THE *NEW* POOR LAB'S GUIDE TO THE REGULATIONS (CLIA, The Joint Commission, CAP & COLA)

2023 - 2024

Successful Strategies & Specific Applications of the Regulations

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Library of Congress Control Number: 2023937364

ISBN-13 978-1-886958-37-1
Published by Westgard QC, Inc.
7614 Gray Fox Trail
Madison, WI 53717

Phone 608-833-4718

But wait, there's more...

This book cannot contain all the information that is useful for compliance. For additional resources, please visit **http://www.westgard.com/poor-lab-extras.htm** for instructions on how to access a special online section related to this book.

This special section is available only to those who have purchased the book. Those individuals will have access to:

- downloadable forms – copies of the forms and worksheets presented here for your use and re-use
- updates on new developments in compliance and regulations
- additional articles, lessons, and advice on compliance, quality, and regulatory topics

Foreword by Delia Gates, MT(ASCP)

I had the opportunity to meet Dr. Sharon Ehrmeyer in May of 2010 when she was a speaker at a 3-day "Westgard Workshop" on Quality Control practices and planning in Madison, Wisconsin. Her presentations featured QC in the real world and expert advice on accreditation requirements. When her 2012 edition of the "New" *Poor Lab's Guide* was published, I found it to be a clear and useful companion to navigating government regulations. Thus began my collection of successive editions whose pages have been reread, highlighted and flagged with sticky notes.

My career in clinical laboratory science began a decade prior to CLIA '88, at the teaching hospital where I had attended MT school, moonlighting in POLs on the side. Life's path led to small hospitals as a generalist, to a state hospital in RIA and toxicology, to a primate center in virology research as HIV study was emerging. Eventually I turned to diagnostic manufacturers of chemistry and immunochemistry for the technical applications and customer support experience.

Currently I enjoy my role as field specialist and trainer for a clinical chemistry manufacturer whose clientele are veterinary hospitals, research and pharmaceutical companies, MLT educational settings, plus CLIA labs in the smaller hospital, urgent care and physician office practices. The majority of customers I visit are POLs, who may have no prior lab experience and are most in need of guidance.

It is exciting to serve as a resource for my customers and colleagues, where the *Poor Lab's Guide*, over the years, has been a primary reference. Even if you're a laboratorian with more than a few inspections and PT events under your belt, there is something you haven't encountered in the notes, excerpts from the Interpretive Guidelines, Do's and Don'ts, FAQs, sample forms and inspection survival tips. It delights me to recommend the *"New" Poor Lab's Guide to the Regulations*. I offer this advice, if I may: Don't "do lab" without it!

Delia Gates, MT(ASCP)

Account Manager, Alfa Wassermann Diagnostic Technologies

Foreword by Diane Davis, MT(ASCP)SH

As a young technologist and newly minted supervisor, I struggled to find a concise guide to the many rules, regulations, and procedures I needed to know in order to run my lab according to "best practices." In my experience, the standards published by various regulatory bodies were opaque, conclusory, and difficult to navigate; moreover, these materials offered little in the way of *practical* guidance for end users. I quickly learned that seemingly simple questions (e.g., "How closely should between-analyzer correlations match?" and, "Is it okay to use quality controls to determine accuracy of a new method?") often had surprisingly complex answers. I acquired these answers over the years by exchanging anecdotes with peers, soliciting advice from mentors, and reading a variety of books unearthed in the course of my own research, but it proved to be a slow and laborious process of accumulation that only intermittently yielded the critical knowledge that diligent practitioners should have at their disposal.

When I discovered *The Poor Lab's Guide* in 2012, it was nothing short of a revelation. At the time, I was working as a manager in a hospital laboratory, and the *Guide* was precisely the resource I had sought in vain at the beginning of my laboratory career. Here it was: one-stop shopping for all of the answers to those nagging and complicated questions that had once plagued me, and have since tormented so many others in our field. While packing up my home office to move to a new home, I recently rediscovered that very first copy, with all of the tabbed pages that I zealously marked for my important references. *The Poor Lab's Guide* has not lost any of its extraordinary utility over the years; as regulations have changed, the Guide has been updated to reflect the most recent directives. It truly is a "living document," and I have purchased a copy of each and every update without hesitation or regret.

In 2014, I became a manager and subsequently a director for an in-vitro diagnostic company, leading a team of Applications Specialists. My team and I routinely encounter customers who are supervisors and managers in hospital laboratories who have all of the same questions that I did as a new supervisor, and who have similarly struggled to find a succinct, definitive reference guide for regulatory compliance. As a vendor, we are not in a position to make decisions for laboratories, but we are frequently asked for advice. I have provided each of the Applications Specialists on my team with a copy of the *Guide*, which has proven itself to be an invaluable resource that enables us to competently and confidently provide our customers with up-to-date guidance, regardless of the regulatory organization that accredits a particular laboratory.

I continue to provide *The Poor Lab's Guide* for my team, and recommend that all laboratorians consider this a "must-have" resource. For me, there will always be a copy at my desk.

Diane Davis MT(ASCP)SH

Director, Clinical Applications, Werfen

Preface

In the early 1990's, Dr. Ron Laessig and I often found ourselves teaching courses or giving lectures on the newly emerging federal regulations. They were based on the 1988 federal law, the "Clinical Laboratory Improvement Amendments of 1988" (CLIA'88 or CLIA) for short.

In 2003 CLIA was revised and in 2004, CMS published Appendix C of the State Operations Manual, *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services*, which "interprets" the CLIA'03 regulations for both inspectors and laboratories. And, the CMS-deemed accreditation agencies continually "tweaked" their requirements along the way. This *Poor Man's Guide* is up to date with CLIA regulations along with the latest requirements for CAP, The Joint Commission and COLA.

Various organizations asked us to repeat the presentations because of the significant implications for laboratories and the complexity of the regulations. We initially arranged our lecture notes in a series of booklets that were later pulled together into a single volume for our AACC, ASCP, etc., workshops. Now the information is continuously updated.

One objective in compiling these materials was to give the reader an easy to understand, practical means of addressing the complexities of the CLIA regulations as well as the testing requirements from the CMS-deemed accreditation agencies. In the process, the Guide tries to provide practical solutions to the problems facing laboratories such as:

- How to extend reportable range beyond the highest calibrator the "Poor Lab's Way"?
- How "good" is "good enough" – QC tolerances, QC rules and empowerment?
- What's going on with POCT – is everyone getting into the act?
- What about electronic and process controls and the "equivalent" QC options?
- What is Risk Analysis and how will it eventually replace "equivalent" QC?
- Where does QC and quality assurance fit into the new term – Quality Assessment?
- How should the mandated proficiency testing requirements and on-going accuracy assessments be met?

For the record, Dr. Ronald Laessig conceived of the idea for what is now "THE NEW POOR LAB'S GUIDE TO THE REGULATIONS: CLIA, The Joint Commission, CAP & COLA." The name came out of the concept of extending the calibration beyond the highest calibrator using a patient specimen with an appropriately elevated result. Since the technique did not cost much (it's actually free), this approach led to the working title of "Poor Man's Guide." I insisted on making the document politically correct and added "Person's" to the title. For the sake of simplicity, we changed from the NEW POOR MAN'S (PERSON'S) GUIDE to the more concise (and neutral) POOR LAB'S GUIDE.

