

IAQG 9100:2009 ***Revision Overview***

Prepared by IAQG 9100 Team
Rev: 2 Dated: 17 June 2009

Overview Objectives



- **Provide an overview of:**
 - **9100 Team Membership**
 - **9100 Revision Process**
 - **9100:2009 Key Changes (Revisions/Relocated, Additions, Deletions Requirements)**
 - **9100 Implementation Schedule**

9100 Team Membership



- 18 Members on 9100 Team
- Representing:
 - Americas, Europe, and Asia-Pacific IAQG Sectors
 - 10 Different Countries
 - 16 Different IAQG Companies



9100 Stakeholders



- **Civil Aviation Authorities**
- **Defense Industry and Authorities**
- **Space Industry and Authorities**
- **Certification / Registration Bodies**
- **Trade Associations**
- **Suppliers**
- **IAQG Member Companies**
- **IAQG Strategy Streams and Teams**

9100 Revision Objectives



- **Incorporate ISO 9001:2008 changes**
- **Expand scope to include land and sea based systems for defense applications**
- **Ensure alignment with IAQG strategy (on-time, on-quality performance)**
- **Adopt new requirements based on stakeholder needs**
- **Improve existing requirements where stakeholders identified need for clarification, including when a documented procedure is required.**

9100 Revision Process



Project Mgmt Design Specification & IAQG Strategy > 9100 objectives

9100 Design Specification
Key considerations

- Stakeholder requests for changes to ISO 9001 are out of scope
- Changes/additions to be considered are those that:
 - constitute quality management system requirements that are not contractual in nature or contain product specific requirements, and that
 - enhance clarity of requirements of address stakeholder needs, and that
 - are auditable and define "what" not "how," and that
 - are compatible for use by all stakeholder segments and by organizations of all types and sizes, and when
 - the benefit of the proposed change/addition outweighs the impact of implementation

Objectives for the 9100 QMS Standard (IAQG Strategy)

The 9100 standard shall:

1. Improve the suppliers performance and customer satisfaction, especially: Quality of the products & On-time deliveries
2. Be the foundation of the requirements applicable to the whole aerospace and defense industry
3. Be recognized by the authorities
4. Be applicable to 10 000 suppliers in 35 countries, applied and adapted to: primes, systems manufacturers, equipment manufacturers, sub-contractors, components manufacturers (mechanics, electronics, ...) ...
5. Allow a common interpretation of the 9100 standard by auditors, audited companies, at all levels
6. Take into account the new requirements from the aerospace and defense industry

IAQG Stakeholder Focals & 9100 Team Liaisons

Stakeholder	IAQG Focal	9100 Team Liaison
• Certification/Registration Bodies	Rick DOWNS	Hans LUIJT
• Civil Aviation Authorities	Edward BAYNE	Alan DANIELS
• Defense / NATO	Mike HAYWARD	Francisco LOSADA
• Space	Roberto CIASCCHI	Roberto CIASCCHI
• OASIS Suppliers	Hans LUIJT	Hans LUIJT
• IAQG & Sector Companies		
• IAQG Strategy Streams: <ul style="list-style-type: none"> - People Capability - Product and Supply Chain 	Herbert MAROSE Susan ARMSTRONG Larry WING	Henry JOHANSSON Buddy CHESSONNE Jean-Louis DOULIERE

9100 Team Sector Leads

Stakeholder
Input
Web survey

Started in April 2005

- 1st 9100 Team Meeting
November 2005

MCRT
(Master Comments
Review Template)

**Data mining and
Consolidation**
- 366 items

MCRT
Accept/Reject/
Proposals/
Comments

40 % accepted

Review process

• Design Specification &
IAQG Strategy > 9100
objectives

- April 2006, October 2006,
April 2007

9100 Revision Process

9100 draft

18 June 2007

Writing the first draft - prepared by the scribe

- *Sub-team : scribe + 2 people per sector)*

* 9100 Writing Team July 2007



9100 draft

7 August 2007

Review of the first draft

- Issued by the writing sub-team
 - in each 9100 WG sector
 - by the whole team (in Orlando)

