CLIA Update 2013

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Topics For Discussion

- CMS/CLIA Laboratory Enrollment Data
- Enforcement Actions Summary Data
- Regulations Update
  - PT Revisions
  - Patient Access
  - Burden PT Referral
- Test Act Next Steps
- IQCP Implementation Plan & Status
- GPRA Goal—Waived Labs
- Competency Brochure Published
- Resources

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Current Statistics--Enrollment

Total Number of Laboratories	**235,828**
Total Non-Exempt	**228,535**
Compliance	19,235
Accredited	15,760
Waived	156,653
Provider Performed Microscopy	36,887
Exempt	**7,293**
NY	3.583
WA	3,710

CMS data base 1/2013

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Current Statistics

Physician Office Laboratories by CLIA Certificate Type

(Non-Exempt Only)

- Waiver: 58.8%
- Provider Performed Microscopy: 25.4%
- Compliance: 10.8%
- Accreditation: 4.9%

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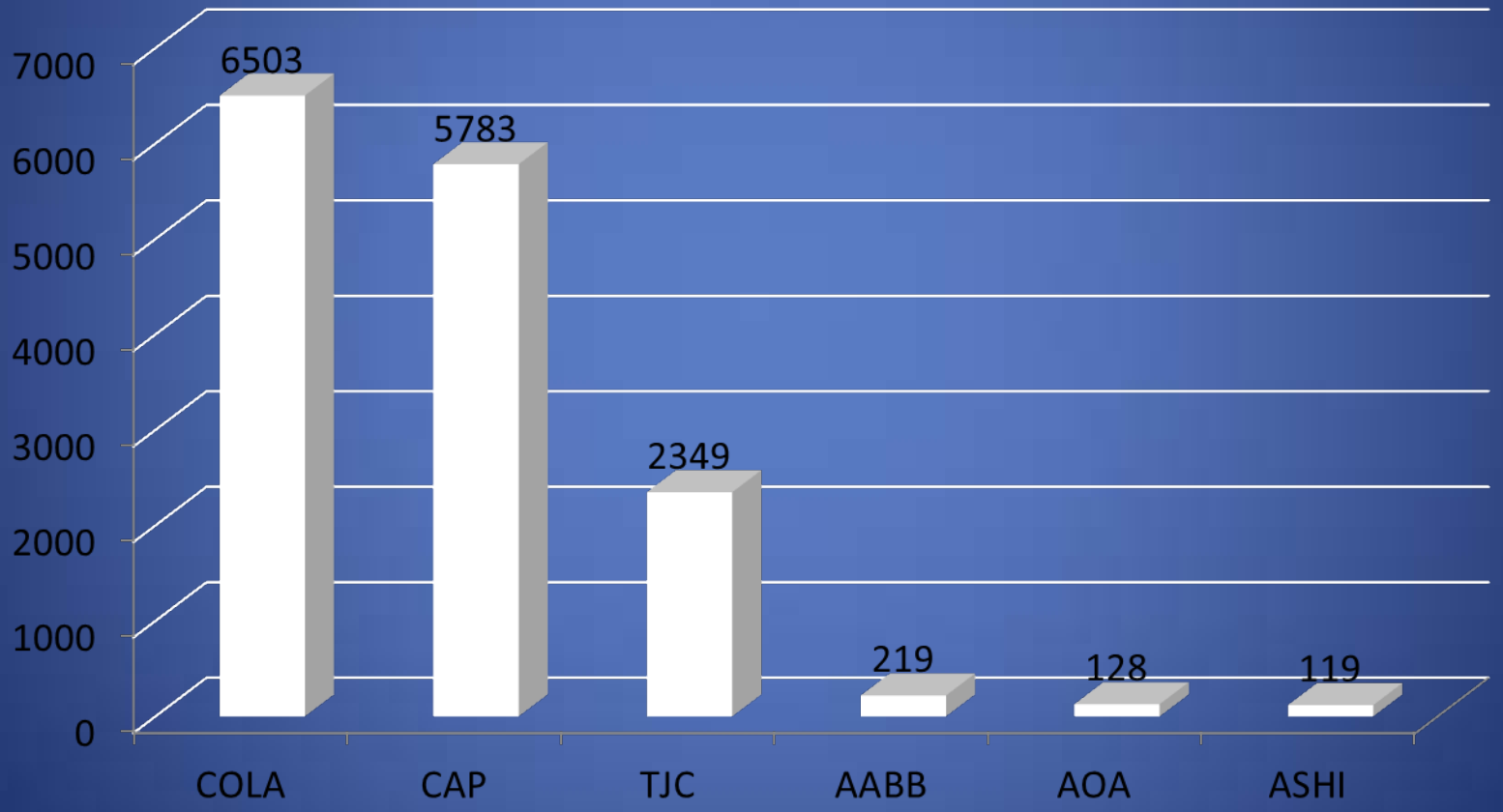
Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



