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MAKE COMPLIANCE EASY

Laboratory Compliance Simplified: Part 2

November 7, 2023

Learning Objectives

- Review key CLIA requirements
- Identify the challenges and pitfalls to be avoided in setting up an internal lab compliance system
- Discuss the requirements needed to maintain acceptable personnel files
- Illustrate what's needed to set up and maintain a QA Plan in the laboratory.

Today's Conversation

- Quality Assessment
- Calibration/Calibration Verification
- Quality Control
- Reference and Reportable Ranges
- Critical Values
- Record Retention
- Instrument Validation
- Point of Care vs. Core Lab Testing
- ICQP- Individualized Quality Control Plan

Previous Topics Revisited – We listened to your feedback!

- Personnel
- Competency Evaluation
- Proficiency Testing
- Documentation

Quality Assessment

Each laboratory must develop and implement a comprehensive Quality Assessment Plan to ensure the highest quality of laboratory practices

Three phases:

- Pre-Analytic
- Analytic
- Post-Analytic

Establish procedures and processes that:

- Identify potential problems
- Assessment of problem root cause
- Actions designed to resolve problems
- Documentation and reevaluation to ensure problems do not recur
- Evaluations to include – personnel records, safety, instrument validation, and other laboratory protocols
- Results of evaluations and corrective actions must be documented, reviewed by the Laboratory Director or designee and retained

Quality Control

- Must be performed according to manufacturer's specifications and per regulatory requirements
- Non-waived tests – run daily prior to patient testing (unless IQCP is implemented)
- Incorporate Westgard Multi-Rules as guidelines
- Review reports with Levey-Jennings graphs weekly and monthly for shifts or trends

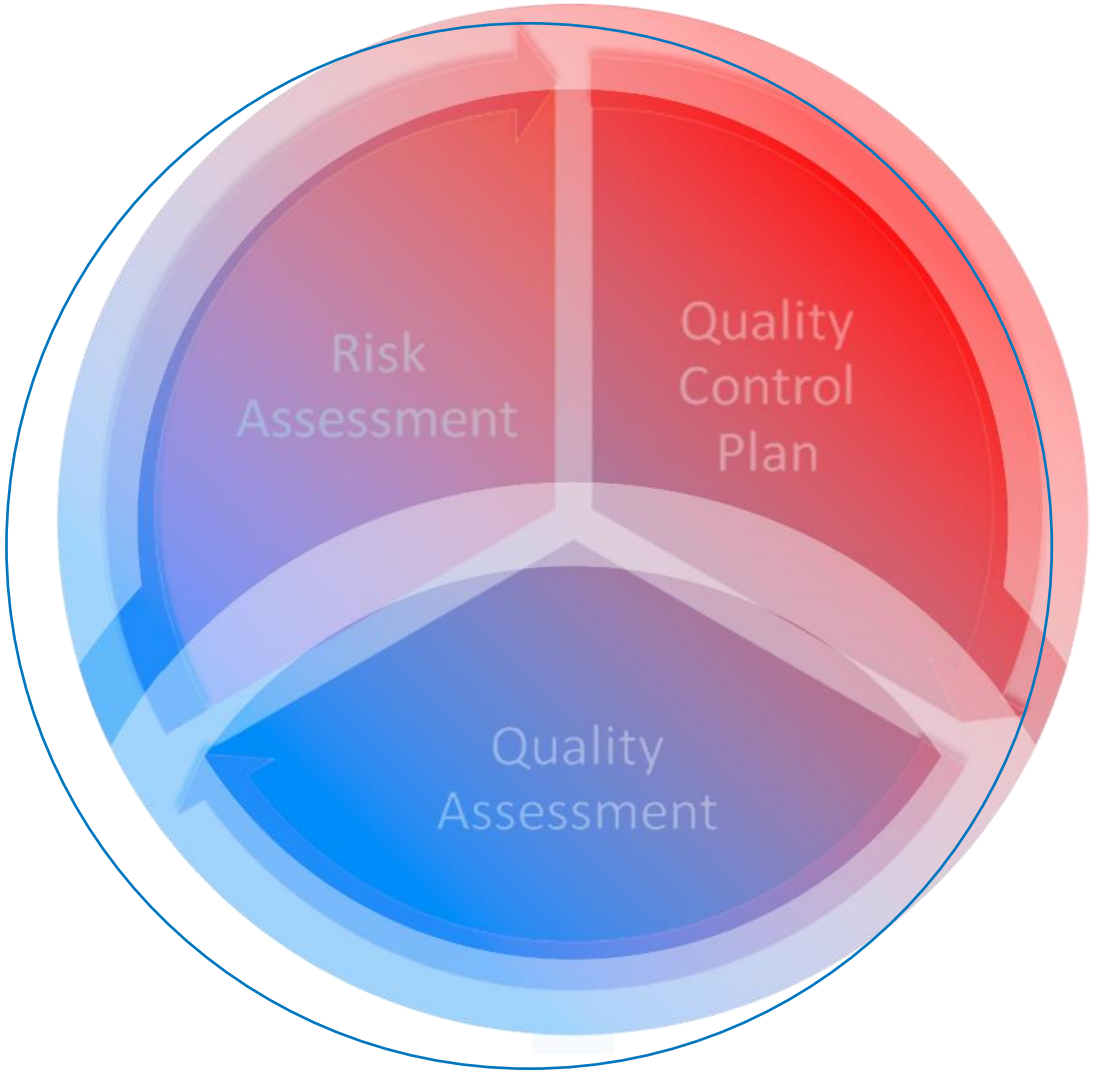
Individualized Quality Control Plan (IQCP)

