

	QUALITY MANUAL	QM Revision 05
Approval Signature:  Luca Bossolari, Quality Manager		Original Issue Date 27/01/21

M PUMPS S.r.l.

Via dell'Artigianato, 120 - 45015 CORBOLA (RO) - ITALY

QUALITY MANUAL

WARNING

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05	27/01/21	AP	AM	LB	General review
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Significant changes are highlighted in *italic*.

1. Scope

This Manual applies to M PUMPS (MP) and, once issued, replaces all previous documents of a similar name and, in case of conflict, takes precedence over all subsidiary documents and manuals.

To achieve full conformance with the Policy, MP has implemented a formal, documented system consistent with the requirements of the ISO 9001:2015. The scope of QMS covers all activities related to product development, delivery and post-delivery processes, as applicable to MP and in particular: DESIGN AND PRODUCTION OF MAGNETIC AND MECHANICAL SEAL PUMPS IN METALLIC AND NON-METALLIC MATERIAL. All employees are required to be familiar with the Policy and to follow QMS Procedures, including all supporting Operative Instructions that are relevant to their work.

2. Objective

The cornerstones of QMS, represented in Figure 1, cover all aspects of product development and product delivery for the MP organization, managing the product's entire lifecycle, from the first expression of a Customer's need to the eventual obsolescence of the product. QMS includes:

- How we operate – standards and procedures that set aspirations and define how we go about meeting them.
- How we manage knowledge – processes that define how we cultivate and maintain knowledge as a principal resource.
- How we organize ourselves – in concurrent teams, groups and functions, utilizing IT systems that support our goals and activities.
- How our business systems evolve and enable all of this activity.

Quality Management System (QMS)		
How we operate	How we manage knowledge	How we organize ourselves
Standards	Competency	Organizational Structure
Procedures	Experience	IT Systems

FIGURE 1: Quality Management System

QMS supports the lifecycle in terms of 5 phases, these phases are groups of activities occurring concurrently, as shown in Figure 2.

- Define: Understanding and precisely defining the Customer's need (the requirements).

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- Enable: Selecting the right technical solution (the specifications) that meets the Customer's requirements.
- Develop: Developing & thoroughly testing the product to confirm that it meets the Customer's requirements.
- Produce: Preparing for and building the product - throughout its life.
- Support: Preparing for, introducing and supporting the product in the field - throughout its life to obsolescence.

Standards point to horizontal systems, as well as management and functional procedures that support the entire lifecycle. Along with these procedures there are templates. The objective is for activities at all levels to be consistent, efficient, and focused towards accomplishing MP goals. The QMS with its standards and procedures and how they are connected to reach MP objectives are shown in figure 3.

Phase	Activity
Define	Opportunities and Risks assessment, Engineering evaluation
Enable	Advantages-costs evaluation, engineering and realization strategy, development plan, records
Develop	Design and industrialization, verification and validation, data sheet
Produce	Supply chain and manufacturing plan, production, quality control/assurance
Support	Market launch, feedback from field , monitor and analysis, support

FIGURE 2: Activities in the 5 phases

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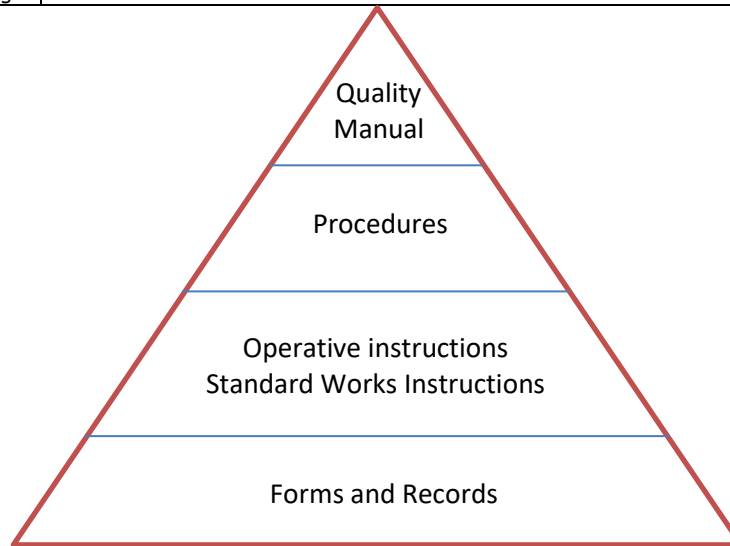


FIGURE 3: QMS Standard and Procedure Structure

3. Terms and Definitions

M PUMPS refers to the terms and definitions set out in the standards listed in Chapter 2; It also uses the following acronyms:

- MP: M PUMPS S.r.l.
- CA: Corrective Action
- RACQ: Purchasing Manager
- ACQ: Procurement dpt.
- AMM: Financial dpt.
- PA: Preventive Action
- QC: Quality Control / Quality Assurance
- PROD: Manufacturing dpt.
- RPROD: Manufacturing Manager
- RCOM: Sales Manager
- COM: Sales dpt.
- DG: General Manager
- ENG: Engineering dpt.
- DT: Engineering Manager
- OI: Operative Instruction
- LOG: Logistic and Shipment
- RMAG: Warehouse Manager
- MAG: Warehouse
- MAN -Manuale Sistema Qualità
- NC -Non Conformità
- PRO -Responsabile Programmazione
- PRO-Resp. Produzione

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- RAC -Richiesta Azione Correttiva
- RSQ -Responsabile Sistema di Gestione Qualità
- RNC-Rapporto Non Conformità
- RVI-Rapporto Verifica Ispettiva
- SGQ-Sistema Qualità
- TCOM-Tecnico Commerciale
- VI-Audit (Verifica Ispettiva interna o esterna)

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4. Context of the Organization

4.1. Understanding the organization and its context

MP Policy, applicable Standards and Objectives along with the MP Quality Management System provide the context in which MP operates always considering the main scope is to DESIGN AND PRODUCE MAGNETIC AND MECHANICAL SEAL PUMPS IN METALLIC AND NON-METALLIC MATERIAL in a really competitive market.

