Quality Manual for North America

Revision	Reason	Date
A	Initial Issue	7/24/11
B	Company Re-Organization (+ Eldre Corp)	4/27/12
C	Company Re-Organization (Update Vital Stats)	6/7/12
D	Company Re-Organization (+El Paso, - Mfg. from Nbpt) New Quality Policy EURAM	2/28/14
E	Change of Scope for Kestrel A and B	3/3/15
F	Update to ISO 9001-2015 standard	1/17/17
G	Quality Manual was updated to apply to Mersen Juarez	3/29/19
H	Quality Manual was updated to add IATF doc ref/clarify content and was added the process map Plant 2, changed the scope for Plant 2 and was added the exclusions for Plant 2	5/15/19

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Contents:

1. Introduction

This Quality Manual describes the policies and North American wide control structure of the **MERSEN** North American Quality Management System (QMS). Our QMS addresses the requirements of the ISO-9001-2015 QMS Standard, the IATF 16949-2016 Automotive QMS Standard, customer specific requirements and any applicable statutory and regulatory requirements.

The story of Mersen, North America

History:
The Shawmut Fuse Wire Company founded in 1885 and based in Boston. The company merged with Chase & Co. in 1893, forming Chase-Shawmut. In 1905, the Chase–Shawmut company moved from Boston to its present site in Newburyport.

In 1953, I-T-E Circuit Breaker Company purchased Chase–Shawmut, retaining the name.

In 1976, Gould purchased ITE, changing the name from Chase Shawmut to Gould Shawmut.

In 1978 Gould Shawmut NEWBURYPORT move MIDGETS & GMG -TUBE MFG to Juarez, MX & the rest is HISTORY.

In 1999, Carbone Lorraine acquired Gould Shawmut and merged the company with its Ferraz Division, renaming the combined company Ferraz Shawmut.

Ferraz, a company founded in 1928, to produce electric motor brush holders. They were then, acquired by Carbone Lorraine in 1950. When Ferraz merged with Gould Shawmut in 1999 Ferraz was a significant presence in the European fuse and electrical equipment market. The combined company, Ferraz Shawmut, was now a major presence in Electrical Protection, worldwide.

In 2010, Carbone Lorraine, in an effort to consolidate all the various company names to a coherent single entity - renamed itself, and all its divisions, Mersen.

In 2013, manufacturing locations in Newburyport MA relocated to a new facility in El Paso TX, with some processes being, transferred to the current facility, in Juarez MX.

In 2015, **MERSEN** EP further defined into two divisions EPC and SPM.

In 2016, all the remaining manufacturing located at the El Paso TX facility transferred to the Juarez MX facility.

2. Management Statement

Mission Statement:
To strives, with our customers, for the world's safest and most reliable electrical solutions.

Values:

- **Customer Focus**: To listen, understand and respond.
- **Employee Commitment**: To develop, recognize and grow.
- **Continuous Improvement:** There's always room for improvement
- **Integrity**: Conduct our business in an honest and ethical manner.

Vision:
Be the world's resource for electrical safety and reliability.

What it means:

- Continue to develop and strengthen customer focused operational excellence.
- Continue to capitalize on fuse and fuse gear product segment market consolidation
- Product portfolio management: Expansion and rationalization programs
- Focused sales and marketing initiatives in high growth markets
- Position the business in overcurrent protection with the convergence of protection – detection – breaking functions.

3. Structure and Control of the Quality Manual

3.1 Manual Structure

This manual is, structured such that it follows the paragraph headings found in ISO 9001-2015 and IATF 16949-2016.

3.2 Manual Control

3.2.1 Review

The VP Quality Assurance conducts an annual review of the Quality manual with inputs from the other North American Quality Managers.

3.2.2 Updates

The current revision of this document is in the header on each page, and the revision history is at the end of the document in the revision history block.

3.2.3 Approval

Each revision, is approved by the VP Quality Assurance, North America

3.2.3.1 Control

The manual is, controlled in accordance with quality documents control procedure (QA-P-001). Any time this is emailed or printed it is considered uncontrolled.

3.2.4 Distribution

All copies printed from the Public Copy are watermarked as, "Uncontrolled". It is the obligation of the user of the manual to insure that the most recent revision referred.

4. Context of the Organization

4.1 Understanding the organization and its context

MERSEN determines external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system using a SWOT form (QA-F026).

MERSEN has established and maintained a Quality Management System, which is, designed to meet the quality objective and policies defined by top management and to meet the requirements of the ISO 9001-2015 and IATF 16949-2016 QMS standards.

Our Quality Management System:

- Identifies our major / critical processes including management, resource allocation, product development, measurement, analysis and improvement actions
- Determine the sequence and interaction of these processes
- Determines the criteria and methods required for effective operation and control of these processes
- Determines the availability of information necessary to support the processes and monitor their outcomes to ensure they are effective
- Ensures the availability of resources necessary to support and monitor our processes
- Measures, analyzes and continually improves these processes.
- Implement the actions necessary to achieved the planned results and continually improve these processes.
- Ensures control over all outsourced processes that effect product conformity to requirements.
- Ensure that product and services provided to customers conform to all contractual, statutory, regulatory and quality management systems requirements that meet or exceed their needs and /or expectations.

The Quality Management System aims to satisfy the requirements of the following interested parties:

- Customers and End Users who expect superior quality products and services, when they need them, at reasonable price
- Suppliers, who need a detailed description of our requirements in order to properly partner with us to provide quality materials, on time at a reasonable price
- Our shareholders, if our business and manufacturing processes are to operate in a cost-effective manner, they must be well defined, efficient and audited.
- Our employees, who must receive support in the form of benefits, stable working environment, adequate training, and clear communication
- Our community, for which we provide employment and must represent ethically and environmentally with all we do
- Our Government, which we share mutual respect in the payment of our taxes and receipt of local and national guidance

MERSEN maintains the information regarding our interested parties, and their relevant requirements, in a table (QA-F-027). The matrix is reviewed annually at management review.

Our Quality Management System is, organized into the following major/critical processes:

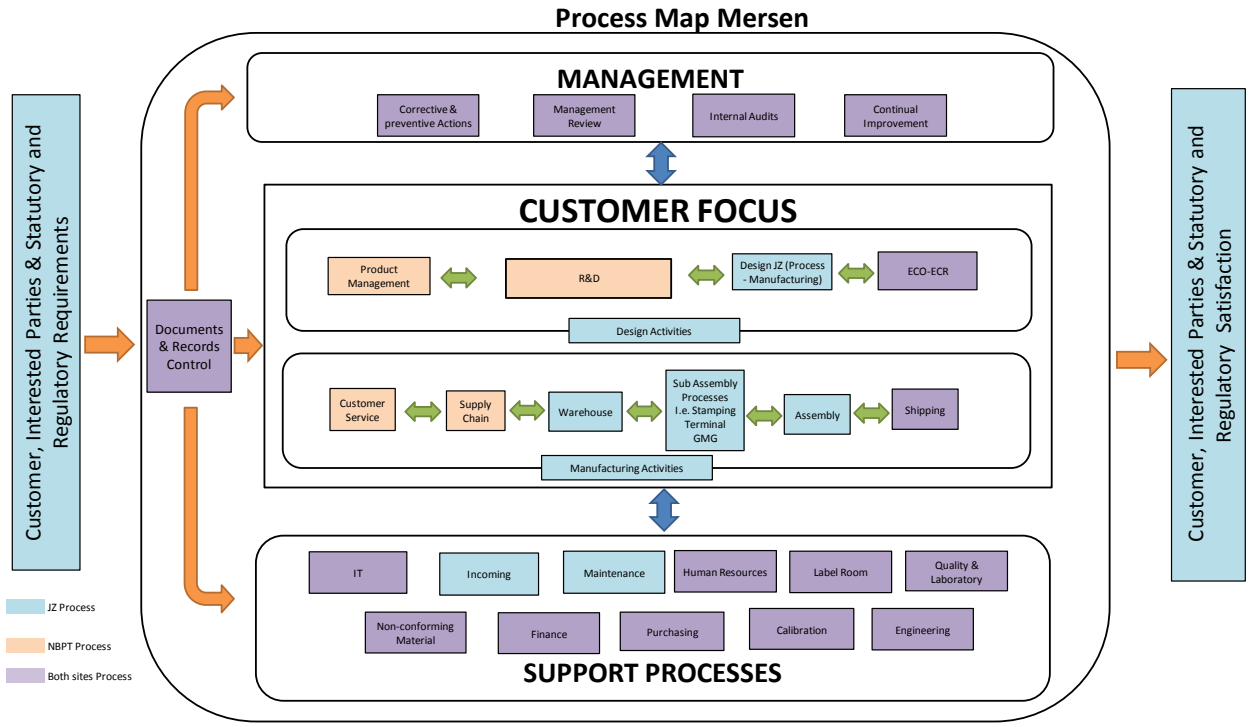
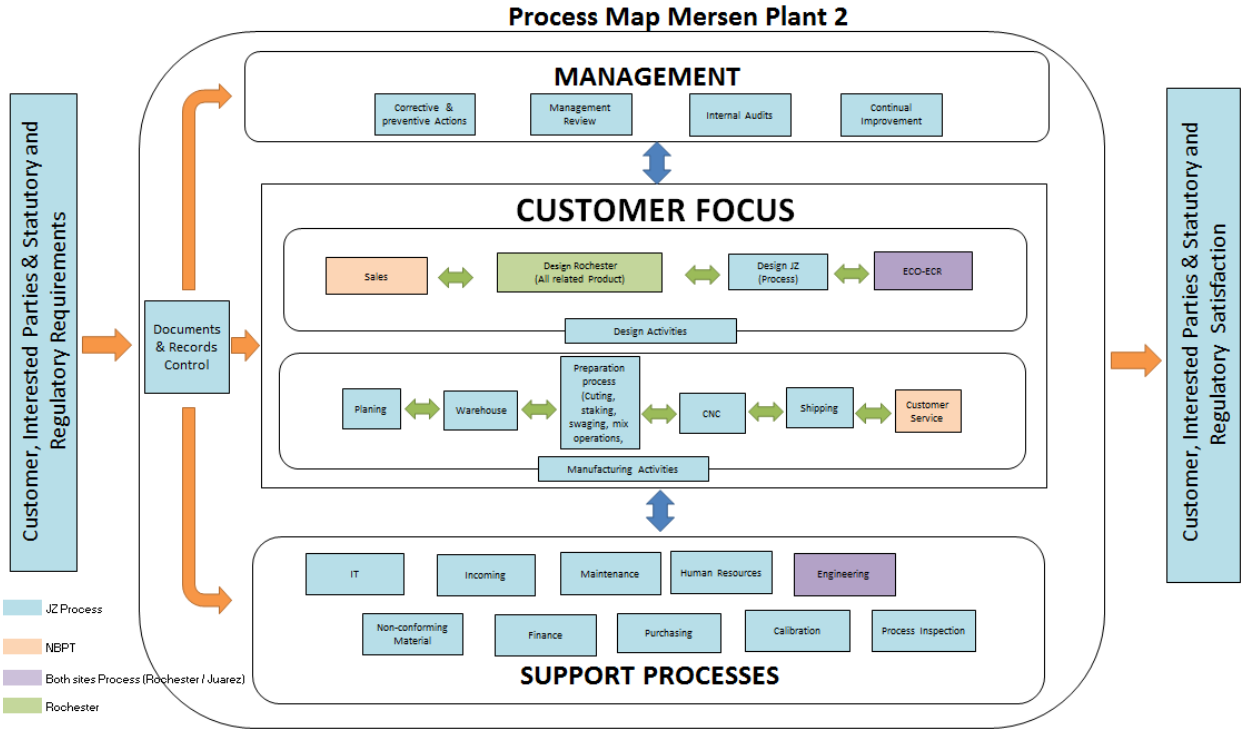


Figure 1.0



Each Process is managed, and continually improved, by the monitoring and supervision loops. These loops include measurement, data analysis, corrective, preventive or improvement actions / decisions and their review (effectiveness and measurement). The use activity, effectiveness and or efficiency measurement indicators scaled to the process concerned.

