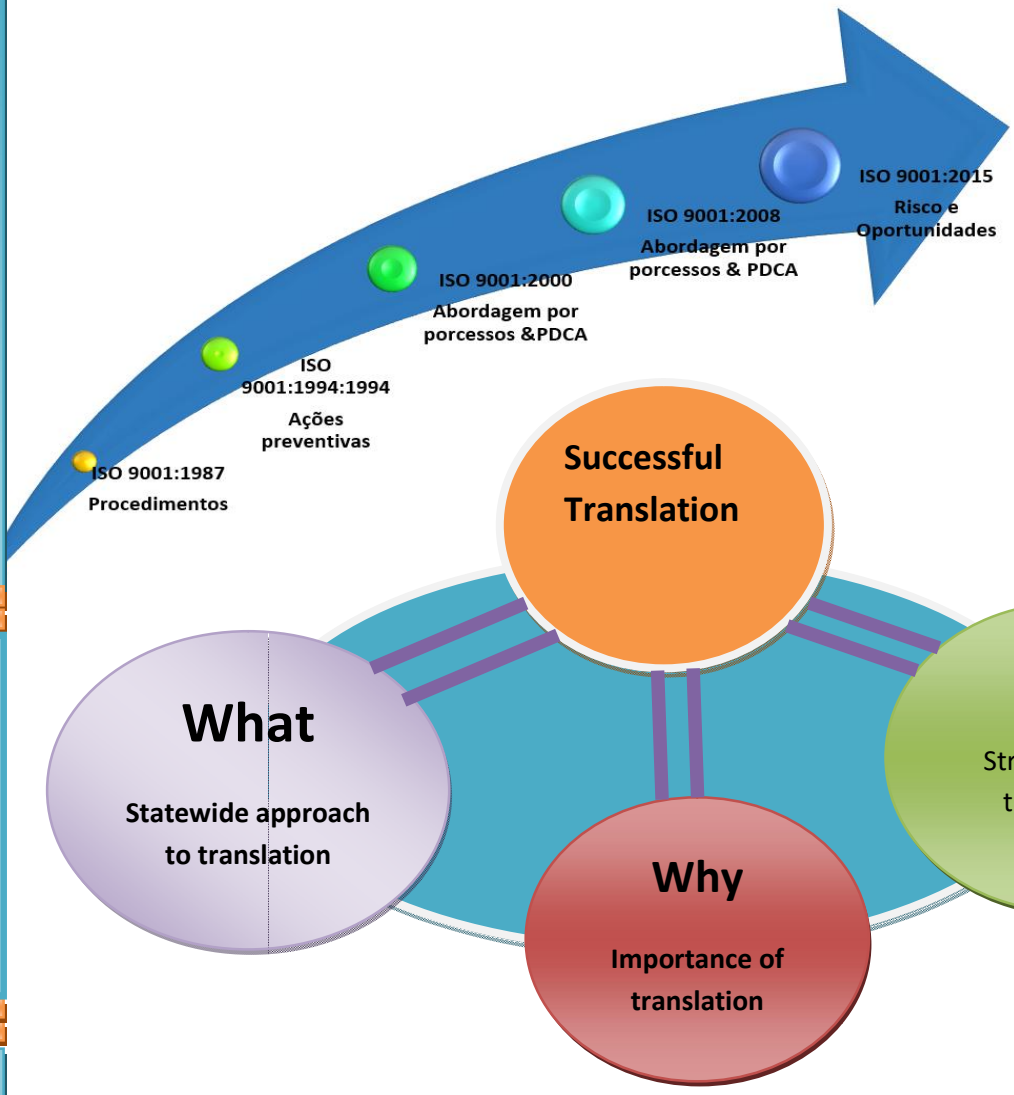
ISO 9001:2008 *to* ISO 9001:2015



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The new ISO 9001:2015 standard includes

three basic core concepts

- Process approach
- Plan-do-check act methodology, and
- Risk based thinking

New structure of ISO 9001 standard has aligned with the common 10-clause to ensure greater harmonization among its many different management system standards. The new revision to ISO 14001 will also adopt this same structure, which is built around the Plan-Do-Check-Act sequence. This will help organizations to integrate the requirements of more than one ISO Management System Standard

