	<u>Title:</u> <b>AS9100D Quality Manual</b>	<u>Revision Date.:</u> 05/04/2018
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The Quality Policy of Monroe Engineering is defined in the following statement:

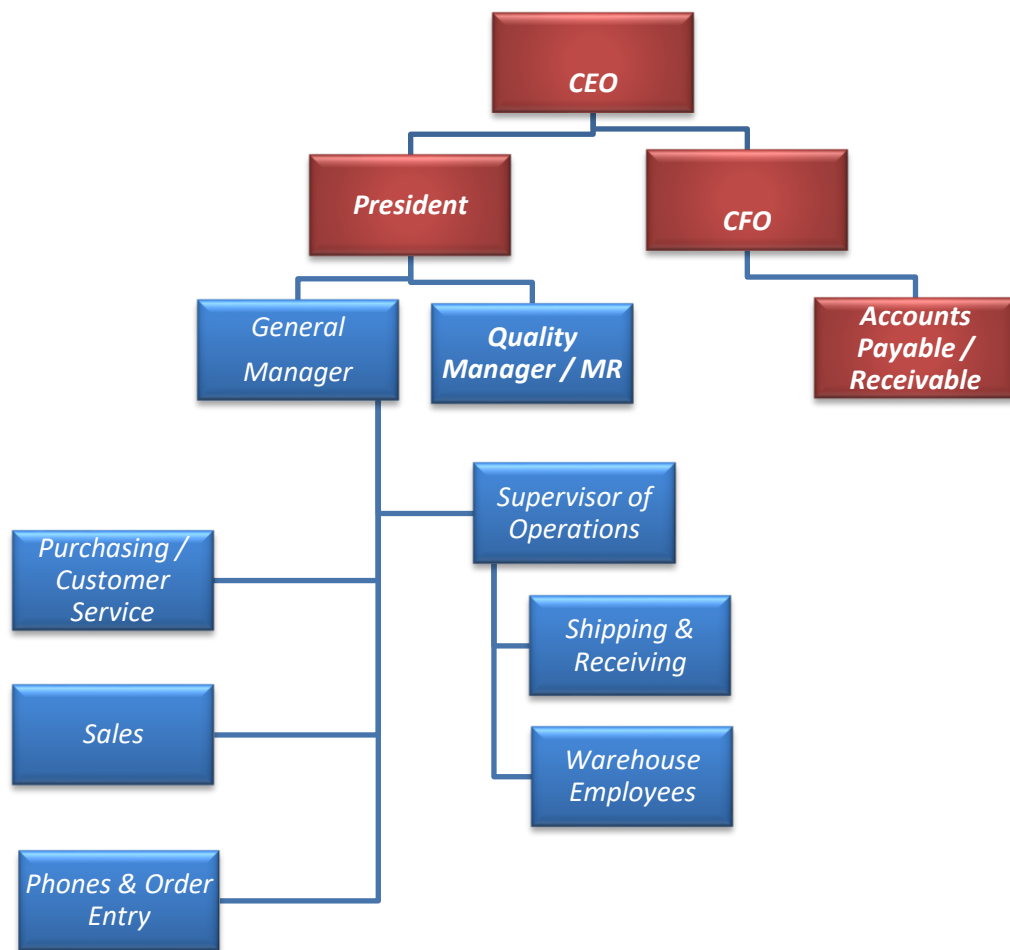
Monroe Engineering is committed to customer satisfaction; we strive for Continuous Improvement in our products and our people.


The policies under which Monroe Engineering will operate its' quality system are contained within the quality manual. The quality system is designed to and operates with the requirements of ISO 9001:2015 and where contractually required **AS9100 Rev D. Requirements specifically for AS9100 are identified in bold throughout this quality manual.** The quality manual issued and controlled by Monroe Engineering defines the quality system that is effective across all disciplines and at all levels within the company. If you have any questions concerning the current status of this manual, please contact the Management Representative at Monroe Engineering 2990 Technology Dr. Rochester Hills, Michigan 48309.

