INTRODUCTIONS

Don't Miss the Intro!

Understanding the introductory material in a standard is key to proper implementation by L.L. "Buddy" Cressionnie

M any users of ISO 9001 and ISO 9001-based sector standards, including AS9100, skip the introductory material and begin reading where the requirements start. But there is a wealth of good information in the introductory material that helps users understand and apply ISO 9001 and AS9100 requirements to their organization.

Many users rush to the requirements because they just want to apply it as a compliance standard instead of trying to gain a complete understanding of the system. The introductory material, however, is the foundation on which the standard is built. It offers critical background information to help users understand the standard's context and applicability. Sections in the introductions of ISO 9001 and AS9100 include:

◗ **General.** The general introduction provides an overview of the standard, including potential benefits to organizations implementing a quality management system (QMS). It introduces concepts and defines terms such as "shall," "should," "may" and "can," and provides guidance in the form of notes for understanding requirements.

◗ **Quality management principles.** There are key principles that flow across all QMS clauses to ensure focus when using and implementing the standard, and they're first introduced in the introductory material. The principles were first developed in 2000 when they were placed in ISO 9000. Even though these principles apply to ISO 9001, they were not included in that standard's text until the 2015 revision. ISO 9000:2015 includes additional details such as rationale regarding organizational importance, benefits and examples. The principles include:

◗ Customer focus.
◗ Leadership.
◗ Engagement of people.
◗ Process approach.
◗ Improvement.
◗ Evidence-based decision making.
◗ Relationship management.[1]

◗ **Process approach.** The process approach has been transformational to the implementation of ISO 9001. Before the introduction of the process approach in 2000, ISO 9001 was documentation- and compliance-centric for the system's 20 elements. The process changed the standard from being focused on compliance to being focused on process effectiveness and efficiency. Applying the process approach in a QMS enables:

◗ Understanding of and consistently meeting requirements.
◗ Considering processes in terms of added value.
◗ Achieving effective process performance.
◗ Process improvement based on evaluating data and information.[2]

◗ **Plan-do-check-act (PDCA) cycle.** The PDCA cycle, a proven technique developed and endorsed by the early quality gurus, was introduced with ISO 9001:2015. The PDCA cycle can be described as:

◗ **Plan:** Establish the objectives of the system and its processes, and the resources needed to deliver results according to customer requirements and the organization's policies. Identify and address risks and opportunities.

Representation of ISO 9001:2015 structure in the PDCA cycle
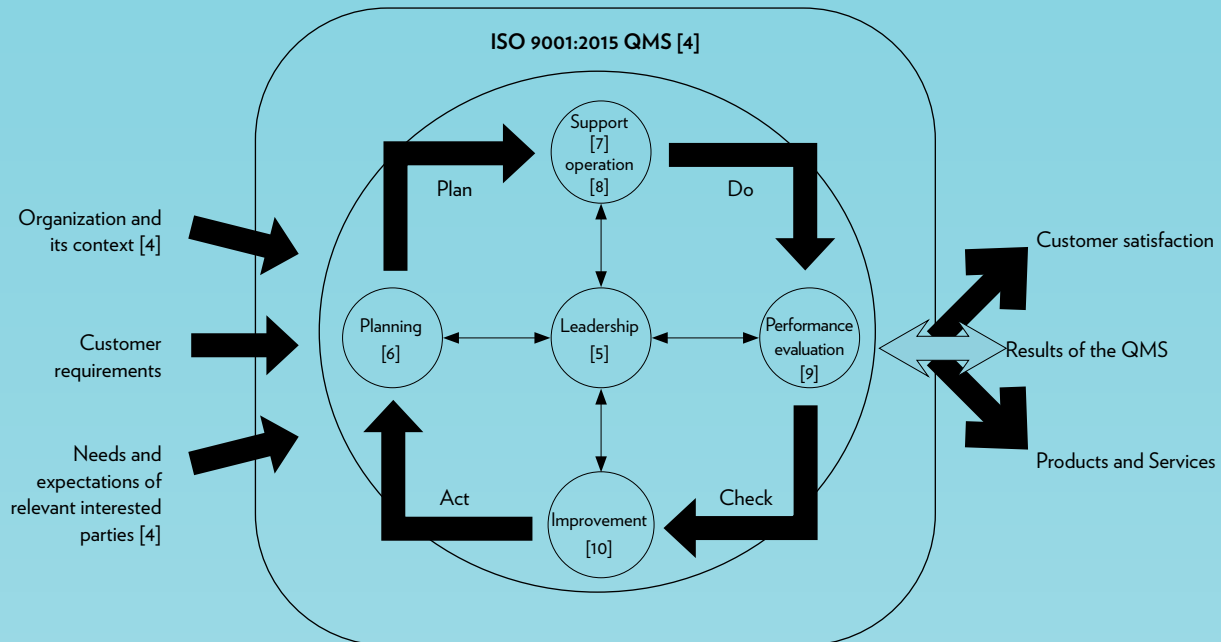
Note: Numbers in brackets refer to the clauses in this international standard.   **PDCA** = plan-do-check-act   **QMS** = quality management system

⬤ **Do:** Implement what was planned.

