9110 Revision 2016

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Introduction
reason for revision, team and timeline
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Reason for the revision
9110 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
The “9110” needs to change, to:

- Incorporate changes made by ISO TC176 to the ISO 9001:2015 requirements *(contribution of 9110 IDR as part of 9100 team)*

- Consider Aviation and Defense stakeholders’ needs identified since the last revision *(involvement of 9110 Contributors by 9110 Team)*

- Consider requests for 9110 clarifications issued by IAQG since the last revision *(requirements clarified or notes added)*

- Consider clarifications to Clause 8.3 Design and Development scope of activities *(clarification of Repair data development and Continuing Airworthiness Management activities)*
9110 revision 2016

Team members and timeline for the revision
<table>
<thead>
<tr>
<th>Name</th>
<th>Role/Position</th>
<th>Company/Representative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agathe Moll</td>
<td>IAQG 9110 IDR – Team Leader</td>
<td>Airbus S.A.S.</td>
</tr>
<tr>
<td>Felipe Reyes</td>
<td>9110 AAQG SDR CHC Helicopter</td>
<td>Leonardo Aircraft</td>
</tr>
<tr>
<td>Flavio Izzo</td>
<td>9110 EAQG SDR</td>
<td>PW/UTC</td>
</tr>
<tr>
<td>David Tan</td>
<td>9110 APAQG SDR PW/UTC</td>
<td>PW/UTC</td>
</tr>
<tr>
<td>Paul Hawthorne</td>
<td>9110 AAQG Representative Moog</td>
<td>PW/UTC</td>
</tr>
<tr>
<td>Erick David</td>
<td>9110 EAQG Representative Safran Aircraft Engines</td>
<td>PW/UTC</td>
</tr>
<tr>
<td>Ricky Au</td>
<td>9110 APAQG Representative Liebherr Singapore</td>
<td>PW/UTC</td>
</tr>
<tr>
<td>Sergio Frutuoso</td>
<td>9110 AAQG Member PW/UTC</td>
<td>PW/UTC</td>
</tr>
<tr>
<td>Daniel Albier</td>
<td>Certified Aviation Auditor ADAC - Thechnowest</td>
<td>PW/UTC</td>
</tr>
</tbody>
</table>
The IAQG is a legally incorporated international not for profit association (INPA) with membership from the Americas, Europe and the Asia Pacific Region.

Representatives of 9110 sector teams at Int’l Meetings

Sector 9110 Team Meetings to gather Sector inputs and develop Sector positions. Operation managed at Sector Level

IAQG 9110 Writing Team collects sector and stakeholder input and creates draft.

IAQG/Sector 9110 Team Structure

- IAQG 9110 Writing Team
- AAQG 9110 Sector Rep
- EAQG 9110 Sector Rep
- APAQG 9110 Sector Rep
- AAQSC Sector 9110 Team
- EAQG Sector 9110 Team
- APAQG Sector 9110 Team

Stakeholders & Contributors

January 2017
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**IAQG 9110 Core Team**
- CHC Helicopter
- Airbus
- PW/UTC
- Moog
- Leonardo Aircraft
- Liebherr Singapore
- Safran
- ADAC

**OAQG 9110 Core Team**
- CHC Helicopter
- Moog
- Leonardo Aircraft
- PW/UTC
- Liebherr Singapore
- Safran
- ADAC

**APAQG Contributors**
- Aviation Insight
- Korean Air
- Indonesian Aerospace
- Thales Aerospace

**EAQG Contributors**
- MTU
- Dolomiti
- AMS
- Air France Industries
- EASA
- Airbus D&S
- Ethiad (ex ADAT)

**AAQG Contributors**
- Air Dolomiti
- Alitalia
- Aermec-canica
- Sabena Technics
- UAE GCAA
- SIAé
- Dassault Aviation

**Contributors**
- CHC Helicopter
- Airbus
- PW/UTC
- Moog
- Leonardo Aircraft
- Liebherr Singapore
- Safran
- ADAC

**Contribution Timeline**
- January 2017
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**91XX Series Revision - Integrated Schedule**

- **2012**
  - San Antonio: 05/2012
  - Nagoya: 10/2012

- **2013**
  - Moscow: 05/2013
  - Montreal: 10/2013

- **2014**
  - Brussels: 04/2014
  - Long Beach: 10/2014

- **2015**
  - Chengdu: 04/2015
  - Madrid: 10/2015

- **2016**
  - Singapore: 04/2016
  - Miami: 10/2016

- **2017**
  - Stockholm: 04/2016

**Internal Dependencies**
- Required for 9100 publication
  - 9100 Revision
  - 9101 Revision
  - 9100 Transition & Training Plan

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

**Training - OPMT**
Development

**Auditor training & Transition**

**Plan & Stakeholders feedback**

**Publications**
- Preparing
- Ballots, reviews and comments

**January 2017**
9110 Revision Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 2013</td>
<td>Stakeholder Feedback Resolution</td>
</tr>
<tr>
<td>Apr 2014</td>
<td>Concept Sub-team Proposals</td>
</tr>
<tr>
<td>Jun 2014</td>
<td>Integrate ISO 9001 Draft with 9110</td>
</tr>
<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>Dec 2015</td>
<td>Ballot (IAQG)</td>
</tr>
<tr>
<td>May 2016</td>
<td>9110 complete through IAQG Ballot</td>
</tr>
<tr>
<td>Oct 2016</td>
<td>Formatting of Sector Versions</td>
</tr>
<tr>
<td>Nov 2016</td>
<td>Publication Approval / Publication</td>
</tr>
</tbody>
</table>

