

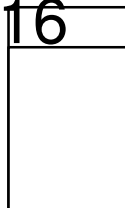
9100 Series 2016 Revision Overview

**9100 Team
July, 2014**

9100 Revision – The Plan

9100 Series Revision High Level Plan

- The 9100 is based on ISO 9001 and is thus affected by the ISO TC176 revision activity
- Revision guidance published in 9100:2016 Design Specification
- 5 IAQG standards are based on the 9100 standard and will require revision in parallel with 9100 (9110, 9120, 9115, 9137, 9101 = 9100 Series)
- Revision focus is to add clarity, enhance ease of use, while addressing industry and stakeholder needs
- The IAQG 9100 Series standards are planned for project completion in 2016



9100 Series

9100 Series includes the following IAQG standards:

- **IAQG 9100** QMS –Req'ts for Aviation, Space and Defense Orgs -
IAQG Series Baseline Standard
 - **IAQG 9110** QMS – Req'ts for Aviation Maintenance Organizations
 - **IAQG 9115** QMS – Req'ts for Aviation, Space and Defense Orgs -
Deliverable Software
 - **IAQG 9120** QMS – Req'ts for Aviation, Space and Defense
Distributors
 - **IAQG 9137** Guidance for the Application of AQAP 2110 within a
9100 QMS
 - **IAQG 9101** QMS Audit Requirements for Aviation, Space and
Defense Organizations
 - **IAQG 9104** Oversight of Certification Scheme

IAQG Review Of ISO 9001 DIS

ISO New Clause Structure

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 Quality policy
- 5.3 Organizational roles, responsibilities and authorities

6. Planning for the quality management system

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

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 Determination of requirements for products and services
- 8.3 Design and development of products and services
- 8.4 Control of externally provided products and services
- 8.5 Production and service provision
- 8.6 Production of products and provision of services
- 8.6 Release of products and services
- 8.7 Control of nonconforming process outputs, products and services

9. Performance evaluation

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

10. Improvement

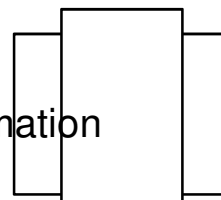
- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.2 Continual Improvement

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ISO Timeline

Jun 2013	CD ballot starts
Sep 2013	Close of CD ballot
Nov 2013	Prepare DIS (Rough Draft)
Jul 2014	DIS Ballot
Oct 2014	DIS Ballot Closed
Nov 2014	Prepare FDIS
Feb 2015	FDIS to ISO Central Secretariat
Jul 2015	FDIS Ballot
Sep 2015	Publish ISO 9001:2015

These dates are contingent on consensus on decisions / ballots to proceed at each stage.



IAQG ISO 9001 DIS Review

- The 9100 baseline ISO 9001:2015 has released their Draft International Standard (DIS) for review
- The International Aerospace Quality Group (IAQG), as a new Liaison member of the ISO group, has an opportunity to provide comments to the DIS
- Action - 9100 Writing Team to review the DIS and provide comments for the IAQG
- Action – Report DIS assessment in the July IAQG SWG meeting and provide a 9100 Team position

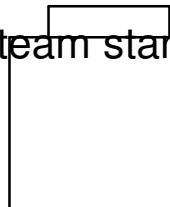
<p>ISO/TC 176/SC 2 Date: 2014-05-8 ISO/DIS 9001 ISO/TC 176/SC 2/WG 24 Secretariat: BSI</p>
<p>Quality management systems — Requirements</p> <p><i>Systèmes de management de la qualité — Exigences</i></p>
<p>Warning</p> <p>This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.</p> <p>Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.</p>
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IAQG ISO 9001 DIS Review

We provided to the 9100 Team for the assessment:

- ISO 9001:2015 DIS
- ISO 9001:2008 to ISO 9001:2015 Cross Reference (before and after)
- Overlay of the ISO 9001:2008 to ISO 9001:2015 standards
- Overlay of the ISO 9001:2015 CD, which was cause for concern, and the much improved ISO 9001:2015 DIS

