

# IA9110 KEY CHANGES SYSTEM VIEW

June 2024



This <u>System view</u> provides visibility on the IA9110 specific clauses, that are new, revised, expanded or enhanced.

It has been completed after the IA9100 CD comments disposition. All the <u>common</u> comments have been already analyzed and:

- if accepted, they have been implemented in IA9110
- if rejected, they will not be included in IA9110

## **Presentation Objectives**



- Describe who develops IA9110 Quality
   Management System requirements for
   Maintenance Organizations
- Provide real-time awareness as to the proposed upcoming evolution of AS9110 to IA9110
- Describe the schedule up to IA9110 publication



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# 9110 QMS Evolution – Looking to the future g



- 1A9110 2024
  - **Elevating quality requirements based on industry needs:** 
    - Product safety
    - Information security (e.g., cyber) & data protection 0
    - Leadership Organizational culture and ethics
    - Advanced Product Quality Planning (APQP)
    - Suspected Unapproved Parts
    - Sub-tier supplier controls
    - First Process Evaluation
    - Transfer of Work
    - Consideration on small organizations

# 9110 QMS Evolution – Requirement



#### **Product Safety**

- Clause 8.1.3 (Elevated to requirement) The organization shall plan, implement, and control
  the processes needed to assure product safety, including as appropriate:
- a. identification of hazards, including reactive and proactive methods;
- b. analysis, assessment, and control of safety risks associated with identified hazards (see 8.1.1);
- c. identification and management of changes that may impact product safety;
- d. assessment of the effectiveness of safety processes;
- e. provision of training on product safety responsibilities to relevant personnel (see 7.2 and 7.3);
- f. communication and awareness of product safety information, including safety-critical items, safety events, and changes to safety procedures, as applicable (see 7.3 and 7.4);
- g. reporting of safety events to the relevant interested parties in accordance with customer and regulatory requirements;
- confidential employee reporting system as a method of product safety hazard identification, without fear of retaliation.

NOTE: reporting system may include also anonymous report submission



### Information Security and Data Protection – Enhanced and New Text

- Control of documented information
  - Clause 7.5.3.2 (Enhanced) When documented information is managed electronically, <u>protection</u> processes shall be defined, implemented, and maintained (e.g., protection from loss, access control, off-site data management, unauthorized changes, unintended alteration, corruption, physical damage).
- Operational Planning and Control
  - Clause 8.1 NOTE: (New) information security and data protection;



#### Information Security and Data Protection - New Text

- Information Security
  - Clause 7.1.7 (New) The organization shall plan, implement, and control information security, appropriate to the organization's product or services, to safeguard the achievements of QMS intended results.
  - Note: Information Security should consider:
    - Organization work environment (e.g., remote work, working away from the fixed location and workforce impacts),
    - Statutory, regulatory and customer requirements,
    - Business disruption risks,
    - Required actions when information security are not achieved (including interested party notification processes),
    - Information for external providers.



#### Organizational Culture - New Text

#### Introduction

 Clause 0.1 – (New) Organizational <u>culture</u> and ethical behavior are critical to an effective QMS and the ability of an organization to achieve its intended results. The organization's <u>culture</u> and ethics are evident in the attitudes, behaviors, shared values and history.

#### Introduction

 Clause 0.2 – (New) Implementation of a quality management system with the above principles are the cornerstones to establishing an organizational <u>culture</u>. Objectives and their measurement can be used to further advance an organizational <u>culture</u> focused on quality products and services.



#### Organizational Culture - Existing Text

- Context of the Organization
  - Clause 4.1 NOTE 3 (ISO) Understanding the internal context can be facilitated by considering issues related to values, <u>culture</u>, knowledge, and performance of the organization.



#### Organizational Culture - New Text

- Leadership
  - Clause 5.1.1.k (New) ensuring goals and objectives enhance organizational <u>culture</u> (See clause 4.).





