

Interpreting Changes to AS9100D

AS9100:2016 Revisions Overview



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Executive Summary

The AS9100 quality management standard builds on ISO 9001, adding requirements for quality, product safety and other relevant requirements specific to aviation, space and defense, and defining quality management systems across each industry. All major manufacturers (OEMs) and suppliers worldwide embrace AS9100 as a valuable tool for improving quality and on-time delivery within their supply chains.

In September 2016 the G-14 Americas Aerospace Quality Standards Committee (AAQSC) released version AS9100:2016 (also known as AS9100D), replacing AS9100:2009 (AS9100C). This paper will outline the major changes and clarify how companies should interpret them to stay compliant.

The revision aims to improve the standard across several areas:

- Incorporating revisions within ISO 9001:2015
- Introducing flexibility to embrace modernized processes
- Expanding on how risk-based thinking should be applied
- Clarifying what is meant by internal and external risk
- Adding elements of product safety throughout product life cycle
- Introducing processes to eliminate counterfeit parts and manage product obsolescence
- Limiting the potential for non-conformities to be determined as the fault of human error

Interpreting Changes to AS9100D

The latest revision streamlines several complexities that were present in the previous standard, making it easier to interpret and follow. Additionally, several clauses have been amended to introduce a strong connection between compliance objectives and end-customer satisfaction, addressing market pushback over a misconception that meeting the mandate interferes with the regular course of business.

The updates are consistent with overall industry goals for continuous improvement, and there is significant focus on simplifying the road to compliance.

FLEXIBILITY AND CLARITY

As noted above, AS9100D provides for more flexibility with documented information. The terminology changes (see Appendix) allow for the use of newer forms of media and communications, enabling organizations to leverage modern technology and still remain compliant. While ISO 9001:2015 removed several requirements for documentation, AS9100D contains additional language for "maintained" and "retained" documentation, as explained in the Appendix.

In places where there is no specific requirement listed, organizations are still obligated to document effective planning, communication and implementation of their Quality Management System processes.

Clause 4 of the standard now states that leadership must determine the organization's external and internal issues, and it provides examples of the types of issues for leadership to consider (i.e., competitive landscape or company culture). It does not, however, require the organization to define itself along a specific set parameters. In effect, leadership is required to understand the factors that drive risks and opportunities, but they retain the flexibility to determine which factors are actually applicable to their organization.

Changes in the configuration management sections likewise drive simplicity. The AAQSC clarified and considerably

improved Clause 8.1.2 to support more effective implementation and better communication of the standard's requirements across the organization. These requirements include specific data around product identification, design, traceability, acceptance, and changes that may occur throughout the product or service lifecycle.

RISK REDUCTION

The new standard takes special care to merge operational risk management with the new ISO 9001:2015 requirements for risk-based thinking. Ultimately, this is simply an adaptation of the "preventive action" requirement from previous versions of the standard. Previously, it was difficult to understand how to apply risk management principles in the real world. AS9100D defines this concept as an ongoing action that is to be applied across all activities of the business.

In AS9100D, the two substantial references for applying risk-based thinking are Clause 6.1, around planning and other management level activities; and Clause 8.1, for operations around product realization processes. This is important because it allows an organization to materially demonstrate that it is taking a proactive approach -- and constantly problem-solving -- to protect all interested parties.

Risk-based thinking also plays a significant role in the

revision's treatment of "organizational knowledge". Clause 7.1.6 now defines knowledge as a resource that must be acquired and effectively managed. Organizations must demonstrate they have a process in place not only for gathering the right knowledge to meet customer and business needs, but also for retaining that knowledge if someone leaves the company.

While the standard defines organizational knowledge as a foundational activity, it also leaves enough latitude to protect businesses from over-engineering such processes in pursuit of compliance.

Meanwhile, there is now a definition for "product safety" (Clause 8.1.3), which calls attention to safety throughout a product's entire lifecycle. The new clause supports aerospace and defense industries' expectations for safety-critical items, and lays out procedural expectations for proper risk assessment methods, failure analysis, appropriate mitigation actions, and reporting.

Clauses 7.3 and 7.4 of the revision expand and clarify the importance of proper organizational awareness, training and communication. These new clauses systematize a method for ensuring all interested parties are on the same page about product safety, quality policy, organizational objectives, ethical behavior and individuals' contributions to product or service conformity. There is also a process required for notifying customers if you are not going to meet their stated requirements, or if internal changes could affect customer requirements.

There is now a specific validation process for any externally provided product, process and service, as well as a separate validation process for any documentation coming from sub-providers such as an independent test lab used for raw materials. For example, if an OEM uses an external lab provider to test the aluminum it received for air wing manufacturing, there is now a process expectation to validate the documentation receives from the testing lab.

Finally, the new standard includes an explicit requirement for counterfeit parts prevention. It lays out specific expectations for programs to prevent suspect parts from entering the supply chain. These programs must be supported with adequate awareness and training regimens, along with external provider controls, traceability to authorized manufacturer(s), documented measures for managing product obsolescence, and information flow of these requirements to all interested parties.

RISK MANAGEMENT IN THE WORK ENVIRONMENT

In keeping with AS9100D's emphasis on risk-based thinking, work environment standards have been updated to require that organizations account for human and physical factors in resource planning for the work environment. Previous versions spoke only to physical factors.

