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

Introduction
reason for revision, team and timeline

May 2016
9100 revision 2016

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
9100 revision 2016

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

### Buddy Cressionnie
- **9100 AAQG SDR**
- **Lockheed Martin**

### Brigitte Clamens
- **9100 EAQG SDR**
- **Zodiac Aerospace**

### Hiroshi Shuto
- **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

<table>
<thead>
<tr>
<th>Team Leader</th>
<th>9100 IDR</th>
<th>Organization</th>
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<tbody>
<tr>
<td>Alan Daniels</td>
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<td>9100 Scribe</td>
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</table>
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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)

**Stakeholder Team Representatives**

- IAQG 9100 Team
  - AAQG 9100 Team
    - AAQSC Sector 9100 Team
  - EAQG 9100 Team
    - EAQG Sector 9100 Team
  - APAQG 9100 Team
    - APAQG Sector 9100 Team
## 9100 Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>Oct 2013</td>
<td>Stakeholder Feedback Resolution</td>
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<tr>
<td>Apr 2014</td>
<td>Concept Sub-team Proposals</td>
</tr>
<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>
</tr>
<tr>
<td>Oct 2014</td>
<td>Working Draft (team)</td>
</tr>
<tr>
<td>July 2015</td>
<td>Coordination Draft (IAQG)</td>
</tr>
<tr>
<td>Nov 2015</td>
<td>Ballot (IAQG)</td>
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<td>Apr 2016</td>
<td>9100 complete through IAQG Ballot</td>
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<tr>
<td></td>
<td>Support Material (issued: May 2015, Dec 2015, )</td>
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9100 Series Revision: an integrated schedule tracked

For more information, see detailed schedule

- Preparing
  - Ballots, reviews and comments
- Publications
9100 Revision 2016

Quality Management Principles

May 2016
Quality Management Principles

<table>
<thead>
<tr>
<th>There were 8 principles</th>
<th>There are now 7</th>
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<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>
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<td>Process approach</td>
<td>Process approach</td>
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<tr>
<td>System approach to management</td>
<td>(included in the process approach)</td>
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<tr>
<td>Continual improvement</td>
<td>Improvement</td>
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<tr>
<td>Factual approach to decision making</td>
<td>Evidence based decision making</td>
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<tr>
<td>Mutually beneficial supplier relationships</td>
<td>Relationship management</td>
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</table>
Key changes in the ISO 9001 content
9100 revision 2016

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
- Introduction of knowledge management
- Concept of preventive action now addressed throughout the standard by risk identification and mitigation

Note to presenter: if using “click for more” links, you will need to skip the associated slides by using the arrow on the next slide.
Key Changes \textit{(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
9100 Revision 2016

Terminology &
High Level Structure (HLS)
### 9100 revision 2016

**Terminology Changes (from ISO 9001)**

<table>
<thead>
<tr>
<th>Previous version</th>
<th>New Version Sept. 2015</th>
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<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</td>
</tr>
<tr>
<td></td>
<td>• maintained = documents or procedures</td>
</tr>
<tr>
<td></td>
<td>• 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>

+ 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>5 Leadership</td>
<td>6 Planning</td>
<td>7 Support</td>
</tr>
<tr>
<td>8 Operation</td>
<td>9 Performance Evaluation</td>
<td>10 Improvement</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
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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
9100 revision 2016
HLS: High Level Structure (from ISO 9001)

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

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
Business Management System around a Value Stream

Customer needs ----> Value Stream ----> Support customers

Governance

- Drive company
- Define strategy
- Manage improvements
- Define Policies

Support

- Human Resource
- Facilities
- Communication
- Finance
- Information Technologies

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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 “prevention” 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 products 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 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

<table>
<thead>
<tr>
<th>Plan</th>
<th>set objectives and build processes necessary to deliver results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do</td>
<td>implement what was planned</td>
</tr>
<tr>
<td>Check</td>
<td>monitor and measure processes and results against the objectives</td>
</tr>
<tr>
<td>Act</td>
<td>take actions to improve results</td>
</tr>
</tbody>
</table>
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 “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 required by the 9100:
  - 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”
The standard has become a dynamic framework which evolves to enable organizations to adapt to their changing environments or circumstances.