The earlier editions included the disclaimer that no federal, state or professional inspector, company or professional organization necessarily agreed with what we said or endorsed our approach. It still holds! However, it should be noted that on more than one occasion inspectors have suggested, during the inspections, this Guide as a practical way to understanding the myriad of complexities associated with implementing the regulations.

Finally, special thanks go to a friend, mentor and colleague, Dr. Laessig who died unexpectedly, but peacefully, in his sleep on March 29, 2009. Ron enriched my life immensely and, like me, those he touched miss him tremendously.

Sharon Ehrmeyer, PhD

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What's new in the 2023 Edition

The biggest change in CLIA regulation history was announced on July 11, 2022 and is scheduled to kick in on July 11, 2024: the Accepability Limits (AL) of current proficiency testing analytes directly regulated by CLIA is shrinking by up to 41% for some analytes. The list of directly regulated analytes has expanded significantly for the first time in CLIA's history. Significant impact to PT, QC, and Method Validation are expected to occur because of those changes. The "end" of the public health emergency means changes to how the global pandemic is being fought, even as Emergency Use Authorization (EUA) continues, raising the question of what methods are still acceptable and what are no longer allowed. Of course, all updates from the accreditation organizations, from The Joint Commission (TJC), to the College of American Pathologists (CAP), and COLA are described and discussed in detail. All this and more is covered in the 2023-2024 edition of the *Poor Lab's Guide*.

Forms, Worksheets and Other Important Resources

Tribute to Ron Laessig

Ron Laessig was Emeritus Director of the Wisconsin State Laboratory of Hygiene and Emeritus Professor of Population Health Sciences (and he liked to say "sometimes clinical chemist") at the University of Wisconsin Medical School. He retired after over 40 years of service to the University and the State of Wisconsin.

The best description of Ron is a "quality builder." And there were many dimensions to his building, from furniture to his home, from clinical chemist to Director of a large testing service, from proficiency testing to total quality management, from in-service training to statewide training seminars, from classroom instruction to national workshops, from committee member to President of NCCLS (now CLSI), from staff building to a new laboratory building that represents the state-of-the-art in environmental and toxicology testing in the US today.

I met Ron in graduate school where we shared a research laboratory. Two memories stand out – coffee that would make your hair stand on end and a work schedule that began at 6:00 am and went until at least 12 midnight, 6 days a week. Having come from ND and grown up working on a farm, I always believed that I had a strong work ethic and could outwork almost everyone. But not Ron! I don't think anyone had the dedication and commitment that he showed as a graduate student and throughout his career. And his accomplishments reflect that willingness to work hard at everything he did!

Our careers started out in a parallel fashion, beginning as clinical chemists in different labs of the University of Wisconsin, but we diverged as Ron acquired more and more management and leadership responsibilities at the State Lab and nationally, while I became more specialized in Quality Control. Yet things also converged at certain periods in time, such as when Ron mentored Sharon Ehrmeyer in her graduate program on External Quality Control, or Proficiency Testing, which paralleled some of my own studies in Internal Quality Control. Ron and Sharon maintained an ongoing collaboration and were spurred on by the laboratory regulatory environment. They co-authored this "Poor Man's Guide" which explained the regulations in a down-to-earth manner to help laboratories adapt to the "CLIA rules." With the advent of the Final CLIA rule in 2003, our interests again converged in opposition to CMS's proposed "equivalent QC" guidelines. And Ron enjoyed it when CMS admitted they "blew it," as Ron and Sharon discussed in an editorial in *Lab Medicine* in October 2005.

Ron always had fun in whatever he was doing! That was part of his formula for life. He liked to tell stories and I can testify that he was very good at it, since I was sometimes on the receiving end of those stories. My worst fear was to have him precede me on a program and have to adjust my presentation on the fly to respond to his statements, such as "…enjoy this because Jim is going to be as dry as cornflakes without milk" or "…Jim will tell you more about that" (and usually mentioned a topic I knew nothing about).

It is a distinct privilege to be able to continue Ron's work in the form of this Poor Lab's Guide. While we have now published five editions since his passing, Ron's spirit still guides this manual. And while I might not agree with everything he and Sharon recommend, I do not dispute the usefulness of having this easy-to-read guide to the labyrinth of regulations, standards, accreditation guidelines that face laboratories in the US.

James O. Westgard, PhD

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Chapter 1: Regulations – An Overview

REGULATIONS – AN OVERVIEW

Historical View of Laboratory Regulations

The first national requirements regulating laboratories were issued as the Clinical Laboratory Improvement Act of 1967. These were followed closely by the Medicare regulations. The individual states and the College of American Pathologists (CAP) provided the major inspection programs.

Beginning with Dr. Sunderman and his pathology colleagues in 1945, and thanks to the CAP's efforts soon thereafter, proficiency testing (PT) programs by states and professional organizations provided a means of documenting the quality of laboratory performance. The state and federal programs monitoring laboratories incorporated PT into the regulatory process. Today, PT is a cornerstone of CLIA – successful participation is a primary indicator of quality in laboratories performing moderate and highly complex tests. These two complexity levels are now combined in the **nonwaived** category.

The CLIA'67 and Medicare regulations covered only a small percentage of U.S. laboratories (basically large hospitals and reference laboratories). The Clinical Laboratory Improvement Amendments (CLIA), replaced these regulations. On February 28, 1992, the Health Care Financing Administration (HCFA) [now renamed the Centers for Medicare and Medicaid Services (CMS)], working with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), published the requirements covering all test sites needing to meet CLIA regulations. Since February 28, 1992, the government has made changes to the regulations published in a series of Federal Registers. The most up to date electronic edition of CLIA can be found at:

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

[An index for the updated CLIA waived regulations is shown in Section 1.1.]

CLIA is unique in that it requires *every* testing site examining *"materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease..."* to be regulated. In short, *all* clinical laboratories (testing sites) are subject to the CLIA regulations and testing must be conducted under the appropriate CLIA certificate.

As of March 2023, approximately 319,000 laboratories were registered under CLIA (this includes laboratories in exempt states). CLIA requires all laboratories to have a certificate that identifies the complexity of testing performed. (http//www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/statupda.pdf)

	# of Labs	# of POLs
Total labs registered	318,901	123,198
Total labs registered in non-exempt states	304,051	120,507
Moderate & high complexity (CMS inspected labs)	16,024	4,703
Accredited Labs (CAP, TJC, COLA, etc.)	17,277	10,273
Provider-Performed Microscopy (PPM)	26,769	20,275
Waived testing only	243,981	85,256

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Chapter 2: Proficiency Testing

Proficiency Testing for Nonwaived Testing

Proficiency Testing (PT), or External Quality Assessment (EQA), as the rest of the world knows the process, is a mechanism for evaluating laboratory performance. Beginning in the 1940's, the College of American Pathologists program showed that voluntary interlaboratory PT participation identified problems, directed improvement efforts, and steadily improved the quality of test results. Because of the benefits, CMS made PT a cornerstone of CLIA for accuracy assessment of more than 80 analytes, generally referred to as **regulated analytes**. All laboratories performing nonwaived test methods MUST at least participate in PT for these regulated analytes and follow the CLIA rules described below. This includes labs seeking accreditation from a CLIA-deemed accreditation organization. Testing performed under a Certificate of Waiver are exempt. Following ALL the rules is imperative! PT Failures continue to be one of the top 10 problems that labs experience.

