Robust Document and Record Management

Document control systems are required by clinical laboratory accreditation programs, such as the program offered through the College of American Pathologists. Despite this, document control often is an underappreciated and underutilized component of a comprehensive quality management system in the clinical laboratory setting. Therefore, it is important to understand the intent of proper document control systems, as well as the benefits such systems can provide.

Clinical laboratories are driven by well-defined policies and standardized procedures, but without a clear and accessible method for documenting its activities, a laboratory cannot be confident that it is consistently producing high quality results. With a well-designed document control system, the laboratory can ensure it utilizes only validated and verified practices that have been shown to produce high quality outcomes.

Document Differentiation

When discussing document and record keeping in the lab, it is easy to overlook the important distinctions that exist between terms used to describe various documents. Most commonly, laboratory documents consist of policies, processes, procedures, job aids, forms, and memos:

- A policy is a written statement of overall intentions and directions that directs the laboratory’s plans and activities.
- A process is a set of interrelated activities that transforms inputs into outputs.
- A procedure is a set of specified, stepwise instructions to carry out an activity or process. Procedures can be further classified into those that are technical, meaning they direct how to perform an analytical procedure (such as a CBC), and those that are non-technical (such as daily decontamination procedures or instrument maintenance).
- Job aids are abbreviated instructions for use at the location where an activity will be carried out, such as at a workbench.

I also propose an additional type of laboratory document: the memo. A memo can be considered a controlled document that contains temporary policy, process, or procedure information. Memos can have an expiration of 30 days unless otherwise indicated and allow quick, document-controlled communication to staff.

Governing these documents requires a master list. A document master list provides a means for the laboratory to track information about each document, including its unique identification number, name, version number, effective dates, author(s), reviewers, due date for next periodic review, and locations of any printed copies.

Document and Record Hierarchy

Documents Versus Records

These terms often are used interchangeably, but they are, in fact, distinctly different. Documents communicate information about how to perform an activity; they tend to be considered living, in that they must be updated and maintained. Examples of documents include policies, standard operating procedures (SOPs), process maps, job aids, and blank forms.

Conversely, records are permanent, static evidence of results achieved or activities performed.\(^4\) Perhaps the most important difference is that records cannot be changed. Examples of records include completed forms, proficiency testing results, competency assessments, validations, and verifications.\(^4\) Although regulatory attention is typically focused on document control or document management systems, management of records is equally important. Fortunately, document control systems can be utilized to manage records and can provide many of the same benefits to record management as they do for document management. Furthermore, records control is a requirement of ISO 15189\(^5\)—an international standard that details requirements for quality and competence in the clinical lab.

Document Control Systems

Whether researching a new system, or augmenting an existing one, a document control system should provide:

- A standardized format with a document numbering system (ie, a unique identifier for each document), which includes a method for identifying the document’s version
- A process for creating and revising documents, including formal approval and distribution of each new version
- A document master list (or inventory) of all documents and their locations
- A process to ensure document availability for all required users
- A method for archiving outdated documents in compliance with regulatory requirements\(^4\)

One of the most prominent benefits of a document control system, aside from regulatory compliance, is preventing outdated and/or obsolete documents from being accessed. In this way, all staff members access and follow the most current version of documents, which include the standardized, validated, or verified process sequences and instructions. Also, this facilitates more organized document retention practices, including easy identification of use and disposal dates for documents, in accordance with regulatory requirements.

By definition, a document control system is a computer-based program used to facilitate management and manipulation of multiple documents. Although it is possible to effectively control documents without an electronic or computerized software solution, this tends to be a viable option only for smaller laboratories that lack budget resources and an expansive library of documents. A number of benefits are associated with an electronic solution, including:

- Instant access to documents anywhere, at any time, via a Web-based platform. Gone are the days of trying to track down the one notebook that contains all of the procedures for the laboratory.
- Improved efficiency through electronic document routing for the review and approval of new documents and revisions. Electronic solutions make delivering documents and waiting for review and approval signatures unnecessary. Similarly, documents cannot get lost on a busy manager’s desk. Documents are routed electronically to the next approver or back to the author for revisions.
- The reduced use of paper means less physical storage space is needed and less money is spent on paper. Likewise, the lab becomes more environmentally responsible.
- With user-friendly indexing of documentation, the search functions in electronic document management systems allow you to access documents by keyword, thereby eliminating the antiquated activity of searching through a table of contents or the network looking for a document that might not be intuitively named.\(^6\)
- Security is improved as access is limited to authorized users, and screens can be programmed to time out.
- Many document management solutions provide secure audit trails that capture the identity of users who create or modify a document and the date/time at which the change was made.
- Users can receive automatic notifications and review acknowledgement when a document that they use is modified.
- Most systems provide guaranteed document recovery in the event of a disaster.

Document Control Tips

Assigning one or two point people, or document controllers, is crucial to maintaining consistency within a document control system. It also may be helpful, depending on the size of the laboratory, to train one person from each laboratory section to serve as a document controller in the event that the primary document
controller cannot address an urgent request in a timely manner. In addition, the following tips will help create a robust, adaptable control and management system for all documents and records:

- Use standardized templates to create consistency among documents and to ensure completeness.
- If a document is printed and not logged on the document master list, it is no longer controlled. The document controller must be aware of all locations of printed controlled documents in order to ensure proper updating with the release of new versions.
- Limit printing of laboratory documents. Printed documents may become outdated.
- If printing a document is necessary, print a watermark that says UNCONTROLLED on every copy. This alerts users that they may not have the most current version of the document.
- Adopt a policy that uncontrolled copies of documents (ie, those not logged on the document master list) will have an expiration date. Set this uncontrolled document expiration date for a short period of time, such as 1 or 2 days, in order to provide a reasonable degree of certainty that a new version will not be released prior to the expiration.
- Never make handwritten changes to laboratory documents. If your lab absolutely cannot avoid these sorts of changes, the laboratory should have a policy that allows handwritten changes for a short period of time while a revision is finalized.
- Each document type associated with a procedure should have its own unique document control number. For example, if performing a coagulation test requires a procedure document, a form for documenting maintenance, and a job aid with reminders for certain important steps, all three documents should be controlled separately.
- If you must refer to handwritten notes daily in order to execute procedures, those notes should be incorporated into an appropriate laboratory document. Keep in mind it is unlikely that everyone performing a particular procedure will write notes exactly the same way. So, if notes are used to carry out an activity, it is likely that variances are occurring in the way the procedure is performed.

Conclusion
Given the depth and scope of today’s clinical laboratory operations, ever-tightening budgets, and the intolerability of error, electronic document management systems are more crucial than ever. With potentially hundreds of policies and procedures guiding daily operations, labs cannot afford to be unsure of how every activity is performed or unable to demonstrate the outcomes of those activities. Although the knowledge that the lab is running smoothly and appropriately under the purview of current regulatory standards should ease the anxiety of laboratory managers and directors, it is the extension of this—enhanced patient safety—that elucidates the full value of proper document and record control.

References