Auditing When Documents Aren't Available

Someone who was involved only in developing a management system often has the perspective that the documentation required to audit it is constraining or bureaucratic. However, a perspective shift often occurs when the same individual becomes an auditor.

As an objective source of information about requirements or results, documentation is a valuable ally to auditors. They can plan assessments by familiarizing themselves with the standards to which management systems operate (e.g., ISO standard, company manual, or procedures), and determine the degree to which the systems are compliant by reviewing the records produced by them.

However, documentation requirements were reduced in revisions of some standards, including ISO 9001:2000, which now specifically requires very little documentation. (See "ISO 9001 Documentation Requirements.") Although most organizations are likely to exceed documentation requirements, auditors still must determine whether more documentation is necessary. The notes in ISO 9001's section 4.2.1 provide criteria that may be included in such a consideration, such as the organization's size, complexity (which could include products, processes, roles, geography, and number of suppliers), and how competently employees carry out their activities without documentation.

ISO 9001:2000 Documentation Requirements

Documents required

- Quality manual (4.2.2)
- Quality policy (5.3)
- Quality objectives (5.4.1)
- Quality procedures
  - Document control (4.2.3)
  - Records management (4.2.4)
  - Internal audits (8.2.2)
  - Nonconforming material (8.3)
  - Corrective action (8.5.2)
  - Preventive action (8.5.3)

Records required

- Employee competency records (6.2.2)
- Management review records (5.6)
- Customer contract/order reviews (7.2.2)
- Design input records (7.3.2)
- Design review records (7.3.4)
- Design verification records (7.3.5)
- Design validation records (7.3.6)
- Design change records (7.3.7)
- Supplier evaluation records (7.4.1)
- Process validation records (7.5.2)
- Traceability records (7.5.3)
- Unsuitable customer property reports (7.5.4)
- Calibration records (7.6)
- Audit records (8.2.2)
- Product inspection records (8.2.4)
- Nonconforming material records (8.3)
- Corrective action records (8.5.2)
- Preventive action records (8.5.3)

The International Organization for Standardization (ISO) has further provided "Guidance on Documentation Requirements" (ISO/TC 176/SC 2/N525R, March 2001), which is available on its Web site (*www.iso.org*). One relevant statement from the document notes that "objective evidence does not necessarily depend on the existence of documented procedures, records, or other documents, except where specifically mentioned in ISO 9001:2000."

So what can auditors do if a process they're auditing isn't documented? Following are several suggestions:

- *Use the standard*. As ISO's "Guidance on Documentation Requirements" states, "It is acceptable for this activity to be conducted using as a basis the relevant clause of ISO 9001:2000." For example, although an organization might not mention in a procedure what it does with measuring devices that aren't in use, ISO 9001 states that the instrument must "be protected from damage and deterioration during… storage." This requirement can be evaluated by looking for physical evidence of damaged or deteriorated instruments. Examining instruments, interviewing personnel who use or calibrate the devices, or perusing the calibration database might determine such evidence.
- *Ask the designer or owner of the process.* Someone in the organization decides how each process should be carried out. For a manufacturing process, this is likely to be a process engineer, but in most organizations it's the process owner who oversees the process on a daily basis. This individual by definition has the responsibility for knowing the process objectives and how they must be achieved. Activities this individual defines during an audit interview then become the process requirements to which the assessment can be done.
- *Ask the trainer*. For some positions a particular training event is set up that includes someone to prepare personnel who will work in the process. These trainers, then, provide instruction that can be used as overall guidelines for assessing the process.
- *Ask the individuals who perform the process*. Sometimes an individual responsible for overseeing a process might not have the technical expertise required to perform the activities. He or she may therefore rely on the competencies of the process owners to determine the appropriate actions. In this case an auditor can interview the individuals who perform the process to obtain descriptions of what's required, which can then be used to compare against observed activities and any subsequent records.
- *Look at the process objectives.* The purpose of organizational and process objectives is to establish performance metrics that allow the organization to predict how well customer and stakeholder requirements will be met. Auditors can ask what activities are necessary to achieve the objectives, assess the degree to which metrics indicate unstable or incapable performance, and how consistently responses to performance problems are managed.
- *Ask the customer or other process stakeholders.* In many ways this is the best option because it's better aligned with any management system standard's true purpose—i.e., ensuring that customer and stakeholder needs are met. Although most auditors probably wouldn't contact external customers or stakeholders, most organizations have many internal customer or stakeholder supplier relationships that can be assessed. Thus, auditors can ask those who receive the output of most processes how well their requirements are met.

Good Process Management Practices

The eight quality management principles used for development of ISO 9001:2000 provide a framework for understanding good process management practices. Following are five principles, along with typical components of each, that could be used for developing auditor questions, regardless of whether or not there is related documentation.

Customer Focus – Every process has one or more customers/stakeholders. Individuals within the process should know: 1) who their customers/stakeholders are, 2) the requirements of their customers/stakeholders, 3) the activities required to fulfill the requirements, and 4) how well the requirements are being met. If the requirements are not being met actions should be taken to modify the process in such a manner as to improve performance, or customers should be notified that their requirements cannot be met.

Leadership – Every process (regardless of level – e.g., the entire organization, a functional department, or a work group) has a process owner who is responsible for the process. The process owner should ensure that: 1) customer/stakeholder requirements are known and communicated, 2) policies and processes are defined that will fulfill the requirements, 3) adequate resources (equipment, people, information, funds) required in order for the processes to be carried out are provided, 4) objectives and metrics (of both effectiveness and efficiency) that will allow determination of how well the processes are working or for control of the processes are developed, 5) process metrics are evaluated for stability and capability and improved as needed.

Involvement of People – Everyone in the organization should be aware of overall organizational policies and objectives as well as those of their department and/or work group. They should work with process owners to align day-to-day activities with policies and objectives, and communicate any problems that retard the ability to achieve them. They should set and achieve individual objectives that continually improve their contributions to the objectives.

Process Approach – Every activity in the organization should be seen as a part of a process that has: 1) customer/stakeholders who have requirements, 2) activities, resources and controls for meeting those requirements, 3) suppliers who provide those resources, and 4) objectives and metrics for monitoring, controlling and improving performance of the process. Feedback is requested of customers/stakeholders, and provided to suppliers, on how well requirements are being met.

Systems Approach to Management – It is recognized that the management system is a set of interrelated processes, and that optimizing the entire system may require sub-optimizing some processes. Cause and effect relationships between processes are known and the overall system assessed in order to determine which processes may be most in need of improvement, based on their contribution to overall performance.

Although assessing a management system might be easier when the system is heavily documented, this can also foster auditor laziness and a tendency to focus solely on compliance. Understanding good process management practices, such as those listed in "Good Process Management Practices'" will encourage auditors to examine nearly any situation, regardless of available documentation. Of course, more care may be needed to triangulate or validate findings, but using good process management practices will provide a better focus on system performance, which is the ultimate objective of any audit.

Notes: Most organizations will have far more procedures and records than specifically required by the ISO 9001:2000 standard. Throughout the standard there are several indications that processes should be defined, and doing so is often easier via documentation. In addition, ISO 9001 derivatives (e.g., ISO 13485 for medical devices, ISO/TS 16949 for the automotive industry) require more documentation due to the greater degree of regulation and/or perceived risks involved in those industries.

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