4.2General

The Management Team reviews the Quality Management System at planned intervals to ensure its continued suitability, adequacy and effectiveness. These reviews include the assessment of opportunities for improvement and the need for any other changes to the system, including the Quality Policy and Objectives.

The actions arising from these reviews, are recorded and acted upon.

4.3 Determining the scope of the Quality Management System

Scope:
This manual covers the North American locations and the processes and systems controlled by North America EPC (Electrical Protection Control).

Vital Statistics, Mersen North America (for reference only - as of December 2018):

	Newburyport	Toronto B	Juarez Plant 1	Juarez Plant 2
Manpower				
Direct	0	12	712	41
Indirect	133	52	152	8
Total	**133**	**64**	**864**	**49**
Square Feet				
Manufacturing	0	23,000	92,089	27,000
Office	51,500	10,500	7,752	4,500
Laboratory	13,500	0	0	760
Eng. Tech.	15,000	0	0	0
Shifts	1	1	2	2

	Newburyport	Toronto B	Juarez Plant 1	Juarez Plant 2
Products / Functions	Design and Engineering of Fuses, Surge Protection Devices and Fuse Accessories (Commercial and automotive)	+ Design Engineering, Mfg., Distribution, and Servicing of Custom High Power Switchgear as well as the Distribution of Enclosures and related products.	Assembly of fuses, fuse holders, Surge protection devices, manufacturing of glass tubes and stamping elements.	Mfg. of Thermal Management devices

		+ Distribution of fuses and fuse gear		
Management	HQ – North America, HQ–EPC	Reports to EPC	Reports to EPC	Reports to EPC
Certificates	ISO 9001-2015 Complaint	ISO 9001-2015	ISO 9001-2015 ISO 14001	ISO9001-2015
Conformity	IATF 16949 (Audit planned Q2 2019		IATF 16949 (Audit planned Q2 2019)	ISO 9001-2015 (Audit planned Q2 2019)
Testing Facilities (see Equip.t master for complete listing):	High Power Test Lab, Surge Lab, Low Power Test Lab & Other test equipment	Low Power Test Lab, X-ray, Optical Comparator	Various test equipment; X-ray, Low power test bench, Oven, Resistance testing, CMM, Vision System	CMM
Exclusions	N/A	N/A	Product Design: See figure 1 (NBPT process) has the product **design.**	8.3Product Design (Rochester) 8.2 Products and service requirements

4.3.2 Specific requirements

MERSEN evaluates and includes in the scope of the organization's quality management system the Customer-specific requirements thought a customer specific requirements matrix QA-F-234.

4.4 Quality Management system and its processes

Quality Manual:

The Quality Manual details the processes and organization put in place to insure that the **MERSEN**, Electrical Protection, North America Quality Systems meet the requirements of ISO 9001-2015. The automotive segment within Juarez and the remote support functions in Newburyport meet the IATF-16949-2016 QMS Standard, customer specific requirements, and any applicable statutory and regulatory requirements.

The **MERSEN** executive team has the responsibility to establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.
MERSEN determines the processes needed for the quality management system and their application throughout the organization, and has:

a) Determine the inputs required and the outputs expected from these processes
e) Determine the sequence and interaction of these processes
b) Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes
c) Determine the resources needed for these processes and ensure their availability
d) Assign the responsibilities and authorities for these processes
e) Address the risks and opportunities as determined in accordance with the requirements of 6.1
f) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results
g) Improve the processes and the quality management system.

The interaction between the processes and the quality management system is, shown in the flow chart in Section 4.1. (Fig. 1)

4.4.1.1 Conformance of products and processes; MERSEN North America ensures that all products, including service parts and those that are outsourced, conform to all applicable customer, statutory, and regulatory requirements.

4.4.1.2 Product Safety
Product manufactured by MERSEN is inherently a safety product by its function. MERSEN has addressed system and product safety within our New Product Development Procedure through the use of Customer specific requirements, DFMEA, PFMEA, and other risk analyses. Additionally MERSEN acknowledges the importance of Safety by implementing the requirement of a certified PSB (Product Safety Representative). Please refer to the New Product Development Manual (NPDM 1.0) for further details.

Exemptions:
The following products and processes are exemptions from the QMS in place at these locations:

Newburyport
The Testing Facilities, their processes, systems and operation are not covered by, the ISO 9001 Quality Management System or manual. The Testing Facilities are compliant under ISO 17025-2005 by U/L.

The Quality Management System documents hierarchy.

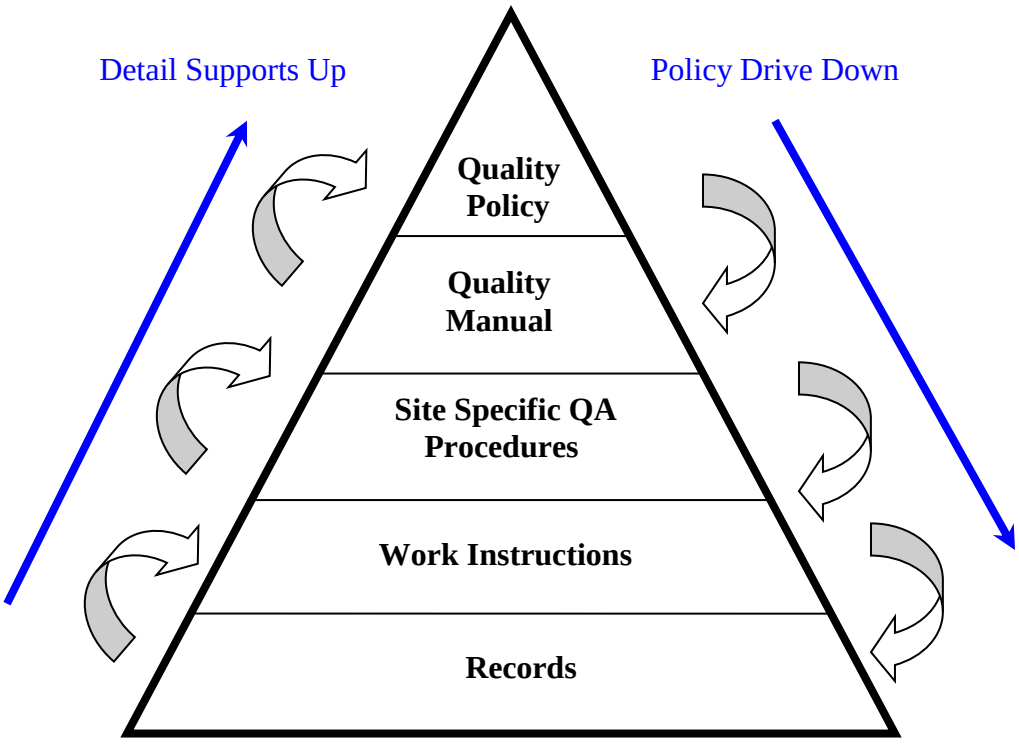


Figure 2.0

5. Leadership

5.1 Leadership and Commitment

Top management expresses its commitment to the development, implementation and continual improvement of the Quality management system through:

- Management takes accountability for the effectiveness of the QMS. We do this by taking an active role in our QMS, and one of the key tools is our Management Reviews.
- We have reviewed and ensure that the Quality Policy and Quality Objectives established for the QMS are compatible with the context and strategic direction of **MERSEN** EP, and these are communicated to all personnel at all locations.
- Our QMS is how we manage our business. As a result, our QMS requirements are integrated into the organization's business processes.
- We promote the use of the process approach and risk based thinking by looking at all of our processes as defined in Section 4.1 including the inputs, outputs, resources, monitoring, measurement, improvement, training, and other considerations.
- Management ensures resources are available by the following methods:
- Budgets: Management establishes budgets for resources, capital, and expenses.

- Management Review **MR-FC-001, MR-P-001 & QCI 14.1**: As a result of the Management Reviews, resources may be identified.
- Changes in Business: If changes in business occur, resources are reviewed and actions are taken to address the business needs.
- Management communicates the importance of effective quality system and importance of conforming to the QMS through daily interaction, meetings, management reviews, etc.
- We ensure that the QMS effectively achieves its intended results through internal audits, customer satisfaction metrics, process performance indicators, supplier performance, and many other factors, which are all included at Management Reviews. (**MR-FC-001, MR-P-001 & QCI 14.1**).
- We foster employee involvement with our QMS by having employees actively involved.
- This engaging activity directly shows how we enable our employees to contribute to the effectiveness of the QMS. This in part is, performed through daily conversation, metric reviews, and various meetings.
- We promote the use of continuous improvement tools across all aspects of **MERSEN**.

5.1.1.1 Corporate Responsibility

We define our corporate responsibilities on the MERSEN Corporate Global Website (https://www.mersen.com/), which includes at a minimum; anti-bribery, code of conduct, and ethics escalation policies.

5.1.1.2 Process Effectiveness and Efficiency

Top Management Reviews the effectiveness and efficiency of the Quality Management System to evaluate and improve the result of the process review activities are included as an input to our Management Reviews.

