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ISO 9001:2015
Official Standard Requirements
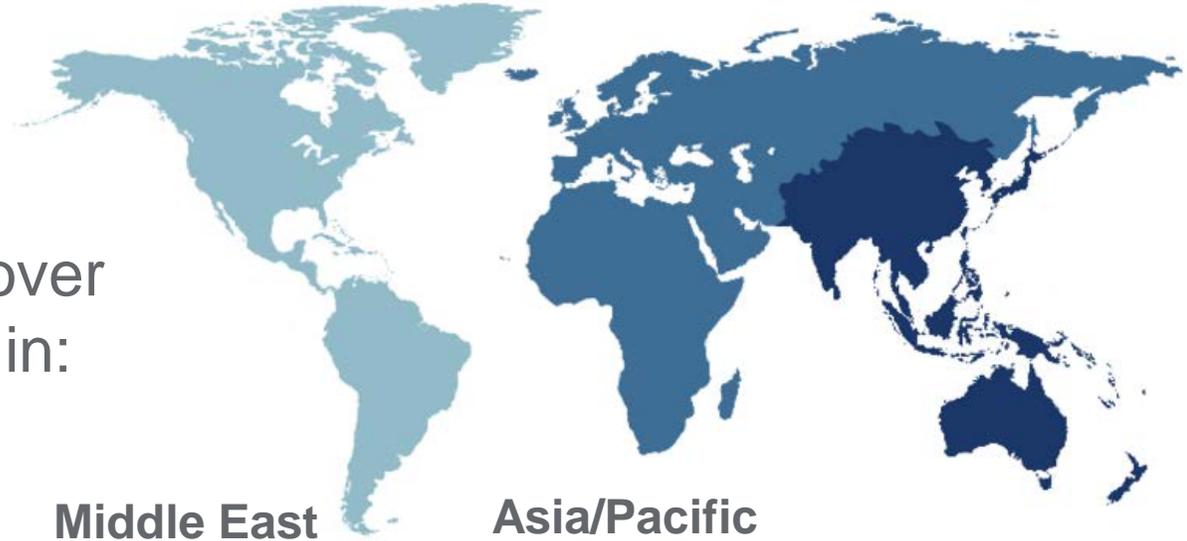Updates and Changes

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Webinar Overview

- Overview of ABS Group
- ISO 9000:2015 Key Terms & Definitions
- ISO 9001:2015 Updates & Changes
- Annex A
- Timelines
- Questions

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Company History and Mission

- ABS Group, based in Houston, Texas, is a subsidiary of <u>ABS</u>, one of the world's leading marine and offshore classification societies

- For more than 40 years, we have built a reputation for setting standards of excellence in the areas of safety, risk and integrity for a broad spectrum of clients in the marine; offshore; oil, gas and chemical; government and power sectors

- The mission of ABS Group of Companies is to be a leading global provider of technical services that better enable our clients to operate safely, reliably, efficiently, and in compliance with applicable regulations and standards. We are focused on adding value to the industries we serve and strategically capturing synergies with ABS.

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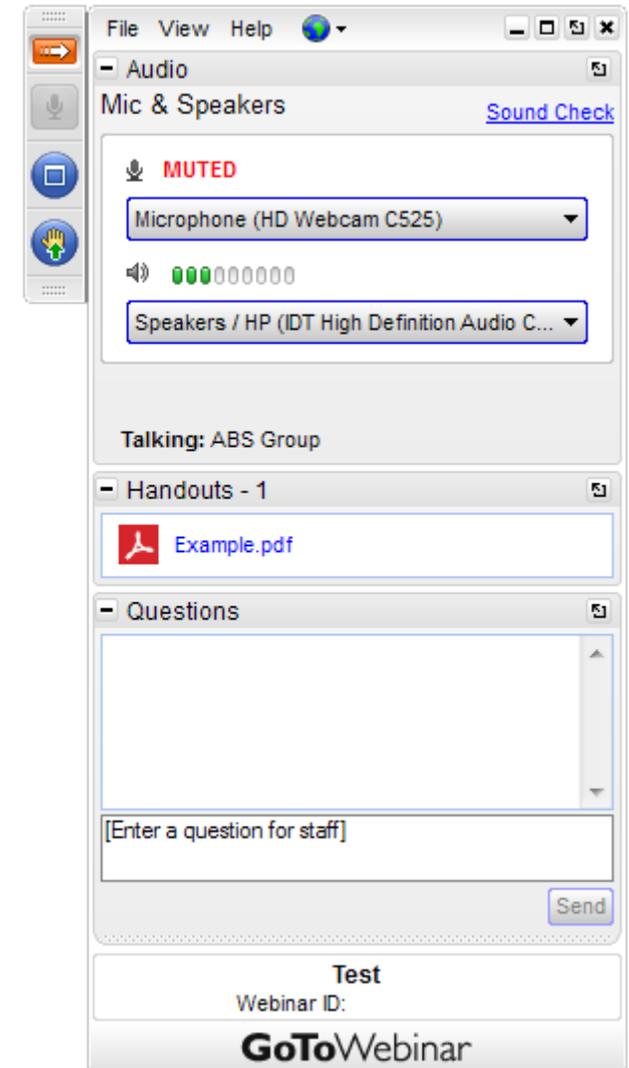
ISO 9000:2015 Key Terms & Definitions

