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C O L L E G E O F A M E R I C A N P A T H O L O G I S T S

Bedeviled by documents, labs seek control

Anne Paxton

Documents—the written instructions for how things should be done in the laboratory—may look harmless on the surface. But they can be quite treacherous things.

Obsolete versions may lurk on shelves or desktops, waiting for unsuspecting users. Unauthorized versions can trick laboratory personnel into getting procedures wrong. Documents can sow confusion by multiplying beyond reason, or by vanishing when laboratory staff most need them. Whenever documents are not properly controlled, “they can come back to haunt managers and supervisors in the form of outdated procedures, unfollowed protocols, and people just not being aware of what they’re supposed to do,” says William J. Castellani, MD, vice chair of the CAP’s Standards Committee.

But document control is no small task. “In labs we deal in words and records and data, and every procedure we do is down on paper, every policy we follow,” says Gerald Hoeltge, MD, president of the Clinical and Laboratory Standards Institute, or CLSI. “That’s how we standardize what we do. And because

these policies and procedures are so important, we have to manage that information efficiently and accurately. But labs that have actually tallied up the number of documents that require control are astounded by the thousands of pages involved.”

In 2003, the CAP introduced questions about document control into the laboratory accreditation checklist to help ensure that labs would have systems to keep track of

CAP’s new ISO 15189 accreditation program, and the evolution of document control software are providing labs with new incentives and new means to improve this important form of quality assurance.

Before 2003, it was well known that in the top 10 deficiencies cited by every lab accrediting organization in the U.S., some of the same items appeared year after year, says Lucia M. Berte, MA, MT(ASCP), SBB, DLM, chair of the CLSI Standing Subcommittee on Quality Management Systems. “Documents were incomplete; a procedure was missing important information; there were different versions of the same document in the lab. As an AABB assessor, I might find two procedures dated 2003 and 2005, with perhaps different content, and people using both versions. Organizations like CAP and AABB realized we’d never get rid of these deficiencies unless we started requiring that people manage their documents.”

Therefore, after ISO 15189 was published in 2003, the CAP added the requirement for a formal means of authorizing revisions of documents, by adding to the ac-

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Document control has long been a struggle for labs, and it’s “one of the biggest stumbling stones in ISO 15189 accreditation,” says 15189 Accreditation Committee chair Dr. Cordelia Sever (left), here with document control specialist Amber Sellers of Tricore Reference Laboratories in Albuquerque.

changes. But only in recent years have laboratories begun to grapple seriously with the complexities of document control. Now, increasingly demanding international standards, the

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creditation checklist two new questions: Does the laboratory have a document control system, and Are all laboratory documents subject to document control? "So, it became no longer acceptable for simply anyone to hand-change a copy of a document without ensuring that all versions had the same change," says Berte, president of Laboratories Made Better P.C., Broomfield, Colo.

But even today, after six years on the accreditation program checklist, document control continues to be not only one of the most frequently cited deficiencies in CAP laboratory inspections but also a frequently recurring deficiency. Each year with regularity, between six percent and seven percent of clinical laboratories inspected by the College are cited for failure to implement a document control system. Between one percent and five percent are cited for failing to review their procedure manuals annually, and one percent to two percent of lab sections are cited for failing to make complete procedure manuals available at the workbench.

The definition of a "document" in the ISO 15189 standard is more en-

compassing and more explicit than that in the CAP Laboratory Accreditation Program, says Cordelia Sever, MD, chair of the CAP's 15189 Accreditation Committee and the CAP's liaison to ISO Technical Committee 212, which produced the 15189 standard. "It includes any information or instructions, policies, statements, textbooks from which exams are taken, flow charts, specifications, tables, calibration tables, memoranda, software. Just about anything that touches on testing."



Berte

However, it's important to note that documents are different from records.

Berte says, "People mistakenly use the terms 'document' and 'record' interchangeably. But in the ISO official quality management glossary, documents provide information and instructions for policies, processes, and procedures. Records are the data and information generated when staff perform those policies, processes, and procedures."

What things can go wrong when document control fails? Dr. Hoeltge explains: "Let's say we have a test in our lab that requires 50 microliters of reagent to be added to a reaction

well, and the vendor changes formulations, or we change vendors, and we now require 100 microliters of reagent to do the same test. Everybody doing that test has to be told at the same time that there's been a change. We'll put the change in a written procedure; we'll use that procedure as a training tool, so everyone knows we've just doubled the amount of reagent required. But if someone then goes back to refer to the procedure and they happen to access an older version that fell out of control, they're only going to use half the reagent required. The effect is that they're going to get the wrong answer."

