9100 revision 2016
Key changes presentation

IAQG 9100 Team

December 2015

9100 revision 2016

Table of contents

- Reasons for revision
- Team members and timeline for the revision
- Key changes & implementation benefits
- Clause-by-Clause summary of changes
- Sections containing the “Click for More” contents on:

→ Terminology & High Level Structure
→ Risk Based Thinking
→ Process Approach
→ Concept of Change
→ Product Safety
→ Prevention of Counterfeit Parts
→ Human Factors
→ Quality Management Principles

The intent of the presentation is to be dual purpose…for both general users and experts (using ‘click for more’ options to view additional information)

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Reason for the revision

9100 revision 2016

The “ISO 9001” needs 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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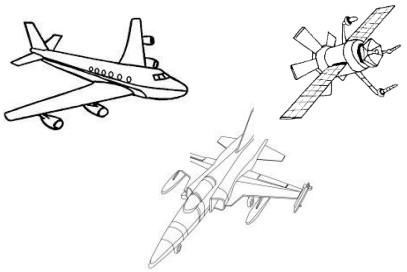

The “9100” needs to change, to:

- 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)

IAQG 9100 Series Team

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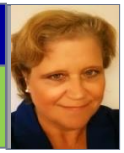

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IAQG/Sector 9100 Team Structure

IAQG 9100 Writing Team collects sector and stakeholder input and creates a rough draft. (8)

IAQG 9100 Team collects sector and stakeholder input and writes the revision (14)

Representatives of Sector 9100 Team at International Meetings (9)

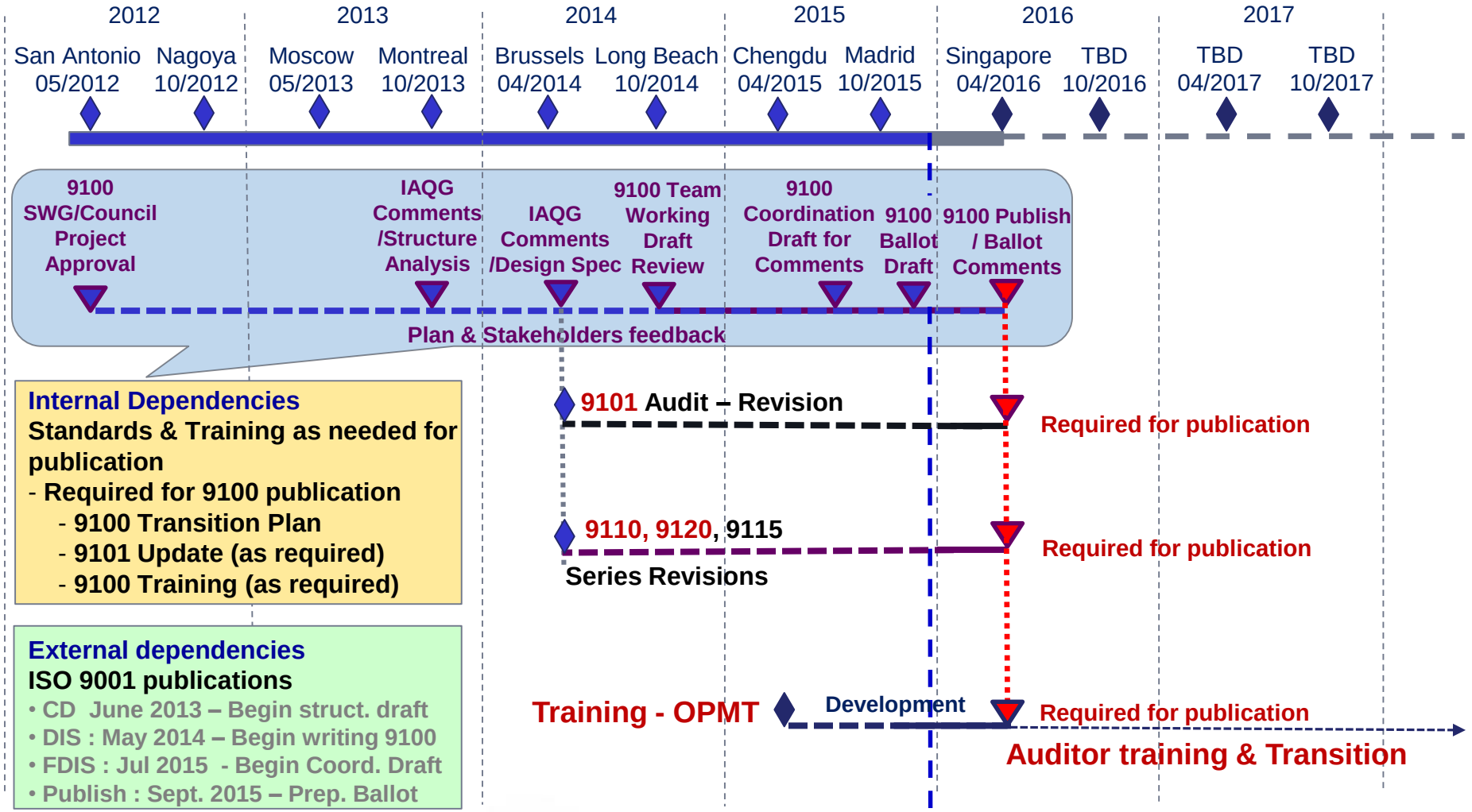
Sector 9100 Team Meetings to gather Sector inputs and develop Sector positions. Operation managed at Sector Level (58)

9100 Revision Timeline

Complete	Oct 2013	Stakeholder Feedback Resolution
Complete	Apr 2014	Concept Sub-team Proposals
Complete	Jun 2014	Integrate ISO 9001 Draft with 9100
Complete	Jul 2014	ISO 9001:2015 Draft Comments
Complete	Jul 2014	Structure Draft (team)
Complete	Oct 2014	Working Draft (team)
Complete	July 2015	Coordination Draft (IAQG)
→	Dec 2015	Ballot (IAQG)
	Apr 2016	9100 Series Publication

- These dates are contingent on consensus on decisions / ballots to proceed at each stage
- Actual standards publication depends on sector publication scheme & schedule

9100 Series Revision - Integrated Schedule



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Key changes

in the ISO 9001 text

and in the 9100 additions

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Key Changes *(from ISO 9001:2015)*

- High level structure (HLS) & Terminology
- Risk-based thinking
- Process approach strengthened with integration of the QMS into organization's business processes
- Emphasis on change management
- Concept of preventive action now addressed throughout the standard by risk identification and mitigation
- Introduction of knowledge management

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Key Changes *(from ISO 9001:2015)*

- 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

Not required to adjust strictly the organization QMS to the new structure and terminology

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Key Changes *(in the ASD 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 *(in the ASD 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
- Configuration management
  clarified and improved to address stakeholder needs
- Awareness
  reinforced requirements for awareness of individual contribution to quality
- Human factors
  included as a consideration in nonconformity / corrective action

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9100 Series 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	▪Quality manual not required, maintained documentation is required ▪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 (preventive) ▪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 <u>implemented and managed well:</u>
  - 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 and managed
  - 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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End of presentation for general audience

Questions

The remainder of the presentation contains

- Clause-by-Clause summary of changes in ISO 9001 and the 9100 additions
- Sections containing the “Click for More” information contents
  - → Terminology & High Level Structure
  - → Risk Based Thinking
  - → Process Approach
  - → Concept of Change
  - → Product Safety
  - → Prevention of Counterfeit Parts
  - → Human Factors
  - → Quality Management Principles

9100 Revision 2016

Summary of changes
- clause by clause -

9100 revision 2016

The following slides will provide you a summary, clause by clause of the key changes

- **from the 9100:2009**
- **to the 9100:2016 Ballot Draft**

Key changes are identified by:

- ISO 9001 >>>>>>>
- ***9100 additions*** >>

9100 revision 2016

Summary of changes - clause by clause

Foreword, Revision summary/Rationale, Intended application

Introduction

- 0.1 General
- 0.2 Quality management principles
- 0.3 Process approach
  - Plan-Do-Check-Act cycle
  - Risk-based thinking
- 0.4 Relationship with other management system standards

0.1 General → Includes verbal significations of "shall, should, may, can"

0.2 Quality management principles → 7 principles to consider

0.3 Process approach → Schematic representations of a
- a process
- the standard (with a PDCA approach)

Requirements

1. Scope

2. Normative references

3. Terms and definitions

- *Special requirements*
- *Critical items*
- *Key characteristic*
- *Counterfeit part* → *Definition added*
- *Product safety* → *Definition added*

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Summary of changes - clause by clause

4. Context of the organization

4.1 Understanding the organization and its context	Determine relevant external issues (legal, technological, competitive, market, cultural, social, and economic environments) and internal issues (values, culture, knowledge, and performance of the organization)
4.2 Understanding the needs and expectations of interested parties	Determine relevant interested parties and their requirements (such as customers, partners, authorities)
4.3 Determining the scope of the quality management system	Document the scope of the QMS and justification for any case where a requirement cannot be applied (exclusion)
4.4 Quality management system and its processes	Define the documented information to be maintained or to be retained "to the extent necessary"
	Explicit requirement for a documented information maintained with content defined (can be called quality manual) *(not required by ISO)*

9100 revision 2016

Summary of changes - clause by clause

5. Leadership

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

Leadership instead of only management of responsibilities (management to demonstrate their leadership)

Top management to ensure integration of QMS into business processes (now explicit)

Policy aligned with organization strategic direction

A "management representative" required as focal point for QM issues (removed from ISO 9001:2015)

6. Planning

- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes

Determine risks and opportunities, considering the issues raised and requirements identified.

Plan appropriate actions to reduce undesired effects on the QMS and evaluate effectiveness

Planning the achievement of objectives more prescriptive and includes the evaluation of results

Changes to the QMS to be carried out in a planned manner

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Summary of changes - clause by clause

7. Support

- **7.1 Resources**
  - 7.1.1 General
  - 7.1.2 People
  - 7.1.3 Infrastructure
  - 7.1.4 Environment for the operation of processes
  - 7.1.5 Monitoring and measuring resources
  - 7.1.6 Organizational knowledge
- **7.2 Competence**
- **7.3 Awareness**
- **7.4 Communication**
- **7.5 Documented information**
  - 7.5.1 General
  - 7.5.2 Creating and updating
  - 7.5.3 Control of documented Information

Environment includes human and physical factors

Determine necessary knowledge gained from experience, lessons learned, success, failures, conferences, …

Added the requirement for persons to be aware of:

- ***their contribution to product or service conformity***
- ***their contribution to product safety***
- ***the importance of ethical behavior***

New terminology (replacing “documents” and “records”)

No requirement for 6 mandated procedures, but still a requirement to identify the documented information & processes needed for the QMS

Added the requirement to define data protection processes for documented information managed electronically

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Summary of changes - clause by clause

8. Operation

8.1 Operational planning and control

***Project Management** (9100:2009 clause 7.1.1) and Control of **Work Transfers** (9100:2009 clause 7.1.4) no more separated clauses but incorporated in clause 8.1 (with risk concept introduced for work transfer) and clarified*

Reinforce the planning and control activities with dispositions to ensure On-Quality and On-Time delivery of products or services

8.1.1 Operation risk management

Based on the requirements of 9100:2009 (7.1.1) this clause is related to risks in operational processes defined in clause 8 (no major change) while 6.1 is related to risks in QMS of the organization

8.1.2 Configuration management

Based on the requirements of 9100:2009 (7.1.3), revised to clarify stakeholders expectations

8.1.3 Product safety

Added new requirements to address "product safety" considerations throughout the product lifecycle

8.1.4 Prevention of counterfeit parts

Added new requirements to prevent the use of counterfeit or suspect counterfeit parts

9100 revision 2016

Summary of changes - clause by clause

8. Operation

8.2 Requirements for products and services

- 8.2.1 Customer communication
- 8.2.2 Determining the requirements related to products and services
- 8.2.3 Review of the requirements related to products and services
- 8.2.4 Changes to requirements for products and services

Added requirement that review shall be coordinated with applicable functions of the organization

Added requirement for actions in case of not meeting some customer requirements

8.3 Design and development of products and services

- 8.3.1 General
- 8.3.2 Design and development planning
- 8.3.3 Design and development inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes

Clause re-structured to allow for a more process orientated approach

Added requirement to take account of handling obsolescence, where applicable

Added requirement for a process and criteria for notifying customers, about changes that affect customer requirements

9100 revision 2016

Summary of changes - clause by clause

8. Operation

8.4 Control of externally provided processes, products and services

New terminology. Clause covering the previous "purchases" and "outsourcing"
Externally provided processes include "outsourced processes" (processes needed for the QMS, for which 4.4 applies in addition to 8.4).

8.4.1 General

Explicit requirement for external providers to apply appropriate controls to their direct and sub-tier external providers

8.4.2 Type and extent of control

Added evaluation of data on test reports provided, to confirm the results comply with requirements *(e.g. results of test reports received from external providers checked regarding tolerances requirements)*

Added validation process of tests reports accuracy for raw materials identified as a significant operational risk *(e.g. periodic scheduled tests performed on samples for critical raw materials)*

8.4.3 Information for external providers

More explicit topics to be considered to communicate requirements to external providers

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Summary of changes - clause by clause

8. Operation

8.5 Production and service provision

8.5.1 Control of production and service provision

8.5.2 Identification and traceability

8.5.3 Property belonging to customers or external providers

8.5.4 Preservation

8.5.5 Post-delivery activities

8.5.6 Control of changes

8.6 Release of products and services

8.7 Control of nonconforming outputs

This clause considers monitoring and measurement activities will ensure the control of processes and outputs, and that acceptance criteria for products and services are met.

