



9100 revision 2016

Key changes presentation

IAQG 9100 Team
June 2016

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9100 Revision 2016

Introduction

reason for revision, team and timeline

May 2016

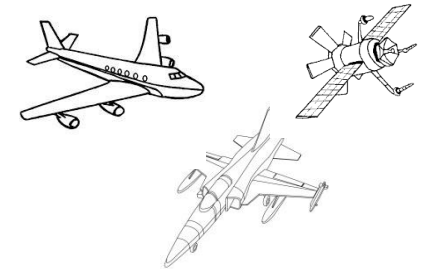
The “ISO 9001” needed to change, to:

- Adapt to a changing world
- Enhance an organization's ability to satisfy its customers
- Provide a consistent foundation for the future
- Reflect the increasingly complex environments in which organizations operate
- Ensure the new standard reflects the needs of all interested parties
- Integrate with other management systems



The “9100” needs to change, to:

- Incorporate changes made by ISO TC176 to the ISO 9001:2015 requirements
(ISO liaison organized to collaborate with the IAQG 9100 team and to obtain consideration for IAQG requirements)
- Consider Aviation, Space and Defense stakeholders’ needs identified since the last revision
(web survey performed in 2013)
- Consider clarifications to 9100 series requests issued by IAQG since the last revision
(requirements clarified or notes added)



IAQG 9100 Series Team



IAQG 9100 Series Team

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9100 Scribe
IAQG



IAQG/Sector 9100 Team Structure



IAQG 9100 Writing Team collects sector and stakeholder input and creates a rough draft. (8)



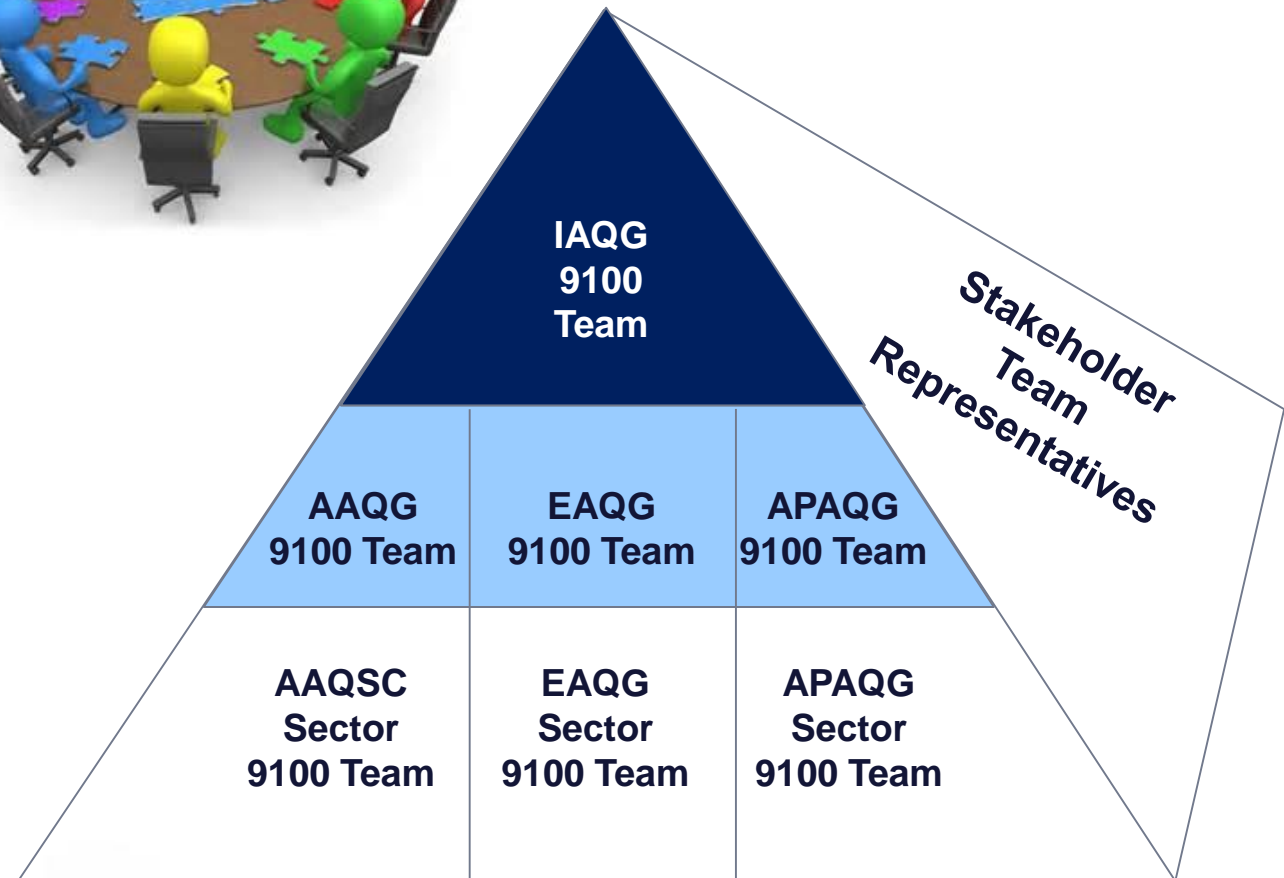
IAQG 9100 Team collects sector and stakeholder input and writes the revision (14)



