Learning Objectives

• As a result of participating in this activity, you will be able to:
  – Explain the origins of regulations governing those who work in clinical labs
  – Better assess the personnel policies and practices of your laboratory
  – Help insure regulatory compliance for testing done outside the laboratory
Clinical Laboratory Improvement Act (CLIA ’88)

• Background
  – Scandal in mid-’80s over “Pap Mills”
    • Labs offered cut rate Pap Smears screened by unqualified personnel
    • Essentially criminal enterprises masquerading as real laboratories

• CLIA ‘88 established government oversight of clinical laboratories (Accreditation)
  – Designed to weed out the “bad apples”
  – Oversight by Center for Medicare Services (CMS)
What CLIA ‘88 Requires

• Mandates all laboratories implement quality assurance programs
• Mandates proficiency testing for “regulated analytes”
• Requires periodic accreditation inspections
• Classifies tests by level of complexity
  – Waived, moderate and high complexity
• Defines personnel training and oversight requirements for each level of complexity
CLIA ’88 and the CFR

• Regulations guiding enforcement of this law are found in 42 CFR Part 493
  – Personnel requirements in subpart M
Understanding Personnel Requirements

- Matches testing complexity with training requirements
- Tries to balance formal education and real-life experience
Case Study #1

• Hematology runs 3 levels of QC each shift
  – High QC for hemoglobin has been out as much as 3 SD several times in one week
  – Since only 2 levels of QC are required, and two of the three QC samples were in control, the supervisor approved release of test results
Deficiencies

• HEM. 20140 Are the results of controls verified for acceptability before reporting results?
• Hem.20143 Is there documentation of corrective action when control results exceed defined acceptability limits?
Case Study #1 (cont.)

- The supervisor was an MLT with six months of work experience who was recently given the job when the old supervisor retired.
What is required?

- HEM.40000 Does the person in charge of technical operations in hematology have education and experience equivalent to an MT (ASCP) and at least 4 years experience (one of which is in clinical hematology) under a qualified director?
Technical Supervisor

• A qualified laboratory director may serve as the technical supervisor

• An individual who meets alternate qualifications defined in the CLIA ‘88 regulations can be designated as technical supervisor by the lab director
  – CFR Sec. 493.1449
What is required?

• GEN.53500 Do technical supervisors fulfill the responsibilities defined by CLIA ‘88?
Technical Supervisor

• Not required to be on site at all times

• Responsibilities as defined by CLIA:
  – Selection of test methodology
  – Verification of test performance characteristics
  – Participation in appropriate Proficiency Testing
  – Establish appropriate Quality Control
  – Resolve technical problems
  – Oversee hiring, training, and competency assessments
Case study #1

- HEM.20140
- HEM.20143
- HEM.40000
- GEN.53500
Case Study #2

While reviewing Surgical Pathology personnel practices, you find that gross tissues are handled by:

– Pathology Residents
– Medical student fellows
– Licensed Pathology Assistants
– Unlicensed laboratory assistants with high school degrees
What is required?

- ANP.11600 Are all macroscopic tissue examinations performed by a pathologist or pathology resident, or under the supervision of a qualified pathologist?
Medical Student Fellows

- Medical student fellows do one year of pathology usually after their 2\textsuperscript{nd} or 3\textsuperscript{rd} year of medical school
- Usually treated like 1\textsuperscript{st} year Pathology Residents
“Under Supervision”

• CLIA defines supervision as “onsite, direct supervision by a qualified person”
  – This means the qualified person is there when the activity takes place
• MS fellows do unsupervised grossing on weekends
  – Pathologists review gross descriptions from the weekend on the next business day
What is required?

- ANP.11610 If individuals other than a pathologist or pathology resident assist in gross examinations, do such individuals qualify as high complexity testing personnel under CLIA ‘88 regulations?
  - 42CFR493.1489 and 1491
High Complexity Testing Personnel Requirements

• Possess a current state license if one is required
  – Unrestricted licenses
  – Limited licenses

• Education
  – Pathologist or pathology resident
High Complexity Testing
Personnel Requirements (cont.)

• The minimum training/experience required of non-pathologists is:
  – An earned associate degree in a laboratory science or medical laboratory technology, obtained from an accredited institution, OR
  – Education/training equivalent to the above
High Complexity Testing
Personnel Requirements (cont.)

– 60 semester hours or equivalent from an accredited institution with additional requirements regarding content

• 24 hours of medical laboratory technology courses or
• 24 semester hours of science courses that include 6 hours of chemistry and six hours of biology
High Complexity Training Requirements

- Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, ASCP or other organization approved by HHS.
- Have at least 3 months of documented laboratory training in each specialty in which the individual performs high complexity testing.
Macroscopic Tissue Examination

- **Grossing**
  - Requires knowledge of anatomy to perform dissection of the specimen and exercise of judgment in the selection of tissue samples for submission to histology
    - The specimen description not necessarily standardized.

- **Processing**
  - Limited to description, inking and cutting of the specimen (if applicable), and submission of the entire specimen to histology
    - Can be performed using standardized protocols
What is required?

