Practical Strategies for Meeting POCT Regulations and Passing Inspections

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Definition Of Patient Safety

Patient Safety is freedom from
unintentional or preventable harm due to
avoidable adverse events (medical errors)
that directly impact the quality of patient care and potentially impact patient safety

Patient Safety

Quality Lab Test Results and Patient Safety Go Together

Quality Results Require Planning "QUALITY" Throughout

- Correct test ordered
- Correct patient
- Correct time for specimen collection
- Correct specimen and processing

Pre-analytical

- Correct test result generated

Analytical

- Correct test result reported
- Correct clinical interpretation
  - leading to the correct and timely clinical response

Post-analytical

When "wrong" replaces "correct"
Quality is compromised

Be Prepared - Get "your" Act Together

- Check out inspection information for your agency
  - CAP – frequently asked questions about unannounced inspections
    - One-Hour Security Notice
    - Unannounced Inspections
  - Joint Commission Accreditation Process
    - Laboratory Accreditation Overview Guide (http://www.jointcommission.org/assets/1/18/2011_SAG.pdf)
  - COLA – www.COLA.org
  - AOA – HFAP (Healthcare Facilities Accreditation Program) www.hfap.org/
  - CLIA - www.cms.hhs.gov/CLIA/

Be Prepared – Arrival Plan in Place

- Once notified that you are being inspected
  - Follow an organizational policy
    - Who notifies whom?
      - ✓ Contact ALL that need to know
    - Assigned duties for making necessary adjustments
      - ✓ Cancel meetings
      - ✓ Adjust staffing
      - ✓ Obtain rooms
      - ✓ Order food
      - ✓ Clear space, have coat rack,
      - ✓ Handle any HIPAA concerns with inspectors
      - ✓ Etc., etc., etc.

Be Prepared – Documentation Ready

- Have documentation ready (up to date) and accessible (inspection NOT dependant on managers)
  - Organization chart
  - Goals of laboratory
  - Scope of service
  - General test site information
  - Answers to each checklist/survey item
    - Annotated checklist/survey items
      - ✓ Include supporting data or where it can be found

Be Prepared - Documentation Ready

- QA Plans, monitors, method comparisons, accuracy assessments
- Essential personnel records - training, competency
- Procedure manuals
- Policies and procedures for the 3 phases of testing
- QC Plan, QC results and evaluation, and documentation
- Proficiency testing – enrollment, performance, review

Be Prepared - Documentation Ready

- Reagent, QC, calibrators; storage; refrigerator temperatures
- Patient test results -- critical values, documentation, reference ranges, audit trail to link everything together
- Safety issues – biological, fire, electrical, disaster plan
- Instrument maintenance
- Instrument performance evaluation – accuracy, precision, reportable range, reference range

Be Prepared

- Have route mapped out for inspector
  - Don’t just let inspectors roam
- Make sure staff can respond to inspector correctly
  - Safety goals
  - Critical calls
  - QC, QA, PT
  - Disaster plan
  - Location of safety equipment
  - Etc., etc., etc.
- Make sure staff adheres to all safety protocols

Be Prepared – Look Good

- Have all manuals, records and files ready, orderly, and accessible (or quickly retrievable)
- Maintain a clean and uncluttered environment
  - No messy storage areas
- Be mindful of hallway and bathroom conversation
- Adhere to “clean” area requirements (lab coats, gloves)

Be Prepared – Look Good (cont)

- Keep food/drink out of lab/test site refrigerators
  - Have "no flammables" and "no food" signs on door
- Keep food/drink away from lab entry ways
- Understand hazardous chemical labeling and what to do in case of accident
- Verify labels on controls, reagents, bottles, kits
  - Check expiration dates

Be Prepared – Know Your Inspectors' Approach

CAP's Approach

- READ – OBSERVE – ASK
  - READ to review records and documents
  - OBSERVE to verify practices with policy/procedure; ensure that problems have been identified and resolved
  - ASK questions for clarification
- Follow specimens throughout entire testing process
  - check pre-analytic, analytic and post analytic processes
- Verify that PT problems have been resolved
  - Correlate PT problems to QC or maintenance records
- Review correction of previous deficiencies and ensure that they have been appropriately addressed

