

12TH MEETING OF ICAO AIS-AIM IMPLEMENTATION TASK FORCE

5-9 JUN 2017, BANGKOK, THAILAND



QUALITY MANAGEMENT SYSTEM FOR AIS (ISO 9001:2015)

Quality Managed migration of legacy aeronautical information into digital database

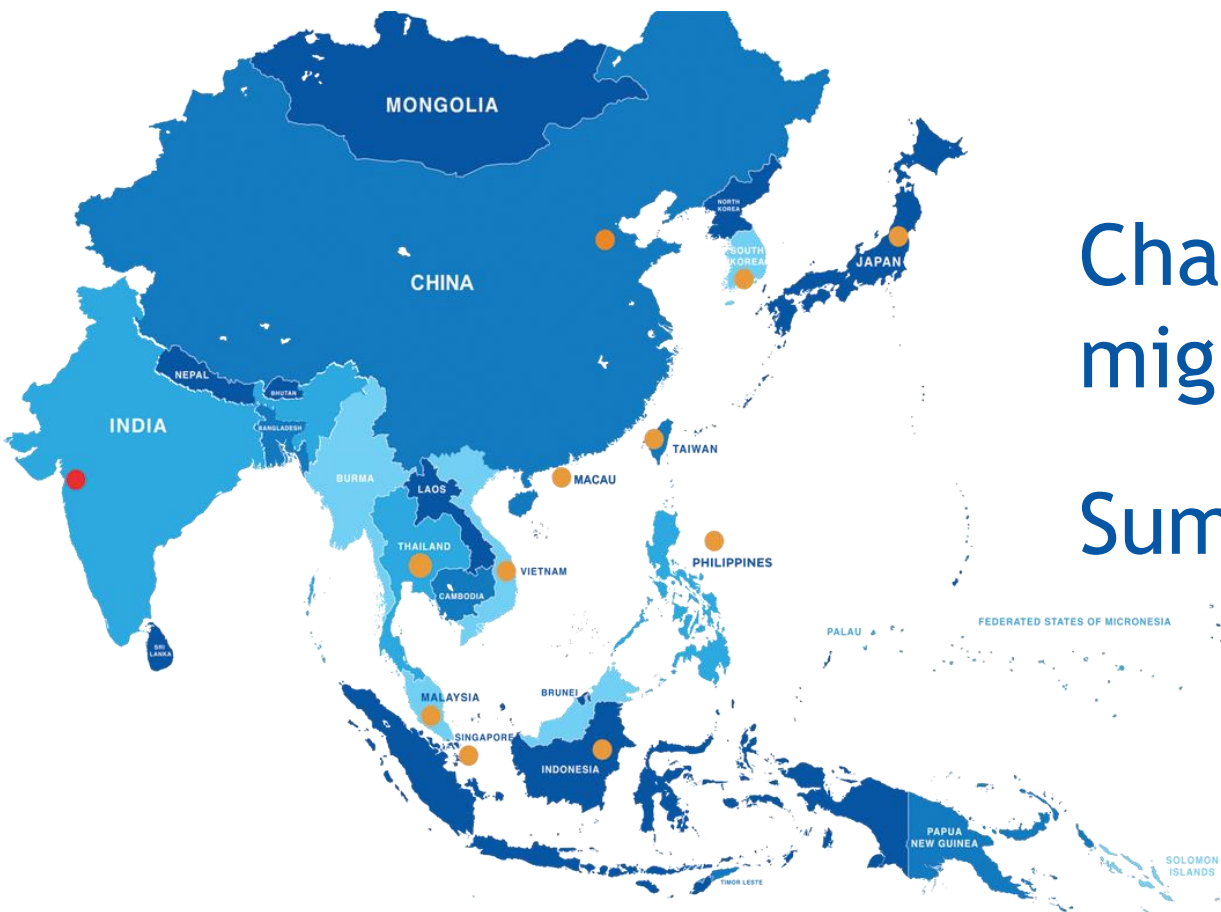
ERDENEBAATAR Davaasuren

IFAIMA - APAC Regional Director





Quality managed migration of legacy aeronautical information into digital database