- Specific plan designed by individual laboratory to ensure quality and to mitigate risk of erroneous patient test results

Plan includes three parts:

1. Risk Assessment
2. Quality Control Plan
3. Quality Assessment Plan

- Meeting the required criteria may allow for reduction in frequency of QC materials
- Laboratory Director must review the plan and document that review at least annually



Instrument Calibration

Must be performed according to manufacturer's requirements or minimally every 6 months

Recommended:

- Following major maintenance or repair
- Repeated analytic issues
  1. QC out of range
  2. Shifts or trends
- Following Calibration – Acceptable QC required prior to initiation of patient testing

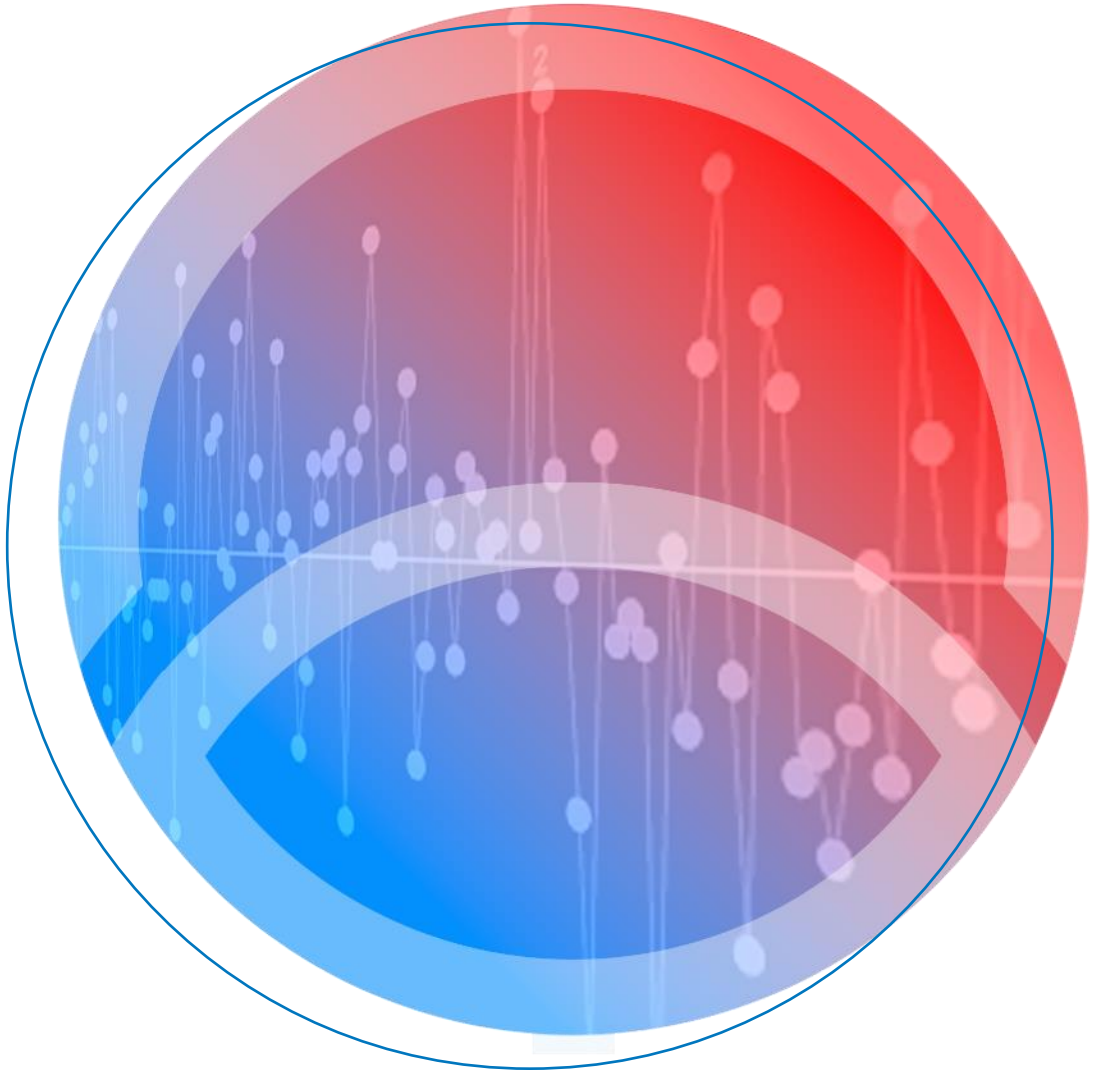
Instrument Calibration Verification

- Ensure continuous accuracy and linearity of the analytic measurement range (AMR)

- Performed every 6 months on all test methods with <3pt calibration or recommended by manufacturer

- Verify the accuracy of cut-off levels for qualitative screening assays based on a threshold

