



MANAGING RISK

DNV

# AS9100 Rev. C: Key Changes



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# 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**

- **Structure of Key Changes Slides**
  - **Revision/Relocation, Addition, or Deletion**
  - **Rationale**
  - **Implementation/Audit Considerations**
  
- **9100 Revision Key Changes** (Covered in this presentation)
  - **5 Additions**
  - **6 Revisions/Relocations**
  - **3 Deletions**

## ■ 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.

## ■ 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 state-of-the-art
    - requirements determined by the organization to be at the limit of their technical or process capabilities.

## ■ 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.

## ■ 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

## ■ Clause 3.3 - Critical Items (Continued)

### - Rationale:

- Improve understanding of “Critical Items” coming from Special Requirements.
- 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 critical items processes in the applicable clauses.

## ■ 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
- **Implementation/Audit Considerations:**
  - Auditors need to identify appropriate documented procedures as an inherent part of carrying out the audit

## ■ **Clauses 5.2/8.2.1 – Customer Focus/Satisfaction**

### - **Addition:**

- **Management responsibility for measuring “product conformity” and “on-time delivery” and for taking appropriate remedial actions (5.2)**
- **Requirement to evaluate customer satisfaction using specific QMS information, then develop plans that address deficiencies (8.2.1)**

### - **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**

## ■ 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?**

## ■ 7.1.2 - Risk Management

### - Addition:

- **New requirement to implement a risk management process applicable to the product and organization covering: responsibility, criteria, mitigation & acceptance**

### - Rationale:

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

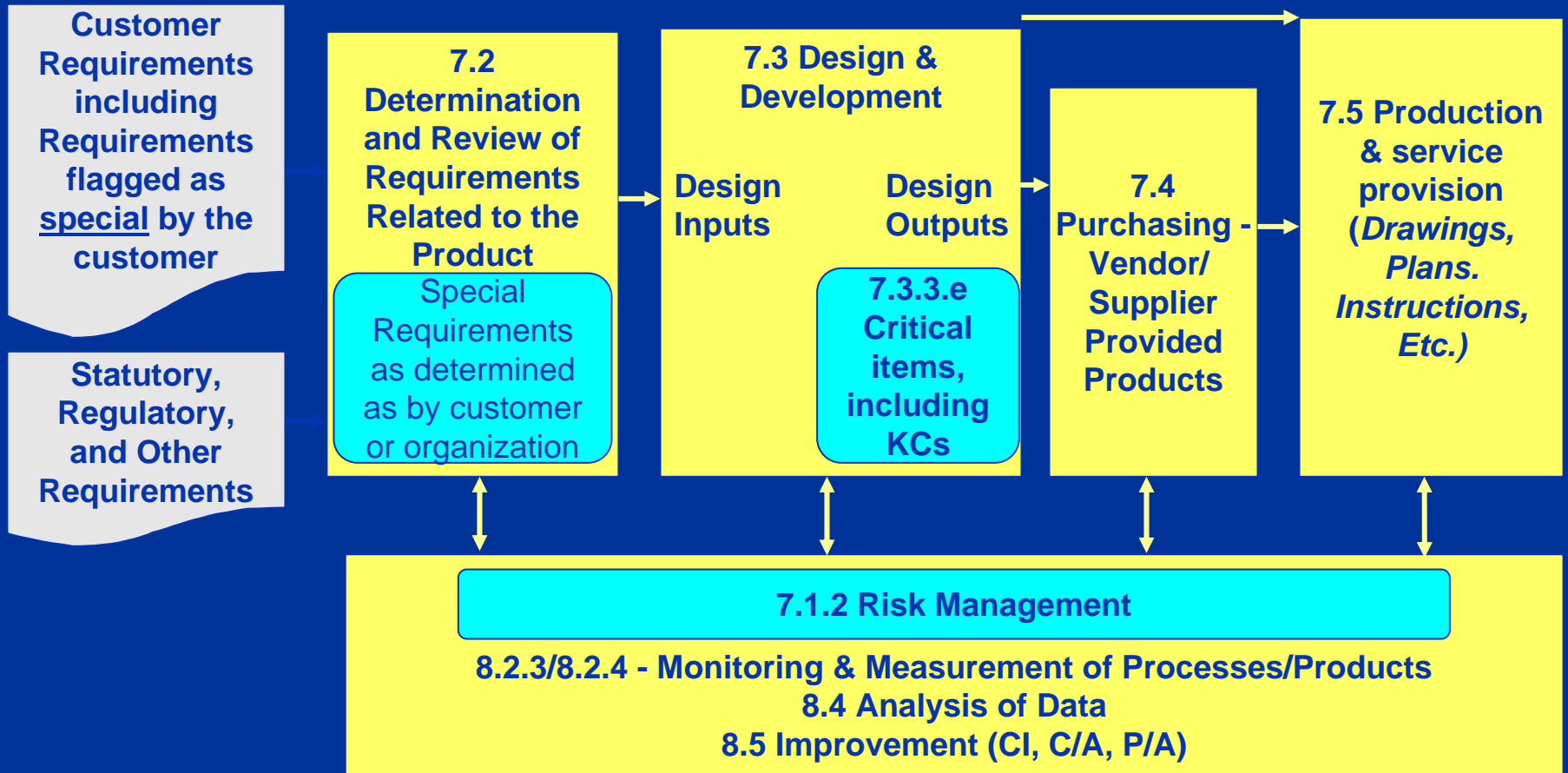
### - Implementation/Audit Considerations:

- **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? Concept of risk is intertwined within the revised 9100.**

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

### 7.1 Planning of Product Realization



## ■ 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

## ■ 7.1.4 – Work Transfer

### - Revision/Relocation:

- Moved from clause 7.5 (Production) to clause 7.1
- The organization must have a process to plan and control the transfer activities
- Expanded to cover permanent transfer

### - 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.

- **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
  - **Implementation/Audit Considerations:**
    - Note only

## ■ 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
  - Unable to develop a process applicable to all stakeholders
- **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.

## ■ 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 validate 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).

### - Rationale:

- Movement to clause 7 acknowledges that this requirement is not primarily a measuring and monitoring process, but a process that will be used to assure product realization 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).

## ■ 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:

- Redundant to the ISO text and 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.

## ■ 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.

# Questions



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