9110 revision 2016
Key changes presentation

IAQG 9110 Team

January 2017

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

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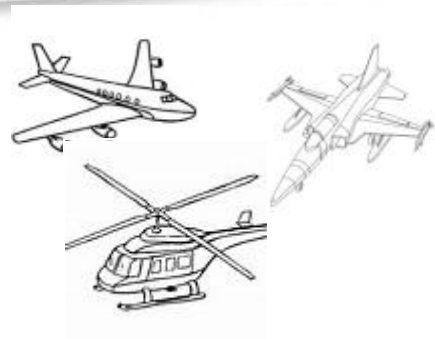

The “9110” needs to change, to:

- 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

IAQG 9110:2016 Writing Team

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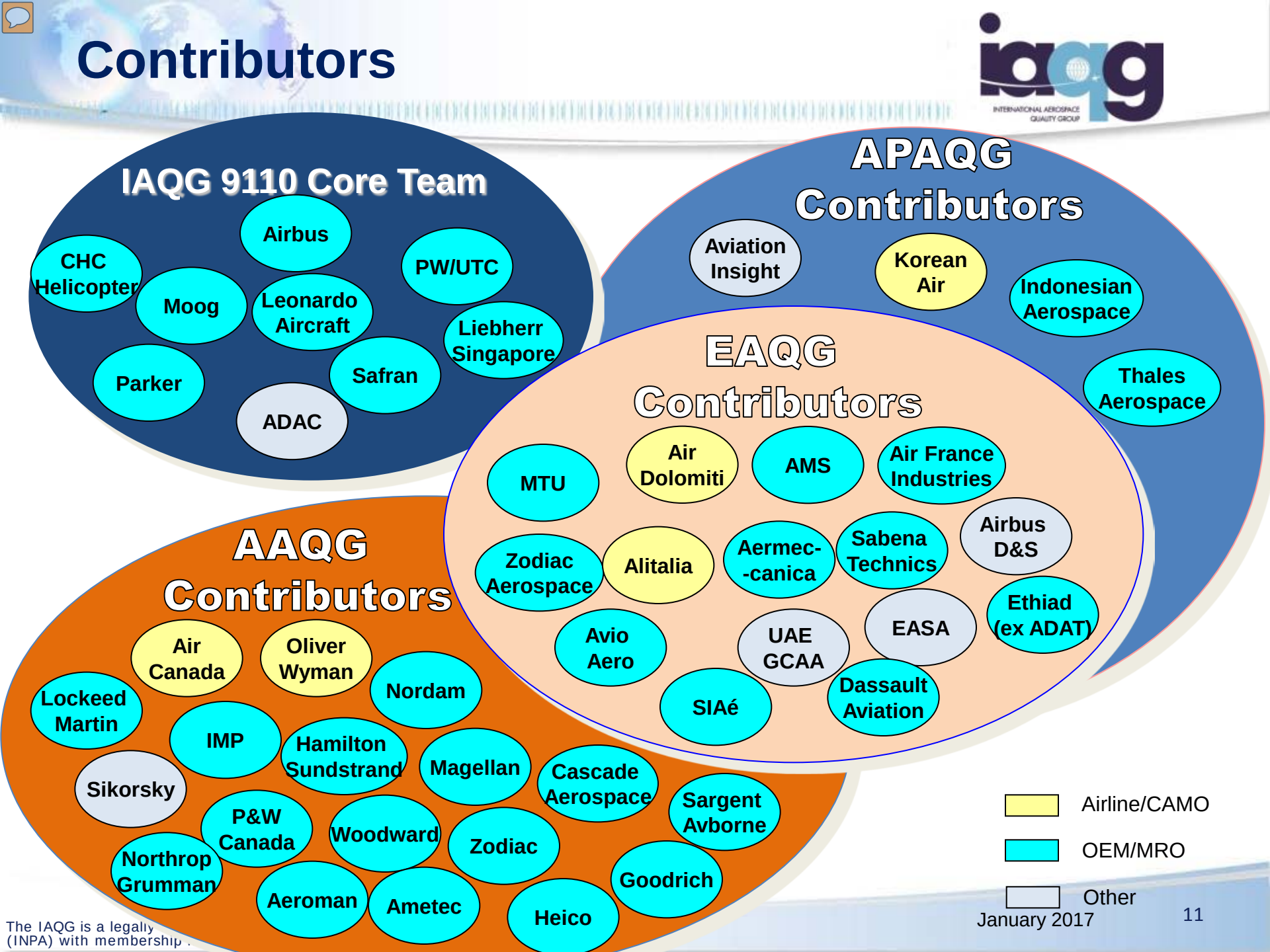
IAQG/Sector 9110 Team Structure