⬤ **Check:** Monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities. Report the results.

⬤ **Act:** Take actions to improve performance, as necessary.[3]

The PDCA cycle can be applied for process understanding for implementation and auditing. ISO 9001 and ISO 9001-based sector standards are structured according to the PDCA structure, as shown in Figure 1. Most QMS processes should include aspects of PDCA for completeness.

Many auditors use a PDCA method for conducting audits. They first verify how the process is planned, performed (do), checked or verified, and take improvement actions based on the check and verification.

⬤ **Risk-based thinking.** Risk-based thinking reinforces the proactive and preventive aspects of ISO 9001 to ensure

an effective system and prevent negative effects. Unlike previous versions of ISO 9001, risk-based thinking is peppered throughout the standard in addition to being an ISO 9001 clause. ISO 9001 users should evaluate opportunities to generate additional sales, new potential customers, new or modified products and services, technological or method improvements, and efficiency improvements.

⬤ **Relationship with other management system standards.** We have become an internet search society. Many QMS implementers perform searches to research ways to improve their QMS. Why not use published documents written by experts and harmonized for international use? The AS9100 annexes provide this cross-reference for standards developed by ISO technical committee 176 and International Aerospace Quality Group (IAQG).

Some readers familiar with AS9100 will say, "You skipped the applicability clause!" Most of the rest of this column focuses on that clause.

Why the intended application clauses?

IAQG has released "tailored" versions of the aviation, space and defense (ASD) standard for maintenance organizations and distributors of the ASD industry. Certain AS9100 requirements were removed from these standards, and more requirements were added that apply to the standard scope. All of these standards are equally valid and appropriate for use. Some users consider AS9110 and AS9120 to be lesser standards because "shall" statements were removed.

The intended application clause was drafted and first included in the introductory material of AS9100C:2009. It was meant to provide guidance to organizations that needed assistance to apply each of these standards appropriately. Some certification bodies were trying to get organizations to implement multiple versions of these standards that were not founded on business-based decisions. The standards are:

■ *AS9100—Requirements for ASD organizations.* "This standard is intended for use by organizations that design, develop, or provide aviation, space, and defense products and services; and by organizations providing post-delivery activities, including the provision of maintenance, spare parts, or materials for their own products and services."[4]

More than 90% of certified ASD organizations are certified to AS9100. Organizations can use AS9100 if they're providing post-delivery activities, including maintenance activities, for their own products. If the organization primarily manufactures the product and provides maintenance activities on that product, its QMS still can be certified to AS9100.

■ *AS9110—Requirements for aviation maintenance organizations.* "This standard is intended for use by organizations whose primary business is providing maintenance or continuing airworthiness management services for civil or military aviation articles and products; and original equipment manufacturers with maintenance, repair, and overhaul operations that are operated autonomously, or that are substantially different from their production operations."[5]

If the organization's primary business is providing maintenance operations, or if the maintenance operations are operated under a separate QMS or are substantially different from the rest of the operations, the organization should use AS9110.

■ *AS9120—Requirements for ASD distributors.* "This standard is intended for use by organizations that procure parts, materials and assemblies, and resell these products to a customer in the aviation, space, and defense industry. This includes organizations that procure products and split them into smaller quantities, including those that coordinate a customer or regulatory controlled process on the product."[6]

The organization should use AS9120 if it is a pass-through distributor where the product's form, fit or function is not being altered.

These three standards are broad categories. The organization still must determine applicability for all of the clauses and "shall" statements for the business. Any non-applicability must be justified with documented information in accordance with clause 4.3.

AS9104/1A:2022—Organizational context

As certification bodies start auditing to the newly released AS9104/1, they will be examining the organizational context and scope of certification. These scope statements will be evaluated to ensure the organization's products, services and supporting activities (such as manufacture, design, repair, distribution, servicing and testing) align with the organization's QMS. Certification bodies will ensure the organization is correctly using the right ASD QMS standard given the intended application guidance.

Do you understand?

Users must ensure a full understanding of ISO 9001 and ISO 9001-based sector standards for proper implementation, effectiveness and efficiency. That understanding starts with using the correct standard for the organization and the QMS context by comprehending the introduction. IAQG publishes support material on its website[7] that includes posted clarifications to ensure users are correctly applying and understanding the standards it develops. **QP**

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