The shortcomings of laboratories' management of documents were made clear by a 2008 Q-Probes study, "QP081: Document Control Practices." In a review of 8,814 documents from all lab sections, the participants from 120 institutions found that only 35.3 percent of those documents fulfilled all six document control requirements defined in the study (authorization, availability, currency, archiving, staff review, and management review).

"The labs in this Q-Probes study found that things they thought were in good control really weren't when they started measuring against a benchmark, and the benchmark in this case is CLSI's guideline on document management, GP02-A5," says Dr. Hoeltge, quality review officer of the Cleveland Clinic Pathology and Laboratory Medicine Institute.

The biggest source of difficulty was the archiving requirement, which only 50 percent of the documents fulfilled. Next were staff review (77.3 percent), management review (83.3 percent), and authorization (85.3 percent). Laboratories had the most success in ensuring that documents were available to all shifts and locations (97.2 percent) and were the most recent authorized version (95.1 percent).

Berte ascribes the lapses to two

Document control: 8 requirements of ISO 15189

The ISO 15189 document control standard applies to all quality documentation, including charts, reference ranges, standard operating procedures, and posters. Eight document control processes must be applied to these documents:

- Documents must be reviewed or approved prior to use.
- A document control log must be maintained.
- Only current documents should be in use.
- Documents must be periodically reviewed, revised if necessary, and approved.
- Obsolete documents are ensured against inadvertent use.
- Archived documents are identified as such.
- If hand-edits are allowed, the procedures for doing them must be defined and controlled.
- Computerized document control systems must have defined procedures.

main factors: "First, lab staff don't know what to do to control documents. And second, document control is not easy because labs have lots of documents, and in a paper environment, the catch is: Where are all the copies? If you try to manage them manually by paper, it can be a nightmare. The bigger the lab, the bigger the nightmare."

And just having word processing doesn't create document control, she cautions, pointing to two better ways to perform document control: by using readily available PC software such as Microsoft Excel or Microsoft Access, or by purchasing an electronic document control system.

Basically, the best approach to document control is to have a structured and rigorous program for implementing, modifying, and reviewing all the documents covered by the system, says Dr. Castellani, medical director of clinical chemistry at Penn State Milton S. Hershey Medical Center. "The biggest problem has always been monitoring the entire process of document control all the time. Among the complexities of modern labs and health care delivery systems, it tends to be one of the issues you address when a problem arises, and you tend not to address it systematically."

Such a comprehensive approach could require purchasing a commercial software system for \$20,000 to \$30,000 or more—but not necessarily. Dr. Castellani, for example, says his lab is negotiating the transition between paper and electronic means of document control, and it's his view that labs do not have to have a separate software to handle document control. "Right now, when my lab creates a new procedure for a new test, we have a cover sheet that's signed off by the appropriate people, and a training sheet that documents authorization



Dr. Castellani

and training. Document control can be done with paper documents," he says, "although it requires more attention to the actual physical sheet of paper." The advantage of electronic systems is that "they can be made to ensure you do it right, while paper systems do not have that fail-safe approach."

Dr. Sever agrees that dedicated software is not mandatory. "That's one of the questions that might come up for labs: Do we have to buy a document control software system?" And the answer is no. "Document control is one of the biggest stumbling stones in ISO 15189 accreditation, and all three of the pilot labs in the program started out with some nonconformance in document control and put a significant effort into improving it. One chose to implement a dedicated electronic system to get there, while another one created its own database instead of purchasing a system."

Nevertheless, reliance on paper is going to become more and more difficult, she says. "If you have bigger labs with complex operations and multiple divisions, it's simply going to be unmanageable unless you have some sort of electronic library." The CAP recently inspected a lab with a paper-based system and found the laboratory had several challenges to meet. "I would say most paper-based systems have lapses in annual review cycles," says Dr. Sever, director of clinical pathology at Pathology Associates of Albuquerque.

"I think a lot of people look to commercial systems as a *deus ex machina*," says James D. Faix, MD, member of the CAP's Standards Committee and of the CAP's Council on Scientific Affairs. "They say 'our document control is terrible—let's buy some software,' and they're not thinking through all the different processes they need to reform."

