

LORD

LORD APS/EPM (LAE) Quality Manual

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Note- This document is also available in Spanish.

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2 Introduction

2.1 LORD Corporation

LORD Corporation is a part of Parker Hannifin, a leading global provider of motion and control technologies. The Assembly Protection Solutions (APS) and Elastomer Process Materials (EPM) divisions develop, manufacture, and market innovative adhesive and coating products and services for business-to-business niche markets. LORD Corporation was founded in Erie, Pennsylvania in 1924 and was acquired by Parker Hannifin in 2019. Parker Hannifin, a publicly traded company, is headquartered in Cleveland, Ohio with domestic and international manufacturing facilities and business offices are located throughout the world.

2.2 LORD Quality Management System

The quality management system (QMS) for LORD Assembly Protection Solutions and Elastomer Process Materials (LAE) divisions meets the requirements of ISO 9001:2015, IATF 16949:2016, and specific customer and statutory and regulatory requirements.

Key for quality system requirements:

ISO9001:2015 Selections in regular type apply across the organization.

IATF 16949:2016 Italicized selections in [brackets] are selectively applied to OEM automotive materials/processes.

The purpose of the Quality Manual is to document the quality system and policies and to inform LAE customers of the controls implemented to assure product quality. The Quality Manual provides for a quality management system to:

- consistently provide products that meet customer and applicable statutory and regulatory requirements,
- enhance customer satisfaction through effective application of the quality system, including processes for continual improvement of the system and assurance of conformity to customer and applicable statutory and regulatory requirements.

There are a series of related documents to the Quality Manual for reference as indicated below:

Document Number	Title
LAE-QM-01	Lord APS EPM Process Interaction Model
LAE-QM-02	Lord APS EPM Process Overview
LAE-QM-03	Lord APS EPM Site Specific Scopes
LAE-QM-04	Lord APS EPM Interested Parties
LAE-QM-05	Lord APS EPM Processes vs. ISO9001/IATF16949 Standard Requirements
LAE-QM-06	Lord APS EPM Procedure Cross-Reference to Quality Manual and Requirements

3 Quality Policy

LORD Corporation is committed to providing products and services that consistently meet our customers' expectations of quality and value. We continually monitor and improve our processes as a means to ensure overall customer satisfaction, achieve our quality objectives, and share best practices.

This quality policy has been established by senior management of LORD Corporation to guide the actions of all employees regarding quality. To ensure that it is understood and implemented at all levels of LORD, the quality policy is explained and discussed during general orientation of new employees, and is reviewed annually with all employees.

All employees are responsible for understanding their customers' and co-workers' requirements and the processes by which they are met, and for performing these processes as defined. In addition, all employees are empowered to initiate improvement actions within established change guidelines, and are expected to participate in formal improvement initiatives to assure that changing customer and co-worker value expectations are continually met.

4 Context of the organization

4.1 Understanding the organization and its context

LAE determines external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. LAE monitors and reviews information in regards to these issues.

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 to meet customer and applicable statutory and regulatory requirements, LAE determines, monitors, and reviews information in relation to:

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

4.3 Determining the scope of the quality management system

LAE has considered the following and determined the scope of the quality management system;

- a) External and internal issues;
- b) Requirements of relevant interested parties;
- c) Products and services of the organization.

For site specific QMS scope summaries, see LAE-QM-05. LAE applies the requirements of ISO 9001:2015 and IATF 16949:2016 as they are applicable within the determined scope of the Quality Management System (QMS).

4.3.1 [Determining the scope of the quality management system – supplemental]

[LAE has included supporting functions, whether on-site or remote (such as design centers, corporate headquarters, and distribution centers), in the scope of the QMS.]

4.3.2 [Customer specific requirements]

LAE evaluates and includes in the scope of the organization's quality management system the Customer-specific requirements through the use of a global software system, GUKSA, for evaluation and comparison to IATF requirements and exceptions. This is also supported with a customer specific requirements matrix, LAE-QM-07.

4.4 Quality management system and its processes

4.4.1

LAE maintains and implements a documented quality management system (QMS) and continually improves its effectiveness in accordance with the requirements of the applicable quality system standards and specific customer and statutory and regulatory requirements.

LAE determines the processes needed for the QMS and their application throughout LAE;

- a) determines the inputs required and the outputs expected from these processes;
- b) determines the sequence and interaction of these processes;
- c) determines and applies criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) assigns the responsibilities and authorities for these processes;
- f) addresses the risks and opportunities in these processes;
- g) evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results;
- h) improves the processes and the QMS.

4.4.1.1 [Conformance of products and processes]

[When processes that affect product conformity with requirements are outsourced, LAE maintains responsibility for meeting customer, statutory, and regulatory requirements by ensuring appropriate controls over such processes. LAE identifies the type and extent of control to be applied within the QMS].