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

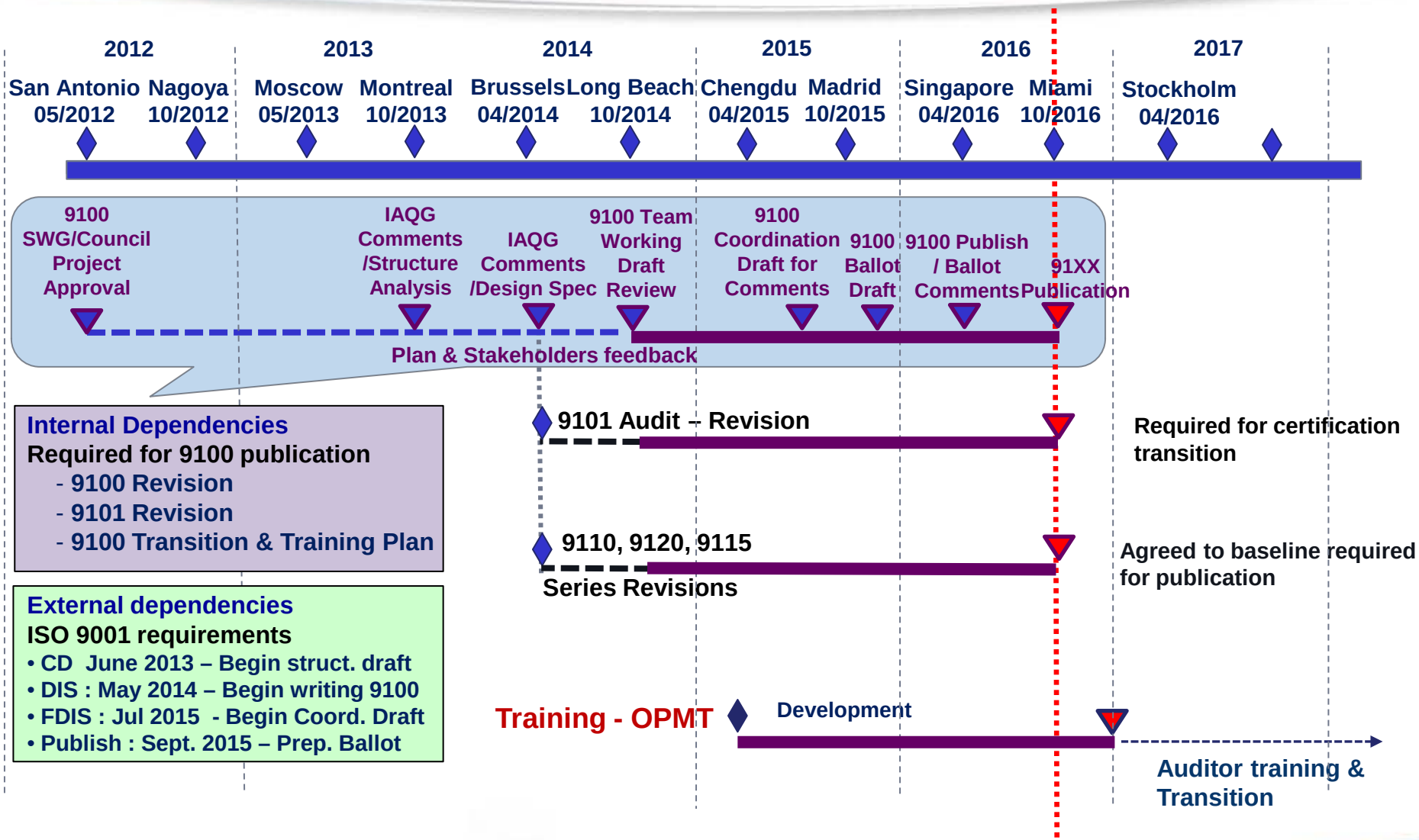
Representatives of 9110 sector teams at Int'l Meetings

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

Contributors



91XX Series Revision - Integrated Schedule



9110 Revision Timeline

Completed

Oct 2013	Stakeholder Feedback Resolution
Apr 2014	Concept Sub-team Proposals
Jun 2014	Integrate ISO 9001 Draft with 9110
Jul 2014	ISO 9001:2015 Draft Comments
Jul 2014	Structure Draft (team)
Oct 2014	Working Draft (team)
July 2015	Coordination Draft (IAQG)
Dec 2015	Ballot (IAQG)
May 2016	9110 complete through IAQG Ballot
Oct 2016	Formatting of Sector Versions
Nov 2016	Publication Approval / Publication

3 years in the making. Team processed a total of 510 comments received from IAQG members and contributors since first draft in 2014.

9110 QMS – Requirements for Aviation Maintenance Organizations

ISO 9001:2015 as baseline requirement

9110 Revision 2016

Quality Management Principles

9110 revision 2016

ISO 9000 Quality Management Principles

There were 8 principles	There are now 7
Customer focus	Customer focus
Leadership	Leadership
Involvement of people	Engagement of people
Process approach	Process approach
System approach to management	(included in the process approach)
Continual improvement	Improvement
Factual approach to decision making	Evidence-based decision making
Mutually beneficial supplier relationships	Relationship management

9110 Revision 2016

Key changes
in the ISO 9001 Baseline content

9110 revision 2016

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

9110 revision 2016

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

9110 Revision 2016

Terminology &

High Level Structure (HLS)

9110 revision 2016

Terminology Changes (from ISO 9001 baseline)

