
ISO 9001 INTERNAL AUDITING PRIMER

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Auditing Aids

MAN IS A TOOL USING ANIMAL ... WITHOUT TOOLS HE IS NOTHING, WITH TOOLS HE IS ALL.

THOMAS CARLYLE

Auditing Aids

Auditing Aids are presented in the following topic areas:

- **Quality manual basics**
- **Procedures/instructions**
- **Process checks**
- **Records**
- **Summaries/binders**
- **Progress checks**
- **Audit strategies**
- **Common audit findings**
- **Progress checks**

Introduction

There are numerous requirements in the ISO standard, and auditing the standard can be an overwhelming task. Fortunately, the requirements of the ISO standard can also facilitate the audit. Many of the requirements become handy auditing aids. The requirement for the quality manual to include or reference applicable procedures is an excellent example of this. Imagine determining the adequacy of a company's quality system without knowing what procedures are included.

Quality Manual Basics

The ISO 9001 standard requires the auditee to have a documented quality manual. The purpose of a quality manual is to define the purpose and scope of the quality system. In many companies it addresses more than just the ISO standard. The quality manual establishes the policies for the organization. When a company writes a quality manual, the best rule to follow is to keep it simple.

One key portion of the ISO 9001 standard, which is also a tremendous aid to the auditor, is the requirement for the quality manual to include, or make reference to, the documented procedures. When auditing for adequacy, this documentation structure is very useful when verifying compliance.

Quality Manual Basics (Continued)

Quality manuals and the supporting documentation structure must address the “shall” statements of the standard. These are the requirements of the ISO 9001:2000 standard. It should be noted that earlier versions of ISO 9001 contained “must” and “will” statements: Coverage of these items was also mandatory.

When determining the adequacy of the quality system, an auditor should use the document structure requirement to identify where each “shall” item is covered. If a “shall” item is not covered in the quality manual, look for compliance in a procedure. The auditor should reference the documentation structure to identify the relevant procedures.

If the “shall” requirement is not covered in a procedure (or the quality manual), an auditor should look for coverage in a work instruction. If the “shall” requirement appears to be absent, the auditor can create an audit question to uncover that fact during the audit. The auditor could also request the documentation that covers the requirement prior to the audit. Failure to address a “shall” requirement indicates an ineffective QMS implementation ;and is a major noncompliance.

Quality manuals come in two broad styles. One type is written following the ISO 9001 standard from beginning to end. This type of quality manual is the easiest to audit because it is structured consistent with the standard’s structure.

The other type of quality manual follows the business processes of the company. This type is more difficult to evaluate for compliance to the ISO 9001 standard because it is not directly aligned with the standard. It is the auditor’s responsibility to keep track of the documentation compliance to the standard’s requirements.

Although it is not required by the standard, companies will sometimes develop a matrix of the standard requirements and where they are addressed in the company's documentation structure. This matrix is often completed during ISO program preparation to ensure that all requirements are covered.

This matrix creates a gap analysis because it shows the differences between the desired state and the actual condition. This approach also makes it easy for the company to confirm that they have addressed all of the requirements. This summary matrix is also a valuable tool for the auditor. However, the auditor must still verify the effective implementation and maintenance of the QMS requirements.

Written Procedures

Each written procedure must have a meaningful purpose. Before writing a procedure ask the following:

- Why is this procedure needed?
- Who is going to use this procedure?
- What is the level of education, experience, and training of the user?
- What will happen if the procedure is not written?

As a general guideline, written procedures are needed where the absence of a written instruction would negatively influence quality. The company should provide general guidelines for writing procedures in order to give them uniformity and readability. When writing procedures, it is best to avoid the temptation to over document.

The procedure author must keep the user (audience) in mind. The procedure needs to be written to the level of the user. A less detailed instruction will suffice when the user is well-trained, skilled, educated, or experienced. The procedure addresses the information needed for the user to execute the task. Written documents should identify who is responsible for performing the duties contained in the document. When auditing, remember that the standard requires the procedures to be accessible to the workers who use them.

Work Instructions

Work instructions tend to be more detailed documents than procedures. Generally, work instructions state the exact action needed, such as:

- Record the voltage at test point B
- Let the adhesive dry for 30 minutes
- Forward the test report to the supervisor

Work instructions come in many different forms. Examples include assembly drawings, routing sheets, checklists, check sheets, build samples, and online data entry prompts. Work instructions can be listed on a form (like: please print name, address, phone number). Work instructions are required, where their absence would negatively influence quality. Remember that trained, educated, and experienced workers need less detail.

