

## YOUR WEBINAR QUESTIONS ANSWERED

**Section 0.1 paragraph 4, there is an addition which contains the word 'statutory', does this give the auditor a free hand to explore compliance to H&S and environmental legislation relevant to the company as well as quality issues?**

The auditor must always stay within the scope of the audit and so will not have a "free hand" to move into areas which are outside the QMS and covered solely by OH&S or Environmental legislation. However, you do need to demonstrate that you provide product that meets applicable statutory and regulatory requirements and it is entirely appropriate for a QMS auditor to seek assurance that this is the case. Of course, should an auditor come across incidents where you are in breach of OH&S or environmental legislation, he or she is obliged to report the matter.

Clause 4.1

**If an exporter obtains full product requirements from their overseas customer, does that fulfil the requirement to verify statutory & regulatory requirements?**

You, the exporter, will need to have appropriate controls to verify that your overseas customer meets applicable customer, statutory and regularity requirements for your product.

**If we export are we required to understand and comply with the standards of the country we are exporting to and do we need to inform our customers of these?**

Yes is the answer to the first part of the question; the answer to the second will depend on a range of factors relating to the product or service and the whereabouts of your customers.

Clause 4.2.1

**If organisations have an effective documented quality system compliant to ISO 9001:2000, will there need to be much change required to procedures?**

There have been some amendments to the clauses that require an organisation to establish documented procedures and you will need to review your procedures to ensure that you do address these amendments.

If your organisation has established procedures to meet other requirements, then again you will need to review these to ensure that the amendments to the standard are being addressed.

The extent to which you may have to "change" procedures will depend on your product, size of organisation, complexity of processes, competence of personnel and so on, and whether your system is operating effectively.

**Many company management system documents refer to ISO 9001:2000. As the 2008 changes are "clarification" is it OK to retain the ISO 9001:2000 references or must all documentation be updated?**

Your QMS documentation must reference the Standard on which it is based. After November 2010, ISO 9001:2000 will no longer be valid and nor will any QMS documentation that references it.

**Can the COA (Certificate of Analysis) concerning incoming raw materials be considered as documents of external origin?**

Not really. A document of external origin would be a document that you have to comply with but is outside of your control, for example, a piece of legislation or a customer's specification. A COA is part of delivery documentation that aids traceability or is proof that an item complies with specification.

Clause 5.5.2

**Whilst the standard requires a member of the management team to hold the position of management representative do you see this as precluding the use of subcontractors for audits and other system activities?**

The requirement is that the organisation's Management Representative must be a member of the management team (clause 5.5.2). However, the day-to-day administrative functions such as revising or amending the QMS documentation or conducting internal audits could be outsourced with the agreement of the organisation's external auditors.

**If the quality manager is not a member of the management team but reports directly to a director on the management team does this meet the requirements?**

In this circumstance, the Director would be the management representative as defined in ISO 9001 and the Quality Manager (a position not recognised in the Standard) would be responsible for the day-to-day administrative functions such as revising or amending the QMS documentation and so on.

**What kind of training does the management representative have to undergo and how do we show evidence of such training?**

The nominated Management Representative needs to be competent in carrying out the role. This is defined clearly in clause 5.5.2 and centre upon management responsibilities and authorities to ensure that the QMS is operating effectively. Critical to this is an understanding of the management system policies, objectives and processes relating to the provision of the organisation's product or service. Training is indeed one way in which a management representative may gain an understanding of the application and requirements of ISO 9001:2008 and appropriate records kept (clause 6.2.2) but competence in the task will come from his or her wider experience within the context of the organisation's business operations.

Clause 6.2.1

**What is evidence of competence?**

Evidence that someone is able to apply their knowledge and skills to any task to ensure, directly or indirectly, that the organisation's product, service or process meets requirements.

**Is a written test or practical test after training required?**

Depending on the training or learning objectives, a written test or practical test after training may be one way of demonstrating competence, but a test as such is not a requirement.

**Is "satisfactory performance" in an appraisal sufficient evidence of competence?**

Depending on the area or level of competence being assessed, "satisfactory performance could be sufficient evidence of competence, but an appraisal as such is not a requirement.

Clause 6.3

**Can you elaborate on the requirements concerning work environment in relation to the warehouse?**

Without knowing the items being stored in your warehouse, it is not possible to provide a detailed response. However, you must ensure that you have provided the infrastructure detailed in clause 6.3a, 6.3b and 6.3c to maintain the conformity of the product to requirements. These product requirements may have been determined by the nature of the product and/or defined by customer, statutory and regulatory requirements. The requirements should be adequately addressed in the objectives and processes for the warehouse. Also you will probably need to ensure that the warehouse processes address the requirements of other clauses in ISO 9001 such as those in sub-clauses in 7.1, 7.2, 7.5 and 7.6.

Clause 7.6

**Can you please clarify the requirement for computer software validation mentioned in the Note?**

Any computer software that you use to monitor or measure products or processes must be "fit for purpose". The Note requires you to confirm this through verification this and to ensure that the software is "configured" appropriately.

Clause 8.2.2

**Clause 8.2.2 now calls for records of audits to be maintained. What does it mean?**

An audit schedule showing when, where and by whom audits had been completed, audit reports and so on would constitute records.

**What transition training will be required for internal auditors?**

Internal auditors must be competent to conduct internal audits to meet the objectives set out in the opening paragraph of clause 8.2.2. If they are already competent in conducting audits on your QMS, then they will need to be advised on how the changes impact on your QMS and how you have addressed the changes. Clause 6.2.2 sets out the process to ensure auditor competence.

Clause 8.2.4

**Is a product release certificate a requirement if the customer does not request it?**

No. But you will have to verify that product requirements have been met and show who authorised release of product for delivery. Also note that *evidence of conformity with acceptance criteria shall be maintained*.