QUALITY MANAGEMENT SYSTEMS

Reaching New Heights

Move past minimum QMS requirements to achieve greater improvement

by L.L. “Buddy” Cressionnie and Alan Daniels

Now that you have successfully achieved certification to the revised International Organization for Standardization (ISO) and aviation, space and defense (ASD) standards, what are the next steps for your organization? A quality management system (QMS) isn’t intended to sit on a shelf between revisions. Rather, it requires maintenance and continual improvement to ensure it effectively meets business needs.

Often, leadership openly wonders why QMS certification doesn’t result in the improvements it envisioned. More often than not, however, leadership stopped implementation or improvement activity after receiving certification.

The key is not looking at a QMS as a project with a beginning and an end, but as a business system providing substantial benefits when time and effort are applied to it.

How do I improve my QMS?
This column discusses how to affect quality in your organization with certification to QMS standards, and by understanding requirements, assessing and improving process maturity, and leveraging published support materials. The authors are active in the international development of ISO and ASD industry standards. This qualifies us to provide insights into ISO concepts and ASD industry requirements beyond ISO that any organization can apply to improve its products and services.

The ASD industry is a trendsetter in the world of standards. It operates in an environment in which quality and product safety are critical to success. The industry is at the forefront of quality innovation that not only is desirable, but also necessary. ASD creatively manages risk and change to meet the ever-changing requirements and expectations throughout the supply chain.

Additional attention must be paid to ensure new requirements in the AS9100:2016-series of standards are understood. Data analytics show there are few nonconformities identified to the new requirements, so it is believed that additional understanding and auditing are necessary for these requirements.

Using ASD standards for improvement
The AS9100 series of standards’ are based on ISO 9001:2015 requirements, which are included in their entirety in the AS9100-series of standards. The ASD industry added requirements to make the standard more robust to drive improvement, a consistent quality output delivered on time with product safety. These ASD requirements can help any organization improve, regardless of the industry it supports.

Customer and applicable statutory and regulatory requirements. The ASD industry is tightly controlled and regulated, making it necessary to understand requirements coming from customers, and statutory and regulatory agencies.
### FIGURE 1

**AS9100:2016 (Rev. D) vs. FAA Part 21 correlation matrix**

Section 1—Correlation of FAA Part 21 paragraphs to AS9100:2016 (Rev. D) clauses

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>4.1 Understanding the organization and its context</td>
<td>21.316</td>
<td>Responsibility of holder</td>
</tr>
<tr>
<td></td>
<td>21.616</td>
<td>Responsibility of holder</td>
</tr>
<tr>
<td>4.2 Understanding the needs and expectations of interested parties</td>
<td>21.2</td>
<td>Falsification of applications, reports, or records</td>
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<tr>
<td></td>
<td>21.3</td>
<td>Reporting of failures, malfunctions, and defects</td>
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<td></td>
<td>21.4</td>
<td>ETOPS reporting requirements</td>
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<td>21.5</td>
<td>Airplane or Rotorcraft Flight Manual</td>
</tr>
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<td></td>
<td>21.6</td>
<td>Manufacture of new aircraft, aircraft engines, and propellers</td>
</tr>
</tbody>
</table>

Section 2—Correlation of AS9100:2016 (Rev. D) clauses to each FAA Part 21 paragraph

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<thead>
<tr>
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<tbody>
<tr>
<td>Subpart A—General 21.1 Applicability</td>
<td>N/A</td>
<td>Understanding the needs and expectations of interested parties</td>
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<tr>
<td>21.2 Falsification of applications, reports, or records</td>
<td>4.2</td>
<td>Control of documented information</td>
</tr>
<tr>
<td></td>
<td>7.5.3.1</td>
<td>Control of documented information</td>
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<tr>
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<td>7.5.3.2</td>
<td>Control of documented information</td>
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<tr>
<td>21.3 Reporting of failures, malfunctions, and defects</td>
<td>4.2</td>
<td>Communication</td>
</tr>
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<td></td>
<td>7.4</td>
<td>Operation risk management</td>
</tr>
<tr>
<td></td>
<td>8.1.1</td>
<td>Product safety</td>
</tr>
<tr>
<td></td>
<td>8.1.3</td>
<td>Customer communication</td>
</tr>
<tr>
<td></td>
<td>8.3.6</td>
<td>Design and development changes</td>
</tr>
<tr>
<td></td>
<td>8.5.5</td>
<td>Post-delivery activities</td>
</tr>
<tr>
<td></td>
<td>8.5.6</td>
<td>Control of changes</td>
</tr>
<tr>
<td></td>
<td>8.7.1</td>
<td>Control of nonconforming outputs</td>
</tr>
<tr>
<td></td>
<td>8.7.2</td>
<td>Control of nonconforming outputs</td>
</tr>
<tr>
<td></td>
<td>9.1.1</td>
<td>General</td>
</tr>
<tr>
<td></td>
<td>9.1.2</td>
<td>Customer satisfaction</td>
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<td>9.1.3</td>
<td>Analysis and evaluation</td>
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<td></td>
<td>10.1</td>
<td>General</td>
</tr>
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<td></td>
<td>10.2.1</td>
<td>Nonconformity and corrective action</td>
</tr>
<tr>
<td></td>
<td>10.2.2</td>
<td>Nonconformity and corrective action</td>
</tr>
</tbody>
</table>

