



9100:2016 Series Transition Timeline

June 2016

9100:2016 Series Publication Timeline:



9100:

Step 5 “Disposition of Comments & Ballot approval” finished:

12 June 2016

Step 6 “Formatting of Sector Versions” complete:

Beginning of August 2016

Step 7 “Publication Approval” complete:

End of August 2016

Step 8 “Publication” complete:

End of September 2016

9110:

Step 5 “Disposition of Comments & Ballot approval” finished:

23 May 2016

Step 5 “SAE Aero Council Ballot approval” complete:

10 July 2016

Step 6 “Formatting of Sector Versions” complete:

Mid of September 2016

Step 7 “Publication Approval” complete:

End of September 2016

Step 8 “Publication” complete:

Beginning of November 2016

9120:

Step 5 “Disposition of Comments & Ballot approval” finished:

17 April 2016

Step 5 “SAE Aero Council Ballot approval” complete:

10 July 2016

Step 6 “Formatting of Sector Versions” complete:

Mid of September 2016

Step 7 “Publication Approval” complete:

End of September 2016

Step 8 “Publication” complete:

End of October 2016

9101:

Step 5 “Disposition of Comments & Ballot approval” finished:

16 June 2016

Step 6 “Formatting of Sector Versions” complete:

End of September 2016

Step 7 “Publication Approval” complete:

Mid of October 2016

Step 8 “Publication” complete:

End of October 2016

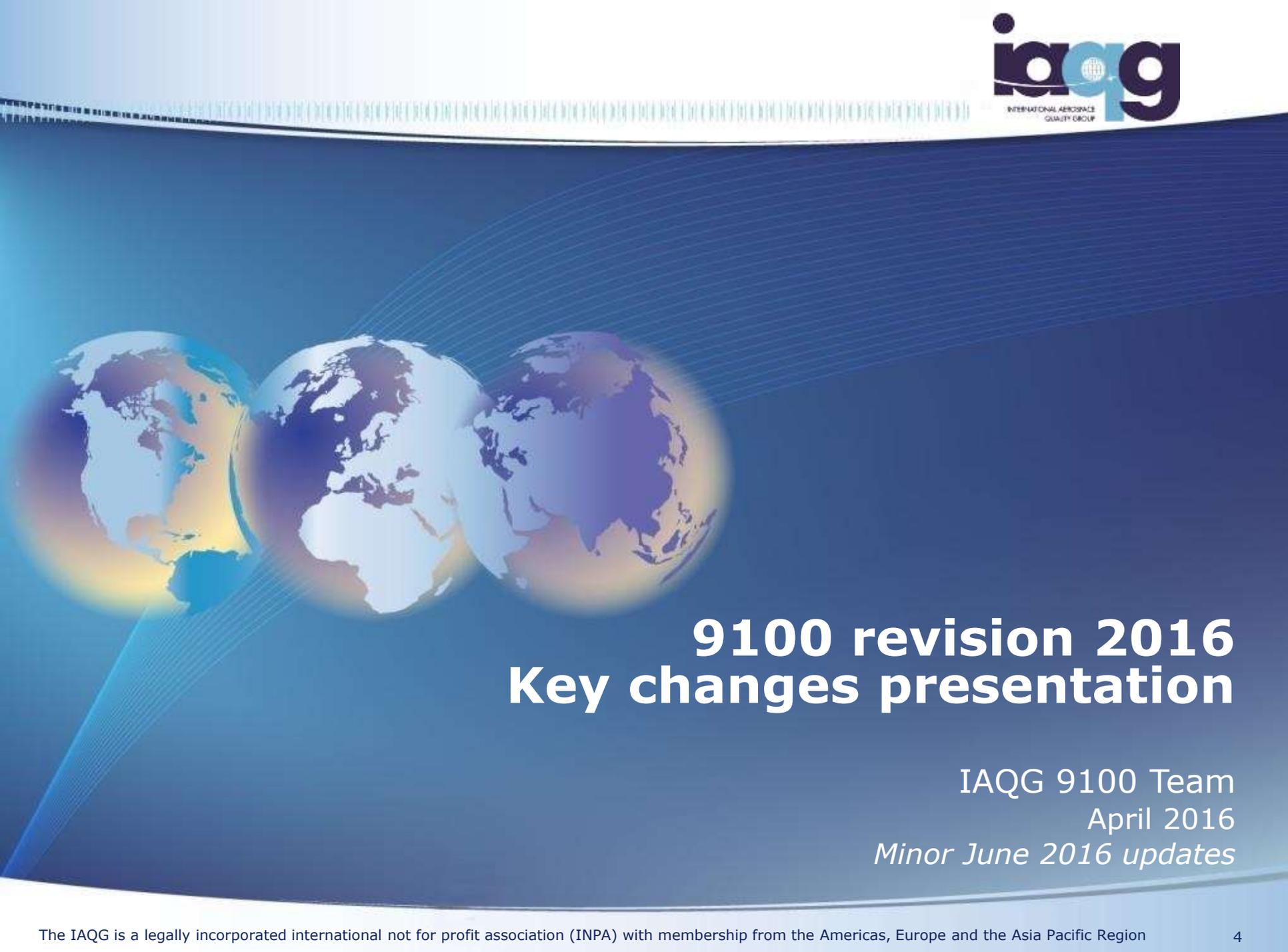
9100/9110/9120:2016 Transition Timeline:



Major Dates	Activities
Jul 2015	<ul style="list-style-type: none"> • ISO 9001:2015 Final Draft Standard (FDIS) • 9100:2016 Coordination Draft to IAQG Members for review.
Sep 2015	<ul style="list-style-type: none"> • ISO 9001:2015 Standard published and a 36 Month Certified Client ISO transition begins (Target: Sept 2018).
Oct 2015	<ul style="list-style-type: none"> • IAQG General Assembly approval of ICOP 9100/9110/9120:2016 Transition Plan.
Oct 2016	<ul style="list-style-type: none"> • Publication of 9100/9110/9120:2016 and 9101:2016 Standards.
Oct/Nov 2016	<ul style="list-style-type: none"> • Publication of Supplemental Rule (SR-003) published after last 91xx:2016 series.
Nov 2016	<ul style="list-style-type: none"> • Mandated Aerospace Auditor “transition” training available in all IAQG languages.
Dec 2016	<ul style="list-style-type: none"> • OASIS Next Gen Project Phase 1 - Database available for Stakeholder use.
Jun 2017	<ul style="list-style-type: none"> • CBs must have completed transition to ISO 17021:2015 and revised their accreditation scope to include 9100/9110/9120:2016. • All future audits must be to the 9100/9110/9120:2016 standard using 9101:2016 audit process. • CB transition to ISO 17021:2015 must be completed. Any CB not transitioned will be withdrawn from ICOP scheme.
Sep 2018	<ul style="list-style-type: none"> • Transition complete all 9100/9110/9120:2009 certificates no longer valid. • Stakeholders shall use OASIS Next Gen to validate certification.

9100

9120



9100 revision 2016 Key changes presentation

IAQG 9100 Team
April 2016
Minor June 2016 updates

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)

9100 Revision 2016

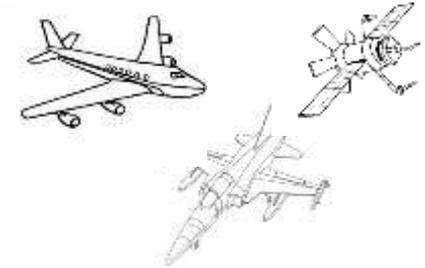
Reason for the revision

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



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



IAQG 9100 Series Team

Alan Daniels	
9100 IDR – Team Leader Boeing	

Buddy Cressionie	
9100 AAQG SDR Lockheed Martin	

Brigitte Clamens	
9100 EAQG SDR Zodiac Aerospace	

Masahiro Kawamoto	
9100 APAQG SDR Mitsubishi Heavy Industries	

Jim Clifford	
9100 AAQG Representative United Technologies Corporation	

Roberto Ciaschi	
9100 EAQG Representative European Space Agency	

Jinfeng Geng	
9100 APAQG Representative Aviation Industry Corporation (AVIC)	

