

CLIA and Point-of-Care Testing

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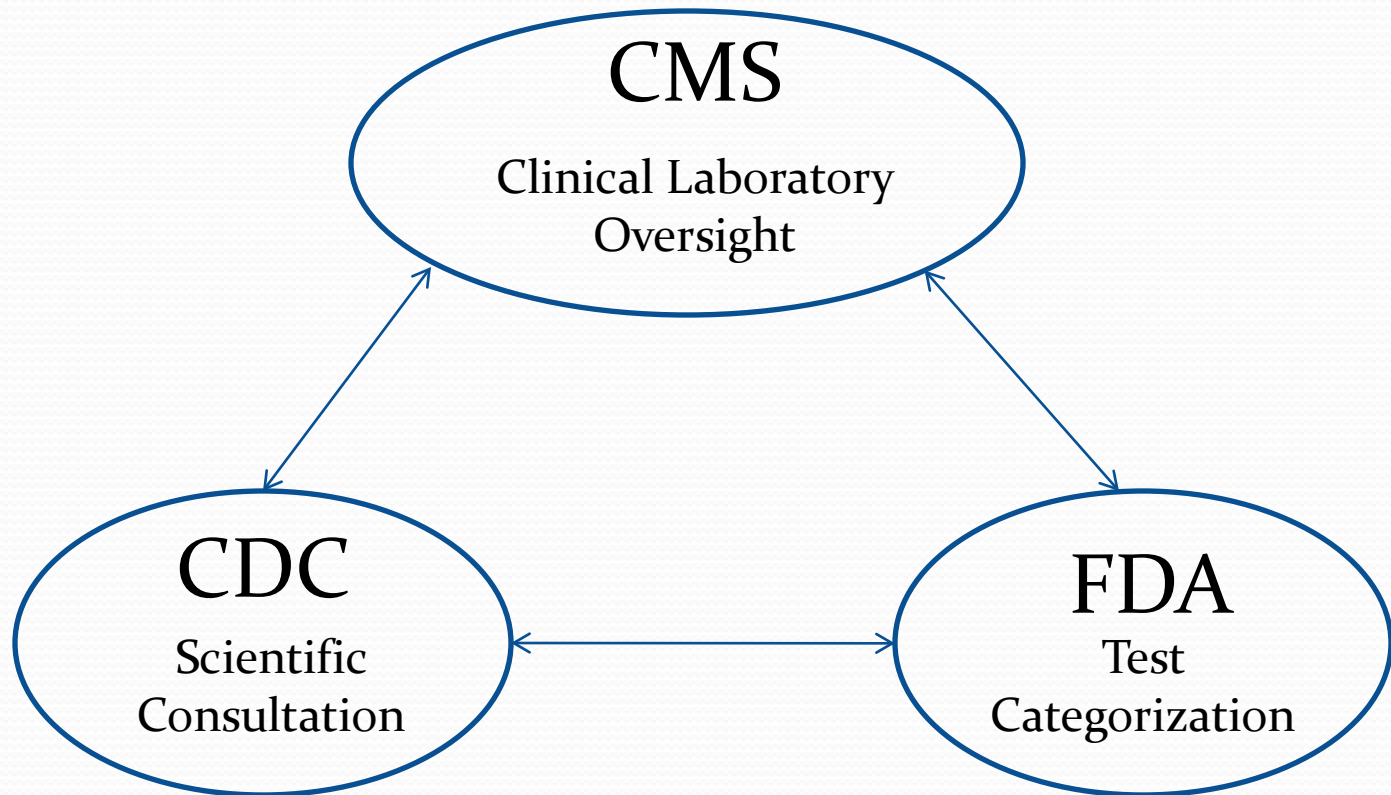
Objectives

- General overview of CLIA
- Guidance on regulations regarding point-of-care testing

What is this thing called “CLIA”?

- Clinical Laboratory Improvement Amendments
- Federal program that establishes quality laboratory standards to protect patient safety and improve health care

CLIA Program Responsibilities



A Bit of History.....

- Final CLIA regulation published in Federal Register on February 28, 1992 and effective on September 1, 1992 as 42 CFR Part 493 Laboratory Requirements
- Established uniform quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test was performed

Laboratory (as defined by CLIA)

- Any facility that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings

All clinical laboratories.....