Progress Checks

✓ Progress Checks	
6.1	<p>The ISO 9001 standard requires the organization to:</p> <ul style="list-style-type: none">I. Create a documentation and requirement matrixII. Write a quality manualIII. Define the documentation structureIV. Create an internal audit procedure <p>A. III only C. II, III, and IV only B. I and III only D. I, II, III, and IV</p>
6.2	<p>Quality manuals:</p> <ul style="list-style-type: none">A. Contain requirements that must be internally auditedB. Can be organized by clauses or business practicesC. Establish the policies of the companyD. All the above
6.3	<p>Procedures must be written:</p> <ul style="list-style-type: none">A. For every activity in the companyB. Where adverse effects would occur without oneC. For everyone's work areaD. For the record control system only
6.4	<p>Work instructions include:</p> <ul style="list-style-type: none">A. Written work detailsB. PrintsC. Routing sheetsD. All the above
6.5	<p>Written procedures and work instructions:</p> <ul style="list-style-type: none">A. Are detailed based upon the user's training, education, and experienceB. Must be approved by the ISO committeeC. Are not covered by the document control elementD. Are controlled by the auditing department

Records

Records are the ultimate audit resource. The auditee demonstrates compliance to the ISO requirements by providing records that support the audit item. Records come in every imaginable form. Examples of records that show compliance to the ISO standard are:

- **Audit checklists - ISO 9001, internal auditor**
- **Meeting notices - management reviews**
- **Agendas - management or design reviews**
- **Internal audit reports**
- **Inspection reports - receiving, in-process, final inspection**
- **Design verification and validation**

Records provide the objective evidence which is noted in the audit working papers. Objective evidence is collated and integrated by the auditor to form an observation. An observation can be either positive or negative. Negative observations may combine to form a finding if the picture is significantly wrong. Findings must be reported in the exit meeting and audit report.

ISO quality records requirements detail a number of items necessary for effective management control. First and foremost, an identified company employee must be responsible for each and every record.

When auditing an ISO element, its compliance must be supported by records. Some ISO clauses require (documented) records, which is a useful auditing tool. These are identified by the appropriate identifying number.

On the following pages are ISO 9001:2008 records as identified by the authors of this *Primer*. Based on a company's size and business model, some of these records may not be required. In many cases, more than one record may be necessary to fulfill a requirement. A company may have many records outside of ISO 9001 coverage. However, those that fulfill ISO requirements must be identified and maintained.

**VI. AUDITING AIDS
RECORDS**

Records (Continued)

Clause	Description	# Records	Comments
4.2.4	Control of Records	(3)	conformity, legibility, control, etc.
5.6.1	Management reviews	1	records maintained
6.2.2	Competence and training	1	training, skills, experience
7.1	Product realization	1	product meets requirement
7.2.2	Product requirements	1	product requirement review
7.3	Design and development	(6)	
7.3.2	inputs	1	
7.3.4	reviews	1	
7.3.5	verification	1	
7.3.6	validation	1	
7.3.7	change review	2	both changes and change review
7.4.1	Supplier evaluations	1	results of evaluations and actions
7.5.2	Process validation	1	validation demonstrations
7.5.3	Identification and traceability	1	identification records
7.5.4	Unsuitable customer property	1	records of unsuitable property
7.6	Measuring devices	(3)	
	Non-standard techniques	1	
	Previous results	1	
	Calibration verification	1	
8.2.2	Internal audit	1	defined procedures and results
8.2.4	Release authority	1	indicate person(s) releasing
8.3	Nonconforming product	1	records of nonconformities
8.5.2	Corrective action	1	results of action taken
8.5.3	Preventive action	1	results of action taken
	Totals	25	

