ASYST

QUALITY MANAGEMENT SYSTEM MANUAL

ASYST Technologies,LLC
5811 99th Avenue
Kenosha, WI 53144

ASYST Tecnologías de México
Tres No. 105-1, Parque Industrial Millennium
San Luis Potosí, México, 78395

Approvals

1 Top Management Approval Record

Signature	Date
President	10/18/2024
Vice President, Sales	10/14/24
Vice President, Finance	10/14/24
Vice President, Operations	10/14/24
Director of Supply Chain	10/14/24
Director North American Sales	10/14/2024
Director of R&D	10/14/24
Operations Manager - SLP	
Quality Manager	10/21/24
Engineering Manager	10/14/24
Human Resources Manager	10/14/24

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Director North American Sales	10/14/2024
Director of R&D	10/14/24
Operations Manager - SLP	10/22/24
Quality Manager	10/21/24
Engineering Manager	10/14/24
Human Resources Manager	10/14/24

Review, Approval, Control and Distribution

2 Top Management - Review, approval, control and distribution

Quality Manager ..... Master Hard Copy Kept On File
..... Electronic Master Kept on Network

ASYST has documented and implemented the Quality Management System (QMS) described in this manual. The Quality Manager has the responsibility for obtaining approvals and maintaining the manual.

Top Management has taken primary responsibility for the processes needed by the quality management system as defined in Exhibit 4A, of this manual.

The Quality Manager has the only hard copy of the QMS Manual as stated above. All other QMS Manual hard copies are uncontrolled and conspicuously marked as such.

QMS Manual changes may be requested by any employee within our organization. The responsibility for review and approval of changes rests with the functions that performed the original review and approval. The manual is redistributed as needed when changes occur. Revisions are automatically distributed to all registered holders.

The following Table of Contents is a master list of all sections and their current revision level.

Amendments

2 Amendment Record

Section/page changed	Brief description of change	Approval Date
Entire Manual	Initial Release	11/01/04
Section 4.2.4 Exhibit 4A	Removed reference to "pareto" analysis of production efficiency. Analysis is performed using trend reports.	11/30/04
Section 4.2.4 Exhibit 4C	Removed reference to "major" and "minor" nonconformances.	11/30/04
Section 4.2.4 Exhibit 4C	Updated Quality Objectives table to clarify corrective and preventive action statements	12/13/04
Section 4.2.4 Exhibit 4A	Updated list of key metrics and objectives	12/13/04
Section 8.2.3	Revised paragraph to clarify need for correction and/or corrective action when deemed appropriate	12/13/04
Section 5.5.2	Changed Management Representative from Operations Manager to Quality Manager	1/3/06
Section 5.5.2.1	Changed Customer Representative from Quality Manager to Materials Manager	1/3/06
Exhibit 4A	Updated COP metrics	1/3/06
Exhibit 4C	Updated Quality Objectives to clarify chart type for premium shipments	10/20/06
Section 8.2.2.4	Added paragraph regarding Customer-Specific Audits	10/20/06
Exhibit 4A	Updated COP 2 metrics to remove 100% On-Time Quote Delivery	1/31/07
Exhibit 4C	Removed requirement to track days late by project for on-time delivery "strategy for success"	1/31/07
Approvals Page	Revised Titles	7/30/08
Section 4.2.4	Revised Procedure 4.2.4 Title	7/30/08
Exhibit 4A	Revised COP 1 Metrics	7/30/08
Section 5.6.1	Revised Form 561-01 Title	7/30/08
Section 6.2.2	Revised Procedure 6.2.2 Title	7/30/08
Section 7.6.1	Revised Procedure 7.6.1 Title	7/30/08
Section 8.2.2	Revised Procedure 8.2.2 Title	7/30/08
Approvals Page	Revised Titles	4/13/09
Exhibit 4A	Revised COP 1 Metrics and titles	4/13/09
Section 4.1	Removed year from ISO/TS 16949	1/10/11
Section 4.2.1	Removed year from ISO/TS 16949	1/10/11
Section 4.2.2	Removed year from ISO/TS 16949	1/10/11
Section 4.2.3	Removed year from ISO/TS 16949	1/10/11
Section 7.4.1.2	Removed year from ISO/TS 16949	1/10/11
Section 8.2.2	Removed year from ISO/TS 16949	1/10/11
Section 8.2.2.5	Removed year from ISO/TS 16949	1/10/11
Approval Page	Revised Titles	2/26/14
Section 4.2.2	Revised Scope – change motor vehicle to parts	2/26/14
Exhibit 4A	Revised Titles, changed COP #1 & #6 objective, Updated COP metric	2/26/14
Exhibit 4B	Removed 6.3 Infrastructure	2/26/14
Section 5.6.2	Added status of COPs, quality manual and performance metric reviewed for adequacy as an input	2/26/14
Exhibit 4A	Revised COP3 – Process Owner: Engineering Manager	4/30/14
Approval Page	Revised Titles	12/18/15

Exhibit 4A	Revised COP 1, 2 & 6 – Process Owner: Vice President, Sales	12/18/15
Exhibit 4C	Removed Customer Satisfaction Survey	12/18/15
Exhibit 4C	Removed "Pareto" from section for "Product Conforms to Requirement" and "On-Time Delivery"	9/26/16
Approval Page	Revised Treasurer to Vice President, Finance	9/26/16
Entire document	Revised to compliance with the IATF 16949: 2016 update	9/21/17
Section 4.4.1	Added Product Safety Procedure 4.4.1	3/1/18
Section 10.3.1	Added additional language re: Continual Improvement Procedure 10.3.1	3/1/18
Section 7.5.3.1	Added additional language re: adequate protection	1/9/19
Section 5.2	Revised Quality Policy formatting	10/25/19
Page 2, Approval Record	Added ASYST Tecnologias de Mexico to cover page	10/25/2021
Section 4.2.2	Removed Vice President, Engineering & Quality; added R&D Engineering Manager & Operations Manager - SLP	
Exhibit 4C	Updated COP 4 Owner to Vice President, Operations Change from "Zero Non-conformances" to "Zero Major Non-conformances"	
Page 2, Approval Record	Updated from Human Resources Administrator to Human Resources Manager	2/2/2022
Section 4.2: Determining the Quality Manual Scope	Update Scope	
Section 5.1.1.2: Process Effectiveness and Efficiency	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 6.1.2.1: Risk Analysis	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 6.1.2.3: Contingency Plan	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 7.1.3.1: Plant, Facility, and Equipment Planning	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 7.1.5.3.2: External Laboratory	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 7.2.1: Competence - Supplemental	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 7.2.3: Internal Auditor Competency	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 7.5.1.1: Quality Management System Documentation	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 8.3.3.3: Special Characteristics	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 8.4.2.1: Type & Extent of Control – Supplemental	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 8.4.2.3: Supplier Quality Management System Development	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 8.4.2.4: Supplier Monitoring	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 8.5.6.1.1: Temporary	Update to include the changes in the sanctioned	

Change of Process Controls	interpretations effective August 2021.	
Section 8.7.1.1: Customer Authorization for Concession	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 9.2.2.2: Quality Management System Audit	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 9.3.2.1: Management Review Inputs – Supplemental	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 10.2.3: Problem Solving	Update to include the changes in the sanctioned interpretations effective August 2021.	
Section 8.2.1: Customer Communication	Update to include customer notification of change in certification status.	
Page 2, Approval Record	Added Director of NA Sales	10/11/24
Section 4.1 and 4.2	Updated to include awareness of impact on climate change.	10/11/24

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4 Quality Management System

4.1 Understanding the Organization and Its Context

ASYST has determined the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system, **with an awareness of how our products and processes have an impact on climate change.**

4.2 Understanding the Needs and Expectations of Interested Parties

ASYST has determined the interested parties that are relevant to the quality management system. Furthermore, they have determined the requirements of those interested parties that are relevant to the quality management system, **including those associated with climate change**. This has been completed due to the effect or potential effect they have on ASYST's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

4.2 Determining the Quality Manual Scope

ASYST shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining the scope, ASYST shall consider:

a) The external and internal issues referred to in 4.1;
b) The requirements of relevant interested parties referred to in 4.2;
c) The products and services of the organization.

The scope shall be available and maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of the IATF 16949 Standard that is determined to not be applicable to the scope of the quality management system.

ASYST's Scope is as follows:

The Scope of our Quality Management System is the Design and Manufacture of Plastic Injection Molded Parts, Sealing Devices and Assembly of Parts and Accessories. The quality manual includes:

a) All requirements of IATF 16949,
b) Reference to the documented procedures established for the quality management system, and
c) A description of the interaction between the processes of the quality management system (see **Exhibit 4B**).

