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AEROSPACE STANDARD

AS9100®	REV. D
Issued 1999-11 Revised 2016-09 Superseding AS9100C	
Technically equivalent writings published in all IAQG sectors.	

(R) Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations

RATIONALE

This standard has been revised to incorporate the new clause structure and content of ISO 9001:2015. In addition, industry requirements, definitions, and notes have been revised in response to both ISO 9001 revisions and stakeholder needs.

FOREWORD

To assure customer satisfaction, aviation, space, and defense organizations must provide, and continually improve, safe and reliable products and services that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products and services from external providers throughout the world and at all levels of the supply chain. External providers have the challenge of delivering products and services to multiple customers having varying quality requirements and expectations.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from aviation, space, and defense companies in the Americas, Asia/Pacific, and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream. This standard has been prepared by the IAQG.

This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, cost, and delivery performance through the reduction or elimination of organization-unique requirements, effective implementation of the quality management system, and wider application of good practice. While primarily developed for the aviation, space, and defense industry, this standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001 system is needed.

This standard includes ISO 9001:2015[1] quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes as shown in bold, italic text.

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INTENDED APPLICATION

This standard is intended for use by organizations that design, develop, or provide aviation, space, and defense products and services; and by organizations providing post-delivery activities, including the provision of maintenance, spare parts, or materials for their own products and services.

NOTE: Organizations whose products are deliverable software, or contain deliverable software, should use the IAQG-developed 9115 standard (see Bibliography) when planning and evaluating the software design, development, or management activities of the organization. The 9115 standard provides guidance to the requirements of the 9100 standard when it is desired to add "software" to the 9100 quality management system scope.

Organizations whose primary business is providing maintenance or continuing airworthiness management services for civil or military aviation articles and products; and original equipment manufacturers with maintenance, repair, and overhaul operations that are operated autonomously, or that are substantially different from their production operations; should use the IAQG-developed 9110 standard (see Bibliography).

Organizations that procure parts, materials, and assemblies and resells these products to a customer in the aviation, space, and defense industry should use the IAQG-developed 9120 standard (see Bibliography). This includes organizations that procure products and split them into smaller quantities, as well as those that coordinate a customer or regulatory controlled process on the product.

INTRODUCTION

0.1 General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a. the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b. facilitating opportunities to enhance customer satisfaction;

c. addressing risks and opportunities associated with its context and objectives;

d. the ability to demonstrate conformity to specified quality management system requirements.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

- uniformity in the structure of different quality management systems;
- alignment of documentation to the clause structure of this International Standard;
- the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

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The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation, and re-organization.

In this International Standard, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

0.2 Quality Management Principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle, and examples of typical actions to improve the organization’s performance when applying the principle.

The quality management principles are:

- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

0.3 Process Approach

0.3.1 General

This International Standard promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

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Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a. understanding and consistency in meeting requirements;

b. the consideration of processes in terms of added value;

c. the achievement of effective process performance;

d. improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process, and will vary depending on the related risks.

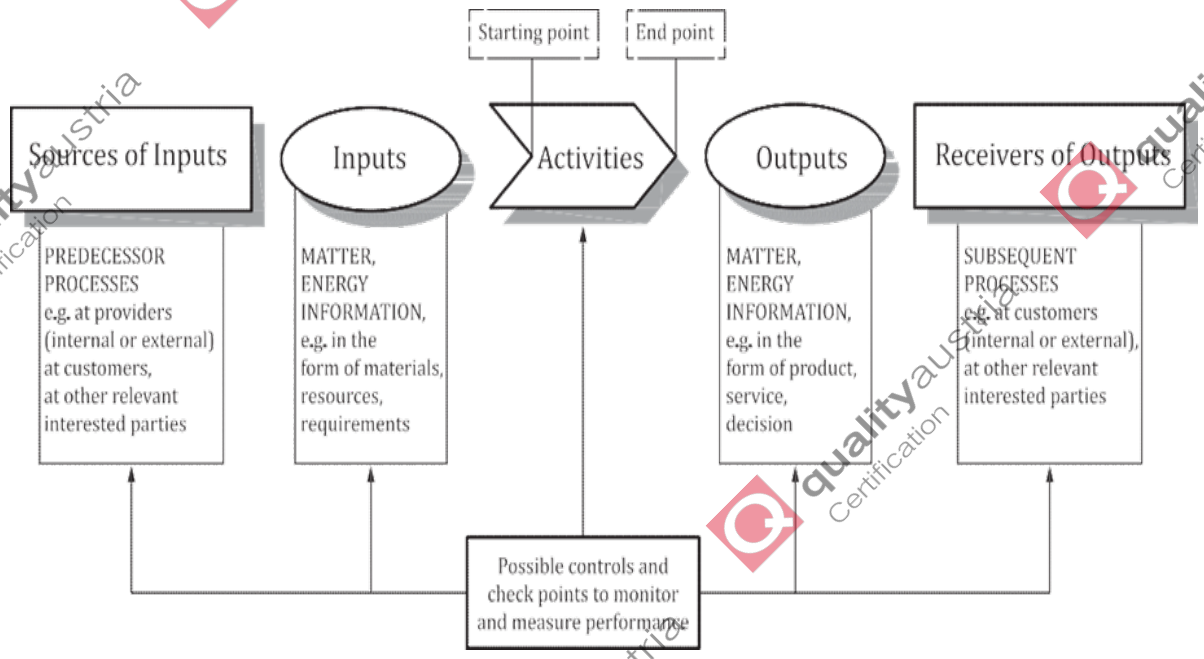

Figure 1 – Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act Cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how clauses 4 to 10 can be grouped in relation to the PDCA cycle.

