Latest checklist takes quality management to next level

Valerie Neff Newitt

November 2021—In the latest edition of the laboratory general checklist, released in September, the requirements of the CAP Accreditation Programs have been edited to be more aligned with CAP 15189 (ISO 15189) accreditation requirements.

A CAP ISO 15189 Synergy Project Team, with members drawn from the CAP's Checklists, CAP 15189, and Quality Practices committees, has been working to build a philosophical and practical synergy between the CAP's Accreditation Programs and the ISO 15189 standard. Checklist changes made with this coordination in mind will ease the learning curve for laboratories that wish to seek CAP 15189 accreditation after earning accreditation through the CAP Laboratory Accreditation Program.

In the new checklist edition, the term "quality management program" has been replaced with "quality management system," and the requirements will make clear that finding and documenting quality gaps must be followed by effective corrective actions.

The decision to use the term "system" instead of "program" is not just a semantic juggle aimed at an adoption of ISO language, say those on the project team. Rather, it indicates the team's collective thinking at the core of these checklist revisions.

"Our thought process was that a 'system' designation helps all of us think in terms of bringing together a host of quality efforts in an interacting system of various components," explains Joe C. Rutledge, MD, a member of the ISO 15189 Synergy Project Team and CAP 15189 Committee. "We don't want checklist requirements that are just 'things to get done and out of the way.' If you move away from just checking off the boxes, you can build a better, more functional, and more effective system."

Checklists Committee chair Harris S. Goodman, MD, a member of the ISO 15189 Synergy Project Team and the CAP Commission on Laboratory Accreditation, says a quality management system is "more encompassing."

Dr. Goodman

"In a system you have your core processes and procedures—preanalytic, analytic, postanalytic. But you also have processes and procedures that support those core components, as well as procedures for monitoring core processes, including quality indicators, quality control and proficiency testing results, self-inspections, external inspections, accrediting inspections."

A quality management system must also include procedures for improving processes, says Dr. Goodman, chief of the Department of Pathology, Alameda Health System Highland Hospital, Oakland, Calif. "That includes a big one we tackled in 2019—investigation of nonconforming events. Now in 2021 we also must have an evaluation of the effectiveness of corrective actions. After all, if a corrective action doesn't work, you haven't accomplished anything. Phrases like 'we will continue to monitor' when a target is missed will not be enough. This is a significant change in mindset and in the requirements."

ISO 15189 project team member James H. Nichols, PhD, D(ABCC), says use of the term “system” strengthens the connection with ISO 15189 and that “system” is more frequently used across an international pathology population that has become familiar with ISO language.

“So while we are adopting the more international language, we are also emphasizing that a system must stretch across all areas of the laboratory and encompass all processes. This overarching inclusiveness may not have been quite as evident within the concept of a ‘program,’” says Dr. Nichols, a member of the CAP’s Quality Practices and Point of Care Testing committees, medical director of clinical chemistry and POC testing at Vanderbilt University Medical Center, and professor of pathology, microbiology, and immunology, Vanderbilt University School of Medicine.

The Quality Management System section of the laboratory general checklist defines a QMS as “a set of processes, policies, procedures, and resources designed to ensure high quality in an organization’s services.”

The GEN.13806 requirement for a quality management system is a “significantly altered requirement that doesn’t look very much like its original form,” Dr. Goodman says. The revised requirement says a laboratory must have a document that describes its overall QMS, and that it can be based on an existing model (such as CLSI QMS01, ISO 15189, ISO 9001 series) or of the laboratory’s own design. It also says such a design must include components that “accurately reflect the operations of the laboratory.”

The checklist requirement provides examples of such components, one of which is “core process and procedures”: preanalytical, such as test ordering and specimen collection; analytical, such as testing results review, equipment validated, quality control; postanalytical, such as results reporting and archiving specimens. Another is “support process and procedures”: document control, information management, contacts/agreements with external vendors and suppliers, and training.