Previous version	New Version
Products	Products and services
Exclusions	Scope of the QMS to be formally defined and all requirements are applicable if they are in the scope
Documentation, records, documented procedures	Documented information • maintained = documents or procedures • retained = records
Purchased product	Externally provided products and services
Supplier	External provider

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

9110 revision 2016

HLS: High Level Structure (from ISO 9001 baseline)

High Level Structure

- **ISO is going from 8 clauses to 10 clauses**

Plan				Do	Check	Act
4 Context of organization	5 Leadership	6 Planning	7 Support	8 Operation	9 Performance Evaluation	10 Improvement

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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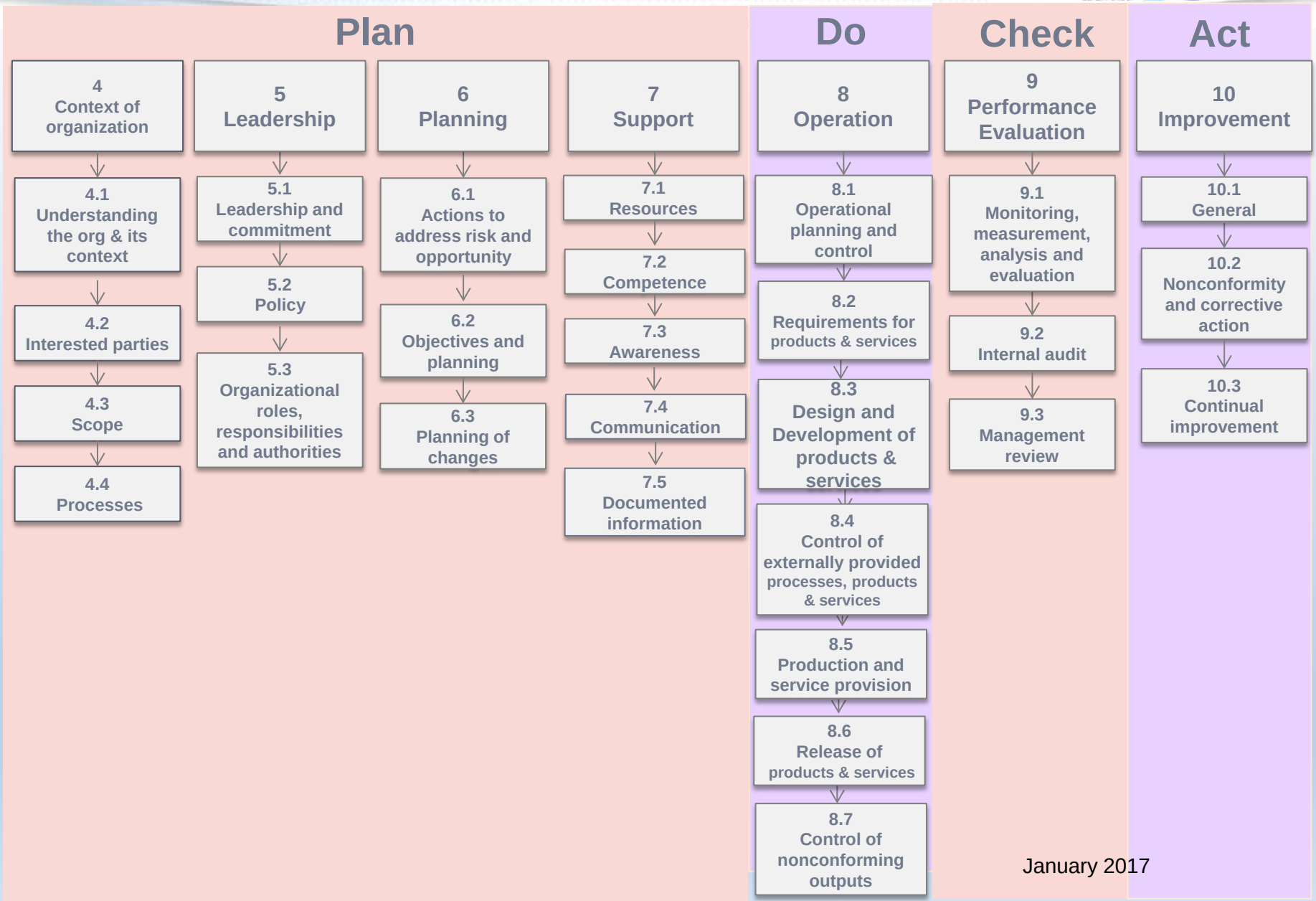
HLS: High Level Structure (from ISO 9001 baseline)



January 2017

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HLS: High Level Structure (from ISO 9001)

