



americhem[®]

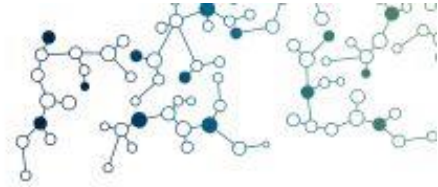
PERFORMANCE | SOLUTIONS | TRUST

Quality Manual

Table of Contents

Table of Contents	1
Our Vision and Strategy Statements	2
Control, Approval and Authorization Signature and Authorized Copy Holders	3
Americhem Process Map	8
Support Functions from Corporate Headquarters	8
Leadership	9
Quality Policy	10
Planning	12
Support	14
Operations	18
Performance Evaluation	35
Revision History	41

OUR VISION



Collaborating with our customers as the global, trusted advisor to shape the future through innovative and sustainable polymer solutions.

OUR STRATEGY STATEMENT

Americhem is the preferred global polymer solutions provider to leading industry manufacturers.

We create value with our customers by providing:

- Quality consistency
- Technical expertise
- Fast flexible service

OUR PRINCIPLES



Our primary responsibility is to ensure the long-term growth and sustainability of the company. Our ability to make sufficient profits ensures our future success and enables the company to achieve the following goals:

1. Maintain steady company growth and independence.
2. Provide working conditions conducive to safety and efficiency.
3. Provide equitable compensation and benefits to employees.
4. Earn a fair return for stockholders commensurate with their investment risk.
5. Provide our employees development and advancement opportunities within the company.

Control and Approval of the Americhem Corporate Quality Manual:

- The Central Office Administrator, shall be the sole approver of the Americhem Corporate Quality Manual.
- The approved manual shall be updated as changes take place.
- Editing privileges are limited to two people; the Global Quality Manager & the Central Office Administrator.
- All significant revisions shall be submitted to the registrar for review and approval prior to implementation.
- A significant revision is one that would change the way a requirement is satisfied within the manual. Name, title changes, and typographical errors are not considered significant changes.
- Significant manual revisions cannot take place within 30 days of an audit.
- An authorized copy of the manual must be presented to ISO auditors for their review at each audit.
- All numbered sections in **bold** text throughout this Manual refer to the corresponding sections of the ISO9001:2015 Standard. Sections in *italics* refer to the IATF16949:2016 standard.
- The Americhem Corporation and its facilities are referred to in this quality manual as "the Company".

Quality Management System Authorization Signature:

DARWIN BROWN: GLOBAL QUALITY MANAGER

Quality Manual Authorized Copy Holders:

DARWIN BROWN: GLOBAL QUALITY MANAGER
JESSE CHAMBERLAIN: QUALITY LEADER/Central Office Administrator, DALTON, GA
JEFF SUTHERLAND: QUALITY LEADER, CUYAHOGA FALLS, OH
ROXANNE HIOTT: QUALITY LEADER, CONCORD, NC
WILLIE MILLER: QUALITY MANAGER, LIBERY, NC
MARK SMOES: QUALITY MANAGER, GRAND RAPIDS, MI
TERESA JORDAN: Quality SYSTEMS MANAGER, SWEDESBORO, NJ
STEVE ROWLAND: QUALITY MANAGER, MANCHESTER, UK
CARRIE WANG: QUALITY SYSTEMS MANAGER, SUZHOU, CHINA
VASUDEV PADAGAL: QUALITY TESTING LEADER, PRESCIENT COLOR, MAHARASHTRA, INDIA

*The above personnel have been issued controlled copies of the Quality Manual. All other copies of the Quality Manual are to be considered "Uncontrolled Copies".

Context of the organization

At Americhem we are continually defining the scope of our business. In doing so, in an objective and unbiased way, we consider the external and internal issues that are relevant to the Company's purpose and direction. These are matters which could impact our business strategy, such as new technologies and potential market forces, any topics that have a bearing on the Company's success.

We accomplish this by identifying the relevant interested parties, those who have a significant effect on our ability to meet customers' requirements. We strive to address their needs and expectations within the context of our business model. We recognize in today's intensely competitive global market this may involve the latest technical innovations and alternative manufacturing techniques.

As part of Americhem's business planning strategy, we ascertain the key functions in our organization, and address the current risks and opportunities associated with each. This includes defining the inputs and outputs of these processes, as well as their interactions. We routinely document the results of our analyses and formally monitor the metrics for effectiveness. Our aim is to manage, control, and continually improve our business.

4 Context of the organization:

4.1 Understanding the organization and its context:

The Company will determine the 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. The Company will monitor and review information about these external and internal issues. Issues can include positive and negative factors or conditions for consideration. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties:

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the Company will determine:

- a. the interested parties that are relevant to its quality management system
- b. the requirements of these interested parties that are relevant to its quality management system

4.3 Determining the scope of the quality management system:

The Company will determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the Company will consider:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the Company's products and services

The Company will apply all the requirements of these International Standards if they are applicable within the determined scope of its quality management system. The scope of the Company's quality management system will be available and be maintained as documented information. The scope will state the types of products and services covered, and provide justification for any requirement of these International Standards that the organization determines is not applicable to the scope of its quality management system. Conformity to these International Standards may only be claimed if the requirements determined as not being applicable do not affect the Company's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

The scope of the Americhem Quality Management System and quality manual includes all ISO 9001:2015 and IATF 16949:2016 Quality System requirements. Each section of this Manual addresses a topic with the corresponding standard elements referenced below. ISO 9001:2015 is the base of the Manual - additional requirements for IATF 16949 are in italic font. This Manual is a Corporate-controlled document. The Quality Management System Representative members represented at each plant, and under Corporate Leadership, work together to maintain the Americhem Quality Manual for compliance with standard revisions or additional standard requirements. Each plant is responsible to comply only with the Quality Manual sections that are relevant to their quality certification.

Americhem, Inc.

- **Designs and manufactures custom color concentrates and specialty dispersions for the polymers industry.**
- **Manufactures custom color concentrates and specialty dispersions for the polymers industry.**
- **Designs custom color concentrates and specialty dispersions for the polymers industry.**

The following Plants comply with the ISO 9001:2015 Standard:

- 723 Commerce Dr., Concord, NC 28025 and warehouse is located at 321 Sign Drive. Concord, NC 28025
- 1015 Abutment Road, Dalton, Georgia 30720
- 7279 Liberty Park Avenue, Liberty, NC 27298

The following exclusions apply to the above listed plants which comply to the ISO 9001:2015 Standard and with International Accreditation Forum (IAF) multi-site requirements:

8.5.5 Post Delivery Activities: There are no special processes at Americhem which require validation only after the product is in use. The results of all processes and customer-required product characteristics are measured – prior to shipment to the customer - via approved test methods and are recorded as quality records.

