9120 revision 2016
Key changes presentation

IAQG 9120 Team
October 2016

9120 revision 2016

Table of contents

- **Introduction** *(reason for revision, team and timeline)*
- **Quality Management Principles**
- **Key changes in ISO 9001**
- **Key changes in 9120 additions**
- **Summary of changes – clause by clause**
- **High level summary of changes**
- **Transition summary - key dates**
- **Guidance material available on the IAQG website**

9120 Revision 2016

Introduction

reason for revision, team and timeline

9120 revision 2016

The “ISO 9001” needed to change, to:

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

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The “9120” 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)

9120 Team Members

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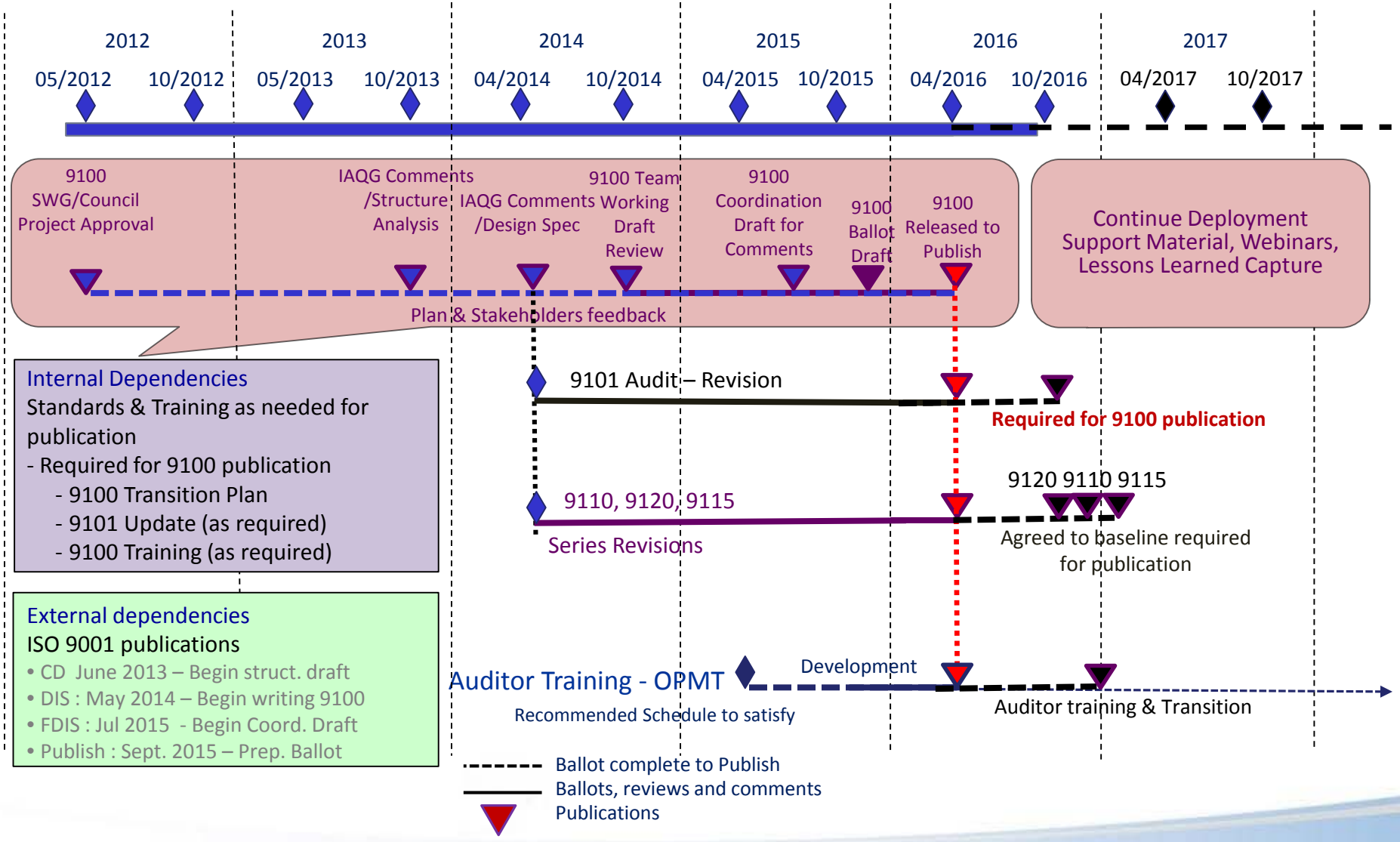
Standard Number	Title	Strategy Focus Stream	IAQG Document Representative (IDR)	SECTOR DOCUMENT REPRESENTATIVES Current Issued Version and Date		
				AAQG Sector Document Representative (SDR)	APAQG Sector Document Representative (SDR)	EAQG Sector Document Representative (SDR)
9120	Quality Management Systems – Requirements for aviation, space and defense distributors	Requirements	Elizabeth Walters +1562-797-0945 elizabeth.a.walters@boeing.com	Elizabeth Walters +1562-797-0945 elizabeth.a.walters@boeing.com - AS9120 Rev A 2009-06-29	Wang Hongyan +86 135 8586 9411 wanghongyan@comac.cc - SJAC9120 2011-02-25	Alexandr Alekseev +7 917 264 39 68 Alekseev_AV@kazanhelicopters.com - EN9120:2010 2010-06-09