Kim Roy	
9100 AAQG Representative Triumph	

Pete Cracknell	
9100 EAQG Representative BAE Systems	

Tatsuya Shirai	
9100 APAQG Representative Kawasaki Heavy Industries	

Integration of Standards

Elizabeth Walters	
9120 IDR Boeing	

Agathe Moll	
9110 IDR Airbus	

Masahiro Kawamoto	
9101 IDR Mitsubishi Heavy Industries	

Ray Wright	
9115 IDR Raytheon	

Wayne Johnson	
9100 Scribe IAQG	

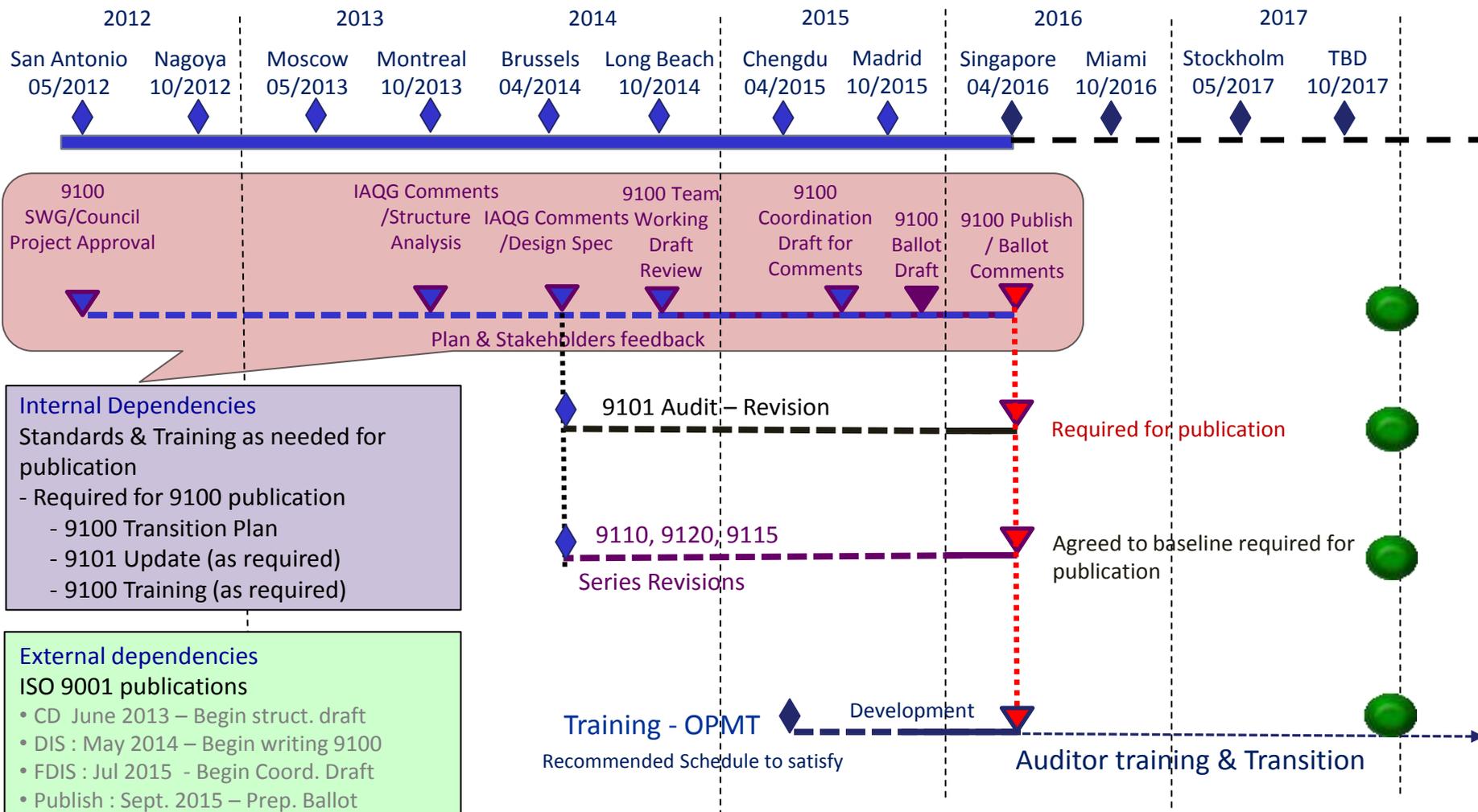
9100 Revision Timeline



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Oct 2013	Stakeholder Feedback Resolution
Apr 2014	Concept Sub-team Proposals
Jun 2014	Integrate ISO 9001 Draft with 9100
Jul 2014	ISO 9001:2015 Draft Comments
Jul 2014	Structure Draft (team)
Oct 2014	Working Draft (team)
July 2015	Coordination Draft (IAQG)
Dec 2015	Ballot (IAQG)
Jun 2016	9100 complete through IAQG Ballot
→ Sep 2016	Sector formatting and publication

9100 Series Revision - Integrated Schedule



For more information,
see detailed schedule

----- Preparing
 ----- Ballots, reviews and comments



Publications



9100 Revision 2016

*Key changes
in the ISO 9001 text
and in the 9100 additions*

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

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

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

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

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

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 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



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

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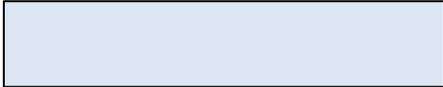
Summary of changes - clause by clause -

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

Includes verbal significations of “shall, should, may, can”

7 principles to consider



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

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)

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

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

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*

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

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

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

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

Added new requirements to address **“product safety”** considerations throughout the product lifecycle

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

8.1.1 Operation risk management

8.1.2 Configuration management

8.1.3 Product safety

8.1.4 Prevention of counterfeit parts

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

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)

8.4.3 Information for external providers

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)

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

9100 revision 2016

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

9100 revision 2016

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

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

10. Improvement

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement

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

Annex (informative)

A. Clarification of new structure, terminology and concepts

B. Standards developed by ISO/TC 176

C. Standards developed by IAQG

For **risk management, added the 9100 clarification**

Bibliography

Full list of IAQG standards available

Questions





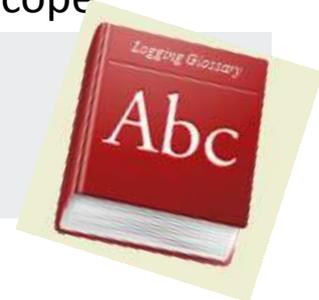
9100 Revision 2016

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 <ul style="list-style-type: none">• 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



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)

9100 revision 2016

HLS: High Level Structure (from ISO 9001)



