9120 revision 2016
Key changes presentation for Auditors

IAQG 9120 Team
MAY 2017

9120 Revision 2016

Key changes
in the common 9100
and unique 9120 additions

9120 revision 2016

Key Changes *(aviation, space and defense requirements)*

- Scope of the QMS
  exclusions and inclusions
- Configuration Management
  as it applies to distribution activity
- Product safety
  added in carefully selected areas
- Unapproved and Counterfeit parts prevention
  added in a separate clause and in selected areas

9120 Revision 2016

Scope of the QMS

Scope of the QMS

9120:2016 no longer refers to "exclusions" in relation to the applicability of its requirements to the organization's quality management system.

The applicability of each requirement of the standard depends on:

- the size or complexity of the organization
- the management model of the organization
- the range of the organization's activities
- the nature of the risks and opportunities for the organization

The organization can decide that a requirement is not applicable, only if this decision will not result in failure to achieve:

- conformity of products and services
- enhancement of customer satisfaction

Justifications must be provided for non applicability

For AS&D, non applicability outside clause 8 (Operation) would be unusual

The negative word « exclusion » is not used
The positive word « applicability » is preferred

Scope of the QMS

9120:2016 is for “Non-Value Added” Distributors

What is “Non-Value Added” versus “Value Added”

- work performed must not affect a product’s “characteristics”
- characteristics are defined in the terms of configuration identification
- the work must not alter how a product’s characteristics are defined
- some work can “affect” a characteristic without altering it’s physical shape (i.e. laser cutting, heat treatment, plating, etc..)

Distributors can “facilitate” value-added work if the work is completely under the control of the customer or regulatory requirements

The 9120:2016 standards now includes requirements for Design and Development

- for a distributor this would be a “design for a service” that can be within their scope
- services might include: customer stocking, logistics support, aftermarket services
- there does not have to be a “current” design activity for it to be applicable

Justifications must be provided for non applicability

9120 Revision 2016

Configuration Management

Configuration Management

Configuration management is redefined for 9120:2016

Configuration Management extends throughout the Distributors operations

- internal change control of processes and procedures
- customer purchase order identification of products to be shipped
- manufacturer's identification of products supplied
- documentation associated with airworthiness and regulatory requirements
- product status including revision level, shelf life and life cycle information

Distributors can "facilitate" value-added work if the work is completely under the control of the customer or regulatory requirements

Requirements on distributors are that they must "maintain" a product's configuration information and condition

- changing a product changes it's configuration (some change is allowed)
- documentation changes can change configuration identification
- substitutions even if "technically equvalient" are configuration changes
- COTS parts versus OEM designed items

9120 Revision 2016

Product safety

9120 revision 2016

Product Safety

Addition

- Product Safety is introduced in the following clauses:

  7.3, 8.1 & 8.4.3

Rationale

- Industry acknowledgement of the importance of increasing safety

Product safety definition (3.6)

- Maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

Implementation considerations

- Heighten product safety awareness throughout the organization and the impacts of handling and packaging on protecting and assuring that product integrity is maintained.

9120 Revision 2016

Prevention of unapproved and counterfeit parts

9120 revision 2016

Unapproved and Counterfeit Parts

Addition

- New clause including requirements for prevention of suspect unapproved, unapproved, and counterfeit parts and a note giving examples of the associated processes *and revision of affected clauses: 3.4, 3.8 & 3.10 (definition), 8.1.2 (prevention of counterfeit parts), 8.1.5 (prevention of suspected unapproved parts) 8.4 (external provisions) & 8.7 (nonconformities)*

Counterfeit Part Definition (3.4)

- "An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

  NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics."

Unapproved Part Definition (3.10)

- A part that was not produced or maintained in accordance with approved or acceptable data and applicable statutory, regulatory, and customer requirements.

**A counterfeit part by definition is an unapproved part*

9120 revision 2016

Unapproved and Counterfeit Parts

Rationale

- Mitigate effects of growing threat of counterfeit products
- Recognize the statutory/regulatory requirements on QMS processes for the control of “unapproved parts” and counterfeit parts in both the production and aftermarket environments.

