Laboratory director duties clarified in 2017 checklist

Anne Ford

Revisions in lab general and histocompatibility checklists

August 2017—Quantum theory is often interpreted to mean an object can be in two places simultaneously. Unfortunately, quantum theory doesn't apply to laboratory directors, at least not on a scheduling level. Like the rest of us, directors can be in only one place at a time, no matter how many laboratories they oversee.

Now a change to the CAP Laboratory Accreditation Program's checklists will clarify expectations for directors who are in charge of more than one laboratory. The 2017 edition of the checklists, released this month, has eliminated the specific requirements for laboratory directors who are not on site full time and has clarified responsibilities for all directors, on site or remote.

Driscoll

"A director can direct, by law, up to five non-waived laboratories, although some states restrict that to only three," says Denise Driscoll, MS, MT(ASCP)SBB, CAP senior director of accreditation and regulatory affairs. "And when you direct more than one lab, you're not going to be there all day, every day. You can have a director who's not on site all the time but who is very involved—constantly emailing, calling, conference-calling in for every meeting, consulting with patients and with other physicians and with the laboratory staff. We don't want to penalize a very involved director who is not there very often."

The change is one of several modifications to the laboratory general checklist, the histocompatibility checklist, and the checklist previously known as the team leader assessment of director and quality checklist. (For coverage of additional changes to the laboratory general checklist and of changes to the all common and microbiology checklists, see page 1. Other checklist changes will be reported in future issues.)

The now-defunct section for laboratory directors not on site full time was in the team leader assessment of director and quality checklist, which is now titled the director assessment checklist. The name change and the eliminated section are part of a stepped-up focus on the director's involvement (rather than mere attendance) in the laboratory.

"The old name—team leader assessment of director and quality checklist—has been around for a while, but it's kind of a mouthful, to say the least," says CAP Checklists Committee chair William W. West, MD, of Physicians Laboratory Services, Omaha, Neb. "The Council on Accreditation decided we need to put more emphasis on the director's duties, the director's involvement in the laboratory, and this checklist is aimed at that issue. It's aimed at: How is the director doing? Is the director fulfilling all the requirements for the director position? Thus the name change. It's shorter, simpler, and comes right to the point."

The items on the checklist will retain the prefix TLC, "at least for the foreseeable future," Dr. West says. "That will be less threatening to some laboratories, simply because if we changed that prefix, they'd have to change a lot of things in their records." Checklist users should know, however, that all versions of the checklist generated after the 2017 edition is published will bear the new name. "If you go onto the CAP website, it will now appear on the drop-

down list and print with the name ‘director assessment checklist,’ ” he says.

Meanwhile, the checklist’s section on laboratory director responsibility and oversight stipulates that the laboratory director’s involvement must be considered adequate by the laboratory administration, medical staff, and inspection team, and must follow written policy or agreement. Listed are examples of insufficient involvement on the part of the laboratory director, such as if the director fails to perform the duties defined in the job description, or if the hospital administrator, chief of staff, laboratory supervisor, or technical staff identify situations in which greater personal involvement on the part of the director is needed. If the lab director routinely conducts duties remotely, his or her on-site visits must take place at a frequency established based on complexity and volume of testing and be defined in writing.

“If the lab directors are in their office behind their microscopes reading glass slides and they never come out, that’s probably not good involvement,” Driscoll says. “If on the day of the inspection, the inspector is walking around with the director of the lab looking at things, and one of the technologists says, ‘Who’s that guy?’ or ‘Who’s that gal?,’ that’s probably not a good sign.”

This section of the checklist also clarifies the director’s responsibility for personnel. Specifically, the checklist states, “The laboratory director must perform an on-site assessment of the adequacy of staffing on a periodic basis, as defined in written policy.” Driscoll explains: “Sometimes directors will say, ‘Well, I don’t get to do the hiring and firing, so it’s not fair for you to hold me responsible for having enough personnel in the lab.’ Actually, that requirement comes directly from CLIA regulations and the law. If the staff shortage is severe enough to compromise the quality of the test results, it is the director’s responsibility to do something. Having enough qualified staff to do the testing safely is part of CLIA, so it’s a federal responsibility that can’t be avoided.”

Requirements have also been strengthened to clarify which duties the director can delegate and to whom. “For example, if you delegate clinical consultations for the medical staff to somebody because you’re not on site full time,” Dr. West says, “it’s got to be a physician or a doctorate-level individual who fulfills those duties. You can’t assign that to somebody who doesn’t have those qualifications.”

Finally, the 2017 TLC checklist puts greater emphasis on the interim inspection, stating, “The laboratory director ensures that a thorough interim self-inspection is performed and all deficiencies are corrected in a timely manner.”

“One of the things we’ve discovered by statistical analysis is that there is a correlation between laboratories that seem to have a lot of problems, a lot of deficiencies when they have their on-site inspection, and their failure to conduct a rigorous interim inspection,” says Accreditation Committee chair Paul Bachner, MD, a professor of pathology and past chair of the Department of Pathology and Laboratory Medicine at the University of Kentucky, Lexington. “So one of the newly emphasized responsibilities for the director is that he or she is responsible for making certain that that interim inspection takes place and is performed in a careful and rigorous way.”

As for the laboratory general checklist, a major change there is the stipulation that the training and qualifications of all personnel trained outside the United States must be evaluated by a nationally recognized organization to determine equivalency to an education obtained within the United States—and records of that evaluation must be available in the personnel file.