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

HLS Table of Contents – ISO 9001 / 9110

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

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.**

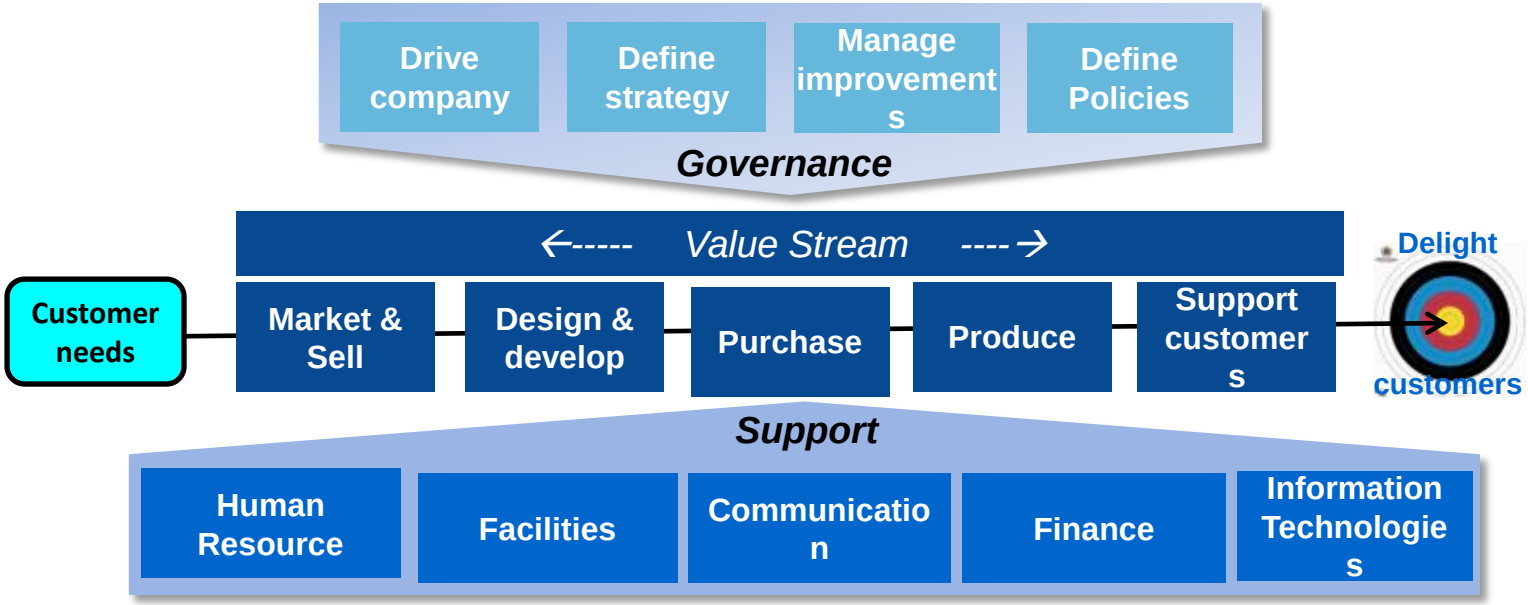
Benefits

- **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 wor***
- **Learn from experience;** ***improve***

9110 revision 2016

Risk-based thinking

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

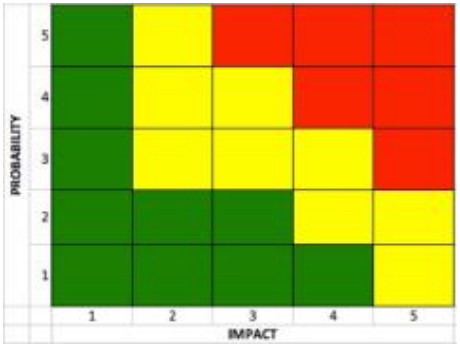
Summary…

- 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, …)

9110 Revision 2016

Process approach

9110 revision 2016

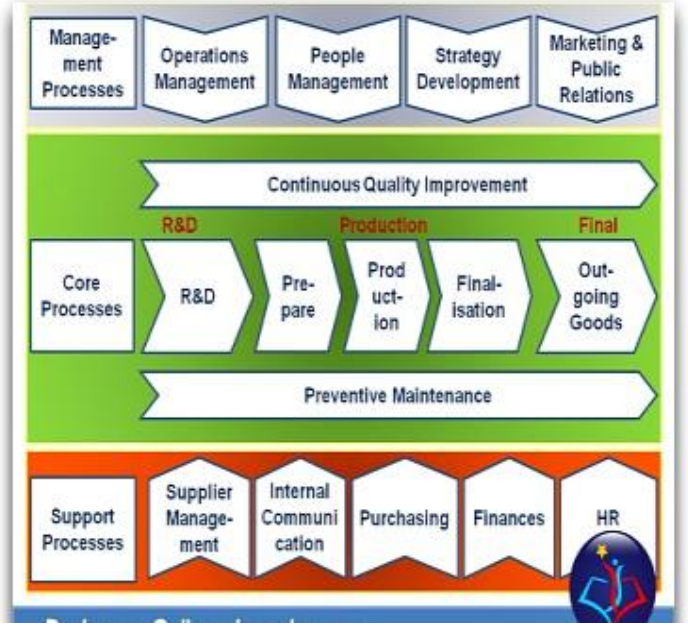
Process Approach

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

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Process Approach

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

Plan	set objectives and build processes necessary to deliver results
Do	implement what was planned
Check	monitor and measure processes and results against the objectives
Act	take actions to improve results

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 it's 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

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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

9110 Revision 2016

Key changes
in the 9110 additions

9110 revision 2016

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

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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
  “Competent Authority”, “Continuing Airworthiness Management”, “Dismantling”, “Life Limited Part”, “Maintenance Data”, “Product Safety” (same as in 9100), “Qualified Person” and “Unapproved Part”

9110 revision 2016

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

9110 revision 2016

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”

9110 Revision 2016

Product Safety

9110 revision 2016

Product Safety

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

9110 revision 2016

Product Safety

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)

9110 Revision 2016

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."