Challenges in the Quality managed migration

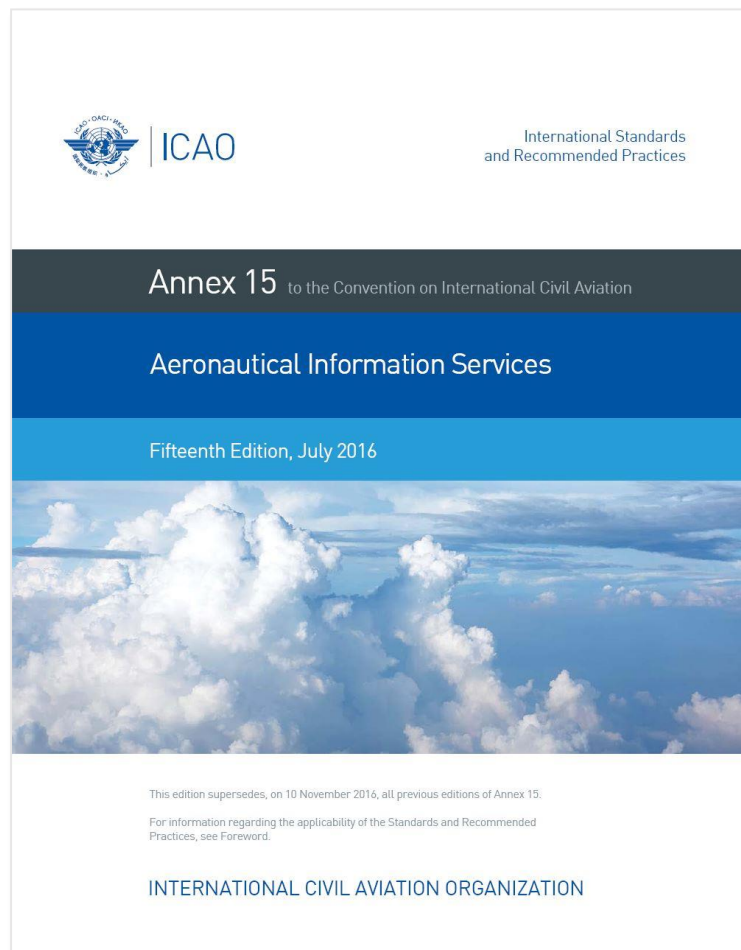
Summary of changes (ISO 9001:2015)



Annex 15 provisions

3.7.1 QMS shall be implemented and maintained encompassing all functions of an AIS. The execution of such quality management systems shall be made demonstrable for each function stage.

- ❖ Receive
- ❖ Collate or assemble
- ❖ Edit
- ❖ Format
- ❖ Publish/store
- ❖ Distribute





