9100 revision 2016

Changes presentation clause-by-clause

IAQG 9100 Team

September 2016

9100 revision 2016

Implementation Benefits

- When implemented and managed well:
  - Produce and continually improve safe and reliable products
  - Meet or exceed customer and regulatory requirements to ensure satisfaction
  - Processes necessary to conduct day-to-day business are defined where necessary and managed
  - Improved integration with business operations and strategy
  - Documentation accurately reflects the work to be performed and actions to be taken
  - Focus on the complete supply chain and stakeholders
  - Fewer customer unique documents
  - Recognized by Regulatory Authorities

9100 revision 2016

This presentation will provide you a summary, clause by clause of the key changes:

- **from the 9100:2009 ➔ to the 9100:2016**

Key changes are identified by:

- ISO 9001 >>>>>>>>
- ***9100 additions*** >>
  (specific to AS&D: Aviation, Space & Defense)

Additional slides provide more information on topics identified with ⓘ

- ✓ Interested parties
- ✓ Scope of a QMS
- ✓ Quality manual
- ✓ Organizational knowledge
- ✓ Awareness
- ✓ Documented information
- ✓ Risk management
- ✓ Product safety
- ✓ Prevention of counterfeit parts
- ✓ Evaluation of test reports
- ✓ Human factors

9100 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

- *Special requirements*
- *Critical items*
- *Key characteristic*
- *Counterfeit part* — *Definition added*
- *Product safety* — *Definition added*

9100 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)*

Interested parties

Definition (ISO 9000)

- stakeholder
- person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

Examples of interested parties**:**

- employees, management, organization owners, unions
- suppliers, customers, partners
- regulatory authorities (Aviation, Space, Defense)
- certification organizations, others?

Criteria to determine interested parties relevancy, requirements and clause applicability:

- **Tier level in the supply chain**: Original Equipment Manufacturers, Production Approval Holders / Design Organization Approval / Production Organization Approval, Systems integrators
- **Product families**: raw materials, components, assemblies
- **Activity**: distribution, design, maintenance, manufacturing, service

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More information about …

Scope of the QMS

9100:2016 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

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More information about …

Quality Manual

- The 9100 requires to establish and maintain documented information describing: Interested Parties; QMS Scope; Process Description, Sequence & Interactions; and Responsibilities and Authorities.
- The requirement can be met in different ways: document, webpages, CD Rom, electronic document management system, etc.
- The intent of the AS&D note "*The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.*" is
  - to convey the practicality to maintain the required information in a centralized location for ease of audit and availability for customers and other interested parties
  - to highlight that this documented information may or not, be called a quality manual. (terms "management handbook" or "company management manual" are often used).

    NOTE: **A document called "quality manual" may be required for the organization by relevant interested parties**

9100 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

9100 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 (social, psychological, physical)

Determine necessary knowledge gained from experience, lessons learned, success, failures, conferences (see next slide)

Added the requirement for persons to be aware of (see following slides):

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

Determine the external communications relevant to the QMS

New terminology (replacing “documents” and “records”) (see next slides)
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

Organizational knowledge

Knowledge specific to the organization is gained by experience.

Rationale:

- To safeguard the organization from loss of knowledge, e.g.,
  - through staff turnover
  - failure to capture and share information
- To encourage the organization to acquire (e.g., learning from experience, benchmarking …) and share knowledge (e.g. mentoring of newcomers);

Implementation consideration

- Activities to benefit from lessons learned, e.g., database, communications, incorporation of lessons learned in processes and procedures
- Identification of experts able to transfer knowledge, on job training, tutorial sessions
- Implement succession planning activities

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More information about …

Awareness

- The 9100:2016 requires the employees aware of:
  - ✓ their contribution to product or service conformity
  - ✓ their contribution to product safety
  - ✓ the importance of ethical behavior

- **Awareness activities** can be performed in different ways:
  - direct communication of expectations between managers and employees
  - communication campaigns on dedicated topics, e.g., posters, pamphlets, fliers, newsletters, videos
  - identification of focal points with responsibility for communication and promotion
  - formal training