* IAQG Meeting - October 2007



9100 coord draft

Nov 2007

Review of Coordination Draft (Nov 2007) :

- 9100 WG sectors
- Stakeholder Comments Reviewed by:
 - Each Sector for consensus response
 - Entire team (in Naples) for final resolutions prior to formal ballot

* IAQG Meeting - April 2008

9100 Revision Process

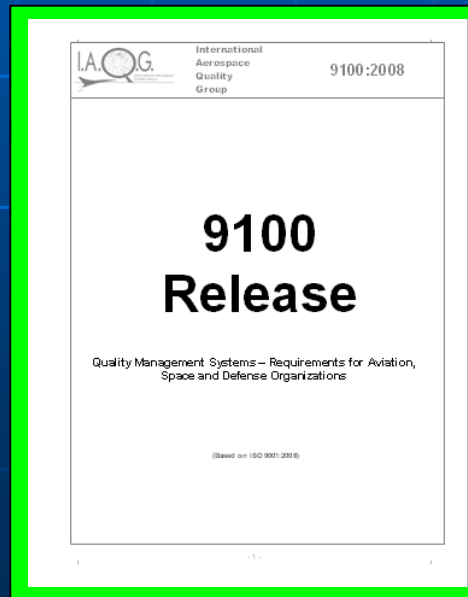
**9100
Formal
Ballot
May 2008**

- Preparation for Formal Sector Ballot
- Development of deployment support material

Formal Ballot
• May 2008

Limit date for comments
• August 2008

IAQG Meeting
• Oct 2008



New ISO 9001 schedule

(TC176 changed their estimated release date from June 2009 to October 2008)

9100 Revision Effort Completion: Dec 2008

AS/EN 9100 Publication: January 2009

JIS Q9100 Publication: April 2009



9100 Change Overview



- **Structure of Key Changes Slides**
 - Revision/Relocation, Addition, or Deletion
 - Rationale
 - Implementation/Audit Considerations

- **9100 Revision Key Changes (Covered in this presentation)**
 - 6 Additions
 - 8 Revisions/Relocations
 - 3 Deletions

9100:2009 Key Changes



■ Clause 1 - 9100 Scope and Application

• Revision:

- Scope extended to include Defense as well as Aviation and Space
- Application guidance provided when 9100, 9110, and 9120 are appropriate for use

• Rationale:

- The 9100 based QMS is applicable to other complex systems and would receive benefit from implementation including land and sea based applications
- Possible additional recognition and synergies with NATO Allied Quality Assurance Publications (AQAPs)

• Implementation/Audit Considerations:

- Increased use and improved understanding of when the various aviation, space, and defense standards are applicable.

9100:2009 Key Changes



■ Clause 3.1 - Risk

- **Addition:** Define new term “risk”
 - An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
- **Rationale:** The understanding of risk is important for an organization to develop a proactive quality management system
- **Implementation/Audit Considerations:**
 - Understanding this term is important to implement a risk management process in the applicable clauses.

9100:2009 Key Changes



■ Clause 3.2 - **Special Requirements**

- **Addition:** Define new term “special requirements”
 - Those requirements which have high risks to being achieved thus, requiring their inclusion in the risk management process.
 - Factors used to determine special requirements include:
 - product or process complexity
 - past experience
 - product or process maturity.
 - Examples include:
 - performance requirements imposed by the customer that are at the limit of the industry’s capability
 - requirements determined by the organization to be at the limit of its technical or process capabilities

9100:2009 Key Changes



■ Clause 3.2 - **Special Requirements** (Continued)

• **Rationale:**

- Improve understanding of “Special Requirements” and the potential chain of flow to “Critical Items” and to “Key Characteristics.”
- Ensure these important requirements are systemically addressed and linked to risk management activities by the organization.

• **Implementation/Audit Considerations:**

- Understanding this term is important to implement special requirement processes in the applicable clauses.