5.1.1.3 Process Owners

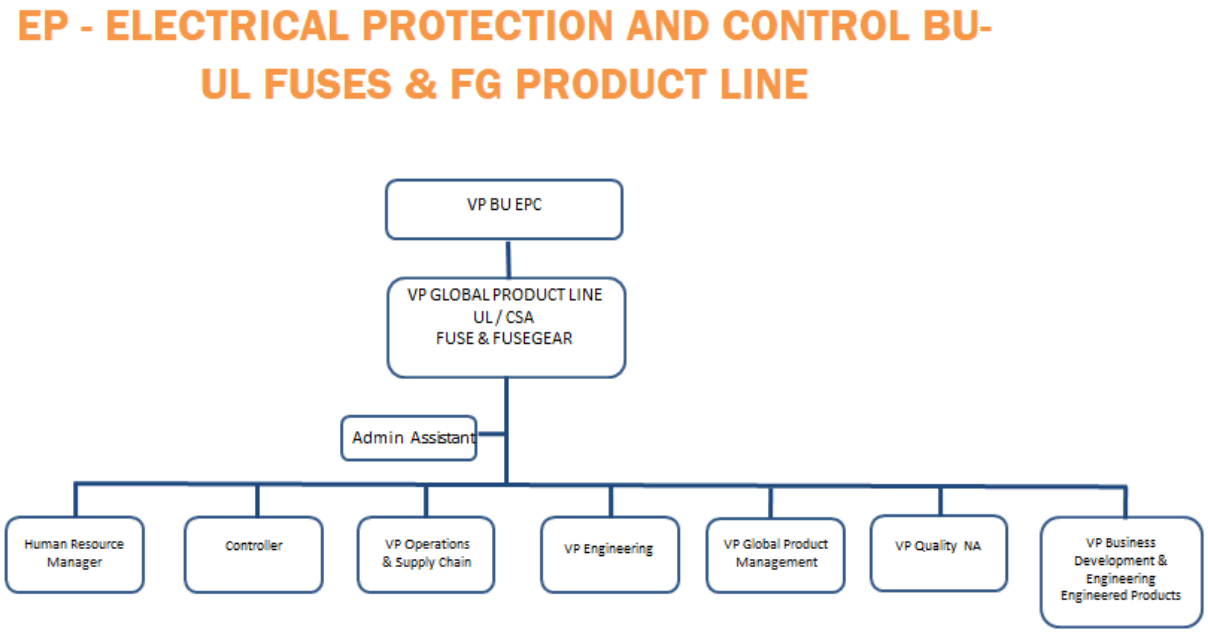


Figure 3.0

5.1.2 Customer Focus

Top management has implemented a customer driven organization supported by:

- Ensuring customer requirements, including statutory and regulatory (legal), are defined, understood, and met.
- Understanding the risks that could impact product and service conformity are understood and actions are taken to eliminate or minimize the risk
- Customer Satisfaction measures are maintained:
  - On Time Delivery
  - Administrative Error Tracking
  - Technical Error Tracking
  - Field Service Returns
- Market Studies
- Product Needs Analysis
- Partnerships with some customers for design of products
- Sales teams which monitor and report on customer needs and issues

The goal of these activities is to enhance customer satisfaction.

5.2 Policy

5.2.1 Establishing the quality policy: Top Management has established a Quality Policy that ensures compliance to the ISO-9001-2015 and IATF 16949-2016 QMS Standards (see Section 4), and which is appropriate to the organization as a whole. It is our expectation to maintain high standards of quality, delivery and service. To ensure the safety, continued education, and wellbeing of our employees. Finally, we will foster continuous improvement across the company utilizing risk based thinking methodology to; improve our products, processes, services, organization and performance to the satisfaction of all interested parties. At a minimum, our quality policy addresses the following factors;

- The quality policy is appropriate to **MERSEN**'s company objectives and direction
- The quality policy provides a framework for setting quality objectives
- The quality policy outlines a commitment to satisfy all applicable requirements
- The quality policy provides a commitment to continual improvement of the QMS system at **MERSEN.**

The policy is issued and communicated to all **MERSEN** personnel at the North American Electrical Protection (EPC) through multiple postings in each location, and to our customers and the general public though the posting of the policy on the internet (company web site).

5.3 Organizational roles, responsibilities and authorities

Each person in **MERSEN** is responsible for understanding and adhering to the requirements of the QMS. Management has defined the responsibilities and authorities of each in their Job Description, and the reporting lines in an Organization Chart. This information is, communicated within the organization.

Mersen, Electrical Protection, North America has facilities in Newburyport, MA, Toronto, CA, & Juarez, MX.

Formal organizational memos, available at each location, detail the current assignments within the **MERSEN**. The functions of each member of the Quality Team are described; in the Job Descriptions available in Human Resources at each location.

The VP Quality is management's representative for Newburyport, USA and the QA Managers in Toronto, CA, and Juarez MX (Plant 1 & Plant 2) are the management representatives for their respective locations. The management representatives at each location are responsible for,

- Understanding, and ensuring, that customer requirements are met and promoted throughout **MERSEN**
- Assuring conformity of product quality; if needed, stop shipping or stopping production,, containing suspect materials, and delegating responsibility for these activities across all shifts.
- Driving the development, implementation and continual improvement of the Quality Management Systems

- Measuring and Reporting Quality System performance
- Participating in the development of the Quality Policies and Objectives
- Acting as the official spokesperson for the company on the Quality Management System to external partners

6. Planning

Every year Electrical Protection, North America, reviews its' action plans against the strategic plans established by the companies Top Management. As part of our Integrated Business Process (IBP), objectives are, brought into line with the strategic plans and the available resources. Goals are set, measures established and tracking mechanisms put into place. Monthly meetings, are held to discuss risks and opportunities in the following content:

- Customer Related Metrics
- Demand
- Supply Chain
- Reconciliation
- Executive Review

6.1 Actions to address risks and opportunities

Actions are taken to address risk prior to the occurrence of non-conformity and act to reduce or eliminate the possibility of a non-conformance actually happening. Additionally we utilize lessons learned from field failures and internal scrap as part of ongoing risk analysis process.

Zero Defect Audits (Error Proofing), APQP, Product and Process FMEA (Risk Management) are good examples of Preventative Actions > as they determine a potential cause, evaluate the need for actions to prevent the potential cause and take actions to insure the potential cause (or risk) is neutralized prior to a non-conformity occurring.

The following risk assessments are required for PAC (product approval committee)

- Technical Risk
- Marketing Risk
- Financial Risk
- Quality Risk

All actions:

- Determine the potential nonconformity and its possible causes
- Evaluate the need for action to prevent the occurrence of a non-conformity
- Determine the actions needed to prevent non-conforming materials
- Evaluate indirect events, such as infrastructure/key equipment failures/natural disasters), and put contingency plans in place to ensure customer requirements are met.
- Implement the actions selected
- Record the results on the action

- Review the actions effectiveness and change as necessary.
- Give assurance that the quality management system can achieve its intended result(s);
- Achieve improvement.

6.1.2 Actions to address risks and opportunities into quality management system processes

Mersen plans actions to address risks and opportunities into the quality system through:

a) Risk and opportunity detection (QA-F-028) to all processes.

b) Evaluation of the potential impact and a prevention action to each risk (QA-F-080).

Preventive Action

MERSEN determines and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions will be appropriate to the severity of the potential issues.

MERSEN establishes a process to lessen the impact of negative effects of risk including the following:

a) Determining potential nonconformities and their causes;
b) Evaluating the need for action to prevent occurrence of nonconformities;
c) Determining and implementing action needed;
d) Documented information of action taken;
e) Reviewing the effectiveness of the preventive action taken;
f) Utilizing lessons learned to prevent recurrence in similar processes.

Contingency plans

MERSEN has development a contingency plan by site.

- Newburyport
- Juarez
- Toronto

6.2 Quality objectives and planning to achieve them

The Management has established a number of key Quality Objectives. They are chosen to be measureable, in line with the Quality Policy, and serve to direct the Company's focus onto information that measures the effectiveness of the Quality Management System and the Company's processes.

It is the responsibility of Management to ensure that the, Quality Policy and Quality Objectives are communicated to and understood by all employees.

Each location Quality manager draws up his own action plans and Quality Goals; based on the strategic plan, capital budgets and available manpower, and the requirements of the location. Top Management reviews these goals and approves them for each location.

The Management has established quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives are:

a) Consistent with the quality policy;
b) Measurable;
c) Take into account applicable requirements;
d) Relevant to conformity of products and services and to enhancement of customer satisfaction;
e) Monitored;
f) Communicated;
g) Documented in English (primary) and in the local language
h) Mersen employs a change management process which attempts to cover all perceivable changes which can be place on the organization. See figure 4 as a company grows, matures and improves change is thus inevitable, managing the change is very important. At Mersen handling change is extremely important to the company and to our customers. In figure 4 is shown a high level flow chart which shows where and how parts of the organization handle change. All is focus on our Document control process which controls and is the repository of all pertinent procedural level documentation. Changes whether at product or process or requested from Customer specific requirements are controlled in this fashion, and can be seen how the 5 P are handled, (Person, Product, Process, Place or Project)

   Each department has its own set of documents and procedures and processes and they are what control Mersen and following these procedures and process consistently and thru improvement is what allows Mersen to succeed with customers.
i) Updated as appropriate.

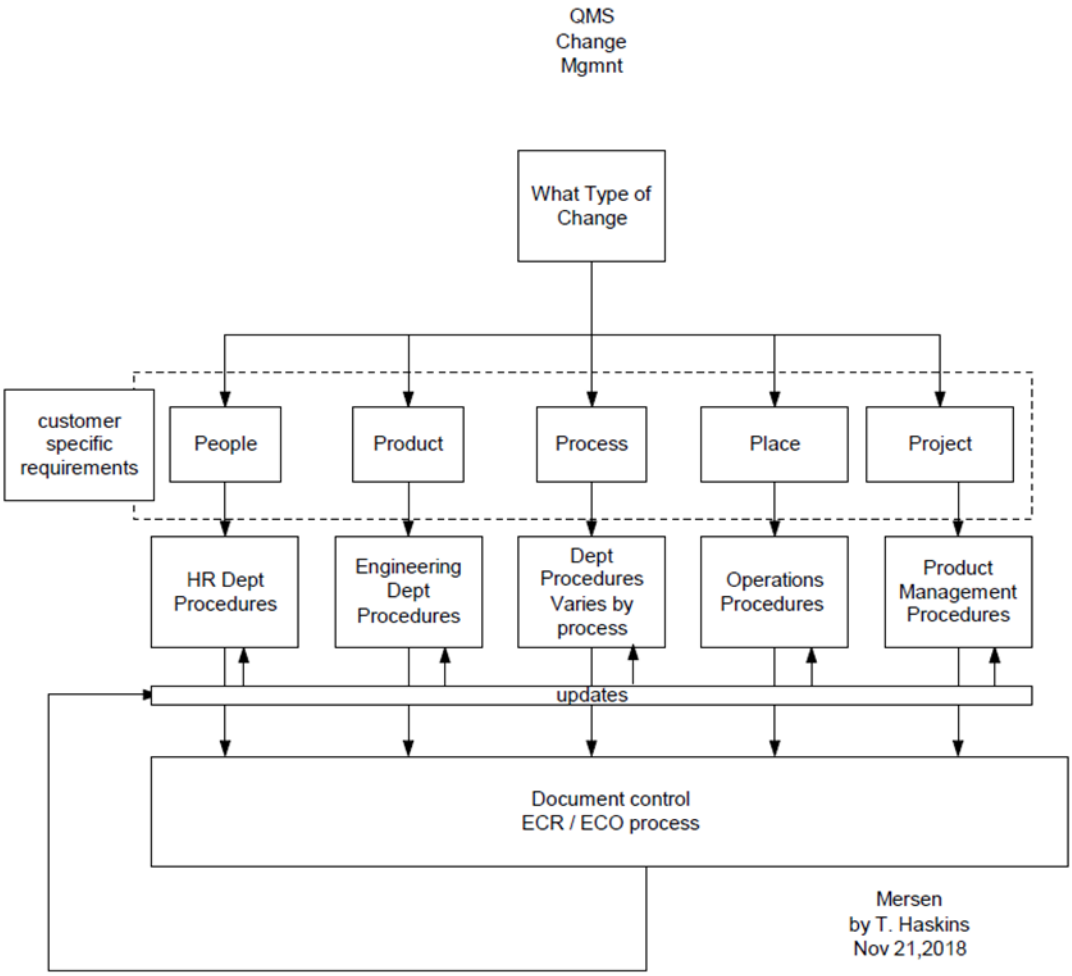


Figure 4.0

When planning how to achieve its quality objectives, **MERSEN** will determine:

a) What will be done;
b) What resources will be required;
c) Who will be responsible;
d) When it will be completed;
e) How the results will be evaluated

The results of **MERSEN**'s review regarding interested parties and their relevant requirements will be, considered when **MERSEN** establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

6.3 Planning changes

When **MERSEN** determines the need for changes to the quality management system, the changes are, carried out in a planned manner as following:

a) The purpose of the changes and their potential consequences;
b) The integrity of the quality management system;
c) The availability of resources;
d) The allocation or reallocation of responsibilities and authorities

7. Support

7.1 Resources

The resources requirements for each process are determined annually through the budget, investment and corporate action plans. The budgets provided through this process include the resources necessary to the Quality Management System to allow it to, continually improve performance and to insure customer satisfaction by exceeding customer expectations.