Be Prepared – Know Your Inspectors' Approach

- JC Surveyors' Tracer Methodology Approach
  - Follows or "traces" a number of patients, residents or clients through the organization's entire care process
    - "Tracers" assess an organization's compliance with selected standards and its systems to provide care and services
  - In essence, tracers "get at" all necessary policies and procedures that impact test results
    - Pre-analytical, analytical and post-analytical

Testing Requirements Depend on Complexity of Test Method

- POCT typically uses:
  - Waived methods
  - Moderately complex, (nonwaived) methods

WAIVED TESTS

Waived Testing: CLIA, COLA, AOA

- Only requirement

  follow manufacturers' directions

- CLIA (CMS), COLA and AOA

  do NOT inspect POCT sites performing waived testing only

TJC Waived Testing Standards (2011)

- WT .01.01.01 - Policies and procedures for waived tests are established, current, approved, and readily available and address:
  - Clinical usage and limitations of test methodology
  - Need for confirmatory testing and result follow-up recommendations
  - Specimen type, collection, and identification, and required labeling
  - Specimen preservation, if applicable
  - Instrument maintenance and function checks
  - Storage conditions for test components
  - Reagent use, including not using a reagent after its expiration date

TJC Waived Testing Standards (2011)

- (cont.):
  - QC (including frequency and type) and corrective action when QC is unacceptable
  - Test performance
  - Result reporting, including not reporting individual patient results unless QC is acceptable
  - Equipment performance evaluation

TJC Waived Testing Standards (2011)

- WT .02.01.01 - Director named on CLIA certificate identifies staff responsible for performing/supervising WT
  - Note 1: Responsible staff may be employees of the organization, contracted staff, or employees of a contracted service
  - Note 2: Responsible staff may be identified within job descriptions or by listing job titles or individual names

TJC Waived Testing Standards (2011)

- WT.03.01.01 - Staff and licensed independent practitioners performing WT are competent using 2 of the following per person per test
  - Performance of a test on a blind specimen
  - Periodic observation of routine work by the supervisor or qualified designee
  - Monitoring of each user's quality control performance
  - Use of a written test specific to the test assessed
- WT.04.01.01 - The [organization] performs QC checks for WT on each procedure
- WT.05.01.01 - The [organization] maintains records for WT

TJC Waived Testing Standards (2011)

What is NOT required?

- Method performance specification verification prior to use
  - Unless specified by organization
- Proficiency testing/accuracy assessment
- Test result correlations with other methods/instruments/sites
- Calibration verification
- Evaluation of manufacturers' approach to built-in QC

TJC - Waived Testing (2011)

What is required?

Inspection

Changes just arrived!

New CAP Checklists -- July 2011

CAP -- Waived Testing (7/11)

- POC.03500 - .03800 - Written QM program, organizational chart, system for reviewing unusual results, troubleshooting, following test manufacturer's instructions
  - All QM requirements in Lab GEN Checklist apply
- POC.01650 - .03432 – PT participation
- POC.03900 -.04270 – PM requirements
- POC.04300 – Specimen handling
  - Documented procedure for patient ID, preparation, collection and labeling, accession and preservation, if appropriate

CAP -- Waived Testing (7/11)

- POC.04400 -.04500 – Patient result handling; reference intervals
- POC.04750 – Reagent handling/storage/verif
  - Follow manufacturers' directions
  - Remaining items in this section do NOT apply
- POC.06300 -.06450 – Instruments and equipment
  - Approval, function checks, maintenance evaluation
- POC.06600-.06900 - Personnel
  - Qualifications, training, authorization, initial training, competency assessment

CAP -- Waived Testing (7/11)

- POC.07037 - QC results are documented for quantitative and qualitative tests
  - QC performed according to manufacturer's instructions
  - Testing personnel or supervisory staff must review QC data; lab director or designee at least monthly
  - Acceptable internal QC must be documented at least once/day
    - Exception – unacceptable instrument control automatically locks the instrument and locks the instrument and prevents release of patient results

CAP -- Waived Testing (7/11)

- POC. 07124 Is there evidence of corrective action when control results exceed defined tolerance limits?
- POC. 07211 Are results of QC verified for acceptability before reporting results?

CAP -- Waived Testing (7/11) What is Missing?