- that perform testing on patient specimens must:
 - apply for a CLIA certificate
 - pay appropriate fees and
 - follow applicable CLIA requirements

Test Complexity

- Waived
- Moderate complexity including the subcategory of Provider Performed Microscopy (PPM)
- High complexity

Laboratories are certified at the highest level of testing performed

CLIA Certificate Types

- Certificate of Compliance (COC)
- Certificate of Accreditation (COA)
- Certificate for PPM procedures (PPMP)
- Certificate of Waiver (CoW)

Current Enrollment Statistics

- Total Number of Laboratories: 221,793
 - Compliance Labs: 19,404
 - Accredited Labs: 15,864
 - Waived Labs: 141,994
 - PPM Labs: 37,795

Laboratory Oversight Options

- CLIA (State Agencies)
- Accreditation Organization (AO)

Certificate of Compliance (COC)

- Laboratories are surveyed for compliance with the CLIA regulations
- Pay biennial certificate fees
- Surveyed by State Agencies
- Routinely surveyed every two years

Certificate of Accreditation

- Laboratory selects Accrediting Organization at time of CLIA application
- Pay biennial certificate fees
- Routinely surveyed every two years by AO survey team

CMS Approved AO's

- College of American Pathologists (CAP)
- The Joint Commission (JC)
- COLA
- AABB
- American Osteopathic Association (AOA)
- American Society for Histocompatibility and Immunogenetics (ASHI)

- Each of the six AO's has been approved by CLIA to provide regulatory oversight
- AO's must meet the minimum CLIA requirements and can be more stringent than CLIA
- Reasons to select an AO for oversight and inspection
 - Organizational decision
 - Prestige associated with accreditation

PPMP Certificate Type

- Pay biennial certificate fees
- Are not subject to routine surveys
- Perform PPM procedures and waived testing only
- Examples include: KOH, wet prep, urine microscopic

Certificate of Waiver (CoW)

- Enroll in the CLIA program
- Pay biennial certificate fees
- Only perform tests categorized as waived
- Not subject to routine inspections
- Must follow manufacturer's instructions

Non-waived Testing

- Includes moderate and high complexity tests
- Must follow:
 - All manufacturer's instructions and
 - Applicable CLIA requirements
 - AO requirements
 - State requirements (ex. Maryland, New York)

When in doubt, always follow the most stringent requirements

Non-waived Testing - QC

- Must perform the appropriate quality control as defined by the manufacturer, CLIA or the AO (**whichever is the most stringent**)
- Minimum two levels of control each day of testing
- EQC
 - If use EQC, need to have plan on how you will re-assess previously tested patients if problems arise
 - Additional information on EQC can be found in the CLIA Interpretive Guidelines

Non-waived Testing

- Proficiency Testing (PT) Required
- Quality Assessment (QA) Required
- Personnel qualifications and responsibilities for ALL personnel

Point-of-Care Testing

- Non-waived
 - PPMP
- Waived

Moderate Complexity Personnel

- Laboratory Director (LD)
- Technical Consultant (TC)
- Clinical Consultant (CC)
- Testing Personnel (TP)

LD Qualifications

Moderate Complexity

- Lab Director that is a MD, DO, DPM must have 20 CMEs unless board certified in AP or CP or
- Have minimum 1 year experience directing or supervising Non-waived testing or
- Grandfathered 2/28/92

NOTE: MD, DO, DPM LD must have minimum 1 year experience to qualify as TC

LD Qualifications

Moderate Complexity

CME accredited courses are also offered through:

*The University of Iowa

*The University of Wisconsin & COLA

http://www.cms.gov/CLIA/15_CME_Courses_for_Laboratory_Directors_of_Moderate_Complexity_Laboratories.asp#TopOfPage