MERSEN determines and provides the resources needed through the budget for the establishment, implementation, maintenance and continual improvement of the quality management system, considering:

a) The capabilities of, and constraints on, existing internal resources;
b) What needs to be, obtained from external providers?
c) The quality management system and the operation and control of its processes, will be effectively implemented by the necessary person(s).

7.1.3 Infrastructure

MERSEN determines, provides and maintains the infrastructure necessary for the operation of its processes and to, achieve conformity of products and services. It can include:

a) Buildings and associated utilities;
b) Equipment, including hardware and software;
c) Transportation resources;
d) Information and communication technology

MERSEN uses a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts, **MERSEN**:

a) Optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and
b) Facilitate synchronous material flow, as applicable.

Methods are developed and implemented to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments include capacity planning. These methods also are applicable for evaluating proposed changes to existing operations.

Assessments of manufacturing feasibility and evaluation of capacity planning are inputs to management reviews.

7.1.4 Environment for the operation of processes

MERSEN determines, provides and maintains the environment necessary for the operation of its processes and to, achieve conformity of products and services.

NOTE: A suitable environment can be a combination of human and physical factors, such as:

a) Social (e.g., non-discriminatory, calm, non-confrontational);
b) Psychological (e.g., stress-reducing, burnout prevention, emotionally protective);
c) Physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise);

These factors can differ substantially depending on the products and services provided.

MERSEN maintains its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.

7.1.5 Monitoring and Measuring Resources

MERSEN determines and provides the resources needed, to ensure valid and reliable results when monitoring or measuring are used to verify the conformity of products and services to requirements. **MERSEN** ensures that the resources provided:

a) Are suitable for the specific type of monitoring, measurement activities being undertaken;
b) Are, maintained to ensure their continuing fitness for their purpose.

MERSEN retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

Statistical studies are conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used are conforming to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be, used if approved by the customer.

Records of customer acceptance of alternative methods are, retained along with results from alternative measurement systems analysis.

Measurement Traceability

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

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as documented information;
b) Identified in order to determine their status;
c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

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

Calibration/Verification Records

MERSEN
Has a documented process for managing calibration/verification records. Records of the calibration/verification activity for all gauges,, measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment), needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements are retained.

Ensure that calibration/verification activities and records include the following details:

a) Revisions following, engineering changes that impact measurement systems;
b) Any out-of-specification readings as received for calibration/verification;
c) An assessment of the risk of the intended use of the product caused by the out-of-specification condition;
d) When, a piece of inspection measurement and test equipment found to be out of calibration or defective during its planned verification or calibration or during its use. The documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment will be retained, including; the associated standard's last calibration date and the next due date on the calibration report.
e) Notification to the customer if suspect product or material, has been shipped;
f) Statements of conformity to specification after calibration/verification;
g) Verification that the software version used for product and process control is as specified;
h) Records of the calibration and maintenance activities for all gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment);
i) Production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).

Laboratory Requirements

Internal Laboratory;

MERSEN's internal laboratory has a defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope is included in the Quality Management Systems documentation. The laboratory specifies, and implements, as a minimum, requirements for

a) Adequacy of the laboratory technical procedures;
b) Competency of the laboratory personnel;
c) Testing of the product;
d) Capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); when no national or international standard(s) is available, **MERSEN** define and implement a methodology to verify measurement system capability;
e) Customer requirements, if any;
f) Review of the related records.

External Laboratory

External/commercial/independent laboratory facilities used for inspection, test, or calibration services by **MERSEN** has a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either:

- The laboratories are accredited to ISO/IEC 17025 or its national equivalent (e.g., CNAS-CL01 in China) by an accreditation body (Signatory) of the ILAC MRA (International Laboratory Accreditation Forum Mutual Recognition Arrangement – www.ilac.org) or national equivalent and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report include the mark of a national accreditation body; or

- In the event a laboratory not certified to ISO/IEC 17025 must be used, then MERSEN will obtain evidence the lab is acceptable to the customer prior to use.

NOTE: Such evidence may be, demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent. The second-party assessment may be, performed by **MERSEN** assessing the laboratory using a customer-approved method of assessment.

Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required.

7.1.6 Organization Knowledge

MERSEN determines the knowledge necessary for the operation of its processes to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary when addressing changing needs, and trends.
MERSEN has considered the current knowledge and determines how to: acquire or access any necessary additional knowledge and required updates.

NOTE: **MERSEN** knowledge may be based on:
a) Internal sources (e.g., intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) External sources (e.g., standards: education: conferences: gathering knowledge from customers or external providers).

7.2 Competence

MERSEN:

a) Determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
b) Ensure that these persons are competent, based on appropriate education, training, or experience;
c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d) Retain appropriate documented information as evidence of competence.

MERSEN has established and maintained a documented process for identifying training needs including awareness and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks are qualified, as required, with particular attention to the satisfaction of customer requirements. (HR-P-004 & HRMS 4.0)

Competence — on-the-job training

MERSEN provides on-the-job training (which includes customer requirements training) for personnel in any new or modified responsibilities affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements; this includes contract or agency personnel. The level of detail required for on-the-job training has commensurate with the level of education the personnel possess and the complexity of the task(s) they are required to perform for their daily work. Persons whose work can affect quality have informed about the consequences of nonconformity to customer requirements.

Internal auditor competency

MERSEN has a documented process to verify that internal auditors are competent, taking into account any requirement defined **MERSEN** and/or customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 19011. **MERSEN** maintains a list of qualified internal auditors. (QA-P-046 & QCI 8.2)

Quality management system, auditors are able to demonstrate the following minimum competencies:

a) Understanding of the automotive process approach for auditing, including risk-based thinking;
b) Understanding of applicable customer-specific requirements;
c) Understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
d) Understanding of applicable core tool requirements related to the scope of the audit;
e) Understanding how to plan, conduct, report, and close out audit findings.

At a minimum, manufacturing process auditors have technical understanding of the relevant manufacturing process to be, audited, including process risk analysis (such as PFMEA) and control plan.

At minimum product auditors demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.

MERSEN personnel provide the training to achieve competency, documented information be, retained to demonstrate the trainer's competency with the above requirements.

Maintenance of and improvement in internal auditor competence is, demonstrated through:

f) Executing a minimum number of audits per year, as defined by **MERSEN**; and
g) Maintaining knowledge of relevant requirements based on internal changes (e.g., process technology, product technology) and external changes (e.g., ISO 9001, IATF 16949, core tools, and customer specific requirements).

Second-party auditor competency

MERSEN demonstrates the competence of the auditors undertaking the second-party audits. Second-party auditors meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of;

a) The automotive process approach to auditing, including risk based thinking;
b) Applicable customer and **MERSEN** specific requirements;
c) Applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
d) Applicable manufacturing process (es) to be, audited, including PFMEA and control plan;
e) Applicable core tool requirements related to the scope of the audit;

f) How to plan, conduct, prepare audit reports, and close out audit findings

7.3 Awareness

MERSEN ensures that persons doing work under the organization's control are aware of;

a) The quality policy;
b) Relevant quality objectives;
c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) Implications of not, conforming to the quality management system requirements and utilization of the escalation procedure to manage non-conformances.

MERSEN maintains documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with non-conforming product.

Employee motivation and empowerment

MERSEN maintains a documented process HR-P-005 to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process includes the promotion of quality and technological awareness throughout the whole organization, Mersen has trained and utilizes the following escalation process, see figure 5.0, to ensure quality objectives are achieved.

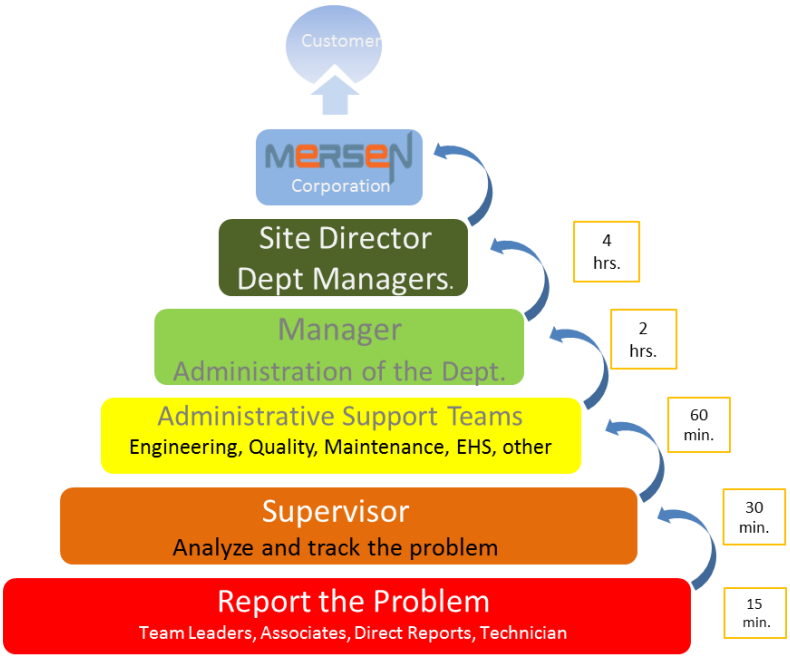


Figure 5.0

7.4 Communication

MERSEN determines the internal and external communications relevant to the quality management system using the following criteria. (HR-F-053).

a) What it will be communicated, and then determining;
   i) When to communicate the information;
   ii) With whom the communication occurs;
   iii) In what language the information is communicated;
   iv) What method of communication will be used
   v) Who will communicate this information

7.5 Documented Information

7.5.1 General

MERSEN's quality management system includes:
a) Documented information required by this International Standard;
b) Documented information determined by **MERSEN** as being necessary for the effectiveness of the quality management system.