- **What is expected:**
  - individuals should be able to explain their own role, how they contribute to quality
  - quality basics (follow instructions, report events, maintain records …)
  - individuals know the use of the products and potential impact of failures

9100 revision 2016

More information about …

“importance of ethical behavior”

- Organizations should make their own determination of what is important to communicate to their employees in regard to ethics
- Below some examples:
  - ✓ Establishing a culture where employees understand their responsibilities
  - ✓ Managers listening to employees and effectively recognizing their work (in addition it can help boost productivity)
  - ✓ Reporting and not passing on defects or non conformances (e.g., line stoppage as appropriate, recalling delivered non conforming product, ..)
  - ✓ A culture allowing unethical behavior can breed all manner of damaging and even criminal activity
  - ✓ Respect the laws, regulations, internal rules, regarding e.g. : conflict of interests, export compliance regulations, intellectual property agreements, acceptance or proposals of gifts, invitations or favors with customers and suppliers

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More information about …

Documented information

There is no longer a requirement for six mandatory documented procedures in the ISO 9001:2015, however…the extent of the documentation that is needed will depend on the business context.

- It is the responsibility of the organization to maintain documented information to support the operation of its processes:
  - **Topics to be documented:**
    - Interested parties; QMS scope; Process description, sequence & interactions; Responsibilities and authorities
    - Quality Policy and Objectives
  - **AS&D requires** maintained documented information regarding nonconformity and corrective action management processes as it is a key process for aerospace.
  - **Various methods** can be used to meet the requirement (e.g., procedures, process flow diagrams, videos, graphic instructions, screen shots, etc.)
- It is the responsibility of the organization to retain the documented information necessary to have confidence that the processes are being carried out as planned.

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Summary of changes - clause by clause

8. Operation

8.1 Operational planning and control

8.1.1 Operation risk management

8.1.2 Configuration management

8.1.3 Product safety

8.1.4 Prevention of counterfeit parts

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 and tie the planning and control activities with dispositions

- ***to ensure On-Quality and On-Time delivery of products or services***
- ***to prevent delivery of nonconforming products and services***
- ***to ensure involvement of representatives from all functions (cross functional team)***

9100 revision 2016

Summary of changes - clause by clause

8. Operation

8.1 Operational planning and control

8.1.1 Operation risk management

8.1.2 Configuration management

8.1.3 Product safety

8.1.4 Prevention of counterfeit parts

Based on the requirements of 9100:2009 (7.1.1) this clause is related to risks in operational processes defined in clause 8 (no major change) while 6.1 is related to risks in QMS of the organization (see next slide)

Based on the requirements of 9100:2009 (7.1.3), revised to clarify stakeholders expectations. Less prescriptive on how to execute. Addresses product lifecycle.

Added new requirements to address "product safety" considerations throughout the product lifecycle (see next slides)

Added new requirements to prevent the use of counterfeit or suspect counterfeit parts (see next slides).

9100 revision 2016

More information about …

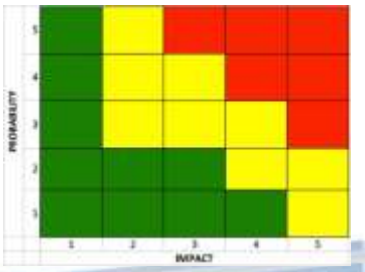
Risk management

Clause 6.1 is related to risks in "QMS of the organization":

- Manage risks at organization / processes level
  (such as: new customers, new market, company partnerships, business localizations, …)

Clause 8.1.1 is related to the risks in "Operational Processes" defined in clause 8:

- Implement a formal process to manage risks
- Adapt the process to the organization and the product
  (e.g. quantitative requirements and probabilistic risk analysis may be required in some cases ; determine people involved in this activity)
- Deploy the risks analysis within the operation activities
  (such as : contract review and signature, new technologies introduction, external providers selection, …)



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More information about …

Risk management

Annex A.4 – ISO 9001

- Risk-based thinking ➔ the organization to understand its context and determine risks as a basis for planning
- Key purpose of QMS is to act as a preventive tool, hence no separate clause on preventive action
- Risk-based thinking has enabled some reduction in prescriptive requirements and greater flexibility
- There is no requirement for formal methods for risk management