The following plants independently conform to the IATF 16949:2016 Standard:

- 2000 Americhem Way, Cuyahoga Falls, Ohio 44221
- 155 East Steels Corners Rd., Cuyahoga Falls, Ohio 44224
- 55 Cottage Grove St. SW Grand Rapids. MI 49507
- Cawdor Street, Eccles, Manchester, UK, M30 0QF

NOTE: The exclusion listed above does not apply to the Steels Corner, OH, and Grand Rapids, MI or Manchester, UK facilities.

Field of Application:

The Americhem Quality Manual field of application includes all ISO 9001:2015 and the IATF 16949:2016 Quality System requirements. Each section of this Manual addresses a topic with the corresponding standard elements referenced below. ISO 9001:2015 is the base of the Manual - additional requirements for IATF 16949 are in italic font. This Manual is a corporately controlled document. The Central Office Administrator plans and manages certain activities (see 5.0 Leadership) which are fully or partially carried out at the branch sites. Each site has a legal link to the Central Office and maintains a common Quality Management System. The Quality Management System is established and subject to continuous surveillance by the Central Office Administrator. The Central Office Administrator receives input from the Quality Management System Representatives at each site. The Central Office Administrator has the responsibility to implement corrective actions when needed at any site. The Quality Management System Representatives represented at each plant, and under Corporate Leadership, work together to maintain the Americhem Quality Manual for compliance with standard revisions or additional standard requirements. Each plant is responsible to comply only with the Quality Manual sections that are relevant to their quality certification.

4.4 Quality management system and its processes:

4.4.1 The Company will establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of these International Standards. The Company will determine the processes needed for the quality management system and their application throughout the Company, and will:

- a) Determine the inputs required and the outputs expected from these processes;
- b) Determine the sequence and interaction of these processes;
- c) 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;
- d) Determine the resources needed for these processes and ensure their availability;
- e) Assign the responsibilities and authorities for these processes;
- f) Address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) Improve the processes and the quality management system.

4.4.2 To the extent necessary, the Company will:

- a) Maintain documented information to support the operation of its processes
- b) Retain documented information to have confidence that the processes are being carried out as planned

IATF 16949

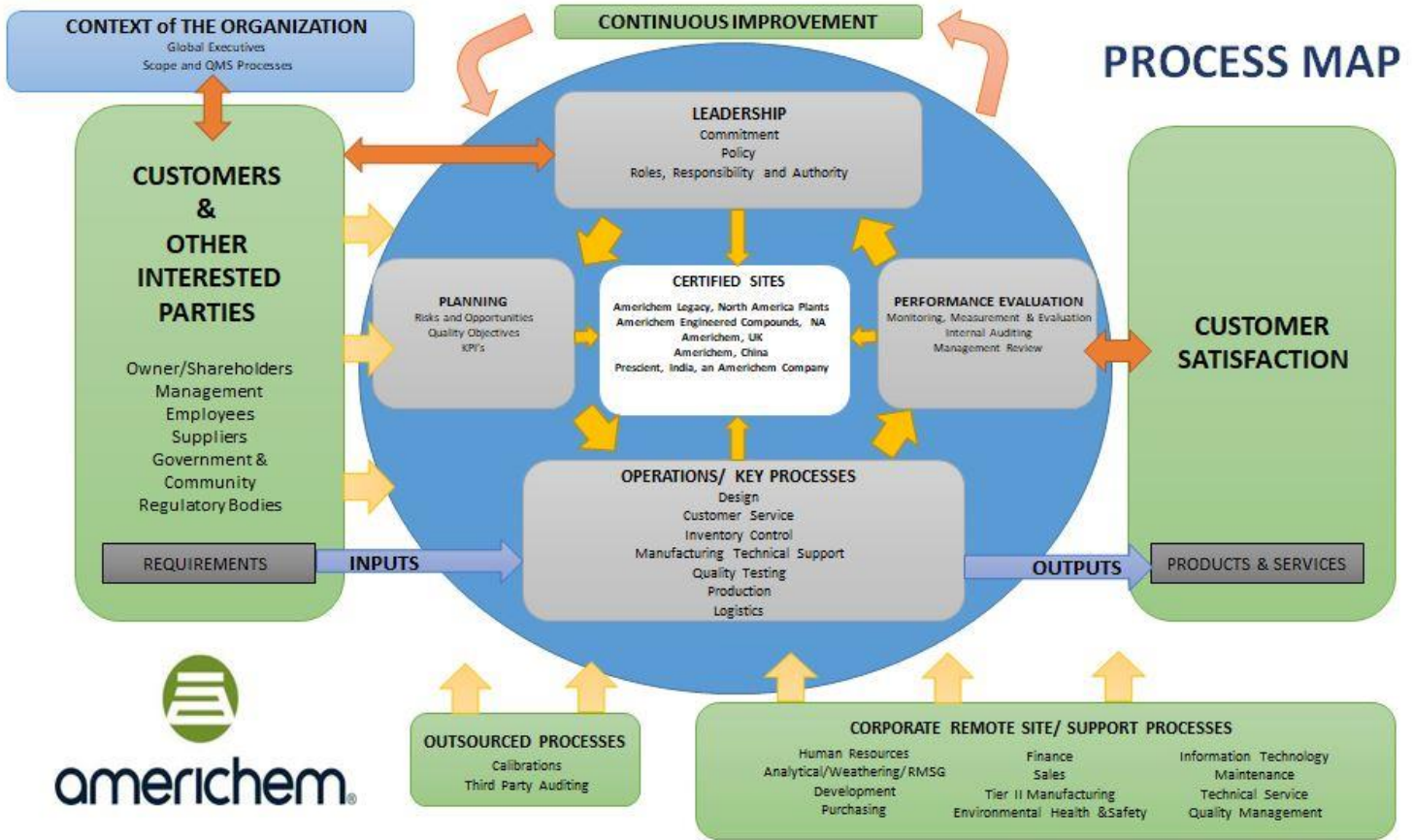
A. Determining the scope of the quality management system - supplemental – Supporting functions, whether on site or remote (such as design centers, corporate headquarters, and distribution centers), are included in the scope of the Quality Management System (QMS).

