9100:2016

EXECUTIVE OVERVIEW

IAQG 9100 Team
January 2020

9100:2016-Series Revision

Table of contents

- **Introduction** *(change activity)*

- **Quality Management Principles**

- **Key changes in ISO 9001 and 9100**

- **High level summary of changes and benefits**

- **Deployment Support Material - Where to find it ?**

9100:2016
QUALITY MANAGEMENT SYSTEM

INTRODUCTION

9100 Relationship to ISO 9001

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

9100:2016
QUALITY MANAGEMENT SYSTEM

QUALITY MANAGEMENT PRINCIPLES

9100:2016-Series Revision

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

9100:2016-Series Revision

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

9100:2016-Series Revision

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

9100:2016-Series Revision
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
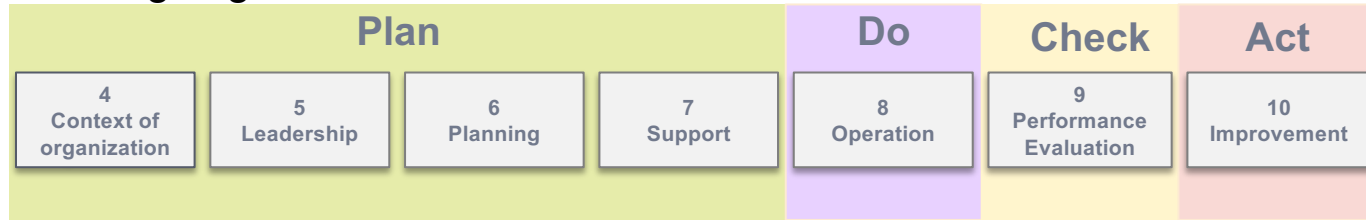
9100:2016-Series Revision
HLS: High Level Structure (from ISO 9001 baseline)

High Level Structure

- ISO is going from 8 clauses to 10 clauses

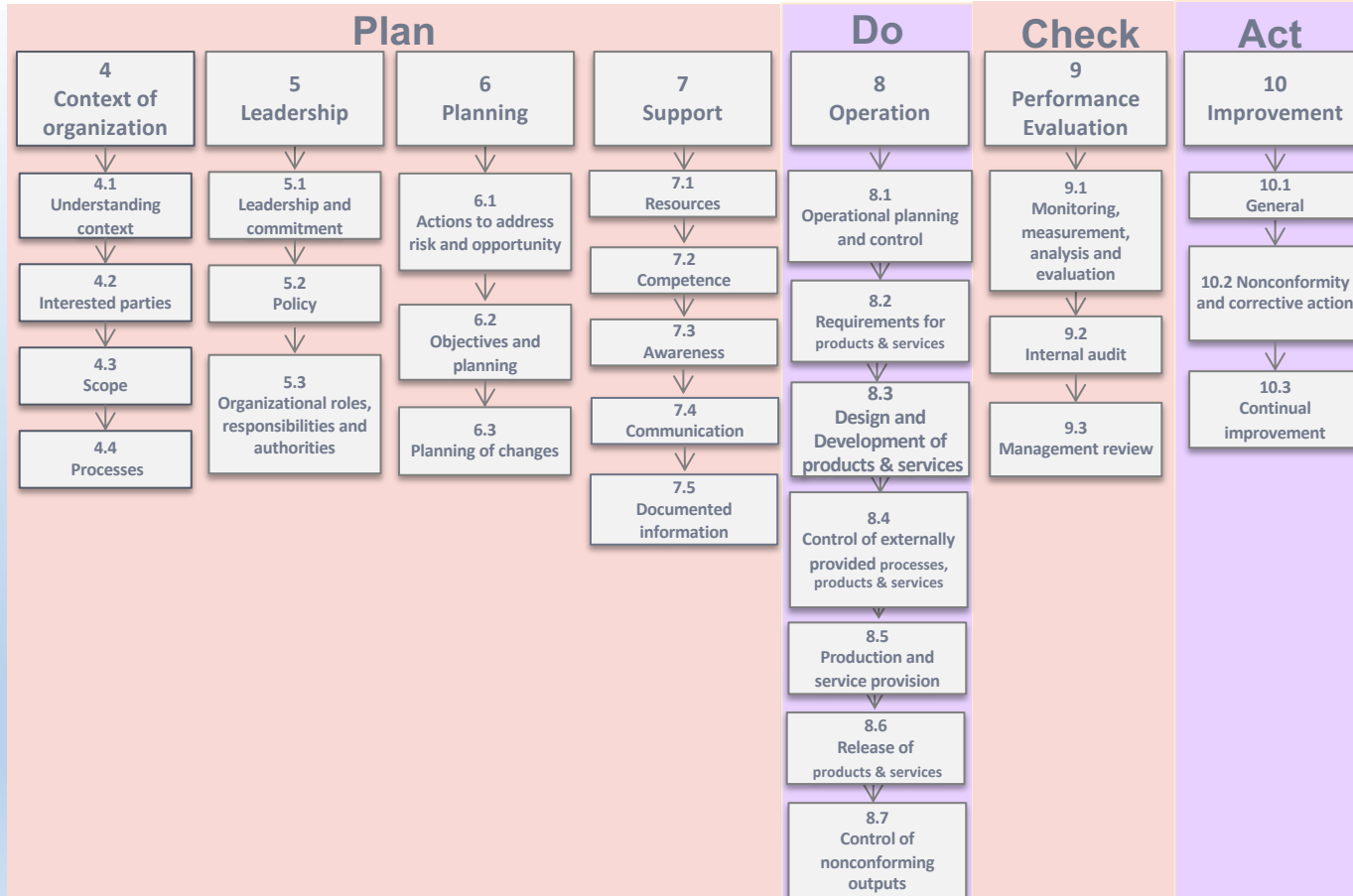| Plan				Do	Check	Act
4 Context of organization	5 Leadership	6 Planning	7 Support	8 Operation	9 Performance Evaluation	10 Improvement

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

9100:2016-Series Revision
HLS: High Level Structure (from ISO 9001 baseline)

Plan

4 Context of organization	5 Leadership	6 Planning	7 Support
4.1 Understanding context	5.1 Leadership and commitment	6.1 Actions to address risk and opportunity	7.1 Resources
4.2 Interested parties	5.2 Policy	6.2 Objectives and planning	7.2 Competence
4.3 Scope	5.3 Organizational roles, responsibilities and authorities	6.3 Planning of changes	7.3 Awareness
4.4 Processes			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

9100:2016-Series Revision

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

As a consequence of the new ISO 9001 structure:

- 9100:2016 additions have been **relocated** into appropriate ISO sections

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

9100:2016-Series Revision

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

9100:2016

QUALITY MANAGEMENT SYSTEM

HIGH LEVEL SUMMARY OF CHANGES AND BENEFITS

9100:2016-Series Revision
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

9100:2016-Series Revision

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 specific documents

  – Recognized by Regulatory Authorities

9100:2016
QUALITY MANAGEMENT SYSTEM

SUPPORT MATERIAL – WHERE TO FIND IT?

Path through the IAQG website

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 (Rev. 08-2015)

Questions

The IAQG is a legally incorporated international not for profit association (INPA) with membership from the Americas, Europe and the Asia Pacific Region (Rev. 08-2015)