18 Records

18.1 INTRODUCTION

When an auditing firm comes to appraise a business' operation for certification to either ISO 9001 or ISO 14001, the auditor will be requesting and evaluating physical evidence of conformance to the specified requirements. Management must make readily available records to demonstrate how effectively their organization is implementing the standards. These documents or "records" and the control of them is over and above the requirements of the document control process found under ISO 14001 (Element 4.4.5) and ISO 9001 (Element 4.5).

Both ISO 9001 and ISO 14001 have the potential for generating a large quantity of records, and without some form of control system, these records may become disorganized and/or unable to be readily located. As a result, the two standards have a requirement to write and implement a procedure to identify and maintain all quality and environmental records. These documents can be in either hardcopy (paper) or softcopy (computer/electronic) form as long as they are readily available and retrievable by personnel who need them.

18.2 COMPARISON OF THE STANDARDS

Table 18.1 shows a side-by-side comparison of the two standards and you will notice that they are almost identical. This table, however, has been expanded to include ISO 9004 and ISO 14004, the guideline documents for the two standards. By including them you will get a much broader picture of the requirements. In general, records management is fairly straightforward and, essentially, there is no reason for the two standards to be substantially different.

ISO 9001 and ISO 9004 contains some very specific requirements regarding customers and subcontractors which do not have a comparative requirement in ISO 14001. Specifically, ISO 9001 states that:

> pertinent quality records from the subcontractor shall be an element of these data and, where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

ISO 9004 states that:

> policies should be established concerning availability and access of records to customers and subcontractors and pertinent subcontractor documentation should be included.

TABLE 18.1
Correlation of "Records" Requirements

ISO 9001		ISO 9004		ISO 14001		ISO 14004	
Section	**Requirement**	**Section**	**Requirement**	**Section**	**Requirement**	**Section**	**Requirement**
The supplier shall establish and maintain documented procedures for …		The supplier shall establish and maintain documented procedures as a means for …		The organization shall establish and maintain procedures for …		The key features include …	
4.16 (i)	identification	17.1	identification	4.5.3 (i)	identification	4.4.4	identification
4.16 (i)	maintenance and	17.1	maintenance	4.5.3 (i)	maintenance and	4.4.4	maintenance
4.16 (i)	disposition of quality records.	17.1	disposition of pertinent quality records	4.5.3 (i)	disposition of environmental records	4.4.4	disposition
4.16 (i)	collection, indexing, access, filing, storage	17.1	collection, indexing, access, filing, storage			4.4.4	collection, indexing, filing, storage
Pertinent quality records from …				These records shall include …			
4.16 (ii)	the subcontractor shall be an element of these data.			4.5.3 (i)	training records and		
				4.5.3 (i)	the results of audits and		
				4.5.3 (i)	reviews		
All quality records shall be …		All documentation should be …		Environmental records shall be …			
4.16 (iii)	legible	17.3	legible	4.5.3 (ii)	legible		
		17.3	readily identifiable	4.5.3 (ii)	identifiable and		
				4.5.3 (ii)	traceable		
		17.3	dated, clean				

				Environmental records shall be …			
4.16 (iii)	stored and			4.5.3 (ii)	stored and		
4.16 (iii)	retained	17.3	maintained	4.5.3 (ii)	maintained		
in such a way that they are …		quality records should be be …		in such a way that they are …			
4.16 (iii)	readily retrievable in facilities that provide suitable environment to	17.1 17.2 17.3	retrieval readily retrievable for analysis retrievable	4.5.3 (ii)	readily retrievable and	4.4.4	retrieval
4.16 (iii)	prevent damage or deterioration and to prevent loss.	17.2	protected in suitable facilities from damage, loss and deterioration	4.5.3 (ii)	protected against damage deterioration and loss		
Retention times of quality records shall be …		Quality records should be retained for a specified time …		Their retention times shall be …		4.4.4	retention
4.16 (iii)	established and	17.3	defining retention times	4.5.3 (ii)	established and		
4.16 (iii)	recorded.			4.5.3 (ii)	recorded.		
Quality records shall be …		The quality system should require that…		Records shall be …			
4.16 (ii)	maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.	17.2	sufficient records be maintained to demonstrate conformance to specified requirements and verify effective operation of the quality system.	4.5.3 (iii)	maintained, as appropriate to the system and to the organization, to demonstrate conformance to the requirements of this International Standard.		

18.3 WHAT IS A RECORD?

A record is defined in the dictionary as a "collection of related items of information (as in a database) treated as a unit." Although a *document* control program and *records* control program appear to have some overlap, there are basic differences between them. *Document control* is mainly concerned with the establishment of procedures that ensure the quality process will function in accordance with the International Standards or any other codes and regulatory requirements. It also determines how procedures are to be created and modified or changed. In contrast, *records control* has its primary focus on the supporting documentation that verifies whether or not the procedures are effective. Records provide information to monitor and measure the quality or environmental management system and to implement the corrective action process.