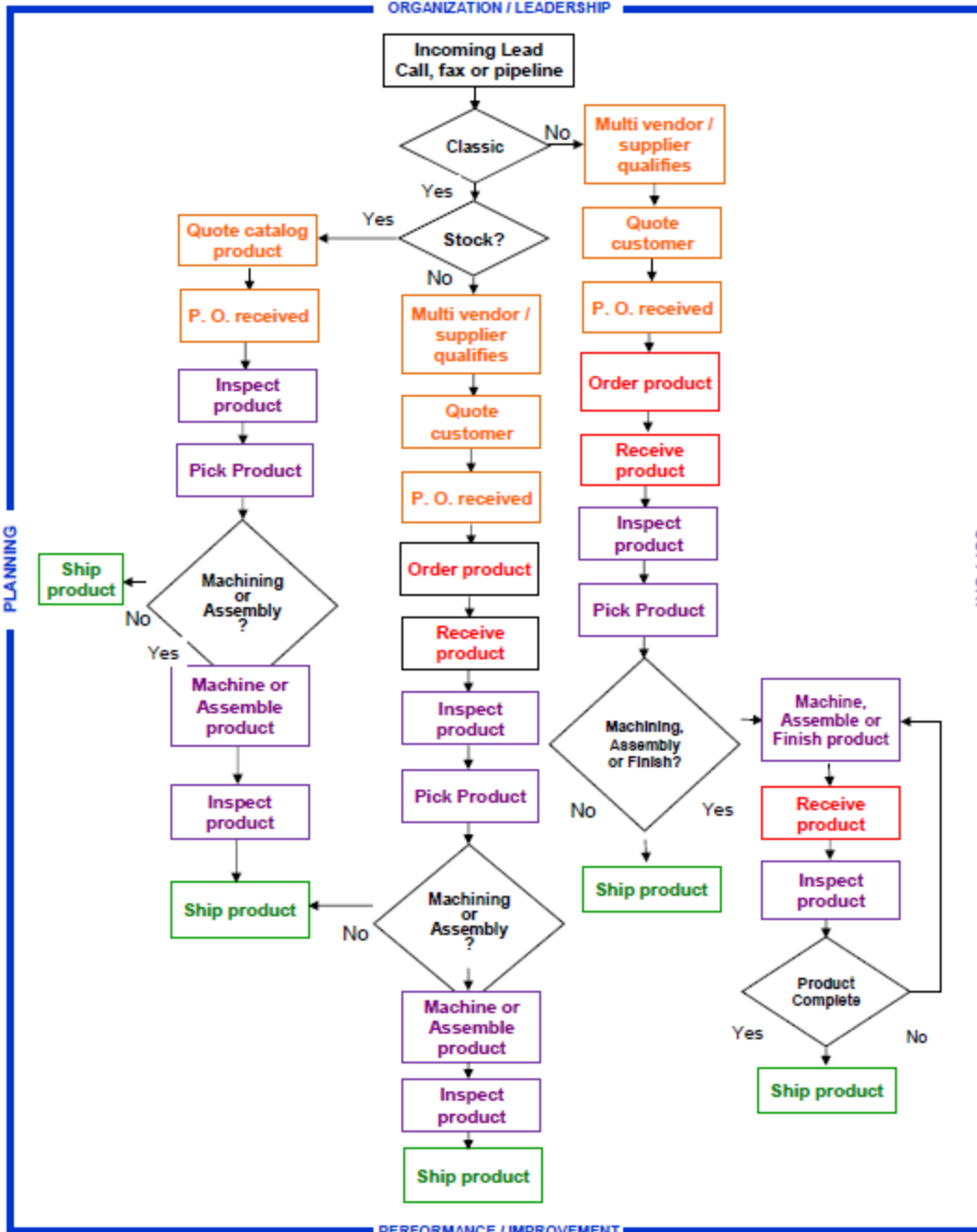


# Organizational Chart for Monroe Engineering

Monroe Corporate Staff  
Monroe Engineering Staff



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	QM BO	D
Title:	Effective Date:	Page 1 of 1
Interaction of Processes	5/4/2018	



Management Process – 4, 5, 6, 7, 9, 10  
 Order Management Process – 6, 8  
 Purchasing Process – 8.4  
 Manufacturing Process – 7, 8  
 Shipping Process – 7, 8

Process owner  
 GM, SOO  
 GM, SOO  
 PM, GM, SOO  
 GM, SOO, QM  
 GM, SOO

GM- General Manager  
 SOO- Supervisor of Operations  
 QM- Quality Manager  
 PM- Purchasing Manager

## 4 Context of the Organization

### 4.1 Understanding the organization and its context

Monroe Engineering has determined the external and internal issues that are relevant to the purpose and strategic direction to achieve the quality management system (QMS) desired. The QMS information will be monitored and reviewed.

### 4.2 Understanding the needs and expectations of interested parties

Monroe Engineering will consistently provide products and services that meet customer and applicable statutory and regulatory requirements. To do this we shall determine, monitor and review information concerning during the Management Review (see 9.3):

- a). the interested parties relevant to the QMS; and
- b). the requirements of the interested parties relevant to the QMS.

### 4.3 Determining the scope of the QMS

This quality manual applies to all activities within Monroe Engineering as a manufacturer and distributor of clamps, knobs, handles, plungers, leveling pads, hinges, and boosters. At this time, Monroe Engineering excludes design (**8.3**), the customer supplies all design work. Post-delivery activities **sections 8.5.5 g & h** are excluded because we do not have technical documentation or have control over work done outside our company. If we determine in the future to add design and/or post-delivery activity, we will update our quality management system to include these sections of the ISO9001 / **AS9100** standard.