PPMP Personnel

- Physician (MD, DO, or DPM)
- Midlevel Practitioner
- Dentist

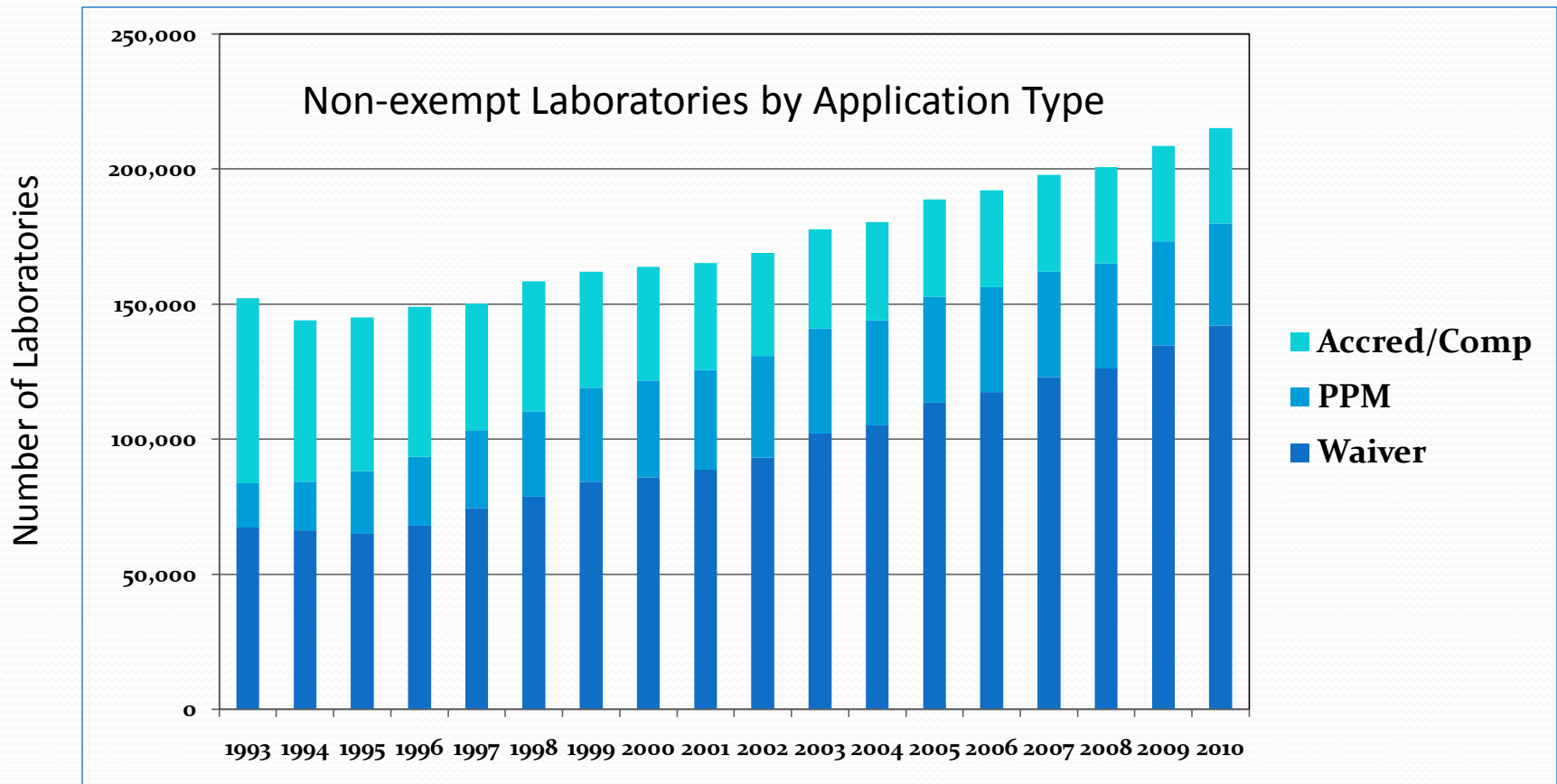
Personnel Requirements for CoW

- A CoW must have a LD
- There are no educational and experiential requirements for LD
- There are no other personnel requirements

Waived Tests....

- Simple laboratory examinations and procedures
- Cleared by FDA for home use;
- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

CMS Waived Project --Waived Laboratory Growth



Certificate of Waiver Project

- 1999 – Initial Pilot in Colorado and Ohio
- 2000 – Expanded Pilot project to 8 additional States
- 2002 – Pilot expanded to remaining States

CoW Site Visits

- Announced, designed to help educate on sound laboratory practices
- Surveyors determine:
 - Testing being conducted in manner that protects patient safety
 - Regulatory compliance
 - Performing tests appropriate for a CoW lab

Findings from Cow Visits

- Fail to have current manufacturer's instructions
- Fail to perform Quality Control as required by the manufacturer
- Fail to follow manufacturer's Instructions
- Performing non-waived testing

CoW Scenario

- Complaint to CMS - Company performing HbA_{1c} as diagnostic test for diabetes in grocery store chain
 - Package insert: test is for screening only
 - Investigation by CMS revealed complaint was substantiated
 - Found moderate complexity testing also being performed (ABO/RH by Eldon Card)
 - Company performing tests notified to stop performing ABO/RH and stop using A_{1c} test as diagnostic test

Example of worse-case scenario

- Lab used all waived instruments
- QC for A1C not performed as per manufacturer's instructions
- User manual for A1C still wrapped in plastic
- TP could NOT identify an invalid test on rapid strep or urine HCG test
- TP was “self-taught”

Next Steps for Waived Testing.....

- Number of CW labs increasing exponentially
- Congress never anticipated this growth
- Education is effective, but resources are lacking
- A CMS “Issue” paper with multi-faceted recommendations for agency management was approved
- CMS collaborating with stakeholders to complete long and short term plans

CMS' Plan Waived Project

- Short Term

- Continue CW project indefinitely
- Educate with every opportunity
- Initiate test menu collection with application
- Collaborate with Partners/CDC/FDA
- Enlist support of professional and patient advocacy organizations
- Evaluate data from AO/ES with CW standards
- Publish comprehensive report

CMS' Plan Waived Project

- Long term
 - Under consideration by CMS...changes to the CLIA law to improve oversight

CDC Educational Materials

- In addition to the information found on the CLIA website.....
 - CDC has published “Ready, Set, Test” booklet - describes recommended practices for physicians, nurses, medical assistants and others performing patient testing under a CLIA Waiver Certificate
 - CDC also pilot testing on-line training course corresponding to “Ready, Set, Test”.