9100 Series Revision
- Integrated Schedule -



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Quality Management Principles

9120 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

9120 Revision 2016

Key changes
in the ISO 9001 Baseline content

9120 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

9120 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

9120 Revision 2016

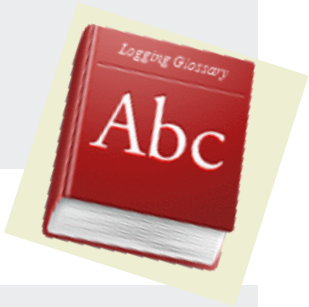
Terminology &

High Level Structure (HLS)

9120 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

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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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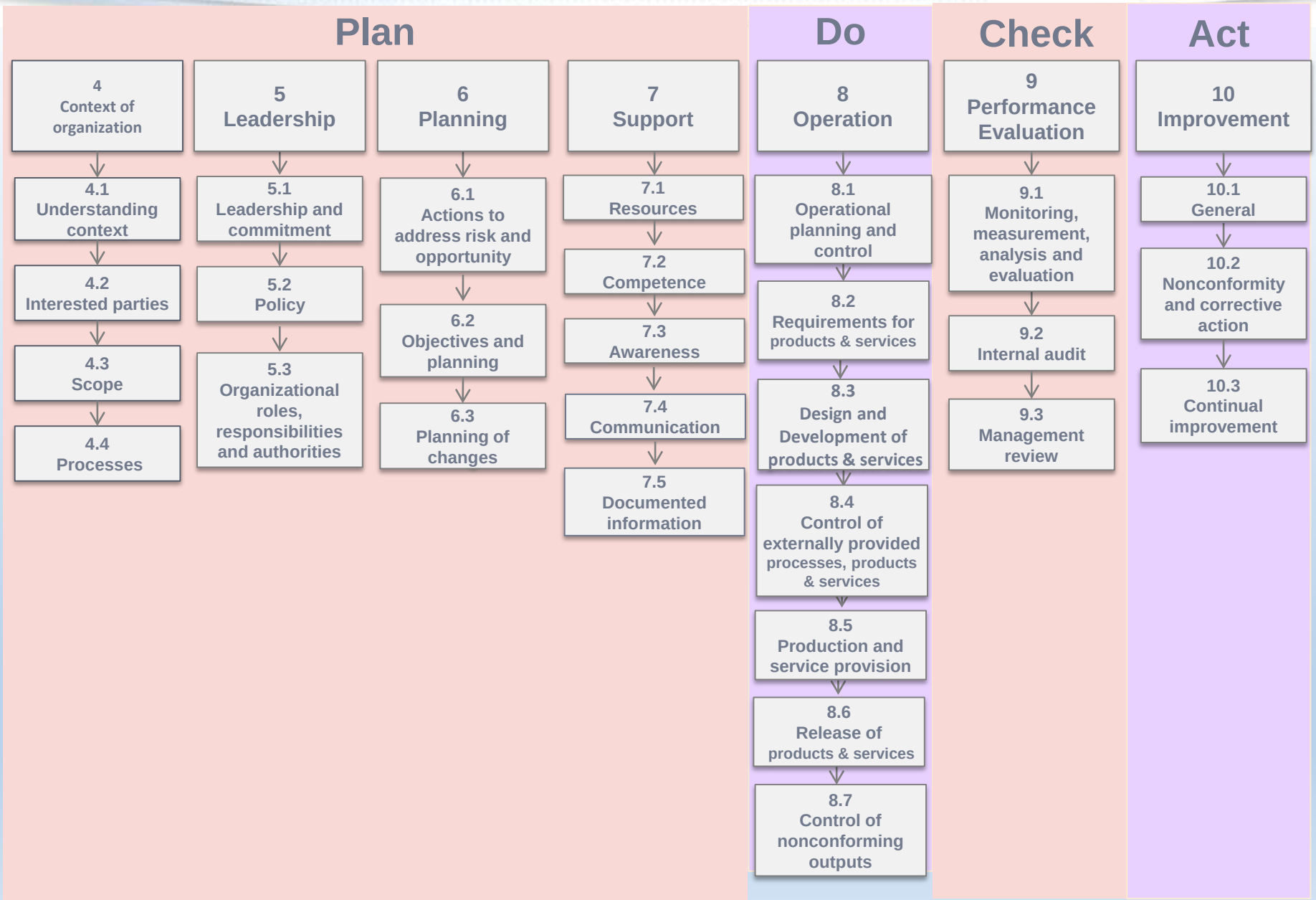
HLS: High Level Structure (from ISO 9001 baseline)



