CLIA &
Your Laboratory

A Guide for Physicians and Their Staff

November 2014

Introduction

The American College of Physicians (ACP) welcomes your interest in this guide to the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). We hope that you will find it helpful in answering many of your questions regarding regulations for clinical laboratory testing.

These CLIA regulations are far-reaching, and now regulate physician-office laboratory (POL) testing on a national scale. ACP originally published this guide in 1988. It has been revised periodically to reflect the changes made to the regulations as a result of its implementation and ongoing modifications to CLIA. Among these changes are:

- The creation of a second moderate testing category
- A revised waived category
- Compliance measures for states that are CLIA-exempt
- Requirements for lab director certification for high-complexity labs
- An updated fee schedule for CLIA certificates

This guide has been divided into nine chapters:

- The first chapter, **"The Origin of CLIA '88: An Overview,"** traces the legislative and regulatory history of CLIA '88 and details some of its key components.
- The second chapter, **"The Implementation of CLIA '88,"** provides a step-by-step process for obtaining a CLIA certificate and the costs of the applicable certificate.
- The third chapter, **"Private-Sector and State Alternatives to Federal Certification,"** explains how POLs can meet federal standards, by becoming accredited by a nonprofit, private accreditation program, such as COLA or a CLIA-exempt state agency.
- The fourth chapter, **"Waived, PPM, Moderate- and High-Complexity Testing: How Will I Be Regulated?"** details the four levels of regulation and the testing that can be performed in each category, and the applicable standards that must be met to comply with CLIA '88.
- The fifth chapter, **"The Proficiency Testing Requirements Under CLIA '88,"** describes proficiency testing (PT) and the standards that physicians owning non-waived laboratories must meet to comply with the CLIA PT requirement.
- The sixth chapter, **"Meeting the Quality Systems Standards,"** details the required quality control (QC) and quality assurance (QA) standards with which physicians owning laboratories must comply. This chapter also addresses PT, test management and recordkeeping requirements.

- The seventh chapter, **"Complying with the CLIA Personnel Standards,"** specifically outlines what testing personnel standards are needed to comply with the requisite moderate- and high-complexity testing personnel standards.
- The eighth chapter, **"The Inspection Process,"** details the process that is used to ensure that POLs are meeting CLIA standards. This chapter also illustrates the average cost of biennial inspections, and addresses the Alternative Quality Assessment Survey (AQAS) form.
- The ninth chapter, **"The Enforcement of CLIA '88,"** details the enforcement procedures and sanctions that the Centers for Medicare and Medicaid Services (CMS) may use to enforce the QA standards.

This guide follows a question and answer format. We hope that we have addressed most of your concerns about the laboratory regulations in this guide. ACP members may call our toll-free hotline at 800/338-2746, if they have additional questions about complying with CLIA '88.

ACP strives to assist its members in navigating the complex and often perplexing regulatory process. ACP has been a leader in reducing the regulatory burdens placed upon physicians who operate their own in-office laboratories. These initiatives include: reduced pre-billing time; the addition of a provider-performed microscopy category (PPM); the AQAS form, which is a written survey in lieu of an onsite inspection; revised personnel requirements; active involvement in COLA's expanded member services; and Medical Laboratory Evaluation—a PT program which operates as a part of ACP. All of these accomplishments have been made on behalf of the entire community of physicians who operate in-office laboratories.

Individual members of ACP benefit from the congressional advocacy provided by staff lobbyists and analysts. ACP staff also mediates with CMS staff and other federal officials on behalf of ACP members' individual concerns: ACP members do not have to navigate regulatory territory alone. For specific questions about CLIA and your laboratory, call ACP at 800/338-2746.

Chapter 1
The Origin of CLIA ’88: An Overview

Section 1.A
The Legislative History of CLIA ’88

1. How did the federal Quality Assurance (QA) standards for POLs originate?

Before the enactment of CLIA ’88, only hospital and independent laboratories were required to meet the federal QA standards mandated by CLIA ’67. Congress first signaled its concern about the accuracy of POL testing by mandating—through the Omnibus Budget Reconciliation Act of 1987 (OBRA ’87)—that “high volume” POLs meet the same Medicare standards as commercial laboratories. It was clear that Congress’ definition of high volume laboratories would have included most POLs, and the task of writing such regulations fell to the Secretary of the Department of Health and Human Services (HHS). By including this last-minute mandate into OBRA ’87, Congress made it clear that POLs no longer would be exempt from federal QAs. Physicians and the laboratory community were forced to come to grips with the need for a workable approach to QA in office laboratories, and OBRA ’87 served as the “stick” to force such action. Following enactment of the OBRA ’87 provisions, media investigations into laboratory practices caught the attention of Congress. Perhaps most notable was a Pulitzer-prize winning series that was broadcasted by a Washington, D.C., television station, and followed by a compelling article in the Feb. 2, 1987, edition of *The Wall Street Journal* that highlighted scandals involving several commercial laboratories which inaccurately analyzed Pap smears. Several women died from undetected cervical cancer because of these inaccurately analyzed tests. Of the tens of thousands of laboratories run by physicians at that time, only a handful performed cytology testing, but the public demanded that Congress take action in response to these preventable deaths. Congress reacted by holding oversight hearings which ultimately guided the drafting of CLIA ’88, which later was signed into public law (PL 100-578) on Oct. 31, 1988.The law is far-reaching and regulates POL testing on a national scale.

2. To whom does CLIA ’88 apply?

CLIA ’88 applies to anyone who performs testing of human specimens for the diagnosis, prevention or treatment of disease or health problems. This includes everyone from physicians performing the most basic tests (e.g., dipstick urinalysis) to the technicians working in POLs. The only exceptions are facilities that perform testing for forensic purposes, research laboratories that do not report patient results, and facilities that are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) to perform urine drug testing only.

3. What were Congress' key objectives in enacting CLIA '88?

Supporters of CLIA '88 believe that it was based on the best of intentions: to protect patients from harm resulting from inaccurate testing. Additionally, the law was designed to assure that all laboratories were meeting reasonable quality standards that recognized the different levels of complexity of tests typically performed in POLs. Drafters of the law tried to design CLIA '88 so that the regulations would be workable and cost-effective, without jeopardizing access to in-office testing. CLIA '88 established requirements to improve the quality of laboratory testing, including standards for the performance of Proficiency Testing (PT), Quality Control (QC), QA, patient-test management and personnel requirements.

4. What has been the effect of the CLIA '88 legislation?

CLIA '88 had a significant adverse impact on the quality and accessibility of POL testing. Specifically, the CLIA regulations have affected the types of tests physicians now are willing to offer in their office labs. To avoid the costs associated with CLIA regulations, many physicians discontinued valuable in-office testing in the moderate-and high-complexity categories. The prompt receipt of such test results and the capability to evaluate specimens directly are useful to the physician and help to expedite decisions about appropriate patient care. As a result, patient's access to timely quality testing had been compromised.

According to a 1995 survey performed by the American Medical Association (AMA) and six other specialty groups, 63.3 percent of POLs had "scaled back or completely eliminated laboratory testing" since the provisions took effect in 1988. Similarly, of those that scaled back or eliminated their in-office testing, 81 percent reported an increase in the time needed for patient diagnosis and treatment onset. Eliminating in-office testing has seriously affected patients in rural areas who travel an average of 15 miles to laboratory testing sites. Furthermore, the survey found that some patients were obtaining more costly care in emergency room settings than in the laboratories referred by their physicians.

However, since that time, hundreds of tests have been approved for the waived category and over 100,000 POLs exist today. The CLIA '88 regulations were rewritten in 2003, and more than a decade of familiarity with them has encouraged many physicians to continue or start up a laboratory within their practice.

Section 1.B
The Rule-Making Process

1. Who is responsible for the implementation of the law?

Like most laws, the responsibility of implementation of CLIA ’88 fell to a federal agency. In this case, Congress delegated to CMS—in consultation with the Centers for Disease Control and Prevention (CDC)—the responsibility of translating legislative intent into workable regulations and then enforcing those regulations.

Unfortunately, many components of CMS’s attempts to translate and enforce the regulations have been unacceptable. Its first proposal in 1990 included regulatory classifications that would have placed most POLs in the same level of complexity as commercial laboratories conducting the most sophisticated testing available—thus requiring them to meet unacceptable and unworkable personnel standards. This proposed rule would have put most POLs out of business. The proposal conflicted with Congress’ intent to recognize the different levels of testing complexity typically performed in office laboratories, and to preserve patient access to in-office testing. Clearly, the proposed regulation had to be changed substantially.

In 1992, CMS published its final rules on the administrative process, quality standards, fee collection and enforcement of CLIA. ACP offered suggestions to CMS on each of these components to make CLIA less burdensome; unfortunately, many suggestions were not incorporated into the final rule. However, ACP continues to work with CMS officials to alleviate unnecessary burdens placed on POLs.

Although CLIA ’88 regulations became effective Sept. 1, 1992, regulations governing Provided Performed Microscopy (PPM) and PT did not become effective until Jan. 1, 1993, and Jan. 1, 1994, respectively. Since then, the testing categorizations have been revised on several occasions. The most recent change was when the Quality Standards section of the regulation was streamlined and rewritten.

Section 1.C
Summary of the Final CLIA '88 Regulations

1. What are the key elements of the final CLIA '88 regulations?

CLIA imposes standards for laboratory personnel, patient-test management, PT, QC and QA. The rule also imposes application procedures, fees for certification, enforcement and sanctions. The key elements are summarized briefly below. Laboratories performing moderate- and high-complexity testing must undergo biennial inspections conducted by CMS or a private accreditation organization. More detailed explanation of each can be found in later chapters of this guide. CMS considers both the volume of testing and the number of specialties (e.g., bacteriology) being tested when determining the biennial inspection fees that laboratories will be charged (see Chapter 8).