Review structure of sub-clauses:

- ***8.5.1.1 "Control of equipment, tools and software programs"***
- ***8.5.1.2 "Validation and control of special processes"***
- ***8.5.1.3 "Production process verification"***

New ISO clause (as per 9100:2009)

Clarified that when problems are detected after delivery the organization shall take appropriate actions

New ISO clause to emphasize on this topic

New ISO clause to verify that all activities have been carried out before release and delivery by authorized persons

Outputs including products and services

Maintained the requirement for a "procedure" to define the NC process and responsibilities on this key topic for ASD

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Summary of changes - clause by clause

9. Performance evaluation

- 9.1 Monitoring, measurement, analysis and evaluation
  - 9.1.1 General
  - 9.1.2 Customer satisfaction
  - 9.1.3 Analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement

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

Annex (informative)

- A. Clarification of new structure, terminology and concepts
- B. Standards developed by ISO/TC 176
- C. Standards developed by IAQG

Bibliography

Specific requirements for analysis and evaluation when using results as inputs to management review
Outputs from the analysis are clearer

Explicit topics to consider for the internal audit programme(s)

Added "on-time delivery performance" as input

Added requirement to evaluate the need for action based on human factors to ensure nonconformities do not recur

Nonconformity and corrective action "procedure" added back-in from ISO

For risk management, added the 9100 clarification

Full list of IAQG standards available

Questions

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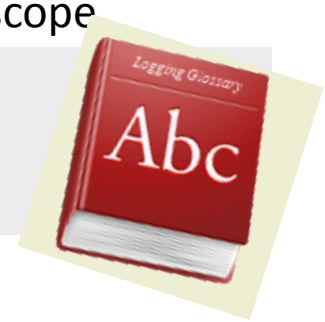
Terminology &

High Level Structure (HLS)

9100 revision 2016

Terminology Changes (from ISO 9001)

Current 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



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

Key benefits of the High Level Structure (HLS)

A new common format has been developed for ISO 9001

- All ISO management systems standards will look the same with the same structure
- More efficient to address multiple management system requirements
- Facilitate the option of having one integrated management system
- Standardized core definitions

As ISO 9001 is the basis for 9100, the new clause structure is duplicated in 9100

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HLS: High Level Structure (from ISO 9001)

High Level Structure

- ISO is going from 8 clauses to 10 clauses

Rationale

- Better alignment to business strategic direction
- PDCA approach
- More compatible with other management system standards

Implementation Considerations

- Need to review your current QMS structure ?
  (preferable to adapt the QMS structure to the Business Processes)