On July 11, 2022, The Federal Register updated CLIA's proficiency testing criteria. This represents the BIGGEST change in regulations since 1992. These regulations officially take effect on July 11, 2024 and include:

- Addition/deletion of regulated analytes requiring PT participation;
- Changes (§§ 493.2 and 493.801 through 493.959) to acceptable performance limits and updates to the administrative processes for approved PT providers;
- Alignment to statute (42 U.S.C. 263a (i)(4)) on improper PT referral; and,
- PT requirement revisions for microbiology analytes.

While the changes won't be implemented for several months, we have included in Section 2.4, both the current regulated analytes and acceptable performance limits as well as the new analytes and their acceptable performance limits. **Note: Some of the new acceptable limits are significantly tighter, between 20 and 41% smaller, than the limits from 1992.**

Section 2.7 further discuss the July 2024 changes so your lab can be ready.

The Poor Lab's View of the Rules

1. **PT Participation:** All laboratories performing nonwaived testing (moderate and high complexity tests) must be enrolled in regulatory PT for each CLIA "regulated" analyte in each specialty/subspecialty of testing performed (see section 2.4). If you are new to PT, see Section 2.2 and 2.3 for an overview of PT issues and a summary of the PT process.

Note: Laboratories must participate in the same program(s) for three events (one year) before switching to another program. The PT program must be approved by CMS and laboratories must authorize the release of data to authorized agencies.

Splitting analytes over more than one PT program (i.e., CAP and the WSLH, Wisconsin State Lab of Hygiene) is acceptable. PT providers report grades to CMS

Section 2.4: CLIA's Proficiency Testing Criteria for Acceptable Performance

CLIA's PT acceptable performance criteria were defined in 1992 and are still used today. Changes are on the way (7/24). These can be found in the CLIA regulations under Subpart I – Proficiency Testing Programs for Nonwaived Testing: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-I

Note: With the current performance limits when two limits are given, e.g., glucose – target value ± 6 mg/dL or ± 10%, use the limit that provides the larger range of acceptable PT results

Note: You will see in the table below, CLIA PT immunohematology and microbiology requirements are not listed. The PT criteria for these two disciplines can be found at the above website.

Routine Chemistry

Test or Analyte	Current Limits	7/24 Limits
Alanine aminotransferase (ALT)	± 20%	**± 6 U/L or ± 15% (greater)**
Albumin	± 10%	**± 8%**
Alkaline phosphatase	± 30%	**± 20%**
Amylase	± 30%	**± 20%**
Aspartate aminotransferase (AST)	± 20%	**± 6 U/L or ± 15% (greater)**
Bilirubin, total	± 0.4 mg/dL or ± 20% (greater)	**± 0.4 mg/dL or ± 20% (greater)**
Blood gas PO_2	± 3 SD	**± 15 mmHg or ± 15% (greater)**
Blood gas PCO_2	± 5 mm Hg or ± 8% (greater)	**± 5 mm Hg or ± 8% (greater)**
Blood gas pH	± 0.04	**± 0.04**
B-natriuretic peptide (BNP)	--	**± 30%**
Pro B-natriuretic peptide (ProBNP)	--	**± 30%**
Calcium, total	± 1.0 mg/dL	**± 1.0 mg/dL**
Carbon Dioxide	--	**± 20%**
Chloride	± 5%	**± 5%**
Cholesterol, total	± 10%	**± 10%**
Cholesterol, HDL	± 30%	**± 6 mg/dL or ± 20% (greater)**

2.7: The Poor Lab's Advice on the Quality Implications of New PT Regulations

There's a curious phrase in the new regulations that invokes a bit of surrealism:

> *"Criteria for acceptable performance is [sic] meant for PT scoring only and not intended to be used to set acceptability criteria for a laboratory's verification or establishment of performance specifications."*

In other words, here are the new goals for proficiency testing: they are not acceptability criteria for verification or performance specifications for laboratories. That begs the question, what are they?

The goals that aren't goals?

We are sympathetic to the plight of the regulator. If the new goals are used as performance specifications, they will have a significant impact to laboratories and the marketplace. The newly tightened goals, if used to determine Sigma-metrics, or used to set individual performance specifications, or used to set performance goals for new instruments, will create new winners and losers in the diagnostic marketplace. Given the time we are in, regulators are understandably reluctant to be seen as interfering with the "free functioning" of the marketplace. Further, if these new goals are used as *individual* laboratory performance specifications, and if this causes many laboratories to reject methods, or declare more runs out-of-control, or even worse, fail PT more often, there will be fewer laboratories that can continue to run tests.

This plight is not unique to laboratory regulation. James Reason, the safety expert, has described what is called "The Regulator's Dilemma": regulators, as tough as they may pretend they are, ultimately are invested in the viability of the industry they regulate. Simply put, inspectors cannot completely shut down the industry that they inspect. If, because of much tighter goals, CMS/CLIA inspectors shut down a large number of laboratories, the disruption to healthcare could be catastrophic. Even if patients weren't denied care, mass lab closures would draw significant ire. Therefore, inspectors need regulations that are tight enough to eliminate a certain number of the "worst" laboratories, but they have to allow the vast majority of labs to stay in business.

Evidence of this approach can be seen in the discussion of how the new goals were determined. Simulations of new goals were generated using existing PT survey data, with an eye on the "miss rates":

> *"While narrowing limits may increase miss rates per challenge, we do not expect a high unsuccessful rate based on the data simulations provided by the PT programs. We expect the rates of unsatisfactory events would be low based on the simulation data, and that the rates of unsuccessful events (two consecutive or two out of three testing events being unsatisfactory) would be even lower; therefore, we believe it is reasonable to propose tighter limits given current analytic accuracy. We used all data available to us to minimize the negative consequences of the proposed changes (for example, too many unsuccessful performances) to acceptance limits, including simulations provided by PT programs."*

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Chapter 3. Procedure Manual

Procedure Manuals – An Overview

Concept: At least for every nonwaived test procedure performed by the laboratory or at point of care, there must be a written and available set of instructions. (Standard Operating Procedures or SOPs) describing how to perform the test. CLIA's term for this is "Procedure Manual (PM)." **Note:** Some accrediting agencies may require a PM for waived testing as well. Check with your accrediting agency.

From "A to Z" or "Alpha to Omega": Laboratories need a Procedure Manual (PM) for *all* laboratory operations and *all* testing performed in the laboratory. These can be organized in one or several PMs to best fit the situation. While the testing process begins with ordering the test, the Procedure Manual (PM) begins with patient preparation and sample acquisition, extends to sample processing and analysis, and concludes with reporting results and archiving results and specimen. These stages of testing are referred to as **pre-analytic** (exam), **analytic** (exam) and **post-analytic** (exam) processes in the PM.

ISO15189:2022, the worldwide standard for laboratory testing, clearly summarizes the intent of having a PM: to ensure the consistent application of laboratory activities and test result validity.

The basic principles of Procedure Manuals (all you ever wanted to know)

- Prepare one for every test and have it available for the staff. Electronic copies are acceptable.
- Follow the CLIA mandates (Page 50) for preparation.
- Use the 16 suggestions (pages 52 through 54) in the self-assessment checklist.
- Include the manufacturer directions (package inserts) as part of your lab's PM to the extent possible for the analytical phase of testing (about 90% of the PM); add your lab/organization-specific information (10%) and you are done.
- Keep Current:
    - For CLIA, the current director must approve any new PM and any changes made.
    - Laboratories not inspected by CMS for CLIA compliance must adhere to their specific accrediting agency directives and director approval/review signature requirements. The CAP, The Joint Commission, and COLA require at least an annual review.
    - Manufacturer product inserts MUST match the **lot of product** in current use.
    - The PM must be part of the initial orientation to testing and annual competency assessment for personnel.
- Maintain a copy of each procedure with the dates of initial use and discontinuance.