The MP organization is described in organization chart.

External and internal issues that affect Customer satisfaction and quality of delivered products and services, as applicable, are monitored and reviewed during Management Reviews risks and opportunities analysis. Examples of external issues include supplier quality and product reliability while internal issues include manufacturing non conformances and OTD.

4.2. Understanding the needs and expectations of interested parties

MP monitor and review the interested parties and their requirements that are relevant to the QMS. Typically, the interested parties include the Customers (like Industrial and Oil & Gas Companies), Employees, population of the area in which Company is located and operate, Suppliers, Statutory and Regulatory bodies and whichever as applicable everyone that may affect or maybe affected to MP business impact.

Requirements from these interested parties are managed through processes defined in the QMS including, but not limited to: Engineering Procedure, Opportunity and Risks Analysis Procedure, Manufacturing Procedure, Supply Chain Management Procedure, Training Management Procedure, Regulatory Compliance Management Procedure.

4.3. Determining the scope of the Quality Management System

The scope of the MP Quality Management System covers all activities related to DESIGN AND PRODUCTION OF MAGNETIC AND MECHANICAL SEAL PUMPS IN METALLIC AND NON-METALLIC MATERIAL.

4.4. Quality management system and its processes

4.4.1.

This Quality Manual documents the QMS, and it is supported by MP procedures, policies and applicable

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standards accessible by MP network.

Figure 4 provides a schematic representation on key MP elements and how checkpoints allow to control risks and evaluate performance for continuous improvements.

Figure 5 illustrates how this Quality Manual is set up and how sections 4 to 10 can be grouped in relation to the plan-do-check-act cycle.

Consideration has been given to the following activities in planning the QMS:

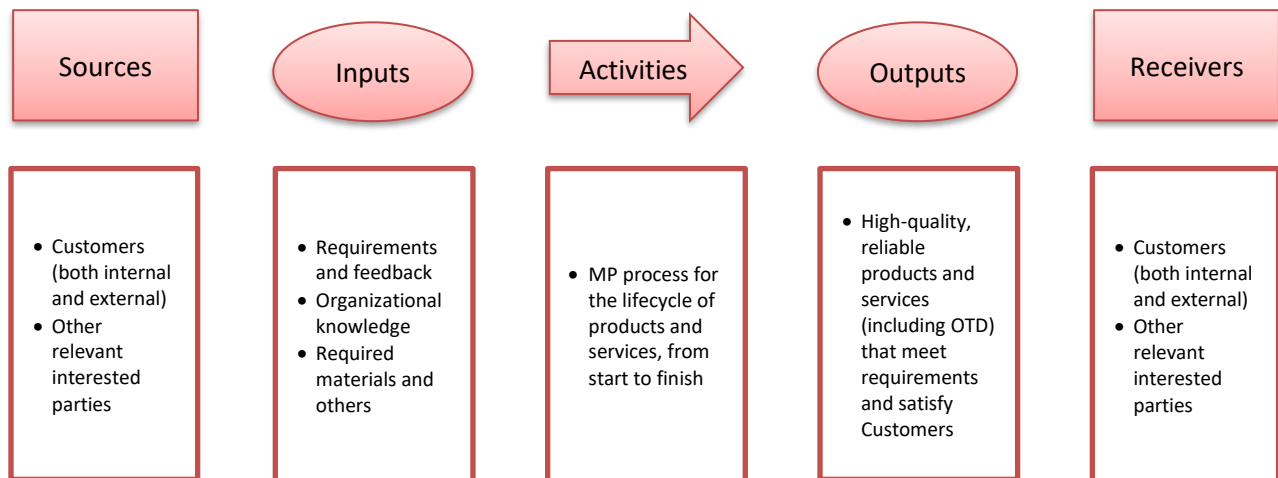
- The preparation of Policy, Procedures, supporting documentation and plans as required to implement the quality management system, ensuring each documented process properly captures the inputs and outputs through appropriate activity diagrams, as applicable
- The responsibilities and authorities for these processes as described in the Responsibilities section of each procedure
- The identification of controls, processes, equipment, resources and skills needed to achieve the required quality
- Ensuring the compatibility of the design, processes, servicing, inspection, test procedures and documentation
- The updating of inspection and testing techniques including development of new instrumentation
- The identification of measurement requirements
- The identification of verification at appropriate stages of design and manufacture
- The clarification of standards of acceptability for all features and requirements, including those which contain a subjective element
- The identification and preparation of quality records
- Adherence to relevant statutory and regulatory requirements
- Maintain responsibility for **product** conformance to specified requirements when processes are outsourced
- Managing risks and opportunities as per the Risk Management Procedure, Opportunity Analysis Procedure
- Managing change and continual improvement of the QMS as per the management of accidents,

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near-miss, injuries, non-conformities, corrective and preventive actions procedure

- Business continuity, emergency preparedness and response procedure
- Exclusions.