7.5.1.1 Quality management system documentation

MERSEN's quality management system has documented a quality manual, which is a document available in electronic and/or hard copy.

The format and structure of the quality manual is at the discretion of **MERSEN**.

The quality manual includes, at a minimum, the following:

a) The scope of the quality management system, including details of and justification for any exclusion;
b) Documented processes established for the quality management system, or reference to them;
c) **MERSEN**'s processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;
d) A document (for example, a table, a list, or a matrix) indicating where within the organization's quality management system their customer-specific requirements are addressed. (QA-F-234).

7.5.2 Creating and updating

When creating and updating documented information, **MERSEN** ensures appropriate:

ii) Identification and description (e.g., a title, date, author, or reference number);
iii) All documentation Top-level procedural documentation in Mersen shall be in English. Process / operational level documents as deemed necessary by the plant concerned could be in another language, which can be defined local plant. However, all changes must be, made in both and then

maintained in both languages when approved. When issues arise, the English version will be the defining document.

iv) Format (e.g., language, software version, graphics) and media (e.g., paper, electronic);
v) Review and approval for suitability and adequacy

Quality Manual Review and Update:
The Quality Manual is reviewed by, the VP Quality and / or his staff on an annual basis. Revisions to the manual are required and recorded on the manual, as a letter revision with an effective date code.

Approval:
The North American Quality Policy is signed by, the Top Management of the Mersen Electrical Protection group, to include the Group Vice President, Electrical Protection (Top Management of Electrical Protection, Worldwide), the Vice President and General Manager of North America (Top Management of Electrical Protection in North America) and each site manager in North America.

The North American Quality Manual is signed; by the Top Management of the Mersen Electrical Protection for North America, to include the VP of Quality and the VP/GM of North America.

Procedures have been, established to ensure that:

- Documents are approved; prior to use and are reviewed/ updated and re-approved as necessary, as per the needs of each process.
- Documents are maintained so that, they are legible, readily available and retrievable.
- Obsolete documents are, systemically destroyed or overwritten and deleted, as required.
- Documents of external origin are, identified and distributed according to the relevant procedures.

Distribution:
A signed master copy of the quality manual is, kept in the Newburyport QA Library. An electronic master copy is stored on the intranet in the Newburyport QA Private folder. Access to this electronic version is limited to by, Information Systems permissions.

Read / Print Only (write permissions are restricted to authorized individuals only) versions of this manual are posted to the company intra-net under the Newburyport QA Public file heading and are available to anyone within the company.

Documents related to the QMS can be, accessed by any employee with access to the company intranet. Any employee that does not have access to the intranet can contact his/her supervisor for the documents

Documents and Records are, managed in a tiered system as shown in Section 4.2.1. The system starts with the Quality Manual, which lays out the general policies of the QMS. Procedures from the other departments add detail and implementation details to the Quality Manuals' policy statements.

At the base of the pyramid are the user documents (actual instructions on what to do) and the records that show the instructions have been, followed. These documents specify the Actions that associates must take in order to be, in compliance with our QMS.

All documents annotated with a revision number or date and an authorizing agent. Copies signed (originals) controlled by the department responsible for them.

When documents kept digitally; the controlled access permissions necessary to manage the documents are, specified and managed.

7.5.3 Control of documented Information

7.5.3.1 Documented information required by, the quality management system and by, this International Standard is, controlled to ensure:

a) It is, available and suitable for use, where and when it is, needed.
b) It is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, MERSEN addresses the following activities, as applicable:

a) Distribution, access, retrieval and use;
c) Storage and preservation, including preservation of legibility;
d) Control of changes (e.g., version control);
e) Retention and disposition

Documented information of external origin determined by **MERSEN** to be necessary for the planning and operation of the quality management system is, identified as appropriate, and be controlled.

Documented information retained as evidence of conformity is, protected from unintended alterations.

7.5.3.2.1 Record retention

MERSEN has defined, documented, and implemented a record retention on each document master list. The control of records satisfy statutory, regulatory, organizational, and customer requirements.

Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments of automotive products are retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.

NOTE: Production part approval documented information of automotive products includes approved product, applicable test equipment records, or approved test data.

7.5.3.2.2 Engineering specifications

MERSEN has a documented process, describing the review distribution and implementation of all, customer engineering; standards/specifications and related revisions based on customer schedules, as required.

When an engineering standard/specification change results in a product design change, refer to the requirements in Section 8.3.6. When an engineering standard/specification change results, in a product, realization process change, refer to the requirements in Section 8.5.6.1. **MERSEN** retains a record of the date on which each change implemented in production. Implementation includes updated documents.

Review should be, completed within 10 working days of receipt of notification of engineering standards/specifications changes.

NOTE: A change in these standards/specifications updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of the production part approval process, such as control plan, risk analysis (such as FMEAs), etc.

8. Operation

8.1 Operational planning and control

MERSEN has a planned, implemented and controlled the processes needed to meet the requirements for the provision of products and services, and to implement the actions determined by:

a) Determining the requirements for the products and services;
b) Establishing criteria for:
    1. The processes;
    2. The acceptance of products and services;
c) Determining the resources needed to achieve conformity to the product and service requirements;
d) Implementing control of the processes in accordance with the criteria;
e) Determining, maintaining and retaining documented information to the extent necessary:
    1. To have confidence that the processes have been, carried out as planned;
    2. To demonstrate: the conformity of products and services to their requirements. The output of this planning is suitable for **MERSEN**'s operations.

MERSEN controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

MERSEN ensures that outsourced processes are, controlled (see 8.4).

When planning for product realization, the following topics are included:

a) Customer product requirements and technical specifications;

b) Logistics requirements;
c) Manufacturing feasibility;
d) Project planning (Section 8.3.2);
e) Acceptance criteria

8.1.2 Confidentiality

MERSEN ensures the confidentiality of customer-contracted products and projects under development, including related product information.

8.2 Requirements for products and services
8.2.1 Customer communication

Communication with customers includes:
a) Providing information relating to products and services;
b) Handling enquiries, contracts or orders, including changes;
c) Obtaining customer feedback relating to products and services, including customer complaints;
d) Handling or controlling customer property;
e) Establishing specific requirements, for contingency actions, when relevant

Written or verbal communication will be in the language agreed upon with the customer. **MERSEN** has the ability to communicate necessary information, including data in a customer-specified computer language and format (e.g., computer-aided design data, electronic data interchange).

Communication includes new product designs to the market, possible amendments to any contracts for a specific product and customer feedback on the product, including complaints.

Product information is provided via various media (e.g.: paper or electronic) for customers.

When amendments to a contract or a tender are necessary, an acknowledgement of the order is, sent to the customer to signify our agreement includes amendments.

Customer complaints are, logged as:

- Technical
- Administrative

Both types are, logged and reviewed by top management. Customers are, informed of the resolution to all customer complaints, which can include credit notes or replacement product or corrective actions.

Both types of complaints are, considered valid forms of customer feedback, along with satisfaction surveys and data provided to Mersen on delivered product quality levels.

8.2.2 Determination of requirements for products and services

When determining the requirements for the products and services to be, offered to customers, **MERSEN** ensures that:

a) The requirements for the products and services are, defined, including:
   1. Any applicable statutory and regulatory requirements;
   2. Those considered necessary by **MERSEN**;

b) **MERSEN** can meet the claims for the products and services it offers.

These requirements include recycling, environmental impact, and characteristics identified as a, result of the **MERSEN**'s knowledge of the product and manufacturing processes.
Compliance to a) 1) as mentioned above this includes but not be limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

8.2.3 Review of the requirements for products and services

MERSEN ensures the ability to meet the requirements for products and services to be offered to customers. **MERSEN** conducts a review before committing to supply products and services to a customer, to include:

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

MERSEN ensures that contract or order requirements differing from those previously defined are resolved.

The customer’s requirements are, confirmed by **MERSEN** before acceptance, when the customer does not provide a documented statement of their requirements.

Customer-designated special characteristics

MERSEN shall conform to the customer requirements for designation, approval documentation, and control of special characteristics when required.

Organization manufacturing feasibility

MERSEN utilizes a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization’s manufacturing processes are capable of consistently producing product that

meets all of the engineering and capacity requirements specified by the customer. **MERSEN** conducts this feasibility analysis for any manufacturing product or technology new to **MERSEN** and for any changed manufacturing process or product design.

Additionally, **MERSEN** validates through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.

8.3 Design and development of products and services

8.3.1 General

MERSEN has established, implemented and maintains a design and development process that is, appropriated to ensure the subsequent provision of products and services.

MERSEN processes design and development focuses on error prevention rather than detection.

MERSEN also documents the design and development processes through, the use of various tools, which include core tools.

8.3.2 Design and development Planning

In determining the stages and controls for design and development, **MERSEN** considers:

a) The nature, duration and complexity of the design and development activities;
b) The required process stages, including applicable design and development reviews;
c) The required design and development verification and validation activities;
d) The responsibilities and authorities involved in the design and development process;
e) The internal and external resource needs for the design and development of products and services;
f) The need to control interfaces between persons involved in the design and development process;
f) The need for involvement of customers and users in the design and development process;
g) The requirements for subsequent provision of products and services;
h) The level of control expected for the design and development process by customers and other relevant interested parties;
i) The documented information needed to demonstrate, that design and development requirements have been met

MERSEN ensures that design and development planning includes all affected stakeholders within **MERSEN** and, as appropriate, its supply chain. As example; using a multidisciplinary approach include but are not limited to the following:

a) Project management (for example, APQP or VDA-RGA);
b) Product and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;
c) Development and review of product design risk analysis (FMEAs), including actions to reduce potential risks;

d) Development and review of manufacturing process risk analysis (for example, PFMEAs, process flows, control plans, and standard work instructions).

Product design skills

MERSEN ensures that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable, tools and techniques are, identified.

Development of products with embedded software

MERSEN shall use a process for quality assurance for products that require embedded software.

8.3.3 Design and development inputs

Inputs for the design planning come primarily from the customer. Tools like "Voice of the Customer" "Quality Function Deployment (QFD)" and "Criniflex" are used to determine customer requirements beyond the requirements that were established by previous designs, stated by the customers or required by the standards (commonly: U/L, CSA and IEC). Inputs to the design process are, reviewed for adequacy – to insure that they are complete, unambiguous and not in conflict with each other.

MERSEN determines the requirements essential for the specific types of products and services to be designed and developed. **MERSEN** considers:

a) Functional and performance requirements;
b) Information derived from previous similar design and development activities;
c) Statutory and regulatory requirements;
d) Standards or codes of practice that **MERSEN** has implemented;
e) Potential consequences of failure due to the nature of the products and services

Inputs are adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs are resolved.

MERSEN retains documented information on design and development inputs.

