9100 Series
2016 Revision Overview
October 2015
Presentation Outline

International Aerospace Quality Group

ISO 9001 Revision Activity

9100 Series Revision Activity

Benefits and Application

Communications

Summary

Resources
A Global Team

International Aerospace Quality Group

IAQG Council

General Assembly Forums

AAQG (Americas)

19 AAQG members

EAQG (Europe)

32 EAQG members

APAQG (Asia Pacific)

13 APAQG members
General Assembly
IAQG/9100 Membership

**Americas (AAQG)***
- Boeing
- GE Aviation
- Honeywell
- Lockheed Martin
- Northrop Grumman
- Parker
- Raytheon
- Rockwell Collins
- Triumph Group
- United Technologies

**Asia Pacific (APAQG)***
- AVIC
- Fuji Heavy Industries (FHI)
- IHI Corporation
- KAI (Korea Aerospace Industries)
- Kawasaki Heavy Industries (KHI)
- Mitsubishi Heavy Industries (MHI)

**Europe (EAQG)***
- AgustaWestland
- Airbus
- Airbus Defense and Space
- Airbus Defense and Space
- Airbus Helicopters
- Alenia Aermacchi
- Avio Areo
- BAE Systems
- Rolls-Royce
- SAAB
- SAFRAN

Blue text = Represented on 9100 Team
## Sector Membership

### Americas
- Aerojet
- ATK
- Ball Aerospace
- Boeing
- Bombardier
- Embraer
- GE Aviation
- General Dynamics-Gulfstream
- Honeywell
- Lockheed Martin
- Moog
- Northrop Grumman
- *Parker
- Raytheon
- Rockwell Collins
- Spirit AeroSystems
- Textron
- Triumph Group
- UTC

### Asia Pacific
- Aerospace Industrial Development Corporation (AIDC)
- AVIC
- COMAC
- DSO
- EGAT
- Fuji Heavy Industries
- IAe
- IHI
- KAI (Korea Aerospace Industries)
- KAL-ASD
- Kawasaki Heavy Industries
- *Mitsubishi Heavy Industries
- ShinMaywa
Sector Membership

Europe

- Advanced Electronics Company
- AgustaWestland
- Airbus
- Airbus Defense and Space
- Airbus Helicopters
- Alenia Aermacchi
- Avio Aero
- BAE Systems
- Dassault Aviation
- ELBIT Systems
- FACC
- Fokker Aerospace
- GKN Aerospace
- HEGAN
- Israel Aerospace Industries
- MBDA
- Meggitt
- Messier-Bugatti-Dowty
- MTU Aero Engines
- PFW
- RAFAEL
- Rolls-Royce
- SAAB Aerospace
- SAFRAN
- SAGEM
- Selex ES
- SNECMA
- SONACA
- THALES
- Turbomeca
- United Aircraft Corporation
- Zodiac Aerospace
Objectives

- Establish **commonality** of aviation, space and defense quality systems, “as documented” and “as applied”

- Establish and implement a process of **continual improvement** to bring initiatives to life

- Establish methods to share **best practices** in the aviation, space and defense industry

- **Coordinate initiatives** and activities with regulatory/government agencies and other industry Stakeholders

Only 1 management system throughout the whole Supply Chain
Why does AS&D have their own standards?

- High risk products
- High cost products
- Tightly controlled industry requirements
  - Statutory
  - Regulatory
  - Customer

- **Safety is a must**
- **Quality is required**
- **Failure is not an option**
IAQG Strategic Focus

Relationship
Growth Strategy
• Civil Authorities - Production
• Space
• Defense
• Maintenance, Repair & Overhaul
• Trade Associations

Improvement Strategy
• Requirements
• People Capability
• Product & Supply Chain Improvement
• Performance

IAQG Operating Management System
IAQG Other Party Management Team
Integration Team