Copyright - limited to team standard development activity



ISO 9001:2015 Cross Reference to ISO 9001:2008 May 15, 2014	
<ul style="list-style-type: none"> • The following includes a cross reference from the ISO 9001:2015 Draft International Standard (DIS) to ISO 9001:2008. • This is not the official cross reference that will be provided in the final version of ISO 9001:2015. In the interim, this document can be used to highlight where the new and revised clauses are located. • Please note Annex A of the DIS states the following: 	
A.1 Structure and terminology	
<ul style="list-style-type: none"> • <i>The clause structure and some of the terminology of this International Standard, in comparison with ISO 9001:2008, have been changed to improve alignment with other management systems standards.</i> • <i>The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization's quality management system.</i> • <i>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 this International Standard.</i> 	
ISO 9001:2008	ISO 9001:2015
4.1 General Introduction	4.1 Understanding the organization and its context
4.1 General	4.2 Understanding the needs and expectations of interested parties
1.2 Application 4.2.2 Quality Manual	4.3 Determining the scope of the quality management system
4.1 General	4.4 Quality management system and its processes
	5 Leadership
5.1 Management Commitment	5.1 Leadership and commitment

9100 Revision ISO 9001 Correlation Matrix

Comparison Matrix ISO 9001:2008 to ISO 9001:2015

ISO 9001:2008 to ISO 9001:2015 Correlation Matrix June 16, 2014	
<ul style="list-style-type: none"> The following includes a correlation matrix from the ISO 9001:2008 to ISO 9001:2015 Draft International Standard (DIS) This correlation matrix will be provided in the published version of ISO 9001:2015. In the interim, this document can be used to highlight where the new and revised clauses are located. Please note Annex A of the DIS states the following: 	
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ISO 9001:2008	ISO 9001:2015
4 Quality management system	4 Context of the organization
4.1 General Introduction	4.1 Understanding the organization and its context
4.1 General	4.2 Understanding the needs and expectations of interested parties
1.2 Application 4.2.2 Quality manual	4.3 Determining the scope of the quality management system
4.1 General	4.4 Quality management system and its processes
5.5 Responsibility, authority and communication	5 Leadership

5.1 Management commitment	5.1 Leadership and commitment
5.1 Management commitment	5.1.1 Leadership and commitment for the quality management system
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Quality policy
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	
5.4.2 Quality management system planning	6 Planning for the quality management system
5.4.2 Quality management system planning	6.1 Actions to address risks and opportunities
8.5.3 Preventive action	
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6.3 Planning of changes
New	7 Support
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General
6.1 Provision of resources	7.1.2 People
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment	7.1.4 Environment for the operation of processes
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
New	7.1.6 Organizational knowledge
6.2.1 General	7.2 Competence
6.2.2 Competence, training and awareness	
6.2.2 Competence, training and awareness	7.3 Awareness
5.5.3 Internal communication	7.4 Communication
4.2 Documentation requirements	7.5 Documented information

9100 Revision ISO 9001 Correlation Matrix

Comparison Matrix ISO 9001:2008 to ISO 9001:2015

4.2.1 General	7.5.1 General
4.2.3 Control of documents	7.5.2 Creating and updating
4.2.4 Control of records	
4.2.3 Control of documents	7.5.3 Control of documented Information
4.2.4 Control of records	
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Determination of requirements for products and services
7.2.3 Customer communication	8.2.1 Customer communication
7.2.1 Determination of requirements related to the product	8.2.2 Determination of requirements related to products and services
7.2.2 Review of requirements related to the product	8.2.3 Review of requirements related to the products and services
7.3.1 Design and development planning	8.3 Design and development of products and services
7.3.1 Design and development planning	8.3.1 General
7.3.1 Design and development planning	8.3.2 Design and development planning
7.3.2 Design and development inputs	8.3.3 Design and development Inputs
7.3.4 Design and development review	8.3.4 Design and development controls
7.3.5 Design and development verification	
7.3.6 Design and development validation	
7.3.3 Design and development outputs	8.3.5 Design and development outputs
7.3.7 Design and development changes	8.3.6 Design and development changes
7.4.1 Purchasing process	8.4 Control of externally provided products and services
7.4.1 Purchasing process	8.4.1 General
7.4.1 Purchasing process	8.4.2 Type and extent of control of external provision

7.4.2 Purchasing information	8.4.3 Information for external providers
7.3 Design and development	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of product	8.5.4 Preservation
7.5.1 Control of production and service provision	8.5.5 Post-delivery activities
New	8.5.6 Control of changes
7.4.3 Verification of purchased product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming process outputs, products and services
New	9 Performance evaluation
8.1 General	9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.2.2 Internal audit	9.2 Internal audit
5.6 Management review	9.3 Management review
8.5 Improvement	10 Improvement
8.5.1 Continual improvement	10.1 General
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.1 Continual improvement	10.3 Continual Improvement