Representatives of Sector 9100 Team at International Meetings (9)



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

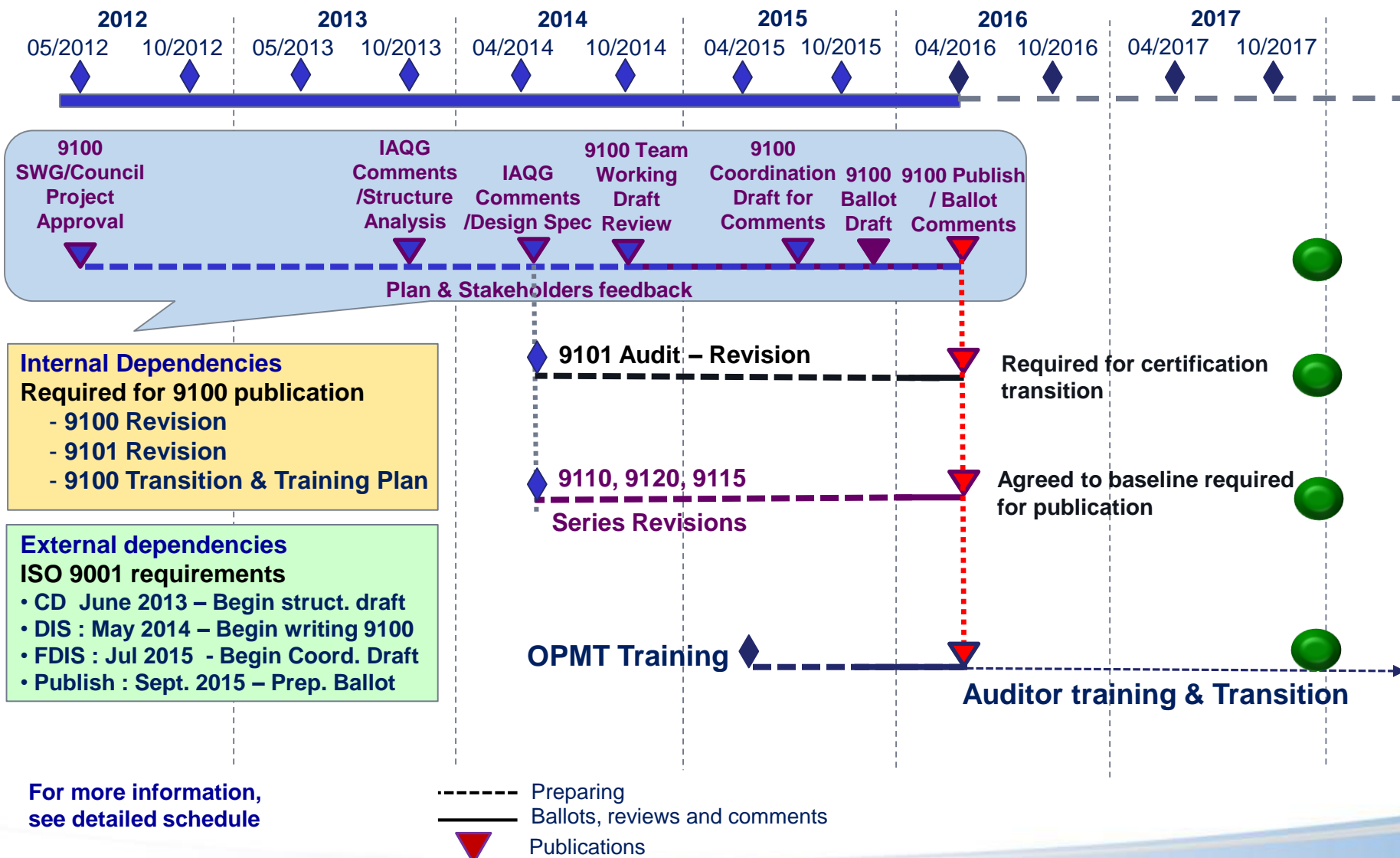


9100 Timeline

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Oct 2013	Stakeholder Feedback Resolution
Apr 2014	Concept Sub-team Proposals
Jun 2014	Integrate ISO 9001 Draft with 9100
Jul 2014	ISO 9001:2015 Draft Comments
Jul 2014	Structure Draft (team)
Oct 2014	Working Draft (team)
July 2015	Coordination Draft (IAQG)
Nov 2015	Ballot (IAQG)
Apr 2016	9100 complete through IAQG Ballot
	Support Material (issued: May 2015, Dec 2015,)

9100 Series Revision: an integrated schedule tracked



For more information,
see detailed schedule

9100 Revision 2016

Quality Management Principles

May 2016

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

9100 Revision 2016

Key changes in the ISO 9001 content

May 2016

Key Changes *(from ISO 9001:2015)*

-  • High level structure (HLS) & Terminology
-  • Risk-based thinking
-  • Process approach strengthened with integration of the QMS into organization's business processes
-  • Emphasis on change management
-  • Introduction of knowledge management
- Concept of preventive action now addressed throughout the standard by risk identification and mitigation

Note to presenter: if using “click for more” links, you will need to skip the associated slides by using the arrow on the next slide

