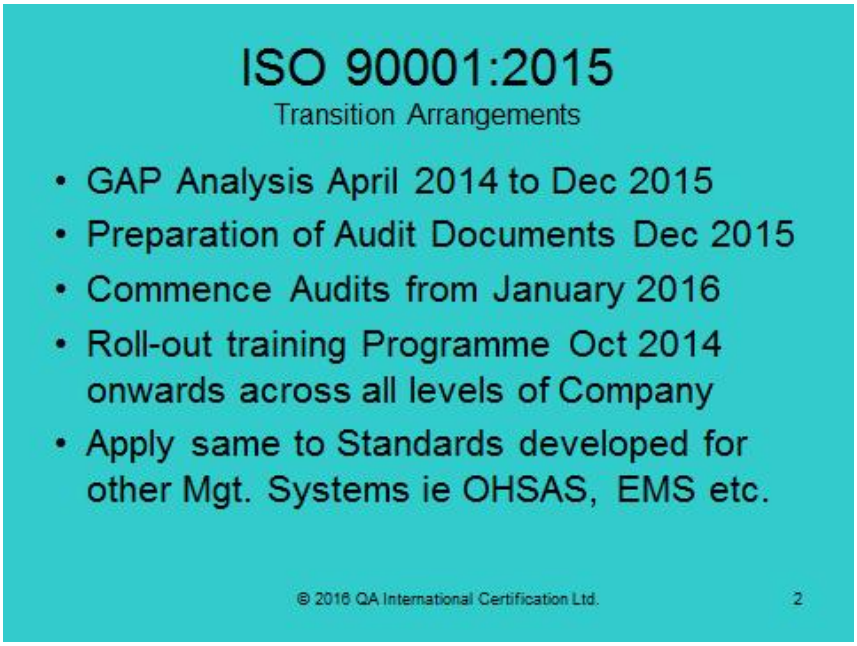
Customer Information Bulletin

ISO 9001:2015 TRANSITION

QA International (QAICL) has now completed a review of the requirements, documented within the new ISO 9001 Standard. This follows previous reviews and initial preparations over the last 12 – 18 Months, whilst the Standard was at Final Draft stage. Information that may be of assistance to potential and existing Customers considering implementation of the new Standard is now presented in this bulletin.

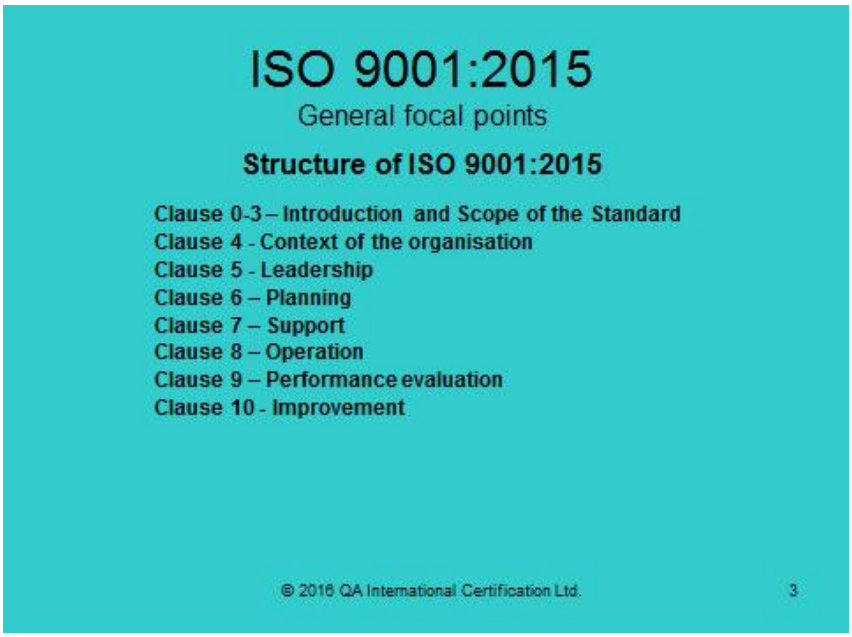
Of fundamental importance, is that customers conduct their own evaluation or 'gap analysis' to determine an approach to the implementation of the Standard in their own organisation, within the transition period ending 15/09/2018. This should be supported by amendments to system(s) and training of staff, in preparation for their new Certification from QAICL. As usual, the technical resources of QAICL are on hand to answer any customer enquiries, and Audit Staff will be available, to clarify any areas of concern whilst conducting their Audits for Initial Certifications, or maintenance of existing Registration through Surveillance or Re-Certification.



This is an extract from QA International's own transition plan for example, Slide provided courtesy of QA International (Training) Limited, all rights reserved…

The New Standard places an emphasis on the involvement of 'Top Management' within the Organisation, in the Design, Implementation, Resourcing, Management and Ongoing Improvement of the Organisation's Quality Management System (QMS). This is where QAICL Auditors will start, when conducting a review of Customer arrangements for meeting the requirements of the Standard.

The structure of the new Standard, whilst containing many of the original requirements from the 2008 version, is laid out under new headings as follows:



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A key change arising within the format of the new Standard, is that of the documentation structure, which should align itself with the needs of the Organisation, it's Processes and the expectations of Stakeholders. These can include employees, statutory and regulatory bodies, it's direct customers, and even, in certain circumstances, the 'end user' of the product or service being supplied, at the latter part of the supply chain.

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All of these elements also need to be considered, in order for the organisation to incorporate 'risk based thinking' in the design of its QMS and associated processes. The correct balance of documented information will support process objectives and targets, which are determined to accord with the key Performance Indicators derived from the Corporate Business Plan or Strategic Management of the organisation. Such information should also help the organisation to maintain evidence of compliance with the new ISO 9001:2015 Standard and thereby, help provide the basis of supporting information for any subsequent claims against its products or services as due diligence defence.

The extent and quality of documented information available within the organisation can influence audit duration to some extent, for the purposes of a Certification Audit. This is determined under the Stage One audit, when it is necessary to confirm the Extent and Scope of the QMS in advance of a more detailed audit at Stage Two of initial assessment.

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The approach of the Stage Two audit, whether for transition purposes or in response to a fresh application, is dictated by several items including; the scope and complexity of the organisation, the extent and maturity of its Processes and associated support systems, and the surrounding management system. New 'Core' areas to be addressed under the new Standard must be clearly understood and demonstrated by the auditee including concepts such as; 'Organisational Context', 'Process Approach', 'Effective Leadership' and 'Risk Based Thinking'. It is the 'structure' surrounding these elements, that differs between organisations and can thereby affect the evidence gathering efficiency of Auditors. In fact this fundamental concept applies for all types of audit.

Whilst the QMS must be suitable for the organisation's requirements, it is the responsibility of QAICL's trained and competent Auditors, to establish the extent of compliance of the system, in relation to the requirements of the assessment standard concerned. This will be no different with the transition to ISO 9001:2015, whereby a balance shall be maintained between interview and sampling techniques to establish compliance with the assessment standard, for the purposes of securing an appropriate Certification Decision.