ISO 9001:2015

Key Changes Summary

Key Changes

- Greater emphasis on processes (51 in 2008 to 73 in 2015)
- Alignment with strategic direction (0 in 2008 to 3 in 2015)
- Integration of the QMS into organization's business processes (0 in 2008 to 1 in 2015)
- Determining risks and opportunities (0 in 2008 to 11 in 2015)
- Emphasis on change management (13 in 2008 to 23 in 2015)
- Introduction of knowledge management (0 in 2008 to 9 in 2015)
- Increased performance evaluation (4 in 2008 to 15 in 2015)
- Improvement expanded – clause (11 in 2008 to 15 in 2015)

(number of times the word shows up in clauses 4-8 & 4-10)

IAQG ISO 9001 DIS Review

ISO 9001:2015 DIS review summary

- Comments consist of clarifications, improvements and editorial proposals
- 111 IAQG comments received on the ISO 9001 DIS
 - 55 Improve
 - 28 Clarify
 - 4 Editorial
 - 2 Delete
 - 22 Filtered (no proposed text, ISO required text, duplicates)
 - 89 IAQG Comments for the ISO 9001:2015 Team

IAQG ISO 9001 DIS Review

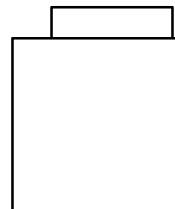
ISO 9001:2015 DIS Review Summary

- 18 identified by the 9100 Team as priorities
 - **Addition proposals:**
 - 4.2.2 Quality manual
 - 5.3 Management representative (2)
 - 7.5.3.2 External documented QMS information – available for use
 - 8.4.3 External provider communication - QMS requirements
 - 9.2.1.b Internal audit - considers related performance indicators
 - **Revision proposals:**
 - 4.1 Issues – revise terminology (factors, elements, aspects, etc)
 - 8.3.1 Design and development process - neg. to pos. statement
 - 8.3.4 Design and development – action when outcome is not achieved
 - 8.4.2.b Perceived effectiveness- revise terminology (measured)
 - 8.5.6 Change control – revise unplanned changes

IAQG ISO 9001 DIS Review

ISO 9001:2015 DIS Review Summary - cont.

- 18 identified by the 9100 Team as priority comments
 - **Definition proposals:**
 - Opportunities - 4.4, 5.1.2, 6.1, 9.1.3,
 - Organizational knowledge - 7.1.6, 8.1, 8.5.6
 - Unplanned changes - 8.1, 8.5.6
 - Incorrect use - customer owned property - 8.5.3
 - **Clarification requests:**
 - 3.04 External providers – outsourced external providers (internal)
 - 3.09 Risk – opportunities are positive effects of uncertainty - 7.1.6
 - 4.2 Interested parties



IAQG ISO 9001 DIS Review

ISO 9001:2015 DIS review summary

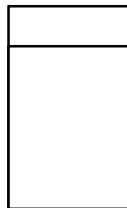
- The IAQG 9100 Team and 9100 Sector Teams all agreed there are no show stopper or critical items
- Common terminology and its use could be better (reason for clarification and definition requests)
- Comparison matrix indicates the 10 clause structure is workable
- Several improvements have been made in the ISO 9001:2015
 - increased use of measures
 - risk analysis
 - Linkage to organizations strategic objectives and business processes
- Flexibility to add requirements and guidance in the 9100 text
- **9100 Team recommendation is to continue use of the ISO 9001 as the 9100 series baseline**