Key Changes *(from ISO 9001:2015)*

- Clearer understanding of the organization's context
- Aligning QMS policy and objectives with the strategy of the organization
- Explicit performance evaluation requirements
- Greater flexibility with documentation
- More compatible with services

Not required to adjust strictly the organization QMS
to the new structure and terminology

Note to presenter: if “click for more” was used in the previous slide, you will need to skip the associated slides by using this arrow, to advance to the next section



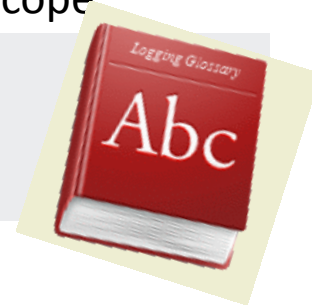
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Terminology & High Level Structure (HLS)

9100 revision 2016

Terminology Changes (from ISO 9001)

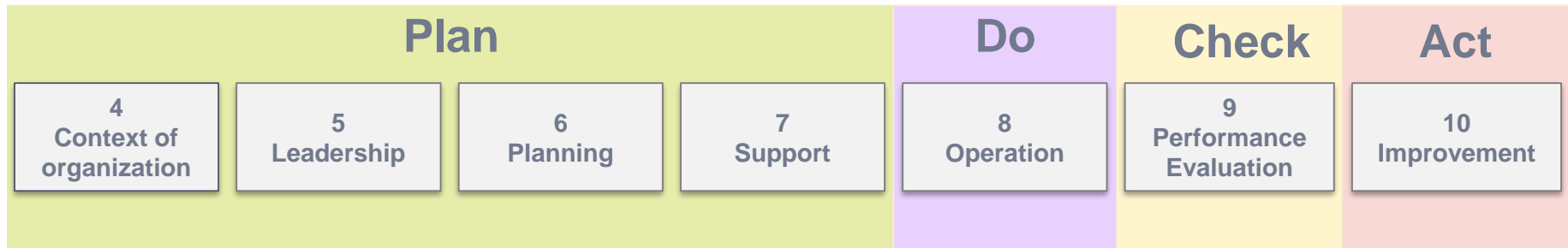
Previous version	New Version Sept. 2015
Products	Products and services
Exclusions	Scope of the QMS to be formally defined and all requirements are applicable if they are in the scope
Documentation, records, documented procedures	Documented information <ul style="list-style-type: none">• maintained = documents or procedures• retained = records
Purchased product	Externally provided products and services
Supplier	External provider



+ Use of simplified language and writing styles to aid understanding and consistent interpretation of requirements

