ISO 9001:2015

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ISO - Introduction

ISO = International Organisation for Standardisation

- ISO standards are usually developed by its Technical Committees ("TC's") and Sub-committees ("SC's")
- ISO/TC176/SC2 (Quality Systems) is responsible for ISO 9001
- ISO 9001:2015 is being developed by a specific SC2 Working Group ("WG24")
- WG23 is responsible for Communications and Product Support

ISO 9001 revisions since beginning

ISO 9001:1987	• Quality Assurance - 20 Elements • 1st Released
ISO 9001:1994	• 20 Elements • Minor Change
ISO 9001:2000	• Quality Management - Process Approach • Major Change
ISO 9001:2008	• Process Approach • Minor Change
ISO 9001:2015	• High Level Structure (Annex SL) • Revision Planned - Major Change

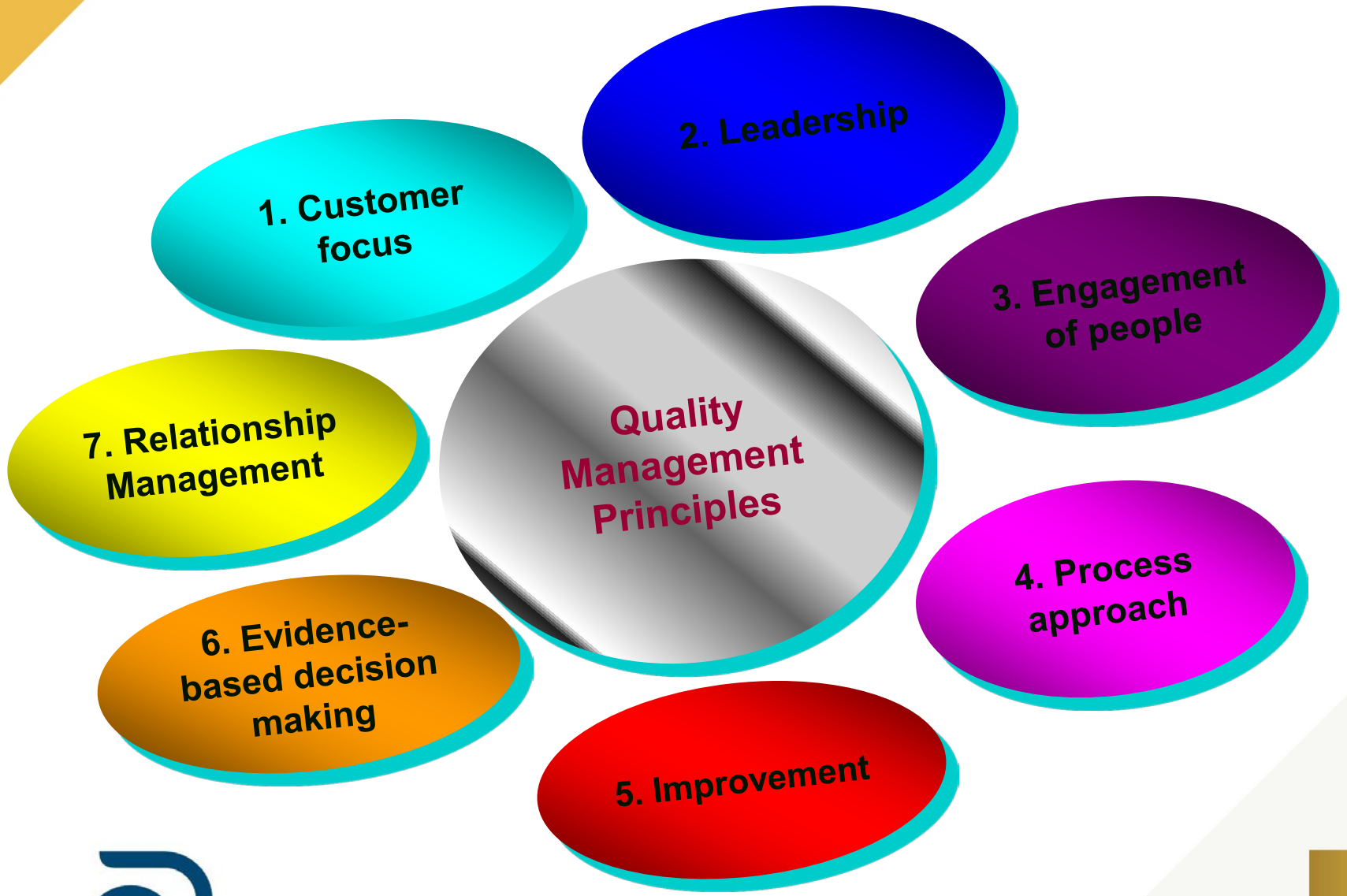
Summary of some key changes

- Complete reformatting
- “Goods and services” instead of “product”
- Changes to “Design & Development” and “Measuring equipment” clauses to be more appropriate for service sector
- Risk management is being added with focus on risk-based thinking. Identification of risk and risk control now is a requirement.
- Elimination of the term “preventive action” (the concept still remains, and is covered by a wider view that looks at risks and opportunities)
- “External provision of goods and services” instead of “purchasing” – includes outsourced processes

Summary of some key changes

- Specifying requirements considered essential to the adoption of a “process approach”.
- The terms “document” and “record” have both been replaced throughout the requirements text by “documented information“
- Integration of strategic planning with the business
- Leadership replaces Management Responsibility
- Need to understand more quality tools
  - FMEA
  - SWOT
  - Hoshin Planning
  - Poke Yoke
  - Customer Surveys

The Revised Quality Principles



High-Level Structure Comparison

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative Reference	2. Normative Reference
3. Terms and Definitions	3. Terms and Definitions
4. Quality Management Systems	4. Context of the organisation
5. Management Responsibility	5.Leadership
	6. Planning
6. Resource Management	7. Support
7. Product Realisation	8. Operation