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Chapter 4: Method Verification,

Calibration and Calibration Verification

Overview

A quick introduction

Method Verification of performance is a "collective term which refers to a series of exercises that the laboratory undertakes to ensure and document that a method is working properly (at minimum, it meets manufacturer claims)" before placing the method into routine use. The process entails performing experiments, collecting data, calculating statistics, and making judgments on those statistics.

Calibration is "setting the device/system so that it yields correct results." The process of setting your watch to the correct time (if you remember watches that needed this activity), or of initially adjusting the bathroom scale to zero, is a calibration. Calibration implies that changes or adjustments are or can be made, although many devices are now "factory-" calibrated and cannot be changed by the lab.

Calibration Verification is the process of checking (no changes or adjustments) the "correctness" of the calibration. In the wristwatch analogy, confirming its time against the "correct" time of an atomic clock is equivalent to calibration verification. With CLIA, this process also defines the reportable range of test results or the range of values (low to high) known to be accurate and precise. The CAP coined the term "analytical measurement range (AMR)," which includes the reportable range.

In the clinical laboratory...

Currently CLIA and accreditation requirements range from rigorous protocols to no verification at all. The supposedly simple, waived tests like "dipsticks" used in the physician's office laboratory require *no* method verification. For FDA-approved nonwaived (moderate and high complexity) methods, laboratories must verify the achievement of manufacturer claims. For FDA-approved tests that are modified and Laboratory-Developed Tests (i.e. home-brewed and not FDA-cleared or approved), laboratories at this time *must establish the performance specifications*. This section walks you through the validation and verification process and identifies what needs to be done according to CLIA and the different accrediting agencies.

Waived tests

CMS (for CLIA), COLA, The Joint Commission and CAP have **NO** specific method verification, calibration or calibration verification requirements for waived testing other than to follow, at a minimum, the manufacturer instructions.

Nonwaived (CLIA Moderate & High Complexity) Tests

In the original rollout of CLIA regulations, in the 1992 *Federal Register*, the government delayed implementation of validation requirements for moderate complexity testing to accommodate newly regulated laboratories, many of whom would not have the necessary resources.

Things changed in 2003 when CMS published the "final" CLIA regulations, which combined the quality requirements – method verification, calibration and/or calibration verification – for FDA-approved moderate and high complexity testing into one set of **nonwaived** testing requirements. Consequently both testing categories follow the same requirements as long as test sites follow manufacturer directions. When a test site (1) modifies manufacturer directions (even with waived methods); or (2) uses "in-house" Laboratory-Developed Tests (LDTs, which are not FDA-approved), the test site must *establish* **all** performance specifications.

April 24, 2003 and Beyond

Under CLIA, test sites that introduce a nonwaived method into their laboratory on or after **April 24, 2003 (that's everyone)** must go through the performance specification verification process. For **unmodified FDA-cleared** systems (§493.1253(b)(1)), this includes the assessment of accuracy, precision, reportable range, and identification of reference intervals (normal values). **For modified or non-FDA cleared systems** (§493.1253(b)(2)), accuracy, precision, and reportable range must be established *as well as* analytical sensitivity (lowest detection limit), analytical specificity (interferences), reference intervals, and any other characteristics (calibration, calibration verification, QC, etc.) necessary for generating quality test results. Section §493.1253(b)(3) states that the laboratory must determine the test system's calibration and control procedures based upon the performance specifications verified or established. Practically, this means test sites using unmodified FDA-cleared tests should follow, at a minimum, the manufacturer directions. This information needs to be available in the procedure manual.

Sections §493.1255(a) and §493.1255(a)(1) direct labs to perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided or specified, and with *at least* the frequency recommended by the manufacturer. Section §493.1253(b)(2)(3), for modified or non-FDA cleared systems, states the laboratory *will need to establish* the calibration procedure based on the performance characteristics established.

Sections §493.1255(b)(1-3) provide information on calibration verification practices: follow the manufacturer's instructions; use the criteria verified (for FDA-approved methods) or established (for modified or LDT methods) by the laboratory; and, established with at least a minimal (or zero) value; a mid-point value, and a maximum value near the upper limit of the reportable range. The calibration verification must be carried out at least once every 6 months. Methods that are routinely calibrated with 3 or more calibrators at least every 6 months, meet the calibration verification requirement. §493.1255(b)(3)(i-iv) identify additional requirements for calibration verification. Specifically a calibration verification must be conducted whenever there

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Chapter 5: Quality Control

Overview of Quality Control (QC)

According to the CLIA Requirements

QC and waived test methods.

For laboratories inspected for CLIA compliance, **waived tests are exempt** from mandated QC requirements, although test sites must meet all manufacturer-specified and/or recommended QC requirements. Test sites performing waived methodologies also are expected to follow the manufacturer directions and apply good laboratory practices. CAP, TJC and COLA have specific QC requirements for all test complexities, including those in the CLIA waived classification (see Chapter 10: Point of Care Testing).

> **Note:** Provider-Performed Microscopy, consisting of specified tests performed by physicians, nurse-practitioners, physician assistants, etc., as part of a patient's medical examination, is a subset of moderately complex (nonwaived) testing. QC is required "whenever possible."

QC and nonwaived test methods.

The original CLIA regulations (1992) broke new ground by mandating **daily** QC for all moderate and high complexity tests. The 2003 CLIA regulations combined these two complexity categories into the **nonwaived** category and both now follow the same CLIA quality control requirements identified in §493.1256. CLIA states that QC must monitor the **complete analytical process** including environmental conditions, the test system and the operator. Section §493.1256 also emphasizes that QC needs to monitor the accuracy and precision for *immediate error detection* and facilitate detection of errors *over time*.

> **Note:** While not specifically mentioned, CLIA implies that QC requirements are achieved through analysis of **external liquid controls**. All other QC approaches (that don't use external, liquid controls) fall under Section §493.1256(d) Laboratories (particularly POCT) wanting to use other QC approaches must develop **Individualized Quality Control Plans (IQCPs).** (See Chapter 6.)
>
> **On April 2016, the definition of acceptable control material changed.** CMS issued a memo stating that acceptable control materials now include on-board (inside the testing device) ampules/cartridges provided they have matrices similar to patient specimens and follow all elements of the analytic process (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-20.pdf). As a result, laboratories may decide after evaluating their testing device(s), that an Individualized Quality Control Plan (IQCP) is not even necessary.

Follow manufacturer directions.

This is the basic premise of CLIA and all other accrediting agencies. If the manufacturer has specific QC requirements, the laboratory must follow these, at a minimum.