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HLS: High Level Structure (from ISO 9001 baseline)

HLS Table of Contents – ISO 9001 / 9120

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

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HLS: High Level Structure (from ISO 9001 baseline)

HLS Table of Contents – ISO 9001 / 9120

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 ***(new for 9120)***
- 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 / 9120

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

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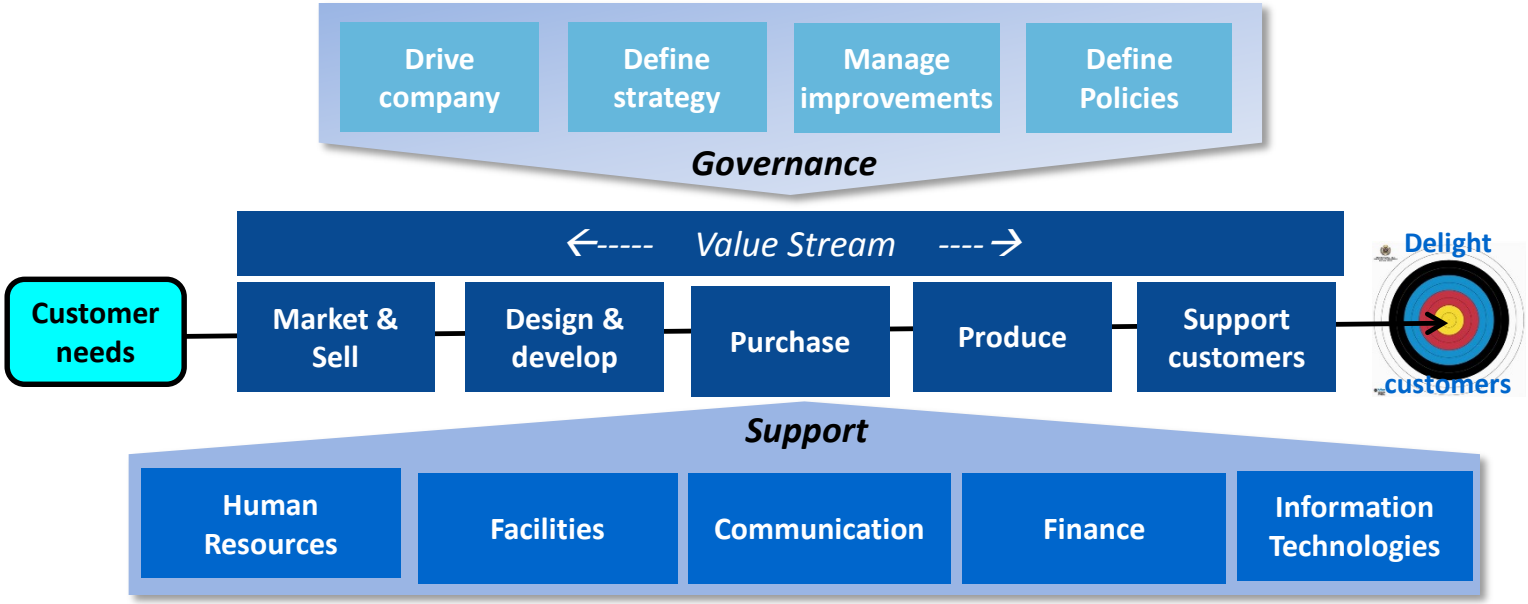
HLS: High Level Structure (from ISO 9001)