Change is addressed in several 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)
- Ensuring appropriate actions are taken about changes relating to requirements for products and services (8.2.4)
- Managing changes relating to design and development (8.3.6)
- Addressing changes affecting production or service provision (8.5.6)
9100 Revision 2016
Organizational knowledge
Knowledge specific to the organization is gained by experience.

**Rationale:**
- To safeguard the organization from *loss of knowledge*, e.g.,
  - through staff turnover;
  - failure to capture and share information;
- To encourage the organization to *acquire* (e.g., learning from experience, benchmarking ... ) and *share knowledge* (e.g. mentoring of newcomers);

**Implementation consideration**
- Activities to benefit from *lessons learned*, e.g., database, communications, incorporation of lessons learned in processes and procedures
- Identification of *experts* able to transfer knowledge, on job training, tutorial sessions
- Implement *succession* planning activities
9100 Revision 2016

Key changes in the 9100 additions

May 2016
Key Changes *(in the AS&D 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 AS&D 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

Note to presenter: if using “click for more” links, you will need to skip the associated slides by using the arrow to move to the next section.
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9100 Revision 2016

*Product safety*
Addition

- New clause (8.1.3) on Product Safety, including requirements to address product safety considerations throughout the product lifecycle (use the NOTE as guidance) + revision for consistency of other clauses related to safety – 7.3, 8.1, 8.4.3 & 8.5.4

- 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

Rationale

- Industry acknowledgement of the importance of increasing safety
- Recognition of the 9100 certifications by authorities is part of IAQG strategy

Definition

- “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 to consider:

- **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 to consider (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 (8.1.4) including requirements for prevention of counterfeit parts and a note giving examples of the associated processes
  + revision of affected clauses: 8.4.2; 8.4.3 (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

Definition

- “An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

  NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.”
Processes to consider:

- **Training** in the awareness and prevention of counterfeit parts
  - ✓ Procurement personnel in trusted source selection and requirements
  - ✓ Inspection personnel for prevention of counterfeit items (visual/test)
  - ✓ Design personnel in obsolescence management

- **Obsolescence monitoring** → design decisions and parts selections to be appropriate for service life of product

- **Controls for acquiring parts** → from original manufacturers, authorized distributors, or other approved sources

- **Assuring traceability** of parts and components to their original manufacturers:
  - ✓ Original Equipment Manufacturer (OEM) or
  - ✓ Authorized manufacturer (e.g., in case of PMA, direct delivery authorizations)
Processes to consider:

- **Verification and test methodologies** to detect counterfeit parts:
  - Parts identification or marking
  - Tests or chemical analysis

- **Counterfeit parts reporting**
  - Monitoring reporting from external sources (access to databases, information letters from OEMs)
  - Quarantine and reporting of internal incidences in appropriate government and industry reporting systems
    (determine the responsibilities in the escalation process, the process to follow to report to authorities / customers)

**Requirement regarding non conformance control:**

- Segregate and control suspected or known counterfeit products
- Ensure these products are not re-introduced into the supply chain
9100 Revision 2016

Risk management
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
- Adapt the process to the organization and the product
  (e.g. quantitative requirements and probabilistic risk analysis may be required in some cases; determine people involved in this activity)
- Deploy the risks analysis within the operation activities
  (such as: contract review and signature, new technologies introduction, external providers selection, …)
9100 Revision 2016

Awareness
The 9100:2016 requires the employees aware of:
- their contribution to product or service conformity
- their contribution to product safety,
- the importance of ethical behavior

**Awareness activities** can be performed in different ways:
- direct communication of expectations between managers and employees
- communication campaigns on dedicated topics, e.g., posters, pamphlets, fliers, newsletters, videos
- identification of focals with responsibility for communication and promotion,
- formal training

**What is expected:**
- individuals should be able to explain their own role, how they contribute to quality,
- quality basics (follow instructions, report events, maintain records …),
- individuals know the use of the products and potential impact of failures
Importance of ethical behavior

- Organizations should make their own determination of what is important to communicate to their employees in regard to ethics.