“This checklist item is the backbone, the very core, requirement for a QMS,” Dr. Goodman says, adding that many labs are already doing most if not all of what is required. “Now we’re organizing them and bringing them all into one system,” he says.

Many of the components found in GEN.13806 were “woven throughout different parts of the checklists in the past,” Dr. Nichols says, but have now been brought together as a way to consider various parts of the QMS as one entity. “The examples offered will get a system started. But there are other examples offered on the CAP website to help build a more comprehensive system,” he says. (Log in to “e-Lab Solutions Suite” under “Accreditation Resources–Quality Management” for QMS document examples and other resources for CAP-accredited labs.)

When Dr. Rutledge began to practice pathology years ago, he says a quality management program was one type of QC activity in one area, another type of QC in another area, as well as proficiency testing. “That was it. Now evolution is building an entire robust system, with a document that ties together this broad array of interrelated processes, extending past traditional areas,” he says.

Dr. Rutledge

He believes greater attention to “support process and procedures” is integral to building a better system. “We have to go beyond the traditional preanalytical, analytical, and postanalytical concerns. As the COVID-19 pandemic pointed out, you can have a great analytical system, but if you can’t get supplies like PPE in the door, it’s not going to work. A lab could incorporate risk management into its QMS by addressing the ‘what ifs.’ What if we can’t get supplies? What if the computer goes down? What if the top three people in the lab can’t get there because of a

snowstorm? In short, you must be able to address your support systems, and often laboratories do not do that."

The QMS document will be a living document that changes as new procedures, technology, and understanding emerge, Dr. Rutledge says. "It cannot be something that is written, signed, then retained by the upper echelon of the lab or institution. Instead, it must be something for the frontline staff who keep our systems running."

"It can also be used as an educational resource for onboarding new employees," he adds.

GEN.13820 Scope of Service is a new requirement ("and a direct transfer from ISO 15189," Dr. Rutledge says) that says laboratories must have a document that describes "the patient care and client services offered by the laboratory (eg, tests offered, hours of operation, turnaround times)." The document (paper or electronic) must be available to the patients and clinicians the laboratory serves. The requirement says the lab's user manual and/or collection manual may meet the intent of this requirement, and that the document does not include financial or business arrangements between the pathology group and institution.

"I don't think labs always clearly outlined the scope of their services when inspectors came through," Dr. Nichols says. "What is the goal of the lab? What is their motto in terms of what they do? This may not be clear to clients. So this requirement directs labs to delineate more clearly their patient care and client services. It is not enough for labs to simply say, 'This is our test menu.'"

"In practice, this is not entirely new," Dr. Goodman says. "For example, even before now, a specimen collection manual had to be present where specimen collections took place. However, this is a little broader because the scope-of-service document must be available to anyone who accesses the lab." Since the document can be electronic, laboratories can have it on their website, he says, noting, "Many already do."

Dr. Rutledge says this requirement should not place much of a burden on laboratories because many labs already need a similar document to satisfy the CMS or the Joint Commission, for example. "By adding it in the checklist, it gets us one step closer to ISO 15189," he says.

GEN.20208 Identification of Non-conforming Events was renamed as such from the prior "QM Patient/Client Services" requirement, and it says a QMS must include a process to identify and record nonconforming events.

GEN.20310 Investigation of Non-conforming Events says the QMS requires a root-cause analysis for sentinel events, and for nonsentinel events (near misses), a "process to define the scope and extent of the investigation required."

"There is an inherent human tendency to want to brush these under the carpet," Dr. Goodman says. "No one likes to point to their mistakes. So it's extremely important that we create a supportive atmosphere that encourages the pointing out of errors. That means having a process to identify and record those nonconforming events, which are errors in most cases."

Breaking the stigma attached to admitting errors is important, he says. "Identifying and recording nonconforming events in a nonjudgmental, nonaccusatory, well-defined, robust process will prevent them from happening in the future."