Table 6.1 A Breakdown of ISO 9001:2008 Required Records

ISO 9001:2008 Records

- 4.2.4 Records shall be maintained to provide evidence of conformity to requirements and effectiveness of the quality management system.**
- 4.2.4 A documented procedure shall be established for the identification, storage, protection, retrieval, retention time, and disposition of records.**
- 4.2.4 Records shall remain legible, identifiable, and retrievable.**
- 5.6.1 Records from management reviews shall be maintained.**
- 6.2.2 Maintain appropriate records of education, training, skills, and experience.**
- 7.1 Records needed to provide evidence that the realization processes and resulting product meet requirements.**
- 7.2.2 Records of the results of the (product) reviews and actions arising from the review shall be maintained.**
- 7.3.2 Design and development inputs relating to product requirements shall be determined and records maintained.**
- 7.3.4 Records of the results of the (design and development) reviews and any necessary actions shall be maintained.**
- 7.3.5 Records of the results of the (design and development) verification and any necessary actions shall be maintained.**
- 7.3.6 Records of the results of the (design and development) validation and any necessary actions shall be maintained.**
- 7.3.7. Design and development changes shall be identified and records maintained.**
- 7.3.7 Records of the results of the review of (design and development) changes and any necessary actions shall be maintained.**
- 7.4.1 Records of the results of (supplier) evaluations and any necessary actions arising from the evaluation shall be maintained.**

ISO 9001:2008 Records (Continued)

- 7.5.2 Records are required for validation of production and service provision where the resulting output cannot be verified by subsequent measurement.**
- 7.5.3 Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.**
- 7.5.4 If customer property is lost, damaged, or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records.**
- 7.6 Where no suitable standards exist, the basis used for calibration or verification shall be recorded.**
- 7.6 The organization shall assess and record the validity of measuring results when the equipment is found not to conform to requirements.**
- 7.6 Records of the results of calibration and verification shall be maintained.**
- 8.2.2 Records of the (internal) audits and their results shall be maintained.**
- 8.2.4 Records shall indicate the person(s) authorizing release of product for delivery to the customer.**
- 8.3 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.**
- 8.5.2 Records of the results of (corrective) actions are required.**
- 8.5.3 Records of the results of (preventive) actions are required.**

Some authorities claim that only 19 records are necessary, not the 25 identified above. They exclude the three 4.24 elements as general record requirements, combine the two 7.3.7 change review statements into one record, and consolidate the three 7.6 calibration and verification statements into the same record requirement.

Summaries

Managers constantly use summaries of information as tools to make judgments. These tools can also be used as auditing aids by internal auditors.

Companies that conduct and review audits have learned to “present” information to the auditor. These companies build management summaries to show compliance. This is often done with financial records where good practices help create a good audit trail. The same applies to quality audits.

The audit schedule presented in Section V is a good management tool. When the audit schedule is enhanced to show the lead auditor, audit team member, and the status of the audit activities, it becomes a great management tool.

A summary of audit activities is what a company will present to the registrar auditor to show compliance to the ISO internal auditing element 8.2.2. The registrar auditor will normally pick several of the internal audits to review the individual, detailed, support records - such as the audit notification, the audit work sheets, the audit report, corrective action request, corrective action responses, and follow-up verification audits.

Generally, the internal audit schedule summary is kept by management or the audit authority. The detailed records should be kept by the lead auditor in a file or a notebook. The auditor’s files may be centrally located or kept with each individual lead auditor. Such details should be included in the internal audit procedure.

Files and Binders

Just as summaries are important auditing aides and management tools, files or binders are also great auditing aids. One file (with all the audit records for one internal audit) helps any concerned party organize the audit details and address action items one at a time, while keeping a working history of the audit. These records, if presented during an audit, will help facilitate the process.

Companies often use binders or files to show compliance to many ISO elements. Common areas include management reviews, employee training records, equipment calibrations, contract reviews, customer supplied materials, and corrective and preventive actions. Incorporating summaries, files, and binders into the management process can greatly improve the presentation of objective evidence. Many companies have gone to electronic documentation systems which greatly facilitates documentation efforts. Assessors have found that auditing is faster using EDS.

Progress Checks

✓ Progress Checks	
6.6	Records are: A. Offered as objective evidence B. Defined by each company C. Retrievable D. All the above
6.7	Usually a company's documentation system includes: A. The quality manual B. Procedures C. Work instructions D. All the above
6.8	Quality records include: A. Management review minutes B. Internal audit reports C. Calibration records D. All the above
6.9	Internal audit records may include: A. Audit notices and schedules B. Audit working papers C. Audit reports and corrective action requests D. All the above
6.10	A company which has learned to "present" an audit will: A. Create summaries to show the status of ISO 9001 requirements B. Support the audit activity with a file or binder of individual records C. Use internal audits as preparation for third-party and customer audits D. All the above