B. Customer-specific requirements - Customer-specific requirements are evaluated and included in the scope of the organization's quality management system.

C. Conformance of products and processes - The Company ensures conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory, and regulatory requirements.

D. Product safety - The Company maintains documented processes for the management of product-safety related products and manufacturing processes, which shall include but not be limited to the following, where applicable:

- 1. identification by the organization of statutory and regulatory product-safety requirements;*
- 2. customer notification of requirements in item 1;*
- 3. special approvals for design FMEA;*
- 4. identification of product safety-related characteristics;*
- 5. identification and controls of safety-related characteristics of product and at the point of manufacture;*
- 6. special approval of control plans and process FMEAs;*
- 7. reaction plans;*
- 8. defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;*
- 9. training identified by the Company or customer for personnel involved in product-safety related products and associated manufacturing processes;*
- 10. changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes;*
- 11. transfer of requirements with regard to product safety throughout the supply chain, including customer designated sources;*
- 12. product traceability by manufactured lot (at a minimum) throughout the supply chain;*
- 13. lessons learned for new product introduction.*



Support Functions from Corporate Headquarters (Americhem Way) to remote sites (IATF 16949:2016 and ISO 9001:2015)

Process	Human Resources	Analytical	Weathering	RMSG	Design/Development	Purchasing	Information Technology	Tier II Manufacturing/Engineering	Environmental Health & Safety	Maintenance	Technical Service	Quality Management	Sales	Finance
Engineering	1,2,3,4,5,6						1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6
Finance	1,2,3,4,5,6						1,2,3,4,5,6					1,2,3,4,5,6		1,2,3,4,5,6
Information Technology	1,2,3,4,5,6						1,2,3,4,5,6	1,2,3,4,5,6				1,2,3,4,5,6		1,2,3,4,5,6
Logistics	1,2,3,4,5,6					1,2,3,4,5,6	1,2,3,4,5,6					1,2,3,4,5,6		1,2,3,4,5,6
Maintenance	1,2,3,4,5,6						1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6				1,2,3,4,5,6
Marketing	1,2,3,4,5,6						1,2,3,4,5,6					1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6
Policy Making	1,2,3,4,5,6						1,2,3,4,5,6		1,2,3,4,5,6				1,2,3,4,5,6	1,2,3,4,5,6
Process Design	1,2,3,4,5,6	1,2,3,4,5,6					1,2,3,4,5,6	1,2,3,4,5,6			1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6
Production Equipment Development	1,2,3,4,5,6						1,2,3,4,5,6	1,2,3,4,5,6				1,2,3,4,5,6		1,2,3,4,5,6
Purchasing	1,2,3,4,5,6			1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6					1,2,3,4,5,6		1,2,3,4,5,6
R&D	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6				1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6
Sales	1,2,3,4,5,6						1,2,3,4,5,6					1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6
Strategic Planning	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6
Supplier Management	1,2,3,4,5,6						1,2,3,4,5,6	1,2,3,4,5,6				1,2,3,4,5,6		1,2,3,4,5,6
Testing	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6				1,2,3,4,5,6	1,2,3,4,5,6		1,2,3,4,5,6
Training	1,2,3,4,5,6						1,2,3,4,5,6		1,2,3,4,5,6			1,2,3,4,5,6		1,2,3,4,5,6

IATF 16949:2016	SCP	1
	GMI	2
	MKG	3
ISO 9001:2015	CNC	4
	DAL	5
	LNC	6

Leadership

5 Leadership:

5.1 Leadership and commitment:

5.1.1 The Company's management demonstrates leadership and commitment with respect to the quality management system by:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
- c) ensuring the integration of the quality management system requirements into the organization's business processes
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality management system requirements
- g) ensuring that the quality management system achieves its intended results
- h) engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;
- i) promoting improvement
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus: The Company's management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy:

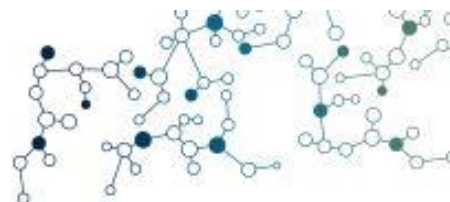
5.2.1 Establishing the quality policy: The Company's management has established, implemented, and maintained a quality policy that:

- a) is appropriate to the purpose and context of Americhem and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management.

5.2.2 Communicating the quality policy: the Company's Quality Policy:

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

OUR QUALITY POLICY



OUR CUSTOMERS

Quality is the degree to which products and services satisfy the expectations and requirements of our customers. The process begins by identifying the absolute standard, understanding the materials involved, and agreeing upon the desired key attributes. A set of specifications is agreed on by both the customer and Americhem when applicable. The process is made dynamic by soliciting frequent reviews of our performance with our customers to ensure quality consistency.

OUR SUPPLIERS

To help accomplish all of the above, Americhem expects its suppliers to deliver materials that conform to our requirements. This process also begins with identifying the absolute standard, understanding the materials involved, and agreeing upon the desired key attributes. A set of specifications is then agreed on by both the supplier and Americhem when applicable. The process is kept active by periodic performance reviews.

OUR EMPLOYEES

By empowering employee teams with the authority to implement innovative quality improvements, Americhem can design and produce better products to the highest standards while providing better customer service.

OUR OBJECTIVES

We are committed to establishing and reviewing objectives as part of our continual improvement process. We will meet customer expectations and improve productivity and efficiencies. We take accountability for the effectiveness of our quality management system, promoting the process approach and risk-based thinking.

5.3 Organizational roles, responsibilities, and authorities:

The Company's management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization. Top management assigns the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of International Standards;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

IATF 16949

A. Corporate responsibility - The Company defines and implements corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blowing policy").

B. Process effectiveness and efficiency - Top management reviews the product realization process and support processes to evaluate and improve their effectiveness and efficiency. The results of the process review activities are included as input to the management review.

C. Process owners - Top management identifies process owners who are responsible for managing the organization's processes and related outputs. Process owners understand their roles and are competent to perform those roles.

D. Organizational roles, responsibilities and authorities - supplemental - Top management assigns personnel with the responsibility and authority to ensure that customer requirements are met. These assignments are documented. This includes but is not limited to the selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.