8. Measurement, Analysis and Improvement	9. Performance Evaluation
	10. Improvement

Significant Changes

ISO 9001:2008	ISO 9001:2015
0. Introduction	**0. Introduction**
1. Scope	**1. Scope**
2. Normative Reference	**2. Normative Reference**
3. Terms and Definitions	**3. Terms and Definitions**

0.3 Terms and definition

- Add some of the terms (e.g. Risk) – These may be included in ISO 9001 or in ISO 9000
- Replace term “Product” with “Goods and Services”
- New “Risk” term is introduced
- Term “Preventive Action” is no longer a term in the new version
- Terms ”Document” and “Record” have been replaced throughout by “Documented Information”
- Replace “Continual improvement” with “Improvement”

4. Quality Management Systems

ISO 9001:2008	ISO 9001:2015
4. Quality Management Systems	**4. Context of the organisation**
4.1. General Requirements	4.1. Understanding the organisation and its context
4.2. Documentation Requirements	7.5. Documented information
	4.2. Understanding the needs and expectations of interested parties
	4.3. Determining the scope of quality management system
	4.4. Quality Management System

Significant Changes

- Determine internal and external issues that are relevant to the objectives and strategic direction
- Determine the interested parties that are relevant to the QMS and the requirements of those parties
- Determine the boundaries and applicability of the quality management system to establish its scope as a documented information. Exclusions limited to clause 7.1.4. Monitoring and measuring devices and 8. Operation
- More emphasis on “process approach” by introducing that as a requirement (4.4.2. Process approach)

Significant Changes

7.5 Documented information

- When creating and updating documented information the organisation shall ensure appropriate
  - a) identification and description (e.g. a title, date, author, or reference number),
  - b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic),
- Documented information shall be controlled to ensure it is adequately protected (e.g. from loss of confidentiality)
- For the control of documented information, the organisation shall address the following activities, as applicable
  - a) distribution, access, retrieval and use, (access implies permission level)