Good Laboratory Practices for Waived Testing Sites

**READY?
SET?
TEST!**

**PATIENT TESTING
IS IMPORTANT.**

Get the right results.

<http://www.cdc.gov/dls/waivedtests>

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office

PATIENT TESTING IS IMPORTANT.

Get the right results.

**READY?
SET?
TEST!**

- Have the latest instructions for ALL of your tests.
- Know how to do tests the right way.
- Know how and when to do quality control.
- Make sure you do the right test on the right patient.
- Make sure the patient has prepared for the test.
- Collect and label the sample the right way.
- Follow instructions for quality control and patient tests.
- Keep records for all patient and quality control tests.
- Follow rules for discarding test materials.
- Report all test results to the doctor.

<http://www.cdc.gov/dls/waivedtests>

Poster and postcards

Educational booklet with job aids

Resources:

- CLIA Website
 - <http://www.cms.gov/CLIA>
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>
 - <http://www.cdc.gov/mmwr/pdf/rr/rr5413.pdf>
- CDC: [Ready, Set, Test](#) booklet
 - <http://www.cdc.gov/dls/waivedtests>

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Clinical Laboratory Improvement Amendments (CLIA)

Equivalent Quality Control Procedures

Brochure #4

What are they, and when can I use them?

*Information to assist your laboratory in meeting this
CLIA quality control requirement option for
nonwaived (moderate and high complexity) test systems!*

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulations (CLIA) that became effective April 24, 2003. A summary of equivalent quality control options is included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at <http://www.phppo.cdc.gov/CLIA/regs/toc.asp>.



BACKGROUND

What is quality control (QC)?

QC consists of the procedures used to detect errors that occur due to test system failure, adverse environmental conditions and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time.

What are equivalent quality control procedures?

For each test system, the laboratory must test, at a minimum, two levels of external QC materials each day it performs a nonwaived test. However, the regulations now also allow the laboratory to reduce the frequency of testing external QC materials (equivalent QC procedure) for certain test systems.

Advances in laboratory technology have led to test systems that often include internal monitoring systems or controls that check all or a portion of the test system's analytic components each time the test is performed. Also, some test systems are capable of maintaining stable performance specifications and are minimally influenced by adverse environmental conditions (such as temperature and humidity) and operator handling or variance (minor differences in testing personnel techniques). In these situations, the CLIA regulations provide laboratories alternatives to the traditional daily testing of two levels of external QC materials.

For eligible test systems, an equivalent QC procedure may be used by the laboratory if it successfully completes a QC evaluation process approved by CMS that demonstrates the stability of the test system over time.

What is the difference between external QC and internal monitoring systems?

In general, external QC is the testing of control material that is not built into the test system. The control material is sampled and tested by the test system in much the same way a patient specimen is sampled and tested; therefore, it checks all components of the test system's analytic process.

Internal monitoring systems are a part of or built into the test system and may be called electronic, internal, or procedural controls. Electronic controls may only monitor a test system's electronic components. Internal or procedural

controls may only monitor a portion of the test system's analytic components, for example, a color change that indicates when a patient's specimen or reagent is added correctly.

What are the analytic components of a test system?

The analytic components of a test system are defined by the test system's manufacturer. Examples of analytic components include, but are not limited to, sample addition, sample/reagent interactions, and test completion time. The test system's package insert should state which components of the test system are checked by its internal monitoring systems. If this information is not available or is unclear, seek written guidance from the test system's manufacturer and include this information in your laboratory's records.

What is the equivalent QC procedure evaluation process?

It is an evaluation the laboratory must perform to demonstrate that a test system is stable and can generate correct test results over time. If the test system's results are acceptable during the evaluation period, the laboratory may reduce the frequency of testing external QC materials (see Table 1). The laboratory may only use an evaluation process approved by CMS and published in *The State Operations Manual*, Appendix C--Interpretive Guidelines (CMS Pub. 7).

EQUIVALENT QC PROCEDURES

How many equivalent QC procedure options are there?

At this time, there are three equivalent QC procedure options. The options are based on whether the test system has an internal monitoring system and if so, whether it checks all or only some of the test system's analytic components. As further technological advances are made and additional data become available, other options may be included or existing options revised.

