AS9100C – Revised Standard Improves Aerospace Quality

Customer satisfaction is one of the newest changes to the international quality management standard for aerospace.

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It is not an understatement to say that the aerospace industry is wide-ranging and diverse. Certainly, in terms of payload, diversity is the rule: passengers, packages, satellites, unmanned aerial vehicles, communication devices, defense systems … the list is truly, and exhaustively, extensive.

Diversity
True diversity, however, is found in the supply chain. For one airplane, thousands of parts come together at the original equipment manufacturer (OEM). A more diverse collection of products would be difficult to find in any industry, ranging from the most complex part such as a near-net shaped turbine on a jet engine to the simplest snack tray that folds down from the back of a passenger's seat.

What this menagerie has in common is the need for quality and continual improvement, critical concepts that help keep aeronautic equipment airborne, and its cargo secure, throughout the many decades of its use.

AS9100
Another commonality is AS9100, the international quality management standard that is a near-to universal requirement for selling to the aerospace market. The overriding tenet of the standard is the continual improvement of a company's processes and procedures, and, ultimately, the finished product. This is why an international technical committee developed a new and improved version of the aerospace standard.
With the new release, aerospace companies and their suppliers may have one other thing in common: urgency.

AS9100C
Deadlines to comply with AS9100C are just around the corner, and the timeframe between when a company can apply for certification, and when they must obtain certification without a compliance interruption is short. Time, for some organizations, is compressed even further by fast-approaching dates to certify to ISO 9001:2008, the

newest version of that international quality system, and a word-for-word foundation for the aerospace standard.

More than a decade ago, AS9100 became the first international effort to formulate a quality management system for the aerospace industry. Thousands of aerospace companies certified to the standard, most of who were already certified to ISO 9000. Most of these companies realized improved quality, reduced costs, and increased sales. In 2004, Revision B was released, which changed the structure of the standard but contained few substantive changes. In January 2009, the newest version, Revision C, was published.

Much like its predecessor, the AS9100 Rev. C, looks to continually improve quality but has expanded its scope and broadened its objectives. It now serves manufacturers of aviation, space, and defense equipment and better reflects the industry for the change. It focuses on the customer satisfaction and on-time delivery of quality parts.

Also, like its predecessor, AS9100C details the framework, if not the actual steps, of a plan to accomplish these goals. Revision C carries on the tradition of flexibility that prescribes what a company should do but leaves the how they should do it up to the individual company. What works best for Company X may not be best for Company Y.

Certification to AS9100C was initially delayed by the need to publish supplemental materials. These materials, part of the AS9100 family of standards, are AS9104 document, which details the management of the standard including requirements for registrars and auditors, and AS9102, the first article inspection checklist. They have subsequently been published. Training courses for registrars and auditors also have been developed and vetted, and auditors from a growing number of companies have been accredited.

NSF International, based in Ann Arbor, MI, was one of the first registrars to earn Revision C accreditation from the ANSI-ASQ National Accreditation Board (ANAB).

And, not a moment too soon. Certification deadlines are intractable.

Beginning July 2, 2011, all AS9100 audits will be to the Revision C standard. Companies already certified to AS9100B have one year from that point to register to the new version. On July 12, 2012, AS9100B will be null and certifications void.

Within that timeframe, many things must happen, new concepts digested, plans and procedures put in place. And, while these activities occur, company’s currently certified to version B must continue to meet those requirements.

(Because of the potential complexity of this conversion, organizations that undertake this endeavor should make sure that the registrar with whom it works is accredited to the new version. If not, the company will have to re-certify to the new version by the 2012 deadline.)

The process for certification to AS9100C begins with ISO 9001. Many changes to ISO 9001:2008 standard were made, of which only a few can be considered here because of space considerations.

- The ISO management representative must be both an employee and a member of management, and the competence of management and support personnel must be considered.
- Information systems such as the enterprise quality management databases must be reviewed for effectiveness and consistency.
- A process must be established to check the status of a product throughout product realization , and internal audit records must be maintained.
- Supplier control and product and process measuring requirements and results must be tied to data analysis.
- Nonconformities are no longer considered a singular problem. Instead, it is recognized that a nonconformance can, and often will, have multiple causes. Corrective actions and preventive actions (CAPA) must be reviewed to determine their effectiveness. When a nonconformance occurs, does CAPA root out the problem, solve it, and verify that it won't happen again? It should.

All clients must upgrade to ISO 9001:2008 before Nov. 12, 2010, and clients with ISO 9001:2000 certificates who are due for audits in the fourth quarter of 2010 need to have their audits conducted earlier to meet the deadline.

When certified to the 2008 standard, companies can then be certified to AS9100C, a process that may take some time. The standard's changes are varied, sometimes subtle, and occur throughout the document. Items have been added, revised, relocated, and omitted. Special care must be taken during conversion because some revisions are not backwards compatible.

