LabGuide 2

COLA
Lab Accreditation Through Education

This LabGuide pertains to QSE Documents and Records and the General Systems, Pre-analytic, Analytic, and Post-analytic Phases of the Path of Workflow.

Laboratory Documentation

Laboratory documentation, whether paper or electronic, is an essential part of your daily operations and regulatory compliance. Required documents include your laboratory's policies, processes and procedures and the records generated by performing daily activities.

Documents not only tell your staff what activities to perform, but also how and when to perform them.

Records provide evidence that the activities were performed. They detail when the activities were done, who performed them and what happened when they were done.

Documentation is a broad term used to describe any policy, procedure, manual, log, file, report, record, etc. kept by the laboratory.

Documentation should allow you to easily review and track your laboratory's activities. It provides an audit trail for federal and state laboratory inspectors and COLA surveyors to see that requirements have been met. It is also especially useful when a problem arises. If you record what happened and the corrective action taken, it will help show that patient results were still reliable even though a problem occurred.

Written documentation is required for:

Record any corrective actions taken in response to problems encountered with any of the above processes

Documentation Storage and Retention information can be found on p5

Personnel Files *(education, experience, training, and continuing education)*

Clinical laboratories are required to maintain detailed documentation about the qualifications of each employee. Examples of required documentation are copies of transcripts, diplomas, letters from former employers, and current licenses. Documentation of continuing education should also be included.

In addition to the usual contents of an employee file (such as job description, job reviews and disciplinary actions) your personnel files should contain additional information which addresses the fact that healthcare workers are at risk of occupational exposure. This information includes records of hepatitis B vaccination status (including dates of vaccination or signed declination statement), annual safety training, and records of any exposure incidents, including appropriate follow-up.

Procedure Manual

The procedure manual must include a procedure for performing every test on your laboratory's test menu as well as instructions for patient identification, specimen collection and handling, documentation, and test reporting. Your laboratory policies may also be included in your procedure manual. Alternately, they may be kept as a separate policy manual. The manual(s) should be accessible to all laboratory personnel, which helps ensure that tests are always performed as stated in the procedure manual.

An up-to-date procedure manual:

- Acts as a training guide for new personnel
- Serves as a quick reference for testing personnel should they forget some aspect of performing a test
- Provides uniformity in testing over time, and from one person to the next

Instrument Files

Each instrument should have a file that contains the following information:

- Instrument name
- Model number and serial number
- Purchase date
- Manufacturer and/or supplier contact information
- Technical service contact information
- Repair service contact information
- Warranty information
- Preventive maintenance and repair services performed by company representatives
- Verification of performance specifications, if applicable

If it wasn't documented, it wasn't done!

Equipment Maintenance

Proper maintenance, according to the manufacturer's procedures, is essential for optimal instrument performance. Maintenance logs should include a place to document instrument function checks, preventive maintenance, and any other required monitoring. The log can be a chart that includes the frequency to perform the maintenance activity, the dates of activity performance and the initials of the staff who performed the activity.

Calibration and Calibration Verification

Most instruments need to be calibrated before initial use, and periodically thereafter. Calibration is the process of testing standards or calibrators of known value and adjusting the instrument readout to establish a correlation between the instrument's measurement of the analyte being tested and its actual concentration. In other words, calibration sets the instrument to produce an accurate result when you test patient specimens.

The manufacturer determines the number, type and concentration of calibrators to be used. Calibration must be performed at the frequency recommended by the manufacturer or at the frequency determined by your laboratory if it is more stringent than the manufacturer's recommendations.

Calibration Verification confirms that the calibration setting continues to allow test results to be accurate throughout the reportable range of the test system. It must be performed according to the manufacturer's instructions at least once every six months or more often, if required by your laboratory's procedures.

Calibration Verification is also performed to verify that a new lot number of reagents, a complete change of reagents, or instrument service of critical parts has not negatively affected the calibration. Additionally, it may be used to troubleshoot unacceptable Quality Control or Proficiency Testing results.

Retain instrument tapes and/or printouts as part of your documentation of performing Calibration and Calibration Verification procedures.

Quality Control (QC)

Quality Control (QC) is the process of testing materials (controls) that have a known concentration of the substance being measured, prior to or concurrently with patient testing. The goal is to obtain results that are within the expected target range of the control material, giving confidence that the test system is accurately measuring the analyte. Analyzing controls ensures that your test system is working properly and that your laboratory is getting the "right" result on your patient tests. Your laboratory must have documented policies and procedures for the performance of quality control. In other words, you must have a written Quality Control Program that describes your quality control activities for each test you perform.

You must document all quality control results, and graph quantitative results for visual evaluation of shifts and trends over time. You must also document that you recognized problems and took corrective actions to address them, when the controls do not produce the expected results.