18.3.1 Types of Records

The following are examples of quality and environmental records which require control:

- Legislative and regulatory requirements
- Inspection reports
- Testing data
- Permits to operate
- Qualification reports
- Environmental aspects and associated impacts
- Training reports
- Internal audit reports
- External audit reports
- Monitoring data
- Maintenance reports
- Calibration data
- Inspection reports
- Cost reports
- Customer inquiries and questionnaires
- Customer complaints
- Details of nonconformances
- Material Review reports
- Drawings
- Material/product specifications
- Management reviews
- Meeting minutes
- Supplier and subcontractor reviews and information and
- Procedures and manuals

Records must include any charts and databases (spreadsheets) that assist in monitoring the system. As you can see this is a very long list and is by no means exhaustive.

TABLE 18.2
Records Retention Requirements

Record Type	Retention Time (yrs.)
Environmental: hazardous waste tracking logs	3
Environmental: Material Safety Data Sheets (MSDS)	30
Environmental: test results, waste analysis, etc.	3
Environmental: air emissions monitoring	2
Environmental: aspects, impacts and programs	5
Management Reviews: meeting minutes, objectives progress, etc.	3
Contracts: agreements with customers (i.e., POs, contracts, etc.)	7 after warrant expiration
Contracts: customer order correspondence	4
Customer: inquiries, questionnaires and complaints	7
Design Reviews: reports	permanent
Design Reviews: laboratory notebooks	permanent
Design Reviews: data, drawings, specifications	15 after discontinued
Manufacturing: process data (i.e., charts, etc.)	3
Training: education and certification records	10 after termination
Training: job descriptions and responsibilities	5 after superseded
Purchasing: Supplier purchase orders	7
Purchasing: Supplier evaluations and quality data	15
Purchasing: Supplier corrective actions	7
Audits: external and internal	7
Calibration and Maintenance	15

18.4 RETENTION REQUIREMENTS

In most cases, the quality system will not be affected by specific regulatory requirements for retaining records. Contractual arrangements with suppliers, subcontractors and customers will generally stipulate those requirements. Table 18.2 gives examples of suggested retention times for various quality documents. Included in this table are retention times for various environmental records and most of them are timeframes established by law. All other records, such as meeting minutes, are generally at the discretion of an organization's management and I have included arbitrary retention times for this example. This can be included in the procedure in the next section.

18.5 IDENTIFICATION, COLLECTION, INDEXING, STORAGE, ACCESS, FILING, MAINTENANCE, AND DISPOSITION

In order to describe all of these requirements, I will again write a procedure based on the format utilized throughout this book. Again, this is just an example, and you must tailor yours specifically to the needs of your own organization.

Purpose This procedure defines the control requirements for records within the organization and outlines the methods used in the identifying, collecting, filing, storage, maintenance, retrieval and disposition of quality and environmental records.

Scope This procedure applies throughout the company and all personnel who generate and maintain records of any type (see list in Appendix B).

Definition of terms

- A *Record* is any unit of information that is recorded either on paper, microfilm, microfiche, computer tape or disk or any other media.
- An *Environmental Record* is a record maintained for either legal compliance (EPA), international standards or company requirements
- A Quality Record is a record that is evidence of conformance to product specifications, technical requirements, contracts and regulatory authorities (ISO 9001).

Referenced documents

- ISO 14001, Element 4.5.3, Records
- ISO 9001, Element 4.16, Control of Quality Records

EH&S precautions NA

Precedence If there is a conflict between this procedure and a customer requirement or regulatory agency, the latter shall take precedence.

Responsibilities

- Each department or area which maintains records of any type shall be responsible for complying with the requirements of this procedure.
- Each department or area is responsible for proper labeling and packaging of records and contacting storage vendor for permanent storage.

Procedure

Collection and Filing

- All records are collected at the point of origin and filed. Types of records are listed in Appendix A.

Retention

- Retention times for records are listed in Appendix A.
- All records are to be retained for the minimal time period indicated.
- A master file shall be kept by each department or areas as to what records have been sent to permanent storage.

Transfer to Permanent Storage

- Fill out proper storage vendor forms.
- Fill out proper labels and affix to each package, box or carton.

Retrieval from Permanent Storage

- Fill out proper retrieval form from storage vendor.
- Contact storage vendor for transfer.

Disposal of Records

- Complete proper forms provided by the storage vendor.
- Vendor will dispose of records under proprietary procedures.

18.6 WHAT AUDITORS WILL LOOK FOR

There are four key questions which an auditor will consider when appraising compliance to this section. First of all, is there evidence that an organization has given consideration to the types of records which must be controlled? Second, has the organization developed a documented procedure for managing records? Third, has the organization identified and tracked key performance indicators (along with corresponding data) to monitor and measure progress against objectives and targets and, ultimately, compliance with the quality and/or environmental policy? Fourth, has the organization developed a system to make the records and other information available to all personnel? If you can safely answer "Yes" to all of these, the audit results should not result in a nonconformance.