Annex A.4 – 9100 additions

- Within aviation, space, and defense, risk is expressed as a combination of severity and likelihood of having a potential negative impact to processes, products, services, customer, or end users.
- Due to the complexity of AS&D processes, products, and services, and the severity of the potential consequences of failures, a formal process to manage operational risks is required

9100 revision 2016

More information about …

Product safety

Addition

- New clause (8.1.3) on Product Safety, including requirements to address product safety considerations throughout the product lifecycle (use the NOTE as guidance) *+ revision for consistency of other clauses related to safety – 7.3, 8.1, 8.4.3 & 8.5.4*
- A full Safety Management System (SMS) as defined by ICAO (International Civil Aviation Organization) is not required by 9100, but the introduction of this new clause contributes to the SMS approach

Rationale

- Industry acknowledgement of the importance of increasing safety
- Recognition of the 9100 certifications by authorities is part of IAQG strategy

Definition

- “The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property”

9100 revision 2016

More information about …

Product safety

Examples of activities to consider:

- **Assessment of hazards and mitigation of associated risks:**
  - ✓ Implement FMEA relating to product (DFMEA) and process (PFMEA)
  - ✓ Perform safety analysis
  - ✓ Identify and mitigate risks relating to the organization and its personnel (human factors, management of responsibilities)
- **Management of safety critical items:**
  - ✓ Define and implement a monitoring control plan for critical items identified through FMEA and safety analysis

Product safety

Examples of activities to consider (cont.)

- **Analysis and reporting of occurred events affecting safety:**
  - ✓ Organize the collection of potential and occurred events, and analyze their impacts with specialists
  - ✓ Organize the internal escalation process and external reporting to interested parties
  - ✓ Analyze the adverse trends of products in service reliability and define appropriate actions (7.5.1.4/8.5.5)

- **Communication of these events and training of personnel:**
  - ✓ Promote safety culture and lessons learned from occurred events (impacts of the parts delivered by the organization on the final product safety)
  - ✓ Prevent occurrence of safety issues by taking into account industry experience (including occurrences on other products with similar functions or based on same technologies or components)

9100 revision 2016

More information about …

Counterfeit parts prevention

Addition

- New clause (8.1.4) including requirements for prevention of counterfeit parts and a note giving examples of the associated processes (training, testing, traceability requirements etc.)
  + revision of affected clauses: 8.4.2 ; 8.4.3 (external provisions) & 8.7 (nonconformities)

Rationale

- Mitigate effects of growing threat of counterfeit / fraudulent product
- Recognize the emerging counterfeit/fraudulent statutory/regulatory requirements on QMS processes

Definition

- "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."

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)
  - ✓ Design personnel in obsolescence management
- **Obsolescence** monitoring ➔ design decisions and parts selections to be appropriate for service life of product
- **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)

Counterfeit parts prevention

Processes to consider:

- **Verification and test methodologies** to detect counterfeit parts:
  - ✓ Parts identification or marking
  - ✓ Tests or chemical analysis

- **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)

Requirement regarding non conformance control:

- ✓ Segregate and control suspected or known counterfeit products
- ✓ Ensure these products are not re-introduced into the supply chain

9100 revision 2016

Summary of changes - clause by clause

8. Operation

8.2 Requirements for products and services

- 8.2.1 Customer communication
  - Extended to requirements regarding contingency actions
- 8.2.2 Determining the requirements related to products and services
  - Added consideration for the organization to meet the claims for products and services
- 8.2.3 Review of the requirements related to products and services
  - ***Added requirement that review shall be coordinated with applicable functions of the organization – cross functional***
- 8.2.4 Changes to requirements for products and services
  - ***Added requirement for actions in case of not meeting some customer requirements to negotiate a mutually acceptable alternative with the customer***

9100 revision 2016

Summary of changes - clause by clause

8. Operation

- 8.3 Design and development of products and services
  - 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

Clause re-structured to allow for a more process orientated approach
Requirement to maintain a "process"

Clear flexibility (nature, duration and complexity) in determining stages and controls

Consider documented information needed for demonstration of compliance to requirements

Added requirement to take obsolescence into account (equipment, material etc.)