ISO 9000:2015 Key Terms & Definitions

Context of the Organization - An organization's context is its business environment. It includes all of the **internal and external factors and conditions that affect its products** and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.

An organization's external context includes all of the **needs and expectations of interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment**.

An organization's internal context includes its values, culture, knowledge, and performance.

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ISO 9000:2015 Key Terms & Definitions

Documented Information - The term documented information refers to **information that must be controlled and maintained and its supporting medium**. Documented information can be in **any format** and on any medium and can come from any source.

Documented information includes information about the management system and related processes.

It also includes all the information that organizations need to operate and all the **information that they use to document the results that they achieve (aka records).**

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ISO 9000:2015 Key Terms & Definitions

Information - Information is "meaningful data". While it's not entirely clear what the word "meaningful" is supposed to mean in this context, dictionaries tend to say that something is meaningful if it is **significant, relevant, material, valid, or important**.

Information System - In the context of this ISO 9001 standard, an information system is a **network of communication channels used within an organization**.

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ISO 9000:2015 Key Terms & Definitions

Interested Party - An interested party is anyone who can affect or be affected by a decision or activity. An interested party is **a person, group, or organization that has an interest or a stake in a decision or activity**.

Knowledge - Knowledge is a collection of information and a justified belief that this information is true with a high level of certainty.

Knowledge is a familiarity, awareness or understanding of someone or something, such as **facts, information, descriptions, or skills, which is acquired through experience or education by perceiving, discovering, or learning.**

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ISO 9000:2015 Key Terms & Definitions

Outsource - When an organization makes an **arrangement with an outside organization to perform part of a function or process, it is referred to as outsourcing**.

To outsource means to ask an **external organization to perform part of a function or process normally done in house.** While an outsourced organization is beyond the scope of your QMS, the outsourced process or function itself falls within your scope.

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ISO 9000:2015 Key Terms & Definitions

Risk - According to ISO 9000, risk is the "**effect of uncertainty on an expected result**" and an **effect is a positive or negative** deviation from what is expected

Risk-based thinking - Risk-based thinking refers to a **coordinated set of activities and methods that organizations use to manage and control the many risks that affect its ability to achieve objectives**. Risk-based thinking replaces what the old standard used to call preventive action.

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ISO 9000:2015 Key Terms & Definitions

Top Management - The term top management normally refers to the people at the top of an organization. It refers to the **people who provide resources and delegate authority and who coordinate, direct, and control organizations**.

However, *if the scope of a management system covers only part of an organization*, then the term top management refers, instead, *to the people who direct and control that part of the organization*.

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ISO 9001:2015 Updates & Changes

Change Has Arrived

ISO 9001:2008	ISO 9001:2015
1. Scope	0. Introduction
2. Normative References	1. Scope
3. Terms and Definitions	2. Normative References
4. Quality Management System	3. Terms and Definitions
5. Management Responsibility	4. Context of the Organization
6. Resource Management	5. Leadership
7. Product Realization	6. Planning
8. Measurement, Analysis and Improvement	7. Support
	8. Operations
	9. Performance Evaluations
	10. Improvement

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ISO 9001:2015 Updates & Changes

Key Changes

- Introduction section simplified.

- Terms and Definitions section contents have been taken out. This section now refers to ISO 9000:2015 Terms & Definitions.

- Leadership section now requires top management to promote awareness of the process approach and risk based thinking.

- Operation section now includes requirements to prevent human error.

- Operation section has included "customer requirements" as a consideration when determining post delivery activities.

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ISO 9001:2015 Updates & Changes

0.2 Quality Management Principles

- customer focus;

- leadership;

- engagement of people;

- process approach;

- improvement;

- evidence-based decision making;

- relationship management.

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ISO 9001:2015 Updates & Changes

0.3 Process Approach

0.3.2 Plan-Do-Check-Act Cycle

0.3.3 Risk-based Thinking

0.4 Relationship with other management system standards

(See Annex A for details)

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ISO 9001:2015 Updates & Changes

Terms and Definitions section contents

have been taken out.