4.4 Quality Management System and Its Processes

4.4.1 ASYST has established, documented, implemented, maintained and continually improve a quality management system, including the processes needed and their interactions, based on the requirements of IATF 16949 and our customers.

Our quality management system

a) identifies the processes needed for the quality management system and their application throughout the organization (see **Exhibit 4B**),
b) determine the inputs required and the outputs expected from these processes,
c) determines the sequence and interaction of these processes (see **Exhibit 4B**),

d) determines and applies the criteria and methods needed to ensure that both the operation and control of these processes are effective (see **Exhibit 4A**),
e) ensures the availability of resources and information necessary to support the operation and monitoring of these processes (see **Exhibit 4A**),
f) monitors, measures and analyzes these processes,
g) assigns responsibilities and authorities for these processes,
h) evaluates the processes and implements any changes needed to ensure that these processes achieve their intended results,
i) improves the processes and the quality management system.

These processes are managed by the organization in accordance with the requirements of IATF 16949.

NOTE: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement. Where we have chosen to outsource any process that affects product conformity with requirements, such as heat treat and plating, we have ensured control over such processes. Ensuring control does not absolve ASYST of the responsibility of conformity to all customer requirements. Control of such outsourced processes is identified within our quality management system.

4.4.1.2 ASYST has set forth Procedure 4.4.1: Product Safety to produce product-safety related products and manufacturing processes.

4.4.2 ASYST shall maintain documented information that supports the operation of its processes and shall retain documented information to have confidence that the processes are being carried out as planned.

Exhibit 4A – Criteria & method to ensure process effectiveness:

COP #	Process Description	Process Owner	Objectives	Key Metrics
COP 1	Sales & Customer Service	Vice President, Sales	• Develop new business opportunities. • Grow Annual Sales.	• 10% annual revenue growth
COP 2	Quote, Order & Contract Review	Vice President, Sales	• Increase Annualized Sales Profitable Growth	• 10% annual revenue growth
COP 3	APQP & Product Development	Engineering Manager	• To develop product that meets customer's needs and is within ASYST capabilities to buy and resell, or to produce	• Project Gates timeliness
COP 4	Product Realization	Vice President, Operations / Operations Manager (SLP)	• Make/ fabricate or buy and resell quality product in a timely and efficient manner	• On time Shipment • Total Cost of Quality • Customer PPM • Machine Efficiencies • On-Time Supplier Delivery
COP 5	Delivery	Materials Manager	• On-time shipments of products to customers	• On-Time Shipment
COP 6	Post Sales & Customer Feedback	Vice President, Sales	• Complete Customer Satisfaction • Understand customer perception on needed improvement to better meet their expectation	• On time Shipment • Internal PPM • Customer PPM • Corrective Actions (8Ds)

Exhibit 4B – Interaction Between Processes (Form 441-15)

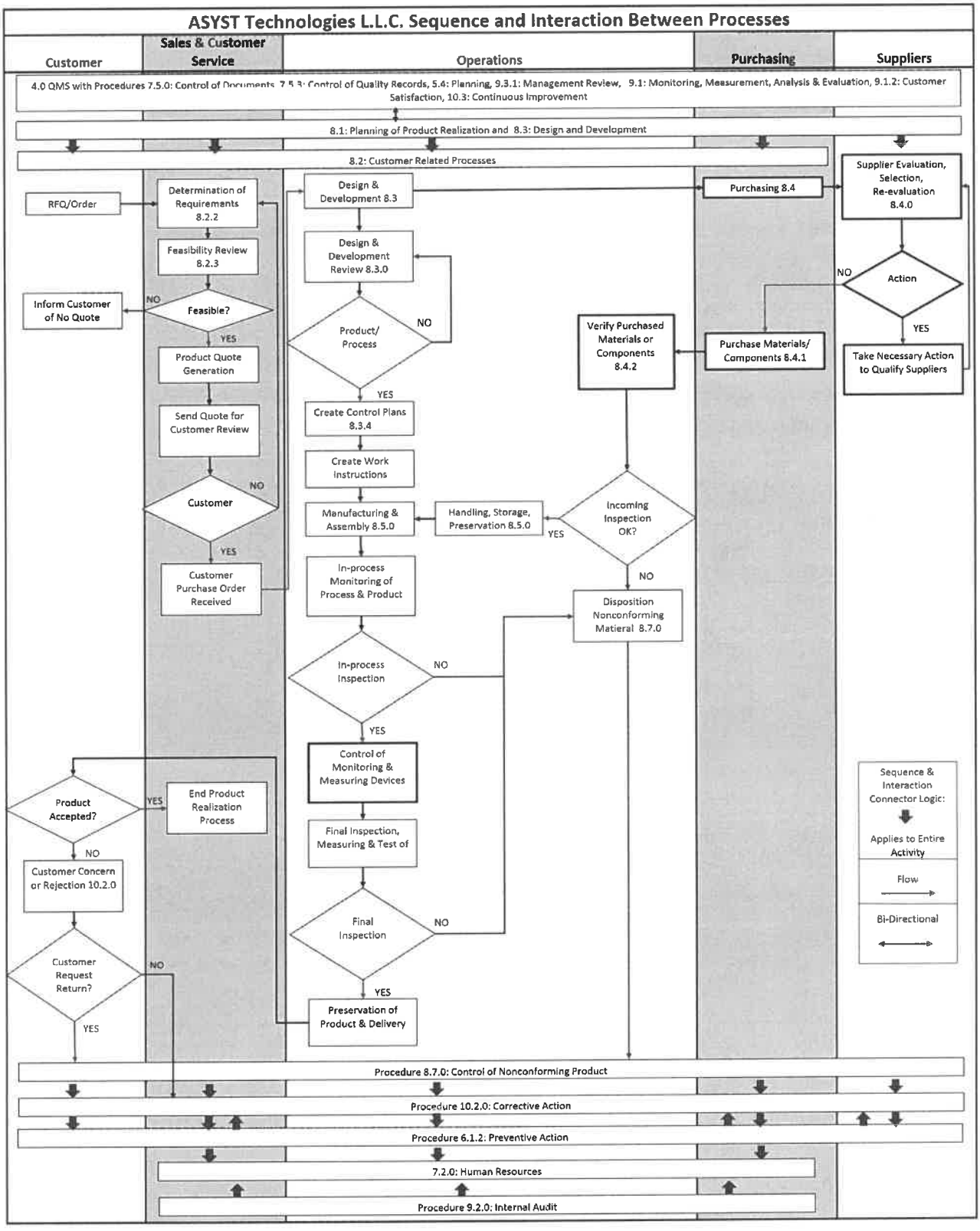


Exhibit 4C – Quality Objectives

Objective	Target	Mechanism	Strategies for Success
Product Conforms to Requirements	100% Conformance	- In-process and Final inspections -Internal Dock Audits -Customer Complaints	Create charts of reject reasons and analyze trends. -Determine if corrective and preventive actions are required to eliminate rejections.
On-Time Delivery (Shipping Variance)	100% On-Time	- Measure On-Time Shipments -Measure Premium Freight (cost) -Document reasons for late delivery.	-Create charts of reasons for late deliveries. -Create run chart showing cost of premium freight as a percent of sales. -Determine if corrective and preventive actions are required to eliminate late deliveries.
Customer Satisfaction	Meet or Exceed Customer Requirements	- Review Customers Performance Reports	-Determine if corrective and preventive actions are required to improve performance.
Improve Core Processes and Effectiveness of Quality Management System	- Zero Major Non-conformances in Quality System Audits - Business Performance meets or exceeds Business Plan	- 8-D Process - Continuous Improvement Process -Record audit findings and discuss issues during management review meetings. -Employee Suggestions	Issue corrective or preventive action when audit findings are classified as nonconformances.

5 Leadership

5.1 Leadership & Commitment

ASYST's top management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

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

5.1.1.1 Corporate Responsibility

ASYST's top management shall define and implement corporate responsibility policies, including an anti-bribery policy, an employee conduct policy and an ethics escalation policy ("whistle-blowing policy"). These are documented in Procedure 5.1.0: Business Ethics and Procedure 5.1.0-01: Employee Conduct Policy.

5.1.1.2 Process Effectiveness & Efficiency

ASYST's top management shall review the effectiveness and efficiency of the quality management system to evaluate and improve the organization's quality management system. The results of the process review activities shall be included as input to the management review.

5.1.1.3 Process Owners

ASYST's top management shall identify process owners who are responsible for management the organization's processes and related outputs. Process owners shall understand their roles and be competent to perform those roles (see 7.2).