### 4.4 Quality management system and its processes

4.4.1 Monroe Engineering has established, implemented, maintained and continually improves their quality management system including their processes and interactions in accordance with the AS9100D requirements.

**The QMS shall also address customer and applicable statutory and regulator QMS requirements.**

Monroe Engineering has determined the processes needed for their QMS and their application throughout and shall:

- a). determine the inputs required and expected outputs from their processes;
- b). determine the sequence and interaction of processes;
- c). determine and apply the criteria and methods needed to ensure the effective operation and control of their processes;
- d). determine the resources needed for their processes and ensure their availability;
- e). assign the responsibilities and authorities for the processes;
- f). address the risks and opportunities determined by the requirements;
- g). evaluate the processes and implement any changes needed to ensure the processes achieve their intended results;
- h). improve their processes and the QMS.

4.4.2 Monroe Engineering shall:

- a). maintain documented information to support the operation of its processes; and
- b). retain documented information to ensure processes are being carried out as planned.

**Documented information includes**

- **A general description of relevant interested parties;**
- **The scope of the QMS, including boundaries and applicability;**
- **A description of the processes need for the QMS and their application throughout our company;**

- **The sequence and interaction of these processes; and**
- **Assignment of the responsibilities and authorities for these processes.**

## 5 Leadership

### 5.1 Leadership and commitment

#### 5.1.1 Top management of Monroe Engineering is committed to the QMS by:

- a). taking accountability for the effectiveness of the QMS;
- b). the quality policy and objectives are established for the QMS and are compatible with the context and strategic direction;
- c). ensuring the integration of the QMS into the business processes;
- d). promote the use of the process approach and risk-based thinking;
- e). the QMS resources are available;
- f). communicating the effectiveness to the QMS;
- g). ensure the QMS achieves its intended results;
- h). engaging, directing and supporting persons to contribute to the effectiveness of the QMS;
- i). promote improvement;
- j). supporting management roles to demonstrate their leadership as it applies to their area of responsibility.

#### 5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- a). determine, understand and consistently meet customer and applicable statutory and regulatory requirements;
- b). determine and address the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction; and
- c). maintain the focus of enhancing customer satisfaction; and
- d). product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.**

### 5.2 Policy

#### 5.2.1 Establishing the quality policy

Top management has established, implemented and maintained a quality policy that:

- a). is appropriate to the purpose and context of Monroe Engineering and supports our strategic direction;
- b). provided a framework for setting quality objectives;
- c). includes a commitment to satisfy applicable requirements; and
- d). includes a commitment to continual improve its QMS.

#### 5.2.2 Communicating the quality policy

The quality policy shall:

- a). is available and maintained as documented information;
- b). is communicated, understood and applied within the organization; and
- c). is available to relevant parties, as appropriate.

### 5.3 Organizational roles, responsibilities and authorities

Top management ensures responsibilities and authorities for relevant roles are assigned, communicated and understood.

Top management has assigned responsibility and authority for:

- a). ensuring the QMS conforms to the requirements of AS9100D;
- b). ensuring the processes are delivering their intended outputs;
- c). reporting on the performance of the QMS and on opportunities for improvement;
- d). ensuring the promotion of customer focus throughout Monroe Engineering; and
- e). ensuring the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

**Top management has appointed the Director of Quality, who has the responsibility and authority for oversight of the QMS as the management representative (MR). The MR has the organizational freedom and unrestricted access to top management to resolve quality management issues.**

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 Our QMS has determined the risks and opportunities that need to be addressed to:

- a). give assurance the QMS has achieved its intended results;
- b). enhance desirable effects;
- c). prevent or reduce undesired effects; and
- d). achieve improvement.

6.1.2 The organization shall plan:

- a). actions to address these risks and opportunities;
- b). how to;
  - 1). Integrate and implement the actions into its QMS processes; and
  - 2). Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

6.2 Quality objectives and planning to achieve them

6.2.1 Monroe Engineering has established quality objectives at relevant functions, levels and processes needed for the QMS.

The quality objectives shall:

- a). be consistent with the quality policy;
- b). be measurable;
- c). take into account applicable requirements;
- d). be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e). be monitored;
- f). be communicated; and
- g). be updated as appropriate.

Quality objectives are maintained as documented information.

6.2.2 When planning how to achieve our quality objectives we shall determine:

- a). what will be done;
- b). what resources will be required;
- c). who will be responsible;
- d). when it will be completed; and
- e). how the results will be evaluated.

6.3 Planning

When changes are made to our QMS they are planned. We shall consider:

- a). the purpose of the changes and their potential consequences;
- b). the integrity of the QMS;
- c). the availability of resources; and
- d). the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

We have determined and provided the resources needed for the establishment,

implementation, maintenance and continual improvement of the QMS.

MONROE ENGINEERING shall consider:

- a). the capabilities of, and constraints on, existing internal resources; and
- b). what needs to be obtained from external providers.

