



# **MANITOWOC TOOL & MACHINING**

## **Quality Manual**

Revision E

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**Conforms to ISO-9001:2015/AS9100D**

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## 0.0 Revision History and Approval

Rev.	Nature of changes	Approval	Date
A	Original release.	Rick Swoboda	4/12/18
B	Added AS-9100D Elements	Rick Swoboda	10/01/18
C	Removed 8.5.5 from exclusion and added procedure/process names to the links.	Rick Swoboda	8/13/19
D	Section 8.5.5 called out as not applicable, this has been revised to support returns and CACI	Rick Swoboda	10/21/19
E	Re-write of the scope per PJR	Rick Swoboda	1/10/20

## 1.0 Welcome to Manitowoc Tool & Machining

### Company History

Manitowoc Tool and Machining (MTM) founded in 1966 under the name of Manitowoc Tool and Die and was located at 925 South 29th Street in Manitowoc, Wisconsin. At that location, design and construction of stamping dies along with sheet metal stamping was the business focus.

In 1980, MTM was relocated to a new facility in Manitowoc's South Industrial Park at 4211 Clipper Drive. Years later added the 1210 South 41<sup>st</sup> address as partial machining, shipping and receiving. At that junction, MTM diversified into production machining as well as the continuation of the core business of die construction and sheet metal stamping. MTM was fortunate to experience continual growth of all the business units. The name was changed to Manitowoc Tool and Machining due to the increasing emphasis on production machining. This growth led to a substantial increase in employees and numerous building additions. MTM added to the facility in 1980, 1983, 1988, 1990, 1993, 1994, 1995, 1997, 2001, and 2004.

During 2008, MTM purchased a third facility that is adjacent to the Clipper Drive facility. In addition to housing a full complement of machining centers, this 88,000 square foot building is the main warehouse and shipping/receiving hub of the company.

Due to continual demands for the sheet metal die and stamping business, a separate 35,000 square foot facility was constructed at 4330 Expo Drive. In 2007 and again in 2008, MTM expanded that facility and decided to create a separate identity for that part of the business. Manitowoc Tool and Manufacturing is a "state of the art" company that builds complicated sheet metal dies, has stamping capacity up to 800 tons, robotic welding, and creates large and small component assemblies. The facility was expanded in 2010 and 2012 to its current size of 95,000 square feet.

The 20 acre MTM campus consists of three plants that total 357,000 square feet and have over 375 employees. MTM has been ISO certified for over 16 years and ships parts world-wide. The customer base includes large OEM: power generating, HVAC, agricultural equipment, heavy truck, aerospace, marine, recreational, hydraulic, and powertrain suppliers.



## 2.0 About The MTM Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015/AS9100D international standard, as well as to demonstrate how the company complies with that standard.

This manual presents "Notes" which are used to define how MTM has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015/AS9100D.

*Notes appear in italics, with gray background.*

Where subordinate or supporting documentation is reference in this manual, these are indicated by **[bold italic links](#)**.

## 3.0 Terms and Definitions

MTM adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in ***ISO 9000: Quality Management – Fundamentals and Vocabulary***. In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or ISO 9000.

### General Terminology

**MTM** – Manitowoc Tool & Machining.

**Document** – written information used to describe how an activity is done.

**Record** – captured evidence of an activity having been done.

### Risk-Based Thinking Terminology

**Risk** – Negative effect of uncertainty

**Opportunity** – Positive effect of uncertainty

**Uncertainty** - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

### Nonconforming Product Terminology

**Rework:** Efforts to bring nonconforming product into conformance through additional operations that do not alter the original design of the product.

**Deviation:** Efforts to bring nonconforming product into conformance through additional operations that alter the original design of the product; this may be through additional operations not specified in the original design, or through altering pre-existing design features.