GEN.20318 Corrective and Preventive Action says a QMS must include processes for recording corrective and preventive actions taken for nonconforming events (errors and incidents) and quality indicators that do not meet defined targets, and for evaluating the effectiveness of the actions taken. Checklist users are directed to a resource for examples of identifying, monitoring, and reducing risks at https://documents.cap.org/documents/cap15189-accreditation-risk-management-guide.pdf.

"We want to help labs. We don't want to make things harder for them. So we wanted to add resources whenever possible," Dr. Goodman says.

GEN.20325 Employee and Patient Quality Communication says a QMS must include a process for employees and

patients to communicate quality and safety concerns to management, and the following has been added: “with appropriate follow-up of such concerns.”

“Most labs already do this, so we thought, ‘Why not make it explicit?’” Dr. Rutledge says. It is an important provision, he adds, because “now all employees and patients have a ‘license’ and a pathway to bring quality and safety issues forward. They don’t have to worry about how they’re going to do it because the required process will tell them how.”

GEN.20326 Assessment of the QMS Implementation says laboratories that have been CAP accredited for more than 12 months must implement the QMS as designed and assess it at least annually for effectiveness. The QMS must include an appraisal of performance of quality indicators, follow-up of issues (including nonconformance) requiring corrective and preventive action (when needed), actions taken when concerns about quality and safety are reported, and effectiveness of actions taken when quality indicators do not meet targets.

“The prior standard said labs had to review quality management programs annually,” Dr. Rutledge says. “Now we’ve added that a QMS must be reviewed at least annually for *effectiveness*. That word doesn’t look like much, but it means a lot. Before, you might review/read over a document, make some changes, and sign your name to it. But now, reviewing for effectiveness means you must examine the data, make sure all of the information that was needed was collected, and determine what can be done to fix any deficits so that the lab can move forward with quality. You want to collect improvement data so you are able to see that something is actually happening with it.”

When inspectors investigate a laboratory’s QMS, they will look for a sampling of the types of quality indicators, or benchmarks, the lab is following, and how it is doing follow-up when those indicators are not met, Dr. Nichols says. “Take turnaround times, for instance. If they aren’t completing stat or routine testing in the expected time, what are they doing to correct and improve their TAT? What steps are being taken? Additionally, inspectors will want to look at other benchmarks a lab is using to assess the overall effectiveness of their QMS. So it’s not just that a lab launched an investigation that matters; it’s the strength of the follow-up, the corrective actions that come out of that investigation, that is essential. We don’t want labs to keep reproducing the same error.”

Dr. Nichols

Dr. Goodman agrees, pointing out that as an inspector, he has seen on quality dashboards that certain targets—for example, blood culture contamination rate or turnaround times—would be consistently unmet. “So someone would say upon review, ‘Target not met, continue to monitor.’ Now that’s not acceptable. You have to figure out why you’re not meeting a target. You have to implement corrective action if a target’s obtainable, or figure out a solution to take care of the problem. You have to evaluate whether your corrective action has worked. The evaluation of the effectiveness of corrective actions has too often been neglected, and these revisions will change that.”

These project team members agree that a quality management system is worth the effort it requires and is key to quality laboratory medicine and the better patient outcomes that eventually flow from it.

“Quality is part of the health care equation—value equals quality divided by cost,” Dr. Rutledge says. “A functioning QMS will raise the numerator, because at the same time you raise quality, you lower the cost of mistakes. Overall costs go down, so for clients and patients, value goes up.”

Dr. Nichols acknowledges that any change is hard for laboratories because resources are limited, particularly during the pandemic.

“But labs need to understand these requirements are not major changes. They expand quality into parts of the lab that may not have been well incorporated into quality programs in the past,” he says. “These changes are going to take a preexisting quality management program and make it more active, more effective, and more consistent in producing high-quality laboratory tests.”

Valerie Neff Newitt is a writer in Audubon, Pa.