A. Under the final rule, CLIA requires moderate- and high-complexity laboratories to participate in three PT events per year. Five challenges (defined as the number of samples that must be tested per analyte) are required per PT event for most testing. CLIA required laboratories to be enrolled in an approved PT program as of Jan. 1, 1994; in 1995, CMS began to impose sanctions for those not enrolled (see Chapter 5).

B. The QC requirements include control and calibration requirements applicable to both moderate and high complexity labs. As of Jan. 1. 1994, QC requirements have been mandatory for all laboratories.

C. The QA and patient-test management requirements refer to the comprehensive, ongoing process of monitoring and evaluating every step of the laboratory's testing process—including patient preparation and specimen collection, test analysis and test-result reporting. Each laboratory performing nonwaived testing must establish and follow written policies and procedures for a comprehensive QA program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process. (The QA requirements are described in Chapter 6.)

D. The personnel requirements for moderately complex laboratories are outlined in detail in Chapter 7.B.There are four personnel functions that must be fulfilled in a moderately complex laboratory, including:
   - The *director*, who is responsible for the overall administration of the laboratory;
   - The *technical consultant*, who is responsible for the technical and scientific oversight of the laboratory and must be available on an as-needed basis;
   - The *clinical consultant*, who serves as liaison between the laboratory and its clients in matters related to reporting and

interpreting results; and

- *Testing personnel*, who are responsible for processing the specimens and reporting results.

E. The personnel standards for highly complex laboratories have modified the qualifications required for directors and supervisors of high-complexity labs. There are five functions that must be fulfilled, including:
   - The *director*;
   - A *technical supervisor*;
   - A *general supervisor*;
   - A *clinical consultant*; and
   - *Testing personnel*

Chapter 2
The Implementation of CLIA '88

1. Who must apply for a CLIA '88 certificate?

Anyone who performs testing of human specimens for the diagnosis, prevention or treatment of disease or health problems must apply for a CLIA certificate. This includes physicians who operate their own in-office laboratories. In fact, 2007 CMS statistics show that POLs constitute 52.9 percent of all CLIA-certified labs. Independent laboratories and others make up the remainder. A separate application must be filed for each laboratory location. However, laboratories owned by the same entity, located in the same building and sharing the same laboratory director only need to apply for one certificate.

2. Do I have to apply for a CLIA certificate even if I am only performing a few simple tests in my office?

Yes. CLIA regulations apply to *all* laboratory testing used to assess human health or to diagnose, prevent or treat disease (even those very basic tests performed as part of a physical examination—including fecal occult blood or dipstick urinalysis—are subject to CLIA '88).These simple tests, which fall in the waived category, are exempt from specific CLIA requirements, such as PT participation, personnel requirements and biennial inspections that apply to moderate- and high-complexity tests. The only requirements that physicians performing waived testing must meet are to apply for a certificate of waiver every two years and follow the manufacturer's instructions including all that relate to QC performance. A description of how to access a complete list of waived tests is included in Appendix C.

3. Do I have to apply for a CLIA certificate if I am not billing Medicare for laboratory testing?

Yes. Physicians with in-office laboratories must apply for a CLIA certificate *regardless of* whether they are billing Medicare. CLIA '88 is intended to ensure quality testing for *all* patients, not just Medicare beneficiaries.

4. What should I do first?

Any physician wishing to perform laboratory tests either waived or non-waived must fill out a "CLIA Application for Certification" – Form CMS-116. This form may be obtained by contacting your State Agency (see Appendix A) or downloaded from the CMS website at www.cms.hhs.gov/clia and click on the link "How to Apply for a CLIA Certificate, Including Foreign Laboratories" After filling out this form it should be submitted to the local CLIA State Agency for processing. A fee remittance coupon and CLIA number will be returned from the State Agency. A formal certificate will be issued upon remittance of the

appropriate fee. Non-waived, non-PPM laboratories will receive a Certificate of Registration if this is an initial application. This will allow the laboratory to bill for testing performed prior to the initial on-site survey by either the State Agency or an approved accreditation body.

5. What is the cost of a Certificate?

There are four types of certifications: Certificate of Waiver, Provider Performed Microscopy (PPM) Certificate, Certificate of Compliance, and Certificate of Accreditation. The fee for a Certificate of Waiver is $150 and the fee for a PPM Certificate is $200. Each certificate is issued for a two-year period. For non-waived, non-PPM laboratories, the fee for the initial Certificate of Registration is $100. After a laboratory is successfully inspected, either by a State Agency or by an Accreditation body, the Certificate of Compliance or Certificate of Accreditation will be issued. The fee schedule for these two certificates is the same and based upon the volume of tests performed in the laboratory. This schedule can be found at the end of this section, in a table called CLIA Certificate Fees. Fees for the inspection are separately billed by either CMS or your Accreditation body.

6. What is the cost of an inspection performed by CMS?

The federal government has negotiated rates for inspection with each State Survey Agency. There is a separate inspection fee schedule for each state. The fee schedule is based upon the same testing volume categories as the Certificate fee. Contact your State Agency for a copy of the inspection fee schedule for your state.

7. What are my rights if my application for a registration certificate is denied?

If CMS denies your laboratory's application for a registration certificate, a certificate of waiver, a certificate of accreditation, or limits the laboratory's certificate, the agency must give the laboratory a statement of the grounds on which the denial or limitation is based, and an opportunity to appeal. The laboratory cannot operate legally as a laboratory unless the limitation or denial of a specified certificate is overturned at the conclusion of the administrative appeals process. Contact ACP for assistance if you encounter this problem.

8. When can I expect an inspection?

Except for waived and PPM laboratories, all laboratories *must* be inspected. CMS randomly selects laboratories for inspections every few weeks. Following an inspection, laboratories will receive the appropriate "certificate" or a "certificate of accreditation" (a certificate of accreditation will be issued to those laboratories that are seeking accreditation by a CMS-authorized accrediting body).This

certificate is renewable every two years. In states with federally approved licensure programs, a laboratory may obtain a state license in lieu of a federal certificate. If your laboratory is located in a state with its own federally approved QA program for laboratory testing, you will have to meet state standards only. See Chapter 3 for information about nonprofit, private accreditation programs—such as COLA—and state-exempt licensure programs.

9. What if the location or ownership of my laboratory changes?

A laboratory owner is required to notify CMS within 30 days if a change occurs in the ownership, name and/or location of the laboratory. Laboratories also must notify CMS within 30 days if the director or supervisor changes. Facilities requesting a revised certificate must pay a modest fee to cover the costs of issuing another certificate.

10. What if I change my testing menu?

In most instances, CMS will *not* require laboratories that add a new test or tests to their testing menu to obtain a revised certificate before they begin the new testing. Rather than list analytes approved for testing, the laboratory's certificate will specify the specialties and subspecialties of testing (e.g., bacteriology) for which the laboratory is certified. Provided the test additions are included in the specialty or subspecialty for which the laboratory is certified, CMS will not require the laboratory to obtain a revised certificate. The lab will, however, be required to notify the agency of changes in its testing menu within six months. If the test is not in the specialty or subspecialty listed on the lab's certificate, CMS may conduct a survey to determine compliance with CLIA standards. A laboratory with a certificate of waiver must notify CMS before performing tests not on the waived list; CMS then will authorize a restricted registration certificate for the new services, granting permission for the laboratory to initiate new testing until it determines whether the laboratory meets CLIA standards.

Laboratories issued a certificate of accreditation (e.g., those labs participating in an approved, private, nonprofit accreditation program), must notify the accreditation program within six months of performing any test or examination within the specialty or subspecialty area that is not included in the laboratory's accreditation. Laboratories also must notify the accreditation program within six months of making any deletions or changes in the test methodologies for any test or examination included in a specialty, subspecialty or both, for which the laboratory has been issued a certificate of accreditation.

Laboratories increasing the volume or scope of testing may increase additional fees for re-certification. Contact your CMS regional office or State Health Department for further information. Currently, there is a charge of $75 to labs that need to re-certify on this basis. There is no fee reduction (during your current certification period) for decreasing the volume or scope of testing.

CLIA Certification Fees

Fee Summary	
Waiver	$150
PPM	$200

CLIA Certificate Fees

Type of Lab	Number of specialties	Annual test volume	Biennial certificate fee
Waived	N/A	N/A	$150
PPM	N/A	N/A	200
Low Volume A	N/A	Less than 2,000	150
Schedule A	3 or fewer	2,000-10,000	150
Schedule B	4 or more	2,000-10,000	150
Schedule C	3 or fewer	10,001-25,000	430
Schedule D	4 or more	10,001-25,000	440
Schedule E	N/A	25,001-50,000	650
Schedule F	N/A	50,001-75,000	1,100
Schedule G	N/A	75,001-100,000	1,550
Schedule H	N/A	100,001-500,000	2,040
Schedule I	N/A	500,001-1,000,000	6,220
Schedule J	N/A	Greater than 1,000,000	7,940

Chapter 3
Private-Sector and State Alternatives to Federal Certification

Section 3.A
Private-Sector Alternatives to Federal Certification and Inspections

1. What are private, nonprofit, accreditation programs, such as COLA?

CMS has approved several private, nonprofit, accreditation programs. These programs are offered by COLA (which is specifically tailored to the POL environment), the College of American Pathologists, the American Association of Blood Banks, the American Society for Histocompatibility and Immunogenetics, the American Osteopathic Association, and The Joint Commission. These organizations are responsible for helping your laboratory meet the federal requirements set forth in CLIA. *ACP strongly recommends that physician-owners of in-office laboratories enroll in COLA. ACP members who have enrolled in COLA experience fewer hassles and feel less of a bureaucratic burden than those who do not.*

2. What is COLA?

COLA is a voluntary education and accreditation program that reflects the efforts of specialists in laboratory medicine and office-based physicians to assure that office-based testing produces high-quality results. ACP co-founded COLA with the College of American Pathologists, the American Academy of Family Physicians, and the American Medical Association. The American Osteopathic Association later joined COLA's governing board.