- Test method validation
- Reagents
  - Follow manufacturer instructions handling/storing
- Calibration of Quantitative Systems
  - Follow manufacturer instructions for calibration, calibration verification, and related functions
- Twice annual inter-instrument comparisons
- AMR validation or calibration verification
- Lot-to-lot reagent checks except if manufacturer requires
- Current and future CMS EQC requirements

CAP - (7/11): What is NOT Missing

- Proficiency testing participation, when available
- Procedure manual for each test
- Initial training / ongoing competency assessment conducted
- Patient results reported with reference ranges
- Policies and procedures for:
  - Specimen handling
  - Quality management
  - Safety

NON-WAIVED TESTS

Moderate Complexity Testing

General requirements for
CLIA, TJC, CAP, COLA and AOA

General Requirements for POCT

- Follow manufacturers' protocols
  - Have procedure manual (current)
- Verify method performance specification claims before routine use
  - Accuracy, precision, reportable, reference range (approve)
- Evaluate manufacturers' approach to QC before routine implementation of EQC
- Have policies and procedures for
  - Pre-analytical, analytical and post-analytical phases of testing

General Requirements for POCT

- Include patient and operator identification with results
- Participate in proficiency testing when applicable
- Participate in ongoing quality assessment/quality improvement activities
- Monitor instrument functions
- Report results with appropriate reference ranges
- Have trained/competent testing personnel

General Requirements - Competency Assessment must include:

1. Direct observations of routine patient test performance, including, as applicable, patient ID and preparation; and specimen collection, handling, processing and testing.

2. Monitoring recording and reporting of test results, including, as applicable, reporting critical results.

3. Review of intermediate test results or worksheets, QC records, PT results and preventive maintenance records.

General Requirements - Competency Assessment must include:

4. Direct observation of performance of instrument maintenance and function checks.

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples.

6. Evaluation of problem-solving skills.

Procedure Manual

- Follow manufacturer's directions; use supplied templates
  - Keep current -- Continually update as manufacturer revises directions
  - Include all relevant information, e.g., patient preparation, sample handling, quality control, corrective actions, data reporting, etc.
- Have director sign and date (for approval)
  - All inspecting agencies require a dated signature for initial approval and with changes
  - TJC and CAP require yearly approval by director or designee

General Verification of Performance Specification Claims

- Demonstrate attainment of specifications "comparable" to those of the manufacturer
  - Accuracy, precision, reportable range of results
  - Approve appropriate reference ranges, e.g., manufacturer's (approve does not mean derive)
- Verification is a one time activity
  - Required for ALL moderately complex test methods
  - Records are kept for life of methods plus 2-years

Verification of Performance Specification Claims

- Manufacturer "assists" in process through:
  - Protocols
  - Necessary verification (e.g., liquid controls) materials
  - Data plots, graphs, interpretation, documentation, etc.
- Director must approve data and sign and date
  - Good to include statement, e.g., "method meets the needs of site's clientele and is ready to be implemented for routine use"

EQC – Concept according to CMS

CLIA QC – liquid, external QC material

All other QC approaches –

From electronic to sophisticated internal quality checks

Must be qualified under 1 of 3 EQC Options

CLIA's 3 Options for EQC Evaluation (Also for COLA and AOA)

	Option #1	Option #2	Option #3
Manufacturers' QC approach	ALL of analytical process	PORTION	NONE
Manufacturer's & External QC Evaluation	10 days	30 days	60 days
External QC analysis once EQC is routine	1/month	1/week	1/week

Specific Evaluation of Manufacturer's "Built-in" QC

Depends on accreditation/inspecting agency

TJC & EQC Requirements

Joint Commission Requirement	Non-waived QSA.02.04.01	
Internal EQC minimums	ABGs: 2 levels daily with one q8 hours All others: 2 levels once daily	
Initial evaluation of internal monitoring system to determine Option	**Option 1** Monitors entire analytical process	**Option 2** Monitors portion of analytical process
Initial parallel validation of EQC vs. external QC	10 consecutive testing days	30 consecutive testing days
Ongoing external QC - Frequency	Once per calendar month & per lot and shipment	Once per calendar week & per lot and shipment
Ongoing external QC - Levels	ABGs: 3 levels (per QSA.06.02.01) All others: 2 levels	

