AS9100D:2016

International Aerospace Quality Management System Standard Aviation, Space, and Defense Organizations

AN EXECUTIVE OVERVIEW

PERRY JOHNSON CONSULTING, INC.

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AS9100D:2016

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

AN EXECUTIVE OVERVIEW

(with additional content provided for AS9110C and AS9120B)

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FOREWORD

In 1999, delegates for the Organization for Standardization (ISO) consisting of representatives from the Americas Aerospace Quality Group (AAQG), the European Association of Aerospace Industries (AECMA), the Society of Japanese Aerospace Companies (SJAC) and the Brazilian aerospace industry, unveiled AS9100. Using ISO 9001 as a base, this international quality management standard is tailored specifically for the aerospace industry. AS9100 was revised in 2001, 2004, 2009, and 2016. The current version is AS9100 Revision D (AS9100D) and is aligned with ISO 9001:2015.

Like the other ISO 9001 derivatives, AS9100D is designed to reduce defects in the supplier chain, continually improve quality and boost customer satisfaction. It can also considerably reduce the number of hours spent on audits, requirements and documentation, because it is an industry-wide standard.

AS9100 also responds to the federal government's cancellation of longtime standards, such as MIL-Q-9858A, by filling the vacuum with a comprehensive quality management systems standard for the aerospace industry. The U.S. Department of Defense (DOD) and Federal Aviation Administration (FAA) have endorsed AS9100 for use in conjunction with their individual specifications.

Like ISO 9001, AS9100 is a voluntary standard, but it is one that has drawn unprecedented support and cooperation from the private and public sectors. Such aerospace prime contractors as Boeing, General Electric Aircraft Engines, Lockheed-Martin, Rolls Royce Allison, and Pratt & Whitney are requiring their suppliers to become registered to AS9100 and ISO 9001. The list continues to expand.

By becoming registered to AS9100 and ISO 9001, companies dealing with the aerospace prime contractors and the government enjoy a competitive advantage. The regulatory burden is lightened, so suppliers can spend more time improving the manufacturing process in an industry that puts a top priority on safety and quality.

This guide was created to aid aerospace and defense suppliers seeking to implement AS9100D or to upgrade from either ISO 9001 or AS9100 Revision C (AS9100C). It outlines the general requirements of AS9100 step by step. Since registering to AS9100 and ISO 9001 is a lengthy and detailed process, it is strongly suggested that firms seeking certification retain the services of a reputable consulting firm.

PERRY JOHNSON CONSULTING, INC.
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THE USERS OF THIS GUIDE

This guide will be useful to all aviation, space, and defense suppliers, in particular those firms that meet any of the following criteria:

- Firms supplying aerospace prime contractors.
- Companies planning for future business with the aerospace industry.
- Firms supplying the U.S. Department of Defense.
- Organizations seeking to remain abreast of worldwide quality management systems standards development.
- Firms planning to improve their quality assurance and management programs.

- Suppliers seeking a competitive advantage in the marketplace.
- Companies desiring to make customer satisfaction a top priority.
- Suppliers responding to customer mandates to become AS9100 registered.
- Organizations already registered to ISO 9001 or AS9100C that seek an upgrade to AS9100D.
- Any other firms interested in becoming registered to AS9100D.

WHAT IS AS9100?

SAE Aerospace Standard AS9100D, *Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations*, is a quality management system standard for the aerospace industry. It is derived from ISO 9001. AS9100D contains ISO 9001:2015 in its entirety, along with additional aerospace and defense specific requirements.

AS9100D also addresses flowdown, an important aerospace industry concept. The major aircraft makers and suppliers have increased their purchases from other suppliers – one estimate is that 60 to 80 percent of airplane components are bought from outside contractors. Like an orchestra performing a symphony, they want to ensure everyone is on the same page.

Thus, the aerospace prime contractors advocate flowdown of quality management system requirements from their own operations to suppliers and on to those companies' subcontractors. This is similar to the subcontractor quality management system development requirements in the ISO/TS 16949 automotive quality standard. Flowdown includes specifications for parts or assembly designs, characteristics, inspections, and other process functions and product features.

AS9100D serves as a single standard, with flowdown supported and stressed. A supplier previously could face a huge compliance burden, with FAA, DOD and MIL-Q standards, as well as private-sector requirements from each customer. For example, an Allied-Signal plant has an average of 23 customers, and at one point, each of them had its own quality management system requirements.

AS9100D has taken hold in the aerospace industry and is growing quickly in acceptance. The International Aerospace Quality Group (IAQG), the governing body for AS9100D, has drafted rules for audit frequency and procedures, and auditor qualifications, just as the International Automotive Task Force (IATF) has done with ISO/TS 16949.

Under IAQG rules, aerospace suppliers register to both AS9100D and ISO 9001:2015. AS9100D and ISO 9001:2015 registration, in turn, requires regular surveillance audits, which follows up to ensure a company is maintaining and applying its quality management system.

Registration is the only objective way to assure your customers that you are providing quality products. To provide objectivity, a registrar (an independent certifying body) performs regular audits to verify whether your quality management system is meeting all requirements. This independent evaluation is important to the customer because it is an unbiased guarantee that your company is performing at its highest level. Without this level of surveillance, companies are not likely to toe the line.

Because ISO 9001:2015 is the major foundation of this standard, one needs a basic knowledge of ISO 9001:2015 to fully understand the fundamentals of AS9100D. A brief description of this series of standards follows.

Annex SL – A Common Structure

ISO 9001:2015 and AS9100D:2016 are structureed per Annex SL. Annex SL exists as part of a larger publication called *"ISO Directives Part 1, Consolidated ISO Supplement – Procedures specific to ISO."* This expansive document can be thought of a "playbook" for the ISO to follow in the development of standards. It is projected that all ISO standards will follow the Annex SL format by 2017. We will learn more about Annex SL and the standardized format over the next several pages of this Executive Overview.

The Origin of ISO 9000

ISO 9000 is the descendant of a number of earlier quality standards, including the British BS 5750 and DEF/STAN 05-8, the NATO AQAP-1 and the U.S. Department of Defense MIL-Q-9858A. The purpose for developing ISO 9000 was to simplify the international exchange of goods and services by creating a common set of quality standards.

BS 5750 had the greatest influence on this international standard when it was first released by ISO in 1987. Most industrialized nations quickly adopted harmonized versions of ISO 9000. These national versions, which are identical to the international standard, include the American ANSI/ISO/ASQ Q9000, sponsored by ANSI and the American Society for Quality (ASQ), and the European Union's EN 29000.

AS9100Dis intended to provide requirements for an organization to establish, document and maintain a quality management system for ensuring the consistency of a process. It is not mysterious or esoteric, consisting instead of a group of common sense and generally well-known precepts laid out in an organized fashion.

When implemented correctly, AS9100D:2016 can offer your company several advantages. It will guide you to build consistency into your products or services, and can help you to avoid costly warranty costs and rework.

Today, the international standards are sanctioned by the European Union (EU), making AS9100D:2016 registration a virtual prerequisite for doing business in its member countries.

Previously, there were more than 20 ISO 9000 standards and documents, and this proliferation raised concerns among ISO 9000 users and consumers. In response, the TC committee agreed that the 2000 revision and all future revisions would consist of four primary standards, supported by several technical reports. In addition to the AS9100D:2016 standard, these three additional primary standards are:

- **ISO 9000:2015**, *Quality Management Systems – Fundamentals and Vocabulary*. This document, which replaced the 2005 revision, provides all sanctioned interpretations for the numerous terms used throughout the various standards. ISO 9000:2015 also provides an examination of the Seven Quality Management Principles, including a statement of rationale. Finally, ISO 9000:2015 provides a number of helpful concept diagrams showing the intended interrelationships between ideas. ISO 9000:2015 is not a certifiable standard, but it can be of great benefit to a company newly starting out in pursuit of AS9100D:2016 certification.

- **ISO 9004:2009**, *Managing for the sustained success of an organization – A quality management approach*. This standard, which replaced ISO 9004-1:1994, *Quality Management and Quality management system Elements – Part 1: Guidelines*, provides guidance beyond AS9100D:2016 towards developing a comprehensive quality management system to improve an organization's overall performance.