**Scrap:** The discard of nonconforming product in lieu of rework or repair.

## 4.0 Procedure-026 Context of the Organization

### 4.1 Understanding the Organization and Its Context

MTM has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern

to MTM and its interested parties (per 4.2 below); the interested parties are identified per the [Procedure-026 Context of the Organization](#). Such issues are monitored and updated as appropriate, and discussed as part of Procedure-006 Management Reviews.

## 4.2 Understanding the Needs and Expectations of Interested Parties

The issues determined per 4.1 above are identified through an analysis of risks facing MTM and its interested parties. “Interested parties” are those stakeholders who receive our products, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified per the [Procedure-026 Context of the Organization](#). This information is then used by senior management to determine the company’s strategic direction. This is defined in records of Procedure-006 Management Review, and periodically updated as conditions and situations change.

## 4.3 Determining the Scope of the Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products, MTM has determined the scope of the management system as follows:

**“A contract manufacturer of precision machined components and assemblies”**

The quality system applies to all processes, activities, and employees of the following locations within the company:

4211 Clipper Drive Manitowoc WI 54220 920-682-8825 <a href="http://www.mantool.com">www.mantool.com</a>	1210 South 41 <sup>st</sup> Street Manitowoc WI 54220 920-682-8825 <a href="http://www.mantool.com">www.mantool.com</a>
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The following clauses of ISO 9001:2015/AS9100D were determined not applicable to MTM.

Any ISO 9001/AS9100 requirements, which are excluded from MTM’S quality management system, are limited to **Section 8** of this Quality Manual. In these cases, justification for exclusions is defined within the applicable section, and is identified in *italics*. *The following ISO 9001/AS9100 clauses are not applicable to MTM: 8.3 – Design and Development of Products and Services - MTM manufactures products to Customer supplied drawings.*

