Are you new to the Clinical Laboratory Improvement Amendments (CLIA)? Have you heard of CLIA but need more information? The CLIA Regulations and Interpretive Guidelines are contained in over 400 pages and consist of over 500 Deficiency Tags (DTags). Who wouldn’t feel overwhelmed and anxious? This CLIA Corner is for you! This issue will highlight helpful CLIA resources and where to find them on the Internet.

**Centers for Medicare & Medicaid Services (CMS) website**

The official website for CLIA can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. The left hand side of the homepage contains links to various topics related to CLIA. Once a topic is selected, information then populates in the main part of the screen, followed by the “Downloads” and “Related Links” sections. Both of these sections give additional information and websites related to CLIA.
**Helpful Links on the CMS website:**

- **How to Apply for a CLIA Certificate, Including International Laboratories**
  - The “Related Links” section contains a link to the CMS-116 CLIA Application Form.

- **State Agency & Regional Office CLIA Contacts**

- **Categorization of Tests**
  - The “Downloads” section includes a list of waived test systems and a list of provider performed microscopy (PPM) tests.
  - The “Related Links” section provides a link to the Food and Drug Administration (FDA) Test Complexity Database. The database is useful for determining complexity for FDA cleared test systems and specialties and subspecialties of specific analytes.

- **Certificate of Waiver Laboratory Project**
  - The information section explains CMS’s Certificate of Waiver Project as well as the requirements for waived testing.
  - The “Ready Set Test Booklet” link in the “Related Links” section is connected to the Centers for Disease Control and Prevention (CDC) CLIA Waived Tests website. CMS and the CDC collaborated to create waived testing educational materials, resulting in a set of booklets, a self-assessment checklist, and a FREE online course designed to guide laboratories on recommended practices for performing patient testing under a CLIA Certificate of Waiver. The educational materials can also be found at the following web address: [https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx](https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx).
  - The “Related Links” section also features a link to the CDC’s 2005 Morbidity and Mortality Weekly Report (MMWR), which highlights good laboratory practices for waived testing sites.

- **CLIA Brochures**
  - Each brochure in the “Downloads” section explains a different part of CLIA. Brochure topics include, but are not limited to, verification of performance specifications, calibration and calibration verification, proficiency testing, assessing laboratory personnel competency, and Individualized Quality Control Plans (IQCP).

- **Interpretive Guidelines for Laboratories**
  - The “Related Links” section contains a link to the State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.

**Quality, Safety & Oversight Letters**

The CMS Quality, Safety and Oversight Group (previously known as the Survey and Certification Group) is responsible for giving guidance, clarification, and instruction with regard to the CLIA regulations. These memoranda to the State Survey Agencies and CMS Regional Offices are available to the public. They can be found at [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html).
The database includes memos for providers other than CLIA; for memos specific to CLIA, type “CLIA” in the filter. Click on the “Posting Date” header to bring the most recent memos to the top of the list.

**CMS Integrated Surveyor Training Website (ISTW)**

In May 2017, CMS released an online CLIA Surveyor Basic Training course, which includes a comprehensive overview of the regulatory requirements and their application to surveyors. All Regional Office and State Agency surveyors are required to complete the course, which consists of 14 web-based, self-paced lessons. The lessons walk an individual through the CLIA regulations, and include information on a wide variety of CLIA topics, such as proficiency testing, quality control, calibration verification, cytology, quality assessment, and personnel requirements.

The online CLIA Surveyor Basic Training course is FREE to the public. To access the course, go to the CMS Surveyor Training Website at [https://surveyortraining.cms.hhs.gov](https://surveyortraining.cms.hhs.gov).

1. Select the “I AM A PROVIDER” link.
2. In the blue bar across the top of the screen, select “Course Catalog.”
3. In the gray filter column on the left, scroll down and click on “CLIA.”
4. Select the web-based “CLIA Surveyor Basic Training.”
5. Scroll down and select the “Launch this Course” button.

**Provider-Performed Microscopy (PPM) Procedures Booklet**

A CLIA Certificate for Provider-Performed Microscopy (PPM) procedures allows physicians, midlevel practitioners, and dentists to perform a limited list of moderate complexity microscopic tests, as well as
waived tests, as part of a patient’s visit. Testing sites performing PPM procedures are not subject to routine biennial inspections. However, a CLIA certificate is required and the testing site must meet the CLIA quality standards for moderate complexity testing. To help providers accomplish these requirements, CMS and the CDC collaborated to create a PPM testing educational booklet that can be found here: https://wwwn.cdc.gov/clia/Resources/PPMP/.

**State Hygienic Laboratory (SHL) Biosecurity Course**

In collaboration with the Association of Public Health Laboratories (APHL), the State Hygienic Laboratory recently developed a new course designed to help clinical laboratories improve their knowledge of biosecurity practices. “Biosecurity for Clinical Laboratories” is FREE and available on the Training-Source.org website. To access the course, go to the website at www.training-source.org. Users must sign on to the website with an existing Training-Source account or create a new account.

**CLIA Corner**

Have you ever thought that you read some helpful information in the CLIA Corner before, but you just cannot find it? Fortunately, all previously published CLIA Corner newsletters have been archived on the SHL’s website. To access them, go to the SHL website at http://www.shl.uiowa.edu/.

1. Select “Lab Certification” from the green bar at the top of the screen.
2. Click on the link for “Clinical Laboratory Improvement Amendments (CLIA) program.”
3. On the left hand side of the screen, click on “CLIA Corner Archive” to view all CLIA Corners written over the years. *NOTE: Some CLIA Corner newsletters have been removed due to inaccurate and/or obsolete information.