7.1.2 People

We have determined and provided the people necessary for the effective implementation of its QMS and for the operation and control of its processes.

7.1.3 Infrastructure

The infrastructure (can include buildings, associated utilities, equipment, transportation resources, information and communication technology) is maintained for the operation of its processes and to achieve conformity of products and services.

7.1.4 Environment for the operation of processes

The environment is maintained for the operation of its processes and to achieve conformity of products and services. (A suitable environment can be a combination of human and physical factors such as: social, psychological, physical)

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements are provided.

We ensure that the resources provided:

- a). are suitable for the specific type of monitoring and measurement activities being undertaken; and

- b). are maintained to ensure their continuing fitness for their purpose.

Documented information is retained as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement or considered to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a). calibrated or verified, or both, at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

- b). identified in order to determine their status; and

- c). safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

**We have a process for the recall of monitoring and measuring equipment requiring calibration or verification. A register of the monitoring and measuring equipment includes the equipment type, unique identification, location and the calibration or verification method, frequency and acceptance criteria. Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions.**

We determine if the validity of previous measurement results has been adversely affected when measuring equipment if found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6 Organizational knowledge (is knowledge specific to Monroe Engineering)

We have determined the knowledge necessary for the operation of our processes and to achieve conformity of products and services. This knowledge will be maintained and made available to the extent necessary. When addressing changing needs and trends, we shall



consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

## 7.2 Competence

Monroe Engineering shall:

- a). determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS;
- b). ensure these persons are competent on the basis of appropriate education, training, or experience **and a periodic review occurs;**
- c). where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and
- d). retain documented information as evidence of competence.

## 7.3 Awareness

Monroe Engineering shall ensure persons doing work under our control are aware of:

- a). the quality policy;
- b). relevant quality objectives;
- c). their contribution to the effectiveness of the QMS, including the benefits of improved performance;
- d). the implications of not conforming with the QMS requirements;
- e). relevant QMS documented information and changes thereto;**
- f). their contribution to product or service conformity;**
- g). their contribution to product safety; and**
- h). the importance of ethical behavior.**

## 7.4 Communication

Monroe Engineering shall determine the internal and external (**feedback**) communications relevant to the QMS, including:

- a). on what it will communicate;
- b). when to communicate;
- c). with whom to communicate;
- d). how to communicate; and
- e). who communicates.

## 7.5 Documented Information

### 7.5.1 General

Monroe Engineering's QMS shall include:

- a). documented information required by AS9100D; and
- b). documented information determined by Monroe Engineering as being necessary for the effectiveness of the QMS.

### 7.5.2 Creating and updating

When documented information is created or updated, we ensure appropriate:

- a). identification and description;
- b). format and media; and
- c). review and approval for suitability and adequacy.

### 7.5.3 Control of documented information

7.5.3.1 Documented information required by our QMS and AS9100D shall be controlled to ensure:

- a). it is available and suitable for use, where and when needed; and
- b). it is adequately protected.

7.5.3.2 For control of documented information, we shall address the following activities, as applicable:

- a). distribution, access, retrieval and use;
- b). storage and preservation, including preservation of legibility;
- c). control of changes;
- d). retention and disposition; and
- e). prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.**

External documented information determined to be necessary for the planning and operation of the QMS shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations.

**When documented information is managed electronically, data protection processes shall be defined.**

- 8 Operations
- 8.1 Operational planning and control

We shall plan, implement and control the processes needed to meet the requirements for the provision of products and services, and to implement the actions determined by:

- a). determining the requirements for the products and services;
  - NOTE: Determination of requirements for the products and services should include consideration of:**
    - **Personal and product safety;**
    - **Producibility and inspectability;**
    - **Reliability, availability, and maintainability;**
    - **Suitability of parts and materials used in the product;**
    - **Selection and development of embedded software;**
    - **Product obsolescence;**
    - **Prevention, detention, and removal of foreign objects;**
    - **Handling, packaging, and preservation;**
    - **Recycling or final disposal of the product at the end of its life.**
- b). establishing criteria for
  - 1). the processes;
  - 2). the acceptance of products and services;
  - NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:**
    - **Design verification;**
    - **Process control;**
      - **Selection and verification of key characteristics;**
      - **Process capability measurements;**
      - **Statistical process control;**
      - **Design of experiments;**
    - **Verification;**
    - **Failure mode, effects, and criticality analysis.**
- c). determining the resources needed to achieve conformity to the product and service requirements **and to meet on-time delivery of products and services;**
- d). implementing control of the processes in accordance with the criteria; and
- e). determining, maintaining and retaining documented information to the extent necessary:
  - 1). To have confidence that the processes have been carried out as planned;
  - 2). To demonstrate the conformity of products and services to their requirements.
- f). determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;**
- g). engaging representatives of affected organization functions for operational**

- planning and control;**
- h). determining the process and resources to support the use and maintenance of the products and services;**
- i). determining the products and services to be obtained from external providers;**
- j). establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.**

**As appropriate, customer requirements, and products and services, we planned and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.**

The output of this planning shall be suitable for our operations.

We shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. We will ensure outsource processes are controlled.

**We have established, implemented, and maintained a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process shall ensure that work transfer impacts and risks are managed.**

#### **8.1.1 Operational Risk Management**

**We have planned, implemented, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to Monroe Engineering and the products and services:**

- a). assignment of responsibilities for operational risk management;**
- b). definition of risk assessment criteria;**
- c). identification, assessment, and communication of risks throughout operations;**
- d). identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;**
- e). acceptance of risks remaining after implementation of mitigating actions.**

#### **8.1.2 Configuration Management**

**We have planned, implemented and control the configuration management process as appropriate to our company and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:**

- a). control product identity and traceability to requirements, including the implementation of identified changes;**
- b). ensure documented information is consistent with the actual attributes of the products and services.**

#### **8.1.3 Product Safety**

**Monroe Engineering has planned, implemented and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to our company and products.**

#### **8.1.4 Prevention of Counterfeit Parts**

**Monroe Engineering has planned, implemented and controls the processes appropriate to us and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.**

## **8.2 Requirements for products and services**

### **8.2.1 Customer communication**

Communication with customers shall include:

- a). providing information relating to products and services;**
- b). handling enquiries, contracts or orders, including changes;**
- c). obtaining customer feedback relating to products and services, including customer complaints;**
- d). handling or controlling customer property; and**
- e). establishing specific requirements for contingency actions, when relevant.**

#### 8.2.2 Determining the requirements for products and services

When determining the product and service requirements to be offered to customers we shall ensure that:

- a). the product and service requirements are defined, including:
  - 1). Any applicable statutory and regulatory requirements;
  - 2). Those considered necessary by us.
- b). we can meet the claims for the products and services it offers;
- c). special requirements of the products and services are determined;**
- d). operational risks have been identified.**

#### 8.2.3 Review of the requirements for products and services

8.2.3.1 Monroe Engineering ensure that it has the ability to meet the requirements for products and services to be offered to customers. We shall conduct a review before committing to supply products and services to a customer, to include:

- a). requirements specified by the customer; including the requirements for delivery and post-delivery activities;
- b). requirements not stated by the customer; but necessary for the specified or intended use, when known;
- c). requirements specified by us;
- d). statutory and regulatory requirements applicable to the products and services; and
- e). contract or order requirements differing from those previously expressed.

**The review shall be coordinated with applicable functions. If we determine that some customer requirements cannot be met or can only partially be met, we shall negotiate a mutually acceptable requirement with the customer.**

Monroe Engineering shall ensure the contract or order requirements differing from those previously defined are resolved. The customer's requirements shall be confirmed before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 Documented information shall be retained as applicable:

- a). on the results of the review; and
- b). on any new requirements for the products and services.

#### 8.2.4 Changes to requirements for products and services

Monroe Engineering shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

### 8.3 Design and development of products and services

#### 8.3.1 General

A design and development process is maintained to ensure the subsequent provision of products and services.

#### 8.3.2 Design and development planning

In determining the stages and controls for design and development we consider:

- a). the nature, duration and complexity of the design and development activities;
- b). the required process stages, including applicable design and development reviews;
- c). the required design and development verification and validation activities;
- d). the responsibilities and authorities involved in the design and development process;
- e). the internal and external resource needs for the design and development of products and services;
- f). the need to control interfaces between persons involved in the design and development process;
- g). the need for involvement of customer's and users in the design and development process;

- h). the requirements for subsequent provision of products and services;
- i). the level of control expected for the design and development process by customers and other relevant interested parties; and
- j). the documented information needed to demonstrate that design and development requirements have been met.

**When appropriate, we will divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs. Design and development planning shall consider the ability to provide, verify, test and maintain products and services.**

#### 8.3.3 Design and development inputs

We have determined the requirements essential for the specific types of products and services to be designed and developed and shall consider:

- a). functional and performance requirements;
- b). information derived from previous similar design and development activities;
- c). statutory and regulatory requirements;
- d). standards or codes of practice that we have committed to implement;
- e). potential consequences of failure due to the nature of the products and services;
- f). when applicable, the potential consequences of obsolescence.**

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. Design and development inputs shall be retained documented information.