## 4.4 Quality Management System and Its Processes

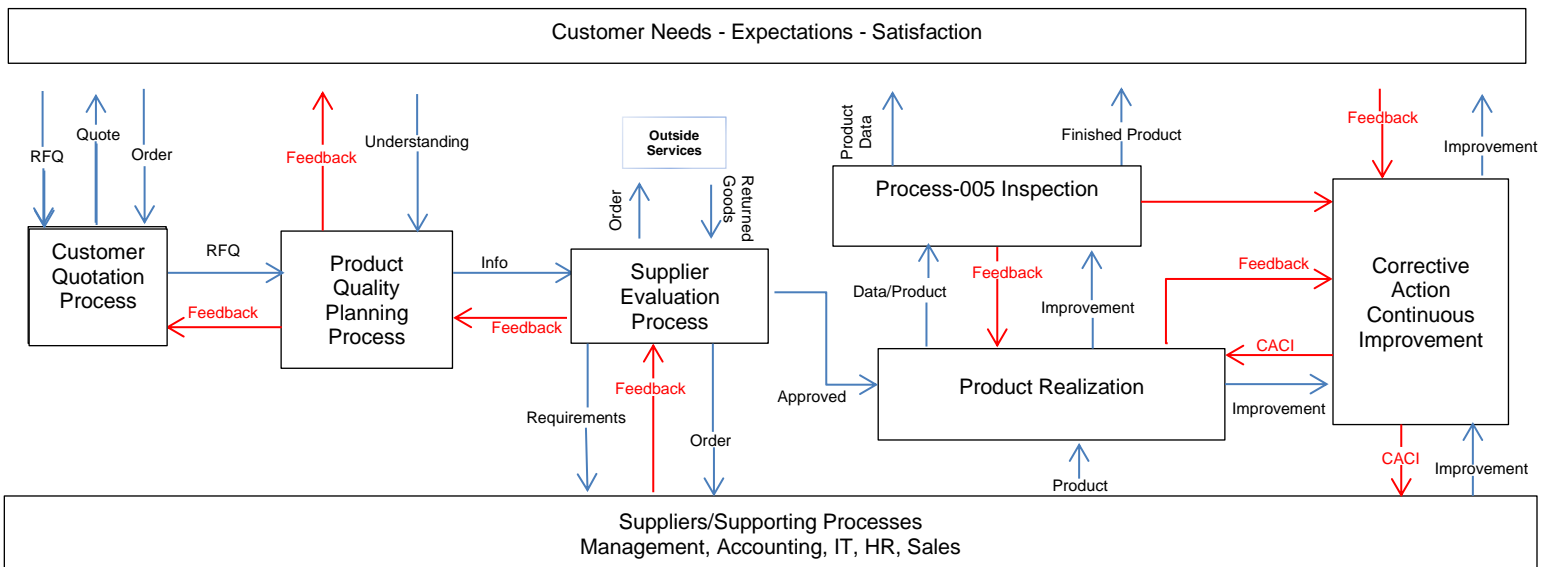
### 4.4.1 Process Identification

MTM has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming products discovered during final processes or after delivery.

Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

*Note: not all activities are considered “processes” – the term “process” in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.*

The following top-level processes have been identified for MTM:



Each top-level process has a **Process Definition** document which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources

#### 4.4.2 Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one “metric” or key performance indicator (KPI) which is then measured to determine the process’ ability to meet the quality objective.

Metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to Top Management. The data is then analyzed by Top Management in order that Top Management may assign action items in order to make adjustments for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable Process Definition document.

When a process does not meet a goal, or an unexpected problem is encountered with a process, corrective and/or preventive action is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

#### 4.4.3 Outsourced Processes

Any process performed by a third party is considered an “outsourced process” and must be controlled, as well. The company’s outsourced processes, and the control methods implemented for each, are defined in [Process-003 Supplier Selection and Evaluation](#).

The type and extent of control to be applied to the outsourced process takes into consideration:



- a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the purchasing contract requirements.

## **5.0 Leadership**

### **5.1 Leadership & Commitment**

#### **5.1.1 General**

Top Management of MTM provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

- a) taking accountability of the effectiveness of the management system;
- b) ensuring that the Quality Policy and Quality Objectives are established for the management system and are compatible with the strategic direction and the Procedure-026 Context of the Organization;
- c) ensuring the integration of the management systems requirements into the organization's other business processes, as deemed appropriate (see note);
- d) promoting awareness of the process approach;
- e) ensuring that the resources needed for the management system are available;
- f) communicating the importance of effective quality management and of conforming to the management system requirements;
- g) ensuring that the management system achieves its intended results;
- h) engaging, directing and supporting persons who contribute to the effectiveness of the management system;
- i) promoting continual improvement;
- j) supporting other relevant management roles to demonstrate their leadership of responsibility.

*Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.*

#### **5.1.2 Customer focus**

MTM adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained;
- d) product and service conformity and on-time delivery performance are measured, and appropriate action is taken if planned results are not achieved.

## 5.2 Policy

Top Management has developed the Quality Policy that governs day-to-day operations to share the MTM quality vision. The Quality Policy is released as a standalone document and is communicated and implemented throughout the organization.

### **The Quality Policy of MTM is as follows:**

**Maintain & Improve a Quality Management System Based on the ISO-9001:2015/AS9100D Standard.**

**To Meet or Exceed our Customer’s Expectations Regarding Quality and Delivery.**

**Monitor Customer Satisfaction and Continually Improve Through Employee Involvement.**

F-500-001 Rev. A

## 5.3 Organizational Roles Responsibilities and Authorities

Top Management has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the combination of the [Organizational Chart](#) and Job Descriptions.