3 years in the making. Team processed a total of 510 comments received from IAQG members and contributors since first draft in 2014.
QMS Requirements specific to Civil, Military Aviation Maintenance and Continuing Airworthiness Industry

ISO 9001 Quality Management System

4. Context
5. Leadership
6. Planning
7. Support
8. Operations
9. Performance Evaluation
10. Improvement

ISO 9001:2015 as baseline requirement
9110 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
9110 revision 2016

Key Changes \((\textit{from ISO 9001:2015 baseline})\)

- 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
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Terminology &
High Level Structure (HLS)
### 9110 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</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>

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

**Definition Hierarchy:** IAQG Standards, ISO 9000:2015, IAQG Dictionary, Oxford Dictionary

**Use of simplified language and writing styles to aid understanding and consistent interpretation of requirements**
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### 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
9110 revision 2016

HLS: High Level Structure (from ISO 9001 baseline)

Plan

- 4 Context of organization
  - 4.1 Understanding the org & its context
  - 4.2 Interested parties
  - 4.3 Scope
  - 4.4 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 Objectives and planning
  - 6.3 Planning of changes

- 7 Support
  - 7.1 Resources
  - 7.2 Competence
  - 7.3 Awareness
  - 7.4 Communication
  - 7.5 Documented information

Do

- 8 Operation
  - 8.1 Operational planning and control
  - 8.2 Requirements for products & services
  - 8.3 Design and Development of products & services
  - 8.4 Control of externally provided processes, products & services
  - 8.5 Production and service provision
  - 8.6 Release of products & services
  - 8.7 Control of nonconforming outputs

Check

- 9 Performance Evaluation
  - 9.1 Monitoring, measurement, analysis and evaluation
  - 9.2 Internal audit
  - 9.3 Management review

Act

- 10 Improvement
  - 10.1 General
  - 10.2 Nonconformity and corrective action
  - 10.3 Continual improvement

January 2017
HLS Table of Contents – ISO 9001 / 9110

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
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
9110 revision 2016
HLS: High Level Structure (from ISO 9001)

HLS Table of Contents – ISO 9001 / 9110

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

There is no requirement for the QMS documentation to reflect the structure and terminology of the standard.

If you choose to change the QMS documentation consider structuring around the business processes of your company.

- A business process (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.

Benefits

- Common management systems (structure, terminology, definitions)
- Additional focus on PDCA (improvement/project management)
- Clearer and better organization of requirements
Implementation Considerations

Example of Process Based QMS

Business Management System around a Value Stream

Each organization has to determine their business processes.
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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.
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**
Benefits

- Change of culture and mindset to be proactive
- Focus on priorities and what adds value to the company
- Ensures alignment of resources to issues/risks
- Ensures greater knowledge of risks and improves preparedness
- Increases the probability of reaching objectives
- Reduces the probability of negative results

Summary…

- Is not new
- Is something many organizations already do already
- Is continuous
- Makes prevention a habit
9110 additions highlight that:

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 “Operation”:
- Implement a formal process to manage risks
- Deploy the risks analysis within the operation activities
  (such as: contract review and signature, new technologies introduction, external providers selection, …)
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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?

- Each organization is required to define key business processes
  - They must follow all the 4.4 requirements (e.g. inputs, outputs, sequence and interaction, resources needed, responsibilities, risks and opportunities, and related performance indicators)
  - 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 organization must also maintain processes to manage functioning / working activities
  - (e.g. risks, products configuration, critical items, product safety, internal audits, nonconformities and corrective actions)
  - Determine whether flowcharts, routines, maps or procedures are needed to ensure effective implementation
What processes to define for my organization?

- The “Key” “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:
  - 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
Applicability of the entire Standard to the Organization?

- The Scope of the organization defines applicability:
  - Must follow the requirements in clause 4.3
  - Certified organizations will be required to show justification in its scope for any parts of the standard or processes required that are declared as not applicable

- Example for an MRO declaring 8.3 is N/A:
  - XYZ MRO is a maintenance organization not having DOA nor CAM capabilities. No products or services are required to be designed and developed per clause 8.3 in order to conform to customer or regulatory requirements. No additional services are provided beyond the maintenance/repair activities being ensured

Each organization has to justify “non-applicability”
Applicability of the entire Standard to the Organization?

