THALES

AS9100 Quality Management System (QMS)Training

THALES Quality Policy

THALES ASW provides quality products, services, and support that meet the requirements and expectations of our customers. We are committed to meeting customer and legal requirements, and the continual improvement of our Quality Management System (QMS).

Note: This Quality Policy is located in the Thales Quality Manual, Document Number A/TAUS/M/06 on the Q-Pulse system.

What does AS9100 stand for?

AS9100 is the international management system standard for the Aircraft, Space and Defense (AS&D) industry. The standard provides suppliers with a comprehensive quality system for providing safe and reliable products to the aerospace industry. AS9100 also addresses civil & military aviation requirements.

What is the meaning of AS9100?

AS9100 is an aerospace standard based on the ISO 9001 quality system requirements. AS9100 takes the ISO 9001 requirements and supplements them with additional quality system requirements, which are established by the aerospace industry in order to satisfy DOD, NASA and FAA quality requirements. Compliance with specification is confirmed through a complex auditing and certification process.

Quality Management Standards facilitate worldwide trade and the production of quality products and services, and encourage good business practices.

It is emphasized that the requirements specified in AS9100 are complementary (not alternative) to customer and applicable statutory and regulatory requirements. If there is a conflict between the requirements of AS9100 and customer or applicable statutory or regulatory requirements, the later shall take precedence.

Who is responsible for adherence to the AS9100 standard?

The short answer is EVERYONE!

Every employee/department has an important role/responsibility in customer satisfaction and continual improvement of the system at THALES. Some departments include:

- **Operations/Production**
- **Purchasing**
- **Quality**
- **Customer Service**
- **Engineering**
- **Logistics/Shipping**
- **Human Resources**

Main clauses of the AS9100 standard

- Clause 4- Context of the organization
- Clause 5- Leadership
- Clause 6- Planning
- Clause 7- Support
- Clause 8- Operation
- Clause 9- Performance Evaluation
- Clause 10- Improvement

Clause 4- Context of the Organization

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its Quality Management System (QMS).

<u>Understanding the Needs and Expectations of Interested Parties</u>

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

- **The interested parties that are relevant to the QMS.**
- **The requirements of these interested parties that are relevant to the QMS.**

The organization shall monitor and review the information about these interested parties and their relevant requirements.

Clause 4- Context of the Organization (continued)

4.3 Determining the Scope of the QMS

The organization shall determine the boundaries and applicability of the QMS to establish its scope. When determining the scope, the organization shall consider:

- **The external and internal issues**
- **The requirements of relevant interested parties**
- **The products and services of the organization.**

The organization shall apply all the requirements of AS9100 if they are applicable within the determined scope of its QMS. The scope of the organization's QMS shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirements of AS9100 that the organization determines is not applicable to the scope of its QMS.

Clause 4- Context of the Organization (continued)

4.4 QMS and its Processes

The organization shall establish, implement, maintain and continually improve a QMS, including the processes needed and their interactions, in accordance with the requirements of the AS9100. The organization's QMS shall also address customer and applicable and statutory and regulatory QMS requirements. The organization shall determine the processes needed for the QMS and their application throughout the organization, and shall:

- **Determine inputs required and the outputs expected from these processes;**
- **Determine the sequence and interaction of these processes;**
- **Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation, and control of these processes**

Clause 4- Context of the Organization (continued)

- Determine resources needed for these processes and ensure their availability;
- Assign the responsibilities and authorities for these processes;
- Address the risks and opportunities
- Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- Improve the processes and the QMS.

4.4.2 To the extent necessary, the organization shall:

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

Clause 5- Leadership

5.1 Leadership and Commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the QMS by:

- **Taking accountability of effectiveness of the QMS;**
- **Ensuring the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization;**
- **Ensuring the integration of the QMS requirements into the organization's business processes;**
- **Promoting the use of the process approach and risk-based thinking;**
- **Ensuring the resources needed for the QMS are available;**

Communicating the importance of an effective QMS and of conforming to the QMS requirements;

Clause 5- Leadership (continued)

- **Communicating the importance of an effective QMS and of conforming to the QMS requirements;**

Ensuring the QMS achieves its intended results;

Engaging, directing, and supporting persons to contribute to the effectiveness of the QMS;

Promoting improvement;

Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE: Reference to "business" in AS9100 can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit, or not for profit.