Because the standard is still in its relatively new, additional audit days should be built into the timeframe to ensure that the quality management systems meet the new requirements. Audit pre-planning can help. Prior to the audit, the auditor may ask the aerospace company to send them "scorecards," forms developed to track customer satisfaction. Auditors may request information on customer complaints, and any new processes or products that were introduced since the last audit. A company can take it upon themselves to verify compliance by conducting internal audits and management review of the QMS.

If management reviews the QMS, it should now find an emphasis on structured design and validation methodologies, configuration management, and product identification and traceability. Based on the new version, the system must incorporate into its QMS new requirements and clauses for planning, project management, and risk management. It must establish a formal system such as the scorecards for monitoring customer satisfaction trends, and formal plans to ensure continual improvement based on that information.

Customer Focused
This intense focus on the customer is a new addition to the standard, and is perhaps the most important component. Of this concept, the standards says that, "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."

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product conformity, on-time delivery performance, customer complaints, and corrective action requests.

Companies should keep these scorecards and develop ways to use the information to inform the auditors. For example, are internal performance measures linked to customer satisfaction, or can internal audit plans be adjusted based on the results of customer satisfaction or perception?

Additional Terms Defined
Also new to AS9100C is the definition of new terms, including special requirements and critical items. Special requirements are those identified by the customer, or determined by an organization, explain what this means: that has high risks to being achieved. Factors used to determine special requirements include product or process complexity, past experience, and product or process maturity. Again, not sure what the following sentence is trying to explain. An example of this might be a customer's performance requirements that are determined to be at the limit of the manufacturer's technical or process capabilities.

Critical items are the processes, characteristics, parts, and software that have a significant effect on product realization, and the use of the product. Critical items include safety critical items, fracture critical items, mission critical items, and key characteristics. This includes safety, performance, form, fit, function, ability to manufacture, and product life cycle that require specific actions to ensure that they are adequately managed.

Much of this can fall under the purview of project management, another addition to the standard. Companies must incorporate planning and managing product realization into their QMS in a structured and controlled way to meet requirements within resource and scheduling constraints.

Configuration Management
Configuration management was revised, and relocated, so that it aligns with ISO 10007: Quality management systems -- Guidelines for configuration management, a standard that establishes a QMS for confirmation management. This clause focuses configuration management on the product and how it is sustained throughout the product realization process. Some level of configuration management is expected for all products and at all levels of the supply chain, and this will require companies to develop a more formal and robust configuration management approach. Auditors will need to see documentation of training and the competence of involved personnel.

Risk Management
Risk management is also prominent in the standard. The term "risk" is defined as an "undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence."

This emphasis on risk management serves to reduce liability by documenting that risks were understood, taken seriously, and that subsequent measures were taken to deal with these items.

Essentially, it requires organizations to establish a process for managing risks to achieve customer, and statutory and regulatory requirements. It also may require audit trails for planning and design. The organization should evaluate risk for all products, and determine whether to integrate into their procedures a disciplined quality evaluation method such as Failure Mode Effects Analysis. A company should consider integrating risk management with CAPA, customer returns, and management review.

Additional Components of the Standard
Other elements of the standard include:

- a mandatory suspension for corrective action responses (CARS) that have been open for 60 days;
- adding more hours to shorten days will not be allowed;
- enhanced certification transfer requirements;
- and, one checklist for all AQMS standards

The Supply Chain
This checklist may also include the supply chain. The standard focuses on tracking part quality from suppliers, and makes several additions, deletions, and revisions. Managing the parts and services from outside vendors has always been a critical component of AS9100, which is understandable considering the thousands of companies up and down the supply chain and myriad industries. These industries may, or may not, have specifications as exact as does the aerospace industry.

To help assure the quality of products from the supply chain, the standard oversees such items as clarifying engineering requirements and product acceptance. The company can choose to conduct a receiving inspection, inspect the product at the supplier's facility, or formally delegate the task to the supplier.

Previously, under Rev. B, if a non-conforming product was identified during a sample inspection, the entire lot of parts had to be rejected. Rev. C does not contain this requirement. Instead, it allows companies to use statistical process control principles. A company can match the sampling plan to the criticality of the product and to the process capability.

Verification
The standard also requires that a company verify production processes, documentation, and tooling to ensure they are capable of producing parts and assemblies that meet requirements. If a change occurs that invalidates the original results, this process needs to be repeated.

If the emphasis on quality begins with the suppliers, it does not end there. New standards that are part of the AS9100 family oversee repair and maintenance of parts and equipment, as well as part distribution (see sidebar). The standards require maintenance and repair manuals, documentation of the service work, the personnel who completed the work, their qualifications, the equipment they used, and subsequent data related to the task such as calibration reports, non-conformances, and the quality test results.

