One lab’s path to a quality-management system

By Melissa Moran, MT(ASCP)

The most fundamental understanding that we took away from observations in our own lab and expanded at Mayo was that lab quality management is not a single process or step but a way of thinking. A lab’s quality system touches on every aspect of operations in the lab. It is not a piece of software, or a manual, or a single tangible thing — it is a conceptual framework for assessing how the lab should do everything it does.

FSH followed Mayo Health System’s example and adopted the QSEs, which are helpful in breaking down the lab and its functions into component parts, so that we could analyze each one as we developed our quality program (For more about the QSEs, refer to Table 1.)

Priorities emerge
This led us to the next step on our path to quality management. We formed a quality GAP-analysis committee, consisting of our lab’s leadership. We asked, “Where are we now?” and “Where do we want to be?” The difference between the two is the GAP — how we are now compared to where we want to be.

Table 1. The 12 quality system essentials are the building blocks for a quality framework
going to get there. Making document control our first quality priority made sense. Our analysis had shown an especially high proportion of gaps in how we controlled and managed our standard operating procedures (SOPs), as well as our policy distribution and revisions. Like many labs, we had been cited by the College of America Pathologists (CAP) for our document-control deficiencies. We needed better management and control as we redeveloped and updated these documents, including our quality manual and other SOPs.

With our focus now narrowed to a search for better document-control processes, we paid another visit to Rochester’s Mayo Laboratory quality-management team. We wanted to know how many FTEs and how much time it had taken them to develop their quality-management and document-control system. They had hired a quality-systems consultant to provide three eight-hour educational sessions for all 250 lab supervisors and laboratory directors. Many of their focus groups were formed to assess the missing pieces of the quality program with a GAP analysis prior to the arrival of the consultant. The consultant helped identify and prioritize these gaps, and then facilitated a team of 10 management and quality-assurance staff to draft their quality manual. Their implementation of the document and records QSE took two years, and full implementation of all 11 QSEs took four years to accomplish.

**Reassessing our needs as a smaller lab**

What worked for the large Mayo lab facility would not be practical for a smaller lab like FSH, but we still would need more resources than a quality coordinator could provide working just one day a week. To support our efforts, Mayo’s laboratory-quality manager and one of her colleagues brought their quality-school

---

The proposal highlighted the increasing regulatory requirements for document control that labs face — a “soft cost” in running a lab, but one for which we pay a price if we do not control our documents properly.

---

The operation of all 11 QSEs in the lab. The Mayo team offered several recommendations based on their experience, one being not to underestimate the time and commitment needed to develop and implement a quality system. Another was to appoint a document manager to facilitate the document-management process. We all agreed that a full-time quality coordinator gave us a better chance of getting where we needed to be.

The second reassessment we made was about the “how,” not just the “who.” If it took Mayo more than four years to develop a homegrown system with many staff and various divisions working on it, then one person working alone could not effectively develop such a system for Franciscan Skemp. We would need to purchase a ready-made tool to help us achieve a better document-control system. We attended a local conference where previewed software offerings for lab-quality management and document control, through which our lab leadership group was able to arrange and view a software demonstration online, as well as ask questions and get answers regarding the product.

**Coordinating decision-making to make progress along the path**

We agreed the software was a good fit, so the next step was to get funding. We wrote a proposal comparing the product costs vs. benefits analysis. The proposal highlighted the increasing regulatory requirements for document control that labs face — a “soft cost” in running a lab, but one for which we pay a price if we do not control our documents properly. The proposal — submitted through the hospital’s IT steering committee, as well as our administrative coordinating group — referenced what we had learned about the main Mayo site’s path to implementing a homegrown system and the length of time it had taken to get its system up and running. Based on our estimate that three to five years would be needed to develop our own homegrown document-control system, the proposal was approved. The software was quickly implemented in our lab, and all of our existing documents were batch imported into the system. We saved many months — years, in fact — over developing a homegrown system. Our techs and SOP authors and approvers now use the online system to access and control all of our documentation, including SOPs, manuals, forms, and other files. When our recent unannounced CAP inspection occurred, we were much better prepared for the inspection and, more importantly, we experienced an 87% reduction in inspection findings. The document-control software project has been a real success for us.