Implementation considerations

- **Risk**
  - ✓ Understand risks associated with procurement and sourcing that could cause unapproved / counterfeit parts to be delivered
  - ✓ Create preventions and mitigation actions to address unapproved / counterfeit part procurement risks
- **Procurement, source selection, supplier control, & inspection**
  - ✓ Understand correlation of risk associated with source selection with procurement, supplier control and inspection options
  - ✓ Apply appropriate actions in supplier control and inspections based on identified risks

9120 revision 2016

Unapproved and Counterfeit Parts prevention

Processes to consider:

- **Training** in the awareness and prevention of counterfeit parts
  - ✓ Procurement personnel in trusted source selection and requirements
  - ✓ Inspection personnel for prevention of counterfeit items (visual/test)
- **Controls for acquiring parts** → from original manufacturers, authorized distributors, or other approved sources
- **Assuring traceability** of parts and components to their original manufacturers :
  - ✓ Original Equipment Manufacturer (OEM) or
  - ✓ Authorized manufacturer (e.g., in case of PMA, direct delivery authorizations)
- **Verification and test methodologies** to detect counterfeit parts:
  - ✓ Parts identification or marking
  - ✓ Tests or chemical analysis
- **Requirement regarding non conformance control:**
  - ✓ Segregate and control suspected unapproved or counterfeit products
  - ✓ Ensure these products are not re-introduced into the supply chain

9120 revision 2016

Unapproved and Counterfeit parts prevention

Processes to consider:

- **Unapproved / Counterfeit parts reporting**
  - ✓ Monitoring reporting from external sources (access to databases, information letters from OEMs)
  - ✓ Quarantine and reporting of internal incidences in appropriate government and industry reporting systems (determine the responsibilities in the escalation process, the process to follow to report to authorities / customers)

Benefits

- **Minimize opportunity of counterfeit part deception**
- **Assures only "approved" parts are sold to customers**
- **Improves supplier evaluation and control of purchases to prevent fraud**
- **Control of counterfeit parts prevents re-entry into the supply chain**

9120 revision 2016

Summary of changes - Clause-by-Clause

9120 revision 2016

The following slides will provide you a summary, clause by clause of the key changes

- **from the 9120:2009 to the 9120:2016**

Key changes are identified by:

- ISO 9001 >>>>>>>>
- ***9100 additions*** >>
- ***9120 additions*** >>

Additional slides provide more information on topics identified with ⓘ

- ✓ Interested parties
- ✓ Scope of a QMS
- ✓ Quality manual
- ✓ Documented information
- ✓ Evaluation of test reports

9120 revision 2016

Summary of changes - clause by clause

Foreword, Revision summary/Rationale, Intended application

Introduction

- 0.1 General
- 0.2 Quality management principles
- 0.3 Process approach
  - Plan-Do-Check-Act cycle
  - Risk-based thinking
- 0.4 Relationship with other management system standards

Includes verbal significations of "shall, should, may, can"

7 principles to consider

Schematic representations of
- a process
- the standard (with a PDCA approach)

Requirements

1. Scope

2. Normative references

3. Terms and definitions

- *Counterfeit product* — ***Definition added***
- *Product safety* — ***Definition added***
- *Suspect unapproved product* — ***Definition added***

9120 revision 2016

Summary of changes - clause by clause

4. Context of the organization

4.1 Understanding the organization and its context	Determine relevant external issues (legal, technological, competitive, market, cultural, social, and economic environments) and internal issues (values, culture, knowledge, and performance of the organization)
4.2 Understanding the needs and expectations of interested parties	Determine relevant interested parties and their requirements (such as customers, partners, authorities)
4.3 Determining the scope of the quality management system	Document the scope of the QMS and justification for any case where a requirement cannot be applied (exclusion)
4.4 Quality management system and its processes	Define the documented information to be maintained or to be retained "to the extent necessary"
	Explicit requirement for a documented information maintained with content defined (can be called quality manual) (not required by ISO)

9120 revision 2016

Summary of changes - clause by clause

5. Leadership

- 5.1 Leadership and commitment
- 5.2 Policy
- 5.3 Organizational roles, responsibilities and authorities

Leadership instead of only management of responsibilities (management to demonstrate their leadership)

Top management to ensure integration of QMS into business processes (now explicit)

Policy aligned with organization strategic direction

A "management representative" required as focal point for QM issues *(removed from ISO 9001:2015)*

6. Planning

- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes

Determine risks and opportunities, considering the issues raised and requirements identified.