Ensure monitoring and measuring devices used for testing are properly controlled

Outputs shall be approved by authorized person(s) prior to release

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

9100 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, to ensure the consistency in the whole supply chain
NB: a sub-tier external provider means the external providers of a direct external provider of an organization.

8.4.2 Type and extent of control

Added evaluation of data on test reports provided, to confirm the results comply with requirements (see next slide)

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

8.4.3 Information for external providers

More explicit topics to be considered to communicate requirements to external providers beyond what is in AS9100C

9100 revision 2016

More information about …

Requirements added back-in from previous 9100 version

Evaluation of data on test reports

Rationale

- Avoid non compliance 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 before accepting the parts

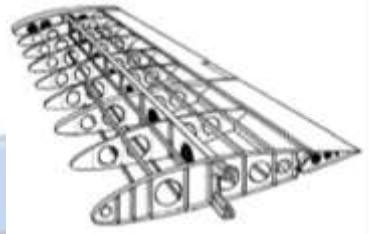
Validation process of tests reports accuracy for raw materials

Rationale

- Inaccurate, incomplete or unduly altered test reports for raw materials have introduced undue risks on critical applications

Implementation

- Determine the critical raw material for which this clause will apply (according to customers requirements or as design outputs, safety analysis outputs)
- Define the process to be applied (e.g. periodic scheduled retests performed on samples)
- Apply the process and take necessary actions



9100 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 outputs, and that acceptance criteria for products and services are met.

8.5.2 Identification and traceability

8.5.3 Property belonging to customers or external providers

8.5.4 Preservation

8.5.5 Post-delivery activities

New ISO clause (as per 9100:2009)

Clarified that when problems are detected after delivery the organization shall take appropriate actions. Not necessarily tied to warrantee work.

8.5.6 Control of changes

New ISO clause to emphasize on this topic

8.6 Release of products and services

New ISO clause to verify that all activities have been carried out before release and delivery by authorized persons

8.7 Control of nonconforming outputs

Outputs including products and services

Maintained the requirement for "documented information" to define the NC process and responsibilities on this key topic for AS&D

9100 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 (see slides)

Nonconformity and corrective action "documented information" added back-in

For risk management, added the 9100 clarification

Full list of IAQG standards available

9100 revision 2016

More information about …

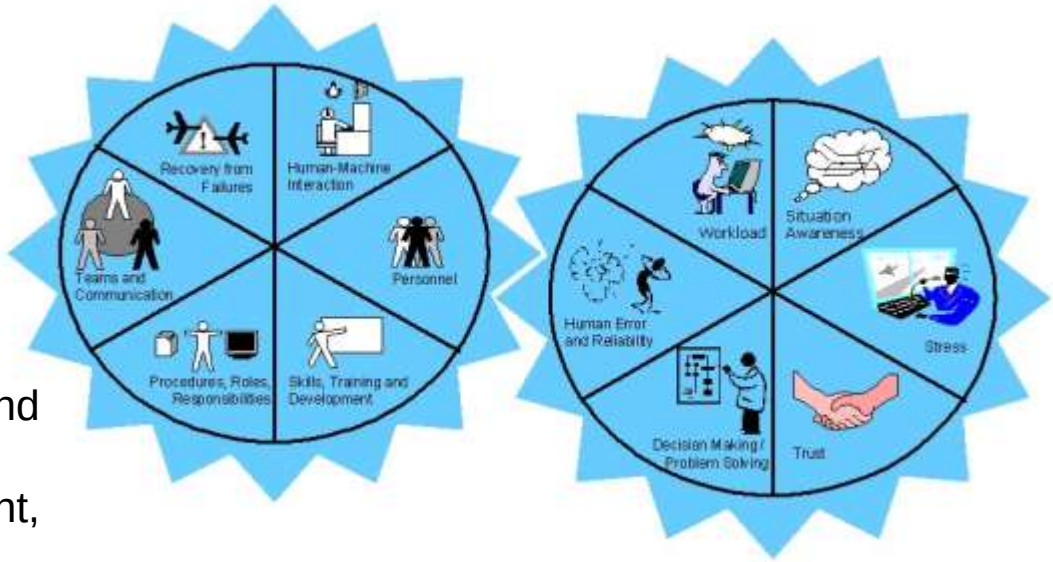
Human factors

Addition

- Requirement to include the human factors considerations in the root causes analysis of nonconformities

Definition

- The understanding of the interactions between people, machines and each other and their impact on human performance.
- Example: Recognition that persons 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 persons and all other environmental elements such as other persons, equipment, facilities, procedures and data.