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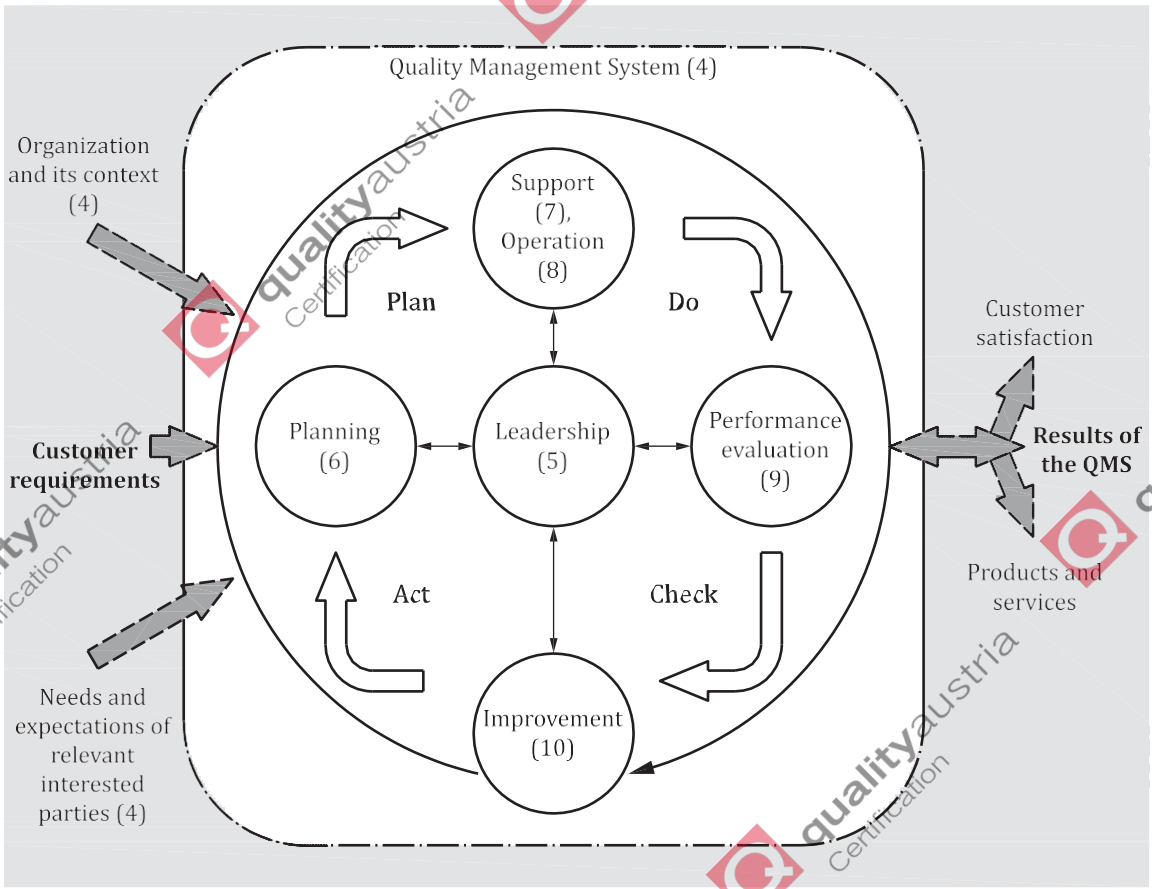
The PDCA cycle can be briefly described as follows:

- Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;
- Do: implement what was planned;
- Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements, and planned activities, and report the results;
- Act: take actions to improve performance, as necessary.



NOTE: Numbers in brackets refer to the clauses in this International Standard.

Figure 2 – Representation of the structure of this International Standard in the PDCA cycle

0.3.3 Risk-Based Thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results, and preventing negative effects.

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Opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste, or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with Other Management System Standards

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standard relates to ISO 9000 and ISO 9004 as follows:

- ISO 9000, "*Quality management systems – Fundamentals and vocabulary*", provides essential background for the proper understanding and implementation of this International Standard;
- ISO 9004, "*Managing for the sustained success of an organization – A quality management approach*", provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

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QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS

1. SCOPE

This standard includes ISO 9001:2015[2] quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.

It is emphasized that the requirements specified in this standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

If there is a conflict between the requirements of this standard and customer or applicable statutory or regulatory requirements, the latter shall take precedence.

This International Standard specifies requirements for a quality management system when an organization:

a. needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b. aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1: In this International Standard, the terms “product” or “service” only apply to products and services intended for, or required by, a customer.

NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.

2. NORMATIVE REFERENCES

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015 Quality management systems – Fundamentals and vocabulary

ISO 9001:2015 Quality management systems – Requirements

3. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2015 ***and the following*** apply.

3.1 Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

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3.2 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.3 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

3.4 Product Safety

The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Special Requirements

Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

NOTE: Special requirements (3.5) and critical items (3.2), along with key characteristics (3.3), are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

4. CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and Its Context

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.

The organization shall monitor and review information about these external and internal issues.

NOTE 1: Issues can include positive and negative factors or conditions for consideration.

NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional, or local.

NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of the organization.