4.4.1.2 [Product safety]

[LAE maintains documented processes for the management of all product-safety related products and manufacturing processes, which include but are not limited to the following, where applicable:

- a) identification by the organization of statutory and regulatory product-safety requirements;*
- b) customer notification of requirements in item a.);*
- c) special(customer) approvals for design FMEA;*
- d) identification of product safety-related characteristics;*
- e) identification and controls of safety-related characteristics or product and at the point of manufacture;*
- f) special(customer) approval of control plans and process FMEAs;*
- g) reaction plans;*
- h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;*
- i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;*
- j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes;*
- k) transfer of requirements with regard to product safety throughout supply chain, including customer-designated sources;*
- l) product traceability by manufactured lot (at a minimum) throughout the supply chain;*
- m) lessons learned for new product introduction.]*

4.4.2

LAE maintains documented information to support the operation of its processes and retains documented information to have confidence that the processes are being carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Executive management (Division General Managers) provides evidence of its leadership and commitment to the development and implementation of the QMS and continually improving its effectiveness by:

- a. Taking accountability for the effectiveness of the QMS;
- b. Ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization;
- c. Ensuring the integration of the QMS requirements into the LAE business processes;
- d. Promoting the use of the process approach and risk-based thinking;
- e. Ensuring the resources needed for the quality QMS are available;
- f. Communicating the importance of effective quality management and of conforming to the QMS requirements;
- g. Ensuring that the QMS 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.

5.1.1.1 [Corporate Responsibility]

[LAE has defined and implemented corporate responsibility in our Parker Hannifin Code of Conduct, which includes anti-bribery and ethics, with hot line. The Code of Conduct is re-affirmed annually.]

5.1.1.2 [Process effectiveness and efficiency]

[Top management reviews the product realization processes and support processes to evaluate and improve their effectiveness and efficiency. The results of these reviews are included as input to the management review.]

5.1.1.3 [Process Owners]

[LAE 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 these roles.]

5.1.2 Customer Focus

Senior management (responsible functional managers) ensures that customer; statutory and regulatory requirements are determined, understood and met with the aim of enhancing customer satisfaction, by ensuring the establishment of processes for identification, review and implementation of customer requirements and monitoring of customer satisfaction.

There is a focus on ensuring;

- a) Risks and opportunities that can affect conformity to products and services and the ability to enhance customer satisfaction are determined and addressed;
- b) Enhancing customer satisfaction is maintained.

5.2 Policy (see section 3 of this manual)

Executive management (Division General Managers) ensures that the quality policy:

- a.) Is appropriate to the purpose and context of LAE 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 system.

The quality policy is maintained as documented information in Policy 10-57. The policy is communicated, understood and applied within the organization.

5.3 Organizational roles, responsibilities and authorities

Senior management (responsible functional managers) defines and communicates responsibilities and authorities for relevant roles within LAE through organization charts, position descriptions, and operating policies and procedures. This includes responsibilities and authorities for;

- a.) Ensuring that the quality management system conforms to the requirements of the applicable international standards;
- b.) Ensuring that the processes are delivering their intended outputs;
- c.) Reporting on the performance of the QMS and on opportunities for improvement, in particular to top management;
- d.) Ensuring the promotion of customer focus throughout LAE;
- e.) Ensuring that the integrity of the QMS maintains when changes to the QMS are planned and implemented.

5.3.1 [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 and includes 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]

5.3.2 [Responsibility and authority for product requirements and corrective actions]

[Managers with responsibility and authority for corrective action are promptly informed of products and processes that do not conform to requirements.]

Personnel responsible for product quality have the authority to stop production to correct quality problems.

Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring product quality.]

6. Planning

6.1 Actions to address risks and opportunities

Senior management (responsible functional managers) ensure that when planning for the QMS, LAE shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine 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.

LAE senior management (responsible functional managers) shall plan:

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

6.2 Quality objectives and planning to achieve them

6.2.1

Executive management (Division General Managers) ensures that quality objectives, including those needed to meet product requirements, [*customer requirements*] and to deploy the quality policy, are established and documented at relevant functions and levels within LAE. Measurable quality objectives are established during the annual planning process and are included in the business plan and documented in Corporate Policy 10-58.

LAE Quality objectives are:

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

6.2.2

When planning how to achieve its quality objectives, LAE 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.

6.2.2.1 [Quality objectives and planning to achieve them – supplemental]

[The results of LAE's review regarding interested parties and their relevant requirements are considered when LAE establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).]

6.3 Planning of Changes

Senior management (responsible functional managers) ensures that the integrity of the QMS is maintained when changes to the QMS are planned and implemented. Changes to the quality system are approved by applicable regulatory authorities and customers, if required, prior to implementation. When planning changes LAE considers:

- a) the purpose of changes and their potential consequences;
- b) the integrity of the QMS;

- c) the availability of resources;
- d) the allocation or reallocation of responsibilities and authorities.

7. Support

7.1 Resources

7.1.1 General

LAE determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. LAE considers:

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

7.1.2 People

LAE 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

LAE determines, provides, and maintains the infrastructure necessary for the operation of its processes; and to achieve conformity of products and services. To include:

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

7.1.3.1 [Plant, facility, and equipment planning]

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

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

Methods are developed and implemented to evaluate manufacturing feasibility for new product/new operations and proposed changes to existing operations. Manufacturing feasibility assessments are included in capacity planning.

LAE maintains process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance(8.5.1.1), and verification of job set-ups(8.5.1.3).

Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management reviews (9.3)]

7.1.4 Environment for the operation of processes

LAE determines and manages the work environment needed to achieve conformity to product requirements. Additionally, LAE strives to ensure productive, quality-oriented employees by providing appropriate compensation and a safe and healthy work.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

LAE determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

LAE ensures that the resources provided for monitoring and measurement are suitable for the specific type of monitoring and measurement activities being undertaken. The resources are maintained to ensure their continuing fitness for purpose.