5. Management Responsibility

ISO 9001:2008	ISO 9001:2015
5. Management Responsibility	**5. Leadership**
5.1. Management commitment	5.1. Leadership and commitment
5.2. Customer focus	4.2. Understanding the needs and expectations of interested parties
5.3. Quality policy	5.2. Quality policy
5.4. Planning	**6. Planning**
	6.1. Actions to address risks and opportunities
5.4.1. Quality objectives	6.2. Quality objectives and planning to achieve them
5.4.2. Quality management system planning	
	6.3. Planning of changes
5.5. Responsibility, authority and communication	5.3. Organisational roles, responsibilities and authorities 7.4. Communication
5.6. Management review	9.3. Management review

Significant Changes

- More emphasis on leadership and its role in establishment of quality policy and objectives aligned with the strategic direction of the organisation.
- Promoting, engaging , and supporting improvement, innovation and leadership
- Top management shall be accountable for the effectiveness of the quality management system
- Term “Management Representative” has been removed, however the tasks remain.

Significant Changes

- Determine Risks and opportunities and their potential effects on conformity of goods and services and customer satisfaction and have a plan to take actions to address these risks and opportunities (e.g. SWOT, FMEA, etc.).
- More emphasis on having a plan to achieve the quality objectives and determine the needs and opportunities for change to maintain and improve the performance of the quality management system, identifying risks and opportunities and reviewing the potential consequences of change.
- Determine the need for internal and external communications through a communication plan including what, when and with whom to communicate)

6. Resource Management

ISO 9001:2008	ISO 9001:2015
6. Resource Management	**7. Support**
6.1. Provision of resources	7.1. Resources
6.2. Human resources (6.2.2. Competence , training and awareness)	7.2. Competence 7.3. Awareness 7.5. Knowledge
6.3. Infrastructure	7.1.2 Infrastructure
6.4. Working Environment	7.1.3. Process Environment

Significant Changes

➢7.2. Awareness

Persons doing work under the organisation‘s control shall be aware of

- the quality policy,
- relevant quality objectives,
- their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance, and
- the implications of not conforming with the quality management system requirements.

➢7.3. Knowledge

- Competence remains, but knowledge is a new requirement
- Determine the knowledge necessary for the operation of the QMS and its processes.
- This knowledge shall be maintained, protected and made available as necessary.
- Acquiring additional knowledge where any changes needed (refer to 6.3. planning of changes)

7. Product Realisation

ISO 9001:2008	ISO 9001:2015
7. Product Realisation	**8. Operation**
7.1. Planning of product realisation	8.1. Operational planning and control 8.3. Operational planning process
7.2. Customer-related processes	8.2. Determination of market needs and interactions with customers
7.3. Design and development	8.5. Development of goods and services
7.4. Purchasing	8.4. Control of external provision of goods and services
7.5. Production and service provision	8.6. Production of goods and provision of services
7.6. Control of monitoring and measuring equipment	7.1.4. Monitoring and Measuring Devices

Significant Changes

➢8.1. Operational planning and control

The organisation shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

➢8.3 Operational Planning Process

Implement a process to determine the following:

- b.) Actions to identify and address the risks related to achieving conformity of goods and services to requirements. (such as FMEA)

Significant Changes

- 8.4 Control of External Provision of Goods and Services

- Term “Purchasing” is replaced by “Outsourcing” and “external provision”
- The type and extent of control shall be dependent upon the risks identified and the potential impacts,
- Documented information shall be provided to the external provider describing, where appropriate:
  - e) the control and monitoring of the external provider’s performance to be applied by the organisation,
  - g) the requirements for handling of external provider’s property provided to the organisation.