E. Responsibilities and authority for product requirements and corrective actions – Top management ensures that:

- 1) personnel responsible for conformity of product requirements have the authority to stop shipment and stop production to correct quality problems;*
- 2) personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained;*
- 3) production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.*

Planning

6 Planning:

6.1 Actions to address risks & opportunities:

6.1.1 When planning for the quality management system, the Company considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determines the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

6.1.2 The Company plans:

- a) actions to address these risks and opportunities;
- b) how to :
 - 1) integrate and implement the actions into its quality management system processes;
 - 2) evaluate the effectiveness of these actions.

6.2 Quality objectives and planning to achieve them:

6.2.1 The Company establishes quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives will:

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

The Company maintains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the Company determines:

- 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.

6.3 Planning of changes:

When the Company determines the need for changes to the quality management system, the changes are carried out in a planned manner. The Company considers:

- 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.

IATF 16949

A. Risk analysis - The Company includes in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap and rework. The Company retains documented information as evidence of the results of risk analysis.

B. Preventive action - The Company determines and implements action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the severity of the potential issues. The Company establishes processes to lessen the impact of negative effects of risk including the following:

- 1) determining potential nonconformities and their causes;*
- 2) evaluating the need for action to prevent occurrence of nonconformities;*
- 3) determining and implementing action needed;*
- 4) documented information of action taken;*
- 5) reviewing the effectiveness of the preventive action taken;*
- 6) utilizing lessons learned to prevent recurrence in similar processes*

C. Contingency plans - the Company:

- 1) identifies and evaluates internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;*
- 2) defines contingency plans according to risk and impact to the customer;*
- 3) prepares contingency plans for continuity of supply in the event of any of the following: key equipment failures, interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; labor shortages; or infrastructure disruptions;*
- 4) includes, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;*
- 5) periodically tests the contingency plans for effectiveness (e.g., simulations, as appropriate)*
- 6) conducts contingency plan reviews (at a minimum) annually using a multidisciplinary team including top management, and update as required;*
- 7) documents the contingency plans and retains documented information describing any revision(s), including the person(s) who authorized the change(s). The contingency plans include provisions to validate the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.*

D. Quality objectives and planning to achieve them – supplemental Top management ensures that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization. The results of the Company's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

Support

7 Support:

7.1 Resources:

7.1.1 General - The Company determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The Company considers:

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

7.1.2 People - The Company determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure - The Company determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure can include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.4 Environment for the operation of processes - The Company determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. A suitable environment can be a combination of human and physical factors, such as:

- 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).

7.1.5 Monitoring and measuring resources:

7.1.5.1 General - The Company determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The Company ensures that the resources provided:

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

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

7.1.5.2 Measurement traceability - When measurement traceability is a requirement, or is considered by the Company 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.

The Company will determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and then take appropriate action as necessary. A number or another identifier traceable to the device calibration record will meet the intent of the requirements in ISO 9001:2015.

7.1.6 Organizational knowledge- The Company determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained and is made available to the extent necessary. When addressing changing needs and trends, the Company considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates. Organizational knowledge is knowledge specific to the Company; it is gained by experience. It is information that is used and shared to achieve the Company's objectives.

7.1.6.1 Organizational knowledge can 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; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence:

The Company:

- 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) ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, takes actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retains appropriate documented information as evidence of competence. Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness:

The Company 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) the implications of not conforming with the quality management system requirements.

7.4 Communication:

The Company determines the internal and external communications relevant to the quality management system, including:

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

7.5 Documented information:

7.5.1 General - The Company's quality management system includes:

- a) documented information required by International Standards;
- b) documented information determined by the Company as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and updating - When creating and updating documented information, the Company ensures appropriate:

- a) identification and description (e.g. a title, date, author, or reference number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

7.5.3 Control of documented information:

7.5.3.1 Documented information required by the quality management system and by International Standards shall be 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, the Company addresses the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

Documented information of external origin determined by the Company to be necessary for the planning and operation of the quality management system is identified as appropriate, and is controlled. Documented information retained as evidence of conformity is protected from unintended alterations. Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

Operations

8 Operations:

8.1 Operational planning and control:

The Company plans, implements, and controls the processes needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, 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 and keeping documented information to the extent necessary, i.e., maintaining and retaining documented information,
 - 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 the Company's operations. The Company controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The Company ensures that outsourced processes are controlled.

8.2 Requirements for products and services:

8.2.1 Customer communication - Communication with customers shall include:

- a) providing information relating to products and services;
- b) handling inquiries, 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.

8.2.2 Determining the requirements for products and services - When determining the requirements for the products and services to be offered to customers, the Company 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 the organization;
- b) the Company can meet the claims for the products and services it offers.

8.2.3 Review of the requirements for products and services:

8.2.3.1 The Company ensures that it has the ability to meet the requirements for products and services to be offered to customers. The Company 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;
- b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) requirements specified by the Company;
- d) statutory and regulatory requirements applicable to the products and services;
- e) contract or order requirements differing from those previously expressed.

The Company ensures that contract or order requirements differing from those previously defined are resolved. The customer's requirements are confirmed by the Company before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 The Company retains documented information, as applicable:

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

8.2.4 Changes to requirements for products and services - The Company ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services:

8.3.1 General - The Company establishes, implements, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning - In determining the stages and controls for design and development, the Company 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;
- g) the need for involvement of customers and users in the design and development process;
- h) the requirements for subsequent provision of products and services;
- i) the level of control expected for the design and development process by customers and other relevant interested parties;
- j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs - The Company determines the requirements essential for the specific types of products and services to be designed and developed. The Company 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 the Company has committed to implement;
- 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. The Company retains documented information on design and development inputs.

8.3.4 Design and development controls - The Company 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.

Design and development reviews, verification, and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the Company.

8.3.5 Design and development outputs - The Company 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.

The Company retains documented information on design and development outputs.

8.3.6 Design and development changes - The Company identifies, reviews, and controls 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. The Company 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.

8.4 Control of externally provided processes, products and services:

8.4.1 General - The Company ensures that externally provided processes, products and services conform to requirements. The Company 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 the Company's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of the Company;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by the Company.

The Company determines and applies criteria for the evaluation, selection, monitoring of performance, and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The Company retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control - The Company ensures that externally provided processes, products and services do not adversely affect the Company's ability to consistently deliver conforming products and services to its customers. The Company:

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

8.4.3 Information for external providers - The Company ensures the adequacy of requirements prior to their communication to the external provider. The Company 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 the Company;
- e) control and monitoring of the external providers' performance to be applied by the Company;
- f) verification or validation activities that the Company, or its customer, intends to perform at the external providers' premises.