3 Axes
Aligned to Address Challenges
# IAQG Requirements Team

## IAQG Leader: Alan DANIELS *(Boeing)*

### AAQG Leader
**Buddy CRESSIONNIE** *(Lockheed Martin)*

### EAQG Leader
**Judy LASLEY** *(Rolls-Royce)*

### APAQG Leader
**Tatsuya SHIRAI** *(Kawasaki Heavy Industry)*

## IAQG Document Representatives

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Company</th>
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<tbody>
<tr>
<td>9100</td>
<td>Alan DANIELS</td>
<td>Boeing</td>
</tr>
<tr>
<td>9101</td>
<td>Masahiro KAWAMOTO</td>
<td>MHI</td>
</tr>
<tr>
<td>9102</td>
<td>Carl ZIMMERMAN</td>
<td>Spirit AeroSystems</td>
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<tr>
<td>9103</td>
<td>Hervé BIGAND</td>
<td>Snecma</td>
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<tr>
<td>9104-1</td>
<td>Tim LEE</td>
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<td>Ed BAYNE</td>
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<td>9110</td>
<td>Agathe MOLL</td>
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<td>9114</td>
<td>Ed BAYNE</td>
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<td>Raymond WRIGHT</td>
<td>Raytheon</td>
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<td>9116</td>
<td>Mike QUINN</td>
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<tr>
<td>9117</td>
<td>Jan SOMMARBERG</td>
<td>GKN</td>
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<td>Elizabeth WALTERS</td>
<td>Boeing</td>
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<tr>
<td>9131</td>
<td>Claus MAYR</td>
<td>MTU</td>
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<td>Craig MANERS</td>
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<td>Albrecht FELDSMANN</td>
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<td>9136</td>
<td>Bernard LAURAS</td>
<td>Airbus</td>
</tr>
<tr>
<td>9137</td>
<td>Juan I. MARTIN</td>
<td>Airbus Military</td>
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<tr>
<td>9138</td>
<td>Dan FITZSIMMONS</td>
<td>Boeing</td>
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<td>9139</td>
<td>Jesse MANGUAL</td>
<td>Moog</td>
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<td>9145</td>
<td>Deborah OBERHAUSEN</td>
<td>PW/UTC</td>
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<td>Matt BARRON</td>
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<tr>
<td>9147</td>
<td>Jerome AUPHAND</td>
<td>Airbus</td>
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<tr>
<td>9162</td>
<td>Mark VOGEL</td>
<td>Triumph</td>
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IAQG Document Publications

- **Requirements to harmonize the Quality Management System**
  - **9100** “QMS – Requirements for Aviation, Space & Defense Organizations”
  - **9110** “QMS – Requirements for Aviation Maintenance Organizations”
  - **9120** “QMS – Requirements for Aviation, Space & Defense Distributors”
  - **9101** “QMS – Aviation, Space and Defense Audits”
  - **9104/1** “Requirements for Aviation, Space, and Defense Quality Management System Certification Programs”
  - **9104/2** “Requirements for Oversight of Aerospace Quality Management System Certification /Registration Programs”
  - **9104/3** “Requirements for Aerospace Auditor Competency and Training Courses”
  - **9115** “QMS - Deliverable Software”
  - **9137** “Guidance for the Application of AQAP 2110 within a 9100 QMS”

**Supports Certification Requirements**
Requirements to Improve Product Integrity

- **9102** “Aerospace First Article Inspection Requirements”
- **9103** “Variation Management of Key Characteristics”
- **9107** “Direct Delivery Authorization – Guidance”
- **9114** “Direct Shipment – Guidance for Aerospace Companies”
- **9131** “Non-conformance Documentation”
- **9132** “Data Matrix - Quality Requirements for Parts Marking”
- **9133** “Qualification Procedure for Aerospace Standard Parts”
- **9134** “Supply Chain Risk Management Guidelines”
- **9162** “Aerospace Operator Self-Verification Programs”