3. What advantages will physicians-owners of in-office laboratories reap from participating in COLA, as opposed to seeking federal certification?

Unlike the CMS-certification program, COLA has indicated that it will provide the following services to laboratories participating in the program:

- The opportunity to conduct a comprehensive *self-inspection* using the same criteria as COLA inspectors, to prepare for the survey.
- An evaluation of the self-inspection and a report of deficiencies that should be corrected before the onsite inspection.
- Well-trained inspectors to assist laboratory staff and to offer suggestions, hints and advice to improve your laboratory's performance.
- Up to 15 hours of Category 2 continuing medical education (CME) credit for physicians participating in the COLA program.
- An expert staff of medical technologists offering toll-free telephone assistance.
- Timely information regarding all office-laboratory regulations,

including CLIA, the Stark amendments, Occupational Safety and Health Administration (OSHA) and others.

- ❖ Concise articles on various aspects of office laboratory practice—articles that are easily understood and that provide specific information to solve problems. The articles may be received via fax the same day the request is made.

COLA's fee schedule is competitive with the cost of federal certification. Additionally, COLA offers many added services (listed above) that the federal government does not have the resources to provide. ACP members should note that privately accredited laboratories are included in CMS's random 5 percent validation survey of accredited laboratories.

COLA also offers ACP members discounts and will pay any switching fee from CMS for the POL. Additional discounts can be obtained by using ACP's Medical Laboratory Evaluation (MLE) program in conjunction with COLA.

4. How can I find out more about COLA?

Contact COLA at the following location and phone number:

COLA
9881 Broken Land Parkway, Suite 200
Columbia, MD 21046
800/981-9883

Section 3.B
State-Exempt Licensure Programs for Laboratories

1. **What if my POL already is regulated by the state?**

Some states already regulate POLs. According to CLIA '88 regulations, labs are exempt from CLIA's requirements (and therefore, do not need to apply for federal certification, pay any federal certificate fees, or undergo routine, federal, biennial inspections) if they are located in states that have licensure and inspection programs approved by CMS. In these cases, the lab must comply with state standards, which must be equal to or more stringent than the federal CLIA requirements, to renew exemption status.

2. **What states currently are CLIA-exempt?**

- Washington and
- New York (not including POLs).

3. **What states now impose additional regulations on POLs?**

The following states impose additional rules on POLs, over and above federal regulations:

- Arizona (has a comprehensive program that regulates all POLs).
- California (has a comprehensive program that regulates all POLs).
- Connecticut (state law requires all POLs to have a state license).
- District of Columbia (requires D.C. licensure of in-office testing).
- Florida (requires state licensure of in-office testing).
- Louisiana (requires state licensure of in-office testing).
- Maine (regulates POLs performing referral testing only).
- Maryland (has a comprehensive program that regulates all POLs).
- Massachusetts (regulates group practices with three or more physicians).
- Michigan (only regulates group-practice laboratories with six or more physicians doing patient or referral testing).
- Nevada (requires state licensure of all in-office testing).
- New Jersey (group practices with five or more physicians operating laboratories must meet independent laboratory standards).
- Oregon (requires state licensure of in-office testing).
- Pennsylvania (has a comprehensive program that regulates all POLs).
- Washington (has a comprehensive program that regulates all laboratories).
- Puerto Rico (requires state licensure of in-office testing and also requires physicians to prove laboratories are "necessary" prior to obtaining permission to run an in-office laboratory).

Chapter 4
Waived, PPM, Moderate- and High-Complexity Testing: How Will I Be Regulated?

Section 4.A
Waived Tests

1. What are the criteria for waived testing?

The Centers for Disease Control and Prevention (CDC) performed the determination of waiver for tests until January 2000, after that time the Food and Drug Administration (FDA) took over this function. Under the current process, waivers may be granted to : 1) Any test listed in the regulation; 2) Any test system for which the manufacturer or producer applies for waiver if that test meets the statutory criteria and the manufacturer provides scientifically valid data verifying that the waiver criteria have been met; and 3) test systems cleared by the FDA for home use. The statutory criteria include 1) they employ simple yet accurate methodologies rendering the likelihood of erroneous results negligible; and 2) they pose no reasonable risk of harm to the patient if performed incorrectly.

2. What tests are on the waived list?

As of February 6, 2008, the FDA (or CDC) has granted waived status to at least one test system for each of 110 separate anlaytes. The FDA maintains a list of these analytes with links from each analyte to a listing of the test systems waived for that analyte at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm. It would be wise to check this listing prior to implementing any test indicated as "waived" by the manufacturer. There have been a number of test systems placed on the market indicating they were CLIA Waived when they were not. There has been some confusion among distributors that purchase test systems for remarketing under a "private label" that if they purchased an already "waived" test system from another manufacturer and put their label on it that it was still "waived." The FDA has stated this is not the case and that each test system must be separately approved by the FDA even if the only change is the name of the test system, so the mislabeling generally was not an intentional effort on the part of these distributors to mislead laboratories, but was a misunderstanding of the requirements for obtaining waived status for their test system. However, laboratories are still held accountable for ensuring that the test systems they are using are in the "waived" category, and thus a check of the official listing at the FDA website is advised.

3. Must I meet any standards at all if I am performing waived tests only?

Waived laboratories must register and apply for certificates of waiver biennially through CMS and affirm that they will conduct good laboratory practices (i.e., following a manufacturer's recommendation for the performance of the tests, *and only performing tests approved for the waived category*).Waived laboratories are not subject to PT, specific QC, personnel standards or regular biennial inspections.
Note: CMS is currently conducting random surveys of approximately 2% of all waived laboratories each year as a result of pilot studies conducted that demonstrated that a substantial number of laboratories holding a Waived Certificate were either performing non-waived tests or not following the manufacturer's instructions.

4. What will it cost me to comply with CLIA '88 as a waived laboratory?

A waived certificate costs $150 every two years.

Section 4.B
Provider-Performed Microscopy Category (PPM)

1. What is the PPM category?

This is a sub-category of Moderate Complexity that was added to the CLIA regulations by the Jan. 19, 1993, technical corrections regulation responding to a 1992 recommendation made by the Clinical Laboratory Improvement Advisory Committee (CLIAC). *This was instituted to allow physicians and mid-level practioners that perform direct microscopic examinations of patient specimens as part of their evaluation of the patient during a visit to continue to perform these tests without having to undergo a routine inspection of their laboratory every two years. The specimens examined are usually labile and difficult to transport to another laboratory for analysis and generally control materials are not available for these procedures. Only Pysicians, Dentists, Nurse Practioners, nurse midwives, and Physician's Assistants are allowed to perform these tests if performing them under a PPM Certificate.*

2. What are the criteria for the PPM category?

Tests must meet the following criteria to qualify for the PPM certificate category:

A. During a patient's visit, a physician or a mid-level practitioner personally performs the procedure on the specimen obtained from his or her own patient or from a patient treated by the physician's group practice;
B. The procedure is categorized as moderately complex;
C. The microscope serves as the primary instrument for performing the test;
D. The specimen is unstable, or a delay in performing the test could compromise accuracy of the result;
E. Control materials are not available to monitor the entire testing process; and
F. Limited specimen handling or processing is required.

3. What tests are on the PPM list?

The PPM list currently includes the following nine tests:

A. Urine sediment examinations;
B. All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites and human cellular elements (including red and white blood cells, epithelial cells, etc.), including wet mounts of vaginal, cervical or skin specimens. Wet mounts must be performed using a limited- to bright-field, or phase-contrast microscope. This should not include any procedures in which definitive identification or enumeration is made or any staining is performed.
C. Pinworm examinations;

D. Fern tests;
E. Potassium hydroxide (KOH) preparations;
F. Post-coital direct, qualitative examinations of vaginal or cervical mucus;
G. Nasal smear examinations for granulocytes;
H. Fecal leukocyte examinations; and
I. Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

Laboratories with PPM certificates may also perform waived testing.

4. What CLIA standards apply to PPM laboratories?

Laboratories must register and apply for PPM certificates. They must comply with the following standards:

A. *Participation in an approved PT program if applicable.* PT is not specifically required for any of the PPM procedures – although enrolling in a PT program is a convenient way to meet the requirement that these procedures be compared with an entity outside of the laboratory at least twice yearly. The specimens included in the PPM category are generally not easily transportable, so PT is usually easier than splitting a sample with another laboratory to compare results.
B. *The personnel standards for PPM laboratories.* The following personnel are qualified to perform PPM tests: physicians, dentists, nurse-practitioners, nurse-midwives and physician assistants. Emergency personnel, registered nurses, licensed practical nurses and medical assistants are not qualified to perform PPM tests under the PPM certificate (although they may under a moderate-complexity certificate).They may, however, draw the specimen and prepare it. However, the PPM certificate requires that only qualified personnel view the specimen and make the final determination of results.
C. *The appropriate QA and QC standards for a moderately complex laboratory, as applicable.* Daily quality controls are not typically available for these tests. External QC checks (e.g., PT or split-samples with an outside laboratory) must be performed twice yearly. Quality assurance includes such things as slide cleanliness, microscope maintenance, and fresh reagents or stains (if any).There should be a procedure manual that includes a short description of how the test should be performed and what troubleshooting activities should be used if any problems occur.

