Final CLIA Quality System Regulation & Guideline Overview

Judy Yost
Director
Division of Laboratory Services

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

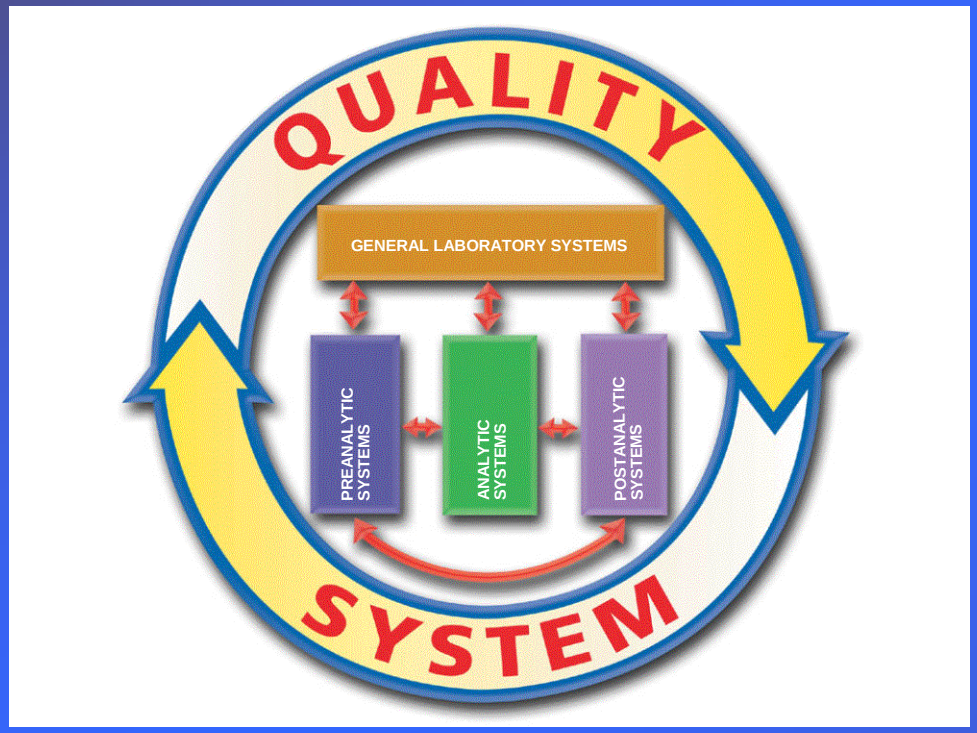
CLIA Final Quality System Regulation

- Published Jan. 24, 2003.
- Effective April 24, 2003.
- Surveyors trained Aug.-Sept. 2003.
- Revised Surveyor Guidelines published Jan. 12, 2004.
- Guidelines on CLIA Web site at: www.cms.hhs.gov/clia under “Current CLIA News”.

What are Guidelines?

- Interpretations or clarifications of the regulation.
- Questions or probes for surveyors to check when surveying the lab.
- Tips about meeting the requirements.
- Guidelines do not have the legal authority of the regulation, cannot be more stringent, are cleared by CMS legal counsel.

Quality System is a comprehensive & coordinated effort to ensure **Quality Objectives** are met.



→ **ACCURATE**

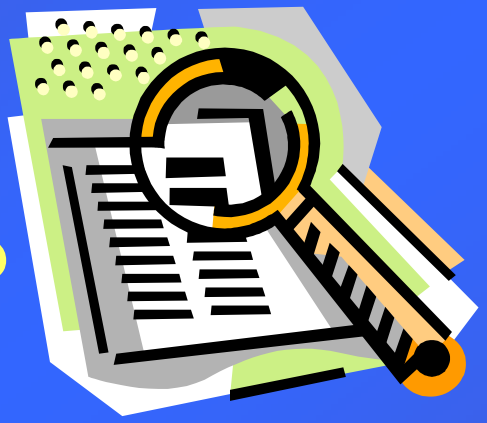
→ **RELIABLE**

→ **TIMELY**

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

What happened to Quality Assurance?



Quality **A**ssurance = **Q**uality **A**ssessment

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Quality Assessment Program Lab Responsibilities

- Establish & follow policies/procedures addressing ongoing QA activity.
- Take corrective actions as necessary.
- Review the effectiveness.
- Revise policies/procedures as necessary to prevent recurrence.
- Communicate to staff & document.
- Quality Assessment is interspersed throughout all phases of testing.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Organization

- Consolidates Patient Test Management, Quality Control & Quality Assurance into:

Facility Administration

Quality System

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Organization

- Parallels the flow of a patient specimen through the lab.
- Reflects total testing process:
  - General Laboratory Systems
  - Pre-analytic Systems
  - Analytic Systems
  - Post-analytic Systems

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Subpart K - Quality System for Nonwaived Testing

- General Laboratory Systems
- Pre-Analytic Systems
- Analytic Systems
- Post-Analytic Systems

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Analytic Systems

- Most of the changes in the Final regulation occurred in the Analytic Systems section.

