Few but notable— new accreditation checklist changes

Valerie Neff Newitt

August 2023—Climate control, calculation verification, block retention, and histocompatibility section director (technical supervisor) qualifications are among the areas in which laboratories can expect to see revisions in the new edition of the CAP laboratory accreditation checklists, to be released this month.

But the number of revisions in the 2023 edition overall is relatively limited, and the decision to limit them to a handful of priorities was deliberate.

“We wanted to clarify language if there has been confusion, on the part of laboratories or inspectors, about how to interpret a checklist requirement. At the same time, we tried to keep changes to a minimum” because of the labor shortage and other stressors affecting all labs, says Stephen Sarewitz, MD, chair of the CAP Checklists Committee. The focus for the 2023 edition was therefore on what could help to address advancements in technology, ensure regulatory compliance, clarify requirements that are commonly cited as deficiencies, and improve patient care.

One such revision now includes biopsies of pediatric tumors in a requirement (ANP.12350) related to cancer protocols, says Jessica L. Davis, MD, a member of the CAP Cancer Committee. “Previously, pediatric pathology CAP cancer synoptics have not been required for biopsies or resections. They’ve been optional. So historically no cancer synoptic reporting was required in the pediatric pathology space. This requirement change moves them from optional synoptics or templates to required synoptics,” says Dr. Davis, Lawrence M. Roth professor of pathology and laboratory medicine and director of surgical pathology, Indiana University School of Medicine.

One major reason for the move to synoptic reporting for biopsies of pediatric tumors is because the large majority of pediatric neoplasia is treated neoadjuvantly, Dr. Davis explains. “The management and the key data elements are being obtained in that initial biopsy.” She cites neuroblastoma as an example. “The risk stratification of a patient is performed at the time of biopsy, which dictates patient management, and limited new data is gathered at the resection.”

Dr. Davis

In general, Dr. Davis notes, there is a shortage of pediatric cancer data. “There are large initiatives trying to collect that data, not just for research but for clinical care. There is good evidence showing that patients are better treated when synoptic reports are available.”

Many pathologists at children’s hospitals already use the available synoptic reports, she says, though some do not. “It will require some additional work, but I’ve heard from many pathologists that they’re excited about this [requirement] to help in standardization. And our clinical partners in the oncology space are looking forward to obtaining the data to better treat our patients.” Yes, it’s a change, she says, but a beneficial one. “I’m happy we’re able to do this and move this forward.”

In the laboratory general checklist, the climate control requirement that calls for the room temperature and humidity to be adequately controlled in all seasons (GEN.61300) now has a note that says laboratories must follow the manufacturer’s instructions for temperature and humidity for proper functioning of instruments, equipment, and test systems.

“This one looks like a humble checklist requirement,” Dr. Sarewitz says, “but there have been problems with that, particularly with humidity but also temperature, where they may be outside the range that’s specified in the manufacturer’s instructions for proper operation.” If humidity or temperature are not maintained within range due to extreme weather conditions, he says, a proper step would be for the laboratory to work with its facilities department to adjust environmental conditions or consider the use of portable equipment—a humidifier, for example—to adjust conditions near the instrument.

If the environment cannot be controlled such that variances in humidity or temperature outside the manufacturer’s range are a chronic problem, continued operation of the instrument would be considered a modification to the instrument requiring the laboratory to perform validation studies of analytical accuracy, precision, reportable range, sensitivity, and specificity to ensure proper operation of the instrument.

GEN.43450 Verification of Calculations Producing Patient Results was revised to clarify which computer-based functions are considered calculations that require the lab to verify them every two years or when a system change is made that may affect the calculations. The requirement applies to laboratory information systems, middleware, and analyzer calculations modifiable by the user. The checklist defines calculated test result as a reportable patient test result that is not directly measured but rather calculated from one or more directly measured results.

“If there’s a calculation that is hardwired into the instrument, that is not covered by this,” Dr. Sarewitz says. “But when there is something the laboratory can modify, errors can creep in, and those results should be reviewed. It doesn’t apply to calculations that do not produce patient results or to such things as reference ranges.”

Those would fall under GEN.43022 LIS Testing, which says computer programs must be checked for proper performance when first installed and after changes or modifications; however, a check every two years is not required. Dr. Sarewitz notes that this requirement does not apply to calculated patient results but instead to reference intervals, critical values and/or verification limits, and operational rules/algorithms.

In the anatomic pathology checklist is a requirement for record and material retention in surgical pathology (ANP.12500), which has been revised in the 2023 edition to include different retention requirements for paraffin blocks for deceased patients to improve the availability of material for research. The CAP requires that paraffin blocks used to support a patient’s diagnosis be retained for 10 years, Dr. Sarewitz says, because often it is several years post-diagnosis when the patient needs additional treatment. The revision in the new checklist edition shortens the retention period for deceased patients from 10 years to two years. If a patient is deceased, only one block containing normal tissue (if it exists) needs to be retained for the full 10-year period. “A germline genetic mutation that might affect other family members” is the reason for retaining the block containing normal tissue, Dr. Sarewitz explains.