Plan appropriate actions to reduce undesired effects on the QMS and evaluate effectiveness

Planning the achievement of objectives more prescriptive and includes the evaluation of results

Changes to the QMS to be carried out in a planned manner

9120 revision 2016

Summary of changes - clause by clause

7. Support

- **7.1 Resources**
  - 7.1.1 General
  - 7.1.2 People
  - 7.1.3 Infrastructure
  - 7.1.4 Environment for the operation of processes
  - 7.1.5 Monitoring and measuring resources
  - 7.1.6 Organizational knowledge
- **7.2 Competence**
- **7.3 Awareness**
- **7.4 Communication**
- **7.5 Documented information**
  - 7.5.1 General
  - 7.5.2 Creating and updating
  - 7.5.3 Control of documented Information

Environment includes human and physical factors

Determine necessary knowledge gained from experience, lessons learned, success, failures, conferences, …

Added the requirement for persons to be aware of:

- ***their contribution to product or service conformity***
- ***their contribution to product safety***
- ***the importance of ethical behavior***

New terminology (replacing “documents” and “records”)
No requirement for 6 mandated procedures, but still a requirement to identify the documented information & processes needed for the QMS

Added the requirement to define data protection processes for documented information managed electronically

Retained documented information includes: evidence of product origin, conformity and shipment…

9120 revision 2016

Summary of changes - clause by clause

8. Operation

8.1 Operational planning and control	***Project Management** (9100:2009 clause 7.1.1) and Control of **Work Transfers** (9100:2009 clause 7.1.4) no more separated clauses but incorporated in clause 8.1 (with risk concept introduced for work transfer) and clarified*
	Reinforce the planning and control activities with dispositions to ensure On-Quality and On-Time delivery of products or services
8.1.1	***Not Used***
8.1.2 Configuration management	***Based on the requirements of 9100:2009 (7.1.3), revised to clarify stakeholders expectations***
8.1.3	***Not Used***
8.1.4 Prevention of counterfeit parts	***Added new requirements to prevent the use of suspect unapproved, unapproved parts and counterfeit parts***
8.1.5 Prevention of Suspect Unapproved Parts	

9120 revision 2016

Summary of changes - clause by clause

8. Operation

8.2 Requirements for products and services

- 8.2.1 Customer communication
- 8.2.2 Requirements related to products and services
- 8.2.3 Review of requirements related to products and services
- 8.2.4 Changes to requirements for products and services

Added requirement that review shall be coordinated with applicable functions of the organization

Added requirement for actions in case of not meeting some customer requirements

8.3 Design and development of products and services

Not excluded per ISO 9001:2015 clause 4.3

- 8.3.1 General
- 8.3.2 Design and development planning
- 8.3.3 Design and development Inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes

Added requirement for a process and criteria for notifying customers, about changes that affect customer requirements

9120 revision 2016

Summary of changes - clause by clause

8. Operation

8.4 Control of externally provided processes, products and services

New terminology. Clause covering the previous "purchases" and "outsourcing"
Externally provided processes include "outsourced processes" (processes needed for the QMS, for which 4.4 applies in addition to 8.4).

8.4.1 General

Explicit requirement for external providers to apply appropriate controls to their direct and sub-tier external providers

8.4.2 Type and extent of control

Added evaluation of data on test reports provided, to confirm the results comply with requirements i

Added validation process of tests reports accuracy for raw materials identified as a significant risk i

8.4.3 Information for external providers

More explicit topics to be considered to communicate requirements to external providers i

Added verbiage to include prevention of unapproved and suspect unapproved products
Added requirement for certificate of conformity, test reports and authorized release certificate

9120 revision 2016

More information about …

Evaluation of data on test reports

Rationale

- Avoid noncompliance of test reports results with the requirements

Implementation

- Determine the products for which test reports will be required
- At receiving, check the test results are compliant to the stated requirements before accepting the parts

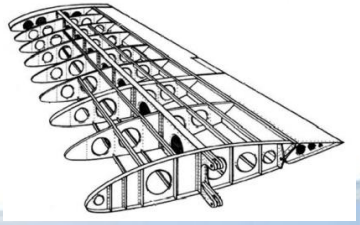
Validation process of tests reports accuracy for raw materials

Rationale

- Inaccurate or incomplete test reports for raw materials have introduced undue risks on customer applications

