



IA9100 KEY CHANGES SYSTEM VIEW

November 2023

9100 QMS Evolution – In the beginning



- **9000 New 1994-1997** – Americas 9100 (AS) developed based on Boeing D1-9000 supplier flow down quality requirements and ISO9001 QMS
 - Major breakthrough in rival collaboration for common quality requirements
 - Expanded requirements for complex products (e.g., design, supplier management, test, build, delivery, post delivery)
- **9100 1999** – International Aerospace Quality Group (IAQG) established and a global 9100 is published with Europe (EN) concurrence
- **9100 2001** – International Aerospace Quality Group (IAQG) established and a global 9100 is published with Asia/Pacific (JIS Q) concurrence
- **9100 2004** – Structure change, no change in requirements

9100 QMS Evolution – Standing on its own



- **9100** **2009** – Accepted by DCMA for supplier flow down requirements
 Significant changes in quality requirements including:
 - Special requirements, critical Items, key characteristics
 - Risk Management, configuration management, project management
 - Work transfer, expanded supplier management

- **9100** **2016** – Taking quality requirements to **the next level**:
 - Product safety, risk-based thinking, software/data protection
 - Product conformity and on-time delivery performance measures, more focus on proactive measures, performance, conformance
 - Awareness (e.g., contribution to product or service conformity; contribution to product safety, the importance of ethical behavior), human factors

9100 QMS Evolution – Looking to the future



- **IA9100 2026** – Elevating quality requirements based on industry needs:
 - Product safety
 - Information security (e.g., cyber) & data protection
 - Leadership - Quality culture and ethics
 - Advanced Product Quality Planning (APQP)
 - Counterfeit parts
 - Sub-tier supplier controls

9100 Series Writing Guidelines



The 9100-series standards project teams will use a disciplined process for assessing proposed changes that ensures they:

- supports the IAQG **strategy and mission**,
- aligns with the Design Specifications **scope**,
- constitute **quality management system** requirements,
- are **not contractual** in nature,
- do not contain product or **sector specific** requirements,
- enhance **clarity** or address **stakeholder needs**,
- are **auditable** and define “what” not “how”,
- are compatible for use by **all stakeholder segments** and by organizations of **all types and sizes**,
- Doesn't alter **ISO text**,
- the **benefit outweighs the impact** of implementation.

**IAQG needs dictate
the requirement
criteria**

Achievements



2021

- **Q2: Launch of the IAQG 9100-Series 5 Year Review**
- **Q4:** Revision kick-off meeting of the sector 9100-series teams

2022

- **Q1:** 3 surveys (voting members, IAQG Stakeholders-Relationship Growth/regulatory agencies, IAQG Standards Teams)
- **Q1:** Identified 247 potential improvements reviewed and pre-dispositioned by each sector team
- **Q2:** Disposition by IAQG 9100 team during the Brussels meeting
- **Q3:** 14 concept teams established to propose a way to implement the associated items
- **Q4:** Disposition by the IAQG 9100-series team of the implementations proposed by the 3 sectors
- **Q4: IA9100 Revision officially launched**

Achievements



2023

- **Q1: First IA9100 Working Draft established by the IAQG writing team and reviewed by sectors teams**
- **Q2: Review and disposition by the IAQG 9100-series team of all comments raised on the initial IA9100 Working Draft by 9100 sector teams**
- **Q3: IAQG 9100 team update and clean-up of the Working Draft, and distribution to the 9100 sector teams**
- **Q3: Start of update of the support material (Key Changes, Clarifications file)**
- **Q3: Review of a new proposal from the SCMh team aiming to clarify the definitions of Special Requirements, Critical Items and Key Characteristics**
- **Q3: ISO/TC176 decision: The ISO9001 will be revised (2026-2027)**
- **Q4: IA9100 Coordination Draft distribution**

IAQG 9100 Series Team

9100 Communications

- **Open sector meetings** - whereas most teams have closed meetings
- A larger overall team if you include the sectors with **over 65 representatives**
- An **equally balanced team** – Aviation, space and defense
- Design Specification - A set **unbiased processes and scope** that everyone follows for content and the acceptance of comments
- Written **articles about the revisions scope** (Quality Progress – on IAQG website)
- Provided IAQG **9100 Team open sessions**
- **Presentations** – Sector reviews, Key Changes, 9100 Evolution
- etc.

9100 QMS Evolution – Enhanced Concept



Quality Culture – New Text

■ Introduction

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

■ Introduction

- Clause 0.2 – (New) ***Implementation of a quality management system and the management principles are the cornerstones to establishing a culture of quality within the organization. The definition of objectives and measurement can be used to further advance a culture focused on quality products and services.***

9100 QMS Evolution – Enhanced Concept



Quality 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, culture, knowledge, and performance of the organization.