- 9110 is built on the “complete” 9001:2015 Standard
  - 9001:2015 shifts to “Products and Services”
  - Maintenance is a Service

- Rationale for 8.3 application in 9110 context
  - Design and Development is “applicable” to organizations (i.e. Airlines or external providers) ensuring the Continuing Airworthiness management or to organizations having Repair definition capabilities.
  - Services are related to:
    - Developing Repair data
    - Developing aircraft maintenance programs using maintenance schedules
    - Preparing continuing airworthiness management activities up to the issuance of the work-order used as an input for the maintenance organization (MRO)
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Concept of “change”
9110 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)

Benefits:

- Business continuity when changes
- Consideration of potential consequences
- QMS integrity maintained
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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

**Benefits**
- Continuity of business operations when personnel turnover
- Mitigates impact of losing personnel
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Key changes in the 9110 additions
Key Changes *(aviation, space and defense requirements)*

As a consequence of the new ISO 9001 structure:

- 9110 additions have been *relocated* into appropriate ISO sections

- the requirements are better *organized* and *clarified*, with notes and examples to enhance understanding
Key Changes *(new or reinforced requirements vs 9110:2012)*

- Product safety / Safety management
  - added in a separate clause and in selected areas with safety performance evaluation requested
- Counterfeit Part and Suspected Unapproved Parts prevention
  - added in a separate clause and in selected areas. Introduction of unsalvageable parts
- Installation of Approved Parts
  - added in a separate clause with a focus on use of dismantled parts, Life Limited Parts, parts involved in an accident or incident
- Continuing Airworthiness Management
  - covered as a service in 8.3 Design and development with key activities such as the AD assessment and Maintenance programme development
- New terms introduced in 9110
Key Changes *(clarified compared to 9110:2012)*

- **Evaluation of New Capability**  
  equivalent of Maintenance process verification

- **Risk Management**  
  merged current 9110 requirements with the new ISO requirements and emphasis on risks in operational processes as well as risks during transition period

- **Awareness**  
  clarified and improved to address stakeholder needs including a focus on safety and Human Factors as already covered in previous version

- **Management Representative**  
  quality manager and post holders added in addition to the accountable manager
Key Changes *(adapted or removed compared to 9110:2012)*

- **Post Delivery Support**
  ISO requirements completed with requirements relevant to 9110 in appropriate context considering that Post Delivery Support is very limited for MRO.

- **Control of Work Transfer**
  Covered through the planning of organization changes under 6.3 and requiring significant regulatory approval and oversight.

- **Quality Manual**
  Quality Manual was removed from ISO as more a “how to” requirement. The exposition or manual required by the competent authority can be construed as “documented information” of the QMS.

- **Removed definitions from 9110**
  “Key characteristic” and “Critical items” as not fully applicable. “Special requirements”, “Release certificate” and “Human factors” even if applicable.

- **Removed reference to IAQG 9115 related to “Deliverable Software”**
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Revision / Addition

- New clause on Product Safety, including requirements to assure product safety and a note giving examples of the associated processes and revision for consistency of other clauses related to safety – 7.3, 8.1, 8.4.3 & 8.5.4

Rationale

- Industry acknowledgement of the importance of increasing safety
- Recognition of the 9110 certifications by authorities is part of IAQG strategy

Implementation considerations

- Address product safety considerations throughout the product lifecycle (use the NOTE as guidance)
- A full Safety Management System (SMS) as defined by ICAO (International Civil Aviation Organization) is not required by 9110, but the introduction of this new clause contributes to the SMS approach
Product safety definition (3.4)

- 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

- Assessment of hazards and mitigation of associated risks
- Evaluation of the safety performance
- Avoidance of conflicting situation with customer satisfaction
- Improvement of product safety management and performance
- Opportunities for prevention of maintenance error
- Flow down of product safety principles to applicable external providers
Examples of activities (cont’d)

- **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)
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Prevention of counterfeit parts
9110 revision 2016
Counterfeit Parts prevention

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.”
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Prevention of suspected unapproved parts
Addition

- New clause including requirements for prevention of suspected unapproved parts and a note giving examples of the associated processes and revision of affected clauses: 3 (definition).

Rationale

- Counterfeit parts addressed in 8.1.4 is a subset of Unapproved Parts.
- The credible evidence indicating that the part was likely not produced or maintained in accordance with approved or acceptable data can be termed as a Suspected Unapproved Part (SUP).
- Growing threat of SUP in global supply chain.
- Recognize the emerging regulatory requirements governing the prevention and reporting of SUP.

Implementation considerations

- To address SUP risks in:
  - Internal activities such as: nonconformance control, reporting, training
  - Activities regarding external providers such as: procurement, sources selection, control & inspection
Implementation considerations

- **Risk**
  - Understand risks associated throughout the Operational Processes for introducing SUP into delivered product
  - Create preventions and mitigations within individual process steps to address SUP risks

- **Procurement, source selection, supplier control, & inspection**
  - Understand correlation of risk associated with Source Selection with Procurement, Supplier Control and Inspection options
  - Apply appropriate actions in Supplier Control and Inspections based on identified risks
Implementation considerations

- **Nonconformance control**
  - Segregate and control suspected or known unapproved parts.
  - Ensure these products are not re-introduced into the supply chain.

- **Reporting**
  - Report incidences of SUP in appropriate government and industry reporting systems.