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2012 Enforcement Rates for CMS Regional Offices (Proposed v. Imposed)

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CMS 2319-P: Patient Access Rule

- Final rule currently undergoing HHS clearance w/ tentative publication date of late summer 2013.
- CDC, Office of Civil Rights (OCR) & CMS collaborative effort.
- CLIA Interpretive Guidelines will be revisited to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.

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Updating PT Regulations

- CMS collaborating w/ CDC
- Received CLIAC recommendations, based on expert input
- Requires significant levels of data compilation & analysis
- Reviewing list of analytes, grading criteria & target values, etc.
- Proposed rule will solicit comments on changes
- Final standards will be phased in to allow time for implementation

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PT Burden Rule

- Proposed regulations carves out one-time exception for confirmatory & reflex testing, if PT sample goes to another lab for testing
- Comments received generally in support
- Final under development
- Guidance will be provided to surveyors & labs

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Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Amendment to the CLIA statute signed by the President on 12/4/12.
- Clarifies that PT samples are to be tested in the same manner as patient specimens, EXCEPT that no PT samples shall be sent to another laboratory for analysis.

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Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Allows the Secretary discretion for:
  - Revocation of the CLIA certificate for PT referral; and
  - Imposition of the 2 year owner/operator ban when sanctioned for PT referral

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Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Next steps:
  - Rulemaking to detail adverse actions for PT referrals (define when the discretion will be applied & when revocation will be imposed).

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Individualized Quality Control Plan (IQCP) Topics

- Background & History of CLIA QC
  - In the beginning…
  - 2003 Quality System Regulations
  - Inception of EQC--2004
- 2005 'QC for the Future' Meeting
  - Partnership w/ CLSI & development of EP-23
  - Publication of EP-23 in 2011
- CMS' High Level Implementation Plan for Individualized Quality Control Plan(IQCP)
  - Education & Transition Period
  - Implementation Status

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IQCP Background & History

- CLIA Law passed—1988
- Final CLIA Regulations published—1992
  - 5 basic QC requirements—mod. complexity phase-in
    - Follow manufacturer's instructions
    - All QC actions acceptable during phase- in
  - All QC requirements apply to high complexity
- Many expert meetings convened by CDC/CMS to find better QC, but to no avail
- Quality System (QS) Regulations pub.—2003
  - Updated all QC requirements

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IQCP Background & History

- 2003 QS regulation--new provision for alternative QC in CMS' Interpretive Guidelines (IG) in lieu of changing regulations w/ new technology, as long as "equivalent quality testing" is provided--*42 CFR 493.1250 & 1256(d)*.
- Default: 2 levels external QC/day of testing

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Inception of EQC

- Equivalent QC or 'EQC' developed in IG as a voluntary alternative QC--2004
  - Option employed depends on the extent internal QC monitors total testing process
  - Minimizes frequency of external QC required
  - Helps save costs/resources for labs
  - Acknowledges technological advances
  - Director responsible for choice of QC plan
  - Remaining quality systems must be acceptable

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Inception of EQC

- Concerns expressed by industry, laboratories, experts, etc.
- Many laboratories adopted EQC successfully & have no quality issues; but no flexibility
  - EQC limited in scope
- CMS reached out to CLSI to facilitate development of an scientific, objective consensus QC guideline