EQC Evaluation and CAP (7/11)

POC.07300 – Daily controls may be limited to electronic/procedural/built-in controls for tests meeting the following:

EQC Evaluation and CAP (7/11)

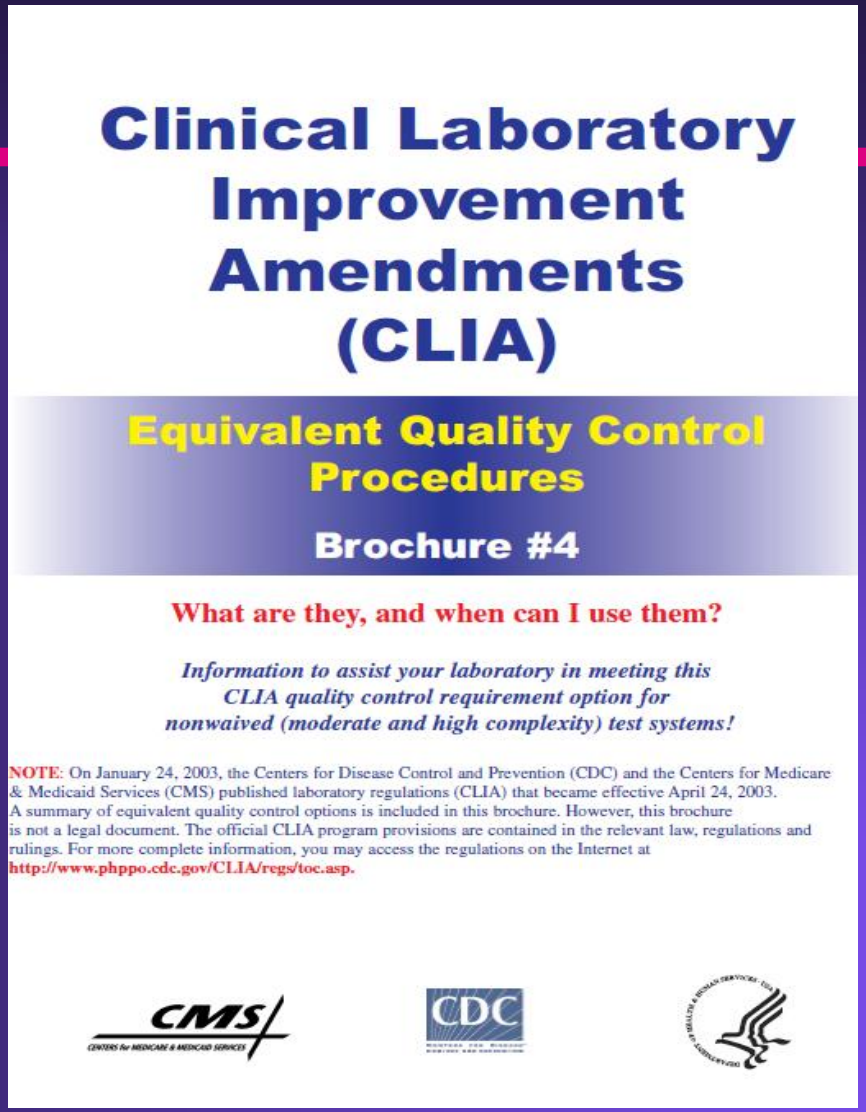
- Validation must include comparison of external and manufacturer's approach for a least 20 consecutive days
  - For multiple identical devices, the 20 day minimum applies to the initial device; the director is responsible for determining the sample size for the other devices (begins 1/31/12)
  - The director is responsible for determining criteria for acceptability and other details of the validation
  - External controls are run:
    - For each new lot number or shipment of materials
    - After major maintenance and software upgrades
    - At the manufacturer's recommended frequency or every 30 days (>frequency)

EQC Evaluation Data Collection (*collect data for <u>every</u> analyte tested)*

Days (date)	External QC acceptable range (XXX – XXX)	External QC acceptable range (XXX – XXX)	Manufacturer's EQC		Manufacturer's EQC		Anal. Initials
			Pass	Fail	Pass	Fail	
1							
2							
3							
4							
5							
6							
Etc.							