**ETOPS** = extended-range twin-engine operational performance standards  
**FAA** = Federal Aviation Administration  
**Rev.** = revision  
ISO/TC 176 quality management and quality assurance

What is ISO/Technical Committee (TC) 176?

ISO/TC 176 Technical Committee ("TC") on Quality management and quality assurance has been a leader in the development of standards in the field of quality management systems and tools since 1979. We lead standardization in the field of quality management, as well as quality management standardization in specific sectors at the request of the effective sector and the ISO Technical Management Board.

TC 176 develops standards and tools in the field of quality management, through its three subcommittees (SCs):

- SC 1 - Concepts and terminology (ISO 9000)
- SC 2 - Quality systems (e.g. ISO9001, ISO 9004, ISO 19011-5-7)
- SC 3 - Supporting technologies (e.g. ISO 10006-4, ISO 10006-18)

TC 176 membership includes approximately 130 countries. We also actively support liaison bodies, including international organizations, conformity assessment groups and related technical committees.

Please use the "Projects" tab at the top of this page to find further information on the products that are currently being developed or are under review.

- Method for improving these processes are provided later.

**Leadership.** Leadership commitment and focus are critical to QMS success. Leadership’s full engagement in management reviews establishes a successful QMS culture. The ASD industry requires an annual interview with top management to determine whether it is meeting leadership and engagement requirements.

**Measurement traceability.** The ASD industry sets additional requirements for measurement traceability to ensure the tight tolerances required in the industry are consistently met.

**Documented information.** The ASD industry also sets additional requirements for documented information to ensure processes are repeatable and records are retained. Additional information from the latest revision to AS9100 also has been included for data integrity and information protection.

**Quality awareness.** New requirements in the AS9100-series of standards pertain to developing a culture in which employees understand how they contribute to product or service conformity, and product safety. The importance of ethical behavior also was added because customers expect honest and truthful dealings throughout the QMS.

**Planning.** Many QMS failures occur because of poor planning and failure to address changes. The ASD standards focus on upfront planning to prevent problems, including controls to prevent nonconformance escapes to the customer. Additional controls include engaging functional organizations in the process and change management.

**Risk management.** Risk has been in AS9100 since the standard’s initial release in 1999. ISO 9001:2015 added the concept of risk-based thinking that transcends the QMS. The ASD industry also focuses on operational risks in AS9100, Clause 8—Processes. Many users only look for the word “risk” in the standard. However, there are numerous other ASD processes that are introduced to reduce or eliminate risk—such as production process verification, which is when the organization ensures the production process can produce products that meet requirements.

**Configuration management.** The ASD industry has requirements to ensure the identification and control of physical and functional attributes delivered match what was contracted, designed, procured, built and maintained.

**Product safety.** Product safety always has been required in the ASD industry to protect the flying public, astronauts, warfighters and anyone engaged with the product. Providing a safe product to users is fundamental to any organization that delivers product.

