Checklist changes put out fire (drills), for starters

Anne Ford

Dr. Hoeltge

May 2014—Though pathologists have many talents, precognition—foretelling the future à la Nostradamus or the Amazing Kreskin—isn't generally thought to be among them. That said, Gerald Hoeltge, MD, chair of the CAP Checklists Committee, is pretty sure he knows exactly the way many laboratories will react to a particular change in the latest edition of the Laboratory Accreditation Program checklists, which launch this month.

The change in question? "Fire exit drills will no longer be required," he says happily, referring to requirement GEN.75400 of the laboratory general checklist's safety section. "For 40 years, people have had to participate in fire drills on an annual basis, with many institutions doing them at least quarterly. Everybody, every year, has had to show they've walked the exit route.

"At the time those drills were instituted," he explains, "labs were very different places vis-à-vis the quantity of flammable solvents and the use of open-tissue processors and open flames. Now the National Fire Protection Association's fire code for these settings has changed, and the emphasis has moved to planning, the use of alarms, isolation of the fire, and so forth. Somebody does have to evaluate the escape routes every year, but not everybody has to actually walk them. This is the part where people will pencil in a happy face in the margin of CAP TODAY when they read it."

Not to kill anyone's buzz, but don't be too quick to sketch a smile beside those words. Not all of the checklist changes, as Dr. Hoeltge himself points out, will be so welcome. Take, for example, the changes to the provider-performed testing section of the point-of-care testing checklist. The entire section has been revised to address provider competency and to eliminate credentialing as an acceptable method of establishing this competency. To wit, checklist requirement POC.09500 now says laboratories must document that providers have satisfactorily completed initial training in the performance of specific tests, and that medical staff credentialing is not acceptable documentation of training.

"They have to have their competency assessed just like any other testing personnel," Dr. Hoeltge explains. "This can be a tough thing if we're talking about the chairman of the Department of Urology doing a urine microscopic examination. These people are doing something they've done since they got out of training, and now they've got to have documentation that they're actually trained to do it. But that's the way it is. And hey, let's face it: Sometimes it's no fun to be the messenger." He eases the blow a bit by reassuring checklist users that the documentation for this training has to be done only once.

The new edition of the checklists contains changes that are likely to delight, changes that may spark a bit of initial dismay, and changes that will probably fall somewhere midpoint on the emotional spectrum of the average user. Of course, emotions are not the issue here—patient care and patient safety are. As Dr. Hoeltge says of the changes to the provider-performed testing section: "This is important for compliance to federal regulations. It just has to be done."

Professional competency is also the focus of a new requirement in the surgical pathology quality management section of the anatomic pathology checklist: ANP. 10255, which says, “The laboratory director ensures the professional competency of pathologists who provide interpretive services to the anatomic pathology laboratory,” and which mandates that there be a written policy for assessing this competency.

Dr. Gomez

“This comes,” says Richard R. Gomez, MD, “from a CMS requirement for competency assessment of technical laboratory personnel. Basically, what CMS has decided is that the interpretation of a pathology slide—in other words, the diagnosis—is a laboratory test. So, as part of our CMS-deemed authority for laboratory accreditation, we need to include this to assess pathologists who are interpreting anatomic pathology tests at their facility.” Dr. Gomez is chair of the CAP Council on Accreditation and medical director of the laboratory at St. Francis Health in Topeka, Kan.

Though this change may come as a surprise, Dr. Gomez doubts it will affect checklist users in any significant way. “We’ve always thought that diagnostic interpretation was part of the practice of medicine,” he says. “We never realized that CMS would classify it as a laboratory test.” Astonishment aside, he points out that “most of our members are already doing this.” That is, they’re using quality assurance products from the CAP, such as slides from the Performance Improvement Program in Surgical Pathology. “These products will help pathologists demonstrate, ‘We’re doing this, and our competency is assessed by the laboratory medical director through these functions,’” he says. “We’re pleased that our discussions with CMS regarding this have resulted in requirements for compliance by our members that are not very onerous, and we believe the checklist requirement is very reasonable.”

