

CAP TODAY

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A SoftTech Health case study

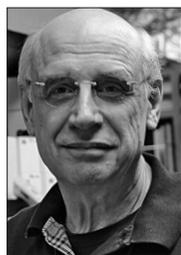
Excerpted from "Document Control: Three Case Studies," CAP TODAY

The Department of Pathology and Laboratory Medicine of Children's Hospital of Los Angeles, like many other such departments, has been struggling with document control for years, says Clark B. Inderlied, PhD, director of microbiology and pathology informatics. "Of all the regulatory requirements we contend with, it's the one that has resonated most with both administrative and technical staff."

In Dr. Inderlied's experience, just having a common server that makes documents available to everyone in the lab is not enough to carry out document control. "We looked at products such as MS Office's Sharepoint, which is very attractive and is used at this institution for a variety of purposes, but it was missing an application specific to the needs of pathology and lab medicine."

About a year and a half ago, Children's Hospital chose SoftTech Health's Quality Management System, an intranet-based system that resides on a server within the hospital. "Though it's not Web-based, you actually access it using Internet Explorer on a local network, and it can be accessed from off site through VPN access." In implementing the system, SoftTech Health performed a "bulk upload" of the laboratory's documents and users, as well as the CAP checklists. "So we started out with a fairly robust database, rather than having to build that," he says.

"We decided on this system because it is oriented to pathology. It includes document review and a revision process that not only meets but I think really exceeds ISO and CAP requirements, by allowing you to assign review dates for documents and then automatically notifying the appropriate people that the review date is coming up." All the tracking of version changes and assigning of version



Dr. Inderlied

numbers is automatic. "So for a large section like chemistry, which has many policies and procedures, this has become a godsend," Dr. Inderlied says.

In line with document control standards, the system makes only current policies and procedures available. "But we did allow people to print them out. Not all of us are entirely comfortable with reading documents on a monitor." To ensure that only the most recent policies and procedures are being distributed, "the software allows you to put a watermark on each page of documents, called an LTR number, basically an accession number, so you can immediately determine whether it's current or not."

Somewhat unexpectedly, once the system was implemented, laboratory staff started accessing the policies and procedures electronically more than they did when they were in printed format. "It was mostly because the printed versions tended to reside in note-

books on the shelves of supervisors or managers who were not on the bench. So they were readily available as CAP requires, but some of the staff indicated that, mistakenly, they didn't ever realize they had access to some of this information on policies."

The system's archiving function turns out to be valuable, Dr. Inderlied says. "It allows you to maintain obsolete documents on the server but no longer make them available to the common user. Those with a high level of access, however, can look at archived documents, and even bring them up side by side with current versions, much as in the document comparison function within Microsoft Word."

Dr. Inderlied actually created user names and passwords for the CAP inspectors who came in March, to allow them to access the laboratories' documents electronically. "They seemed impressed that we were getting that part of our regulatory requirements under control. Of course, inspection teams always seem to find something—but in terms of our document control system, they found no deficiencies."

There is some pain associated with implementing software like this, Dr. Inderlied notes. "It's similar to what we and I would assume most labs have gone through in implementing an LIS. As with an LIS, the system has some aspects to it that are unforgiving." The automatic notification feature, for example, "creates some stress because you're aware you have to do something." But in the end, he says "what you find is it's really a way of forcing you, or coercing you, into complying with requirements."

—Anne Paxton