8.5 Production and service provision:

8.5.1 Control of production and service provision - The Company implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

a) the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

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. Suitable infrastructure includes appropriate manufacturing equipment required to ensure product compliance. Monitoring and measuring resources include appropriate monitoring and measuring equipment required to ensure effective control of manufacturing processes.

8.5.2 Identification and traceability - The Company uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The Company identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The Company controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability. Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted if the status is clearly identified, documented, and achieves the designated purpose.

8.5.3 Property belonging to customers or external providers - The Company exercises care with property belonging to customers or external providers while it is under the Company's control or being used by the Company. The Company identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the Company reports this to the customer or external provider and retains documented information of what has occurred. A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation - The Company preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities - The Company meets any requirements for post-delivery activities associated with its products and services. In determining the extent of post-delivery activities that are required, the Company 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.

8.5.6 Control of changes - The Company reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The Company retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services:

The Company implements 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 does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The Company 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.

8.7 Control of nonconforming outputs:

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

8.7.2 The Company 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.

IATF 16949

A) Operational planning and control - supplemental - When planning for product realization, the following topics are included:

- 1) customer product requirements and technical specifications*
- 2) logistics requirements;*
- 3) manufacturing feasibility;*
- 4) project planning;*
- 5) acceptance criteria.*

The resources identified in ISO 9001, Section 8.1 c), refer to the required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance.

B) Confidentiality - The Company ensures the confidentiality of customer-contracted products and projects under development, including related product information.

C) Customer communication - supplemental - Written or verbal communication is in the language agreed with the customer. The Company has the ability to communicate necessary information, including data in customer specified computer language and format (e.g., computer-aided design data, electronic data interchange.)

D) Determining the requirements for products and services - supplemental - These requirements can include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes. Compliance to ISO 9001, Section 8.2.2 item a) 1), includes but is not limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

E) Review of the requirements for products and services - supplemental - The Company retains documented evidence of a customer-authorized waiver for the requirements stated in ISO 9001, Section 8.2.3.1, for formal review.

F) Customer-designated special characteristics - The Company conforms to the customer requirements for designation, approval documentation, and control of special characteristics.

G) Organizational manufacturing feasibility - The Company utilizes a multidisciplinary approach to conduct an analysis to determine if it is feasible that the Company's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer. Additionally, the Company validates through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.

H) Design and development of products and services - supplemental - The requirements of ISO 9001, Section 8.3.1, apply to product and manufacturing process design and development and focus on error prevention rather than detection. The Company documents the design and development process.

I) Design and development planning - supplemental - The Company ensures that design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach can include but are not limited to the following:

- 1) project management (for example, APQP or VDA-RGA);*
- 2) product and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;*
- 3) development and review of product design risk analysis (FMEAs), including actions to reduce potential risks;*
- 4) development and review of manufacturing process risk analysis (for example, FMEAs, process flows, control plans, and standard work instructions). A multidisciplinary approach may include the Company's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.*

J) *Product design skills - The Company ensures that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques as identified by the Company.*

K) *Development of products with embedded software - The Company will use a process for quality assurance for any products with internally developed embedded software. A software development assessment methodology will be utilized to assess the Company's software development process. Using prioritization based on risk and potential impact to the customer, the Company will retain documented information of a software development capability self-assessment. The Company will include software development within the scope of their internal audit program (see Section 9.2.2.1).*

L) *Product design input - The Company identifies, documents, and reviews product design input requirements as a result of contract review. Product design input requirements can include but are not limited to the following:*

- 1) product specifications including but not limited to special characteristics (see Section 8.3.3.3);*
- 2) boundary and interface requirements;*
- 3) identification, traceability, and packaging;*
- 4) consideration of design alternatives;*
- 5) assessment of risks with the input requirements and the Company's ability to mitigate/manage the risks, including from the feasibility analysis;*
- 6) targets for conformity of product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;*
- 7) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;*
- 8) embedded software requirements. The Company 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.*

M) *Manufacturing process design input - The Company identifies, documents, and reviews process design input requirements including but not limited to the following:*

- 1) product design output data including special characteristics;*
- 2) targets for productivity, process capability, timing and cost;*
- 3) manufacturing technology alternatives;*
- 4) customer requirements, if any;*
- 5) experience from previous developments;*
- 6) new materials;*
- 7) product handling and ergonomic requirements; and*
- 8) 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.*

N) *Special characteristics - The Company 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 the Company, and includes the following:*

- 1) documentation of all special characteristics in the drawing (as required), risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are cascaded through each of these documents.*
- 2) development of control and monitoring strategies for special characteristics of products and production processes;*
- 3) customer-specified approvals, when required;*
- 4) compliance with customer-specified definitions and symbols or the Company's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table is submitted to the customer, if required.*

O) 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 (see Section 9.3.2.1). 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. When appropriate, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.

P) Design and development validation - Design and development validation is performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standard. The timing of design and development validation is planned in alignment with customer-specified timing, as applicable. When contractually agreed with the customer, this will include evaluation of the interaction of the organization's product, including any embedded software, within the system of the final customer's product.

Q) Prototype program - When required by the customer, the Company will have a prototype program and control plan. The Company will use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production. All performance-testing activities are monitored for timely completion and conformity to requirements. When services are outsourced, the Company will include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to the requirements (see ISO 9001, Section 8.4).

R) Product approval process - The Company establishes, implements, and maintains a product and manufacturing approval process conforming to requirements defined by the customer(s). The Company approves externally provided products and services per ISO 9001, Section 8.4.3, prior to submission of their approval to the customer. The Company obtains documented product approval prior to shipment, if required by the customer. Records of such approval are retained. Product approval will be subsequent to the verification of the manufacturing process.