In addition, the following overall QMS responsibilities and authorities are assigned as follows:

Responsibility	Assigned To
Ensuring that the management system conforms to applicable standards of ISO-9001:2015/AS9100D	Top Management
Ensuring that the processes are delivering their intended outputs	Applicable process owner
Reporting on performance of the management system, providing opportunities for improvement	Top Management
Ensuring the promotion of customer focus throughout the organization	Top Management
Ensuring the integrity of the management system is maintained when changes are planned and implemented	QMS Representative

The Quality Systems Coordinator has been assigned the role of QMS Management Representative when having a single point of contact to represent the MTM quality system is useful or required by customer or regulations. Other duties of the QMS Management Representative may be defined herein or within other documented processes and procedures. *The Management Representative is granted organizational freedom to manage the QMS and unrestricted access to top management.*

## 6.0 Planning

### 6.1 Actions to Address Risks and Opportunities

*Note: MTM deviates slightly from the approach towards risk and opportunity presented in ISO-9001:2015/AS9100D. Instead, MTM views “uncertainty” as neutral, but defines “risk” as a negative effect of uncertainty, and “opportunity” as a positive effect of uncertainty. MTM has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and recordkeeping will be performed to the level deemed appropriate for each circumstance or application.*

MTM considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of the “Procedure-026 Context of the Organization Exercise” defined in [Procedure-026 Context of the Organization](#), as well as throughout all other activities of the QMS.

Risks and opportunities are managed in accordance with the [Procedure-027 Risk and Opportunity Management](#). This procedure defines how risks are managed in order to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit.

## 6.2 Quality Objectives and Planning to Achieve Them

### MTM Quality Objectives:

**Achieve an on time delivery performance that meets or exceeds our customers stated requirements by monitoring and supporting MTM Supplier's for continual improvement of Supplier on time delivery.**

**Maintain a Customer return rate that is 1% or < of MTM total sales or show positive trend in doing so.**

F-500-002 Rev. A

As part of the process approach, MTM utilizes its process objectives as the main quality objectives for the QMS.

The process objectives have been developed in consideration that they:

- 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, to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

Quality objectives are discussed in the minutes of Procedure-006 Management Review per section 9.3 below.

The planning of quality objectives is defined in section 4.4. above.

## 6.3 Planning of Changes

Changes to the quality management system and its processes are carried out in a planned manner per the [Procedure-001 Control of Quality Management Systems Documentation](#).

## 7.0 Support

### 7.1 Resources

#### 7.1.1 General

MTM is fully committed to providing adequate resources required for the establishment, implementation, maintenance and continual improvement of our QMS. Our committed resources include: competent employees, state of industry equipment, well maintained work environment and financial resources. The process for determining and communicating resource requirements is an integral part of our Procedure-006 Management Review process. Our infrastructure resources considerations include:

- a) Procedure-006 Management Review meeting inputs and outputs
- b) capabilities and constraints on existing internal and external resources
- c) requirements and expectations of our external interested parties

## 7.1.2 People

**MTM recognizes several aspects that affect the Human Factor. To combat these human factors MTM provides required training, skill management, team building, environmental improvements, work/life balance, updated/properly maintained equipment and EAP assistance.**

Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Records of personnel qualification and training are maintained.

## 7.1.3 Infrastructure

MTM determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) buildings, workspace and associated facilities;
- b) process equipment, hardware and software;
- c) supporting services such as transport;
- d) information and communication technology and protection thereof.

Equipment is validated per the [Procedure-012 Equipment Maintenance](#) and fixtures are maintained per [Procedure-013 Fixture Handling](#).

## 7.1.4 Environment for the Operation of Processes

Top management identifies and manages the human and physical factors of the work environment considered to be important in controlling processes in order to achieve conforming products and services.

- a) assessment of product requirements to identify where human and/or physical factors will affect product quality, this is also conducted during the quality planning stage
- b) assessment of current working environmental conditions to determine if the work environment is suitable to achieve conforming product
- c) continual assessment of work environment to ensure that adequate human and physical factors are maintained

*Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.*

## 7.1.5 Monitoring and Measuring Resources

Where equipment is used for critical measurement activities, such as inspection and testing, the equipment is subject to control by either calibration or verification; see [Procedure-018 Calibration Control](#).

*Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, MTM determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.*

### 7.1.6 Organizational Knowledge

MTM determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

- a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
- b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, MTM shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

## 7.2 Competence

Employees performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. The [Procedure-007 Human Resource Development](#) defines these activities in detail.