Clause 5- Leadership (continued)

5.1.2 Customer Focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

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

Product and service conformity and on-time delivery performance are measured and appropriate action is taken if intended results are not, or will not be, achieved.

Clause 5- Leadership (continued)

5.2 Policy

5.2.2 Communicating the Quality Policy

The quality policy shall:

- Be available and be maintained as documented information;
- Be communicated, understood, and applied within the organization;
- Be available to relevant interested parties, as appropriate.

5.3 Organizational Roles, Responsibilities and Authorities

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

Clause 5- Leadership (continued)

Top management shall assign the responsibility and authority for:

- **Ensuring that the QMS conforms to the requirements of AS9100;**
- **Ensuring processes are delivering intended outputs;**
- **Reporting on the performance of the QMS and on opportunities for improvement, reference clause 10.1, in particular to top management;**
- **Ensuring the promotion of customer focus throughout the organization;**
- **Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.**

Top management shall appoint a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements. The management representative shall have the organizational freedom and unrestricted access to top management to resolve quality management issues.

Clause 6- Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the QMS, the organization shall :

- Give assurance the QMS can achieve its intended result(s);
- Enhance desirable effects;
- Prevent, or reduce, undesired effects;
- Achieve improvement.
- Evaluate the effectiveness of these actions

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and service.

Clause 6- Planning (continued)

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the QMS. The quality objectives shall:

- **Be consistent with quality policy;**
- **Be measurable;**
- **Take into account applicable requirements;**
- **Be relevant to conformity of products and services and to enhancement of customer satisfaction;**
- **Be monitored;**
- **Be communicated;**
- **Be updated as appropriate.**

The organization shall maintain documented information on the quality objectives.

Clause 6- Planning (continued)

6.2 Quality Objectives and Planning to Achieve Them (CONT.)

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

- What will be done;
- What resources will be required;
- Who will be responsible;
- When it will be completed;
- How the results will be evaluated.

Clause 6- Planning (continued)

6.3 Planning of Changes

The organization shall consider the:

- **The purpose of the changes and any of its potential consequences;**
- **The integrity of the QMS;**
- **The availability of resources;**
- **The allocation or reallocation of responsibilities and authorities.**

Clause 7- Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS.

The organization shall consider:

- The capabilities of, and constraints, on existing internal resources;
- What needs to be obtained from external providers.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of the QMS and for the operation and control of its processes.

Clause 7- Support (continued)

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes to achieve conformity of products and services.

NOTE : Infrastructure can include:

- **Buildings and associated utilities;**
- **Equipment, including hardware and software;**
- **Transportation resources;**
- **Information and communication technology.**

Clause 7- Support (continued)

7.1.4 Environment for the Operation of Processes

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

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

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

Clause 7- Support (continued)

7.1.5 Monitoring and Measuring Resources

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

- **Are suitable for the specific type of monitoring and measurement activities being undertaken;**
- **Are maintained to ensure their continued fitness for their purpose.**

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

Clause 7- Support (continued)

7.1.5.2 Measurement Traceability

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

- **Calibrated or verified, or both, at specified intervals, or prior to the use, against measurement standards traceable to the international or national measurement standards: where no such standards exist, the basis for calibration or verification will be retained as documented information;**
- **Identified in order to determine their status;**
- **Safeguarded from adjustment, damage or deterioration that would invalidate the calibration status and subsequent measurement results.**

Clause 7- Support (continued)

7.1.5.2 Measurement Traceability (CONT.)

The organization shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

The organization shall maintain a register of the monitoring and measuring equipment. The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software automated test equipment (ATE) and plotters used to product verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

Clause 7- Support (continued)

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions.

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

7.1.6 Organizational Knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

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

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge and required updates.

Clause 7-Support (continued)

7.1.6 Organizational Knowledge (CONT.)

NOTE: 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE: 2 Organizational knowledge can be based on:

- **Internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience: the results of improvements in processes, products and services);**
- **External sources (e.g. standards, academia, conferences, gathering knowledge from customers or external providers).**

Clause 7-Support (continued)

7.2 Competence

The organization shall:

- **Determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS;**
- **Ensure that these persons are competent on the basis of appropriate education, training, or experience;**
- **Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;**
- **Retain appropriate documented information as evidence of competence.**

NOTE: Consideration should be given for the periodic review of the necessary competence.

NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

Clause 7-Support (continued)

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control will be aware of:

- **The quality policy;**
- **Relevant Quality Objectives;**
- **Their contribution to the effectiveness of the QMS, including the benefits of improved quality performance;**
- **The implications of not conforming with the QMS requirements;**
- **Relevant QMS documented information and changes thereto;**
- **Their contribution to product or service conformity;**
- **Their contribution to product safety;**
- **The importance of ethical behavior.**

Clause 7-Support (continued)

7.4 Communication

The organization shall determine the internal and external communications relevant to the QMS, including:

- **On what it will communicate;**
- **When to communicate;**
- **With whom to communicate;**
- **How to communicate;**
- **Who communicates.**

NOTE: Communication should include internal and external feedback relevant to the QMS.

Clause 7- Support (continued)

7.5 Documented Information

7.5.1 General

The organization's QMS shall include:

- Documented information required by AS9100
- Documented information determined by the organization as being necessary for the effectiveness of the QMS.

NOTE: The extent of documented information for a QMS can differ from one organization to another due to:

- The size of the organization and its type of activities, processes, products and services;
- The complexity of processes and their interactions;
- The competence of persons.

Clause 7- Support (continued)

7.5 Documented Information (CONT.)

7.5.2 Creating and Updating

When creating and updating documented information, the organization shall ensure appropriate:

- **Identification and description (e.g. a title, date, author, or reference number);**
- **Format (e.g. language, software version, graphics) and media (e.g. paper, electronic);**
- **Review and approval for suitability and adequacy.**

NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.

Clause 7- Support (continued)

7.5 Documented Information (CONT.)

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the QMS and AS9100 shall be controlled to ensure:

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

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

- **Distribution, access, retrieval and use;**
- **Storage and preservation, including preservation of legibility;**
- **Control of changes (e.g. version control);**
- **Retention and disposition.**
- **Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for an purpose.**

Clause 7- Support (continued)

Documented information of external origin determined by the organization to be necessary for the planning and operation for the QMS shall be identified as appropriate, and be controlled.

7.5.3 Control of Documented Information (CONT.)

7.5.3.2 (CONT,)

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

When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

Clause 8- Operation

8.1 Operational Planning and Control

The organization shall plan, implement and control the processes, reference clause 4.4, needed to meet requirements for the provision or products and services, and to implement the actions determined by clause 6, by:

a) Determining requirements for the product and services;

NOTE: Determination of requirements for the products and services should include consideration of:

- **personal and product safety;**
- **producibility and inspectability;**
- **reliability, availability and maintainability;**
- **suitability of parts and materials used in the product;**
- **selection and development of embedded software;**

Clause 8- Operation (continued)

8.1 Operational Planning and Control (CONT.)

- product obsolescence;
- prevention, detection, and removal of foreign objects;
- handling, packaging and preservation;
- recycling or final disposal of the product at the end of its life.
- Establishing criteria for:
- The processes;
- The acceptance of products and services;

b) Establishing criteria for:

- The processes;
- The acceptance of products and services;

c) Determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

Clause 8- Operation (continued)

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;**

f) Determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

g) Engaging representatives of affected organization functions for operational planning and control;

h) Determining the process and resources to support the use and maintenance of the products and services;

Clause 8- Operation (continued)

i) Determining the products and services to be obtained from external providers;

j) Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

NOTE: One method to achieve operational planning and control can be through using integrated phased processes.

As appropriate to the organization, customer requirements, and products and services, the organization shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

8.1 Operational Planning and Control (CONT.)

NOTE: This activity is generally referred to as project planning, project management, or program management. The output of this planning shall be suitable for the organization's operations.

Clause 8- Operation (continued)

NOTE As an output of this planning, documented information specifying the processes of the QMS and the resources to be applied to a specified product, service, project, or contract can be referred to as a quality plan.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled, reference clause 8.4.

The organization shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work to ensure the continuing conformity of the work to requirements. The process shall ensure that work transfer impacts and risk are managed.

NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, reference clause 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, reference clause 8.5.