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CMS-CLSI Partnership

- CLSI convened the well-attended 'QC for the Future' meeting in 2005
- Sponsored by accrediting orgs., industry, professional orgs. & gov't. agencies
- Outcome:
  - Stakeholder concern that manufacturers don't provide labs sufficient information
  - 'One-size-fits-all' QC doesn't work w/ new technology

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EP-23 Becomes IQCP

- CLSI meeting directed the development of Evaluation Protocol (EP)-*23—Laboratory Quality Control Based on Risk Management*
  - Chaired by James Nichols, PhD
  - Assembled expert group
  - Published October, 2011
- CMS incorporated key EP-23 concepts into CLIA IG as QC policy, called **IQCP**

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IQCP Policies

- Applies to CMS-certified non-waived labs
- Covers all phases of the testing process
- May or may not reduce QC amt. or frequency
- IQCP is optional
- Default is regulation
- Includes existing & new analytes/test systems & specialties, except cytology/histopathology

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IQCP Pro's

- Can be customized based on patient pop., environment, test system, personnel, test uses
- Offers flexibility to achieve QC compliance for each test; broad in scope
- Adaptable to future technology advancements
- Permits labs to develop a QCP using their existing quality practices/information
  - E.g., test verification data is a start
- Considers known risks mitigated by mfgr &
- Formalizes laboratories' risk mgt. decisions

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IQCP Facts

- Once effective, IQCP will supersede the current EQC policy
- Existing CLIA QC & QS concepts won't change
- No regulations will change!
- CMS' outcome oriented survey won't change

- Minimally, labs must follow mfr's. instructions
- Lab director has overall responsibility for QCP

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IQCP Facts

- There'll be an education & transition period for labs before IQCP is fully effective
- National Surveyor Training on IQCP will be conducted
- Info & Guidance will be provided to labs

www.cms.hhs.gov/clia/

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IQCP

In the interim, CMS certified labs should:

- Continue to follow existing QC protocols
- Learn about EP-23 concepts & IQCP
- Plan & complete their transition accordingly
  - Phase out EQC (if using it)
  - Decide to implement default QC or IQCP

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IQCP Dates

- CMS will notify labs of important dates:
  - Beginning of transition & education period
  - End of education & transition period
- At the end, labs must be in compliance w/ their QC choice
- Or deficiencies will be cited

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IQCP & Accredited Labs

- CMS will solicit accrediting orgs (AO) to determine their interest in IQCP

- Accredited labs should continue to meet their accrediting org.'s QC standards until they receive notice from their AO

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IQCP Educational Period

- No control procedure regulatory citations will be issued during the education & transition (E/T) period, unless serious test quality problems are found
- All questions regarding IQCP may be directed to the CMS electronic mailbox

IQCP@cms.hhs.gov

- Please stay tuned for more information…..

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IQCP Planning Team

- CMS convened a planning team in 2011 to oversee the implementation of IQCP
- Volunteer members from Central Office w/ expertise in CLIA & lab medicine
  - includes Regional reps & former div. mgr.
- Planning team instituted WG's to work simultaneously to accomplish multiple tasks
  - Training planning
  - Interpretive Guidelines
  - Communications
  - AO/ES re-approvals
  - Brochures

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IQCP Interpretive Guidelines (IG)

- CMS Central/Regional Office (CO/RO) Meeting
  - learned & discussed EP23
  - described potential content of a new CLIA alternative QC option, IQCP
- Convened IQCP Interpretive Guidelines WG
  - co-leads from CO & RO
  - CO & RO staff volunteers collaborated to write draft IG w/ subgroups to draft each section

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IQCP Interpretive Guidelines (IG)

- Worked via webinars to complete draft IGs
- Final draft approved by IQCP Planning Team for review by selected stakeholders
- Late Sept. 2012 – Solicited comments from internal & external affected parties
- Winter 2012 - Reconciled comments & revisions made to draft IGs
- Final draft approved by IQCP Planning Team
- Third S&C Letter to transmit the IG's is going through CMS clearance process