Implementation

- If specified by the customer that raw material is a risk to their application this clause will apply (according to customer requirements)
- Define the process to be applied (e.g. periodic scheduled retests performed on samples) and take necessary actions



9120 revision 2016

More information about …

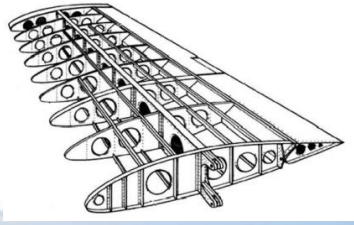
Flow down of requirements

Rationale

- Expanded list of requirements to be considered for flow-down to the next level in the supply chain

Implementation

- Identify the mandated requirements to be flowed down based on customer contracts.
- Identify the NEED for a requirement to be flowed down based on the product or service being offered to the customer and the need to assure product conformity and meet applicable regulatory requirements
- Identify what unique requirements of the procurement need to be specified based on the product or service being distributed



9120 revision 2016

Summary of changes - clause by clause

8. Operation

8.5 Production and service provision

8.5.1 Control of production and service provision	This clause considers monitoring and measurement activities will ensure the control of processes and output, and that acceptance criteria for products and services are met. ***Added requirement to take into account obsolescence, where applicable***
8.5.2 Identification and traceability	*Clarified requirements for traceability and accountability when splitting product.*
8.5.3 Property belonging to customers or external providers	New ISO clause (as per 9100:2009)
8.5.4 Preservation	***Clarified that when problems are detected after delivery the organization shall take appropriate actions***
8.5.5 Post-delivery activities	New ISO clause to emphasize on this topic
8.5.6 Control of changes	New ISO clause to verify that all activities have been carried out before release and delivery by authorized persons

8.6 Release of products and services

Outputs including products and services

8.7 Control of nonconforming outputs

Maintained the requirement for a "procedure" to define the NC process and responsibilities on this key topic for ASD

9120 revision 2016

Summary of changes - clause by clause

9. Performance evaluation

- 9.1 Monitoring, measurement, analysis and evaluation
  - 9.1.1 General
  - 9.1.2 Customer satisfaction
  - 9.1.3 Analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement

- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement

Annex (informative)

- A. Clarification of new structure, terminology and concepts
- B. Standards developed by ISO/TC 176
- C. Standards developed by IAQG

Bibliography

Specific requirements for analysis and evaluation when using results as inputs to management review
Outputs from the analysis are clearer

Explicit topics to consider for the internal audit programme(s)

Added "on-time delivery performance" as input

Added requirement to evaluate the need for action based on human factors to ensure nonconformities do not recur