Clause 8- Operation (continued)

8.1.1 Operational Risk Management

The organization shall plan, implement and control a process for managing operational risks to the achievement of requirements, which includes as appropriate to the organization and the products and services:

- **Assignment of responsibilities for operational risk management;**
- **Definition of risks assessment criteria (e.g., likelihood, consequences, risk acceptance);**
- **Identification, assessment and communication of risks throughout operations;**
- **Identification, implementation and management of actions to mitigate risks that exceeded the defined risk acceptance criteria;**
- **Acceptance of risks remaining after implementation of mitigating actions.**
- **NOTE 1: While clause 6.1 addresses the risks and opportunities when planning for the QMS of the organization, the scope of this, reference clause 8.1.1 is limited to the risks associated to the operational processes needed for the provision of products and services, reference clause 8.**

Clause 8- Operation (continued)

8.1.1 is limited to the risks associated to the operational processes needed for the provision of products and services, reference clause 8.
NOTE 2: Within aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.

8.1.2 Configuration Management
The organization shall plan, implement and control a process for configuration management as appropriate to the organization and its Products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

a) Control product identity and traceability to requirements including the implementation of identified changes;

b) Ensure that the documented information (e.g., requirements, design, test, and acceptance documentation) is consistent with the actual attributes of the products and services.

Clause 8- Operation (continued)

8.1.3 Product Safety

The organization shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.

NOTE: Examples of these processes include:

- **Assessment of hazards and management of associated risks, reference clause 8.1.1;**
- **Management of safety critical items;**
- **Analysis and reporting of occurred events affecting safety;**
- **Communication of these events and training of persons.**

Clause 8- Operation (continued)

8.1.4 Prevention of Counterfeit Product

The organization shall plan, implement and control the processes, appropriate to the organization and product, for the prevention of counterfeit part use and their inclusion in product(s) delivered to the customer.

NOTE: Counterfeit product prevention processes should consider:

- Training of appropriate persons in the awareness and prevention of counterfeit parts;
- Application of a parts obsolescence monitoring program;
- Controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;
- Requirements for assuring traceability of parts and components to their original or authorized manufacturers;
- Verification and test methodologies to detect counterfeit parts;
- Monitoring of counterfeit parts reporting from external sources;
- Quarantine and reporting of suspect or detected counterfeit parts.

Clause 8- Operation (continued)

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers shall include:

a) Providing Information relating to products and services;

b) Handling enquires, contracts or orders, including changes;

c) Obtaining customer feedback relating to products and services, including complaints;

d) Handling or controlling customer property;

e) Establishing specific requirements for contingency actions, when relevant.

Clause 8- Operation (continued)

8.2.2 Determining the Requirements for Products and Services

The determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) The requirements for products and services are defined, including:

1)Any applicable statutory and regulatory requirements;

2)Those considered necessary by the organization;

b) The organization can meet the claims for the products and services it offers;

c) Special requirements of the products and services are determined;

d) Operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

Clause 8- Operation (continued)

8.2.3 Review of the Requirements Related to Products and Services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to the customer, to include:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) Requirements not stated by the customer, but necessary for the customers' 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.

Clause 8- Operation (continued)

8.2.3 Review of the Requirements Related to Products and Services CONT.)

8.2.3.1 (CONT.)

This review shall be coordinated with applicable functions of the organization.

If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

Clause 8- Operation (continued)

8.2 Determination of Requirements for Products and Services (CONT.)

8.2.3 Review of the Requirements Related to Products and Services CONT.)

8.2.3.2 The organization shall retain documented information, as applicable:

a) On the results of the review;

b) On any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

Verification/Validation

Verification: activities an organization can do within their control to prove the design concept meets performance parameters and quality characteristics. Examples - visual inspection, dimensional inspection, NDT, any type of test to prove out the configuration and some of the performance requirements.

Validation: Can't always be done by some companies. Proof the design meets its intended use where known. Companies may be able to go to a test lab (which could be part of verification) and test some of the intended performance requirements. For example: companies can’t always prove a design will be able to withstand the required force/thrust (G's) when installed in an aircraft operating in high salt, high temperature (120F+), low temperature (-45F), sandy environment. Some companies may be able to simulate the intended use and environment for the design.