Annex 15 provisions

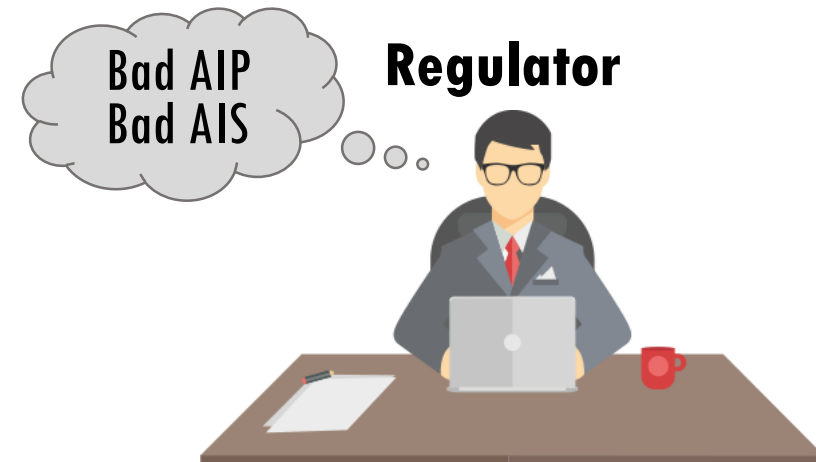
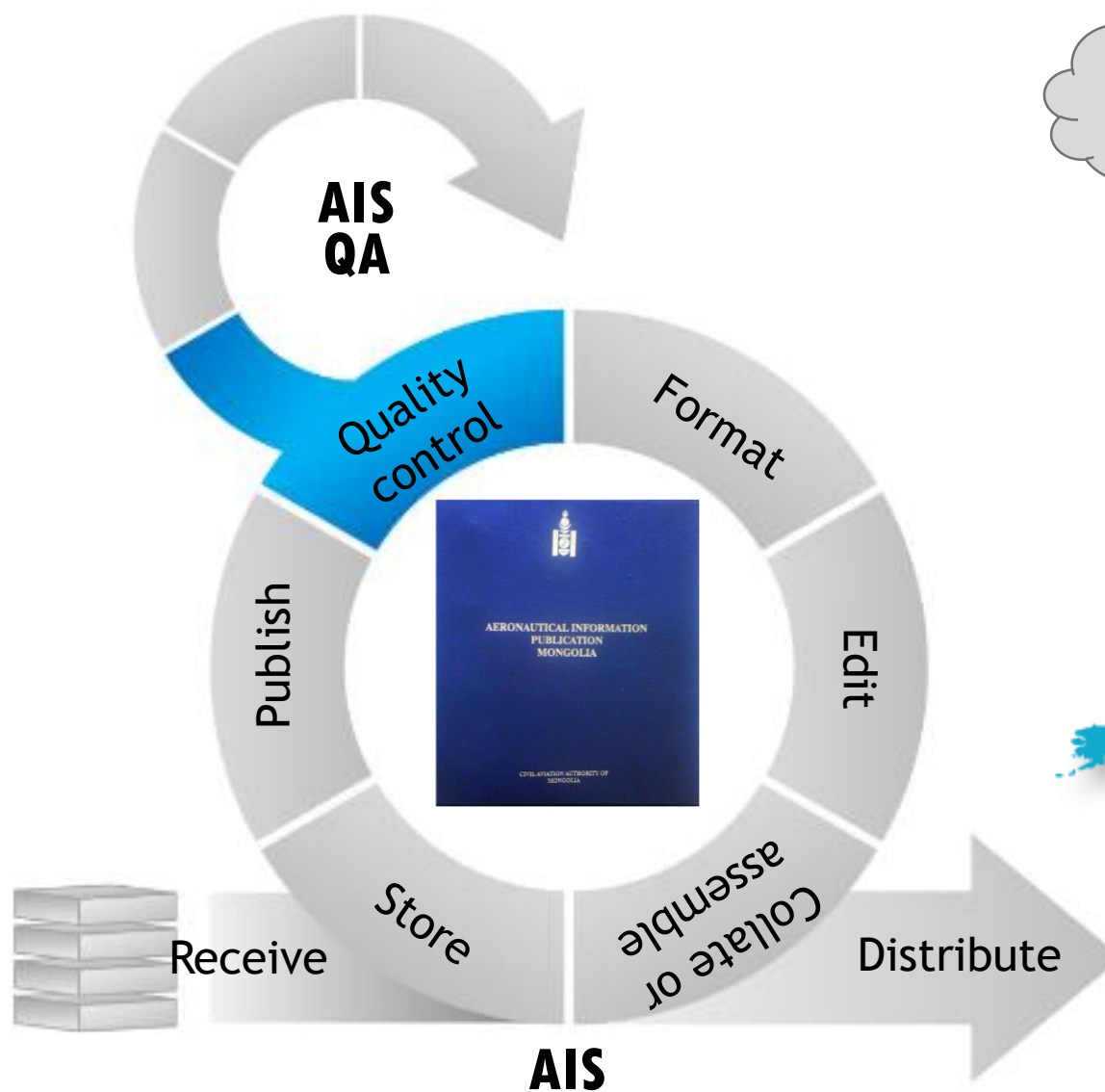
3.7.2 Quality management should be applicable to the whole aeronautical information data chain **from data origination to distribution to the next intended user**, taking into consideration the intended use of data



AIS vs Data Originator



Data Originator





AIS/AIM could accept and distribute erroneous aeronautical data and aeronautical information. Because of:



High risk we have to mitigate.