  This document gives guidance on all aspects of a quality management system, based on the seven quality management principles found in ISO 9000:2015. ISO 9004 is useful in auditing the effectiveness of a company's quality management system, with the goal of achieving benefits for all stakeholder groups through sustained customer satisfaction. It is a reference standard in that a company cannot become registered to ISO 9004.

- **ISO 19011:2011**, *Guidelines for* A*uditing Management Systems*. Initially, ISO/TC 176 was to draft ISO 10011, *Guidelines for Auditing Quality Systems*, which would integrate and replace the three quality management system auditing standards: ISO 10011-1:1990, *Guidelines for Auditing Quality Systems – Part 1: Auditing*, ISO 10011-2:1991, *Guidelines for Auditing Quality Systems – Part 2: Qualifications Criteria for Quality Systems Auditors*, and ISO 10011-3:1991, *Guidelines for Auditing Quality Systems – Part 3: Management of Audit Programs*. Instead, the Joint Working Group (JWG) on Quality and Environmental Auditing, consisting of experts from ISO/TC 176/SC 3, Auditing and ISO/TC 207, Environmental Management, SC 2, Environmental Auditing, agreed to draft a joint quality and environmental management systems auditing standard, ISO 19011. It applies to first, second and third party audits; auditor qualification criteria; and audit program management. ISO 19011 replaced ISO 10011-1, ISO 10011-2 and ISO 10011-3, along with the three environmental auditing standards: ISO 14010:1996, *Guidelines for Environmental Auditing – General Principles*, ISO 14011:1996, *Guidelines for Environmental Auditing – Audit Procedures – Auditing of Environmental Management Systems*, and ISO 14012:1996, *Guidelines for Environmental Auditing – Qualification Criteria for Environmental Auditors*.

REGISTERING TO AS9100D:2016

AS9100D:2016 registration is a tangible expression of a firm's commitment to quality that is internationally understood and accepted. AS9100D registered organizations almost universally realize major increases in customer acceptance, as well as reductions in costs. Many American firms, already subject to quality management system standards imposed by major customers, find that the major effect of AS9100D registration is on their non-manufacturing functions, which tend to be overlooked by manufacturing-based quality systems.

AS9100D registration is carried out by certification bodies (commonly called registrars), which are accredited organizations that review the facility's quality manual and other documentation to ensure that they meet the standard, and audit the firm's processes to ensure that the quality management system described in the documentation is in place and is effective. Once registration is obtained, the registrar conducts regular surveillance audits of the facility to determine if its quality management system continues to meet the standard's requirements.

As it typically takes 6 to 18 months to complete the AS9100D registration process, organizations are advised not to put off registration for too long.

Key Steps to Completing a New Registration

Before an organization can be considered for registration, several preliminary steps should be taken.

The first step is to implement a quality management system that meets AS9100D:2016 requirements.

To qualify for registration, it's not enough to just conform to the standard. Organizations must determine what their processes are, and what their intentions are for controlling their processes. Methodologies for the myriad requirements for records (called "Retained Documented Information in AS9100D:2016) must also be determined. Many other questions of approach have to be answered as well, for requirements ranging from competency records to external provider evaluation. Organizations must ensure that the system they establish is robust, effective, transparent, and consistent.

After successfully completing the preliminary steps, a relationship must be established with a registrar. The registrar's job is to verify whether an organization's quality management system has been properly implemented and conforms to AS9100D:2016 and any other applicable requirements.

Once the services of an accredited registrar have been obtained, a formal application must be filed. When all of the documentation has been submitted, the registrar conducts a two stage audit. The first stage involves an audit of basic documentation including records of a full system internal audit followed by a formal management review. According to the ISO standard that controls registrar activities (ISO 17021), "Stage 1" audits may be done off-site. A telephone conference may occur in place of an on-site visit. The "Stage 1" auditor will identify items that require correction before the "Stage 2" audit can begin. Once the registrar determines that the Stage 1 basic documentation and data requirements are met, the "Stage 2" audit may proceed.

The Stage 2 audit is a full system audit that takes place after the Stage 1 corrections are verified by the Stage 2 auditor. Performance data is checked for effectiveness relative to documented objectives. Product and service realization activities within the facility are checked for conformity to quality control plans as well as to effectiveness. Other management system activities are checked relative to documented processes and procedures. Please note, firms that are interested in registration to both AS9100D:2016 and ISO 14001:2015 should discuss this objective with their registrar to determine whether the audits to the two standards may be conducted simultaneously.

During the on-site "Stage 2" audit, the registrar auditor interviews employees, reviews records, and performs a detailed inspection of the facility's quality management system documents. The purpose of the audit is to ensure that the facility's quality management system is functioning adequately and conforms to all AS9100D:2016 requirements.

Afterward, the registrar reports its findings in an audit report. If any major or minor nonconformities are found, the organization (or auditee) must take corrective action to remedy the cause of the nonconformity. Nonconformities must be remedied within a set time frame, determined by the registrar. Once the registrar has closed out all outstanding nonconformities, a certificate of registration is issued.

To ensure that organizations are following AS9100D:2016 requirements after registration is obtained, the registrar conducts on-site surveillance audits at least once each year.

Remember: In order to achieve registration to AS9100D:2016, the organization must completely embrace the standard, which focuses on performance, consistency, and objective/audit evidence.

What to Look For in a Registrar

In selecting a registrar, it is extremely important for every organization to be aware of the relevant qualifications.

A registrar must:

- Be accredited by a national accreditation body, such as the ANAB (ANSI-ASQ National Accreditation Board) of the United States, the Raad voor Accreditatie (RvA) of the Netherlands, or the United Kingdom Accreditation Service (UKAS); to the requirements of ISO/IEC 17021 *Requirements for Bodies providing audit and certification of management systems.* Among other benefits, using an accredited registrar assures the following:

  – The registrar is required to provide a fair and documented process for any disputed findings, client complaints, or other similar situations;

  – The registrar can be reported, and by extension held accountable to the requirements of ISO 17021 by the accreditation bodies;

  – The registrar must ensure that their auditors are full competent for the audits they perform; and

  – All audits are subject to a wide ranging review process by numerous persons, assuring a fair and unbiased process.

- Maintain a listing of its AS9100D qualified auditors;

- Have personnel on its executive (registration) committee or governing board with industry experience and expertise in the appropriate Standard Industrial Classification (SIC), North American Industry Classification System (NAICS) or European Accreditation of Certification (EAC) codes;

What to Look For in an Auditor

Requirements have been established for the auditors working for accredited AS9100D registrars. Before an auditor can evaluate an organization's facility to verify whether its quality management system conforms to AS9100D:2016 requirements, the auditor must satisfy the following conditions:

1) Auditors must have satisfactorily completed AS9100D training courses and demonstrated their knowledge of AS9100D:2016. Certificates are awarded to those auditors who have successfully completed this training;

2) Auditors must comply with ISO 19011:2011, *Guidelines for auditing management systems*;

3) They must be recognized and qualified as AS9100D auditors under the registrar's criteria; and,

4) At least one member of an audit team must have relevant industry knowledge in the appropriate SIC, NAICS or EAC codes, as determined by the registrar's qualification process, for each client.

Before hiring the services of a registrar, it's a good idea to make sure the registrar and its auditors have met the above qualifications.

Auditors and other relevant registrar personnel are required to demonstrate knowledge and understanding of AS9100D:2016 requirements; the seven quality management principles on which the revised standards are based, and the standard's many terms and definitions, both of which appear in ISO 9000:2015.

Registrars must take particular care in defining the scope of AS9100D:2016 registration certificates and any cited "non-applicable clauses", as set forth in AS9100D:2016, Section 4.3. When issuing a tailored registration certificate, a registrar must keep in mind that "such non-applicable clauses do not affect the organization's ability, or responsibility, to provide product that fulfills customer and applicable regulatory requirements."

THE BENEFITS OF AS9100D:2016

AS9100D is an ideal quality management system for facilities that are serious about quality, with AS9100D:2016 registration providing a competitive edge. AS9100D:2016 registration gives the facility the benefit of an objectively evaluated and enforced quality management system.

