

International Aerospace Quality Group

9110:2009

Frequently Asked Questions (FAQs)

FOREWORD

To assist in the deployment and sustainment of 9110:2009, the International Aerospace Group (IAQG) 9110 Writing Team has developed a collection of questions and responses for users of the standard.

IAQG Procedure 103 defines the process for providing "clarifications" to published standards. It is intended that these FAQs be updated, as appropriate, as new questions are received and responded by the Sector Document Representatives (SDRs) and IAQG Document Representative (IDR).

NOTE: Due to the dependence/interrelationship between 9100 and 9110, applicable 9100 FAQs have been integrated into this document. If you want to see the 9100 FAQs in their entirety, please visit the IAQG website at: <u>http://www.iaqg.sae.org/iaqg/organization/requirements.htm#ipr</u>.

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A. GENERAL:

Where can I find more information about the IAQG and the standards it has published?

 The International Aerospace Quality Group (IAQG) website is located at <u>http://www.iaqg.org</u> and provides general information and background on the IAQG organization/membership and associated activities, standards, and publications.

> What are the benefits of implementing IAQG quality standards?

- International Aerospace Quality Group (IAQG) member companies agree to utilize standards internally and flow down to the supply chain, as appropriate.
 - One voice, minimize variation, shared resources, reduced duplication and waste.
- Focus on the complete supply chain and stakeholders.
- True global aviation, space, and defense industry cooperation and harmonization.
- Higher quality products at reduced cost.
- Fewer, customer-unique documents.
- Industry Controlled Other Party (ICOP) scheme for third party approval (certification) of Aerospace Quality Management System (AQMS) standards (i.e., 9100, 9110, 9120).
- Shared supplier approval database.
- Recognition by Regulatory Authorities.
- Open sharing of "Best Practices".
- Rapid consensus and deployment.

> What is the purpose of the 9110 standard?

 The 9110 standard on quality management system requirements is intended to be used at all levels of the supply chain. Its' use should result in improved quality, schedule, and cost performance.

This standard is primarily developed for use by maintenance organizations whose primary business is providing maintenance, repair, and overhaul services for aviation commercial and military products; and for Original Equipment Manufacturer (OEM) organizations with maintenance, repair, and overhaul operated autonomously or that are substantially different from their manufacturing/production operations.

It is tailored for organizations with National Aviation Authority (NAA) repair station certification and those that provide maintenance, repair, and overhaul services for military aviation products; but the standard could significantly benefit non-certificated maintenance organizations that choose to adopt it.

> Who is responsible for updating the 9110 standard?

 The International Aerospace Quality Group (IAQG) is responsible for the development and maintenance of the 9110 standard. For further details see IAQG Procedure 103, "Maintenance of Standards Issued by the IAQG".

> How can I get clarification regarding the content of the 9110 standard?

 The standard user shall submit their written request to the Sector Document Representative (SDR) for their standard in question. SDRs are shown on the International Aerospace Quality Group (IAQG) public and private websites. A written response will be provided to the requestor.

Who are the Sector Document Representatives (SDRs) and IAQG Document Representative (IDR) for 9110?

- Americas 9110 SDR: Jeff Wood (jeffrey.d.wood @boeing.com).
- o Asia/Pacific 9110 SDR: Masahiro Kawamoto (masahiro kawamoto@mhi.co.jp).
- European 9110 SDR: Jean-Francis Suquet (<u>Jean-Francis.Suquet@eurocopter.com</u>).
- 9110 IDR: Jeff Wood (jeffrey.d.wood@boeing.com).

Where can copies of the new/revised IAQG standards (e.g., 9110, 9100, 9101) be obtained?

- There are numerous national and regional standards bodies. Each has their own publication schedule requirements. The sector standard bodies are identified on the following websites:
 - SAE International (Americas): <u>http://.aerospace.sae.org/</u>.
 - ASD STAN (Europe): <u>http://www.asd-stan.org/</u>.
 - SJAC (Asia/Pacific): <u>http://www.sjac.or.jp/en_index.html</u>.

NOTE: The 9110 standard is currently only published in the Americas (AS) and Europe (EN).

What is the relationship between IAQG 9100 and 9110 standards?

- The 9110 standard utilizes the 9100 document as a baseline to evaluate the need for an aviation maintenance supporting/emphasis statement, additional requirement, and/or clarifying NOTE.
 - NOTE: The key changes in 9100:2009 were in most cases integrated into the 9110 standard, but these items were in addition to any specific aviation maintenance revisions.