9110 Revision 2016

Prevention of suspected unapproved parts

9110 revision 2016

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

9110 Revision 2016

Risk management

9110 revision 2016

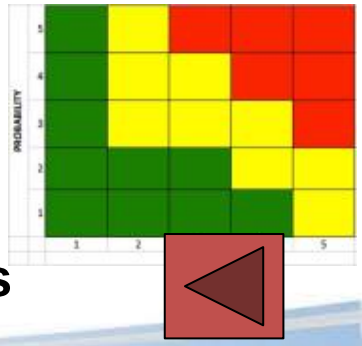
Risk management

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, …)



Benefits: Addition of risk-based thinking across entire QMS for planning and achieving planned results

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Awareness

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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**

9110 Revision 2016

Human Factors

9110 revision 2016

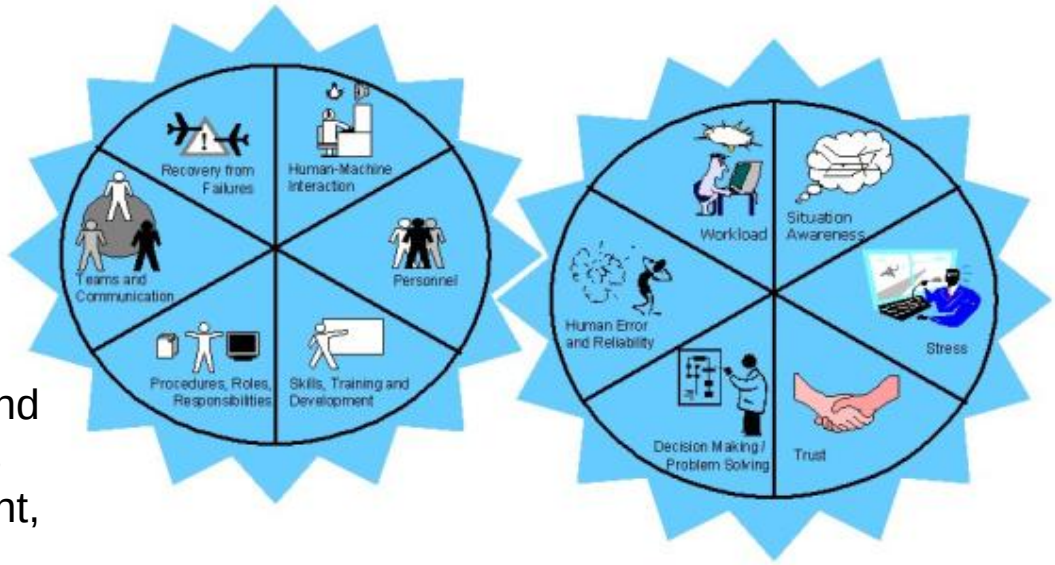
Human Factors

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.



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Human Factors

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

No Requirements

Introduction & Clause 1 Scope	▪ New process model ▪ Added a PDCA cycle ▪ Added "Risk-based thinking" ▪ Emphasis on defining the QMS and context of the organization ▪ Expanded scope to include civil & military aviation maintenance and continuing airworthiness activities.
Clause 2 Normative ref	▪ ISO 9000:2015 referenced
Clause 3 Terms and definitions	▪ ISO 9001 terms and definitions moved to ISO 9000 ▪ 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.
Clause 4 Context of the organization	▪ Quality manual not required, maintained documentation is required ▪ Justified exclusions not limited to Realization/Operations processes ▪ QMS processes have performance indicators ▪ Establish & maintain documented information as required by competent authority ▪ Establish record keeping system
Clause 5 Leadership	▪ QMS compatible with strategic direction ▪ QMS requirements integrated into business processes ▪ Processes deliver their intended outputs ▪ Leadership ensuring ▪ safety policy & safety objectives are established. ▪ corrective actions are implemented timely ▪ Establishing & communicating the Safety Policy ▪ Management Representative appointed ▪ Appointment of key post holders – Accountable Manager, Quality Manager and other appointed managers.
Clause 6 Planning for the QMS	▪ When planning the QMS, determine the actions needed to address opportunities and risks (preventive) ▪ Increases requirements for planning of changes ▪ Consider risks and mitigations during the transition period of change.
Clause 7 Support	▪ Means for segregation of products / articles ▪ Org shall considers the availability of resources and qualified personnel ▪ Determine knowledge management requirements ▪ Establishing competency requirement of personnel & establishing competency training & assessment program ▪ Awareness on product conformity, product safety, ethical behavior ▪ Establishing notification to owner of maintenance data any inaccurate, incomplete or ambiguous maintenance data.

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

9110 High Level Structure Summary

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..