Laboratories performing only PPM tests are not subject to biennial inspections, however, they are subject to the same random inspections as waived laboratories.

5. What will it cost to comply with CLIA '88 as a PPM laboratory?

Regardless of the volume of testing, certifying as a PPM laboratory costs $200

every two years.

6. How can I apply for a PPM certificate?

To apply for a PPM certificate, contact your State Agency (see Appendix A). In your request, make sure to include your existing CLIA number—if applicable—as well as a list of the tests you plan to perform.

Section 4.C
Moderate-Complexity Testing

1. What are the criteria for moderate-complexity testing?

CMS considered the following criteria when deciding whether a test method should be categorized as moderately complex: (a) scientific and technical knowledge required to perform the test; (b) decision-making required to perform the test; (c) training required to perform the test; (d) experience required to perform the test; (e) the difficulty and specifications for handling reagents and materials required in the testing process; (f) the characteristics (i.e., the ease of control) of the operational steps (e.g., pipetting, temperature monitoring, or timing of steps); (g) the stability and availability of calibration, QC and PT materials; (h) the requirements for troubleshooting and equipment maintenance (e.g., the degree to which judgment and training is required); and (i) the amount of interpretation and judgment required in the testing process.

2. What tests are classified as moderate-complexity tests?

Tests are classified according to the assessment of the test system used. So knowing the name of the analyte tested, such as Cholesterol, does not indicate whether the method used in a given laboratory is classified as Waived, Moderate or Highly complex. The specific test system (Kit name, Instrument/Reagent combination) must be known in order to discover its complexity. The FDA maintains a searchable database on the Internet that contains the classifications on all test systems it has approved. See Appendix C for description of how to access and use this database to determine the complexity of the tests in your laboratory or tests you are considering implementing.

3. What CLIA standards must my laboratory meet to qualify as moderately complex?

There are four standards with which physicians owning in-office laboratories must comply before becoming certified to perform moderately complex testing:

A. Participation in an approved PT program (mandatory as of Jan. 1, 1994).The program evaluates the laboratory's accuracy with interpretation and judgment. Participation is verified and testing is checked for satisfactory performance (see Chapter 5).
B. The personnel standards for moderately complex facilities (see Chapter 7.B). Laboratory personnel must have the knowledge needed to perform tests and an appropriate amount of training and experience.
C. The appropriate QA and QC standards (see Chapter 6). Reagents and materials are evaluated for proper preparation and analysis. Operational steps and calibration methods also are reviewed.
D. Biennial onsite inspections (see Chapter 8). Laboratories are surveyed to see if they are meeting appropriate standards.

Section 4.D
High-Complexity Testing

1. What are the criteria for high-complexity testing?

CMS considered the following criteria when determining whether a test method should be categorized as highly complex: (a) scientific and technical knowledge required to perform the test; (b) decision-making required to perform the test; (c) training required to perform the test; (d) experience required to perform the test; (e) the difficulty and specifications for handling reagents and materials required in the testing process; (f) the characteristics (i.e., the ease of control) of the operational steps (e.g., pipetting, temperature monitoring, or timing of steps); (g) the stability and availability of calibration, QC and PT materials; (h) the requirements for troubleshooting and equipment maintenance (e.g., the degree to which judgment and training is required); and (i) the amount, interpretation and judgment that is required in the testing process.

2. What tests are classified as high-complexity tests?

Tests are classified according to the assessment of the test used. So knowing the name of the analyte tested, such as Cholesterol, does not indicate whether the method used in a given laboratory is classified as Waived, Moderate or Highly Complex. The specific test system (Kit name, Instrument/Reagent combination) must be known in order to discover its complexity. The FDA maintains a searchable database on the Internet that contains the classifications on all test systems it has approved. See Appendix C for a description of how to access and use this database to determine the complexity of the tests in your laboratory or tests you are considering implementing. Test systems not yet included in this database, no matter how simple they may appear, are considered "highly complex" until they are classified officially.

3. What CLIA standards must my laboratory meet to qualify as highly complex?

The standards for high-complexity testing are listed below.

A. Participation in an approved PT program (mandatory as of Jan. 1, 1994) for newly regulated laboratories. Laboratories required to perform PT under CLIA '67 must continue their participation in PT (see Chapter 5).
B. The personnel standards for highly complex facilities (see Chapter 7.C).
C. The applicable QA and QC standards (see Chapter 6.B and 6.C).
D. Biennial, onsite inspections (see Chapter 8).

4. **How do I find out which level of regulation (PPM, moderate- or high-complexity) applies to my particular test, assay or examination (e.g., how is Abbott Spectrum categorized)?**

The most recent categorization of test systems can be obtained through the Internet (see Appendix C for instructions on how to access). Additionally, you also may ask your manufacturer whether your particular instrument or kit is moderately or highly complex.

Chapter 5
The Proficiency Testing Requirements Under CLIA '88

Section 5.A
Proficiency Testing Requirements for Waived Laboratories

1. If my laboratory is performing waived testing, do I have to comply with any CLIA '88 proficiency testing requirements?

No. Waived laboratories do not have to meet any PT standards.

Section 5.B
Proficiency Testing Requirements

1. What is proficiency testing?

CLIA ’88 mandates PT, which is a source of external quality control. This practice of testing unknown specimens from an outside source provides an additional means to assure quality laboratory testing results. Although most laboratories perform daily internal quality control—with high, low or normal assayed controls—external quality control allows for important interlaboratory comparisons to determine the accuracy of testing procedures. By participating in a PT program, laboratories receive specimens at scheduled shipping times for testing. PT programs will be required to ship specimens at least three times a year at approximately equal intervals and to include five challenges (specimens) for each analyte. After your laboratory has tested the samples, you must return the results to the PT program for grading, where your laboratory’s results will be compared with your peers’ lab results, using similar methodologies. CMS does not offer a PT program, so laboratories must look to the private sector for enrollment.

2. Who must enroll in PT?

All laboratories performing tests in the moderate- or high-complexity categories. The most often cited deficiency for all laboratories enrolled in the CLIA program is failure to enroll in a PT program.

3. Does ACP offer a proficiency testing program?

Yes. Beginning in 1973, ACP offered a proficiency testing program—the Medical Laboratory Evaluation (MLE) Program. For information about ACP’s MLE program contact:

The American College of Physicians
The Medical Laboratory Evaluation (MLE) Program
Suite 800, 25 Massachusetts Ave., NW
Washington, DC 20001-7401
800/338-2746
http://www.acponline.org/MLE

All proficiency testing programs must be approved by CMS to make sure they meet federal standards for purposes of CLIA ’88.

4. What occurs after I participate in a PT event?

After your laboratory performs the tests and returns the results to the PT program, you will receive data comparing your laboratory’s performance with that of other

laboratories performing the same procedures by identical (or similar) methods.

5. When must I enroll in a proficiency testing program?

Laboratories must be enrolled in PT anytime they are testing patients. Some states require that PT testing be performed prior to a new laboratory testing patients, however, the federal regulations do not have this requirement. PT programs operate on a calendar year basis. Enrollment or re-enrollment in PT programs typically occurs in the fall. However, laboratories may enroll at any point during the year. It is recommended that enrollment or re-enrollment take place as early as possible in the fall to ensure that your laboratory can obtain specimens for the first event of the year. PT programs generally must place their orders with manufacturers of the PT material in the late fall and they generally order enough to cover all the laboratories already enrolled and then more for anticipated enrollees. Sometimes enough material is not available to serve all late enrolling laboratories and these laboratories would then be unable to perform PT for the first event. This could lead to regulatory problems, since non-participation is considered by CMS to be a failure.

6. How do I enroll in a proficiency testing program?

Appendix B lists the proficiency testing programs that are approved by CMS. Each differs slightly in price and in the tests (analytes) offered. Physicians may contact each program for information and assistance in finding a program best suited for their testing needs. Enrollment in proficiency programs runs from Jan. to Jan. Although laboratories may enroll mid-year at a lower fee, it is necessary to enroll in the program in the fall prior to the program year to ensure receipt of all shipments.

7. What are the federal requirements for enrolling in PT?

The laboratory must:

A. Notify CMS of the approved program(s) in which it chooses to participate.
B. Designate the program(s) to be used for each specialty, subspecialty, analyte or test if the laboratory participates in more than one approved PT program.
C. Participate for one year before designating a different PT program, and notify CMS of the change.
D. Authorize the PT program to release testing data required to show compliance.
E. Establish and maintain the accuracy and reliability of any testing procedure not included in the list of regulated analytes.

8. What are the federal requirements for the performance of proficiency testing?

To comply with the PT requirements, the laboratory must:

A. Test the samples it receives from the proficiency testing program *in the same manner as it tests patients' specimens*. Specifically, the laboratory must:
   - ❖ Utilize the routine testing personnel for the examination or testing of the PT samples. The individual testing the samples *and* the laboratory director must attest to the routine integration of the samples with the patient runs; and
   - ❖ Test the samples the same number of times routinely performed for patient samples.

B. *Not* engage in any inter-laboratory communications pertaining to the results of the PT samples. This also applies to laboratories with multiple testing sites.

C. *Not* send PT samples or portions of samples to another laboratory for analysis. Specifically,
   - ❖ Any laboratory that intentionally refers its PT samples to another laboratory for analysis will have its certification revoked for one year.
   - ❖ Any laboratory that receives PT samples from another laboratory for testing must notify CMS of the receipt of those samples.