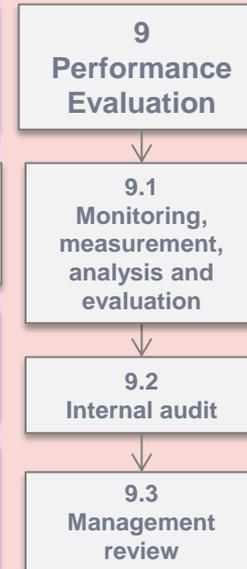
Plan



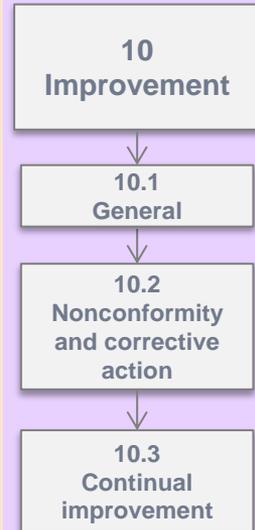
Do



Check



Act



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

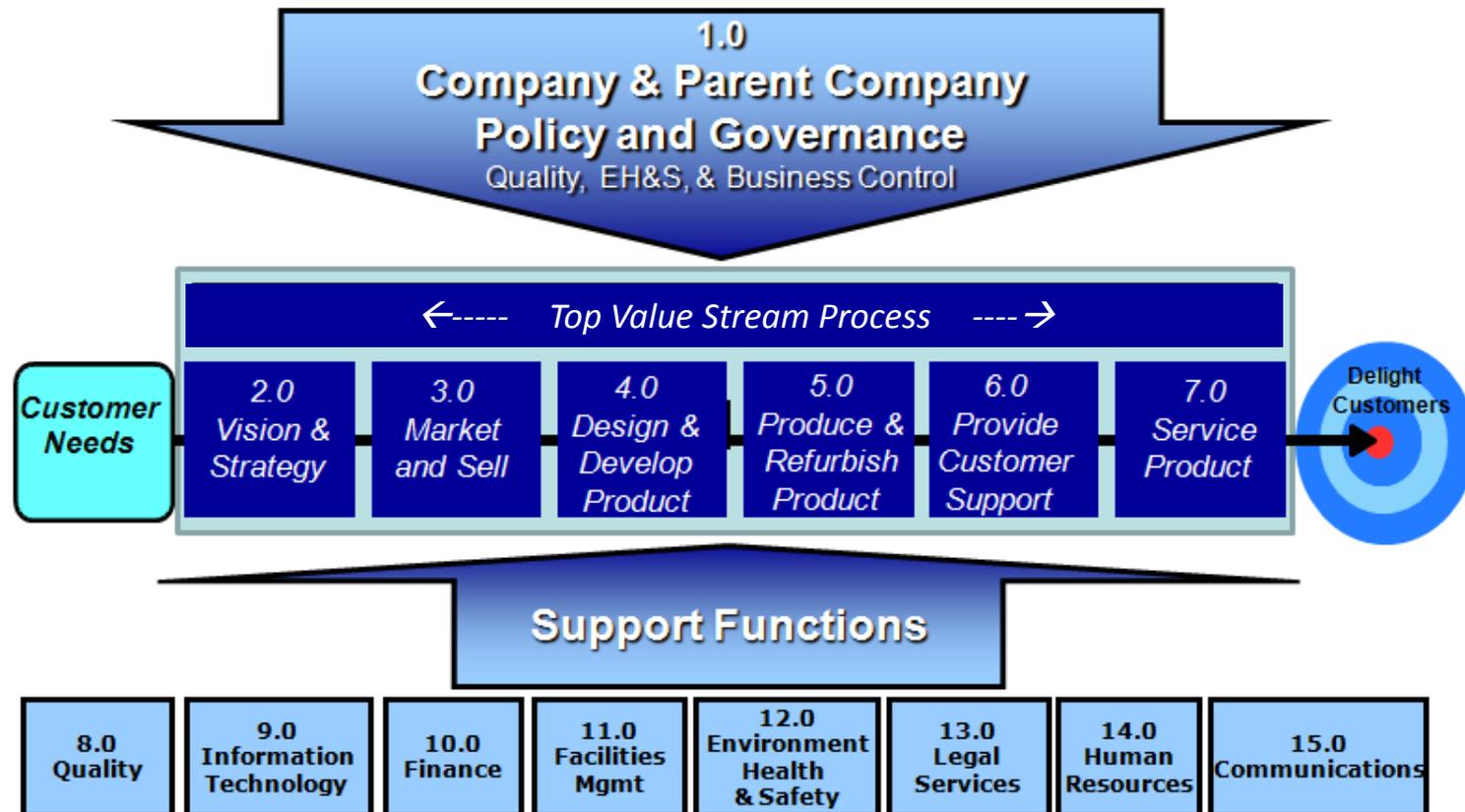
If your current documentation system is structured (based) on a previous revision of the standard, **consider re-arranging your QMS documentation around the value stream of your company!**

- 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.

Implementation Considerations

Example of Process Based QMS

Company Management System around a Value Stream





9100 Revision 2016

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:

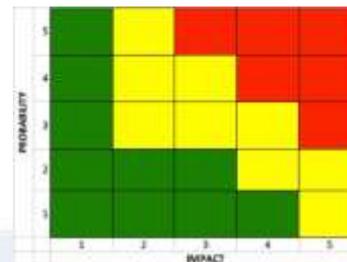
Clause 6.1 is related to risks in “QMS of the organization”:

- 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, ...)





9100 Revision 2016

Process approach

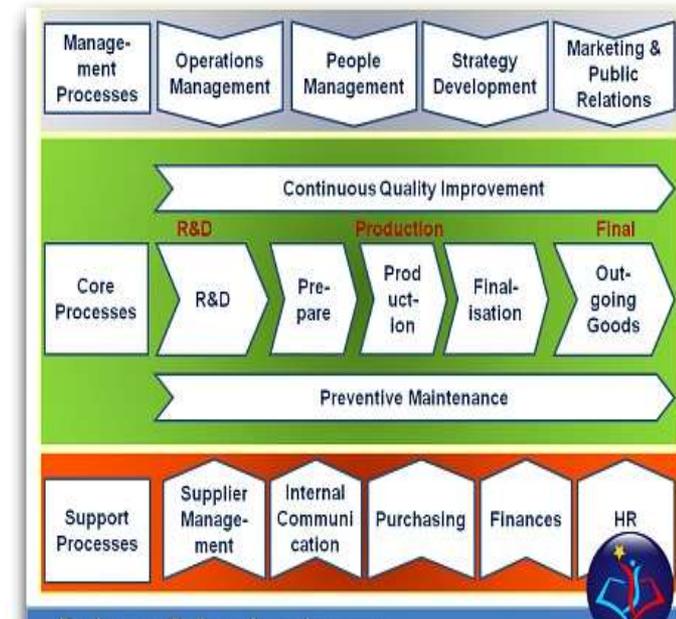
What is the process approach?

- 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





9100 Revision 2016

Concept of “change”

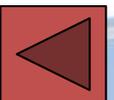
Introducing the concept of change

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)





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

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

Addition

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

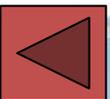


Rationale

- 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

Quality Management Principles

There were 8 principles

Customer focus

Leadership

Involvement of people

Process approach

System approach to management

Continual improvement

Factual approach to decision making

Mutually beneficial supplier relationships

There are now 7

Customer focus

Leadership

Engagement of people

Process approach

(included in the process approach)

Improvement

Evidence based decision making

Relationship management





9120 revision 2016

*Key changes
in the ISO 9001 text
common 9100 requirements
and unique 9120 additions*

IAQG 9120 Team Members



- Alekseev, Aleksandr (Kazan Helicopters)
- Gallant, Guylaine (Bombardier)
- Gordon, Dale (Contract)
- Hensley, Debra (Bell Helicopter - Textron)
- Ringger, George (ASA)
- Shirai, Tatsuya (KHI)
- Walters, Liz (Boeing)
- Wang, Hongyan (Comac)