*Training and competency needs, including refresher training are considered as part of the Procedure-006 Management Review process.*

*Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance or disciplinary actions.*

## 7.3 Awareness

MTM has determined to the extent necessary persons performing work are aware of:

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

## 7.4 Communication

What	When	With Whom	How	Who
Top Management of MTM ensures internal and external communication takes place regarding the effectiveness of the management system. Communication methods include:				
Quality Policy	Continuous	All Employees/Interested Parties	Display/Card/Training/Website	Management
Effective QMS	Continuous	All Employee/Interested Parties	Training/Display/Audits	Management/QSC
Responsibilities/Authorities	Yearly	Affected Employees/Customer	Organizational Chart	Management
Quality Objectives	Monthly	All Employees/Staff/Customers	MMR/Quarterly Meetings/Audits	Management/QSC
Data Analysis	As needed	Affected Employees	Statistical	QA
Corrective Actions	As needed	All Employees/Management/Customers	Display/VQ/Customer portals	QSC
Preventive Actions	As needed	All Employees/Management/Customers	Display/VQ/Customer portal	QSC
Process Audits Results	Monthly	All Employees/Staff/Customers	Interview/Display	Management/Staff
Internal Audits Results	Yearly	All Employee/Management	Display/Management Meeting/CAPAs	QSC
Registrar Audits Results	Yearly	All Employee/Management	Display/Management Meeting/CAPAs	QSC
Customer Returns	Daily/Monthly	All Employee/Management/Customers	Display/Management Meeting/CAPAs	QSC
Quality Alerts	As Needed	All Employees/Management	Display/Management Meeting	QSC
Supplier Quality	As Needed	All Employees/Management/Supplier/Customers	Display/Management Meeting/CAPAs	QSC
State of Business	Quarterly	All Employees/Management	Plant Wide Meeting	President/VP/Staff
Orientation/Safety Training	Random	All Employees/Management	Training	Trainer
Performance Appraisals	30/60/90, Annual	All Employees/Management	One on One	HR
Genera Email/Inputs	As Needed	All Employees	Visual Quality	All Employees
Bulletin Board	As Needed	All Employees	Posting	HR
FOD Awareness	As Needed	All Employees	Posting	HR
Counterfeit Parts	As Needed	All Employees	Posting	HR
Open Door Policy	As Needed	All Employees	Request	All Employees
Human Factor	As Needed	All Employees	Request/Advised	EAP/HR
<b>Covid-19</b>	<b>As Needed</b>	<b>All Employees</b>	<b>Display/Meetings/Announcement/Readiness Plan/Requirements</b>	<b>President/Staff/Safety Director</b>

## 7.5 Documented Information

F-400-003 Rev. A

The management system documentation includes both documents and records.

*Note: the ISO 9001/AS9100 standards use the term “documented information”; MTM does not use this term, but instead relies on the terms “document” and “record” to avoid confusion. In this context the terms are defined by MTM as provided for in section 3.0 above. Documents and records undergo different controls as defined herein.*

The extent of the management system documentation has been developed based on the following:

- a) the size of MTM
- b) complexity and interaction of the processes
- c) risks and opportunities
- d) competence of personnel

Documents required for the management system are controlled in accordance with [Procedure-001 Control of Quality Management Systems Documentation](#). The purpose of document control is to ensure that everyone has access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained.

A documented [Procedure-005 Control of Records](#) has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. There is also a procedure which defines the methods for controlling records that are created by suppliers and customers found in [Procedure-002 Control of Drawings](#). These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of product requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system. The entire quality management system is protected as defined in [Procedure-004 Control of Electronic Data](#).

## 8.0 Operation

### 8.1 Operational Planning and Control

MTM plans and develops the processes needed for realization of its products. Planning of product realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the Procedure-026 Context of the Organization (see section 2.0), current resources and capabilities, as well as product requirements.

