subsequent supplier surveys are maintained.

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

- Verification of purchased products by receiving inspection personnel. Reference *(QP-0022) Shipping and Receiving* and *(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 department.
- 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.

2.4 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 actions.
- Formal review request of supplier scorecard.
- Quality audit at the supplier location.

Suppliers that do not adhere to any of these action, may be discontinued as an active supplier or, a minimal risk to EDi probation period may be applied. Retained records of corrective actions, supplier monitoring, quality audits, supplier scorecards, vendor returns, and re-evaluations are maintained in the enterprise software, or other formats.

3. **Supplier Information**

3.1 Purchasing documents are prepared by purchasing agents. The documents clearly and completely describe ordered processes, products, and services when applicable. This includes precise product identification and quality requirements.

8.5 Production and Service

1. **Control of production and services *(WI-002) Standard Production Order Process Flow***

1.1 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 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 and service.

1.2 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.

1.3 The production job packet including a printed copy of an operations folder:

- Provides a platform for recording completion of production and verification operations and their results, and for recording material and process traceability data.
- Provides product identification and inspection service status identification throughout the production process.

1.4 Control plans define controls used for the manufacturing process control, methods for monitoring special characteristics as critical to quality for either individual process

control or final customer specification critical characteristics, and reaction plans for responding to process instability.

1.5 Work instructions are established for operators of processes that impact product quality. Work instructions include job set-up instruction, process instructions, control plans, production jobs, rework instructions (as applicable), inspection and test instructions and calibration instructions, etc.

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

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

1.8 Production tooling is individually identified and managed by a system which includes storage location, maintenance and record of repair retained documents. Tool set-up instructions, tooling design and design modification records are retained. Tool identification is designated by location within the shop and/or through the use of ID tags or stamped directly into the tool.

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

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

2. Identification and Traceability *(QF-0062)Raw Material Inventory Tag/(QF-0017) Sheet Metal Form/(QF-0078) W.I.P. Tag*

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

2.2 Inspection and test status of products is 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 (W.I.P) tags, jobs, colored tags, or placement of products in designated locations, such as containment quarantines (for nonconforming product) or staging areas (for further processing of conforming product).

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

3. Customer or external provider property

3.1 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.

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

4. **Preservation *(QF-005) Operation Sheet Template***

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

4.2 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 enterprise software system.

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

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

5. **Post-delivery activities**

5.1 Engel Diversified Industries Inc. determines customer requirements prior to acceptance of a purchase order.
Customer requirements include:

- Previous customer requirements;
- Statutory and regulatory requirements related to product;
- Any additional requirement determined by Engel Diversified Industries Inc.

6. **Control of changes *(WI-003) Customer Specification Revision Change Process***

6.1 Changes to the 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 stocked parts in inventory. All results relating to the review of changes are retained as documented information.

8.6 Release of products and services

1. **Release of products and services *(QF-0057) First Article Inspection Report Template/(QF-0044) Characteristic Data Collection Report/ (QF-005) Operation Sheet Template/ (QF-0074) Inspection Report Template***

1.1 The quality manager has overall responsibility for planning and implementing the inspection and test activities needed to verify that product and service requirements are met at appropriate stages of the product realization process.

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

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

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

1.4 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.

1.5 All products that have had a final inspection completed will have a product acceptance label affixed to their container (typically a "green tag").

8.7 Control of nonconforming outputs

1. **Identification and documentation *(QP-0021) Control of Non-conforming product***

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

1.2 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.

1.3 In the case that nonconforming product is caused by EDi, management looks for trends and implements appropriate actions to prevent recurrence.

1.4 The quality manager with input from other top management team members is responsible for the disposition of nonconforming products which may include scrap, reworking, re-labeling or authorizing use or release.

1.5 Retained documented records of nonconformities and subsequent actions are retained in the enterprise software and on rework jobs printed for the production personnel as applicable.

1.6 Nonconforming product received from the customer or supplier are received and appropriately identified as nonconforming with a Quality Hold tag and placed in the

Quality Hold designated area until disposition is obtained. Returns and complaints will be logged in the enterprise software and appropriate actions will be taken.

1.7 Quality personnel will ensure proper containment, evaluation, validation and determination of nonconforming product rather internal or external is obtained.