ISO 9001:2015 Revision

Next Steps

Next Steps

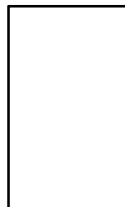
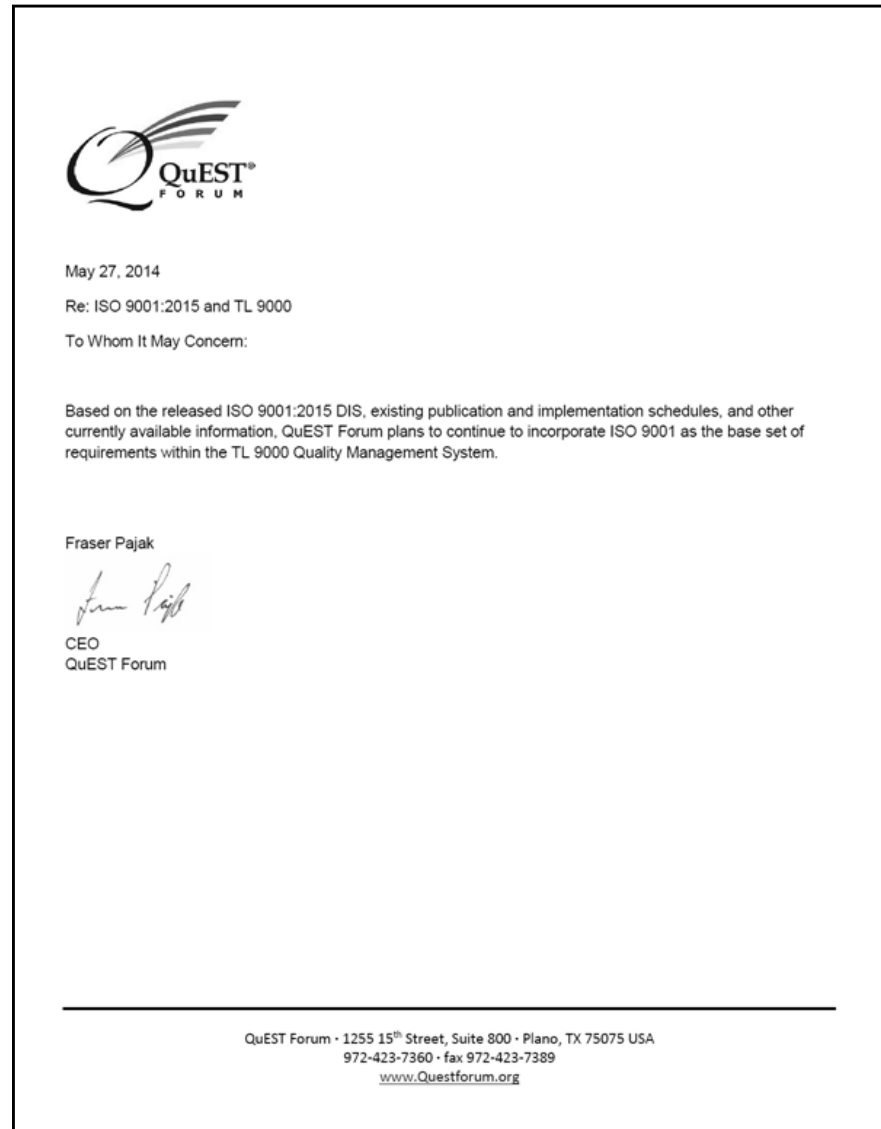
- IAQG ISO 9001:2015 prioritized comments will be actively lobbied for implementation and tracked
- The ISO 9001:2015 FDIS (Final Draft International Standard) is scheduled to be available in February 2015 and begin ballot in July 2015
- **Writing to begin on 9100:2016 using ISO 9001:2015 DIS as a baseline July 14th, 2014**



ISO 9001:2015 Key Changes Summary

Telecommunications

- After reviewing the ISO 9001:2015 DIS the QuEST Forum (telecommunications) has made the decision to continue using ISO 9001 as their TL 9000 standards baseline



IAQG 9100 Revision

9100 Timeline

Oct 2013	Stakeholder Feedback Resolution
Apr 2014	Concept Sub-team Proposals
Jun 2014	Integrate ISO 9001 DIS with 9100
Jul 2014	ISO 9001:2015 DIS Comments
Jul 2014	Structure Draft (team)
Oct 2014	Working Draft (team)
May 2015	Coordination Draft (IAQG)
Dec 2016	Ballot (IAQG)
Apr 2016	Support Material

These dates are contingent on consensus on decisions / ballots to proceed at each stage.

9100 New Concepts

- **Concepts being evaluated (sub-teams):**
 - Safety - product, flight (evaluate enhancement)
 - Human Factors (consider inclusion)
 - Risk (balance ISO 9001 addition)
 - Preventive Action (assess ISO 9001 approach)
 - Counterfeit Parts (consider inclusion)
 - Configuration Management (request to enhance)
 - Product Realization Planning (requested FAI, APQP linkages)
 - Post-Delivery Support (9110/MRO linkages)
 - Supplier Management (request to enhance)



Next Steps – 2014

- 9100 Team to review and comment to ISO 9001 DIS
- Integrate ISO 9001 DIS with 9100 requirements and accepted proposals into a rough draft for the 9100 Team review
- Begin work on the 9110 Maintenance and 9115 Software standards
- Launch 9120 in the fall IAQG meeting

