# In 2020 checklist, a ‘gentle push’ to next quality level

## Valerie Neff Newitt

August 2020—For quality management in the laboratory, it’s not enough to have checks and balances. The checks and balances have to work to improve quality.

That’s how Stephen J. Sarewitz, MD, vice chair of the CAP Checklists Committee, characterizes the changes to the quality management requirements in the 2020 laboratory general checklist, released in June. They are changes that bring the CAP accreditation program requirements into greater alignment with ISO 15189 standards.

“We’re closing the loop on quality management wherever we can,” Dr. Sarewitz says.

Significant progress has been made in laboratory quality over time, thanks to people, instrumentation, and processes, says Joe C. Rutledge, MD, member of the CAP 15189 Committee and professor of laboratory medicine, University of Washington.

“It’s been fantastic,” he says. “But now we can take it to the next level by embracing what other industries have done—adopt a quality management system that is robust and living—and continually ask the questions, ‘Are we effective with our improvements and with our corrections? Are we serving our customers—patients, clinicians, hospitals, and others—in the best way possible?’

Dr. Rutledge

“It’s not a leap for anyone. Everybody wants to do this,” Dr. Rutledge continues. “Now we are giving labs structure through our Laboratory Accreditation Program by changing the requirements around quality management and gently pushing them to the next level of excellence.”

One of the changes is GEN.20318 “Corrective and Preventive Action,” a new requirement that says a lab’s quality management program must include processes for recording corrective and preventive actions taken for errors and incidents (i.e. non-conforming events) and for quality indicators that do not meet defined targets, as well as for evaluating the effectiveness of the actions taken.

These requirements were implicit in the prior edition of the checklist, Dr. Sarewitz says. “For the purposes of clarity, this requirement was added and includes ISO concepts, the point being that not only does a laboratory have to record corrective and preventive actions taken for non-conforming events and quality indicators that do not meet targets, but the lab also must evaluate how effective its corrective and preventive actions are. It’s not enough just to have taken an action; it has to have made a difference. That’s a key to closing the loop when dealing with problems in the laboratory.” Evidence of compliance requires records of actions taken and of the effectiveness evaluation.

Dr. Goodman

Harris S. Goodman, MD, Checklists Committee chair and clinical laboratory director, Alameda Health System Highland Hospital, Oakland., Calif., says GEN.20318 underscores that there is no point in taking actions that do not accomplish anything. “There are several reasons why it could happen,” he says. “It may be that you chose the wrong action or the action was never implemented. Perhaps there is another action that is better. Possibly the action taken is applied to a problem you thought was present, though all the while it was another problem that was present and causing problems. To uncover and understand all the possibilities, you must evaluate the effectiveness of your actions.”

The new requirement follows the addition in 2019 of GEN.20310 “Investigation of Non-conforming Events,” which Dr. Goodman calls “a significant movement toward the introduction of ISO concepts to the CAP checklists. It says a root cause analysis *must* be performed for sentinel events. It is something that should have been done without the requirement, but this makes it crystal clear it must be done,” he says.

It also introduced the term “non-conforming event,” which is an ISO term for an error or problem that results from a laboratory procedure or process not having gone as it should have. “Sentinel events require a root cause analysis to determine the cause and prevent recurrence. Less severe non-conforming events require investigation but not a full root cause analysis,” Dr. Sarewitz says.

Dr. Rutledge says the addition of the requirement in 2019 pushed labs to look at how the whole system is doing and determine if it is a “living” system.

“It’s one thing to have a procedure on paper and a few written records. But those things don’t always accomplish the goal of effective change,” he says. “Incorporating a management review piece brings it all to life and keeps the wheel of quality turning at all times.”

An existing requirement, GEN.13806 “QM Program,” previously said a laboratory had to have a written quality management program. “Written” has been removed and it now says a lab must have a QM program. The note calls for a written policy that describes the overall program, in sufficient detail “to describe the objectives and essential elements” of the program. While the aim of the changes was to simplify and clarify, Dr. Rutledge says, “We’re getting away from the idea that there can be just a written document that sits there and fulfills the requirement. There has to be a QM program that comes to life through action, through real understanding of objectives, and is not static.”

Here is a look at other changes to the quality management section of the 2020 laboratory general checklist:

- GEN.20208 “QM Patient Care/Client Services” says the QM program must include a process to identify and evaluate non-conforming events. This requirement was tweaked, Dr. Sarewitz says, “to add the phrase ‘non-conforming events’ to cover errors and incidents that affect patient care. The requirement also specifies that it applies to “clinical, rather than business/financial issues. “Business/financial/contractual issues are certainly important, but they are not within the purview of the CAP program,” Dr. Sarewitz says.
- GEN.20316 “QM Indicators of Quality” says a QM program must include monitoring key indicators of quality in the preanalytic,

analytic, and postanalytic testing phases by regularly comparing performance against targets defined by the laboratory. While there is no conceptual change to the requirement, Dr. Goodman says, the revision now specifies that the laboratory director should determine the number of monitored indicators. “There’s no specific indicator any lab must monitor, although there remain certain ones that are commonly monitored and have been listed as examples in the note. They include test order accuracy, test turnaround time, critical result reporting, and blood culture contamination, among others.” New to the list of suggested indicators is laboratory test utilization, an indicator Dr. Goodman says he focuses on at his hospital. “Just today I canceled the third hemoglobin electrophoresis test order on a patient. It is a test you only need once. There are other tests that are done redundantly, excessively, and are noncontributory to good patient care. So this addition can eventually benefit labs and patients alike.” The frequency for evaluation is to be defined by the laboratory. “When labs define the frequency,” Dr. Rutledge says, “it means they have a plan for revisiting the indicator appropriately. It brings a little more rigor into the system.”


