ISO 9001:2015 Revision

TÜV UK Ltd – Guidance & Self Evaluation Checklist

Why ISO 9001 is changing

All ISO management system standards are subject to a periodic review under the rules by which they are written. Following a user survey the ISO Committee responsible for ISO 9001 determined that a review was appropriate and created the following objectives to maintain its relevance in today's market place:

- Integrate with other management systems
- Provide an integrated approach to organisational management
- Provide a consistent foundation for the next 10 years
- Reflect the increasingly complex environments in which organisations' operate
- Ensure the new Standard reflects the needs of all potential user groups
- Enhance an organisation's ability to satisfy its customers.

The key changes in the proposed standard for 2015 are:

- Context of the organisation
- The emphasis on leadership
- The focus on risk management
- Emphasis on objectives, measurement and change
- Communication and awareness
- Fewer prescriptive requirements

This document provides an overview of the key changes between the 2008 and 2015 version of ISO 9001 and has been designed to help you assess your company's readiness for an ISO 9001:2015 certification audit.

You will need to prepare for change and adapt your quality management system to meet the new requirements and transitional timelines.

TÜV UK are encouraging clients to do early gap analysis and be able to interpret standard requirements.

TÜV UK will offer transition audits after the publication and certificates after successful accreditation (expected towards the end of 2015).

If you would like us to conduct a GAP analysis or review your self evaluation form for you, please complete the questionnaire (including your contact details), and email it to us at: enquiries.uk@tuv-nord.com

In addition to ISO 9001 auditing TÜV UK offer the following ISO 9001:2015 related services

GAP Analysis

Checklist Review

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Guidance

ISO 9001:2015 CLAUSES	ISO 9001:2008 CLAUSES	GUIDANCE
4 Context of the organisation		
4.1 Understanding the organisation and your context	**New requirement!**	This new concept relates to the factors and conditions affecting organisational operation E.g. regulation, governance and stakeholders.
4.2 Understanding the needs and expectations of interested parties	**New requirement!**	Consider who the interested parties might be and what their relevant interests might be, e.g. customers, shareholders, board members, competitors, regulators.
4.3 Determining the scope of the QMS	**1 Scope**	Reference to "exclusions" has been removed. Elements which do not apply can and should be justified under Clause 4.3 of 9001:2015.
4.4 Quality management system and your processes	**4.1, 5.4.2, 7.1, 8.1 and 8.2.3**	An elevated focus on processes. Adoption of the process approach is now mandatory and will be audited accordingly.
5 Leadership		
5.1 Leadership and commitment	**5 Management Responsibility**	Enhances 5.1, Management commitment, from the 2008 Standard. The 2015 FDIS repositions some requirements to "leadership", not management. The emphasis has shifted from ensuring to "engaging".
5.2 Quality policy	**5.3 Quality policy**	Enhanced requirements from the 2008 version: more attention to be paid to the application of the policy across the organisation. There is a need for "documented information", as opposed to a documented statement.
5.3 Organisational roles, responsibilities and authorities	**5.5 Responsibility, authority and communication**	The role of the Management Representative has disappeared; however the requirements of the 2008 clause 5.5.2 still need to be met. There is a new requirement that someone is tasked with preserving the integrity of the QMS while it is in the process of change.
6 Planning for the QMS		
6.1 Actions to address risks and opportunities	**New requirement!**	Organisations must determine its context, and the arising risks and opportunities. Actions to address risk must be proportional to the potential impact.
6.2 Quality objectives and planning to achieve them	**5.4 Planning**	Extension of 2008 clauses, 5.4.1, and 5.4.2. Stronger emphasis on the importance of objectives, which should be set for processes. The organisation must retain documented information on quality objectives.
6.3 Planning of changes	**5.4.2 Quality management system planning**	An extension of the existing requirement: organisations must identify the purpose and likely consequences of change, and the necessary resources and responsibilities.