Quality throughout the product stream, from widget supplier to the field technician, is a major factor in satisfying the customer. By combining the ideas found in AS9100C, organizations can develop a quality management system that works for them and their customers. Despite the numbers of changes, and the prescriptive nature of some of them, a company's QMS can be tailored to that organization and be an effective tool regardless of the complexity of the part or the depth of service.

Changes In a Nutshell
Changes determined to be essential to the continual improvement of AS9100 include:
-- The scope was changed from aerospace to aviation, space, and defense.
-- Special requirements are those identified by the customer or determined by the organization that has high risks to being achieved.
-- Critical items such as functions, parts, software, characteristics, and processes are those having significant effect on product realization and use of the product.
-- Product conformity and on-time delivery is to be measured and appropriate actions taken if planned results are not achieved.
-- Customer satisfaction data is to be monitored to develop improvement plans that address deficiencies.

Standards for Repair and Part Distribution
The new AS9110 Rev. A standard for maintenance and repair includes new and revised terminology that looks at safety policies, counterfeit parts, and suspect unapproved parts. It incorporated AS9100:2009C changes that are applicable to maintenance activities.

The term "safety policy" is defined as a management's formally expressed commitment to product safety. This policy should reflect the organization's philosophy of safety management and outline the methods and processes that the organization will use to achieve desired safety outcomes.

The maintenance organization must establish and maintain a quality manual that includes a description of key maintenance processes and procedures. It should address how these processes and procedures are consistent with most sector authority requirements.

The standard includes clauses that relate to: Analysis of Data (clause 8.4); Corrective Action (8.5.2); and Preventive Action (8.5.3). It calls for an analysis of human factors to ensure it has been integrated into these clauses and processes. Human error can be used to explain failures or potential failures. However, auditors will examine how the organization identifies and compensates for these factors to prevent or correct nonconformance.

The new AS9120 Rev. A distributor requirements standard also includes new and revised terminology for safety policies, counterfeit parts, and suspect unapproved parts. AS9100C changes are included, such as clause 7.1, planning or product realization. ISO 9001:2008 stated that the word "product" is interchangeable with the word "service." Because distribution is a service, the requirements of 7.1 apply as other requirements in section 7 are subordinate to 7.1.

The requirement to retain records for a minimum of seven years has been deleted. Instead, the length of time an organization must retain records is based on other factors such as customer and regulatory requirements.

Configuration management language was also included. Auditors will verify how the organization determines that the correct configuration is being distributed based on customer requirements for the product ordered.

A Rundown of Changes
Revision: Clause 1 -9100 Scope and Application
Scope extended to include defense as well as aviation and space.

Addition: Clause 3.1 – Risk
Define new term "risk" as an undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

Addition: Clause 3.2 - Special Requirements
Defines new term "special requirements" as those requirements that have high risks to being achieved thus requiring their inclusion in the risk-management process.

Addition: Clause 3.3 - Critical Items
Define new term "critical item" as those items (e.g., functions, parts, software, characteristics, and processes) having significant effect on the product realization and use of the product, including safety, performance, form, fit, function, producibility, and service life, which require specific actions to ensure that they are adequately managed.

Revision/Relocation: Clause 4.1 – QMS General Requirements
The organization's QMS shall address customer and applicable statutory and regulatory QMS requirements (previously located in the QMS documentation §4.2.1)

Deletion: Clause 4.2.2 – Quality Manual Relationships

Requirement to create a document showing the relationship between AS9100 requirements and the organization's documented procedures

Addition: Clauses 5.2/8.2.1 – Customer Focus/Satisfaction
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.

Addition: 7.1.1 - Project Management
New requirement for planning and managing product realization in a structured and controlled way to meet requirements at an acceptable risk, within resource and schedule constraints.

Addition: 7.1.2 - Risk Management
New requirement to implement a risk management process applicable to the product and organization covering: responsibility, criteria, mitigation, and acceptance.

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

Revision/Relocation: 7.1.4 – Work Transfer
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.

Revision: Clause 7.4.1 – Recognition of Supplier Quality Data
Added note to recognize one factor that may be used during supplier selection and evaluation is objective and reliable data from external sources.

Revision: Clause 7.4.1 – Approval status for suppliers
Added and provided examples of "approval status" and examples of "scope of approval." The organization must define the process for supplier's approval status decisions or changes.

Deletion: Clause 7.4.3 – Validation of Test Reports
The following clause was deleted: 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.

Revision/Relocation: Clause 7.5.1.1 – Production Process Verification
Moved from 8.2.4.2 (measurement) to 7.5.1.1 (production). Requirement to verify the production processes, documentation, and tooling that are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results.

Deletion: Clause 8.2.2 – Detailed Tools and Techniques

The following clause was deleted: “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.”

Revision: Clause 8.2.4 – Sampling Inspection
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 appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).
Source: Edited from International Aerospace Quality Group (IAQG) materials

For more information on NSF-ISR’s range of aviation quality management systems registrations available globally, please contact information@nsf-isr.org or visit www.nsf-isr.org