Note: CMS has revoked certificates of laboratories comparing PT. In some instances the laboratories had employee(s) in common and the respective laboratory directors did not even know each other. CMS did not consider it an acceptable excuse that the Laboratory Director was unaware that the comparison took place. These rulings have been upheld through all levels of appeal in the Administrative Law Court.

D. *Document the testing process* for the PT samples by:
   - ❖ Maintaining a copy of the PT results on the test result form as furnished by the PT program;
   - ❖ Showing proof of the attestation statement as signed by *both* the laboratory director and the analyst performing the proficiency testing; and
   - ❖ Keeping these records for two years.
   - ❖ Document the review of the evaluation report received from the Proficiency Testing program. If there are any Unsatisfactory or Unsuccessful results (see Section 5.D) document all corrective action and the verification that these actions were successful in correcting the problem.

E. *Enroll in PT for only the test system, assay or examination used as the primary method for patient testing* during the PT event.

9. Are there any special enrollment requirements?

Microbiology is considered differently for PT purposes than any other specialty. Other specialties (Chemistry, Hematology, etc.) have individual analytes, such as Hematocrit or Glucose. Microbiology has been separated into five sub-specialities as the lowest level of grading: Bacteriology, Mycology, Mycobacteriology, Virology, and Parasitology. Within each of these categories it is required that at least five challenges per testing event be performed. However, these challenges need to include utilizing all the various methods for identifying the organism. For example, if a laboratory performed a Rapid strep (non-waived) test, a back-up culture plate for negative rapid tests, and performed gram stains all of these procedures would need to be included. If the Rapid strep kit was waived, then only the throat culture plate and gram stain would count toward the 5 regulated challenges required. Each PT program has its own way of handling this, but there must be at least one of each regulated component included in the 5 challenges each event for Bacteriology. These requirements make Microbiology the most confusing area of PT enrollment. Do not hesitate to contact prospective PT programs for assistance in determining the proper enrollment in Microbiology sub-specialties for your particular combination of testing.

10. What if I change my test menu mid-way through my PT enrollment?

If physicians change their test menu mid-way through PT enrollment, they must notify the PT provider immediately in writing. CMS also needs to be notified of this change. Fees will be prorated according to appropriate increases or decreases in the testing menu.

Section 5.C
Successful and Satisfactory Performance of Proficiency Testing

1. **Does the PT program have to send my proficiency testing data to the CMS?**

The CLIA regulation requires that, to be in compliance, all non-waived laboratories participating in an approved PT program authorize that PT program to release its testing data. However, the proficiency testing program will send your testing data to CMS *only* if you provide written authorization to do so. ACP recommends that you provide this written authorization to the PT program at the time of your enrollment.

2. **What will CMS do with my testing data?**

CMS will be using the testing data to determine whether your laboratory complies with the CLIA requirements for satisfactory performance and successful performance (both terms are defined below) of proficiency testing. These requirements are intended to serve as an external QA measure to make sure the laboratory is performing accurate testing.

3. **What is the definition of satisfactory PT performance?**

Generally, *satisfactory* PT performance means attainment of the minimum satisfactory score for an analyte, test, specialty or subspecialty *for a testing event.*

4. **What is the definition of successful PT performance?**

Generally, *successful* PT performance means attainment of the minimum satisfactory score for an analyte, test, subspecialty or specialty for *two consecutive, or two of three consecutive testing events*.

5. **What are the specific requirements for satisfactory performance and successful performance of proficiency testing for each specialty and subspecialty?**

The subspecialties in *bacteriology*, as well as the subspecialties of *microbiology, mycology and syphilis serology* must meet the following:

A. ***Satisfactory performance*** means attaining an overall testing score in each subspecialty of at least 80 percent per event, i.e., attaining correct results for four out of five samples *in the testing event*.
B. ***Successful performance*** means maintaining this satisfactory score *for two consecutive testing events, or two out of three consecutive testing events*.

For the specialty of *hematology* and the subspecialties of routine *chemistry,*

toxicology, general immunology, ABO group + D(Rho) typing and unexpected antibody identification:

A. ***Satisfactory performance*** means:
   - ❖ Attaining a score of at least 80 percent (100 percent for ABO group + Rh type) of acceptable responses for each analyte in each testing event; and
   - ❖ Attaining an overall event score of at least 80 percent (100 percent for ABO + Rh type) in each specialty and subspecialty.

B. ***Successful performance*** means:
   - ❖ Achieving satisfactory scores for the same analyte/test in two consecutive testing events, or two out of three consecutive testing events; and
   - ❖ Achieving an overall event score of at least 80 percent (100 percent for ABO + Rh type) for two consecutive testing events, or two out of three consecutive testing events.

6. How will I know if I have performed satisfactorily in proficiency testing?

The evaluation and reporting of a laboratory's results is the responsibility of the PT program, which will provide you with an evaluation of your testing results, including a cumulative report of whether you meet CLIA standards for satisfactory performance of PT for each analyte per testing event. If you are not satisfactorily performing PT, the technical representative for your instrument manufacturer or test system and/or your PT program, can provide you with the technical assistance you need to assess the problem.

Section 5.D
Unsuccessful Participation in Proficiency Testing

1. **What is the definition of unsatisfactory PT performance?**

Unsatisfactory PT performance means failure to attain the minimum satisfactory score for an analyte, test, specialty or subspecialty *for a testing event.*

2. **What is the definition of unsuccessful PT performance?**

Unsuccessful PT performance means a failure to attain the minimum satisfactory score for an analyte, test, specialty, or subspecialty *for two consecutive, or two of three consecutive testing events*.

3. **When will CMS consider my proficiency testing data unsatisfactory?**

CMS will consider performance in a proficiency testing event *unsatisfactory performance* for the following reasons:

A. If a laboratory fails to attain the minimum acceptable testing event score (80-90 percent).
B. If a laboratory fails to return results within the time-frame specified by the program.
C. If a laboratory fails to participate in a testing event.*

4. **What must I do following an unsatisfactory testing event?**

As follow up for any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must:

A. Undertake *appropriate training* and employ the technical assistance necessary to correct problems associated with a PT failure;
B. *Document* remedial action taken to correct the problem; and
C. *Maintain* the documentation records for two years from the date of participation in the PT program.

5. **Will CMS limit or revoke my laboratory's approval or certification for an entire specialty or subspecialty if my laboratory performs PT unsuccessfully for a given analyte in that specialty or subspecialty?**

No. CMS will allow a laboratory that performs PT unsuccessfully for a given analyte or challenge to elect to withdraw performance of that analyte voluntarily until the laboratory can demonstrate proficiency in performing the assay. Demonstration of proficiency in performing the assay usually entails successful participation in two PT events. Many PT providers, including MLE, offer off-schedule testing, which allows a laboratory to demonstrate proficiency in a timely fashion. A laboratory may be required by an accreditation body to stop testing a failed analyte after repeated unsuccessful PT performance. In this case, a

laboratory will be required to perform two PT events successfully prior to performing any further patient testing. These two events can either be the regularly scheduled events, which could take up to 6 or more months or by purchasing off-schedule PT events.

6. What must I do if my laboratory's certificate is limited or revoked as a result of a failure to participate successfully in PT?

If a laboratory's certificate is suspended or Medicare or Medicaid approval is terminated because it fails to participate successfully, the laboratory must:

A. Demonstrate sustained satisfactory participation on two consecutive PT events, one of which may be onsite; and

B. Take corrective action and reapply for certification if the laboratory's certificate is suspended.

** Consideration may be given to those laboratories failing to participate in a testing event only if: Patient testing was suspended during the time-frame allotted for testing and reporting PT results; The laboratory notifies the inspecting agency and the PT program within the time-frame for submitting PT results of the suspension of patient testing and the circumstances associated with failure to perform PT testing on the samples; and the laboratory participated in the two previous testing events*.

Chapter 6
Meeting the Quality Systems Standards

Section 6.A
Quality Systems Standards

1. **How is Chapter 6 organized (i.e., what sections apply to my office laboratory)?**

   A. Section 6.B discusses the Quality System standards that apply to all physicians performing non-waived laboratory tests.
   B. Section 6.B discusses the "general" CLIA Analytic Systems requirements for physicians performing testing.
   C. Section 6.D discusses the additional specialty and subspecialty requirements for Analytic Systems. All physicians performing tests in these specialties must comply with these standards and facilities requirements.
   D. Section 6.E discusses the pre- and post-analytic system requirements.
   E. Section 6.F outlines a recommended practice for meeting laboratory systems record keeping standards and facilities requirements.

Section 6.B
Complying with the Quality System Standards

1. **If my laboratory is performing only waived testing, do I have to comply with any CLIA '88 laboratory systems standards?**

No. Waived laboratories do not have to meet any specific laboratory systems standards. They only need to follow the manufacturers' instructions, including any QC related instructions contained in the package insert.

2. **What is a quality system?**

A quality system is the comprehensive, ongoing process for monitoring and evaluating every step of the laboratory's testing process from patient preparation and specimen collection, through test analysis and test result reporting. It assesses the success of the laboratory's pre-analytic, post analytic, and analytic systems.

The inspection process will place the greatest emphasis on the quality component of the CLIA regulation. The survey process will involve observing laboratory personnel at work, interviewing the personnel, and reviewing records. This process will look at the pre-analytic, analytic, and post-analytic stages. However, if upon initial review, the laboratory appears to be functioning well and things appear to be in good order, a short interview and review of the records is all that is needed. Exhaustive surveys should be done only if the surveyor identifies significant problems early on in the survey.

