December 2020
Vol. 16, Issue 4

Management
BULLETIN

Laboratory Records Retention

In our last Management Bulletin, we discussed "Going Paperless" in the laboratory in an era of electronic record keeping. So, what do you do with all of those laboratory records that may still remain?

Retention of records is a fact of life for the clinical laboratory. The Clinical Laboratory Improvement Amendments of 1988 state how long laboratory records must be maintained for laboratory compliance. In addition, the North Carolina Department of Natural and Cultural Resources, Division of Archives and Records has issued a Records Retention and Disposition Schedule for Local Health Departments. The College of American Pathologists (CAP) also has criteria in its Laboratory General Checklist regarding record retention.

The Regulations

42 CFR§ 493.1105 states the requirements that the following laboratory records be retained for at least a minimum of two full years:

- Test requisitions and authorizations, including the patient's chart or medical record if used as the test requisition or authorization.
- Test procedures for at least two years after a procedure has been discontinued or superseded. Each test procedure must include the dates of initial use and discontinuance.
- Analytic systems records, which include quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities. This also includes records of test system performance specifications, or validations, that are established or verified during the period of time the laboratory uses the test system.

Other analytic systems records that must be retained for at least two full years are:

- Immunohematology records, blood and blood product records, and transfusion records
- Proficiency testing records
- Quality system assessment records

Note that patient test reports must be retained, or the laboratory must be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) for at least two years after the date of reporting. This also includes Immunohematology patient reports.

There are exceptions to the two-year records retention rule for cytology, histopathology, pathology reports and records documenting the transfer of samples to NCDHHS for HIV test processing. The record retention requirements for these categories of laboratory records are:

- Laboratory records and logs documenting the transfer of samples to NCDHHS for HIV test processing must be retained for at least five full years. This may include test results and patient information.
- Pathology test reports must be retained for at least 10 years after the date of reporting.
- Cytology slide preparations must be retained for at least five years from the date of examination, including fine needle aspirates. (see § 493.1274(f) for proficiency testing exception).
- Retain histopathology slides for at least 10 years from the date of examination. The laboratory must maintain documentation to acknowledge the donation of each slide submitted to a proficiency testing program or loaned for other purposes.
- Retain pathology specimen blocks for at least two years from the date of examination.
- Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

Considerations for Records Maintained by Electronic Means

For data transmitted by computer interface (an online system), it is not necessary to retain paper worksheets or printouts if the computer system retains the data for at least two years. Manual entry of patient result data requires that all worksheets and printouts be retained by the laboratory for at least two years. If the results are entered via download or direct interface to a Laboratory Information System (LIS), the instrument printouts need not be saved. If, however, results are transcribed from instrument printouts into the computer or into the patient report, the printouts need to be retained for two years. In the event that the interface is down and the results are manually entered, a hard copy or original must be kept in case there is a question about the transcription.

Storage of Laboratory Records

The laboratory must make arrangements for storage of laboratory records that are hard copy (on paper). Paper records should be stored in a dry location, and be easily accessible in the event the results of a past test report comes under question, if laboratory records are included as part of a legal litigation, or if requested by a surveyor.

Laboratory records maintained electronically, either onsite or in a cloud environment, should be backed up on a regular basis per facility policies.

Destruction of Laboratory Records

When records retention periods have ended, and prior to disposition, all records being disposed of should be recorded on a Laboratory Records Destruction Log. Remember that any laboratory record involved in a legal transaction or dispute cannot be destroyed before the action is resolved. Once the retention period has been reached, those records that contain patient information must be shredded before disposal. Records that do not contain patient information can be disposed of with regular trash and taken to the landfill.

What If the Laboratory Closes?

If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in the CLIA regulations.

Although it may seem tedious, laboratory records retention and destruction regulations can be successfully implemented when the correct information is known.

References:

Centers for Medicare and Medicaid Services. December 9, 2019. *CLIA Law & Regulations*. Centers for Disease Control and Prevention. Accessed 11/18/20. www.cdc.gov/clia/law-regulations.html

NC General Assembly. December 2012. *CLIA Regulations: Retention Requirements (42CFR§493.1105)*. Accessed 11/18/20. www.ncleg.gov/documentsites/committees/PMC-LRC2011//December%205,%202012/CLIA%20Regulations%20Record%20Retention%20%20(42CFR%C2%A7493.1105).pdf

Cornell Law School Legal Information Institute. January 24, 2003, August 22, 2003. *42 CFR § 493.1105 - Standard: Retention requirements.* Legal Information Institute. Accessed 11/18/20. www.law.cornell.edu/cfr/text/42/493.1105

Stephen J. Sarewitz, MD. February 2004. *CAP Today Queries and Comments. College of American Pathologists.* Accessed 11/18/20. www.captodayonline.com/Archives/feature_stories/0204Queriesandcomments.html

Karen Wall, BSMT(ASCP). September 21, 2015. *Retention and Disposition of Laboratory Records.* NC State Laboratory of Public Health CLIA Contract Program policy.

North Carolina Department of Cultural Resources Archives and Records Section. March 1, 2019. Records *Retention and Disposition Schedule for Local Health Departments.* Accessed 11/18/20. https://archives.ncdcr.gov/documents/local-health-departments-schedule

■ Submitted by: Linda B. Cleve BSMT(ASCP), Lab Improvement Technical Consultant