How can you tell the difference between the ISO 9001:2008 text and the 9110 text?

• The **bold**, *italic* text represents the specific aviation maintenance industry additions (i.e., requirements, definitions, notes).

> Will the 9111 standard be updated to reflect the revised 9110 standard?

 The 9111 checklist, "Aerospace Series – Quality Management System Assessment for Maintenance Organizations (Based on ISO 9001:2000)" will be superseded by the new 9101 standard.

The 9101 standard will provide a process-based approach to verify conformance to the 9100-series QMS standards (i.e., 9100, 9110, 9120) and is expected to be published later this year (2009). This standard will normalize the requirements for conducting and reporting of Quality Management System (QMS) certification audits performed by Certification Bodies (CBs).

B. CHANGES ASSOCIATED TO THE 9100:2009 REVISION:

> Did the ISO 9001:2008 changes affect or impact 9100:2009?

Yes – the 9100 standard has been updated to remain aligned with ISO 9001:2008, which continues to be the 9100 standard's baseline. The changes incorporated into ISO 9001:2008 were considered an amendment and minor in nature, but required that the 9100 clauses/requirements were evaluated and any identified impacts/issues were resolved.

> Why change the 9100 standard?

- The revision to the 9100 standard was to address the following needs:
 - Incorporate ISO 9001:2008 changes.
 - Expand the scope of the standard to include land and sea based systems for defense applications.
 - Ensure alignment with International Aerospace Quality Group (IAQG) strategies (e.g., on-time, on-quality performance).
 - Adopt new requirements based on stakeholder needs.
 - Improve existing requirements where stakeholders identified need for clarification (e.g., when a documented procedure is required).

> Who provided input to the 9100 revision?

 The International Aerospace Quality Group (IAQG) was provided input from a wide range of industry stakeholders [i.e., IAQG sector member companies, IAQG Strategy Streams and supporting teams, suppliers, civil airworthiness authorities, Certification Bodies (CBs), Accreditation Bodies (ABs), defense industry and authorities, space industry companies, regulatory authorities, trade group associations].

> What process was used to determine the changes to 9100?

- The 9100 team used a project management approach to solicit input and manage the revision, as follows:
 - Project Management developed a 9100 Standard Design Specification that defined the International Aerospace Quality Group (IAQG) Strategy and 9100 objectives.

- Data Mining and Consolidation facilitated collection of stakeholder inputs, including web survey feedback; Master Comments Review Template (MCRT) was used to collect and present over 400 stakeholder comments and proposals.
- Review Process IAQG 9100 writing team reviewed stakeholder inputs based on the criteria defined in the 9100 Standard - Design Specification; approximately 40% acceptance rate.
- Draft Coordination and Voting initial draft developed in July 2007; 9100 team review conducted in October 2007; informal coordination draft issued in November 2007; stakeholders comments reviewed in April 2008; formal ballot draft issued in May 2008; ballot draft closed and feedback resolved in October 2008; 9100 standard released in January 2009.

> What were some of the key changes to 9100:2009?

- **7.1.1 Project Management** new requirement for planning and managing product realization in a structured and controlled way.
- 7.1.2 Risk Management new requirement for implementation of a risk management process applicable to the product; responsibilities, criteria, mitigation, and acceptance to be defined as appropriate to the organization.
- 7.1.3 Configuration Management moved from clause 4.3 to clause 7.1 and process expectations/requirements further defined.
- 7.1.4 Control of Work Transfer moved from clause 7.5 (Production and Service Provision) to clause 7.1 (Planning of Product Realization) to add emphasis on having a process to plan and control work transfer activities.
- 8.2.1 Formal Monitoring of Customer Satisfaction Data added the requirement to monitor and evaluate customer satisfaction data, and to develop and implement improvement plans that address deficiencies identified, including assessment of the plan effectiveness. The intent is to promote continual improvement of the product and customer satisfaction.
- 8.2.1 Customer Satisfaction (Product Quality and on-time Delivery Performance) – added requirement for "product conformity" and "on-time delivery performance" to be monitored and evaluated, and that appropriate actions taken, if planned results are not achieved. The intent is to provide linkage between the quality management system and organizational performance.
- Process to be required to address control of special requirements, critical items, and key characteristics key characteristic requirements remain unaltered, but the concept of identifying special requirements (either from the customer or by the organization) which require additional controls (e.g., risk management), that translate into critical items, which then may flow to key characteristics for variation control is a new concept.