Supports Improving the Quality Management System
IAQG Document Development

- **New - Requirements to Improve Product Integrity**
  - **9116** “Aerospace Series – Notice of Change (NOC) Requirements”
  - **9117** “Delegated Product Release Verification (DPRV)”
  - **9136** “Root Cause Analysis and Problem Solving”
  - **9138** “Statistical Product Acceptance”
  - **9139** “Bodies of Knowledge”
  - **9138** “Statistical Product Acceptance”
  - **9139** “Bodies of Knowledge”
  - **9136** “Root Cause Analysis and Problem Solving”
  - **9138** “Statistical Product Acceptance”
- **9145** “Advance Product Quality Planning (APQP) / Production Parts Approval Process (PPAP)”
  - **9146** “Foreign Object Debris (FOD)”
  - **9147** “Management of Unsalvageable Items”

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**RATIONALE**

This standard was created to define the process requirements and data expectations for the submission of proposed changes in design information that requires concurrent approval of the design authority, when the design authority is different from the design activity. This standard provides for the organizational requirements, definitions, and data submission, including suggested data descriptions and formats (paper or electronic submission).

This standard was created to provide for the uniform submittal of change notifications and/or approval when contractually required at any level or as guidance within the aviation, space, and defense industries. This standard can be invoked as a standalone requirement or used in conjunction with 9100-series standards (i.e., 9139, 9140).

**FOREWORD**

To assure customer satisfaction, aviation, space, and defense industry organizations must produce and continually improve safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the industry and the resulting diversity of international requirements and expectations have complicated this objective. End-product manufacturers face the challenge of assuring that the design and manufacturing processes meet or exceed customer and regulatory requirements and at all levels of the supply chain. Industry suppliers and processors face the challenge of delivering products to multiple customers having varying quality expectations and requirements.

The aviation, space, and defense industry established the International Aerospace Quality Group (IAQG) for the purpose of achieving significant improvements in quality and safety, and reductions in cost throughout the value stream. This international organization includes representation from companies in the Americas, Asia/Pacific, and Europe. This international standard has been prepared by the IAQG.

A change process consists of design change management and/or manufacturing process change to a previously approved design (baseline configuration) of the product. This standard establishes the organizational requirements for the definition and documentation for the aviation, space, and defense industries. This standard is intended to improve quality, safety, and decrease costs by the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.
### IAQG Document Relationships

<table>
<thead>
<tr>
<th>IAQG Owners</th>
<th>Quality Standards and Best Practices</th>
<th>Data Type</th>
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<tr>
<td>IAQG Owners</td>
<td>Certification Scheme</td>
<td>Cert Scheme</td>
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<td>QMS Standards</td>
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<td>Oversight of Certification Scheme</td>
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<td>Revision</td>
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<td>9110 (Maintenance)</td>
<td>Sustain</td>
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<td>9120 (Distributors)</td>
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#### Certification Scheme

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#### QMS Standards

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### REQUIREMENTS

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<td>Sustain</td>
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### Strategy Stream

- REQUIREMENTS
- Best practices

### People Capability Strategy Stream

- Market & Sell
- Design & Develop
- Make (incl. Assemble & test)
- Buy
- Deliver
- Customer Support
- Plan & Manage
- Stakeholders relationship and communication

### People Capability documents & structure (skills matrix)

### Supply Chain Management Handbook (SCMH)

- Make (incl. Assemble & test)
- Buy
- Deliver
- Customer Support
- Plan & Manage
- Stakeholders relationship and communication
ISO 9001:2015
Revision activity
ISO 9001 Revision

Why revise ISO 9001?

- 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
## ISO 9001 Revision Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tr>
<td>Jun 2013</td>
<td>CD ballot starts</td>
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<tr>
<td>Sep 2013</td>
<td>Close of CD ballot</td>
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<tr>
<td>Nov 2013</td>
<td>Prepare DIS (Rough Draft)</td>
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<tr>
<td>Jul 2014</td>
<td>DIS Ballot (89 IAQG comments)</td>
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<tr>
<td>Oct 2014</td>
<td>DIS Ballot Closed (89% acceptance)</td>
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<tr>
<td>Nov 2014</td>
<td>Prepare FDIS (3500 comments)</td>
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<tr>
<td>Feb 2015</td>
<td>FDIS Review (IAQG Liaison)</td>
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<tr>
<td>Jul 2015</td>
<td>FDIS Ballot (100% acceptance)</td>
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**CD** = Committee Draft  
**DIS** = Draft International Standard  
**FDIS** = Final Draft International Standard
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 Policy
   5.3 Organizational roles, responsibilities and authorities

