9100 revision 2016
Key changes presentation

IAQG 9100 Team
February 2017

9100 revision 2016

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9100 Revision 2016

Introduction

reason for revision, team and timeline

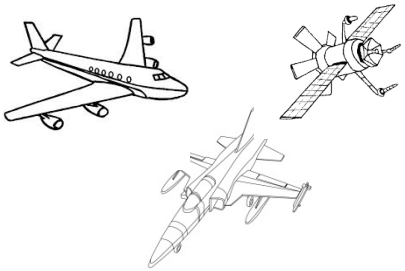
9100 Series Relationship to ISO 9001:2015 as Baseline Text

9100 revision 2016

The “ISO 9001” needed to change, to:

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

9100 revision 2016



The “9100” needs to change, to:

- Incorporate changes made by ISO TC176 to the ISO 9001:2015 requirements
  (ISO liaison organized to collaborate with the IAQG 9100 team and to obtain consideration for IAQG requirements)

- Consider Aviation, Space and Defense stakeholders’ needs identified since the last revision
  (web survey performed in 2013)

- Consider clarifications to 9100 series requests issued by IAQG since the last revision
  (requirements clarified or notes added)

IAQG 9100 Series Team

IAQG 9100 Series Team

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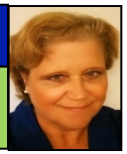

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Integration of Standards

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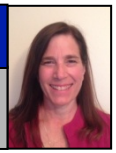

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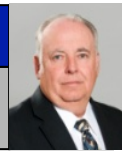

Wayne Johnson
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IAQG/Sector 9100 Team Structure

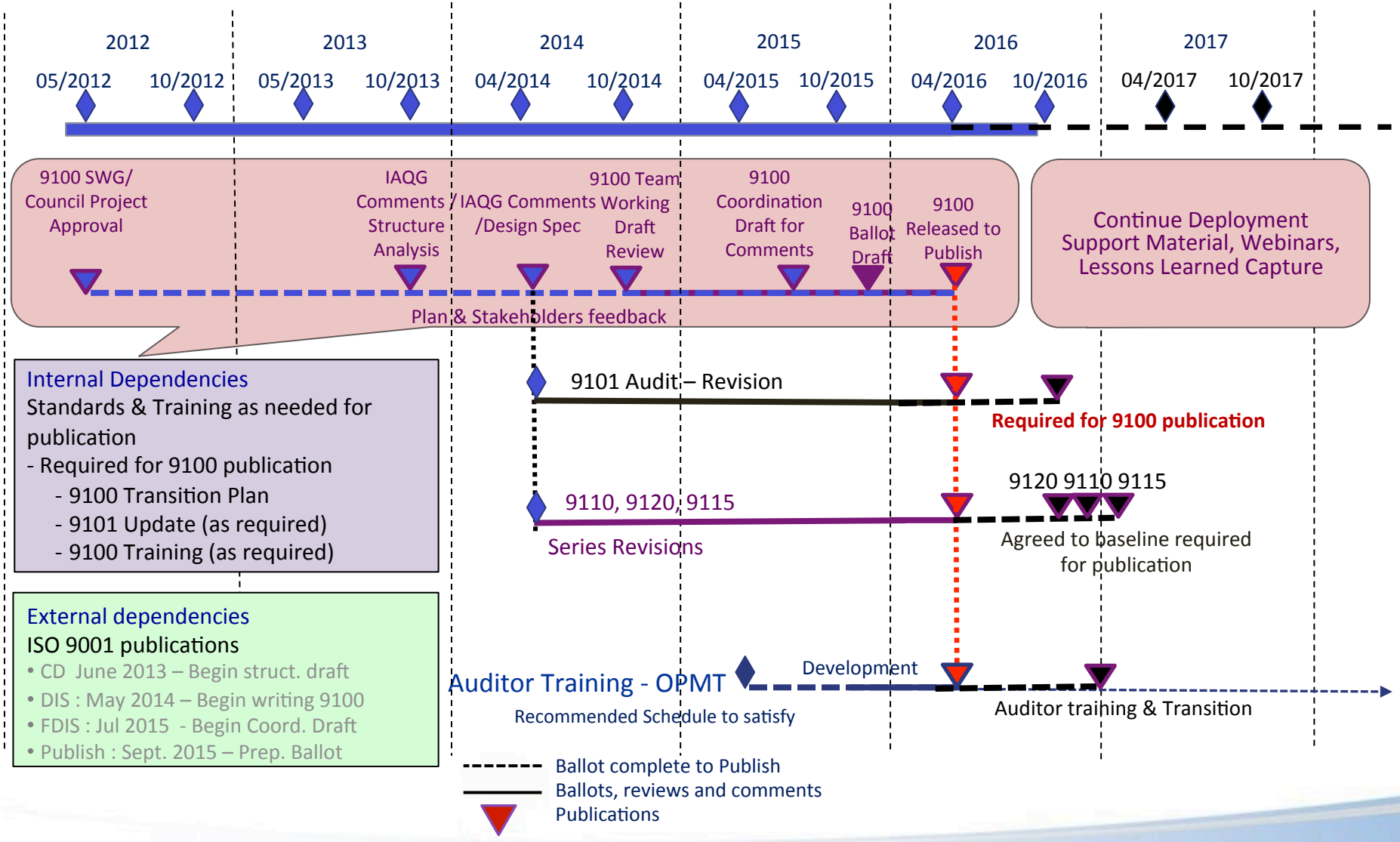
IAQG 9100 Writing Team collects sector and stakeholder input and creates a rough draft. (8)

