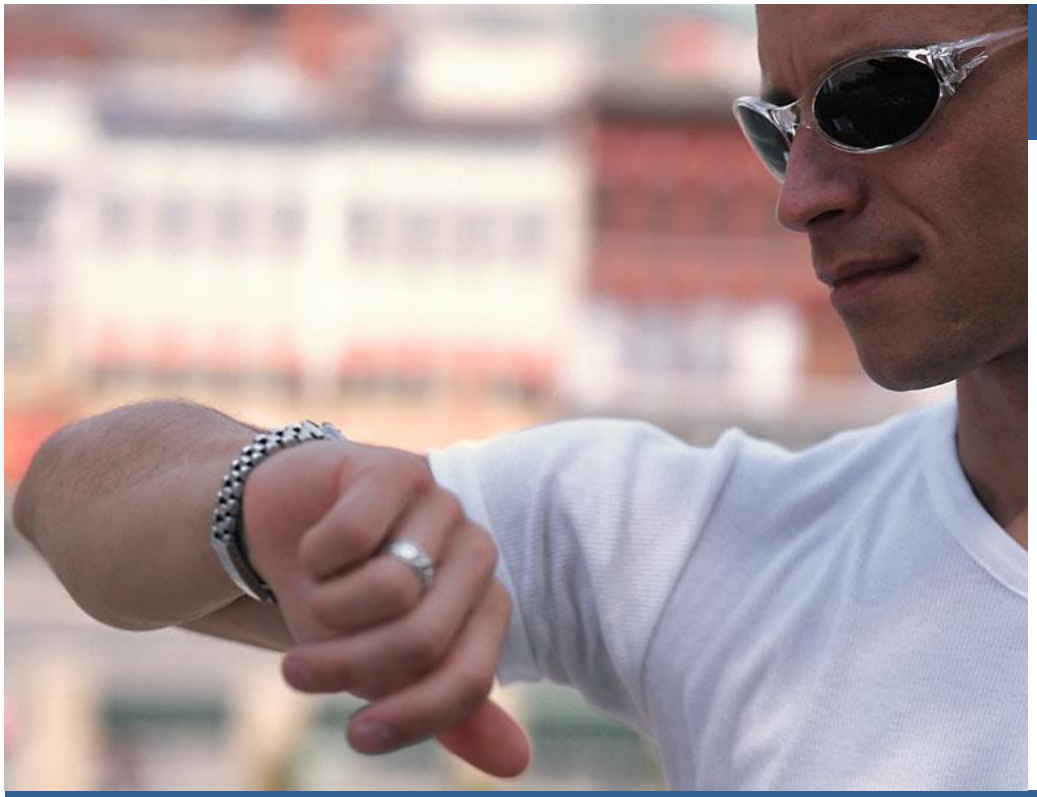

It's time…

To transition your QMS (Quality Management System) to ISO 9001:2015

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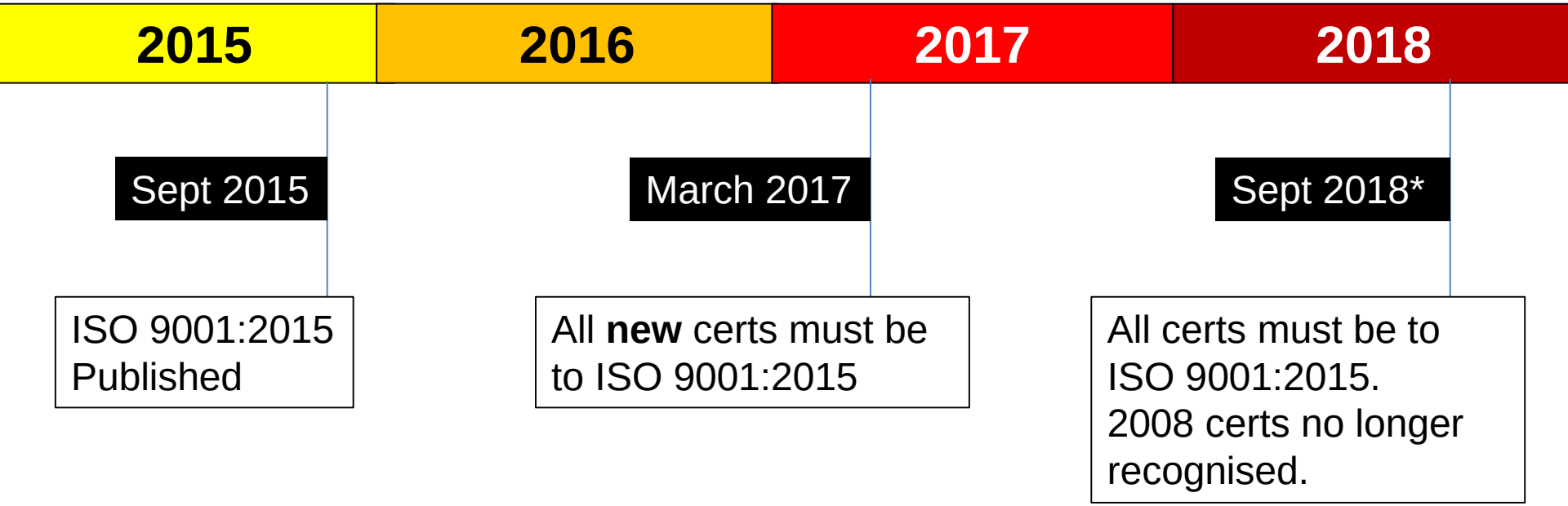
Timeframe



Source: ISO document N1223 - Transition Planning Guidance for ISO 9001:2015
*Check with your certification body or registrar – some may require an earlier transition.

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Headline News
- the big changes

- Explicit requirements for the process approach.
- Serious consideration of risk.
- Reduced emphasis on documents – quality manual and procedures no longer mandatory.
- Enhanced requirements for top management to demonstrate leadership.
- A new high-level clause structure and terminology.

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3 reasons why ISO 9001 changed

1. **Evolving management system methods**
   - risk-based thinking, process management, and greater use of I.T.
2. **To increase relevance across industry sectors** and diverse business models.
3. **Standardising the standards** – ISO taking a common approach to management system standards.

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ISO strategy for a common approach

- High-level structure – common across a range of management system standards.
- Standards to have additional, specific clauses as required.
- Common terminology.

This makes it simpler for integrated systems.

ISO 27001 Infosec	ISO 9001 Quality	ISO 14001 Environment	ISO 45001 OHS