   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 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 process outputs

   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
    10.3 Continual Improvement
QMS Structure

4 Context of the organization
   4.1 Understanding of the organization and its context
   4.2 Expectations of interested parties
   4.3 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 risk and opportunity
   6.2 Quality objectives and planning to achieve
   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
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   8.2 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 Release of products and services
   8.7 Control of nonconforming process outputs

9 Performance and 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

PLAN → DO → CHECK → ACT

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Key Changes Summary

Key Changes in the ISO 9001 Baseline Draft

- Greater emphasis on processes
- Alignment with strategic direction
- Integration of the QMS into organization’s business processes
- Determining risks and opportunities
- Emphasis on change management
- Introduction of knowledge management
- Increased performance evaluation
- Improvement expanded – clause
ISO Communications

- Lead Working Group 23 in the development of:
  - ISO 9001 Revision Overview – General Users
  - ISO 9001 Revision Overview – Experts
  - Risk Based Thinking Guide
  - Correlation Matrix (before and after side by side)
  - Frequently Asked Questions (FAQs)
  - Transition Plan - coordination with IAG (training and registrations)
  - Guidance Material

- ISO 9001 Revision Webinars (over 3000 participants)

- Updated ISO 9001 information is on the ISO website
9100 Series Revision activity
IAQG 9100 Revision

9100 Series needs to change to:

• incorporate changes to the ISO 9001:2015

• consider Aviation, Space and Defense stakeholders’ needs (*web survey performed in 2013*)

• incorporate clarifications to 9100 series requested by IAQG users since the last revision (*requirements clarified or notes added*)
What is 9100?

9100 Series
International Aviation, Space and Defense Quality Model

APPROXIMATELY 105 ADDITIONAL REQUIREMENTS
- Configuration Management
- Risk Management
- Special Requirements
- Critical Items
- On Time Delivery
- Project Management
- Supplier Scope of Approval

ISO 9001
Quality Management System
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
- Revision focus is to add clarity, enhance ease of use, while addressing industry and stakeholder needs
- The 3 IAQG standards that are based on the 9100 standard are being revised in parallel (9110, 9120, 9115 = 9100 Series)
The term “9100-series standards” includes the following IAQG standards, with 9100 being the IAQG Series Baseline Standard:

<table>
<thead>
<tr>
<th>IAQG 9100</th>
<th>Quality Management Systems - Requirements for Aviation, Space and Defense Organizations</th>
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<td>IAQG 9110</td>
<td>Quality Management Systems - Requirements for Aviation Maintenance Organizations</td>
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<tr>
<td>IAQG 9115</td>
<td>Quality Management Systems - Requirements for Aviation, Space and Defense Organizations - Deliverable Software</td>
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<tr>
<td>IAQG 9120</td>
<td>Quality Management Systems - Requirements for Aviation, Space and Defense Distributors</td>
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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 Int’l Meetings (9)

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

IAQG/Sector 9100 Team Structure

Stakeholder Team Representatives

<table>
<thead>
<tr>
<th>IAQG 9100 Team</th>
<th>AAQG 9100 Team</th>
<th>EAQG 9100 Team</th>
<th>APAQG 9100 Team</th>
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<tr>
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<td>AAQSC Sector 9100 Team</td>
<td>EAQG Sector 9100 Team</td>
<td>APAQG Sector 9100 Team</td>
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### 9100 Timeline