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4.2 Understanding the Needs and Expectations of Interested Parties

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

a. the interested parties that are relevant to the quality management system;

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

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

4.3 Determining the Scope of the Quality Management System

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

When determining this scope, the organization 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 organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system 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 requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality Management System and Its Processes

4.4.1 The organization shall establish, implement, maintain, and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a. determine the inputs required and the outputs expected from these processes;

b. determine the sequence and interaction of these processes;

c. determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d. determine the resources needed for these processes and ensure their availability;

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e. assign the responsibilities and authorities for these processes;

f. address the risks and opportunities as determined in accordance with the requirements of 6.1;

g. evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h. improve the processes and the quality management system.

4.4.2 To the extent necessary, the organization shall:

a. maintain documented information to support the operation of its processes;

b. retain documented information to have confidence that the processes are being carried out as planned.

The organization shall establish and maintain documented information that includes:

- ***a general description of relevant interested parties (see 4.2 a);***
- ***the scope of the quality management system, including boundaries and applicability (see 4.3);***
- ***a description of the processes needed for the quality management system and their application throughout the organization;***
- ***the sequence and interaction of these processes;***
- ***assignment of the responsibilities and authorities for these processes.***

NOTE: The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.

5. LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

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

a. taking accountability for the effectiveness of the quality management system;

b. ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

c. ensuring the integration of the quality management system requirements into the organization's business processes;

d. promoting the use of the process approach and risk-based thinking;

e. ensuring that the resources needed for the quality management system are available;

f. communicating the importance of effective quality management and of conforming to the quality management system requirements;

g. ensuring that the quality management system achieves its intended results;

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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.

NOTE: Reference to "business" in this International Standard 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.

5.1.2 Customer Focus

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***;***

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

5.2 Policy

5.2.1 Establishing the Quality Policy

Top management shall establish, implement, and maintain a quality policy that:

a. is appropriate to the purpose and context of the organization and supports its strategic direction;

b. provides a framework for setting quality objectives;

c. includes a commitment to satisfy applicable requirements;

d. includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The quality policy shall:

a. be available and maintained as documented information;

b. be communicated, understood, and applied within the organization;

c. 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.

Top management shall assign the responsibility and authority for:

a. ensuring that the quality management system conforms to the requirements of this International Standard;

b. ensuring that the processes are delivering their intended outputs;

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c. reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d. ensuring the promotion of customer focus throughout the organization;

e. ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

6. PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a. give assurance that the quality management system can achieve its intended result(s);

b. enhance desirable effects;

c. prevent, or reduce, undesired effects;

d. achieve improvement.

6.1.2 The organization shall plan:

a. actions to address these risks and opportunities;

b. how to:

1. integrate and implement the actions into its quality management system processes (see 4.4);

2. 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 services.

NOTE 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

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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 quality management system.

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.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization 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.

6.3 Planning of Changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization 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

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

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The organization 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

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

7.1.3 Infrastructure

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

NOTE: Infrastructure can include:

a. buildings and associated utilities;

b. equipment, including hardware and software;

c. transportation resources;

d. information and communication technology.

7.1.4 Environment for the Operation of Processes

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

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

a. social (e.g., non-discriminatory, calm, non-confrontational);

b. psychological (e.g., stress-reducing, burnout prevention, emotionally protective);

c. physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

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

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

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:

a. are suitable for the specific type of monitoring and measurement activities being undertaken;

b. are maintained to ensure their continuing fitness for their purpose.

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

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7.1.5.2 Measurement Traceability

When measurement traceability is a 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:

a. calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b. identified in order to determine their status;

c. safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

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 produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).

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 be 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 any necessary additional knowledge and required updates.

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:

a. internal sources (e.g., intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b. external sources (e.g., standards; academia; conferences; gathering knowledge from customers or external providers).

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7.2 Competence

The organization shall:

a. determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b. ensure that these persons are competent on the basis of appropriate education, training, or experience;

c. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d. retain appropriate documented information as evidence of competence.

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.

7.3 Awareness

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

a. the quality policy;

b. relevant quality objectives;

c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d. the implications of not conforming with the quality management system requirements***;***

e. relevant quality management system documented information and changes thereto;

f. their contribution to product or service conformity;

g. their contribution to product safety;

h. the importance of ethical behavior.

7.4 Communication

The organization shall determine 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.

NOTE: Communication should include internal and external feedback relevant to the quality management system.

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7.5 Documented Information

7.5.1 General

The organization's quality management system shall include:

a. documented information required by this International Standard;

b. documented information determined by the organization as being necessary for the effectiveness of the quality management system.

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

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

7.5.2 Creating and Updating

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

a. identification and description (e.g., a title, date, author, or reference number);

b. format (e.g., language, software version, graphics) and media (e.g., paper, electronic);

c. review and approval for suitability and adequacy.

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

7.5.3 Control of Documented Information

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

a. it is available and suitable for use, where and when it is needed;

b. it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall 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. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

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

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.

8. OPERATION

8.1 Operational Planning and Control

The organization shall plan, implement, and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by:

a. determining the requirements for the products and services;

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;***
- ***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.***

b. establishing criteria for:

1. the processes;
2. the acceptance of products and services;

NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

- ***design verification (e.g., reliability, maintainability, product safety);***
- ***process control;***
  - ***selection and verification of key characteristics;***
  - ***process capability measurements;***

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- ***statistical process control;***
- ***design of experiments;***

– ***verification;***

– ***failure mode, effects, and criticality analysis.***

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

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;

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.