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

9120 revision 2016

Risk-based thinking

Rationale

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

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, …)*

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*

9120 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

9120 Revision 2016

Process approach

9120 revision 2016

Process Approach

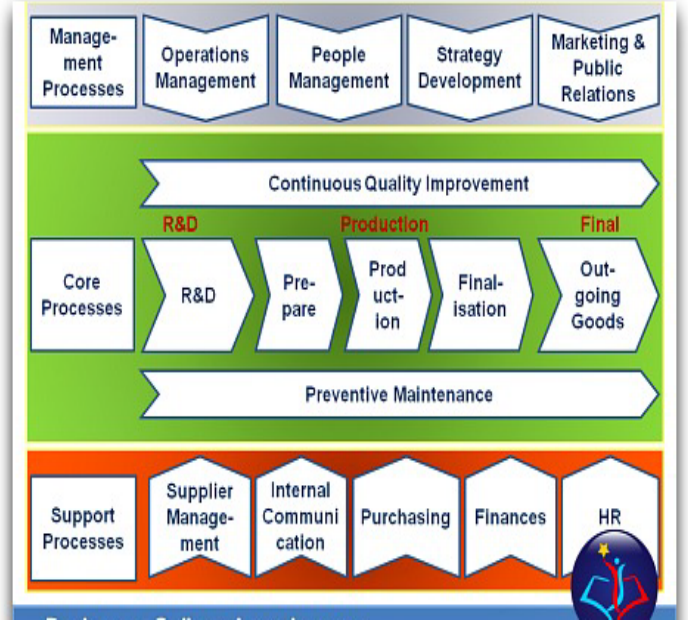
What is the process approach?

- 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

Example



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

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

Benefits

- increases accountability
- increases ability to focus on key processes
- improves internal integration of processes
- more consistent business performance and results
- better use of resources
- improves customer confidence in the organization

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 *(see A.5 in Annex A)*
- Example for a Distributor declaring 8.3 is "not applicable":
  - ➔ XYZ Distribution is a supplier of electronic components to the aviation, space and defense industry for OEM and aftermarket use. No products or external 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 products being supplied.

Each organization has to justify "non-applicability"

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

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Concept of “change”

9120 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 occur
- 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

9120 Revision 2016

Key changes
in the common 9100 requirements and unique 9120 additions

9120 revision 2016

Key Changes *(aviation, space and defense requirements)*

As a consequence of the new ISO 9001 structure:

- 9120 additions have been **relocated** into appropriate ISO sections
- the requirements are better **organized** and **clarified**, with notes and examples to enhance understanding
- design and development of goods and services is included for organizational determination of applicability

9120 revision 2016

Key Changes *(aviation, space and defense requirements)*

- Product safety
  added in carefully 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 into 9120 in appropriate areas
- 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

9120 revision 2016

Key Changes *(aviation, space and defense requirements)*

- Product Realization & Planning
  limited for application to a Distributor
- Post Delivery Support
  merged new 9100 and ISO requirements into 9120 in appropriate areas
- Project Management & Work Transfer
  combined with Operation Planning clause and worded in the context of a Distributor
- Quality Manual
  note added pointing to the requirements that make up a Quality Manual or the equivalent
- Management Representative
  requirement added back in for QMS oversight

9120 Revision 2016

Product safety

9120 revision 2016

Product Safety

Addition

- Product Safety is introduced in the following clauses:

  7.3, 8.1 & 8.4.3

Rationale

- Industry acknowledgement of the importance of increasing safety

Product safety definition (3.6)

- Maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

Implementation considerations

- Heighten product safety awareness throughout the organization and the impacts of handling and packaging on protecting and assuring that product integrity is maintained.

9120 revision 2016

Product Safety

Benefits

- Increased awareness of how organization contribute to product safety
- Minimize safety risk
- Safety integrated and embedded with processes
- Ensures flowdown on product safety issues and criteria

9120 Revision 2016

Prevention of unapproved and counterfeit parts

9120 revision 2016

Unapproved and Counterfeit Parts

Addition

- New clause including requirements for prevention of suspect unapproved, unapproved, and counterfeit parts and a note giving examples of the associated processes *and revision of affected clauses: 3.4, 3.8 & 3.10 (definition), 8.1.2 (prevention of counterfeit parts), 8.1.5 (prevention of suspected unapproved parts) 8.4 (external provisions) & 8.7 (nonconformities)*

Counterfeit Part Definition (3.4)

- "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."

Unapproved Part Definition (3.10)

- A part that was not produced or maintained in accordance with approved or acceptable data and applicable statutory, regulatory, and customer requirements.

**A counterfeit part by definition is an unapproved part*

9120 revision 2016

Unapproved and Counterfeit Parts

Rationale

- Mitigate effects of growing threat of counterfeit products
- Recognize the statutory/regulatory requirements on QMS processes for the control of “unapproved parts” and counterfeit parts in both the production and aftermarket environments.