5.1.2 Customer Focus

ASYST's top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

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

5.2 Quality Policy

Our quality policy:

We at ASYST Technologies recognize that our products and services are vital to our customers' success and it is every employee's responsibility to take an active role in this success.

Our policy is to:

- **Provide products and services that meet or exceed our customers' requirement.**
- **Measure our performance and commit ourselves to the unending goal of improving our Core Processes and the Quality Management System.**
- **Take an active role in Defect Prevention, Continual Improvement, and Customer Satisfaction.**

ASYST's top management ensures that this quality policy:

a) Is appropriate to the purpose and context of our organization and supports our strategic direction,
b) Includes a commitment to comply with requirements and continually improve the effectiveness of our quality management system,
c) Provides a framework for establishing and reviewing quality objectives,
d) Is communicated, understood and applied within our organization,
e) Is available and maintained as documented information,
f) Is available to relevant interested parties, as appropriate,
g) Is reviewed for continuing suitability.

5.3 Organizational Roles, Responsibilities & Authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign responsibility and authority to the Quality Manager for:

a) Ensuring that the quality management system conforms to the requirements of the standards,
b) Ensuring that the processes are delivering their intended outputs,
c) Reporting on the performance of the quality management system and on opportunities for improvement,
d) Ensuring the promotion of customer focus throughout the organization,
e) Ensuring the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.3.1 Top management has appointed the Director of Supply Chain, a member of management, with responsibility and authority to ensure that customer requirements are addressed. This 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 Top management shall ensure that:

a) Managers with responsibility and authority for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that nonconforming

product is not shipped to the customer and that all potential nonconforming product is identified and contained.

b) Personnel responsible for product quality and conformity to product requirements have the authority to stop shipment and stop production to correct quality problems. If it is not possible to stop production immediately, the affected batch must be contained and shipment to the customer prevented.

c) Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring product quality and conformance to product requirements.

6.0 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 ASYST shall consider the issues in 4.1 and requirements in 4.2 when planning for the quality management system 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.

6.1.2 ASYST shall plan actions to address the risks and opportunities. We shall also plan how to integrate and implement the actions into the quality management system and evaluate the effectiveness of the actions. Actions taken must be proportionate to the potential impact on the conformity of products and services.

6.1.2.1 Risk Analysis

ASYST shall include, at a minimum:

a) Lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework,
b) Cyber-attack threats to information technology systems.

The organization shall retain documented information as evidence of the results of risk analysis.

6.1.2.2 Preventive Action

ASYST determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the severity of the potential problems. Procedure 6.1.2: Preventive Action has been established to define requirements for:

a) Determining potential nonconformities and their causes,
b) Evaluating the need for action to prevent occurrence of nonconformities,
c) Determining and implementing action needed,
d) Documented information of action taken,
e) Reviewing the effectiveness of preventive action taken,
f) Utilizing lessons learned to prevent recurrence in similar processes (see 7.1.6).

6.1.2.3 Contingency Plans

ASYST shall:

a) Identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met,
b) Define contingency plans according to risk and impact to the customer,
c) Prepare contingency plans for continuity of supply in the event of any of the following**, but not** limited to: key equipment failures (see also 8.5.6.1.1); interruption from externally provided products, processes and services; recurring natural disasters; fire; pandemics; utility interruptions; cyber-attacks on information technology systems; labor shortages; or infrastructure disruptions,
d) Include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations,
e) Periodically test the contingency plans for effectiveness (e.g. simulations, as appropriate); for cybersecurity: testing may include a simulation of a cyber-attack, regular monitoring of specific threats, identification of dependencies and prioritization of vulnerabilities. The testing is

appropriate to the risk of associated customer disruption. Note: cybersecurity testing may be managed internally by the organization or subcontracted as appropriate.
f) Conduct contingency plan reviews annually, at a minimum, using a multidisciplinary team, including top management, and update as needed,
g) Document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).
h) Include in the contingency plans the development and implementation of appropriate employee training and awareness.

Contingency plans shall include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

6.2. Quality Objectives and Planning to Achieve Them

6.2.1 Top management has established quality objectives, including those needed to meet requirements for product [see 8.1 a)], at relevant functions and levels within the organization (see Exhibit 4C) and shall maintain documented information on the objectives.

The quality objectives shall:
a) Be consistent with the quality policy,
b) Be measurable,
c) Take into account applicable requirements,
d) Be relevant to conformity of products and services and to enhancement of customer satisfaction,
e) Be monitored,
f) Be communicated,
g) Be updated as appropriate.

6.2.2 When planning how to achieve its quality objectives, ASYST shall determine:
a) What will be done,
b) What resources will be required,
c) Who will be responsible,
d) When it will be completed,
e) How the results will be evaluated.

6.2.2.1 Top management shall ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.

The results of the review regarding interested parties and their relevant requirements shall be considered when top management establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

6.3 Planning of Changes

When ASYST determines the need for changes to the quality management system, the changes shall be carried out in a planned manner.

ASYST shall consider:
a) The purpose of the changes and their potential consequences
b) The integrity of the quality management system,

c) The availability of resources,
d) The allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

ASYST has determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

ASYST shall consider:

a) The capabilities of, and constraints on, existing internal resources,
b) What needs to be obtained from external providers.

7.1.2 People

ASYST has determined and provided 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

ASYST determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure includes our:

a) Buildings, workspace and associated utilities,
b) Process equipment, both hardware and software, and
c) Supporting services such as transport or communication,
d) Information and communication technology.

7.1.3.1 Plant, Facility, and Equipment Planning

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

a) Optimize material flow, material handling, and value-added use of floor space including control of nonconforming product,
b) Facility synchronous material flow, as applicable,
c) Implement cyber protection of equipment and systems supporting manufacturing.

ASYST has developed and implemented methods, including lean manufacturing principles, to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments include capacity planning and are also applicable for evaluating proposed changes to existing operations.

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

7.1.4 Environment for the Operation of Processes

ASYST determines, provides and maintains the work environment needed for the operation of its processes and to achieve conformity to product requirements and services.

A suitable environment is a combination of human and physical factors, which take into consideration:

a) Social factors,
b) Psychological factors,
c) Physical factors.

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

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General
ASYST determines the monitoring and measurement to be undertaken and the monitoring and measuring resources needed to provide evidence of conformity of product to determined requirements.

ASYST ensures that the resources provided:
a) Are suitable for the specific type of monitoring and measurement activities being undertaken,
b) Are maintained to ensure their continuing fitness for their purpose and retains documented information as evidence of fitness for purpose.

7.1.5.1.1 Measurement Systems Analysis
ASYST conducts statistical studies to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used conforms to those in customer reference manuals on measurement system analysis (such as the AIAG Measurement System Analysis-MSA manual). Other methods may be used if approved by the customer.

7.1.5.2 Measurement Traceability
ASYST has established and maintains Procedure 7.1.5: Control of Monitoring and Measuring Devices, to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. When measurement traceability is a requirement, or is considered to be an essential part of providing confidence in the validity of measurement results, the measuring equipment shall be:
a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification are recorded,
b) Adjusted or re-adjusted as necessary,
c) Identified to enable the calibration status to be determined,
d) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

In addition, ASYST assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. ASYST takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained in accordance with clause 7.5.3.

7.1.5.2.1 Calibration/Verification Records
Records of calibration/verification activity for all gauges, measuring and test equipment, including employee and customer-owned equipment, needed to provide evidence of conformity of product to internal requirements, legislative and regulatory requirements, and customer-defined requirements are retained.

ASYST ensures that the calibration/verification activities and records include the following:
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 is us, 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 gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment),
i) Production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment or on-site supplier-owned equipment).

7.1.5.3 Laboratory Requirements

7.1.5.3.1 Internal Laboratory

ASYST's internal laboratory facility has a defined scope that includes capability to perform the required inspection, test or calibration services. The lab scope is included in the quality management system documentation. The lab specifies and implements, as a minimum, technical requirements for:

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

7.1.5.3.2 External Laboratory

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

a) Accreditation to ISO/IEC 17025 or its national equivalent (e.g., CNAS-CL1 in China) by an accreditation body (Signatory) of the ILAC MRA (International Laborary Accreditation Forum Mutual Recognition Arrangement – www.ilac.org) and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report shall include the mark of a national accreditation body.
b) Where a non-accredited laboratory is utilized (for example, but not limited to: specialist or integrated equipment, parameters with no international traceable standard reference, or original equipment manufacturers), the organization is responsible to ensure that there is evidence that the laboratory has been evaluated and meets the requirements of Section 7.1.5.3.1 of IATF 16949.

Note: Integrated self-calibration of measurement equipment, including use of proprietary software, does not meet the requirements of calibration.

