Need a written policy or procedure? Look for icon

Valerie Neff Newitt

September 2022—A new icon in the accreditation checklist edition to be released next month will make it easier to know if a written policy or procedure is needed for compliance with a requirement, and easier to inspect and be inspected.

The icon, a stylized document page, appears under the requirement number to flag that a written policy or procedure is required for compliance. The icon does not mean that a separate policy or procedure is required to address individual requirements. A single policy or procedure can cover multiple checklist requirements.

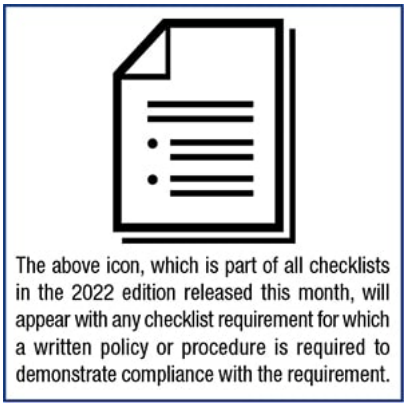
Harris Goodman, MD, chair of the CAP Checklists Committee and member of the CAP Council on Accreditation, describes the addition of the icon as a "significant improvement with no downside."

"We could eliminate the discrepancies we were seeing between laboratories and inspectors, as well as regional commissioners, in their varying interpretations of checklist requirements," says Dr. Goodman, chief of the Department of Pathology, Alameda Health System Highland Hospital, Oakland, Calif.

Stephen Sarewitz, MD, vice chair of the Checklists Committee, predicts fewer disputes, less discussion, and more clarity and points to longstanding issues that led to the addition of the symbol to certain requirements in every checklist. "One was somewhat minor and internal; the other was more major," he says.

The minor issue was that checklist requirements, having been written over many years by different teams of authors, were crafted with inconsistent language. "In other words, some requirements said, 'There is a procedure' for doing such and such activity. But what does that really mean? Do we mean that the laboratory must do the activity, or that the laboratory must have a procedure for doing it? Or both? Does that procedure have to be captured in a written policy? All of this led to a second problem, which was the major concern: inconsistent interpretation of checklist requirements in terms of whether a written procedure was needed or not," Dr. Sarewitz says.

"The important thing," he adds, "is that everyone is on the same page."



The above icon, which is part of all checklists in the 2022 edition released this month, will appear with any checklist requirement for which a written policy or procedure is required to demonstrate compliance with the requirement.

Some inspection team leaders and inspectors assumed that requirements needed a written policy and procedure while others did not, Dr. Goodman says. "Even regional commissioners who reviewed inspection findings found themselves caught in this interpretive inconsistency. While some of the requirements explicitly called for written policies," he says, "it was the ones that did not have that stipulation that caused the problems."

Although some of the requirements did not say that a written policy or procedure was needed, an inspector might expect to see it in writing nonetheless, says Earle Smitty Collum, MD, a member of the Council on Accreditation and the accreditation program's Western Central regional commissioner. "And some labs wrote policies and procedures for every requirement, even when they weren't needed, just to be sure they were compliant. That put an unnecessary work burden on them." The icon is quickly identifiable and removes, for all parties, the need for

subjective interpretation, says Dr. Collum, medical director of Labcorp's Mid-America Division.

Dr. Collum

It also makes it possible to shorten the checklists, Dr. Sarewitz says. "We don't have to ask over and over, in each requirement, 'Is there a written procedure for this?'" The icon makes it clear. "It sounds like a minor thing, but when you make that change to over a thousand checklist requirements, it helps to shorten things. Anything we can do to simplify this voluminous checklist document is a good thing. It becomes more user-friendly."

The policy/procedure icon is not applied to certain requirements that directly ask for another type of document, Dr. Sarewitz says, citing COM.01200 Laboratory Activity Menu as an example of a non-tagged requirement that requires labs to provide the CAP with an accurate list of their tests and activities. "The real issue is not *how* a lab fills out an activity menu, but simply that they *do* fill out an accurate activity menu," Dr. Sarewitz explains. "So this checklist requirement would not have an icon."

