9100 revision 2016
Key changes presentation

IAQG 9100 Team

December 2015

9100 revision 2016

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- 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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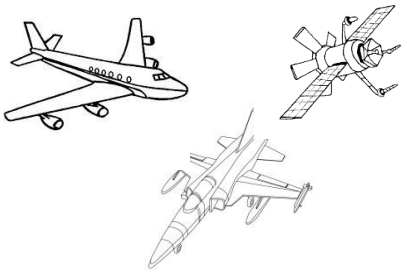

The “9100” needs to change, to:

- 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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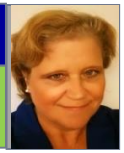

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IAQG/Sector 9100 Team Structure

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)

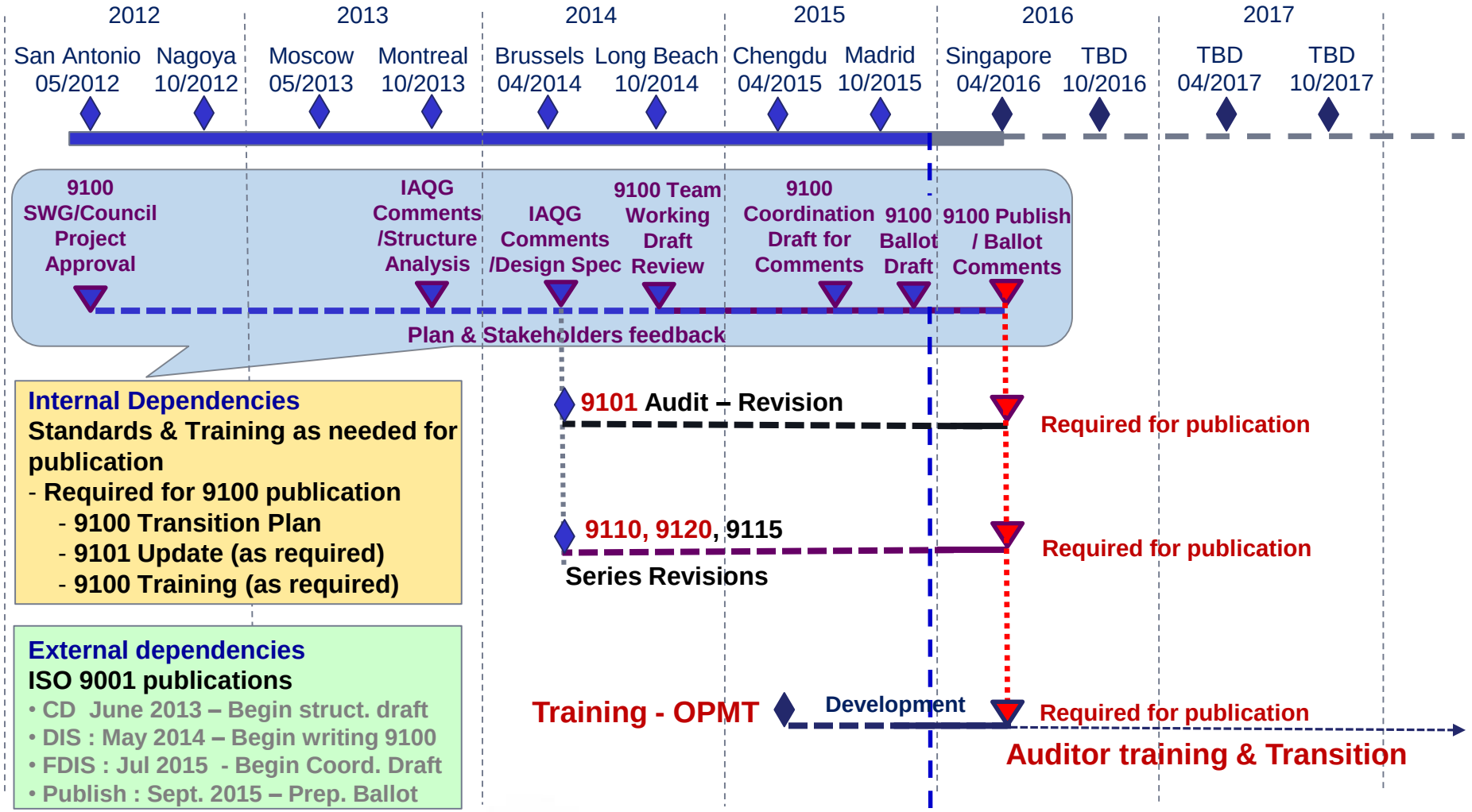
Sector 9100 Team Meetings to gather Sector inputs and develop Sector positions. Operation managed at Sector Level (58)

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)*

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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

9100 Revision 2016

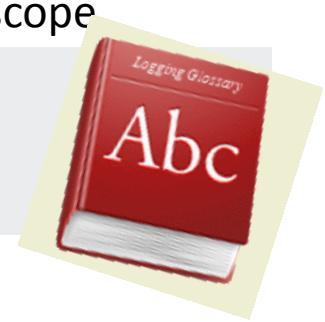
Terminology &

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 • 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