- **Training**
  - Ensure training of appropriate personnel on awareness of impacts of SUP in Aviation, Space and Defense products.
  - Create understanding of process methods for ensuring prevention of SUP from entering the product.
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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, …)

Benefits: Addition of risk-based thinking across entire QMS for planning and achieving planned results
9110 Revision 2016
Awareness
9110 revision 2016

Awareness

- The 9110:2016 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

- **Benefits:** Leadership flowdown and understanding to all employees
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
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 factor considerations in determining the causes of the nonconformity

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

Benefits

- Enables root causes to get robust corrective actions so problems do not recur
9110 Revision 2016

High Level Summary of Changes
Implementations benefits
# 9110 High Level Structure Summary

<table>
<thead>
<tr>
<th>Introduction &amp; Clause 1 Scope</th>
<th>Clause 2 Normative ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ New process model</td>
<td>▪ ISO 9000:2015 referenced</td>
</tr>
<tr>
<td>▪ Added a PDCA cycle</td>
<td>▪ ISO 9001 terms and definitions moved to ISO 9000</td>
</tr>
<tr>
<td>▪ Added “Risk-based thinking”</td>
<td>▪ Added new terms (on top of 9110 existing ones): Competent Authority, Continuing Airworthiness management, Dismantling, Life Limited Part, Maintenance Data, Product Safety, Qualified Person, Unapproved Parts.</td>
</tr>
<tr>
<td>▪ Emphasis on defining the QMS and context of the organization</td>
<td></td>
</tr>
<tr>
<td>▪ Expanded scope to include civil &amp; military aviation maintenance and continuing airworthiness activities.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clause 3 Terms and definitions</th>
<th>Clause 4 Context of the organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Quality manual not required, maintained documentation is required</td>
<td>▪ Quality manual not required, maintained documentation is required</td>
</tr>
<tr>
<td>▪ Justified exclusions not limited to Realization/Operations processes</td>
<td>▪ Justified exclusions not limited to Realization/Operations processes</td>
</tr>
<tr>
<td>▪ QMS processes have performance indicators</td>
<td>▪ QMS processes have performance indicators</td>
</tr>
<tr>
<td>▪ Establish &amp; maintain documented information as required by competent authority</td>
<td>▪ Establish &amp; maintain documented information as required by competent authority</td>
</tr>
<tr>
<td>▪ Establish record keeping system</td>
<td>▪ Establish record keeping system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clause 5 Leadership</th>
<th>Clause 6 Planning for the QMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ QMS compatible with strategic direction</td>
<td>▪ When planning the QMS, determine the actions needed to address opportunities and risks (preventive)</td>
</tr>
<tr>
<td>▪ QMS requirements integrated into business processes</td>
<td>▪ Increases requirements for planning of changes</td>
</tr>
<tr>
<td>▪ Processes deliver their intended outputs</td>
<td>▪ Consider risks and mitigations during the transition period of change.</td>
</tr>
<tr>
<td>▪ Leadership ensuring</td>
<td></td>
</tr>
<tr>
<td>▪ Safety policy &amp; safety objectives are established.</td>
<td></td>
</tr>
<tr>
<td>▪ Corrective actions are implemented timely</td>
<td></td>
</tr>
<tr>
<td>▪ Establishing &amp; communicating the Safety Policy</td>
<td></td>
</tr>
<tr>
<td>▪ Management Representative appointed</td>
<td></td>
</tr>
<tr>
<td>▪ Appointment of key post holders – Accountable Manager, Quality Manager and other appointed managers.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clause 7 Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Means for segregation of products / articles</td>
</tr>
<tr>
<td>▪ Org shall considers the availability of resources and qualified personnel</td>
</tr>
<tr>
<td>▪ Determine knowledge management requirements</td>
</tr>
<tr>
<td>▪ Establishing competency requirement of personnel &amp; establishing competency training &amp; assessment program</td>
</tr>
<tr>
<td>▪ Awareness on product conformity, product safety, ethical behavior</td>
</tr>
<tr>
<td>▪ Establishing notification to owner of maintenance data any inaccurate, incomplete or ambiguous maintenance data.</td>
</tr>
</tbody>
</table>

Note: subjects in black are imported from ISO9001. subjects in blue are specific to 9110.

All ISO QMS standards will now have this common 10 clause structure
### Clause 8: Operation
- Manage critical maintenance tasks
- Ensure delivery of products with approved configuration.
- Plan activities needed to assure product safety
- Prevention of counterfeit parts
- Prevention of suspected unapproved parts
- Process governing the use & installation of approved parts
- Using technical data at contractually specified revision or at current revision.
- Provisions for out-of-scope defects discovered during maintenance.
- Encompasses design approval (i.e. DOA) and Continuing Airworthiness Management Organisation (CAMO) activities to 8.3 Design & Development clause.
- Ensuring relevant product safety principles are flowed down to external providers
- Ensuring external providers holds the required approvals & certificates. And for non-certified external providers a method of qualification and oversight.
- Evaluation of New Capability
- Requirements surrounding the Release of products and services
- Control, identification, segregation and disposal of Non-Conforming parts.

### Clause 9: Performance evaluation
- Assess performance of QMS processes
- Expanded management reviews to cover safety performance, personnel training program and changes to authority requirements impacting the organization.

### Clause 10: Improvement
- Consider human factors in nonconformity / corrective action
- Improvement activities as a result of lessons learnt from problem resolutions and benchmarking.
- Improving the performance & effectiveness of the safety management.