Standard Number	Title	Strategy Focus Stream	IAQG Document Representative (IDR)	SECTOR DOCUMENT REPRESENTATIVES Current Issued Version and Date		
				AAQG Sector Document Representative (SDR)	APAQG Sector Document Representative (SDR)	EAQG Sector Document Representative (SDR)
9120	Quality Management Systems – Requirements for aviation, space and defense distributors	Requirements	Elizabeth Walters +1562-797-0945 elizabeth.a.walters@boeing.com	Elizabeth Walters +1562-797-0945 elizabeth.a.walters@boeing.com - AS9120 Rev A 2009-06-29	Wang Hongyan +86 135 8586 9411 wanghongyan@comac.cc - SJAC9120 2011-02-25	Alexandr Alekseev +7 917 264 39 68 Alekseev_AV@kazanhelicopters.com - EN9120:2010 2010-06-09

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 in risk & opportunities, nonconformance & corrective action clauses
- Introduction of knowledge management

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

Key Changes *(in the ASD requirements)*

As a consequence of the new ISO 9001 structure:

- 9120 additions have been **relocated** into appropriate ISO sections
- the requirements are better **organized** and **clarified**, with notes and examples to enhance understanding

Key Changes *(in the ASD requirements)*

-  ■ **Product safety**
added in carefully 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 into 9120 in appropriate areas
- **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

Key Changes *(in the ASD requirements)*

- Product Realization & Planning
limited for application to a Distributor
- Post Delivery Support
merged new 9100 and ISO requirements into 9120 in appropriate areas
- Project Management & Work Transfer
combined with Operation Planning clause and worded in the context of a Distributor
- Quality Manual
note added pointing to the requirements that make up a Quality Manual or the equivalent
- Management Representative
requirement added back in for QMS oversight

9120 Series Changes - High Level Summary

No Requirements

Clause 1 Scope	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ ISO 9000:2015 referenced
Clause 3 Terms and definitions	<ul style="list-style-type: none"> ▪ ISO 9001 terms and definitions moved to ISO 9000 ▪ <i>Added “product safety” and unapproved parts, updated “counterfeit parts”</i>
Clause 4 Context of the organization	<ul style="list-style-type: none"> ▪ Quality manual not required, maintained documentation is required ▪ Justified exclusions not limited to Realization/Operations processes ▪ QMS processes have performance indicators
Clause 5 Leadership	<ul style="list-style-type: none"> ▪ QMS compatible with strategic direction ▪ QMS requirements integrated into business processes ▪ Processes deliver their intended outputs

Clause 6 Planning for the QMS	<ul style="list-style-type: none"> ▪ When planning the QMS, determine the actions needed to address opportunities and risks (preventive) ▪ Increases requirements for planning of changes
Clause 7 Support	<ul style="list-style-type: none"> ▪ Determine knowledge management requirements ▪ <i>Awareness of contribution to compliance and product safety</i>
Clause 8 Operation	<ul style="list-style-type: none"> ▪ <i>Control of product obsolescence</i> ▪ <i>Prevention of counterfeit parts</i> ▪ <i>Process to validate test reports for raw material when risks are present</i> ▪ Release of products and services ▪ <i>Product identification and traceability for splitting</i>
Clause 9 Performance evaluation	<ul style="list-style-type: none"> ▪ Assess performance of QMS processes ▪ <i>Added Note to evaluate performance indicators on internal audits</i>
Clause 10 Improvement	<ul style="list-style-type: none"> ▪ <i>Consider human factors in nonconformity / corrective action</i>

All ISO MS standards will now have this common 10 clause structure

- Implementation Benefits
- When implemented and managed well:
 - Meet or exceed customer, statutory 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



End of presentation for
general audience

Questions



The remainder of the presentation contains

- Clause-by-Clause summary of changes in ISO 9001, 9100 and 9120 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

9120 revision 2016

*Summary of changes
- Clause-by-Clause*

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

- from the 9120:2009
- to the 9120:2016 Ballot Draft

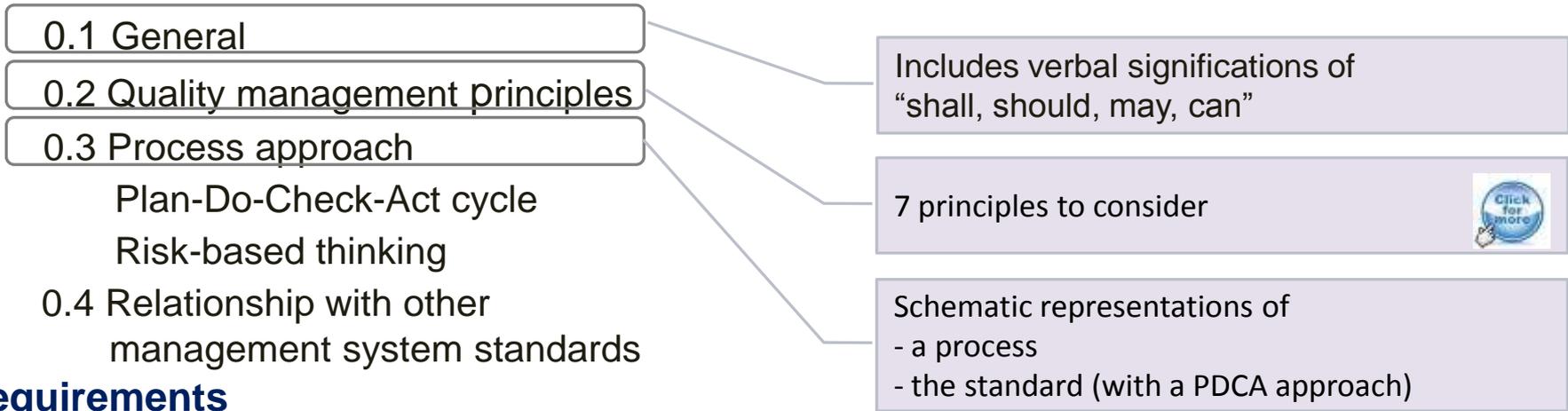


Key changes are identified by:

- ISO 9001 >>>>>> ————— 
- **9100 additions** >> ————— 
- **9120 additions** >> ————— 

Foreword, Revision summary/Rationale, Intended application

Introduction

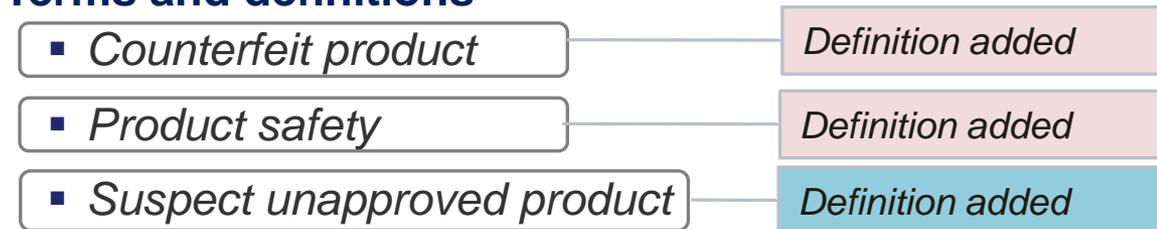


Requirements

1. Scope

2. Normative references

3. Terms and definitions



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)*

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

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***

Retained **documented information** includes: evidence of product origin, conformity and shipment...

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

Not Used

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

Not Used

Added new requirements to *prevent the use* of *suspect unapproved, unapproved parts and counterfeit parts*

8.1.1

8.1.2 Configuration management

8.1.3

8.1.4 Prevention of counterfeit parts

8.1.5 Prevention of Suspect Unapproved Parts

8. Operation

8.2 Requirements for products and services

8.2.1 Customer communication

8.2.2 Requirements related to products and services

8.2.3 Review of 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

Not excluded per ISO 9001:2015 clause 4.3

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

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*

8.4.3 Information for external providers

*Added validation process of tests reports accuracy for **raw materials** identified as a significant risk*

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

*Added verbiage to include prevention of unapproved and suspect unapproved products
Added requirement for certificate of conformity, test reports and authorized release certificate*

9120 revision 2016

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 output, and that **acceptance criteria** for products and services are met.

Added requirement to take into account *obsolescence*, where applicable

Clarified requirements for traceability and accountability when splitting product.

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*

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

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*

10. Improvement

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement

*For **risk** management, added the 9100 clarification*

***Full list** of IAQG standards available*

Annex (informative)

A. Clarification of new structure, terminology and concepts

B. Standards developed by ISO/TC 176

C. Standards developed by IAQG

Questions





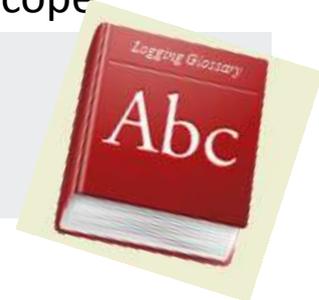
9120 Revision 2016

Terminology & High Level Structure (HLS)

9120 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 <ul style="list-style-type: none">• 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 9120, the new clause structure is duplicated in 9120



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

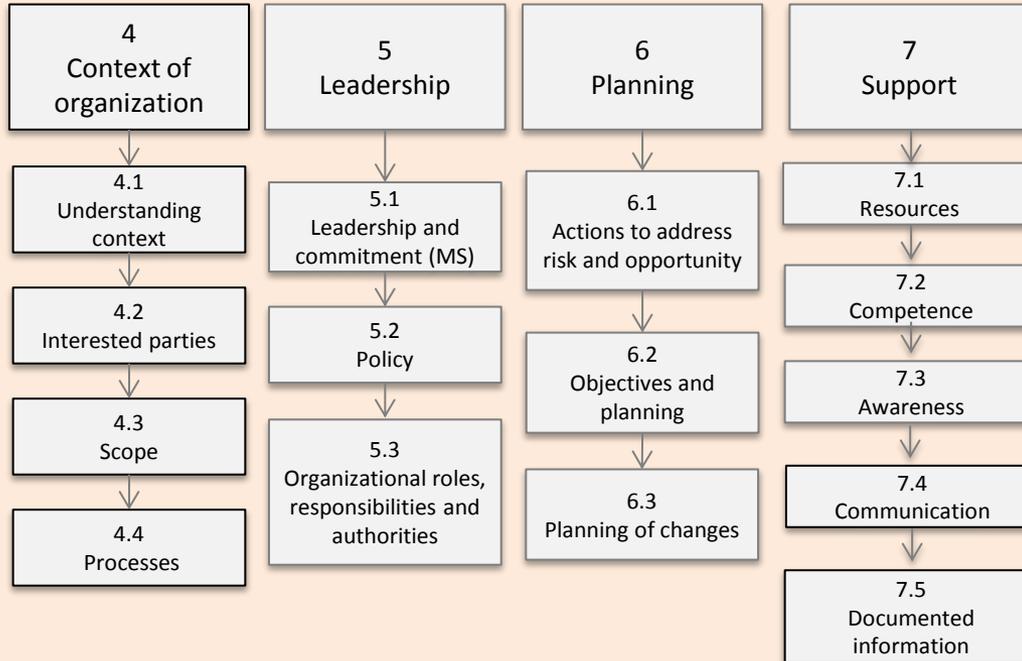
- Need to review your current QMS structure ?
(preferable to adapt the QMS structure to the Business Processes)