9100 QMS Evolution – Enhanced Concept



Quality Culture – New Text

- Leadership
 - **Clause 5.1.1.k – (new) ensuring goals and objectives intended to build a quality culture are consistent with policies, vision, mission, values, and the context of the organization (See clause 4.).”**
- Environment for the Operation of Processes
 - **Clause 7.1.4 NOTE: d. – (NEW) culture (e.g., quality, ethical behavior, product and personnel safety, quality of work life).**



9100 QMS Evolution – Enhanced Concept



Ethics – New Text

- Introduction
 - **Clause 0.1 – (New) Organizational culture and ethical behavior are critical to an effective QMS and the ability of an organization to achieve its intended results. The organizations culture and ethics are evident in the attitudes, behaviors, shared values and history.**
- Leadership
 - **Clause 5.1.1.1. – (New) promoting an ethical work environment**
 - **NOTE: For example, policy, expectations of conduct, periodic training and awareness, reporting channels, investigation, resolution of concerns, and ensuring no punitive action from reporting concerns)**
- Environment for the Operation of Processes
 - **Clause 7.1.4 NOTE: d. – (New) culture (e.g., quality, ethical behavior, product and personnel safety, quality of work life).**

9100 QMS Evolution – Enhanced Concept



Ethics – Existing Text

- Awareness
 - *Clause 7.3 – the importance of ethical behavior*
- Information for External Providers
 - *Clause 7.4.3 m.3. – the importance of ethical behavior.*



9100 QMS Evolution – Enhanced Concept



Information Security and Data Protection – New Text

- Control of documented information
 - Clause 7.5.3.1 – *(Enhanced) When documented information is managed electronically, data protection processes shall be defined implemented, and maintained (e.g., protection from loss, access control, off-site data management, unauthorized changes, unintended alteration, corruption).*
- **Information Security**
 - *Clause 7.1.7 – (New) The organization shall plan, implement, and control information security to safeguard the QMS to achieve its intended results.*
- Operation Planning and Control
 - *Clause 8.1 NOTE: – (New) information security and data protection;*

9100 QMS Evolution – Enhanced Concept



Product Safety

- ***Clause 8.1.3 – (Enhanced) The organization shall plan, implement, and control the processes needed to assure product safety.***

These processes include, 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 (see 9.1.3 and 10.1);*
- 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 information, safety events, and changes to safety procedures, as applicable (see 7.3 and 7.4);*
- g. reporting of safety events to the customer, authorities, and type certificate holder in accordance with customer and regulatory requirements.*

Prevention of Counterfeit Parts

- ***Clause 8.1.4 – (Enhanced) The organization shall plan, implement, and control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.***

These processes shall include, as applicable:

- a. training of appropriate persons in the awareness and prevention of counterfeit 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 their original or authorized manufacturers;***
- e. verification and test methodologies to detect counterfeit parts;***
- f. monitoring of counterfeit parts reporting from external sources;***
- g. segregation, containment and reporting of suspect or detected counterfeit parts.***

9100 QMS Evolution – Expanded Concept



Sub-tier Control

- **Control of Externally Provided Processes, Products, and Services**
 - *Clause 8.4.1 – (Existing) The organization shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.*

- **Information for External Providers**
 - *Clause 8.4.3.k.d. – (New) Determining the level of control of their direct and sub-tier external providers;*

9100 QMS Evolution – Expanded Concept



Advanced Product Quality Planning

■ Monitoring and Measuring Resources

- *Clause 7.1.5.1 – (New) NOTE: The extent to which measurement introduces variation in measurement results can be determined by measurement systems analysis, gauge R&R, or attribute analysis.*

■ Operational Planning and Control

- *Clause 8.1.b. – (Enhanced) NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:*
- *process control;*
 - *selection and verification of key characteristics;*
 - *process capability studies;*
 - *measurement systems analysis;*
 - *statistical process control;*
 - *design of experiments;*
 - *control plans;*



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 and debris.*
- *NOTE: One method to achieve operational planning and control can be through using integrated phased processes.*
- *Product and service provision shall be planned and managed 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.*
- *NOTE 1: This activity is generally referred to as project planning, project management, or program management.*
- *NOTE 2: One method to achieve operational planning and control can be through the use of a methodology such as Advanced Product Quality Planning (APQP). See Annex B .*

9100 QMS Evolution – Expanded Concept



Advanced Product Quality Planning

- Operational Planning and Control

- *Clause 8.3.2.1 – (Enhanced) ~~When appropriate~~, The organization shall divide the design and development effort into distinct activities **defining** the tasks, necessary resources, responsibilities, design content, and inputs and outputs for each activity.*

9100 Key Change Summary



Next Steps

- IA9100 Coordination Draft distributed by end of 2023
- Disposition Coordination Draft comments
- Formal Ballot and Dispositioning in 2024-2026
- 2026: publication of the new revision in alignment with ISO 9001 release