3. **Do all laboratories have to perform quality system activities?**

All laboratories performing non-waived testing must establish and follow written policies and procedures for a comprehensive quality system program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process. Only laboratories performing waived testing are exempt. These policies and procedures must be revised as necessary, based on the results of evaluating the total laboratory operation. ***All*** quality system activities must be documented. Problems that arise must be assessed and documented with subsequent performance of corrective actions.

4. **What should guide the development of a quality system?**

The standards as outlined in the regulations can act as a guide for your laboratory as you design a quality system that is appropriate for the services offered, the complexity of the testing performed, and the unique practices of the testing entity. The extent of your laboratory's quality system should be proportional to the laboratory's test volume, scope and complexity of the operation.

5. Who is responsible for the quality system?

Although all laboratory personnel should be involved in quality system activities, the laboratory director ultimately is responsible for the overall management of the laboratory quality system.

6. What are the key elements of a quality system for non-waived laboratories?

The laboratory's **quality system** must:

A. Evaluate the effectiveness of its policies and procedures;
B. Identify and correct problems;
C. Assure the accurate, reliable and prompt reporting of test results; and
D. Assure the adequacy and competency of the staff (and consultants, if applicable).

7. What specific activities are required to assess the quality system?

The laboratory must have an ongoing mechanism to evaluate the effectiveness of corrective actions taken as required by the **quality systems assessment** standards This mechanism must evaluate and review the effectiveness of corrective actions taken for:

A. Problems identified during any analytic systems activity.
B. Problems identified during any pre-analytic or post-analytic systems activity.

Policies and procedures shuld be revised to prevent the recurrence of problems. Discussion of the above mentioned reviews are to be held with appropriate personnel. Documentation of all quality system assessment activity is vital.

8. What are the general laboratory system requirements ?

Greneral Laboratory system requirements include:

A. *Comparison of test results*—If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using different methodologies, instruments or testing sites. If a laboratory performs tests that are not included in a PT program, the laboratory must have a system for verifying the accuracy and reliability of these test results at least twice a year. One of the ways this may be accomplished is by split sample testing.

B. *Relationship of patient information to patient test results*—Ultimately, it is the responsibility of the physician to evaluate whether the test results received are consistent with the patient's condition. However, the laboratory must have a mechanism to identify and evaluate patient results that are inconsistent with relevant criteria. POLs are unique in that their testing is more easily correlated with patient history than that of hospitals or independent laboratories. Key components of a patient test-management plan should include: (a) patient's age; (b) sex; (c) diagnosis or pertinent clinical data, when provided; (d) distribution of patient test results, when available; and (e) relationship with other test parameters when available within the laboratory.
C. *Personnel assessment*—The regulation allows the laboratory the flexibility to develop its own mechanism to evaluate staff performance. However, the laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.
D. *Communications*—The laboratory must have a system in place to document problems that occur as a result of problems in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. The corrective actions taken to resolve the problem and minimize miscommunications must be documented. It is not necessary to employ sophisticated computer software to assess breakdowns in communication.
E. *Complaint investigations*—The laboratory must have in place a system to assure the documentation of all complaints and problems that are reported to the laboratory. Investigations of complaints must be made, when appropriate, and corrective actions must be instituted, as necessary. The regulations allow the laboratory to decide when and to what extent an investigation will be made based on its established policies and procedures.
F. *Confidentiality of patient data*—The laboratory must maintain the confidentiality of patient information throughout all phases of the total testing process.

Section 6.C
General Control and Analytic Systems Requirements

1. What are control procedures?

Control procedures are a part of the overall analytic quality system Each laboratory must establish and follow written control procedures to monitor and evaluate the quality of the testing process for each test method, to assure accurate and reliable patient test results. CMS requires compliance with both *"general"* and *" individual specialties and subspecialties requirements" stated in the regulations.*

2. With what kinds of general CLIA analytic systems standards must I comply?

The manufacturer instructions should include guidelines for the general QC standards: (a) test methods, equipment, instrumentation, reagents, materials and supplies; (b) procedural manual; (c) establishment and verification of method performance specifications; (d) equipment maintenance and function checks; (e) calibration and calibration verification procedures; (f) control procedures; and (g) remedial actions. These standards are explained in Questions 3 through 11.

3. What are the CLIA analytic systems standards for test methods, equipment, instrumentation, reagents, materials and supplies?

The laboratory must:

A. Select methods and equipment, and perform testing to provide test results within its stated performance specifications; and
B. Use appropriate equipment, supplies and materials for the type (as presented in the procedure manual) and the volume of testing.
C. Define criteria essential for proper storage of reagents and specimens, including, if applicable, for water quality, temperature, humidity and protection from electrical fluctuations.
D. Document remedial action taken to correct any condition that fails to meet the criteria.
E. Label reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, to indicate the following:
   - ❖ Identity, and when significant, titer, strength or concentration;
   - ❖ Recommended storage requirements;
   - ❖ Preparation and expiration date; and
   - ❖ Other pertinent information.

Note: Containers (vials) too small to label may be stored in larger containers that are properly labeled.

F. Prepare, handle and store appropriately reagents, solutions, culture media, controls, calibration materials and other supplies to ensure that:

- ❖ Supplies are not used if they have exceeded their expiration date, are deteriorated, or are of substandard quality; and
- ❖ Components of reagent kits with different lot numbers are not interchanged unless otherwise specified by the manufacturer.

4. What is a procedural manual, how can I develop one, and what are the analytic system standards for a procedure manual?

The procedure manual provides a reference to the laboratory's operation and will be an important focus of an inspection. Laboratory consultants also are accustomed to developing procedure manuals. The laboratory should establish a means to document that each employee performing the tests has read the manual initially and is made aware of any changes to a procedure. The protocols for a comprehensive quality systems program (Chapter 6.B) do not need not to be documented in the procedure manual, but if not included, should be available to all personnel in its own manual.

The analytic systems standard requires a written procedure manual for the performance of *all* analytical methods used by the laboratory. It must be readily available and followed by the laboratory personnel. Manufacturers' inserts or operator's manuals may be used when applicable. However, any section not provided by the manufacturer must be provided by the laboratory. Textbooks may be used as supplements to the written procedure manual, but cannot be used in place of it. Specifically:

A. The *procedure manual* must include, when applicable to the test procedure:
   1. Requirements for specimen collection *and* criteria for specimen rejection;
   2. Requirements for patient preparation, specimen processing, transportation (if applicable), and referral (if applicable);
   3. Procedures for microscopic examinations, including detection of inadequately prepared slides;
   4. Step-by-step performance of the procedure, including test calculations, and interpretations of results;
   5. Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;
   6. Calibration and calibration verification procedures;
   7. Reportable range for patient results (include demographic variables such as age and sex, if applicable);
   8. Control procedures;
   9. Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;
   10. Limitations in methodologies, including interfering substances;
   11. Reference ranges (normal values);
   12. Panic values;

13. Literature references;
14. Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;
15. How to report results and the protocol for reporting panic values;
16. What to do when the test system is inoperable; and
17. Criteria for referral of specimens.

B. *Procedures must*:
- ❖ Be approved, signed and dated by the director prior to use;
- ❖ Be re-approved, signed and dated if the directorship changes; and
- ❖ Changes to procedures must be approved, signed and dated by the director.

5. What are the CLIA analytic system standards for establishing and verifying method performance specifications?

Laboratories are not required to verify or establish performance specifications for any test system in use prior to April 24, 2003. Any test introduced into the laboratory after April 24, 2003 that is FDA approved and unmodified must be verified as follows.

Verification may be accomplished by thoroughly testing reference samples or by comparing results of tests performed by an established alternative method. If reference materials or alternative methods are not available, verification may be accomplished by comparing split sample results with results obtained from a method that has been shown to provide clinically valid results. Method verification should provide evidence that the accuracy, precision, and reportable range of the method will be adequate to meet the physicians' needs in managing their patients' health care. For each method, a laboratory may use the manufacturer's performance specifications, adjusted as necessary to meet any special patient testing conditions and addressing particular patient populations. The manufacturer's validation must correlate with the in-house test performance, and the laboratory should verify the manufacturer's claims before initiating any patient testing.

If the laboratory introduces a *new* procedure using a modified procedure, uses an in-house procedure, or a procedure without performance standards provided by the manufacturer, it must verify or establish the performance characteristics for: (a) accuracy; (b) precision; (c) analytical sensitivity (that how much analyte must be present to be detected); (d) analytical specificity (the method measures only the analyte it is reporting; what causes interference or affects the test method); (e) reportable range of patient results; (f) reference ranges; and (g) other performance characteristics.

The laboratory then must establish calibration and control procedures for the test method, and be able to document the verification or establishment of all

applicable test performance specifications. For quantitative methods, the laboratory must define and verify minimum detection limits, specificity and sensitivity, and document that the concentration to be detected can be measured or observed.

6. What are the CLIA analytic system standards for equipment maintenance and function checks?

Daily activities and checks are performed before patient testing to ensure that an instrument is functioning correctly and is properly calibrated. In many cases, the performance of control procedures serves as an instrument function check, since the testing of the control samples checks all of the operating characteristics of a test system, including instrument stability and calibration.

For ease in record-keeping and documentation purposes, it is advisable to develop and maintain a separate instrument maintenance manual in conjunction with the procedure manual or other laboratory records. All maintenance records for each instrument should be documented and maintained in this manual for easy referral by the laboratory director or for inspection purposes. A separate information sheet should be developed for each instrument or piece of equipment. The references provide examples of such forms.

A laboratory's maintenance program should be divided into two parts:

- ❖ Unscheduled repair work when needed; and
- ❖ Scheduled preventive maintenance to prevent breakdowns or malfunctions, to prolong the life of an instrument and to maintain optimum operating characteristics.

