

RISK

# Did You Understand The Assignment?

Making sense of AS9100D risk requirements by L.L. “Buddy” Cressionie



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any aviation, space and defense organizations struggle to understand risks and opportunities, and the relationship between risk-based thinking introduced in AS9100D:2016 and operational risk introduced in AS9100C:2009.

AS9100 has required risk identification and mitigation since the standard was introduced in 1999 with the requirement to assess risk during contracting. The International Aerospace Quality Group® 9100-series team intended to add a requirement pertaining to operational orders in 2009 and overall organizational risks in 2016.

These requirements are intended to make organizations develop a risk and opportunity culture to be proactive and preventive in improving aerospace quality management system (AQMS) results. Implementing an effective risks and opportunities process increases AQMS effectiveness, enhances desirable effects, prevents or reduces undesirable effects, and achieves improved results. Leadership is responsible for establishing and promoting this risk-based thinking culture.

## Risk handled as a clause

Often, organizations approach AS9100 implementation from a clause-based perspective to be compliant with clauses 6.1 and 8.1.1, but risk is intertwined throughout the entire standard.

Unlike the preventive action clause in previous standards, risk is peppered throughout the standard from clause 0.1 through clause 10.2. Risk is a proactive and preventive tool to ensure the AQMS achieves its intended results and contributes to customer satisfaction. The standard requires top management to demonstrate leadership and commitment by promoting the process approach and risk-based thinking throughout the organization.

Figure 1 gives a schematic representation of a generic process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and vary depending on the related risks.<sup>1</sup> This schematic representation is for any process that demonstrates how risks flow through the entire AQMS.

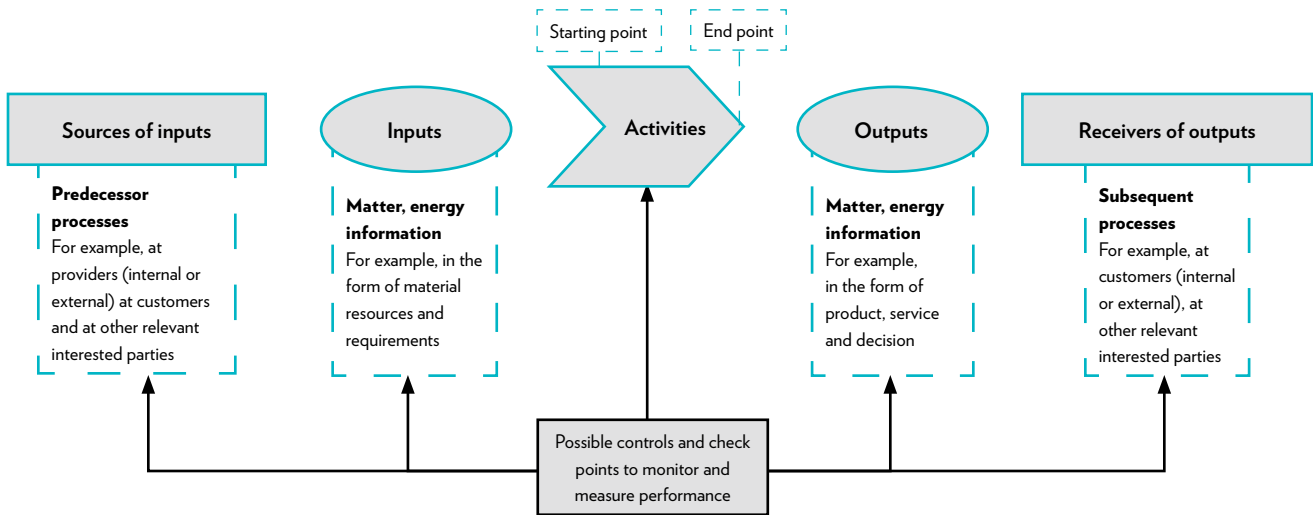
The plan-do-check-act cycle starts with planning to establish the system's objectives and processes. The planning ensures resource availability to deliver results in accordance with requirements, and to identify and address risks and opportunities. This is another example of why risk cannot be addressed as a standalone clause but rather as a cross-cutting theme toward improvement.

## Is risk implicit and thinking sufficient?

Annex A.4 states that the concept of risk-based thinking has been implicit in previous versions of AS9100D. Because

FIGURE 1

# Schematic representation of the elements of a single process



Source: International Aerospace Quality Group, ASD9100D:2016—Quality management systems—requirements for aviation, space and defense organizations, clause 0.3.1.

AS9100D refers to risk-based thinking, does that mean no further action is required to comply due to risk being implicit? Or do organizations only need to “think” about risk?

Clause 6.1.2 is clear that the organization shall plan actions to address risks and opportunities, and evaluate the effectiveness of those actions (see Figure 2, p. 48). The organization must produce evidence of planning actions with mitigation steps to demonstrate how this requirement is met.

