

Changes in AS9100C

Goal and Objectives of Changes to AS9100:2009

- Emphasis on product and process improvement (e.g. risk management, critical items, project management)
- Expand the AS9100 scope to include Aviation, Space & Defense
- Provide additional focus on objective of on-time and on-quality deliveries
Ensure AS9100 standard is compatible for use by all stakeholder segments and by organizations of all types and sizes
- Ensure AS9100 stays recognized by authorities
- Ensure extensive stakeholder involvement in revision effort by the use of a project management approach to solicit input and manage the revision.

Summary of Significant Changes

- 7.1.1 Project Management - New requirement for planning and managing product realization in a structured and controlled way.
- 7.1.2 Risk Management - New requirement of implementation of a risk management process applicable to the projects & products; responsibility, criteria, mitigation & acceptance.
- 7.1.3 Configuration Management - Moved from clause 4.3 to clause 7.1 and added details on the different activities to be covered.
- 7.1.4 Control of Work Transfer - Moved from clause 7.5 (Production) to clause 7.1 to add emphasis on having a process for planning and control of transfer activities.
- Product quality and on-time delivery performance - Added requirement to measure "product conformity" and "on-time delivery" and take appropriate actions if planned results are not achieved. The intent is to provide a linkage between the QMS and organization performance.
- Process to be required to address control of Special Requirements, Critical Items and Key Characteristics
- Key characteristic requirements remain unaltered but a new concept is added to identify special requirements from the Customer or internal sources that require additional controls (e.g. risk management) that translates into Critical Items that may flow to Key characteristics for variation control.
- Formal monitoring of Customer satisfaction data - Added the requirement to monitor data and to develop improvement plans that address deficiencies. The intent is to promote continuous improvement of the product and Customer satisfaction.
- Requirements from regulatory authorities. - A general requirement has been introduced in 4.1 to address all the applicable statutory and regulatory QMS requirements in the organization's QMS instead of keeping detailed requirements in chapters.
- First Article Inspection (FAI) moved to clause 7.5.1.1 and renamed Production process verification "FAI" is the requirement to validate the production process's

- documentation and tooling and repeat the process when necessary (i.e. when engineering or manufacturing processes change). The requirement was moved from 8.2.4.2 (measurement) to 7.5.1.1 (production) because it is part of product realization and is not intended to be a follow-on activity.
- Difference between Key Characteristics, Special Requirements and Critical Items. Special Requirements are those requirements that have high risks to being achieved, which require their inclusion in the risk management process. Critical Items, including key characteristics, are those items that have significant effect on product realization and use of the product, which require specific actions to assure they are adequately managed.
 - ISO 10007 is referenced after Configuration Management. ISO 10007 is included in a Note for reference only.
 - ISO 9001 changes affect AS9100:2009. The AS9100 standard has been updated to stay consistent with ISO 9001, which will continue to be the baseline. The changes being incorporated into ISO 9001:2008 are considered an amendment and minor in nature. No structural changes.
 - Length of time to transition to AS9100:2009. 30 months. Companies will be encouraged to upgrade on their scheduled audit cycle.
 - New "Scope" statement suggests alternate registrations. If an organization applies multiple standards in addition to AS9100 such as AS9110 (Maintenance) or AS9120 (Distributor) then the registration requirements should be determined by Customer and regulatory requirements. More than one standard registration may be necessary if the Company provides other industry-standard products and services according to its scope of business activities (i.e. a Company that manufactures products and also sells maintenance services). Clause 1.2 Introduction outlines the new applicability statements for AS9100, AS9110 and AS9120.
 - Deleted text from Clause 4.2.2 Quality Manual Relationships. The deletion of the requirement to create a document showing the relationship between AS9100 requirements and the organization's documented procedures was seen as adding no value to assuring product quality above the existing ISO text. Users of AS9100 will still need to identify appropriate documented procedures as an inherent part of carrying out an audit.