9100 revision 2016

More information about …

Human factors

Rationale

- To reinforce the controls linked to clause 7.1.4 (environment for the operation of processes) and clause 8.5.1 g (prevention of human errors)
- Recognize the importance of human factors in the origin of nonconformities

Implementation considerations

- Determine the human factors to be considered according to the products, workplaces, equipment and people of the organization
- Include the elements to be reviewed during the root causes analysis of nonconformities
- Capitalize with lessons learned on occurred human errors

9100 Revision 2016

High Level Summary of Changes

May 2016

9100 revision 2016

9100 Series Changes - High Level Summary

No Requirements

Clause 1 Scope	▪New process model ▪Added a PDCA model ▪Added "Risk-based thinking" ▪Emphasis on defining the QMS and context of the organization
Clause 2 Normative ref	▪ISO 9000:2015 referenced
Clause 3 Terms and definitions	▪ ISO 9001 terms and definitions moved to ISO 9000 ▪ *Added 9100 "product safety", "counterfeit part"*
Clause 4 Context of the organization	▪Maintained documented information is required, *can be named Quality Manual* ▪Justified exclusions not limited to Realization/Operations processes ▪QMS processes have performance indicators
Clause 5 Leadership	▪QMS compatible with strategic direction ▪QMS requirements integrated into business processes ▪Processes deliver their intended outputs
Clause 6 Planning for the QMS	▪When planning the QMS, determine the actions needed to address opportunities and risks (prevention) ▪Increases requirements for planning of changes
Clause 7 Support	▪Determine knowledge management requirements ▪*Awareness on product conformity, product safety, ethical behavior*
Clause 8 Operation	▪*Planning for product obsolescence* ▪*Plan activities needed to assure product safety* ▪*Prevention of counterfeit parts* ▪*Process to validate test reports for raw material based on risks* ▪Release of products and services
Clause 9 Performance evaluation	▪ Assess performance of QMS processes ▪ *Added Note to evaluate performance indicators on internal audits*
Clause 10 Improvement	▪*Consider human factors in nonconformity / corrective action*