S) Design and development outputs - supplemental - The product design output is expressed in terms that can be verified and validated against product design input requirements. The product design output can include but is not limited to the following, as applicable:

- 1) design risk analysis (FMEA);*
- 2) reliability study results;*
- 3) product special characteristics;*
- 4) results of product design error-proofing, such as DFSS, DFMA, and FTA;*
- 5) product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning and tolerancing (GD&T);*
- 6) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);*
- 7) product design review results;*
- 8) service diagnostic guidelines and repair and serviceability instructions;*
- 9) service part requirements;*
- 10) packaging and labeling requirements for shipping. Interim design outputs can include any engineering problems being resolved through a trade-off process.*

T) Manufacturing process design output - The Company documents the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The Company verifies the outputs against manufacturing process design input requirements. The manufacturing process design output includes but is not limited to the following:

- 1) specifications and drawings;*
- 2) special characteristics for product and manufacturing process;*
- 3) identification of process input variables that impact characteristics;*
- 4) tooling and equipment for production and control, including capability studies of equipment and process(es);*
- 5) manufacturing process flow charts/layout, including linkage of product, process, and tooling;*
- 6) capacity analysis;*
- 7) manufacturing process FMEA;*
- 8) maintenance plans and instructions;*
- 9) control plan;*
- 10) standard work and work instructions;*
- 11) process approval acceptance criteria;*
- 12) data for quality, reliability, maintainability, and measurability;*
- 13) results of error-proofing identification and verification, as appropriate;*
- 14) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.*

U) Design and development changes - supplemental - The Company evaluates all design changes after initial product approval, including those proposed by the Company or its suppliers, for potential impact on fit, form, function, performance, and/or durability. These changes are validated against customer requirements and approved internally, prior to production implementation. If required by the customer, the Company obtains documented approval, or a documented waiver, from the customer prior to production implementation. For products with embedded software, the Company will document the revision level of software and hardware as part of the change record.

V) General - supplemental - The Company includes all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

W) Supplier selection process - The Company has a documented supplier selection process. The selection process includes:

- 1) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the Company's product to their customers;*
- 2) relevant quality and delivery performance;*
- 3) an evaluation of the supplier's quality management system;*
- 4) multidisciplinary decision making; and*
- 5) an assessment of software development capabilities, if applicable. Other supplier selection criteria that can be 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 and process)*
 - adequacy of available resources (e.g., people infrastructure);*
 - design and development capabilities (including project management);*
 - change management process;*
 - business continuity planning (e.g., disaster preparedness, contingency planning);*
 - logistics process;*
 - customer service.*

X) Customer-directed sources (also known as "Directed-Buy") - When specified by the customer, the Company will purchase products, materials, or services from customer-directed sources. All requirements of section 8.4 (except the requirements in IATF 16949, Section 8.4.1.2) are applicable to the Company's control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.

Y) Type and extent of control - supplemental - The Company has a 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 (Company) 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.

Z) Statutory and regulatory requirements - The Company documents 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, the Company ensures they are implemented and maintained as defined, including at suppliers.

AA) *Supplier quality management system development - The Company requires their suppliers of automotive products and services to develop implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer [e.g., item a) below], with the ultimate objective of becoming certified to the Automotive QMS Standard. Unless otherwise specified by the customer, the following sequences should be applied to achieve this requirement:*

- 1) *compliance to ISO 9001 through second-party audits;*
- 2) *certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the Company 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;*
- 3) *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;*
- 4) *certification to ISO 9001 with compliance to IATF 16949 through second-part audits;*
- 5) *certification to 16949 through third-part audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).*

BB) *Automotive product-related software or automotive products with embedded software – As applicable, the Company will require 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, the Company will require the supplier to retain documented information of a software development capability self-assessment.*

CC) *Supplier monitoring - The Company 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:*

- 1) *delivered product conformity to requirements;*
- 2) *customer disruptions at the receiving plant, including yard holds and stop ships;*
- 3) *delivery schedule performance;*
- 4) *number of occurrences of premium freight if provided by the customer, the Company will also include the following, as appropriate, in their supplier performance monitoring:*
- 5) *special status customer notifications related to quality or delivery issues;*
- 6) *dealer returns, warranty, field actions and recalls.*

DD) *Second-party audits - The Company will include a second-party audit process in their supplier management approach. Second party audits may be used for the following:*

- 1) *supplier risk assessment;*
- 2) *supplier monitoring;*
- 3) *supplier QMS development;*
- 4) *product audits;*
- 5) *process audits.*

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

EE) *Supplier development - The Company will determine the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs will include but are not limited to the following:*

- 1) *performance issues identified through supplier monitoring*
- 2) *second party audit findings*
- 3) *third-party quality management system certification status;*
- 4) *risk analysis*

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

FF) *Information for external providers - supplemental - The Company will 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.*

GG) *Control plan - The Company will develop control plans at the system, subsystem, component, and/or material level for the relevant manufacturing site and all product 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. The Company will have 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):*

- 1) *controls used for the manufacturing process control, including verification of job set-ups;*
- 2) *first-off/last-off part validation, as applicable;*
- 3) *methods for monitoring of control exercised over special characteristics defined by both the customer and the Company;*
- 4) *the customer-required information, if any;*
- 5) *specified reaction plan; when nonconforming product is detected, the process becomes statistically unstable or not statistically capable. The Company will review control plans, and update as required, for any of the following:*
- 6) *the organization determines it has shipped nonconforming product to the customer;*
- 7) *when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA);*
- 8) *after a customer complaint and implementation of the associated corrective action, when applicable;*
- 9) *at a set frequency, based on a risk analysis. If required by the customer, the Company will obtain customer approval after review or revision of the control plan.*

HH) *Standardized work - operator instructions and visual standards - The Company ensures that standardized work instructions are:*

- 1) *communicated to and understood by the employees who are responsible for performing work;*
- 2) *legible;*
- 3) *presented in the language(s) understood by the personnel responsible to follow them;*
- 4) *accessible for use at the designated work area(s) The standardized work documents will also include rules for operator safety.*

II) *Verification of job set-ups - the Company will:*

- 1) *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;*
- 2) *maintain documented information for set-up personnel;*
- 3) *use statistical methods of verification, where applicable;*
- 4) *perform first-off/last-off part validation, as applicable; 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;*
- 5) *retain records of process and product approval following set-up and first-off/last-off part validations.*

JJ) Verification after shutdown - The Company will define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

KK) Total productive maintenance - The Company will develop, implement, and maintain a documented total productive maintenance system. At a minimum, the system will include the following:

- 1) identification of process equipment necessary to produce conforming product at the required volume;*
- 2) availability of replacement parts for the equipment identified in item a);*
- 3) provision of resource for machine, equipment, and facility maintenance;*
- 4) packaging and preservation of equipment, tooling, and gauging;*
- 5) applicable customer-specific requirements;*
- 6) 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 shall form an input into management review.*
- 7) regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;*
- 8) use of preventive maintenance methods;*
- 9) use of predictive maintenance methods, as applicable;*
- 10) periodic overhaul*

LL) Management of production tooling and manufacturing, test, inspection tooling and equipment - The Company will provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable. The Company will establish and implement a system for production tooling management, whether owned by the organization or the customer, including:

- 1) maintenance and repair facilities and personnel;*
- 2) storage and recovery;*
- 3) set-up;*
- 4) tool-change programs for perishable tools;*
- 5) tool design modification documentation, including engineering change level of the product;*
- 6) tool modification and revision to documentation;*
- 7) tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location. The Company will verify the 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. The Company will implement a system to monitor these activities if any work is outsourced.*

MM) Production scheduling - The Company 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. The Company 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.