A. *For instruments and procedures unmodified and approved by the FDA, the laboratory must:*
   - ❖ Perform maintenance and function checks as defined by the manufacturer;
   - ❖ Perform maintenance and function checks with at least the frequency specified by the manufacturer; and
   - ❖ Document the maintenance and function checks performed.

B. *For procedures modified or developed in-house, or for which no maintenance and function check protocols are provided by the manufacturer, the laboratory must:*
   - ❖ Establish a maintenance protocol to ensure accurate testing;
   - ❖ Perform the maintenance at the frequency established;
   - ❖ Document all maintenance performed;
   - ❖ Document all function checks and include function check protocol and background or baseline checks; and
   - ❖ Document all calibration and calibration verification procedures.

Note: Function checks must be within the laboratory's established limits before patient testing can be conducted. There are many reference books, particularly the COLA Guide, that detail these steps.

7. What are the CLIA analytic system standards for calibration and calibration verification procedures?

Procedures for both calibration and calibration verification standards are outlined in the CLIA regulation. The requirements are based on the methodologies used in the laboratory. Many of the instruments used in the POL have "built-in" calibrators, or simple calibration methods. Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test results.

A. *Calibration* is the process of testing and adjusting an instrument to provide a measurement of the value of the substance being tested.
B. *Calibration verification* is the assaying of a calibration material in the same manner as patient samples to confirm the calibration.

Both of these procedures are performed to verify the continued accuracy of the test method. For each quantitative test method or analytical system, the laboratory must evaluate the stability of calibration and other operating characteristics in establishing the calibration schedule. The calibration records should reflect the use of calibration materials for both the high and low end of the laboratory's reportable range.

- Perform calibration procedures:
  1. According to the manufacturer's instructions, using calibration materials and with at least the frequency recommended by the manufacturer;
  2. Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification, and
  3. In accordance with the criteria established in the laboratory. Criteria must include:
     a. The frequency of calibration (if not provided by the manufacturer);
     b. The number, type and concentration of the calibration materials;
     c. Acceptable limits for calibration verification; and
     d. Appropriate materials for the methodology, if possible, traceable to a reference method or reference material of known value.
- Perform calibration verification procedures:
  1. In accordance with manufacturer's calibration verification instructions when the instructions meet or exceed the requirements established by the laboratory; and
  2. In accordance with the criteria established by the laboratory. Criteria must include:
     a. The frequency of calibration (if not provided by the manufacturer);
     b. The number, type and concentration of the calibration materials; and

c. Appropriate materials for the methodology—if possible, traceable to a reference method or reference material of known value.

[The calibration materials must be appropriate for the methodology and verify the laboratory's reportable range of patients' test results, which must include at least a minimal (or zero) value, a mid-point value and a maximum value at the upper limit of that range.]

d. Calibration must be completed at least once every six months or whenever the following occur:

i. A complete change of reagents for the procedure is introduced unless the laboratory can demonstrate that changing lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes *(Note: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment, and contain the same lot numbers.)*

ii. There is major preventive maintenance or replacement of critical parts that may influence test performance.

iii. Controls reflect an unusual trend or shift or are outside of the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem.

iv. The laboratory's established schedule for verifying the reportable range of patient test results require more frequent calibration verification.

Document all calibration and calibration verification procedures.

8. What are the CLIA standards for control procedures?

The laboratory must determine what control procedures must be performed based on the methods used. Control procedures are performed on a routine basis to monitor the stability of the method or test system; control and calibration material provide a means to indirectly assess the accuracy and precision of patient test results.

The regulations state certain parameters that must be met for control procedures to adequately meet the goal of verifying proper performance of a test system prior to patient testing by that system. The general control procedure standards are superceded by the specialty or subspecialty specific control requirements. The

specialty and subspecialty requirements can be found in section 6.D.
Listed below are the general control standards included in the regulations.

A. For each test system, perform control procedures using the number and frequency as specified by the manufacturer or established by the laboratory as long as they meet or exceed the following requirements;

   Each day the patient specimens are assayed or examined:
   a. For quantitative procedures, include two control materials of different concentrations
   b. For qualitative procedures, include a positive and negative control material
   c. For procedures with graded or titered results, include one negative control and one control with graded or titered reactivity
   d. For procedures including an extraction phase, include two controls, at least one of which tests the extraction phase portion of the test system

   There are further requirements for molecular amplification, thin layer chromatography, and electrographic procedures.

B. Whenever there is a complete change of reagents, a major preventive maintenance is performed, or any critical part of a test system is changed, control material testing is required prior to the start of any patient testing subsequent to these events.

C. Control material testing is required to be rotated over the time among all operators performing each test system.

D. Control material is tested in the same manner as patient specimens.

E. If calibration material is used as the control material, the material used as a control must be from a different lot of calibration material from that used to calibrate or verify the test system.

F. Each laboratory must verify the acceptability criteria for each control material used. For quantitative testing, statistical information must be defined and available (e.g. Mean and Standard Deviation). Manufacturer defined statistical information is acceptable provided the stated value is for the methodology and instrumentation used by the laboratory and the laboratory has verified the material. Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control material having previously determined statistics.

G. For reagent, media, and supply checks the laboratory must do the following:

a. Check each batch (prepared in-house) or lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, and identification systems when prepared or opened for positive, negative, and graded reactivity (if applicable).
b. Test staining materials with positive and negative control material each day of use
c. Immunohistochemical and fluorescent stains must be checked for positive and negative reactivity each time of use.
d. Prior to each initial use:
    i. Each batch of media must be checked for sterility
    ii. Each batch of media must be checked for its ability to support growth and, if appropriate, select or inhibit organisms
    iii. Document the physical condition of the media if it appears deteriorated or otherwise compromised and report this to the manufacturer
e. Follow the manufacturer's specifications for use

H. Control material must perform within the laboratory's acceptability criteria (be within the acceptable range) prior to patient testing.

I. Document results of all control material testing.

J. If no control materials are available for a test system, the laboratory must develop an alternative method to detect immediate errors and to monitor and the system over time. Document all checks.

9. What are the CLIA analytic systems assessment standards?

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.

It is most important, with regard to control procedures, that corrective action be taken and documented regarding any control material testing results that fall outside of the laboratory's established acceptable range. No patient testing may take place until corrections are made and control material testing results are again within the acceptable range for that test system.

Section 6.D
Control Procedures for Specialties and Subspecialties

1. What are the specific control requirements for specialties and subspecialties of testing?

This manual reviews the specific requirements of those specialties and subspecialties commonly performed in a POL, in addition to the general control requirements.

A. Bacteriology

Laboratories performing *bacteriology* procedures must:

- ❖ Document all control activities.
- ❖ Check positive and negative reactivity with control organisms:
  1. When each batch, lot number, and shipment of antisera is prepared or opened and every 6 months thereafter;
  2. Each day of use for beta-lactamase except when using the Cefinase ™ method.
  3. Each week of use for Gram stains.
- ❖ For antimicrobial susceptibility tests, check each new batch of media and each lot of antimicrobial discs before or concurrent with initial use—using approved reference organisms. (These may be purchased through the media supplier, or through an agreement with a hospital or reference laboratory.)
  1. The laboratory's zone sizes or "minimum inhibitory concentration" (MIC) for reference organisms must be within established limits before reporting patient results.
  2. *Each day tests are performed*, the laboratory must use the appropriate control organism(s) to check the procedure.

Note: *"Approved reference organism(s)" means either an appropriate control strain or an equivalent commercial strain. American Type Culture Collection (ATCC) control organisms are not necessarily required. If a laboratory uses "in-house" isolates for control organisms, however, it must have established reactivity for each organism. The CLSI (formerlyNCCLS) standard, M2-A9 "Performance Standards for Antimicrobial Disk Susceptibility Tests," Nnth Edition, provides validation methods for susceptibility testing procedures.*

B. Parasitology

It is the laboratory's responsibility to: accurately and reliably identify the organisms it examines; specify on the test-report the laboratory's method for screening fecal specimens; and upon request, provide information to clients that may affect the interpretation of test results. If a laboratory is performing parasitology testing, it must:

- ❖ Document all control activities;
- ❖ Supply a reference collection of slides or photographs, and if available, gross specimens for identification of parasites. The lab must use these references in the laboratory for appropriate

comparison with diagnostic specimens;
- ❖ Calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter; and
- ❖ Check the permanent stains each month, using a fecal sample control that will demonstrate staining characteristics. For example, since the working iodine solution for parasitology staining is stable for approximately two weeks, it is advisable to make up and use solution that is less than two-weeks old and to check for its staining characteristics.

C. Chemistry

Laboratories performing blood-gas analysis must:

- ❖ Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;
- ❖ Test one sample of control material for each eight hours of testing;
- ❖ Use a combination of calibrators and control materials that includes both low and high values on each day of testing; and
- ❖ Include one sample of calibration or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.
- ❖ Document all control activities.

D. Hematology

For the specialty of *hematology*, the laboratory must meet the general control requirements, as well as the following specific requirements:

- ❖ Document all control activities; and
- ❖ Laboratories performing manual cell counts (hemocytometer) must perform cell counts in duplicate (both patient and controls); one control is required for each eight hours of operation;

E. Coagulation

All laboratories using *automated coagulation* systems must:

1. Include two levels of controls for each eight hours of testing; and
2. Include two levels of controls each time a change in reagents occurs.

Each individual performing coagulation tests using manual coagulation systems must:

- ❖ Test two levels of controls before testing patient samples and each time a change in reagents occurs; and
- ❖ Perform patient and control testing in duplicate.
- ❖ Document all control activities.