Evaluation of Manufacturer's Alternate (EQC) Approach to QC

- Demonstrates that manufacturer's approach adequately monitors method performance
  - Data collected as part of verification of method performance specification claims, if feasible
  - Document results
  - Director reviews and, if appropriate, approves acceptability of approach for daily monitoring of method
    - Director's signature, date and attests approval
    - Keep records for life of method plus 2-years
  - Usually one time activity for particular device
    - See specifics for each accrediting agency and CMS' Brochure on EQC



*http://www.cms.gov/CLIA/downloads/6066bk.pdf

Proficiency Testing (PT)

- External evaluation of quality (accuracy)
  - CLIA, TJC, COLA and AOA
    - Mandated for CLIA regulated analytes only
    - Occurs 3 times / year
  - CAP wants all analytes in PT, if available
  - POCT participation depends on CLIA certificate arrangement
- For analytes not in PT, must demonstrate accuracy twice each year
- Always play by the PT rules

Quality Assessment / CQI

- On an on-going basis:
  - Look at what you do as stated in policies and procedures
  - Fix problems
  - Improve processes
  - Document what was done

Self-Inspection -- Discovery….

Find and FIX Problems BEFORE Inspection

Successful Strategy; More Tips!

Meet the inspector with confidence and class!

Audit Trail – Be Ready to Recreate

Make sure all processes/information can be recreated to assure RIGHT:

Order
Patient
Timing of collection
Specimen and Specimen handling
Result
Timely reporting of result
Documentation of result

Fail-Safe Tips

- Things that should never occur
  - Dirty laboratory/testing area
  - Unsafe practices
  - Uncorrected old citations
    - Always have a plan!
  - Messy storage areas
  - Staff who are not in the loop regarding policies/procedures/inspection process

Fail-Safe Tips

- With inspectors:
  - Be courteous, cordial and professional
  - Be honest; display a positive attitude
  - Just answer the question; be to the point
    - Ask for clarification when uncertain; ask for suggestions
    - Don't volunteer "extra" information
      - But don't get "dingy"
  - Have everyone ready to explain the why and how
  - Don't argue; resolve if possible, otherwise explain in writing later
  - Always use safe practices
  - Always follow practices and protocols

Inspection - DO / DON'T List

- Don't delegate inspection duties to an unprepared staff member
  - Unknowledgeable staff communicating with the inspector is disaster
- Do have an alternative plan if the assigned staff member (to be with inspector) becomes unavailable
  - All staff must be prepared; inspectors will talk to most
- Do present an organized front
  - Quality NOT associated with mismanagement, hostilities, "in-fighting," disorganization
- Do understand the proper utilization of a plan of correction
  - State your case in the written plan of correction

Be Prepared – Be Aware

Review frequently cited standards for your regulator/accrediting agency

Frequent Problems with POCT*

- Lack of required competency documentation
- Lack of required quality control (QC) performance
- Failure to recognize out-of-range QC values
- Improper or lack of required records for instrument maintenance, validations (if necessary)
- Lack of appropriate personal protective equipment
- Lack of awareness that sites must have appropriate CLIA certificates for the type of testing performed

* - Peggy Mann, MS, MT(ASCP), Avoiding POCT Deficiencies, PointofCare.net

On-going POC Testing Problems*

- Following manufacturer's instructions
- Documenting patient and operator ID
- Testing conducted by authorized operators
- Using outdated/expired reagents
- Performing and responding to QC data
  - Failure to perform QC
  - Failure to review QC
  - Failure to respond to out-of-control situations
- Documenting patient results in patient record

*Plebani M. www.bloodgas.org Jan 2009; Goldsmith B. *Clin Chem News* 2001; 3:6-8

After the Inspection

- Final decision usually up to regulator's oversight function, e.g., its board
- Review all citations
- Perform follow up per regulator's guidelines
  - Prepare plan of correction
  - Implement needed corrections
  - Provide evidence to regulator per guidelines
- Keep inspection ready
  - Goal of unannounced inspections

Sources of Information

- TJC - http://www.jointcommission.org
- CAP - http://www.cap.org
- CLIA - http://www.cms.hhs.gov/CLIA/
- COLA - http://cola.org
- HFAP (AOA) - http://hfap.org