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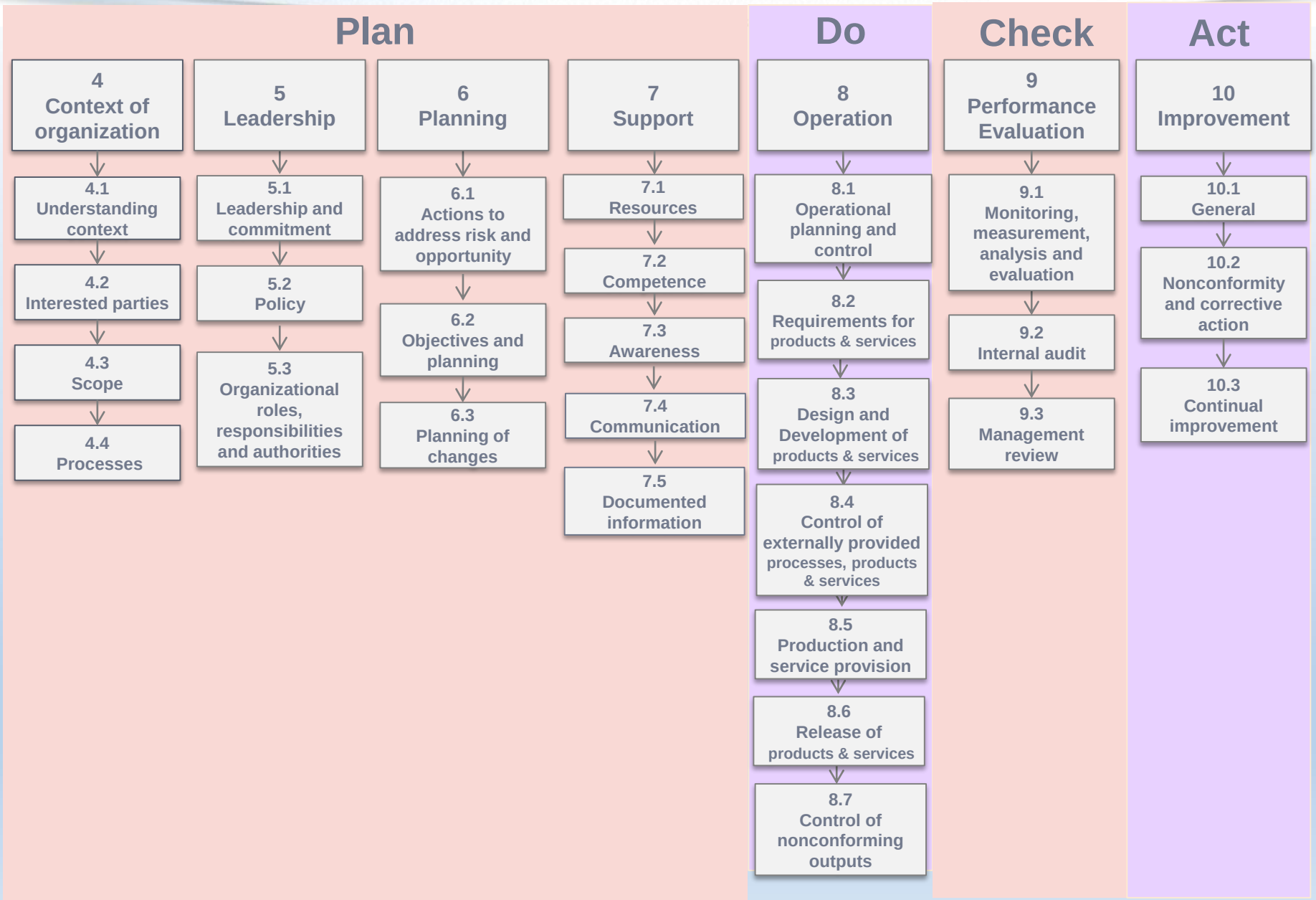
HLS: High Level Structure (from ISO 9001)



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HLS: High Level Structure (from ISO 9001)

HLS Table of Contents – ISO 9001 / 9100

1 Scope

2 Normative references

3 Terms and definitions

4 Context of the organization

4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Determining the scope of the quality management system
4.4 Quality management system and its 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 risks and opportunities
6.2 Quality objectives and planning to achieve them
6.3 Planning of changes

HLS Table of Contents – ISO 9001 / 9100

7 Support

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

8 Operation

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

HLS Table of Contents – ISO 9001 / 9100

9 Performance evaluation

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

10 Improvement

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

Implementation Considerations

Annex A in 9100:2016 states the following:

- The clause structure and some of the terminology have been changed to improve alignment with other management systems standards.
- The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization's quality management system.
- The structure of clauses is intended to provide a coherent presentation of requirements rather than a model for documenting an organization's policies, objectives and processes.
- There is no requirement for the structure of an organization's quality management system documentation to mirror that of the International Standard.

Implementation Considerations

If your current documentation system is structured (based) on a previous revision of the standard, consider re-arranging your QMS documentation around the value stream of your company!

- A value-stream based QMS allows you to customize your documentation to your unique business needs that makes sense to your leadership and associates – it describes what you do
- It supports compliance to the new requirement to integrate your QMS to your business processes
- It sets a foundation for the future. Change will be dictated by the business – not by a structure change of the standard on which it is based.

