Using ISO 15489 as an Audit Tool

ISO 15489, the first international standard devoted to records management, provides a comprehensive and practical basis for auditing full and partial records management programs

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ISO 15489 (1:2001 Information and Documentation – Records Management – Part 1: General) is the first international standard devoted to records management. It was developed from the Australian standard (AS 4390.1 - 1996) and provides detailed specifications for the structure, content, and implementation of records management programs. The guidance it contains is applicable to records management for any organization and covers all media.

At the Core

This article

- examines using ISO 15489 as the basis for auditing a records management program
- discusses complying with standards and regulations when auditing a records program
- provides tips on audit information gathering and report writing

The standard is intended to provide a framework for planning and implementing a records management program. The comprehensive nature of the standard with regard to current and non-current records and the clear categorization of its requirements also makes it an obvious choice on which to base audits of records management programs.

A critical review of the standard as a basis for an audit is important. It is critical to walk through the preparation phases for the audit, including the development of assessment tools based on the standard, the audit process itself, and audit report writing. To ensure its newly implemented records management program complied with industry best-practices, one small European pharmaceutical company used ISO 15489 to help guide it through those critical processes. Examples from an actual audit of a newly developed records management program involving the pharmaceutical company's non-current, clinical trials department records provide many lessons for any organization that wants to use or test the standard in its own records management program.

Methodology, Background Research, and Scoping

The methodology for an audit has four main components:

1. Initial background research and scoping of project
2. Preparation, including familiarization with the company's records management program documentation, and development of audit tools to establish compliance with ISO 15489
3. Audit information gathering
4. Report writing

The first component involves dialog

with the records manager to gather enough data to estimate the project's size and time requirements. The data required includes information about the company, its mission, and functions; the number of employees; details about the records management operation; and the context of the audit. This information is crucial to scoping the project, estimating time required, and allocating time to the various phases of the audit process.

In this instance, the audit scope contained:

- The records of one department of the organization (although there was a realization that good records management practices could be transferred to other parts of the company)
- The non-current phase of the records life cycle
- Paper records only, because the records management program did not yet include digital media

The audit context was:

- A young pharmaceutical company
- Limited functions to be considered

The records management system had not yet been implemented; consequently, the audit would not be large or lengthy, there would be few record series to cover, and there would be no user base to canvass. So why was the audit undertaken? There were two main reasons: the pharmaceutical company's records manager was new to records management and wanted to make sure she had set up a system that was compliant with accepted best practices; and the pharmaceutical industry's strong audit culture. The records manager intended to roll out the system to other areas and wanted to ensure that it was a good one before doing so.

Since the audit, the pharmaceutical company has been searching for a full-time qualified records manager – a need that was identified in the audit report as a result of the records manager only spending about 10 percent of her time on records management. That was not necessarily something the company expected to come out of the audit, but the company has since taken advantage of the findings to improve its records management program.

Preparation

Preparation for auditing a records management program consists of:

- Reading and evaluating record management documentation provided by the records manager (See Table 1)
- Developing an evaluation tool that will map collected data to ISO 15489 (See Table 2)

Reading through the assembled records management program documentation has a dual purpose: it provides a complete overview of the program and its components, and it allows the auditor to assess the documentation for compliance.

Mapping audit findings to the standard can be done through use of a form or checklist designed for this purpose. Developing such a checklist, or audit assessment tool (AAT), involves turning the relevant requirements of ISO 15489 into a series of questions. The checklist

Table 1:
Checklist of Documentation Required for Records Management Audit

Relevant organizational structure chart	
Mission statements for organization and/or department	
Records management mission statement	
Records management policy	
Records management procedures (might be a manual) used by the records management team, including any in-house training material or details of other training	
Specifications for automated records management systems for paper records	
Specifications of records management systems for digital records	
Retention schedules	
Access authorizations	
Accession records	
Documentation on records destruction or contracted-out services	
Written specifications for shelving, boxing, and storage facilities	
Vital records inventory	
Vital records protection procedures, including recovery in event of disaster	
Business continuity plan	
Agreements with any third-party service providers for business continuity services	
Surrogacy program (digitization or microfilm/fiching) documentation	
Staff job descriptions both within and outside records management team	

Table 2:
Section from Part 1 of the Audit Assessment Tool Dealing with the Regulatory Environment