Proficiency Testing Performance

- Verify accuracy of test performance.
- Reduces level of consensus for PT provider grading from 90% to 80% to minimize ungradable PT specimens.

CLIA

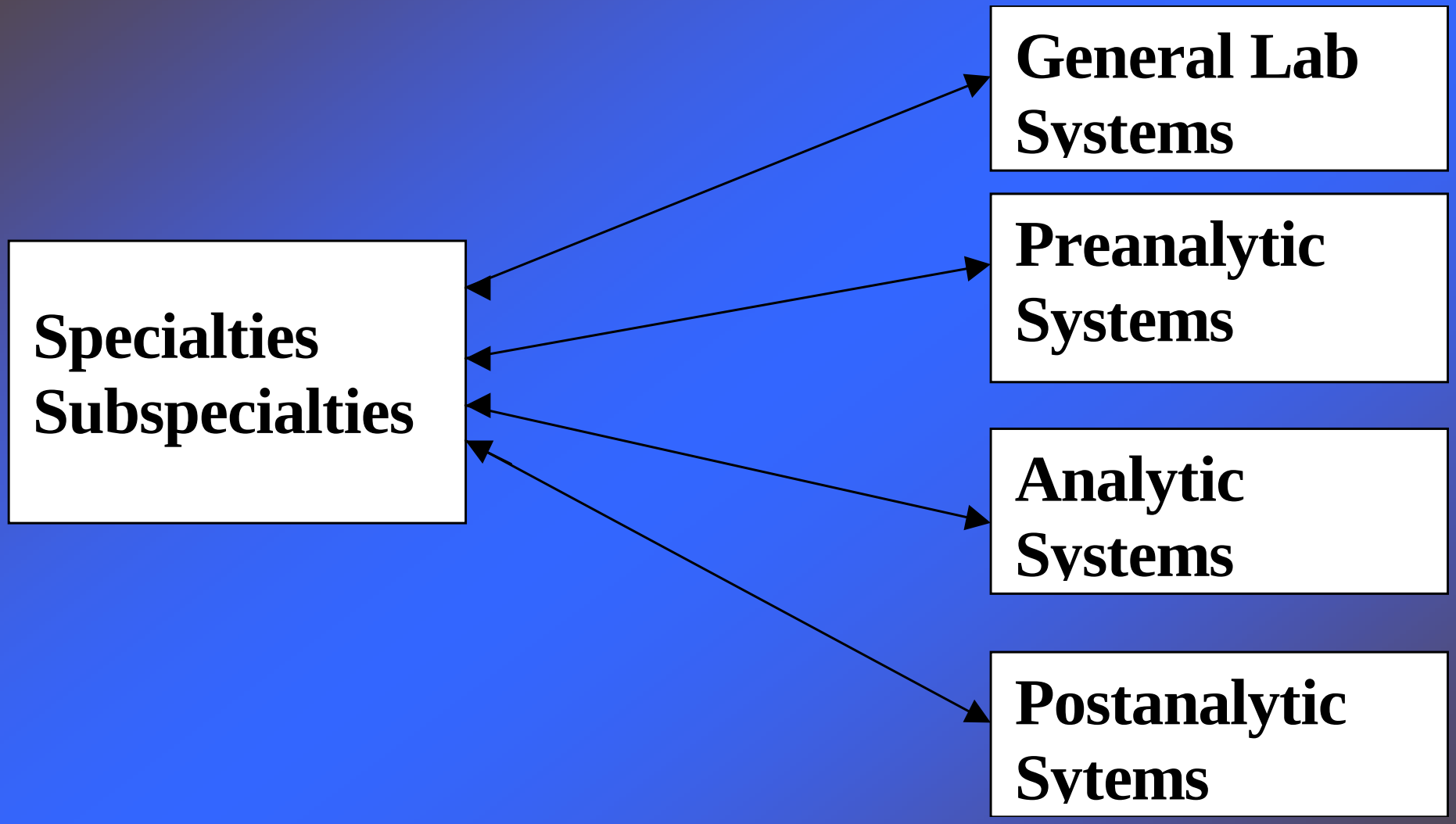
CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Proficiency Testing Performance

GUIDELINE:

- The lab can evaluate the accuracy of tests not regulated by CLIA in Subpart I by performing blind testing of known samples, other external assessment programs, split samples with another lab instrument, comparison with Kodachromes from a reference source.

Quality System Conditions



CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Analytic Systems

- Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements unless HHS approves a procedure, specified in the Interpretive Guidelines, that provides equivalent quality testing.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

What's Different ?