There are no exclusions that apply across MP. MP should document any exclusion needed to conform to external certification based on the requirements and allowed exclusion of each applicable standard and procedure. If applicable, MP management should create a documented statement of defined exclusions and justification of this manual.



Defined processes to control risks and check performance for continual improvement

Figure 4: Key Elements in the MP Process and Risk Based approach

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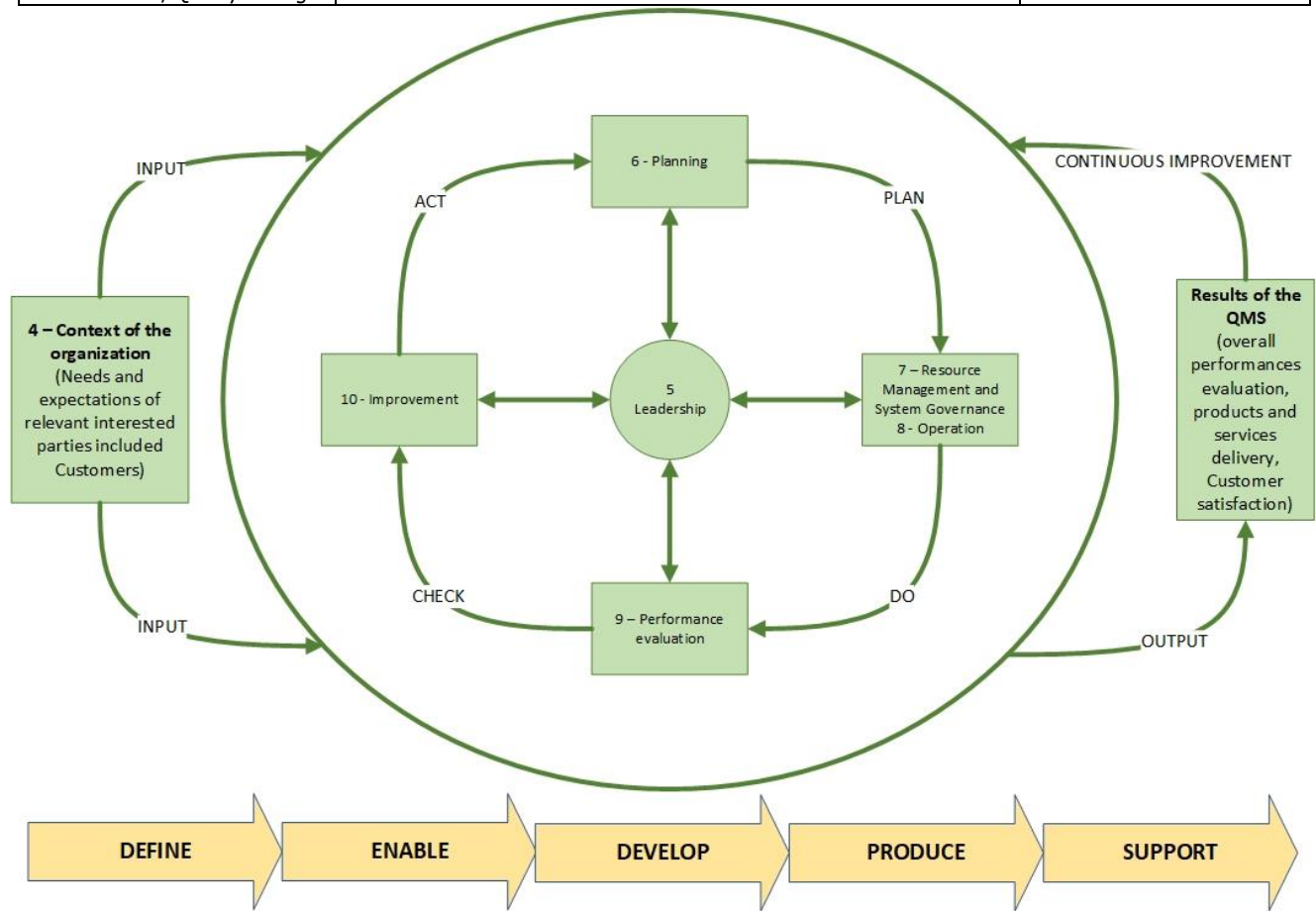


Figure 5 - MP Quality Management System

4.4.2.

This Quality Manual and MP documents shall be maintained, controlled and published in MP network and communicated to the organization thru email or dedicated training.

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5. Leadership

5.1. Leadership and commitment

5.1.1. General

Management Commitment is evident in the MP Policy, Quality objectives and this Quality Manual. The records from planned Management Reviews as per Section 9.3.3 demonstrate continual commitment. The availability of resources is defined in section 7.1.2 of this manual. Risk-based thinking is explicit in the QMS as described in the Risk Management Procedure. Tools such as Failure Modes and Effects Analysis and Risk Assessment and Management (RAM) are used for risk identification, as applicable. Improvements to the Quality Management System are promoted and reviewed during Management Reviews.

MP General Management ensures support for line management to lead and take ownership of strategic efforts in their areas of responsibility.