All ISO QMS standards will now have this common 10 clause structure

9110 revision 2016

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

9110 revision 2016

Summary of changes - clause by clause

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

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

9110:2016 Content		Summary of Change
Quality management systems — Requirements		
1	**Scope**	
2	**Normative references**	
3	**Terms and definitions**	
	- Certified Person	changed "personnel" to "person", revised definition for improved clarity
	- Competent Authority	append "competent" to the term "authority" to align with 9110 context
	- Continuing airworthiness management	newly added term used in 9110.
	- Counterfeit Parts	revised definition for improved clarity
	- Dismantling	newly added term used in 9110.
	- Life Limited Part	newly added term used in 9110.
	- Maintenance	revised definition for improved clarity
	- Maintenance data	newly added term used in 9110.
	- Product Safety	newly added term used in 9110.
	- Qualified person	newly added term used in 9110.
	- Technical Data	revised definition for improved clarity
	- Unappoved Part	newly added term used in 9110.

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

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Summary of changes - clause by clause

9110:2016 Content		Summary of Change
4	**Context of the organization**	
4.1	Understanding the organization and its context	Determine relevant external issues (legal, technological, competitive, market, cultural, social, and economic environments) and internal issues (values, culture, knowledge, and performance of the organization)
4.2	Understanding the needs and expectations of interested parties	Determine relevant interested parties and their requirements (such as customers, partners, authorities)
4.3	Determining the scope of the quality management system	Document the scope of the QMS and justification for any case where a requirement cannot be applied (exclusion)
4.4	Quality management system and its processes	Define the documented information to be maintained or to be retained “to the extent necessary” …
		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

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

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

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

9110:2016 Content		Summary of Change
6	**Planning**	
6.1	Actions to address risks and opportunities	Determine risks and opportunities, considering the issues raised and requirements identified. Plan appropriate actions to reduce undesired effects on the QMS and evaluate effectiveness
6.2	Quality objectives and planning to achieve them	Planning the achievement of objectives more prescriptive and includes the evaluation of results
6.3	Planning of changes	Changes to the QMS to be carried out in a planned manner
		consider the risks and mitigation actions during transition period

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

9110:2016 Content		Summary of Change
7	**Support**	
7.1	Resources	
7.1.1	General	consider the availability of tools, equipment, maintenance data, facilities, materials and qualified persons to ensure safe completion of activities.
7.1.2	People	
7.1.3	Infrastructure	means to segregate articles and products (serviceable fm unserviceable, aviation from non aviation)
7.1.4	Environment for the operation of processes	Environment includes human and physical factors
7.1.5	Monitoring and measuring resources	
7.1.6	Organizational Knowledge	Determine necessary knowledge gained from experience, lessons learned, success, failures, conferences,
7.2	Competence	ensure persons performing tasks are qualified and certified in accordance to competent authority or customer requirements
		maintain the competencies and currency of persons through established training program.
		maintain documented information of persons involved in continuing airworthiness management or maintenance activities
		a process shall exist for the surveillance/assessment of non qualified persons prior to performing unsupervised work
7.3	Awareness	Added the requirement for persons to be aware of: -their contribution to product or service conformity -their contribution to product safety -the importance of ethical behavior
		- safety policy and objectives related to product safety.
		- human factors and potential consequences on maintenance activites
7.4	Communication	
7.5	Documented information	New terminology (replacing “documents” and “records”) No requirement for 6 mandated procedures, but still a requirement to identify the documented information & processes needed for the QMS
7.5.1	General	include documented information necessary for the effectiveness of product safety management
7.5.2	Creating and updating	
7.5.3	Control of documented Information	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.

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

9110:2016 Content		Summary of Change
8	**Operation**	
8.1	Operational planning and control	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
		establish process to manage critcal maintenance tasks identified by customer or type certificate holder
8.1.1	Operation risk management	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
8.1.2	Configuration management	Based on the requirements of 9100:2009 (7.1.3), revised to clarify stakeholders expectations
8.1.3	Product safety	Org shall plan, implement and control processes needed to assure product safety as appropriate to the organization
8.1.4	Prevention of Counterfeit Parts	prevention of counterfeit or suspect counterfeit part from being introduced to the product
8.1.5	Prevention of suspected unapproved parts (SUP)	prevention of suspected unapproved parts from being used
8.1.6	Installation of approved parts	ensures aproved 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
8.2	Requirements for products and services	
8.2.1	Customer communication	
8.2.2	Determination of requirements related to products and services	special requirements are determined , operational risks identified
8.2.3	Review of requirements related to products	Added requirement that review shall be coordinated with applicable functions of the organization
		Added requirement for actions in case of not meeting some customer requirements
		usage of technical data at contractually specified revision or at current revision if not specified
		contract process shall include provision for out of scope defects rectification
8.2.4	Changes to requirements for products and services	

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Summary of changes - clause by clause

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

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

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Summary of changes - clause by clause

9110:2016 Content		Summary of Change
8.5	Production and service provision	
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 maintenace 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	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