Facilities that operate AS9100Dquality management systems tend to exhibit a philosophy of prevention rather than detection; risk management of potential concerns, continuous review of critical process points; corrective actions and outcomes; consistent communication within the process, and among facility, suppliers and customers; thorough record keeping and efficient control of critical documents; total quality awareness by all employees; and a high level of executive management confidence and support.

These attributes lead to dependable process input, control of quality costs, increased productivity and reduced waste. A well-designed and implemented AS9100D quality management system creates a process that tends to be lean, sensitive to customer needs, highly reactive, efficient and positioned at the leading edge of its marketplace.

Any company that becomes registered to AS9100D:2016 will be better positioned to do business overseas, especially in countries where the standard has become a virtual necessity for market entry. Registration also enables facilities to protect existing markets when their customers mandate it. It offers the potential of reducing time-consuming and expensive supplier audits, and is a powerful strategic benefit for facilities having current or planned business ties with the European Union (EU).

The EU Council of Ministers now mandates AS9100D registration for makers of such products as commercial scales, construction products, gas appliances, industrial safety equipment, medical devices, and telecommunications terminal equipment.

More products may be added to this list under additional product directives. This is especially likely for products and services that are potentially hazardous involve personal safety or are otherwise affected by product liability or similar regulations.

Organizations that register to AS9100D:2016 also enjoy a clear competitive edge over companies that are not registered. Registered organizations are authorized to display a special mark or logo, and firms throughout the U.S., the EU and elsewhere understand the significance behind that mark.

Bottom line: An organization that chooses to conform to AS9100D will be operating a top-notch quality management system that focuses on informed and competent management decision making, control of quality costs, increased productivity and reduced waste.

The Seven Quality Management Principles

ISO 9000:2005, Section 2.3 set forth seven quality management principles, which have been identified for leading an organization toward improved performance. Beyond simply listing the Principles, ISO 9000 also provides rationale, benefits, and information on possible approaches to each Principle. These Principles are the basis of AS9100D:2016. They are:

a. Customer Focus. Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b. Leadership. Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c. Engagement of People. Competent, empowered, and engaged people at all levels are the essence of an organization and drive the organization's ability to create and deliver value.

d. Process Approach. Desired results are achieved more efficiently when activities and related resources are managed as processes within a coherent system.

e. Improvement. Improvement of the organization's overall performance should be an ongoing focus of the organization.

f. Evidence Based Decision Making. Decisions based on the analysis of data and information is more likely to deliver desired results.

g. Relationship Management. An organization and its external interested parties are interdependent and share a role in each other's success.

AS9100D:2016 Process-Based Structure and Clauses

The revised continues to be consistent with the plan-do-check improvement cycle, and continues to use the process management structure widely used in business today. It introduces several new clauses intended to drive Risk Based Thinking.

The reader is reminded that the Annex SL format provided in this structure is the same used by ISO 14001:2015 and all other ISO issued standards.

Non-Auditable clauses of AS9100D:2016 are:

1. **Scope** – which provides a general statement about to whom AS9100D:2016 is intended to apply.

2. **Normative Reference** – which provides an explanation of the linkage between AS9100D:2016 and ISO 9000:2015.

3. **Terms and Definitions** – which establishes the use of ISO 9000:2015 for all official definitions.

Auditable clauses of AS9100D:2016 are:

4. **Context of the Organization** (4 clauses), which mandate an organization to determine the scope of its system, ascertain interested parties, and in general determine the breadth of their quality management system, which defines and manages processes in order to produce a consistent product or service and allow for continual improvement.

5. **Leadership** (3 clauses), under which management defines policy, organizational roles, and assures focus on the customer. It is emphasized that Leadership means a shared responsibility for the management of the quality system.

6. **Planning** (3 clauses), under which the primary requirements related to risk management, as well as objectives (planning, reporting, etc.) are found. A set of requirements pertaining to management of changes is also found here.

7. **Support** (5 clauses), which provide requirements pertaining to all of the various resources an organization needs to effectively operate their quality system, including people (competency) measurement devices (calibration/verification), and documented information (maintained and retained.)

8. **Operation** (7 clauses), which provides requirements pertaining to the crucial and central activities of a quality management system. All of the "day-to-day" activities are found here, including interaction with customers, design of products/services, and interface with external providers, and control of production/service provision.

9. **Performance Evaluation** (3 clauses), which provide requirements pertaining to three of the most crucial methods used by Organizations to self-regulate their quality management system and ensure its effectiveness. These are Management Review, Internal Audit, and Customer Satisfaction.

10. **Improvement** (3 clauses), which provides requirements pertaining to the actions that should be taken as a result of evaluations and other output monitoring actions discussed in earlier parts of the standard. Ideas covered here include Corrective Action and Continual Improvement.

Taken together these seven auditable sections can be thought of as a three part approach to the functioning of a quality management system, as follows:

Foundation/Basic Building Blocks (Sections 4-7)

The first four sections of auditable content taken together represent the basic pieces that an organization needs to establish to enable a successful quality management system. Without these pieces, the later requirements will likely not be successful.

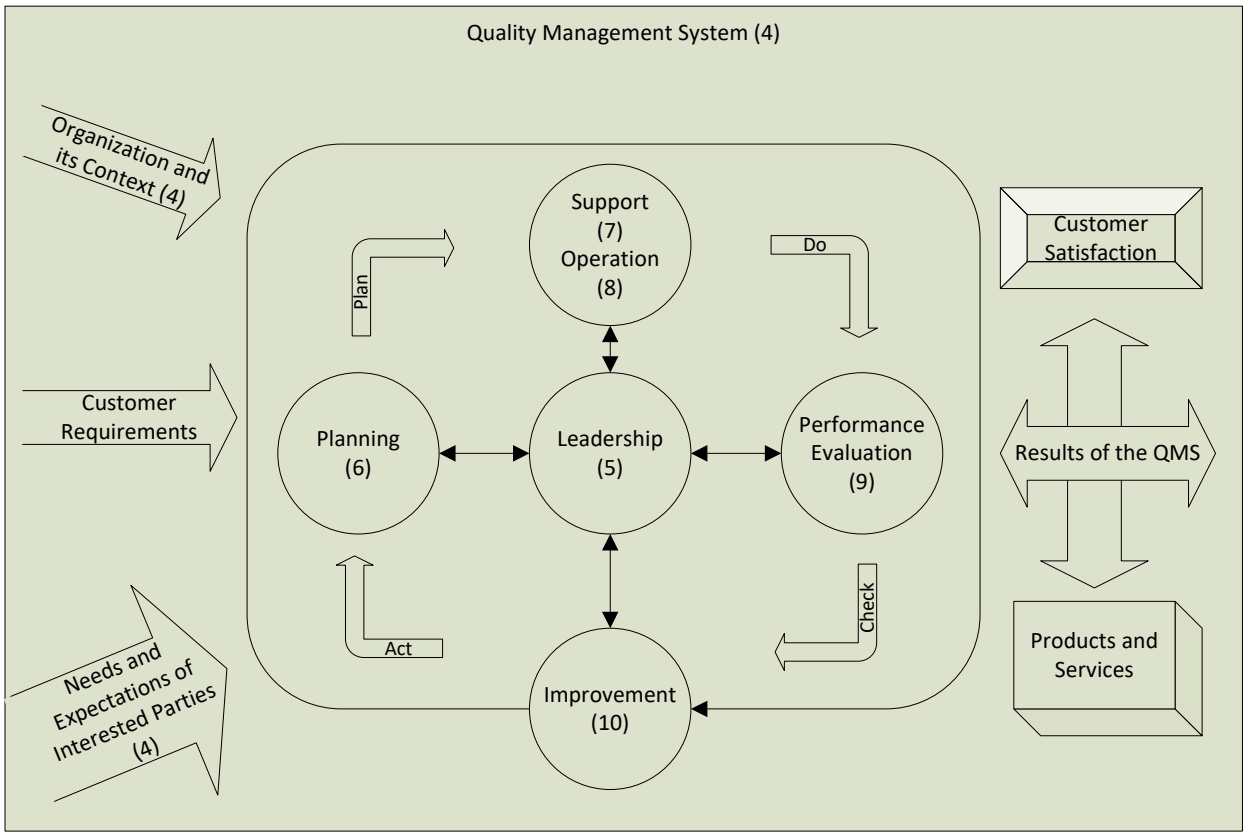
Day to Day Activities (Section 8)

Taken together, the requirements provided in Section 8 are almost a process flow in and of themselves. Beginning with Operational Planning in 8.1 and Customer Requirements Determination in 8.2 the organization is supposed to figure out what is needed, later taking steps such as designing the product (8.3), purchasing materials (8.4) and ensuring that production/service is carried out consistently (8.5.1.) Auditors typically spend at least 60% of available audit time in Section 8. The processes it attempts to control are inevitably the most important in any organization.

