9100 revision 2016
Executive Level Presentation

IAQG 9100 Team
October 2019

9100 revision 2016

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Introduction
reason for revision, team and timeline

What is 9100?
ISO 9001:2015 Baseline Text

9100 Series

International Aviation, Space and Defense Quality Requirements

ADDITIONAL REQUIREMENTS
- Operations Risk Management
  - Product Safety
    - Special Requirements
    - Critical Items
      - Configuration Management
        - On Time Delivery
          - Counterfeit Parts
            - Expanded requirements for production and external providers
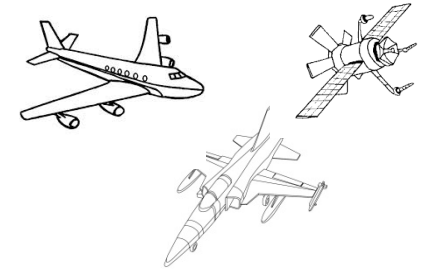
ISO 9001

Quality Management System

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The "ISO 9001" needed to change, to:

- Adapt to a changing world

- Enhance an organization's ability to satisfy its customers

- Provide a consistent foundation for the future

- Reflect the increasingly complex environments in which organizations operate

- Ensure the new standard reflects the needs of all interested parties

- Integrate with other management systems

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The "9100" needs to change, to:

– Incorporate changes made by ISO TC176 to the ISO 9001:2015 requirements
  (ISO liaison organized to collaborate with the IAQG 9100 team and to obtain consideration for IAQG requirements)

– Consider Aviation, Space and Defense stakeholders' needs identified since the last revision
  (web survey performed in 2013)

– Consider clarifications to 9100 series requests issued by IAQG since the last revision
  (requirements clarified or notes added)

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Quality Management Principles

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ISO 9000 Quality Management Principles

There were 8 principles	There are now 7
Customer focus	Customer focus
Leadership	Leadership
Involvement of people	Engagement of people
Process approach	Process approach
System approach to management	(included in the process approach)
Continual improvement	Improvement
Factual approach to decision making	Evidence based decision making
Mutually beneficial supplier relationships	Relationship management

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Key changes
in the ISO 9001 Baseline content

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Key Changes *(from ISO 9001:2015 baseline)*

- High level structure (HLS) & Terminology

- Risk-based thinking - Concept of preventive action now addressed throughout the standard by risk identification and mitigation

- Process approach strengthened with integration of the QMS into organization's business processes

- Emphasis on change management

- Introduction of knowledge management

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Key Changes *(from ISO 9001:2015 baseline)*

- Clearer understanding of the organization's context

- Aligning QMS policy and objectives with the strategy of the organization

- Explicit performance evaluation requirements

- Greater flexibility with documentation

- More compatible with services

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Terminology Changes (from ISO 9001 baseline)

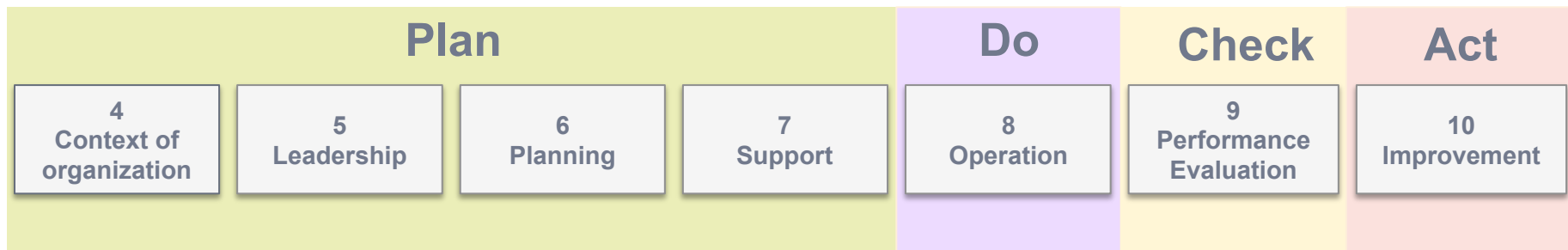| Previous version	New Version
Products	Products and services
Exclusions	Scope of the QMS to be formally defined and all requirements are applicable if they are in the scope
Documentation, records, documented procedures	Documented information • maintained = documents or procedures • retained = records
Purchased product	Externally provided products and services
Supplier	External provider

Documented information does not need to be changed to incorporate new terminology

Definition Hierarchy: IAQG Standards, ISO 9000:2015, IAQG Dictionary, Oxford Dictionary

Use of simplified language and writing styles to aid understanding and consistent interpretation of requirements