- We aren't Superman. We don't have deep knowledge about:
 - ❖ ATS, CNS, AGA, Flight procedure design
 - ❖ MET etc.
- We can't verify aeronautical information and aeronautical data whether it's correct or not
- We can't check accuracy of aeronautical information and aeronautical data
- There isn't no any requirement of Language proficiency
- Regulators don't implement any corrective actions related to the Data Originators



Service Level Agreement

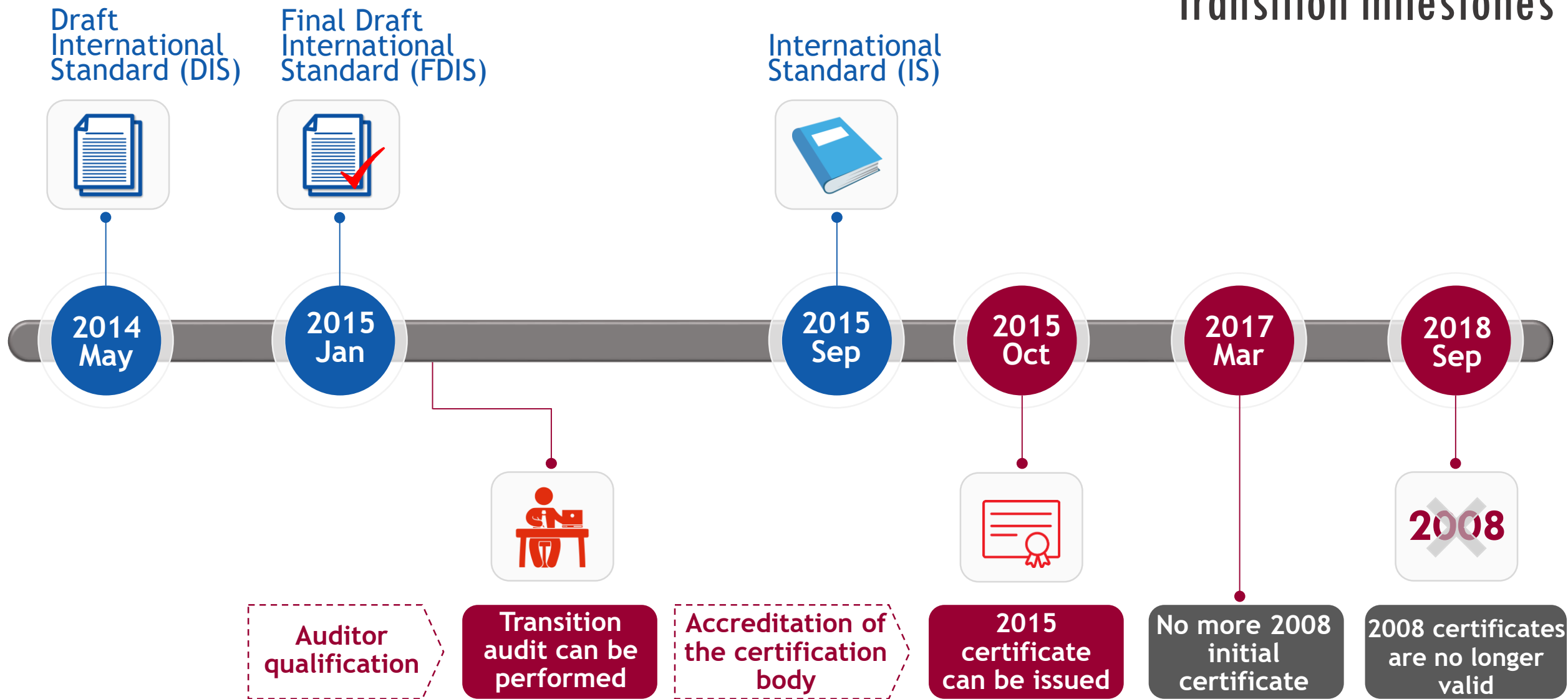
Annex 15 provisions

3.7.2 Quality management should be applicable to the whole aeronautical information data chain **from data origination to distribution to the next intended user**, taking into consideration the intended use of data

Note: Letters of agreement concerning data quality between originator and distributor and between distributor and next intended user may be used to manage the aeronautical information data chain.