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IQCP Surveyor Training

- IQCP Training Team: CO/RO formed late 2011
- Training approach & modules planned via conference calls & face- to-face meetings
- RO/SA training will occur prior to E/T period start
- Training Team will continue to support RO/SAs post training
  - presenting at upcoming consortia meetings
  - webinars for possible “advanced” IQCP training
  - other venues as requested

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IQCP Training Modules

- History & Rationale for IQCP
- CLIA IQCP Policies
- Overview of Risk Assessment
- Scope of IQCP
- Citations (D-tags) for IQCP
- Surveying for Compliance
- Sample Quality Control Plan (QCP) Evaluations
- Education & Transition Period

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IQCP Surveyor Training

- The IQCP SA Training will be conducted in Baltimore from November 18-22, 2013
- AOs, Exempt States, & our other Partners are welcome to attend
- We can accommodate up to 2 individuals per AO/ES/Agency

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IQCP Educational Outreach

- **CLIA BROCHURES**
  - First in a series of IQCP brochures to debut soon
  - Focus is introductory level Q&A addressing:
    - What is IQCP
    - Application
    - Participation
    - Manufacturer Instructions
    - Director Responsibility
  - Distribution
    - CLIA website
    - On-site survey of Certificate of Compliance (COC) labs
    - Booths, public venues, Partners
  - Anticipate the 2nd brochure release by end of 2013

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IQCP Educational Outreach

- **COLLABORATION with CDC**
  - CMS is collaborating w/ CDC on further educational material
  - Focus geared towards Physician Office Laboratories (POLs) & other smaller labs

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IQCP Communications

- CLIA website: two S&C letters w/ FAQs
- Mailbox for inquiries: IQCP@cms.hhs.gov
- Educational Brochures: series to be posted on CLIA website: www.cms.hhs.gov/clia/
- Working on possible CMS media venues for IQCP press release
- IQCP information/materials will be shared w/ Partners & stakeholders

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IQCP Planning

- IQCP Education & Transition (E/T) Period
  - Two years long
  - Learn about IQCP & ask questions
  - Determine QC option
  - Make transition plans
  - Begin to implement choice
- IQCP is optional for AO/ES Standards

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IQCP AO/ES Planning

- During Education & Transition (E/T) Period
  - AO/ESs evaluate their standards
  - Ensure AO/ES standards contain acceptable QC options
    1. CLIA QC regulations as written or
    2. IQCP
- End of E/T Period
  - EQC no longer acceptable
- Changes in AO/ES standards
  - Submit to CMS prior to implementation
  - CMS evaluation: must be equal to or more stringent than the CMS IQCP procedure

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IQCP AO/ES Planning--Validation

- Validation Surveys for IQCP
  - Surveyors to be trained to follow the standard process of surveying w/ the CLIA requirements
- Validation Surveys: Education & Transition Period
  - Labs will be cited for not following CLIA QC requirements, only if a surveyor identifies **quality testing problems**
    - doing no QC at all
    - serious test quality concerns
    - immediate jeopardy (real or potential harm to patients)