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

Representatives of Sector 9100 Team at International Meetings (9)

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

9100 Series Revision
Integrated Schedule



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Quality Management Principles

9100 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

9100 Revision 2016

Key changes
in the ISO 9001 Baseline content

9100 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

9100 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

9100 Revision 2016

Terminology &
High Level Structure (HLS)

9100 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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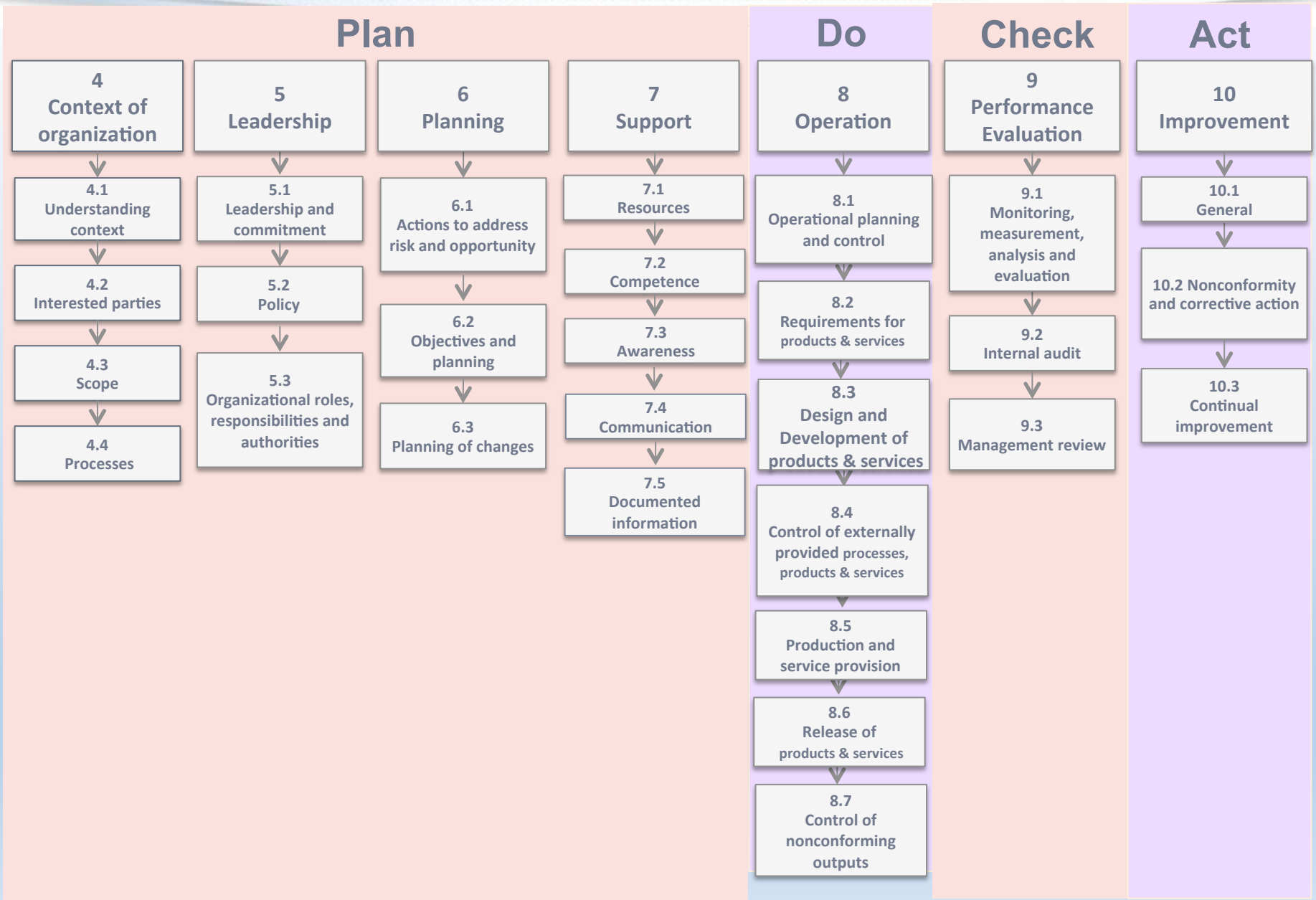
HLS: High Level Structure (from ISO 9001 baseline)