> Where can I find additional information on the primary changes to 9100:2009?

 International Aerospace Quality Group (IAQG) website: <u>http://www.iaqg.sae.org/iaqg/</u> (see link "9100C Published – Click here for Deployment Support Materials"); or 9100 Deployment Support Materials (e.g., Changes Presentation, FAQ): http://www.iagg.sae.org/iagg/organization/requirements.htm#ipr.

9100 – Quality Management Systems: Aviation, Space, and Defense Organizations

- 9100 Press Release
- <u>Changes Presentation</u>
- <u>FAQ</u>
- <u>Clarifications</u> (coming soon)
- 9100 Changes and Rationale
- <u>Article "Revised AS&D Standards Take Flight"</u>

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> What about the requirements from regulatory authorities, is there any change?

 A general requirement has been introduced in clause 4.1 to address all the organization's applicable statutory and regulatory quality management system requirements, instead of keeping detailed requirements in subsequent clauses throughout the standard.

What is the difference between special requirements, critical items, and key characteristics?

- **Special Requirements** are those requirements that have high risks to being achieved, hence requiring their inclusion in the risk management process.
- Critical Items, including key characteristics, are those items that have significant effect on the product realization and use of the product, and hence require specific actions to assure they are adequately managed.
- Key Characteristics are those attributes or features whose variation has a significant effect on product fit, form, function, performance, service life, or producibility that require specific actions for the purpose of controlling variation.

Why was the text associated to defining the relationship between the requirements of the 9100 standard and the organizations documented procedures deleted from clause 4.2.2.b?

 The deletion of the requirement to create a document showing the relationship between 9100 requirements and the organizations documented procedures was seen as adding no value to assuring product quality above the existing ISO text. Users of 9100 will still need to identify appropriate documented procedures as an inherent part of being audited. The rational is there are other ways to show the relationships and we need to be flexible, recognizing alternate methods of achieving the same intended result.

ISO 10007 is referenced in clause 7.1.3 Configuration Management, does this mean it is required?

 No, ISO 10007 is included as a NOTE for reference/guidance only – where additional information on configuration management can be obtained.

C. CHANGES ASSOCIATED TO THE 9110:2009 REVISION:

> Did the ISO 9001:2008 changes affect or impact 9110:2009?

Yes – the 9110 standard has been updated to remain aligned with ISO 9001:2008, which continues to be the 9110 standard's baseline. The changes incorporated into ISO 9001:2008 were considered an amendment and minor in nature, but required that the revised 9100 clauses/requirements and existing 9110 clauses/requirements be evaluated and any identified impacts/issues resolved.

> Why change the 9110 standard?

- The revision to the 9110 standard was done to address the following needs:
 - Incorporate ISO 9001:2008 changes.
 - Incorporate 9100:2009 changes.
 - Ensure alignment with International Aerospace Quality Group (IAQG) strategies (e.g., on-time, on-quality performance).
 - Adopt new requirements based on stakeholder needs.
 - Improve existing requirements where stakeholders identified need for clarification.

> Who provided input to the 9110 revision?

The International Aerospace Quality Group (IAQG) was provided input from a wide range of industry stakeholders [e.g., IAQG sector member companies; IAQG Strategy Streams and supporting teams; Maintenance, Repair, & Overhaul (MRO) organizations; civil airworthiness authorities; Certification Bodies (CBs); defense authorities].

> What process was used to determine the changes to 9110?

- The 9110 team used a project management approach to solicit input and manage the revision, as follows:
 - Project Management developed a 9110 Standard Design Specification that defined the International Aerospace Quality Group (IAQG) Strategy and 9110 objectives.
 - Data Mining and Consolidation facilitated collection of stakeholder inputs, including web survey feedback; Master Comments Review Template (MCRT) was used to collect and present over 160 stakeholder comments and proposals.
 - Review Process IAQG 9110 writing team reviewed stakeholder inputs based on the criteria defined in the 9110 Standard - Design Specification; approximately 45% acceptance rate.

 Draft Coordination and Voting – initial draft developed in November 2007; 9100 team review conducted in April 2008; informal coordination draft issued in June 2008; stakeholders comments reviewed in September 2008; formal ballot draft issued in November 2008; ballot draft feedback resolved in April 2009; re-affirmation ballot taken in Americas sector in May 2009; 9110 standard released in June 2009.