NN) Identification and traceability - supplemental - 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, the Company will implement identification and traceability to processes as described below. The Company will conduct an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels or risk or failure severity for employees, customers, and consumers. The plans shall define the appropriate traceability systems, processes, and methods by product, process, process and manufacturing location that:

- 1) enable the Company to identify nonconforming and/or suspect product;*
- 2) enable the Company to segregate nonconforming and/or suspect product;*
- 3) ensure the ability to meet the customer and/or regulatory response time requirements;*
- 4) ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the Company to meet the response time requirements;*
- 5) ensure serialized identification of individual products, if specified by the customer or regulatory standards;*
- 6) ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.*

OO) Preservation - supplemental - 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, the Company will assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment. The Company will use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO). The Company will ensure that obsolete product is controlled in a manner similar to that of nonconforming product. The Company will comply with preservation, packaging, shipping, and labeling requirements as provided by the customers.

PP) Feedback of information from service - The Company will ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

QQ) Service agreement with the customer - When there is a service agreement with the customer, the Company will:

- 1) verify that the relevant service centers comply with applicable requirements;*
- 2) verify the effectiveness of any special purpose tools or measurement equipment;*
- 3) ensure that all service personnel are trained in applicable requirements.*

RR) Control of changes - supplemental - The Company will have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the Company, the customer, or any supplier, will be assessed. The Company will:

- 1) define verification and validation activities to ensure compliance with customer requirements;*
- 2) validate changes before implementation;*
- 3) document the evidence of related risk analysis;*
- 4) retain records of verification and validation Changes, including those made at suppliers, should 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, the Company will:*
- 5) notify the customer of any planned product realization changes after the most recent product approval;*
- 6) obtain documented approval, prior to implementation of the change;*
- 7) complete additional verification or identification requirements, such as production trial run and new product validation.*

SS) *Temporary change of process controls* - The Company will identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices, that includes the primary process control and the approved back-up or alternate methods. The Company will document the process that manages the use of alternate control methods. The Company will include 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 was inspected or tested using the alternate method, if required, the Company will obtain approval from the customer(s). The Company will maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan. Standard work instructions shall be available for each alternate process control method. The Company will review 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:

- 1) daily quality focused audits (e.g., layered process audits, as applicable);
- 2) 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.

The Company will implement 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.)

TT) *Release of products and services - supplemental* - The Company will ensure that the planned arrangements to verify the product and service requirements have been met encompass the control plan and are documented as specified in the control plan. The Company will ensure that the planned arrangements for initial release of products and services encompass product and service approval. The Company will ensure that product and service approval is accomplished after changes following initial release.

UU) *Layout inspection and functional testing* - A layout inspection and 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.

VV) *Appearance items* - For manufactured parts designated by the customer as "appearance items", the Company will provide the following:

- 1) appropriate resources, including lighting, for evaluation;
- 2) masters for color, grain, gloss, metallic brilliance, texture, distinctness or image (DOI), and haptic technology, as appropriate;
- 3) maintenance and control of appearance masters and evaluation equipment;
- 4) verification that personnel making appearance evaluations are competent and qualified to do so.

WW) *Verification and acceptance of conformity of externally provided products and services* - The Company will have a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:

- 1) receipt and evaluation of statistical data provided by the supplier to the Company;
- 2) receiving inspection and/or testing, such as sampling based on performance;
- 3) second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements;
- 4) part evaluation by a designated laboratory;
- 5) another method agreed with the customer.

XX) *Statutory and regulatory conformity* - Prior to release of externally provided products into its production flow, the Company 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.

YY) Acceptance criteria - Acceptance criteria will be defined by the Company and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects.

ZZ) Customer authorization for concession - The Company will obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The Company will obtain customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit. The Company will maintain a record of the expiration date or quantity authorized under concession. The Company will also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchase product). The Company will approve any requests from suppliers before submission to the customer.

AAA) Control of nonconforming product - customer-specified process - The Company comply with applicable customer-specified controls for nonconforming product(s).

BBB) Control of suspect product - The Company will ensure that product unidentified or suspect status is classified and controlled as nonconforming product. The Company will ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

CCC) Control of reworked product - The Company will utilize 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, the Company will obtain approval from the customer prior to commencing rework of the product. The Company will have a documented process for rework confirmation in accordance with the control plan and other relevant documented information to verify compliance to original specifications. Instructions for disassembly or rework, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel. The Company will retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

DDD) Control of repaired product - The Company will utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. The Company will obtain approval from the customer prior to commencing repair of the product. The Company will have a documented process for repair confirmation in accordance with the control plan and other relevant documented information. Instructions for disassembly or repair, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel. The Company will obtain a documented customer authorization for concession for the product to be repaired. The Company will retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

EEE) Customer notification - The Company 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.

FFF) Nonconforming product disposition - The Company will have a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, the Company will verify that the product to be scrapped is rendered unusable prior to disposal. The Company will not divert nonconforming product or service for other use without prior customer approval.

Performance Evaluation

9 Performance Evaluation:

9.1 Monitoring, measurement, analysis and evaluation:

9.1.1 General - the Company 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 shall be performed;
- d) when the results from monitoring and measurement will be analyzed and evaluated.

The Company will evaluate the performance and the effectiveness of the quality management system.

The Company will retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction - The Company will monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The Company will determine the methods for obtaining, monitoring and reviewing this information. Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, and warranty claims.

9.1.3 Analysis and evaluation - The Company will analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis will be 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. Methods to analyze data can include statistical techniques.