This section now refers to ISO 9000:2015

Terms & Definitions.

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ISO 9001:2015 Updates & Changes

Section 4 - Context of the Organization

Expects you to start by **understanding your organization and its context before you start developing** its quality management system (QMS).

It expects you to **consider the external and internal** issues that are relevant to your organization's purpose and strategic direction and to think about the influence these issues could have on its QMS and the results it intends to achieve.

This means that you need to understand your organization's external environment, its culture, its values, its performance, and its interested parties before you develop its QMS.

Why? Because your QMS will need to be able to **manage all of these influences**. Once you've considered all of this, you're ready to **define the scope** of your QMS and to begin its development.

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ISO 9001:2015 Updates & Changes

Section 5 - Leadership:

Expects your organization's top management to **provide leadership** for its QMS by expecting people to **focus on quality and on customers**, by showing that they support it, by:

- expecting them to provide compliant products and services,

- expecting them to manage risks and opportunities.

It also expects top management to **establish a quality policy** and to **assign QMS roles, responsibilities, and authorities**.

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ISO 9001:2015 Updates & Changes

Section 5 – Leadership (cont'd)

Leadership section *now* requires top management to promote awareness of the process approach and risk based thinking.

Section 5.1.1 General

d) promoting the use of the process approach and risk-based thinking;

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ISO 9001:2015 Updates & Changes

Section 6 - Planning:

Expects you to plan the development of your QMS.

- It expects you to **address the risks and opportunities that could influence** your organization's QMS or **disrupt its operation** and to consider how its **context and its interested parties** could affect its QMS and the results it intends to achieve.

- It also expects you to **set quality objectives** and to **develop plans to achieve them**.

- Finally, it asks you to **control changes to your QMS**.

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ISO 9001:2015 Updates & Changes

Section 7 - Support:

Expects you to support your QMS by **managing communications** and by **providing the necessary resources**.

It expects you to provide

- competent people,

- an appropriate infrastructure and environment,

- suitable monitoring and measuring technologies,

- the knowledge that is needed to support process operations

- documented information.

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ISO 9001:2015 Updates & Changes

Section 7 – Support (cont'd)

Expects you to start by

- figuring out how extensive your documented information should be

- select and include all the documentation your organization needs in order to ensure that its processes are being carried out as planned

- ensure that you have all the documentation needs in order to comply with the ISO 9001:2015 standard.

- manage the creation and modification of this documentation and to control how it is used.

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ISO 9001:2015 Updates & Changes

Section 8 - Operation:

Expects you to **develop, implement, and control the operational processes** that your organization needs in order to provide products and services and **to manage and control risks and opportunities**.

It requires you to **clarify how product and service requirements will be managed** and **how communications with customers will be handled**.

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ISO 9001:2015 Updates & Changes

Section 8 – Operation (cont'd)

Also expects you to establish a product and service design and development process (when necessary), to monitor externally provided products and services, to manage production and service provision, to supervise product and service release, and to control nonconforming outputs in order to prevent unintended use.

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ISO 9001:2015 Updates & Changes

Section 8 – Operation (cont'd)

Operation section now includes requirements to prevent human error.

Section 8.5.1 Control of production and service provision

g) the implementation of actions to prevent human error;

Operation section has included "customer requirements" as a consideration when determining post delivery activities.

Section 8.5.5 Post-delivery activities

d) customer requirements;

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ISO 9001:2015 Updates & Changes

Section 9 - Performance Evaluation:

Expects you to monitor, measure, analyze, and evaluate the performance of your organization's QMS.

It asks you to monitor customer satisfaction, to evaluate monitoring and measuring results, to audit conformance and performance, and to review the suitability, adequacy, and effectiveness of your QMS.

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ISO 9001:2015 Updates & Changes

Section 10 - Improvement:

Expects you to **identify opportunities to improve** your organization's processes, products and services, and **to enhance customer satisfaction**.

It also asks you to **control nonconformities**, to **take corrective actions**, and to **enhance the suitability, adequacy, and effectiveness** of your QMS.

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Annex A

Annex A

A.1 Structure & Terminology

1. Product is *now* Product and Services

2. Process Approach is *now* a stated requirement (Clause 5.1.1 d)

3. "Risk" is defined as effect of uncertainty

- Reference ISO 31000

4. Monitoring and Measurement are *now* separate (Clause 4.4.1 c)

- Monitoring: status of a system, a process or an activity

- Measurement: a process to determine a value

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Annex A

A.1 Structure & Terminology **(cont'd)**

5) Management representative Not used

(Similar responsibilities and authorities are assigned but no requirement for a single management representative)

6) Documentation, quality manual, documented procedures, records, now Documented information

7) Work environment, *now* Environment for the operation of processes

8) Purchased product, *now* Externally provided products and services

9) Supplier, now External provider

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Annex A

A.2 Products & Services

This edition of this International Standard uses "products and services". The term "products and services" includes all output categories (hardware, services, software and processed materials).