High Level Structure

- ISO is going from 8 clauses to 10 clauses



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

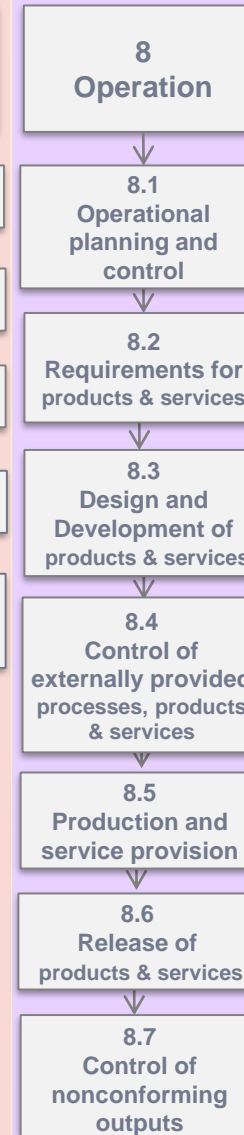
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HLS: High Level Structure (from ISO 9001)

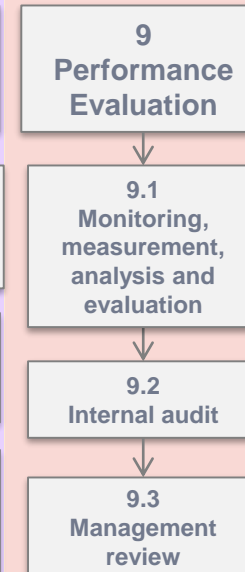
Plan



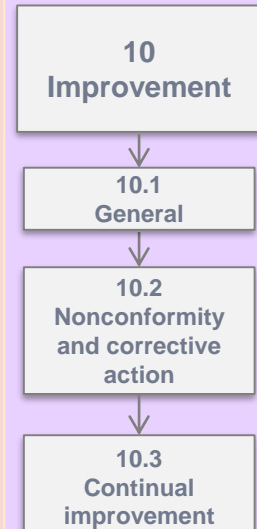
Do



Check



Act



HLS Table of Contents – ISO 9001 / 9100

- 1 Scope**
- 2 Normative references**
- 3 Terms and definitions**
- 4 Context of the organization**
 - 4.1 Understanding the organization and its context
 - 4.2 Understanding the needs and expectations of interested parties
 - 4.3 Determining the scope of the quality management system
 - 4.4 Quality management system and its processes
- 5 Leadership**
 - 5.1 Leadership and commitment
 - 5.2 Policy
 - 5.3 Organizational roles, responsibilities and authorities
- 6 Planning**
 - 6.1 Actions to address risks and opportunities
 - 6.2 Quality objectives and planning to achieve them
 - 6.3 Planning of changes



HLS Table of Contents – ISO 9001 / 9100

7 Support

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

8 Operation

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

HLS Table of Contents – ISO 9001 / 9100

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review

10 Improvement

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement

Implementation Considerations

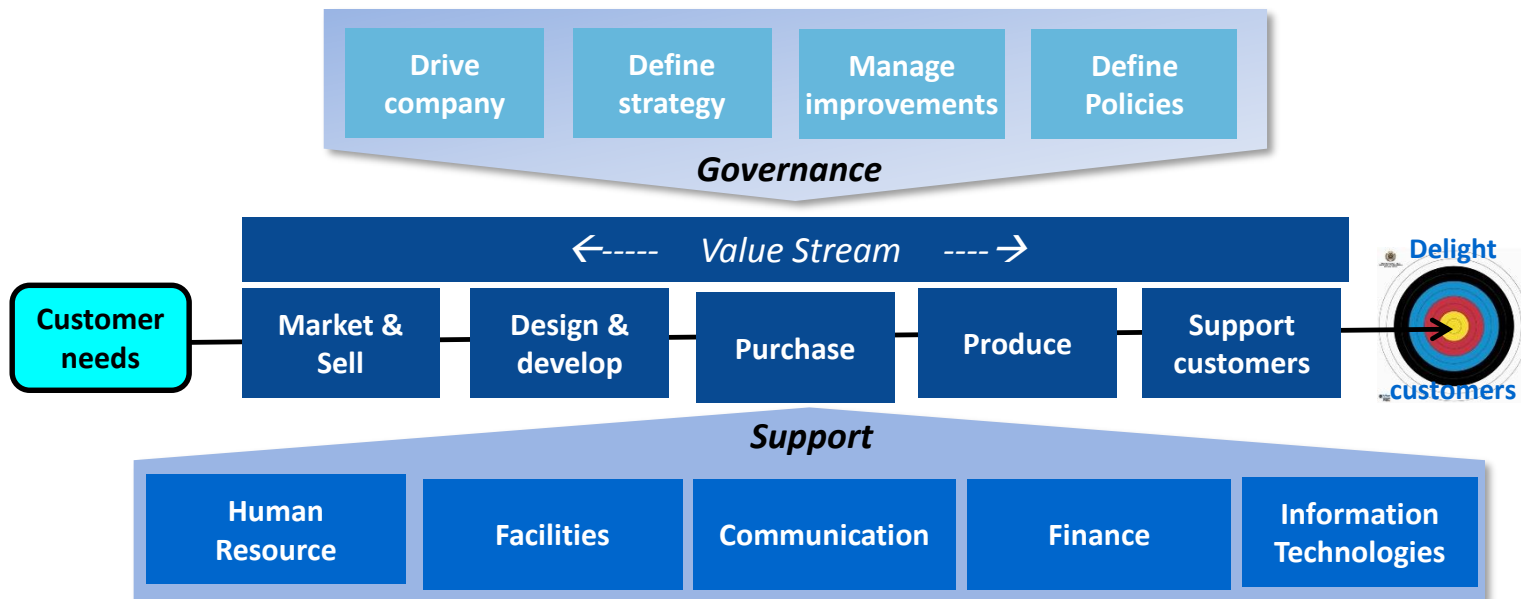
If your current documentation system is structured (based) on a previous revision of the standard, **consider re-arranging your QMS documentation** around the value stream of your company!