Analysis and Improvement (Sections 9 and 10)

The standard concludes with a pair of Sections that attempt to collect all of the best methods that a company should use to ensure that its processes are effective, its customers are satisfied, and that continual improvement is being achieved. Many auditors review these sections early in an audit to develop audit trails.

All quality management system requirements for achieving conformity of product and/or service may be placed within this process model. Leadership can be thought of as impacting all of the various activities of the quality management system. The Plan-Do-Check-Act cycle follows the various processes of the organization. Careful planning based on input from customers and other interested parties leads to effective operations, which in turn are evaluated with improvement actions taken where needed or desired. The ultimate goal of these interacting activities is a consistent effective product/service that satisfies all customers.


Quality Management System (4)
Organization and its Context (4)
Customer Requirements
Needs and Expectations of Interested Parties (4)
Support (7) Operation (8)
Plan
Do
Planning (6)
Leadership (5)
Performance Evaluation (9)
Act
Check
Improvement (10)
Customer Satisfaction
Results of the QMS
Products and Services

AS9100D:2016 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

All AS9100D:2016 clauses are briefly described below.

4 – Context of the Organization

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

4.2 Understanding the needs and expectations of interested parties requires an organization to determine the interested parties and requirements therein that are relevant to the quality management system. The organization is also required to monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system requires the organization to determine the boundaries and applicability of the quality management system to establish its scope. When doing so, the organization should consider the external and internal issues referred to in 4.1, the requirements of relevant interested parties referred to in 4.2, and what their products and services are. Organizations are required to apply all the requirements of AS9100D:2016 if they are applicable within the determined scope of the quality management system. The scope of the organization's quality management system has to be available and maintained as documented information. The scope must stipulate the types of products and services covered, and provide justification for any requirement of AS9100D:2016 that the organization has determined as not applicable to the scope of its quality management system. Conformity to AS9100D:2016 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 establish two different sets of requirements:

4.4.1 Requires the organization to establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of AS9100D:2016. It also requires the organization to address customer and applicable statutory and regulatory quality management system requirements. It requires the organization to determine the processes needed for the quality management system and their application throughout the organization. It requires the organization to determine the inputs required and the outputs expected from these processes, determine the sequence and interaction of these processes, to 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, to determine the resources needed for these processes and ensure their availability, to assign the responsibilities and authorities for these processes, to address the risks and opportunities as determined in accordance with the requirements of 6.1, to evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results, and to improve the processes and the quality management system.

4.4.2 Requires the organization to maintain documented information to support the operation of its processes, and to retain documented information to have confidence that the processes are being carried out as planned.

In addition, the organization must establish and maintain documented information that includes a general description of relevant interested parties, the scope of the quality management system, including boundaries and applicability, a description of the processes needed for the quality management system and their application throughout the organization, the sequence and interaction of these processes, and assignment of the responsibilities and authorities for these processes.

There is a note added to suggest the above description of the quality management system can be in a quality manual.

5 – Leadership

5.1 Leadership and commitment

5.1.1 General requires top management to demonstrate leadership and commitment with respect to the quality management system by taking accountability for the effectiveness of the quality management system, 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, ensuring the integration of the quality management system requirements into the organization's business processes, promoting the use of the process approach and risk-based thinking, ensuring that the resources needed for the quality management system are available, communicating the importance of effective quality management and of conforming to the quality management system requirements, ensuring that the quality management system achieves its intended results, engaging, directing and supporting persons to contribute to the effectiveness of the quality management system, promoting improvement, and supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus requires top management to demonstrate leadership and commitment with respect to customer focus by ensuring that customer and applicable statutory and regulatory requirements are determined, understood and consistently met, the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed, that the focus on enhancing customer satisfaction is maintained, and that 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 requires top management to establish, implement and maintain a quality policy that is appropriate to the purpose and context of the organization and supports its strategic direction, provides a framework for setting quality objectives, includes a commitment to satisfy applicable requirements, and includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy requires the quality policy to be available and be maintained as documented information, be communicated, understood and applied within the organization, and be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities requires top management to ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. It further requires top management to assign the responsibility and authority for ensuring that the quality management system conforms to the requirements of AS9100D:2016, ensuring that the processes are delivering their intended outputs, reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management, ensuring the promotion of customer focus throughout the organization, and ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

In addition, the standard requires the appointment of a management representative with similar requirements found in AS9100C:2009. Please note there is no such specific call out in ISO 9001:2015.

6 – Planning

6.1 Actions to address risks and opportunities

6.1.1 Requires the organization to consider the issues referred to in 4.1 and the requirements referred to in 4.2 and then to determine the risks and opportunities that need to be addressed to give assurance that the quality management system can achieve its intended result(s), to enhance desirable effects, to prevent, or reduce, undesired effects, and to achieve improvement.

6.1.2 Requires the organization to plan actions to address these risks and opportunities, to determine how to integrate and implement the actions into its quality management system processes and to evaluate the effectiveness of these actions. Actions taken to address risks and opportunities must be proportionate to the potential impact on the conformity of products and services.

6.2 Quality objectives and planning to achieve them

6.2.1 Requires the organization to establish quality objectives at relevant functions, levels and processes needed for the quality management system. It further requires that quality objectives be consistent with the quality policy, be measurable, take into account applicable requirements, be relevant to conformity of products and services and to enhancement of customer satisfaction, be monitored, be communicated, and be updated as appropriate. Lastly, it requires the organization to maintain documented information on the quality objectives.

6.2.2 Requires the organization (with regards to Quality Objectives) to determine what will be done, what resources will be required, who will be responsible, when it will be completed, and how the results will be evaluated.

6.3 Planning of changes requires (when an organization determines that there is a need for changes to the quality management system,) that those changes be carried out in a planned manner (per 4.4.) Furthermore, it requires the origination to consider the purpose of the changes and their potential consequences, the integrity of the quality management system, the availability of resources, and the allocation or reallocation of responsibilities and authorities.

7 – Support

7.1 Resources

7.1.1 General requires the organization to determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. It further requires the organization to consider the capabilities of, and constraints on, existing internal resources, and what needs to be obtained from external providers.

7.1.2 People requires the organization to 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 requires the organization to determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure is understood to include buildings and associated utilities, equipment, including hardware and software, transportation resources, and information and communication technology.

7.1.4 Environment for the operation of processes requires the organization to determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. Environment is understood to include a combination of human and physical factors, such as social (e.g. non-discriminatory, calm, non-confrontational), psychological (e.g. stress-reducing, burnout prevention, emotionally protective), and 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 requires the organization to 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. It further requires the organization to ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken, and are maintained to ensure their continuing fitness for their purpose. Finally, it requires the organization to retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability requires that 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 be 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 to be retained as documented information. It also requires that measuring equipment be identified in order to determine their status, and safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The standard requires that the organization provide a recall process for calibration and verification and that a register is maintained with specific information related to equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Finally, it requires the organization to 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 to take appropriate action as necessary.

7.1.6 Organizational knowledge requires the organization to determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. It also requires that knowledge be maintained and made available to the extent necessary. When addressing changing needs and trends, the organization must consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence requires the organization to determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system, to ensure that these persons are competent on the basis of appropriate education, training, or experience, to take actions (where applicable) to acquire the necessary competence, to evaluate the effectiveness of the actions taken; and to retain appropriate documented information as evidence of competence.

7.3 Awareness requires the organization to ensure that persons doing work under the organization's control are aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the quality management system, including the benefits of improved performance, the implications of not conforming with the quality management system requirements, relevant quality management system documented information and changes, their contribution to product or service conformity, their contribution to product safety, and the importance of ethical behavior.