Statutes, Case Laws, Standards	*Considerations*
• Records • Archives	Any national archival law covering records, including storage standards
• Access	Any legislation governing access to records
• Privacy and data protection	Concerned with records containing personal data
• Evidence	If required as evidence in court of law, are records available? Do they meet requirements to be used as evidence? (Should be addressed later in the AAT.)
• Electronic commerce	Do the records meet the requirements of legislation pertaining to electronic commerce?
• Access to public information	"Access to information" legislation that may affect the way records are kept and access obligations
• Environmental recordkeeping legislation	Are records required by environmental legislation being created and retained?
• Regulations governing	What industry-specific regulations affect sector-specific environment recordkeeping?
• Regulations governing general business environment	Health and safety
• Mandatory standards of practice	These could be industry-specific or department-specific (for example, legal counsels in the United Kingdom need to maintain records of continuing professional development)

or form will need to be modified to reflect what the records management program covers, whether the full records life cycle or only a segment of it. Do not underestimate the length of time this can take; allow at least two days.

The AAT can be divided into two parts: the first focuses on assessing compliance with the standard proper in terms of records management; the second reflects the requirement for compliance with any relevant regulatory bodies' guidance on recordkeeping. The final product can be quite long and should be very detailed. Tables 2, 3, and 4 provide examples of an AAT developed for the audit undertaken. Comparison with ISO 15489 gives an idea of the tool's practical use (see "ISO 15489-1:2001 Sections Useful for Auditing" on page 52).

Auditing Regulatory Environment

Section 5 of the standard specifies recordkeeping practice. It deals with the regulatory environment, including those regulatory obligations and standards of practice pertaining to the industry/sector, as well as national/international law, best practice, codes of conduct and ethics, and identifiable community expectations. Because this is an international standard meant to be applied globally, it does not give detailed guidance on which legislation or regulations have a bearing on records management, so research into the relevant regulatory environment will be needed. It is useful to compile a list of legislation and regulations likely to pertain to the particular recordkeeping environment in which the audit is operating. The list can be reviewed by the records manager and other interested colleagues, such as the legal team and the quality control department, so that their knowledge and expertise can be fed into the AAT. The list for the pharmaceutical industry, for example, included items such as:

- International law/agreements
- European Union (EU) directives
- National Archives law
- National Freedom of Information legislation
- Data protection legislation
- Environmental legislation pertaining to recordkeeping
- Legislation covering businesses and how they are constituted and run
- Industry-specific regulation (in this case, FDA regulations and the EU Directive 2001/83/EC relating to medicinal products for human use)
- Health and safety legislation/regulations

Other factors considered included:

- ISO 9000 registration
- Electronic records management system specifications (such as the EU-funded Model Requirements)

Table 2 shows the AAT section that deals with the regulatory environment.

In an assessment tool tailored for a specific organization, regulatory requirements should be listed with cross-references to other AAT sections regarding compliance. For example, "access" to records of certain industry sectors may be governed by regulation; environmental legislation might oblige organizations to make records available; and the public may also have a right to access government information. That the company provides appropriate access will be recorded in the standard's sections dealing with access in detail, which are:

7.2.5 Records management requirements: characteristics of a record: usability

8.3.6 Design and implementation of a records system: designing and implementing records systems: access, retrieval, and use

9.7 Access

Section 9.2 of ISO 15489, "Determining How Long to Retain Records," outlines good practice with respect to development of retention schedules. Not surprisingly, it does not stipulate what the retention schedule format should be or give any detailed retention data. The standard's guidance can be turned into a set of questions, as shown in Table 3.

Table 3:
Section from Part 1 of the Audit Assessment Tool Dealing with Retention

• Is the retention schedule appropriate?
• Is retention schedule compliant with legislation and regulation?
• Are all stakeholders' needs met by retention schedule? (What are their needs?)
• Are records of no continuing value being destroyed promptly?
• Is how to properly destroy records properly documented in the manual/ procedures?

When it comes to assessing compliance with respect to records retention, the auditor needs to refer back to the regulatory environment and consider general business requirements as well as the needs of individual record creators and users.