**Preventing counterfeit and suspect counterfeit parts.** Controls are required to ensure counterfeit or suspect counterfeit parts are not included in products. At one time, counterfeit parts were easy to identify and were...
Standard Issues

FIGURE 3
International Aerospace Quality Group support materials

IAQG 9100 - Quality Management Systems - Requirements for Aviation, Space and Defense Organizations

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

- 9100:2016-Series - QMS: Aviation, Space and Defense Organizations Standards Clarifications
  - 9100:2016 Series Clarification Table

- 9100:2016 - QMS: Aerospace Improvement Maturity Model (AIMM) (in Development)

- 9100:2016 - QMS: Aviation, Space and Defense Organizations Guidance Materials
  - Support Materials
    - Frequently Asked Questions (FAQs)
    - Gap Assessment Worksheet
    - 9100 Evaluation Guidance Material
    - Relationship between IAQG Standards and 9100:2016 Standard (Table C1)
  - Correlation Materials
    - Correlation of 9100:2016 mapped against EASA Commission Regulation (EU) 748/2012 Part-21
    - Correlation of 9100:2016 mapped against FAA Part-21
  - Presentations
    - Executive Level Summary Presentation
    - Key Changes Presentation
    - Clause-by-Clause Presentation
    - 9100:2016-Series Major Changes Recording (in Development)
  - Articles: Reprinted with permission from Quality Progress © 2019 ASQ, www.asq.org. All rights reserved. No further distribution allowed without permission.
    - 2019 February ASQ Quality Progress: We Have Liftoff
    - 2019 May ASQ Quality Progress: The Complete Package

a risk for high-dollar parts. Now, counterfeit parts are difficult to identify and even operate in performance characteristics at nominal values. Counterfeit parts are becoming a concern for public commodities that cost a single dollar. They also can include falsified test reports that indicate the product meets certain requirements.

- Design and development. The ASD industry has put in additional controls for robust design and development processes focused on verifying and validating products and services, and designing for manufacturability to external providers and production activities.

- External provider controls. Effective external provider control is essential to the ASD industry, where 70% to 80% of the airframe cost comes from suppliers. So, the industry provides additional requirements—including direct and sub-tier controls, supplier risk assessment, supplier performance evaluation and management, and flow-down requirements—to ensure suppliers understand expectations.

- Special process. ASD products frequently require special processes, so additional requirements were added to the AS9100-series of standards for situations in which the resulting output can’t be verified by subsequent monitoring or measurement. The industry also has introduced the National Aerospace and Defense Contractors Accreditation Program (called Nadcap) certification to ensure special process products follow the defined process.

- Nonconforming output control. ASD products must conform to specifications and product safety requirements. Therefore, rigorous additional requirements were added for dispositioning nonconforming outputs, including controlling these outputs and scrap.

Understanding customer, statutory and regulatory requirements

Enhancing the organization’s focus on the customer and improving customer satisfaction by understanding requirements—including customer, statutory and regulatory requirements—are fundamental to an effective QMS. Organizations must ensure these requirements are identified and ensure compliance with requirements.

The newly published aviation correlation matrix (Figure 1, p. 68), which maps
FIGURE 4

SCMH content

1. Market and Sell
   - Sales, master scheduling and sequencing

2. Design and Develop
   - Special requirements and critical items
   - Deployment and support material (rev.)
   - Notice of change (tool)
   - Engineering tolerancing analysis

3. Make (including assemble and test)
   - Managing product and process variation (rev.)
   - First article inspection (rev.)
   - Counterfeit parts and prevention (rev.)
   - Control of nonconforming outputs product (rev.)
   - Foreign object debris
   - Human factors in new manufacturing
   - Authority acceptance media/ stamping
   - Operator self-verification (rev.)
   - Collection and use of shop floor gembka input
   - Manufacturing work instructions
   - Product safety awareness
   - Measurement systems analysis
   - Statistical product acceptance (rev.)
   - Unsalvable items (rev.)

4. Buy
   - Supplier selection and capability assessment (NextGen)
   - Sub-tier supplier control
   - Supplier quality management basics
   - Product performance detailed assessment checklists

5. Deliver
   - Delivery metrics definition
   - Certificate of Conformance

6. Customer Support
   - Product entry into service

Appendices:
- Alphabetical index
- IAQG international dictionary
- 9100 deployment support
- PCAP 001
- ICOP executive overview
- Relative positions among 9100/SSCA/PPDAC
- SCMH content
- Statistical product acceptance training modules
- SCMH communication pack

Webinar section:
Copies/recordings/Q&A

Sessions in progress
Sessions published

IAQG = International Aerospace Quality Group
ICOP = industry controlled other party
KPI = key performance indicator
PCAP = people capability
PPDAC = product performance detailed assessment checklist
Q&A = question and answer
Rev. = revision
SCMH = supply chain management handbook
SSCA = supplier selection and capability assessment

the Federal Aviation Administration and European Union Aviation Safety Agency airworthiness requirements to AS9100, is a good resource for understanding regulatory requirements. It shows relationships between aviation airworthiness regulatory requirements and AS9100 clauses. The AS9100 standard does not meet all of these requirements because some apply only to commercial aviation, so it is still the organization’s responsibility to understand how it meets these requirements.