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HLS: High Level Structure (from ISO 9001 baseline)

HLS Table of Contents – ISO 9001 / 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

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

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

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

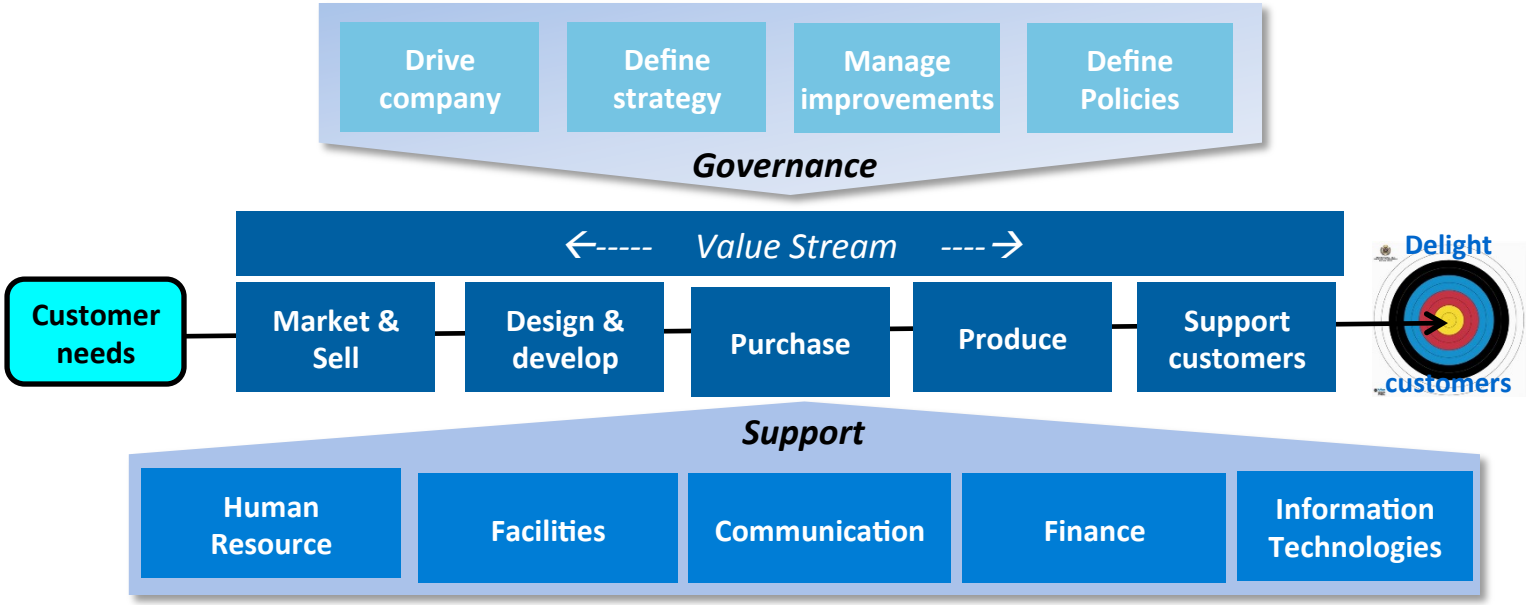
Benefits

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

Implementation Considerations

Example of Process Based QMS

Business Management System around a Value Stream



Each organization has to determine their business processes

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Risk-based thinking

What is risk-based thinking?