9.2 Internal audit:

9.2.1 The Company will conduct internal audits at planned intervals to provide information on whether the quality management system:

- a) conforms to:
 - 1) the Company's own requirements for its quality management system;
 - 2) the requirements of International Standards;
- b) is effectively implemented and maintained.

9.2.2 The Company will:

- a) plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which will take into consideration the importance of the processes concerned, changes affecting the Company, and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure 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 program and the audit results.

9.3 Management review:

9.3.1 General - Top management will review the Company's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the Company.

9.3.2 Management review inputs - The management review will be 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 to 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.

9.3.3 Management review outputs - The outputs of the management review will include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

The Company will retain documented information as evidence of the results of management reviews.

IATF 16949

A) Monitoring and measurement of manufacturing processes - 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. The Company will maintain manufacturing process capability or performance results as specified by the customer's part approval process requirements. The Company will verify that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

- 1) measurement techniques;*
- 2) sampling plans;*
- 3) acceptance criteria;*
- 4) records of actual measurement values and/or test results for variable data;*
- 5) reaction plans and escalation process when acceptance criteria are not met. Significant process events, such as tool change or machine repair, will be recorded and retained as documented information.*

The Company 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 the Company indicating specific actions, timing, and assigned responsibilities to ensure the process becomes stable and statistically capable. The plans will be reviewed with and approved by the customer, when required. The Company will maintain records of effective dates of process changes.

B) Identification of statistical tools - The Company will determine the appropriate use of statistical tools. The Company will 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.

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

D) Customer satisfaction - supplemental - Customer satisfaction with the Company will be monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements. Performance indicators will be based on objective evidence and include but not be limited to the following:

- 1) delivered part quality performance;*
- 2) customer disruptions;*
- 3) field returns, recalls, and warranty (where applicable);*
- 4) delivery schedule performance (including incidents of premium freight);*
- 5) customer notifications related to quality or delivery issues, including special status.*

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

E) Prioritization - Trends in quality and operational performance will be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

F) Internal audit program - The Company will have a documented internal audit process. The process will include 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 will be prioritized based upon risk, internal and external performance trends, and criticality of the process(es). The frequency of audits will be 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 will be reviewed as part of management review.

G) Quality management system audit - The Company will audit all quality management system processes over each three-year calendar period, according to an annual program, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the Company will sample customer-specific quality management system requirements for effective implementation.

H) Manufacturing process audit - The Company will audit 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, the Company will determine the approach to be used. Within each individual audit plan, each manufacturing process will be audited on all shifts where it occurs, including the appropriate sampling of the shift handover. The manufacturing process audit will include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

I) Product audit - The Company will audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements. Where not determined by the customer, the Company will define the approach to be used.

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

K) Management review inputs - supplemental - Inputs to management review will include:

- 1) cost of poor quality (cost of internal and external nonconformance);*
- 2) measures of process effectiveness;*
- 3) measures of process efficiency;*
- 4) product conformance;*
- 5) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product*
- 6) customer satisfaction*
- 7) review of performance against maintenance objectives;*
- 8) warranty performance (where applicable);*
- 9) review of customer scorecards (where applicable);*
- 10) identification of potential field failures identified through risk analysis (such as FMEA);*
- 11) actual field failures and their impact on safety or the environment.*

L) Management review outputs - supplemental - Top management will document and implement an action plan when customer performance targets are not met.

Improvement

10 Improvement:

10.1 Improvement - The Company will determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These will 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.

Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action:

10.2.1 When a nonconformity occurs, including any arising from complaints, the Company will:

- a) react to the nonconformity and, as applicable:
 - 1) take action to control and correct it;
 - 2) deal with the consequences;
- b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) reviewing and analyzing the nonconformity;
 - 2) determining the causes of the nonconformity;
 - 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. Corrective actions will be appropriate to the effects of the nonconformities encountered.

10.2.2 The Company will retain documented information as evidence of:

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

10.3 Continual improvement - The Company will continually improve the suitability, adequacy and effectiveness of the quality management system. The Company will consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

IATF 16949

A) *Problem solving - The Company will have a documented process(es) for problem solving including:*

- 1) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings;*
- 2) containment, interim actions, and related activities necessary for control of nonconforming outputs*
- 3) root cause analysis, methodology used, analysis, and results;*
- 4) implementation of systemic corrective actions, including consideration of the impact on similar processes and products;*
- 5) verification of the effectiveness of implemented corrective actions;*
- 6) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan) Where the customer has a specific prescribed processes, tools, or systems for problem solving, the Company will use those processes, tools, or systems unless otherwise approved by the customer.*

B) *Error-proofing - The Company will have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used will be documented in the process risk analysis (such as PFMEA) and test frequencies will be documented in the control plan. The process will include the testing of error proofing devices for failure or simulated failure. Records will be maintained. Challenge parts, when used, will be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures will have a reaction plan.*

C) *Warranty management systems - When the Company is required to provide warranty for their product(s), the Company will implement a warranty management process. The Company will include in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, the Company will implement the required warranty management process.*

D) *Customer complaints and field failure test analysis - The Company will perform analysis on customer complaints and field failures, including any returned parts, and will initiate problem solving and corrective action to prevent recurrence. Where requested by the customer, this will include analysis of the interaction of embedded software of the organization's product within the system of the final customer's product. The Company will communicate the results of testing/analysis to the customer and also within the organization.*

E) *Continual improvement - supplemental - The Company will have a documented process for continual improvement. The Company will include in this process the following:*

- 1) identification of the methodology used, objectives, measurement, effectiveness, and documented information*
- 2) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste*
- 3) risk analysis (such as FMEA)*

Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.

Revision History

Manual Revision	Document, Section, Paragraph Changed	Page Number	Change Made	Date	Editor
1-27	Previous Records Stored in QSi				ST
28	Authorized Signature and Copy Holders	3	Removed H.L. and replace with S.T. Updated Authorized Copy Holders	4/30/2019	ST
	Process Map	8	Updated Site Wording		
	All		Modified Format Replaced CIC with QMS Representatives		
29	Support Functions	9	Added Support Function Link (IATF)	7/3/2019	ST
	Authorized Copy Holders	3	Replaced Michael Xu with Carrie Wang		
30	Authorize Copy Holders	3	Replaced Sarah Stanton with Steve Rowland	10/7/2019	ST
	Support Functions	9	Updated to Reflect All Remote Sites		
31	Site Locations	3	Update Locations	3/3/2020	DB