It is highly recommended that organizations identify, understand and ensure compliance through internal audits that verify that customer, statutory and regulatory requirements are being met by their QMSs.

**Support materials and supply chain management handbook (SCMH)**

ISO and the International Aerospace Quality Group (IAQG) publish an extensive array of support materials to help users understand requirements and improve:

- ISO technical committee (TC) 176 (quality management and quality assurance), technical group 1 (communications and product support). Guidance information on TC 176 standards can be found on the ISO TC 176/TG 1 website (see Figure 2, p. 69).

- **IAQG support materials.** The IAQG requirements team publishes support materials to aid organizations in implementing any of the AS9100-series standards. The support material topics include published clarification, frequently asked questions, evaluation guidance materials on what to look for and what to ask, correlation matrixes (including to the previous revision of the standard and regulations), presentations describing the standard and new changes, and published articles (see Figure 3, p. 70).

- **SCMH.** The IAQG product and supply chain improvement team provides guidance materials to improve quality and on-time delivery throughout the entire ASD value stream. By sharing best practices of subject matter experts for a wide range of activities, the objective is to help the supply chain improvement team provide guidance materials to improve quality and on-time delivery throughout the entire ASD value stream.
chain improve its quality performance through a better understanding of ASD industry QMS requirements and expectations. The SCMH sections are structured around the seven elements of a supply chain business process model, covering the entire product life cycle (see Figure 4, p. 71).  

Using improvement standards

ISO and ASD requirement standards, such as ISO 9001 and the AS9100-series of standards, set the minimum expectations for effective organizational performance. These standards do not stand alone—they have a complete suite of improvement standards. The ISO and ASD improvement standards and tools can be applied to any organization, regardless of industry. These standards include ISO/Technical Specification (TS) 9002, ISO 9004, the ISO 10000-series and AS9100-series of improvement documents. Organizations embarking on new processes or improving existing ones should examine these standards to understand global industry expectations.

ISO/TS 9002 provides guidance, with a clause-by-clause correlation to clauses 4 through 10 of ISO 9001:2015 to aid users in understanding requirements. It also provides guidance and examples of what an organization can do— it is not intended for audit or evaluation purposes. ISO/TS 9002 is an excellent guidance document that does not add new requirements to ISO 9001.

Previous Standard Issues columns offer additional details on these topics:
+ ISO 9004  
+ ISO 10000-series of standards.  
+ AS9100-series of standards.

Using maturity criteria

Many ISO and AS9100-series certified organizations receive feedback from their internal and certification body audits about which aspects of their QMS conform or don’t conform to the standard requirements. Nonconforming evaluation results certainly generate improvement opportunities, but how can organizations improve QMS effectiveness that is deemed conforming? By assessing their processes against maturity model criteria and taking actions to get to higher levels of maturity.

These maturity models are included in the ISO 9004 Annex A self-assessment tool and the new IAQG aerospace improvement maturity model (see Figure 5). These maturity models can be focused on a particular activity or applied to the entire QMS. Certified and noncertified organizations can apply these maturity models to measure and improve the performance and effectiveness of their QMS.

Get the most out of it

An effectively implemented QMS is directly tied to organizational performance and future sustainability. As discussed earlier, many tools are available to help organizations identify improvement opportunities in their QMSs through QMS certification and improvement standards, and by understanding requirements, assessing and improving process maturity, and leveraging published support materials. Organizations must leverage these resources to improve their QMSs to ensure they effectively meet business needs and achieve the full benefit of a QMS after certification.  

NOTE AND REFERENCES


L.L. “Buddy” Cressionnie is the president of ASD Expertise LLC, with industry leadership positions of Americas Aerospace Quality System Committee (AAQSC) chair and AAQSC leader of requirements, projects and AS9100. He is active in standards development as a liaison member to the International Organization for Standardization (ISO) Technical Committee (TC) 176, including writing ISO 9001:2015 and ISO 9004:2018, and participating in the ISO 9001 Interpretations Committee.

Alan Daniels is the manager of quality management system strategies and industry standards at Boeing Co. in Seattle. He holds industry leadership positions in the International Aerospace Quality Group (IAQG) as the requirements/standards leader and AS9100 team leader. He also is the chair of Technical Advisory Group (TAG) 176, a liaison member to the ISO TC 176, the convenor of Technical Group 1, communications and product support.