



## ISO 9001:2008 - briefing note and transition requirements for IRCA QMS auditors

### Scope:

This document:

1. Summarizes the differences between ISO 9001:2000 & ISO 9001:2008
2. Explains the transition requirements that you need to meet in order to maintain your IRCA QMS auditor certification

### 1. Summary of ISO 9001:2000 & ISO 9001:2008

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Below you will see the main changes by clause and implications to QMS auditors. The changes are mainly clarification or minor changes to align ISO9001 with ISO14001 and are provided as guidance only.

	ISO 9001:2000 Clauses	ISO 9001:2008
<b>General Requirement 4.1</b>	<i>'Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.'</i>	Although outsourcing of processes is still an integral part of the new standard it emphasizes that the processes should comply with both legal and customer requirement. Although your organization is outsourcing, it is still your organization's responsibility to ensure all the necessary processes are in place to meet all regulatory, mandatory and customer requirements. The clause defines the responsibilities of the organization more to help you determine any impacts or problems that may occur between you and your supplier, and to ensure they are effectively managed in your core processes.

	<b>ISO 9001:2000 Clauses</b>	<b>ISO 9001:2008</b>
<b>Documentation Requirements 4.2.1</b>	<i>'Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.'</i>	<p>This note now includes reference to situations where a single document can contain one or more procedures. Documented procedures can also be covered by one or more documents.</p> <p>More flexibility in creation of documented procedures</p>
<b>Documentation Requirements 4.2.3 (f)</b>	<i>'To ensure that documents of external origin are identified and their distribution controlled, and...'</i>	The organization is now required to determine the extent of the external documentation that requires controlling to maintain and operate the management system.
<b>Management Representative 5.5.2</b>	<i>'Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes...'</i>	The standard determines that the member of management must be a member of the organization's management team and not an external member of management.
<b>Human Resources - General 6.2.1</b>	<i>'Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.'</i>	Competence is a key issue, and more so in the new standard. It specifies the competence of personnel affecting the performance of conformity to product requirements directly or indirectly must be controlled by the organization.
<b>Infrastructure 6.3 (c)</b>	<i>'Supporting services (such as transport or communication)'</i>	Within the examples in brackets this now includes 'information systems' to ensure product release.
<b>Work environment 6.4</b>	<i>'The organization shall determine and manage the work environment needed to achieve conformity to product requirements.'</i>	The definition of work environment is now more defined to include physical, environments and other factors like weather, lighting, sound and temperature to ensure product requirements are being met.

	<b>ISO 9001:2000 Clauses</b>	<b>ISO 9001:2008</b>
<b>Determination of requirements related to the produce 7.2.1 (a)</b>	<i>'Requirements specified by the customer, including the requirements for delivery and post-delivery activities.'</i>	The new standard provides a description of what post-delivery is. These include contractual obligations such as maintenance services and supplementary services (recycling or disposal) and warranty provisions.
<b>Design and Development planning 7.3.1</b>	<i>'The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility Planning output shall be updated, as appropriate, as the design and development progresses'</i>	An additional guidance note has been included to expand on the definition of this clause. The standard informs users that the activities listed in this clause can be done as one activity or separately, whichever is best to meet product realization.
<b>Design and development outputs 7.3.3</b>	<i>'The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.'</i>  <i>Design and development outputs shall</i> <ul style="list-style-type: none"> <li>a) Meet the input requirements for design and development,</li> <li>b) Provide appropriate information for purchasing, production and for service provision,</li> <li>c) Contain or reference product acceptance criteria, and</li> <li>d) Specify the characteristics of the product that are essential for its safe and proper use</li> </ul>	An additional description has been added to identify the meaning of service provision to include details of product preservation.
<b>Control of monitoring and measuring devices</b>	<i>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be</i>	Additional guidance has been added for extra guidance to cover the ability to constantly monitor the effectiveness of the software being used, and

	<b>ISO 9001:2000 Clauses</b>	<b>ISO 9001:2008</b>
<b>7.6</b>	<i>confirmed. This shall be undertaken prior to initial use and re-confirmed as necessary.'</i>	determine its suitability for its purpose.
<b>Customer satisfaction 8.2.1</b>	<i>'As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.'</i>	Additional guidance has been added to explain the different methods on measuring and monitoring customer satisfaction through data analysis, surveys, claims, warranties, dealer reports.
<b>Internal Audit 8.2.2</b>	<i>'The old standard does not state that internal audit records must be maintained.'</i>	The standard specifies the requirement for internal audit records to be maintained.
<b>Monitoring and measurement of processes 8.2.3</b>	<i>'The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.'</i>	Additional guidance has been added to explain "suitable methods", to specify that the organization needs to consider the type and extent of monitoring and measuring for each process to determine the impact on the conformity for product requirements and its effectiveness within QMS.
<b>Monitoring and measurement of product 8.2.4</b>	<i>'Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, the customer.'</i>	The standard is clearer in specifying that products are released for delivery to the customer. The organization must maintain records of who is responsible to sign off the product for delivery.

Auditors must be aware that changes will be required to management systems in order to ensure effective audits against the new standard.

## **2. Transitioning your QMS Auditor Certification**

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This revision to ISO 9001:2008 is important and we will require you (IRCA certificated QMS auditors) to demonstrate that you have updated yourselves with the changes in the revision and that you understand the implications of these changes in the context of your QMS auditing activities.

### **Transition requirement for IRCA certificated QMS auditors**

All IRCA certificated QMS auditors will need to complete a minimum of **2 hours** professional development focused on the changes in ISO 9001:2008 **before** completing any acceptable audits to the revised version ISO 9001:2008. This development and your completed audits will be reviewed during your normal tri-annual renewal of certification. You must include details of your relevant development in the CPD log that you submit as part of this process, and note which version of the standard each audit was conducted against in your audit log.

**Note: We have intentionally not specified whether this CPD should be structured, semi-structured or unstructured, as we believe a minimum of 2 hours actual development is enough. We have provided a list of acceptable methods below, and it is down to you as the auditor to decide which method suits you best.**

### **What kind of CPD will IRCA accept?**

You may achieve the CPD requirement in a number of ways:

- On the job training
- In-house training and seminars with your company
- Attendance at relevant conferences, seminars and workshops
- Reading (this briefing note and other relevant articles)
- A specific QMS auditor transition course



**When does this start?**

We will accept transition CPD and audits to the new standard from November 2008.

IRCA will provide a list of ISO 9001:2008 events and seminars that are acceptable for transition: this will not be an exhaustive list and other CPD is acceptable. These events are offered by IRCA approved training organizations and OEAs, but are not formally certified by IRCA and, therefore, do not fall under IRCA control even though we accept them for CPD along with other training and events. See IRCA/632 for details of the recommended content for transitional training/events. You will find a list of such courses and events on our website, [www.irca.org](http://www.irca.org), as soon as they become available.

**If you have any questions, please contact us at [registration@irca.org](mailto:registration@irca.org)**

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**End**