Quality Management System QMS - ISO 9001:2008
Compliance Audit Tool

PERFORMANCE REQUIREMENTS

#	Requirement	Auditor Note / Guidance	Example / Intent of Evidence	Evidence Sighted	Comments / Recommendations	Potential	Actual
1 General Requirements							
1.1.1	Has the system been documented, implemented, maintained and continually improved in accordance with ISO 9001?	*a) Determined the processes needed and their application?* *b) determined the sequence and interaction of these processes?* *c) determined criteria/methods to ensure effective operation and control of these processes?* *d) ensured availability of information necessary to support the operation and monitoring of these processes?* *e) monitored, measured where applicable, and analysed these processes?* *f) implemented action necessary to achieve planned results and*	*Quality Management Plan* *Management tool*				
1.1.2	Have all amendments to the Quality Management Plan been recorded and communicated?	*a) Review pane evident in PLAN*	*Quality Management Plan*				
2 Control of Document Requirements							
2.2.1	Does the quality management system exist	*a) documented statements of quality policy and quality objectives?* *b) a quality manual?* *c) documented procedures and records required by ISO 9001: 2008?* *d) documents, including records, determined to be necessary to ensure effective planning, operation & control of its processes?*	Quality Management Plan				
2.2.2	Has a quality manual been established and maintained	*a) scope of QMS including details and justification of any exclusion?* *b) the documented procedures established for the QMS or reference to them?* *c) a description of the interaction between the processes of the QMS?*	Quality Management Plan				
2.2.3	Has a documented procedure been established to define controls	*a) approve documents for adequacy prior to use?* *b) review and update as necessary and re-approve?* *c) ensure changes and current revision status of documents are identified?* *d) ensure relevant versions of applicable documents are available at points of use?* *e) ensure documents remain legible and readily identifiable?* *f) ensure documents of external origin determined by the organisation to be necessary for planning and operation of the QMS are identified and their distribution controlled?* *g) prevent unintended use of obsolete documents and to apply suitable*	Quality Management Plan				
2.2.4	Control of document	*a) Are records established to provide evidence of conformity to requirements and of the effective operation of the QMS controlled?* *b) Do records provide evidence of effective operation of the QMS?* *c) Do records remain legible, readily identifiable and retrievable?* *d) Has a documented procedure been established that defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?*	Quality Management Plan Related documents Document control numbering system				