#### 8.3.4 Design and development controls

We shall apply controls to the design and development process to ensure that:

- a). the results to be achieved are defined;
- b). reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c). verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d). validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e). any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f). documented information of these activities is retained; and
- g). progression to the next stage is authorized.**

**Participants in design and development reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.**

##### **8.3.4.1 When test are necessary for verification and validation, the tests are planned, controlled, reviewed and documented to ensure and prove the following:**

- a). test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;**
- b). test procedures describe the test methods to be used, how to perform the test, and how to record the results;**
- c). the correct configuration of the test item is submitted for the test;**
- d). the requirements of the test plan and the test procedures are observed;**
- e). the acceptance criteria are met.**

**Monitoring and measuring devices used for testing shall be controlled. At the completion of design and development, reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.**

### 8.3.5 Design and development outputs

We ensure the design and development outputs:

- a). meet the input requirements;
- b). are adequate for the subsequent processes for the provision of products and services;
- c). include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d). specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision;
- e). specify, as applicable, any critical items, including and key characteristics, and specific action to be taken for these items;**
- f). are approved by authorized person(s) prior to release.**

**The data required is defined to allow the product to be identified, manufactured, verified, used, and maintained.**

Documented information of the results of the design and development outputs shall be retained.

### 8.3.6 Design and development changes

Changes made during or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. **There is a process to notify our customers, prior to implementation, about changes that affect customer requirements.**

Documented information shall be retained on:

- a). design and development changes;
- b). the results of reviews;
- c). the authorization of the changes; and
- d). the actions taken to prevent adverse impacts.

**Changes to design and development are controlled in accordance with our configuration management process requirements.**

## 8.4 Control of externally provided processes, products and services

### 8.4.1 General

Monroe Engineering ensures externally provided processes, products and services conform to our requirements. **We are responsible for the conformity of all externally provided processes, products and services, including sources defined by the customer. We ensure, when required, that customer-designated or approved external providers, including process sources are used. We shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers. We require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.**

We have determined the controls to be applied to externally provided processes, products and services when:

- a). products and services from external providers (known as suppliers) are intended for incorporation into our products and services;
- b). products and services are provided directly to the customer(s) by external providers on behalf of Monroe Engineering; and
- c). a process, or part of a process, is provided by an external provider as a result of a decision by Monroe Engineering.

We evaluate, select, monitor their performance and re-evaluate our external providers based on their ability to provide processes or products and services in accordance with our requirements. Documented information is retained of these activities and any necessary actions arising from the evaluations.

- 8.4.1.1 We shall:**
- a). define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of external providers depending on their approval status;**
  - b). maintain a register of its external providers that includes approval status;**
  - c). periodically review external provider performance including process, product and service conformity, and on-time delivery performance;**
  - d). define the necessary actions to take when dealing with external providers that do not meet requirements; and**
  - e). define the requirements for controlling documented information created by and/or retained by external providers.**

8.4.2 Type and extent of control

Monroe Engineering ensures that externally provided processes, products and services do not adversely affect our ability to consistently deliver conforming products and services to its customers.

Monroe Engineering shall:

- a). ensure externally provided processes remain within the control of its QMS;
- b). define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; and
- c). take into consideration:
  - 1). The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
  - 2). The effectiveness of the controls applied by the external provider;
  - 3). The results of the periodic review of external provider performance.**
- d). determine the verification, or other activities necessary to ensure that the externally provided processes, products and services meet requirements. **Verification activities of externally provided processes, products and services shall be performed according to the risks identified by us. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.**

**When externally provided product is released for production use pending completion of all required verification activities, it will be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.**

**When we delegate verification activities to the external provider, the scope and requirements for delegation is defined and a register of delegations are maintained. We will periodically monitor the external provider's delegated verification activities.**

**When external provider test reports are utilized to verify externally provided products, we have implemented a process to evaluate that data in the test reports to confirm that product meets requirements. When a customer has identified raw material as a significant operational risk we will implement a process to validate the accuracy of test reports.**

8.4.3 Information for external providers

Monroe Engineering ensures the adequacy of requirements prior to their communication to the external provider. We shall communicate to the external providers its requirements for:

- a). the process, products and services to be provided **including the identification of relevant technical data;**
- b). the approval of:
  - 1). Products and services;

- 2). Methods, processes and equipment; and
- 3). The release of products and services;
- c). competence, including any required qualification of persons;
- d). the external providers' interactions within the organization;
- e). control and monitoring of the external providers' performance to be applied by us;
- f). verification or validation activities that we or our customer, intend to perform at the external provider's premises;
- g). design and development control;**
- h). special requirements, critical items, or key characteristics;**
- i). test, inspection, and verification;**
- j). the use of statistical techniques for product acceptance and related instructions for acceptance;**
- k). the need to:**
  - **Implement a QMS;**
  - **Use customer-designated or approved external providers, including process sources;**
  - **Notify the organization of nonconforming processes, products or services and obtain approval for their disposition;**
  - **Prevent the use of counterfeit parts;**
  - **Notify the organization of changes to processes; products or services, including changes of their external providers or location of manufacture, and obtain their approval;**
  - **Flow down to external providers applicable requirements including customer requirements;**
  - **Provide test specimens for design approval, inspection/verification, investigation or auditing;**
  - **Retain documented information, including retention periods and disposition requirements;**
- l). the right of access by Monroe Engineering, our customer and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;**
- m). ensuring that persons are aware of:**
  - **Their contribution to product or service conformity;**
  - **Their contribution to product safety;**
  - **The importance of ethical behavior.**

## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

Monroe Engineering has production and service provision under controlled conditions.