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ISO 9001 Clause structure vs. the PDCA cycle

PLAN				DO	CHECK	ACT
4. Context of the organisation	**5. Leadership**	**6. Planning for the QMS**	**7. Support**	**8. Operation**	**9. Performance evaluation**	**10. Improvement**
4.1 Understanding the organization and its context	5.1 Leadership and commitment	6.1 Actions to address risks and opportunities	7.1 Resources	8.1 Operational planning and control	9.1 Monitoring, measurement, analysis and evaluation	10.1 General
4.2 Understanding the needs and expectations of interested parties	5.2 Quality policy	6.2 Quality objectives and planning to achieve them	7.2 Competence	8.2 Determination of requirements for products & services	9.2 Internal audit	10.2 Nonconformity and corrective action
4.3 Determining the scope of the QMS	5.3 Organizational roles, responsibilities and authorities	6.3 Planning of changes	7.3 Awareness	8.3 Design and development of products & services	9.3 Management review	10.3 Continual improvement
4.4 QMS and its processes			7.4 Communication	8.4 Control of externally provided products & services		
			7.5 Documented information	8.5 Production and service provision		
				8.6 Release of products & services		
				8.7 Control of nonconforming process outputs, products & services		

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Major changes include…

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Context of the organization

4.1 Understanding the organization and its context.

New requirement.