Table 1 Equivalent QC options for eligible test systems

EQUIVALENT QC OPTIONS				
Equivalent QC Option	Test System Description	Evaluation Process:		Equivalent QC Procedure Testing Frequency
		Internal Monitoring Systems*	Test Two Levels of External Controls	
Option 1	Test Systems with Internal Monitoring System that Checks ALL <u>Analytic</u> Components	Daily testing with acceptable results	Results acceptable for 10 consecutive testing days	Testing external controls at least once per calendar month and daily testing by the internal monitoring system*
Option 2	Test Systems with Internal Monitoring System that Checks SOME <u>Analytic</u> Components	Daily testing with acceptable results	Results acceptable for 30 consecutive testing days	Testing external controls at least once per calendar week and daily testing by the internal monitoring system*
Option 3	Test Systems WITHOUT Internal Monitoring System	N/A	Results acceptable for 60 consecutive testing days	Testing external controls at least once per calendar week

* Internal monitoring system checks must be performed in accordance with the manufacturer’s instructions, but not less frequently than daily.

Is the test system I’m using eligible for an equivalent QC procedure?

To determine eligibility for an equivalent QC procedure, the laboratory must consider the following:

Test System Criteria: Whether or not the test procedure includes an extraction step, and the specialty/subspecialty of the test procedure, affect the test system’s eligibility for equivalent QC procedures. Table 2 will help you to determine if a test system is eligible for equivalent QC and if so, which options might be used.

Manufacturer’s Instructions: Manufacturers’ test system instructions must always be followed. Therefore, if the test system instructions require testing external control materials more frequently than required by equivalent QC procedures, or testing more than two levels of external control materials, the test system is not eligible for equivalent QC.

Excluded Methods: Test systems that use molecular amplification, thin layer chromatography, or electrophoretic procedures are not currently eligible for equivalent QC procedures.

Table 2 Determining test system eligibility for equivalent QC

TEST SYSTEM MEETS THESE CRITERIA			
Subject to specialty/ subspecialty requirements for routine chemistry and hematology?*	Subject to specialty/ subspecialty requirements other than routine chemistry and hematology?	Test Procedure includes an extraction phase?***	TEST SYSTEM ELIGIBLE FOR THESE EQUIVALENT QC OPTIONS (refer to Table 1):
No	No	No	Options 1, 2, or 3
Yes	No	No	Options 1 or 2
Yes	No	Yes	Options 1 or 2
No	No	Yes	Options 1 or 2
No	Yes	Yes	None
No	Yes	No	None

* Test systems subject to specialty/subspecialty requirements for routine chemistry or hematology must have an internal monitoring system to be eligible for equivalent QC.

** Contact the manufacturer if it is unclear from the manufacturer’s package insert if the test procedure includes an extraction phase.

What should I consider before choosing to evaluate a test system for equivalent QC?

In general, test systems that have a history of infrequent QC failures, and that are simple to use, very stable, and routinely performed in your laboratory, are the most suitable for equivalent QC procedures. Therefore, you should take into account the following:

- *Instrumentation and reagents*—Test systems using reliable and easy-to-maintain instruments, and reagents that are stable and do not require special handling or storage are good candidates for equivalent QC procedures.
- *Technique dependence of the test method*—Test methods with few and uncomplicated procedural steps are less prone to operator error.
- *Frequency and volume of test performance*—Frequently performed tests or high volume tests are more familiar to the laboratory’s testing personnel, making them less prone to operator error.
- *Frequency of control failures*—Test systems with few control failures over time are more suited for equivalent QC procedures.
- *Testing personnel*—Well-trained, proficient testing personnel are essential for quality test performance.

May I use data from the test system’s manufacturer to establish an equivalent QC procedure?

No. Although manufacturers may assist laboratories by providing quality control instructions, the laboratory is ultimately responsible for the establishment, performance, documentation and evaluation of its quality control procedures, which take into account the laboratory’s particular testing environment and personnel.

EQUIVALENT QC EVALUATION PROCESS

I have determined that my test system is eligible for an equivalent QC procedure. What are my next steps?

As stated previously, an evaluation process must be performed by the laboratory to demonstrate that the test system is stable and can generate correct test results over time.

5.

If the test system’s control results are acceptable throughout the evaluation you may begin using the equivalent QC procedure. The evaluation process consists of the following:

1. Two levels of external control materials must be tested for the number of consecutive testing days specified in the option chosen (see Table 1). The control results must be acceptable.
2. For options 1 and 2, internal monitoring systems must be checked, at a minimum, daily for the number of consecutive testing days specified in the option chosen. The results must meet the test system’s instructions for acceptability.
3. For option 3, during the evaluation process, all personnel who are likely to perform the test and report patient test results must participate in the evaluation process.

What do I do if an internal or external control fails during the evaluation process?

If any internal or external control result is unacceptable during the evaluation process, the laboratory must re-test the unacceptable control one time. If the repeat control result is acceptable, no further corrective action is necessary and the laboratory may continue the evaluation process. If the repeat control result is unacceptable, the laboratory must identify the problem and take appropriate corrective action. This includes evaluating all patient test results obtained in the unacceptable test run, and since the last run with both internal and external acceptable QC to determine if the patient test results were adversely affected, before reporting the results and/or, if necessary, issuing corrected reports. Once appropriate corrective action has been taken, the laboratory must restart the evaluation process from the beginning.