Transition milestones





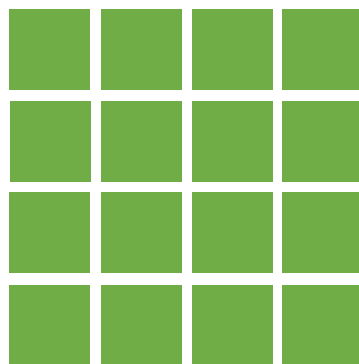
ISO 9001 needs to change, to:

- Adapt to a changing world
- Reflect the increasingly complex environments in which organizations operate
- Provide a consistent foundation for the future
- Ensure the new standard reflects the needs of all relevant interested parties
- Ensure alignment with other management system standards





Key feature changes:

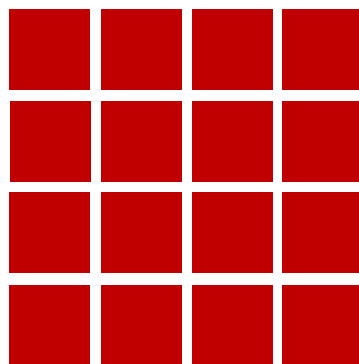


- 10-clause structure and core text for all Management System Standards (MSS)
- More compatible with services and non-manufacturing users
- Clearer understanding of the organization's context is required "one size doesn't fit all"
- Process approach strengthened/more explicit

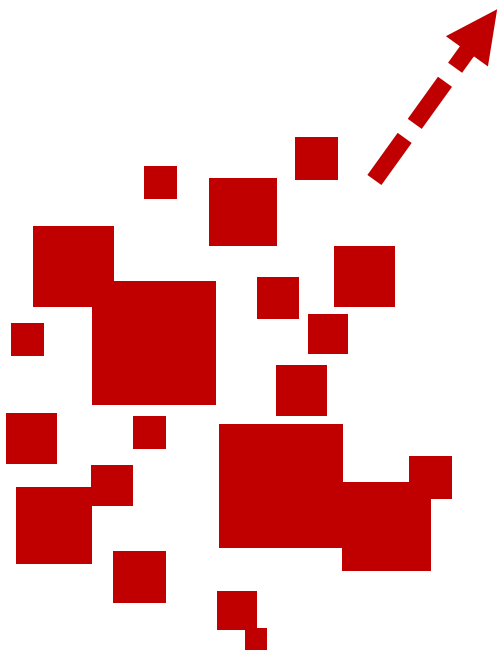




Key feature changes:



- Concept of preventive action now addressed throughout the standard by **risk identification and mitigation**
- The term **documented information** replaces the terms document and record
- **Control of externally provided products and services** replaces purchasing/outsourcing
- Increased emphasis on seeking opportunities for improvement





Beneficial changes to 9001



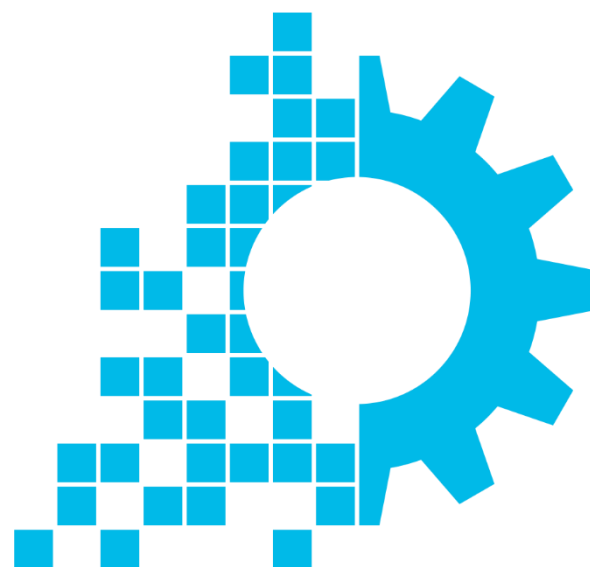
- Enhanced leadership involvement in the management system
- Risk-based thinking
- Simplified language, common structure and terms
- Aligning QMS policy and objectives with the strategy of the organization



ISO 9001 Key Differences

ISO 9001:2008

- 0 Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Quality management system
- 5 Management responsibility
- 6 Resource management
- 7 Product realization
- 8 Measurement, analysis and improvement



CHANGE →

ISO 9001:2015

- 0 Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Context of the organization
- 5 Leadership
- 6 Planning
- 7 Support
- 8 Operation
- 9 Performance evaluation
- 10 Improvement



ISO 9001:2015 additions

4
Context of organization

5
Leadership

6
Planning

7
Support

8
Operation

9
Performance Evaluation

10
Improvement



4.1
Understanding context

Clause 4.1

Determine what relevant external and internal issues are for your organization, and that are relevant to its strategic direction