Clause 8- Operation (continued)

8.4 Control of Externally Provided Products and Services

8.4.1 General

The organization shall ensure that externally provided processes, products, and services conform to specified requirements.

The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

The organization shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

The organization shall require that external providers apply appropriate controls to their direct and sub-tier providers, to ensure that requirements are met.

Clause 8- Operation (continued)

8.4.1 General (CONT.)

The organization shall determine the controls to be applied to externally provided processes, products, and services when:

a) Products and services are provided by external providers for incorporation into the organization's own products and services;

b) Products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited QMS or process certification bodies, external provider approvals from government authorities or customers). Use of such data would be only one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.

Clause 8- Operation (continued)

8.4 Control of Externally Provided Products and Services (CONT.)

8.4.1.1 The organization shall:

a) Define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;

b) Maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

c) Periodically review external provider performance including process, product and service conformity, and on-time delivery performance;

d) Define the necessary actions to take when dealing with external providers that do not meet requirements;

e) Define the requirements for controlling documented information created by and/or retained by external providers.

Clause 8- Operation (continued)

8.4.2 Type and Extent of Control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) **Ensure that externally provided processes remain within the control of its QMS;**

b) **Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;**

c) **Take into consideration:**

1. **The potential impact of the externally provided processes, products, and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;**

2. **The effectiveness of the controls applied by the external provider;**

3. **The results of the periodic review of external provider performance, reference clause 8.4.1.1 c;**

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

Clause 8- Operation (continued)

8.4.2 Type and Extent of Control (CONT.)

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including or counterfeit parts.

NOTE: 1 Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.

Clause 8- Operation (continued)

8.4.2 Type and Extent of Control (CONT.)

NOTE 2: Verification activities can include:

- **Review of objective evidence of the conformity of the processes, products and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);**
- **Inspection and audit at the external provider's premises;**
- **Review of the required documentation;**
- **Review of production part approval process data;**
- **Inspection of products or verification of services upon receipt;**
- **Review of delegations of product verification to the external provider.**

Clause 8- Operation (continued)

8.4.2 Type and Extent of Control (CONT.)

When externally provided products are released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When the organization delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations maintained. The organization shall periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, the organization shall have a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified a raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy or test reports.

Clause 8- Operation (continued)

8.4.3 Information for External Providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) The processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);

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;

Clause 8- Operation (continued)

8.4.3 Information for External Providers (CONT.)

d) The external providers' interactions with the organization;

e) Control and monitoring of the external providers' performance to be applied by the organization;

f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises;

g) Design and development control;

h) Special requirements, critical items, or key characteristics;

i) Test, inspection, and verification (including production process verification);

Clause 8- Operation (continued)

j) The use of statistical techniques for product acceptance and related instructions for acceptance by the organization;

k) The need to:

- **Implement a QMS;**
- **Use customer-designated or approved external providers, including process sources (e.g., special processes);**
- **Notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;**
- **Prevent the use of counterfeit products, reference clause 8.1.4;**
- **Notify the organization of changes to processes, products, or services, including changes of external providers or location of manufacture, and obtain the organization's approval;**

Clause 8- Operation (continued)

8.4.3 Information for External Providers (CONT.)

- Flow down to external providers applicable requirements including customer requirements;
- Provide test specimens for design approval, inspection/verification, investigation, or auditing;
- Retain documented information, including retention periods and disposition requirements.

l) The right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

m) Ensuring persons are aware of:

- Their contribution to product or service conformity;
- Their contribution to product safety;
- The importance of ethical behavior.

Clause 8- Operation (continued)

8.5 Production and Service Provision

Control of Production and Service Provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall 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;

NOTE 1: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.

NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.

Clause 8- Operation (continued)

8.5.1 Control of Production and Service Provision (CONT.)

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;

1) Ensuring that documented information for monitoring and measurement activity for product acceptance includes:

- **Criteria for acceptance and rejection;**
- **Where in the sequence verification operations are to be performed;**
- **Measurement results to be retained (at a minimum an indication of acceptance or rejection);**
- **Any specific monitoring and measurement equipment required and instructions associated with their use;**

Clause 8- Operation (contined)

8.5.1 Control of Production and Service Provision (CONT.)

2) Ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

d) The use of suitable infrastructure and environment for the operation of processes;

NOTE: Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.

e) The appointment of competent persons, including any required qualification;

f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

NOTE: These processes can be referred to as special processes, reference clause 8.5.1.2.