• ANP.11605 When individuals other than a pathologist or pathology resident process specimens, or assist in gross examinations, is the extent of their activities (including the types of specimens examined) defined in a documented protocol?
High Complexity Testing Summary

• CLIA and CAP restrict who can perform and supervise high complexity testing.
  – Requirements are complex and vary considerably with the task and the discipline
  – State or CAP regulations may be more restrictive than federal laws and can also apply to out of state testing originating from the state with the tight restrictions
POC Testing
Personnel Challenges

• Programs often operate under hospital CLIA number and be supervised by non-laboratorians
• Training, competency and proficiency documentation may not be lab’s responsibility
• The sheer volume of providers can be overwhelming
What is required?

- POC.06600 Is the director of the POCT program a physician (preferably a pathologist) or a doctoral scientist?
What is required?

• POC.06700 Is there evidence that testing personnel have adequate, specific training to ensure competence?
What is required?

• POC.06800 Is there a current list of POCT personnel that delineates the specific tests that each individual is authorized to perform?
Case study #3

- Nursing students rotate through the clinical wards where they learn how to do testing
- The hospital issues instrument passwords only to fulltime employees who have successfully completed training
- Nursing students use the passwords of their mentors to learn how to test
  - Sometimes they do testing without direct supervision before being certified as competent
Case study #3 (cont.)

- POC.67000
  - Students sharing passwords
- POC.06800
  - Students not on list of approved providers
Case study #3 (cont.)

- Recommendations:
  - Nursing students training during orientation on the instruments they will use
  - Hospital should issue a password to the student and put them on a list of people who are approved to do supervised testing only
  - Supervised testing requirement can be eased when competency is achieved
What is required?

• GEN.55200 Are there annual reviews of the performance of existing employees and an initial review of new employees within the first six months?

• GEN.55500 Has the competency of each person to perform his/her assigned duties been assessed?
POC Words of Wisdom

• Don’t get overwhelmed with sheer volume of testers
• Enlist the support of Human Resource Department to help with training and documentation
• Take advantage of password options if they’re available with the instruments you use
POC Words of Wisdom

• Frequent face to face meetings between providers and lab is the key to compliance

• Ensure effective communication
  – Keep it short and focused
  – Use SOCO strategy
    • Single over-riding communication objective

• Train the Trainers
Case study #4

- Review of testing records shows one technologist does a lot of retests for equivocal DAT results
- The works full time at your hospital but also holds down two part time jobs elsewhere
- He passed the online DAT competency
- You watch him do testing, & notice that he’s adding a step that’s not in your procedure
  - Once the extra step is eliminated, he no longer gets the weak results
Competency Assessment

• Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing

• Monitoring the recording and reporting of test results, including, as applicable, reporting critical results

• Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records

• Direct observation of performance of instrument maintenance and function checks, as applicable

• Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

• Evaluation of problem-solving skills
Online Competency Programs

• Online competency programs help with competency documentation
• Programs are provided by CAP and other providers
• Products are targeted at a national audience
• May not address specific test platforms
Provider Performed Testing (PPT)

- PPT is a subset of moderately complex tests personally performed by a physician or midlevel practitioner credentialed by the hospital’s medical staff
- PPT is not the same as the CLIA term physician provided microscopy
What is required?

- POC.09500 Is there a documented process for training providers in the performance of specific tests?
- POC.09600 Is there evidence of competency assessment specific to the type(s) of laboratory testing performed by each provider?
Case study #5

• A respiratory therapist failed two separate blood gas PT challenges in one year
• PT failure investigation showed that both failures were due to operator error
  – After the first error, the RT was told to “be more careful”
  – After the second error, he was told he’d have to be retrained
What is required?

- GEN.54400 Do technical personnel records include all of the following mandatory items?
  - Summary of training and experience
  - Formal certification or license, if required by state
  - Description of current duties (may be generic to a position)
  - Records of continuing education
  - Records of radiation exposure where applicable (such as with *in vivo* radiation testing), but not required for low exposure levels such as certain *in-vitro* testing
What is required?

- GEN.57000 If an employee fails to demonstrate satisfactory performance on the competency assessment, does the laboratory have a plan of corrective action to retrain and reassess the employee's competency?
Summary

• CLIA ‘88 was designed to make sure that tests are performed by competent individuals with good training and adequate experience

• The personnel requirements demanded by CLIA are contained in the CFR work their way into the CAP checklists
Questions?
Resources

• Personnel requirements for non-waived testing
  – 42 CFR493 SUBPART M

• CAP Competency Assessment Program Brochure
Technical Assistance

http://www.cap.org

Email: accred@cap.org

800-323-4040, ext. 6065
Past Audioconferences

- Missed part/all of an audioconference?
- Want to hear it again?
- Want to tell a co-worker?
- Virtual Library of Past Audioconferences
  - Available 24/7 on www.cap.org 4 weeks post session (see Attachment A for steps on how to access post audioconferences).
  - Laboratory Improvement and Accreditation tab
  - Preparing to Inspect
Attachment A: Steps to Access the Virtual Library of Past Audioconferences

2. Navigate to the Accreditation and Laboratory Improvement section.
3. Access the Virtual Library of Past Audioconferences.

More information and resources can be found on the College of American Pathologists' website.