- A value-stream based QMS allows you to **customize** your documentation to your unique business needs that makes sense to your leadership and associates – it describes what you do
- It supports **compliance** to the new requirement to integrate your QMS to your business processes
- It sets a **foundation** for the future. Change will be dictated by the business – not by a structure change of the standard on which it is based.

Implementation Considerations

Example of Process Based QMS

Business Management System around a Value Stream



9100 Revision 2016

Risk-based thinking

What is risk-based thinking?

- Risk-based thinking is something we all do **automatically** and often sub-consciously to get the best result
- The concept of risk has always been **implicit** in ISO 9001 - this edition makes it more explicit and builds it into the whole management system
- Risk-based thinking ensures risk is considered **from the beginning** and throughout
- Risk-based thinking makes “**prevention**” part of strategic and operational planning



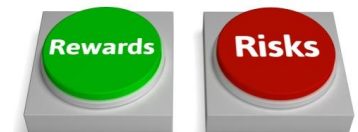
Rationale

- **Successful companies intuitively take a risk-based approach because it brings benefits**
 - ✓ Understand the **impact** of risk on operational processes
 - ✓ Improve **customer** confidence and satisfaction
 - ✓ Assure **consistency** of quality of products and services
 - ✓ Establish a proactive **culture** of prevention and improvement



Implementation considerations

- Use a **risk-driven approach** throughout your organizational processes
- Identify and **prioritize** what the risks are in your organization (*it depends on context: product or process complexity, organizational complexity*)
 - ✓ *what is acceptable?*
 - ✓ *what is unacceptable?*
- **Plan actions** to address the risks
 - ✓ *how can I avoid, eliminate or mitigate risks?*
- **Implement** the plan; *take action*
- **Check** the effectiveness of the action; *does it work?*
- **Learn** from experience; *improve*



Conclusion: Risk-based thinking

- Is not new
- Is something you do already
- Is continuous
- Ensures greater knowledge of risks and improves preparedness
- Increases the probability of reaching objectives
- Reduces the probability of negative results
- Makes prevention a habit



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Process approach

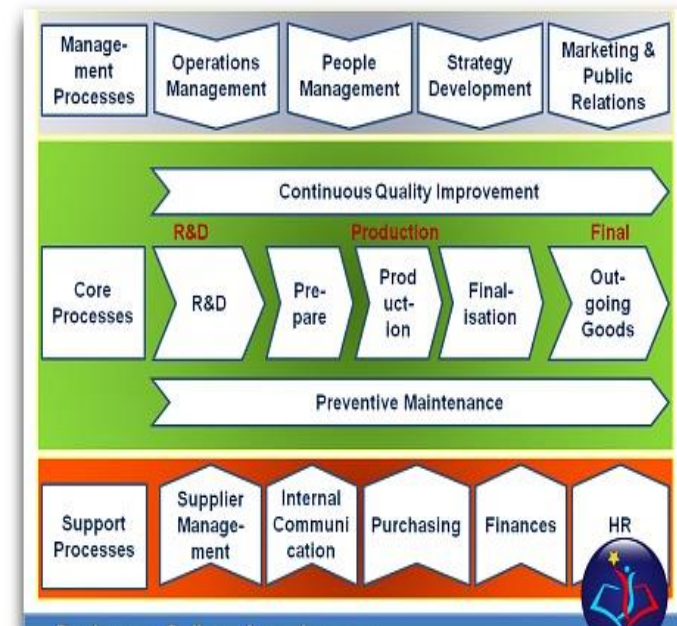
What is the process approach?