9100:2009 Key Changes



■ Clause 3.3 - Critical Items

- **Addition:** Define new term “critical item”
 - Those items (*e.g., functions, parts, software, characteristics, processes*) having significant effect on the product realization and use of the product; *including safety, performance, form, fit, function, producibility, service life, etc.* that require specific actions to ensure they are adequately managed.
 - Examples of critical items include:
 - safety critical items
 - fracture critical items
 - mission critical items
 - key characteristics

9100:2009 Key Changes



■ Clause 3.3 - **Critical Items** (Continued)

• **Rationale:**

- Improve understanding of “Critical Items” coming from Special Requirements.
- Ensure these items are systemically addressed and linked to risk management activities by the organization.

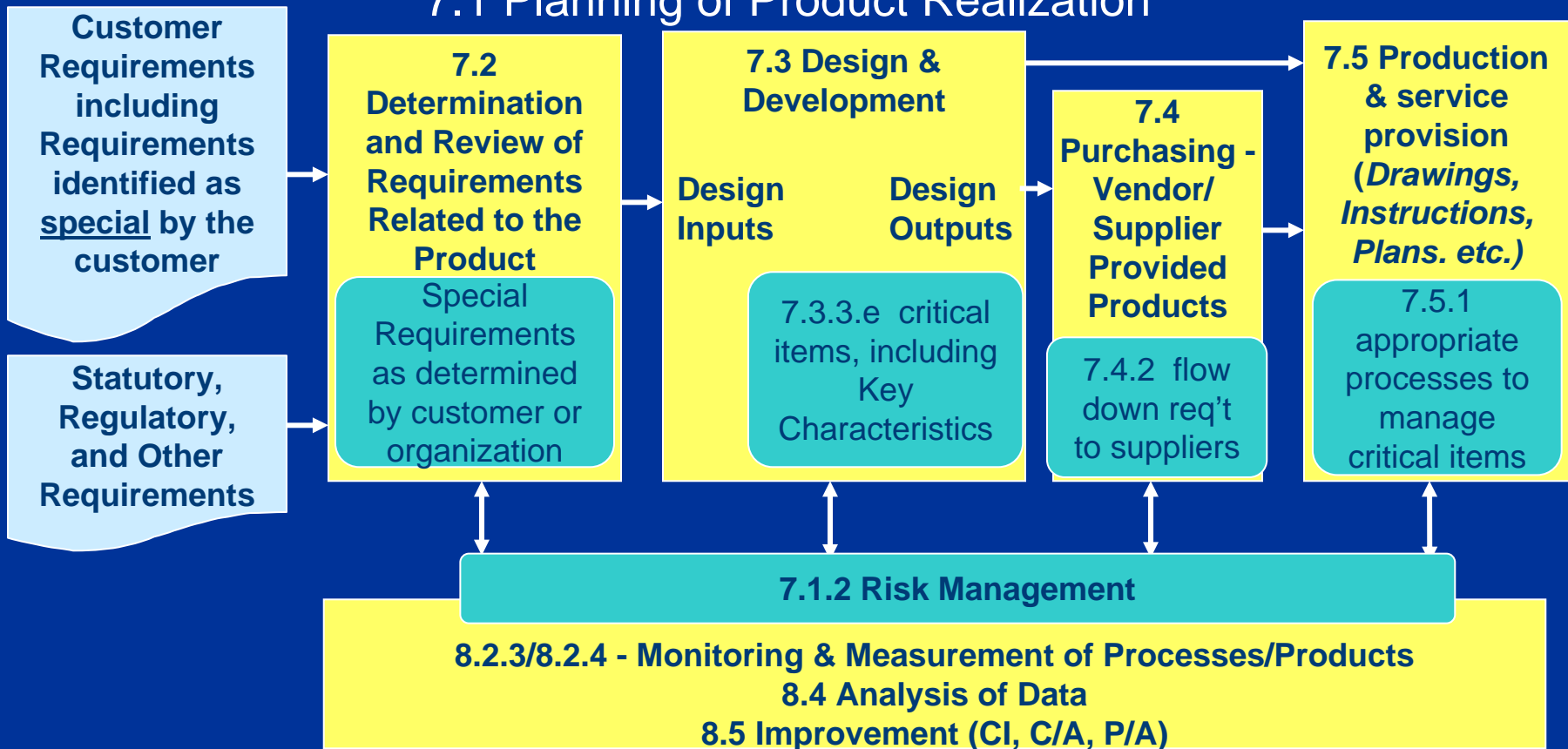
• **Implementation/Audit Considerations:**

- Understanding this term is important to implement critical items processes in the applicable clauses.