Product design input

MERSEN has identified, documented, and reviewed product design input requirements as a result of contract review. Product design input requirements include but are not limited to the following:

a) Product specifications including but not limited to special characteristics (see Section of Special Characteristics);
b) Boundary and interface requirements;
c) Identification, traceability, and packaging;
d) Consideration of design alternatives;

e) Assessment of risks with the input requirements and the **MERSEN**'s ability to mitigate/manage the risks, including from the feasibility analysis;
f) Targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;
g) Applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;
h) Embedded software requirements

MERSEN has a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

Manufacturing process design input

MERSEN has identified, documented, and reviewed manufacturing process design input requirements that including but are not limited to the following:

a) Product design output data including special characteristics;
b) Targets for productivity, process capability, timing, and cost;
c) Manufacturing technology alternatives;
d) Customer requirements, if any;
e) Experience from previous developments;
f) New materials;
g) Product handling and ergonomic requirements; and
h) Design for manufacturing and design for assembly.

The manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

Special characteristics

MERSEN uses a multidisciplinary approach to establish, document, and implement its process (es) to identify special characteristics, including those determined by the customer and the risk analysis performed by **MERSEN**, and includes the following:

a) Documentation of special characteristics in the drawings (as required), risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings, documented in the manufacturing documents which show the creation of, or the control required, for these special characteristics;
b) Development of control and monitoring strategies for special characteristics of products and production processes;
c) Customer-specified approvals, when required;
d) Compliance with customer-specified definitions and symbols or the **MERSEN**'s equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table will be, submitted to the customer, if required.

8.3.4 Design and development of controls

MERSEN applies controls to the design and development process to ensure that:

a) The results to be, achieved are defined;
b) Reviews are, conducted to evaluate the ability of the results of design and development to meet requirements;
c) Verification activities are, conducted to ensure that the design and development outputs meet the input requirements;
d) Validation activities are, conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
e) Any necessary actions are, taken on problems determined during the reviews, or verification and validation activities;
f) Documented information of these activities is retained.

8.3.4.1 Monitoring

Measurements at specified stages during the design, and development of products and processes are defined, analyzed, and reported with summary results, as an input to management review.

When required by the customer, measurements of the product and process development activity are reported to the customer at stages specified, or agreed to, by the customer.

8.3.4.2 Design and development validation

Design and development validation is, performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation is, planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, this includes evaluation of the interaction of the **MERSEN**'s product, including embedded software, within the system of the final customer's product.

8.3.4.3 Prototype program

When required by the customer, **MERSEN** will have a prototype program and control plan. **MERSEN** will use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be, used in production.

All performance-testing activities will be, monitored for timely completion and conformity to requirements. When services are outsourced, MERSEN will include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to requirements.

8.3.4.4 Product approval process

MERSEN has established, implemented, and maintains a product and manufacturing approval process conforming to requirements defined by the customer(s).

MERSEN approves externally provided products and services, prior to submission of their part approval to the customer.

MERSEN obtains documented product approval prior to shipment, if required by the customer. Records of such approval will be, retained.

8.3.5 Design and development of outputs

MERSEN ensures that design and development outputs:

a) Meet the input requirements;
b) Are adequate for the subsequent processes for the provision of products and services;
c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

8.3.5.1 Design and development outputs

The product design output are, expressed in terms that can be, verified and validated against product design input requirements. The product design output is included but is not limited to the following, as applicable:

a) Design risk analysis (FMEA);
b) Reliability study results;
c) Product special characteristics;
d) Results of product design error proofing, such as DFSS, DFMA, and FTA;
e) Product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerance (GD&T);
f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerance (GD&T);
g) Product design review results;
h) Service diagnostic guidelines and repair and serviceability instructions;
i) Service part requirements;
j) Packaging and labeling requirements for shipping

8.3.5.2 Manufacturing process design output

MERSEN documents the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. **MERSEN** verifies the outputs against

manufacturing process design input requirements. The manufacturing process design output includes but is not limited to the following:

a) Specifications and drawings;
b) Special characteristics for product and manufacturing process;
c) Identification of process input variables that influence characteristics;
d) Tooling and equipment for production and control, including capability studies of equipment and process (es);
e) Manufacturing process flow charts/layout, including linkage of product, process, and tooling;
f) Capacity analysis;
g) Manufacturing process PFMEA;
h) Maintenance plans and instructions;
i) Control plan;
j) Standard work and work instructions;
k) Process approval acceptance criteria;
l) Data for quality, reliability, maintainability, and measurability;
m) Results of error-proofing identification and verification, as appropriate;
n) Methods of rapid feedback and correction of product/manufacturing process nonconformities.

8.3.6 Design and development changes

MERSEN identifies, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

MERSEN retains documented information on:

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

8.3.6.1 Design and development changes

MERSEN evaluates all design changes after initial product approval, including those proposed by **MERSEN** or its suppliers, for potential impact on fit, form, function, performance, and/or durability.

These changes will be, validated against customer requirements and approved internally, prior to production implementation.
If required by the customer, **MERSEN** will obtain documented approval, or a documented waiver, from the customer prior to production implementation.
For products with embedded software, **MERSEN** will document the revision level of software and hardware as part of the change record.

8.4 Control of externally provided processes, products and services

8.4.1 General

MERSEN ensures that externally provided processes, products and services conform to requirements. (Ref QCI 17.1 Supplier Quality Manual)

MERSEN determines the controls to be, applied to externally provided processes, products and services when:

a) Products and services from external providers are intended for incorporation into **MERSEN**'s own products and services;
b) Products and services are provided directly to the customer(s) by external providers on behalf of **MERSEN**;
c) A process, or part of a process, is provided by an external provider as a result of a decision by **MERSEN**.

MERSEN determines and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

8.4.1.1 General

MERSEN will include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework, calibration, warehousing, logistics, and external services in the scope of their definition of externally provided products, processes, and services.

8.4.1.2 Supplier selection process

MERSEN has a documented supplier selection process. The selection process includes:

a) An assessment of the selected supplier's risk to product conformity and uninterrupted supply of **MERSEN**'s product to their customers;
b) Relevant quality and delivery performance;
c) An evaluation of the supplier's quality management system;
d) Multidisciplinary decision making;
e) An assessment of software development capabilities, if applicable

Other supplier selection criteria that are considered include the following:

- Volume of automotive business (absolute and as a percentage of total business);
- Financial stability;
- Purchased product, material, or service complexity;
- Required technology (product or process);
- Adequacy of available resources (e.g., people, infrastructure);
- Design and development capabilities (including project management);

• Manufacturing capability;
• Change management process;
• Business continuity planning (e.g., disaster preparedness, contingency planning);
• Logistics process;
• Customer service

8.4.1.3 Customer-directed sources (also known as "Directed–Buy")

When specified by the customer, **MERSEN** will purchase products, materials, or services from customer-directed sources.

All requirements are applicable to **MERSEN**'s control of customer-directed sources unless specific agreements are otherwise defined by the contract between **MERSEN** and the customer.

8.4.2 Type and extent of control

MERSEN ensures that externally provided processes, products and services do not adversely affect **MERSEN**'s ability to consistently deliver conforming products and services to its customers.

MERSEN will:

a) Ensure that externally provided processes remain within the control of its quality management system;
b) Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) Take into consideration:
    1. The potential impact of the externally provided processes, products and services on the **MERSEN**'s ability to consistently meet customer and applicable statutory and regulatory requirements;
    2. The effectiveness of the controls applied by the external provider;
d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.2.1 Type and extent of control

MERSEN has documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.

The process includes the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.

Where characteristics or components "pass through" **MERSEN**'s quality management system without validation or controls, **MERSEN** will ensure that the appropriate controls are in place at the point of manufacture.

8.4.2.2 Statutory and regulatory requirements

MERSEN has documented their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided.
If the customer defines special controls for certain products with statutory and regulatory requirements, **MERSEN** ensures they are implemented and maintained as defined, including at suppliers.

8.4.2.3 Supplier quality management system development

MERSEN requires their suppliers of automotive products and services to develop, implement, and improve a quality management system (QMS) with the ultimate objective of eligible organizations becoming certified to this Automotive QMS Standard.
Using a risk-based model, **MERSEN** has defined a minimum acceptable level of QMS development and a target QMS development level for each supplier.

Unless otherwise authorized by the customer, a QMS certified to ISO 9001 is the initial minimum acceptable level of development. Based on current performance and the potential risk to the customer, the objective is to move suppliers through the following QMS development progression:

a) Certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to **MERSEN** will demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021;

b) Certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSR] or equivalent) through second-party audits;

c) Certification to ISO 9001 with compliance to IATF 16949 through second-party audits;

d) Certification to 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).

8.4.2.3.1 Automotive product-related software or automotive products with embedded software

MERSEN requires their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

A, software development assessment methodology will be utilized to, assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer,

MERSEN will require the supplier to retain documented information of a, software development capability self-assessment.

8.4.2.4 Supplier monitoring

MERSEN has a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.

At a minimum, the following supplier performance indicators are, monitored:

a) Delivered product conformity to requirements;
b) Customer disruptions at the receiving plant, including yard holds and stop ships;
c) Delivery schedule performance;
d) Number of occurrences of premium freight

If provided by the customer, **MERSEN** will also include the following, as appropriate, in their supplier performance monitoring:

a) Special status customer notifications related to quality or delivery issues;
b) Dealer returns, warranty, field actions, and recalls

8.4.2.4.1 Second-party audits

MERSEN includes a second-party audit process in their supplier management approach. Second-party audits may be, used for the following:

a) Supplier risk assessment;
b) Supplier monitoring;
c) Supplier QMS development;
d) Product audits;
e) Process audits

Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, **MERSEN** has documented the criteria for determining the need, type, frequency, and scope of second-party audits.

MERSEN will retain records of the second-party audit reports.

If the scope of the second-party audit is to assess the supplier’s quality management system, then the approach will be consistent with the automotive process approach.

8.4.2.5 Supplier development

MERSEN has determined the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs include but are not limited to the following:
a) Performance issues identified through supplier monitoring;
b) Second-party audit findings;
c) Third-party quality management system, certification status;
d) Risk analysis

MERSEN will implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

8.4.3 Information for external providers

MERSEN ensures the adequacy of requirements prior to their communication to the external provider.

MERSEN communicates to external providers its requirements for:

a) The processes, products and services to be, provided;
b) The approval of:
1. Products and services;
2. Methods, processes and equipment;
3. The release of products and services;
c) Competence, including any required qualification of persons;
d) The external providers' interactions with **MERSEN**;
e) Control and monitoring of the external providers' performance to be, applied by **MERSEN**;
f) Verification or validation activities that **MERSEN**, or its customer, intends to perform at the external providers' premises.