7.1.5.1.1 [Measurement system analysis]

[LAE conducts statistical studies to analyze the variation present in the results of each type of measuring and test equipment system. This requirement applies to measurement systems referenced in the control plan. The analytical methods and acceptance criteria conform to those in the customer reference manuals on measurement system analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

Records of customer acceptance of alternative methods are retained along with results from alternative measurement systems analysis (9.1.1.1).]

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered 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 shall be 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.

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

7.1.5.2.1 [Calibration/Verification records]

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

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

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

7.1.5.3 [Laboratory requirements]

7.1.5.3.1 [Internal laboratory]

[LAE's internal laboratories have a defined scope that includes its capability to perform the required inspection, test or calibration services. This laboratory scope is included in the quality management system documentation.

The laboratories specify and implement, as a minimum, technical requirements for:

- a) *adequacy of the laboratory procedures,*
- b) *competence of the laboratory personnel,*
- c) *testing of the product,*
- d) *capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); when no national or international standard is available, LAE defines and implements a methodology to verify measurement system capability;*
- e) *customer requirements if any;*
- f) *review of related records].*

7.1.5.3.2 [External laboratory]

[External/commercial/independent laboratory facilities used for inspection, test or calibration services by LAE have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration. The external laboratory shall be:

- a) *evidence that the external lab is acceptable to the customer;*

- b) be accredited to ISO/IEC 17025 or national equivalent and include the relevant inspection, test, or calibration service in the scope of the accreditation; the certificate of the calibration or test report shall include the mark of a national accreditation body;*
- c) performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment].*

7.1.6 Organizational knowledge

LAE determines the knowledge necessary for the operation of processes and to achieve conformity of products and services. LAE strives to maintain this knowledge and make available to the correct persons at the extent needed to ensure continuances of processes. LAE reviews changing needs and trends, and considers its current knowledge and determines whether to acquire any necessary additional knowledge and required updates. LAE reviews skill levels and needs within processes ongoing and adjusts to future needs and requirements.

7.2 Competence

Personnel performing work directly or indirectly affecting conformity to product requirements are competent on the basis of appropriate education, training, skills, and experience.

LAE assures that personnel are adequately prepared for their responsibilities. Each department manager:

- a) determines the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provides training or takes other actions to achieve the necessary competence,
- c) evaluates the effectiveness of the actions taken,
- d) ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintains appropriate records of education, training, skills, and experience.

7.2.1 [Competence – supplemental]

[LAE has established and documented a process for identifying training needs including awareness (7.3.1) and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements]

7.2.2 [Competence – on-the-job-training]

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

7.2.3 [Internal auditor competency]

[LAE maintains a documented process verifying internal auditors are competent, taking into account any customer-specific requirements. LAE maintains a list of qualified auditors. Documented information is retained to demonstrate the trainer's competency for all requirement's.

LAE quality management system auditors, manufacturing process auditors, and product auditors shall all be able to demonstrate the following minimum competencies:

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

Additionally, manufacturing process auditors demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis(PFMEA) and control plan. Product auditors demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.

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

- f) *executing a minimum number of audits per year, as defined by LAE; and*
- g) *maintaining knowledge of relevant requirements based on internal changes and external changes.]*

7.2.4 [Second-party auditor competence]

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

- a) *the automotive process approach to auditing, including risk based thinking;*
- b) *applicable customer and organization specific requirements;*
- c) *applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;*
- d) *applicable manufacturing process(es) to be audited, including PFMEA and control plan;*
- e) *applicable core tools requirements related to the scope of the audit;*
- f) *how to plan, conduct, prepare audit reports, and close out audit findings.*

7.3 Awareness

LAE ensures that persons performing work 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;

7.3.1 [Awareness – Supplemental]

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

7.3.2 [Employee motivation and empowerment]

[LAE has processes (such as team incentive and lean manufacturing) to motivate employees to achieve quality objectives, make continual improvements, and to create an environment to promote innovation. These processes include the promotion of quality and technical awareness throughout the organization.]

7.4 Communication

LAE has established appropriate internal and external communication processes and communicates information regarding the QMS including:

- a) on 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

LAE quality management system includes:

- a) documented information required by the relevant international standards;
- b) documented information determined to be necessary for the effectiveness of the QMS.

7.5.1.1 [Quality management system documentation]

[This manual is maintained by Global Quality Management in accordance with document control requirements and includes:

- a) *the scope of the QMS, including details of and justification for any exclusion;*
- b) *documented processes established for the QMS, or reference to them;*
- c) *a description of the interaction between the processes of the QMS (see associated document LAE-QM-01);*
- d) *a document indicating where within the organization's quality*

Documented procedures have been established for the QMS. LAE maintains a cross-reference of the relationship between the various QMS requirements and the documented QMS procedures (see associated document LAE-QM-06, "Procedure Cross-Reference to Requirements").]

