



6 Floor Audit - Review an Undocumented Process

- ◀ Use the Universal Items Checklist to interview the person.
 - ◀ Have the person describe the process steps.
 - ◀ Observe the process in action to ensure steps match the verbal description.
 - ◀ Review records with an **emphasis** on ensuring all output goals are met.
- ➔ Get a copy of any document with a nonconformity (when possible).
 - ➔ Have all nonconformities confirmed by another person.

6 Review an undocumented process

An auditor may be assigned to audit an undocumented process. An undocumented process means that there is not a written description, such as an Operating Procedure or Work Instruction, that tells how work should be performed.

An undocumented process can exist because:

1. The ISO 9001:2008 standard does not require a written procedure for every process.
2. Many organizations use training to inform people how work should be done instead of using written documentation. This includes both formal training programs and on-the-job training.
3. The work to be done may be computer-system driven and not require written documentation.
4. The person who performs the activity has the education, skill or experience required to do the work.

The Quality Manual tells you some information about the process

When a process is not documented, the Quality Manual must identify:

- ___ the process name
- ___ who is responsible for the process (the process owner)
- ___ who is responsible for the process activities (who does what)
- ___ what processes interact with the process

When a process is only identified in the Quality Manual, the Quality Manual must state who is responsible for the process and the activities performed, even if the steps of how the process is performed are not documented. The exception to this is a very small organization (usually less than 10 people) where everyone knows who does what. In this situation, the process owner must be identified in the Quality Manual and you and everyone else in the organization should know who performs activities that relate to the process.

Clause 4.2.2 Quality manual states that the Quality Manual must include "a description of the interaction between the processes of the quality management system." An interacting process is a process that provides input to the process or receives output from the process. Some processes also depend on other processes to do something for them, such as a forklift to move product. A process that provides a service is also an interacting process. These processes are referred to as "dependencies." Interactions that a process has with other processes can be 1) stated in writing in the Quality Manual, 2) can be identified by making a reference to a document that describes the interaction, and 3) can be shown on a flowchart that explains the interaction in a written statement somewhere on the flowchart.

Therefore, even if there is not a written description of how activities are performed, the Quality Manual identifies who does what — so you know who to interview. And, the Quality Manual tells you what processes interact with the process — so you know that you should be checking to see that these interactions are happening as they should be happening.

Information about output requirements

The process must meet the output requirements for the work performed. The output requirements are the specifications (or acceptance criteria) that must be achieved. This information will be found on the quality plan (traveler or routing card) for the work order. The output requirement for a process could be to just complete the operational step(s) and indicate that this activity did take place.

Information that indicates work was done and that requirements were met

Records must indicate that the work to be done was done and that requirements have been met.

Evidence that work was completed could be a sign-off on a traveler or a sign-off on the computer record for the work. A completed form, document, or report also provides evidence that work was completed.

Providing evidence that an operational step was completed may be the only record requirement that a process must meet. This situation exists because a number of activities may be performed before an inspection or test takes place.

The record of an inspection or test indicates if the requirements (or acceptance criteria) have been met. A completed form, document or report should contain all the required information.

An undocumented process is audited against the ISO 9001:2008 standard

The Auditor "audits against the standard" when the process is not documented and when there is minimal documentation for the process. A checklist or a flowchart that only lists the steps that must be performed is considered minimal documentation.

To "audit against the standard" means that the auditor checks to see that all the ISO 9001:2008 requirements that apply to the process are being followed. The ISO 9001:2008 checklist for the clause is used when the undocumented process relates to an ISO clause.

All undocumented processes must follow the requirements of other ISO clauses that apply to the process. The ISO requirements that apply to the process are included on the Universal Items Checklist in the form of questions that the Auditor asks when the process is audited. When you performed Document Review, you selected the appropriate version of the Universal Items Checklist to use and the questions that apply to the process.

6.1 Use the Universal Items Checklist to interview the person

When you are assigned to audit an undocumented process that relates to an ISO clause, you use both the ISO Checklist for the clause (in Tab 5 in the Auditor Manual) and the appropriate version of the Universal Items Checklist for the process.

You use only the appropriate version for the Universal Items Checklist to audit the process when the process does not relate to an ISO clause.

The Auditor determines the number of people to interview when several people perform the activity. The rule is that the number of people in the sample should allow you to determine if a problem does or does not exist. The Auditor also checks to see who was interviewed the last time the process was audited and selects different people to interview this time.

6.2 Have the person describe the process steps

You use the Universal Items Checklist to perform the audit and do this:

- ___ Ask the person to describe how the activity is performed.
- ___ Write down the activity steps on the back of page 1 of the Universal Items Checklist.

6.3 Observe the process in action to ensure steps match the verbal description

After writing down the activity steps, do the following:

- Ask the person to demonstrate how the activity is performed. This should match the verbal description.
- If the activity relates to an ISO clause, how the activity is performed should meet the ISO requirements.
- Ask any questions from the ISO Checklist about how the activity is performed that were not included in the person's verbal description.
- Ask the rest of the interview questions on the Universal Items Checklist.
- Ask to see the output of the activity and check to see if the output meets requirements.

If the person is not engaged in presently doing the activity, you can ask the person to come and find you when he or she next performs the activity. If this activity is not being performed today, you need to be satisfied with the verbal description of the activity. In this situation, you ask to see the output of the last work that was performed. For example, if the person prepares purchase orders, ask to see the last purchase order that was prepared.

Summarize interview results and thank the person interviewed

The results of the interview should be summarized with the person who is interviewed. Thank the person you interviewed for his or her cooperation.

6.4 Review records with an emphasis on ensuring all output goals are met

Records should indicate that the work to be done was done and that requirements have been met.

"Just completed work" records are checked to determine:

- 1. if the traveler sign-off or computer sign-off is present (if applies)
- 2. if the specifications (or acceptance criteria) for outputs have been met (when applies)
- 3. if forms, documents, or reports contain the required information

The Records Review Form may be used to review maintained records.

Maintained (stored) records are checked to determine:

- 1. if they contain the information they should contain
- 2. if the output goals (requirements) were not met, the record should indicate what action was taken to meet requirements — this must be documented.
- 3. if rework was done, the record should indicate the item was reinspected or tested and that requirements were met
- 4. if output goals (requirements) were not met, the record should indicate what corrective action was taken, if any. Corrective action taken should be appropriate to the situation.
- 5. if the records are maintained as defined on the Records Matrix or other document that defines the requirements for maintaining the type of record

There is a special emphasis on checking records when a process is not documented.

Check the training records of the people you interviewed.

6.5 Get a copy of any document or record with a nonconformity (when possible)

6.6 Have all nonconformities confirmed by another person

All nonconformities found must be confirmed by another person before leaving the area audited.

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