7.4 Communication requires the organization to determine the internal and external communications relevant to the quality management system, including on what it will communicate, when to communicate, with whom to communicate, how to communicate, and who communicates.

7.5 Documented information

7.5.1 General requires the organization's quality management system to include documented information required by AS9100D:2016, documented information, as well as documented information determined by the organization as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and updating requires that when creating and updating documented information, the organization ensures appropriate identification and description (e.g. a title, date, author, or reference number), format (e.g. language, software version, graphics) media (e.g. paper, electronic) and review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Requires documented information required by the quality management system and by AS9100D:2016 to be controlled to ensure it is available and suitable for use, where and when it is needed. It further requires that documented information be adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 Requires the organization (as it pertains to control of documented information) to address the following activities, as applicable. Distribution, access, retrieval and use, storage and preservation, including preservation of legibility, control of changes (e.g. version control), and retention and disposition. It further required that documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system be identified as appropriate, and be controlled. It requires documented information retained as evidence of conformity is protected from unintended alterations. Finally, the organization must prevent the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

8 – Operation

8.1 Operational planning and control requires the organization to 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. This is to be accomplished by determining the requirements for the products and services, establishing criteria for the processes and the acceptance of products and services, determining the resources needed to achieve conformity to the product and service requirements, implementing control of the processes in accordance with the criteria, determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements and to meet on-time delivery of products and services.

Additional requirements include determining the processes and controls needed to manage critical items (including production process controls when key characteristics have been identified), engaging representatives of affected organization functions for operational planning and control, determining the process and resources to support the use and maintenance of the products and services, determining the products and services to be obtained from external providers, and establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

As appropriate, the organization must 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.

Furthermore it requires that the output of this planning be suitable for the organization's operations. The organization must control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. It requires that the organization ensures control of the outsourced processes (per 8.4), establishing, implementing, and maintaining 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 must ensure that work transfer impacts and risks are managed.

Specific plans must be planned, implemented, and maintained for Operational Risk Management, Configuration Management, Product Safety, and Prevention of Counterfeit Parts.

8.2 Requirements for products and services

8.2.1 Customer communication requires that communication with customers includes providing information relating to products and services, handling enquiries, contracts or orders, including changes, obtaining customer feedback relating to products and services, including customer complaints, handling or controlling customer property, and establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services requires that when determining the requirements for the products and services to be offered to customers, the organization must ensure that the requirements for the products and services are defined, including any applicable statutory and regulatory requirements, as well as those considered necessary by the organization. The organization must determine that it can meet the claims for the products and services it offers. It also must ensure that special requirements of the products and services are determined and operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

8.2.3 Review of the requirements for products and services

8.2.3.1 Requires the organization to ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization must conduct a review before committing to supply products and services to a customer. This review must include requirements specified by the customer, including the requirements for delivery and post-delivery activities, requirements not stated by the customer, but necessary for the specified or intended use, when known, requirements specified by the organization, statutory and regulatory requirements applicable to the products and services and contract or order requirements differing from those previously expressed. Furthermore it mandates that the customer's requirements must be confirmed by the organization before acceptance when the customer does not provide a documented statement of their requirements.

This review must 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.

8.2.3.2 Requires the organization to retain (as applicable) documented information on the results of the review, and on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services require the organization to 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 requires the organization to 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 requires the organization (when they determine the stages and controls for design and development) to consider the nature, duration and complexity of the design and development activities, the required process stages, including applicable design and development reviews, the required design and development verification and validation activities, the responsibilities and authorities involved in the design and development process, the internal and external resource needs for the design and development of products and services, the need to control interfaces between persons involved in the design and development process, the need for involvement of customers and users in the design and development process, the requirements for subsequent provision of products and services, the level of control expected for the design and development process by customers and other relevant interested parties, and the documented information needed to demonstrate that design and development requirements have been met.

When appropriate, the organization must 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 must 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 requires the organization to determine the requirements essential for the specific types of products and services to be designed and developed. It further requires the organization to consider functional and performance requirements, statutory and regulatory requirements, standards or codes of practice that the organization has committed to implement, and potential consequences of failure due to the nature of the products and services. When applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products) must be considered. It further requires that inputs be adequate for design and development purposes, as well as complete and unambiguous. Finally, it requires that conflicting design and development inputs be resolved and that the organization retain documented information on design and development inputs.

8.3.4 Design and development controls requires the organization to apply controls to the design and development process to ensure that the results to be achieved are defined, that reviews are conducted to evaluate the ability of the results of design and development to meet requirements, that verification activities are conducted to ensure that the design and development outputs meet the input requirements, that validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use, that any necessary actions are taken on problems determined during the reviews, or verification and validation activities, that documented information of these activities is retained, and that progression to the next stage is authorized.

When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove 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; test procedures describe the test methods to be used, how to perform the test, and how to record the results; the correct configuration of the test item is submitted for the test; the requirements of the test plan and the test procedures are observed; and, the acceptance criteria are met.

Monitoring and measuring devices used for testing must be controlled as defined in clause 7.1.5. At the completion of design and development, the organization must 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 requires the organization to ensure that design and development outputs meet the input requirements, are adequate for the subsequent processes for the provision of products and services, include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria, specify the characteristics of the 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, and are approved by authorized person(s) prior to release. Furthermore, it requires the organization to define the data required to allow the product to be identified, manufactured, verified, used, and maintained, and to retain documented information on design and development outputs.

8.3.6 Design and development changes requires the organization to 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. It further requires the organization to retain documented information on design and development changes, the results of reviews, the authorization of the changes, and the actions taken to prevent adverse impacts. Design and development changes must be controlled in accordance with the configuration management process requirements.

8.4 Control of externally provided processes, products and services

8.4.1 General requires the organization to ensure that externally provided processes, products and services conform to requirements; be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer; ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used; 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; and require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

It further requires the organization to determine the controls to be applied to externally provided processes, products and services when products and services from external providers are intended for incorporation into the organization's own products and services, when products and services are provided directly to the customer(s) by external providers on behalf of the organization, or when a process, or part of a process, is provided by an external provider as a result of a decision by the organization. This requirement further stipulates that the organization must 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. Lastly the organization is required to retain documented information of these activities and any necessary actions arising from the evaluations.

Finally the organization must 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; 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); periodically review external provider performance including process, product and service conformity, and on-time delivery performance; define the necessary actions to take when dealing with external providers that do not meet requirements; and, define the requirements for controlling documented information created by and/or retained by external providers.

8.4.2 Type and extent of control requires the organization to 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. Furthermore, it requires the organization to ensure that externally provided processes remain within the control of its quality management system, to define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output, to take into consideration 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, the effectiveness of the controls applied by the external provider, and the results of the periodic review of external provider performance. This requirement also stipulates that the organization must 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 must be performed according to the risks identified by the organization. These must include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

When externally provided product is released for production use pending completion of all required verification activities, it must 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 must 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 must 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 must implement a process to validate the accuracy of test reports.

8.4.3 Information for external providers requires the organization to ensure the adequacy of requirements prior to their communication to the external provider. It further requires the organization to communicate to external providers its requirements for the processes, products and services to be provided through the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions, including specific products and services, methods, processes, equipment; and requirements pertaining the release of products and services. This requirements further requires that the organization communicate additional information to external providers including required competence, including any required qualification of persons, the external providers' interactions with the organization, control and monitoring of the external providers' performance to be applied by the organization, and verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

Specific information must also be flowed down. The information includes:

- design and development control;
- special requirements, critical items, or key characteristics;
- test, inspection, and verification (including production process verification);
- the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;
- 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;
- 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;
- 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 requires the organization to implement production and service under controlled conditions. Controlled conditions are understood to include (as applicable) the availability of documented information that defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed, as well as the results to be achieved. Controlled conditions is also taken to include the availability and use of suitable monitoring and measuring resources, 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, the use of suitable infrastructure and

environment for the operation of processes, the appointment of competent persons, including any required qualification, 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities.

Additional requirements include 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; and 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).

Documented information must also include the:

- establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
- accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
- control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
- identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
- availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- provision for the prevention, detection, and removal of foreign objects;
- 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);
- 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.

Control of Equipment, Tools, and Software Programs- equipment, tools, and software programs used to automate, control, monitor, or measure production processes must be validated prior to final release for production and must be maintained. Storage requirements must be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

Validation and Control of Special Processes- for processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization must establish arrangements for these processes including, as applicable:

- definition of criteria for the review and approval of the processes;
- determination of conditions to maintain the approval;
- approval of facilities and equipment;
- qualification of persons;
- use of specific methods and procedures for implementation and monitoring the processes;
- requirements for documented information to be retained.

Production Process Verification – the organization must implement production process verification activities to ensure the production process is able to produce products that meet requirements. The organization must retain documented information on the results of production process verification.

8.5.2 Identification and traceability requires the organization to use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. It further requires the organization to identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. Lastly, it requires the organization to control the unique identification of the outputs when traceability is a requirement, and to retain the documented information necessary to enable traceability.

The organization must 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.

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

8.5.3 Property belonging to customers or external providers requires the organization to exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. It further requires the organization to identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. Lastly, it requires that when the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization must report this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation requires the organization to preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

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

- cleaning;
- prevention, detection, and removal of foreign objects;
- special handling and storage for sensitive products;
- marking and labeling, including safety warnings and cautions;
- shelf life control and stock rotation;
- special handling and storage for hazardous materials.

8.5.5 Post-delivery activities require the organization to meet requirements for post-delivery activities associated with the products and services. It further requires the organization (when determining the extent of post-delivery activities that are required) to consider any applicable statutory and regulatory requirements, the potential undesired consequences associated with its products and services, the nature, use and intended lifetime of its products and services, any applicable customer requirements, any relevant customer feedback, collection and analysis of in-service data (e.g., performance, reliability, lessons learned), control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul, controls required for work undertaken external to the organization (e.g., off-site work), and 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.

8.5.6 Control of changes requires the organization to review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. It further requires the organization to 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. Persons authorized to approve production or service provision changes must be identified.

8.6 Release of products and services requires the organization to implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. It further requires the release of products and services to the customer not to proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. Lastly it requires the organization to retain evidence of conformity with the acceptance criteria, and ensure traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, the organization must ensure that retained documented information provides evidence that the products and services meet the defined requirements. The organization must 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 Requires the organization to ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. It further requires the organization to take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

Additionally, this requirement mandates that the organization deal with nonconforming outputs in one or more of the following ways. These include correction, segregation, containment, return or suspension of provision of products and services, informing the customer, and obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

The organization's nonconformity control process must 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; and defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

Dispositions of use-as-is or repair for the acceptance of nonconforming products must 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 and after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

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

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

Finally conformity to the requirements must be verified when nonconforming outputs are corrected.

8.7.2 Requires the organization to retain documented information that describes the nonconformity, describes the actions taken, describes any concessions obtained, and 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 requires the organization to determine what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, when the monitoring and measuring to be performed, and when the results from monitoring and measurement to be analyzed and evaluated. Furthermore, it requires the organization to evaluate the performance and the effectiveness of the quality management system. Lastly, it requires the organization to retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction requires the organization to monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. Further the organization is required to determine the methods for obtaining, monitoring and reviewing this information.

Information to be monitored and used for the evaluation of customer satisfaction must include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. The organization must 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 requires the organization to analyze and evaluate appropriate data and information arising from monitoring and measurement. Furthermore, it requires that the results of analysis be used to evaluate conformity of products and services, the degree of customer satisfaction, the performance and effectiveness of the quality management system, if planning has been implemented effectively, the effectiveness of actions taken to address risks and opportunities, the performance of external providers, and the need for improvements to the quality management system.

9.2 Internal audit

9.2.1 Requires the organization to conduct internal audits at planned intervals to provide information on whether the quality management system conforms to the organization's own requirements for its quality management system, as well as the requirements of AS9100D:2016, and to ensure that the quality management system is effectively implemented and maintained.

9.2.2 Requires the organization to plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which must take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. The organization is further required to define the audit criteria and scope for each audit, to select auditors and conduct audits to ensure objectivity and the impartiality of the audit process, to ensure that the results of the audits are reported to relevant management, to take appropriate correction and corrective actions without undue delay, and to retain documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management review

9.3.1 General requires top management to 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 stipulates that the management review be planned and carried out taking into consideration the status of actions from previous management reviews, any changes in external and internal issues that are relevant to the quality management system, any information on the performance and effectiveness of the quality management system, including trends in customer satisfaction/feedback from relevant interested parties, the extent to which quality objectives have been met, process performance and conformity of products and services, nonconformities and corrective actions, monitoring and measurement results, audit results, the

performance of external providers, and on-time delivery performance. It further requires that inputs include a discussion of the adequacy of resources, the effectiveness of actions taken to address risks and opportunities (per 6.1), and any opportunities for improvement.

9.3.3 Management review outputs requires the outputs of the management review to include decisions and actions related to opportunities for improvement, any need for changes to the quality management system, resource needs, and risks identified. It further requires the organization to retain documented information as evidence of the results of management reviews.

10 – Improvement

10.1 General requires the organization to determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. It further requires that improvement action must include improving products and services to meet requirements as well as to address future needs and expectations, as well as correcting, preventing or reducing undesired effects and improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action

10.2.1 Requires that when a nonconformity occurs, including those arising from complaints, the organization must react to the nonconformity and, as applicable take action to control and correct it and deal with the consequences. Furthermore, it requires the organization to evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by reviewing and analyzing the nonconformity, by determining the causes of the nonconformity, by determining if similar nonconformities exist, or could potentially occur, by implementing any action needed, by reviewing the effectiveness of any corrective action taken, updating risks and opportunities determined during planning, if necessary, by making changes to the quality management system, if necessary, flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity, and take specific actions when timely and effective corrective actions are not achieved.. Furthermore it requires that corrective actions be appropriate to the effects of the nonconformities encountered. The organization must maintain documented information that defines the nonconformity and corrective action management processes.

10.2.2 Requires the organization to retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken, as well as the results of any corrective action. The organization must monitor the implementation of improvement activities and evaluate the effectiveness of the results.

10.3 Continual improvement requires the organization to continually improve the suitability, adequacy and effectiveness of the quality management system.

AS9110C:2016 QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS FOR AVIATION, MAINTENANCE ORGANIZATIONS

AS9110C is a sector specific standard geared towards organizations that strictly provide maintenance and repair services for the aerospace industry. In the past many of these organizations sought certification as a certified FAA Repair Station under the 14 CFR Part 145 Repair Station Standard. Realizing the necessity to incorporate these requirements into an international standard the IAQG issued the first version of AS9110 in 2003. Following an update in 2009 to incorporate the changes to the ISO 9001 standard published in 2008, the AS9110's was revised in 2012. It was transitioned to the Annex SL format in 2016.

The revisions in 2012 were issued in response to concerns raised by the European Aviation Safety Agency (EASA) in an effort to promote usage of the AS9110 standard by NAA (National Aviation Authorities.) Critical revisions included several additional definitions as well as clarifications of clauses necessary to promote international usage of the standard. The revisions in 2016 were made to align with ISO 9001:2015 and AS9100D:2016.

The AS9110C standard defines the quality management system requirements and offers additional comprehensive requirements/criteria for overhaul facilities and maintenance repair for the aircraft industry at all levels of the MRO (Maintenance, Repair & Overhaul) process.

AS9110C incorporates nearly all of the additional requirements found in AS9100D. In numerous cases, however, the requirement is modified to more appropriately reflect an MRO process.

The primary additional clauses found in AS9110C that are not found in AS9100D primarily focus on safety. These are Safety Objectives and Safety Policy. The implication is that an MRO operation has a heighted level of responsibility for ensuring the safety and overall airworthiness of the components and aircraft that it services. Please note the product safety is addressed in several places of AS9100D.

Additional unique requirements include the appointment of an Accountable Manager, Quality Manager, and Other Accountable Manager(s) (5.3.1-5.3.3) The implication of these requirements is to give assurance that all management resources will be made available to ensure compliance with all applicable customer and industry regulations.

Companies whose primary business is providing maintenance, repair, and overhaul services for aviation sector products should investigate if AS9110C certification is right for them. It is also intended to be used by organizations with maintenance, repair, and overhaul operations that operate autonomously, or that are substantially different from their manufacturing operations.