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.

NOTE: As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific 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 any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

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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 risks 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, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.

8.1.1 Operational Risk Management

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

a. assignment of responsibilities for operational risk management;

b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);

c. identification, assessment, and communication of risks throughout operations;

d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e. acceptance of risks remaining after implementation of mitigating actions.

NOTE 1: While clause 6.1 addresses the risks and opportunities when planning for the quality management system of the organization, the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8).

NOTE 2: Within the 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, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

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 (see 8.1.1);***
- ***management of safety critical items;***
- ***analysis and reporting of occurred events affecting safety;***
- ***communication of these events and training of persons.***

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8.1.4 Prevention of Counterfeit Parts

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

NOTE: Counterfeit part 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.***

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 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.

8.2.2 Determining the Requirements for Products and Services

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

a. the requirements for the products and services are defined, including:

   1. any applicable statutory and regulatory requirements;

   2. those considered necessary by the organization;

b. the 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.

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8.2.3 Review of the Requirements for 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 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.

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.

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.

8.3 Design and Development of Products and Services

8.3.1 General

The organization shall establish, implement, and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and Development Planning

In determining the stages and controls for design and development, the organization shall consider:

a. the nature, duration, and complexity of the design and development activities;

b. the required process stages, including applicable design and development reviews;

c. the required design and development verification and validation activities;

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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.

When appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.

Design and development planning shall consider the ability to provide, verify, test and maintain products and services (reference output of 8.1 a).

8.3.3 Design and Development Inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a. functional and performance requirements;

b. information derived from previous similar design and development activities;

c. statutory and regulatory requirements;

d. standards or codes of practice that the organization has committed to implement;

e. potential consequences of failure due to the nature of the products and services***;***

f. when applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products).

Inputs shall be adequate for design and development purposes, complete, and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

NOTE: The organization can also consider as design and development inputs other information such as benchmarking, external provider feedback, internally generated data, and in-service data.

8.3.4 Design and Development Controls

The organization shall apply 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;

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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***;***

g. progression to the next stage is authorized.

Participants in design and development reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.

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

8.3.4.1 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:

a. test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;

b. test procedures describe the test methods to be used, how to perform the test, and how to record the results;

c. the correct configuration of the test item is submitted for the test;

d. the requirements of the test plan and the test procedures are observed;

e. the acceptance criteria are met.

Monitoring and measuring devices used for testing shall be controlled as defined in clause 7.1.5.

At the completion of design and development, the organization shall ensure that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.

8.3.5 Design and Development Outputs

The organization shall ensure that design and development outputs:

a. meet the input requirements;

b. are adequate for the subsequent processes for the provision of products and services;

c. include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d. specify the characteristics of products and services that are essential for their intended purpose and their safe and proper provision***;***

e. specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;

f. are approved by authorized person(s) prior to release.

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The organization shall define the data required to allow the product to be identified, manufactured, verified, used, and maintained.

NOTE: Data can include:

- ***the drawings, part lists, and specifications necessary to define the configuration and the design features of the product;***
- ***the material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service;***
- ***the technical data and repair schemes for operating and maintaining the product.***

The organization shall retain documented information on design and development outputs.

8.3.6 Design and Development Changes

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

The organization shall implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.

The organization shall retain documented information on:

a. design and development changes;

b. the results of reviews;

c. the authorization of the changes;

d. the actions taken to prevent adverse impacts.

Design and development changes shall be controlled in accordance with the configuration management process requirements.

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

The organization shall ensure that externally provided processes, products, and services conform to 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 external providers, to ensure that requirements are met.

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

a. products and services from external providers are intended for incorporation into the 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 quality management system 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.

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.

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 quality management system;

b. define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c. take into consideration:

1. the potential impact of the externally provided processes, products, and services on the 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 (see 8.4.1.1 c);

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

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 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.

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.***

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

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;

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c. competence, including any required qualification of persons;

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);

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

k. the need to:

- ***implement a quality management system;***
- ***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 parts (see 8.1.4);***
- ***notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;***
- ***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 that persons are aware of:

- ***their contribution to product or service conformity;***
- ***their contribution to product safety;***
- ***the importance of ethical behavior.***

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

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

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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.

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;***

   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 infrastructure 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 (see 8.5.1.2).

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);

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j. the accountability for all products 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 conformity cannot be performed at later stages;

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 (see 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.

8.5.1.1 Control of Equipment, Tools, and Software Programs

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.

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.

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.

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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 First Article Inspection (FAI).

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

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 differences 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 controls for the media.

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.***

8.5.3 Property Belonging to Customers or External Providers

The organization shall exercise care with property belonging to customers 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 customers' or external providers' property provided for use or incorporation into the products and services.

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

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

8.5.4 Preservation

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

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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.

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***;***

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).

When 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.

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 requirements.

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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.

8.6 Release of Products and Services

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

The release of products and services to the customer 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.

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 products, during or after the provision of services.

The organization's nonconformity 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;***
- ***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 (see 10.2).***

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

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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.***

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.

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 shall be performed;

d. when the results from monitoring and measurement shall be analyzed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

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

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 requests. 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.

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 quality management system;

d. if planning has been implemented effectively;

e. the effectiveness of actions taken to address risks and opportunities;

f. the performance of external providers;

g. the need for improvements to the quality management system.