Such planning is accomplished through:

- a) determining the requirements for the products;
- b) establishing criteria for the processes and the acceptance of products;
- c) determining the resources needed to achieve conformity to the product requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) Determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products to their requirements.

Determining operational processes or changes to operational processes are in accordance with the [Process-002 Product Quality Planning](#).

Outsourced processes and the means by which MTM controls them are defined in the documented in [Process-003 Supplier Selection and Evaluation](#).

#### 8.1.1 Operational Risk Management

*MTM plans, implements and controls a process for managing operation risks to the achievement of applicable requirements, which includes as appropriate to our products and services:*

- a) assignment of responsibilities for risk management;
- b) definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
- 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.

MTM plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints, as appropriate to our organization and the product.

### **8.1.2 Configuration Management**

MTM plans, implements and controls a process for configuration management as appropriate to the organization and product in order to ensure the visibility and control of physical and functional attributes throughout the product lifecycle.

This process:

- a) controls product identity and traceability to requirements, including the implementation of identified changes;
- b) ensures that the documented information (e.g., requirements, specifications, programs, test, and acceptance documentation) is accurate and consistent with the actual attributes of the products and services.

### **8.1.3 Product Safety**

MTM plans, implements and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.

MTM identifies all product safety considerations including characteristics designated by the design authority as “flight safety” or “safety critical” during the customer requirements review process, these requirements are identified on company control plans, and are flowed down to suppliers when appropriate.

### **8.1.4 Counterfeit Parts**

MTM plans, implements and controls a process, appropriate to the product, that prevents the use of counterfeit or suspect counterfeit product and their inclusion in product(s) delivered to the customer.

The organization’s counterfeit product prevention process considers, as applicable:

- a) training of appropriate persons in the awareness and prevention of counterfeit product;
- b) application of a parts obsolescence monitoring program;
- c) procurement requirements for assuring traceability of parts and components to their original authorized manufacturers;
- d) verification and test methodologies to detect counterfeit product;
- e) monitoring of counterfeit product reporting from external sources; quarantine and reporting of suspect or detected counterfeit product.

## **8.2 Requirements for Products and Services**

### **8.2.1 Procedure-008 Customer Communications**

MTM has implemented effective communication with customers in relation to:



- a) providing information relating to products;
- b) handling enquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including Procedure-021 Customer Complaints;
- d) handling or controlling customer property;
- e) Establishing specific requirements for contingency actions, when relevant.

These activities are defined in greater detail in [Procedure-008 Customer Communications](#).

### **8.2.2 Determining the Requirements Related to Products and Services**

During the intake of new business MTM captures:

- a) requirements specified by the customer
- b) requirements not stated by the customer but necessary for specified/intended use, as known
- c) statutory and regulatory requirements related to products;
- d) Any additional requirements determined by MTM.

These activities are defined in greater detail in [Process-001 Customer Quotation](#).

### **8.2.3 Review of Requirements Related to Products and Services**

Once requirements are captured, MTM reviews the requirements prior to its commitment to supply the product. This review ensures that MTM has the capability and capacity to:

- a) meet all requirements specified by the customer, including requirements for delivery activities;
- b) meet any requirements not stated by the customer, but which MTM knows as being necessary;
- c) meet all requirements determined necessary by MTM itself;
- d) meet all related statutory and regulatory requirements;
- e) meet any contract or order requirements differing from those previously expressed (i.e., from a previous MTM quote).

These activities are defined in greater detail in [Procedure-014 Work Order Improvement](#), [Procedure-011 Work Order](#) and [Process-004 Product Realization](#).

### **8.2.4 Changes to Requirements for Products and Services**

MTM updates all relevant requirements and documents when the requirement are changed, and ensures that all appropriate staff is notified; see the documented [Process-002 Product Quality Planning](#).