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<td>Oct 2013</td>
<td>Stakeholder Feedback Resolution</td>
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<td>Apr 2014</td>
<td>Concept Sub-team Proposals</td>
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<tr>
<td>Jun 2014</td>
<td>Integrate ISO 9001 Draft with 9100</td>
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<tr>
<td>Jul 2014</td>
<td>Structure Draft (team)</td>
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<tr>
<td>Oct 2014</td>
<td>Working Draft (team)</td>
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<td>July 2015</td>
<td>Coordination Draft (IAQG)</td>
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<td>Dec 2015</td>
<td>Ballot (IAQG)</td>
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<td>Apr 2016</td>
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<td>Apr 2016</td>
<td>9100 Series Publication</td>
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- 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

Internal Dependencies
Standards & Training as needed for publication
- Required for 9100 publication
  - 9100 Transition Plan
  - 9101 Update (as required)
  - 9100 Training (as required)

External dependencies
ISO 9001 publications
- CD June 2013 – Begin struct. draft
- DIS : May 2014 – Begin writing 9100
- FDIS : Jul 2015 - Begin Coord. Draft
- Publish : Sept. 2015 – Prep. Ballot

For more information, see detailed schedule

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# 9100 Areas of Focus

<table>
<thead>
<tr>
<th>Areas of focus</th>
<th>Team approach</th>
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<tbody>
<tr>
<td><strong>Product Safety</strong></td>
<td>Added in carefully selected areas and consistent with 9110</td>
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<tr>
<td><strong>Human Factors</strong></td>
<td>Added as a consideration in Nonconformity / Corrective Action</td>
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<tr>
<td><strong>Risk</strong></td>
<td>Merged current 9100 requirements with the new ISO requirements</td>
</tr>
<tr>
<td><strong>Preventive Action</strong></td>
<td>Current clause requirements absorbed into Risk, Opportunities and Nonconformance</td>
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<tr>
<td><strong>Counterfeit Parts</strong></td>
<td>Enhanced in carefully select areas and limited new requirements</td>
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<tr>
<td><strong>Configuration Management</strong></td>
<td>Clause clarified and improved considerably to address stakeholder needs</td>
</tr>
<tr>
<td><strong>Product Realization &amp; Planning</strong></td>
<td>Clarified and enhanced planning throughout the standard</td>
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# 9100 Areas of Focus

<table>
<thead>
<tr>
<th>Areas of focus</th>
<th>Team approach</th>
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<tbody>
<tr>
<td>Post Delivery Support</td>
<td>Merged current 9100 requirements with the new ISO requirements</td>
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<tr>
<td>Project Management</td>
<td>Combined with Operation Planning clause to address user interpretation issues</td>
</tr>
<tr>
<td>Design Development and Supplier Management</td>
<td>Gap analysis - ISO text has been added back in a few places to meet the IAQG needs</td>
</tr>
<tr>
<td>Quality Manual</td>
<td>Note added pointing to the requirements that make up a Quality Manual or the equivalent</td>
</tr>
<tr>
<td>Management Representative</td>
<td>Requirement added back in for Management Representative QMS oversight</td>
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## 9100 Series Changes - High Level Summary

### 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
- No normative references

### Clause 3: Terms and definitions
- ISO 9001 terms and definitions moved to ISO 9000
- Added 9100 “product safety”, “counterfeit product”

### 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 organizational knowledge requirements
- Awareness of contribution to compliance and product safety

### Clause 8: Operation
- Planning for product obsolescence
- Plan activities needed to assure product safety
- Prevention of counterfeit products
- Process to validate test reports for raw material used in critical item
- 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
- Evaluation the need for action based on human factors

---

**All ISO MS standards will now have this common 10 clause structure**
IAQG 9100 Revision:
Benefits and Application
Implementation Benefits

When implemented and managed well can improve:

- 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
9100:2016
Quality Management System

9100 “Quality Management Systems – Requirements for Aviation, Space and Defense Organizations”

- Establishes commonality of aviation, space and defense QMS requirements
- Takes into account new requirements from aviation, space & defense and other QMS standards
- Incorporates stakeholder feedback
- Provides a common baseline with ISO 9001 which benefits:
  - Suppliers with dual certification requirements
  - Sub-tier suppliers who only need ISO 9001
  - Commonality enhances both auditor flexibility and reduced training
Industry Application