NOTE: Methods to analyze data can include statistical techniques.

9.2 Internal Audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system;

a. conforms to:

1. the organization's own requirements for its quality management system;

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

2. the requirements of this International Standard;

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b. is effectively implemented and maintained.

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

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 the 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: See ISO 19011 for guidance.

9.3 Management Review

9.3.1 General

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

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 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***;***

8. on-time delivery performance;

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d. the adequacy of resources;

e. the effectiveness of actions taken to address risks and opportunities (see 6.1);

f. opportunities for improvement.

9.3.3 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 quality management system;

c. resource needs;

d. risks identified.

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

10. IMPROVEMENT

10.1 General

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

These 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 quality management system.

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

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, the 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;

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c. implement any action needed;

d. review the effectiveness of any corrective action taken;

e. update risks and opportunities determined during planning, if necessary;

f. make changes to the quality management system, if necessary***;***

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.

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 quality management system.

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 shall 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.

11. NOTES

11.1 Revision Indicator

A change bar (I) located in the left margin is for the convenience of the user in locating areas where technical revisions, not editorial changes, have been made to the previous issue of this document. An (R) symbol to the left of the document title indicates a complete revision of the document, including technical revisions. Change bars and (R) are not used in original publications, nor in documents that contain editorial changes only.

PREPARED BY SAE COMMITTEE G-14, AMERICAS AEROSPACE QUALITY STANDARDS (AAQSC)

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ANNEX A – CLARIFICATION OF NEW STRUCTURE, TERMINOLOGY AND CONCEPTS (INFORMATIVE)

A.1 STRUCTURE AND TERMINOLOGY

The clause structure (i.e., clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives, and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g., using "records", "documentation", or "protocols" rather than "documented information"; or "supplier", "partner", or "vendor" rather than "external provider"). Table A1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

A.2 PRODUCTS AND SERVICES

ISO 9001:2008 used the term "product" to include all output categories. This edition of this International Standard uses "products and services". "Products and services" include all output categories (hardware, services, software, and processed materials).

The specific inclusion of "services" is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the interface with the customer. This means, for example, that conformity to requirements cannot necessarily be confirmed before service delivery.

In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example, a tangible or intangible product can have some associated service or a service can have some associated tangible or intangible product.

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Table A1 – Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See clause A.5 for clarification of applicability.)
Management representative	Not used (Similar responsibilities and authorities are assigned, but no requirement for a single management representative.) ***NOTE: The 9100 standard has retained the term management representative***
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

A.3 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

Sub-clause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

A.4 RISK-BASED THINKING

The concept of risk-based thinking has been implicit in previous editions of this International Standard (e.g., through requirements for planning, review, and improvement). This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4), and will assist in determining the extent of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information, and organizational responsibilities.

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Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard (e.g., through the application of other guidance or standards).

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

Within aviation, space, and defense, risk is expressed as a combination of severity and likelihood of having a potential negative impact to processes, products, services, customer, or end users.

Due to the complexity of aviation, space, and defense processes, products, and services, and the severity of the potential consequences of failures, a formal process to manage operational risks is required in clause 8.1.1.

The operational risk management process is supported by specific requirements throughout clause 8, with the goal of developing an enhanced focus on:

- ***understanding risk impacts on operational processes;***
- ***making decisions on operational processes and actions to manage (e.g., prevent, mitigate, control) potential undesired effects.***

A.5 APPLICABILITY

This International Standard does not refer to "exclusions" in relation to the applicability of its requirements to the organization's quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities, and the nature of the risks and opportunities it encounters.

The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

A.6 DOCUMENTED INFORMATION

As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained, and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose (e.g., to retain previous versions of it).

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Where this International Standard refers to “information” rather than “documented information” (e.g., in 4.1: “The organization shall monitor and review the information about these external and internal issues”), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

A.7 ORGANIZATIONAL KNOWLEDGE

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure the operation of its processes and that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of:

a. safeguarding the organization from loss of knowledge, e.g.,

   - through staff turnover;
   - failure to capture and share information;

b. encouraging the organization to acquire knowledge, e.g.,

   - learning from experience;
   - mentoring;
   - benchmarking.

A.8 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS, AND SERVICES

All forms of externally provided processes, products, and services are addressed in 8.4, e.g., whether through:

a. purchasing from a supplier;

b. an arrangement with an associate company;

c. outsourcing processes to an external provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

The controls required for external provision can vary widely depending on the nature of the processes, products, and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products, and services.

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ANNEX B – OTHER INTERNATIONAL STANDARDS ON QUALITY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS DEVELOPED BY ISO/TC 176 (INFORMATIVE)

The International Standards described in this annex have been developed by ISO/TC 176 to provide supporting information for organizations that apply this International Standard, and to provide guidance for organizations that choose to progress beyond its requirements. Guidance or requirements contained in the documents listed in this annex do not add to, or modify, the requirements of this International Standard.

Table B1 shows the relationship between these standards and the relevant clauses of this International Standard.

This annex does not include reference to the sector-specific quality management system standards developed by ISO/TC 176.

This International Standard is one of the three core standards developed by ISO/TC 176.

- ISO 9000, *"Quality management systems – Fundamentals and vocabulary"*, provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles are described in detail in ISO 9000 and have been taken into consideration during the development of this International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. ISO 9000 also defines the terms, definitions, and concepts used in this International Standard.