5.1.2. Customer focus

Customer focus is inherent in the QMS, which ensures that Customer's requirements and applicable statutory and regulatory requirements are well determined, fully traceable and achieved, both for product development and product delivery as described in section 4.2. Customer focus is maintained throughout the lifecycle of the product including post-delivery activities as described in section 8.5.5.

5.2. QHSE (Quality, Health, Safety and Environmental) policy

5.2.1. Establishing the quality policy

MP is committed to the implementation and continuous improvement of processes as defined in the QHSE Policy.

5.2.2. Communicating the quality policy

All MP personnel have access to QHSE Policy through Company network and bulletin board.

QHSE Policy is also available for interested parties, included Customers and MP personnel, on Company website: <https://www.mpumps.it/>

5.3. Organizational roles, responsibilities and authorities

General Manager shall appoint Quality Systems Manager as management representative for MP who has authority and responsibility to plan, implement, and maintain the center QMS. He/she has direct access to

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management and the organizational freedom to ensure that all aspects of operations are in compliance with the QMS and MP policy and applicable standards, and has authority for reporting on the performance of the QMS for review, and continual improvement. He/she ensures that actions are initiated to minimize the likelihood of the occurrence of nonconformities.

General Management shall ensure awareness of applicable Customer requirements is promoted within the relevant functions at MP.

All personnel are given the freedom and responsibility to support the QHSE Policy through:

- Identifying problems affecting Quality, Health, Safety, and the Environment
- Stopping any process where Quality, Health, Safety, or the Environment are compromised
- Initiating, recommending, or providing solutions to Quality related matters
- Verifying implementation of solutions to problems.

Personnel working in the center are bound by the requirements of this Quality Manual. Management is responsible for ensuring the continual effectiveness of the system, continual improvement of the QMS, and for the MP's ability to produce conforming products consistently and effectively.

Roles and responsibilities are further described in job descriptions.

Line Managers may delegate the performance of their duties to personnel who report to them; however, the responsibility cannot be delegated. Line Managers may perform the duties of their personnel provided they are qualified to do so.

An organization chart is available in MP network. In the absence of a manager, the manager can delegate activities to suitably qualified, competent persons; such delegation can be via any media.

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6. Planning

6.1. Actions to address risks and opportunities

Consideration shall be given to the internal and external issues determined in section 4.1 and the requirements of relevant interested parties determined in section 4.2 when identifying the actions to address risks and opportunities identified by the organization. Opportunities and risks are addressed throughout the lifecycle of the products and services developed and delivered by MP as outlined in the applicable procedures included, but not limited to, engineering, risks and opportunities assessment, manufacturing and planning, maintenance, accidents, near accidents, non-conformities ad CAPA's.

6.2. Quality objectives and planning to achieve them

Quality objectives are established by MP Management and communicated to all personnel at regular intervals. Quality Objectives shall be measurable and consistent with the MP QHSE Policy. Management and review of Objectives is defined during Management Review.

6.3. Planning of changes

Any changes to the QMS, if required, are planned and executed using the MP Process Documentation Management Procedure.

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7. Resource Management and System Governance

7.1. Resources

7.1.1. General

MP management identify resource requirements and provide adequate resources, including trained personnel, to implement and maintain the Quality Management System, enhance Customer satisfaction by meeting Customer requirements, and for performance of work and verification activities including internal quality audits to ensure the proper functioning and continual improvement of the QMS and its effectiveness.

7.1.2. People

People management processes are described in the Training Management Procedure, job description and minimum requirement document.

7.1.3. Infrastructure

Where specialized facilities are required to support QMS activities, they are defined and planned during the budgeting process and/or management review meetings. The site, facilities, site utilities and process equipment are installed and maintained by dedicated personnel in the center. Preventive maintenance is carried out as per the Maintenance Procedure.

MP have emergency, preparedness, response and business continuity plans that are maintained and regularly reviewed.

7.1.4. Environment for the operation of processes

Where an environment abnormal to that regularly maintained by MP is required, this special requirement is defined in documented procedures. The following factors need to be considered: temperature, humidity, electrical conductivity, vibration, air quality, lighting, PPE, ergonomics, etc. Additionally these factors are regularly assessed and documented where necessary by MP Management, and HSE department including other departments if necessary.

7.1.5. Monitoring and measuring resources

7.1.5.1. General

MP maintain documented procedures and other documents to control, calibrate and maintain inspection, measuring and test equipment used to demonstrate conformance of standard product to specified requirements as required by the applicable Quality Control Plan(s). All measuring and test equipment are

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registered and calibrated to demonstrate their capability to measure or test a component, assembly or standard product to a specified standard or performance requirement.

Verification that the inspection, measuring or test equipment is functionally adequate is made available to a Customer if requested. Where necessary to ensure valid results, measuring equipment shall be:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be recorded
- Adjusted or re-adjusted as necessary
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed prior to initial use and reconfirmed as necessary.

Calibration records shall be maintained and shall include:

- Equipment identification;
- Measurement standard against which the equipment is calibrated;
- Any out-of-specification readings as received for calibration;
- An assessment of the impact of out-of-specification condition; and
- Notification to the Customer if suspect product or material has been shipped.