4.2
Interested parties

4.3
Scope

4.4
QMS

S **W** **O** **T**
Strengths Weaknesses Opportunities Threats

ANALYSIS



ISO 9001:2015 additions

4
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Improvement

4.1
Understanding context

 4.2
Interested parties

4.3
Scope

4.4
QMS

Clause 4.2

Identify relevant interested parties and their relevant requirements

- management
- employees
- trade unions
- suppliers
- partners
- client
- government agencies
- any other person or organization interested in the organization





ISO 9001:2015 additions

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Understanding context

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Interested parties

4.3
Scope

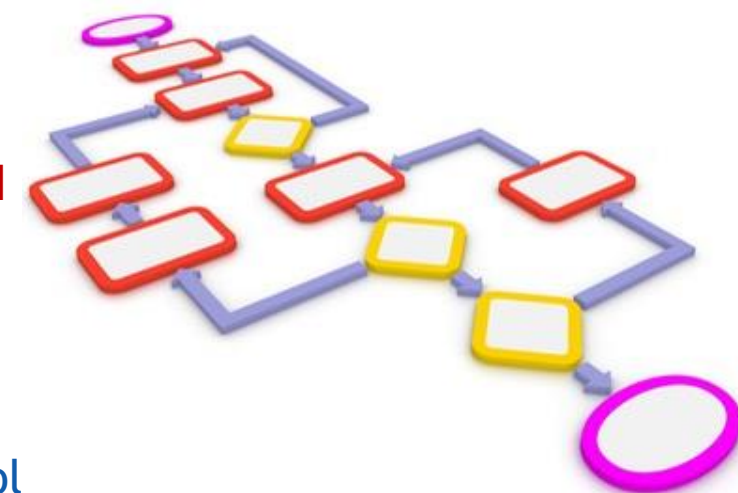
4.4
QMS

Clause 4.4.1

The organization shall establish, implement, maintain and continually improve QMS, including the process needed and their interactions.

The organization shall:

- determine **inputs required and outputs expected** from these processes
- determine sequence and interaction
- determine and apply criteria and methods needed to ensure effective operation and control





ISO 9001:2015 additions

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4.1
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4.2
Interested parties

4.3
Scope

4.4
QMS

Clause 4.4.1

The organization shall:

- determine resources needed for processes and ensure their availability
- assign **responsibilities and authorities** for these processes
- address **risk and opportunities**
- evaluate processes and implement any changes improve processes and the quality management system





ISO 9001:2015 additions



5.1
Leadership and
commitment

5.2
Policy

5.3
Organizational
roles,
responsibilities
and authorities

Clause 5.1.1 - General

Top management shall demonstrate leadership and commitment by:

- take accountability for effectiveness of QMS
- ensure that quality policy and quality objective are established and are compatible with the context and strategic direction of organization
- ensure integration of QMS requirements into the organization's business processes
- promote use of the process approach and risk-based thinking
- ensure that resources needed for QMS are available





ISO 9001:2015 additions

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5.1
Leadership and
commitment

Clause 5.1.2 – Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

5.2
Policy

→ customer and applicable statutory and regulatory requirements are determined, understood and consistently met

5.3
Organizational
roles,
responsibilities
and authorities

→ risk and opportunities that ability to enhance customer satisfaction are determined and addressed

→ the focus on products and services meeting customers and other requirements





ISO 9001:2015 additions



5.1
Leadership and
commitment

5.2
Policy

5.3
Organizational
roles,
responsibilities
and authorities

Clause 5.2.2 – Communicating the quality policy

Quality policy shall be:

- available and be maintained as documented information
- communicated, understood and applied within the organization
- available to relevant interested parties





ISO 9001:2015 additions



5.1
Leadership and commitment

Clause 5.3 – Organizational roles, responsibilities and authorities

Top management shall ensure that responsibilities and authorities are assigned, communicated and understood within organization

5.2
Policy

Top management shall assign the responsibility and authority for:

- ensure that QMS conforms to the requirements of ISO 9001
- ensure that processes are delivering their intended outputs
- report performance of the QMS and opportunities for improvement in particular to top management