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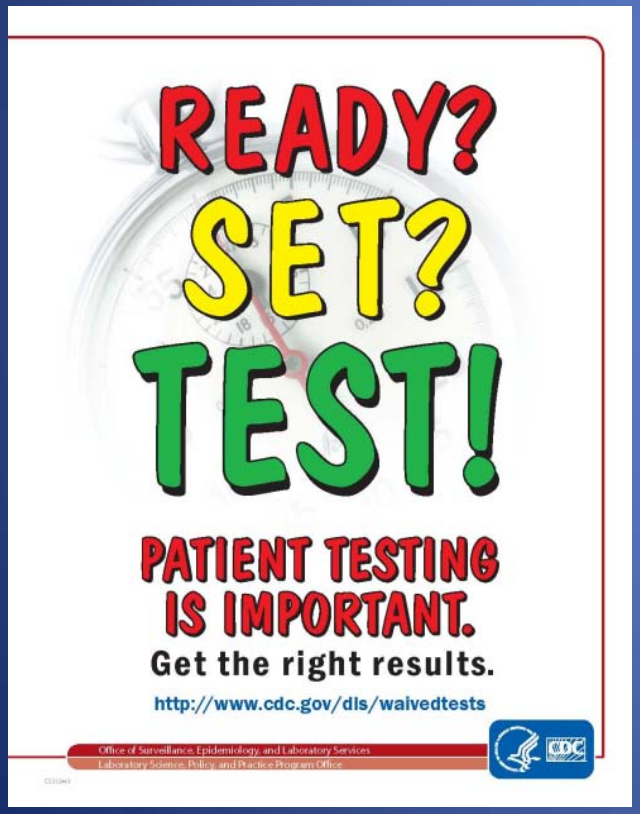
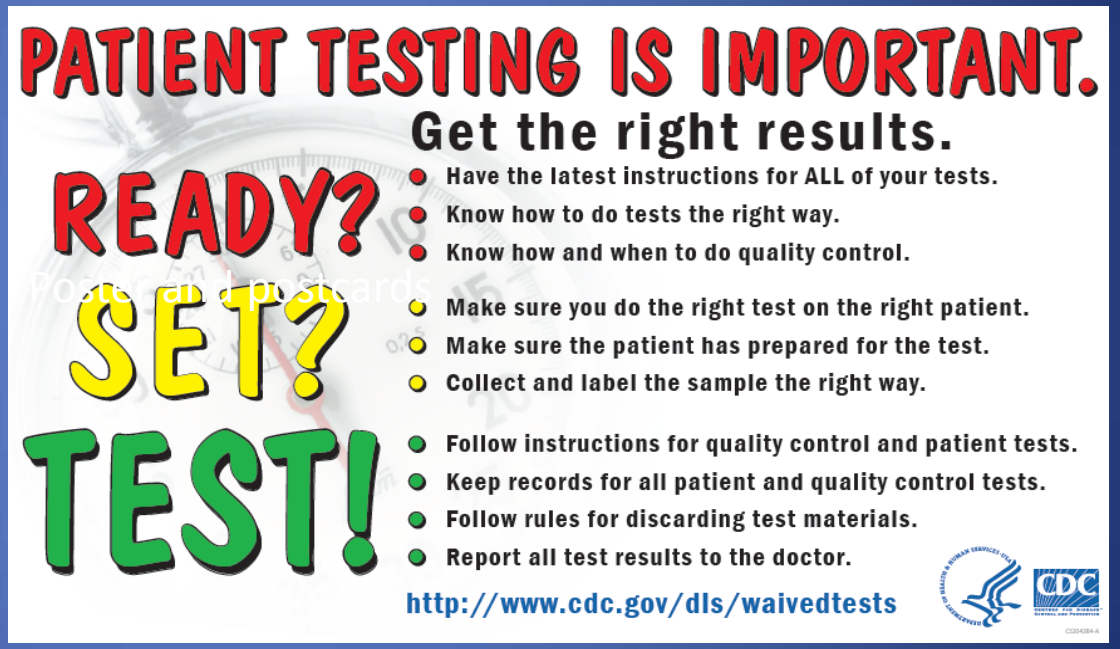
Good Laboratory Practices for Waived Testing Sites

- Educational booklet with job aids





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GPRA Waived Project

Government Performance Review Act

- Goal – Increased compliance with CLIA standards as measured by increased percentage of Letters of Congratulations (no problems found).