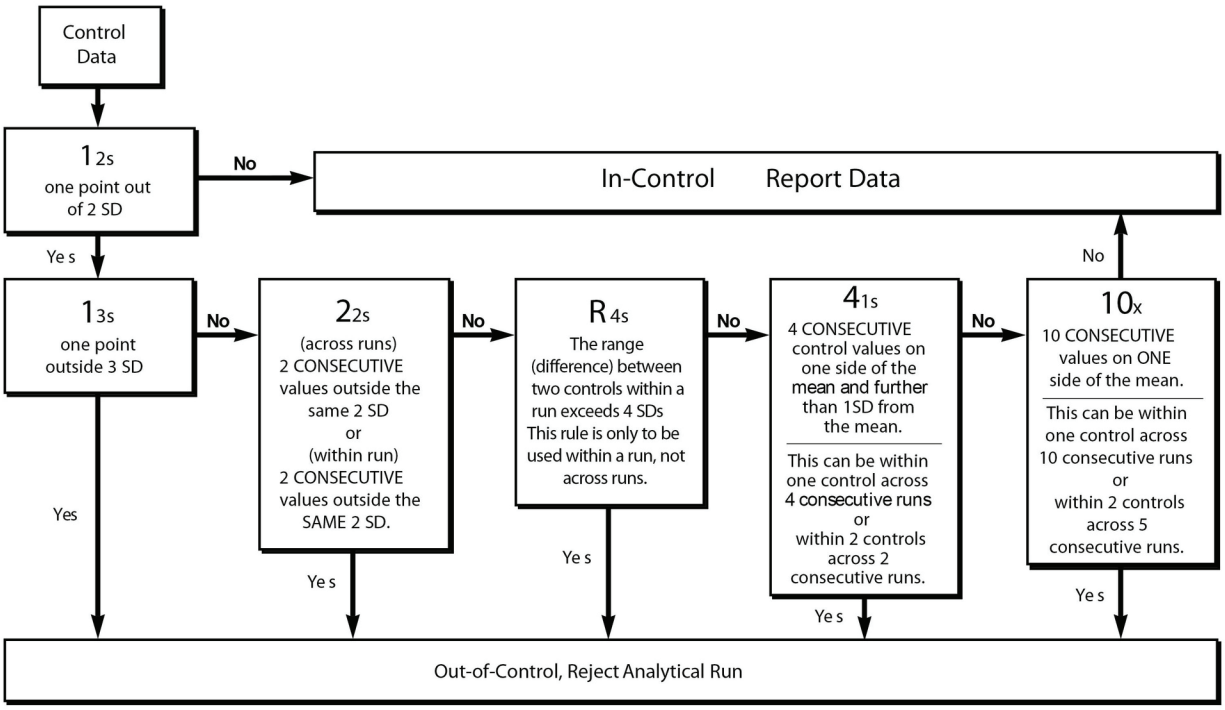

Figure 1: Westgard Multirule Approach, one common combination of rules

"Westgard Rules" – In the 1970s, Dr. James Westgard came up with a unique approach for assessing QC data. This approach is officially known as multirule QC, but more commonly called the "Westgard Rules." Multiple rules are used because different QC rules can detect different kinds of errors – bias, drift, imprecision, etc. Together, these rules are more powerful than a single rule. This approach is depicted in Figure 1 and further explained in Figure 2. In Figure 1, we see the classic "Westgard Rules" are evaluated in a two step process – a *primary* warning rule and a *secondary* series of rejection rules. Rejection rules are interpreted only after the warning rule is violated. Rejection rules are selected to detect systematic and random errors. Knowing which rule is violated gives the lab a headstart on troubleshooting.

In other words, evaluate the QC result first with the warning rule and if it has not been violated, accept the data and report patient results. If the warning rule **is** violated, check the rejection rules. If NO rejection rule is violated, the system is still in-control and patient data can be reported. Violation of any rejection rule is considered an out-of-control situation and requires remedial action. The particular rule violated provides valuable clues to the cause of the out-of-control situation, i.e., imprecision, bias, drift, etc., expediting troubleshooting.

What about QC Charts?

Levey-Jennings control charts have long been the heart and soul of laboratory QC. When possible, laboratories should continue to use them because:

1) Inspectors expect them.
2) They are very useful for long and short-term test management.
3) They are a highly efficient way to meet documentation requirements.

However, Levey-Jennings charts may be superfluous for laboratories with instrument or laboratory information systems that perform data analysis. For laboratories with low test volume (especially those only running two controls per day), QC charts are an effective way of monitoring both daily QC and long-term test management. (Section 5.3 shows a possible QC plan for low volume laboratories.)

Laboratories, particularly smaller ones, may want to consider:

1) Charts heavily annotated by laboratory analysts.
2) Fully annotated charts with lot changes, etc., can fulfill virtually every QC record-keeping requirement:
    a) Daily decisions to report patients.
    b) Periodic management reviews of the method's performance.
    c) Lot numbers and records of reagent shipments.
    d) Dates of calibrations (and calibration verifications, when required).
    e) Reruns of controls and/or use of alternate rules to decide to release patient data even when a statistical rule is violated.

Using Multi-level (not multi-rule) QC

For most tests, CLIA and all accrediting agencies require two levels of control per test every day (usually the length of a run is considered to be a day). Multi-level control means evaluating the levels together, either by computer or by hand. For example, when you are running 2 levels of control, there are three ways to interpret the 2:2s control rule. You can interpret each level (high and low) individually, where you consider the control values in the current run and the previous run. But you can also consider the high and low control values in the same run. This last interpretation is sometimes called across-level or across-material. To see all the ways you can interpret the "Westgard Rules" visit https://www.westgard.com/50-ways-westgard-rules.htm

The process of combining levels into one chart is technically a "normalization" process. It satisfies the minimum regulatory requirement of two controls per test per day but uses only a single QC chart. Running multiple controls, 1, 2, 3, 4, *n* per day but only evaluating one level at a time is not multilevel QC.

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Chapter 6: Individualized Quality Control Plans (IQCPs)

Individual Quality Control Plan (IQCP)

On January 1st, 2016, the **Individual Quality Control Plan (IQCP)**, a new CMS approach to QC, became official. This *voluntary* option replaced Equivalent Quality Control (EQC) procedures that had been included in the 2003 update of CLIA. What this means is that test sites, typically point-of-care sites, need to develop and follow their IQCPs to rely on a device's "built-in" quality assessments to meet CLIA's current daily QC requirements. While CLIA and all accrediting organizations now allow the IQCP option, some specialties and subspecialties are excluded. Test sites need to follow the specifics of their accrediting organizations.

When an IQCP is not developed, performance must be evaluated *daily* with external, liquid QC as described in Chapter 5.

The Backstory of IQCP (QC questions, unaddressed & unanswered)

When CLIA began in 1992, sites were mandated to evaluate the performance of all testing daily usually using two levels of external, liquid QC materials. In the mid-1990s, point-of-care (near-patient, bedside) testing arrived. Many of these small, self-contained, handheld instruments included manufacturer *"built-in"* quality assessments – electronic checks, procedural and/or internal controls, and a variety of internal function checks. While CMS did not agree with these alternative assessment approaches at that time, CMS did not require test sites to perform additional daily external QC. Instead, CMS stated that "future" CLIA revisions would address the issue, postponing any solution.

In 2003, CMS added an equivalent quality option (section §493.1256(d). [**Note: this option does not apply to waived testing.]** Few laboratories seemed to understand the meaning of "equivalent quality testing" or the "equivalent quality control" (EQC) concept. It took CMS several years to explain the approach and develop studies for labs to qualify manufacturers' alternative quality assessments. The EQC option lasted from 2003 through 2015. Finally on January 1, 2016, the IQCP era began.