7.1.5.2. Measurement traceability

Each type of inspection, measuring and test equipment used for standard product acceptance is assessed to ensure it is capable of verifying acceptance criteria, and to establish calibration requirements and frequencies. Calibration methods and procedures are documented and detail device type, unique identification, location, frequency of checks, check method and acceptance criteria. For inspection, measuring and test equipment used for product development and design changes, an assessment is performed to determine if the equipment is capable of verifying acceptance criteria, and to establish calibration requirements and frequencies.

No personal owned equipment shall be used for standard product acceptance.

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To ensure maintenance of calibration schedules a record keeping system for inspection, measuring and test equipment is established and maintained. A record is set up and maintained for each calibrated item. Records indicate the equipment serial number, calibration accuracy, type of measuring or test equipment, calibration master, calibration frequency, as found condition, calibrated by and date.

The handling and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained and equipment is safeguarded from adjustments, which would invalidate the calibration setting.

Whenever inspection, measuring and test equipment is found to be out of calibration, items known to have been measured with that equipment need to be reviewed for the validity of measurement during the out of calibration period by taking appropriate actions to assess the impact of the out of specification readings or test results.

7.1.6. Organizational knowledge

QMS documents capture the knowledge necessary for the operation of the organization processes. Project documents and Product Files capture the knowledge necessary to achieve conformity of products and services. Re-use of the organizational knowledge is critical input to improving both the products and the development process.

Organizational knowledge is maintained and available in MP IT network.

Changes in trends and external knowledge are captured, maintained and available in MP IT network.

7.2. Competence

Employee competence is determined and evaluated for effectiveness in job performance. Competence is an explicit, defined requirement or in the case of an experienced hire, a combination of education, training, skill, understanding or demonstrated familiarity.

Ongoing developmental training needs are recorded annually through the training records and dedicated database. Additional training may be organized throughout the year as the need arises. Competence, training and awareness are described in the Training Management Procedure, job description and minimum requirement document.

7.3. Awareness

Various methods of creating awareness of the MP QHSE Policy, the relevant quality objectives and how specific MP personnel contributions impact the effectiveness of the QMS, including benefits of improved

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performance and implications of not conforming are employed within the Center. Safety Stand Down meetings, face to face interactions, emails, notice boards are some methods used within the organization to create awareness. The communication is planned and executed as described in the Communications Management Procedure.

7.4. Communication

All personnel have access to QMS process documentation via MP IT network.

MP determine the internal and external communications relevant to the QMS and plan and execute the communication as established in the Communications Management Procedure.

7.5. Documented Information

7.5.1. General

Standards, Procedures, and supporting documentation are established and maintained to control documents and data that relate to the QMS. These include documents of external origin such as standards.

7.5.2. Creating and updating

The creating and updating of QMS process documentation is regulated by the Documentation Management Procedure.

7.5.3. Control of documented information

The control of documents describing the products produced by MP, as well as the processes used to produce them, is regulated by the Engineering Procedure and its supporting procedures and specifications. This includes the control of external documents used to describe the MP products (e.g. supplier data sheets in the Engineering Product File), and the control of Customer owned documents used to drive the design of the MP products (e.g. Customer requirement documents in the Project Plan and Product File).

For the Control of Records Documentation, MP's Management Procedure defines the means of record identification, collection, indexing, access, filing, storage, maintenance, disposition and retention.

Records shall be identifiable, legible and retrievable, and protected from damage, deterioration and protected against security loss. Responsibility for records collection and maintenance shall be established. Records may be stored in any media format.

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8. Operation

MP Operation encompasses all activities as defined within all five MP Standards (Define, Enable, Develop, Produce and Support).

8.1. Operational planning and control

The planning of Product lifecycle is defined in the QMS standards and the supporting procedures. The Records needed to provide evidence that the development processes and resulting product meet requirements shall be maintained in accordance with requirements given in section 7.5.3.

The control of documents, as well as the processes used to produce them, is regulated by the Manufacturing Procedure.

Consequences of unintended changes are reviewed within MP Management, as applicable and actions taken to mitigate any adverse effects are established as necessary. The requirements and process that guide these activities are described in the Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure.

8.2. Requirements for products and services

8.2.1. Customer communication

Communication with Customers regarding performance and complaints is defined in the QMS through Engineering and Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions procedures. Communication with Customers regarding concessions is performed as described in section 8.7. The Customer Service interface is defined in the Customer processes procedure.

Product information is managed and published by MP through appropriate sales catalog or dedicated software.

8.2.2. Determining the requirements for products and services

Figures 2 and 3 illustrate the model and structure for the determination of requirements related to products and services.

Requirements for a new product or service are defined by the Project Manager and the Business Sponsor (e.g. Customers Sales or Management). This process is governed by the Engineering Procedure.

Requirements for a commercial product and the management of such are defined in the Manufacturing Procedure.

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8.2.3. Review of the requirements for products and services

The reviews of requirements are defined in the Customer Processes Procedure for new product development. For commercial products the Customer Processes Procedure and Manufacturing Procedure manage the review of product orders.

The relevant department will establish and maintain additional documents for contract review and for the co-ordination of these activities as needed.

8.2.4. Changes to requirements for products and services

When product or services requirements are changed, the relevant documents are amended per Engineering Procedure both for new product development and for commercialized products. Changes to the requirements of orders for commercial products are managed through the Customer Processes Procedure. Relevant personnel are made aware of the changes as per section 7.4.

8.3. Design and development of products and services

8.3.1. General

MP commitment to establishing processes that are appropriate for the design and development of its products and services is evident within the [QMS](#). The following sections describe how the design and development processes are established, implemented and maintained.