- ISO 9001 (this International Standard) specifies requirements aimed primarily at giving confidence in the products and services provided by an organization and thereby enhancing customer satisfaction. Its proper implementation can also be expected to bring other organizational benefits, such as improved internal communication, better understanding, and control of the organization's processes.

- ISO 9004, *"Managing for the sustained success of an organization – A quality management approach"*, provides guidance for organizations that choose to progress beyond the requirements of this International Standard, to address a broader range of topics that can lead to improvement of the organization's overall performance. ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system.

The International Standards outlined below can provide assistance to organizations when they are establishing or seeking to improve their quality management systems, their processes, or their activities.

- ISO 10001, *"Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations"*, provides guidance to an organization in determining that its customer satisfaction provisions meet customer needs and expectations. Its use can enhance customer confidence in an organization and improve customer understanding of what to expect from an organization, thereby reducing the likelihood of misunderstandings and complaints.

- ISO 10002, *"Quality management – Customer satisfaction – Guidelines for complaints handling in organizations"*, provides guidance on the process of handling complaints by recognizing and addressing the needs and expectations of complainants and resolving any complaints received. ISO 10002 provides an open, effective, and easy-to-use complaints process, including training of people. It also provides guidance for small businesses.

- ISO 10003, *"Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations"*, provides guidance for effective and efficient external dispute resolution for product-related complaints. Dispute resolution gives an avenue of redress when organizations do not remedy a complaint internally. Most complaints can be resolved successfully within the organization, without adversarial procedures.

- ISO 10004, "*Quality management – Customer satisfaction – Guidelines for monitoring and measuring"*, provides guidelines for actions to enhance customer satisfaction and to determine opportunities for improvement of products, processes, and attributes that are valued by customers. Such actions can strengthen customer loyalty and help retain customers.

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- ISO 10005, *"Quality management systems – Guidelines for quality plans"*, provides guidance on establishing and using quality plans as a means of relating requirements of the process, product, project, or contract, to work methods and practices that support product realization. Benefits of establishing a quality plan are increased confidence that requirements will be met, that processes are in control and the motivation that this can give to those involved.

- ISO 10006, *"Quality management systems – Guidelines for quality management in projects"*, is applicable to projects from the small to large, from simple to complex, from an individual project to being part of a portfolio of projects. ISO 10006 is to be used by personnel managing projects and who need to ensure that their organization is applying the practices contained in the ISO quality management system standards.

- ISO 10007, *"Quality management systems – Guidelines for configuration management"*, is to assist organizations applying configuration management for the technical and administrative direction over the life cycle of a product. Configuration management can be used to meet the product identification and traceability requirements specified in this International Standard.

- ISO 10008, *"Quality management – Customer satisfaction – Guidelines for business-to-consumer electronic commerce transactions"*, gives guidance on how organizations can implement an effective and efficient business-to-consumer electronic commerce transaction (B2C ECT) system, and thereby provide a basis for consumers to have increased confidence in B2C ECTs, enhance the ability of organizations to satisfy consumers and help reduce complaints and disputes.

- ISO 10012, *"Measurement management systems – Requirements for measurement processes and measuring equipment"*, provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. ISO 10012 provides quality management criteria for a measurement management system to ensure metrological requirements are met.

- ISO/TR 10013, *"Guidelines for quality management system documentation"*, provides guidelines for the development and maintenance of the documentation necessary for a quality management system. ISO/TR 10013 can be used to document management systems other than those of the ISO quality management system standards (e.g., environmental management systems and safety management systems).

- ISO 10014, *"Quality management – Guidelines for realizing financial and economic benefits"*, is addressed to top management. It provides guidelines for realizing financial and economic benefits through the application of quality management principles. It facilitates application of management principles and selection of methods and tools that enable the sustainable success of an organization.

- ISO 10015, *"Quality management – Guidelines for training"*, provides guidelines to assist organizations in addressing issues related to training. ISO 10015 can be applied whenever guidance is required to interpret references to "education" and "training" within the ISO quality management system standards. Any reference to "training" includes all types of education and training.

- ISO/TR 10017, *"Guidance on statistical techniques for ISO 9001:2000"*, explains statistical techniques which follow from the variability that can be observed in the behavior and results of processes, even under conditions of apparent stability. Statistical techniques allow better use of available data to assist in decision making, and thereby help to continually improve the quality of products and processes to achieve customer satisfaction.

- ISO 10018, "*Quality management – Guidelines on people involvement and competence"*, provides guidelines which influence people involvement and competence. A quality management system depends on the involvement of competent people and the way that they are introduced and integrated into the organization. It is critical to determine, develop, and evaluate the knowledge, skills, behavior, and work environment required.

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- ISO 10019, *"Guidelines for the selection of quality management system consultants and use of their services"*, provides guidance for the selection of quality management system consultants and the use of their services. It gives guidance on the process for evaluating the competence of a quality management system consultant and provides confidence that the organization's needs and expectations for the consultant's services will be met.

- ISO 19011, *"Guidelines for auditing management systems"*, provides guidance on the management of an audit program, on the planning and conducting of an audit of a management system, as well as on the competence and evaluation of an auditor and an audit team. ISO 19011 is intended to apply to auditors, organizations implementing management systems, and organizations needing to conduct audits of management systems.