Reference and Reportable Ranges



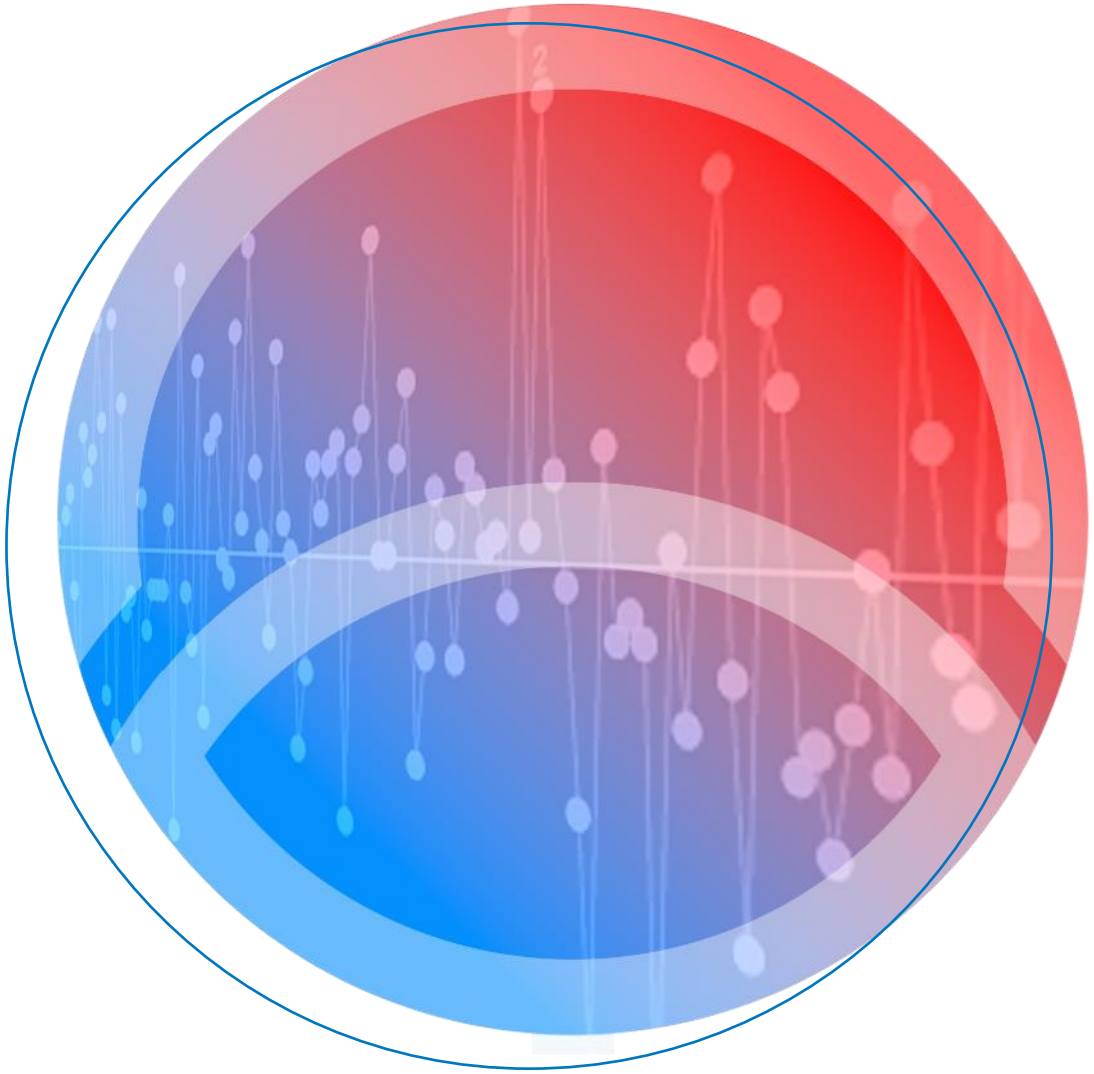
- Must be established and published for each test method
- May utilize the manufacturer's recommended reference ranges which then may be adjusted based on local population studies
- Abnormal flagging is based on reference ranges
- Reportable ranges are set based on linearity studies performed during instrument validation, and manufacturer's published ranges
- Patient results outside the established reportable range should not be reported