Clause 6.1.2 requires actions to be proportionate to the potential impact on product and service conformity. It is expected that risk actions be implemented with a business mindset to avoid spending dollars chasing dimes.

Clause 8.1.1 requires the organization to plan, implement and control an operational risk management process to achieve requirements (see Figure 3, p. 48). The process includes responsibilities for operational risk management; risk criteria; risk identification, assessment and communication; identification, implementation and mitigation actions; and acceptance of residual risks. It is expected that evidence of operational risk management is present throughout the product life cycle.

Regarding evidence of risk implementation, organizations must remember clause 4.4.2b, which states that retained documented information is required to have confidence that all processes are performed as planned.

## Risk-based thinking and operational risk

Often, risk-based thinking is referred to as organizational risk because it applies to processes across organizational AQMSs. Examples of risks to the quality management system not achieving its objectives include processes, products and services failing to meet their requirements, or the organization not achieving customer satisfaction.<sup>2</sup>

Risk-based thinking applies beyond planning to all facets of the AQMS, including:

- Clause 4 requirements, which include understanding organizational context with external and internal issues; interested party requirements, needs and expectations; and AQMS process risks.
- Clause 5 requirements, which include leadership promoting risk-based thinking, customer focus affecting conformity, policy and organizational structure risks.
- Clause 6 requirements, which include risk-based thinking and risks to achieving quality objectives.
- Clause 7 requirements, which include adequate training/competence, maintenance, work environment, asset calibration, organizational knowledge and documentation risks.
- Clause 8 requirements, which include operational risks.
- Clause 9 requirements, which include monitoring,

FIGURE 2

## AS9100D, clause 6.1

- 6.1 Actions to Address Risks and Opportunities
- 6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:
- give assurance that the quality management system can achieve its intended result(s);
  - enhance desirable effects;
  - prevent, or reduce, undesired effects;
  - achieve improvement.
- 6.1.2 The organization shall plan:
- actions to address these risks and opportunities;
  - how to:
    - integrate and implement the actions into its quality management system processes (see 4.4);
    - evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

**NOTE 1:** Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

**NOTE 2:** Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

**Source:** International Aerospace Quality Group, *ASD9100D:2016—Quality management systems—requirements for aviation, space and defense organizations*, clause 6.1.

FIGURE 3

## AS9100D, clause 8.1.1

- 8.1.1 Operational Risk Management
- The organization shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:
- assignment of responsibilities for operational risk management;
  - definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
  - identification, assessment, and communication of risks throughout operations;
  - identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;
  - acceptance of risks remaining after implementation of mitigating actions.

**NOTE 1:** While clause 6.1 addresses the risks and opportunities when planning for the quality management system of the organization, the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8).

**NOTE 2:** Within the aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.

**Source:** International Aerospace Quality Group, *ASD9100D:2016—Quality management systems—requirements for aviation, space and defense organizations*, clause 8.1.1.

measuring, analysis, evaluation, customer satisfaction, internal audits and management review risks.

- Clause 10 requirements, which include corrective action and improvement risks.

Operational risks are a subset of risk-based thinking that applies to the operational process in AS9100D, clause 8 (see Figure 4). Usually, these risks are associated with a contract or an order throughout the entire product life cycle. There are various ways to implement operational risk management, but typically:

- Program management controls overall programmatic, work transfer, configuration, product safety and planning risks elevated across the functions (clause 8.1).
- Contracts control product and service requirement risks, including identifying special requirements (clause 8.2).
- Engineering controls design and development risks, the potential consequences of failure due to the nature of products and services, and preventing adverse impacts due to design changes (clause 8.3).
- Procurement controls external provider risks, verification activities including counterfeit parts, and raw material testing (clause 8.4).
- Production controls critical items, special requirements, verification points, foreign object debris prevention, equipment/tool/software program controls, special processes, production product verification, product traceability, preservation, post-delivery, delivery and nonconforming output risks (clauses 8.5, 8.6 and 8.7).

### Risk escapes

Some organizations establish thresholds for risk management, and the criteria aren't tripped to invoke the risk management process. It must be exciting to have such a perfect process delivering 100% conformity and on-time delivery without corrective actions.

As part of corrective action, clause 10.2.1e requires organizations to update risks and opportunities determined during planning, as necessary, when a corrective action is generated. There was an escape from the organization's risk management process that resulted in a corrective action. Are there other risks that were missed and must be addressed?