> What were some of the key changes to 9110:2009?

- 3.3 Counterfeit Parts and 3.12 Suspect Unapproved Parts the standard addresses the need for systems to detect and prevent the introduction of counterfeit and/or suspect unapproved parts and components into aviation products. "Unapproved" or "bogus" parts are extremely dangerous to aviation safety.
- **3.5 Human Factors** expanded upon definition and requirements (use and application) for 'human factors'.

"The study of how humans behave physically and psychologically in relation to particular environments, products or services and the potential effect on safety. Recognition that personnel performing tasks are affected by physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication and attitude in order to ensure a safe interface between the personnel and all other environmental elements such as other personnel, equipment, facilities, procedures and data."

- 3.10 Safety Policy and 5.4.3 Safety Objectives introduces some initial components of a Safety Management System (SMS) (i.e., establishment and maintenance of a safety policy and safety objectives); the primary focus being product safety. Formally expressed commitment to product safety; this policy should reflect the organization's philosophy of safety management and outlines the methods and processes that the organization will use to achieve desired safety outcomes.
- 3.13 Technical Data defines requirements to ensure the availability of technical data necessary to ensure that the aircraft or aircraft component can be maintained in a condition such that serviceability and airworthiness of the aircraft and related operational and emergency equipment is assured. This data includes maintenance programs, airworthiness directives, service bulletins, major repairs/modifications, operator maintenance manuals, drawings, engineering orders, component maintenance manuals, technical orders, etc.
- 7.1.1 Project Management new requirement for planning and managing product overhaul, repair, and maintenance in a structured and controlled way. Maintenance, repair, and modification of aircraft and aircraft components can be large and often complex projects, which need to be adequately managed.
- 7.1.2 Risk Management new requirement for the development, implementation, and maintenance of a risk management process applicable to the organization's products and services provided; with process responsibilities, criteria, mitigation, and acceptance well-defined.
- **7.1.3 Configuration Management** relocated content from clause 4.3 to clause 7.1 and further defined process expectations/requirements.

- 7.1.4 Control of Work Transfer relocated content from clause 7.5 (Production and Service Provision) to clause 7.1 (Planning of Product Realization) to add emphasis on having a process to plan and control work transfer activities.
- 8.2.1 Customer Satisfaction (Formal Monitoring of Customer Satisfaction Data) – added the requirement to monitor and evaluate customer satisfaction data and to develop and improvement plans that address deficiencies identified; including assessment of the plan effectiveness. The intent is to promote continual improvement of the product and customer satisfaction.
- 8.2.1 Customer Satisfaction [Product Quality and On-time Delivery (OTD) Performance] – added requirements for "product conformity" and "OTD" to be measured, and to take appropriate action, if planned results are not achieved. The intent is to provide a linkage between the quality management system and organization performance.
- Process to be required to address control of Special Requirements, Critical Items and Key Characteristics – key characteristic requirements remain unaltered, but the concept of identifying special requirements (either from the customer or by the organization) which require additional controls (e.g. risk management), that translate into critical items, which then may flow to key characteristics for variation control is a new concept.

> Will the 9111 standard be updated to align with 9110:2009?

 The 9111 checklist, "Aerospace Series – Quality Management System Assessment for Maintenance Organizations (Based on ISO 9001:2000)" will be superseded by the new 9101 standard.

The 9101 standard will provide a process-based approach to verify conformance to the 9100-series QMS standards (i.e., 9100, 9110, 9120) and is expected to be published later this year (2009). This document will standardize the requirements for conducting and reporting of Quality Management System (QMS) certification audits by accredited Certification Bodies (CBs).

> Where do I find definitions of some of the terms used in 9110?

• Clause 3 of the 9110 standard provides definitions of some terms used within the standard. In addition, the terms and definitions given in ISO 9000 apply.

Is it a requirement to have implemented a Safety Management System to comply with the new 9110 requirements?

 No – unless required by the applicable Authority(s), which is defined in clause 4.1 (The organization's quality management system shall also address customer and applicable statutory and Authority quality management system requirements).

What are the new requirements related to product safety management included in the new 9110 standard?