Note: If more than two restarts are required for an evaluation process without success and you have verified that you are performing the test correctly, you should reconsider using equivalent QC for the test system.

What do I have to do if I want to use an equivalent QC procedure for multiple instruments that perform the same test?

An evaluation must be performed for each instrument that performs the test, even if it is the exact same make and model. This ensures that each individual instrument or test system exhibits the necessary stability to qualify for equivalent QC.

6.

If I have historical (existing) QC data for my test system, may I immediately reduce the frequency of testing external control materials?

Yes. If a laboratory's existing QC data for the test system successfully fulfills the requirements of the applicable equivalent QC evaluation process, the laboratory may immediately begin the reduced frequency for testing external control materials.

May I reduce the frequency of internal monitoring system checks to less than once a day after I have successfully completed the evaluation process?

No. Internal monitoring system checks must be performed as specified by the manufacturer, but not less frequently than once each day of testing.

REMINDER: The laboratory must document all of its equivalent QC evaluation process activities and retain the records for 2 years.

MONITORING EQUIVALENT QC PROCEDURES

What do I do if an internal or external control result is unacceptable after I have implemented the equivalent QC procedure? May I continue reporting patient test results?

If any internal or external control result is unacceptable, the laboratory must re-test the unacceptable control one time. If the repeat result is acceptable, no further corrective action is necessary. If the repeat control result is unacceptable, the laboratory must identify the problem and take appropriate corrective action before reporting patient test results. This includes evaluating all patient test results obtained in the unacceptable test run and since the last run with both internal and external acceptable QC to determine if the results were adversely affected, before reporting the results and/or issuing corrected reports, if necessary. The laboratory must repeat and successfully complete the evaluation process before again reducing the frequency of testing external controls.

Are there any other quality monitoring activities I have to perform?

The laboratory must continue to perform the following on-going assessments:

- Quality assessment activities
- Proficiency testing
- Analytic system quality assessment
- Personnel competency assessments
- Calibration verification

What do I do if one of the on-going assessment indicators fails?

If unacceptable results are obtained for any of the above assessment activities, the laboratory must discontinue using the equivalent QC procedure, investigate, identify the problem, and document the actions taken to correct the problem. The evaluation process will have to be repeated and successfully completed before the laboratory may resume using the equivalent QC procedure.

REMINDER: Even though the laboratory has implemented an equivalent QC procedure, it is still responsible for testing external control materials with each complete change of reagents, with each new lot number or shipment of reagents, following major preventive maintenance, or following replacement of critical parts that may influence the test system's test performance.

Where can I find additional information about the CLIA requirement pertaining to equivalent QC?

You may refer to the State Operations Manual, Appendix C—Interpretive Guidelines, §493.1256(d), available on the CMS web site at: www.cms.hhs.gov/clia.

Links to other laboratory-related resources can be found at these websites:

CDC: www.phppo.cdc.gov/clia/default.asp

FDA: www.fda.gov/cdrh/CLIA/index.html (for a listing of waived, moderate complexity and high complexity tests).

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-10-07-CLIA

DATE: November 6, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Consolidation of Personnel Policies for Individuals Directing or Performing Non-waived Tests under the Clinical Laboratory Improvement Amendments (CLIA)

Memorandum Summary

Presently CLIA-related personnel policies and procedures are dispersed throughout the regulations, State Operations Manual (SOM), Interpretive Guidelines, training presentations and in other less formal venues. This memo attempts to consolidate and clarify them for the surveyor's use and understanding.

Introduction

State survey agencies are required to make compliance determinations as to whether individuals in prescribed positions meet the CLIA personnel qualification and responsibility requirements stated in 42 CFR, Part 493, Subpart M. This includes the positions of laboratory director (LD), clinical consultant (CC), technical supervisor and consultant (TS, TC), general supervisor (GS), testing personnel (TP), cytology general supervisor (CGS), and cytology technologist (CT).

A laboratory is not considered in compliance if a required position is not filled, if an individual does not meet the required qualifications based on education, training and experience for that position, or if an individual does not meet the responsibilities of the position. If these criteria are not met, the laboratory is subject to a mandatory condition-level citation.

General Surveyor Guidance

- Qualification determinations must be done at the highest level of academic achievement.
- The LD's qualifications are reviewed by the State Agency for all new laboratory applications (form CMS-116) prior to acceptance for enrollment in CLIA for provider-performed microscopy (PPM), accreditation, and compliance certificates and when there is a change in director for a compliance or PPM certificate.