The specific **inclusion of "services" is intended to highlight the differences between products and services** in the application of some requirements.

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Annex A

A.3 Understanding needs & expectations of interested parties

Sub clause 4.2 specifies requirements for the organization to determine the **interested parties that are relevant to the quality management system and the requirements of those interested parties.**

However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system.

It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

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Annex A

A.4 Risk-based Thinking

The concept of **risk-based thinking has been implied in previous editions** of this International Standard, e.g. through requirements for planning, review and improvement.

This International Standard specifies requirements for the organization to **understand its context (see 4.1) and determine risks as a basis for planning** (see 6.1).

This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and **will assist in determining the extent of documented information**.

A.4 Risk-based thinking (cont'd)

One of the key purposes of a quality management system is to act as a **preventive tool**. Consequently, this International Standard does not have a separate clause or sub clause on preventive action.

The concept of **preventive action is expressed through the use of risk-based thinking** in formulating quality management system requirements.

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements.

There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities.

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Annex A

A.4 Risk-based thinking (cont'd)

Although Section 6.1 specifies that the organization shall plan actions to address risks, **there is no requirement for formal methods for risk management or a documented risk management process.**

Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards. i.e. ISO 31000:2010

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations.

Under the requirements of 6.1, the organization is responsible for its application of risk based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

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Annex A

A.5 Applicability

This International Standard does not refer to "exclusions" in relation to the applicability of its requirements to the organization's quality management system.

However, an *organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.*

The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system.

The organization can **only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services**.

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A.6 Documented Information

As part of the alignment with other management system standards, a common clause on "*documented information*" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements.

Consequently, *"documented information"* is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to **"maintain documented information"**.

Annex A

A.6 Documented Information (cont'd)

Where ISO 9001:2008 used the term **"records"** to denote documents needed to provide evidence of conformity with requirements, this is _now_ **expressed as a requirement to "retain documented information".**

The organization is responsible for determining what **documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.**

A requirement to **"maintain" documented information** _does not exclude the possibility that the organization might also need to_ **"retain" that same documented information** for a particular purpose, e.g. to retain previous versions of it.

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Annex A

A.6 Documented Information (cont'd)

Where this International Standard refers to *"information"* rather than *"documented information"* (e.g. in 4.1: "The organization shall monitor and review the *information* about these external and internal issues")

There is **no requirement that this information is to be documented.**

In such situations, the *organization can decide whether or not it is necessary or appropriate to maintain documented information.*

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Annex A

A.7 Organizational Knowledge

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure that it can achieve conformity of products and services. *Requirements regarding organizational knowledge were introduced for the purpose of:*

a) *safeguarding the organization from loss of knowledge*, e.g.

- through staff turnover;
- failure to capture and share information;

b) *encouraging the organization to acquire knowledge*, e.g.

- learning from experience;
- mentoring;
- benchmarking.

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Annex A

A.8 Control of Externally Provided Products & Services

All forms of externally provided products and services are addressed in 8.4, e.g. whether through:

a) purchasing from a supplier;

b) an arrangement with an associate company;

c) outsourcing processes to an external provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