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7. Support

7.1	Resources		
7.1.1	General	**6.1 Provision of resources**	Need to evidence external as well as internal resource requirements.
7.1.2	People	**6.2 Human Resources, 6.2.1 General**	No significant change
7.1.3	Infrastructure	**6.3 Infrastructure**	Enhanced reference to examples, e.g. hardware, software, transportation
7.1.4	Environment for the operation of processes	**6.4 Work environment**	More prescriptive than before with a requirement to determine, provide and maintain a suitable environment. There is a note in the new clause that examples of "environment for the operation of processes" include social, psychological and environmental
7.1.5	Monitoring and measuring Resources	**7.6 Control of monitoring and measuring equipment**	Measuring "equipment" becomes measuring "resource", acknowledging that professional judgment and human senses may also be a measuring resource, e.g. tea tasting.
7.1.6	Organisational knowledge	**New Requirement!**	Examples of such knowledge could be intellectual E.g. design or software and external sources of knowledge e.g. academia or conferences
7.2	Competence	**6.2 Human resources**	The requirement has been extended to include people performing work under the organisation's control, i.e. outsourced resource such as agencies.
7.3	Awareness	**6.2.2 Competence, training and awareness**	This is more expansive and now applies to all persons doing work under the organisation's control. People must be aware of policy, objectives, how they contribute and the implications of not conforming to the QMS.
7.4	Communication	**5.5.3 Internal communication**	This is now much more prescriptive and includes external communications. Organisations must now determine what, when, with whom and how communications should take place.
7.5	Documented information	**4.2 Documentation requirements**	The FDIS does not mention manual, procedures or records. Documented information must be controlled but there is no longer a requirement to have a documented procedure for this process. Requirements now extend to access and usage, recognising that electronic information can be accessed as read only, without authority to change.

Guidance

8. Operation

8.1 Organisational planning and control	**7.1 Planning of product realisation**	This is a reworking and reorganising of the 2008 Clause 7.1 requirements. The requirement to plan and develop processes is not new, but has been extended to include implementation and control.
8.2 Determination of requirements for products & services	**7.2 Customer related processes**	A subtle change in the supplier customer relationship: the FDIS starts from the position that the organisation has already determined the products and services it intends to offer, reflecting a more common business environment for certification customers. Requirements should include those from interested parties and also include statutory and regulatory requirements relating to the product.
8.3 Design and development of products and services.		
8.3.1 General	**New requirement!**	This new clause mandates the introduction of a design and development process where this activity is required.
8.3.2-8.3.6 Design and development process requirements: planning, inputs, controls, outputs, changes	**7.3 Design and development**	Builds on existing 2008 clauses 7.3.1 - 7.3.6. Design and development needs to be approached as a process.
8.4 Control of externally provided products and services	**7.4 Purchasing**	Enhanced emphasis on external providers and the extent of employment of contractors in current commercial practice. Extent of controls needs to take account of the potential impact on the organisation's ability to consistently meet requirements. Risk assessment will be applicable here.
8.5 Production and service provision	**7.5 Production and service Provision**	No significant changes.
8.6 Release of products and services	**8.2.4 Monitoring and measurement of product**	No substantive change needed. Note refreshed terminology referring to services in addition to product.
8.7 Control of nonconforming process outputs, products and services	**8.3 Control of nonconforming product**	Some minor changes. There is no longer a requirement for a documented procedure, but there is a requirement to maintain documented information on actions taken, including concessions and authorisations.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation	**8.2.1 Customer satisfaction, and 8.4 Analysis of data**	An enhanced emphasis on evaluation of results, in addition to measurement and analysis. Monitoring should be based on risk. Customer perception now includes soliciting perceptions about the organisation and its products and services. Preventive action and statistical techniques are no longer referenced.
9.2 Internal audit	**8.2.2 Internal audit**	There is no longer a need for a documented procedure. Internal audit programme shall take into consideration changes to the organisations.
9.3 Management review	**5.6 Management Review**	Overall purpose remains the same, however inputs should now include strategic items relating to context, risk and opportunities. Trends and indicators should be used to monitor quality performance.

