ISO 9001:2015 TRANSITION GAP ANALYSIS

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This document provides an overview of the key changes between the 2008 and 2015 version of ISO 9001 – there are six new requirements in addition to changes to key definitions. You will need to prepare for change and adapt your quality management system to meet the new requirements and transitional timelines.

ISO 9001:2015

- Draft International Standard (DIS) - published in May 2014
- Final Draft International Standard (FDIS) - expected January 2015
- ISO Standard - published September 2015

STRUCTURE OF ISO 9001:2015

The structure of ISO 9001:2015 follows the high level structure defined in Annex SL:

1. Scope
2. Normative References
3. Terms and Definitions
4. Context of the Organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

WE ARE HERE TO HELP

We will help you understand the changes, interpret the new concepts and act on the implications.

Keep updated with the changes at **www.nqa.com/change**

Please get in touch if you have any questions – call **08700 135145.**

"The Virgin Media Business approach to quality management has evolved over the years as we have strived to understand, sustain and improve delivery of services to our customers.

ISO 9001:2015 drives significant improvement, embedding strategy and true end to end customer delivery at the heart of our organisation."

Eva Newberry, Governance Manager, Virgin Media Business

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GAP ANALYSIS AND GUIDANCE

ISO 9001:2015 CLAUSES	ISO 9001:2008 CLAUSES	GUIDANCE
4 Context of the organisation		
4.1 Understanding the organisation and its context	**New requirement!**	This new concept relates to the factors and conditions affecting organisational operation e.g. regulation, governance and interested parties. Be prepared to discuss the implications of your context with your assessor.
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. Be prepared to discuss with your assessor.
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 its 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. Also read clause 0.3 Process approach, in the 2015 standard.
5 Leadership		
5.1 Leadership and commitment	**5 Management Responsibility**	Enhances 5.1, Management commitment, from the 2008 standard. The 2015 standard repositions some requirements to "leadership", not management. The emphasis has shifted to "engaging" as well as "ensuring".
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 the policy to be available as "documented information", as opposed to a documented statement.
5.3 Organisational roles, responsibilities and authorities	**5.5 Responsibility, authority and communication**	The explicit requirement for a 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 management must ensure the preservation of 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 2008 requirement: organisations 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 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 physical factors.
7.1.5 Monitoring and measuring resources	**7.6 Control of monitoring and measuring equipment**	Measuring "equipment" becomes measuring "resource", acknowledging that professional judgement 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 internal, eg intellectual property 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 standard 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.

8. Operation

8.1 Operational 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 Requirements for products & services	**7.2 Customer related processes**	A subtle change in the supplier customer relationship: the standard 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. The process approach is strongly emphasized here.
8.4 Control of externally provided processes, 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 outputs	**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 must cover customer feedback, organisational changes and quality objectives.
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!**	Proactive improvement must be sought, and this may be as a result of corrective action, innovation or reorganisation.
		The requirement for a documented preventive action procedure has gone.
10.2 Nonconformity and corrective action	**8.5.2 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, but please also refer to our document on key concepts for additional guidance:

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
Term not used	Organizational Knowledge