Compliance, in referring to a laboratory setting, can be defined as conformity in fulfilling official requirements.

Accreditation is the approval of an institution, portion of an institution, or program regarding minimum acceptable criteria.

Compliance with federal regulations and accreditation standards for medical laboratories is required by the following organizations:

- Centers for Medicare and Medicaid Services (CMS)
- Occupational Safety and Health Administration (OSHA)
- Food and Drug Administration (FDA)
- College of American Pathologist (CAP)
- Commission on Laboratory Assessment (COLA)
- American Association of Blood Banks (AABB)

Laboratories need to comply with all applicable requirements to maintain licensure and accreditation.
Purpose of Accreditation

☐ To recognize quality
☐ To inform the public that an institution has met minimum standards
☐ To improve quality care

Accrediting Agencies

☐ Agencies cover all aspects of the clinical laboratory, hospital, and programs/schools for allied health (Health professions)
☐ Agencies commonly include the following
  ☐ The Joint Commission [http://www.jointcommission.org/]
  ☐ CAP (College of American Pathologists)
  ☐ AABB (American Association of Blood Banks)
  ☐ Commission of Laboratory Assessment (COLA)

Review Process

☐ Agencies review all aspects of the laboratory operation.
  ☐ QC, performance improvement, PT testing, safety, personnel requirements, policies and procedures, the facility, specimen collection and handling, quality of water used for testing, LIS, storage of patient information, etc.
Requirements

- General laboratory requirements
- Each section (departments) has to meet specific requirements as well
  - AABB accredits blood bank services (every two years) only and includes both transfusion services and donor/processing of blood bank blood products

The Joint Commission

- The world’s leading heath-care standard-setting and accrediting nonprofit organization
- Every two years for hospital and labs
- If lab is accredited by CAP, and the hospital is accredited by Joint Commission, the lab will not have to undergo the full Joint Commission inspection; just an abbreviated inspection
- Citations are identified as type I
  - Lab has 6 months to provide evidence of compliance

(College of American Pathologist) CAP

- Medical society that serves more than 15,000 physician members and the laboratory community throughout the world
- 2nd largest association composed exclusively of pathologists and is considered the leader in providing laboratory quality improvement programs
- Identifies deficiencies as phase I or phase II
  - Phase I not as serious. (lack of space is example)
  - Phase II must be corrected in 30 days (No PT program)
- Two year cycle;
  - Year 1 self-evaluation
  - Year 2 on-site inspection
AABB

- Inspection every two years
- For transfusion services (blood bank) only
- Inspector is usually a blood banker from another accredited blood service
- Deficiencies handled the same as CAP
- http://www.aabb.org/Pages/Homepage.aspx

NAACLS (National Accrediting Agency for CLS)

- Accreditation of educational programs for CLS
- University/colleges and hospital programs
- Accreditation can be awarded up to seven years
- If a program is not in compliance with a standard, the program must submit a progress report within a specified time documenting compliance.
- Continued accreditation is contingent upon a satisfactory progress report

Clinical and Laboratory Standards Institute (CLSI)

- CLSI is a World Health Organization Collaborating Center for Clinical Laboratory Standards and Accreditation.
- CLSI helps develop standards as well as products to guide you along the path to accreditation through
  - Education
  - Providing templates for writing policies and procedures
  - Membership
Recap

- Almost all areas of health care require some type of accreditation.
- It is important that we as health care professionals educate ourselves on accreditation requirements and procedures.

CLINICAL LABORATORY IMPROVEMENT ACT (CLIA)

WHAT IS CLIA-88?

- Congress passed CLIA-88, as a means for the Secretary of Health to develop comprehensive, quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.
- A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.
- CLIA is a user fee funded government program; therefore, all costs of administering the program must be covered by the regulated facilities. Facilities that do not accept Medicare or Medicaid or accept only cash must be certified under CLIA. It is the act of performing a laboratory test that defines the requirement of certification and not how the test is paid for.
Test Complexity

- The final CLIA regulations were published on February 28, 1992 and were based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements.
- Three categories of tests have been established:
  - waived complexity, moderate complexity, including the subcategory of provider-performed microscopy (PPM), and high complexity.
  - CLIA specifies quality standards for proficiency testing (PT), patient test management, quality control, personnel and quality assurance.

CLIA History

- Beginning in 1987, a series of newspaper and magazine articles were published on the quality of laboratory testing. Also, simultaneously television programs were aired concerning the number of laboratories that were not subject to either federal or state regulations.
- Congress held hearings in 1988 and heard testimony from “victims” of faulty laboratory testing. Specific concerns were raised about the validity of cholesterol screening and the accuracy of Pap smear results.

History

- On October 31, 1988, Congress enacted Public Law 100-578 in response to the congressional hearings. PL 100-578 greatly revised the authority (PHS Act) for the regulation of laboratories.
- This law revised section 353 of the PHS Act amending CLIA-88 by expanding the Department of HHS's authority from regulation of laboratories that only accepted and tested specimens in interstate commerce to the regulation of any laboratory that tested specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.
History

- On February 28, 1992, the final regulations for CLIA-88 were published with an implementation date of September 1, 1992.
- Sections of the CLIA requirements were to be phased in allowing previously non-regulated laboratories to become accustomed to the regulations.
- The regulations adding Provider-Performed Microscopy Procedures (PPMP) were published on March 24, 1995.
- The 1992 CLIA requirements have been modified and clarified in a series of Federal Registers. The most up-to-date (2003) versions of the CLIA requirements that include all of the changes, can be downloaded from the CMS website.