- Below some items for considerations:
  - Establishing a culture where employees understand their responsibilities.
  - Managers listening to employees and effectively recognizing their work (in addition it can help boost productivity).
  - Reporting and not passing on defects or non-conformances (e.g., line stoppage as appropriate, recalling delivered non-conforming product, ..).
  - A culture allowing unethical behavior can breed all manner of damaging and even criminal activity.
  - Respect the laws, regulations, internal rules, regarding e.g.: conflict of interests, export compliance regulations, intellectual property agreements, acceptance or proposals of gifts, invitations or favors with customers and suppliers.
9100 Revision 2016

Human Factors
Addition

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

Definition

- The understanding of the interactions between people, machines and each other and their impact on human performance.
- Example: Recognition that persons performing tasks are affected by physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication and attitude in order to ensure a safe interface between the persons and all other environmental elements such as other persons, equipment, facilities, procedures and data.
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 the elements to be reviewed during the root causes analysis of nonconformities
- Capitalize with lessons learned on occurred human errors
High Level Summary of Changes
Implementations benefits

9100 Revision 2016

May 2016
<table>
<thead>
<tr>
<th>Clause 1 Scope</th>
<th>No Requirements</th>
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<tbody>
<tr>
<td>New process model</td>
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<tr>
<td>Added a PDCA model</td>
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<tr>
<td>Added “Risk-based thinking”</td>
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<td>Emphasis on defining the QMS and context of the organization</td>
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<th>ISO 9000:2015 referenced</th>
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<th>ISO 9001 terms and definitions moved to ISO 9000</th>
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<td>Added 9100 “product safety”, “counterfeit part”</td>
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<table>
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<th>Clause 4 Context of the organization</th>
<th>Maintained documented information is required, can be named Quality Manual</th>
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<tbody>
<tr>
<td>Justified exclusions not limited to Realization/Operations processes</td>
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<tr>
<td>QMS processes have performance indicators</td>
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<thead>
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<th>Clause 5 Leadership</th>
<th>QMS compatible with strategic direction</th>
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<tbody>
<tr>
<td>QMS requirements integrated into business processes</td>
<td></td>
</tr>
<tr>
<td>Processes deliver their intended outputs</td>
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<table>
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<th>Clause 6 Planning for the QMS</th>
<th>When planning the QMS, determine the actions needed to address opportunities and risks (prevention)</th>
</tr>
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<tbody>
<tr>
<td>Increases requirements for planning of changes</td>
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<thead>
<tr>
<th>Clause 7 Support</th>
<th>Determine knowledge management requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness on product conformity, product safety, ethical behavior</td>
<td></td>
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<tr>
<th>Clause 8 Operation</th>
<th>Planning for product obsolescence</th>
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</thead>
<tbody>
<tr>
<td>Plan activities needed to assure product safety</td>
<td></td>
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<tr>
<td>Prevention of counterfeit parts</td>
<td></td>
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<tr>
<td>Process to validate test reports for raw material based on risks</td>
<td></td>
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<tr>
<td>Release of products and services</td>
<td></td>
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</tbody>
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<thead>
<tr>
<th>Clause 9 Performance evaluation</th>
<th>Assess performance of QMS processes</th>
</tr>
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<tbody>
<tr>
<td>Added Note to evaluate performance indicators on internal audits</td>
<td></td>
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<thead>
<tr>
<th>Clause 10 Improvement</th>
<th>Consider human factors in nonconformity / corrective action</th>
</tr>
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</table>

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

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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
9100 Revision 2016

Deployment Support Material

Where to find it?

May 2016
The IAQG is a legally incorporated international not for profit association (INPA) with membership from the Americas, Europe and the Asia Pacific Region.
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 - Quality Management System: Aviation, Space and Defense Organizations
  - Changes Presentation
  - FAQ
  - 2015 July Quality Progress
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  - For questions, please contact the IAQG and Sector Document Representatives

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Questions