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

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

9110:2016 Content		Summary of Change
9	**Performance evaluation**	
9.1	Monitoring, measurement, analysis and evaluation	
9.1.1	General	evaluation of safety performance related to the product and services rendered.
9.1.2	Customer satisfaction	
9.1.3	Analysis and evaluation	Specific requirements for analysis and evaluation when using results as inputs to management review Outputs from the analysis are clearer
		Evaluation of opportunities arising out of maintenance errors.
9.2	Internal audit	Explicit topics to consider for the internal audit programme(s)
9.3	Management review	Added “on-time delivery performance” as input
		Review of safety policy and objectives , data derived from safety performance monitoring effectiveness of personnel training program and regulation changes.
9.3.1	General	
9.3.2	Management review input	
9.3.3	Management review output	

Color Code	
no change	originates from 9100:2016
originates from ISO9001:2015	specific to 9110:2016

9110 revision 2016

Summary of changes - clause by clause

9110:2016 Content		Summary of Change
10	**Improvement**	
10.1	General	Added requirement to improve the performance and effectiveness of safety management
10.2	Nonconformity and corrective action	Nonconformity and corrective action “procedure” added back-in from ISO
		Added requirement to evaluate the need for action based on human factors to ensure nonconformities do not recur
10.3	Continual impovement	

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Transition summary

9100/9110/9120:2016 Transition Summary

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

AQMS transition timeline revised based upon change in key dependencies completion dates

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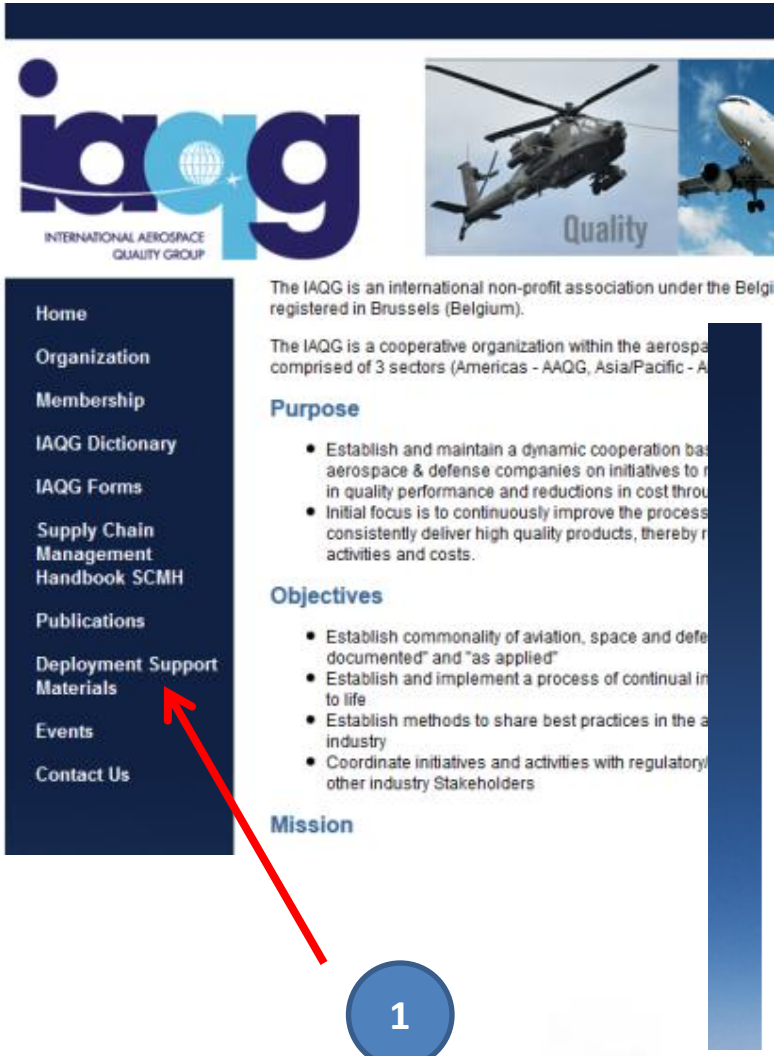
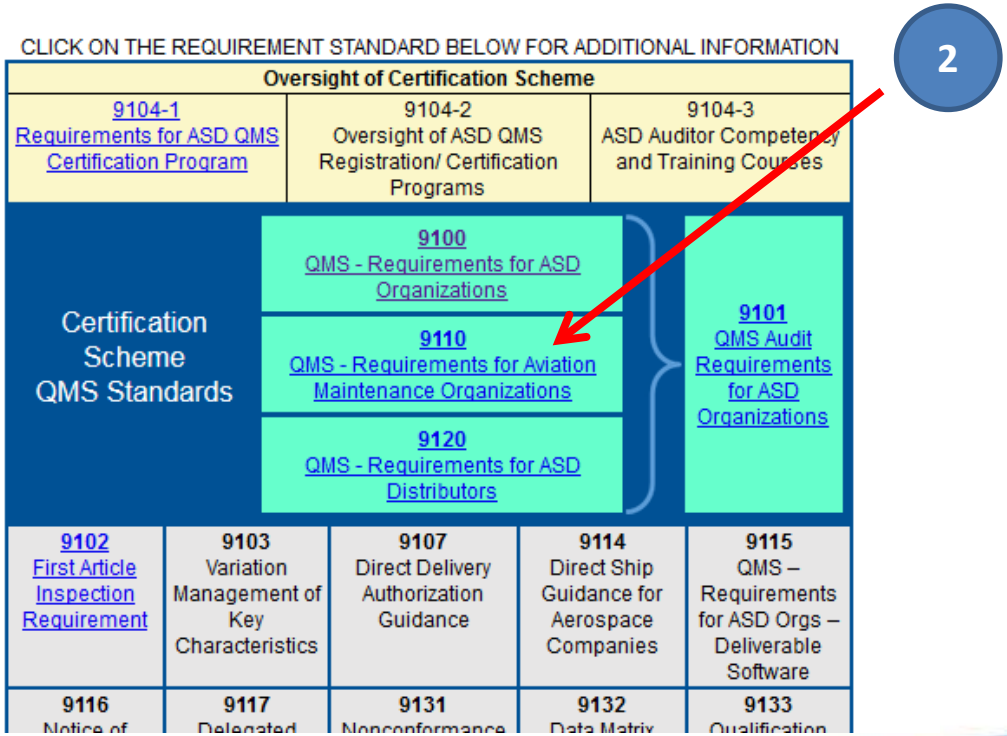
Deployment Support Material