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GPRA Waived Project

- Pilot Study – 2 states in each Region
  - Selected Waived labs received copy of 'Ready, Set, Test' prior to their CoW survey
  - Post survey information collected regarding lab use of booklet to improve lab practices

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GPRA Waived Project

- 2010 Baseline – 18% received Letters of Congratulations
  - Results from 2011 – 32%
  - Results from 2012 – 44%

Conclusion – Educational materials like 'Ready, Set, Test' serve as excellent means of improving quality of laboratory testing

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CLIA Competency Assessment Introduction

- Competency assessment (CA) is used to ensure that laboratory personnel are fulfilling their duties, as required by Federal regulations; i.e., are capable of providing accurate & reliable test results.
- See CMS Brochure: *"What Do I Need to Do to Assess Personnel Competency?"*

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CLIA Competency Assessment Definition

- Competency is the ability of laboratory personnel to apply their skill, knowledge, & experience to perform their duties correctly.

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CLIA Competency Assessment Policy

- Annual CA is required for all technical, supervisory & testing personnel.
- Various related requirements are interspersed throughout regulations.
- Six elements are necessary for all who perform non-waived testing, for all tests performed.
- Operator training prior to testing is critical & required.
- Competency assessments must be documented.

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CLIA Competency Assessment Rationale

- Studies indicate that more education & training produce higher quality results.
- The means to confirm training effectiveness is CA.
- In CLIA, laboratory director's qualifications are stringent due to overall quality responsibility.
- But qualifications for testing personnel are minimal, based on test complexity.

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CLIA Competency Assessment Rationale

- CLIA survey experience indicates problems caused by human errors & may have a patient impact.
- Routine CA helps to prevent errors.
- This highlights the significance of competency, regardless of education.
- Quality management includes personnel, processes & procedures, as does competency.

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CLIA Competency Assessment- Key Regulation

493.1413(b)(8)(9) & 1451(b)(8)(9)—

Tech. Consultant/Supervisor *Responsibilities:*

- *Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently.*
- Laboratory Director has overall responsibility.

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CLIA Competency Assessment Required Elements

Competency for all tests performed must include:

- *1. **Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.***
- *2. **Monitoring the recording & reporting of test results***

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CLIA Competency Assessment Required Elements

Competency for all tests performed must include:

- *3. **Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records***
- *4. **Direct observation of performance of instrument maintenance & function checks***

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CLIA Competency Assessment Required Elements

Competency for all tests performed must include:

- *5. **Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and***
- *6. **Assessment of problem solving skills.***

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CLIA Competency Assessment Tips

- Individual conducting CA must be qualified as TS/GS or TC, based on test complexity.
- *Competency is not PT!* PT can be used to meet some elements of competency, but not all!
- Pathologists who read slides should be evaluated by the laboratory director as TS.
- Competency is NOT the same as performance evaluation or training.

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CLIA Competency Assessment Tips

- Competency records should match the laboratory's actual procedures as performed by its personnel.
- When observing test performance, use the procedure manual (PM)/package insert (PI) to ensure PM is current & it's being followed.
- Competency for clinical & technical consultants/supervisors is based on their regulatory responsibilities.

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CLIA Competency Assessment Tips

- Can use competency assessment for QA when confirming tests ordered match reported results.
- Checklists are only minimally ok.
- Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals =moderate complexity.
- Waived testing personnel, non-testing pre/post analytic personnel & those not in regulatory positions aren't subject to CA, but it's good QA.

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CLIA Competency Assessment Tips

- Follow up on QC corrective actions or PT failures will demonstrate problem-solving ability.
- Don’t have to do CA all at one time; can spread over the year’s time.
- Can combine elements; e.g., pre, analytic & post observation, if it works for you.
- Can combine analytes tested on the same platform, but not test systems w/ different platforms/methods/manufacturers.

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CLIA Competency Assessment Tips

- If a service contract is used for PM, it's ok to review maintenance records.
- Lab director is accountable; must also demonstrate proficiency. Responsibilities are checked on surveys.
- If test methods are added or changed, competency must be re-evaluated prior to reporting test results.
- Build CA into existing quality practices, procedures. (Quality System)

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Where to Obtain Information

CMS/CLIA Web site:

www.cms.hhs.gov/clia/

CMS CLIA Central Office:

410-786-3531

Judy Yost's Email: **Judith.yost@cms.hhs.gov**

IQCP Link: IQCP@cms.hhs.gov

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THE END!

THANK YOU!!

QUESTIONS??

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