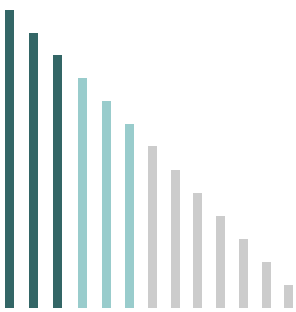
Temperature and Humidity Logs

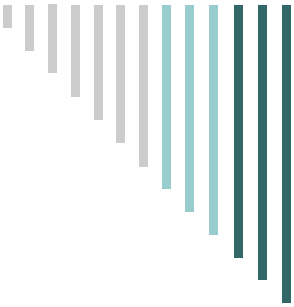
If environmental temperature affects your instruments and/or test kits, the laboratory room temperature must be checked and recorded daily, prior to testing QC or patient specimens. In addition, temperatures of any temperature-dependent equipment (such as water baths, heat blocks, refrigerators, freezers, etc.) must be monitored and recorded daily. Finally, if the humidity in the laboratory can affect instruments and/or test kits, it must be monitored and recorded daily. If any temperature and/or humidity reading is out of range, corrective actions must be taken and recorded in the log.

Test Tracking System *(test requisitions, testing records and test reports)*

The test tracking system is your laboratory's method for monitoring and keeping track of a given test and its components (test request, patient, specimen, analysis, results, report, etc.) across the entire path of workflow. The system should track the test from the time it is ordered, as the specimen is obtained from the patient, through analysis in the lab (including transfers of the specimen from the original container into cuvettes, tubes, slides, etc.), until the result is reported to the physician. Misidentification and/or mislabeling of specimens and/or requisitions are two of the most common laboratory errors, and can have disastrous effects on patients.

Test requisitions - Before the laboratory performs a test, an authorized person must submit a requisition, in either written or electronic form. Verbal orders are allowable, but must be followed by a written request within 30 days. Upon receipt of a specimen, the laboratory must record the following on the





requisition:

- The patient's unique identification, e.g., name, SSN, lab#, accession#, or client# (two forms of identification are usually required)
- Date and time of specimen / requisition receipt
- Condition of the specimen (acceptable or unacceptable)
- Date of testing
- Test results.

Testing records – A worksheet and/or log must be kept at each testing station documenting dates and results of all patient and quality control specimens analyzed. In addition, information on specimens sent to a reference lab must be recorded in an accession log.

Test reports - The final report must include the patient's unique identification, the name and address of the laboratory where testing was performed, the tests performed, the test report date, the specimen source when appropriate (blood, serum, plasma, urine, body fluid, etc.), test results (with units of measurement and/or interpretation when applicable), and reference or normal ranges.

If you don't have the proper documents, manuals, files, logs, records and reports, now is the time to start creating them!

Some laboratories combine the test requisition and the test report on a single form.

Proficiency Testing (PT)

COLA and the federal government require that every laboratory keep detailed documentation of its participation in a Proficiency Testing (PT) program. This file should include:

- A copy of the PT enrollment order form
- The instructions that come with the samples
- All worksheets and instrument printouts of testing
- A copy of the final completed result form that you send to the PT provider, including the signed attestation statement
- The reviewed PT score report, including the CMS summary page
- Documentation of investigations and corrective actions for any PT failures

Quality Assessment (QA)

Quality Assessment (QA) is a planned, ongoing review process that observes the performance and evaluates the quality of all laboratory-related activities. You must have a Quality Assessment plan and use it to perform and document QA reviews.

Activities that have value, impact your laboratory, and improve patient care should be reviewed and documented as part of your QA plan.

- Evaluate your current policies and procedures to see if they are effective and ensure they are being followed by all staff
- Identify activities that have the potential for problems that can impact the quality of your test results (each category in this LabGuide is a potential topic for QA review)

- Detect and keep track of errors over time
- Find the root cause of errors and formulate solutions
- Make corrections and improvements
- Reduce errors and prevent the same errors from recurring

Documentation Storage and Retention

Storing documentation in an orderly fashion, which allows information to be promptly retrieved by the laboratory director, the laboratory consultant, inspectors, and accreditation agency surveyors, reflects the general organization of the laboratory.

To determine if your information is easily accessible, ask a few questions:

- Can I find information if I only have the date of service?
- Can I find information by using a patient's name or other unique identifier?
- Can I show that corrective actions were taken in response to a problem in the lab, for example, when the chemistry analyzer is out of control?

Be sure that all documentation is maintained for the proper length of time. Most documents and records generated in the office laboratory must be available for two years; however, some must be stored for a longer time period. These time frames are applicable even if your laboratory closes or otherwise ceases to perform testing.

Additional Resources

For more detailed information, see the LabGuides menu under *Educatlonal Resources* on the member site at www.COLA.org.

Relevant COLA Accreditation Criteria:			
ORG 7, 11-20	PER 1-6	PT 13-18	PRE 1-13
MA 6-14, 16-21, 24-26	APM 1-19	PST 1-16, 19-27	QA 1-22
QC 1-7, 10, 16, 26-30	TS 7-16, 85-103		
Reference: COLA Accreditation Manual; June 2007			

Additional Reference: CLIA Requirements: 42CFR, Part 492, Subpart M