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

Implementation considerations

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

9100 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

9100 Revision 2016

Process approach

9100 revision 2016
Process Approach

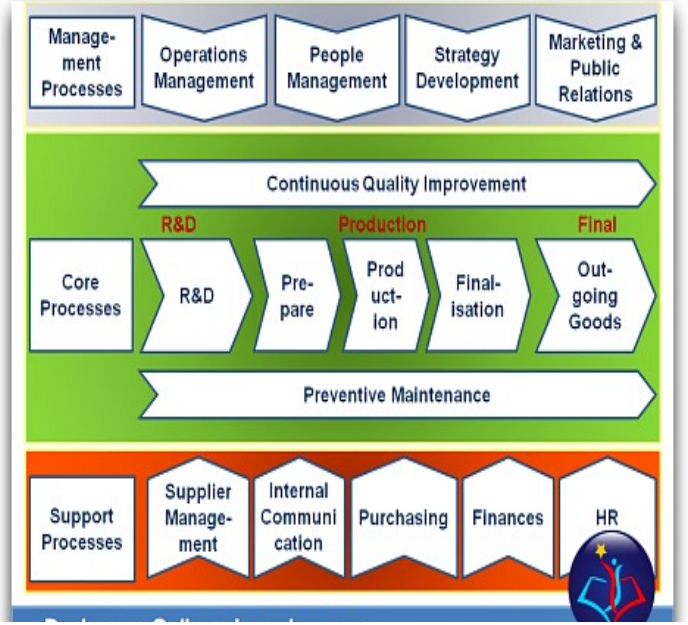
What is the process approach?

- The systematic management of processes and their interactions to achieve intended results

All organizations use processes to:

- set interrelated or interacting activities
- transform inputs into outputs
- build in checks to meet objectives and
- promote continuous improvement

Example

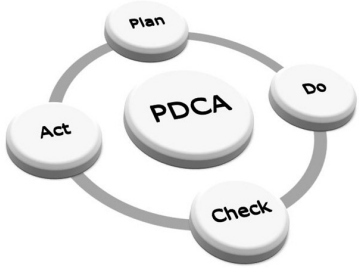


The process approach integrates processes into a holistic system in order to achieve strategic and operational objectives

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

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

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"

9100 revision 2016

Concept of Change

The standard has become a dynamic framework which evolves to enable organizations to adapt to their changing environments or circumstances

Change is addressed in several clauses:

- Planning/implementing changes to the QMS (6.3)
- Organizational knowledge - for addressing changing needs and trends, with respect to knowledge (7.1.6)
- Controlling operational changes, planned and unintended (8.1)
- Ensuring appropriate actions are taken about changes relating to requirements for products and services (8.2.4)
- Managing changes relating to design and development (8.3.6)
- Addressing changes affecting production or service provision (8.5.6)

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

9100 Revision 2016

Key changes
in the 9100 additions

9100 revision 2016

Key Changes *(aviation, space and defense 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

9100 revision 2016

Key Changes *(aviation, space and defense 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

9100 Revision 2016

Product safety

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
- **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

Examples of activities to consider (cont.)

- **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)

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**

9100 Revision 2016

Prevention of counterfeit parts

9100 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."

9100 revision 2016

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

9100 revision 2016

Counterfeit parts prevention

Processes to consider:

- **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

Benefits

- **Minimize opportunity of counterfeit part deception**
- **Improve awareness regarding obsolescence to prevent counterfeit part risk**
- **Suppliers to evaluate and improve control of purchases to prevent fraud**
- **Control of counterfeit parts prevents re-entry into the supply chain**

9100 Revision 2016

Risk management

9100 revision 2016

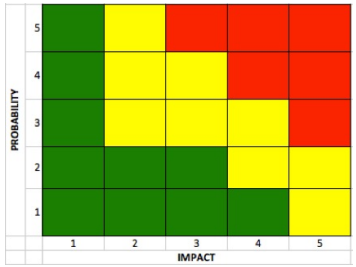
Risk management

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

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

Clause 8.1.1 is related to the risks in "Operational Processes" defined in clause 8:

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



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

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Awareness

9100 revision 2016

Awareness

- The 9100:2016 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 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 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