One change to the personnel section of the laboratory general checklist is the clarification added to the competency assessment requirement GEN.55500 for the qualifications of the individuals who can perform the assessments. “For moderately complex point-of-care testing, the assessment has to be done by somebody who is qualified to be what CLIA calls a technical consultant,” Dr. Hoeltge explains. “For the most part, that means a bachelor’s degree with two years of laboratory experience. And most of the point-of-care testing is done in hospitals in nursing areas, and there aren’t too many senior nurses out there who have two years of lab experience. That is a challenge people are going to have to sort through.”

A lesser challenge but a change worth noting is new requirement GEN.53625, “Performance Assessment of Supervisors/Consultants,” which also appears in the personnel section of the laboratory general checklist, and says: “The performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.” It’s likely that laboratories have been doing this, but it now needs to be documented.

Dr. Sarewitz

One area that has undergone significant change is the predictive markers section of the anatomic pathology checklist. “This isn’t a huge volume of changes,” says Stephen J. Sarewitz, MD, vice chair of the CAP Council on Accreditation and staff pathologist, Valley Medical Center, Renton, Wash. “The basic checklist requirements are the same, but there are certain very important revisions” to the items pertaining to HER2 testing.

The minimum number of samples required to validate HER2 assays has been changed. “The previous requirement was a range of 25 to 100 cases, but that has been changed to 20 positive and 20 negative samples for FDA-approved or -cleared assays. For tests that are not FDA approved or cleared, the requirement is 40 positive and 40 negative samples,” he says. In addition, the new requirement says that samples that give an equivocal result need not be used in a validation study, on the grounds that, Dr. Sarewitz explains, “If they’re not clearly positive or clearly negative, you get into a gray area, and significance of concordance of the samples with a reference method might be uncertain.”

Then, too, the requirement for the time of fixation has changed. The previous requirement called for six to 48 hours in formalin, but “there really wasn’t a lot of good evidence for that upper limit,” Dr. Sarewitz says. “And in fact, the requirement for fixation for estrogen or progesterone receptors was six to 72 hours, so it was a bit difficult for laboratories in that we had different allowable time periods for fixing the sample for two types of tests that are generally performed on the same sample.” The fixation time requirement for HER2 is now the same as that for estrogen or progesterone receptors: six to 72 hours.

A third change affects the scoring system for both immunohistochemistry and in situ hybridization. “Most or all of the FDA-cleared or -approved tests for immunohistochemistry indicate in the manufacturer instructions that if greater than 10 percent of invasive tumor cells have strong staining, the test should be considered HER2 positive,” says Dr. Sarewitz. “However, in the previous [2007] ASCO/CAP guidelines, reflected in the previous edition of the checklist, that criterion was 30 percent, not 10 percent.”

More checklist requirement information online

Two 90-minute CAP online educational sessions will cover the checklist requirement changes.

On Aug. 20, Denise Driscoll, MS, MT(ASCP)SBB, will present “The Truth About Personnel Competency.” She is director of accreditation and regulatory affairs, CAP Laboratory Accreditation Program.

On Sept. 17, Gerald Hoeltge, MD, in his “Checklist Updates” webconference, will cover the changes that affect the laboratory as a whole, the changes in pre- and postanalytics, entirely new sections, and changes within selected specialties and to test method management. He will also share the most common deficiencies reported in 2013. Dr. Hoeltge is chair of the CAP Checklists Committee.

Both Web sessions will begin at noon CT and will be available online within four weeks after the live event. Registered participants will have unlimited access to the files for one year.

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In his view, that’s because of heightened concern at that time regarding false-positives—a concern that has now shifted to the matter of identifying every patient who might benefit from trastuzumab or other anti-HER2 treatments. “So the new edition has changed the criteria for immunohistochemistry back to greater than 10 percent of tumor cells,” he says.