Controlled condition shall include, as applicable:

- a). the availability of documented information that defines:
  - 1). The characteristics of the products to be produced, the services to be provided or the activities to be performed; and
  - 2). The results to be achieved.
- b). the availability and use of suitable monitoring and measuring resources;
- c). the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
  - 1). Ensuring documented information for monitoring and measurement activity for product acceptance includes:**
    - **Criteria for acceptance and rejection;**
    - **Where in the sequence verification operations are to be performed;**
    - **Measurement results to be retained;**
    - **Any specific monitoring and measurement equipment required and instructions associated with their use;**



**2). Ensure when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use.**

- d). the use of suitable infrastructure and environment for the operation of processes;
- e). the appointment of competent persons, including any required qualification;
- f). the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g). the implementation of actions to prevent human error; and
- h). the implementation of release, delivery and post-delivery activities;
- i). the establishment of criteria for workmanship;**
- j). the accountability for all products during production;**
- k). the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;**
- l). the determination of methods to measure variable data;**
- m). the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;**
- n). the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;**
- o). the provision for the prevention, detection, and removal of foreign objects;**
- p). the control and monitoring of utilities and supplies to the extent they affect conformity to product requirements;**
- q). the identification and recording of products released for subsequent production pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.**

**8.5.1.1 Equipment, tools and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and be maintained.**

**8.5.1.2 Validation and control of special processes**

For processes where the resulting output cannot be verified by subsequent monitoring and measurement, we shall establish arrangements for these processes including, as applicable:

- a). definition of criteria for the review and approval of the processes;
- b). determination of conditions to maintain the approval;
- c). approval of facilities and equipment;
- d). qualification of persons;
- e). use of specific methods and procedures for implementation and monitoring of processes; and
- f). requirements for retained documented information.

**8.5.1.3 Monroe Engineering production process verification activities (could include risk assessments, capacity studies, capability studies and control plans) to ensure the production process is able to produce products that meet requirements.**

**Monroe Engineering will use a first piece to verify that the processes, documentation, and tooling if applicable are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results. Documented information on the results of production process verification is retained.**

8.5.2 Identification and traceability

Monroe Engineering uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services. **We maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.** Products are identified

with respect to monitoring and measurement requirements throughout production and service provision. **When acceptance authority media are used we shall establish controls for the media.** Documented information will be retained for outputs that require traceability.

8.5.3 Property belonging to customers or external providers

Monroe Engineering exercises care with property belonging to customer or external providers while it is under our control or being used by us. We will identify, verify protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. If customer or external providers' property is lost, damaged or otherwise found to be unsuitable for use, we will report this to the customer or external provider and documented information will be retained.

8.5.4 Preservation

We will preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. **Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:**

- a). cleaning;
- b). prevention, detection and removal of foreign objects;
- c). special handling and storage for sensitive products;
- d). marking and labeling, including safety warnings and cautions;
- e). shelf life control and stock rotation; and
- f). special handling and storage for hazardous materials.

8.5.5 Post-delivery activities

We will meet requirements for post-delivery activities associated with the products and services. We will consider the extent of post-delivery activities that are required by:

- a). statutory and regulatory requirements;
  - b). the potential undesired consequences associated with its products and services;
  - c). the nature, use and intended lifetime of its products and services;
  - d). customer requirements;
  - e). customer feedback;
  - f). collection and analysis of in-service data;
  - g). control, updating, and provision of technical documentation relating to product use, maintenance, repair and overhaul;
  - h). controls required for work undertaken external to our company;
  - i). product/customer support.
- When problems are detected after delivery, Monroe Engineering shall take appropriate action including investigation and reporting.**

8.5.6 Control of changes

We review and control changes for production and service provision, to the extent necessary to ensure continuing conformity with requirements. **Persons authorized to approve production or service provision changes shall be identified.** Documented information is retained of the review of changes, the person(s) authorizing the change and any necessary actions arising from the review.

8.6 Release of products and services

Monroe Engineering has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. Retained documented information of the release of products and services shall include:

- a). evidence of conformity with the acceptance criteria; and
- b). traceability to the person(s) authorizing the release.