Implementation considerations

- **Risk**
  - ✓ Understand risks associated with procurement and sourcing that could cause unapproved / counterfeit parts to be delivered
  - ✓ Create preventions and mitigation actions to address unapproved / counterfeit part procurement 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

9120 revision 2016

Unapproved and Counterfeit Parts prevention

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)
- **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)
- **Verification and test methodologies** to detect counterfeit parts:
  - ✓ Parts identification or marking
  - ✓ Tests or chemical analysis
- **Requirement regarding non conformance control:**
  - ✓ Segregate and control suspected unapproved or counterfeit products
  - ✓ Ensure these products are not re-introduced into the supply chain

9120 revision 2016

Unapproved and Counterfeit parts prevention

Processes to consider:

- **Unapproved / 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)

Benefits

- **Minimize opportunity of counterfeit part deception**
- **Assures only "approved" parts are sold to customers**
- **Improves supplier evaluation and control of purchases to prevent fraud**
- **Control of counterfeit parts prevents re-entry into the supply chain**

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Awareness

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Awareness

- The 9120:2016 requires the employees to be 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 persons with responsibility for communication and promotion (awareness)
  - 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 are some items for consideration
  - ✓ 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

9120 Revision 2016

Human Factors

9120 revision 2016

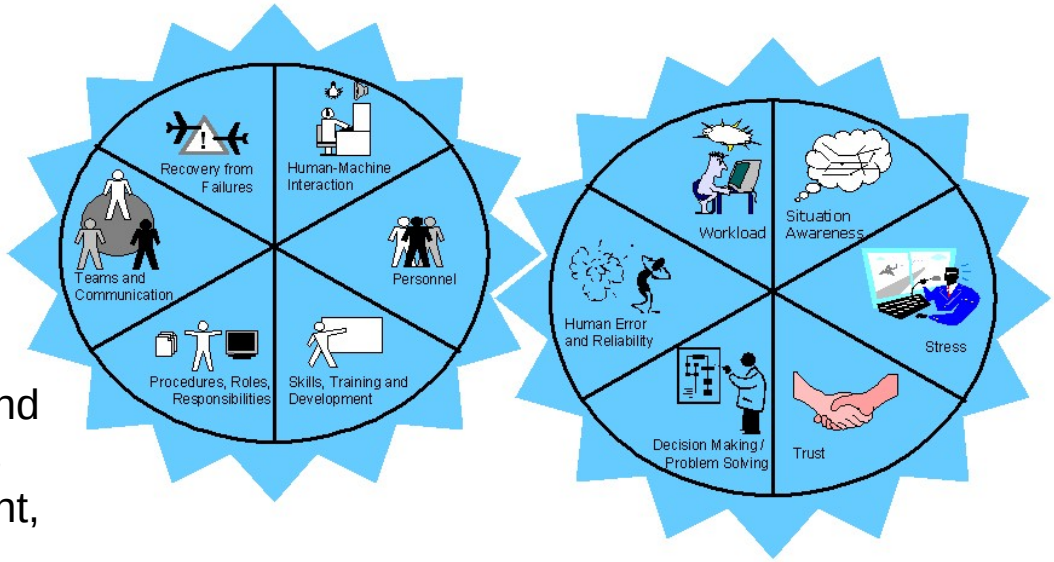
Human Factors

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

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Summary of changes - Clause-by-Clause

9120 revision 2016

The following slides will provide you a summary, clause by clause of the key changes

- **from the 9120:2009 to the 9120:2016**

Key changes are identified by:

- ISO 9001 >>>>>>>
- ***9100 additions*** >>
- ***9120 additions*** >>

Additional slides provide more information on topics identified with ⓘ

- ✓ Interested parties
- ✓ Scope of a QMS
- ✓ Quality manual
- ✓ Documented information
- ✓ Evaluation of test reports

9120 revision 2016

Summary of changes - clause by clause

Foreword, Revision summary/Rationale, Intended application

Introduction

- 0.1 General
- 0.2 Quality management principles
- 0.3 Process approach
  - Plan-Do-Check-Act cycle
  - Risk-based thinking
- 0.4 Relationship with other management system standards

Includes verbal significations of "shall, should, may, can"

7 principles to consider

Schematic representations of
- a process
- the standard (with a PDCA approach)

Requirements

1. Scope

2. Normative references

3. Terms and definitions

- *Counterfeit product* — ***Definition added***
- *Product safety* — ***Definition added***
- *Suspect unapproved product* — ***Definition added***

9120 revision 2016

Summary of changes - clause by clause

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"

Explicit requirement for a documented information maintained with content defined (can be called quality manual) (not required by ISO)

Interested parties

Definition (ISO 9000)

- stakeholder
- person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

Examples of interested parties**:**

- employees, management, organization owners, unions,
- suppliers, customers, partners
- regulatory authorities (Aviation, Defense, Space),
- certification organizations, …

Criteria to determine interested parties relevancy, requirements and clause applicability:

- Tier level in the supply chain: Original Equipment Manufacturers, Production Approval Holders, Design Organization Approval, Production Organization Approval, Systems integrators
- Product families: raw materials, components, assemblies
- Activity: distribution, design, maintenance, manufacturing, service

Scope of the QMS

9120:2016 no longer refers to **"exclusions"** in relation to the applicability of its requirements to the organization's quality management system.