Table B1 – Relationship between other International Standards on quality management and quality management systems and the clauses of this International Standard

Other International Standards	Clause in this International Standard						
	4	5	6	7	8	9	10
ISO 9000	All	All	All	All	All	All	All
ISO 9004	All	All	All	All	All	All	All
ISO 10001					8.2.2, 8.5.1	9.1.2	
ISO 10002					8.2.1	9.1.2	10.2.1
ISO 10003						9.1.2	
ISO 10004						9.1.2, 9.1.3	
ISO 10005		5.3	6.1, 6.2	All	All	9.1	10.2
ISO 10006	All	All	All	All	All	All	All
ISO 10007					8.5.2		
ISO 10008	All	All	All	All	All	All	All
ISO 10012				7.1.5			
ISO/TR 10013				7.5			
ISO 10014	All	All	All	All	All	All	All
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	All	All	All	All	All	All	All
ISO 10019					8.4		
ISO 19011						9.2	

NOTE: "All" indicates that all the sub-clauses in the specific clause of this International Standard are related to the other International Standards.

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ANNEX C – OTHER STANDARDS ON QUALITY MANAGEMENT *AND QUALITY MANAGEMENT SYSTEMS DEVELOPED BY THE INTERNATIONAL AEROSPACE QUALITY GROUP (INFORMATIVE)*

The International Aerospace Quality Group (IAQG) standards described in this annex have been developed by the IAQG to provide supporting information for organizations that apply the 9100 standard, and to provide guidance for organizations that choose to progress beyond its requirements. Guidance or requirements contained in the documents listed in this annex do not add to, or modify, the requirements of the 9100 standard.

Table C1 shows the relationship between these standards and the relevant clauses of the 9100 standard.

The 9100 standard is one of the three quality management system standards developed by the IAQG.

- ***9100, "Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations": This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, cost, and delivery performance through the reduction or elimination of organization-unique requirements, effective implementation of the quality management system, and wider application of good practice. While primarily developed for the aviation, space, and defense industry, this standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001 system is needed.***

- ***9110, "Quality Management Systems – Requirements for Aviation Maintenance Organizations": This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, schedule, and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practice. While primarily developed for the civil and military aviation industry organizations providing maintenance services, this standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001 system is needed.***

- ***9120, "Quality Management Systems – Requirements for Aviation, Space and Defense Distributors": This standard is for use by organizations that procure parts, materials, and assemblies and resells these products to a customer in the aviation, space, and defense industries. This includes organizations that procure products and split them into smaller quantities including those that coordinate a customer or regulatory controlled process on the product. This standard is not intended for organizations that maintain or repair products, or for organizations that perform work that affect or could affect product characteristics or conformity.***

The IAQG standards outlined below can provide assistance to organizations when they are establishing or seeking to improve their quality management systems, their processes or their activities.

- ***9101, "Quality Management Systems – Audit Requirements for Aviation, Space, and Defense Organizations": This standard defines requirements for the preparation and execution of the audit process. In addition, it defines the content and composition for the audit reporting of conformity and process effectiveness to the 9100-series standards, the organization's QMS, and customer and statutory/regulatory requirements.***

- ***9102, "Aerospace First Article Inspection Requirement": This document standardizes FAI process requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world to provide a consistent process and documentation requirements for verification of aviation, space, and defense product. Its use should result in improved quality, schedule, and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practices. While primarily developed for the aviation, space, and defense industry, this standard can also be used in other industry sectors where a standardized FAI process is needed.***

- ***9103, "Variation Management of Key Characteristics": This document standardizes requirements for "key characteristic" identification, control, documentation, and approval for the industry. The establishment of common requirements, for use at all levels of the supply chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.***

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— ***9107, "Direct Delivery Authorization Guidance for Aerospace Companies": This document provides guidance to a production organization and a design organization on how to comply with the direct delivery authorization, including appropriate arrangement requirements.***

— ***9114, "Direct Ship Guidance for Aerospace Companies": This document standardizes requirements for the direct shipment of articles from a supplier of an approved manufacturer to a customer of an approved manufacturer and was originally produced as a cooperative effort between the Federal Aviation Administration (FAA) and the IAQG. The establishment of common expectations, for use at all levels of the supply-chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.***

— ***9115, "Quality Management Systems – Requirements for Aviation, Space and Defense Organizations – Deliverable Software": This document supplements the 9100 standard requirements for deliverable software and contains quality management system requirements for organizations that design, develop, and/or produce deliverable software and services for the aviation, space, and defense industry. This includes, as required, support software that is used in the development and maintenance of deliverable software and services. The deliverable software may be stand-alone, embedded, mobile application, or loadable into a target computer.***

— ***9116, "Aerospace Series – Notice of Change (NOC) Requirements": This document was created to provide for the uniform submittal of change notifications and/or approval when contractually invoked at any level or as guidance within the aviation, space, and defense industries. This standard can be invoked as a stand-alone requirement or used in conjunction with AS/EN/JISQ 9100-series standards (i.e., 9100, 9110, 9120).***

— ***9131, "Quality Management Systems – Aerospace – Nonconformance Documentation": This document standardizes requirements for nonconformance data definition and documentation for the industry. The establishment of common requirements, for use at all levels of the supply-chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.***

— ***9132, "Data Matrix Quality Requirements for Parts Marking": This document standardizes data matrix quality requirements for parts marking for the industry. The establishment of common requirements, for use at all levels of the supply-chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.***