9100 Revision 2016

Human Factors

9100 revision 2016

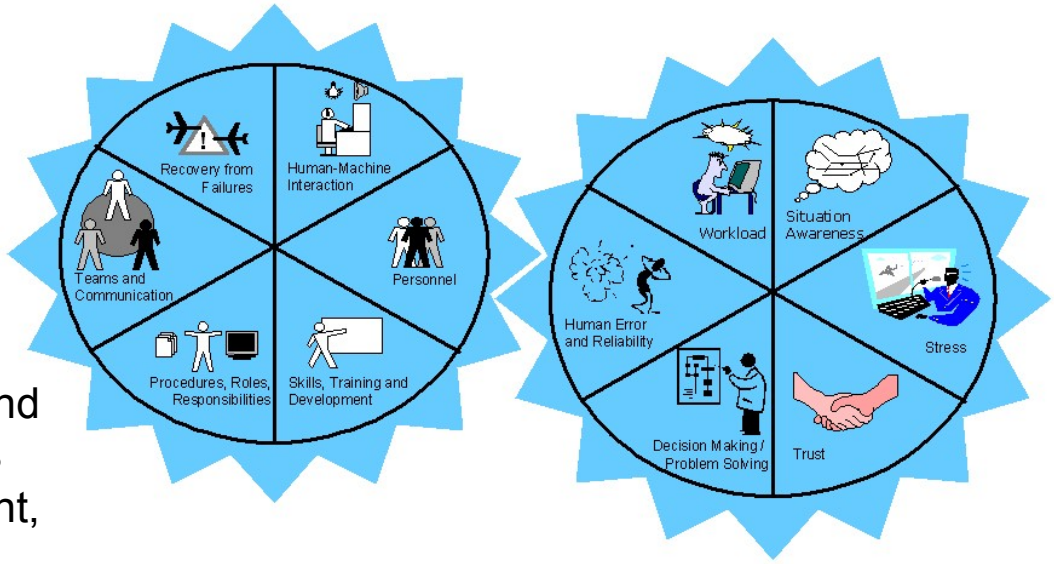
Human Factors

Addition

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

Definition

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



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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

9100 Revision 2016

High Level Summary of Changes Implementations benefits

October 2016

9100 revision 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

9100 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 specific documents
  - Recognized by Regulatory Authorities