Note: subjects in black are imported from ISO9001. subjects in blue are specific to 9110..
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
9110 Revision 2016

Summary of Changes
Clause-by-clause
<table>
<thead>
<tr>
<th>9110:2016 Content</th>
<th>Summary of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td></td>
</tr>
<tr>
<td>Revision summary/Rationale</td>
<td></td>
</tr>
<tr>
<td>Intended Application</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td>0.1 General</td>
<td>Includes verbal significations of “shall”, “should”, “may”, “can”</td>
</tr>
<tr>
<td>0.2 Quality management principles</td>
<td>7 QMS principles to consider</td>
</tr>
<tr>
<td>0.3 Process approach</td>
<td>Schematic representations of a</td>
</tr>
<tr>
<td></td>
<td>- a single process</td>
</tr>
<tr>
<td></td>
<td>- this Standard in a PDCA cycle</td>
</tr>
<tr>
<td>0.3.1 General</td>
<td></td>
</tr>
<tr>
<td>0.3.2 Plan-Do-Check-Act cycle</td>
<td></td>
</tr>
<tr>
<td>0.3.3 Risk-based thinking</td>
<td></td>
</tr>
<tr>
<td>0.4 Relationship with other management system standards</td>
<td></td>
</tr>
</tbody>
</table>
## 9110:2016 Content

<table>
<thead>
<tr>
<th>Quality management systems — Requirements</th>
<th>Summary of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Normative references</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Terms and definitions</strong></td>
<td></td>
</tr>
<tr>
<td>- Certified Person</td>
<td>changed &quot;personnel&quot; to &quot;person&quot;, revised definition for improved clarity</td>
</tr>
<tr>
<td>- Competent Authority</td>
<td>append &quot;competent&quot; to the term &quot;authority&quot; to align with 9110 context</td>
</tr>
<tr>
<td>- Continuing airworthiness management</td>
<td>newly added term used in 9110.</td>
</tr>
<tr>
<td>- Counterfeit Parts</td>
<td>revised definition for improved clarity</td>
</tr>
<tr>
<td>- Dismantling</td>
<td>newly added term used in 9110.</td>
</tr>
<tr>
<td>- Life Limited Part</td>
<td>newly added term used in 9110.</td>
</tr>
<tr>
<td>- Maintenance</td>
<td>revised definition for improved clarity</td>
</tr>
<tr>
<td>- Maintenance data</td>
<td>newly added term used in 9110.</td>
</tr>
<tr>
<td>- Product Safety</td>
<td>newly added term used in 9110.</td>
</tr>
<tr>
<td>- Qualified person</td>
<td>newly added term used in 9110.</td>
</tr>
<tr>
<td>- Technical Data</td>
<td>revised definition for improved clarity</td>
</tr>
<tr>
<td>- Unapproved Part</td>
<td>newly added term used in 9110.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Color Code</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>9110:2016 Content</td>
<td>Summary of Change</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------</td>
</tr>
<tr>
<td><strong>4.1</strong> Understanding the organization and its context</td>
<td>Determine relevant external issues (legal, technological, competitive, market, cultural, social, and economic environments) and internal issues (values, culture, knowledge, and performance of the organization)</td>
</tr>
<tr>
<td><strong>4.2</strong> Understanding the needs and expectations of interested parties</td>
<td>Determine relevant interested parties and their requirements (such as customers, partners, authorities)</td>
</tr>
<tr>
<td><strong>4.3</strong> Determining the scope of the quality management system</td>
<td>Document the scope of the QMS and justification for any case where a requirement cannot be applied (exclusion)</td>
</tr>
<tr>
<td><strong>4.4</strong> Quality management system and its processes</td>
<td>Define the documented information to be maintained or to be retained “to the extent necessary” …</td>
</tr>
</tbody>
</table>

QMS shall address customer & applicable statutory & regulatory QMS requirements including but not limited to approvals, certificates, ratings, capability list or licenses.

Establish and maintain documented information
- as required by the competent authority
- includes the details of the system used to maintain & retain records of work

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<tr>
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<tbody>
<tr>
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<tr>
<td>9110:2016 Content</td>
<td>Summary of Change</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Leadership</strong></td>
<td></td>
</tr>
<tr>
<td>5.1 Leadership and commitment</td>
<td>Leadership instead of only management of responsibilities (management to demonstrate their leadership)</td>
</tr>
<tr>
<td>5.1.1 General</td>
<td>Top management to ensure integration of QMS into business processes (now explicit)</td>
</tr>
<tr>
<td><strong>5.1.2 Customer focus</strong></td>
<td></td>
</tr>
<tr>
<td><strong>5.2 Policy</strong></td>
<td></td>
</tr>
<tr>
<td>5.2.1 Developing the quality policy</td>
<td>Policy aligned with organization strategic direction</td>
</tr>
<tr>
<td>5.2.2 Communicating the quality policy</td>
<td></td>
</tr>
<tr>
<td>5.2.3 Developing and communicating the safety policy</td>
<td>Safety policy shall:</td>
</tr>
<tr>
<td></td>
<td>- defined safety objective</td>
</tr>
<tr>
<td></td>
<td>- include a statement that encourages safety reporting &amp; ensures that no punitive action will result</td>
</tr>
<tr>
<td></td>
<td>- include a commitment to continual improvement of safety management</td>
</tr>
<tr>
<td><strong>5.3 Organizational roles, responsibilities and</strong></td>
<td></td>
</tr>
<tr>
<td><strong>authorities</strong></td>
<td>A &quot;management representative&quot; required as focal point for QM issues (removed from ISO 9001:2015)</td>
</tr>
<tr>
<td>5.3.1 Accountable Manager</td>
<td>Appointment of key position holder as required by competent authority</td>
</tr>
<tr>
<td>5.3.2 Quality Manager</td>
<td>Appointment of key position holder as required by competent authority</td>
</tr>
<tr>
<td>5.3.3 Other appointed Manager(s)</td>
<td>Appointment of key position holder as required by competent authority</td>
</tr>
</tbody>
</table>

