AS9110 Internal Audit Checklist

4. REQUIREMENTS	Observations/Comments	Results
4. Quality Management System **4.1 General Requirements**		
a) Check for documentation of the processes included in the QMS		
b) Check for information on the relationship and sequence of the QMS processes.		
c) Ask Management if operation and control of processes is effective. How do they know if it is effective?		
d) Ask how they are able to know if resources and information needed to support processes have been provided.		
e) Is there any information on the effectiveness of processes?		
f) How are improvements made to processes?		
What processes does your organization outsource? How is the process controlled?		
Additional Questions:		
4.2 Documentation Requirements		
Is there a list or other means of identifying other documentation required by your QMS?		
Does your quality system documentation include the documentation required by the standard?		

a. Quality Policy and Objectives b. Quality Manual c. Procedures		
Check for documents for planning and control of processes: for example work instructions, quality plans		
Are there records to show that you follow any existing documented procedures and work instructions? (This will be verified in more detail in the records section)		
Any documentation required by regulatory authorities		
Are all employees aware of procedures that are relevant to them?		
Are the relevant procedures available to employees?		
Does the organization have a method of giving access to customers and regulatory authorities?		
Additional Questions:		
4.2.2 Quality Manual		
Review the Quality Manual if available.		
a) What is the scope of your QMS?		
b) What processes have been excluded? Is this appropriate?		
c) Is a description or illustration of the interrelation of the processes included?		
d) Does it clearly indicate the relationship between the standard and the documented procedures?		
Additional Questions:		
4.2.3 Control of Documents		

Do you have a formal procedure regarding the control of documents for your organization?		
a) Are documents approved?		
b) Are documents updated and re-approved?		
c) How are changes identified?		
d) Are documents available to those that need to use them? How is the most current version kept in the correct locations?		
e) Can users easily identify documents? Can users easily read the documents?		
f) If documents such as reference books, users manuals and other outside documents are used, how are they controlled?		
g) How are old documents handled? Are they removed from use? Are they labeled? Is a copy maintained for reference? Is there any chance that an old document could be used by accident?		
h) How are document changes coordinated with customer or regulatory authorities? (When required by contracts)		
Additional Questions:		
4.2.4 Control of Quality Records		
Is there a documented procedure in place for records control?		
Where are records kept? Is this identified somewhere so users can easily find records? Can users identify the records? Are the records legible?		

How are the storage time, storage requirements, and disposition identified?		
Does the records procedure include a process for controlling records created by or retained by suppliers?		
Are records available for review by customers or regulatory authorities? (When required by contracts or regulations?)		
Is there a configuration management process in place?		
Additional Questions:		