Clause 8- Operation (continued)

8.5.1 Control of Production and Service Provision (CONT.)

g) The implementation of actions to prevent human error;

h) The implementation of release, delivery, and post-delivery activities;

i) The establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);

j) The accountability for all product during production (e.g., parts quantities, split orders, nonconforming product;

k) The control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

l) The determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);

m) The identification of in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages;

Clause 8- Operation (continued)

8.5.1 Control of Production and Service Provision (CONT.)

n) The availability of evidence that all production and inspection/ verification operations have been completed as planned, or as otherwise documented and authorized.

o) The provision for the prevention, detection, and removal of foreign objects;

p) The control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, reference clause 7.1.3);

q) The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

Clause 8- Operation (continued)

8.5 Production and Service Provision (CONT.)

8.5.1.1 Control of Equipment, Tools, and Software Equipment

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and shall be maintained.

Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

Clause 8- Operation (continued)

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization shall establish arrangements for these processes including, as applicable:

a) Definition of criteria for the review and approval of the processes;

b) Determination of conditions to maintain the approval;

c) Approval of facilities and equipment;

d) Qualification of persons;

e) Use of specific methods and procedures for implementation and monitoring the processes;

f) Requirements for documented information to be retained.

Clause 8- Operation (continued)

8.5.1.3 Production Process Verification

The organization shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.

NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.

The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

NOTE: This activity can be referred to as a First Article Inspection (FAI).

The organization shall retain documented information on the results of production process verification.

Clause 8- Operation (continued)

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall maintain the identification of the configuration of the products and services in order to identify any difference between the actual configuration and the required configuration.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.

Clause 8- Operation (continued)

8.5.2 Identification and traceability (CONT.)

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

NOTE: Traceability requirements can include:

- **The identification to be maintained throughout the product life;**
- **The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., | delivery, scrap);**
- **For an assembly, the ability to trace its components to the assembly and then to the next higher assembly;**
- **For a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.**

Clause 8- Operation (continued)

8.5.3 Property Belonging to Customers or External Providers

The organization shall exercise care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect, and safeguard the customers' or external providers' property provided for use or incorporation into the products and services.

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

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

Clause 8- Operation (continued)

8.5.4 Preservation

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

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

a) Cleaning;

b) Prevention, detection, and removal of foreign objects;

c) Special handling and storage for sensitive products;

d) Marking and labeling, including safety warnings and cautions;

e) Shelf life control and stock rotation;

f) Special handling and storage for hazardous materials.

Clause 8- Operation (continued)

8.5.5 Post-Delivery Activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

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;

Clause 8- Operation (continued)

8.5.5 Post-Delivery Activities (CONT.)

f) Collection and analysis of in-service data (e.g., performance, reliability, lessons learned);

g) Control, updating, and provision of technical documentation relating to product use, maintenance, repair and overhaul;

h) Controls required for work undertaken external to the organization (e.g., off-site work);

i) Product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

Where problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.

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.

Clause 8- Operation (continued)

8.5.6 Control of Changes

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

Persons authorized to approve production or service provision changes shall be identified.

NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.

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

Clause 8- Operation (continued)

8.6 Release of Products and Services

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

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

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) Evidence of conformity with the acceptance criteria;

b) Traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, the organization shall ensure that retained documented information provides evidence that the products and services meet the defined requirements.

The organization shall ensure that all documented information required to accompany the products and services are present at delivery.

Clause 8- Operation (continued)

8.7 Control of Nonconforming Outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of the products, during or after the provision of the services.

The organization's nonconformance control process shall be maintained as documented information including the provisions for:

- Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions.

Clause 8- Operation (continued)

8.7 Control of Nonconforming Outputs

8.7.1 (CONT.)

- Taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;

- Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;

- Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts, reference clause 10.2.

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

Clause 8- Operation (continued)

8.7.1 (CONT.)

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) Correction;

b) Segregation, containment, return or suspension of provision of products and services;

c) Informing the customer;

d) Obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:

- **After approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization.**

- After authorization by the customer if the nonconformity results in a departure from the contract requirements.

Clause 8- Operations (continued)

8.7.1 (CONT.)