7.1.6 Organizational Knowledge

ASYST has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services. Organizational knowledge is knowledge specific to ASYST and generally gained by experience, to be used and shared to achieve ASYST's objectives.

Organizational knowledge is based on:

a) Internal sources, such as intellectual property, knowledge gained from experience, lessons learned from failures and successful projects, capturing and sharing undocumented knowledge and experience, and the results from improvements in processes, products and services.
b) External sources, such as standards, academia, conferences, and gathering knowledge from customers or external providers.

This knowledge will be maintained and made available to the extent necessary.

When addressing changing needs and trends, ASYST considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

ASYST has developed Procedure 7.2.0, Training and Competence of Employees, which includes:

a) Determining the necessary competence for personnel performing work under ASYST's control that affects the performance and effectiveness of the quality management system,
b) Ensuring that the personnel are competent on the basis of appropriate education, training, or experience,
c) Taking actions, where applicable, to acquire the necessary competence, and evaluate the effectiveness of the actions taken,
d) Retaining appropriate documented information as evidence of competence.

7.2.1 Competence – supplemental

Training needs are identified, including awareness (see 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.

To reduce or eliminate risks to the organization, the training and awareness shall also include information about prevention relevant for the ASYST's working environments and employee's responsibilities, such as recognizing the symptoms of pending equipment failure and/or attempted cyber-attacks.

7.2.2 On-the-Job Training

ASYST provides on-the-job training (which includes customer requirements training) for personnel, including contract or agency personnel, in new or modified jobs affecting conformity to quality requirements, internal requirements, and regulatory or legislative requirements. The level of detail required for on-the-job training shall be 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. All employees whose work affects quality are informed of the consequences to the customer of nonconformity to quality and customer requirements.

7.2.3 Internal Auditor Competency

ASYST has developed Procedure 9.2.0: Internal System Audits, which includes a process for verifying the competence of internal auditors, taking into account any requirements defined by the

organization and/or customer-specific requirements. A list of qualified internal auditors is maintained.

Quality management system auditors shall be able to demonstrate the following minimum competencies:

a) An understanding of the automotive process approach for auditing, including risk-based thinking,
b) An understanding of applicable customer-specific requirements,
c) An understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit,
d) An understanding of applicable core tool requirements related to the scope of the audit,
e) An understanding of how to plan, conduct, report, close out audit findings,
f) For manufacturing process auditors, they shall demonstrate, at a minimum, technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan,
g) For product auditors, they shall demonstrate, at a minimum, competence in understanding product requirements and use of relevant measuring and testing equipment to verify product conformity.
h) If the organization's personnel provide the training to achieve competency, documented information shall be retained to demonstrate the trainer's competency with the above requirements.

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

a) Executing a minimum number of audits per year, which ASYST has defined as at least one (1) audit per year,
b) Maintaining knowledge of relevant requirements based on internal changes (e.g., process technology, product technology) and external changes (e.g., ISO 9001, IATF 16949, core tools, and customer specific requirements).

7.2.4 Second-party Auditor Competency

In Procedure 9.2.0: Internal System Audits, the competency requirements of auditors undertaking the second-party audits is also set forth. Second-party auditors meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of:

a) The automotive process approach to auditing, including risk based thinking,
b) Applicable customer and 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 tool requirements related to the scope of the audit,
f) How to plan, conduct, prepare audit reports, and close out audit findings.

7.3 Awareness

ASYST ensures that persons doing work under their control are aware of:

a) The quality policy,
b) Relevant quality objectives,
c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance,
d) The implications of not conforming with the quality management system requirements.

7.3.1 Awareness – Supplemental

ASYST 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

ASYST has established a process to motivate employees to achieve quality objectives, make continual improvements, and to create an environment to promote innovation. This process includes the promotion of quality and technological awareness throughout the organization.

7.4 Communication

Top management has established Procedure 7.4.0: QMS & EMS Communication, which determines the internal and external communications relevant to the quality management system, 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

ASYST's quality management system includes:

a) Documented information required by ISO 9001 and IATF 16949,
b) Documented information ASYST has defined as being necessary for the effectiveness of the quality management system.
c) In addition to our quality policy and quality objectives the following types of documents are used in our quality management system:

Quality Manual	Our *quality manual* provides information about our quality management system.
Procedures	*Procedures* that are required by IATF 16949 and/or by our organization. They specify the way to carry out an activity or process and may cover many different tasks.
Work Instructions	*Work instructions* define "how-to" perform certain tasks where their absence may adversely affect quality and include other documents needed for effective control and operation of our processes.
Specifications	*Specifications* such as customer drawings communicate internal or external requirements.
Records	*Records* are documents that provide objective evidence that activities were performed that may also include the results of those activities.

7.5.1.1 Quality Management System Documentation

ASYST's quality management system is documented through this quality manual, along with the associated procedures, work instructions and forms. A process has been developed as set forth in Procedure 7.5.0: Control of Documents and Data.

At a minimum, the quality manual shall include the following:

a) The scope of the quality management system, including details and justification for any exclusions,
b) Documented processes established for the quality management system, or reference to them,
c) ASYST's processes and their sequence and interactions (inputs and outputs), including the type and extent of control of any outsourced processes,

d) A document (for example, a table, a list, or a matrix) indicating where within the quality management system ASYST's customer-specific requirements are addressed on Form 822-02: Customer Specific Requirements Log.

Note: A matrix of how the requirements of the IATF 16949 standard are addressed by ASYST's processes may be used to assist with linkages of ASYST's processes and the IATF 16949 standard.

7.5.2 Creating and Updating

When creating and updating documented information, ASYST shall ensure appropriate:

a) Identification and description,
b) Format and media,
c) Review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documents required by the quality management system are controlled to ensure:

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

7.5.3.2 For the control of documented information, ASYST has developed Procedure 7.5.0: Control of Documents and Data to address the following activities, as applicable:

a) Distribution, access, retrieval and use,
b) Storage and preservation, including preservation of legibility,
c) Control of changes (e.g. version control),
d) Retention and disposition,
e) Ensure that documents of external origin are identified and their distribution controlled,
f) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.
g) Protect documented information retained as evidence of conformity from unintended alterations.

Quality records are a special type of document and are controlled according to the requirements given in clause 7.5.3.2.1.

7.5.3.2.1 Record Retention

A documented procedure, Procedure 7.5.3, Control of System Records, has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition (including disposal) of quality records. Where applicable and required, records also include those that are customer-specified. The control of records shall satisfy statutory, regulatory, organizational and customer requirements.

Production part approvals (which may include approved product, applicable test equipment records or approved test data), tooling records (including maintenance and ownership), product and process design records, purchase orders, or contracts and amendments shall be 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*

ASYST has a documented process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule found in Procedure 8.3.0: Design and Development and associated work instructions and forms. The review will be as soon as possible but shall not exceed two working weeks. ASYST will maintain a

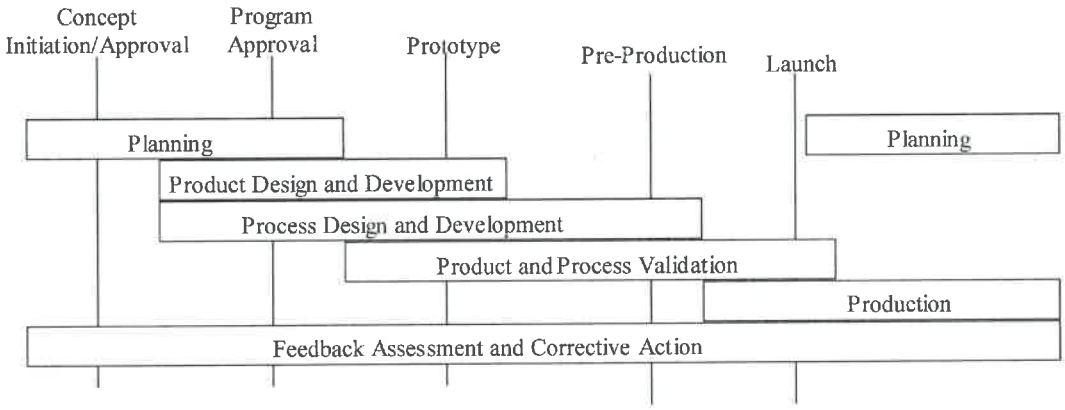
record of the date on which each change is implemented (including updated documentation) in production.

Note: A change in these standards/specifications requires an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, PFMEA, etc.

