

ISO 9001 & Quality Management Systems

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The following is an overview of the general requirements and responsibilities of having a Quality Management System (QMS) and of being ISO certified:

- The organisation shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.
- The organisation shall:
 - Identify the processes needed for the quality management system and their application throughout the organisation
 - Determine the sequence and interaction of these processes
 - Determine criteria and methods needed to ensure that both the operation and control of these processes are effective
 - Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
 - Monitor, measure and analyse these processes
 - Implement actions necessary to achieve planned results and continual improvement of these processes
- These processes shall be managed by the organisation in accordance with the requirements of this International Standard.
- Where an organisation chooses to outsource any process that affects product conformity with requirements, the organisation shall ensure control over such processes. Control of outsourced processes shall be identified within the quality management system.

The QMS referred to above should include processes for management activities, provision of resources, product realisation and measurement.

The following points should be useful in considering how to implement QMS in order to comply with the ISO standard:

- Always think of ISO and Quality Assurance as a means of improving business quality and performance, not just getting a certificate on the wall.
- Define what you do, how you do it, who is responsible, how you monitor it.
- Quality should be considered holistically. There should be a consideration of the overall business process – the interactions of each element of the business.
- Need to react to external changes (e.g. legislation, standards, etc.)

- Streamline business processes as appropriate; continually review your own documentation.
- Gauge your performance at an informal level among clients. Plotted over time, this can allow for new and innovative thinking in the way you do business.
- The present ISO 9001:2008 refers to the 'Management Representative' (S.5.5.2). However, the Standard is currently under review and when ISO 9001:2015 is released, there will be greater Quality Assurance responsibility on all parties – not just the Management Representative.
- The results of audits should allow a review of the effectiveness of the management system, with a view toward improving it.
- Use the information the company has about its individuals to enhance overall improvement of the company.
- Institute criteria to govern how your suppliers (e.g. sub-consultants) are selected. Are they meeting your needs fully? Periodic evaluation of this is important and any necessary actions resulting should be recorded.
- Where possible, base company performance objectives on data streams (analysis of data).
- External auditors will look for the following three essentials in their assessment:
 - Are reviews taking place?
 - Have Corrective Action Reports (CAR) been attended to?
 - Are internal audits being carried out?
- All of the recommendations or opportunities raised in the audit report by the external auditor must be responded to in some way.
- Think about factors that may affect internal audits such as new legislation, Codes of Practice, etc.
- Have an internal audit checklist and be prepared to modify it. It should not be rigid. The checklist must be made against your own business systems procedures.