Where to find it?

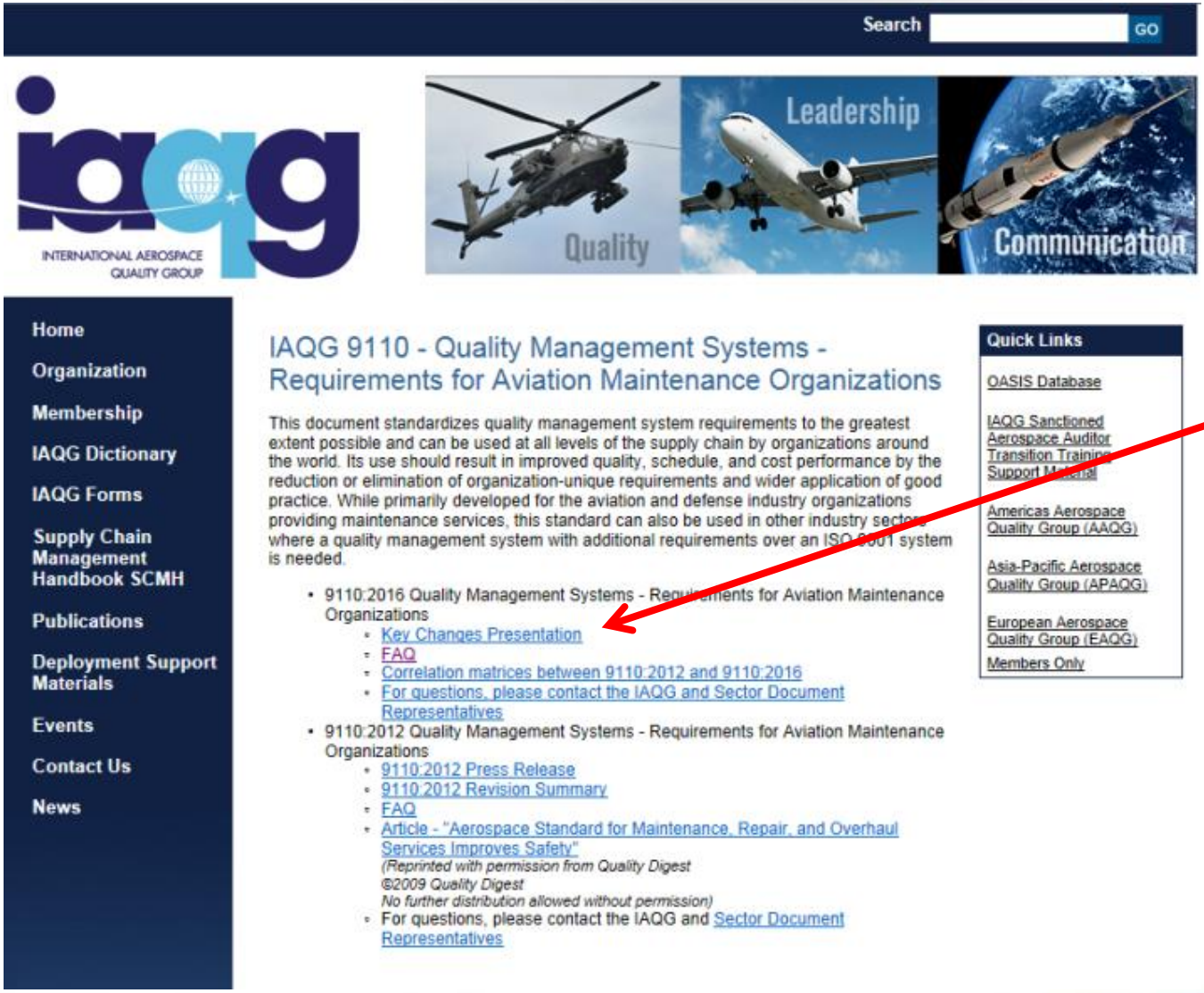
Path through the IAQG web site



www.iaqg.org



9110 Deployment Support Material



Questions