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10. Improvement

10.1 General	**New requirement!**	The requirement for a documented preventive action procedure has gone.
10.2 Nonconformity and corrective action	**5.2 Corrective action**	When corrective action has been completed, the organisation can move on to consider whether any further action is required to prevent a similar nonconformity occurring in future. This requires the organisation to determine what caused the nonconformities and then to consider whether the potential for a similar problem remains. The organisation is then required to implement any actions identified as needed, review their effectiveness and make changes to the quality management system if necessary.
10.3 Continual improvement	**8.5.1 Continual improvement**	Organisations will now need to demonstrate that they are using the outputs from their analysis and evaluation processes to identify areas of underperformance and opportunities for improvement. Appropriate tools and methodologies should be employed by the organisation to support this activity.

Major differences in terminology

You will find that some of the familiar terminology of ISO 9001:2008 has either been changed or removed. Here are the highlights:

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Supplier	External provider
Documentation and records	Documented information
Work environment	Environment for the operation of processes
Purchased product	Externally provided products and services
Exclusions	*Term not used*
Management representative	*Term not used*
Documented procedure	*Term not used*
Quality manual	*Term not used*
Preventive action	*Term not used*
Term not used	Leadership
Term not used	Risk

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Self Evaluation Checklist

Context of the organisation

- [ ] Have you determined the external and internal issues that are relevant to your organisation's purpose and the achievement of customer satisfaction and the organisation's strategic direction?
- [ ] Do you have a way of reviewing and monitoring these on a regular basis?
- [ ] Have you determined the needs and expectations of interested parties that are relevant to the Quality Management System (QMS)?
- [ ] Has the scope of the QMS been determined taking into account the external and internal issues, interested parties and your products and services?
- [ ] Has your QMS been established including the processes needed and their sequence and interaction?
- [ ] Have the criteria for managing these been established together with responsibilities, methods, measurements and related performance indicators needed to ensure the effective operation and control?

Leadership

- [ ] Has top management taken accountability for the effectiveness of the QMS?
- [ ] Have the policy and objectives for the QMS, which are compatible with the strategic direction of the organisation, been established and communicated?
- [ ] Have the objectives been established at relevant departmental and individual levels with the business?
- [ ] Have the requirements for the QMS been integrated into the business processes and have management promoted awareness of the process approach?
- [ ] Have customer requirements and applicable statutory and regulatory requirements been determined, met and communicated throughout the organisation?
- [ ] Have the risks and opportunities that are relevant to the QMS been established?
- [ ] Has the organisation established and communicated the responsibilities and authorities for the effective operation of the QMS?

Planning

- [ ] Have the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended result(s) been established?
- [ ] Has the organisation planned actions to address these risks and opportunities and integrated them into the system processes?
- [ ] Is there a defined process for the determining the need for changes to the QMS and managing their implementation?

Support

- [ ] Has the organisation determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS (including people, environmental and infrastructure requirements)?
- [ ] If monitoring or measuring is used for evidence of conformity of products and services to specified requirements, has the organisation determined the resources needed to ensure valid and reliable monitoring and measuring of results?
- [ ] Has the organisation determined the knowledge necessary for the operation of its processes and achievement of conformity of products and services and implemented a lessons learnt process?
- [ ] Has the organisation ensured that those persons who can affect the performance of the QMS are competent on the basis of appropriate education, training, or experience or taken action to ensure that those persons can acquire the necessary competence?
- [ ] Has the documented information required by the standard and necessary for the effective implementation and operation of the QMS been established?

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Self Evaluation Checklist

Operation

Is there a defined process for the provision of products and services that meet requirements defined by the customer? ☐

When changes are planned are they carried out in a controlled way and actions taken to mitigate any adverse effects? ☐

Are any outsourced processes managed and controlled? ☐

Is there a defined process for reviewing and communicating with customers in relation to information relating to products and services, enquiries, contracts or order handling? ☐

Is this review conducted prior to the organisation's commitment to supply products and services? ☐

If you design and develop products or services, are these processes established and implemented in line with the requirements of the standard? ☐

Do you ensure that externally provided processes, products, and services conform to specified requirements? ☐

Do you have criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers? ☐

Is the provision of products and services carried out in controlled conditions which include: ☐