Authority

- Originally, the CMS with the Centers for Disease Control and Prevention (CDC) were responsible for test categorization, development of technical standards and CLIA studies; as well as, responsibility for the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approval of Proficiency Testing (PT) providers, accrediting organizations and exempt states.
- Currently the CMS handles most of the responsibilities and the FDA categorizes test methodologies for complexity.

Who needs a CLIA certificate?

- Any person or facility that performs laboratory tests on human specimens for the purpose of diagnosis and/or treatment is required by federal law to have a CLIA certificate.
- Medicare requires the CLIA certificate number before any claims can be processed. Certificates must be renewed every two years for as long as testing is being performed.
- Changes in ownership, location, and type of testing performed must be reported within 30 days of the change.
What certificate types are available?

- Certificate of Waiver
- Provider Performed Microscopy
- Certificate of Compliance
- Certificate of Accreditation

Certificate of Waiver

- Certificate of Waiver
- These tests have been approved by the FDA for home use and require very little training to perform. The only requirements for this type of testing are that the manufacturer’s instructions are followed exactly and that there is documentation that the testing personnel have been trained to perform the test. Proficiency testing is not required for this level of testing but the quality of the tests performed must be evaluated at least twice a year.

PPM

- Provider Performed Microscopy
- These are tests performed by a health care provider such as a doctor, physician’s assistant, or nurse practitioner. These tests include: microscopic sediment analysis, wet preps, KOH preps, and other microscope based procedures. All waived tests may be performed with this level of certificate with the same requirements as a certificate of waiver. Proficiency testing is not required for this level of testing but the quality of the tests performed must be evaluated at least twice a year.
Certificate of Compliance

- Tests performed under this type of certificate have been classified as moderate or high complexity and have regulations that are more stringent.
- Facilities performing moderate or high complexity testing must be enrolled in an approved Proficiency Testing program for each regulated analyte.
- Analytes that do not have a Proficiency Testing program available must be evaluated at least twice a year. Each facility must establish a Quality Assurance program that includes quality control, personnel policies, patient test management, and proficiency testing. These facilities are inspected every two years to ensure compliance with federal regulations.
- Certificate of Compliance is issued to facilities that are inspected by CMS directly.

Certificate of Accreditation

- These certificates have the same standards as the Certificate of Compliance, but are inspected by a CMS-deemed professional organization, not CMS directly.

Requirements for Personnel

- What are the requirements for testing personnel?
  - For tests classified as waived or moderately complex, testing personnel must have at least a high school diploma or G.E.D. and documentation of training before performing tests.
  - For tests classified as high complexity, testing personnel must have an associate of science degree or higher and documentation of training before performing tests.
  - High complexity testing examples are as follows:
    - MP testing, blood banking, manual differential, microbiology ID and susceptibility, etc..
  - All personnel must be evaluated within six months of hire and annually after that.
What is the Survey or Inspection Process?

- The surveyor will schedule routine surveys within six months of the certificate expiration date. Complaints and revisit surveys are always unannounced. The surveyor will review all documents related to laboratory testing including but not limited to procedure manuals, test records, personnel files, and patient records.
- Failure to voluntarily provide this information may result in termination of your CLIA certificate and Medicare reimbursements. If the surveyor finds condition level or severe deficiencies, the facility’s CLIA number may be terminated.
- Except in rare cases, facilities are given the opportunity to correct all deficiencies within a specified period before termination occurs. Standard or minor deficiencies must be corrected within a reasonable period not to exceed 12 months. Assistance is always available to facilities.

PROFICIENCY TESTING

What is PT testing?

- CLIA approved PT programs allow laboratories to regularly evaluate their performance and improve the accuracy of the patient results they provide.
- PT provides individual laboratories with unknown specimens for testing.
- Results are analyzed and submitted for evaluation. In turn, each participating laboratory receives a report of their performance as well as a report summarizing the results of all participating laboratories.
- Performed to assess the skills (competency) of laboratory personnel performing assays as well as the performance of the assay itself.
PT Not Available?

☐ If proficiency specimens are not commercially available (most commonly seem in molecular testing)
  ☐ Laboratories can exchange blind split samples
  ☐ Blinded specimens measured or documented by independent means such as chart review

PT

☐ PT is performed usually two - three times a year
☐ Must be treated the same as patient samples
☐ Specific procedures should be defined and documented in the laboratory
☐ Errors or incorrect responses for PT specimen are documented along with the corrective action taken, if necessary
☐ You cannot share results with other laboratories

requirements for PT

☐ Must fulfill all standards
☐ Keep Results for at least 2 years, signed by person who completed the PT, and lab director
### Example of Evaluation

#### CLIA Performance Standards for Specimen Reporting Under the Clinical Laboratory Improvement Amendments of 1988

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<thead>
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