## **8.3 Design and Development of Products and Services**

**MTM is not a product design-responsible supplier. Due to the nature of MTM products, MTM is excluded from compliance to the design and development requirements of ISO 9001:2015/AS-9100D, clause 8.3., limited design input is supplied to customers, as appropriate.**

***This exclusion does not affect the ability or responsibility of MTM to provide product that meets customer specifications and applicable statutory/regulatory requirements.***

## 8.4 Control of Externally Provided Processes, Products and Services

MTM ensures that purchased product conform to specified purchase requirements.

The type and extent of control applied to the supplier and the purchased products or services are dependent on the effect on subsequent product realization or the final product.

Although customers primarily require MTM to use customer chosen suppliers, MTM does evaluate and select suppliers based on their ability to supply products and services in accordance with the organization's requirements found in [MTM Supplier Quality Assurance Manual](#).

Approved suppliers are maintained on the Approved Suppliers List contained within the company database.

Purchases are made via the release of formal [Procedure-009 Purchase Orders](#) which clearly describe what is being purchased.

Received products or services are then verified against requirements to ensure satisfaction of requirements.

Suppliers who do not provide conforming products or services may be subject to Customer Audits or are requested to conduct formal corrective action.

These activities are further defined in [Procedure-009 Purchase Order](#), [Procedure-010 Verification of Purchased Product](#) and [Process-003 Supplier Selection and Evaluation](#).

## 8.5 Production and Service Provision

### 8.5.1 Control of Production and Service Provision

To control its provision of products, MTM considers, as applicable, the following:

- a) the availability of documents or records that define the characteristics of the products as well as the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of Procedure-023 Monitoring and Measurement activities;
- d) the use of suitable infrastructure and environment;
- e) the appointment of competent persons, including any required qualifications;
- f) the validation and revalidation of special processes if applicable (see below);
- g) ***the implementation of actions to prevent and reduce human error by considering and identifying issues that lead to human factors failures;***
- h) the implementation of release;
- i) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product);
- j) control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- k) determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
- l) identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages;

- m) having evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- n) provision for the prevention, detection and removal of foreign objects;
- o) control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);
- p) establishing criteria for workmanship (e.g., written standards, representative samples, illustrations, ***consideration to Human Factor***).

#### **8.5.1.1 Control of Production Equipment, Tools and Software Programs**

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

Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

#### **8.5.1.2 Validation and Control of Special Processes**

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, MTM has established 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 qualification of persons;
- d) use of specific methods and procedures for implementation and monitoring the processes;
- e) requirements for documented information to be retained.

At this time, MTM does not utilize any in-house “special processes” where the result of the process cannot be verified by subsequent monitoring or measurement. Any such special processes are sent to outside suppliers, and controlled per [Process-003 Supplier Selection and Evaluation](#).

#### **8.5.1.3 Production Process Verification**

MTM implements production process verification activities to ensure the production process is capable of producing products that consistently meet requirements per [Process-004 Product Realization](#). At the start of manufacture a FAI layout is performed to assure product is conforming to print.

### **8.5.2 Identification and Traceability**

Where appropriate, MTM identifies its product or other critical process outputs by suitable means. Such identification includes the status of the product with respect to Procedure-023 Monitoring and Measurement requirements. Unless otherwise indicated as nonconforming, pending inspection, waiting on disposition, or some other similar identifier, all products shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, MTM controls and records the unique identification of the product.

The documented [Procedure-015 Product Identification and Traceability](#) defines these methods in detail.

### 8.5.3 Property Belonging to Customers or External Providers

MTM exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

This activity is defined in greater detail in [Procedure-016 Control of Customer-Supplier Property](#) and [Procedure-003 Control of Customer Specifications](#).

### 8.5.4 Preservation

MTM preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection.

Preservation also applies to the constituent parts of a product.

The documented [Procedure-017 Product Preservation](#) defines the methods for preservation of product.