8 Operation

Exhibit 8A – Design & Development Stages

Asyst APQP Product Realization



8.1 Operational Planning and Control

ASYST has planned, implemented and controlled the processes needed for product realization (see Exhibit 8A). Planning of product realization is consistent with the requirements of the other processes of our quality management system (see clause 4.4) and to implement the actions determined in Clause 6, by:

a) Determining the requirements for the products and services,
b) Establishing criteria for:
   1) The processes,
   2) The acceptance of products and services,
c) Determining the resources needed to achieve conformity to the product and service requirements,
d) Implementing control of the processes in accordance with the criteria,
e) Determining, 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 our organization's method of operations.

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

ASYST ensures that outsourced processes are controlled as set forth in section 8.4.

NOTE 1: ASYST uses the AIAG Advanced Product Quality Planning (APQP) process as a means to achieve product realization. The ASYST Project Plan is the document that specifies the processes of the quality management system and the resources to be applied to a specific product, project or contract.

8.1.1 Operational Planning and Control – Supplemental

When planning for product realization, the following topics shall be included:

a) Customer product requirements and technical specifications,
b) Acceptance criteria,
c) Manufacturing feasibility,
d) Project planning (see 8.3.2),
e) Acceptance criteria.

8.1.2 Confidentiality

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

8.2 Requirements for Products and Services

8.2.1 Customer Communication

ASYST has determined and implemented effective arrangements for communicating with customers, which includes:

a) Providing information relating to products and services,
b) Handling enquiries, contracts or orders, including changes,
c) Obtaining customer feedback relating to products and services, including customer complaints,
d) Handling or controlling customer property,
e) Establishing specific requirements for contingency actions, when relevant.
f) Notifying the customer of any change in the status of ASYST's certification to IATF 16949.

8.2.1.1 Written or verbal communication shall be in the language agreed with the customer. ASYST has the ability to communicate necessary information, including data, in a customer-specified computer language and format (e.g. computer-aided design data, electronic data exchange).

8.2.2 Determining the Requirements for Products and Services

When determining the requirements for products and services, ASYST ensures that:

a) The requirements for the products and services are defined, including:
   1) Any applicable statutory and regulatory requirements, including but not limited to, all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material,
   2) Those considered necessary by ASYST,
b) The organization can meet the claims for products and services it offers.

8.2.2.1 The requirements for products and services include recycling, environmental impact, and characteristics identified as a result of ASYST's knowledge of the product and manufacturing processes.

8.2.3 Review of Requirements for Products and Services

8.2.3.1 ASYST has developed Procedure 8.2.0: Contract Review, to ensure the effective review of customer requirements related to the product and ensure that it has the ability to meet the requirements for products and services offered to the customers. This review shall be conducted before committing to supply products and services to the customer, and shall include:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities, and if requirements are not specified by the customer, they shall be

confirmed before acceptance. These requirements are maintained on Form 822-01: Customer Requirements Quality Manual Log,
b) Requirements not stated by the customer, but necessary for the specified or intended use, when known,
c) Requirements specified by the organization,
d) Statutory and regulatory requirements applicable to the products and services,
e) Contract or order requirements differing from those previously expressed, which shall be resolved before commitment and relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review covers relevant product information such as catalogs or advertising material.

8.2.3.1.1 Only the customer can waive the requirement shown in 8.2.3.1. A formal waiver must be obtained from the customer and kept on file.

8.2.3.1.2 Customer-Designated Special Characteristics
ASYST conforms to customer requirements for designation, approval documentation, and control of special characteristics.

8.2.3.1.3 Organization Manufacturing Feasibility
ASYST utilizes a multidisciplinary approach to conduct an analysis to determine if it is feasible that its manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirement specified by the customer. This feasibility analysis is conducted for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design. This is recorded on Form 820-05: RFQ, Feasibility & Quote Sheet, which is retained as documented information.

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

8.2.3.2 ASYST retains documented information, as applicable:
a) On the results of the review,
b) On any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services
ASYST has developed and implemented a process to control and react to changes that impact product realization. The effects of any change, including those changes caused by any supplier, are assessed, and verification and validation activities defined to ensure compliance to customer specifications. Changes are validated prior to implementation and all relevant documented information is amended. All relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

Regarding proprietary designs, ASYST shall review any changes affecting form, fit or function with the customer prior to implementation to ensure all possible effects are evaluated.

When required by the customer, ASYST shall conduct additional verification/validation to ensure that product still meets stated requirements. Any product realization change (product and/or process) that affects customer requirements requires formal customer notification and approval prior to implementation.

8.3 Design and Development of Products and Services

8.3.1 General

The ASYST has established, implemented and maintains a design and development process to ensure the subsequent provision of products and services.

8.3.1.1 The process shall apply to product and manufacturing process design and development, and focus on error prevention rather than detection.

8.3.2 Design and Development Planning

ASYST has developed Procedure 8.3.0 - Design and Development, to effectively plan and control the design and development of product. In determining the stages and controls for design and development, ASYST considers:

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

8.3.2.1 ASYST ensures that design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of where a multidisciplinary approach (which includes manufacturing, engineering, quality, production, purchasing, etc.) is included are:

a) Project management,
b) Product and manufacturing process design activities, such as consideration of the use of alternative designs and manufacturing processes,
c) Development and review of product design risk analysis, including actions to reduce potential risks,
d) Development and review of manufacturing process risk analysis.

8.3.2.2 Product Design Skills

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

8.3.2.3 Development of Products with Embedded Software

At this time, ASYST does not design, develop or manufacture any parts with embedded software. If this should change at any time, a process for quality assurance for these parts will be implemented.

8.3.3 Design and Development Inputs

Inputs relating to product requirements are determined and recorded in the final quotation accepted by the customer and maintained in accordance with clause 7.5.3. These include

a) Functional and performance requirements,

b) Information derived from previous similar design and development activities,
c) Applicable statutory and regulatory requirements,
d) Standards and codes of practice that ASYST has committed to implement,
e) Potential consequences of failure due to the nature of the products and services,

These inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.

8.3.3.1 Product Design Input
ASYST identifies, documents, and reviews the product design input requirements as a result of contract review, which include, but are not limited to the following:

a) Product specifications, including, but not limited to special characteristics (see section 8.3.3.3)
b) Boundary and interface requirements,
c) Identification, traceability and packaging,
d) Consideration of design alternatives,
e) Assessment of the risks with the input requirements and ASYST's ability to mitigate/manage the risks, including 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, if applicable.

8.3.3.2 Manufacturing Process Design Input
ASYST identifies, documents and reviews the manufacturing process design input requirements, including, but not limited to the following:

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

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

8.3.3.3 Special Characteristics
ASYST 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 ASYST, and shall include the following:

a) Documentation of special characteristics in the product and/or manufacturing documents (as required), relevant risk analysis (such as Process FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and documented in the manufacturing documents which show the creation of, or the controls required, for these special characteristics.
b) Development of control and monitoring strategies for special characteristics of products and production processes.
c) Customer-specified approvals, when required,

d) Compliance with customer-specified definitions and symbols or the organization's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table shall be submitted to the customer, if required.

8.3.4 Design and Development Controls

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

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

8.3.4.1 Monitoring

Measurements at specified stages during the design and development of products and processes shall be defined, analyzed, and reported with summary results as an input to management review (see 9.3.2.1).

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

8.3.4.2 Design and Development Validation

Design and development validation are performed in accordance with planned arrangements and customer requirements (see 8.3.2), including any applicable industry and governmental agency-issued regulatory standards, to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of the validation and any necessary actions are maintained in accordance with clause 7.5.3.

Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software (if applicable), within the system of the final customer's product.

8.3.4.3 Prototype Programme

When required by the customer, ASYST develops prototype project plans that include the development of prototype control plans. ASYST also ensures the use, wherever possible, of the same suppliers, tooling and manufacturing processes that will be used in production.

Prototype performance testing is monitored for conformance to requirements and timely completion as part of the overall project plan.

If any services need to be outsourced, ASYST maintains overall responsibility and technical leadership.

8.3.4.4 Product Approval Process
ASYST has established, implemented, and maintains a product and manufacturing approval process based on the guidelines documented in the AIAG PPAP (Production Part Approval Process) reference manual. ASYST also ensures customer-specific requirements for PPAP are met as required and has passed on these same requirements to suppliers.

ASYST approves externally provided products and services as set forth in 8.4.3 prior to submission of part approval to the customer.

ASYST obtains documented product approval prior to shipment, if required by the customer and retains this approval pursuant to section 7.5.3.

8.3.5 Design and Development Outputs
The outputs of design and development are provided in a form, such as a drawing and/or bill of materials, that enables verification against design and development input and are approved prior to release. This information is retained according to clause 7.5.3.