AS9100 Revision "C" Key Changes

- 6 Additions
- 8 Revisions/Relocations
- 3 Deletions

Detailed Description of Changes in AS9100C

Clause 1 - AS9100 Scope and Application

Revision: Scope extended to include Defense as well as Aviation and Space.

Application guidance provided when AS9100, AS9110 and AS9120 are appropriate for use. AS9101 will incorporate AS9111 and AS9121 audit requirements.

Reason: The AS9100 QMS is applicable to other complex quality management systems and would receive benefit from implementation including land and sea applications. Possible additional recognition and synergies with NATO Allied Quality Assurance Publications (AQAPs).

Considerations: Increased use and improved understanding of when the various aviation, space and defense standards are applicable.

Clause 3.1 - Risk

Addition: Define new term "risk"

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

Reason: The understanding of risk is important for an organization to develop a proactive quality management system.

Considerations: Understanding this term is important to implement a risk management process in the applicable clauses.

Clause 3.2 - Special Requirements

Addition: Define new term "special requirements"

Those requirements that have high risks to being achieved thus requiring their inclusion in the risk management process.

Factors used to determine special requirements include:

- past experience
- product or process complexity
- product or process maturity.

Examples include:

- performance requirements imposed by the Customer that are at the limit of the industry's capabilities
- requirements determined by the organization to be at the limit of its technical or process capabilities

Reason: Improve understanding of "Special Requirements" and the potential chain of flow to "Critical Items" and to "Key Characteristics."

Ensure these important requirements are systematically addressed and linked to risk management activities by the organization.

Considerations: Understanding this term is important to implement special requirement processes in the applicable clauses.

Clause 3.3 - Critical Items

Addition: Define new term "critical item"

Those items having significant effect on the product realization and use of the product (e.g. functions, parts, software, characteristics, processes); including safety performance, form, fit, function, producibility, service life, etc. that require specific actions to ensure they are adequately managed.

Examples of critical items include:

- fracture critical items
- key characteristics
- mission critical items
- safety critical items

Reason: Improve understanding of "Critical Items" coming from Special Requirements. Ensure these items are systematically addressed and linked to risk management activities by the organization.

Considerations: Understanding this term is important to implement critical item(s) processes in the applicable clauses.

Clause 4.1 – QMS General Requirements

Revision/Relocation: The organization's QMS shall address Customer and applicable statutory and regulatory QMS requirements (previously located in the QMS documentation 4.2.1).

Reason: Clarify that the requirement is placed at the QMS level and not only at the documentation level.

Considerations: The concept of "basic QMS" may be used (processes applicable to all Customers / activities) but the documents such as Quality Management Plans that address specific Customers requirements shall be considered as part of the QMS.

Clause 4.2.2 – Quality Manual Relationships

Deletion: Requirement to create a document showing the relationship between AS9100 requirements and the organizations documented procedures.

Reason: Requirement adds no value to assuring product quality.

Requirement was viewed as prescriptive in that it specifies a particular method of assuring the requirements of the standard have been met.

Considerations: Auditors need to identify appropriate documented procedures as an inherent part of carrying out the audit.

Clauses 5.2/8.2.1 – Customer Focus/Satisfaction

Addition: Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not or will not be achieved. (5.2)

Information to be monitored and used for the evaluation of Customer satisfaction shall include but is not limited to:

- corrective action requests.
- Customer complaints
- on-time delivery performance
- product conformity

Organizations shall develop and implement plans for improvement of Customer satisfaction that addresses deficiencies identified by these evaluations and assess the effectiveness of the results. (8.2.1)

Reason: Establish clear relationship between the QMS and organizational performance in line with AS9100 strategy. To promote continuous improvement of Customer satisfaction.

Considerations: Review of management focus and organizational process to measure Customer satisfaction and plan improvements.

Clause 7.1.1 - Project Management

Addition: New requirement for planning and managing product realization in a structured and controlled way to meet requirements at acceptable risk within resource and schedule constraints.

Reason: Most aviation space and defense products are complex and involve multi-tier partners and suppliers. This clause provides additional focus on upfront planning and the management of project plans throughout product realization.

Considerations: The organization must have a process to manage product realization planning to ensure quality and schedules are not compromised. Project plans should be used to manage the successful completion of projects.

Clause 7.1.2 - Risk Management

Addition: New requirement to implement a risk management process applicable to the product and organization covering: responsibility, criteria, mitigation and acceptance. The concept of risk is integrated within the revised AS9100.

Reason: Risk Management was placed in clause 7.1.2 to provide additional focus on product risk during product realization.

Considerations: The organization must have a risk management process that addresses all of the applicable requirements, such as verification of chemical/physical test reports. The definition of risk must be appropriately understood and applied in that process. Risks must be successfully managed in the organization.

Clause 7.1.3 - Configuration Management

Revision/Relocation: Moved from Clause 4.3 to 7.1.3. Structured in line with ISO 10007 requirements.

Reason: Focuses configuration management on the product and how it is sustained throughout product realization.

Considerations: Some level of configuration management is expected for all products at all levels of the supply chain in compliance with exclusion criteria (see clause 1.2).

Clause 7.1.4 – Work Transfer

Revision/Relocation: Moved from clause 7.5.1.4 (Production) to clause 7.1.4. The organization must have a process to plan and control the transfer activities. Expanded to cover permanent transfer (e.g. from one organization to another, from one organization to supplier, from one supplier to another).

Reason: Work transfer can occur at anytime during product realization.

Addresses problems that often occur during work transfers .

Considerations: A process must exist to control the transfer of work including planning and subsequent control of the transfer.

Clause 7.4.1 – Recognition of Supplier Quality Data

Revision: Added note to recognize that one factor that may be used during supplier selection and evaluation is "objective and reliable data from external sources".

Reason: Recognition that the industry trend is to use externally provided supplier performance data (e.g. Online Aerospace Supplier Information System – OASIS, Nadcap)

Considerations: Note only

Clause 7.4.1 – Approval status for suppliers

Revision: Added and provided examples of "approval status" (e.g. approved, conditional, disapproved) and examples of "scope of approval" (e.g. product type, process family). The organization must define the process for supplier approval status decisions or changes.

Reason: Clarify that the conditions for using a supplier depends on its approval status.

Considerations: The process responsibilities and authority must be defined for this process.

Clause 7.4.3 – Validation of Test Reports

Deletion: Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.

Reason: Misunderstood concept that was frequently misapplied.

Requirement was prescriptive, not applicable to all stakeholders (especially small organizations) and for all types of products and was subject to varying interpretation.

Considerations: The organization must verify test reports as part of the risk management process if it is making critical items where the material chemical/physical requirements are important.

Clause 7.5.1.1 – Production Process Verification

Revision/Relocation: Moved from 8.2.4.2 (measurement) to 7.5.1.1 (production)

Requirement to verify production process documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g. engineering or manufacturing process changes, tooling changes).

Reason: Movement to clause 7 acknowledges that this requirement (previously called first article inspection - FAI) is not primarily a measuring and monitoring process but a process that will be used to assure product realization capability under controlled conditions. Allows justifiable exclusion for unique and individual products.

Considerations: Validation of requests for exclusion (unique and individual products vs. production run).

Clause 8.2.2 – Detailed Tools and Techniques

Deletion: "Detailed tools and techniques shall be developed such as check sheets, process flowcharts or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance."

Reason: Requirement was too prescriptive - reference to specific tools in a "such as" statement is more appropriate as guidance material.

Considerations: Methods and effectiveness measures remain intact in the ISO text. Tools and techniques may still be needed to support the audit process.

Clause 8.2.4 –Sampling Inspection

Revision: When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriateness for use (i.e. matching the sampling plan to the criticality of the product and to the process capability).

Reason: Numerous requests were received to improve clause 8.2.4. The comments ranged from it was statistically inaccurate to comments that it was too prescriptive.

Considerations: Validation of recognized statistical principles utilized. Process used to determine criticality of product.

Allowable time for Recertification

Maximum 30 month Implementation from Publication date (January 2009).