- **9100 “Quality Management Systems – Requirements for Aviation, Space and Defense Organizations”**

  - All IAQG aviation, space and defense companies are certified to a version of 9100, 9110 or 9120

  - All IAQG and Sector member companies flow down 9100, 9110 or 9120 to their supply chain

  • Note: Supply chain flow down of 9100 is based on eligibility criteria and the organization may allow deviations as applicable
IAQG
9100 Series
Revision
Communications
## 9100 Series Support Material & Communications

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### Requirements Newsletter
- **Buddy**
- Leadership: X
- Oct 2015: X
- Apr 2016: X
- Recurring: X

### Key Changes Presentation
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- Oct 2015: X
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### Correlation Matrix
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- Oct 2015: X
- Apr 2016: X
- Recurring: X

### FAQ
- **Kim**
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- Oct 2015: X
- Apr 2016: X
- Recurring: X

### Clarifications
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- Leadership: X
- Oct 2015: X
- Recurring: X

### Webinars
- **IDR/SDRs/Team**
- Leadership: X
- Oct 2015: X
- Apr 2016: X
- Recurring: X

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**International Aerospace Quality Group (IAQG) Requirements Newsletter**

**Spring 2015 Edition**

The International Aerospace Quality Group (IAQG) Requirements Team is committed to communicating with its many stakeholders and has decided to start publishing a semi-annual newsletter. This newsletter and other communication content is available on the www.iaqg.org website. The goal is to communicate information via our website to the aviation, space and defense industries. The goal is to communicate information via our website to the aviation, space and defense industries.

**9100 revision 2016 Summary of changes in Aviation, Space and Defense requirements**

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Tools for review and implementation

9100 Series Key Changes

Process Approach
Risk-based Thinking/Management
Counterfeit Product
Product Safety

And more…

Frequently Asked Questions

1. Why has it been decided to issue a new version of 9100?
Business needs and the needs and expectation of other interested parties have changed significantly since the last major revision of ISO 9001 in the year 2000. Examples of these changes are ever more demanding customers, the emergence of new technologies, increasingly more complex supply chains and a much greater awareness of the need for sustainable development initiatives.

2. Does 9100 still apply to all organizations - big, small, different sectors and different items – products, services?
The concept of the standard has not changed; it’s applicable to any type of organization, regardless of the size, type or core business.

3. Has the structure of the standard been substantially changed?
Yes, the structure has been changed to align with the common SD clause high level structure developed by ISO to ensure greater harmonization among its many different management system standards. The new revision to ISO 14001 will also adopt this same structure, which is built around the PDC (Plan-Do-Check-Act) sequence. It will make it easier for organizations to address the requirements of more than one ISO Management System Standard within a single, integrated system.

4. What are the structural differences between the old and new version?
[Details of changes listed here, including new clauses and restructured content]

5. What are the main differences in content between the old and new version?
There is more flexibility regarding documentation, but with a greater emphasis on the organization being able to manage its processes in order to provide consistently conforming products and services. The application of the standard to service organizations is emphasized, as well as those making tangible products; there are more stringent requirements for leadership by top management; the term preventive action is replaced by the concept of risk based thinking that permeates.

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9100 Series Next Steps

- Continue to leverage ISO 9001 deployment support material for use with the 9100 Series
- Coordination draft and support material routed to IAQG member companies for comment
- Disposition of comments to be completed in October (Madrid)
- Launch of ballot targeted for December
- Resolution of comments April 2016 (Singapore)
- Release for publication in 2016
Excellent starting points for resources.
Supply Chain Management Handbook (SCMH)

- The SCMH provides guidance material to help continuously improve On Time, On Quality Delivery (OTOQD)

- It is provided at no cost and is available to all levels of the supply chain

- Link: http://www.sae.org/scmh/
9100 Resources

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Questions?