— ***9133, "Qualification Procedure for Aerospace Standard Products": This standard defines a system for the qualification of standard products for aviation, space, and defense applications. It defines the principles that shall be adhered to carry out product qualification; applied in conjunction with the rules and procedures of the Certification Authority (CA). The system enables the CA to confirm compliance is achieved and maintained, in accordance with the requirements of its product definition and associated controlling technical specifications by an Original Component Manufacturer (OCM) of standard products.***

— ***9134, "Supply Chain Risk Management Guideline": The guideline focuses on Quality as a key risk assessment factor taking into account elements from all aspects of the business having a direct link to global quality management. While traditional "small q" Quality is a key element to be assessed, from a company business point of view, other elements play an important part in minimizing risk. This guideline defines such risk factors for consideration.***

— ***9162, "Aerospace Operator Self-Verification Programs": This standard is focused on standardizing, to the extent possible, operator self-verification practices in the aviation, space, and defense industry. Establishing common requirements practices should result in improved quality and safety, decreased costs, and elimination or reduction of organization-unique requirements.***

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Table C1 – Relationship between other International Aerospace Quality Group standards on quality management and quality management systems and the clauses of the International Aerospace Quality Group 9100 standard

Other IAQG Standards	Clauses in the 9100 Standard						
	4	5	6	7	8	9	10
9101	4.4					9.2	
9102					8.4.2, 8.5.1.3		
9103					8.1, 8.3.5, 8.4.3, 8.5.1		
9107					8.6		
9114					8.6		
9115	All	All	All	All	All	All	All
9116					8.3.6, 8.4.3, 8.5.6		
9131					8.7		10.2
9132					8.5.2		
9133					8.4.2, 8.6		
9134					8.4.1		
9162					8.5.1, 8.6		

NOTE: "All" indicates that all the sub-clauses in the specific clause of the 9100 standard are related to the other IAQG standard.

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ANNEX D – BIBLIOGRAPHY

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[2] ISO 10001, "*Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations"*

[3] ISO 10002, "*Quality management – Customer satisfaction – Guidelines for complaints handling in organizations"*

[4] ISO 10003, "*Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations"*

[5] ISO 10004, "*Quality management – Customer satisfaction – Guidelines for monitoring and measuring"*

[6] ISO 10005, "*Quality management systems – Guidelines for quality plans"*

[7] ISO 10006, "*Quality management systems – Guidelines for quality management in projects"*

[8] ISO 10007, "*Quality management systems – Guidelines for configuration management"*

[9] ISO 10008, "*Quality management – Customer satisfaction – Guidelines for business-to-consumer electronic commerce transactions"*

[10] ISO 10012, "*Measurement management systems – Requirements for measurement processes and measuring equipment"*

[11] ISO/TR 10013, "*Guidelines for quality management system documentation"*

[12] ISO 10014, "*Quality management – Guidelines for realizing financial and economic benefits"*

[13] ISO 10015, "*Quality management – Guidelines for training"*

[14] ISO/TR 10017, "*Guidance on statistical techniques for ISO 9001:2000"*

[15] ISO 10018, "*Quality management – Guidelines on people involvement and competence"*

[16] ISO 10019, "*Guidelines for the selection of quality management system consultants and use of their services"*

[17] ISO 14001, "*Environmental management systems – Requirements with guidance for use"*

[18] ISO 19011, "*Guidelines for auditing management systems"*

[19] ISO 31000, "*Risk management – Principles and guidelines"*

[20] ISO 37500, "*Guidance on outsourcing"*

[21] ISO/IEC 90003, "*Software engineering – Guidelines for the application of ISO 9001:2008 to computer software"*

[22] IEC 60300-1, "*Dependability management – Part 1: Guidance for management and application"*

[23] IEC 61160, "*Design review"*

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ANNEX E – AVIATION, SPACE, AND DEFENSE BIBLIOGRAPHY

9101*	***Quality Management Systems – Audit Requirements for Aviation, Space, and Defense Organizations***
9102*	***Aerospace First Article Inspection Requirement***
9103*	***Variation Management of Key Characteristics***
9107*	***Direct Delivery Authorization Guidance for Aerospace Companies***
9110*	***Quality Management Systems – Requirements for Aviation Maintenance Organizations***
9114*	***Direct Ship Guidance for Aerospace Companies***
9115*	***Quality Management Systems – Requirements for Aviation, Space and Defense Organizations – Deliverable Software***
9116*	***Aerospace Series – Notice of Change (NOC) Requirements***
9120*	***Quality Management Systems – Requirements for Aviation, Space and Defense Distributors***
9131*	***Quality Management Systems – Aerospace – Nonconformance Documentation***
9132*	***Data Matrix Quality Requirements for Parts Marking***
9133*	***Qualification Procedure for Aerospace Standard Products***
9134*	***Supply Chain Risk Management Guideline***
9162*	***Aerospace Operator Self-Verification Programs***
ISO 9001	***Quality management systems – Requirements***
www.iaqg.org	***IAQG Standards Support Material*** ***IAQG Supply Chain Management Handbook***

** Refers to the internationally harmonized standards published world-wide under the authority of the International Aerospace Quality Group (IAQG), coordinated by each of the IAQG sectors: the Americas Aerospace Quality Group (AAQG), Asia-Pacific Aerospace Quality Group (APAQG), and the European Aerospace Quality Group (EAQG).*

The IAQG Standards Register lists the current standards published within each IAQG sector; see *http://www.sae.org/iaqg/publications/standardsregister.pdf*.