Critical Values

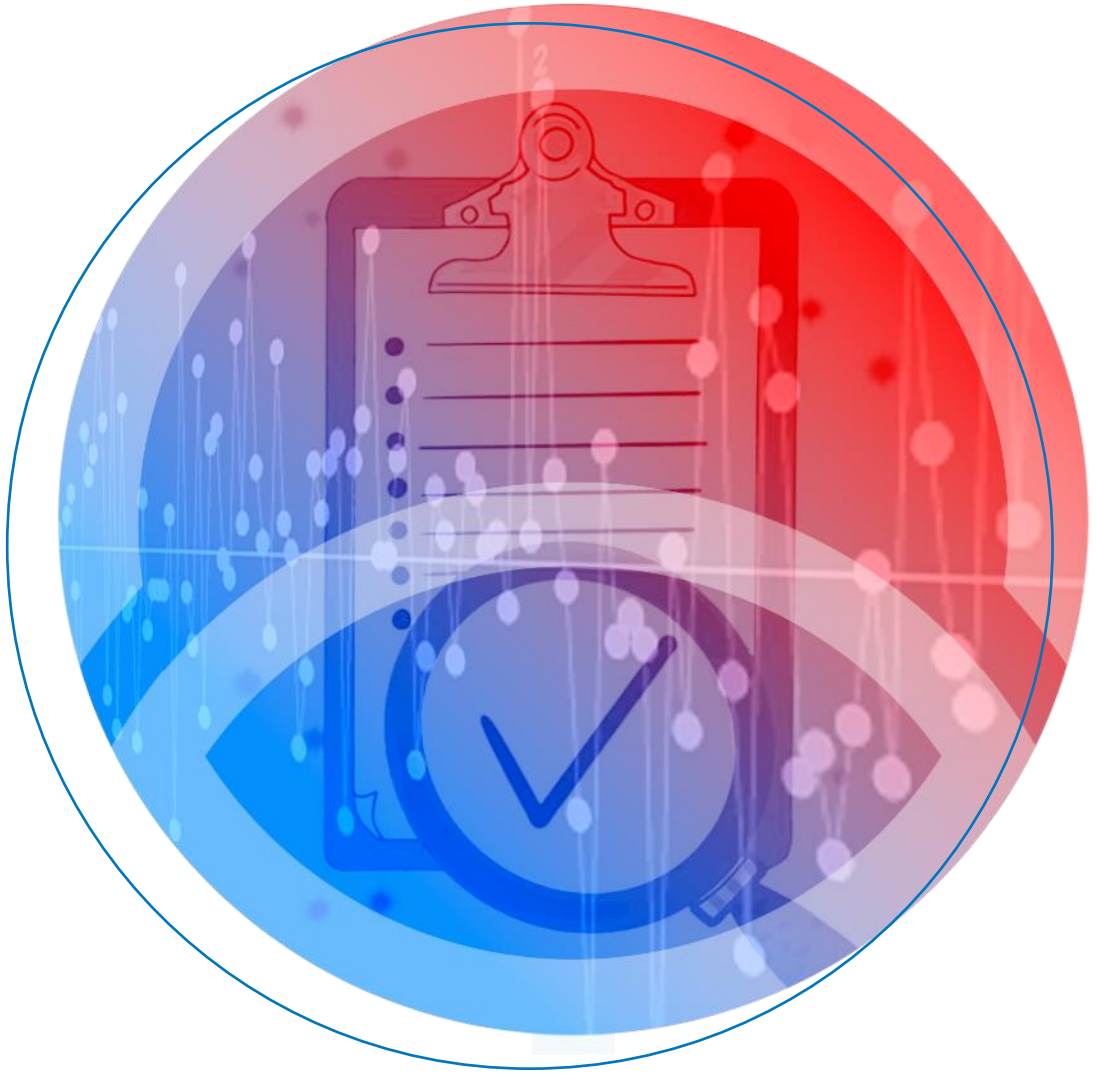
Patient test results that reflect a potentially life-threatening situation or may result in an extremely negative patient outcome

Immediate protocol must be followed according to laboratory policy/procedure and specific accreditation agency requirements

- Read-Back of Critical Values/Critical Results example: A glucose of <40 or >700
- All actions must be documented appropriately



Corrected Reports



Erroneous reports must be corrected, and copies posted/sent to the ordering provider with comments/disclaimer regarding errors

Original copies must be retained for follow-up or legal requests

Poll #1

What is your lab's top 3 challenges with compliance?

a. Time

b. Manpower

c. Training

d. Interpretation of requirements

e. Staff turnover

Record Retention

All records must be retained based on specific time requirements provided by:

- CLIA
- State
- Accreditation Agencies (if appropriate)

Clinical Laboratory Improvement Amendments

Instrument Validation

Validation procedures are performed to:

- Substantiate instrument manufacturer performance claims
- Compare existing to new methodology
- Examine performance under laboratory conditions

Manufacturers and CLIA often establish requirements that need to be followed for new instrument validations. Requirements include:

- Accuracy
- Precision (within run and day to day)
- Linearity
- Correlation (instrument to instrument)
- Normal Range

Validation Studies should be retained for a minimum of 2 years following retirement of the test method

Point of Care vs. Core Lab Testing

- POC testing is performed outside the core laboratory at that POC site

- Testing performed in the core laboratory is not considered POC even while utilizing the same kit/test/method

- Misconceptions and misinterpretations of POC testing may result in citations or deficiencies

POC vs. Core Lab Testing Examples – Common Mistakes

All POC testing is Waived – true or false?