ISO 9001:2015

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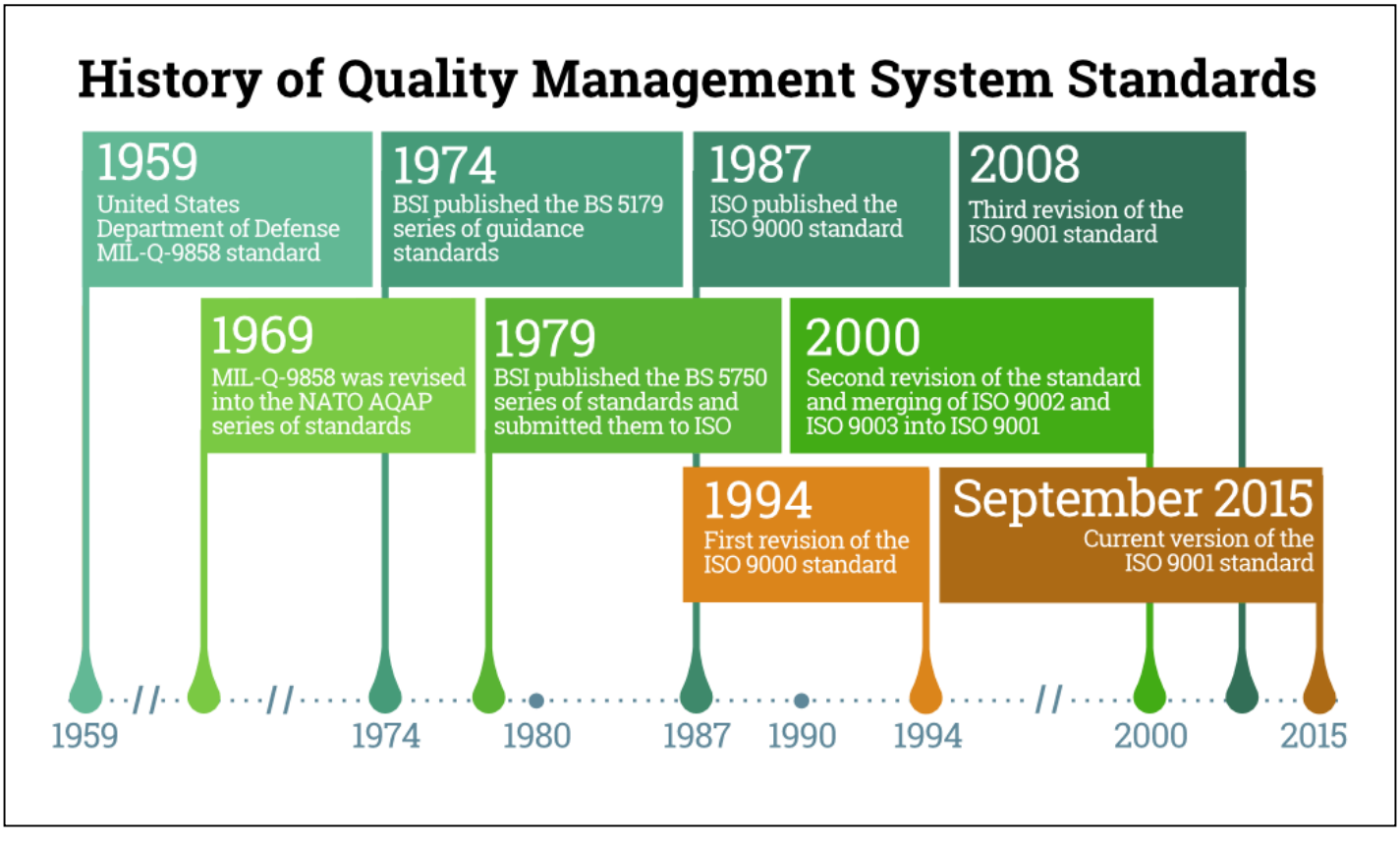
The main differences in content between the old and new version?