5.3
Organizational roles, responsibilities and authorities





ISO 9001:2015 additions

4
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6.1
Actions to
address risks and
opportunities

6.2
Quality
objectives and
planning

6.3
Planning of
changes

Clause 6.1.1

When planning for QMS, the organization shall consider issues (4.1) and requirements (4.2) and determine risks and opportunities

Clause 6.1.2

The organization shall plan:

- actions to address these risks and opportunities
- how to integrate and implement actions into its QMS processes
- how to evaluate effectiveness of these actions





ISO 9001:2015 additions

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6.1
Actions to address risks and opportunities

6.2
Quality objectives and planning

6.3
Planning of changes

Clause 6.2.1

The organization shall establish quality objectives at relevant functions, levels and **processes**

Quality objectives shall:

- be consistent with quality policy
- be measurable
- take into account applicable requirements
- be relevant to conformity of products and services
- be relevant to enhancement of customer satisfaction
- be monitored, communicated and updated





ISO 9001:2015 additions



6.1
Actions to
address risks and
opportunities

6.2
Quality
objectives and
planning

6.3
Planning of
changes

Clause 6.3

When the organization determines the need for changes to QMS, changes shall be carried out in a planned manner.

The organization shall consider:

- purpose of changes and their potential consequences
- integrity of QMS
- availability of resources
- allocation or reallocation of responsibilities and authorities





ISO 9001:2015 additions



7.1
Resources

7.2
Competence

7.3
Awareness

7.4
Communication

7.5
Documented info

Clause 7.1.6 **NEW**

The organization shall determine knowledge necessary for operation of its processes and to achieve conformity of products and services.

This knowledge shall be:

- maintained
- made available to the extent necessary

Organizational knowledge can be based on:

- internal sources (*knowledge gained from experience, lessons learned from failures etc.*)
- external sources (*standards, academia, conferences, gathering knowledge from customer*)





ISO 9001:2015 additions

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Competence

7.3
Awareness

7.4
Communication

7.5
Documented info

Clause 7.3

The organization shall ensure that **persons doing work under organization's control** are aware of:

- quality policy
- relevant quality objectives
- **implications of not conforming** with the QMS requirements
- **their contribution to the effectiveness of QMS**





ISO 9001:2015 additions



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

Clause 7.4

The organization shall determine **internal and external** communications relevant to the QMS, including:

- on **what** it will communicate
- **when** to communicate
- with **whom** to communicate
- **how** to communicate
- **who** communicates

Effective Communication





ISO 9001:2015 additions



8.1
Operational planning and control

Clause 8.1

Organization shall plan, implement and control the processes needed to meet the requirements for the provision of products and services:

8.2
Requirements for products and services

- determine requirements
- establish **criteria** for the processes and **acceptance** of products and services
- determine resources
- implement control of the processes in accordance with criteria
- determine and keeping documented information

8.3
Design and development of products & services





ISO 9001:2015 additions



8.1
Operational
planning and
control

8.2
Requirements for
products and
services

8.3
Design and
development of
products &
services

Clause 8.2.1 – Customer communication

Communication with customers shall include:

- ➔ provide information relating to products and services
- ➔ handle enquiries, contracts or orders, including changes
- ➔ obtain customer feedback, including customer complaints
- ➔ handle or control customer property
- ➔ establish specific requirements for **contingency actions**, when relevant





ISO 9001:2015 additions



8.1
Operational
planning and
control

Clause 8.2.2 – Determining the requirements

When determining requirements for products and services to be offered to customers, the organization shall ensure that:

8.2
Requirements for
products and
services

- requirements for the products and services are defined, including:
 - ❖ any applicable statutory and regulatory requirements
 - ❖ those considered necessary by the organization

8.3
Design and
development of
products &
services

- the organization can meet the claims for the product and services it offers





ISO 9001:2015 additions



8.4
Control of externally provided process, products and services

Clause 8.4.1 - General

The organization shall ensure that externally provided **processes**, products and services conform to requirements

8.5
Product and service provision

The organization shall determine the controls when:

- products and services from external providers are intended for incorporation into the organization's own product and services
- **product and services are provided directly to the customer by external providers on behalf of organization**
- a process or part of process is provided by an external provider as a result of a decision by the organization