MERSEN shall, pass down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

8.5.1 Control of Production and Service Provision

MERSEN has implemented production and service provision under controlled conditions. Controlled conditions include:
a) The availability of documented information that defines:
    1. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
    2. The results to be achieved;
b) The availability and use of suitable monitoring and measuring resources;
c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria, for products and services have been met;

d) The use of suitable infrastructure and environment for the operation of processes;
e) The appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) The implementation of actions to prevent human error;
h) The implementation of release, delivery and post-delivery activities

8.5.1.1 Control plan

MERSEN develops control plans at the system, subsystem, component, and/or material level for the relevant manufacturing site and all products supplied, including those for processes producing bulk materials as well as parts. Family control plans are acceptable for bulk material and similar parts using a common manufacturing process.

MERSEN has a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis (if provided by the customer), process flow diagram, and manufacturing process risk analysis outputs (such as FMEA).

MERSEN, if required by the customer, shall provide measurement and conformity data collected during execution of either the pre-launch or production control plans. **MERSEN** includes in the control plan:

a) Controls used for the manufacturing process control, including verification of job set-ups;
b) first-off/last-off part validation, as applicable;
c) Methods for monitoring of control exercised over special characteristics defined by both the customer and **MERSEN**;
d) The customer-required information, if any;
e) Specified reaction plan; when nonconforming product is detected, the process becomes statistically unstable or not statistically capable.

MERSEN documents are review control plans, and update as required, for any of the following:
a) **MERSEN** determines it has shipped nonconforming product to the customer;
b) When any change occur affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA);
c) After a customer complaint and implementation of the associated corrective action, when applicable;
d) At a set frequency based on a risk analysis

If required by the customer, **MERSEN** shall obtain customer approval after review or revision of the control plan.

8.5.1.2 Standardized work — operator instructions and visual standards

MERSEN ensures that standardized work documents are:

a) Provides the operator the necessary rules to perform the work safely. As well the appropriate PPE (Personal Protection Equipment).
b) Accessible for use at the designated work area(s).
c) Communicated to and understood by the employees who are responsible for performing the work;
d) The work instruction shall be in English as needed by site managers, the work instruction can be re-written in the appropriate language for the site.
e) Accessible for use at the designated work area(s).
f) Legible;

8.5.1.3 Verification of job set-ups

MERSEN Shall:
a) Verify job set-ups when performed, such as an initial run of a job, material changeover, or job change that requires a new set-up;
b) Maintain documented information for set-up personnel;
c) Use statistical methods of verification, where applicable;
d) MERSEN performs first-off/last-off part validation, as applicable, and for automotive product. Where appropriate, first-off parts should be retained for comparison with the last-off parts; where appropriate, last-off-parts should be retained for comparison with first-off parts in subsequent runs;
e) Retain records of process and product approval following set-up and first-off/last-off part validations.

8.5.1.4 Verification after shutdown

MERSEN has defined and implemented the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

8.5.1.5 Total productive maintenance

MERSEN has developed, implemented, and maintained a documented total productive maintenance system; the system includes the following (MT-P-001, MT-P-002):
a) Identification of process equipment necessary to produce conforming product at the required volume;
b) Availability of replacement parts for the equipment identified in item a);
c) Provision of resource for machine, equipment, and facility maintenance;
d) Packaging and preservation of equipment, tooling, and gauging;
e) Applicable customer-specific requirements;
f) documented maintenance objectives, for example: OEE (Overall Equipment Effectiveness), MTBF (Mean Time Between Failure), and MTTR (Mean Time To Repair), and Preventive Maintenance compliance metrics. Performance to the maintenance objectives forms an input into management review;

g) Regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
h) Use of preventive maintenance methods;
i) use of predictive maintenance methods, as applicable;
j) Periodic overhaul.

8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment

MERSEN provides resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable.

MERSEN has established and implemented a system for production tooling management, whether it is owned by **MERSEN** or the customer, including:

a) Maintenance and repair facilities and personnel;
b) Storage and recovery;
c) Set-up;
d) tool-change programs for perishable tools;
e) Tool design modification documentation, including engineering change level of the product;
f) Tool modification and revision to documentation;
g) Tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.
MERSEN verifies that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.
MERSEN has implemented a system to monitor these activities if any work is outsourced.

8.5.1.7 Production scheduling

MERSEN ensures that production is scheduled in order to meet customer orders/demands such as Just-In-Time (JIT) and is supported by an information system that permits access to production information at key stages of the process and is order driven.

MERSEN includes relevant planning information during production scheduling, e.g., customer orders, supplier on-time delivery performance, capacity, shared loading (multi-part station), lead time, inventory level, preventive maintenance, and calibration.

8.5.2 Identification and traceability

MERSEN uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

MERSEN identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

MERSEN controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety-related nonconformities. Therefore, **MERSEN** has implemented the identification and traceability processes as described below.

MERSEN shall conduct an analysis of internal, customer, regulatory and traceability requirements for all automotive products. This includes developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans have defined the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

a) Enable **MERSEN** to identify nonconforming and/or suspect product;
b) Enable **MERSEN** to segregate nonconforming and/or suspect product;
c) Ensure the ability to meet the customer and/or regulatory response time requirements;
d) Ensure documented information is retained in the format (electronic, hardcopy, archive) that enables **MERSEN** to meet the response time requirements;
e) Ensure serialized identification of individual products, if specified by the customer or regulatory standards;
f) Ensure the identification and traceability requirements are extended to externally provided products and services with safety/regulatory characteristics.

- **See procedure MT-P-002 Total Productive Maintenance.**

8.5.3 Property belonging to customers or external providers

MERSEN exercises care with property belonging to customers or external providers while it is under **MERSEN**'s control or being used by **MERSEN**.

MERSEN identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services. **MT-P-002 & QA-P-033.**

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, **MERSEN** shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

MERSEN shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation applies to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.
In order to detect deterioration, **MERSEN** assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment.

MERSEN uses an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO).

MERSEN ensures that obsolete product is, controlled in a manner similar to that of nonconforming product.

MERSEN complies with preservation, packaging, shipping, and labeling requirements as provided by their customers.

8.5.5 Post-delivery activities

MERSEN meets requirements for post-delivery activities associated with the products and services.
In determining the extent of post-delivery activities that are required, **MERSEN** considers:

a) Statutory and regulatory requirements;
b) The potential undesired consequences associated with its products and services;
c) The nature, use and intended lifetime of its products and services;
d) Customer requirements;
e) Customer feedback

MERSEN ensures that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities are established, implemented, and maintained.

8.5.5.2 Service agreement with customer

When there is a service agreement with the customer, **MERSEN**:

a) Verify that the relevant service centers comply with applicable requirements;
b) Verify the effectiveness of any special purpose tools or measurement equipment;
c) Ensure that all service personnel are, trained in applicable requirements.

8.5.6 Control of changes

MERSEN shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

MERSEN shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

MERSEN has a documented process to control and react to changes that, impact product realization. The effects of any change, including those changes caused by **MERSEN**, the customer, or any suppliers are, assessed.

MERSEN:

a) Defines the verification and validation activities to ensure compliance with customer requirements;
b) Validates changes before implementation;
c) Documents the evidence of related risk analysis;
d) Retains records of verification and validation

Changes, including those made at suppliers, will require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.
When required by the customer, **MERSEN**:

a) Notify the customer of any planned product realization changes after the most recent product approval;
b) Obtain documented approval, prior to implementation of the change;
c) Complete additional verification or identification requirements, such as production trial run and new product validation.

8.5.6.1.1 Temporary change of process controls

MERSEN has identified, documented, and maintains a list of the process controls, including inspection, measuring, test, and error-proofing devices.

MERSEN has documented the process that manages the use of alternate control methods. **MERSEN** includes in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be, obtained prior to production implementation of the alternate control method.

Before shipping product that is, inspected or, tested using the alternate method, if required, **MERSEN** shall obtain approval from the customer(s). **MERSEN** maintains and periodically reviews a list of approved alternate process control methods that are, referenced in the control plan.

Standard work instructions will be available for each alternate process control method. **MERSEN** reviews the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. Example methods include but are not limited to the following:

a) Daily quality focused audits (e.g., layered process audits, as applicable);

b) Daily leadership meetings

Restart verification is, documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively, reinstated.

MERSEN implements traceability of all product produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

8.6 Release of products and services

MERSEN shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been, met.

The release of products and services to the customer will not proceed until the planned arrangements have been, satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

MERSEN retains documented information on the release of products and services. The documented information includes:

a) Evidence of conformity with the acceptance criteria;
b) Traceability to the person(s) authorizing the release

8.6.1 Release of products and services

MERSEN ensures that the planned arrangements to verify that the product and service requirements have been, met encompass the control plan and are documented as specified in the control plan.

MERSEN ensures that the planned arrangements for initial release of products and services encompass product or service approval.

MERSEN ensures that product or service approval is, accomplished after changes following initial release.

8.6.2 Layout inspection and functional testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards will be, performed for each product as specified in the control plans. Results will be available for customer review.

NOTE 1: Layout inspection is the complete measurement of all product dimensions shown on the design record(s).

NOTE 2: The frequency of layout inspection is, determined by the customer.

8.6.3 Appearance items

When customers have identified products with appearance characteristics **MERSEN** will provide the following:

a) Appropriate resources, including lighting, for evaluation;
b) Masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), and haptic technologies, as appropriate;
c) Maintenance and control of appearance masters and evaluation equipment;
d) Verification that personnel making appearance evaluations are, competent and qualified to do so

8.6.4 Verification and acceptance of conformity of externally provided products and services

MERSEN has a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:

a) Receipt and evaluation of statistical data provided by the supplier to **MERSEN**;
b) Receiving inspection and/or testing, such as sampling based on performance;
c) second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements;
d) Part evaluation by a designated laboratory;
e) Another method agreed with the customer.

8.6.5 Statutory and regulatory conformity

Prior to release of externally provided products into its production flow, **MERSEN** will confirm and be able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and in the customer-identified countries of destination, if provided.

8.6.6 Acceptance criteria

Acceptance criteria will be, defined by **MERSEN** and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level will be zero defects.

8.7 Control of nonconforming outputs

8.7.1 MERSEN ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

MERSEN takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This will also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

MERSEN deals with nonconforming outputs in one or more of the following ways:

a) Correction;
b) Segregation, containment, return or suspension of provision of products and services;
c) Informing the customer;
d) Obtaining authorization for acceptance under concession.

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

8.7.1.1 Customer authorization for concession

MERSEN will obtain a customer concession or deviation permission prior to further processing whenever the product or manufacturing process is different from that which is currently approved. **MERSEN** will obtain customer authorization prior to further processing for "use as is" and for repair of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse will be clearly communicated to the customer in the concession or deviation permission.

MERSEN will maintain a record of the expiration date or quantity authorized under concession.

MERSEN also ensures compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession will be, properly identified on each shipping container (this applies equally to purchase product). **MERSEN** will approve any requests from suppliers before submission to the customer.

8.7.1.2 Control of nonconforming product — customer-specified process

MERSEN will comply with applicable customer-specified controls for nonconforming product(s).

