LabGuide 1

The Procedure Manual

The Procedure manual is a key component of laboratory quality. The CLIA requirements state that the Lab Director has the responsibility to:

> *Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.*

Therefore, every laboratory should have a procedure manual for all laboratory operations and all testing performed in the laboratory. The procedure manual must include a procedure for performing every test on your lab's test menu, as well as instructions for specimen collection and handling, documentation, test reporting and specimen disposal.

Your laboratory policies may be included in your procedure manual, or kept as a separate policy manual. The manual(s) should be accessible to all laboratory staff, and tests should always be performed as specified in the procedure manual.

This LabGuide will briefly outline the development of a procedure manual with a focus on meeting the requirements for proper written test procedures that make up the manual.

Steps to develop a Procedure Manual include:

(p1) Plan the Development

(p1) Write Content

(p3) Revise and Update

Developing a Procedure Manual

There are three activities to address when developing a Procedure Manual for your laboratory:

1. Plan the development of the manual.
2. Write the content of the manual.
3. Revise and update the manual as needed to keep it current.

Plan the Development

It is important to devise a plan for developing your procedure manual. Advance planning will result in a more organized, consistent, and complete manual.

- Decide who will develop the manual. This could be an individual or a team.
- Determine how the manual will be organized. For example, one or more 3-ring binders with tabs and plastic sheet protectors can be used to organize procedures by specialty or instrument, and then alphabetically by test. You could also create an electronic version of your manual, using a laboratory information system (LIS).
- Make a list of all tests performed and all instruments and test systems used. Gather reference materials for each test, instrument, and/or test system. Be sure to include operator's manuals and package inserts.
- Decide on a development schedule and a realistic completion date.

Write the Content

You will need a written procedure for every test performed in your laboratory, whether it is an automated method or a manual method, such as urine sediment examination.

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You should use a standard and consistent format for your procedures, regardless of the methodology.

Package inserts may be used as your test procedures, but they cannot stand alone. **You must add details about how tests are ordered, documented, and reported in your laboratory.** You must also ensure that your manual contains the most current inserts and that staff are following those instructions. Multiple-fold package inserts can be photocopied onto standard 8½ x 11 paper to make them easier to use and easier to see in plastic sleeves. You should retain copies of the most current package inserts for reference, even if you also write your procedures.

To ensure that you always have the latest version, check the dates and look for manufacturer updates to package inserts when each shipment is received. Even though this step is extremely important, it is often overlooked and it is not unusual to see updated inserts periodically. Replace your copies when changes occur and ensure that the staff knows about, and follows, any procedural modifications.

Each of the following elements (if applicable) must be included in your procedure:

1. The test name
2. Directions for specimen collection:
   (may be included in a separate section or in a specimen collection manual)
   - Type and amount of specimen required
   - Proper collection container
   - Patient preparation, e.g., fasting
   - Instructions for specimen handling, preservation, storage, retention, and disposal
   - Criteria for specimen acceptability
   - Criteria for rejection of unacceptable specimens
   - Instructions for notification of patients and physicians when specimens are not acceptable
   - Written instructions for patients for the collection and storage of specimens that patients collect themselves
3. Directions for preparing and storing reagents, solutions, stains, calibrators, and controls, including any necessary safety precautions
4. Directions for calibration and calibration verification:
   - The type and concentration of materials to use
   - The number of calibrators required
   - Step-by-step instructions for calibration and calibration verification performance
   - Acceptable limits and/or criteria for interpretation of results
   - Corrective actions to take if the calibration or the calibration verification is unacceptable
5. Quality control procedures:
   (may be included in a separate section or in a quality control manual)
   - The number and type of controls to run
   - The frequency of running controls
   - The proper handling of all control materials
   - Criteria for control acceptability
   - Corrective actions to take when controls are not acceptable
   - How quality control will be documented and reviewed
6. Step-by-step directions for performing the test

Procedure Manual contents can be grouped in sections in one manual or can be separated into different manuals.

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7. Directions for microscopic examinations, including directions for slide preparation, and criteria to assure slides are adequately prepared
8. How the test result is derived, i.e., by direct readout, calibration curve, calculation from a standard, etc.
9. Directions for calculations or interpretation of test results
10. The reportable range of test results, and how to handle and report results that exceed the reportable range
11. Reference ranges, alert values, and guidelines for immediate physician notification
12. How the laboratory reports results (including descriptions of how reports are created, distributed, and maintained for future reference) and how the laboratory provides test results to the ordering practitioner
13. Laboratory information system (LIS) procedures, if a computer is used for work lists, test calculations, test reports, or other test functions
14. The limitations of the test method, including interfering substances and potential sources of error
15. Literature and other references, special requirements, safety procedures, etc.
16. Steps to take when a test system is not working or when the laboratory is unable to perform the test

Test procedures can consist of the manufacturers' package inserts and your lab-specific information. Ensure that the most current package inserts are always in use.

As stated earlier, current manufacturers' package inserts or operator manuals may be the basis of your procedures but that information needs to be supplemented with your lab specific information. Ensure that each applicable element listed above is included in every procedure.

Once the procedures are written they must be reviewed by the laboratory director, who documents the review by signing and dating each new procedure. The date that procedures are first put into use must also be documented on the procedures.

A special note for newly-appointed lab directors: you should review the entire procedure manual, initialing each procedure, to document familiarity with, and approval of, all procedures in the manual. This responsibility cannot be delegated.

Thereafter, if there have been no changes, the lab director should review the manual annually, and sign and date the procedure manual cover sheet to document the review. If there have been no changes, the lab director may delegate the annual review to a qualified designee.

Organize your procedures into sections or separate manuals according to your previously established development plan.

Revise and Update as Needed

Update the manual whenever a procedure is added, changed, or deleted.

Prior to implementation, the laboratory director must sign and date:

1. Each new procedure — each new procedure should be signed and dated prior to use to document the director's review and approval.
2. Any changes in a procedure — any changes to the test method, package inserts and/or laboratory operations must be reflected in the procedure manual. The laboratory director should initial and date the changed procedure prior to implementation of the change.

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3. Discontinued procedures as they are archived — discontinued procedures should be marked with the discontinued date and retained for a minimum of two years for historical reference.

In these three circumstances, the laboratory director is solely responsible for approving and signing procedures; this responsibility may not be delegated.

Summary

A Procedure Manual:

- Serves as a reference for all the information needed to perform testing and report test results.
- Contains a written procedure that includes all the required elements for every test performed in the lab.
- Can be used as a training tool for new or current employees.
- Ensures that everyone in the laboratory performs each test the same way.
- Is a guidebook for good laboratory practices that promote quality.

A Procedure Manual contains much more information than just step-by-step testing instructions.

Relevant COLA Accreditation Criteria:

ORG 11-20, PRE 12, APM 1-19, WAV 7, 8

References:

CLIA Requirements: 42CFR, Part 493, Subpart K, 493.1251

Clinical and Laboratory Standards Institute; Wayne, PA, 2013
Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition (Replaces GP02-A5: *Laboratory Documents: Development and Control; Approved Guideline*)

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