The revised standard acknowledges that conformity of products and services can be influenced by physical factors (e.g., lighting, temperature, humidity, etc.) as well as human elements such as social (discriminatory, confrontational) and psychological (stress, burnout, emotional) issues.

AS9100D now requires organizations to ask why there was a human error and take appropriate action, rather than merely defining human error as a determining cause of nonconformities. This is intended to eliminate instances where an individual could be deemed to have been at fault. The root cause cannot be simply, "An operator forgot to do something." The corrective actions must include a process for error-proofing against human factors, thus removing them. The same should be considered when developing or modifying products, processes and systems, as a measure against failures and non-conformities.

The Benefits of AS9100D Certification

Whether you are already AS9100-certified, or considering certification for your organization, there are many tangible benefits to be gained from certifying under the AS9100D revision. Based on feedback received from AS9100 companies, you can expect:

INCREASED PRODUCTIVITY, JOB SATISFACTION, AND REDUCED EMPLOYEE STRESS

The AS9100D implementation process improves training and qualification of employees, results in better documentation and process control and ultimately leads to more consistent performance, less scrap and rework. In turn, managers experience fewer late night troubleshooting calls, and employees are in the proper position to troubleshoot problems on their own.

MORE CUSTOMER SATISFACTION

By rule, AS9100D helps an organization put processes into place that account for customer needs. It defines standards for consistently seeking, receiving and analyzing customer feedback. Goals and objectives begin to skew toward the customer, and the organization spends less time focusing on the goals of individual departments and more time working together to meet customer needs.

FINANCIAL PAYOFF

Management researchers from several global business schools conducted a study on the empirical results of ISO certification in the United States, and found that publicly-traded firms who become ISO 9000 certified experience "significant abnormal improvements in financial performance."¹ The gains are statistically significant.

As a whole, organizations are recognizing that an effective Quality Management System, based on AS9100 or ISO 9001, leads to better management, reduced costs, and greater operating margins.

What will it do for you?

¹ Management Science, "The Financial Impact of ISO 9000 Certification in the United States: An Empirical Analysis;" Charles J. Corbett (Anderson School of Management, UCLA), María J. Montes-Sancho (Universidad Carlos III de Madrid) and David A. Kirsch (R.H. Smith School of Business, University of Maryland); Vol. 51, No. 7, July 2005; http://www.environment.ucla.edu/perch/resources/pdfcc25.pdf

Important AS9100D Timelines and Milestones



All organizations must transition to AS9100D by **September 15, 2018**.



Current AS9100C certificates will not be valid after **September 15, 2018**.



Organizations currently certified under AS9100C are encouraged to transition to the updated standard early. Transitions may occur at any point.



Organizations must maintain a valid and current certificate until they are successfully issued one for AS9100D.



TÜV Rheinland North America strongly recommends that audits against AS9100D should be completed no later than **June 15, 2018**, allowing for sufficient time for non-conformance report (NCR) closure, if needed.

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For more information on TÜV Rheinland North America Management Systems Certification, or to certify your organization to AS9100D, please call us toll-free at 1-TUV-RHEINLAND (1-888-743-4652) or visit <u>www.tuv.com/us</u>.

Appendix: New Terms and Definitions

To expedite review and understanding of AS9100D, please refer to the below summary of terminology changes relevant to the revision.

CONFIGURATION MANAGEMENT

The revision simplifies this term to improve implementation and communication of requirements.

COUNTERFEIT PART

This is an entirely new term, added as means to explicitly state requirements for preventing delivery of nonconforming products or services.

ETHICAL BEHAVIOR

This is a new requirement under the concept of risk-based thinking, added to clarify organizational understanding about how every individual's work affects product conformity.

EXTERNAL PROVIDER

The revised standard combined all terms such as vendor, supplier, subcontractor, and outsourcing partner into a single term: external provider.

HUMAN FACTORS

This addition expressly identifies "human factors" in determining cause of nonconformities. The corrective actions should include elimination of human factors by error proofing, and reflects the standard's aim to avoid ever laying blame at the feet of a specific individual for nonconformities.

INTERESTED PARTIES

Replaces the term "stakeholders" from prior versions.

MAINTAINED INFORMATION

To facilitate greater flexibility with documentation, the new standard introduces new terminology as pertains to documented information. Maintained information refers to procedures.

ON-TIME DELIVERY PERFORMANCE

Under the section for performance review, the standard now includes this factor as an input for management review.

ORGANIZATIONAL CONTEXT

This new term is introduced to support organizational leadership in understanding every internal and external factor that affects their business. It identifies needs and expectations, and uses the information to clarify potential risks, opportunities and planning activities.

ORGANIZATIONAL KNOWLEDGE

Newly defined as a resource that must be acquired and effectively managed.

RETAINED INFORMATION

Refers to records, or historical evidence of compliance.

RISK-BASED THINKING

This is an adaptation of prior references to "risk management." The change was made in order to promote the concept that organizational risk must be applied in all activities of the business.

SERVICES

Throughout the new standard, there is reference to products and services. Prior versions mentioned only products.

WORK ENVIRONMENT

While previous versions of the standard only addressed the physical factors of a work environment, the revised standard indicates that conformity of products and services can be influenced by physical factors (E.g., Lighting, temperature, humidity, etc.) as well as human factors such as social (discriminatory, confrontational and other) and psychological (stress, burnout, emotional and others).

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