Dr. Sarewitz

Another requirement not bearing an icon is COM.01300 Proficiency Testing Participation, which requires laboratories to participate in appropriate required proficiency testing or an external quality assessment program accepted by the CAP for the patient testing the lab performs. "This is a big requirement," Dr. Goodman says, "and it contains an extensive note about what is required. There is a lot in it. However, if a laboratory participates in the appropriate required proficiency testing programs, then they are compliant, whether or not they have a written policy that says they do. This is a requirement that does not need a policy/procedure icon. However, there are other important things with regard to PT, such as the handling of PT products, for which the lab still does need written policies and procedures, for example."

In contrast, COM.01600 PT and Alternative Performance Assessment Specimen Testing does carry the icon. "This checklist item requires a lab to integrate all of its proficiency testing and alternative performance assessment specimens within the routine laboratory workload, as much as possible," Dr. Sarewitz says. "In other words, you're testing the real laboratory process. This is a fairly complicated process and the inspector may be able to inspect only a subset, particularly because the laboratory may not be engaging in every process on a given day. So we want to see a procedure for that, and for that reason we did assign a policy/procedure icon."

GEN.13806 Quality Management System requires the laboratory to have a document that describes its overall quality management system. "Even though that's almost self-explanatory, that will have an icon," Dr. Sarewitz says, because the inspector is looking for a written document on the procedure for the quality management system. A subsidiary checklist requirement, GEN.20316 Indicators of Quality, says the lab's quality management system must include monitoring key quality indicators. "This does not have an icon because it is covered by the previous requirement, encompassing the entire quality management system. So a separate procedure is not needed for this, but the inspector is going to look at specific records of the quality indicators and the data in those records," he says.

A pilot study provided insight into how the icon would be received. “A great majority of those surveyed, whether labs or inspectors, were positive about it,” Dr. Sarewitz says.

“And why not?” says Dr. Goodman. “It just makes everything much clearer.” It will not create additional work for laboratories, he says. “Many of the requirements already had that written policy statement, so it doesn’t change any of those requirements. And there will be some requirements for which labs were keeping up a policy or procedure that wasn’t necessary, so that suggests a work reduction. We expect it’ll make things easier for laboratories.”

Dr. Goodman

And easier for inspectors. “I’ve done many inspections,” Dr. Goodman says, “and it was not that uncommon to come across the situation where the laboratory is meeting the intent of the checklist requirement but there’s no policy and procedure.” He cites as an example a requirement in the anatomic pathology checklist about paraffin microtomy and the correct thickness of paraffin-embedded tissue sections. “I’ve inspected many labs that do anatomic pathology and I have yet to find a lab that wasn’t sectioning its tissue to appropriate thickness. But if there was no written procedure, should they be cited? As an inspector, I found that difficult. The requirement specifically says there’s a written procedure. And the lab folks would say, ‘Well, we’re not doing anything wrong.’ And I’d say, ‘Yes, I know, but the requirement is for a written procedure.’ Those situations will be eliminated now.”

He calls attention to a related issue that he says laboratories sometimes overlook: Practice must match policy and procedure. “Often laboratories are cited because their practice doesn’t match their own written policy and procedure. They can get themselves into hot water if that’s the case.”

“For example, COM.30820 is the pipette accuracy and reproducibility requirement,” he continues. “It simply says pipettes are checked according to the manufacturer’s recommended interval, or at least annually. I inspected a lab that didn’t have manufacturer’s recommendations, so they were checking pipettes annually, per CAP’s requirement. But their own policy and procedure said they would do it every six months. They were meeting the intent of the checklist requirement but not following their own policy and procedure. So I had to cite them. Everything has to match up.”

He and the others expect the small icon to bring big improvement, in addition to greater clarity. “Today is a difficult, stressful time for laboratories,” Dr. Sarewitz notes. Whatever can be done to “make the inspection process a little more straightforward, a little more consistent, has to be good in the long run.”

“Standardization of the accreditation process,” Dr. Collum adds, citing one of the benefits. “Any time you can standardize to a best practice, you’ve removed one of the variables that might be weak and you are more likely to get an accurate result. In the end, that is safer for patients.”n

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