The controls required for external provision can vary widely depending on the nature of the products and services. *The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided products and services.*
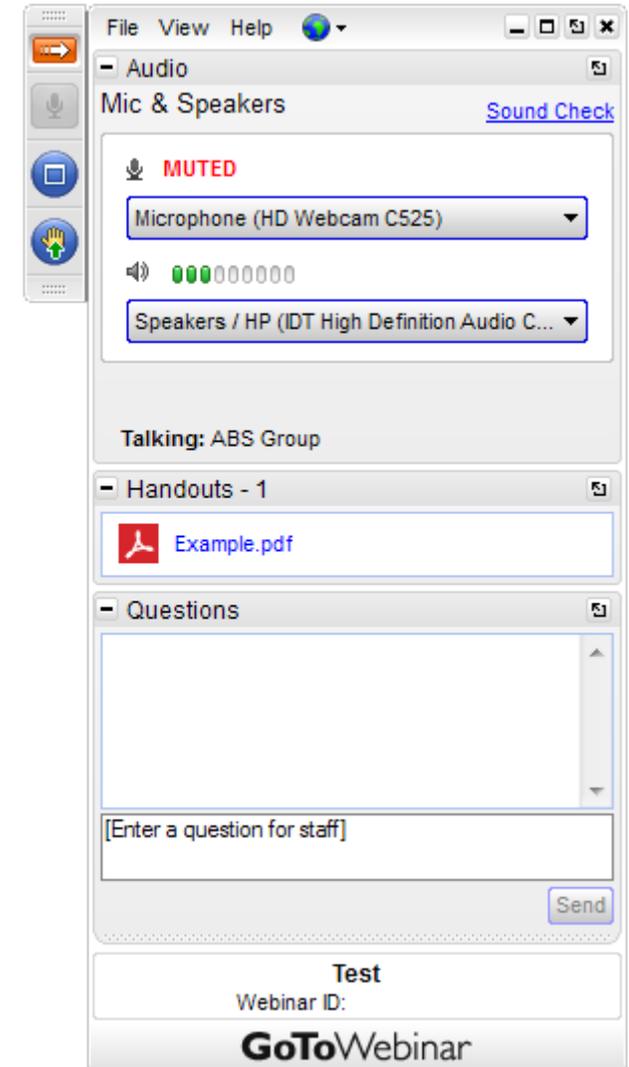
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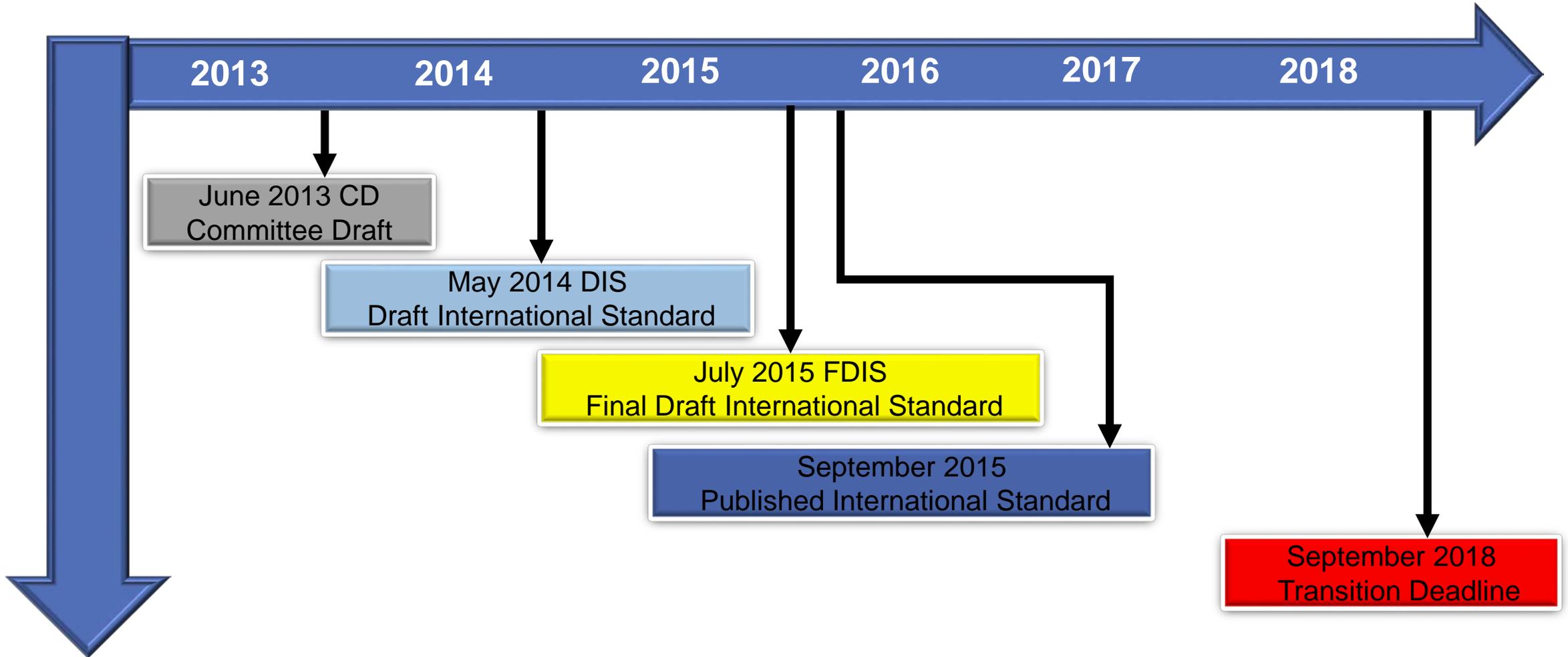
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