8.6
Release of product and service provision



ISO 9001:2015 additions



8.4
Control of externally provided process, products and services

8.5
Product and service provision

8.6
Release of product and service provision

Clause 8.4.2 – Type and extent of control

The organization shall:

- ensure that externally provided processes remain within the control of its QMS
- define both the controls that is intends to apply to an external provider and to the resulting output
- take into consideration:
 - ❖ potential impacts of the externally provided processes, products and services on the organization’s ability to consistently meet customer and applicable statutory and regulatory requirements
 - ❖ effectiveness of the controls applied by the external provider



ISO 9001:2015 additions



8.4
Control of externally provided process, products and services

8.5
Product and service provision

8.6
Release of product and service provision

Clause 8.5.1 - Control of production and service provision

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include:

- availability of documented information
 - ❖ **Characteristics of the product and services**
- availability and use of suitable monitoring and measuring resources
- implementation of monitoring and measurement activities at appropriate stages
- use of suitable infrastructure and environment for the operation of process





ISO 9001:2015 additions



8.4
Control of externally provided process, products and services

8.5
Product and service provision

8.6
Release of product and service provision

Clause 8.5.1 - Control of production and service provision

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include:

- ➔ appointment of competent persons, including any required qualification
- ➔ validation and periodic revalidation of the ability to achieve planned result
- ➔ implementation of actions to prevent human error
- ➔ implementation of release, delivery and post-delivery activities





ISO 9001:2015 additions

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8.4
Control of externally provided process, products and services

8.5
Product and service provision

8.6
Release of product and service provision

Clause 8.5.3 – Property belonging to customer **or external providers**

The organization shall:

- exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization
- identify, verify, protect and safeguard customers' or external providers' property
- report to the customer or external provider that property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use
- retain documented information on what has occurred





ISO 9001:2015 additions



8.4
Control of externally provided process, products and services

8.5
Product and service provision

8.6
Release of product and service provision

Clause 8.5.6 – Control of changes **NEW**

The organization shall:

- review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements
- retain documented information describing the result of the review of changes, the person(s) authorizing the change, and any necessary actions arising from review





ISO 9001:2015 additions



9.1
Monitoring,
measurement,
analysis and
evaluation

Clause 9.1.1 – General

The organization shall:

- determine **what** needs to be monitored and measured
- determine the **methods** for monitoring, measurement, analysis and evaluation
- determine **when** monitoring and measuring shall be performed
- determine **when** the results shall be analysed and evaluated

- evaluate the performance and effectiveness of the QMS
- retain appropriate documented information as a evidence of the results

9.2
Internal audit

9.3
Management
review



ISO 9001:2015 additions



10.1
General

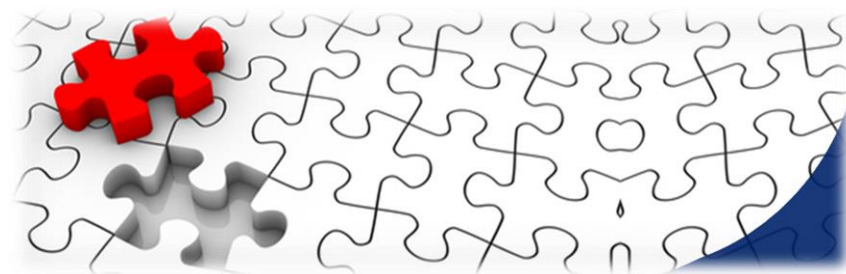
10.2
Nonconformity
and corrective
action

10.3
Continual
improvement

Clause 10.2.1

When a nonconformity occurs, including any arising from complaints the organization shall:

- react to nonconformity and, as applicable:
 - ❖ take action to **control and correct it**
 - ❖ **deal with consequences**



- evaluate the need for action to eliminate the cause(s) of nonconformity, **in order that it does not recur or occur elsewhere**, by
 - ❖ review and analyse nonconformity
 - ❖ **determine the causes** of the nonconformity
 - ❖ **determine if similar nonconformities exist, or could potentially occur**

AERONAUTICAL INFORMATION MANAGEMENT (AIM) SEMINAR

1-2 & 5 JUN 2017, BANGKOK, THAILAND



THANK YOU FOR YOUR ATTENTION

Contact: erdenebaatar.d@mcaa.gov.mn
erdenebaatar@ifaima.org