- When the director changes for an accredited laboratory, the accreditation organization is responsible for checking credentials. See SOM, Chapter 6, Section 6006.7.
- When surveying the laboratory initially, evaluate the qualifications of the LD, TS or TC, CC, GS, CT, CGS, and a sample of TP.
- For subsequent surveys, evaluate any new or changed personnel since the previous survey and another sample of TP, if the staffing warrants.
- Request appropriate documents to be provided within a reasonable timeframe (the time it takes to complete the survey or within 1 week afterwards). These will include: diplomas, certificates, licenses, degrees, transcripts, training, experience, continuing education (CE), competency assessment, duties and responsibilities.
- Certain positions are NOT evaluated by the surveyor; for example, phlebotomists who do not perform testing or individuals who do reagent preparation, specimen preparation, microbiology plating, etc., but no actual testing.
- Surveyors cannot require an individual to test for and obtain a General Education Degree (G.E.D.) if a high school diploma or G.E.D. is required and records for a high school diploma are not available, or the individual hasn't attained a high school diploma. This individual is determined to be unqualified, however.
- Agency evaluations, except for foreign credentials, are not acceptable to determine if an individual's qualifications meet CLIA.
- If a high school is closed, it is possible for the individual to solicit documentation from the local school board or State Board of Education to verify graduation.

Professional Certification and State Licensure Requirements

We continue to receive inquiries as to whether the laboratory can present the surveyor an individual's professional certification, such as MT (ASCP) or nursing licenses, as the only type of documentation to meet the CLIA requirements. This information is not considered sufficient evidence. Therefore, more detailed information, like degrees and transcripts, is required.

One exception to this exists where professional certification is required by the regulations; i.e., cytotechnologist (CT) and cytology general supervisor (CGS) positions require American Society of Clinical Pathology (ASCP) certification, in addition to documentation of their highest level of academic achievement in educational, training, and experiential requirements.

When the CLIA regulation specifies that the individual must possess a license, if required by the State, such as a physician (Doctor of Medicine: MD, Doctor of Osteopathy: DO, Doctor of Podiatric Medicine: DPM, Doctor of Dental Surgery: DDS), Midlevel practitioner (as defined at 42 CFR §493.2), testing personnel or otherwise, the laboratory need only produce a copy of the individual's State license as proof of academic achievement. No further academic documentation is required.

Survey Efficiency and Scope of Personnel Record Reviews

The survey process makes provisions for surveyors to verify qualifications at the highest level of academic achievement for the individuals in the required personnel categories.

The regulation considers each personnel category's academic achievement, training, and experience necessary to meet the respective CLIA personnel requirements for the regulated position in which the individual currently functions. Thus, the surveyor will request an academic diploma or degree and/or transcript(s) that were earned by the individual at his or her highest level of academic achievement and will verify the individual's specific laboratory training and experience for that position. It is not necessary to review a high school diploma, for example, of an individual whose position requires an advanced degree.

One must also consider the test complexity/categorization and specialty and subspecialty of the non-waived tests performed by the laboratory when making personnel qualification determinations because many of the positions in these areas have unique qualification and experiential requirements.

If the surveyor identifies serious isolated or pervasive test quality problems that may be attributable to unqualified or untrained individuals performing or directing the laboratory's testing, the surveyor may expand the request for documentation, as necessary.

Provider Performed Microscopy (PPM) Personnel Qualifications

To obtain a certificate of PPM, the director must be an M.D., D.O., DDS or midlevel practitioner, as defined at 493.2 (nurse midwife, nurse practitioner, physician assistant, and must be licensed by the State in which the laboratory is located, if required by that State). Only these individuals can perform PPM tests; otherwise, routine moderate complexity personnel and other applicable requirements apply and the laboratory must obtain a certificate of accreditation or compliance.

Practical Application of the Personnel Qualification Determinations

Surveyors are instructed to cite the most appropriate mandatory deficiency(s) if the laboratory does not meet the personnel requirements for the CLIA position categories which are included on Forms CMS-1557 (Survey Report Form: CLIA) and CMS-209 (Laboratory Report Form). Some simple examples are included here.

Example 1: A dentist (DDS) is previously listed on Forms CMS-1557 and CMS-209 as moderate complexity TC via §493.1409 & 493.1411. This dentist earned a master's degree in chemistry in accordance with §493.1411(b)(3)(i) and a bachelor's degree in medical technology in accordance with §493.1411. The laboratory is now upgrading its CLIA certificate to include high complexity tests within the specialty of pathology and the subspecialty of oral pathology. The DDS will now serve as either: LD, CC, TS, or TP. The surveyor must also verify if the DDS obtained board certification with the American Board of Oral and Maxillofacial Pathology or other board certifications to complete the qualification determination.

Example 2: A phlebotomist never obtained a high school diploma or a G.E.D. and does not perform any laboratory testing; therefore, there are no qualification requirements prescribed by CLIA and this individual's credentials are not evaluated during the CLIA survey.