Industry-Specific Compliance Assessment

Heavily regulated industries have to comply with very detailed specifications for the types and content of records to be created and kept. Such specifications provide the basis for a checklist of required records and enable an assessment of the record creation phase of the records management programs being audited. The pharmaceutical industry, for example, must comply with FDA regulations and an EU directive from the International Committee on Harmonisation. The FDA Guidelines for Good Clinical Practice Section 8 sets out "Essential Documents for the Conduct of a Clinical Trial." The section gives detailed and stringent requirements for the types of documents that must be created by both sponsors of and investigators participating in clinical trials. The European Union, in Directive 2001/83/EC and "Detailed Guidelines on the Trial Master File and Archiving (2002)," adopts this defini-

Table 4:
Checklist of Required Records

Title of Document	*FDA Regulations/ICH Directive*	*Sponsor's file*	*Investigator's file*	*Retention Period*
Investigator's brochure	8.2.1			
Signed protocol and amendments (if any) and sample case report form (CRF)	8.2.2			
Information given to trial subject, including informed consent form advertisement (if used)	8.2.3			
Financial agreement(s) between sponsor and investigator	8.2.4			

tion of essential documents as its minimum. Therefore, only a detailed analysis of the FDA requirements would be required, augmented by attention to the EU archiving requirements to create a table that

- lists the documents to be created
- references the regulation that requires them
- specifies who should create them
- notes any specified retention period

Table 4 (page 50) suggests a format for such an initial listing.

From the table, it is possible to extrapolate two checklists of documents to be created by sponsors and investigators. The lists can be used to show that the clinical trial documentation being created is compliant with FDA and EU Good Clinical Practice regulations governing the sector as required by ISO 15489. Furthermore, the analysis of regulatory retention requirements and EU procedural requirements for accession, tracking, and destruction of essential documents provides a baseline that can be used for observing whether the appropriate records are being retained for the required time and whether procedures are in place to comply with the EU archiving requirements. Such comparison highlights conformance with the ISO requirement to observe the sector-specific regulatory environment.

Analyzing regulations to establish the essential foundation for sector-specific recordkeeping is a time-consuming exercise. However, it greatly assists in understanding the nature of the records in the program and provides useful checklists for auditors and audited alike. Such checklists can be an appendix to the final report and used for future reference.

Audit Information Gathering

The audit itself can be divided into several parts. First, the record management program documentation provided prior to the audit can be checked against the AAT. This is a two-way process, as the documentation provides answers to the audit questions, and the AAT also lists program expectations. For example, the policy's objective is to create and manage authentic, reliable, useable records, capable of supporting business functions and activities for as long as required. Expectations include that the policy

- is communicated to and implemented by the whole organization
- is endorsed by high-level manager/committee
- has compliance responsibility assigned
- includes a definition of legislation, regulation, and standards governing records management
- makes provision for a review process

The second stage of the audit is a series of interviews with stakeholders in the records management process. These might include:

- Senior manager
- Records manager

Table 5:
Audit Questions for Staff

Questions for records creators:	
Do you know about the records management policy?	☐ Yes ☐ No
Have you had records management training?	☐ Yes ☐ No
Do you have access to a manual or set of procedures for records management?	☐ Yes ☐ No
Describe how you create records.	
Describe how you file records.	
Describe how you retrieve records.	
Describe how you review or destroy records.	
Do you know what records you are expected to create to comply with legislation?	☐ Yes ☐ No
Do you know what records you are expected to create to comply with industry regulations?	☐ Yes ☐ No
Do you know what records you are responsible for making sure others (either within the organization or outside contractors) create and retain?	☐ Yes ☐ No
Do you know what a retention schedule is and how to use it?	☐ Yes ☐ No
Do your records meet your requirements and needs?	☐ Yes ☐ No
Questions for records management staff:	
Do you have enough authority?	☐ Yes ☐ No
Do you get enough support from management?	☐ Yes ☐ No
How long have you been doing records management work in this organization?	
Have you had records management work experience in previous employment?	☐ Yes ☐ No
What training have you had?	
What training (if any) do you feel you need?	

- Records management staff member
- Records creator
- Representative from an interested department (e.g., quality management)

Table 5 (page 51) lists questions to ask staff as part of the audit. Questions can be tailored to suit the particular legal and regulatory environment.

Finally, the audit must involve observing the processing and storage areas and using the audit tool as a checklist to assess compliance with relevant sections of the standard.

Report Writing

Strictly speaking, the audit itself can be documented solely by the completed audit tool form. However, this may not be the most helpful way of communicating to the operating staff what the audit has discovered, and it is always worth

ISO 15489-1:2001 Sections Useful for Auditing

Records management programs should encompass:

- Setting policies and standards
- Assigning responsibilities and authorities
- Establishing and promulgating procedures and guidelines
- Providing records management services
- Designing, implementing, and administering specialized records management systems
- Integrating records management into business systems and processes
- Appropriate staff training

Regulatory environments must be identified, including:

- National and international law and regulations
- Sector-specific regulation
- Standards and codes of best practice

Main principles of records management include:

- Records are created to support business activity, provide accountability, and comply with regulatory environments.
- Records management rules should be embedded in all business processes requiring documentation.
- Business continuity should ensure identification and protection of vital records.

