
AS 9100:2009 Revision Overview

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 Change Overview

- **Structure of Key Changes Slides**
 - Revision/Relocation, Addition, or Deletion
 - Rationale
 - Implementation/Audit Considerations
- **The changes in this presentation are not inclusive of all the changes in the 9100 standard.**

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

- **New Definitions**

- **Clause 3.1 – Risk**

- » An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

- **Clause 3.2 - Special Requirements**

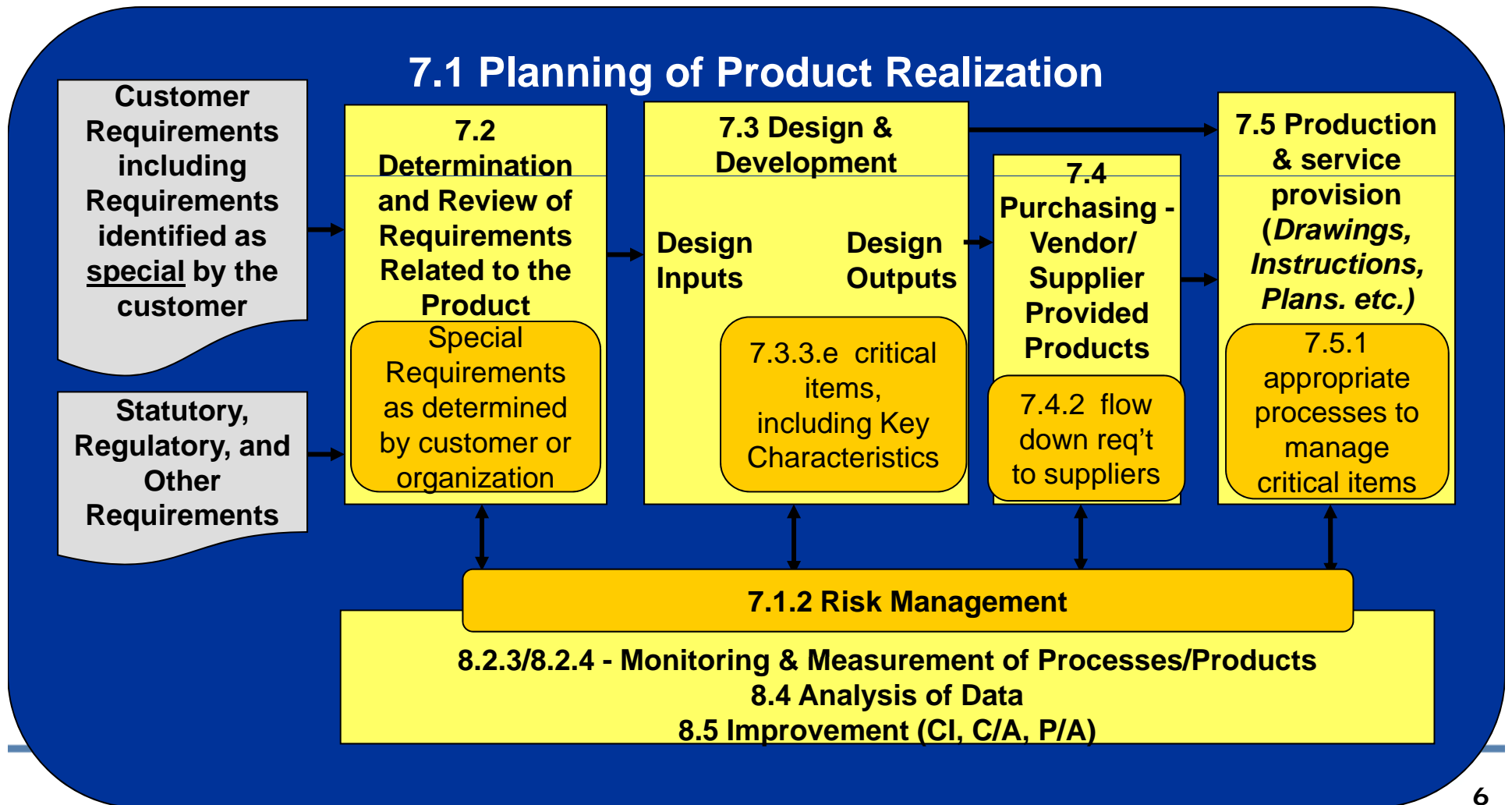
- » Those requirements which have high risks to being achieved thus, requiring their inclusion in the risk management process.

- **Clause 3.3 - Critical Items**

- » 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.

9100:2009 Key Changes

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



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:**
 - » Even though this is only a Note, IAQG encourages use of external sources to understand supplier risks.

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 – Internal Audits (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.

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**

ABS Quality

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

Principals

- Purpose
 - The IAQG Other Party Management Team is a Global, Industry-Controlled, Oversight Committee chartered to manage the Industry Controlled Other Party Aerospace Quality Management System certification process.
- Objective
 - IAQG Quality Management System certification program that is robust, recognized, and valued.