The Birth of IQCP (the path from EQC to EP23 to IQCP)

EQC was controversial from the beginning. Many laboratory professionals thought the equivalency evaluation studies were unscientific and insufficiently robust to truly judge the ability of alternative assessments for error detection. The former director of CLIA, at a CLSI/CMS Forum in 2005, even admitted "We blew it," in response to EQC concerns. CMS encouraged CLSI committees to develop new guidelines to replace EQA: one for manufacturers to describe the capabilities of their alternative assessment approaches and one for laboratories to facilitate appropriate QC selection. Unfortunately, the CLSI manufacturer guideline was ultimately abandoned. The second guideline, **EP-23: Laboratory Quality Control Based on Risk Management**, was officially released in October 2011. EP-23 describes how laboratories can use risk management concepts to customize their QC activities based on testing technology and potential risks throughout the entire testing process.

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Chapter 7: Quality (Assurance) Assessment

Where QA (Quality Assurance) becomes QA (Quality Assessment)

Introduction

In the CLIA 2003 update and the accompanying *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services* (Appendix C in the SOM), the term "quality assurance" became "quality assessment," with requirements integrated into the entire testing process – pre-analytical, analytical and post-analytical. CMS also suggested that the progression to Quality Assessment is an evolutionary change, which improves and aligns the regulations with current practices in competent laboratories.

Historically, the concept of Quality Assurance is tied closely to the theories of Total Quality Management, Risk Management and Quality Management Systems, which now permeate laboratory activities worldwide. The Joint Commission, CAP, and COLA formally include these concepts in their laboratory inspection process as well.

Quality Assessment

Curiously, while CMS mandates a ***"Quality Management Systems (QMS) Approach"*** for all phases of clinical laboratory operations, QMS is never, in the extensive SOM or CLIA regulations, actually *defined*. The closest to a definition is in the introduction (§493.1200), where CMS gives three key components (from its viewpoint) of a quality management systems approach:

Subpart K – Quality Systems for Nonwaived Testing

§493.1200 Introduction

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor quality systems for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) Each of the laboratory's quality systems must include an assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality systems are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

Let's extract some of the key ideas:

a) Develop a quality system **appropriate for your particular laboratory** that covers the pre-analytic, post-analytic and analytic phases of testing.

b) On an ongoing basis, select Quality Indicators to check on the system to ensure the integrity of the total testing process.

c) Evaluate data collected from Quality Indicators to identify, evaluate and resolve problems.

Section 7.1: Suggested Monitors for CLIA, CAP, TJC, and COLA Testing Requirements

Requirements and Suggestions, Pre-analytical Phase of Testing

Typical requirements for CLIA and accrediting agencies:

- Patient preparation, specimen collection, labeling, preservation and transportation criteria.
- Completeness, relevance and necessity of test requisition information.
- Use and appropriateness of specimen rejection criteria.
- Completeness, usefulness, accuracy of information necessary for interpretations/utilization of test results.
- Appropriateness of turnaround times (TAT's).

Examples of QA Monitors:

- Evaluate turnaround times for all STAT tests.
- Assess timeliness of stored records retrieval.
- Assess frequency of mislabeled/unlabeled samples.
- Measure frequency of hemolyzed potassium samples.
- Monitor number of samples for blood gas analysis contaminated with air.

Example of how a QA Activity is addressed:

Once per week, results from three blood gas samples performed on each shift will be evaluated, using computer records, to determine turnaround times (draw to reporting of results). The laboratory supervisors are responsible for collecting the data; the Director of clinical chemistry reviews this data on a monthly basis. The standard for TAT is 15 minutesor less.

Section 7.4: Example Competency Assessment Forms

NEWBORN SCREENING LABORATORY COMPETENCY

Date: _____ Employee: _____ Evaluator: _____

Evaluator Instructions: Directly observe the employee in the performance of the procedures/specific tasks listed below. For each step of the procedure that conforms to the current Newborn Screening Laboratory Protocol, circle **"Yes."** If any step is performed incorrectly, circle **"No"** and give instructions on corrective action and follow up / verification plans.

After the first year of testing, competency assessment will be performed annually by employee's supervisor. During the first year of testing, competency assessment will be performed twice.

Testing Area	**Performance Acceptable YES / NO (Circle)**	**Corrective Action Successful Evaluator / Date**
Read/Understand/Follow SOP	YES NO	
Create batches and worksheets	YES NO	
Prepare CAH, TSH, IRT trays	YES NO	
Punch CAH, TSH, IRT	YES NO	
Set up CAH assay	YES NO	
Set up TSH assay	YES NO	
Set up IRT assay	YES NO	
Process CAH run/ determine acceptability	YES NO	
Process TSH run/ determine acceptability	YES NO	
Process IRT run/ determine acceptability	YES NO	
Create "Possible Abnormal" CAH/TSH report	YES NO	
Create "Definite Abnormal" CAH/TSH report	YES NO	
Create "Out-of-state" Reports and transmit	YES NO	

Corrective Action Required: _____

Follow-up verification: _____

Conclusion of assessment: _____

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Chapter 8. Personnel

Personnel

Requirements under CLIA, COLA, TJC and CAP

Under CLIA, no specific educational requirements apply to personnel performing only waived testing. These tests may be performed by anyone, although the Centers for Medicare and Medicaid Services (CMS) expect personnel to follow the manufacturer's instructions and apply good laboratory practices. CAP, TJC, COLA and other accrediting agencies have training, competency assessment, and other requirements for waived testing. Check your agency.

For the Provider-Performed Microscopy (PPM) category (CLIA § 493.19), testing is done by physicians, dentists, and mid-level practitioners – nurse practitioners, nurse midwives, or physician assistants – when the specimen is collected as part of a physical exam. Individuals performing PPM are expected to follow good laboratory practices in terms of training, competency assessment, QC, QA, and comply with all applicable CLIA regulations. CAP recognizes 13 PPM and waived tests in this category (see details in CAP's POC checklist). When staff who are not physicians or mid-level practitioners perform these tests, the testing is conducted under a certificate of compliance or accreditation and analysts are expected to follow all the test complexity requirements.

Note: PPM testing can be excluded from the laboratory's and/or POCT CAP inspection when a separate CLIA number is obtained for testing.

On January 24, 2003, CMS updated CLIA to combine moderate and high complexity testing into the **nonwaived** testing category. However, for the purposes of personnel, the two categories **remain separate**. For a laboratory performing FDA-approved **moderate complexity testing**, individual(s) need to be identified for 4 positions: (Subpart M, §§493.1403 – .1425)

- Director
- Technical Consultant
- Clinical Consultant
- Testing Personnel

For high complexity testing, 5 positions are needed: (Subpart M, §§493.1441 - .1495)

- Director
- Technical Supervisor
- Clinical Consultant
- General Supervisor
- Testing Personnel

Note: It is important to consider the CLIA implications before modifying any FDA-approved test (even waived). Modified tests automatically become high complexity. Laboratory Developed Tests (LDTs) are high complexity and require appropriate personnel and additional validation studies.

Note: Specific qualifications for each position vary according to test complexity. The position titles identified above by CMS **do not** have to correspond to organizational titles.

DIRECTOR POSITION QUALIFICATION FORM

Check the appropriate education level and qualification (numbers 1-8; selection #2 requires additional clarification -- a, b or c):

□ 1. M.D., D.O. with current medical license to practice in State of laboratory's location **and** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications.