Significant Changes

- 8.5 Development of Goods and Services
  - 8.5.1 Development Processes

    Consistent with the Process Approach and considering risks and opportunities (DFMEA, etc.]

  - 8.5.2 Development Controls

    Merging and de-emphasising design and development verification, validation and change control and make them more generic

  - 8.5.3 Development Transfer

    The organisation shall ensure that transfer from development to production or service provision only takes place when actions outstanding or arising from development have been completed

Significant Changes

8.6 Production of Goods, Provision of Services

8.6.1 Control of production of goods and provision of services

i.) prevention of nonconformity due to human error, such as unintentional mistakes and intentional rule violations (Poke Yoke)

8.6.2 Identification and Traceability

8.6.3 Property belonging to customers or external providers

8.6.4 Preservation of Goods and Services

Significant Changes

8.6.5 Post Delivery Activities

Determine and meet requirements for post delivery activities (warranty provisions, maintenance services, etc.). Taking into account of

a) the risks associated with the goods and services,

b) customer feedback, and

c) statutory and regulatory requirements.

8.6.6 Control of Changes

The organisation shall undertake change in a planned and systematic manner, considering the review of the potential consequences of changes (see 6.3. planning of changes) and taking action as necessary, to ensure the integrity of goods and services are maintained.

Significant Changes

- 7.1.4. Monitoring and Measuring Devices
  - In its attempt to make “calibration” requirements less manufacturing-centric, many of the requirements of ISO 9001:2008 have been removed.
  - Customer surveys, etc. can now be considered as a monitoring device

8. Measurement, analysis and improvement

ISO 9001:2008	ISO 9001:2015
8. Measurement, analysis and improvement	**9. Performance Evaluation**
8.1. General	9.1. Monitoring, measurement, analysis and evaluation (9.1.1. General)
8.2. Monitoring and measurement	
8.2.1. Customer Satisfaction	9.1.2. Customer satisfaction
8.2.2. Internal Audit	9.2. Internal Audit
8.2.3. Monitoring and measurement of processes	9.1.1. Genera
8.2.3. Monitoring and measurement of product	8.7. Release of goods and services
8.3. Control of nonconforming product	8.8. Nonconforming goods and services
8.4. Analysis of data	9.1.3. Analysis and evaluation of data
8.5. Improvement	10.1. Nonconformity and corrective action 10.2. Improvement

Significant Changes

- 9.1. Monitoring, measurement, analysis and evaluation

The organisation shall take into consideration the determined risks and opportunities