8.7.1.3 Control of suspect product

MERSEN ensures that product with unidentified or suspect status is classified and controlled as nonconforming product. **MERSEN** ensures that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

8.7.1.4 Control of reworked product

MERSEN utilizes risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, **MERSEN** will obtain approval from the customer prior to commencing rework of the product.

MERSEN has a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance to original specifications.

Instructions for disassembly or rework, including re-inspection and traceability requirements, are accessible to and utilized by the appropriate personnel.

MERSEN retains documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.5 Control of repaired product

MERSEN will utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. **MERSEN** will obtain approval from the customer before commencing repair of the product.
MERSEN has a documented process for repair confirmation in accordance with the control plan or other relevant documented information.

Instructions for disassembly or repair, including re-inspection and traceability requirements, will be accessible to and utilized by the appropriate personnel.

MERSEN will obtain a documented customer authorization for concession for the product to be repaired.

MERSEN retains documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.6 Customer notification

MERSEN will immediately notify the customer(s) in the event that nonconforming product has been shipped. Initial communication will be, followed with detailed documentation of the event.

8.7.1.7 Nonconforming product disposition

MERSEN has a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, **MERSEN** will verify that the product to be scrapped is rendered unusable prior to disposal.

MERSEN will not divert nonconforming product to service or other use without prior customer approval.

8.7.2 MERSEN retains documented information that:

a) Describes the nonconformity;
b) Describes the actions taken;
c) Describes any concessions obtained;
d) Identifies the authority deciding the action in respect of the nonconformity

9. Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

MERSEN will determine:

a) What needs to be monitored and measured?
b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) When the monitoring and measuring will be, performed;
d) When the results from monitoring and measurement will be analyzed and evaluated.

MERSEN evaluates the performance and the effectiveness of the quality management system. **MERSEN** retains appropriate documented information as evidence of the results.

9.1.1.1 Monitoring and measurement of manufacturing processes

MERSEN performs processes studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics.

NOTE: For some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods such as batch conformance to specification may be used.

MERSEN maintains manufacturing process capability or performance results as specified by the customer's part approval process requirements. **MERSEN** verifies the process flow diagrams, PFMEAs, and control plans are, implemented, including adherence to the following:

a) Measurement techniques;
b) Sampling plans;
c) Acceptance criteria;
d) Records of actual measurement values and/or test results for variable data;
e) Reaction plans and escalation process when acceptance criteria are not met.

Significant process events, such as tool change or machine repair, are recorded and retained as documented information.

MERSEN will initiate a reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. These reaction plans will include containment of product and 100 percent inspection, as appropriate. A corrective action plan will be developed and implemented by **MERSEN** indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable. The plans will be reviewed with and approved by the customer, when required.

MERSEN maintains records of effective dates of process changes.

9.1.1.2 Identification of statistical tools

MERSEN determines the appropriate use of statistical tools. **MERSEN** verify that appropriate statistical tools are included as part of the advanced product quality planning (or equivalent) process and included in the design risk analysis (such as DFMEA) (where applicable), the process risk analysis (such as PFMEA), and the control plan.

9.1.1.3 Application of statistical concepts

Statistical concepts, such as variation, control (stability), process capability, and the consequences of over-adjustment, are understood and used by employees involved in the collection, analysis, and management of statistical data.

9.1.2 Customer satisfaction

MERSEN monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. **MERSEN** determines the methods for obtaining, monitoring and reviewing this information.

9.1.2.1 Customer satisfaction

Customer satisfaction with **MERSEN** is monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements.

Performances indicators are based on objective evidence and include but not be limited to the following:

a) Delivered part quality performance;
b) Customer disruptions;
c) Field returns, recalls, and warranty (where applicable);
d) Delivery schedule performance (including incidents of premium freight);
e) Customer notifications related to quality or delivery issues, including special status.

MERSEN shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency. The monitoring includes the review of customer performance data including online customer portals and customer scorecards, where provided.

9.1.3 Analysis and evaluation

MERSEN analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis are used to evaluate:

a) Conformity of products and services;
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;
g) The need for improvements to the quality management system.

NOTE: Methods to analyze data can include statistical techniques.

9.1.3.1 Prioritization

Trends in quality and operational performance are compared with progress toward objectives and lead to actions to support prioritization of actions for improving customer satisfaction.

9.2 Internal audit

9.2.1 MERSEN conducts internal audits at planned intervals to provide information on whether the quality management system, QA-P-018 (ISO9001) & QA-P-048 (IATF), QCI 8.2, QCI 8.4).

a) Conforms to:
1. **MERSEN**'s own requirements for its quality management system;
2. The requirements of this International Standard;

b) Is effectively implemented and maintained.

9.2.2 MERSEN has:

a) Planned, established, implemented and maintained an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which are taken into consideration the importance of the processes concerned, changes affecting **MERSEN**, and the results of previous audits;
b) Defines the audit criteria and scope for each audit;
c) Selects the auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d) Ensure that the results of the audits are reported to relevant management;
e) Take appropriate correction and corrective actions without undue delay;
f) Retain documented information as evidence of the implementation of the audit programmed and the audit results.

9.2.2.1 Internal audit program

MERSEN has a documented internal audit process. The process includes the development and implementation of an internal audit program that covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits.

The audit program is prioritized based upon risk, internal and external performance trends, and criticality of the process (es).

Where **MERSEN** is responsible for software development, **MERSEN** includes software development capability assessments in their internal audit program.

The frequency of audits is reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints. The effectiveness of the audit program is reviewed as a part of management review.

9.2.2.2 Quality management system audit

MERSEN audits all quality management system processes, at a minimum, over each three-year calendar period according to an annual program. MERSEN uses the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, **MERSEN** samples customer-specific quality management system requirements for effective implementation.

9.2.2.3 Manufacturing process audit

MERSEN audits all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Where not defined by the customer, **MERSEN** determines the approach to be used.

Within each individual audit plan, each manufacturing process is audited on all shifts where it occurs, including the appropriate sampling of the shift handover.

The manufacturing process audit includes an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

9.2.2.4 Product audit

MERSEN audits products using customer-specific industrial standards, or applicable standards, where required at appropriate stages of production and delivery to verify conformity to specified requirements. Where not defined by the customer, **MERSEN** defines the approach to be used.

9.3 Management review

9.3.1 General

Top management reviews the **MERSEN**'s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of **MERSEN**. (MR-P-001, QCI 14.1).

9.3.1.1 Management review

Management review is conducted at least annually. The frequency of management review(s) is increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues.

9.3.2 Management review inputs

Management review is, planned and carried out taking into consideration:

a) The status of actions from previous management reviews;
b) Changes in external and internal issues that are relevant to the quality management system;
c) Information on the performance and effectiveness of the quality management system, including trends in:

1. Customer satisfaction and feedback from relevant interested parties;
2. The extent in which, quality objectives have been met
3. Process performance and conformity of products and services;
4. Nonconformities and corrective actions;
5. Monitoring and measurement results;
6. Audit results;
7. The performance of external providers;

d) The adequacy of resources;
e) The effectiveness of actions taken to address risks and opportunities;
f) Opportunities for improvement

9.3.2.1 Management review inputs

Input to management review includes:

a) Cost of poor quality (cost of internal and external nonconformance);
b) Measures of process effectiveness;
c) Measures of process efficiency for product realization processes, as applicable;
d) Product conformance;
e) Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product;
f) Customer satisfaction;
g) Review of performance against maintenance objectives;
h) Warranty performance (where applicable);
i) Review of customer scorecards (where applicable);
j) Identification of potential field failures identified through risk analysis (such as FMEA);
k) Actual field failures and their impact on safety or the environment.

9.3.3 Management review outputs

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

a) Opportunities for improvement;
b) Any need for changes to the quality management system;
c) Resource needs.

MERSEN retains documented information as evidence of the results of management reviews.

9.3.3.1 Management review outputs

Top management documents and implements an action plan when customer performance targets are not met

10. Improvement

10 .1 General

MERSEN determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

This Include:

a) Improving products and services to meet requirements as well as to address future needs and expectations;
b) Correcting, preventing or reducing undesired effects
c) Improving the performance and effectiveness of the quality management system

NOTE: Examples of improvement can include correction, corrective action and continual improvement.

10.2 Nonconformity and corrective action

10.2.1 When nonconformity occurs, including any arising from complaints, MERSEN:

a) Reacts to the nonconformity and, as applicable:
    1. Take action to control and correct it;
    2. Deal with the consequences;

b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
    1. Reviewing and analyzing the nonconformity;
    2. Determining the causes of the nonconformity;
    3. Determining if similar nonconformities exist, or could potentially occur;
c) Implement any action needed;
d) Review the effectiveness of any corrective action taken;
e) Update risks and opportunities determined during planning, if necessary;
f) Make changes to the quality management system, if necessary.

10.2.2 MERSEN retains documented information as evidence of,

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

10.2.3 Problem solving

MERSEN has a documented process (es) for problem solving including:

a) Defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
b) Containment, interim actions, and related activities necessary for control of nonconforming outputs;
c) Root cause analysis, methodology used, analysis, and results;
d) Implementation of systemic corrective actions, including consideration of the impact on similar processes and products;
e) Verification of the effectiveness of implemented corrective actions;
f) Reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).

Where the customer has specific prescribed processes, tools, or systems for problem solving, **MERSEN** use those processes, tools, or systems unless otherwise approved by the customer.

10.2.4 Error-proofing

MERSEN has a documented process to determine the use of appropriate error-proofing methodologies. Details of method are documented in the process risk analysis (such as PFMEA), and test frequencies are documented in the control plan.

The process includes the testing of error-proofing devices for failure or simulated failure, records are maintained Challenge parts, when used, are identified, controlled, verified, and calibrated where feasible. Error-proofing device failures have a reaction plan..

10.2.5 Warranty management systems (Ref. QCI 5.3 Control of Non-Conforming Finished Goods Field Service Reports (FSR) and Material Review Board.)

When **MERSEN** is required to provide warranty for their product(s), **MERSEN** has implemented a warranty management process. **MERSEN** includes in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, **MERSEN** will carry out the required warranty management process.

10.2.6 Customer complaints and field failure test analysis

MERSEN performs analysis on customer complaints and field failures, including any returned parts, and initiates problem solving and corrective action to prevent recurrence.

Where requested by the customer, this includes analysis of the interaction of embedded software of MERSEN's product within the system of the final customer's product.

MERSEN will communicate the results of testing/analysis to the customer, also within the organization.

10.3 Continual improvement

MERSEN continually improves the suitability, adequacy and effectiveness of the quality management system.

MERSEN will consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that will be, addressed as part of continual improvement.

10.3.1 Continual improvement

MERSEN has a documented process for continual improvement (MC-P-001) **and** includes in this process the following:

a) Identification of the methodology used, objectives, measurement, effectiveness, and documented information;
b) A manufacturing process improvement action plan; with emphasis on the reduction of process variation and waste
c) Risk analysis (such as FMEA)

NOTE: Continual improvement will be implemented once manufacturing processes are statistically capable, and stable, or when product characteristics are predictable and meet customer requirements.