Nonconformity and corrective action "procedure" added back-in from ISO

For risk management, added the 9100 clarification

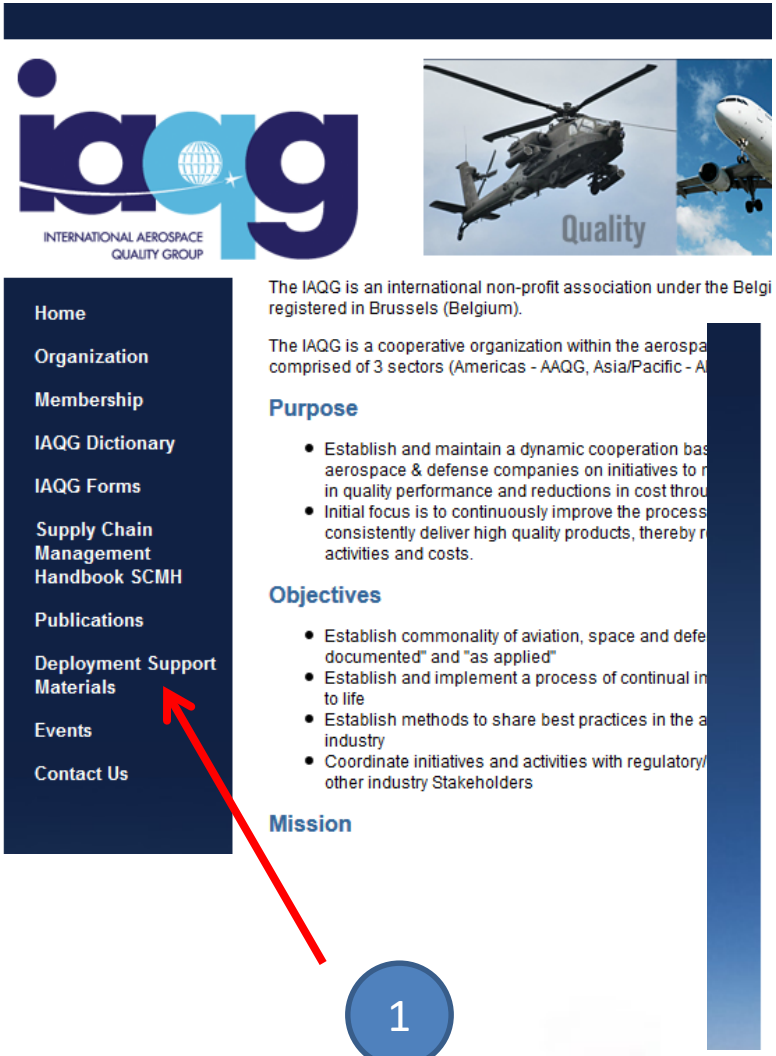
Full list of IAQG standards available

9120 Revision 2016

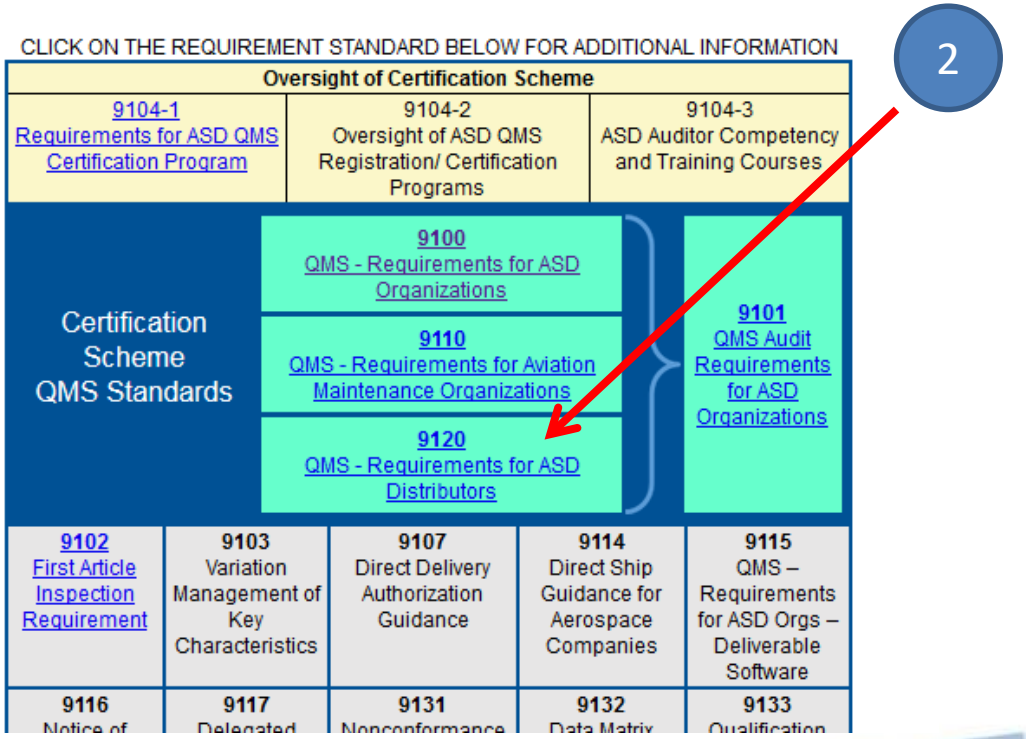
Deployment Support Material

Where to find it ?

Path through the IAQG web site



www.iaqg.org



9120 Deployment Support Material

IAQG 9120 - Quality Management Systems – Requirements for Aviation, Space and Defense Distributors

This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, schedule and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practice. While primarily developed for the aviation, space and defense industry, this standard can also be used in other industry sectors where a quality management system with additional requirements over an ISO 9001 system is needed.

- 9120:2016 - Quality Management Systems: Aviation, Space and Defense Organizations
  - Changes Presentation
  - Correlation matrices between 9120:2009 and 9120:2016
  - FAQ
  - For questions, please contact the IAQG and Sector Document Representatives

Questions