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- no change
- originates from 9100:2016
- originates from ISO9001:2015
- specific to 9110:2016
### 9110:2016 Content

<table>
<thead>
<tr>
<th>Planning</th>
<th>Summary of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1 Actions to address risks and opportunities</td>
<td>Determine risks and opportunities, considering the issues raised and requirements identified. Plan appropriate actions to reduce undesired effects on the QMS and evaluate effectiveness</td>
</tr>
<tr>
<td>6.2 Quality objectives and planning to achieve them</td>
<td>Planning the achievement of objectives more prescriptive and includes the evaluation of results</td>
</tr>
<tr>
<td>6.3 Planning of changes</td>
<td>Changes to the QMS to be carried out in a planned manner consider the risks and mitigation actions during transition period</td>
</tr>
</tbody>
</table>

### Color Code

- **no change** originates from 9100:2016
- **originates from ISO9001:2015** specific to 9110:2016
<table>
<thead>
<tr>
<th>9110:2016 Content</th>
<th>Summary of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7</strong> Support</td>
<td></td>
</tr>
<tr>
<td><strong>7.1</strong> Resources</td>
<td></td>
</tr>
<tr>
<td>7.1.1 General</td>
<td>consider the availability of tools, equipment, maintenance data, facilities, materials and qualified persons to ensure safe completion of activities.</td>
</tr>
<tr>
<td>7.1.2 People</td>
<td></td>
</tr>
<tr>
<td>7.1.3 Infrastructure</td>
<td>means to segregate articles and products (serviceable from unserviceable, aviation from non-aviation)</td>
</tr>
<tr>
<td>7.1.4 Environment for the operation of processes</td>
<td>Environment includes human and physical factors</td>
</tr>
<tr>
<td>7.1.5 Monitoring and measuring resources</td>
<td></td>
</tr>
<tr>
<td>7.1.6 Organizational Knowledge</td>
<td>Determine necessary knowledge gained from experience, lessons learned, success, failures, conferences,</td>
</tr>
<tr>
<td><strong>7.2</strong> Competence</td>
<td></td>
</tr>
<tr>
<td>7.2.1 General</td>
<td>maintain the competencies and currency of persons through established training programs.</td>
</tr>
<tr>
<td>7.2.2 People</td>
<td></td>
</tr>
<tr>
<td>7.2.3 Infrastructure</td>
<td></td>
</tr>
<tr>
<td>7.2.4 Environment for the operation of processes</td>
<td>Environment includes human and physical factors</td>
</tr>
<tr>
<td><strong>7.3</strong> Awareness</td>
<td></td>
</tr>
<tr>
<td>7.3.1 General</td>
<td>Added the requirement for persons to be aware of:</td>
</tr>
<tr>
<td>7.3.2 People</td>
<td>- their contribution to product or service conformity</td>
</tr>
<tr>
<td>7.3.3 Infrastructure</td>
<td>- their contribution to product safety</td>
</tr>
<tr>
<td>7.3.4 Environment for the operation of processes</td>
<td>- the importance of ethical behavior</td>
</tr>
<tr>
<td><strong>7.4</strong> Communication</td>
<td></td>
</tr>
<tr>
<td><strong>7.5</strong> Documented information</td>
<td></td>
</tr>
<tr>
<td>7.5.1 General</td>
<td>include documented information necessary for the effectiveness of product safety management</td>
</tr>
<tr>
<td>7.5.2 Creating and updating</td>
<td></td>
</tr>
<tr>
<td>7.5.3 Control of documented information</td>
<td>Added the requirement to define data protection processes for documented information managed electronically, organisation shall notify to author of maintenance data any inaccurate, incomplete or ambiguous information.</td>
</tr>
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## 9110:2016 Content