- 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

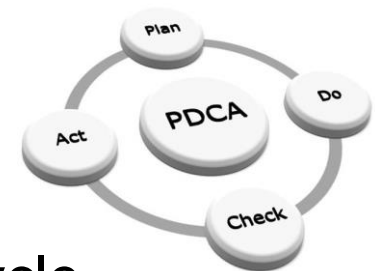


Process approach & risk-based thinking

- 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



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?

- The “Core” or “Business” processes:
 - ➔ They must follow all the 4.4 requirements
 - ➔ Certified organizations will be audited for their effectiveness: a PEAR sheet (*Process Effectiveness Assessment Report*) will be established by the certification body auditor for all Operation Processes (*refer to 9101*)
- The other processes required by the 9100:
 - ➔ Necessary processes to manage functioning / working activities (*e.g. the risks, the products configuration, the critical items, the product safety, the internal audits, the nonconformities and corrective actions*)
 - ➔ Determine whether flowcharts, routines, maps or procedures are needed to ensure effective implementation

Each organization has to determine these processes

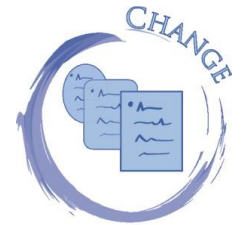


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Concept of “change”

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)



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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



9100 Revision 2016

Key changes in the 9100 additions






May 2016

Key Changes *(in the AS&D requirements)*

As a consequence of the new ISO 9001 structure:

- 9100 additions have been **relocated** into appropriate ISO sections
- the requirements are better **organized** and **clarified**, with notes and examples to enhance understanding

Key Changes *(in the AS&D requirements)*

-  ■ Product safety
added in a separate clause and in selected areas
-  ■ Counterfeit parts prevention
added in a separate clause and in selected areas
-  ■ Risk
merged current 9100 requirements with the new ISO requirements and
emphasis on risks in operational processes
-  ■ Awareness
reinforced requirements for awareness of individual contribution to quality
-  ■ Human factors
included as a consideration in nonconformity / corrective action
- Configuration management
clarified and improved to address stakeholder needs

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



9100 Revision 2016

Product safety

Addition

- New clause (8.1.3) on **Product Safety**, including requirements to address product safety considerations throughout the product lifecycle (use the NOTE as guidance) + *revision for consistency of other clauses related to safety – 7.3, 8.1, 8.4.3 & 8.5.4*
- A full Safety Management System (SMS) as defined by ICAO (International Civil Aviation Organization) is not required by 9100, but the introduction of this new clause contributes to the SMS approach

Rationale

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



Definition

- “The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property”

Examples of activities to consider:

- **Assessment of hazards and mitigation of associated risks:**
 - ✓ Implement FMEA relating to product (DFMEA) and process (PFMEA)
 - ✓ Perform safety analysis
 - ✓ Identify and mitigate risks relating to the organization and its personnel (human factors, management of responsibilities)
- **Management of safety critical items:**
 - ✓ Define and implement a monitoring control plan for critical items identified through FMEA and safety analysis

Examples of activities to consider (cont.)

- **Analysis and reporting of occurred events affecting safety:**
 - ✓ Organize the collection of potential and occurred events, and analyze their impacts with specialists
 - ✓ Organize the internal escalation process and external reporting to interested parties
 - ✓ Analyze the adverse trends of products in service reliability and define appropriate actions

- **Communication of these events and training of personnel:**
 - ✓ Promote safety culture and lessons learned from occurred events (impacts of the parts delivered by the organization on the final product safety)
 - ✓ Prevent occurrence of safety issues by taking into account industry **experience** (including occurrences on other products with similar functions or based on same technologies or components)



9100 Revision 2016

Prevention of counterfeit parts

Addition

- New clause (8.1.4) including requirements for prevention of **counterfeit parts** and a note giving examples of the associated processes
+ revision of affected clauses: 8.4.2 ; 8.4.3 (external provisions) & 8.7 (nonconformities)

Rationale

- Mitigate effects of growing threat of counterfeit / fraudulent product
- Recognize the emerging counterfeit/fraudulent statutory/regulatory requirements on QMS processes



Definition

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

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

Processes to consider:

- **Training** in the awareness and prevention of counterfeit parts
 - ✓ Procurement personnel in trusted source selection and requirements
 - ✓ Inspection personnel for prevention of counterfeit items (visual/test)
 - ✓ Design personnel in obsolescence management
- **Obsolescence monitoring** → design decisions and parts selections to be appropriate for service life of product
- **Controls for acquiring parts** → from original manufacturers, authorized distributors, or other approved sources
- **Assuring traceability** of parts and components to their original manufacturers :
 - ✓ Original Equipment Manufacturer (OEM) or
 - ✓ Authorized manufacturer (e.g., in case of PMA, direct delivery authorizations)

Processes to consider:

- **Verification and test methodologies** to detect counterfeit parts:
 - ✓ Parts identification or marking
 - ✓ Tests or chemical analysis
- **Counterfeit parts reporting**
 - ✓ Monitoring reporting from external sources (access to databases, information letters from OEMs)
 - ✓ Quarantine and reporting of internal incidences in appropriate government and industry reporting systems
(determine the responsibilities in the escalation process, the process to follow to report to authorities / customers)

Requirement regarding non conformance control:

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



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Risk management

Clause 6.1 is related to risks in “QMS of the organization”:

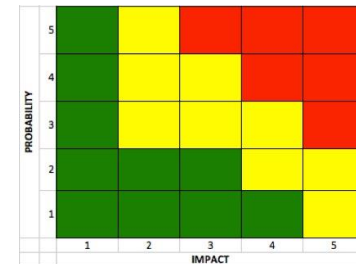
- Manage risks at organization / processes level
(such as: new customers, new market, company partnerships, business localizations, ...)



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, ...)



9100 Revision 2016

Awareness

- The 9100:2016 requires the employees aware of:
 - ✓ their contribution to **product or service conformity**
 - ✓ their contribution to **product safety**,
 - ✓ the importance of **ethical behavior**
- **Awareness activities** can be performed in different ways:
 - direct communication of expectations between managers and employees
 - communication campaigns on dedicated topics, e.g., posters, pamphlets, fliers, newsletters, videos
 - identification of focals with responsibility for communication and promotion,
 - formal training
- **What is expected:**
 - individuals should be able to explain their own role, how they contribute to quality,
 - quality basics (follow instructions, report events, maintain records ...),
 - individuals know the use of the products and potential impact of failures

Importance of ethical behavior

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



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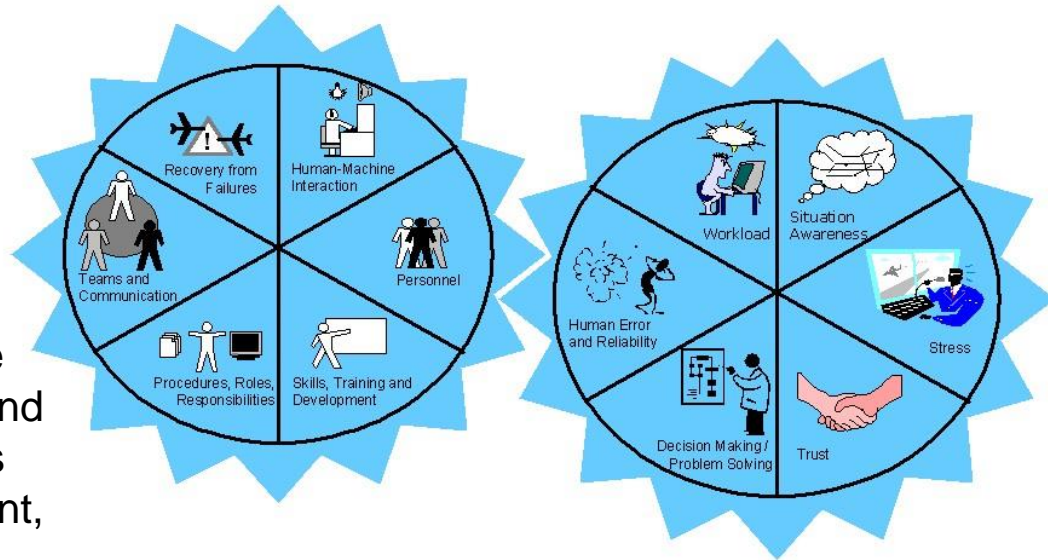
Human Factors

Addition

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

Definition

- The understanding of the interactions between people, machines and each other and their impact on human performance.
- Example: Recognition that persons performing tasks are affected by physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication and attitude in order to ensure a safe interface between the persons and all other environmental elements such as other persons, equipment, facilities, procedures and data.