4.2 Understanding the needs and expectations of interested parties.

Wider consideration – not just customers.

4.3 Determining the scope of the QMS.

Must refer to products / services.

4.4 The QMS and its processes.

Major change that specifies factors to be considered – emphasis on a process-planning approach.

Leadership

5.1 Leadership and commitment.

Places greater emphasis on the role of top management.

5.2 Quality policy.

Policy requirements are enhanced.

5.3 Organizational roles, responsibilities and authorities.

Requirement for a Management rep. is no longer specified.

6 Planning for the QMS

6.1 Actions to address risks and opportunities.

Major change to require a risk-based approach.

6.2 Quality objectives and planning to achieve them.

Requirements for objective planning tightened up. An objective should describe who, what, when, and progress must be monitored.

6.3 Planning of changes.

Changes to the QMS to be carried out in a planned manner – generally referred to as ‘change management’.

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Support

7.1 Resources.

New requirements for maintaining knowledge – generally referred to as ‘knowledge management’.

7.2 Competence.

7.3 Awareness.

7.4 Communication.

Includes external communication about the QMS.

7.5 Documented information.

No requirement for documented quality manual or procedures.

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Operations

8.1 Operational planning and control.

8.2 Determination of requirements for products / services.
Includes communications with customers about contingency actions.

8.3 Design and development of products / services.
May be interpreted that more organizations do some form of design and development.

8.4 Control of externally provided products / services.
Expansion of scope from just suppliers.

Operations

8.5 Production and service provision.

Includes some expansion on previous requirements e.g. actions to prevent human error, and documented information to specify intended results, and to determine the nature and extent of any post-delivery (after-sales) activities.

8.6 Release of products / services.

8.7 Control of nonconforming outputs.

Considers outputs form processes in addition to products and services.

Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation.

9.2 Internal audit.

Audit schedule must take customer feedback into account.

9.3 Management review.

Expanded requirements for management review inputs or agenda.

Improvement

10.1 General.

10.2 Nonconformity and corrective action.

Specific reference to preventive action is removed.

Requirement to record the nature of nonconformities.

On discovering a nonconformity, there is now an explicit requirement to determine whether other, similar nonconformities actually exist, or could potentially exist.

10.3 Continual improvement.

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You don’t have to…

- Throw away your quality manual and procedures.
- Renumber documents to match new clause numbers.
- Change the terminology you use.

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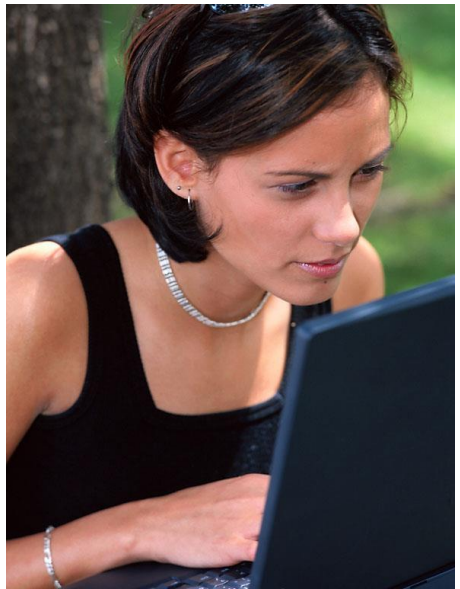
So, what do you need to do?

- Get a good **understanding** of the changed requirements.
- Do an **ISO gap analysis** to consider the changes in the context of your organisation and its QMS.
- **Plan** the development of your new system.
- **Document** and **implement** the system.
- Facilitate **Training and awareness**.



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For help with your QMS transition.

- **Qudos^3 –** Integrated management systems software to digitally transform your QMS or IMS.
- Professional **ISO Gap analysis** and **Consulting** services.
- **Qudos Club** – extensive online library for ISO 9001 **guidance and planning resources** and **sample documents**

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