9120 revision 2016

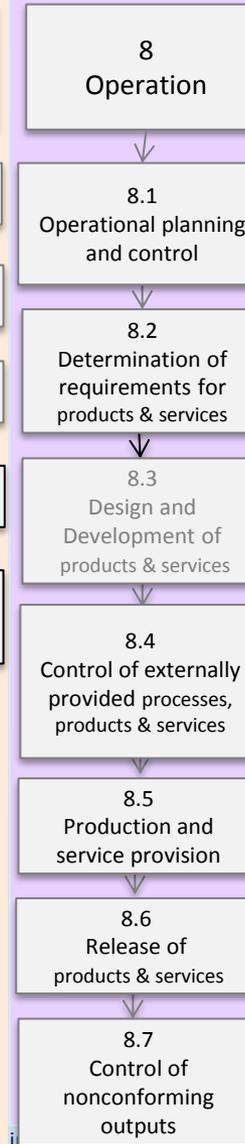
HLS: High Level Structure (from ISO 9001)



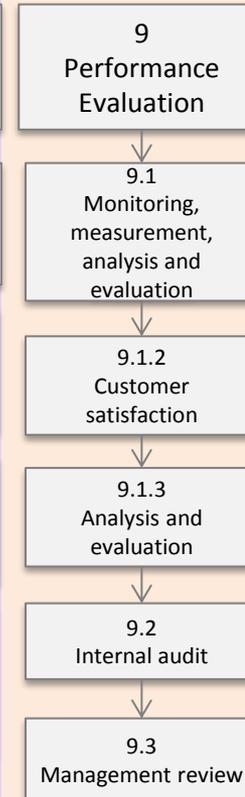
Plan



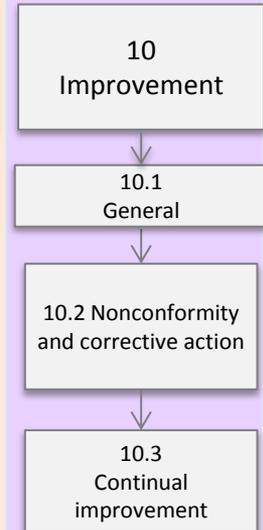
Do



Check



Act



HLS Table of Contents – ISO 9001 / 9120

- 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 / 9120

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 / 9120

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 9120:2016 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

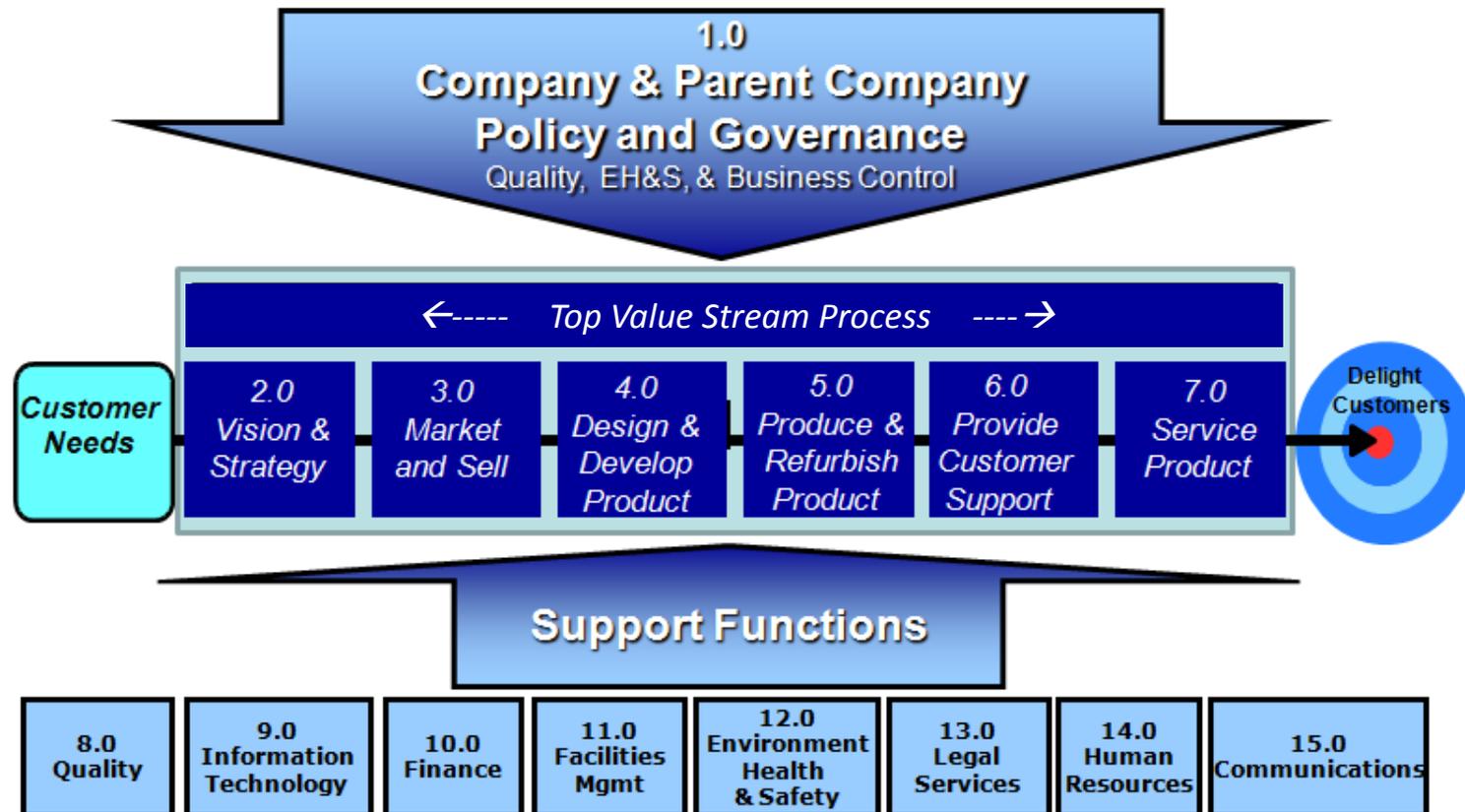
If your current documentation system is structured (based) on a previous revision of the standard, **consider re-arranging your QMS documentation around the value stream of your company!**

- 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.