1.8 The quality manager with input from other top management members will then dictate whether the parts are to be re-worked, replaced, or scrapped. Actions are documented in the enterprise software and on re-work jobs as applicable.

1.9 Product that has been re-worked or replaced, will have at minimum a final inspection by quality personnel, documented as retained information of recorded results prior to release, and then released for shipment to the customer or stock as applicable.

1.10 Whenever product or manufacturing processes differ from that which is currently approved, the customer will receive a deviation request. Deviations, associated communications and record of deviation are retained.

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

1. **General *(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***

1.1 Measurement and monitoring activities to verify product and manufacturing processes (including improvement activities) are planned in 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).

1.2 The effectiveness of the quality system is monitored by internal audits, measuring quality performance and customer satisfaction in operations meetings and management review meetings. Results of these activities are reported to top management and are used to identify opportunities for improvement.

1.3 Quality control 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 the process operator training.

1.4 Monitoring and measurement of processes *(QP-0018) Internal Audit* are monitored by a variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

- Internal process audits of the quality system;
- 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;

1.5 When a quality management system process does not conform to requirements or desired outputs, corrective action and/or risk mitigation actions are implemented.

1.6 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 piece inspections;
- Ongoing process monitoring during production (via in-process inspections)

1.7 Manufacturing processes are controlled through implementation of control plans (operations folders), 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.

1.8 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 corrections and/or corrective actions to assure that the process becomes stable and capable.

1.9 Where required by the customer or other relevant interested parties, important process events such as a tool change or machine repair are recorded.

2. Customer satisfaction *(QP-0017) Management Meetings*

2.1 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

3. Analysis of data *(QP-0017) Management Meetings*

3.1 Data and information recorded in quality records are 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.

3.2 The quality manager or designee is responsible for coordinating these activities, and for reporting conclusions and trends to the top management team. The collected and trends are reported to the top management team, and are evaluated with the framework of Management Review and Operations meetings of the quality system.

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

- Risk management;
- Customer and other relevant interested parties' satisfaction;
- Conformity of product and process requirements;
- Characteristics and trends of products and processes,
- Supplier quality performance

3.4 Trends in quality and operational performance are used for:

- Development of solutions to eliminate and/or mitigate customer and other relevant interested parties' problems;
- Development of solutions to address risks and opportunities;
- Determination of customer and other relevant interested parties' satisfaction trends and correlation for status reviews, decision making, and longer term strategic planning;
- As an information system for reporting product information arising from usage.
- The data is compared with progress toward achieving quality objectives and continual improvement activities.

9.2 Internal audit *(QP-0018) Internal Audit/(QF-00117) Management Meetings*

1. **Internal Audits**

1.1 EDi conducts internal system and process audits to determine whether the quality system is:
- Effectively achieving its expected outputs;
- Effectively implemented and maintained;
- Conforms to the planned arrangements (see 8.1), to the requirements of the ISO 9001:2015 International Standard and to the quality management system requirements established by the organization.

1.2 The process audit schedule covers the scope of the organizations 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 the processes and applicable quality procedures, work instructions, quality forms, etc. is utilized as an input in planning the scope of a particular audit assessment. The scope or boundary of each process audit and its objective is planned by the quality manager or designee.

1.3 A lead auditor and an assistant auditor plans and compiles the criteria to be used for each process audit. This may include the quality manual, the ISO 9001 standard, Quality operating procedure, process 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 or other criteria.

1.4 Previous education and trained, and/or EDi directed trained audit assessors conduct the internal process or system audits, recording objective evidence. The quality manager and/or other top 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 reviews the completed audit summary, ensuring the adequate coverage of the planned objective 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 documented in the enterprise software.

1.5 Audits may include a formal or informal closing meeting as needed. If conducted, a meeting agenda could include, by example; a thank you to the owner of the process, attendance, confirmation of the objective and scope, areas of good practice, nonconformities identified, general trends, risk mitigation and opportunities for

improvement activities, questions and the agreed upon time for responses. Internal auditors may read the nonconformities during the closing meeting.

1.6 The lead and assistant audit team shall develop an assessment summary report that is located in the enterprise software when completed. This includes any corrective action and/or risk mitigation actions assigned to the appropriate personnel. Summaries (QF-00117) and actions provide the retained documented information for each audit assessment and are retained within the enterprise software.