“Sometimes it’s hard to tell” the U.S. equivalent of the degree of someone trained overseas, Driscoll says, “particularly with MDs. An MD in China, for example, does not have the same educational requirements as someone does to be a physician in the U.S. Therefore, CMS requires that a formal equivalency be documented, and they give a couple of organizations that are acceptable,” namely, the National Association of Credential Evaluation Services and the Association of International Credential Evaluators.

“We mentioned this in the checklist before,” she adds, “but people were still missing that this wasn’t a general suggestion, but an actual requirement. This is a CMS requirement, and they’re very strict on this, and so we’re trying to make it more clear what to expect. This might be frustrating to people, but you only have to do it once.”

Also new in the laboratory general checklist: The competency assessment requirements for non-waived testing have been revised, thanks to CMS clarification that this type of testing has to be assessed at the laboratory that performs the testing. This change is expected to be most relevant for laboratory systems within which staff may work at more than one facility.

One of those revisions pertains to GEN.55500, which Driscoll calls "a famous checklist ID number that every med tech in the world, including me, knows by heart."

"It's now going to be just for non-waived testing," she says, "and there'll be another requirement just preceding it that will pertain to waived testing." GEN.55500 now reads, "The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed," while the new GEN.55499 for waived testing reads, "The competency of personnel performing waived testing is assessed at the required frequency." Simple enough.

In addition, a separate requirement, GEN.55510, was also split out of GEN.55500, and it states that "Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed." An accompanying note says the evaluators' required qualifications—section director, technical consultant, and so forth—vary according to how complex the testing is.

More significant revisions have been made to the histocompatibility checklist, says Histocompatibility Committee chair Patricia Kopko, MD, a professor and director of transfusion medicine and associate director of the immunogenetics and transplantation laboratory at the University of California, San Diego, School of Medicine.

"A number of the changes were made to reflect changes that are going on in molecular diagnostics, specifically next-gen sequencing," Dr. Kopko explains. "As more and more laboratories have started using next-gen sequencing to perform HLA typing for transplantation, we realized we had to update our checklist to reflect that."

Other changes were made in an effort to align the CAP's accreditation requirements with the transplantation for cellular therapy requirements of the Foundation for the Accreditation of Cellular Therapy. "We are aligning our checklist with FACT requirements so that if the labs that use the College for accreditation know they are okay with the CAP checklist, they are okay with FACT," she says.

For example, the checklist requires that the laboratory have in place written agreements for histocompatibility testing with each transplant program, organ procurement organization, or donor registry that the laboratory serves (unless clinical urgency prevents such an agreement). The new edition of the checklist notes that these written agreements must be reviewed annually by the histocompatibility section director/technical supervisor and/or clinical consultant and be revised as necessary, and that if the laboratory supports a program accepted through FACT, the agreements must contain the requirements defined in the sixth edition of the FACT standards. The checklist now also says that if the laboratory supports a program that is participating in the National Marrow Donor Program/Be the Match, the agreement must contain the provisions defined in the November 2015 NMDP U.S. Transplant Center Participation Criteria.

A section on stem cell engraftment monitoring has been added as well. "We had some checklist items for that prior, but we've pulled them out and put them into their own section," Dr. Kopko says. "You'll see that there are now 11 requirements, and I think there were only four before that were specific for engraftment monitoring. Most of the changes have to do with how you do the analysis and what you look for. For example, there's preferential amplification, in which you optimize your analysis so that you minimize preferential amplification of one allele over another."

These same requirements were added to the molecular pathology checklist because stem cell engraftment monitoring is commonly performed in molecular diagnostic laboratory settings.

"An analysis of proficiency testing results made it clear that some labs were performing stem cell engraftment

analysis but it was still on a single locus, and therefore we added a requirement that you need a minimum of three informative loci to do the calculations. You get more accurate results if you use at least three loci."

Another significant addition: a section on additional molecular testing methods, namely, ABO and RhD typing by molecular methods.

Dr. Kopko

"The problem is this: When somebody gets registered on a registry as a potential stem cell donor, they do that with a buccal swab," Dr. Kopko says. "Well, when you do that, you want the HLA type, but you kind of want to know what the donor's ABO type is. If you've got a buccal swab, you can't do ABO by serologic methods, which is how we do it in the blood bank and the transfusion service. In fact, ABO by molecular methods is not licensed for patient usage, but yet we still have to find a way for the National Marrow Donor Program and other donor registries to take that buccal swab and get a presumptive ABO type, so that when somebody is searching for a donor for their patient, one of the things that weighs into the consideration is that if there's a donor who's ABO-matched, that would be preferable to a donor who's not ABO-matched. But if we say, 'You have to do serologic testing,' they don't have a sample that can be used.

"So we wrote this long note in the checklist explaining that you can use molecular methods for presumptive ABO and RhD typing only for donor registry purposes, and that for transfusion and the actual transplant you have to use FDA-cleared or -approved serologic methods. For a presumptive type, you can use ABO molecular methods, and there's an explanation there in the checklist that it's only for preliminary information, and you can't use it for transplant."

Finally, an effort was made, as elsewhere, to harmonize the language in the histocompatibility checklist with that of others, such as the laboratory general checklist, "so that if you're talking about something we do in multiple types of labs, the wording is the same," Dr. Kopko says. "For example, we harmonized a lot with the molecular checklist because so much of the work done in an HLA lab is done with molecular testing. We didn't want to have one set of requirements/language in one checklist and use completely different wording in another checklist." n
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