7.5.2 Creating and updating

When creating and updating documented information, LAE ensures appropriate:

- a) identification and description (title, date, owner, document 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 QMS and by relevant international standards is controlled to ensure:

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

7.5.3.2

A documented process is maintained to define the controls needed:

- a) to ensure proper distribution, access, retrieval and use;
- b) to ensure proper storage and preservation, including preservation of legibility;
- c) to ensure control of changes (version control);
- d) to ensure that documents of external origin that are necessary as determined by LAE for the planning and operation of the QMS are identified and their distribution controlled, and
- e) for retention and disposition;

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

[7.5.3.2.1 Record retention]

[LAE establishes and maintains records that provide evidence of conformity to requirements and of the effective operation of the QMS. These records are controlled to assure that they remain legible, readily identifiable and retrievable. A documented procedure has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records, [including records that are created by and/or retained by suppliers]. Records are available for review by customers and/or regulatory authorities in accordance with contract or regulatory requirements, for the specified record retention period.]

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

[7.5.3.2.2 Engineering specifications]

[LAE has implemented a process to ensure the timely review, distribution, and implementation of all customer engineering standards/specifications and changes based on customer-required schedule. The review of customer engineering standards/specifications and changes that impact delivery of customer requirements are completed within 2 weeks of receipt of notification of change. LAE maintains a record of the date on which each change is implemented in production. Implementation includes updated documents and if required, customer approval of changes.]

8. Operation

8.1 Operational planning and control

LAE plans, implements, and controls the processes needed to meet the requirements for the provision of products and services, and to implement the actions determined to address risks and opportunities by;

- a) determining the requirements for the products and services;
- b) establishing criteria for:
 - 1. the processes;
 - 2. the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and service requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information to the extent necessary;

- (1) to have confidence that the processes have been carried out as planned;
- (2) to demonstrate the conformity of products and services to their requirements.

The output of this planning is in a form suitable for LAE's method of operation and may vary based on the producing plant. LAE controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. LAE ensures that outsourced processes are controlled.

8.1.1 [Operational planning and control – supplemental]

[LAE includes customer the following when planning for product realization:

- a) customer product requirements and technical specifications;*
- b) logistics requirements;*
- c) manufacturing feasibility;*
- d) project planning;*
- e) acceptance criteria.]*

8.1.2 [Confidentiality]

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

8.2 Requirements for products and services

8.2.1 Customer communication

LAE determines and implements effective arrangements for communicating with customers in relation to:

- a) providing information in relation to products and services;
- b) handling enquiries, contract, or order handling, including changes;
- c) customer feedback, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

8.2.1.1 [Customer communication – supplemental]

[Written or verbal language is in the language agreed upon with the customer. When required, LAE communicates necessary information, including data, in a customer specified language and format (e.g. computer-aided design data, electronic data exchange).]

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, LAE 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 LAE;
 - (3) *supplemental [includes but not limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.]*
- b) the claims for the products and services offered, can be met.

8.2.2.1 [Determining the Requirements for Products and Services – supplemental]

[These requirements include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes.]

8.2.3 Review of the requirements for products and services

8.2.3.1

LAE reviews the requirements related to products and services, during quotation or order review/entry. This review is conducted prior to LAE's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and includes:

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

Where the customer provides no documented statement of requirement, LAE confirms the customer requirements before acceptance via a confirmation document provided to the customer.

Where product requirements are changed, LAE ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

8.2.3.1.1 [Review of the requirements for products and services – supplemental]

[LAE retains documented evidence of customer-authorized waiver for requirements]

8.2.3.1.2 [Customer-designated special characteristics]

[LAE demonstrates conformity to customer requirements for designation, documentation and control of special characteristics].

8.2.3.1.3 [Organization manufacturing feasibility]

[LAE utilizes a multidisciplinary approach to conduct an analysis to determine it is feasible that LAE's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer. LAE conducts feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design.]

8.2.3.2

Documented information is retained on the results of the review and on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

LAE 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

LAE maintains a *[documented]* design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.1.1 [Design and Development of Products and services – supplemental]

LAE's design and development processes focus on error prevention rather than detection.

8.3.2 Design and development planning

During the design and development planning, LAE considers:

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

8.3.2.1 [Design and development planning – supplemental]

[LAE ensures that design and development planning includes all affected stakeholders within LAE and, as appropriate, its supply chain. This multidisciplinary approach typically includes design, manufacturing, engineering, quality, production, purchasing, supplier, and other functions as appropriate.]

8.3.2.2 [Product design skills]

[LAE 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 LAE.]

8.3.2.3 [Development of products with embedded software]

[LAE does not have any products with embedded software. A process for embedded software does not apply.]

8.3.3 Design and development inputs

In determining the requirements essential for the specific type of products and services to be designed and developed. LAE 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 LAE 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. All conflicting design and development inputs are resolved. Documented information on design and development inputs are retained.

8.3.3.1 [Product design input]

[LAE identifies, documents, and reviews product design input requirements as a result of contract review. Product design input requirements include but are not limited to the following:

- a) product specifications including special characteristics;*
- b) boundary and interface requirements;*
- c) identification, traceability, and packaging;*
- d) consideration of design alternatives;*
- e) assessment of risks with the input requirements and LAE's ability to mitigate/manage the risks, including from the feasibility analysis;*
- f) targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;*
- g) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;*
- h) embedded software requirements.*

LAE 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 similar nature.]

