



Guidance and 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 organizational management
- Provide a consistent foundation for the next 10 years
- Reflect the increasingly complex environments in which organizations' operate
- Ensure the new Standard reflects the needs of all potential user groups
- Enhance an organization's ability to satisfy its customers.

The key changes in the proposed standard for 2015 are:

- Context of the organization
- 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.

K&S Quality Associates are encouraging clients to do early gap analysis and be able to interpret standard requirements.

K&S Quality Associates now offers consulting services and gap analysis to ensure a successful transition to the 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:

contact@qualityassociates.org

ISO 9001:2015 CLAUSES

ISO 9001:2008 CLAUSES

GUIDANCE

4 Context of the organization

4.1 Understanding the organization and your context	New requirement!	This new concept relates to the factors and conditions affecting organizational 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 removed.	1 Scope	Reference to “exclusions” has been 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 organization. There is a need For “documented information”, as opposed to a documented statement.
5.3 Organizational 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!	Organizations 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 organization 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: organizations must identify the purpose and likely consequences of change, and the necessary resources and responsibilities.

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 Workenvironment		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 Organizational 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 organization'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 organization'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. Organizations 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, recognizing that electronic information can be accessed as read only, without authority to change.

8. Operation

8.1 Organizational planning and control	7.1 Planning of product realization	This is a reworking and reorganizing 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 organization 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 organization'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 authorizations.

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 organization 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 program shall take into consideration changes to the organizations.
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.

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	<p>When corrective action has been completed, the organization can move on to consider whether any further action is required to prevent a similar nonconformity occurring in future.</p> <p>This requires the organization to determine what caused the nonconformities and then to consider whether the potential for a similar problem remains.</p> <p>The organization is then required to implement any actions identified as needed, review their effectiveness and make changes to the quality management system if necessary.</p>
10.3 Continual improvement	8.5.1 Continual improvement	<p>Organizations 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.</p> <p>Appropriate tools and methodologies should be employed by the organization to support this activity.</p>

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

Products
Supplier
Documentation and records
Work environment
Purchased product
Exclusions
Management representative
Documented procedure
Quality manual
Preventive action
Term not used
Term not used

ISO 9001:2015

Products and services
External provider
Documented information
Environment for the operation of processes
Externally provided products and services
Term not used
Term not used
Term not used
Term not used
Leadership
Risk

Self-Evaluation Checklist

Context of the organization

Have you determined the external and internal issues that are relevant to your organization's purpose and the achievement of customer satisfaction and the organization'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 them?

Have the policy and objectives for the QMS, which are compatible with the strategic direction of the organization, 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 organization?

Have the risks and opportunities that are relevant to the QMS been established?

Has the organization 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 organization 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 organization 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 organization determined the resources needed to ensure valid and reliable monitoring and measuring of results?

Has the organization 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 organization 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?

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 organization'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 organization 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 organization established a process for an internal audit of them?

Has an approach to perform management reviews been established and implemented

Improvement

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

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

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

Why K&S Quality Associates

K&S Quality Associates Founded in 1997

K&S has had a long standing reputation in the industry for providing some of the best guidance and coaching for technical services with worldwide activities, headquartered in Los Angeles California.

Our approach:

Over the years we have been known for our customized service to streamline existing Management System and simplify the existing system to make the system something that is useful for you and your employees. We have been hired over and over again to clean up the work of another consulting firm that makes things more complicated than is necessary. With this newest revision to the standard perhaps it is time for a fresh new system or time for us to give your ideas that will make your life easier.

I'm interested in the follow services:

- Self-Evaluation Form Review
- On-site Gap Analysis
- On-site Consulting
- Transition Training

I'd like someone to call e il me

Contact Information:

Contact Name: _____

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