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

8.3.5.1 ASYST ensures that product design output is expressed in terms that can be verified and validated against product design input requirements. Product design outputs include, but are not limited to the following, as applicable:
a) Design risk analysis (FMEA),
b) Reliability study results,
c) Product special characteristics, specifications,
d) Results of product design error-proofing, as appropriate,
e) Product definition including drawings or mathematically based data,
f) 2D drawings, product manufacturing information, and geometric dimensioning and tolerancing,
g) Product design review results,
h) Service diagnostic guidelines and repair and serviceability instructions, where applicable,
i) Service part requirements, if applicable,
j) Packaging and labeling requirements for shipping.

8.3.5.2 Manufacturing Process Design Output
ASYST ensures that manufacturing design output is expressed in terms that can be verified against manufacturing design input requirements and validated. Manufacturing process design output includes, but is not limited to the following:
a) Specifications and drawings,
b) Special characteristics for product and manufacturing process,
c) Identification of process input variables that impact characteristics,
d) Tooling and equipment for production and control, including capability studies of equipment and process(es),
e) Manufacturing process flowchart/layout, including linkage of product, process and tooling,
f) Capacity analysis,
g) Manufacturing process FMEA,

h) Maintenance plans and instructions,
i) Control plan (see 8.5.1.1),
j) 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

Work Instruction 830-01, ECN/ECR Control, has been developed to ensure that design and development changes are identified, reviewed and controlled during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and delivered product.

Records of the results of the review of changes and any necessary actions are maintained in accordance with clause 7.5.3. and include:
a) Design and development changes,
b) The results of reviews,
c) The authorization of the changes,
d) The actions taken to prevent adverse effects.

8.3.6.1 ASYST evaluates all design changes after initial product approval, including those proposed by ASYST 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, ASYST obtains documented approval, or a documented waiver, from the customer prior to production implementation.

8.4 Purchasing

8.4.1 Purchasing Process

ASYST has developed and maintains Procedure 8.4.0: Purchasing to ensure that purchased product, processes and services conform to specified requirements.

ASYST determines the controls to be applied to purchased processes, products and services when:
a) Products and services from external providers are intended for incorporation into ASYST's own products and services,
b) Products and services are provided directly to the customer(s) by external providers on behalf of ASYST,
c) A process, or part of a process, is provided by an external provider as a result of a decision by ASYST.

ASYST determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of suppliers based on their ability to supply processes or products and services in accordance with requirements. Criteria for selection, evaluation and re-evaluation are established and documented. These records are maintained in accordance with clause 7.5.3.

8.4.1.1 Purchased products include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework and calibration.

8.4.1.2 Supplier Selection Process
ASYST has a documented supplier selection process, utilizing Form 841-03: Supplier Assessment. Form 841-01, Approved Supplier List shall be used to list key suppliers. The selection process includes:

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

Other supplier selection criteria that should be considered include the following:

a) Volume of automotive business,
b) Financial stability,
c) Purchased product, material, or service complexity,
d) Required technology (product or process),
e) Adequacy of available resources,
f) Design and development capabilities (including project management),
g) Manufacturing capability,
h) Change management process,
i) Business continuity planning,
j) Logistics process,
k) Customer service.

8.4.1.3 Customer-directed Sources (Directed-Buy)
Where specified by the customer, ASYST purchases products, materials or services from customer-directed sources. The use of customer-designated sources, including tooling/gage suppliers, does not relieve ASYST of the responsibility for ensuring the quality of purchased products. All requirements of Section 8.4 (with the exception of 8.4.1.2) are applicable to ASYST's control of customer-directed sources unless specific agreements are otherwise defied by a contract between ASYST and the customer/

8.4.2 Type and Extent of Control
ASYST has established and implemented Procedure 8.4.2, Verification of Purchased Product, to detail the activities necessary for ensuring that provided services, products and services do not adversely affect ASYST's ability to consistently deliver conforming products and services to its customers.

ASYST shall:

a) Ensure that externally provided processes remain within the control of its quality management system,
b) Define both the controls that it intends to apply to a supplier and those it intends to apply to the resulting output,
c) Take into consideration:
    1. The potential impact of the externally provided processes, products and services on the its ability to consistently meet customer and applicable statutory and regulatory requirements,
    2. The effectiveness of the controls applied by the external provider,

d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

Where ASYST or its customer intends to perform verification at the supplier's premises, ASYST has stated the intended verification arrangements and method of product release in the purchase requisition.

8.4.2.1 ASYST has a 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 (see 8.4.2).

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

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

8.4.2.2 Statutory and Regulatory Requirements
ASYST has a 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 (see 8.4.2).

If the customer defines special controls for certain products with statutory and regulatory requirements, ASYST ensures that they are implemented and maintained as defined, including at suppliers.

8.4.2.3 Supplier Quality Management System Development
ASYST performs supplier quality management system development with the goal of supplier conformity to IATF 16949. Prioritization of suppliers for development depends on upon the supplier's quality performance, the potential risk to the customer, and the importance of the product being supplied. Unless otherwise specified by the customer, key suppliers (those manufacturing production-intent components or resin) are required to be third-party registered to ISO 9001 by an accredited third-party certification body.

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

Supplier performance is monitored through the following indicators, as a minimum:
a) Delivery product conformity to requirements,
b) Customer disruptions at the receiving plant, including stop ships and yard holds,
c) Delivery schedule performance;
d) Special status customer notifications related to quality or delivery issues,
e) Dealer returns, warranty, field actions and recalls.

ASYST strongly recommends that suppliers monitor the performance of their manufacturing processes.

8.4.2.4.1 Second-party Audits
ASYST includes a second-party audit process in their supplier management approach. The second-party audits may be used for:

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

Based on a risk analysis, including product safety/regulatory requirements, performance of the suppliers, and QMS certification level, at a minimum, ASYST documents the criteria for determining the need, type, frequency and scope of second-party audits, which records are maintained pursuant to section 7.5.3.

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

8.4.2.5 Supplier Development
ASYST has determined the priority, type, extent and timing of required supplier development actions for its active suppliers. Determination inputs include, but are not limited to:

a) Performance issues identified through supplier monitoring (see 8.4.2.4),
b) Second-party audit findings (see 8.4.2.4.1),
c) Third-party quality management system certification status,
d) Risk analysis.

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

8.4.3 Purchasing Information
ASYST ensures the adequacy of requirements prior to communication to the supplier. ASYST communicates to suppliers its requirements for:

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

8.4.3.1 ASYST passes 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
ASYST plans and carries out production and service provision under controlled conditions.

Controlled conditions include, as applicable:

a) The availability of documented information that defines:
   1. The characteristics of the products to be produced, the services to be provided, or the activities to be performed,
   2. The results to be achieved,
b) The availability and use of suitable monitoring and measuring resources,
c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met,
d) The use of suitable infrastructure and environment for the operation of processes,
e) The appointment of competent persons, including any required qualifications,
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

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

ASYST has a control plan for pre-launch and production that shows linkage and taking into account information from the design FMEA, process flow diagram, and manufacturing process FMEA risk analysis outputs.

If required by the customer, ASYST provides measurement and conformity data collected during execution of either the pre-launch or production control plans. The following shall be included in the control plan:

a) Controls used for 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 ASYST,
d) The customer required information, if any,
e) A specified reaction plan when nonconforming product is detected, the processes become statistically unstable or not statistically capable.

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

f) ASYST determines it has shipped nonconforming product to the 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, ASYST shall obtain customer approval after review or revision of the control plan.

8.5.1.2 Work Instructions

ASYST has prepared documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. Instructions are accessible and used at the work

station. Instructions have been derived from sources such as the APQP review process, the control plan and the product realization process. The work instructions also 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) Include rules for operator safety,
e) Include any special characteristics for those processes.

8.5.1.3 Verification of Job Set-ups

ASYST ensures that:

a) Job set-ups are verified whenever performed, such as an initial run of a job, material change-over, or job change-over,
b) Work instructions for set-up are available and maintained for set-up personnel,
c) Statistical verification methods are used, as applicable,
d) First-off/last-off part validation is performed, 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

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

8.5.1.5 Total Productive Maintenance

ASYST has identified key process equipment and provides resources for machine/equipment maintenance. ASYST has also developed, implemented and maintains a documented total productive maintenance system which includes at a minimum:

a) Identification of process equipment necessary to produce conforming product at the required volume,
b) Availability of replacement parts for key manufacturing equipment,
c) Provision of resource for machine, equipment, and facility maintenance,
d) Packaging and preservation of equipment, tooling and gauging,
e) Applicable customer-specific requirements,
f) Documented maintenance objectives, which shall be an input to Management Review,
g) Regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved,
h) Use of preventive maintenance methods,
i) Use of predictive maintenance methods, as applicable,
j) Periodic overhaul.

