Clinical Laboratory Improvement Amendments (CLIA) Certification Process

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Objectives

- Briefly discuss COVID-19 testing and CLIA.
- Briefly discuss the main differences between ISO/IEC 17025 and CLIA.
- Discuss the application and accreditation process for CLIA.
COVID-19 Testing

- In response to the global pandemic, COVID-19 testing has become a hot topic around the world.

- In the United States, if a laboratory plans to be testing human samples for diagnostic testing, the laboratory must obtain a CLIA certificate.
What is CLIA 1988?

- Regulatory Standard created to correct specific conditions that existed in US labs in late 1980s and early 90s.
- This standard has a very strong focus in the following areas:
  - Personnel requirements,
  - QC requirements,
  - Proficiency Testing requirements, and
  - Enforcement requirements.
What is CLIA 1988?

- CLIA also addresses the following pieces of a management system:
  - Confidentiality,
  - Specimen identification,
  - Complaint investigation,
  - Communication breakdown,
  - Lab personnel competency assessments,
  - Corrective action and monitoring, and
  - Procedure manual for pre-examination, examination and post examination.
**Differences Between ISO/IEC 17025 and CLIA**

**ISO/IEC 17025**
- Focuses on management system as well as technical requirements including:
  - Internal Audits,
  - Impartiality, and
  - Metrological Traceability.

**CLIA**
- Specific focus and detailed requirements to critical technical lab processes including:
  - PT,
  - QC, and
  - Laboratory Personnel Requirements.
Process for Applying for a CLIA Certificate

- To apply for a CLIA certificate, it is a two part process.

  Apply for a CLIA Certificate through CMS 116 Form and Obtain a Certificate of Registration

  Complete Accreditation Process and Receive a Certificate of Accreditation

  Complete Compliance Process and Receive a Certificate of Compliance
Definitions

- **Certificate of Registration:**
  - Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations.
  - A registration certificate is valid until an inspection is conducted and compliance is determined.

- **Certificate of Compliance:**
  - Issued to a laboratory once the State Agency or CMS surveyors conduct a survey (inspection) and determine that the laboratory is compliant with the applicable CLIA requirements.

- **Certificate of Accreditation:**
  - Issued to a laboratory on the basis of the laboratory’s accreditation by an accreditation organization (AO) approved by CMS.
Application Process for CLIA Accreditation Certificate

For the application process for CMS, laboratories must fill out the CMS 116 form and provide the form to their local CMS office.

The laboratory will also have to supply CMS with their laboratory director qualifications.

Once the laboratory is processed and qualified by CMS laboratories will receive their CLIA ID and can start testing.

Once a laboratory pays their fee remittance coupon, they will receive a Certificate of Registration.

At the same time as applying to CMS, laboratories need to apply for accreditation.

When a laboratory applies for a Certificate of Accreditation on the CMS 116, the laboratory must receive accreditation within 11 months of receiving the Certificate of Registration.

A2LA’s Accreditation Process
CMS 116

- The CMS 116 form must be filled out and submitted to appropriate state agency for laboratories that would like to gain a CLIA certificate.
- Laboratories must estimate their annual test volume prior to submitting CMS 116.
- Before submitting the CMS 116 form, laboratory director qualifications must be added to the application.
When a laboratory is submitting the CMS 116 form, the laboratory must include the following information for their laboratory director:

- Verification of State Licensure,
- Education Information such as transcript, diploma, etc.,
- Credentials, and
- Laboratory experience.

Specific laboratory director qualifications can be found in subpart M 42 CFR Part 493.
When Can Testing Occur?

- After a laboratory’s CLIA ID is provided to them, the laboratory can begin testing.
  - Please note that this only for COVID-19 testing. Traditionally, a laboratory would have to wait until their Certificate of Registration is received before testing could begin.

- Payment of the fee remittance coupon will need to occur to receive the Certificate of Registration.
Accreditation Process: Application

- Lab completes application and checklist and submits Procedure Manual(s), SOPs, Work Instructions, Quality Manual, Copy of CMS 116, etc.

- Lab also provides a listing of all tests performed, an equipment list, and service provider list.

- AO staff reviews it for completeness.

- Assessment team *proposed* to lab.
Assessor Teams

- The clinical assessors at A2LA:
  - Are Pathologists, MDs, PhDs, or Medical Technologists,
  - Have successfully completed A2LA’s five day classroom and interactive training course,
  - Have passed a written examination,
  - Have been evaluated by direct observation conducting assessments,
  - Have a minimum of ten years of direct technical experience in their chosen areas of expertise—many have well over twenty years experience.
Assessor Teams

- In addition to the requirements listed on the previous slide, clinical assessor at A2LA also:
  - Have extensive experience in assessing CLIA laboratories,
  - Are 3rd party independent sub-contractors not peer surveyors,
  - Are involved in Clinical & Laboratory Standards Institute (CLSI) and the writing of other standards, and
  - Are provided refresher training during A2LA’s Annual Technical Forum.
Accreditation Process: Assessor Assignment

- The assessors are provided application material prior to coming on site, so they will be familiar with the laboratory.

- Please note document reviews will not be provided to the laboratory prior to the assessment.

- Please note the assessment is unannounced, and the agenda will be provided to your laboratory within 2 weeks of the assessment occurring.
Accreditation Process: Assessment

- On-site visit evaluates implementation of CLIA requirements.
  - General Requirements
  - Specialty/Subspecialty Requirements
- Assessors will spend time in the laboratory interviewing and observing technicians.
- A deficiency report detailing non-conformances provided at exit briefing.
Accreditation Process: Corrective Actions

- Corrective action response required within 30 days.

- Corrective action with objective evidence and root cause analysis is reviewed by A2LA staff; additional information is requested, if needed.
Accreditation Process: Accreditation Council

- The Accreditation Council is balloted.

- Accreditation is granted when all issues are resolved with objective evidence.
Certificate of Accreditation

- Once the Certificate of Accreditation is granted, the laboratory must provide HHS with the Certificate of Accreditation.

- The laboratory must receive accreditation within 11 months of receiving their Certificate of Registration.
Key Differences Between ISO/IEC 17025 Assessment and CLIA Assessment

- The assessment must be unannounced.

- All CLIA assessments must be completed in person.

- The document review is not shared with the laboratory prior to the assessment.
Resources

- CMS website

- CMS Brochure Page

- CMS 116
Questions?
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