**When required to demonstrate product qualification, Monroe Engineering shall ensure documented information provides evidence that the products and services meet the defined requirements. Monroe Engineering ensures that all documented information required to accompany the products and services are present at delivery.**

## 8.7 Control of nonconforming outputs

8.7.1 Monroe Engineering ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. We will take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

**Monroe Engineering's nonconformity control process shall be maintained as documented information including the provisions for:**

- **Define the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;**
- **Take actions necessary to contain the effect of the nonconformity on other processes, products or services;**
- **Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;**
- **Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.**

Nonconforming outputs can be dealt with in one or more of the following ways:

- a). correction;
- b). segregation, containment, return or suspension of provision of products and services;
- c). informing the customer;
- d). obtaining authorization for acceptance under concession **by a relevant authority and, when applicable, by the customer.**

**Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:**

- **After approval by an authorized representative for design or by persons having delegated authority from the design organization;**
- **After authorization by the customer, if the nonconformity results in a departure from the contract requirements.**

**Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable. Counterfeit or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.**

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 Documented information shall be retained for:

- a). describes the nonconformity;
- b). describes the actions taken;
- c). describes any concessions obtained;
- d). identifies the authority deciding the action in respect of the nonconformity.

## 9 Performance evaluation

### 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

We shall determine:

- a). what needs to be monitored and measured;
- b). the methods for monitoring, measurement, analysis and evaluation needed to ensure

- valid results;
  - c). when the monitoring and measuring shall be performed;
  - d). when the results from monitoring and measurement shall be analysed and evaluated.
- Performance and the effectiveness of the QMS is evaluated and documented information of the results are retained.

#### 9.1.2 Customer satisfaction

Monroe Engineering will monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. **Information monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. We have developed and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.**

#### 9.1.3 Analysis and evaluation

The data and information arising from monitoring and measurement is analysed and evaluated. The results of analysis shall be used to evaluate:

- a). conformity of products and services;
- b). the degree of customer satisfaction;
- c). the performance and effectiveness of the QMS;
- d). if planning has been implemented effectively;
- e). the effectiveness of actions taken to address risks and opportunities;
- f). the performance of external providers;
- g). the need for improvements to the QMS.

### 9.2 Internal audit

9.2.1 Internal audits are conducted at planned intervals to provide information on whether the QMS:

- a). conforms to:
  - 1). Our requirements for the QMS; and
  - 2). AS9100D requirements.
- b). is effectively implemented and maintained.

9.2.2 Monroe Engineering has:

- a). planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, shall take into consideration the importance of the processes concerned, changes affecting us, and the results of previous audits;
- b). define the audit criteria and scope for each audit;
- c). select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d). ensure the audit results are reported to management;
- e). take appropriate correction and corrective actions without undue delay; and
- f). Evidence of the implementation of the audit program and the audit results are retained as documented information.

### 9.3 Management Review

9.3.1 Top management review the QMS, are scheduled on a bi-annual basis, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction.

9.3.2 Management review inputs

Management reviews are planned and carried out taking into consideration:

- a). the status of actions from previous management reviews;
- b). changes in external and internal issues that are relevant to the QMS;
- c). information on the performance and effectiveness of the QMS, including trends in:

- 1). Customer satisfaction and feedback from relevant interested parties;
  - 2). The extent to which quality objectives have been met;
  - 3). Process performance and conformity of products and services
  - 4). Concerns relevant to Interested Parties;
  - 5). Procedure Review
  - 6). Nonconformities and corrective actions;
  - 7). Monitoring and measurement results;
  - 8). Audit results;
  - 9). The performance of external providers;
  - 10). On-time delivery performance;**
- d). the adequacy of resources;
- e). the effectiveness of actions taken to address risks and opportunities; and
- f). opportunities for improvement.

### 9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

- a). opportunities for improvement;
- b). any need for changes to the QMS;
- c). resource needs;
- d). risks identified.**

Documented information is retained of the results of management review.

## 10 Improvement

### 10.1 General

We have determined opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include:

- a). improving products and services to meet requirements as well as to address future needs and expectations.
- b). correcting, preventing or reducing undesired effects; and
- c). improving the performance and effectiveness of the QMS.

### 10.2 Nonconformity and corrective action

10.2.1 When a nonconformance occurs, including any arising from complaints, we shall:

- a). react to the nonconformity and, as applicable:
  - 1). Take action to control and correct it;
  - 2). Deal with the consequences.
- b). evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - 1). Reviewing and analyzing the nonconformity;
  - 2). Determining the causes of the nonconformity **including, as applicable, those related to human factors;**
  - 3). Determine if similar nonconformities exist, or could potentially occur;
- c). implement any action needed;
- d). review the effectiveness of any corrective action taken;
- e). update risks and opportunities determined during planning, if necessary;
- f). make changes to the QMS, if necessary;
- g). flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;**
- h). take specific actions when timely and effective corrective actions are not achieved.**

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

**Documented information is maintained that defines the nonconformity and corrective action management processes.**

10.2.2 Documented information is retained as evidence of:

- a). the nature of the nonconformities and any subsequent actions taken;
- b). the results of any corrective action.

### 10.3 Continual improvement

We continually improve the suitability, adequacy and effectiveness of the QMS.

The results of analysis and evaluation and the outputs from management review, to determine if there are needs or opportunities shall be addressed as part of continual improvement. **We monitor the implementation of improvement activities and evaluate the effectiveness of the results.**