9100:2009 Key Changes

Interrelationship between Special Requirements, Critical Items, Key Characteristics, and Risk Management process

7.1 Planning of Product Realization



9100:2009 Key Changes



■ Clause 4.1 – QMS General requirements

• Revision/Relocation:

- The organization's QMS shall address customer and applicable statutory and regulatory QMS requirements (previously located in the QMS documentation § 4.2.1)

• Rationale:

- Clarify that the requirement is placed at the QMS level and not only at the documentation level

• Implementation/Audit Considerations:

- The concept of “basic QMS” may be used (processes applicable to all customers / activities), but the documents such as Quality Management Plans, which address specific customers requirements, shall be considered as part of the QMS.

9100:2009 Key Changes



■ Clause 4.2.2 – Quality Manual Relationships

• Deletion:

- Requirement to create a document showing the relationship between 9100 requirements and the organizations documented procedures

• Rationale:

- Requirement adds no value to assuring product quality.
- Requirement was viewed as prescriptive in that it specifies a particular method of assuring the requirements of the standard have been met.

• Implementation/Audit Considerations:

- Auditors need to identify appropriate documented procedures as an inherent part of carrying out the audit

9100:2009 Key Changes



■ Clauses 5.2/8.2.1 – Customer Focus/Satisfaction

• Addition:

- Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved. (5.2)
- Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to:
 - product conformity
 - on-time delivery performance
 - customer complaints
 - corrective action requests.
- Organizations shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results. (8.2.1)

9100:2009 Key Changes



- **Clauses 5.2/8.2.1 – Customer Focus/Satisfaction** (Continued)
 - **Rationale:**
 - Establish clear relationship between the QMS and organizational performance, in line with IAQG strategy
 - To promote continuous improvement of customer satisfaction
 - **Implementation/Audit Considerations:**
 - Review of management focus and organizational process to measure customer satisfaction and plan improvements

9100:2009 Key Changes



■ 7.1.1 - Project Management

• Addition:

- New requirement for planning and managing product realization in a structured and controlled way to meet requirements at acceptable risk, within resource and schedule constraints.

• Rationale:

- Most aviation, space and defense products are complex and involve multi-tier partners and suppliers
- This clause provides additional focus on upfront planning and the management of project plans throughout product realization

• Implementation/Audit Considerations:

- Does the organization have a process to manage product realization planning to ensure quality and schedule are not compromised?
- How are project plans used to manage the successful completion of projects?

9100:2009 Key Changes



■ 7.1.2 - Risk Management

• Addition:

- New requirement to implement a risk management process applicable to the product and organization covering: responsibility, criteria, mitigation and acceptance.
- The concept of risk is integrated within the revised 9100.

• Rationale:

- Risk Management was placed in clause 7.1.2 to provide additional focus on product risk during product realization.

• Implementation/Audit Considerations:

- Does the organization have a risk management process that addresses all of the applicable requirements?
- Is the definition of risk appropriately understood and applied in that process?
- Are risks successfully managed in the organization?

9100:2009 Key Changes



■ 7.1.3 - Configuration Management

• Revision/Relocation:

- Moved from Clause 4.3 to 7.1.3.
- Structured in line with ISO 10007 requirements

• Rationale:

- Focuses configuration management on the product and how it is sustained throughout product realization

• Implementation/Audit Considerations:

- Some level of configuration management is expected for all products at all levels of the supply chain in compliance with exclusion criteria (see clause 1.2).