1.7 Follow up activities are taken and are 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 will take place per the timetable or during the next scheduled audit of the area the actions were written against.

1.8 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.

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

2. Management review *(QP-0017) Management Meetings/(QF-003) Quarterly Management Review Meeting Minutes*

2.1 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 needed to achieve organizational goals;

2.2 Management review meetings are chaired by the President or designee based upon agenda developed by the top management team and are typically attended by representatives as defined in QF-0098 Organizational Charts document.

2.3 Management review meetings are conducted on a quarterly basis at minimum. More frequent reviews may be scheduled in periods when organizational, product change, or other circumstances require increased attention and input from the top management team.

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

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

2.6 Input into the management review meeting agenda consist of information and data related to quality performance of the organization. At a minimum, this includes:

- Follow-up actions from the last management review and/or operation review meeting;
- Status, schedule and results of audits both internal and external as applicable;
- Process performance and conformity data;
- Status of corrective action and actions to address risks and opportunities;
- Risk mitigation actions typically in the form of corrective actions;
- Changes that could affect the quality system;
- Customer satisfaction including feedback, complaints and customer scorecard data;
- On-time delivery performance data;
- Recommendations for improvement;
- Quality objectives and quality policy;

2.7 Management reviews meetings are concluded with actions related to improvement of the organization, quality management system, and improvement of processes and products to better meet customer and other relevant interested parties' requirements. The review also identified resource need to implement these actions.

2.8 Results of management reviews are documented in meeting minutes of the review meeting and copies of the presentation material are retained.

10. Improvement

10.1 General

1. General Improvement *(QF-0079) Quick Win*

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 risks and opportunities for improvement and to implement improvement projects. The top management team is responsible for coordinating and monitoring the continual improvement effort.

2. Nonconformity and corrective action *(QP-0020) Corrective Action*

2.1 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 top management discretion.

2.2 Enterprise software entries include data fields for description of issue, short term or interim action taken, correction of issue, root cause analysis, corrective actions to address occurrence and detection, including 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 timing for implementing corrections or short-term actions, and timing of implementing completion of long term corrective actions when required. The quality manager reviews all corrections and corrective actions for completeness prior to closure.

2.3 The quality manager determines the assignee for corrective action. Assignees are responsible to ensure actions are taken to eliminate 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 the corrective action retained documented information is recorded with information of verification of implementation.

2.4 The quality manager validates the effectiveness of corrective actions taken on major nonconformities and monitors correction actions taken on minor nonconformities.

2.5 Corrective actions are an input to the management and operations review process.

2.6 EDi analyzes parts rejected by the customer's manufacturing facilities and where appropriate, retains the analysis results. EDi performs analysis and initiates containment of product, correction of issue, and/or corrective actions as required. This is dependent upon the magnitude of the issue as to the determination of actions taken. EDi may choose to accept the consequences in the case of what appears to be an anamoly by example, one part returned for a scuff etc. indicating an anamoly.

3. Continual Improvement

3.1 Opportunities for improvement can be identified from:

- Analysis and evaluation of data regarding product conformity, manufacturing process performance, customer and other relevant party satisfaction, effectiveness of the quality system, and other quality performance indicators via management review and operations review meetings;
- Internal and external audits of the quality management system;
- Employees suggestions for improving their processes and work environment; routinely through the "Quick Win" submission and implementation process or other verbal discussions.
- Immediate need to address risks and opportunities, and new or changing requirements;
- Customer or other relevant interested party feedback or complaints,
- Risk mitigation projects

3.2 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 projects, they may be as a result of corrective actions identifying other like processes or products that may require similar corrective actions and are typically retained as documented information within the corrective action system within the enterprise software.

3.3 Risk mitigation actions are appropriate to the effects of the potential issues which could occur and include but are not limited to the following:

- New process design;
- Preventive maintenance;
- Internal process audit results;
- Management reviews;
- Employee suggestions;

3.4 Items are discussed at management review and operations review meetings including the need for actions and retained results of actions taken. The top management team or any combination of the team determines the need for action, root cause analysis of potential problems that may arise and ensures the implementation of needed actions and reviews the retained information 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-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