Please refer to the grids beginning on the following page for an explanation of the differences between AS9110B and AS9110C.

AS9110B:2012 TO AS9110C:2016 COMPARISON CHART

AS9110B:2012	AS9110C:2016
1. Scope	1 Scope
1.1 General	1.1 General
1.2 Application	1.2 Application
2 Normative references	2 Normative references
ISO 9000:2005	ISO 9000:2015
3 Terms and definitions	3 Terms and definitions
3.1 Airworthy	3.1 Airworthy
3.2 Article	3.2 Article
3.3 Authority	3.3 Certified Person
3.4 Certified Personnel	3.4 Certifying Staff
3.5 Certifying Staff	3.5 Competent Authority
3.6 Counterfeit Part	3.6 Continuing Airworthiness Management
3.7 Critical Items	3.7 Counterfeit Part
3.8 Human Factors	3.8 Dismantling
3.9 Key Characteristic	3.9 Life Limited Part
3.10 Maintenance	3.10 Maintenance
3.11 Release Certificate	3.11 Maintenance Data
3.12 Risk	3.12 Product Safety
3.13 Safety Policy	3.13 Qualified Person
3.14 Special Requirements	3.14 Safety Policy
3.15 Suspected Unapproved Part	3.15 Suspected Unapproved Part
3.16 Technical Data	3.16 Technical Data
	3.17 Unapproved Part

AS9110B:2012	AS9110C:2016
4 Quality management system	**4 Context of the organization** 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.4 Quality management system and its processes
4.1 General requirements	4.4 Quality management system and its processes 8.4 Control of externally provided processes, products and services
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality Manual	4.3 Determining the scope of the quality management system 7.5.1 General 4.4 Quality management system and its Processes
4.2.3 Control of Documents	7.5.2 Creating and updating 7.5.3 Control of documented Information
4.2.4 Control of Records	7.5.2 Creating and updating 7.5.3 Control of documented Information

AS9110B:2012	AS9110C:2016
5 Management responsibility	**5 Leadership**
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 General
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy 5.2.1 Establishing the Quality policy 5.2.2 Communicating the Quality policy
5.4 Planning	**6 Planning**
5.4.1 Quality Objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality Management System Planning	5.3 Organizational roles, responsibilities and authorities 6 Planning 6.1 Actions to address risks and opportunities 6.3 Planning of changes
5.4.3 Safety Objectives	**5 Leadership** 5.1.1k
5.5 Responsibility, Authority & Communication	**5 Leadership**
5.5.1 Responsibility and Authority	5.3 Organizational roles, responsibilities and authorities
5.5.1.1 Accountable Manager	5.3.1 Accountable Manager
No AS9110B:2012 requirement	5.3.2 Quality Manager
5.5.1.2 Maintenance Manager(s)	5.3.3 Other Appoimted Manager(s)
5.5.2 Management Representative	5.3 after e.
5.5.3 Internal Communication	7.4 Communication
5.6 Management Review	4 Quality management system 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 9.3 Management review
5.6.1 General	9.3.1 General
5.6.2 Review Input	9.3.2 Management review input
5.6.3 Review Output	9.3.3 Management review output

AS9110B:2012	AS9110C:2016
6 Resource management	**7 Support** 7.1 Resources
6.1 Provision of Resources	7.1.1 General 7.1.2 People
6.2 Human Resources	7.2 Competence
6.2.1 General	7.2 Competence
6.2.2 Competence, Training and Awareness	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work Environment	7.1.4 Environment for the operation of processes

AS9110B:2012	AS9110C:2016
7 Product realization	**8 Operation**
7.1 Planning of Product Realization	8.1 Operational planning and control
7.1.1 Project Management	8.1 Operational planning and control
7.1.2 Risk Management	8.1.1 Operational Risk Management
7.1.3 Configuration Management	8.1.2 Configuration Management
No AS9110B:2012 requirement	8.1.3 Product Safety
No AS9110B:2012 requirement	8.1.4 Prevention of Counterfeit Parts
No AS9110B:2012 requirement	8.1.5 Prevention of Suspected Unapproved Parts
No AS9110B:2012 requirement	8.1.6 Installation of Approved Parts
7.1.4 Control of Work Transfers	8.4 Control of externally provided processes, products and services 8.5 Production and service provision
7.2 Customer-Related Processes	8.2 Requirements for products and services
7.2.1 Determination of Requirements Related to the Product	8.2.2 Determination of requirements for products and services
7.2.2 Review of Requirements Related to the Product	8.2.3 Review of the requirements for products and services 8.2.4 Changes to requirements for products and services
7.2.3 Customer Communication	8.2.1 Customer communication
7.3 Design and Development	8.3 Design and development of products and services
7.3.1 Design and Development Planning	8.3.1 General 8.3.2 Design and development planning
7.3.2 Design and Development Inputs	8.3.3 Design and development Inputs
7.3.3 Design and Development Outputs	8.3.5 Design and development outputs
7.3.4 Design and Development Review	8.3.4 Design and development controls
7.3.5 Design and Development Verification	8.3.4 Design and development controls
7.3.6 Design and Development Validation	8.3.4 Design and development controls

AS9110B:2012	AS9110C:2016
7 Product realization (continued)	**8 Operation (continued)**
7.3.6.1 Design & Development Verification & Validation Testing	8.3.4 Design and development controls
7.3.6.2 Design and Development Verification and Validation Documentation	8.3.4 Design and development controls
7.3.7 Control of Design and Development Changes	8.3.6 Design and development changes 8.5.6 Control of changes
7.4 Purchasing	8.4 Control of externally provided processes, products and services
7.4.1 Purchasing Process	8.4 Control of externally provided processes, products and services 8.4.1 General 8.4.2 Type and extent of control
7.4.2 Purchasing Information	8.4.3 Information for external providers
7.4.3 Verification of Purchased Product	8.4.2 Type and extent of control 8.4.3 Information for external providers 8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of Production and Service Provision	8.5.1 Control of production and service provision 8.5.5 Post-delivery activities
7.5.1.1 Maintenance Process Verification	8.5.1.3 Production Process Verification (not applicable) 8.5.1.4 Evaluation of a New Capability
7.5.1.2 Control of Maintenance Process Changes	8.5.1.4 Evaluation of a New Capability
7.5.1.3 Control of Maintenance Equipment, Tools and Programs	8.5.1.1 Control of Equipment, Tools, and Software Programs
7.5.1.4 Post-Delivery Support	8.5.5 Post-Delivery Activities
7.5.2 Validation of Processes for Production and Service Provision	8.5.1.2 Validation and Control of Special Processes
7.5.3 Identification and Traceability	8.5.2 Identification and traceability
7.5.4 Customer Property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of Product	8.5.4 Preservation
7.6 Control of Monitoring and Measuring Equipment	7.1.5 Monitoring and measuring resources 7.1.5.1 General 7.1.5.2 Measurement traceability

AS9110B:2012	AS9110C:2016
8 Measurement, analysis and improvement	**9 Performance evaluation** 9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer Satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal Audit	9.2 Internal audit
8.2.3 Monitoring and Measurement of Processes	9.1.1 General
8.2.4 Monitoring and Measurement of Product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs 10.2 Nonconformity and corrective action
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	**10 Improvement**
8.5.1 Continual Improvement	10.1 General 10.3 Continual Improvement
8.5.2 Corrective Action	10.2 Nonconformity and corrective action
8.5.3 Preventive Action	6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2) 10.3 Continual Improvement

AS9120B:2016 QUALITY MANAGEMENT SYSTEM STANDARD REQUIREMENTS FOR AVIATION, SPACE, AND DEFENSE DISTRIBUTORS

AS9120B is a sector specific standard designed for organizations that provide warehousing and distribution services and do not perform any value added services. In general, value added services would include any form of repair, rework, modification, or other similar activity.

AS9120B certified distributors are permitted to provide re-packaging (for example from a larger quantity to smaller quantities) labeling, and inspection services.

AS9120 was originally published in 2003, later revised in 2009 to accommodate the changes made in 2008 to the ISO 9001 standard. AS9120B transitions the standard to align with Annex SL, ISO 9001:2015, and AS9100D:2016.