All ISO MS standards will now have this common 10 clause structure

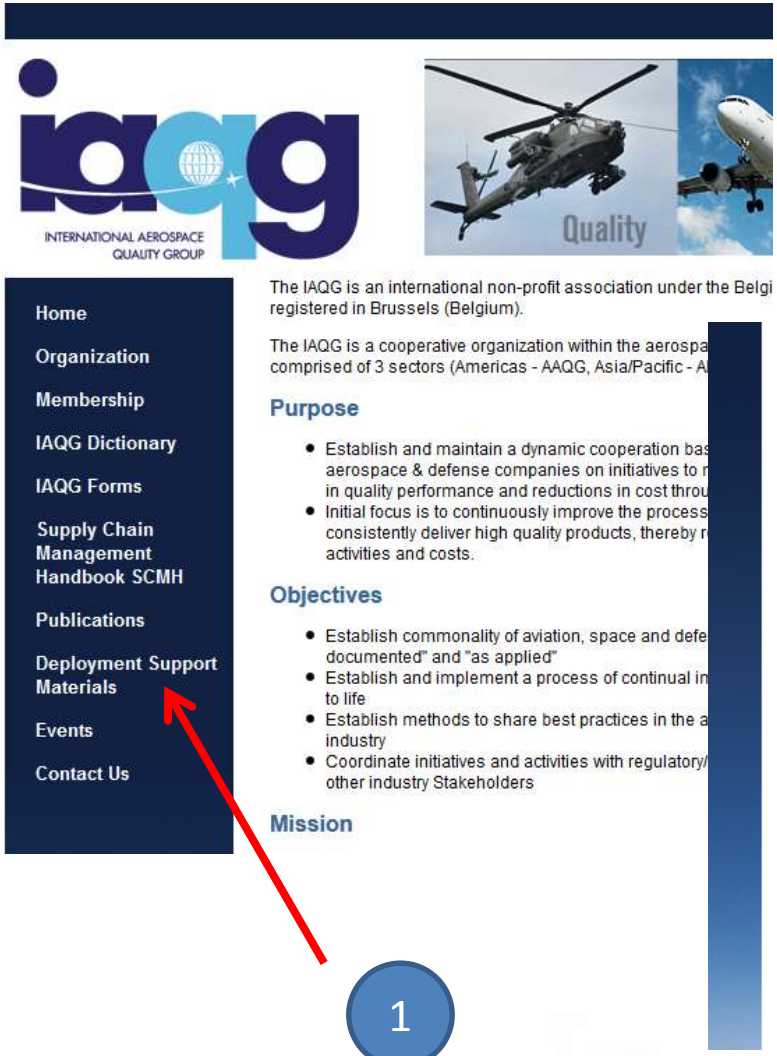
9100 Revision 2016

Deployment Support Material

Where to find it ?

May 2016

Path through the IAQG web site



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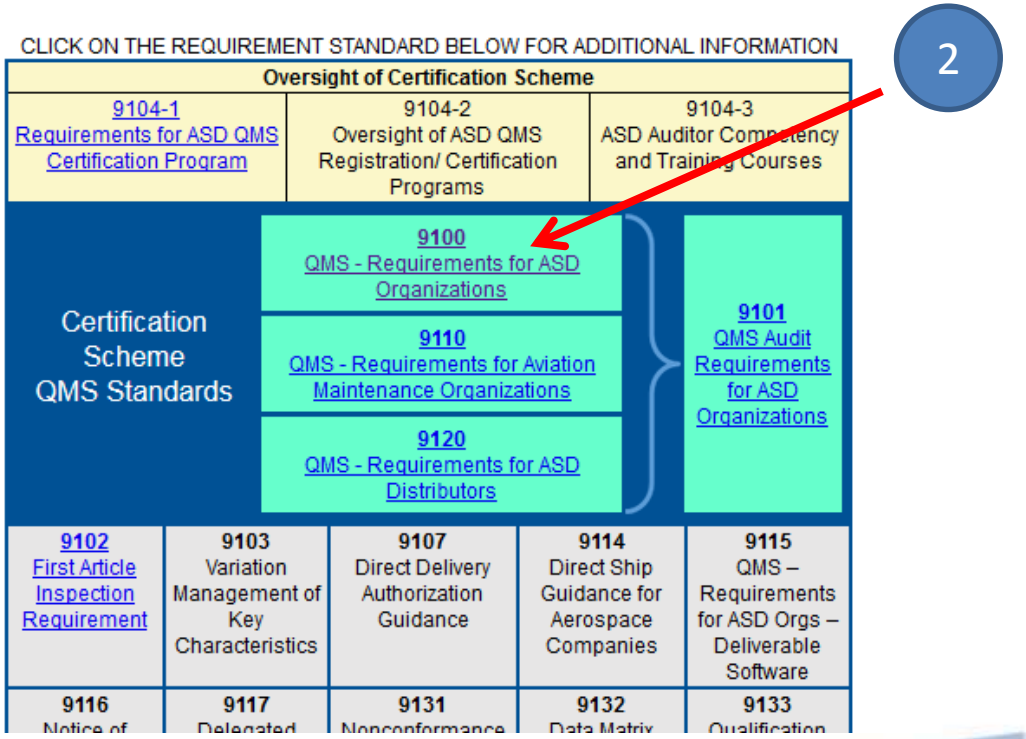

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IAQG 9100 - Quality Management Systems - Requirements for Aviation, Space and Defense Organizations

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.

- 9100:2016 - Quality Management Systems - Aviation, Space and Defense Organizations
  - Changes Presentation
  - Correlation matrices between 9100:2009 and 9100:2016
  - Matrix of 9100:2009 mapped against the 9100:2016
  - FAQ
  - 2015 July Quality Progress
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  - For questions, please contact the IAQG and Sector Document Representatives

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