CLIA'S NEW IQCP

SEABB

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OBJECTIVES

Clinical Laboratory Improvement Amendment

- What is IQCP?
- What are the parts of IQCP.
- What & who does it affect.
- How does IQCP affect AABB members.

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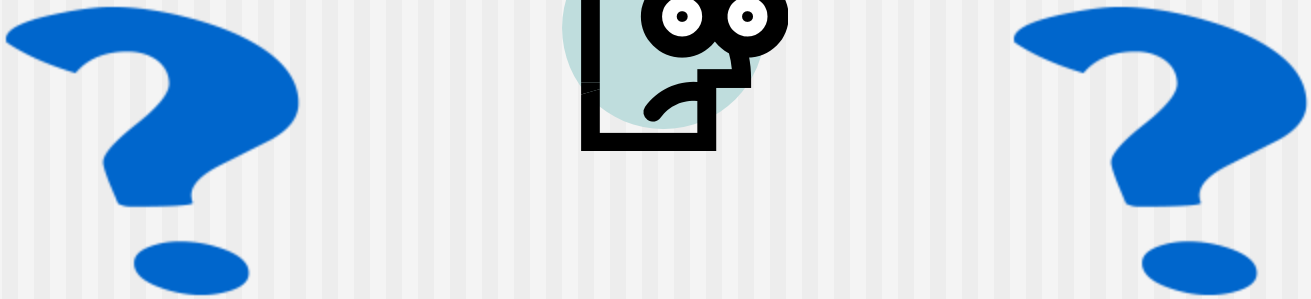

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Current Statistics-Enrollment

- Total Number Laboratories 244,564
- Total Non Exempt Laboratories 236,882
  - Compliance 18,959
  - Accredited 16,081
  - Waived 165,058
- Total Exempt 7,682
  - NY 3,810
  - WA 3,872

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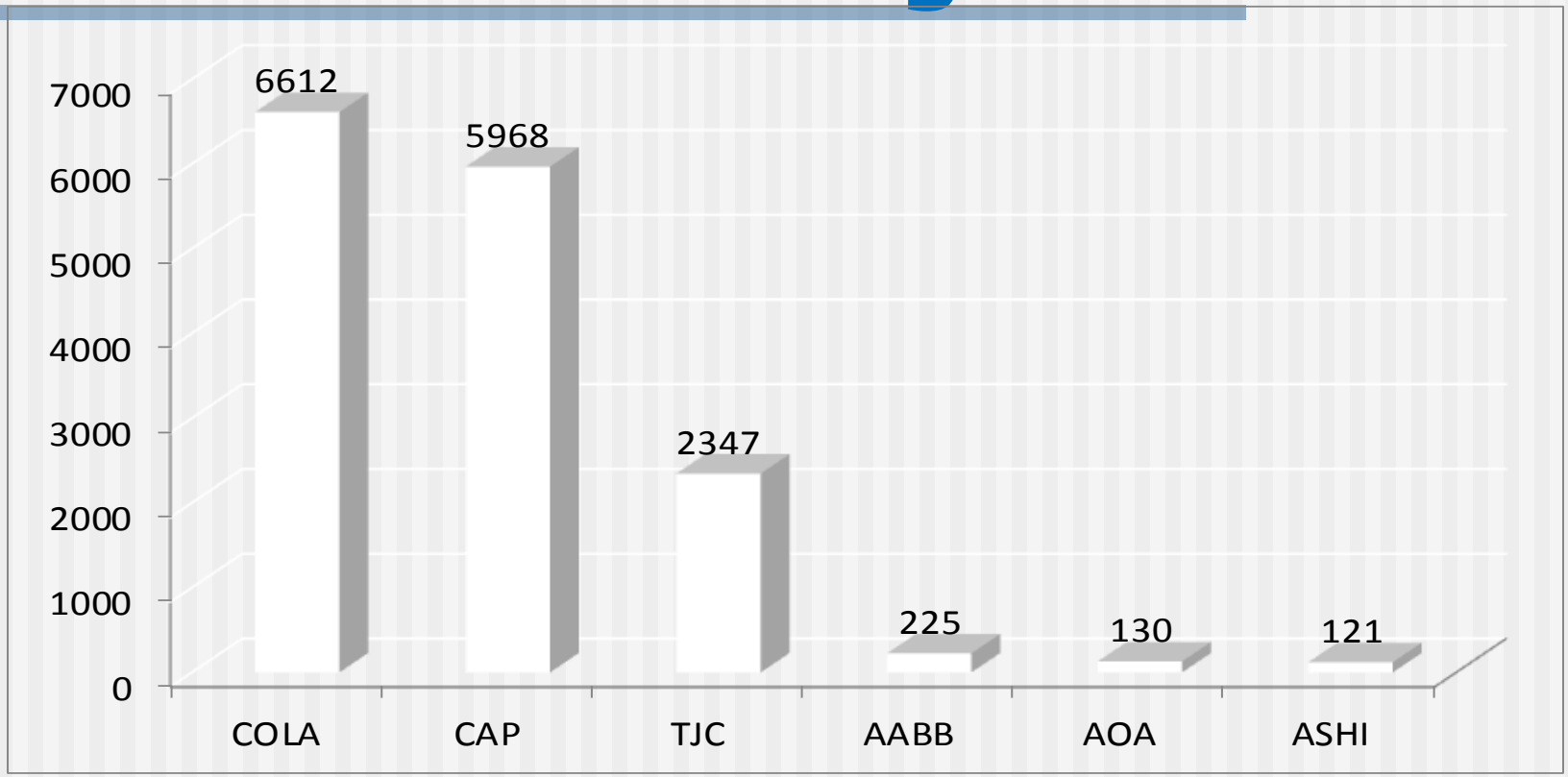
Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



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IQCP

Individualized Quality Control Plan

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Quality Control History

- CLIA Law passed 1988
- Final Regulation passed 1992
- Review & Updated 2003
- Equivalent QC 2004
- Begin Design IQCP 2005

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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

IQCP

- Voluntary
- Replaces Equivalent Quality Control
- Will have 2 options:
  1. CLIA QC regulation as written 493.1256
  2. Implement IQCP

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IQCP

IQCP CAN ONLY be used when manufacturers directions (MI) for QC are absent or less stringent than the Analytic System Control Procedures as mandated by CLIA.

