

Quality Manual ISO 9001:2008 Compliance Summary

The new ISO9001:2008 standard has revised terminology which is summarised below. Our Manual is fully compliant with this standard as highlighted in the table.

Clause	Title	Changes	Our Document Reference	Relevant Section from our Quality Manual Procedure
Clause 4.1	General Requirements	<p>Processes are monitored, but may not need to be measured.</p> <p>If the company outsources a process, the company is still responsible to ensure that both customer and legal requirements are met.</p> <p>Reads “determine the processes” instead of “identify the processes”.</p> <p>Realistically this needs to be treated the same as any other purchase.</p>	QM 001 Quality Manual	<p>Should the site be required to outsource any process that may affect product conformity to the defined standards of the Quality Management System then the site will assume control over this process. This is further defined in the Control of Sub-Contract Processes.</p>
Clause 4.2.1	General Documentation Requirements	<p>Quality management system documentation also includes records.</p> <p>One document may include the requirements of one or more procedures and vice versa</p>	<p>QM 003 Document Control</p> <p>QM 005 Record Control</p>	<p>All records determined by the company to be necessary to ensure the effective planning, operation and control of the process are controlled and maintained within the quality system.</p>

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Clause 4.2.3	Control of Documents	Not all external documents have to be identified and controlled; only those needed for the planning and operation of the quality management system.	QM 003 Document Control	All documents determined by the company to be necessary to ensure the effective planning, operation and control of the process are controlled within the quality system.
Clause 4.2.4	Control of Records	Records being "maintained" changed to having them "controlled". Controlling the records means to regulate their use rather than maintained which could be interpreted as kept in good condition.	QM 005 Record Control	All records determined by the company to be necessary to ensure the effective planning, operation and control of the process are controlled and maintained within the quality system.
Clause 5.5.2	Management Representative	The Management Representative must be a member of the company's own management and should not be merely a consultant.	QM 001 Quality Manual	The Technical Manager is a member of the Senior Management team and has been appointed the Management Representative.
Clause 6.2.1	General Human Resources	Work affecting "product quality" changed to work affecting "conformity to product requirements".	QM 010 Resources and Training	It is company policy that all personnel affecting conformity to product requirements shall be competent on the basis of