**The next steps on our quality path**

Now that our document-control system is in place and being used successfully by our staff, we have turned our attention to our next quality priorities. We are in the midst of a Lean reorganization where we are revamping the physical layout of the lab and focusing on utilizing Lean tools to develop a more efficient process design. Interestingly, since Lean thinking focuses on reducing wasted labor and resources, we realized that our document-control software has proved to be the first Lean process-improvement for our laboratory.

We also realized that our two sister hospitals and affiliated clinics could be spending much less time on their own document-control processes if they shared our document-control system. Rather than duplicating our efforts to create and manage their own policies and procedures, we could be sharing a common body of policies and procedures among the three labs. We are
currently assessing this possibility, since the application is Web-enabled and can be shared among multiple physical locations.

We are also returning to our original GAP analysis and looking at the other gaps we found in adherence to the QSEs. We intend to use the other quality-management aspects of the software (i.e., the equipment manager module) after our Lean reorganization is complete and some new equipment has been installed. We are also utilizing the feedback manager module as we move forward with our Lean culture. Our laboratory has developed an “Innovative Ideas” program where staff members can initiate suggestions and solutions for process improvement in the laboratory. We are now using the software’s online forms module for staff members to complete surveys, competencies, and various other forms.

**Lessons learned along the journey**

Our path seems clear and straightforward, but, at the time, it did not always seem that way. As a smaller lab and one with no history of dedicated quality expertise, we were fortunate to be able to call on the Mayo family. Our focus on the QSEs also turned out to be an excellent guide to a quality system.

More specifically, in terms of our first big priority, we learned some lessons during the process of implementing a document-control system. We were glad we had not taken the wrong path at the first fork in the road that we came to, which was developing a homegrown system. We now know that in purchasing a document-control product — or any software product — we should bring the right people to the table as early as possible. In our hospital, these people included representatives from IT, our LIS coordinator, the lab director/pathologist, and representatives from the lab who would actually use the software, especially the supervisors. Respectively, since the IT and LIS staff will be called on for the practical aspects of the software implementation, they should be on board and aware of the project. Upper lab management should also be brought in to help provide momentum throughout the process.

And finally, getting the input of the prospective users of the software gets them excited about the project and gets the word out to other members of the staff.

We also now know that getting the technical and contractual aspects spelled out in advance is useful, so that both the vendor and the hospital are using the same definitions and understand the terms in the same way. For our document-control project, the vendor worked with our team to make sure that any hurdles were overcome, which was an important contribution.

The path to a laboratory-quality system is ongoing, of course: We have not stopped traveling in search of more quality improvements in an effort to continuously improve patient care. For Franciscan Skemp, getting the right conceptual framework in place and having the right tools in place were important early milestones to speed us on our way.

Melissa A. Moran, MT(ASCP), has a BS in Medical Technology with a chemistry minor. She is currently the laboratory quality improvement coordinator for Franciscan Skemp Healthcare in LaCrosse, WI.

---

**WHY DCL?**

**WE CAN GIVE YOU 500,000,000 REASONS.**

500,000,000 diagnostic tests are performed in clinical laboratories around the world using DCL products. Our distinctive offering of liquid stable chemistry reagents, enhanced by our unique L3K® technology, and rapid testing assays offer impeccable quality, reliability and performance test after test, time after time. Coupled with an extensive listing of instrument applications, a broad offering of complementary support products and dedicated Technical Services personnel, the real question should be “why aren’t you already using DCL”? 

Visit us at MEDICA Düsseldorf - Nov. 14-17
Hall 3 - Booth 3B36