High Level Structure

- ISO is going from 8 clauses to 10 clauses

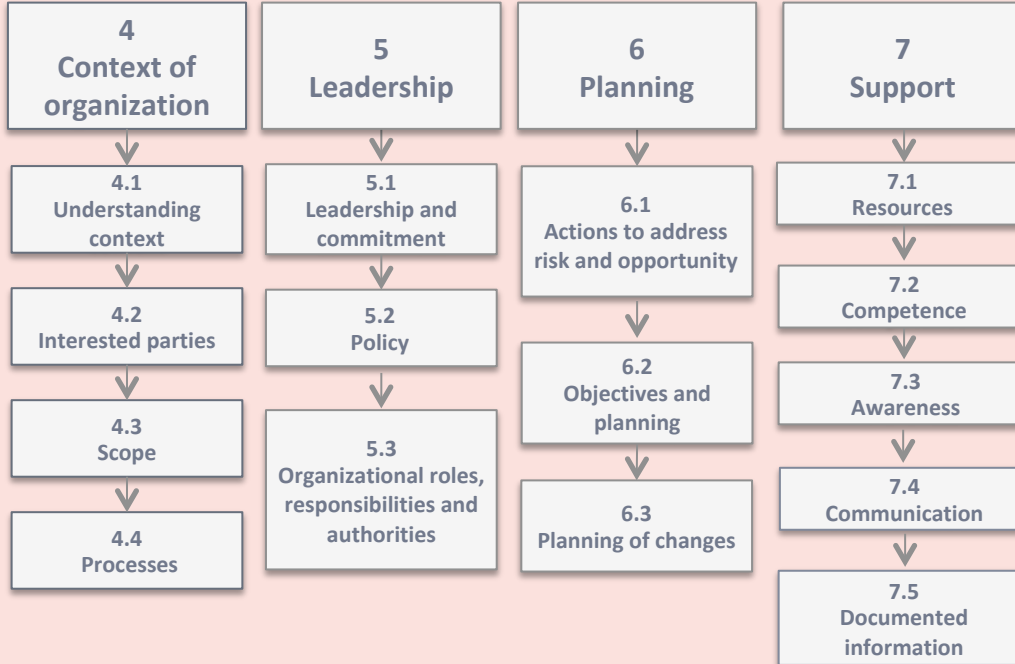| Plan				Do	Check	Act
4 Context of organization	5 Leadership	6 Planning	7 Support	8 Operation	9 Performance Evaluation	10 Improvement

Rationale

- Better alignment to business strategic direction

- PDCA approach

- All ISO management systems standards built on the same structure and same terminology, to facilitate the option of having one integrated management system

- This structure is intended to provide a coherent presentation of requirements rather than a model for documenting an organization's policies, objectives and processes

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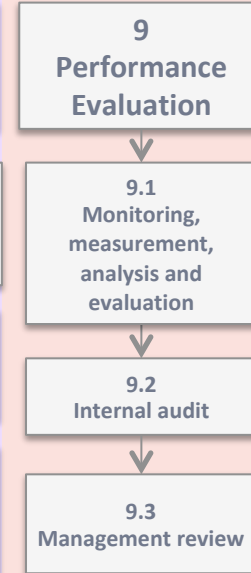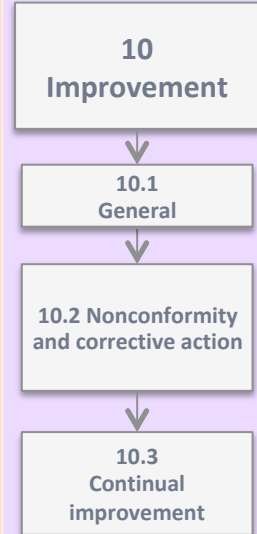## HLS: High Level Structure (from ISO 9001 baseline)

Plan				Do	Check	Act

Plan

4 Context of organization
- 4.1 Understanding context
- 4.2 Interested parties
- 4.3 Scope
- 4.4 Processes

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

6 Planning
- 6.1 Actions to address risk and opportunity
- 6.2 Objectives and planning
- 6.3 Planning of changes

7 Support
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

Do

8 Operation
- 8.1 Operational planning and control
- 8.2 Requirements for products & services
- 8.3 Design and Development of products & services
- 8.4 Control of externally provided processes, products & services
- 8.5 Production and service provision
- 8.6 Release of products & services
- 8.7 Control of nonconforming outputs

Check

9 Performance Evaluation
- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

Act

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

9100 Revision 2016

Key changes
in the 9100 additions

9100 revision 2016

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

As a consequence of the new ISO 9001 structure:

- 9100 additions have been **relocated** into appropriate ISO sections

- the requirements are better **organized** and **clarified**, with notes and examples to enhance understanding

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

- **Product safety**
  added in a separate clause and in selected areas

- **Counterfeit parts prevention**
  added in a separate clause and in selected areas

- **Risk**
  merged current 9100 requirements with the new ISO requirements and emphasis on risks in operational processes

- **Awareness**
  reinforced requirements for awareness of individual contribution to quality

- **Human factors**
  included as a consideration in nonconformity / corrective action

- **Configuration management**
  clarified and improved to address stakeholder needs

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High Level Summary of Changes Implementation benefits

9100 revision 2016

9100 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

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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

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Deployment Support Material
Where to find it ?

Path through the IAQG web site

www.iaqg.org

The IAQG is a legally incorporated international not for profit association (INPA) with membership from the Americas, Europe and the Asia Pacific Region

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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-Series - QMS: Aviation, Space and Defense Organizations Standards Clarifications
  - 9100:2016 Series Clarification Table

- 9100:2016 - QMS: Aerospace Improvement Maturity Model (AIMM) *(In Development)*

- 9100:2016 - QMS: Aviation, Space and Defense Organizations Guidance Materials
  - Support Materials
    - Frequently Asked Questions (FAQs)
    - Gap Assessment Worksheet
    - 9100 Evaluation Guidance Material
    - Relationship between IAQG Standards and 9100:2016 Standard (Table C1)
  - Correlation Materials
    - Correlation matrices between 9100:2009 and 9100:2016
    - Matrix of 9100:2009 mapped against the 9100:2016
    - Correlation of 9100:2016 mapped against EASA Commission Regulation (EU) 748/2012 Part-21
    - Correlation of 9100:2016 mapped against FAA Part-21
  - Presentations
    - Executive Level Summary Presentation
    - Key Changes Presentation
    - Clause-by-Clause Presentation
    - 9100:2016-Series Major Changes Recording (in Development)
  - Articles: Reprinted with permission from Quality Progress © 2019 ASQ, www.asq.org. All rights reserved. No further distribution allowed without permission.
    - 2019 February ASQ Quality Progress: We Have Liftoff
    - 2019 May ASQ Quality Progress: The Complete Package

Questions

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