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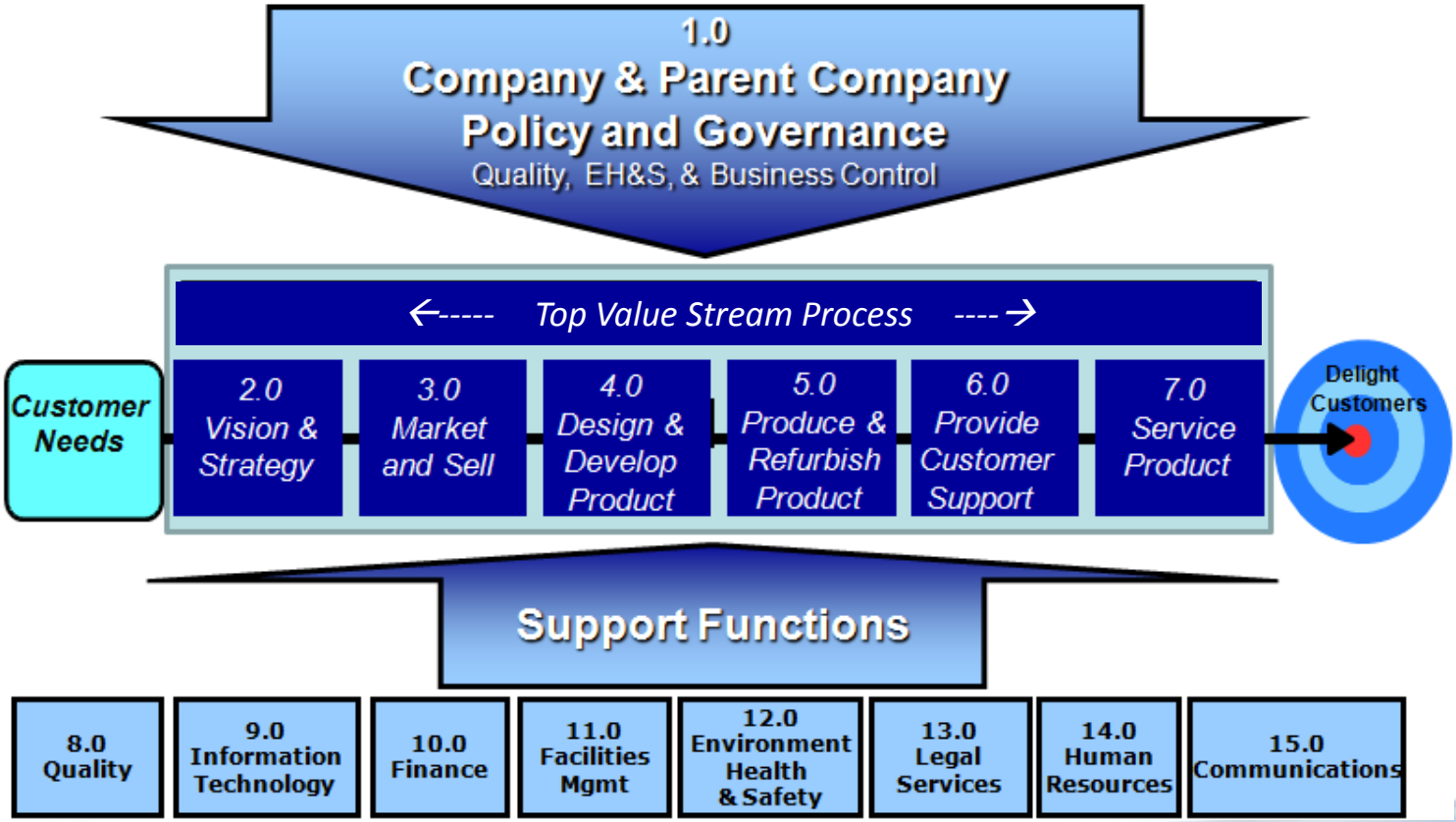
HLS: High Level Structure (from ISO 9001)

Implementation Considerations

Example of Process Based QMS

Company Management System around a Value Stream



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Risk Based Thinking

What is risk-based thinking?

- Risk-based thinking is something we all do automatically and often sub-consciously to get the best result
- The concept of risk has always been implicit in ISO 9001 - this edition makes it more explicit and builds it into the whole management system
- Risk-based thinking ensures risk is considered from the beginning and throughout
- Risk-based thinking makes preventive action part of strategic and operational planning

Rationale

- **Successful companies intuitively take a risk-based approach because it brings benefits**
  - ✓Understand the impact of risk on operational processes
  - ✓Improve customer confidence and satisfaction
  - ✓Assure consistency of quality of goods and services
  - ✓Establish a proactive culture of prevention and improvement

Implementation considerations

- Use a risk-driven approach throughout your organizational processes
- Identify and prioritize what the risks are in your organization *(it depends on context: product or process complexity, organizational complexity)*
  - ✓ *what is acceptable?*
  - ✓ *what is unacceptable?*
- Plan actions to address the risks
  - ✓ *how can I avoid, eliminate or mitigate risks?*
- Implement the plan; *take action*
- Check the effectiveness of the action; *does it work?*
- Learn from experience; *improve*

Conclusion: Risk-based thinking

- Is not new
- Is something you do already
- Is continuous
- Ensures greater knowledge of risks and improves preparedness
- Increases the probability of reaching objectives
- Reduces the probability of negative results
- Makes prevention a habit