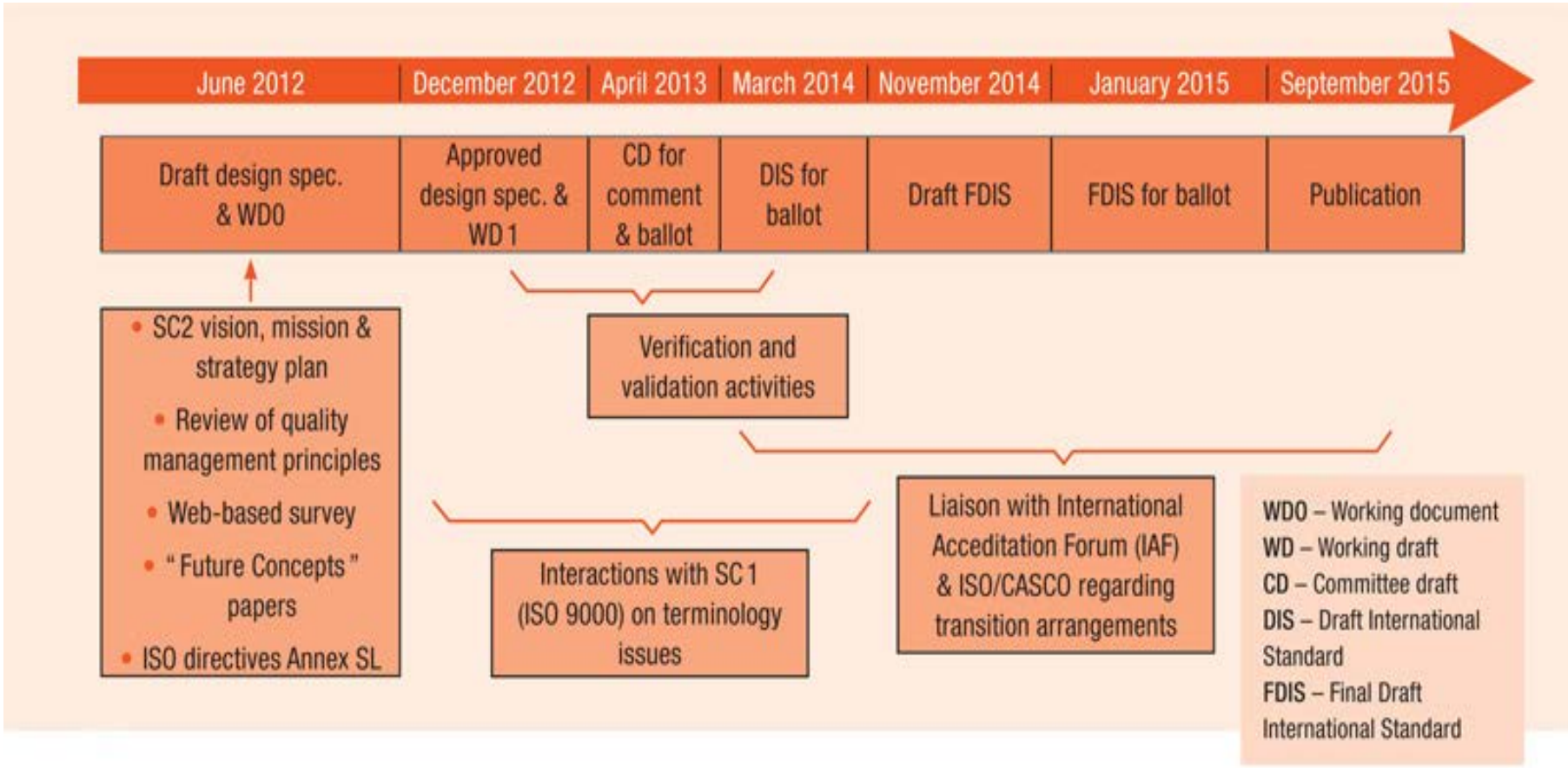
- 9.2. Internal Audit

The audit programme(s) shall take into consideration the quality objectives, the importance of the processes concerned, the related risks, and the results of previous audits;

Significant Changes

- 10. Improvement
  - Clarify the difference between “Correction” and “Corrective action”
  - Remove term “preventive action”, but Preventive Action concepts are deployed throughout the Standard (eg. New clauses 4.1 and 6.1)
  - Replace “Continual Improvement” with “ Improvement”
  - Improve the quality management system through responding to changes in identified risk (see 6.1. Actions to address risks and opportunities)
  - The organisation shall evaluate, prioritise and determine the improvement to be implemented.

ISO 9001:2015 Timeline



What Should an Organisation do Now?

- ✓ Still too early in the 2015 revision process of ISO 9001 to make any significant changes to an existing QMS.
- ✓ Some issues drafted may change or disappear in upcoming drafts or with final version.
- ✓ Looking ahead…existing registered system documentation should conform with some small adjustments. In most cases, existing registered organisations should have enough documentation and records.
- ✓ Since risk is documented in most sections of proposed revision to ISO 9001, consider starting your risk management plan, if you don't have one. Begin thinking how to address risk in your business.

ISO 14001:2015

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what is new in ISO 14001:2015?