Example 3: A phlebotomist performs moderate complexity bleeding time tests, so it is necessary to determine if this person meets the applicable CLIA moderate complexity testing personnel qualification requirements at the highest level of academic achievement.

Foreign Trained Personnel

Surveyors are requested to not review foreign academic credentials, but instead, to recommend that the individual obtain the services of a nationally recognized foreign credential evaluation agency to determine equivalency. (See SOM, Chapter 6, Section 6122 and Interpretive Guidelines at 42 CFR 493.2)

Mandatory Citations

These circumstances must be cited at the condition level if not met; i.e., the individual does not meet the required education, training, or experience, the position is not filled, or the corresponding responsibilities of that position are not met at the time of survey. See attached list of mandatory citations.

Competency Assessment

The current CLIA policy for competency assessment is attached. Personnel competency is addressed in CLIA for the director responsibilities at 493.1407, for moderate complexity, and 493.1445 for high complexity; as well as for the TC and TS, 493.1413 and 493.1451, respectively. Competency is not assessed for solo practitioners.

We request that you address any further questions on this topic to Janet Perryman-Butler at: janet.perrymanbutler@cms.hhs.gov.

Effective Date: The information contained in this memorandum is current policy and is in effect for all laboratory facilities. The State Agency should disseminate this information within 30 days of the date of this memorandum.

Training: The information contained in this announcement should be shared with all survey and certification staff including managers and surveyors and their manager. The policies and procedures will be formalized in the appropriate sections of the Interpretive Guidelines.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments: Mandatory Citations Personnel
Competency Assessment Guidelines Final

Personnel Mandatory Citations

Requirement:	Cite the Std. at least:	Cite the Cond. at least:
Laboratory Director (LD) high complexity	D6078	D6076
Technical Supervisor (TS) high complexity	D6111	D6108
Clinical Consultant (CC) high complexity	D6135	D6134
General Supervisor (GS) high complexity	D6143	D6141
Cytology General Supervisor (CGS) high complexity	D6155	D6153
Cytotechnologist (CT) high complexity	D6164	D6162
Testing Personnel (TP) high complexity	D6171	D6168
Laboratory director (LD) moderate complexity	D6003	D6000
PPM Laboratory Director moderate complexity	D5981	D5980
PPM Testing Personnel moderate complexity	D5991	D5990
Technical Consultant (TC) moderate complexity	D6035	D6033
Clinical Consultant (CC) moderate complexity	D6057	D6056
Testing Personnel (TP) moderate complexity	D6065	D6063

Competency Assessment Guidelines

Technical consultant, clinical consultant, technical supervisor, general supervisor

Documented competency assessment is required for the following named positions on the Form CMS-209: technical consultant, clinical consultant, technical supervisor, general supervisor. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must be performed at a frequency determined by the laboratory. Cite D5209 (§493.1235). Exception: If the laboratory director is filling multiple positions, competency evaluation is not feasible. For example, the laboratory director may also fill the position of technical consultant or clinical consultant, if qualified.

Note: The individual named on the CMS-209 must be the individual who is actually responsible for the functions of the position for CLIA purposes, whether that individual is an employee or a contracted consultant, and must meet the qualifications for the position.

Testing personnel

All testing personnel must be listed on the CMS-209 and must undergo documented competency assessment using the 6 criteria denoted under the technical consultant/supervisor's responsibilities for all testing performed. Depending on the situation, non-compliance can be cited at general lab systems (D5209), lab director (D6030/§493.1407 or D6103/§493.1445) or technical consultant/supervisor (D6046-6055, D6121-D6129).

Testing personnel in laboratories with a PPMP certificate

Testing personnel in PPMP laboratories are required to undergo competency assessment. (Exception: In certain circumstances it is not feasible to perform competency assessment, for example, a solo practitioner.) The requirements for performing the assessment and its frequency are determined by laboratory policy and procedure. If it is necessary to cite non-compliance, use D5209.

Other staff

Personnel performing pre-analytic and post-analytic activities are not required to be listed on the CMS-209. Surveyors do not normally check for documented competency evaluation on these individuals. However, if you discover problems in the laboratory and you find that a factor in these problems is poor performance of incompetent staff, cite D6030 or D6103 (lab director).

Quality assessment

Problems in competency assessment that are not picked up and/or corrected by QA should be cited at D5291.

Discussion: Regular competency assessment is an important element of assuring that all personnel are capable of performing their duties correctly. In situations in which more than one citation may be used, choose the one that is most applicable to the situation. For example, if the assessments of testing personnel do not include all six required elements, cite the Technical Consultant.

KEY POINT: Use the most appropriate citation for non-compliance with competency assessment requirements, depending on the situation. Use the citation that will best allow the laboratory to understand the problem and correct it.