□ 2. M.D., D.O., or D.P.M (after September 1, 1993). with current medical license to practice in State of laboratory's location **and** laboratory training/experience consisting of (check one):

- □ a. 1 year directing or supervising nonwaived tests.
- □ b. 20 CME credit hours in laboratory practice commensurate with director responsibilities.
- □ c. Equivalent laboratory training (20 CMEs) obtained during medical residency.

□ 3. Doctorate in chemical, physical, biological or clinical laboratory science from an accredited institution **and** certification by HHS-approved Board.

□ 4. Doctorate in chemical, physical, biological or clinical laboratory science **and** 1 year directing or supervising nonwaived testing.

□ 5. Master's in clinical laboratory science, medical technology or chemical, physical or biology science **and** 1 year laboratory training/experience in nonwaived testing **and** 1 year supervisory experience in a laboratory in nonwaived testing.

□ 6. Bachelor's in clinical laboratory science, medical technology or chemical, physical or biological science **and** 2 years laboratory training/experience in nonwaived testing **and** 2 years supervisory experience in a laboratory in nonwaived testing.

□ 7. **ON OR BEFORE 2/28/92** qualified or could have qualified as a director under the laboratory regulations published March 14, 1990 (see § 493.1406).

□ 8. **ON OR BEFORE 2/28/92** qualified as a director by the State in which the laboratory is located.

Official Name of Laboratory, Organization, Hospital	
Director (CLIA) (Print)	Phone
Certification-Boards (Identify)	State License (If Applicable)
Director's Signature	Date

Laboratory Director, Moderate Complexity Testing Responsibilities

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures; and record and report test results promptly, accurately, and proficiently; and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§ 493.1409, 493.1415, and 493.1421, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.

The laboratory director may delegate in writing to the Technical Consultant, the responsibilities in: §§493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13); and Clinical Consultant, in writing, the responsibilities in: §§493.1407(e)(8) and (9).

(d) Each individual may direct no more than five nonwaived certified laboratories.

(e) The laboratory director must –

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that –

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

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Chapter 9: Preparing for Inspection

Keep your laboratory inspection ready!

CLIA mandates in Subpart Q that all test sites performing nonwaived testing undergo an inspection every two years. CMS or state agencies inspect laboratories for CLIA compliance. Professional accrediting organizations have their own inspectors/surveyors or use practicing laboratory professionals to assess compliance. All inspections are unannounced (but normally conducted within a known timeframe). All have a similar focus. And all inspections need to take place while the test site's CLIA certificate is valid.

Certainly being "inspection ready" makes good sense. While readiness can't guarantee a stress-free inspection, it should make the process less of a hassle and, hopefully, the preparation will impress the inspector. First impressions count! Make sure that all of the inspecting agency's requirements are met and the proof (documentation) to show compliance is understandable and readily available for the inspector's review. In preparing, take full advantage of your agency's "get inspection ready/self-assessment" tools so that problems are found and corrected *before* the actual inspection. CMS and all the accrediting organizations want test sites to be ready and to successfully pass inspections.

Laboratories being inspected for CLIA compliance need to make sure to review the testing mandates (the regulations) in the Federal Register. The *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Service,* which serve as a companion to CLIA. For every CLIA requirement, these *Interpretive Guidelines* clarify the requirements, so laboratories know what is needed. They provide probes for inspectors to use in determining compliance. All CLIA requirements are associated with a "D" or deficiency tag. When a laboratory is found to be noncompliant with a particular requirement, the inspector cites the "D tag" rather than repeating the specific requirement.

Hints: Be Inspection-Ready; Be Ready to Successfully Pass Inspection

- Regulatory compliance is a MUST! Know and comply with your inspecting agency's requirements.
- Be aware of your agency's top deficiencies. Competency assessment, incomplete procedure manuals, proficiency testing enrollment and alternate assessments seem to top the lists year after year. Don't get caught in the same traps.
- Be prepared – leadership saves the day. Find problems before inspectors do. Be proactive and look carefully at all the laboratory's practices and procedures; don't assume all is fine. Self-inspection is important, so "do" what surveyors "do" before the actual mandated inspection.
- Make sure activities are consistently monitored; have a QA plan and a continuous quality improvement philosophy.
- Look good! Keep food/drink out of lab, have "no food"/"no flammables" signs on refrigerator doors, understand hazardous chemical labels, unclutter and clean workspace, practice safety first.

Section 9.1
MOCK LABORATORY/TESTING SITE INSPECTION

Inspection site: _____

Inspector(s): _____

Date: _____

GENERAL

1. Is testing performed under an appropriate CURRENT CLIA certificate? Yes____No _____

   Test site is under "whose" - Central Lab, Respiratory Care, Other (specify)_____- CLIA certificate.

   Type of CLIA certificate - waived, PPM, registration, compliance, accreditation
   CLIA certificate number_____
   Expiration date _____
   (inspections must be conducted while the CLIA certificate is valid)
   Director named on certificate _____
   Supervisor(s) of testing site _____

2. Which agency inspects? TJC____CAP_____COLA____CMS(CLIA)_____Other, specify)_____

QUALITY ASSURANCE

1. Is a Quality Assurance (Assessment) Plan(s) covering all three phases of testing been developed, implemented, and available to all staff? Yes____No _____

2. Which important processes or outcomes were monitored or improved during the last 12 months?

   1) patient identification / preparation;
   2) communication;
   3 appropriateness of test (test utilization);
   4) needs, expectations and satisfaction of patients;
   5) staff views regarding ongoing competency and improvement opportunities;
   6) data collected from risk management activities;
   7) QC activities including review of corrective actions;
   8) Accuracy assessment of all analytes (at least twice each year);
   9) Others_____

3. Have the Director/ Supervisor of testing signed off/approved the QA plan? Yes____No _____

PERSONNEL

1. Do the Director/Supervisor meet CLIA personnel requirements and applicable state/local laws? Yes____No _____

2. Are the qualified (listed) testing personnel authorized for specific testing? Yes____No _____

3. Have the testing personnel received adequate training for all tests performed? Yes____No _____

Section 9.2: A TJC Tracer-style checklist

Quality System	Process	?#	Specimen Trail Questions	Y, N, or N/A	Comments
Pre-analytical	Order Entry	1	Do orders include patient name, sex, and unique identifier (e.g. DOB, SS#, chart#) ?		
		2	Is order documented in chart? (inpt, outpt) Do physician orders match lab orders?		
		3	If order was verbal, was it followed up by written or electronic order?		
		4	Can you find date and time order was placed?		
		5	Did the order provide information to support the medical necessity (Dx)? If not, was there an ABN obtained?		
Collection		6	Were all collection requirements met (proper anticoagulant, sufficient quantity) ?		
		7	Were special requirements met, if applicable (fasting, before/after meds, time since last dose) ?		
		8	Is date and time of collection indicated?		
		9	Was the requirement for positive patient identification met? (e.g. two forms of ID) (Answer only if you observed collection)		
		10	Person who collected the specimen identified?		
		11	Is the source indicated, if appropriate?		

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Chapter 10. Point of Care Testing

All POCT is Regulated by CLIA

All testing, regardless of where performed, is regulated by CLIA. CLIA regulates *every* testing site examining "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease..." In short, *all* testing sites are subject, at a minimum, to CLIA's testing regulations.