8.3.3.2 [Manufacturing process design input]

[LAE identifies, documents, and reviews manufacturing process design input requirements including the following:

- a) product design output data including special characteristics;*
- b) targets for productivity, process capability, timing, and cost;*
- c) manufacturing technology alternatives;*
- d) customer requirements, if any;*
- e) experience from previous developments;*
- f) new materials;*
- g) product handling and ergonomic requirements; and*
- h) design for manufacturing and design for assembly.*

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

8.3.3.3 [Special characteristics]

[LAE 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 LAE, including the following:

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

8.3.4 Design and development controls

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

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

8.3.4.1 [Monitoring]

Measurements at specified stages of design and development of products and processes are defined, analyzed and reported with summary results as an input to management review. When required by the customer, these measurements are reported to the customer at stages specified, or agreed to.]

8.3.4.2 [Design and development validation]

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

Where contractually agreed with a customer, this includes evaluation of the interaction of the organization's product, including imbedded software, within the system of the final customer's product.]

8.3.4.3 [Prototype program]

[When required by the customer, LAE has a prototype program and control plan. LAE uses, whenever possible, the same suppliers, tooling and manufacturing processes that will be used in production.

All performance testing activities are monitored for timely completion and conformity to requirements.

While services may be outsourced, LAE is responsible for the outsourced services, including technical leadership.]

8.3.4.4 [Product approval process]

[LAE maintains and implements a product and manufacturing approval process conforming to requirements defined by the customer. LAE approves externally provided products and services per ISO 9001, section 8.4.3, prior to submission of their part approval to the customer.

LAE obtains documented product approval prior to shipment, if required by the customer. Records of approvals are retained.]

8.3.5 Design and development outputs

LAE 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.

LAE retains documented information on design and development inputs.

8.3.5.1 [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 outputs include, as applicable:

- a) design risk analysis (FMEA);*
- b) reliability study results;*
- c) product special characteristics;*
- d) results of product design error-proofing, such as DFSS, DFMEA, and FTA;*
- e) product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);*
- f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T)*
- g) product design review results;*
- h) service diagnostic guidelines and repair and serviceability instructions;*
- i) service part requirements;*
- j) packaging and labeling requirements for shipping.]*

8.3.5.2 [Manufacturing process design output]

[LAE documents the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The outputs are verified against the manufacturing process design input requirements. The manufacturing process design output includes:

- a) specification and drawings;*
- b) special characteristics for product and manufacturing processes;*
- c) identification of process input variables that impact characteristics;*
- d) tooling and equipment for production and control, including capability studies of equipment and processes;*
- e) manufacturing process flow charts/layout, including linkage of product, process, and tolling;*
- f) capacity analysis;*
- g) manufacturing process FMEA;*
- h) maintenance plans and instructions;*
- i) control plan;*
- j) standard work and work instructions;*
- k) process approval acceptance criteria;*
- l) data for quality, reliability, maintainability, and measurability;*
- m) results of error-proofing identification and verification, as appropriate;*
- n) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.]*

8.3.6 Design and development changes

LAE 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.

Documented information is retained on:

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

8.3.6.1 [Design and development changes – supplemental]

[All design changes are evaluated after initial product approval, including those proposed by LAE 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, documented approval or a documented waiver is obtained from the customer prior to production implementation.

For products with embedded software, the revision level of software and hardware shall be recorded as part of the change record.]

8.4 Control of externally provided processes, products, and services

8.4.1 General

LAE ensures that externally provided processes, products and services conform to requirements.

LAE 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 LAE products and services;
- b) products and services are provided directly to the customer by external providers on behalf of LAE;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by LAE.

Criteria is determined and applied for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Documented information is retained on these activities and any necessary actions arising from the evaluations.

8.4.1.1 [General supplemental]

[LAE 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.]

8.4.1.2 [Supplier selection process]

[LAE manages a documented supplier selection process, which includes:

- a) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;*
- b) relevant quality and delivery performance;*
- c) an evaluation of the supplier's quality management system;*
- d) multidisciplinary decision making; and*
- e) an assessment of software development capabilities, if applicable.]*

8.4.1.3 [Customer-directed sources (direct buy)]

[When specified by the customer, LAE purchases products, materials, or services from customer-directed sources. All requirements of 8.4 (except 8.4.1.2) are applicable to LAE's control of customer-directed sources unless specific agreements are defined by contract between LAE and the customer.]

8.4.2 Type and extent of control

LAE ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers by:

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

8.4.2.1 [Type and extent of control – supplemental]

[LAE 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 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.]

8.4.2.2 [Statutory and regulatory requirements]

[LAE 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, LAE ensures they are implemented and maintained as defined, including at suppliers.]

8.4.2.3 [Supplier quality management system development]

[LAE 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, with the ultimate objective of becoming certified to IATF 16949.]

8.4.2.3.1 [Automotive product-related software or automotive products with imbedded software]

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

A software development assessment methodology is utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, LAE requires the supplier to retain documented information of a software development capability self-assessment.]