- **The adoption of the high level structure as set out in Annex SL of ISO Directives Part 1**
- **An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach Fewer prescriptive requirements**
- **More flexibility regarding documentation**
- **Improved applicability for services**
- **A requirement to define the boundaries of the QMS**
- **Increased emphasis on organizational context**
- **Increased leadership requirements Greater emphasis on achieving desired process results to improve customer satisfaction**

Transition means extra paperwork?

No! New ISO 9001:20015 standard requires an organization to document a number of things but, these are relatively less as compare to previous version of standard, new standard gives you flexibility to document system (Except mandatory requirement) without unnecessary paperwork. You may refer clause by clause changes in the below guidance note.



ISO 9001:2015 Clause	Requirement	Guidance
4. Context of the organization	4.1 Understanding the organization and its context	This concept relates that that you understand your organization and determined internal issues such as related to values, culture, knowledge and performance of the organization and external issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local
	4.2 Understanding the needs and expectations of interested parties	Who are the relevant interested parties (the preferred term to stakeholders) and what are their requirements? Generally customers of course – so what do they want? Always good products or services as per their requirements, and on time. Other interested parties could be end users, suppliers, distributors, retailers or others in the supply chain, regulators etc.
	4.3 Determining the scope of the quality management system	scope of the quality management system You need to determine QMS scope and where are the boundaries of the management system? What's in and what's out? This needs to be appropriate to the organisation and its objectives Exclusion term is now not used and replaced by applicability and non applicability. You need to document the scope
	4.4 Quality management system and its processes	There is no change in this requirement just an improved version. You need to determine what your processes are (including support/management processes.)
5 Leadership	5.1 Leadership and commitment	There is more here; top management now have to have a greater involvement in the management system. Clients have to demonstrate their commitment by making sure that the management system achieves its intended outcome(s) and has adequate resources.

		Also, they have to inform everyone that the management system is important and that everyone should participate in its effective implementation
	5.2 Quality Policy	The ISO 9001 policy has been strengthened More Focus on application of the policy across the organization. There is a need for "documented information", as opposed to a documented statement
	5.3 Organizational roles, responsibilities and authorities	Top-level commitment and empowerment of senior management has been raised up now, and of course now the responsibility will not lie on one person. Job descriptions are a good way to define roles and responsibilities
6 Planning	6.1 Actions to address risks and opportunities	Risk Based Thinking is a new and welcome addition to ISO 9001. How will the organisation prevent, or reduce, undesired effects? How will the organisation ensure that it can achieve its intended outcomes and continual improvement? One big plus is that preventive action does not now appear. The assumption is that the risk management process has features which creates inherent preventive actions via the improvement cycle.
	6.2 Quality objectives and planning to achieve them	The requirements around the ISO 9001 objectives have also been made more detailed. They are to be consistent with the ISO 9001 policy, measurable (if practicable), monitored, communicated, and updated as appropriate. They have to be established at relevant functions and levels. Now planning how to achieve its quality objectives is introduced which includes steps like What will be done? – describe the process flow and consider customer requirements What resources will be needed? – equipment, work environment etc. Who will be responsible? – An owner of the process and other staff – all to be competent to do the work