### 8.5.5 Post-Delivery Activities

***Post-delivery activities include but are not limited to; nonconformance investigation including RMA management and customer satisfaction assessment. Statutory and regulatory requirements as required by customer. Monitoring of customer satisfaction.***

### 8.5.6 Control of Changes

MTM reviews and controls both planned and unplanned changes to processes and procedures to the extent necessary to ensure continuing conformity with all requirements.

*Persons authorized to approve production and service changes are identified.*

Process and procedure change management is defined in the procedure.

## 8.6 Release of Products and Services

Acceptance criteria for products are defined in appropriate subordinate documentation. Reviews, inspections and tests are conducted at appropriate stages to verify that the requirements have been met. This is done before products are released.

Each process utilizes different methods for measuring and releasing products. These methods are defined in [Procedure-019 Statistical Techniques](#).

## 8.7 Control of Nonconforming Outputs

MTM ensures those products or other process outputs that do not conform to establish requirements are identified and controlled to prevent their unintended use or delivery.

Only the design authority, or those designated by the design authority are authorized to release NCP or have these items repaired.

Any items suspected of being counterfeit are handled as NCP.

The controls for such nonconformances are defined in [Procedure-024 Control of Non-conforming Materials](#).

Products found non-conforming but acceptable to the Customer shall be handled according to the [Procedure-025 Product Deviation](#).

## 9.0 Performance Evaluation

### 9.1 Monitoring, Measurement, Analysis and Evaluation

#### 9.1.1 General

MTM has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Quality Manual and subordinate documentation.

Procedure-023 Monitoring and Measurement of the processes, as defined in 4.4 above, ensure that the Top Management evaluates the performance and effectiveness of the quality management system itself. The measurement of quality management effectiveness is found in [Procedure-023 Monitoring and Measurement](#).

#### 9.1.2 Customer Satisfaction

As one of the measurements of the performance of the management system, MTM monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

- recording customer corrective actions and preventive actions
- product returns
- changing volume of orders for product
- trends in on-time delivery
- customer scorecards
- supplier assessment/audit score

[Procedure-008 Customer Communications](#), [Procedure-021 Customer Complaint](#) and [Procedure-020 Customer Satisfaction Monitoring](#) shall be used to develop and implement plans for customer satisfaction improvement which address deficiencies identified by these evaluations, and assess the effectiveness of the results.

#### 9.1.3 Analysis and Evaluation

MTM analyzes and evaluates the data and information arising from [Procedure-023 Monitoring and Measurement](#) in order to evaluate:

- a) conformity of products;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;

- f) the performance of external providers;

## 9.2 Procedure-022 Internal Audit

MTM conducts Procedure-022 Internal Audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO-19011:2018, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in [Procedure-022 Internal Audits](#).

## 9.3 Management Review

The Top Procedure-006 Management Reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The reviews are defined by [Procedure-006 Management Review](#) and reviews include assessing opportunities for improvement, and the need for changes to the management system, including the Quality Policy and Quality Objectives.

Procedure-006 Management Review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in the documented Procedure-006 Management Review Process. Records from Procedure-006 Management Reviews are maintained.

# 10.0 Improvement

## 10.1 General

MTM uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by the analysis of data; 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 management system;
- d) the effectiveness of actions taken to address risks and opportunities;
- e) the performance of external providers;
- f) other improvements to the management system.

## 10.2 Nonconformity and Corrective Action

**MTM determines the root cause(s) including as applicable, those related to human factor and takes corrective action to eliminate the cause of nonconformity in order to prevent recurrence.** Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

Corrective action requirements are flowed down to external suppliers when it is determined that the supplier is responsible for the nonconformity.

Specific actions are taken in cases where timely corrective action is not achieved.

These activities are done through the use of the formal (**CACI**) system, and are defined in the [Process-006 Corrective Action and Continuous Improvement](#).

### 10.3 Continual Improvement

MTM works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement. The implementation of a “Process Approach” to include the PDCA cycle provides verification that MTM management system is robust and provides effective process performance.

The effectiveness of implemented continuous improvements are reviewed as part of the RAIL process.