- ✓ Integrate EMS into business processes
- ✓ Organisations shall consider impacts across value chains - extend control and influence to the environmental impacts associated with product use and end-of-life treatment or disposal. This does not imply a requirement to do a life cycle assessment.
- ✓ Stronger senior management commitment to ensure that established environmental policy and objectives are compatible with the strategic direction of the organisation (Leadership)
- ✓ Stronger emphasis on environmental opportunities
- ✓ Using performance indicators for each environmental objective to track improvement in consistent with the organisation's policy commitments the organisation would, as applicable, reduce emissions, effluents and waste to levels set by the organisation.

what is new in ISO 14001:2015?

- ✓ Identify stakeholders and their needs
- ✓ Determine external environmental risks which could impact an organisation
- ✓ Emphasise the relationship between environmental management and the core business at a strategic level.
- ✓ Specific commitments to sustainable development and social responsibility (sustainable resource use, climate change mitigation and adaptation, protection of biodiversity and ecosystems, etc.)
- ✓ To align with ISO 9001:2015, reflecting the evolution of computer and cloud based systems for running management systems, the revision incorporates the term ‘documented information’, instead of ‘documents’ and ‘records’.

Comparison

ISO 14001:2004	ISO 14001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative Reference	2. Normative Reference
3. Terms and Definitions	3. Terms and Definitions

Comparison

ISO 14001:2004	ISO 14001:2015
4. Environmental Management Systems	**4. Context of the organisation**
	4.1. Understanding the organisation and its context
	4.2. Understanding the needs and expectations of interested parties
4.1. General Requirements	4.3. Determining the scope of Environmental management system
	4.4. Environmental Management System
	10.2. Continual Improvement

Comparison

ISO 14001:2004	ISO 14001:2015
4.2. Environmental Policy	5.2. Environmental Policy
4.3. Planning	6. Planning
	6.1. Actions to address risks and opportunities
	6.1.1. General
4.3.1. Environmental Aspects	6.1.2. Identification of Environmental Hazards
	6.1.4. Determining Significant environmental aspects and organisational risks and opportunities
4.3.1. Legal and other requirements	6.1.3. Determination of compliance obligations
4.3.3. Objectives, targets and programme(s)	6.2. Environmental objectives and planning to achieve them
	6.2.1. Environmental objectives
	6.2.2. Planning to achieve objectives

Comparison

ISO 14001:2004	ISO 14001:2015
4.4. Implementation and operation	
4.4.1. Resources, roles, responsibility and authority	7.1. Resources
	5.1. Leadership and Commitment
	5.3. Organisational roles, responsibilities and authorities
4.4.2. Competence, Training and Awareness	7.2. Competence
	7.3. Awareness
4.4.3. Communication	7.4.1. General
	7.4.2. Internal Communication
	7.4.3. External Communication and Reporting