As for in situ hybridization, the definition of a positive result has been changed from a HER2-to-CEP (chromosome enumeration probe) ratio of greater than 2.2 to a ratio of greater than or equal to 2. At the same time, “there is one other point that is new about scoring regarding in situ hybridization, and that is the issue of tumor heterogeneity,” says Dr. Sarewitz. “In a given tumor, the majority of the cells may be HER2 negative, but there may be clones within it that are HER2 positive. The new checklist item states that the slides need to be scanned at

low power, and if you can find a subpopulation of tumor cells that represents at least 10 percent of the total tumor cells, and those cells are positive, you have to report the case as positive. The provision is, you need to be able to count at least 20 cells in this subpopulation; it can't be a three-cell population or something similar."

These scoring changes may cause concern, Dr. Sarewitz acknowledges, about whether patients whose results were declared negative in the past should be re-tested on the chance their results would be considered positive under the new requirement. "The answer is not simple, but it's basically no," he says. "First of all, the number of patients this affects is probably pretty small. I think pathologists should have a discussion with their oncologist colleagues about this, and if there are patients whom the oncologists feel might benefit from HER2 therapy, then the tests could be repeated or the scoring could be looked at again. But it shouldn't be a huge issue."

The new edition of the checklist also requires that if a previously diagnosed patient returns with a recurrence, either in the breast or in a metastatic site such as a lymph node, the recurrence or metastasis be tested for HER2. "However, if a patient presents with a mass in the breast and a metastasis, both don't have to be tested at that time, just one," Dr. Sarewitz emphasizes.

Finally, the issue of histologic discordance has been raised. "What this means is, if the appearance of the tumor under the microscope does not fit with the HER2 result, then consider repeating the HER2 test. For example, if it's a very low-grade tumor that's estrogen- and progesterone-receptor positive, well, those tumors generally are HER2 negative. If you got a HER2 positive result on that tumor, question that result. Conversely, if you have a very high-grade tumor that looks very aggressive under the microscope and is negative for estrogen and progesterone receptors, well, it might be HER2 negative, but if it is, question that. Also, if a core biopsy has an equivocal result by immunohistochemistry, and the laboratory then goes ahead to test it by in situ hybridization, and that's also equivocal, then it's recommended that the test be repeated on an excisional specimen."

Dr. Henry

Another significant change to the anatomic pathology checklist: the addition of a portion on circulating tumor cell analysis. In previous editions, this section appeared in the immunology checklist. "We asked around and found that in most laboratories, this type of analysis is done in the anatomic pathology or molecular anatomic pathology area," says Checklists Committee member Michael Henry, MD, director of cytopathology at the Mayo Clinic. "So we felt it needed to be taken out of the immunology checklist, and plus the existing requirements were not necessarily directly related to the performance of circulating tumor cell analysis."

That's changed now, with the introduction of a comprehensive set of requirements that cover circulating tumor cell testing.

"They start with validation and calibration, and they go through quality control and into specimen analysis, including rejection criteria," Dr. Henry says. The new checklist requirements mandate that there are documented guidelines for differentiating circulating tumor cells from other nucleated circulating cells, and that all reports are reviewed and signed by the pathologist. "We had a discussion about this requirement," he says, "and we decided that because circulating tumor cells require morphologic interpretation in order to be performed correctly, the pathologist should be involved." In addition, if the preliminary morphologic observations are performed by non-pathologist personnel, the qualifications of those personnel must be assessed.

In developing these new requirements, Dr. Henry and his colleagues purposely kept them somewhat general. That's because while to date only one platform has been approved by the FDA for circulating tumor cell analysis,

other platforms may be approved in the future, and the Checklists Committee wanted to ensure that these requirements are likely to be appropriate for those platforms as well.

Dr. Henry was also involved with changes to the whole-slide imaging section of the laboratory general checklist. “We decided to put this in laboratory general because this particular set of requirements, and there are only two of them, is very generic,” he says. “What you use the images for is covered in other areas of the checklist. This part is very simple.” The first requirement calls for documentation that users of the imaging system have been trained. “And the other one says that if you’re using a whole-slide imaging system, you have to have validated that system under the direction of the laboratory director. There’s not a specific protocol that is required,” Dr. Henry says, “but in the note in that particular requirement, there are some guiding principles that should be used.”

