The IAQG is a legally incorporated international not for profit association (INPA) with membership from the Americas, Europe and the Asia Pacific Region.
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9100 Revision 2016

Introduction
reason for revision, team and timeline
What is 9100?
ISO 9001:2015 Baseline Text

9100 Series
International Aviation, Space and Defense Quality Requirements

**ADDITIONAL REQUIREMENTS**
- Operations Risk Management
- Product Safety
- Special Requirements
- Critical Items
- Configuration Management
- On Time Delivery
- Counterfeit Parts
- Expanded requirements for production and external providers

ISO 9001
Quality Management System
The “ISO 9001” needed 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)*
9100 Revision 2016

Quality Management Principles
ISO 9000 Quality Management Principles

<table>
<thead>
<tr>
<th>There were 8 principles</th>
<th>There are now 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer focus</td>
<td>Customer focus</td>
</tr>
<tr>
<td>Leadership</td>
<td>Leadership</td>
</tr>
<tr>
<td>Involvement of people</td>
<td>Engagement of people</td>
</tr>
<tr>
<td>Process approach</td>
<td>Process approach</td>
</tr>
<tr>
<td>System approach to management</td>
<td>(included in the process approach)</td>
</tr>
<tr>
<td>Continual improvement</td>
<td>Improvement</td>
</tr>
<tr>
<td>Factual approach to decision making</td>
<td>Evidence based decision making</td>
</tr>
<tr>
<td>Mutually beneficial supplier relationships</td>
<td>Relationship management</td>
</tr>
</tbody>
</table>
Key changes in the ISO 9001 Baseline content
Key Changes *from ISO 9001:2015 baseline*

- High level structure (HLS) & Terminology
- Risk-based thinking - Concept of preventive action now addressed throughout the standard by risk identification and mitigation
- Process approach strengthened with integration of the QMS into organization’s business processes
- Emphasis on change management
- Introduction of knowledge management
Key Changes *(from ISO 9001:2015 baseline)*

- 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
### 9100 revision 2016

**Terminology Changes (from ISO 9001 baseline)**

<table>
<thead>
<tr>
<th>Previous version</th>
<th>New Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products</td>
<td>Products and services</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Scope of the QMS to be formally defined and all requirements are applicable if they are in the scope</td>
</tr>
<tr>
<td>Documentation, records, documented procedures</td>
<td>Documented information&lt;br&gt;• maintained = documents or procedures&lt;br&gt;• retained = records</td>
</tr>
<tr>
<td>Purchased product</td>
<td>Externally provided products and services</td>
</tr>
<tr>
<td>Supplier</td>
<td>External provider</td>
</tr>
</tbody>
</table>

**Documented information does not need to be changed to incorporate new terminology**


Use of simplified language and writing styles to aid understanding and consistent interpretation of requirements
High Level Structure

- ISO is going from 8 clauses to 10 clauses

<table>
<thead>
<tr>
<th>Plan</th>
<th>Do</th>
<th>Check</th>
<th>Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Context of organization</td>
<td>8 Operation</td>
<td>9 Performance Evaluation</td>
<td>10 Improvement</td>
</tr>
<tr>
<td>5 Leadership</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Planning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Support</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rationale

- Better alignment to **business** strategic direction
- **PDCA** approach
- All ISO management systems standards **built** on the same structure and same terminology, to facilitate the option of having one integrated management system
- This structure is intended to provide a **coherent presentation of requirements rather than a model** for documenting an organization’s policies, objectives and processes
9100 revision 2016
HLS: High Level Structure (from ISO 9001 baseline)
9100 Revision 2016

Key changes in the 9100 additions
Key Changes (aviation, space and defense 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 *(aviation, space and defense 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

- **Awareness**
  reinforced requirements for awareness of individual contribution to quality

- **Human factors**
  included as a consideration in nonconformity / corrective action

- **Configuration management**
  clarified and improved to address stakeholder needs
9100 Revision 2016

High Level Summary of Changes
Implementation benefits
### 9100 Changes - High Level Summary

<table>
<thead>
<tr>
<th>Clause 1 Scope</th>
<th>Clause 2 Normative ref</th>
<th>Clause 3 Terms and definitions</th>
<th>Clause 4 Context of the organization</th>
<th>Clause 5 Leadership</th>
<th>Clause 6 Planning for the QMS</th>
<th>Clause 7 Support</th>
<th>Clause 8 Operation</th>
<th>Clause 9 Performance evaluation</th>
<th>Clause 10 Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>New process model</td>
<td>ISO 9000:2015 referenced</td>
<td>ISO 9001 terms and definitions moved to ISO 9000</td>
<td>Maintained documented information is required, can be named Quality Manual</td>
<td>QMS compatible with strategic direction</td>
<td>When planning the QMS, determine the actions needed to address opportunities and risks (prevention)</td>
<td>Determine knowledge management requirements</td>
<td>Planning for product obsolescence</td>
<td>Assess performance of QMS processes</td>
<td>Consider human factors in nonconformity / corrective action</td>
</tr>
<tr>
<td>Added a PDCA model</td>
<td></td>
<td>Added 9100 “product safety”, “counterfeit part”</td>
<td>Justified exclusions not limited to Realization/Operations processes</td>
<td>QMS requirements integrated into business processes</td>
<td>Increases requirements for planning of changes</td>
<td>Awareness on product conformity, product safety, ethical behavior</td>
<td>Plan activities needed to assure product safety</td>
<td>Added Note to evaluate performance indicators on internal audits</td>
<td></td>
</tr>
<tr>
<td>Added “Risk-based thinking”</td>
<td></td>
<td></td>
<td>QMS processes have performance indicators</td>
<td>Processes deliver their intended outputs</td>
<td></td>
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</tr>
<tr>
<td>Emphasis on defining the QMS and context of the organization</td>
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</tbody>
</table>

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 where necessary and managed
  – Improved integration with business operations and strategy
  – 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 Revision 2016

Deployment Support Material
Where to find it?
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Path through the IAQG web site

www.iaqg.org
IAQG 9100 - Quality Management Systems - Requirements for Aviation, Space and Defense Organizations

This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, schedule and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practice. While primarily developed for the aviation, space and defense industry, this standard can also be used in other industry sectors where a quality management system with additional requirements over an ISO 9001 system is needed.

- 9100:2016-Series - QMS: Aviation, Space and Defense Organizations Standards Clarifications
  - 9100:2016 Series Clarification Table

- 9100:2016 - QMS: Aerospace Improvement Maturity Model (AIMM) (In Development)

- 9100:2016 - QMS: Aviation, Space and Defense Organizations Guidance Materials
  - Support Materials
    - Frequently Asked Questions (FAQs)
    - Gap Assessment Worksheet
    - 9100 Evaluation Guidance Material
    - Relationship between IAQG Standards and 9100:2016 Standard (Table C1)
  - Correlation Materials
    - Correlation of 9100:2016 mapped against EASA Commission Regulation (EU) 748/2012 Part-21
    - Correlation of 9100:2016 mapped against FAA Part-21
  - Presentations
    - Executive Level Summary Presentation
    - Key Changes Presentation
    - Clause-by-Clause Presentation
    - 9100:2016-Series Major Changes Recording (in Development)
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    - 2019 May ASQ Quality Progress: The Complete Package
Questions