QSE 6 – Documents and Records

Key Concepts

This QSE focuses on the need to maintain all documents and records in a manner that ensures their confidentiality, traceability, completeness, uniformity, and ability to be retrieved and located in a time deemed adequate. This QSE also includes the need to ensure data integrity and that all data can be backed up and retrieved.

Key Terms

Backup: Digital data and/or physical storage containing copies of relevant data.

Confidentiality: The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure.

Data Integrity: The accuracy, completeness, and consistency of information resources.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

Document (verb): To capture information through writing or electronic media.

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany a product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the *RT Standards,* including information for document control.

Record (noun): Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record (verb): To capture information for use in records through writing or electronic media.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Records of activities performed.
- Record system.
- Master list of documents.
- An electronic record system, if applicable.
- Uniform storage media and ability to track newer technologies to older ones as needed.
- Evidence of document and record review.
- Evidence of standardized formats for all documents and records.
- Record retention periods.
- Record traceability.
- Data backup plans.
- Record change process.
- Obsolescence of records and disposition.
- Record destruction.

6. Documents and Records

6.0 Documents and Records

The organization shall ensure that documents and records are created, stored, and archived in accordance with record retention policies.

Guidance

Documents are written or electronically captured materials that define how or what is to be accomplished. Examples of documents include:

1. Policies.
2. Processes.
3. Procedures.
4. Forms that are designed to capture the desired outcomes. Forms are controlled in the same manner as documents. Forms should contain clear instructions for their completion. Once completed, a form becomes a record.

For a more detailed explanation on the difference between a policy, process, and procedure, see guidance for Standard 1.3.

Examples of appropriate document control include the following:

1. Laboratory forms (blank worksheets) should be identified with the name and location (city and state) of the laboratory.
2. Each form should have a title to indicate its use; columns and rows should be labeled to indicate the type of items contained.
3. Errors in documents should be corrected with a single-line strikeout through the written error, the correct data placed adjacent to the strikeout, and the initials or identification of the corrector adjacent to the correction. Correction tape or fluid should not be used.

In addition, each laboratory should identify 1) who will review the documents, 2) how they will be reviewed, including manner and scope, and 3) what level of authority will approve the final documents. The same person may perform all functions.

6.1 Document Control

The organization shall control all documents that relate to the requirements of these *RT Standards*. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.

Guidance

Standard 6.1, Document Control, is a commonly cited standard for nonconformances. Examples of the reasoning behind the nonconformances include the following:

1. Policies, processes, and procedures for document control are not being followed.
2. Outdated SOPs or forms are in use when they have been revised.

6.1.1 Format

Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual or published in the AABB *Technical Manual*) may be incorporated by reference.

G u i d a n c e

To promote ease of use, all documents that are created by the laboratory are required to be in a standardized format, although other external documents may be incorporated by reference. The documents should include the purpose, materials, equipment needed, and identified endpoints. Additional procedures developed by manufacturers or other laboratories (such as those found in an operator's manual) may be incorporated by reference and need not be in the standardized format. These other documents may not be used as a substitute for laboratory-developed operating procedures. Where procedures developed by manufacturers are incorporated by reference, the reference must include the insert or manual version number, and which procedure is referenced, if there is more than one. Incorporation by reference is intended for unmodified procedures. Modified procedures must be incorporated into the laboratory's own documentation.

6.1.2 Document Review, Approval, and Distribution

The document control process shall ensure that documents:

1) Are reviewed by personnel trained and/or qualified in the subject area.
2) Are approved by an authorized individual.
3) Are identified with the current version and effective date.
4) Are available at all locations where operations covered by these *RT Standards* are performed.
5) Are not used when deemed invalid or obsolete.
6) Are identified as archived or obsolete when appropriate.

6.1.3 Document Changes

Changes to documents shall be reviewed and approved by an authorized individual.

6.1.3.1 The organization shall track changes to documents.

6.1.4 Master List of Documents

The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the requirements of these *RT Standards*.

G u i d a n c e

All laboratories are required to maintain a master list of current policies, processes, procedures, and forms. The master list may be in printed or electronic format. It is recommended that a master list include the following information: title of document, holder (owner or person responsible) of document, and current version number of the document.

Laboratories may organize a master list by linking a policy with related processes, related procedures, and related forms. Alternatively, there may be a comprehensive list of all policies, another list of processes, a list of procedures, and a list of forms. It is not necessary to maintain a master manual of the text of all policies, processes, and procedures.

It is important to identify the individuals who control the master list. Often it is the individual departments that control the master list. For example, the department director's assistant might control the master list on their computer. The intent is that it is acceptable to have multiple master lists as long as the document control system is defined in the processes and procedures. Regardless of who controls the master list, executive management should always have a list of all departmental master lists or access to all departmental master lists.