The applicability of each requirement of the standard depends on:

- the size or complexity of the organization
- the management model of the organization
- the range of the organization's activities
- the nature of the risks and opportunities for the organization

The organization can decide that a requirement is not applicable, only if this decision will not result in failure to achieve:

- conformity of products and services
- enhancement of customer satisfaction

Justifications must be provided for non applicability

For AS&D, non applicability outside clause 8 (Operation) would be unusual

The negative word « exclusion » is not used
The positive word « applicability » is preferred

Quality Manual

- The 9120 requires to establish and maintain documented information describing: Interested parties; QMS scope; Process description, sequence & interactions; and Responsibilities and authorities.
- The requirement can be met in different ways: document, webpages, CD Rom, electronic document management system, etc.
- The intent of the AS&D note "*The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.*" is
  - to convey the practicality to maintain the required information in a centralized location for ease of audit and availability for customers and other interested parties.
  - to highlight that this documented information may or not, be called a quality manual. (terms "management handbook" or "company management manual" are often used).

    NOTE: A document called "quality manual" may be required for the organization by relevant interested parties (e.g. regualtory bodies might require a quality manual)

9120 revision 2016

Summary of changes - clause by clause

5. Leadership

- 5.1 Leadership and commitment
- 5.2 Policy
- 5.3 Organizational roles, responsibilities and authorities

Leadership instead of only management of responsibilities (management to demonstrate their leadership)

Top management to ensure integration of QMS into business processes (now explicit)

Policy aligned with organization strategic direction

A "management representative" required as focal point for QM issues *(removed from ISO 9001:2015)*

6. Planning

- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes

Determine risks and opportunities, considering the issues raised and requirements identified.

Plan appropriate actions to reduce undesired effects on the QMS and evaluate effectiveness

Planning the achievement of objectives more prescriptive and includes the evaluation of results

Changes to the QMS to be carried out in a planned manner

9120 revision 2016

Summary of changes - clause by clause

7. Support

7.1 Resources

7.1.1 General

7.1.2 People

7.1.3 Infrastructure

7.1.4 Environment for the operation of processes

7.1.5 Monitoring and measuring resources

7.1.6 Organizational knowledge

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

7.5.1 General

7.5.2 Creating and updating

7.5.3 Control of documented Information

Environment includes human and physical factors

Determine necessary knowledge gained from experience, lessons learned, success, failures, conferences, …

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***

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

Added the requirement to define data protection processes for documented information managed electronically

Retained documented information includes: evidence of product origin, conformity and shipment…

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More information about …

Documented information

There is no longer a requirement for six mandatory documented procedures, however…the extent of the documentation that is needed will depend on the business context.

- It is the responsibility of the organization to maintain documented information to support the operation of its processes:
  - **Topics to be documented:**
    - Interested parties; QMS scope; Process description, sequence & interactions; Responsibilities and authorities
    - Quality Policy and Objectives
  - **AS&D requires** maintained documented information regarding nonconformity and corrective action management processes, as it is a key process for aerospace.
  - **Various methods** can be used to meet the requirement (e.g., procedures, process flow diagrams, videos, graphic instructions, screen shots, etc.)

- It is the responsibility of the organization to retain the documented information necessary to have confidence that the processes are being carried out as planned.

9120 revision 2016

Summary of changes - clause by clause

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*
8.1.1	***Reinforce the planning and control activities with dispositions to ensure On-Quality and On-Time delivery of products or services***
8.1.2 Configuration management	***Not Used***
8.1.3	***Based on the requirements of 9100:2009 (7.1.3), revised to clarify stakeholders expectations***
8.1.4 Prevention of counterfeit parts	***Not Used***
8.1.5 Prevention of Suspect Unapproved Parts	***Added new requirements to prevent the use of suspect unapproved, unapproved parts and counterfeit parts***

9120 revision 2016

Summary of changes - clause by clause

8. Operation

8.2 Requirements for products and services

- 8.2.1 Customer communication
- 8.2.2 Requirements related to products and services
- 8.2.3 Review of requirements related to products and services
- 8.2.4 Changes to requirements for products and services

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

8.3 Design and development of products and services

Not excluded per ISO 9001:2015 clause 4.3

- 8.3.1 General
- 8.3.2 Design and development planning
- 8.3.3 Design and development Inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes

Added requirement for a process and criteria for notifying customers, about changes that affect customer requirements

9120 revision 2016

Summary of changes - clause by clause

8. Operation

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 external providers to apply appropriate controls to their direct and sub-tier external providers