8.3.2. Design and development planning

Design planning and design control are supervised by the relevant department where the design specifications are controlled. Designs are stored as drawings, specifications and design documentation.

Documented methods are defined for the design of products. If design or development is outsourced the same controls are applied as for in-house work including objective evidence that the requirements have been met. Design documentation includes the methods, assumptions, formulas and calculations.

Design and development planning are documented and the plan updated as required in the Engineering Procedure.

The management and planning of the project are according to the process described in the Engineering Procedure.

8.3.3. Design and development inputs

Design inputs are determined, documented and reviewed, including Customer, statutory and regulatory requirements together with the results of any pertinent contract review activities. Design inputs include,

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as necessary, functional and performance requirements, information derived from previous similar designs, and other information essential for design and development. Design input is documented as described in the Engineering Procedure.

8.3.4. Design and development controls

8.3.4.1. Design and development review

Design reviews is documented and conducted by qualified personnel and supplemented by others who can take an objective view.

Design reviews for products and projects are planned, executed and documented in accordance with the Engineering Procedure.

The design review shall include representatives of functions concerned with the design and development stages being reviewed and shall address the ability of the results of design and development to meet requirements. Problems shall be identified and necessary actions proposed. Records of the review and any actions arising from the review shall be maintained. As a minimum there shall be a final design review and approval of the final design shall be by individuals other than those who developed the design.

8.3.4.2. Design and development verification

Design verification is performed according to the product design and development plan from as per section 8.3.2 to ensure the design stage output meets the design stage input requirements. Verification may be by calculation, comparison with proven designs, tests, demonstrations or review of design stage documents before release. Design verification for products and projects are done and kept in accordance with the Engineering Procedure.

8.3.4.3. Design and development validation

Design validation follows successful verification and ensures that the new product conforms to the predetermined requirements defined in 8.2.2. Validation is completed prior to the delivery or implementation of the product in accordance with the Engineering Procedure.

Validation of modifications to components, sub-assemblies or software are assessed by Engineering and may be validated by analytical means or appropriate testing. Assessment of new manufacturing or finished product testing techniques may be conducted in parallel with existing techniques. Design validation for products and projects are documented, and records maintained, in accordance with requirements stated in the Engineering Procedure.

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8.3.5. Design and development outputs

All design outputs are documented in the form of drawings, specifications and design documents which are verified by Engineering against the design input criteria and objectives. Drawings and specifications will include component or assembly acceptance criteria and procedures as applicable.

Design outputs identify characteristics which are critical to the safe and proper functioning of the product, provide adequate information for purchasing, production, shipping, service provision, operation, and preservation of product and will be subject to review before release. Design Outputs are defined in the Engineering Procedure.

8.3.6. Design and development changes

Changes to designs are managed through the Engineering Procedure. All affected drawings, procedures and specifications are amended in accordance with the amendments defined in this procedure. Design and development changes, including changes to design documents, require the same controls as the original design and development, and design documentation. Changes are reviewed, verified and validated, as appropriate, and approved before implementation.

The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered. All product design document changes are identified, documented and archived in MP IT Network.

8.4. Control of externally provided processes, products and services

8.4.1. General

MP Supply Chain organization follows the Procurement and Sourcing Procedure reflected in the overall QMS along with any associated procedures, as applicable.

8.4.2. Type and extent of control

Purchasing is conducted under a controlled system to ensure that purchased materials, items and services supplied to the center for incorporation into the product or sold directly to the field conform to specified requirements as defined in the Procurement and Sourcing Procedure.

Approved suppliers are identified on the Approved Suppliers List present in the ERP. All updates, additions, and deletions to this list are made by the Supply Chain team Suppliers Management Procedure.

The criteria for selection, evaluation and re-evaluation of suppliers is risk based as outlined in the Suppliers Management Procedure.

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Supplier's performance is reviewed through a risk-based evaluation. This evaluation shall be performed at least annually by Supply Chain. Suppliers are evaluated and documented on a periodic basis, dependent on the Performance Metric, for which acceptable performance levels are established.

New suppliers are qualified for approval by audit and/or first article inspection per the Suppliers Management Procedure. New parts from current suppliers are subject to first article inspection. The Supply Chain group manage subsequent supplier verification.

Due to the impact of subcontracted work on final product quality, suppliers may be removed from the Approved Supplier List in accordance with the Suppliers Management Procedure.

When a special process is outsourced MP shall require that the supplier complies with the same controls as for in-house work.

8.4.3. Information for external providers

Purchase Orders clearly state the requirements for purchased materials, parts or services, which affect product quality. Purchase Orders state and include information as required in the applicable PO Creation and Management specification and PO Acknowledgement Entry specification in accordance with the ERP requirements.

Procurement activities are governed by the Procurement and Sourcing Procedure.

Verification of purchased product is carried out before transfer of goods into stores for use. There are documented methods for the verification of purchased products and records are maintained of verification results. Products determined to be unverified are transferred to the pertinent designated area. This process is controlled according to the Incoming Procedure.

If MP intends to perform verification at the suppliers premises the verification arrangements and method of product release are stated in the Purchase Order.

8.5. Production and service provisions

The overall control of production and service provisions is managed by the Quality Plan. This procedure calls out steps to control the various production phases.