Education & Transition Period

- January 1, 2014 – January 1, 2016

- During 2 year period facilities may use:

1) CLIA regulatory requirements as written
2) Continue follow EQC as described in current Interpretative Guidelines in Appendix C
3) Implement IQCP

Exempt states will determine as to incorporation of IQCP.

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IQCP

- 42CFR 493.1250 gives HHS Authority
- For Nonwaived Testing only
- Except: Pathology, Histopathology
  Oral pathology, Cytology

Three Parts of IQCP

IQCP=RA + QCP + QA

- Risk Assessment (RA)
- Quality Control (QCP)
  - Quality Assessment (QA)

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Risk Assessment

Risk assessment (RA) is the identification and evaluation of potential failures and sources of errors in a testing process

5 Components of RA

- Specimen
- Environment
- Reagent
- Test System
- Testing Personnel

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5 Components of RA cont.

- Specimen examples
  - Patient preparation; sample collection; sample labeling; sample storage, preservation and stability; specimen transportation; processing; referral.
- Environment examples
  - Temperature; Airflow/ventilation ; Lighting ; Humidity , Altitude; Dust Water, Utilities, Adequate Space.
- Reagent examples
  - Shipping/receiving conditions; Storage conditions; Expiration Date

5 Components of RA cont.

- Test Systems examples
  - Inadequate sampling, Clot detection capabilities; Capabilities for detection of interfering substances (e.g hemolysis, lipemia, icterus, turbidity); failure of systems controls and function checks (e.g temperature monitors).
- Testing Personnel
  - Appropriate education and experience qualifications; training ; Competency; Adequate staffing

RA Continue

- Identify sources of potential failure/errors
- Evaluate frequency/impact of failures
- Document the RA activities:

  i.e Tables, Fishbone diagrams, lists

  Highlighting MI, Process flow charts

RA 3 Phases of Testing

Must include all phases:

- Pre-Analytic
- Analytic
- Post-Analytic

Quality Control Plan

Quality Control Plan (QCP) is a document that describes the practices, resources, and procedures to control the quality of a particular test process.

The Written Procedures.

Quality Assessment (QA)

- The laboratory must establish a review system for the on-going monitoring of the effectiveness of their QA.
- Data should support QA

QA

- QC Review
- PT Testing Review
- Patient Result Review
- Specimen Rejection Log Review
- Turnaround Time Reports
- Training & Competency

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Quality Assessment Cont.

- Labs must investigate identifies failures and adjust the QCP as necessary to prevent failures in the future.
- All patients potentially affected by the failures should be identified and corrective action taken.

Responsibility

The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur.

Who IS Affected

- Non Wavied Test
- MI requires less QC than 41 CFR 493.1256.
- Test is not in the specialites of subspecialties of pathology or cytology area.

Blood Bank Specialty

Table 1: Eligibility for IQCP

CLIA Specialty/ Subspecialty	Eligible for IQCP?	General Regulations Eligible for IQCP	Specialty/Subspecialty Regulations Eligible for IQCP	Specialty/ Subspecialty Regulations NOT Eligible for IQCP
Routine Chemistry	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1267(b),(c)	§493.1267(a), (d)
Urinalysis	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Endocrinology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Toxicology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Hematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1269	N/A
Immunohematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1271
Clinical Cytogenetics	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1276

CMS CLIA 22

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CFR493.1271

Title: Standard Immunohematology

(a) *Patient testing*. The laboratory must perform ABO grouping D(Rho) typing, unexpected antibody detection, ……. By following MI if provided, and as applicable, 21 CFR 606.151(a)-(e)

Where to Obtain Information

MS/CLICA Web site:

www.cms.hhs.gov/clia/

CMS CLIA Central Office:

410-786-3531

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

IQCP Mailbox: IQCP@cms.hhs.gov

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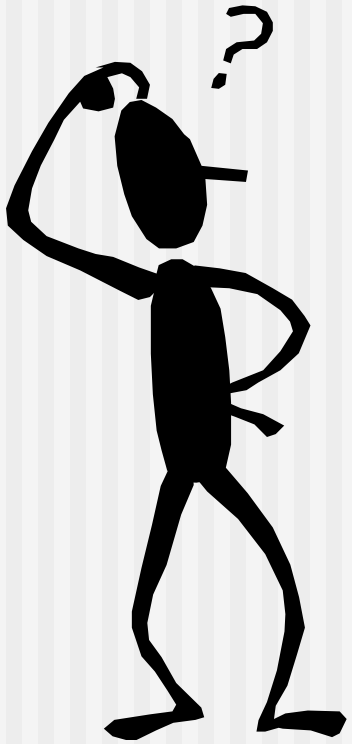
Thank you



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