CLIA Certificates

All POCT must be done under an appropriate CLIA certificate. Information on applying for a CLIA certificate is discussed in Chapter 1 and available on the CLIA website. POCT conducted in most organizations fits into one of two broad scenarios: 1) the central laboratory holds a single CLIA certificate that covers all testing, including POCT, or 2) one or more POCT sites within the institution have separate CLIA certificates. There is no one right way; the choice is organizational and most often depends on who wants to be in charge, cost and administrative concerns.

Each certificate has a fee schedule, which is dependent upon test volume, number of specialties, and test complexity. CLIA regulations divide test methods into three categories: waived, moderate and high complexity. CLIA'03 combined moderate and high complexity into a single, **nonwaived** category with essentially the same testing requirements. Typically, POCT sites perform only *waived and nonwaived* (moderately complex) testing. Under CLIA and the other accrediting agencies, the *waived and nonwaived* categories have DIFFERENT regulatory requirements in terms of personnel, QC, performance verification, proficiency testing, etc. These will be discussed in detail.

Note: While most POCT uses waived methods, if a site develops its own test procedure or chooses to ***modify*** an existing FDA-approved procedure, the test automatically becomes **high complexity**. Modifications include not following the manufacturer's directions and/or performing the test on a sample or from an age group, e.g., pleural fluid, serum, etc., not specified in the manufacturer's labeling. As a result, the modified method now is subject to *all* of CLIA's more stringent nonwaived (high complexity) personnel and performance specification requirements mandated for modified, FDA-approved tests and/or Laboratory-Developed Tests.

Note: In 2014 the FDA published draft guidelines for glucose meters used to test "critically ill" patients (see section 10.4). Most currently-used POCT meters are **not** FDA-approved for this patient population. Consequently, testing "critically ill" patients with these glucose meters is considered a modification ("off-label") use and automatically makes the device *highly complex*, and subject to the high complexity performance and personnel qualifications. Test sites can continue to use these meters, but must develop and follow a policy that defines "critically ill" and how to test these patients with an "approved" method (typically POC sends specimen to the central laboratory). Otherwise, for POC to continue to test critically ill patients, sites need to perform appropriate validation studies or implement a FDA-meter approved for this population. As of 2023, very few methods were officially cleared by the FDA for use with "critically ill" patients.

In other words, ***never*** modify a POCT method unless you are prepared to meet much more demanding regulatory requirements. **Please see the end of this chapter for more advice on how to handle glucose meters with the "critically ill."**

Overview of CLIA Regulations for POCT Testing

When POCT is under the lab's certificate, the lab is responsible for the overall quality of testing and establishing a Total Quality Management (TQM) relationship among all test sites including the central laboratory. While the POCT sites must adhere to the appropriate CLIA regulations, the central laboratory generally is the primary focus of the inspection and is ultimately responsible for POCT oversight and test quality.

When the POCT site has its own CLIA certificate, CMS views the site as an independent lab responsible for meeting all regulations. It inspects accordingly.

CLIA and Waived Testing (see Sections 10.1 and 10.2)

In 1992 when the requirements for meeting CLIA were first published in the Federal Register, there were only 8 waived analytes – dipstick/tablet reagent urinalysis (visually read), fecal occult blood, visual urine pregnancy and ovulation tests, non-automated erythrocyte sedimentation rate, blood glucose by monitoring devices cleared by FDA for home use, hemoglobin by copper sulfate (automated), and spun hematocrit. The waived list keeps expanding and includes over 100 analytes and 1,000+ methodologies that the approximately 244,000 laboratories having a Certificate of Waiver can now test. (Additional sites perform waived testing under a Certificate of Compliance or Accreditation). This list is updated regularly by the FDA. Section 10.1 lists waived analytes as of January 2023. Categories for all test methods are available on the FDA and CMS (CLIA) websites. Reagent/instrument manufacturers also have classification information on their products.

CLIA has *no* requirements for waived testing other than to follow manufacturer directions. CMS inspectors responsible for determining adherence to CLIA regulations *will not inspect* waived testing unless a specific complaint has been lodged or fraudulent activities are suspected. Section 10.2 compares CLIA's waived testing requirements (none) to those of the CMS-deemed accrediting organizations.

Just because CMS/CLIA has no waived testing requirements does not mean laboratories should assume that waived testing is error free. A 2015 Morbidity and Mortality Weekly Report identified quality and patient safety concerns with waived testing. The Report identified: failing to follow current manufacturer instructions; using expired reagents; storing reagents improperly; not performing function or calibration checks; lack of documentation; inadequate training; and lack of knowledge about using good laboratory practices. In 2022, Irwin Rothenberg, a quality advisor for COLA, published strategies for physicians to address these concerns. (Strategies Necessary to Achieve Quality Waived Testing. ((https://www.physiciansofficeresource.com/articles/point-of-care-testing/quality-waived-testing/)) The strategies presented in this article are excellent and appropriate for all testing categories and laboratories.

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Chapter 11. Pandemic Testing

Past, Present, and Future

The End of the Pandemic?

It's difficult to remember the world before the COVID-19 pandemic. For the US, the pandemic hit in March 2020, causing panic, even terror, that eventually mutated into a long despair, and a horrible mourning as the fatalities grew. Then, as vaccinations and better treatments gained purchase, the worst of the pandemic ebbed. Even as the SARS-CoV-2 virus fades into history for the public, the challenges inside the lab endure.

Simply put, SARS-CoV-2 has become endemic. What was a terrifying sprint in early 2020, that turned into a marathon in 2021, which became an ultra-marathon in 2022, has now become a race that will never end. Similar to the flu, COVID-19 variants will continue to emerge, from Delta to Omicron and beyond. With its ability to find shelter in so many species, from humans to deer to mink, the virus will continue to evolve and inflict more suffering and death, and laboratories everywhere will need to have a robust strategy to deal with supply logistics (shortages), novel methods, and dramatic changes in testing demands (surges, droughts, and everything in between).

As of spring 2023, SARS-CoV-2 was killing around 1,500 patients per week in the US, significantly more deaths than what we expect in even a bad flu season. Whether warranted or not, however, the panic is over and the inconvenience of precautions and restrictions seems to have exhausted the public. Officially, the public health emergency ended on May 11, 2023, but the Emergency Use Authorization lives on.

Theoretically, when a public health emergency ends, the Emergency Use Authorization should also end. But there are hundreds of testing methods that can only continue to be used in "emergency" conditions. From February 28th, 2023, FDA listed:

> *"As of today, 444 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 299 molecular tests and sample collection devices, 84 antibody and other immune response tests, 60 antigen tests, and one diagnostic breath test. There are 78 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one EUA for a molecular prescription at-home test, two EUAs for antigen prescription at-home tests, 28 EUAs for antigen over-the-counter (OTC) at-home tests, and five for molecular OTC at-home tests.*
>
> *"The FDA has authorized 45 antigen tests and eight molecular tests for serial screening programs. The FDA has also authorized 1257 revisions to EUA authorizations."*

Only a handful of tests are cleared for use by the traditional FDA 510k process. Until the FDA can convince (or force) hundreds of diagnostic manufacturers to convert their EUA into a 510k, we're likely to see the EUA era continue.

So what we had hoped was going to be a short-term crisis has evolved instead into a long emergency. Temporary regulatory rule-bending will eventually have to be straightened out. Those EUA methods will eventually have to convert into regular, non-emergency approved and regulated methods. Learning how to stay compliant, how to assure the quality of these new critical tests, will mark the great challenge of the career of every laboratory professional of this time.

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