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<thead>
<tr>
<th>9110:2016 Content</th>
<th>Summary of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.1</strong> Operational planning and control</td>
<td>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.</td>
</tr>
<tr>
<td><strong>8.1.1</strong> Operation risk management</td>
<td>Based on the requirements of 9100:2009 (7.1.1) this clause is related to risks in operation (no major change) while 6.1 is related to risks in QMS of the organization.</td>
</tr>
<tr>
<td><strong>8.1.2</strong> Configuration management</td>
<td>Based on the requirements of 9100:2009 (7.1.3), revised to clarify stakeholders expectations.</td>
</tr>
<tr>
<td><strong>8.1.3</strong> Product safety</td>
<td>Org shall plan, implement and control processes needed to assure product safety as appropriate to the organization.</td>
</tr>
<tr>
<td><strong>8.1.4</strong> Prevention of Counterfeit Parts</td>
<td>Prevention of counterfeit or suspect counterfeit part from being introduced to the product.</td>
</tr>
<tr>
<td><strong>8.1.5</strong> Prevention of suspected unapproved parts (SUP)</td>
<td>Prevention of suspected unapproved parts from being used.</td>
</tr>
<tr>
<td><strong>8.1.6</strong> Installation of approved parts</td>
<td>Ensures approved parts are a. properly identified b. acceptable for installation c. airworthy d. life limits not reached e. not involved in accidents / incidents f. dismantled parts special provisions are met.</td>
</tr>
<tr>
<td><strong>8.2</strong> Requirements for products and services</td>
<td>Additional requirement that review shall be coordinated with applicable functions of the organization.</td>
</tr>
<tr>
<td><strong>8.2.1</strong> Customer communication</td>
<td>Special requirements are determined, operational risks identified.</td>
</tr>
<tr>
<td><strong>8.2.2</strong> Determination of requirements related to products and services</td>
<td>Added requirement for actions in case of not meeting some customer requirements.</td>
</tr>
<tr>
<td><strong>8.2.3</strong> Review of requirements related to products</td>
<td>Usage of technical data at contractually specified revision or at current revision if not specified.</td>
</tr>
<tr>
<td><strong>8.2.4</strong> Changes to requirements for products and services</td>
<td>Contract process shall include provision for out of scope defects rectification.</td>
</tr>
</tbody>
</table>
### 9110:2016 Content vs. Summary of Change

<table>
<thead>
<tr>
<th>9110:2016 Content</th>
<th>Summary of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.3</strong> Design and development of products</td>
<td><strong>Clause re-structured to allow for a more process orientated approach</strong></td>
</tr>
<tr>
<td>and services</td>
<td><strong>New requirement for organisations authorised by competent authorities to perform Design &amp; Development of</strong></td>
</tr>
<tr>
<td><strong>8.3.1 General</strong></td>
<td><strong>Technical Data; develop aircraft maintenance program</strong></td>
</tr>
<tr>
<td><strong>8.3.2 Design and development planning</strong></td>
<td><strong>Added requirement to take account of handling obsolescence, where applicable</strong></td>
</tr>
<tr>
<td><strong>8.3.3 Design and development inputs</strong></td>
<td><strong>New requirement to include continuous airworthiness requirements are evaluated as applicable.</strong></td>
</tr>
<tr>
<td><strong>8.3.4 Design and development controls</strong></td>
<td></td>
</tr>
<tr>
<td><strong>8.3.5 Design and development outputs</strong></td>
<td><strong>New requirement to ensure outputs are incorporated into work orders when developing aircraft maintenance</strong></td>
</tr>
<tr>
<td><strong>8.3.6 Design and development changes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>8.4 Control of externally provided processes, products and services</strong></td>
<td><strong>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).</strong></td>
</tr>
<tr>
<td><strong>8.4.1 General</strong></td>
<td><strong>Explicit requirement for the control of Externally Provided Processes/Products and Services</strong></td>
</tr>
<tr>
<td><strong>8.4.2 Type and extent of control</strong></td>
<td><strong>Added note to allow use of quality data provided by external sources for the evaluation/selection of external providers</strong></td>
</tr>
<tr>
<td><strong>8.4.3 Information for external providers</strong></td>
<td><strong>Added requirements for organisation to exercise control of processes, product and services obtained from external providers.</strong></td>
</tr>
<tr>
<td><strong>8.4.2 Type and extent of control</strong></td>
<td><strong>External providers to hold the required approvals and certificates. Non-certificated external providers shall be subject to qualification and oversight by organization.</strong></td>
</tr>
<tr>
<td><strong>8.4.3 Information for external providers</strong></td>
<td><strong>Added evaluation of data on test reports provided, to confirm the results comply with requirements</strong></td>
</tr>
<tr>
<td><strong>8.4.3 Information for external providers</strong></td>
<td><strong>Added the need to communicate to external providers additional requirements governing approval requirements, documentation package, defect reporting, etc</strong></td>
</tr>
</tbody>
</table>

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- **no change**  
- **originates from 9100:2016**  
- **originates from ISO9001:2015**  
- **specific to 9110:2016**
### 9110:2016 Content

<table>
<thead>
<tr>
<th>Clause</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5</td>
<td>Production and service provision</td>
</tr>
<tr>
<td>8.5.1</td>
<td>Control of production and service provision</td>
</tr>
<tr>
<td>8.5.2</td>
<td>Identification and traceability</td>
</tr>
<tr>
<td>8.5.3</td>
<td>Property belonging to customers or external providers</td>
</tr>
<tr>
<td>8.5.4</td>
<td>Preservation</td>
</tr>
<tr>
<td>8.5.5</td>
<td>Post-delivery activities</td>
</tr>
<tr>
<td>8.5.6</td>
<td>Control of changes</td>
</tr>
</tbody>
</table>

### Summary of Change

#### 8.5.1 Control of production and service provision
This clause considers monitoring and measurement activities will ensure the control of processes and output, 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”