Dr. Sarewitz

- GEN.20325 “Employee and Patient Quality Communication” folds communication into the QM program, with a process that makes it possible for employees and patients to share with management their concerns about quality and safety. It requires that any such concerns be included in laboratory QM records. “Employees must feel there is no barrier,” Dr. Sarewitz says. “People who are on the line doing the testing may see something that is the start of an important issue. By being able to bring that to management’s attention they are able to help safeguard both patients and the lab. We don’t want any fear of whistleblower blowback in labs. That would be a recipe for big problems.” Dr. Rutledge says it is not

enough to have a procedure that says employees can talk to the lab director and patients can call a number. “What if patients call the number and no one records their complaints? Labs need to have a complaint/non-conforming event resolution system. And employees must have a way of bringing observations and suggestions forward.” Evidence of compliance calls for records of employee and patient complaints with appropriate follow-up. “This all helps to close gaps in quality management,” Dr. Rutledge says.

- GEN.20326 “Assessment of the QM Program Implementation” is a revised requirement that existed previously as GEN.16902 “QM Program Implementation.” GEN.20326 says that in any lab that has been CAP accredited for more than 12 months, the QM program must be implemented as designed and assessed at least annually for effectiveness. In GEN.16902, QM programs needed only to be “reviewed,” not “assessed.” The focus of what is now an annual assessment has been expanded beyond simply evaluating the performance of the quality indicators to also evaluating other aspects of the QM program, such as follow-up on non-conforming events that require corrective/preventive action and actions taken to address concerns about quality and safety. “And this must be done minimally once a year. Many labs will do it more often,” Dr. Goodman says.

As the 2020 laboratory general checklist now drills deeper into quality management, it incorporates more terminology found in ISO. Standardizing terminology has been an area of interest to the CAP project team (composed of members of the Checklists, CAP 15189, and Quality Practices committees) charged with working to improve technical alignment between ISO standards and CAP checklists.

“ISO is very different in its approach from the CAP in that it is much more general,” Dr. Sarewitz explains. “The CAP, on the other hand, provides many technical details in its checklists. But ISO has more emphasis on the actual quality management system of a laboratory—more documentation, the audit trail, the entire process the lab needs to maintain quality. It takes quality management to another level. While we do not want to turn the CAP program into ISO 15189, we do see value in aligning the terminology so that where the two overlap, the CAP is consistent in wording with ISO.”

Dr. Rutledge says the checklists and ISO standards are “quite different philosophically.”

“CAP’s checklists are like the 10 Commandments—clear-cut and specific. ISO’s standards are like the New Testament’s Golden Rule: ‘Do unto others as you would have others do unto you.’ It’s general, it’s all encompassing, and while you may understand the objective, you don’t have a step-by-step plan for accomplishing it. The 10 Commandments are all there in the background, but the Golden Rule is powerful and superseding. In short, ISO tells you where you should arrive in quality but not how to get there. The CAP checklists dictate ‘thou shalt’ do everything that is required. The checklists are very prescriptive; everyone knows exactly what they must do.”

The adoption of relevant ISO terminology provides a more uniform language throughout laboratories, Dr. Rutledge says. “ISO terminology is very rich. Each word is profound in what it requires and elevates a lab’s perspective on quality management. So bringing this terminology to CAP and making a translation into the checklists has its benefits. It incorporates a lot of checks and balances on the ‘plan, do, check, and act’ concept that is fundamental to all quality management systems. And by adopting more universal ISO terminology, we can bring various aspects of laboratory medicine closer together. For example, blood banks already use this terminology for FDA requirements. So now we are bringing blood bank terminology into laboratory accreditation parlance, which will be helpful for labs that have blood banks.”

Universal terms would also make the transition to 15189 easier, should a CAP-accredited lab also want to meet ISO standards, Dr. Rutledge says. “We get a lot of feedback from those labs that decided to tackle ISO 15189, and they tell us, ‘We’re getting a lot better, we have fewer errors, we’re cutting costs, our customers are happier, and we’re happier.’ So it makes good sense to align with ISO when it is practicable.”

Dr. Goodman says to look for more QM changes in the 2021 checklist.

“The next step will be to change from a QM ‘program’ to a QM ‘system.’ The simplicity or complexity of that system will depend on the size of the laboratory and the scope of activities,” he says. “But that doesn’t necessarily mean a QM system will be large and cumbersome. Rather, it will be organized and include core processes and support processes. And while I can’t absolutely promise this, I think greater organization and streamlined QM requirements will lead to less work for some labs.”

*Valerie Neff Newitt is a writer in Audubon, Pa.*