In fact, Dr. Faix, associate professor of pathology at Stanford University School of Medicine, believes it's easy to go overboard with docu-

mentation requirements—to the point where they interfere with important functions. "One good example may be overly elaborate guidelines for procedure writing. I think procedures should be living documents useful to a person trying to figure out how to do their job—not repositories of every single piece of data that's related. The organization should focus first on whether a person can use the procedure, not 'does it meet international guidelines.'" Quoting the former Chinese political leader Deng Xiaoping, Dr. Faix suggests, "It doesn't matter if a cat is black or white as long as it catches mice."

To keep documents within reasonable bounds, Berte says labs would be well advised to read CLSI's *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (GP02-A5)*. Most standard operating procedures are written in sentences and paragraphs because that's the way the writers were taught, but a better way to present the information, especially information that requires judgment or decision-making, is in a table with rows and columns. "If a positive result is a blue ring with a yellow stripe down the center and three black dots, and this means the patient has the antibody we're looking for, let's make a table showing the blue ring, what it means, how to report the result, and what to do next."

What about the danger of too many documents? CLIA '88 has been mistakenly interpreted, she says, as requiring that each procedure have every single one of the 16 pieces of information called for in a procedures manual. "It can get out of hand because labs write an SOP for each analyte done by their analyzer, and that's not required. That's the old 'NCCLS format' mentality."

So one of the fastest ways to reduce the number of standard operating procedures a lab has, Berte says, is to follow the guidance in CLSI GP02-A5

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about how to use a process flow chart and analyte tables and shorter instructions to accomplish the accreditation groups' objectives. "Right there, you can knock off several hundred SOPs out of any given lab." Using process flow charts, she says, "you can do on one page what takes maybe four inches in a three-ring binder that you often can't find."

D. Sever says there are two leading problems with document control. The first is getting rid of obsolete documents: the "little rogue notes and custom instructions that people have from years back that still float around the lab." The other difficulty is sticking to the review cycle.

An important component in complex systems is tracking the reading and signing off on of procedures. "There's a competency piece to it and we see that's one of the newer challenges," Dr. Sever says. "Some software systems have the ability to train everybody on revised documents and put them into competencies, while others don't. That's a distinguishing sales pitch of systems." Dr. Sever says the CAP's Competency Assessment Program can manage this task well.

Clearly, with 6,000 labs to accredit, the College can benefit from reducing the paper flow. "In the CAP 15189

program we have desk assessments where everything is in PDF files, so we do not shuffle paper. We've also had labs give us access to their document systems electronically and that dramatically reduces shuffling back and forth," Dr. Sever says.

One of the more vexing issues in document control can be dealing with the memory aids, referred to as "job aids," that lab personnel use as reminders. The Post-it note that says, "Use the material in the refrigerator instead of standard QC on that test," may be an accurate instruction when it is posted, but a note has an indeterminate lifespan, Dr. Castellani says. "You may need to have a deviation from an SOP, but you can't still be using it July 2 if it expired July 1. There has to be a process by which a deviation from SOP has a limited lifespan."

"It's very difficult," Dr. Sever says, "to eradicate all those little notes, and every lab you ask will have some stories where people got very upset." But does document control really require regulating job aids? Yes it does, she asserts.

"There is some leeway in how you handle these job aids, but the document control system has to specify how they are handled. There are different 'tiers' of rigor in a document control system, but the idea is if they are really good, then everybody should have them and know about them; if not, then you shouldn't have

them because it introduces variation into the process."

Admittedly, some job aids are essential, Berte says. "For example, some vendors don't provide compact instructions for how to log on to computers and click your way through, so what labs do is make a little 'rolodex' for codes to enter to order a test, get a patient record or result, or change a password. It's perfectly okay to have a little rolodex as a job aid—provided the information there is exactly the same as in the master document and is subject to document control. It's okay as long as that job aid gets a version number and an effective date."

There's no one recipe for document control, Dr. Sever emphasizes. "There are a few basic requirements which all really aim to have optimal standardization and have everything current at the best evidence-based level. How exactly that is done will depend heavily on the resources, size, and complexity of the individual labs."

Though it is occasionally pitched this way, document control has nothing to do, really, with "defensive medicine," Dr. Hoeltge says. "Certainly using tools like this increases the reliability of your program, and to the extent that that's more defensible," the term is relevant. "But that's not the motivation. The motivation is to do the test right." □

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