- the availability of documented information that defines the characteristics of the products and services; ☐
- the availability of documented information that defines the activities to be performed and the results to be achieved? ☐
- monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met? ☐
- the people carrying out the tasks are competent? ☐

Do you have effective methods of ensuring traceability during the operation process? ☐

Where property belonging to customers or external providers is used in the provision of the product or service, is this controlled effectively? ☐

If there is a requirement for post-delivery activities associated with the products and services such as warranty, maintenance services, recycling or final disposal, are these defined and managed? ☐

Are any nonconforming process outputs managed so as to prevent their unintended use? ☐

Performance evaluation

Has the organisation determined ☐

- what needs to be monitored and measured and ☐
- the methods for monitoring, measurement, analysis and evaluation, to ensure valid results? ☐

Has it established when the results from monitoring and measurement shall be analyzed and evaluated? ☐

Have methods of monitoring customer perceptions of the provision of products and services been established? ☐

Has it determined the need or opportunities for improvements within the QMS and how these will be fed into management reviews? ☐

Has the organisation established a process for an internal audit of the QMS? ☐

Has an approach to perform management reviews been established and implemented ☐

Improvement

Has the organisation determined and selected opportunities for improvement and implemented the necessary actions to meet customer requirements and enhance customer satisfaction? ☐

Has the organisation appropriate processes for managing nonconformities and the related corrective actions? ☐

Has the organisation decided on how it will address the requirement to continually improve the suitability, adequacy, and effectiveness of the QMS? ☐

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Contact Form

Certification process

TÜV UK proposal issued → Proposal acceptance by client → Stage 1 Pre-Audit → Stage 2 Certification Audit → Issue of certificate (validity: 3 years) → Annual surveillance audits

Why TÜV UK

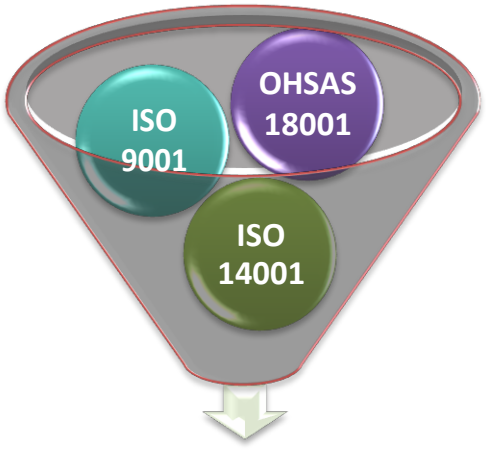
Founded in 1979 TÜV UK Ltd. forms part of the TÜV NORD GROUP.

The TÜV NORD GROUP is a technical service provider with worldwide activities, founded in 1869 and headquartered in Hanover, Germany; the Group employs more than 14,000 people in more than 70 countries across Europe, Asia, America and Africa.

Our approach:

TÜV UK can audit and certify your QMS system to ISO 9001 as a standalone, or if you wish to reduce your overall costs and audit durations, as part of an Integrated Management System (IMS), by combining your ISO 9001 audits with new or existing ISO 14001 and OHSAS 18001 management system audits.

ISO 9001 is designed to complement and integrate with other management systems



Continual Improvement

I'm interested in the following ISO 9001:2015 services:

☐ Self Evaluation Form review

☐ Onsite Gap Analysis

☐ Transition training

I'd like someone to call ☐ email ☐ me.

I'd also like information on the upcoming revisions for

ISO 14001 ☐ OHSAS 18001 (ISO 45001) ☐

Contact information:

Contact name: _____

Position: _____

Company: _____

Address: _____

_____

Postcode: _____

Telephone: _____

Mobile: _____

Email: _____

Company information:

Employees: _____

Number of Sites: _____

Nature of business: _____

TÜV UK Ltd
AMP House, Suites 27-29, Fifth Floor
Dingwall Road, Croydon, CR9 1XZ

Phone: +44 (0) 20 8680 7711
Fax: +44 (0) 20 8680 4035
E-mail: enquiries.uk@tuv-nord.com

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