Dr. Oglesbee

As for the clinical biochemical genetics checklist, it now contains a section dedicated to hemoglobin separation and aimed at laboratories that perform newborn screening. “Commonly, the laboratories that perform hemoglobin separation perform it in a diagnostic application,” says Devin Oglesbee, PhD, a member of the CAP-ACMG Biochemical and Molecular Genetics Resource Committee. “Screening laboratories, unfortunately, don’t have the luxury of large amounts of sample. They’re using blood screening cards and dried-blood spots, and have methodologies that are designed essentially to perform screening functions—meaning they will detect clinically relevant hemoglobinopathies, but there may also be other types of hemoglobin proteins present that need to be resolved through additional analysis. And these laboratories often don’t have enough sample to perform the additional assays that are required.

“And so this part of the checklist,” he continues, “addresses that primary screen assay, making it more applicable to newborn screening. It also recommends specific follow-up tests that would essentially differentiate between sickle cell trait and other hemoglobin variants.” Dr. Oglesbee is co-director of Mayo Clinic’s biochemical genetics laboratory in the Division of Laboratory Genetics and assistant professor of laboratory medicine and pathology and medical genetics, Mayo College of Medicine.

Finally, checklist users will notice a new instruments and equipment section in the all common checklist, though the requirements in this section aren’t new at all: They’ve been taken from each of the discipline-specific checklists, grouped, and streamlined for the sake of consistency and simplicity. “Things like thermometers and instrument maintenance function checks—they’re used all across the laboratory,” says CAP checklist editor Lyn Wielgos, MT(ASCP). “This consolidation is helpful for laboratories, because it promotes standardization across their processes and reduces the burden of having to prepare for inspection using multiple different checklist requirements.”

“Having these requirements in the all common checklist will help laboratories identify systemic issues across their different laboratory sections,” she adds.

During the streamlining process, Wielgos and her colleagues discovered gaps and remedied them. “One example is that we did not have a requirement in all of the checklists that addressed performance verification before initial use or after a repair. Another example is that some of the requirements didn’t refer to setting tolerance limits for something like a function check and performing corrective action. We realized this was a good opportunity to make

sure these requirements are applied across the board," she says.

In addition, Wielgos took the opportunity to address some common queries: "We get a lot of questions from laboratories about standardized thermometers, noncertified thermometers, and the checks they need to have done. So the checklist requirements have been revised to go into a little more detail about what the expectations are once a standardized thermometer expires."

On a related note, she'd like laboratories to know that if they find themselves receiving what seems like a superfluous number of all common checklists, there's a remedy for that. "This is one of the complaints we receive periodically," she says. "Sometimes when we investigate these concerns, we find out that the laboratory could reduce the number of all common checklists it's receiving by making sure the information it has reported to the CAP on its application reflects the actual organization of its laboratory." For example, if a laboratory has a core laboratory set up under the supervision of one manager, it should put that under one section or department for the CAP. "That way, it would have just one all common checklist for that grouping of tests. Historically, the laboratory setup has been more siloed, but that's changed a lot over the years, and some laboratories haven't updated their application section information to reflect that," she says.

Dr. Sarewitz, too, has a checklist-related message for laboratories. "Let's say that a laboratory's inspection isn't scheduled for an extended period of time, for another year or 18 months or whatever," he says. "One question we get sometimes is: Can and should the laboratory reflect the new ASCO/CAP guidelines as reflected in the new edition of the checklist immediately?"

His answer: a resounding yes. "Adopt them as soon as possible," he says. "It's good practice. The concern is, 'Well, the new checklist takes five or six months to get out there. If we get inspected with the old edition of the checklist, will we be cited?' The answer is no, you should not be cited. And if you are, that citation will be removed during the inspection review process afterward. So that shouldn't be a problem."
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