8.4.2.4 [Supplier monitoring]

[LAE maintains 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. The following supplier performance indicators are monitored:

- a) delivered product conformity to requirements;*
- b) customer disruptions at the receiving plant, including yard holds and stop ships;*
- c) delivery schedule performance;*
- d) number of occurrences of premium freight.*

If provided by the customer, LAE also includes the following as appropriate, in the supplier performance monitoring:

- e) special status customer notifications related to quality or delivery issues;*
- f) dealer returns, warranty, field actions, and recalls.]*

8.4.2.4.1 [Second-party audits]

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

- a) supplier risk assessment;*
- b) supplier monitoring;*
- c) supplier QMS development;*
- d) product audits;*
- e) process audits.*

Based on risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, LAE documents the criteria for determining the need, type, frequency, and scope of second-party audits. Records are maintained of second-party audit reports.

If the scope of the second-party audit is to assess the supplier's QMS, then the approach is consistent with the automotive process approach.]

8.4.2.5 [Supplier development]

[LAE determines the priority, type, extent and timing of required supplier development actions for its active suppliers. Determination inputs include the following:

- a) performance issues identified through supplier monitoring;*
- b) second-party audit findings;*
- c) third-party quality management system certification status;*

d) *risk analysis.*

LAE implements actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.]

8.4.3 Information for external providers

LAE ensures the adequacy of requirements prior to their communication to the external provider:

- a) the processes, products and services to be provided;
- b) the approval of:
 - a. products and services;
 - b. methods, processes and equipment;
 - c. the release of products and services;
- c) competence, including and required qualification of persons;
- d) the external providers interactions with LAE;
- e) control and monitoring of the external providers performance to be applied by LAE;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers premises.

8.4.3.1 [Information for external providers – supplemental]

[LAE flows down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.]

8.5. Production and service provision

8.5.1 Control of production and service provision

LAE maintains production and service provision under controlled conditions, including as applicable:

- a) the availability of documented information that defines:
 - a. the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - b. the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
- d) the use of suitable infrastructure and environment for the operation of processes;
- e) the appointment of competent persons, including any required qualification;
- f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery and post-delivery activities.

8.5.1.1 [Control plan]

[LAE develops 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. LAE maintains control plans for pre-launch and production that shows linkage and incorporates information from the design risk analysis, process flow diagram, and manufacturing process risk analysis outputs.

LAE provides, when required by the customer, measurement and conformity data collected during execution of either the pre-launch or production control plans. Control plans include:

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

LAE reviews control plans, and updates as required, for any of the following:

- f) *determination of shipped nonconforming product to customer;*

- g) *when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis(FMEA);*
- h) *after a customer complaint and implementation of the associated corrective action, when applicable;*
- i) *at a set frequency based on a risk analysis.*

If required by the customer, LAE obtains customer approval after review or revision of the control plan.]

8.5.1.2 [Standardized work – Operator instructions and visual standards]

[LAE ensures that standardized work documents are:

- a) *communicated to and understood by the employees who are responsible for performing the work;*
- b) *legible;*
- c) *presented in the language(s) understood by the personnel responsible to follow them;*
- d) *accessible for use at the designated work area(s), and*
- e) *include rules for operator safety.]*

8.5.1.3 [Verification of job set-ups]

[LAE facilities:

- a) *verify job set-ups when performed, such as an initial run of a job, material changeover, or job change that requires a new set-up.*
- b) *maintain documented information for set-up personnel;*
- c) *use statistical methods of verification, where applicable;*
- d) *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;*
- e) *retain records of process and product approval following set-up and first-off/last-off part validations.]*

8.5.1.4 [Verification after shutdown]

[LAE defines and implements the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.]

8.5.1.5 [Total productive maintenance]

[LAE maintains a documented total productive maintenance system, including the following:

- a) *identification of process equipment necessary to produce conforming product at the required volume;*
- b) *availability of replacement parts for the equipment identified in item a);*
- c) *provision of resource for machine, equipment, tooling, and gaging;*
- d) *packaging and preservation of equipment, tooling, and gaging;*
- e) *applicable customer-specific requirements;*
- f) *documented maintenance objectives and preventive maintenance compliance metrics;*
- g) *regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;*
- h) *use of preventive maintenance methods;*
- i) *use of predictive maintenance methods, as applicable;*
- j) *periodic overhaul.]*

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

[LAE provides resources for tool and gage design, fabrication and verification activities.

LAE establishes and implements a system for production tooling management, whether owned by LAE or the customer including:

- a) *maintenance and repair facilities and personnel;*
- b) *storage and recovery;*
- c) *set-up;*
- d) *tool-change programs for perishable tools;*
- e) *tool design modification documentation, including engineering change level of the product;*
- f) *tool modification and revision to documentation, and*
- g) *tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.*

LAE verifies that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

LAE monitors these activities when work is outsourced.]

8.5.1.7 [Production scheduling]

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

LAE includes relevant planning information during production scheduling, e.g., customer orders, supplier on-time-delivery performance, capacity, shared loading, lead time, inventory level, preventive maintenance, and calibration.]

8.5.2 Identification and traceability

LAE uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The status of outputs are identified with respect to monitoring and measurement requirements throughout production and service provision. LAE controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

8.5.2.1 [Identification and traceability – supplemental]

[LAE conducts an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans define the appropriate traceability systems, processes, and methods by product, process and manufacturing location that:

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

8.5.3 Property belonging to customers or external providers

LAE exercises care with customer property while it is under LAE's control or being used by LAE. LAE identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the product and services. If the customers' or external providers' property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or external provider and records maintained.