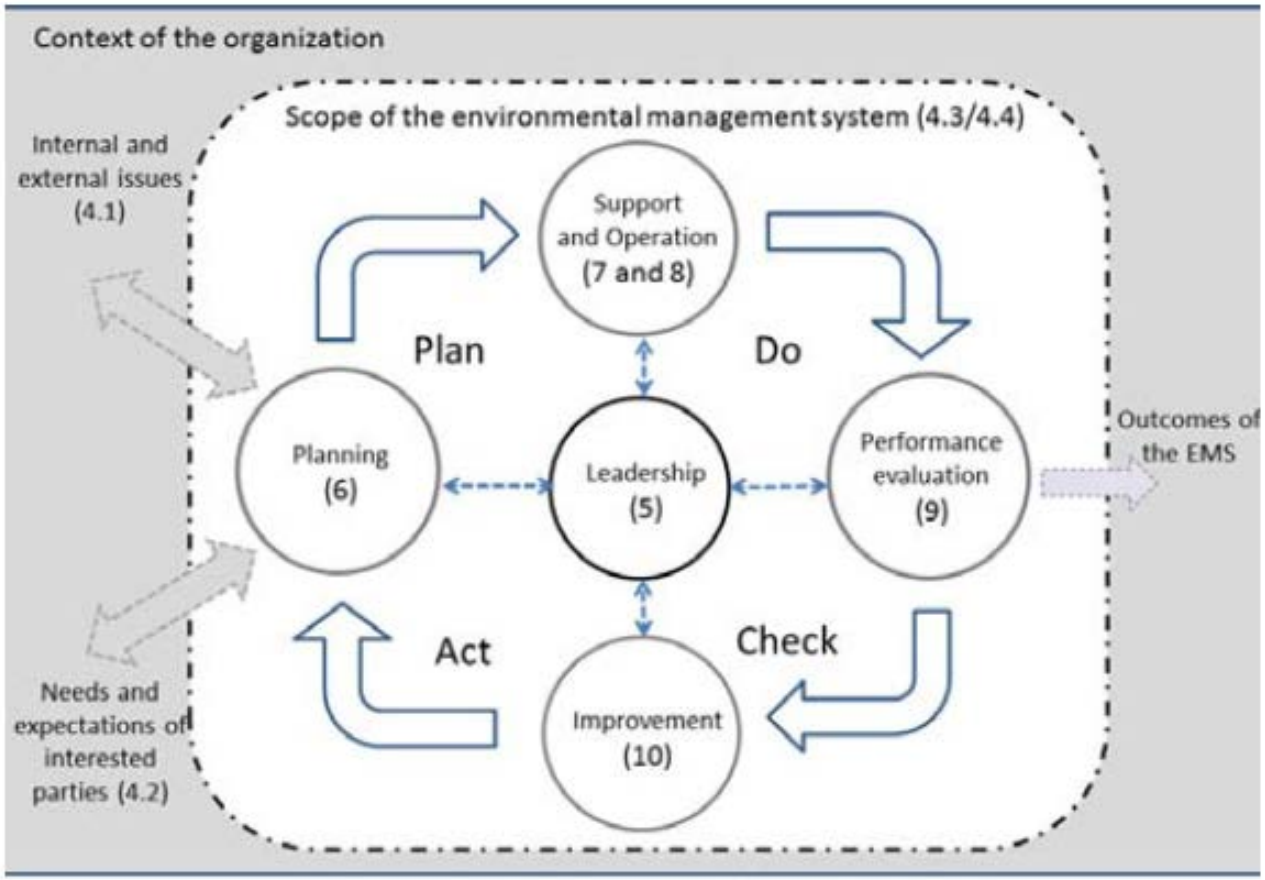
Comparison

ISO 14001:2004	ISO 14001:2015
4.4.4. Documentation	7.5. Documented information
	7.5.1. General
4.4.5. Control of documents	7.5.2. Creating and Updating
	7.5.3. Control of documented information
4.4.6. Operational Control	8.1. operational Planning and Control
	8.2. Value Chain Control
4.4.7. Emergency Preparedness and Response	8.3. Emergency Preparedness and Response

Comparison

ISO 14001:2004	ISO 14001:2015
4.5. Checking	9. Performance Evaluation
4.5.1. Monitoring and Measurement	9.1. Monitoring and Measurement, Analysis and Evaluation
	9.1.1. General
4.5.2. Evaluation of Compliance	9.1.2. Evaluation of Compliance
4.5.3. Nonconformity, Corrective action and Preventive action	10.1. Nonconformity, Corrective action
4.5.4. Control of Records	7.5.3. Control of documented information
4.5.3. Internal Audit	9.2. Internal Audit
4.6. Management Review	9.3. Management review
	10. Improvement