Dr. Sarewitz

The requirement revision, while it may increase the complexity of the documentation that’s required before the blocks are released (documenting the death and distinguishing tumor blocks from normal blocks), has the potential to make more pathologic material available for research purposes.

No changes were made in the block retention requirements for living patients.

In cytopathology, CYP.07600, which requires statistical records for gynecologic cytopathology cases to be maintained and evaluated at least annually, already states that the benchmarking data provided in the requirement may not be applicable to labs that use primary HPV screening for a significant portion of their cervical

cancer screening. Additional language in the note will state that in the benchmarking data, which are based on 2021 case volumes, results were excluded for labs that included primary HPV screening results in the interpretive totals when more than 25 percent of their cervical/gynecologic cytology slides were from positive primary HPV screening. "The table is meant to apply to patients who come in for primary cytologic screening but not those who have been reflexed to cytology because of a positive HPV test," Dr. Sarewitz says. (See "Impact of primary HPV testing on cytology lab statistical analysis," in Cytopathology in Focus.)

In the histocompatibility checklist, requirement HSC.40000 on section director/technical supervisor qualifications contains changes for laboratories whether or not they participate as members of the Organ Procurement and Transplantation Network (OPTN) or United Network for Organ Sharing (UNOS). This is part of a new process that the CAP will implement to evaluate changes in HLA section directors (technical supervisors). "If a new person becomes the HLA section director," Dr. Sarewitz says, "the laboratory must submit information to the CAP on the qualifications of the new section director, whether or not the laboratory participates in the United Network for Organ Sharing/Organ Procurement and Transplantation Network."

For laboratories that participate as members of OPTN/UNOS, part of the information requested may include a portfolio from the new director of 50 cases of transplantation (10 in detail and a log of 50 total) to cover the programs they support (solid organ transplantation, hematopoietic progenitor cell transplantation, or transfusion support), and several additional items, he says, among them proof of active interaction with transplant professionals and a statement of experience. Submission of the portfolio may not be required if the laboratory can provide evidence that the portfolio has been reviewed and approved by a certifying board such as the American College of Histocompatibility and Immunogenetics or similar agency.

For laboratories that do not participate as members of OPTN/UNOS, when a new section director was brought on, the prior checklist edition required that the director provide a portfolio of 10 cases to be examined by the inspector during the inspection. The 2023 edition will require that information on the qualifications of the section director be submitted to the CAP instead of reviewed by the onsite inspector. If portfolio review is required, the case requirement number for the 2023 edition is larger: at least 20 cases (10 in detail and a log of 20 total) that cover the programs the laboratory supports.

In the laboratory general and point-of-care testing checklists, two requirements related to competency assessment were revised to contain specific information for laboratories with California laboratory licensure. GEN.55499 and POC.06875, Competency Assessment—Waived Testing, require that the competency of personnel who perform waived testing be assessed for each test system after an individual has performed duties for one year and at least annually thereafter (as well as when problems with an individual's performance are identified). If state and local regulations are more stringent, they must be followed. The requirements now clarify that laboratories with California laboratory licensure must also assess competency for waived testing at least semiannually during the first year an individual tests patient specimens and annually thereafter.

"Because the CAP has deemed status with the state of California, the CAP must ensure that labs there follow both CLIA and California lab regulations," Dr. Sarewitz says.

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all common, hematology and coagulation,
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In addition, the requirements list six elements of competency assessment for assessment of waived testing personnel. "Laboratories with California laboratory licensure must evaluate five of the six elements for competency assessment for waived testing, whereas the generic portion of the CAP requirement allows labs to select any element or elements as the lab itself sees fit," Dr. Sarewitz explains.

GEN.55510 and POC.06920, Competency Assessment—Assessor Qualifications, contain requirements for the qualifications of those who perform competency assessments for all levels of test complexity. For waived testing, those qualifications may be determined by the lab director, except for labs with California licensure. "For California

laboratories, personnel responsible for assessment of waived testing must meet the qualifications of a waived laboratory supervisor," as detailed in GEN.78250, Dr. Sarewitz says.

The CAP will provide on Oct. 18 (noon to 1 pm CST) its Focus on Compliance webinar (registration open on www.cap.org), during which the key checklist changes in the new edition will be explained. Other compliance-related resources for CAP-accredited labs can be found on www.cap.org, including past Focus on Compliance webinars and lab inspection preparation videos, answers to the most common checklist-related questions, a self- and post-inspection toolbox, and customizable templates and forms for, among other things, competency assessment and quality management.

Valerie Neff Newitt is a writer in Audubon, Pa.