8.5.4 Preservation

LAE preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.4.1 [Preservation –supplemental]

- a) [Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.*
- b) It 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.*
- c) In order to detect deterioration, LAE assesses at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment.*
- d) LAE uses inventory management systems to optimize inventory turns over time and ensure stock rotation.*
- e) LAE ensures that obsolete product is controlled in a manner similar to that of nonconforming product.*
- f) LAE complies with preservation, packaging, shipping, and labeling requirements as provided by their customers.]*

8.5.5 Post-delivery activities

LAE meets requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the following are considered:

- 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;

8.5.5.1 [Feedback of information from service]

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

8.5.5.2 [Service agreement with customer]

[When there is a service agreement with the customer, LAE:

- a) verifies that the relevant service center complies with applicable requirements;*
- b) verifies the effectiveness of any special purpose tools or measurement equipment;*
- c) ensures that all service personnel are trained in applicable requirements.]*

8.5.6 Control of changes

LAE reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. Documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review is retained.

8.5.6.1 [Control of changes – supplemental]

[LAE maintains a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by LAE, the customer, or any supplier, are assessed. LAE:

- a) defines verification and validation activities to ensure compliance with customer requirements;*
- b) validates changes before implementation;*
- c) documents the evidence of related risk analysis;*
- d) retains records of verification and validation.*

Changes including those made at suppliers, require a production trial run for verification of changes (including changes of part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.

When required by the customer, LAE:

- e) notifies the customer of any planned product realization changes after the most recent product approval;*
- f) obtains documented approval, prior to implementation of the change;*
- g) completes additional verification or identification requirements, such as production trial run and new product validation.]*

8.5.6.1.1 [Temporary change of process controls]

[LAE identifies, documents, and maintains 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.

LAE documents the process that manages the use of alternate control methods. This process includes, based on risk analysis, severity, and the internal approvals to be obtained prior to production implementation of the alternative control method.

Before shipping product that was inspected or tested using the alternate method, if required, LAE obtains customer approval. LAE maintains and periodically reviews the list of approved alternate process control methods that are referenced in the control plan as applicable.

Standard work instructions are available for each alternate process control method. LAE reviews the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. 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.

LAE maintains traceability of all product produced while any alternate process control device or process is being used.]

8.6 Release of products and services

LAE 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.

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

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

8.6.1 [Release of products and services – supplemental]

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

LAE ensures that the planned arrangements for initial release of products and services encompass product or service approval. Product and service approval is accomplished after changes following initial release.]

8.6.2 [Layout inspection and functional testing]

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

8.6.3 [Appearance items]

[For manufacturing parts designated by the customer as “appearance items”, LAE provides:

- a) appropriate resources, including lighting, for evaluation;*
- b) masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), and haptic technology, as appropriate;*
- c) maintenance and control of appearance masters and evaluation equipment;*
- d) verification that personnel making appearance evaluations are competent and qualified to do so.]*

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

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

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

8.6.5 [Statutory and regulatory conformity]

[Prior to release of externally provided products into the production flow, LAE confirms and provides evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and in the customer-identified countries of destination, if provided.]

8.6.6 [Acceptance criteria]

[Acceptance criteria is defined by LAE, and where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level is zero defects.]

8.7 Control of nonconforming outputs

8.7.1

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

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

LAE 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 is verified when nonconforming outputs are corrected.

8.7.1.1 [Customer authorization for concession]

[LAE obtains a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.]

LAE obtains customer authorization prior to further processing for “use as is” and rework dispositions of nonconforming product. If sub-components are re-used in the manufacturing process, that sub-component re-use is clearly communicated to the customer in the concession or deviation permit.

LAE maintains a record of the expiration date or quantity authorized under concession. LAE also ensures compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession is properly identified on each shipping container. LAE approves any requests from suppliers before submission to customer.]

8.7.1.2 [Control of nonconforming product – customer-specified process]

[LAE complies with applicable customer-specified controls for nonconforming product(s).]

8.7.1.3 [Control of suspect product]

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

8.7.1.4 [Control of reworked product]

[LAE utilizes risk analysis methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, LAE obtains approval from the customer prior to commencing rework of the product.]

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

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

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

8.7.1.5 [Control of repaired product]

[LAE utilizes risk analysis methodology to assess risks in the repair process prior to a decision to repair the product. LAE obtains approval from the customer before commencing repair of the product.]

LAE has a documented process for repair confirmation in accordance with the control plan or other relevant documented information.

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

LAE obtains a customer documented authorization for concession for product to be repair. LAE retains documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.]

8.7.1.6 [Customer notification]

[LAE immediately notifies the customer in the event that nonconforming product has been shipped. Initial communication is followed with detailed documentation of the event.]

8.7.1.7 [Nonconforming product disposition]

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

LAE does not divert nonconforming product to service or other use without prior customer approval.]

8.7.2

LAE retains documented information that:

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

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

LAE determines:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when monitoring and measuring is performed;
- d) when the results from monitoring and measurement shall be analyzed and evaluated.

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

9.1.1.1 [Monitoring and measurement of manufacturing processes]

[LAE performs process studies on all new manufacturing processes to verify process capability and to provide additional input for process control, including those for special characteristics.

LAE maintains manufacturing process capability or performance results as specified by the customer's part approval process requirements. LAE verifies that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

- a) measurement techniques;
- b) sampling plans;
- c) acceptance criteria;
- d) records of actual measurement values and/or test results for variable data;
- e) reaction plans and escalation process when acceptance criteria are not met.