8.4.2 Type and extent of control

Added evaluation of data on test reports provided, to confirm the results comply with requirements

Added validation process of tests reports accuracy for raw materials identified as a significant risk

8.4.3 Information for external providers

More explicit topics to be considered to communicate requirements to external providers

Added verbiage to include prevention of unapproved and suspect unapproved products
Added requirement for certificate of conformity, test reports and authorized release certificate

9120 revision 2016

More information about …

Evaluation of data on test reports

Rationale

- Avoid noncompliance of test reports results with the requirements

Implementation

- Determine the products for which test reports will be required
- At receiving, check the test results are compliant to the stated requirements before accepting the parts

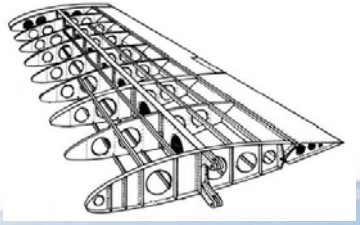
Validation process of tests reports accuracy for raw materials

Rationale

- Inaccurate or incomplete test reports for raw materials have introduced undue risks on customer applications

Implementation

- If specified by the customer that raw material is a risk to their application this clause will apply (according to customer requirements)
- Define the process to be applied (e.g. periodic scheduled retests performed on samples) and take necessary actions



9120 revision 2016

Summary of changes - clause by clause

8. Operation

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. ***Added requirement to take into account obsolescence, where applicable***
8.5.2 Identification and traceability	*Clarified requirements for traceability and accountability when splitting product.*
8.5.3 Property belonging to customers or external providers	New ISO clause (as per 9100:2009)
8.5.4 Preservation	***Clarified that when problems are detected after delivery the organization shall take appropriate actions***
8.5.5 Post-delivery activities	New ISO clause to emphasize on this topic
8.5.6 Control of changes	New ISO clause to verify that all activities have been carried out before release and delivery by authorized persons

8.6 Release of products and services

Outputs including products and services

8.7 Control of nonconforming outputs

Maintained the requirement for a "procedure" to define the NC process and responsibilities on this key topic for ASD

9120 revision 2016

Summary of changes - clause by clause

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation
9.1.1 General
9.1.2 Customer satisfaction
9.1.3 Analysis and evaluation

9.2 Internal audit

9.3 Management review

Specific requirements for analysis and evaluation when using results as inputs to management review
Outputs from the analysis are clearer

Explicit topics to consider for the internal audit programme(s)

Added "on-time delivery performance" as input

10. Improvement

10.1 General
10.2 Nonconformity and corrective action
10.3 Continual improvement

Added requirement to evaluate the need for action based on human factors to ensure nonconformities do not recur

Nonconformity and corrective action "procedure" added back-in from ISO

Annex (informative)

A. Clarification of new structure, terminology and concepts
B. Standards developed by ISO/TC 176
C. Standards developed by IAQG

For risk management, added the 9100 clarification

Full list of IAQG standards available

Bibliography

9120 Revision 2016

High Level Summary of Changes Implementations benefits

October 2016

9120 revision 2016

9120 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 "product safety" and unapproved parts, updated "counterfeit 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
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 (preventive) ▪Increases requirements for planning of changes
Clause 7 Support	▪Determine knowledge management requirements ▪*Awareness of contribution to compliance and product safety*
Clause 8 Operation	▪*Control of product obsolescence* ▪*Prevention of counterfeit parts* ▪*Process to validate test reports for raw material when risks are present* ▪Release of products and services ▪*Product identification and traceability for splitting*
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 QMS standards will now have this common 10 clause structure

9120 revision 2016

Implementation Benefits

- When implemented and managed well:
  - 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

9120 series Revision 2016

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	9100 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