Principals

- ICOP is based on:
 - The use of identical or equivalent international, sector and national standards based on 9104 series of standards
 - An industry oversight system at international, sectorial and national levels to ensure that scheme's requirements are fulfilled
 - Auditors authenticated against identical requirements
 - All information related to the scheme is collected in the OASIS database (Online Aerospace Supplier Information System)

Demographics

	National Schemes	NABs	CBs	Auditors	Oasis Entries
Americas	1 (1)	2 (2)	41 (41)	582 (442)	6150 (5607)
Asia Pacific	1 (1)	1 (1)	4 (4)	32 (25)	479 (408)
Europe	7 (7)	7 (7)	37 (38)	347 (339)	4389 (4104)
Total	9 (9)	10 (10)	82 (83)	961 (806)	11018 (10119)

NAB - National Accreditation Body

CB - Certification Body

October 2009

(April 2009)

Standards Update

- **9104-1: Globally harmonized standard defining the certification / accreditation process. Currently being updated, latest comment period complete, team is working to disposition/ incorporate comments. Ballot expected later this year.**

- **Key Changes**

- *Audit Day Table based on IAF MD5 gives minimum audit days based on organization population*
- *Improved process for multiple site organization certification*
- *Improved process for handling identified issues in ICOP process*
- *Incorporated all applicable IAQG OPMT resolutions*

Standards Update

- **9104-2:** Globally harmonized standard defining the surveillance and oversight processes. Currently being updated, team has collected comments and is in process of developing first draft. Expected publication Jan 2011.
- **Key Changes**
 - *Updating oversight of ICOP to incorporate risk based model*

Standards Update

- **9104-3:** Globally harmonized standard defining the auditor qualification and auditor training processes. Currently being updated, team has collected comments and is in process of developing first draft. Expected publication Jan 2011.

- **Key Changes**

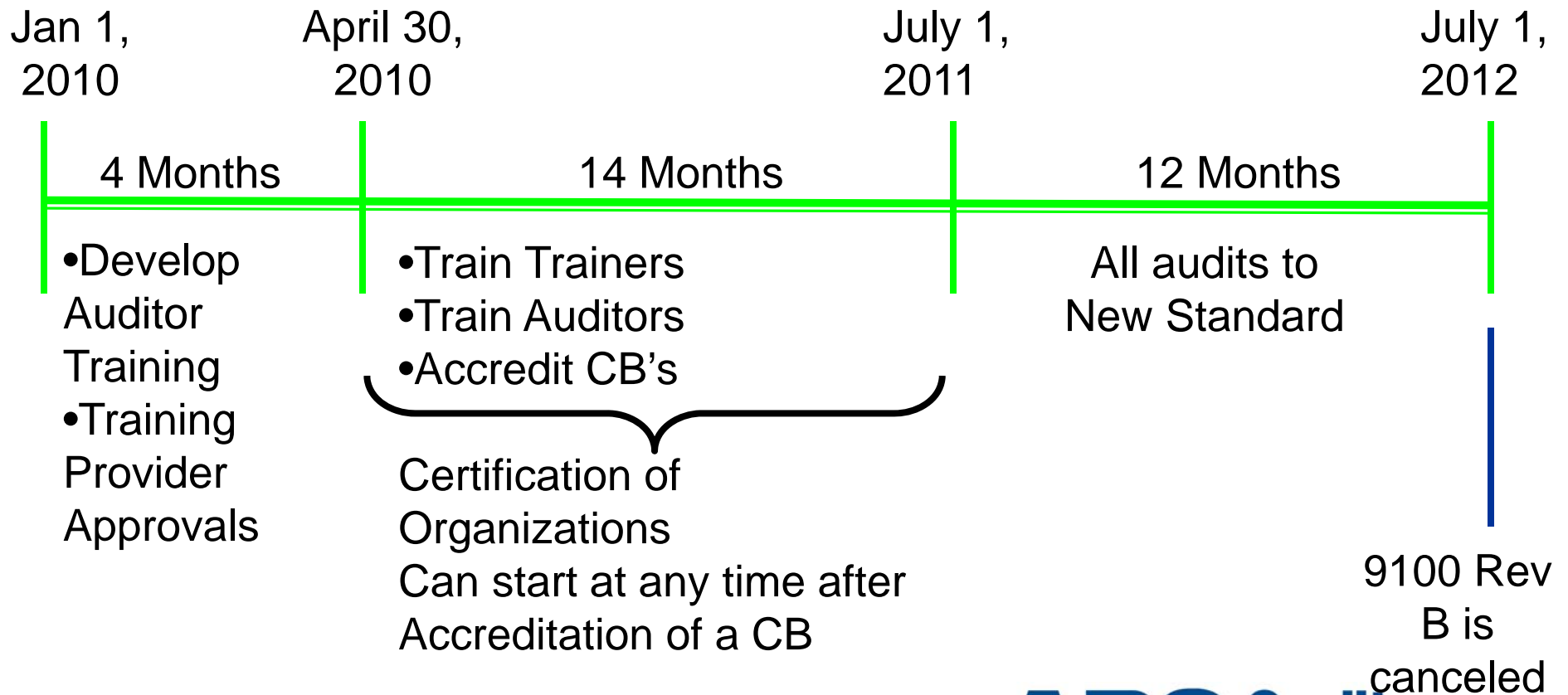
- *Key change is move to a competency based auditor authentication process.*

*Standards Updates are the Path to
Improvement*

91XX:2009 Transition Schedule

- Overall schedule provides for full deployment of 91XX:2009 AQMS Standards by July 1, 2011
- Full implementation of 9104/1 requirements required for 91XX:2009 certification (July 1, 2011)
- IAQG Sanctioned Training for all ICOP authenticated auditors

30 Month Transition Schedule



91XX:2009 Transition Requirements

- All CB's shall be accredited for 9104/1 to conduct 91XX:2009 audits
- 91XX:2009 surveillance upgrade audit shall require use of "recertification" audit day table of 9104/1
- 91XX:2009 recertification upgrade audit shall require use of "Initial" audit day table of 9104/1
- Multiple Site 91XX:2009 surveillance upgrade shall include central function and planned sites shall require 9104/1 conformance and use of Category 1 table (based on existing audit cycle)
- Multiple Site 91XX:2009 recertification upgrade shall require 9104/1 conformance and use of Category 1 table