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

LAE initiates 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 include containment of product and 100 percent inspection, as appropriate. A corrective action plan is developed and implemented indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable. The plans are reviewed with and approved by the customer, when required.

LAE maintains records of effective dates of process changes.]

9.1.1.2 [Identification of statistical tools]

[LAE determines the appropriate use of statistical tools and verifies that appropriate statistical tools are included as part of the advanced product quality planning (APQP) process and included in the design risk analysis (DFMEA), the process risk analysis (PFMEA), and the control plan.]

9.1.1.3 [Application of statistical concepts]

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

9.1.2 Customer satisfaction

LAE monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled.

9.1.2.1 [Customer satisfaction – supplemental]

[Customer satisfaction with the organization is 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 are based on objective evidence and include:

- a) delivered part quality performance;*
- b) customer disruptions;*
- c) field returns, recalls, and warranty (where applicable);*
- d) delivery schedule performance (including incidents of premium freight);*
- e) customer notifications related to quality or delivery issues, including special status.*

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

9.1.3 Analysis and evaluation

LAE analyzes and evaluates appropriate data and information arising from monitoring and measurement. The results of analysis are used to evaluate:

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

9.1.3.1 [Prioritization]

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

9.2 Internal audit

9.2.1

LAE conducts internal audits at planned intervals to determine whether the quality management system:

- a) conforms to the planned arrangements, applicable QMS standards, customer requirements, applicable statutory and regulatory authority requirements and the QMS requirements established by LAE, and
- b) is effectively implemented and maintained.

9.2.2

LAE includes the following in the internal audit program:

- a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of the 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 action without undue delay;
- f) retain documented information as evidence of the implementation of the audit program and the audit results.

9.2.2.1 [Internal audit program]

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

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

Where LAE is responsible for software development, software development capability assessments are included in the internal audit program.

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

9.2.2.2 [Quality management system audit]

[LAE audits all quality management system processes over each three-year calendar period, according to an annual program, using the process approach to verify compliance with the Automotive QMS standard. Integrated with these audits, LAE samples customer-specific quality management system requirements for effective implementation.]

9.2.2.3 [Manufacturing process audit]

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

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

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

9.2.2.4 [Product audit]

[LAE audits products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements. Where not defined by the customer, LAE defines the approach used.]

9.3 Management review

9.3.1 General

Top management reviews the organization's management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with LAE's strategic direction.

9.3.1.1 [Management review – supplemental]

[Management review is conducted at least annually. The frequency of management review(s) is increased based on risk to compliance with customer requirements.]

9.3.2 Management review inputs

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

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the QMS;
- c) information on the performance and effectiveness of the quality management system, including trends in:
 - a. customer satisfaction and feedback from relevant interested parties;
 - b. the extent to which quality objectives have been met;
 - c. process performance and conformity of products and services;
 - d. nonconformities and corrective actions;
 - e. monitoring and measurement results;

- f. audit results;
- g. the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) opportunities for improvement;

9.3.2.1 [Management review inputs – supplemental]

[Input to management review includes:

- a) cost of poor quality (cost of internal and external nonconformance);*
- b) measures of process effectiveness;*
- c) measures of process efficiency;*
- d) product conformance;*
- e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities of new product;*
- f) customer satisfaction*
- g) review of performance against maintenance objectives;*
- h) warranty performance (where applicable);*
- i) review of customer scorecards (where applicable);*
- j) identification of potential field failures identified through risk analysis;*
- k) actual field failures and their impact on safety or the environment.]*

9.3.3 Management review outputs

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

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

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

9.3.3.1 [Management review outputs – supplemental]

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

10 Improvement

10.1 General

LAE determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These opportunities include:

- a) improving products and service 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 QMS.

10.2 Nonconformity and corrective action

10.2.1

When a nonconformity occurs, including any arising from complaints, LAE:

- a) reacts to the nonconformity and, as applicable:
 - a. takes action to control and correct, it;
 - b. deal with the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - a. reviewing and analyzing the nonconformity;
 - b. determining the causes of the nonconformity;
 - c. determining if similar nonconformities exist, or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the QMS, if necessary.

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

10.2.2

LAE retains documented information as evidence of:

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

10.2.3 [Problem solving]

[LAE maintains a documented process for problem solving including:

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

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

10.2.4 [Error-proofing]

[LAE maintains a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used is documented in the process risk analysis (such as PFMEA) and test frequencies are documented in the control plan.

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

10.2.5 [Warranty management systems]

[LAE implements a warranty management process when required to provide warranty on products. A method for warranty part analysis, including NTF (no trouble found) is included in the process. When specified by the customer, LAE implements the required warranty management process.]

10.2.6 [Customer complaints and field failure test analysis]

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

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

LAE communicates the results of the testing/analysis to the customer and internally.]

10.3 Continual improvement

LAE continually improves the suitability, adequacy, and effectiveness of the QMS. LAE considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities to address as part of continual improvement.

10.3.1 [Continual improvement – supplemental]

[LAE has a documented process for continual improvement, including the following:

- a) identification of the methodology used, objectives, measurement, effectiveness, and documented information;*
- b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;*
- c) risk analysis.]*