- The following clauses address elements associated to product safety management:
 - 4.2.1.e requires documented statements of a safety policy and safety objectives (reference clause 3.10 – Safety Policy).
 - **5.1.f** requires establishment of the safety policy.
 - **5.1.g** requires establishment of safety objectives.
 - **5.4.3** defines safety objectives expectations/requirements.
 - 5.6.1 ensures that management review assesses opportunities for improvement and/or necessary changes to the safety policy and objectives.
 - **5.7** defines safety policy expectations/requirements.
 - 7.1.g ensures that during planning of product realization that consideration is given to safety objectives and requirements for the product.
 - **7.1.2 Risk Management** requires an organization establish, implement, and maintain a process for managing risk.

What are the new human factors requirements? Is this limited to providing training to applicable personnel?

- No human factors requirements is not limited to providing training; the following clauses address elements associated to human factors (reference clause 3.5):
 - 6.2.2.g does require the organization to implement a training program (initial/recurrent) that, among other elements, covers specific knowledge regarding human factors.
 - 8.4.e requires that analysis of data provide information relating to human factors events
 - 8.5.2.j and 8.5.3.f require that the need for action based on human factors are considered when conducting corrective and preventive actions respectfully.

Which organizations could potentially have need and/or benefit from adopting the 9110 quality management standard?

• Aviation maintenance organizations (civil and defense), including those certificated and non-certificated by an Authority.

The standard is intended for use by maintenance organizations whose primary business is providing maintenance, repair, and overhaul services for aviation commercial and military products; and for Original Equipment Manufacturer (OEM) organizations with maintenance, repair, and overhaul operated autonomously or that are substantially different from their manufacturing/production operations.

It is tailored for organizations with National Aviation Authority (NAA) repair station certification and those that provide maintenance, repair, and overhaul services for military aviation products; but the standard could significantly benefit non-certificated maintenance organizations that choose to adopt it.

If there is a conflict between the 9110 standard and statutory or regulatory requirements, which takes precedence?

• The statutory and regulatory requirements take precedence.

It is emphasized that the requirements specified in the 9110 standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of the 9110 standard and applicable statutory or regulatory requirements; the latter shall take precedence (reference clause 1.1).

Does the 9110 certification replace approvals, certificates, ratings, licenses, and permits required by the responsible authority?

 No – it does not. Certification to the 9110 standard is independent of any National Aviation Authority (NAA) certificated requirements.

> What is the scope of the new requirements related to risk?

- There are four new requirements for organizations associated to risk:
 - 7.1.1- Project Management requires that risk is considered during project management activities.
 - 7.1.2 Risk Management requires the organization to establish, implement, and maintain a process for managing risk; define risk acceptance and management criteria (i.e., likelihood, consequences, risk acceptance).
 - 7.2.2 Review of Requirements Related to the Product requires that the organization consider product risks when reviewing customer requirements.
 NOTE: Though not a new requirement the reference/dependence on clause 7.1.2 has been added.
 - **7.4.1.f Purchasing Process** requires the organization to determine and manage risk when selecting and using suppliers.

D. REGISTRATION / CERTIFICATION:

How long will an organization have to transition their certification to 9110:2009?

- Companies will be encouraged to upgrade during their scheduled audit cycle; possibly upgrade to the new standard during a surveillance audit or recertification audit.
 - A maximum 30 month implementation from publication of both 9110:2009 and 9101 (ECD 4Q 2009) standards.
 - An organization may be impacted by their Certification Body (CB) preparedness; recognize that the CB must wait for the development and availability of industry training on the standards, and ensure that relevant personnel receive the required training.

> Who will provide the auditor and Certification Body (CB) training?

 The IAQG Other Party Management Team (OPMT) is responsible for the development of aerospace auditor 9110/9101 transition training. They are in the process of identifying the organization responsible for development of the training materials; these materials will then be provided to applicable training organizations for deployment.

Our company is currently certified to 9100, but based on the new scope statement should we be registered to 9110?

 If an organization needs other QMS standards in addition to 9100 (e.g., 9110), then the additional registration requirements should be determined by organization and/or customer and regulatory requirements.

More than QMS standard registration may be necessary based on:

- The products/services provided (e.g., a company that manufactures their own products, but also provides maintenance services on customer's product); or
- Whether an organization's maintenance, repair, and overhaul operations are operated autonomously or are substantially different from their manufacturing/production operations.
- NOTE: It is critical that the maintenance organization ensure that whether certified to the 9100 or 9110 standard that their auditor has adequate maintenance knowledge and/or background to ensure that a thorough audit is conducted so that the organization receives the most value/benefit.