Implementation Considerations

Example of Process Based QMS

Company Management System around a Value Stream



9120 revision 2016

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 organizational 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

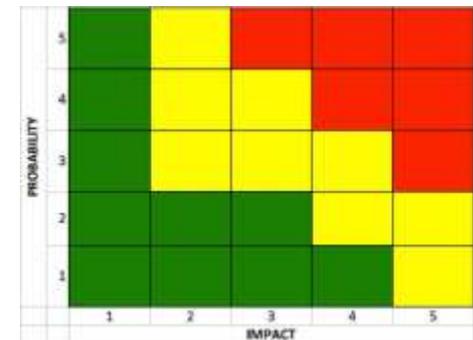
- Is not new
- Is something you do already
- Is continuous
- Ensures greater knowledge of risks and improves preparedness
- Increases the probability of reaching objectives
- Reduces the probability of negative results
- Makes prevention a habit



9120 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, ...)



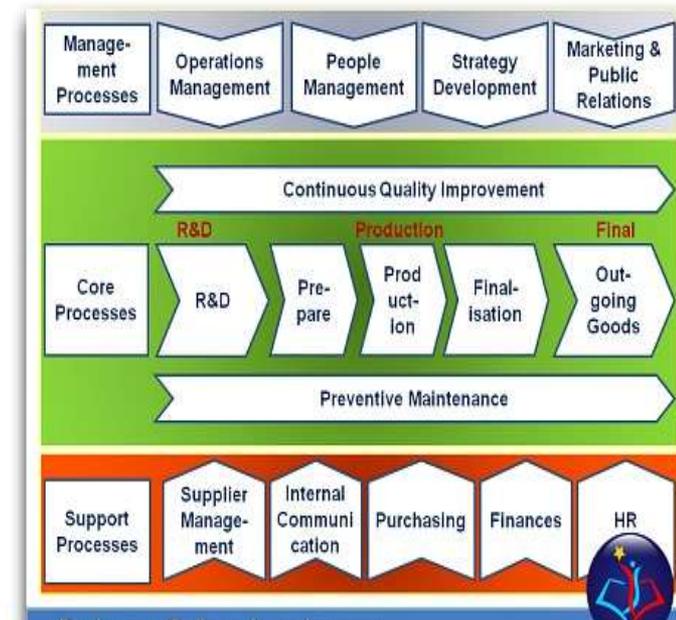


9120 revision 2016

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



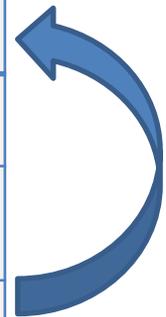
- Process approach & risk-based thinking
 - the process approach incorporates risk-based thinking
 - risk-based thinking ensures risk is considered when establishing, implementing and maintaining a management system, each process and each activity

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



Applicability of the entire Standard to the Organization?

- The Scope of the organization defines applicability:
 - ➔ Must follow the requirements in clause 4.3
 - ➔ Certified organizations will be required to show justification in it's scope for any parts of the standard or processes required that are declared as not applicable
- Example for a Distributor declaring 8.3 is N/A:
 - ➔ XYZ Distribution is a supplier of electronic components to the aviation, space and defense industry for OEM and aftermarket use. No products or services are required to be designed and developed per clause 8.3 in order to conform to customer or regulatory requirements. No additional services are provided beyond the products being supplied from authorized manufacturers.

Each organization has to justify “non-applicability”

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





9120 revision 2016

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)



9120 revision 2016

Product Safety



- Revision / Addition
 - Product Safety is introduced in the following clauses:
7.3, 8.1 & 8.4.3
- Rationale
 - Industry acknowledgement of the importance of increasing safety awareness

Product safety definition (3.6)

- Maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.
- Implementation considerations
 - Heighten product safety awareness throughout the organization and the impacts of handling and packaging on protecting and assuring that product integrity is maintained.



9120 revision 2016

Prevention of unapproved and counterfeit parts

Addition

- New clause including requirements for prevention of **suspect unapproved, unapproved, and counterfeit parts** and a note giving examples of the associated processes *and revision of affected clauses: 3.4, 3.8 & 3.10 (definition), 8.1.2 (prevention of counterfeit parts), 8.1.5 (prevention of suspected unapproved parts) 8.4 (external provisions) & 8.7 (nonconformities)*

Rationale

- Mitigate effects of growing threat of counterfeit products
- Recognize the statutory/regulatory requirements on QMS processes for the control of “unapproved parts” and counterfeit parts in both the production and aftermarket environment.

Implementation considerations

- To address unapproved and counterfeit part 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

- **Obsolescence**

- ✓ Ensure product obsolescence issues are considered as part of distributor processes (e.g. shelf life, configuration, application)

- **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 unapproved and counterfeit products
 - ✓ Ensure these products are not re-introduced into the supply chain
- **Reporting**
 - ✓ Report incidences of unapproved / counterfeit 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 unapproved / counterfeit parts from entering the product





9120 Revision 2016

Human Factors

Addition

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

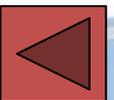


Rationale

- 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





9120 revision 2016

Quality Management Principles

Quality Management Principles

There were 8 principles

Customer focus

Leadership

Involvement of people

Process approach

System approach to management

Continual improvement

Factual approach to decision making

Mutually beneficial supplier relationships

There are now 7

Customer focus

Leadership

Engagement of people

Process approach

(included in the process approach)

Improvement

Evidence based decision making

Relationship management