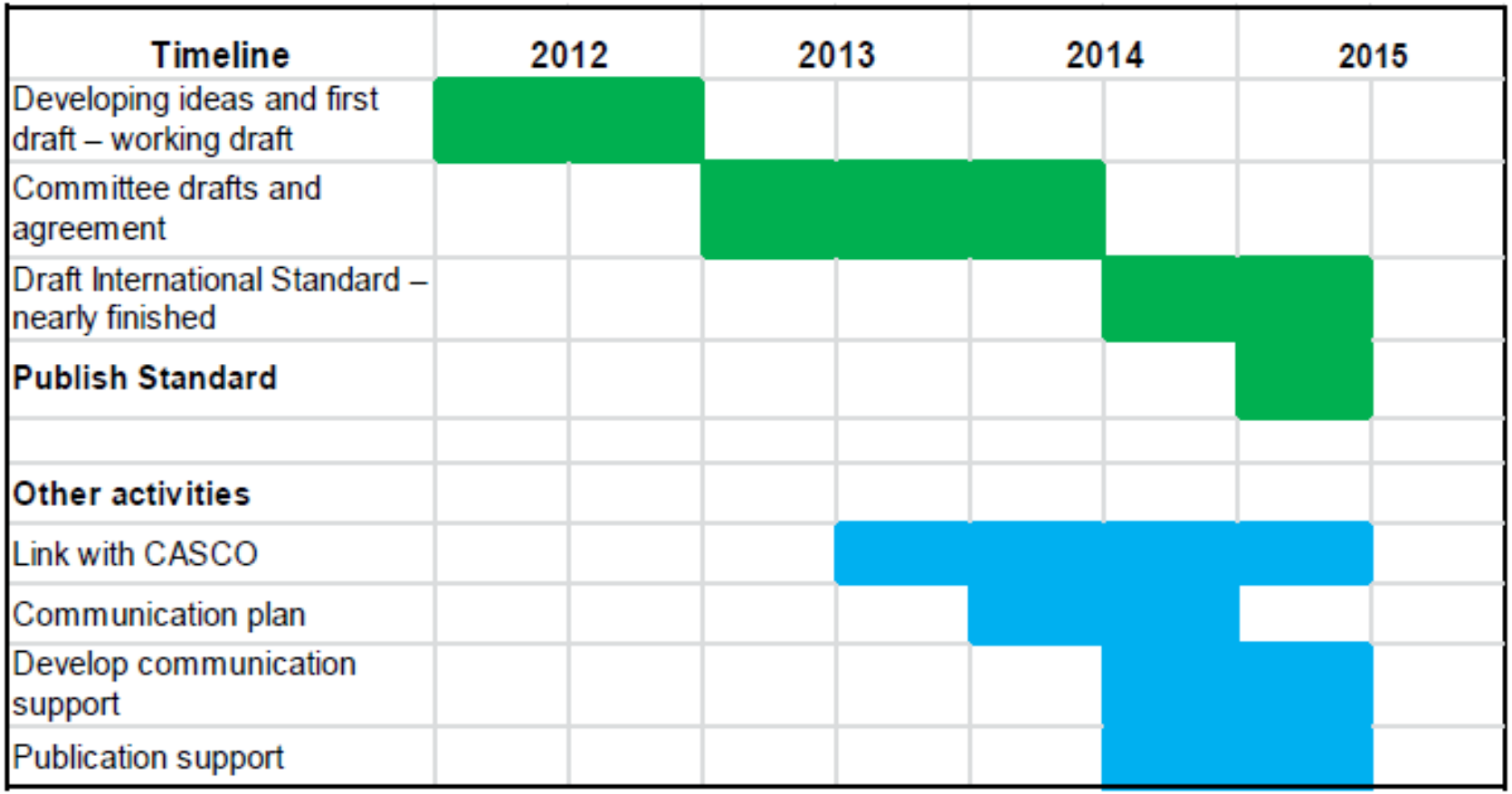
What Happened to PDCA?



Note: Numbers in brackets refer to the clauses in this International Standard.

Ref. ISO/TC 207/SC 1 - 20 No. 2013

New standard Timeline



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