False-all POC testing is not waived. Waived testing is based on CLIA classifications, not where it is performed

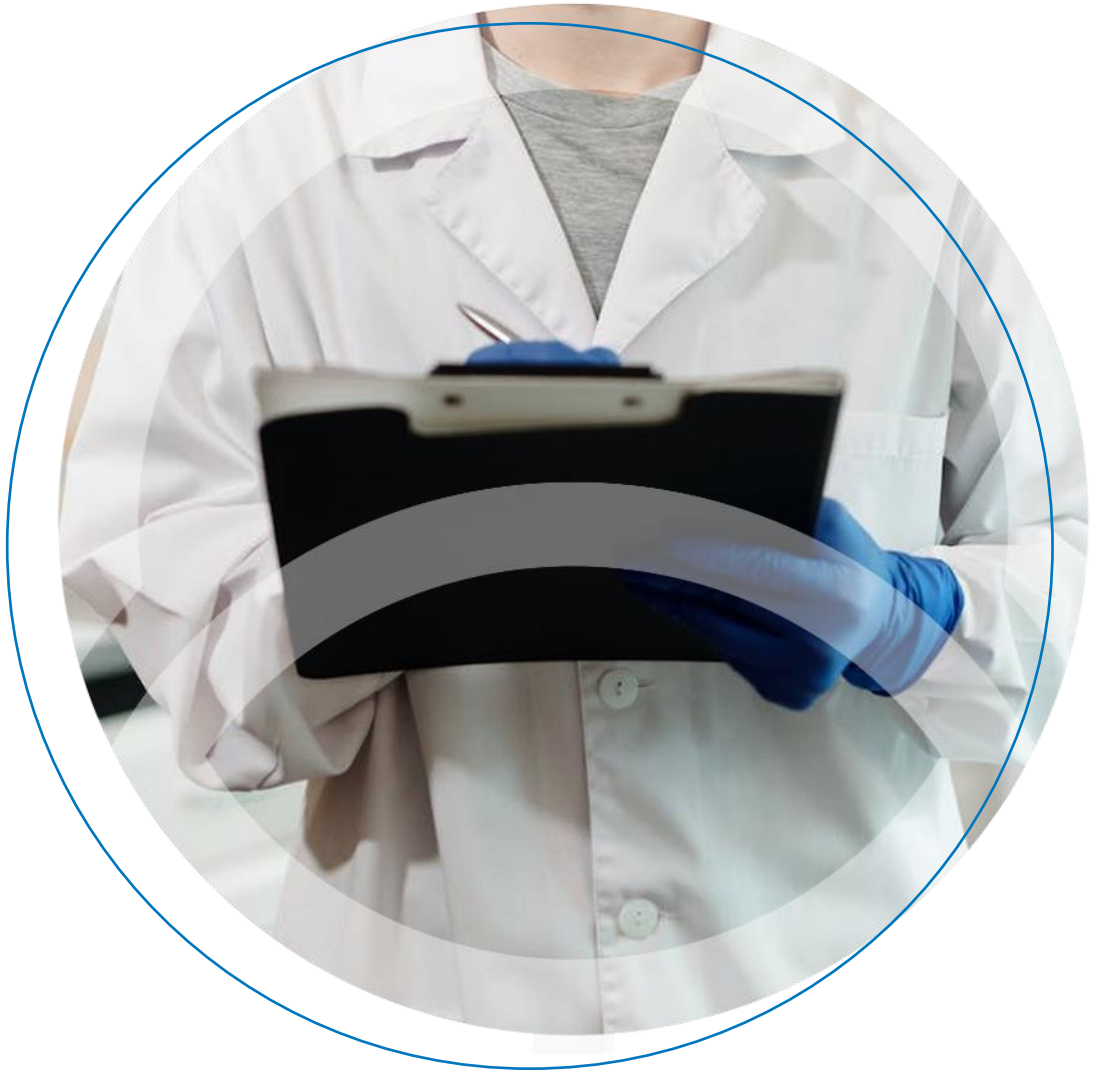
Instrument/test method complexity

Must be equal to or less than the what the CLIA certificate allows

Moderate complexity testing must meet all requirements

Including: QC, PT, competency assessment, split sample testing, calibration verification and any other requirements that apply

Most Common Laboratory Citations



- Successful participation in a CMS approved Proficiency Testing program for all available specialties and subspecialties (23% cited)
- Personnel competency assessment plan is in place and followed (19% cited)
- Lab Director meets the qualification requirements and provides overall management and direction of lab
- Test systems verified for accuracy twice a year
- Defined storage criteria for reagents, kits, and specimens consistent with manufacturer's instructions

Poll #2

In your opinion, what is the main reason labs are reluctant to move from waived to non-waived?

a. Time

b. Experience

c. Compliance

d. Cost

e. Other

Previous Topics Revisited – We listened to your feedback!