8.5.1. Control of production and service provisions

Information that describes the characteristics of the product is defined in the Engineering Procedure.

The manufacturing process is governed by the Manufacturing Procedure generically, and product processes are governed by the related operative instructions. The quality plan requirements are described in the Quality

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Plan, ensuring that the manufacturing process is performed under controlled conditions.

The manufacturing process includes the use of suitable equipment, working environment and Customer's inspection hold or witness points if required.

Process controls are documented in Routings or method sheets and includes requirements for verifying compliance with quality plans, drawings, specifications and standards.

The center shall validate any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or where deficiencies only become apparent after the product is in use or the service has been delivered. The management of this process is described in the Engineering Procedure and controlled through Quality Plan.

The production processes are described in specific documents and/or general standards included in each Product File supported by the Manufacturing Procedure.

8.5.2. Identification and traceability

The Manufacturing Procedure and related OI and applicable documents outlines a traceability strategy for implementing part/product traceability and the implementation of traceability requirements.

The identification and traceability of component part status through manufacture is achieved by the use of serial numbers, part numbers and/or work orders as defined in the Manufacturing Procedure and relate OI and applicable documents and managed in the Quality Plan(s).

Any product or component losing applicable traceability requirements is processed as nonconforming in accordance with Section 8.7, Control of nonconforming product, of this Quality Manual.

8.5.3. Property belonging to Customers or external providers

MP verify, store, maintain and control Customer property. MP shall identify, verify and protect Customer property provided for use or incorporation into the product or for repair. Customer property may include intellectual property or personal data. If Customer property is lost, damaged or otherwise found to be unsuitable this shall be reported to the Customer and records maintained.

The processes used to deal with Customer supplied products is documented in Customer Management Procedure and in the Quality Plan.

8.5.4. Preservation

Procedures for handling, storage, packaging, preservation and delivery of product are referred to in the assembly and test procedures, as required in the Quality Plan, and other procedures such as Manufacturing Procedure and related OI and Incoming Procedure. The components or product are

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handled in a manner which prevent damage or deterioration and stored in designated stores areas. Product are checked for deterioration at specified intervals as defined in the dedicated OI. Protection and packaging are applied where necessary after final inspection and test. Protection is extended to include delivery to the Customer.

8.5.5. Post-delivery activities

Consideration of post-delivery activities is made during product development via the procedures below:

- Customer Management Procedure: captures Customer requirements for product maintenance, maintenance cost, and reliability.
- Engineering Procedure and related OI:
 - defines methods to meet statutory and regulatory requirements and consider unintended consequences of product usage and disposal.
 - defines a set of reliability activities that are performed from the Define phase through to the Support phase, to achieve and maintain the product's reliability requirements.
 - defines a set of Maintainability engineering activities that are performed from the Define phase through to the Support phase, to define, achieve and later improve the product's maintainability requirements.
 - defines the overall framework to ensure the product's usability.
 - defines requirements for development of product operation and maintenance manuals.
- Manufacturing Procedure: defines a set of activities that are performed throughout the project phases from Define to Support, to optimize the fit between the product designs, Supply Chain and Manufacturing capabilities in order to increase Customer satisfaction, minimize total costs, and maximize flexibility.

After delivery to the Customer, the following activities shall be implemented according to:

- Engineering Procedure:
 - provide a framework for securing and maximizing the business value of the product, from the first deployment during field testing, through maturity, and until obsolescence, with a constant focus on Field Operations satisfaction.
 - define requirements for capturing product performance indicators and Customer feedback to support continual improvement and lifecycle management.
 - define how product support activities are executed.
- Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure: Establish requirements for reporting and responding to product non-conformities at Customer sites.
- Manufacturing and Planning Procedure: detail the requirements for product returns to the center of manufacture for repair, exchange or credit.

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8.5.6. Control of changes

Changes to designs after the product or service has been delivered to the Customer are managed through the Engineering Procedure and related OI. All affected drawings, procedures and specifications are amended in accordance with the clauses defined in this procedure. Design and development changes, including changes to design documents, require the same controls as the original design and development, and design documentation. Changes are reviewed, verified and validated, as appropriate, and approved before implementation.

The review of products and services changes includes evaluation of the effect of the changes on constituent parts and shall follow the Engineering Procedure for changes within MP and for products in the field. All product design document changes are identified, documented and archived in the MP IT Network.

8.6. Release of products and services

Verification of purchased product is carried out before transfer of goods into stores for use. There are documented methods for the verification of purchased products and records are maintained of verification results. Products determined to be unverified are transferred to the pertinent designated area. This process is controlled according to the Incoming Procedure.

The center maintains documented inspection and testing procedures to verify that specified product requirements are met. Documented procedures contain the criteria and detail the required recording, inspection and testing. Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. There shall be evidence that product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed unless authorized by a relevant authority and, where applicable, by the Customer.

Non-conformances are processed in accordance with Section 8.7 and the Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure.

All records are held in the appropriate business system.

8.7. Control of nonconforming outputs

Nonconforming items are identified as such, segregated to prevent inadvertent use, and evaluated. Concerned functions are notified, and shall address/disposition both manufacturing acceptance criteria and design acceptance criteria type non-conformances.

Non conformances can be dispositioned as Rework, Repair, Return to Vendor, Scrap, or Use-as-Is, with the policy of minimizing the use of Use-as-Is. The incidence of Use-as-Is must be monitored by the

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Manufacturing function and in case reported to Engineering function for proper evaluation and CA's.

The use of nonconforming product must be under concession signed by the designated authorities. Where required by a contract, the use of product which does not conform to specified requirements must be reported for concession to the Customer or Customer's representative.

Repaired or reworked items must be re-inspected in accordance with acceptance criteria given by Engineering and/or the Customer.

MP shall notify Customers in the event that delivered product does not conform to the Design Acceptance Criteria. Records of such notifications shall be maintained.

The Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure describes in detail the requirements for control of nonconforming product.

The Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure identifies the requirements for documenting and reporting incidents of field nonconformities or product failures and includes requirements for analysis and determination of cause when the product or supporting evidence is available.

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9. Performance Evaluation

9.1. Monitoring, measurement, analysis and evaluation

9.1.1. General

QMS conformity and continual improvement of the effectiveness of the QMS are inherent in the Quality Objectives and Management Review records. Quality objectives are quantifiable and are time lined or based on statistical data.

9.1.2. Customer satisfaction

Recorded sources of Customer satisfaction information include but are not limited to, Field Feedback Meetings, field visits, e-mail, commissioning, feedback or any other mechanisms.

9.1.3. Analysis and evaluation

Quantitative statistical data is compiled explicitly with respect to Quality objectives. Statistical data is analyzed to determine improvements associated with Quality objectives.

Results of analysis of data are communicated as per paragraph 7.4 Communication.

9.1.4. Rights of access

Representatives of third-party auditing firms involved in certification audits are granted the right of access to the premises of MP for the purpose of auditing. Such audits are coordinated by the Quality function.

Customers or their designated representatives are allowed reasonable access to the premises of MP for audits or inspections, as requested and contractually agreed.

All Customers and representatives world-wide, given rights of access to the premises of MP, must comply with local Quality & HSE requirements.

9.2. Internal audit

The objective of quality management system audit is to define how elements of the MP organization demonstrate the effectiveness, implementation of and compliance to the audit criteria, described through Policy, Standards and Procedures.

The Audit Management Procedure defines responsibilities and requirements for planning and conducting audits, reporting results, defining remedial action items and maintaining records.

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Objectives are tracked and reviewed periodically. When necessary, corrective or preventive actions are taken in order to meet the objectives and ensure planned results are achieved.

9.3. Management review

9.3.1. General

General Manager has overall responsibility for ascertaining the suitability, adequacy, effectiveness and alignment of the QMS with the strategic direction of the MP through Management Reviews. He/she shall ensure the QMS continuing suitability and effectiveness in satisfying the Quality Policy and objectives at the Center. The QMS must be reviewed at least once annually; records of reviews are documented and maintained.

9.3.2. Management review input

The Management Review shall include inputs identified in the Management Review Form.

MP can choose to have several management reviews in one year, each required input must be included in at least one of these meetings.

9.3.3. Management review outputs

The record of the review shall be documented on the Management Review Form, or equivalent, and stored in MP IT Network and distributed to attendees and other personnel as deemed necessary by the Center Quality Systems Manager.

Output shall include action points and decisions taken, and where applicable, decisions not to take an action. Additional information presented at the management review can be attached. The minutes include decisions made and action items related to improving the effectiveness of the QMS, objectives and its processes, improvements of products related to Customer requirements and the resource needs to effect the changes.

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10. Improvement

10.1. General

As per the Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure MP management sets objectives for each calendar year to monitor and measure management system process performance. It is the responsibility of each department to take the necessary actions in order to meet the defined objectives.

10.2. Nonconformity, Corrective and Preventive action

Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure describes in detail the requirements for control of nonconforming product.

10.2.1. Corrective Action

Sources of information for corrective action are activities which affect standard, product, service, quality, concessions, records, audit results, Customer complaints and field reports. Corrective action may also be as a result of observations made by personnel carrying out their daily duties. All Customer complaints, manufacturing failures, field failures, nonconformance to procedure and defective purchased items are reviewed by a committee of representatives of functions involved. The Line manager of the affected area is responsible for taking suitable corrective action(s) to eliminate the cause and prevent recurrence using the appropriate media. Corrective actions are documented in the appropriate media and be appropriate to the effects of the nonconformities encountered. Management shall ensure that corrective actions applicable to the risks and opportunities determined during Management Reviews and any changes to the QMS are properly captured and implemented where necessary. Management shall ensure corrective action is effective in correcting the problem and in preventing reoccurrence and identify response times for submission of an action plan to address corrective action.

The detailed requirements of management of corrective actions are in the Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure.

Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure identifies the requirements for documenting and reporting incidents of field nonconformities or product failures and includes requirements for analysis and determination of cause when the product or supporting evidence is available.

10.2.2. Preventive action

Preventive actions are determined from risk-based assessments such as those described in Section 6.1.

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The detailed requirements of management of preventive actions are in the Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure.

10.3. Continual improvement

MP shall continually improve the effectiveness of the QMS through the use of the QHSE Policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. The Management of accidents, near accidents, injuries, non-compliance, corrective and preventive actions Procedure captures the requirements and processes for establishing and implementing continual improvement activities in the Company.

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11. Document Ownership

Table 1: Document Ownership

This document has been reviewed and approved by parties listed in first page.

Owner	Custodian
MP General Management	MP Quality Systems Manager or delegate