FACILITY ADMINISTRATION

In 2003, the CLIA '88 requirements were revised. Changes include a new format, some new terminology, and updated requirements. Subparts J, K, and P of the Code of Federal Regulations, Part 493 have been combined into two new subparts. Subpart J is now Facility Administration for Non-waived Testing (addressed here) and Subpart K is Quality System for Non-waived Testing (addressed in other Fact Sheets). The Facility Administration requirements specify standards for:

- Facilities
- Retention Requirements
- Transfusion Services

Standards for Facilities

According to these requirements, the laboratory needs to be constructed, arranged, and maintained to ensure the following:

- Sufficient space, ventilation, and utilities are available for conducting all phases of the testing process.
- The potential for contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.
- Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and reagent preparation.

The laboratory is required to have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. The laboratory must also be in compliance with applicable federal, state, and local laboratory requirements.

Be sure that your safety procedures are established, accessible, and followed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. Maintain and store your records and, as applicable, slides, blocks, and tissues, under conditions that ensure proper preservation.

Record Retention Requirements

To maintain compliance, you must adhere to the following requirements for record retention in the laboratory. Retain your records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least two years. The laboratory is required to keep copies of each test procedure for at least two years after a procedure has been discontinued. Include the dates of initial use and discontinuance for each test procedure performed in the laboratory.

The laboratory is also required to retain quality control and patient test records (including instrument printouts, if applicable) and all analytic systems activities specified in Subpart K - Quality System for Non-waived Testing for at least two years. In addition, you should keep the following:

- Records of any test system performance specifications the laboratory is required to establish or verify for the period of time the laboratory uses the test system, but no less than two years.
- Immunohematology records, blood and blood product records, and transfusion records for five years.

All proficiency testing records and laboratory quality assessment (quality assurance) records must be stored for at least two years. The laboratory needs to retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least two years after the date of reporting. In addition, keep the following:

- Immunohematology reports for five years.
- Pathology test reports for at least 10 years after the date of reporting.

Specimen Retention

The following bullets detail the requirements for retention of specimens such as slides, blocks, and tissues.

- Slides
  - Retain cytology slide preparations for at least five years from the date of examination.
  - Retain histopathology slides for at least 10 years from the date of examination.
- Blocks
  - Retain pathology specimen blocks for at least two years from the date of examination.
- Tissue
  - Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

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

Transfusion Services

A facility that provides transfusion services is required to meet the requirements below and document all transfusion-related activities.

- Arrangement for services
  - The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.
- Provision of testing
  - The facility must provide prompt ABO grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis. This must be done through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.
- Blood and blood products storage and distribution
  - If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.
  - The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.
- Investigation of transfusion reactions
  - The facility must have procedures for preventing transfusion reactions and promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and to federal and state authorities.

Resources

- View the current laboratory requirements of Part 493, including Subpart J- Facility Administration, at www.phppo.cdc.gov/clia/regs/toc.aspx
- To search the CFR for the additional regulations referenced in the retention requirements go to: www.gpoaccess.gov/cfr/index.html.
- View the CMS Surveyor Procedures and Interpretive Guidelines at www.cms.hhs.gov/clia/03_interpretive_guidelines_for_laboratories.asp (The text written in italics that follows the regulation offers interpretation of the regulation and assistance with compliance.)