

Oregon Public Health Division
Laboratory Compliance Section
7202 NE Evergreen Pkwy., Ste. 100, Hillsboro, OR 97124-7251
503-693-4125 Fax 503-693-5602
www.healthoregon.org/lcqa

PREPARING FOR THE INITIAL LABORATORY SURVEY

The purpose of this document is to provide guidance to facilities preparing for their first CLIA survey. This is not a complete list of requirements, but rather an overview of the major requirements. Failure to perform the functions below will result in the citation of deficiencies. Completion and documentation of these tasks alone does not insure deficiencies will not be cited. It does reasonably assure facilities that no major deficiencies will be cited and the laboratory will be recommended to CMS for certification.

General Laboratory Administration -

- Familiarize yourself with the laboratory regulations.
 - Read the Synopsis of CLIA Regulations for Certificate of Compliance Laboratories (42 CFR Part 493).
 - Larger facilities with multiple tests and specialties should become familiar with the complete regulatory text of 42 CFR Part 493, available on the web at <http://www.cms.hhs.gov/CLIA/>.
 - List all tests in your test menu and verify the complexity of each test at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>
- Write job descriptions for all applicable personnel, including:
 - Moderate complexity Director, Clinical Consultant, Technical Consultant and testing personnel (42 CFR 493.1403 through 493.1425).
 - High complexity Director, Clinical Consultant, Technical Supervisor, General Supervisor and testing personnel (42 CFR 493.1441 through 493.1495).
- Obtain and file evidence of education and clinical laboratory experience of all personnel.
 - College degrees, previous laboratory work experience, on the job training checklists, etc.
- Develop policy and procedure manuals that include the Director's signed and dated review and approval (42 CFR 493.1251).
 - Must include information on pre-analytical, analytical, and post-analytical testing

- in each procedure (package inserts are acceptable for test performance).
 - Determine “critical values” and subsequent actions; post these in the lab.
 - Define specimen requirements for all tests.
 - Define frequency and type of quality control.
 - Define unacceptable specimens and action to be taken.
- Set up a policy and mechanism for reporting communicable diseases and other reportable conditions to the local health department.

Pre-analytical Systems (42 CFR 493.1240 thru 493.1249) -

- Develop written instructions for patients when applicable and prepare a test request form.
 - *Example:* 24-hour urine collection, occult blood, fasting specimens, drug levels.

Analytical Systems (42 CFR 493.1250 thru 493.1289) -

- Validate all test systems.
- Purchase, run and document quality control for all tests for which control material is available (42 CFR 493.1256 through 493.1278).
 - External controls are required for most test systems, two levels of control (normal and abnormal, positive and negative).
 - If external controls are not being run every day of patient testing, or per the regulations in certain subspecialties, the laboratory must provide a Director approved Individual Quality Control Plan (IQCP) for the testing.
- Set up a record keeping system for the following:
 - Quality control
 - Instrument maintenance and trouble-shooting.
 - Temperature validation of equipment and room (if test package insert indicates specific temperature range for storage of reagents or storage and/or performance of tests). (*Example:* refrigerators, freezers, incubators, heat blocks, RPR syphilis tests, some rapid strep tests.) Include acceptable temperature range on log sheet.
 - Tracking specimens that were sent to your reference laboratory.
 - Personnel competency (twice a year for new employees, annually thereafter).
- Order proficiency test (PT) specimens for all regulated analytes from a CLIA-approved PT provider (42 CFR 493.801).
 - Keep evidence of enrollment to show surveyor.

- Set up a process for assuring accuracy for non-regulated analytes (bi-annual verification).
- Calibrate instruments according to manufacturer's instructions.
 - Maintain documentation of calibration.
 - Determine frequency of on-going calibration.
- Perform and document any necessary instrument linearity studies for individual tests.
- Verify reportable range-
 - Particularly for tests in which test values exceed the upper and lower limits of control materials (example: glucose, enzymes, neonatal bilirubin).

Post-analytic Systems (42 CFR 493.1290 thru 493.1299) -

- Develop report forms or mechanism for chart reports (42 CFR 493.1291).
 - Include all elements as indicated by regulations (example: name and address of facility/laboratory performing the test).
 - Determine additional pertinent information to be provided on reports; write policy (example: fasting status, time of last dose of medication, lipemic and hemolyzed specimens).

Quality Assessment -

- Write a Quality Assessment Plan (QA) including a signed review and approval from the Director.
 - The QA Plan must cover pre-analytical, analytical, and post-analytical aspects of testing.
 - Define what is to be monitored, frequency of monitoring (at least 2X per year), threshold (goal), and individuals responsible for each monitor.

We recommend you perform a self-inspection prior to your initial survey and correct any deficiencies found. Quality control and patient results must be available for review prior to the initial onsite inspection. Review your billing policies with your billing department including use of appropriate CPT codes.

Please don't hesitate to contact our office to discuss your initial laboratory survey or any CLIA compliance issue. We look forward to meeting you at the survey.