8.5.1.6 Management of Production Tooling and Manufacturing, Test, Inspection Tooling and Equipment

ASYST has allocated resources for tool and gauge design, fabrication and verification activities for production and service materials and for bulk materials, as applicable.

ASYST has established and implemented a system for production and service tooling management, whether owned by ASYST 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,
f) Tool modification and revision to documentation,
g) Tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.

ASYST 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.

ASYST has also implemented a system to monitor these activities when tooling work is outsourced.

8.5.1.7 Production Scheduling
ASYST schedules production in order to meet customer requirements, utilizing just-in-time methods supported by an information system that permits access to production information at key stages of the process and is order driven.

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

8.5.2 Identification and Traceability
ASYST ensures the identification of product by suitable means throughout product realization. ASYST identifies the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, ASYST controls and records the unique identification of the product in accordance with clause 7.5.3.

8.5.2.1 The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety-related nonconformities. Therefore, ASYST 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 and 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 ASYST to identify nonconforming and/or suspect product,
b) Enable ASYST 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 that enables ASYST 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 Customer Property
ASYST exercises care with customer or external provider property (including customer drawings, see 7.5.3) while it is under its control or being used by the organization. ASYST identifies, verifies, protects and safeguards customer or external provider property provided for use or incorporation into the product. If any customer or external provider property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer or external provider and records maintained in accordance with clause 7.5.3.

NOTE: Customer property can include materials, components, tools and equipment, premises, intellectual property and personal data. Customer owned returnable packaging is included, where applicable and when required.

8.5.4 Preservation of Product

ASYST preserves the conformity of product during internal processing through delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

8.5.4.1 Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. Preservation applies to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.

In order to detect deterioration, ASYST assesses the condition of product in stock at appropriate planned intervals. ASYST uses an inventory management system to optimize inventory turns over time and assure stock rotation using a First-In, First-Out (FIFO) method. Obsolete product is controlled in a similar manner to nonconforming product.

ASYST complies with preservation, packaging, shipping, and labeling requirements as provided by its customers.

8.5.5 Post-Delivery Activities

ASYST meets the requirements of post-delivery activities associated with the products and services, taking into consideration:

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.

Note: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.5.1 Feedback on Information from Service

ASYST has established, implemented and maintains a process for communicating information on service concerns, including results of field failure test analysis, where applicable, to manufacturing, material handling, logistics, engineering and design activities. When issues arise, the ASYST 8D corrective action process ensures proper communication of all details to appropriate personnel.

8.5.5.2 Service Agreement with Customer

When there is a service agreement with a customer, ASYST:

a) Verifies that the relevant service centers comply 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.

Note: There are no current service agreements with customers.

8.5.6 Control of Changes

ASYST reviews and controls changes for production or service provisions, to the extent necessary to ensure continuing conformity with requirements. Documentation describing the results of the

review of changes, the person(s) authorizing the change, and any necessary actions arising from the review is retained pursuant to section 7.5.3.

8.5.6.1 ASYST has a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer or any supplier, shall be assessed. ASYST shall:

a) Define verification and validation activities to ensure compliance with customer requirements,
b) Validate changes before implementation,
c) Document the evidence of related risk analysis,
d) Retain records of verification and validation.

Changes, including those made at suppliers, should require a production trial run for verification of changes to validate the impact of any changes on the manufacturing process. When required by the customer, ASYST shall:

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

8.5.6.1.1 Temporary Change of Process Controls

ASYST identifies, documents and maintains a list of the process controls, including inspection, measuring, test, and error-proofing devices. The list of process controls shall include the primary process controls and the approved back-up or alternate methods, if back-up or alternate methods exist.

ASYST has a documented process to manage the use of alternative control methods. ASYST includes in this process, based on risk analysis, severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.

If required, ASYST will obtain customer approval before shipping product that was inspected or tested using the alternate method. ASYST maintains and periodically reviews a list of approved alternate process control methods that are referenced in the control plan.

Standard work instructions are available for each alternate process control method. ASYST 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 soon as possible. Examples of review methods include, but are not limited to:

a) Daily quality focused audits,
b) Daily leadership meetings.

Restart verification is documented for a defined period based on severity and confirmation that all features on the error-proofing device or process are effectively reinstated. Traceability of the product is implemented when an alternate process control device or processes are used.

8.6 Release of Products and Services

ASYST implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met as set forth in Procedure 8.6.0: Monitoring and Measurement of Processes and Products.

Product release does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, by the customer.

ASYST retains documented information on the release of products and services, which includes:

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

8.6.1 ASYST insures 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. It ensures that the planned arrangements for the initial release of products and service encompass product or service approval. It also ensures that product or service approval is accomplished after changes following initial release.

8.6.2 Layout Inspection and Functional Testing

A layout inspection (complete measurement of all product dimensions shown on the design records) and/or functional verification to applicable customer engineering material and performance standards is performed for each product as specified in the control plan. Results are available for customer review.

8.6.3 Appearance Items

When parts are identified by the customer as "appearance items", ASYST 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

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

8.6.5 Statutory and Regulatory Conformity

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

8.6.6 Acceptance Criteria

Acceptance criteria is defined by ASYST and approved by the customer, if appropriate or required. For attribute data sampling, the acceptance level shall be zero defects.

8.7 Control of Nonconforming Product

8.7.1 ASYST ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Appropriate action is taken based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of product, during or after the provision of services. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in Procedure 8.3.0: Control of Non-Conforming Product.

ASYST dispositions nonconforming product by 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.

When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements.

8.7.1.1 Customer Authorization for Concession

ASYST obtains customer concession or a deviation (from an authorized and appropriate customer representative) prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

ASYST obtains customer authorization prior to further processing for "use as is" and for repair of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit.

ASYST maintains a record of the expiration date or quantity authorized under concession. ASYST also ensures compliance with original or superseding specifications and requirements when the authorization expires. Material shipped under concession is properly identified on each shipping container. This applies equally to purchased product. In this case, ASYST must approve any requests from suppliers before submission to the customer.

8.7.1.2 Control of Nonconforming Product – Customer-Specified Process

ASYST complies with applicable customer-specified controls for nonconforming product(s).

8.7.1.3 Control of Suspect Product

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

8.7.1.4 Control of Reworked Product

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

ASYST 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 used by appropriate personnel.

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

ASYST has a documented process for repair confirmation in accordance with the control plan or other relevant documented information to verify compliance to original specifications. Instructions for disassembly or repair, including re-inspection and traceability requirements, are accessible to and used by appropriate personnel.

A documented customer authorization for concession for the product to be repaired shall be obtained. ASYST retains documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.6 Customer Notification
Customers are promptly informed in the event that nonconforming product has been shipped. Initial communication shall be followed with detailed documentation of the event.

8.7.1.7 Nonconforming Product Disposition
ASYST has a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, ASYST deems that the product to be scrapped is rendered unusable insofar as the product produced by ASYST is not usable on its own and is part of a larger finished assembly. ASYST also deems any part that has fallen on the floor or in the garbage is unusable, so any final product not packaged in ASYST packaging is rendered unusable.

8.7.2 Records of the nature of nonconformities are maintained in accordance with clause 7.5.3. The records shall:

a) Describe the nonconformity,
b) Describe the actions taken,
c) Describe the concessions obtained,
d) Identifies the authority deciding the action in respect to the nonconformity.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

ASYST 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 the monitoring and measuring shall be performed,
d) When the results from monitoring and measurement shall be analyzed and evaluated.

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

9.1.1.1 Monitoring and Measurement of Manufacturing Processes

ASYST performs process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics. For some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods, such as batch conformance to specification may be used.

ASYST maintains manufacturing capability or performance as specified by the customer part approval process requirements. ASYST verifies that the process flow diagram, PFMEA, and control plan are implements, 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.

ASYST initiates a reaction plan from the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or unstable. These reaction plans include containment of product and 100% inspection, as appropriate. A corrective action plan is developed and implemented indicating target time frames as well as responsible managers who will coordinate the problem solving effort to stabilize and bring the process under control. Corrective action plans are reviewed with and approved by the customer when so required. ASYST maintains records of effective dates of process changes.

9.1.1.2 Identification of Statistical Tools

Appropriate statistical tools for each process are determined during advance product quality planning (APQP) and are included in the design risk analysis (where applicable), the process risk analysis and the control plan.

9.1.1.3 Application of Statistical Concepts

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

9.1.2 Customer Satisfaction

As one of the measurements of the performance of the quality management system, ASYST monitors information relating to customer perception as to whether the organization has fulfilled their needs and expectations. Procedure 9.1.2: Customer Satisfaction, has been developed to define the methods for obtaining and using this information.