The issue of a master list of documents is more complex for laboratories that are separated geographically. Some geographically separated laboratories have separate master lists for separate areas. For instance, the main laboratory has its own master list of processes and procedures, and its documents are labeled with a code that begins with ML and ends with a unique number; the Chicago laboratory (use "satellite laboratory") code begins with CL and ends with a unique number. A code on each page signals which area controls that particular document.

In some instances, departments include the master lists of other departments in their manuals so that staff can see whether a process or procedure already exists in another department.

6.1.5 Review of Policies, Processes, and Procedures

Review of each policy, process, and procedure shall be performed by an authorized individual at a minimum of every 2 years.

G u i d a n c e

The laboratory director should review all policies, processes, and procedures that affect relationship testing, including administrative policies. Written documentation of the laboratory director's review is required. This could be accomplished by initials and date of review for policies. Processes and procedures can be documented by a flowchart, and annual review can be documented by initials and date of review. Electronic documentation of directorial review is also acceptable. Directorial review cannot be delegated.

6.1.5.1 Review and approval by the laboratory director of new and revised technical documents before use.

G u i d a n c e

Document control requires that documents be revised in the same manner in which they are created. The laboratory should consider how and when changes to documents would be implemented. When revisions to existing documents are submitted for approval, those making decisions should have the appropriate information (and documented authority) to make the decision. Once changes to documents are made, personnel should be trained on the new processes or procedures.

The laboratory director is responsible for all technical documents used in the facility, and the review and approval of technical documents cannot be delegated.

6.1.6 Document Retention

The organization shall determine which documents shall be archived, destroyed, or made obsolete.

Guidance

When revised documents are distributed, obsolete documents must be identified. The word identification in this standard does not mean that all obsolete documents must be stamped or marked obsolete. Instead, the standard requires the laboratory to determine which, if any, documents should be archived.

6.1.7 Document Storage

Documents shall be stored in a manner that preserves integrity and legibility; protects from accidental or unauthorized access, loss, destruction, or modification; and ensures accessibility and retrievability.

6.1.8 Document Retrieval

The organization shall ensure that documents are retrievable in a timely manner.

6.1.9 The organization shall use only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these *RT Standards* are performed.

Guidance

A distribution list may help to direct where the new or revised documents should be delivered. The laboratory should consider whether to store the most current documents issuing paper copies or electronic files. A benefit of some electronic systems is that all staff can download a file at any time; however, only an approved limited group can make changes to files.

When revised documents are distributed, it may be helpful to provide a cover sheet that summarizes the changes or highlights changes through formatting (eg, underline and strikeout) so that employees do not have to perform a line-by-line comparison. If an errata sheet is distributed and employees make corrections to paper copies, they should be written in ink. Unless authorized, no written changes should be made to documents.

6.2 Record Control

The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.

Guidance

A record is information (captured in writing or in an electronically generated medium) that provides objective evidence that activities were performed or results were achieved, such as test records or assessment results (as defined in the glossary). Records are not complete until the activity is performed and documented. In addition, it is relevant to note that the Uniform Parentage Act (2002) of the National Conference of Commissioners of Uniform State Laws defines "record" as information that is inscribed on a tangible medium or is stored in an electronic or other medium and is retrievable in a perceivable form.

6.2.1 Records

Records shall be complete, retrievable in a period appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

Guidance

Records related to each relationship testing case and all quality control records are required to be retained for a minimum of 5 years or according to applicable law. To conform, the laboratory could save the electropherogram test results or photographs of the results as well as records of reagents, controls, and test conditions. At a minimum, the worksheet reflecting duplicate review and/or interpretations of results should be saved as part of the case file. The disclosure of or access to records should be controlled as an element of the laboratory's confidentiality policy. If a laboratory is acquired by another, the acquired laboratory's records should be retained according to this set of *RT Standards* and all applicable laws. Standards 5.1.12 and 6.2.8 apply.

6.2.1.1 The record system shall make it possible to trace any relationship test report or relationship testing service from its source to final disposition and to review the records applying to the specific relationship test report or relationship testing service.

6.2.2 Record Traceability

The records system shall ensure traceability of:

1) Critical activities performed.
2) The individual who performed the activity.
3) Date the activity was performed.
4) Time the activity was performed, if applicable.
5) Results obtained.
6) Method(s) used.
7) Equipment used.
8) Critical materials used.
9) The organization where the activity was performed.

Guidance

Each facility should define what is critical. What is critical may vary among different facilities. For example, if a facility has only one freezer, it may be critical. Test kits that require storage at a specific temperature may be another example of a critical material. Critical activities may also vary by facility. Many activities that could be considered critical are defined by various standards. The facility should look at critical activities in the context of these standards and define "critical" based on its processes. For example, review of electropherograms may be considered critical and can be performed twice manually, or the review may be performed electronically as a first review and manually as the second review. The facility is responsible for the traceability of the defined critical materials and activities.

6.2.3 Information to Be Retained

Records shall demonstrate that a material, product, or service conforms to specified requirements and that the quality system is operating effectively.

6.2.4 Legibility

All records shall be legible and indelible.