

Audit by Process Method

How the Audit is Identified	How this could be documented	Document review	Perform the audit
<p>Audits are identified by Process name.</p> <p>The process could have the same name or similar name as an ISO clause.</p> <p>OR</p> <p>The process could be an organization-specific process.</p> <p>The Audit Assignment tells <u>the numbered paragraph in the Quality Manual</u> where the process is described or provides the name of the document that describes the process.</p> <p>The Quality Manual or a referenced Operating procedure or document <u>MUST identify processes that interact with this process.</u></p> <p>The Audit assignment (or process documentation) must identify <u>the ISO clauses that contain one or more requirements that apply to the process.</u></p>	<p>The Quality Manual is a "road map." It will tell you which of the following methods is used.</p> <p>The Quality Manual will fully describe how the process is performed and who is responsible for doing what.</p> <p>OR</p> <p>The Quality Manual will make a summary statement and make a reference to an Operating Procedure that describes how the process is performed and who is responsible for doing what.</p> <p>OR</p> <p>The Quality Manual will make a summary statement and tell who is responsible for the process and make a reference to the method that is used to control the process -- for example, forms used or a software program that is used to carry out the steps of the process.</p>	<p>For an organization-specific process, review documentation for the process. →</p> <p>If the process relates to an ISO clause for which there is a written procedure or method: Review the written explanation for the Clause in <u>Manual 1 Requirements ISO 9001 Explained Adobe PDF computer file</u> This tells you what the ISO Clause requirements mean.</p> <p>Then, use the <u>ISO 9001-2008 Checklist questions</u> to determine: Does the Quality Manual or a referenced document or method (in any format) include how each ISO clause requirement is met?</p> <p>Your audit checks to see if the ISO requirements of other processes that apply to this process are being followed.</p> <p>Use the <u>Universal Items Checklist</u> to check for ISO requirements that apply. ISO clause numbers are listed in the left column. Write N/A in the Comments box if a question does Not Apply to the process.</p> <p>On the last page of the <u>Universal Items Checklist</u>, identify ISO clauses (that are not on this Checklist) that have requirements that this process must follow. List what these ISO requirements are that this process must follow. Check these items during the audit.</p>	<p>For an organization-specific process:</p> <ol style="list-style-type: none"> 1. Is the organization's documentation followed? Plus 2. Use the <u>Universal Items Checklist</u> to determine if the ISO requirements of other processes that apply to this process are being met. <p>If the process relates to an ISO requirement clause and is documented:</p> <ol style="list-style-type: none"> 1. Use the questions for the Clause from the <u>ISO 9001-2008 Checklist</u>. Read the instructions for using the Checklist. <p>Is the organization's method for meeting the ISO requirements being followed? Plus</p> <ol style="list-style-type: none"> 2. Use the <u>Universal Items Checklist</u> to determine if the ISO requirements of other processes that apply to this process are being met. <p>For all audits: Identify any nonconformances found. Have someone confirm that this is a nonconformance by signing your paperwork.</p> <p>Put an X in the right margin of your paper at the location of a nonconformance. This helps you locate the item when writing the audit report</p>
<p>If the process is NOT DOCUMENTED, DO THIS → (Read across the page.)</p> <p>The Audit Assignment (or process documentation) must <u>identify the ISO clauses that contain one or more requirements that apply to the process.</u></p>	<p>OR</p> <p>The Quality Manual will state, "We do (whatever the process does)," identify who is responsible for the process, and what <u>processes interact with the audited process.</u></p>	<p>Your audit checks to see that the ISO requirements that apply to the process are followed.</p> <p>Use the <u>Universal Items Checklist</u> to check for ISO requirements that apply. ISO clause numbers are listed in the left column. Write N/A in the Comments box if a question does Not Apply to the process.</p> <p>On the last page of the <u>Universal Items Checklist</u>, identify ISO clauses (that are not on this Checklist) that have requirements that this process must follow. List what these ISO requirements are that this process must follow. Check these items during the audit.</p> <p>You will interview the person(s) who performs this process.</p>	<p>If the process is not documented:</p> <ol style="list-style-type: none"> 1. Interview the person who performs the process. Ask the person to describe how the process is performed. Write down how the process is performed as the person describes it. 2. Observe the process being performed (if possible) to see if what is done matches the verbal description. 3. PLUS, ask the questions on the <u>Universal Items Checklist</u> that apply to the process. 4. AND, <u>records should provide evidence that what was to be done was done and that requirements are met.</u>

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