9.1.2.1 ASYST monitors customer satisfaction through continual evaluation of performance 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, but are not limited to:

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.

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

9.1.3 Analysis and Evaluation

ASYST determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The results of the analysis of data is 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 suppliers,
g) The need for improvement 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 ASYST conducts internal audits at planned intervals to provide information on whether the quality management system:

a) Conforms to:
   1. ASYST's requirements for its quality management system,
   2. The requirements of IATF 16949,
b) Is effectively implemented and maintained.

9.2.2 With respect to the audit program, ASYST shall:

a) Plan, establish, implement and maintain an audit program, including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the status and importance of the processes and areas to be audited, changes affecting the organization, as well as the results of previous audits,
b) Define the audit criteria and scope for each audit,
c) Select auditors and conduct audits to ensure objectivity and impartiality of the audit process,
d) Ensure that they results of the audits are reported to relevant management,
e) Take appropriate correction and corrective actions without undue delay.
f) Retain documented information as evidence of the implementation of the audit program and the audit results.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records in accordance with clause 7.5.3 are defined in Procedure 9.2.0: Internal System Audits.

The manager responsible for the area being audited is responsible to ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up audit activities include the verification of the actions taken and the reporting of verification results (see 10.2).

9.2.2.1 Internal Audit Program

ASYST has a documented internal audit plan as set forth in Procedure 9.2.0: Internal System Audits, which covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits. The audit program is prioritized based on risk, internal and external performance trends and criticality of the process(es).

The frequency of the audits is reviewed and adjusted based on the 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

ASYST audits all quality management system processes over a three-year audit cycle, according to an annual program, using the process approach to verify compliance with IATF 16949. ASYST samples customer-specific quality management system requirements for effective implementation, which is integrated with these audits.

The complete audit cycle remains three years in length. The quality management system audit frequency for individual processes, audited within the three-year audit cycle, shall be based upon internal and external performance and risk. ASYST shall maintain justification for the assigned audit frequency of their processes. All processes are required to be sampled throughout the three-year audit cycle and audited to all applicable requirements in the IATF 16949 standard, including ISO 9001 base requirements, and any customer-specific requirements.

9.2.2.3 Manufacturing Process Audit

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

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

of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

9.2.2.4 Product Audit
ASYST audits products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging, and labeling, at defined frequencies. Where not defined by the customer, ASYST determines the approach to be used.

9.3 Management Review

9.3.1 General
Top management reviews our organization's quality management system, at a minimum of once per year, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of ASYST. The frequency of management review shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues.

The process is documented in Procedure 9.3.1, QMS Management Review. Review records are documented on Form 931-01 QMS Management Review Record, and include the assessment of opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews are maintained in accordance with clause 7.5.3.

9.3.2 Management Review Input
The management review shall be planned and carried out taking into consideration:

a) The status of actions from previous management reviews,
b) Changes in external and internal issues that are relevant to the quality management system,
c) Information on the performance and effectiveness of the quality management system, including trends in:
    1) Customer satisfaction and feedback from relevant interested parties,
    2) The extent to which quality objectives have been met,
    3) Process performance and conformity of products and services,
    4) Nonconformities and corrective actions,
    5) Monitoring and measurement results,
    6) Audit results,
    7) The performance of external providers.
d) The adequacy of resources,
e) The effectiveness of actions taken to address risks and opportunities (see 6.1),
f) Opportunities for improvement.

9.3.2.1 Management Reviews also include an analysis of:

a) Cost of poor quality (cost of internal and external nonconformance),
b) Measures of process effectiveness,
c) Measures of process efficiency for product realization processes, as applicable,
d) Product conformance,
e) Assessments of manufacturing feasibility made for changes to existing operation and for new facilities or new product (see 7.1.3.1),
f) Customer satisfaction (see 9.1.2),
g) Review of performance against maintenance objectives,
h) Warranty performance (where applicable),
i) Review of customer scorecards,

j) Identification of potential field failures identified through risk analysis,
k) Actual field failures and their impact on safety or the environment,
l) Summary results of measurements at specified stages during the design and development of products and processes, as applicable.

9.3.3 Management Review Output

The output from the management review includes any decisions and actions related to:

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

9.3.3.1 Top management shall document and implement an action plan when customer performance targets are not met.

10 Improvement

10.1 General

ASYST determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction, which includes:

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

Note: Improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, ASYST:

a) Reacts to the nonconformity, as applicable:
   1. Take action to control and correct it,
   2. Deal with the consequences,
b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   1. Reviewing and analyzing the nonconformity,
   2. Determining the causes of the nonconformity,
   3. Determining if similar nonconformities exist, or could potentially occur,
c) Implements any action needed,
d) Reviews the effectiveness of any corrective action taken,
e) Updates the risks and opportunities determined during planning, if necessary,
f) Makes changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered. Procedure 10.2.0: Corrective Action has been established to set forth how ASYST will address all nonconformities.

10.2.2 ASYST retains documented information, as set forth in section 7.5.3, to show evidence of:

a) The nature of the nonconformities and any subsequent action taken,
b) The results of any corrective action.

10.2.3 Problem Solving

ASYST has a defined process for problem solving, which prevent(s) recurrence, including:

a) Defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings),
b) Containments, interim actions, and related activities necessary for control of nonconforming outputs (see 8.7),
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 (APQP documents, etc.).

Where the customer has prescribed processes, tools or systems for problems solving, ASYST uses those processes, tools, or systems unless otherwise approved by the customer.

10.2.4 Error-proofing

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

The process includes the testing of error-proofing devices for failure or simulated failure. Records are maintained according to section 7.5.3. Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures have a reaction plan.

10.2.5 Warranty Management Systems

ASYST has a warranty process as set forth in the terms and conditions of the company, which is implemented when specified by the customer.

10.2.6 Customer Complaints and Field Failure Test Analysis

ASYST analyzes parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. ASYST makes every attempt to minimize the cycle time of this process by involving appropriate personnel when needed. Records of the analysis is kept and made available upon request. ASYST performs the analysis and, when warranted, implements corrective action to prevent recurrence.

10.3 Continual Improvement

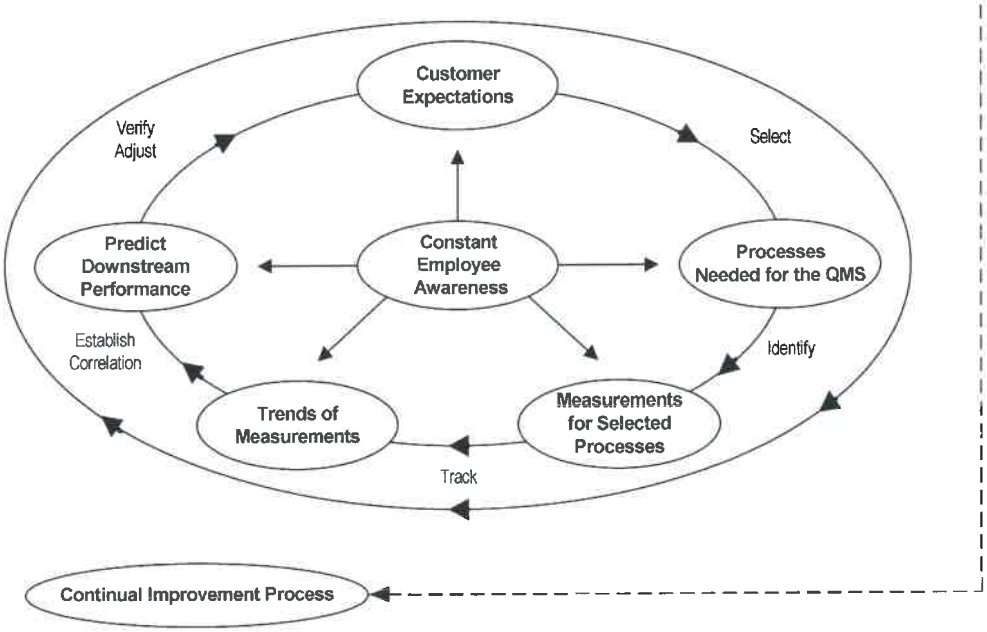
ASYST continually improves the suitability, adequacy and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis and evaluation of data, corrective and preventive actions and management review outputs.

10.3.1 ASYST has a documented process for continual improvement, as set forth in Procedure 10.3.1: Continual Improvement, which includes:

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

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

EXHIBIT 10A: ASYST Continual Improvement Process



1. Select a process to analyze
2. Identify monitoring and, where applicable, measurement opportunities
3. Track trends
4. Identify improvement opportunities
5. Implement actions to improve processes
6. Verify/adjust based on quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review