Rationale

- To reinforce the controls linked to clause 7.1.4 (environment for the operation of processes) and clause 8.5.1. g (prevention of human errors)
- Recognize the importance of human factors in the origin of nonconformities

Implementation considerations

- Determine the human factors to be considered according to the products, workplaces, equipment and people of the organization
- Include the elements to be reviewed during the root causes analysis of nonconformities
- Capitalize with lessons learned on occurred human errors



9100 Revision 2016

High Level Summary of Changes Implementations benefits

May 2016

9100 Series Changes - High Level Summary

No Requirements

Clause 1 Scope

- New process model
- Added a PDCA model
- Added “Risk-based thinking”
- Emphasis on defining the QMS and context of the organization

Clause 2 Normative ref

- ISO 9000:2015 referenced

Clause 3 Terms and definitions

- ISO 9001 terms and definitions moved to ISO 9000
- *Added 9100 “product safety”, “counterfeit part”*

Clause 4 Context of the organization

- Maintained documented information is required, *can be named Quality Manual*
- Justified exclusions not limited to Realization/Operations processes
- QMS processes have performance indicators

Clause 5 Leadership

- QMS compatible with strategic direction
- QMS requirements integrated into business processes
- Processes deliver their intended outputs

Clause 6 Planning for the QMS

- When planning the QMS, determine the actions needed to address opportunities and risks (prevention)
- Increases requirements for planning of changes

Clause 7 Support

- Determine knowledge management requirements
- *Awareness on product conformity, product safety, ethical behavior*

Clause 8 Operation

- *Planning for product obsolescence*
- *Plan activities needed to assure product safety*
- *Prevention of counterfeit parts*
- *Process to validate test reports for raw material based on risks*
- Release of products and services

Clause 9 Performance evaluation

- Assess performance of QMS processes
- *Added Note to evaluate performance indicators on internal audits*

Clause 10 Improvement

- *Consider human factors in nonconformity / corrective action*

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

Implementation Benefits

- When implemented and managed well:
 - Produce and continually improve safe and reliable products
 - Meet or exceed customer and regulatory requirements to ensure satisfaction
 - Processes necessary to conduct day-to-day business are defined and managed
 - Documentation accurately reflects the work to be performed and actions to be taken
 - Focus on the complete supply chain and stakeholders
 - Fewer customer unique documents
 - Recognized by Regulatory Authorities



9100 Revision 2016

Deployment Support Material Where to find it ?

May 2016

Path through the IAQG web site



www.iaqg.org

Home

Organization

Membership

IAQG Dictionary

IAQG Forms

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The IAQG is an international non-profit association under the Belgian law registered in Brussels (Belgium).

The IAQG is a cooperative organization within the aerospace industry comprising of 3 sectors (Americas - AAQG, Asia/Pacific - APQG, Europe - EAQG).

Purpose

- Establish and maintain a dynamic cooperation between aerospace & defense companies on initiatives to improve quality performance and reductions in cost through the process.
- Initial focus is to continuously improve the process to consistently deliver high quality products, thereby reducing activities and costs.

Objectives

- Establish commonality of aviation, space and defense standards documented and "as applied"
- Establish and implement a process of continual improvement to life
- Establish methods to share best practices in the aerospace industry
- Coordinate initiatives and activities with regulatory/other industry Stakeholders

Mission

CLICK ON THE REQUIREMENT STANDARD BELOW FOR ADDITIONAL INFORMATION

Oversight of Certification Scheme				
9104-1 Requirements for ASD QMS Certification Program	9104-2 Oversight of ASD QMS Registration/ Certification Programs	9104-3 ASD Auditor Competency and Training Courses		
Certification Scheme QMS Standards		9100 QMS - Requirements for ASD Organizations	9101 QMS Audit Requirements for ASD Organizations	
		9110 QMS - Requirements for Aviation Maintenance Organizations		
		9120 QMS - Requirements for ASD Distributors		
9102 First Article Inspection Requirement	9103 Variation Management of Key Characteristics	9107 Direct Delivery Authorization Guidance	9114 Direct Ship Guidance for Aerospace Companies	9115 QMS – Requirements for ASD Orgs – Deliverable Software
9116 Notice of	9117 Delegated	9131 Nonconformance	9132 Data Matrix	9133 Qualification

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IAQG 9100 - Quality Management Systems - Requirements for Aviation, Space and Defense Organizations

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

- 9100:2016 - Quality Management Systems: Aviation, Space and Defense Organizations
 - [Changes Presentation](#)
 - [Correlation matrices between 9100:2009 and 9100:2016](#)
 - [Matrix of 9100:2009 mapped against the 9100:2016](#)
 - [FAQ](#)
 - [2015 July Quality Progress](#)
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Questions