9100:2009 Key Changes



■ 7.1.4 – Work Transfer

• Revision/Relocation:

- Moved from clause 7.5.1.4 (Production) to clause 7.1.4
- The organization must have a process to plan and control the transfer activities
- Expanded to cover permanent transfer (e.g. from one organization to another, from one organization to supplier, from one supplier to another).

• Rationale:

- Work transfer can occur at anytime during product realization
- Addresses problems that often occur during work transfers

• Implementation/Audit Considerations:

- A process must exist to control the transfer of work including planning and subsequent control of the transfer.

9100:2009 Key Changes



- **Clause 7.4.1 – Recognition of Supplier Quality Data**
 - **Revision:**
 - Added note to recognize that one factor that may be used during supplier selection and evaluation is objective and reliable data from external sources
 - **Rationale:**
 - Recognition that the industry trend is to use externally provided supplier performance data (e.g. Online Aerospace Supplier Information System – OASIS, Nadcap)
 - **Implementation/Audit Considerations:**
 - Note only

9100:2009 Key Changes



■ Clause 7.4.1 – Approval status for suppliers

• Revision:

- Added and provided examples of “approval status” (e.g. approved, conditional, disapproved) and examples of “scope of approval” (e.g. product type, process family).
- The organization must define the process for suppliers approval status decisions or changes.

• Rationale:

- Clarify that the conditions for using a supplier depends on its approval status

• Implementation/Audit Considerations:

- The process, responsibilities and authority must be defined for this process

9100:2009 Key Changes



■ Clause 7.4.3 – Validation of Test Reports

- **Deletion:** Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.
- **Rationale:**
 - Misunderstood concept that was frequently misapplied
 - Requirement was prescriptive, not applicable to all stakeholders (especially small organizations) and for all types of products, and was subject to varying interpretation.
- **Implementation/Audit Considerations:**
 - If an organization is making critical items where the material chemical/physical requirements are important, are they verifying test reports as part of their risk management process?

9100:2009 Key Changes



■ Clause 7.5.1.1 – Production Process Verification

• Revision/Relocation:

- Moved from 8.2.4.2 (measurement) to 7.5.1.1 (production)
- Requirement to verify the production processes, documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g. engineering or manufacturing processes changes, tooling changes).

• Rationale:

- Movement to clause 7 acknowledges that this requirement (previously called first article inspection - FAI) is not primarily a measuring and monitoring process, but a process that will be used to assure product realization capability under controlled conditions.
- Allows justifiable exclusion for unique and individual products

• Implementation/Audit Considerations:

- Validation of requests for exclusion (unique and individual products vs. production run).

9100:2009 Key Changes



■ Clause 8.2.2 – Detailed Tools and Techniques

• Deletion:

- “Detailed tools and techniques shall be developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.”

• Rationale:

- Requirement was too prescriptive. Reference to specific tools in a “such as” statement is more appropriate as guidance material.

• Implementation/Audit Considerations:

- Methods and effectiveness measures remain intact in the ISO text. Tools and techniques may still be needed to support the audit process.

9100:2009 Key Changes



■ Clause 8.2.4 – Sampling Inspection

• Revision:

- When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

• Rationale:

- Numerous requests were received to improve clause 8.2.4. The comments ranged from that it was statistically inaccurate, to that it was too prescriptive.

• Implementation/Audit Considerations:

- Validation of recognized statistical principles utilized.
- Process used to determine criticality of product.

Proposed 9100 Implementation Schedule



Maximum 30 month Implementation from Publication



In Closing



- **The 9100 Team goals and objectives were to:**
 - Emphasis on product and process improvement (e.g. risk management, critical items, project management)
 - Expand the 9100 scope to include Aviation, Space & Defense
 - Provide additional focus on IAQG objective of on-time and on-quality deliveries
 - Ensure 9100 standard is compatible for use by all stakeholder segments and by organizations of all types and sizes
 - Ensure 9100 stays recognized by authorities
 - Ensure extensive stakeholder involvement in revision effort by the use of a project management approach to solicit input and manage the revision

The key changes are not inclusive of all the changes in the 9100 standard.