The characteristics of records as defined in the standard:

- Records should accurately reflect the communication, action, or decision.
- Records need to be linked to metadata such as format and business and documentary context.
- Records should be authentic, reliable, usable, complete, and unaltered.

Functionality and components of records systems:

- Ability to document records transactions
- Control of physical storage
- Support of a range of distributed storage and custody options
- Facility for controlled conversion and migration of digital records
- Provision for controlled access, retrieval, and use
- Facilitation and implementation of retention and disposition decisions

Records management processes and controls:

- Determining records to be captured into the system
- Specifying metadata that needs to be linked to or embedded in the records
- Deciding how long to keep records (retention schedule development and operation)
- Registration of records
- Classification (within business context, vocabulary controls, indexing and referencing.)
- Storage and handling
- Access
- Tracking
- Implementing retention and disposition
- Documenting records management processes

Monitoring and auditing should encompass:

- Internal monitoring of system to ensure compliance with it as well as required outcomes
- Internal or external audit
- Appropriate modifications to system
- Documentation of compliance, monitoring, and audit

considering producing a report as well. This allows the auditors to make specific recommendations, expand on audit findings as necessary, and perhaps most importantly, highlight good practice that is already in place. The completed AAT then has a context and the organization receives some pointers as to ways forward.

Examples of audit report content based on the standard include:

- Introduction
- Management Support
- Role of Records Manager
- Records Management Staff
- Vital Records and Disaster Planning
- Retention Scheduling
- Record Transfer
- Record Retrieval
- Records Management Database
- Box Labels
- Location Register
- Procedures and Documentation
- Storage
- Next Steps
- Conclusion
- Recommendations
- Appendices

Using the Standard as a Basis for Audit: Lessons Learned

The AAT essentially turns the standard's requirements into a series of questions that are tailored to the particular business sector as required. In practice, these questions cannot usually be satisfied by a "yes" or "no" option. Completion of the AAT, therefore, requires substantial interrogation of the records management program documentation, onsite inspection of procedures and processes, as well as face-to-face interviews in order to determine and document compliance with the standard. Analysis of the records management program documentation can be done prior to the site visit, which will allow both assessment of compliance (with respect to documentation) and raise questions to be answered during interviews and *in situ* inspection.

By its nature the standard is pitched at a high level, but it is comprehensive in its coverage of requirements for records management systems and, therefore, provides a sound basis for an audit. The standard's only self-confessed omission is its lack of coverage for those records selected as archives. If management of records is to be totally integrated from conception to disposal, then the archive cycle must be included. This is especially relevant in countries where archive legislation is in place.

In order to use the standard as an evaluation tool, the auditor must be able to relate its specifications to the details of the records management program in question. The auditor must be able to analyze the findings as itemized in the AAT and assess whether the program is compliant with the standard (or at least to what degree). Most audits should also include recommendations of how the program might be improved. The standard does not assist with this step, as it provides definitions and required elements rather than strategies and methodologies.

For example, in the course of investigations, the auditor may learn that a new IT system is being piloted. This may not fit into the AAT framework suggested by the standard, but it may impact the records management program. An experienced records manager/auditor will realize the IT system's importance and include analysis and recommendations on its possible effect in the audit report. It is the auditor and the records manager who are in a position to evaluate the context and specifics of the individual RM program and develop plans for improvement.

This small European pharmaceutical company required the audit to validate the policies, procedures, and operating framework for a records management program that, at the time of audit, covered only the non-current paper records of one department. Therefore, issues of auditing digital records management, current records, and wider use of the AAT outside the records management team cannot be discussed directly.

For example, there was no opportunity to investigate and develop assessment criteria for the requirements specified in the standard relating to characteristics of electronic records, their authenticity, reliability, integrity, and usability. But it was possible to determine whether records remained complete in their non-current records management regime. The question of how to test compliance with these requirements for current records remains to be answered.

Additionally, some records management activities had not yet been required – for example, the destruction of documents at the end of the overall retention period – but the AAT will measure whether compliant procedures are in place for activities that will be needed in the future. The structure of the standard is such that it is easy to identify sections that are directly relevant to the scope of an audit and those sections that are not applicable.

ISO 15489 provides a comprehensive and practical basis for auditing both full and partial records management programs. Approaching the standard from this perspective and using it to develop an AAT also provided the opportunity to thoroughly test the standard itself.

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