The primary aim of the AS9120B standard is to promote a full line of traceability from the OEM to the customer for all aspects of the aerospace supply chain. It can be applied to any form of distributed product, including tires, fasteners, electronic systems, batteries, and numerous others. AS9120B seeks to ensure a complete chain of custody, full traceability, and availability of all related records.

One section found in the ISO 9001:2015 and AS9100D:2016 standards is addressed differently in the AS9120B standard. Design and Development of Products and Services (Clause 8.3) is reintroduced back into the standard because its applicability should be determined in accordance with section 4.3 and Annex A (see A.5).

Numerous requirements found in AS9100D are also found in AS9120B. These include Configuration Management (8.1.2), Control of Work Transfers (per 8.4 and 8.5), and Foreign Object Controls (8.5.1l and 8.5.4b.) These additional requirements seek to emphasize the role that the distributor has in ensuring that the products it distributes are safe, free of contaminants, and airworthy.

The only unique section found within AS9120A Evidence of Conformity (Clause 8.2.5) is now covered in 9120B, 8.6a. This clause establishes requirements for ensuring full traceability to manufacturer inspection records, including airworthiness certifications where applicable. This is particularly relevant in situations where a product's quantity is split into two or more smaller quantities.

Please refer to the grid beginning on the following page for an explanation of the differences between AS9120A and AS9120B.

AS9120A:2009 TO AS9120B:2016 COMPARISON CHART _____

AS9120A:2009	AS9120B:2016
1. Scope	1 Scope
1.1 General	1.1 General
1.2 Application	1.2 Application
2 Normative references	2 Normative References
ISO 9000:2005	ISO 9000:2015
3 Terms and definitions	3 Terms and Definitions
3.1 Airworthiness Certificate	3.1 Article
3.2 Certificate of Conformity	3.2 Authorized Release Certificate
3.3 Counterfeit Part	3.3 Certificate of Conformity
3.4 Distributor	3.4 Counterfeit Part
3.5 Risk	3.5 Distributor
3.6 Splitting	3.6 Product Safety
3.7 Suspected Unapproved Part	3.7 Splitting
3.8 Test Report	3.8 Suspected Unapproved Part
No AS9120A definition	3.9 Test Report
No AS9120A definition	3.10 Unapproved Part
4 Quality management system	**4 Context of the organization** 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.4 Quality management system and its processes
4.1 General requirements	4.4 Quality management system and its processes 8.4 Control of externally provided processes, products and services
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality Manual	4.3 Determining the scope of the quality management system 7.5.1 General 4.4 Quality management system and its Processes
4.2.3 Control of Documents	7.5.2 Creating and updating 7.5.3 Control of documented Information
4.2.4 Control of Records	7.5.2 Creating and updating 7.5.3 Control of documented Information

AS9120A:2009	AS9120B:2016
5 Management responsibility	**5 Leadership**
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 General
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy 5.2.1 Establishing the Quality policy 5.2.2 Communicating the Quality policy
5.4 Planning	**6 Planning**
5.4.1 Quality Objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality Management System Planning	5.3 Organizational roles, responsibilities and authorities 6 Planning 6.1 Actions to address risks and opportunities 6.3 Planning of changes
5.5 Responsibility, Authority and Communication	5 Leadership
5.5.1 Responsibility and Authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management Representative	5.3 Organizational roles, responsibilities and authorities
5.5.3 Internal Communication	7.4 Communication
5.6 Management Review	4 Quality management system 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 9.3 Management review
5.6.1 General	9.3.1 General
5.6.2 Review Input	9.3.2 Management review input
5.6.3 Review Output	9.3.3 Management review output

AS9120A:2009	AS9120B:2016
6 Resource management	**7 Support** 7.1 Resources
6.1 Provision of Resources	7.1.1 General 7.1.2 People
6.2 Human Resources	7.2 Competence
6.2.1 General	7.2 Competence
6.2.2 Competence, Training and Awareness	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work Environment	7.1.4 Environment for the operation of processes

AS9120A:2009	AS9120B:2016
7 Product realization	**8 Operation**
7.1 Planning of product realization	8.1 Operational Planning and Control
7.1.1 Configuration Management	8.1.2 Configuration Management
7.1.2 Control of Work Transfers	8.4 Control of externally provided processes, products and services 8.5 Production and service provision
No AS9120A:2009 requirement	8.1.4 Prevention of Counterfeit Parts
No AS9120A:2009 requirement	8.1.5 Prevention of Suspected Unapproved Parts
7.2 Customer-Related Processes	8.2 Requirements for products and services
7.2.1 Determination of Requirements Related to the Product	8.2.2 Determination of requirements for products and services
7.2.2 Review of Requirements Related to the Product	8.2.3 Review of the requirements for products and services 8.2.4 Changes to requirements for products and services
7.2.3 Customer Communication	8.2.1 Customer communication
7.3 Design and development – ***NOTE This* clause not required for conformance to this standard**	8.3 Design and Development of Products and Services- ***NOTE: Clause 8.3 applicability should be determined in accordance with section 4.3 and Annex A (see A.5).***
No AS9120A requirement	8.3.1 General
No AS9120A requirement	8.3.2 Design and development planning
No AS9120A requirement	8.3.3 Design and development Inputs
No AS9120A requirement	8.3.4 Design and development controls
No AS9120A requirement	8.3.5 Design and development outputs
No AS9120A requirement	8.3.6 Design and development changes

AS9120A:2009	AS9120B:2016
7 Product realization (continued)	**8 Operation (continued)**
7.4 Purchasing	8.4 Control of externally provided processes, products and services
7.4.1 Purchasing Process	8.4 Control of externally provided processes, products and services 8.4.1 General 8.4.2 Type and extent of control
7.4.2 Purchasing Information	8.4.3 Information for external providers
7.4.3 Verification of Purchased Product	8.4.2 Type and extent of control 8.4.3 Information for external providers 8.6 Release of products and services
7.5 Production and service provision	8.4 Control of externally provided processes, products and services
7.5.1 Control of Production and Service Provision	8.5 Production and service provision
No AS9120A requirement	8.5.1.1 Control of Equipment, Tools, and Software Programs
7.5.2 Validation of Processes for Production and Service Provision – ***NOTE This* clause not required for conformance to this standard**	8.5.1 Control of production and service provision 8.5.5 Post-delivery activities
7.5.3 Identification and Traceability	8.5.2 Identification and traceability
7.5.4 Customer Property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of Product	8.5.4 Preservation
7.6 Control of monitoring and measuring Equipment	7.1.5 Monitoring and measuring resources 7.1.5.1 General 7.1.5.2 Measurement traceability

AS9120A:2009	AS9120B:2016
8 Measurement, analysis and improvement	**9 Performance evaluation** 9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer Satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal Audit	9.2 Internal audit
8.2.3 Monitoring and Measurement of Processes	9.1.1 General
8.2.4 Monitoring and Measurement of Product	8.6 Release of products and services
8.2.5 Evidence of Conformity	8.6a Release of Products and Services
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs 10.2 Nonconformity and corrective action
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	**10 Improvement**
8.5.1 Continual Improvement	10.1 General 10.3 Continual Improvement
8.5.2 Corrective Action	10.2 Nonconformity and corrective action
8.5.3 Preventive Action	6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2) 10.3 Continual Improvement

CONCLUSION

Since its initial release in 1987, the AS9100D quality management systems standard has had an enormous impact on thousands of organizations around the world.

In the short run, implementing an AS9100D:2016 quality management system has a major and positive impact on quality, productivity and cost reduction. And AS9100D:2016 registration can give American businesses unmatched credibility and competitive advantages in the European Union.

In the long run, AS9100D:2016 implementation and registration will preserve and create domestic and international markets for American businesses in virtually every field. Even now, many major American businesses and government agencies are requiring AS9100D:2016 registration as a supplier quality assurance qualification.

The standard furthers a tradition of flexibility, and through its alignment with Annex SL ensures that the organization can easily and seamlessly incorporate as many additional standards (ISO 14001, ISO 50001, etc.) as it sees fit.

THE STANDARD SHOULD BE OBTAINED FROM: www.sae.org