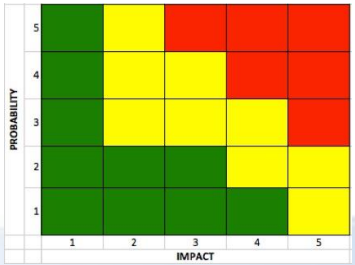
9100 additions highlight that:

Clause 6.1 is related to risks in “QMS of the organization”:

- Manage risks at organization / processes level
  (such as: new customers, new market, company partnerships, business localizations, …)

Clause 8.1.1 is related to the risks in “Operational Processes” defined in clause 8:

- Implement a formal process to manage risks
- Deploy the risks analysis within the operation activities
  (such as : contract review and signature, new technologies introduction, external providers selection, …)



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Process approach

9100 revision 2016

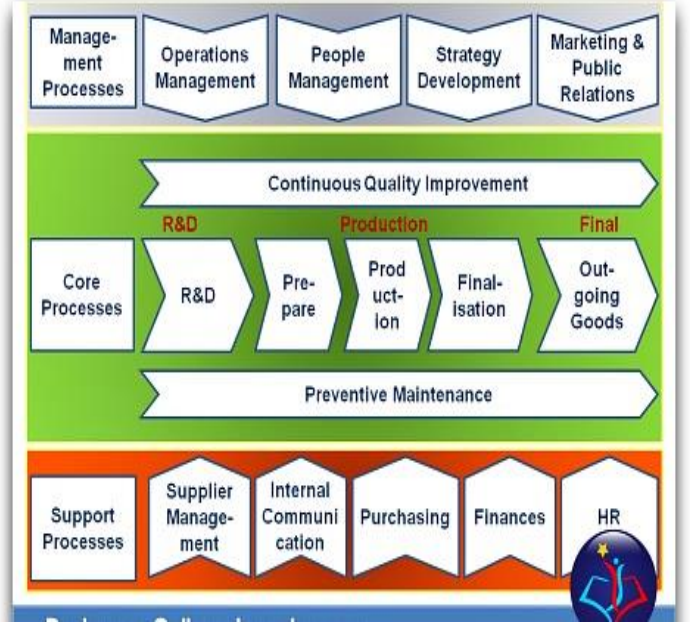
Process Approach

What is the process approach?

- The systematic management of processes and their interactions to achieve intended results

All organizations use processes to:

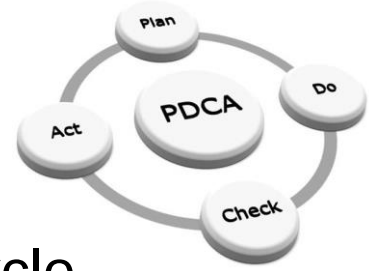
- set interrelated or interacting activities
- transform inputs into outputs
- build in checks to meet objectives and
- promote continuous improvement



The process approach integrates processes into a holistic system in order to achieve strategic and operational objectives

Process approach & risk-based thinking

- the process approach incorporates risk-based thinking
- risk-based thinking ensures risk is considered when establishing, implementing and maintaining a management system, each process and each activity



The process approach & PDCA

- Processes can be managed using the PDCA cycle

Plan	set objectives and build processes necessary to deliver results
Do	implement what was planned
Check	monitor and measure processes and results against the objectives
Act	take actions to improve results

What are the possible benefits?

- increases accountability
- increases ability to focus on key processes
- improves internal integration of processes
- more consistent results
- better use of resources
- improves customer confidence in the organization

What processes to define for my organization?

- The “Key” “Core” or “Business” processes:
  - ➔ They must follow all the 4.4 requirements
  - ➔ Certified organizations will be audited for their effectiveness: a PEAR sheet *(Process Effectiveness Assessment Report)* will be established by the certification body auditor for all Operation Processes *(refer to 9101)*
- The other processes:
  - ➔ Necessary processes to manage functioning / working activities *(e.g. the risks, the products configuration, the critical items, the product safety, the internal audits, the nonconformities and corrective actions)*
  - ➔ Determine whether flowcharts, routines, maps or procedures are needed to ensure effective implementation

Each organization has to determine these processes

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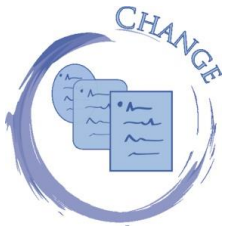
Concept of "change"

Introducing the concept of change

The standard has become a dynamic framework which evolves to enable organizations to adapt to their changing environments or circumstances



Change is addressed in the following clauses:

- Planning/implementing changes to the QMS (6.3)
- Organizational knowledge - for addressing changing needs and trends, with respect to knowledge (7.1.6)
- Controlling operational changes, planned and unintended (8.1)
- Managing changes relating to design and development (8.3.6)
- Addressing changes affecting production or service provision (8.5.6)

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Product Safety

9100 revision 2016

Product Safety

Revision / Addition

- New clause on Product Safety, including requirements to assure product safety and a note giving examples of the associated processes
  and revision for consistency of other clauses related to safety – 7.3, 8.1, 8.4.3 & 8.5.4

Rationale

- Industry acknowledgement of the importance of increasing safety
- Recognition of the 9100 certifications by authorities is part of IAQG strategy

Implementation considerations

- Address product safety considerations throughout the product lifecycle (use the NOTE as guidance)
- A full Safety Management System (SMS) as defined by ICAO (International Civil Aviation Organization) is not required by 9100, but the introduction of this new clause contributes to the SMS approach

Product safety definition (3.4)

- The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property

Examples of activities

- **Assessment of hazards and mitigation of associated risks:**
  - ✓ Implement FMEA relating to product (DFMEA) and process (PFMEA)
  - ✓ Perform safety analysis
  - ✓ Identify and mitigate risks relating to the organization and its personnel (human factors, management of responsibilities)
- **Management of safety critical items:**
  - ✓ Define and implement a monitoring control plan for critical items identified through FMEA and safety analysis

Examples of activities (cont.)

- **Analysis and reporting of occurred events affecting safety:**
  - ✓ Organize the collection of potential and occurred events, and analyze their impacts with specialists
  - ✓ Organize the internal escalation process and external reporting to interested parties
  - ✓ Analyze the adverse trends of products in service reliability and define appropriate actions

- **Communication of these events and training of personnel:**
  - ✓ Promote safety culture and lessons learned from occurred events (impacts of the parts delivered by the organization on the final product safety)
  - ✓ Prevent occurrence of safety issues by taking into account industry experience (including occurrences on other products with similar functions or based on same technologies or components)

9100 Revision 2016

Prevention of counterfeit parts

9100 revision 2016

Counterfeit Parts

Addition

- New clause including requirements for prevention of counterfeit parts and a note giving examples of the associated processes
  and revision of affected clauses: 3 (definition), 8.4 (external provisions) & 8.7 (nonconformities)

Rationale

- Mitigate effects of growing threat of counterfeit / fraudulent product
- Recognize the emerging counterfeit/fraudulent statutory/regulatory requirements on QMS processes

Implementation considerations

- To address counterfeit products risks in:
  - ✓ Internal activities such as: obsolescence management, nonconformance control, reporting, training
  - ✓ Activities regarding external providers such as: procurement, sources selection, control & inspection

Implementation considerations

- **Risk**
  - ✓ Understand risks associated throughout the Operational Processes for introducing Counterfeit/Fraudulent Parts into delivered product
  - ✓ Create preventions and mitigations within individual process steps to address Counterfeit/Fraudulent Parts risks
- **Design/obsolescence**
  - ✓ Ensure design decisions and parts selections are appropriate for contract and service life of product
- **Procurement, source selection, supplier control, & inspection**
  - ✓ Understand correlation of risk associated with Source Selection with Procurement, Supplier Control and Inspection options
  - ✓ Apply appropriate actions in Supplier Control and Inspections based on identified risks

Implementation considerations

- **Nonconformance control**
  - ✓ Segregate and control suspected or known counterfeit products
  - ✓ Ensure these products are not re-introduced into the supply chain
- **Reporting**
  - ✓ Report incidences of counterfeit/fraudulent products in appropriate government and industry reporting systems
- **Training**
  - ✓ Ensure training of appropriate personnel on awareness of impacts of counterfeit parts in Aviation, Space and Defense products
  - ✓ Create understanding of process methods for ensuring prevention of counterfeit parts from entering the product

9100 Revision 2016

Human Factors

9100 revision 2016

Human Factors

Addition

- Requirement to include the human factors considerations in the root causes analysis of nonconformities

Rationale

- To reinforce the controls linked to clause 7.1.4 (environment for the operation of processes) and clause 8.5.1. g (prevention of human errors)
- Recognize the importance of human factors in the origin of nonconformities

Implementation considerations

- Determine the human factors to be considered according to the products, workplaces, equipment and people of the organization
- Include them in the list of fields to be reviewed during the root causes analysis of nonconformities
- Capitalize with lessons learned on occurred human errors

9100 Revision 2016

Quality Management Principles

9100 revision 2016

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