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

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

8.7.2 The organization shall retain documented information that:

a) Describes the nonconformity;

b) Describes the actions taken;

c) Describes any concessions obtained;

d) Identifies the authority deciding the action in respect of the nonconformity.

Clause 9- Performance Evaluation

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

The organization shall determine:

a) What needs to be monitored and measured;

b) The methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;

c) When the monitoring and measuring will be performed;

d) When the results from monitoring and measurement will be analyzed and evaluated.

The organization shall evaluate the performance and the effectiveness of the QMS.

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

Clause 9- Performance Evaluation (continued)

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring, and reviewing this information.

NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action request. The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

Clause 9- Performance Evaluation (continued)

9.1.3 Analysis and Evaluation

The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).

The results of analysis shall be used to evaluate:

a) Conformity of products and services;

b) The degree of customer satisfaction;

c) The performance and effectiveness of the QMS;

d) If planning has been implemented effectively;

Clause 9- Performance Evaluation (continued)

9.1.3 Analysis and Evaluation (CONT.)

e) The effectiveness of actions taken to address risks and opportunities;

f) The performance of external providers;

g) The need for improvement to the QMS.

NOTE: Methods to analyze data can include statistical techniques.

Clause 9- Performance Evaluation (continued)

9.2 Internal Audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the QMS:

a) Conforms to:

1) The organization's own requirements for its QMS;

NOTE: The organization's own requirements should include customer and applicable statutory and regulatory QMS requirements.

2) The requirements of AS9100;

b) Is effectively implemented and maintained.

NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the QMS is effectively implemented and maintained.

Clause 9- Performance Evaluation (continued)

9.2 Internal Audit (CONT.)

9.2.2 The organization shall:

a) Plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of processes concerned, changes affecting the organization, and the results of previous audits;

b) Define the audit criteria and scope for each audit;

c) Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) Ensure that the results of the audits are reported to relevant management;

e) Take appropriate correction and corrective actions without undue delay;

f) Retain documented information as evidence of the implementation of the audit program and the audit results.

NOTE: ISO 19011 can be used for guidance.

Clause 9- Performance Evaluation (continued)

9.3 Management Review

9.3.1 General

Top management shall review the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

Clause 9- Performance Evaluation (continued)

9.3.2 Management Review Inputs

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 QMS;

c) Information on the performance and effectiveness of the QMS, including trends in:

1) Customer satisfaction and feedback from relevant interested parties;

2) The extent to which quality objectives have been met;

3) 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;

8) On-time delivery performance;

Clause 9- Performance Evaluation (continued)

9.3.2 Management Review Inputs (CONT.)

d) The adequacy of resources;

e) The effectiveness of actions taken to address risks and opportunities, reference Clause 6.1;

f) Opportunities for improvement.

9.3.3 Management Review Outputs

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

a) Opportunities for improvement;

b) Any need for changes to the QMS;

c) Resource needs;

d) Risks identified.

The organization shall retain documented information as evidence of the results of management reviews.

Clause 10- Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction.

This shall include:

a) Improving products and services to meet requirements as well as to address future needs and expectations;

b) Correcting, preventing, or reducing undesired effects;

c) Improving the performance and effectiveness of the QMS.

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

Clause 10- Improvement (continued)

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including those arising from complaints, the organization shall:

a) React to the nonconformity, and as applicable:

1) Take action to control and correct it;

2) Deal with the consequences.

b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) Reviewing and analyzing the nonconformity;

2) Determining the causes of the nonconformity, including as applicable, those related to human factors;

3)Determining if similar nonconformities exist, or could potentially occur;

c) Implement any action needed;

Clause 10- Improvement (continued)

10.2.1 (CONT.):

d) Review the effectiveness of any corrective action taken;

e) Update risks and opportunities determined during planning, if necessary;

f) Make changes to the QMS, if necessary;

g) Flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

h) Take specific actions when timely and effective corrective actions are not achieved.

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

The organization shall maintain documented information that defines the nonconformity and corrective action management processes.

Clause 10- Improvement (continued)

10.2.2 The organization shall retain documented information as evidence of:

a) The nature of the nonconformities and any subsequent actions taken;

b) The results of any corrective action.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy, and effectiveness of the QMS.

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

The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.