		When will it be completed? – to meet customer requirements How will the results be evaluated? – collect data to analyse
	6.3 Planning for Change	No good making changes for the sake of it but if they are made, they have to be made under controlled conditions. Consideration has to be given to the effect on other processes etc., The risk management process should be revisited as a result of changes
7. Support	7.1 Resource	Organization is required to provide and maintain adequate resources for the effective implementation of its quality management system and for the operation and control of its processes, such as People, Infrastructure, Environment for the operation of processes (combination of human and physical factors), Monitoring and measuring resources Measuring "equipment" becomes measuring "resource", Organization Knowledge, The organization needs to think about what knowledge is needed to perform certain functions and the implications of that knowledge being lost
	7.2 Competence	The requirement explicitly require to determine competence for the people performing work under the organization's Control and affects its quality performance Competence is achieved by appropriate education, training OR experience. There is no mention of skills as in the current standard
	7.3 Awareness	No Change
	7.4 Communication	Now external communication is added in the requirement with internal communication. Organizations must now determine what, when, with whom and how communications should take place.
	7.5 Documented Information	Organization shall apply appropriate control to control documented information. Documented procedures and records will be removed and replaced with the term 'Documented information'. This is

		information that the organization will be required to keep, control and maintain. How it wishes to record this information is up to the organization itself. This provides a more flexible approach to how companies document their arrangements for quality management
8 Operation	8.1 Operational planning and control	Organization needs to Implement planned activities at appropriate stages to verify that product and services requirements have been met This addresses both in- house and any outsourced processes. This overall process management includes having process criteria, controlling the processes within the criteria, controlling planned change and addressing unintended change as necessary.
	8.2 Requirements for products and services	No Major Charge
	8.3 Design and development of products and services	No Major Charge Design and development controls includes design verification and design validation
	8.4 Control of external provision of Product and services	Scope of Purchasing is extended to include outsourcing, means control over all externally provided product and services
	8.5 Control of production and service provision	No major change. Require controls exercise to prevent human error and extended scope of customer property by including Property belonging to customers or external providers
	8.6 Release of Product and Services	No Major Change just refreshing and includes Services in addition to products. There will need to be checks before the product or service is provided to the customer. As above, the 'checking' criteria needs to be defined. Checks to be by authorised people. Any errors/failures must not be provided to the customer unless the customer has given permission (concession). The type and level of checks needed will depend on many factors including criticality, severity, competence of the people having done the work etc

	8.7 Control of nonconforming outputs	There is no major change. Organization must take appropriate action in case of non conforming outputs. The customer may need to be notified if any non-conforming product/service has already delivered – may need to be recalled, and maintain documented information on actions taken, including concessions and authorisations.
9 Performance Evaluation	9.1 Monitoring, measurement, analysis and evaluation	No Major Change More emphasis on evaluation of results, in addition to measurement and analysis. Monitoring should be based on risk. What the customer wants. They all want good products or services and on-time. If you measure these indicators and you achieve 100% then we can assume the customer is satisfied. They may also want price reductions but that might be difficult but to be competitive, you may find ways to make processes more efficient and be able to pass on some cost savings. Preventive action and statistical techniques are no longer referenced
	9.2 Internal Audit	There is no Major Change. This is self-policing to ensure that the system is working as the organization wants Internal audit must cover customer feedback, organisational changes and quality objectives.
	9.3 Management Review	Objective to this clause remain same, Review inputs should now include strategic items relating to context, risk and opportunities
10	10.1 General	No Change
	10.2 Nonconformity and corrective action	No Change but review your risk determined when problem occur, Organization Must have a structured problem solving process based on root cause analysis.
	10.3 Continual Improvement	Appropriate tools and methodologies should be used to support to demonstrate that organization is using the results from their analysis and evaluation processes to identify areas of Problem, less performance

		and OFI (opportunities for improvement)

Transition Timelines	Steps of Transition:
Organizations are granted a 'three-year' transition period after the revision has been published to migrate their quality management system to the new edition of the standard.	Step 1- Plan for Transition Step 2- Train your Staff on the new requirement of standard Step 3- Arrange Gap Analysis Visit by ICM Certification Step 5 – Fill Gaps (if identified during Gap Analysis) Step 6- Arrange Transition Visit Step 7 – Get New ISO 9001:2015 Certificate

Thanks

CEO

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