- added additional controlled conditions pertaining to:
  - evidence of work completion
  - prevention of human errors
  - establishing workmanship criteria iaw technical data
  - compliance to reference standards, quality plans, specifications.
  - maintaining a list of approved maintenance capability
  - assuring continued airworthiness
  - controlling off site work
  - use of recommended tools, equipment and materials or equivalents

- New requirement added for organisation to evaluate, verify, document new repair capability

#### 8.5.2 Identification and traceability

#### 8.5.3 Property belonging to customers or external providers

#### 8.5.4 Preservation
provisions for suitable transportation or shipping containers to be considered

#### 8.5.5 Post-delivery activities
New ISO clause (as per 9100:2009)

- added consideration for product/ customer support activity

- Clarified that when problems are detected after delivery the organization shall take appropriate actions

#### 8.5.6 Control of changes
New ISO clause to emphasize on this topic

### Color Code

<table>
<thead>
<tr>
<th>Change Description</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>no change</td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>9110:2016 Content</th>
<th>Summary of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.6 Release of products and services</td>
<td>New ISO clause to verify that all activities have been carried out before release and delivery by authorized persons.</td>
</tr>
<tr>
<td></td>
<td>New requirement pertaining to the Release to Service certificate by certifying staff and provision of authority documentation.</td>
</tr>
<tr>
<td>8.7 Control of nonconforming outputs</td>
<td>Outputs including products and services and provision of required documented information.</td>
</tr>
<tr>
<td></td>
<td>Maintained the requirement for a “procedure” to define the NC process and responsibilities on this key topic for ASD.</td>
</tr>
<tr>
<td></td>
<td>Added requirement for identification and control of non-conforming parts.</td>
</tr>
</tbody>
</table>
### 9110:2016 Content

<table>
<thead>
<tr>
<th>9</th>
<th>Performance evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1</td>
<td>Monitoring, measurement, analysis and evaluation</td>
</tr>
<tr>
<td>9.1.1</td>
<td>General</td>
</tr>
<tr>
<td>9.1.2</td>
<td>Customer satisfaction</td>
</tr>
<tr>
<td>9.1.3</td>
<td>Analysis and evaluation</td>
</tr>
<tr>
<td>9.2</td>
<td>Internal audit</td>
</tr>
<tr>
<td>9.3</td>
<td>Management review</td>
</tr>
</tbody>
</table>

| 9.3.1 | General |
| 9.3.2 | Management review input |
| 9.3.3 | Management review output |

### Summary of Change

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<table>
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<tr>
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<td>Summary of Change</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>10 Improvement</td>
<td></td>
</tr>
<tr>
<td>10.1 General</td>
<td>Added requirement to improve the performance and effectiveness of safety management</td>
</tr>
<tr>
<td>10.2 Nonconformity and corrective action</td>
<td>Nonconformity and corrective action “procedure” added back-in from ISO</td>
</tr>
<tr>
<td></td>
<td>Added requirement to evaluate the need for action based on human factors to ensure nonconformities do not recur</td>
</tr>
<tr>
<td>10.3 Continual improvement</td>
<td></td>
</tr>
</tbody>
</table>
91XX series Revision 2016

Transition summary
## 9100/9110/9120:2016 Transition Summary

<table>
<thead>
<tr>
<th>Key Dates</th>
<th>Major activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2015</td>
<td>ISO 9001:2015 Standard published and a 36 Month Certified Client ISO transition begins</td>
</tr>
<tr>
<td>October 2015</td>
<td>IAQG General Assembly approval of ICOP 9100/9110/9120:2016 Transition Plan</td>
</tr>
<tr>
<td>May 2016</td>
<td>9110 completes final approval and editing and is released for publication bodies</td>
</tr>
<tr>
<td>September 2016</td>
<td>9100 standard published in all 3 sectors</td>
</tr>
<tr>
<td>October 2016</td>
<td>9101, 9110 &amp; 9120 published in all 3 sectors</td>
</tr>
<tr>
<td>November 2016</td>
<td>Mandated Aerospace Auditor “transition” training available in IAQG languages. OASIS Next Generation project phase 1 complete. Database available for entry of transition audit results</td>
</tr>
<tr>
<td>June 2017</td>
<td>All future audits must be to the 9100/9110/9120:2016 standard using 9101:2016 audit process.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Transition complete all 9100/9110/9120:2009 certificates are no longer valid.</td>
</tr>
</tbody>
</table>

AQMS transition timeline revised based upon change in key dependencies completion dates.
9110 Revision 2016

Deployment Support Material

Where to find it?
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Path through the IAQG web site

www.iaqg.org

CLICK ON THE REQUIREMENT STANDARD BELOW FOR ADDITIONAL INFORMATION

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<th>Oversight of Certification Scheme</th>
<th>9100 QMS - Requirements for ASD Organizations</th>
<th>9110 QMS - Requirements for Aviation Maintenance Organizations</th>
<th>9101 QMS Audit Requirements for ASD Organizations</th>
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<tbody>
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<td>9104-3 ASD Auditor Competency and Training Courses</td>
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<tr>
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<td>9117 Rejected</td>
<td>9131 Nonconformance</td>
<td>9132 Data Matrix</td>
<td>9133 Qualification</td>
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Questions