#### Ethics - New Text

- Introduction
  - Clause 0.1 (New) Organizational culture and <u>ethical behavior</u> are critical to an effective QMS and the ability of an organization to achieve its intended results. The organization's culture and <u>ethics</u> are evident in the attitudes, behaviors, shared values and history.
- Leadership
  - Clause 5.1.1.l. (New) promoting an <u>ethical</u> work environment
  - NOTE: Ethical work environment should consider:
    - Policy and expectations of conduct
    - periodic training and awareness
    - reporting channels
    - Investigation
    - resolution of concerns
    - ensuring no retaliatory action from reporting concerns



#### Ethics – Existing Text

- Awareness
  - Clause 7.3 (Existing) the importance of ethical behavior
- Information for External Providers
  - Clause 8.4.3 i.3. (Existing) the importance of ethical behavior.



#### **Advanced Product Quality Planning**

- Operational Planning and Control
  - Clause 8.1.k. (Enhanced) planning and implementing operations to prevent, detect and mitigate the risk of foreign objects.
  - NOTE (Expanded): One method to achieve operational planning and control can be through using integrated phased processes (e.g. Advanced Product Quality Planning, project planning, project management or program management).



#### **Prevention of Suspected Unapproved Parts**

 Clause 8.1.5 – (Enhanced) The organization shall plan, implement, and control a process, appropriate to the organization and its scope of work that identifies and prevents the use of unapproved and suspected unapproved parts.

(Existing NOTE elevated to requirement) Suspected unapproved parts prevention processes shall include, as appropriate:

- a. training of appropriate persons in the awareness and identification of suspected unapproved parts (e.g. personnel involved in procurement, receiving inspection, shipping inspection and material control);
- b. application of a parts obsolescence monitoring program;
- c. controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;
- d. requirements for assuring traceability of parts and components to an authorized source;
- e. Inspection processes to detect suspected unapproved parts;
- f. monitoring of suspected unapproved parts reporting from external sources;
- g. segregation, containment and reporting of suspected unapproved parts in accordance with applicable requirements from the competent authority or the customer (see 8.7.1).



#### Sub-tier Control

- Control of Externally Provided Processes, Products, and Services
  - Clause 8.4.1 (New) The organization shall require that external providers apply appropriate controls to their direct and <u>sub-tier</u> external providers, to ensure that requirements are met.
- Information for External Providers
  - Clause 8.4.3.g.7. (New) Determine the level of control of their direct and subtier external providers;



#### First Process Evaluation (FPE) (\*)

- Evaluation of a New Capability
  - Clause 8.5.1.4 (Expanded) An evaluation on documentation, qualified persons, and tooling shall be performed prior to maintaining the first article or product. When required, the result of the evaluation shall be submitted to the competent authority in order to update the capability list. When requested, the result of the evaluation shall be submitted to the customer.
  - First application of maintenance processes shall be evaluated, verified, and documented internally (e.g. by using the First Process Evaluation). When required, it shall be submitted for approval or information to the competent authority and the customer.

(\*) Guidance and supporting material on FPE being developed to create a new SCMH section



#### Transfer of Work

- Operational Planning and Control
  - Clause 8.1. (New)

The organization shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process shall ensure that work transfer impacts and risks are managed.

NOTE 1: For the transfer of work from the organization to an external provider, or from an external provider to another external provider, see 8.4.

NOTE 2: For the transfer of work, within organization's QMS scope, or from an external provider to the organization, see 8.5.

NOTE 3: transfer of work may include procedures for changing location, housings or facilities.



## Consideration on small organizations

- Operational Planning and Control
  - Clause 8.1 As appropriate to the organization, regulatory requirements, customer requirements, and products and services, the organization shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints

## IA9110 Schedule (3 to 6 months later than IA9100)



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May-Jun 2024 IA9110 CD

Jul-Oct 2024 IA9110 CD comments disposition (IAQG week in Tokyo)

Nov-Dec 2024 IA9110 IAQG -1 Standards Management Committee (SMC) ballot



Jan-Apr 2025 IA9110 IAQG -1 SMC ballot comment disposition (IAQG week in Brussels)

May-Oct 2025 ISO 9001 change incorporation (IAQG week in Washington DC)

Nov-Dec 2025 2nd IA9110 IAQG-1 SMC ballot



Jan-Apr 2026 Disposition comments (IAQG week TBD)

May-Jun 2026 IAQG Standards Council ballot

Jul-Oct 2026 Disposition comments (IAQG week TBD)

Nov-Dec 2026 Publish IA9110 (IA9100 publication planned by July 2026)