- One set of analytic requirements
  - Nonwaived = moderate and high.
- Specialty/subspecialty requirements
  - Reduced or removed.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Subpart K - Quality Systems for Nonwaived Testing

Establishment & Verification of Performance Specifications

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Verification of Performance Specifications

- Effective 4/24/03 for new moderate complexity tests.
- For new, unmodified, FDA-cleared or approved test systems, the laboratory must do the following prior to reporting patient results:

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Verification of Performance Specifications

The laboratory must demonstrate that they can obtain performance specifications comparable to those established by the manufacturer, in the laboratory's environment, using the laboratory's testing personnel for the following:

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Verification of Performance Specifications

- Accuracy,
- Precision,
- Reportable range, and
- Verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Verification of Performance Specifications

GUIDELINE:

- Labs may simultaneously verify multiple performance specifications by choosing appropriate samples; e.g., repeatedly test (*precision*) samples with known (*accuracy*) high & low values (*reportable range*).
- This testing should be performed by several testing personnel on different days to determine any operator variance.

Calibration & Calibration Verification

Calibration & calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

.

GUIDELINE:

The calibration requirement does not apply to some procedures including:

*Manual procedures with no instrument; e.g., K-B;

* Microscopic procedures;

*Procedures involving an instrument in which calibration is not practical; e.g., prothrombin times.

*Instruments that cannot be adjusted; e.g., unit use test systems

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Calibration Verification

GUIDELINE:

- If the lab performs a calibration protocol using 3 + levels of calibration materials including a low, medium & high every 6 mos., cal. verif. is met.

- For automated cell counters calibration verification is met if the lab follows the mfgr's. instructions for instrument operation & tests at least 2 levels of controls each day of testing.

Subpart K - Quality Systems for Nonwaived Testing

Analytic Systems Control Procedures

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Analytic Systems Control Procedures

- The regulation requires that the lab perform QC using 2 levels of QC materials per day of testing or
- Select an approved Equivalent QC (EQC) option for tests with or without internal controls-if the test system is eligible.

GUIDELINE:

Environmental conditions that may affect test system performance include :

- Temperature
- Airflow
- Light intensity
- Humidity
- Altitude

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

GUIDELINE:

Operator performance that may affect testing include:

- Improper specimen preparation and handling.
- Incorrect test interpretation.
- Failure to follow the manufacturer's test system instructions.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

GUIDELINE:

External control materials may be:

- Commercially or in-house prepared controls.
- Proficiency testing specimens for which results have been confirmed.
- Reference or control strains of microorganisms.
- Calibrators of different lot numbers & concentration than those used to calibrate the system.
- Previously tested patient specimens with established values.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Equivalent QC (EQC) :

- The EQC options available in Appendix C of the Surveyor Interpretive Guidelines are the only acceptable equivalent quality testing procedures at this time.

- If manufacturer's QC requirements are more stringent than EQC, lab must meet them.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

GUIDELINE:

Internal/Procedural Controls are Part of the Test System:

1. The components of the test system are: operator, analysis, environment.
2. Identify those components monitored by the internal controls.

   -Mfgr. should provide in the pkg. insert or in other written form.

   -CMS will accept mfgr's. & lab's decision.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

GUIDELINE:

Internal/Procedural Controls are Part of the Test System continued:

3. Determine environmental conditions that may affect the test system.
4. Evaluate operator variance to determine affect on the test system.
5. Establish a mechanism to monitor components of the test system not monitored by internal controls.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Three Equivalent QC Options:

#1: Test systems w/ internal or procedural controls that monitor *all* analytic testing components.

#2: Test systems w/ internal or procedural controls that monitor a *portion* of the analytic test system's components.

#3: Test systems *without* internal or procedural controls.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Equivalent QC Eligibility

GUIDELINE:

- Tests w/ QC requirements for quantitative, qualitative & semi-quantitative -- all 3 Options.
- Test procedures w/ an extraction phase--Options 1 & 2.
- Test procedures w/ control requirements for routine chem. & hema.--Options 1 & 2.
- Tests w/o internal QC subject to extraction phase or specialty, subspecialty requirements at 493.1261- 1278--NOT eligible.

GUIDELINE:

During Evaluation Process (EP) unacceptable QC results must be repeated & if correct, the lab can continue the EP; if not, the process should be repeated.

Repeat Evaluation Process if:

- -Fail PT
- -Personnel competency is bad.
- -Analytic systems quality assessment is bad.
- -Calibration verification problems identified.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA Survey Policy

- Each laboratory surveyed by CMS will receive one survey that is entirely educational for the requirements that are **new to that lab** in the Final Regulations.
- Labs with problems meeting the new provisions of the Final regulations will receive a letter in lieu of a deficiency statement.
- Existing requirements must still be met and if not, will be cited on the deficiency statement.

THE END!!

Where to find information:

www.cms.hhs.gov/clia

Questions??

THANK YOU!!!

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES