

Checkpoint	Notes	Comply Y/N
<p>Documentation may include:</p> <ul style="list-style-type: none"> • Quality Management Policy, Manual and Procedures • Operational Procedures • Operational Checklists • Training Documents • Documents sent to/used by customers • Bills of materials • Price Lists • Product & Test Specifications • Art work and packaging proofs • Service Level Agreements • Method Statements • Documentation sent to and from suppliers • Design documentation <p>External documents may include:</p> <ul style="list-style-type: none"> • Product/service legislation • Product/service design standards • ISO standards and other industry requirements • Customer policies and specifications • Service level agreements • Contracts • Customer designs <p>For each type of documentation assess the core controls as follows:</p> <p>For internal documents:</p> <ol style="list-style-type: none"> 1. Is there a documented procedure available to define controls for all document types identified? 2. Does this procedure identify who can approve and issue each type of document? 3. What is the process for updates and changes? <ol style="list-style-type: none"> a. Are changes approved before issue? Is this approval by the same 'authority' as the initial issue or has this changed? If so is this adequate to control the document issue? b. Are documents reviewed from time to time to make sure they are still relevant and being followed? If there is a review period is there evidence this is being followed or are documents out of date? 		

<ul style="list-style-type: none"> c. Are hand amendments allowed in the procedure and if so are these properly authorised? 4. Does each document have a clear title/identification and is there a clear revision level for the document? 5. How are changes to documents communicated to the people who need to use the document? 6. How are documents of each type circulated? Are the right documents available at each point of use? 7. If this is controlled by a computer system, what happens if this system is not available? a. Are any documents used at other/remote locations? If so how do you know the correct version is being used? 8. For external documents – what controls are in place to identify any updates to: <ul style="list-style-type: none"> a. Legislation and standards? b. Changes to customer designs and requirements? c. Changes in any contracts/service level agreements? 9. What happens to obsolete documents? <ul style="list-style-type: none"> a. When new documents are issued are you sure the old documents are removed from use? Is it obvious which documents are obsolete or is there a chance of confusion? b. Are old documents retained for reference and if so are these identified? 		
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