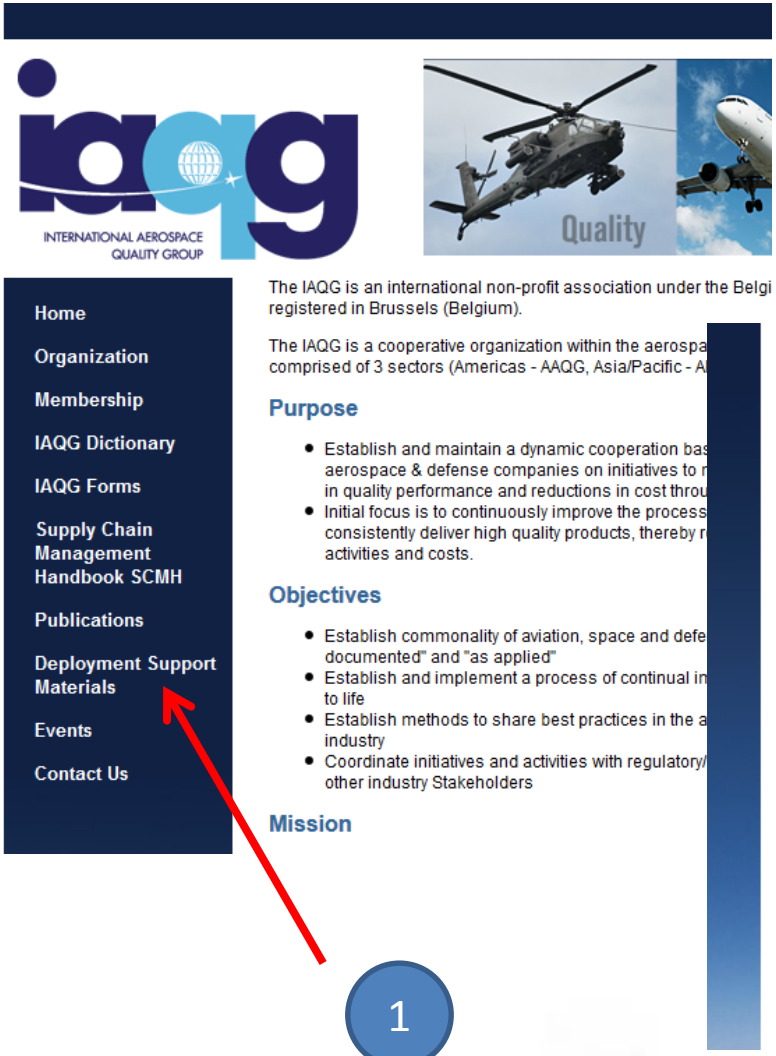
9120 Revision 2016

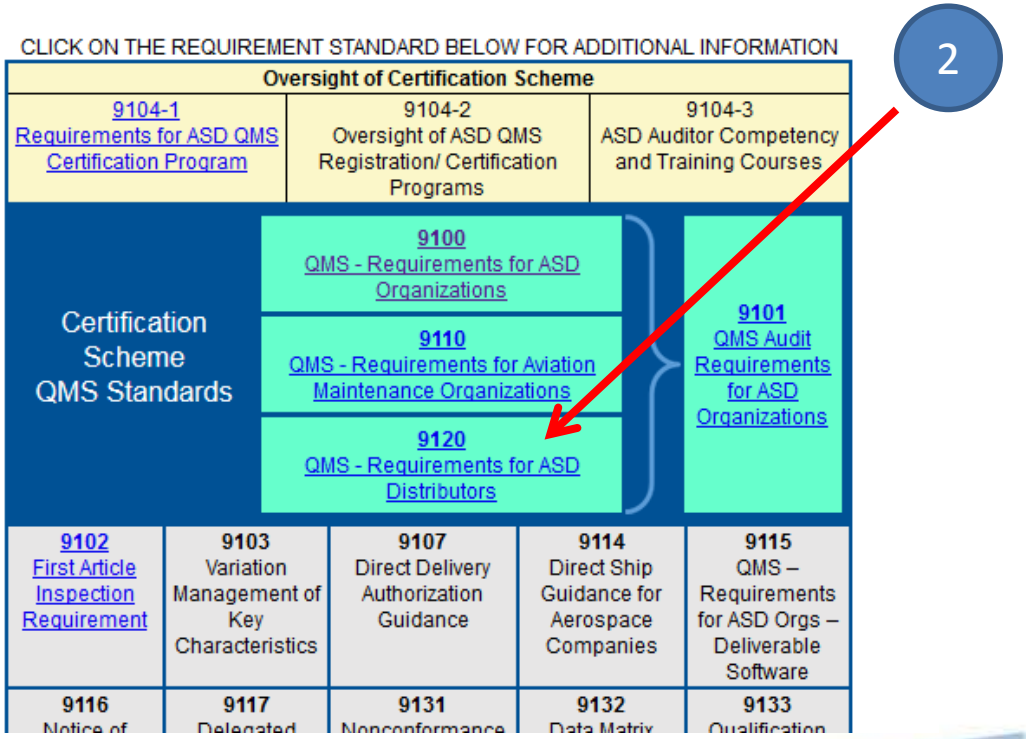
Deployment Support Material

Where to find it ?

Path through the IAQG web site

www.iaqg.org





9120 Deployment Support Material

IAQG 9120 - Quality Management Systems – Requirements for Aviation, Space and Defense Distributors

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.

- 9120:2016 - Quality Management Systems: Aviation, Space and Defense Organizations
  - Changes Presentation
  - Correlation matrices between 9120:2009 and 9120:2016
  - FAQ
  - For questions, please contact the IAQG and Sector Document Representatives

Questions