9100 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

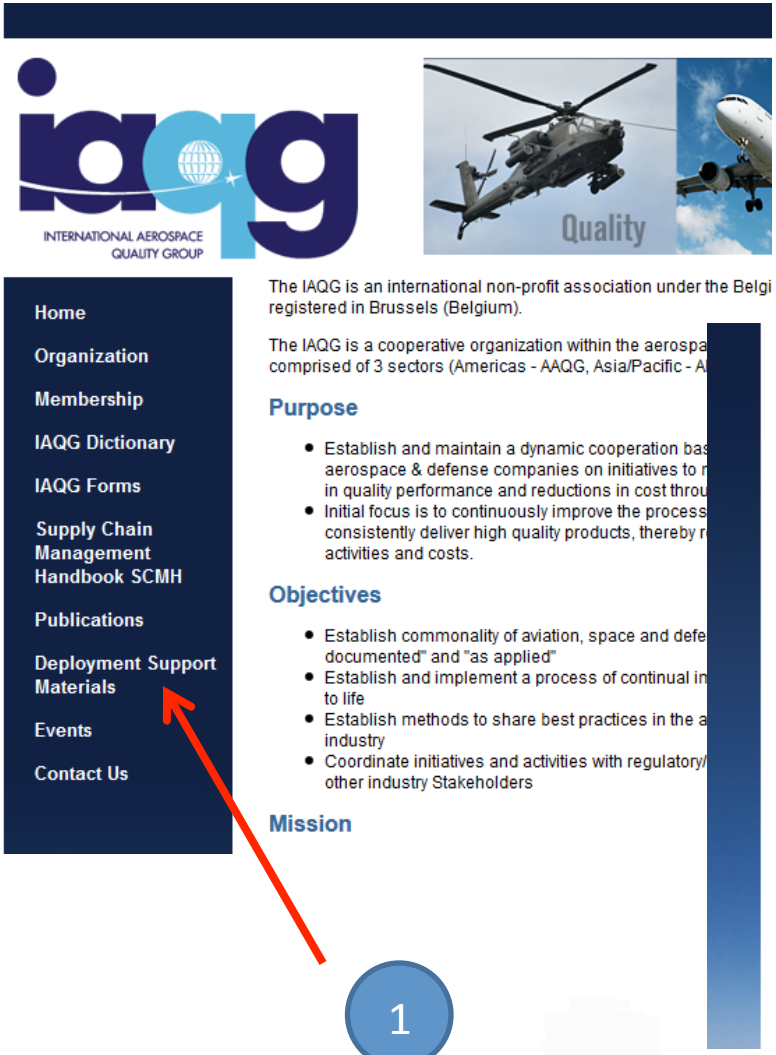
9100 Revision 2016

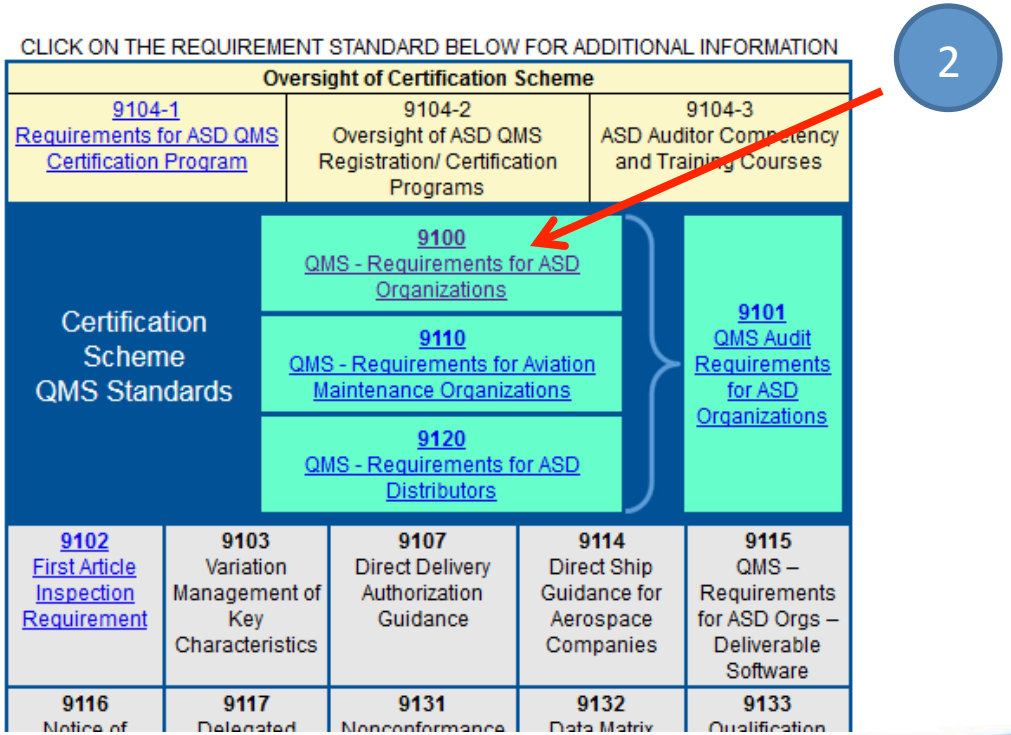
Deployment Support Material

Where to find it ?

Path through the IAQG web site

www.iaqg.org





9100 Deployment Support Material

- 9100:2016 - Quality Management Systems: Aviation, Space and Defense Organizations
  - Executive Level Summary Presentation
  - Key Changes Presentation
  - Clause-by-Clause Presentation
  - Presentation Go-to-Webinar Recordings
    - Key Changes Presentation
    - Clause-by-Clause Presentation
  - Correlation matrices between 9100:2009 and 9100:2016
  - Matrix of 9100:2009 mapped against the 9100:2016
  - FAQ
  - 2016 August Quality Progress: Prepare for Landing - How to get ready for the revised AS9100 series of standards
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  - Gap Assessment Worksheet
  - 9100 Evaluation Guidance Material

- ISO 9001:2015 - The following have been prepared by ISO/TC 176/SC2 to inform and assist organizations in making the ISO 9001:2015 transition
  - News on the ISO 9001 revision
  - A summary of the changes, and on the revision of ISO 9001:2015
  - Transition Planning Guidance for ISO 9001:2015
  - Implementation Guidance for ISO 9001:2015
  - ISO 9001:2008 and ISO 9001:2015 Correlation matrices
  - A paper on ISO 9001 and Risk
  - A presentation on ISO 9001 and Risk Based Thinking
  - Guidance on the requirements for Documented Information of ISO 9001:2015
  - How Change is addressed within ISO 9001:2015
  - A paper on the Process Approach in ISO 9001:2015
  - A presentation on the Process Approach in ISO 9001:2015
  - Frequently Asked Questions (FAQs)
  - ISO Auditing Practices Group

Questions