- Personnel
- Competency Assessment
- Proficiency Testing
- Documentation

Personnel

All personnel must be qualified by CLIA, state and accreditation requirements
Laboratory Director – must be qualified by CLIA before CLIA certificate is issued
Change in laboratory director must be filed with local CLIA office.
Not doing so will result in a citation.

Laboratory Director Responsibilities:

- Fulfill all required responsibilities or delegate certain requirements to the Technical Consultant* overseeing the laboratory. Delegation of requirements must be documented.
- Complete or refer personnel evaluations or refer to another qualified individual
- Training completed and documented per requirements
- Must approve all changes in instrumentation/test methods
- Review and approve validation studies
- All personnel qualifications need to be documented, retained and easily retrieved

Noteworthy: *Technical consultant for moderate complexity labs and technical supervisor for high complexity labs must meet qualifications. Frequently the focus of deficiency.

*CMS reference: brochure7.pdf (cms.gov)

Personnel Competency Assessment

Assessment requirements vary based on licensure status

Assessments must be performed by qualified personnel as required by CLIA and accreditation agencies

Waived labs

Assessment requirements

- For each instrument/test method
- At initial training, before performing patient testing

Establish procedures and processes that:

Non-waived laboratories (Assessment requirements)

- Diploma or transcript documenting completion of education qualification levels must be retained for each staff member
- For each test instrument/test method
- If test methods are added post initial training, it is acceptable to reassess competency for those methods, retrain and document as part of the 6 or 12-month assessment
- At initial training, before performing patient testing
- 6 months post initial training
- 12 months post initial training, then annually
- Annual assessment is not intended to be performed in its entirety at 12 months, this is an on-going process

Personnel Competency Assessment (Continued)

CLIA Test Method Requirements Must be Included in Assessments

Clinical Laboratory Improvement Amendments

- Direct observation of routine patient test performance, patient preparation (if applicable), specimen handling, processing and testing
- Monitoring the recording and reporting of test results
- Review of intermediate test results, worksheets, QC records, proficiency test results and preventive maintenance records
- Direct observation of instrument performance or maintenance checks
- Assessment of test performance- testing previously analyzed specimens, internal blind testing results, preventative maintenance checks
- Assessment of problem-solving skills

Proficiency Testing

- Must be enrolled with a CLIA approved Proficiency provider

- Enroll in all available specialties and subspecialties of testing performed

- Test all PT samples in same manner as patient testing

- Rotate PT sample testing through all testing personnel

- Complete corrective action and explanation for any unscored/ungraded or scores less than 100%

- Not required for waived testing by CLIA but may be required by accreditation agency or state health department

Documentation

CLIA recommends electronic vs paper documentation

Clinical Laboratory Improvement Amendments

We love our paper systems, why?

- We are used to paper – comfortable
- Don't want to recreate documentation system
- Like saving old documentation – "just in case we need it"

Electronic documentation benefits

- Easy to access on-site or remotely
- Save time and money
- Reduce mistakes – easy to make changes, save and retrieve
- Accuracy of information
- Current information instead of outdated records
- Audits/inspections made much more efficient

Compliance Made Easy Wrap Up:

Meeting CLIA regulations and requirements

- Excellent laboratory testing protocols to ensure “best” result outcomes
- Hiring qualified personnel, providing training and retraining ,document and retain accurate records
- Testing plans – all phases of testing, pre-analytic, analytic and post analytic procedure and processes
- POC vs. Core Lab Testing – know the difference in testing licensure and requirements – CITATIONS ARE COMMON

Compliance Made Easy Wrap Up:

Quality processes and procedures – DO THE WORK!

- Instrument Validation
- Calibration and Calibration verification
- Monitor QC as per requirements –
  CLIA and your lab requirements, instrument manufacturer recommendations
- ICQP- not easy but important!
- Proficiency Testing – pass every time!
- Establish your laboratories reference and reportable ranges- use other sources as guidelines
- Critical Values – document, and report timely
- Record Retention – keep accurate records and retain as required

Electronic Documentation: Throw away the binders, make your lab much more efficient and be ready for surveys and inspections

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Thank You