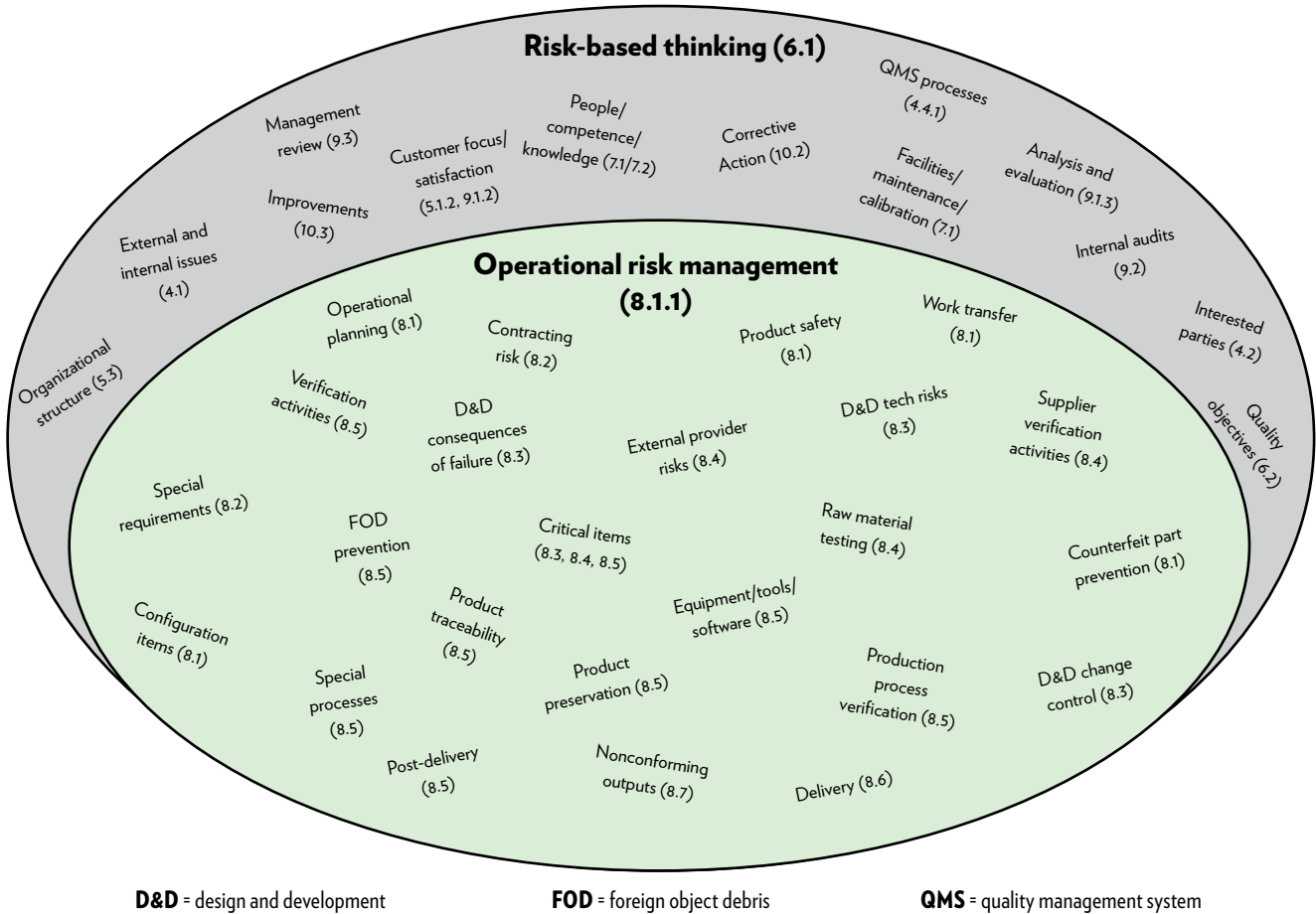
### What about opportunities?

Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. A positive deviation arising from risk can provide an opportunity, but not all positive effects result in opportunities.<sup>3</sup>

Organizations can improve performance and business results further by looking at opportunities. Opportunities, like risks, can occur across the entire organization's AQMS. Examples of opportunities include the potential to identify new customers, determine the need for new products or services and bring them to market, or determine the

FIGURE 4

# Risk-based thinking as applied to the operational process



need for revising or replacing a process by introducing new technology for it to become more efficient.<sup>4</sup>

## Ensuring sustainability

Implementing an effective AQMS improves overall organizational performance, as outlined in an expected outcome paper published by the International Accreditation Forum. A key element to achieving this improvement is implementing risk-based thinking and operational risk management to enhance desirable

effects, prevent or reduce undesirable effects, and achieve improved results. The risk culture must permeate the product life cycle from the initial contract through post-delivery to ensure ongoing organizational sustainability. **QP**

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### EDITOR'S NOTE

References listed in this column can be found on the column's webpage at [qualityprogress.com](http://qualityprogress.com).



**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 176. He helped write ISO 9001:2015 and ISO 9004:2018, and currently develops future concepts, plans the next ISO 9001 revision and participates in the ISO 9001 Interpretations Committee.