F. Immunohematology

Laboratories performing *immunohematology* procedures must:

- ❖ Perform all testing according to manufacturer's instructions;

- Perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents;
- Confirm ABO grouping by testing the unknown serum with known A1 and B red cells;
- Determine D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood grouping reagent. ("Du" variant testing is not addressed; however, when it is performed, it must be in accordance with the manufacturer's instructions); and
- Document all control activities.

Section 6.E
Pre – and Post – Analytic Systems

1. **What is required under CLIA ’88 to assure accurate, reliable and prompt ordering, collecting and reporting of patient testing?**

Each laboratory that is performing non-waived testing must establish and maintain a system that ensures that patients are adequately prepared, as well as for the proper specimen preparation and collection, identification, preservation, transportation, processing and test reporting. This system must assure optimum patient specimen integrity and positive identification throughout the pre-testing, testing, and post-testing processes.

2. **What protocol must be included in a pre- and post-analytic systems?**

The CLIA ’88 regulations require laboratories to review their policies continuously for pre- and post-analytic systems, which include, ordering tests, handling specimens and reporting test results. The review should ensure that everything is being done according to policy, that the policy is achieving its intended results, and that the test reports include all information that the offering physician needs.

Pre- and Post-analytic systems protocol must include:

A. The criteria established for patient preparation, specimen collection, labeling (including name or unique patient identifier), preservation and transportation;
B. The information solicited and obtained on the laboratory’s test requisition for its completeness, relevance and necessity for the testing of patient specimens;
C. The use and appropriateness of the criteria established for specimen rejection;
D. The completeness, usefulness and accuracy of the test report information necessary for the interpretation or utilization of test results;
E. The timely reporting of test results to authorized individuals based on testing priorities (e.g.,“stat,” routine, etc.);
F. The accuracy and reliability of test-reporting systems, appropriate storage of records and retrieval of test results;
G. Specific policy and guidelines related to the referral of specimens;
H. Method for notifying ordering individual when errors are identified and for producing, delivering, and retaining a corrected report; and
I. Establishment of alert or panic values including a procedure for prompt notification when these levels are exceeded.

3. **Should my patients’ laboratory results be reported using automated or manual reporting systems under CLIA ’88?**

The laboratory may use manual or automated test systems, or both. The test record system must be monitored, evaluated and revised on a continual basis. The

lab must document these quality assurance activities, and make the documentation available to CMS upon request. CMS most often makes these requests in connection with surveys. If information regarding test requests is transcribed or entered into a record system or a laboratory information system, a system to ensure that this transcription or entering is accurate must also exist.

4. **For the pre-analytic system, what specific element must be included in the test request?**
   - ❖ Ordered by an authorized person (this is a person that is allowed to order laboratory tests under your individual state law)
   - ❖ Name and address of person ordering test; if submitted by another laboratory, the name and address of that facility is required.
   - ❖ Contact person for reporting life threatening values, if obtained
   - ❖ Patient's name or unique identifier
   - ❖ Patient's sex and age OR date or birth
   - ❖ Tests to be performed
   - ❖ Source specimen, if applicable
   - ❖ Date of specimen collection (time should be added if pertinent to testing)
   - ❖ Any additional information that is relevant to the testing (e.g. drugs patient is on, fasting/non-fasting)

5. **Do I need separate requisition slips to be in compliance with the Pre-analytic systems requirements?**

No, the patient's chart or medical record may be used as the test requisition as long as it is available to the laboratory at the time of testing and is available to CMS or a CMS agent upon request.

6. **Can I accept verbal requests for testing?**

You may accept a verbal request, but you must also ask for a written or electronic authorization within 30 days of the acceptance of the request and must maintain the authorization OR documentation of efforts to obtain the written or electronic authorization.

7. **For the Post-analytic system, what specific elements need to be included in the test report?**
   - ❖ The name and address of the laboratory where the test was performed
   - ❖ The test report date
   - ❖ The test performed
   - ❖ The specimen source, if applicable
   - ❖ The test result and units of measurement when they exist
   - ❖ Interpretation of test result, if applicable
   - ❖ Information about specimen's condition
   - ❖ What was done with the specimen if it did not meet specimen acceptability criteria
   - ❖ Normal values (as determined by the laboratory performing the test) if

not already available to the person using the test results

8. **If I send testing out, can I transcribe the results onto my testing forms for ease of charting?**

No, you may not make any changes to reports received from another laboratory. The results must be given to the authorized person using the tests directly via the test form received from the outside laboratory OR an exact duplicate (photocopy) may be given. An original or exact duplicate of the result from the send out test must be retained by the ordering laboratory.

Section 6.F
Complying with the Laboratory Systems Record-Keeping Standards and Facilities Requirements

1. **What records do I have to keep and for how long?**
   - ❖ Test requisitions – 2 years (including if on a medical chart)
   - ❖ Test procedures – 2 years **after discontinuance of use** (include dates of initial use and when discontinued)
   - ❖ Analytic systems records
     a. Quality control records – 2 years
     b. Patient test records (including instrument printouts) – 2 years
     c. Instrument maintenance records – 2 years
     d. Performance specification initial verification – for length of time of instrument use, but no less than 2 years
     e. Immunohematology records and reports (ABO, Rh, Antibody Screen, etc.) – 5 years (or as required by the FDA)
     f. Proficiency testing records – 2 years
     g. Laboratory system quality assessment records – 2 years
     h. Test reports – 2 years after date of report
     i. Pathology test reports – 10 years after date of report

If the laboratory ceases operation, the laboratory must make provisions to ensure that all records are maintained and available for these time frames.

2. **Do I need to keep specimens for any length of time?**

Generally, you do not. The exception to this is cytologic and histopathologic slides, blocks and tissues. These types of specimens are generally not processed in a physician office laboratory and are beyond the scope of this publication.

3. **What are the CLIA standards for facilities?**

The laboratory must:

A. Ensure adequate space, ventilation and utilities necessary for conducting all phases of the test process, including the pre-analytical, and post-analytical;

B. Establish, post and observe safety precautions to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials;

C. Minimize contamination of patient, specimens, equipment, instruments, reagents, materials, and supplies;

D. Ensure that there is appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs;

E. Comply with all applicable Federal, State, and Local laboratory requirements;

F. Maintain and store records under conditions that ensure proper preservation. Note that many instrument printouts are printed on heat

sensitive paper, which makes temperature control important for these records.

Chapter 7
Complying with the CLIA Personnel Standards

Section 7.A
Personnel Standards for Waived Laboratories

1. **If my laboratory is performing only waived testing, do I have to comply with any CLIA '88 personnel standards?**
   No. Waived laboratories do not have to meet any personnel standards.

Section 7.B
Personnel Standards for Moderate-Complexity, Including PPM, Laboratories

1. **What are the personnel standards for moderate-complexity laboratories?**

There are four personnel functions that must be fulfilled in a moderate-complexity laboratory:

A. The *director* is responsible for the overall administration of the laboratory;
B. The *technical consultant* is responsible for the technical and scientific oversight of the laboratory and must be available as needed;
C. The *clinical consultant* serves as liaison between the laboratory and its clients in matters related to reporting and interpreting results; and
D. *Testing personnel* are responsible for processing the specimens and reporting results.

2. **Must a physician who owns a moderate-complexity in-office laboratory hire four different people to fulfill these four laboratory personnel functions?**

No. A single individual (e.g., a physician), if qualified, could perform multiple personnel functions or all four functions, if needed. For example, in a physician office laboratory, a physician with one year experience in moderate-complexity testing could perform the duties of the director and clinical consultant. The physician also could perform the duties of technical consultant provided he or she has at least one year of training or experience in the appropriate specialty of laboratory testing. If you are a physician and you and your staff perform hematology, chemistry, and microbiology tests in your office, you must have either one year of experience in conducting these tests in your office or at least one year of training or experience in hematology, chemistry, and microbiology to qualify as a technical consultant.

If you cannot meet the technical consultant requirements [e.g., do not have the one year training or experience in the specialty or subspecialty of testing you are performing or do not have a staff person who meets the qualifications of one of the other appropriately-degreed people (see question 4)] you must hire a qualified person as a consultant to perform these technical functions until you or a staff member acquire the necessary experience. The technical consultant must be available on an as-needed basis and is responsible for selecting test methods, implementing a quality control program, and enrolling in and monitoring the laboratory's participation in proficiency testing.

3. **Can a physician qualify to be a laboratory director?**

Yes. The following individuals would be qualified to serve as a *director* in a laboratory performing moderate-complexity testing:

A. Pathologists.
B. Physicians with at least one year of laboratory training or experience (e.g., operating a laboratory that conducts moderate-complexity

testing) qualifies a physician to fulfill the role of director as well as the other three functions. Physicians who do not have the necessary experience to direct moderate-complexity laboratories must obtain the necessary laboratory training. This training can be gained through a residency training program or by completing at least 20 hours of continuing medical education in laboratory practice commensurate with the responsibilities of the moderate-complexity laboratory director. This training should include principles and theory of laboratory practice and hands-on laboratory testing. Physicians gaining laboratory training and experience during their residency training programs for specialty certification will be qualified under the regulations to direct a laboratory performing moderate-complexity testing (e.g., a board-certified hematologist/oncologist).

C. Individuals who have earned a master's degree in chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution and have at least one year of laboratory training or experience or both; *and* at least one year of laboratory supervisory experience.
D. Individuals who have earned a bachelor's degree in chemical, physical, biological, or medical technology from an accredited institution *and* have at least two years of laboratory training or experience; and have at least two years of laboratory supervisory experience.
E. Individuals who qualified by Sept. 1, 1995, as a laboratory director under state law are qualified as a director for moderate-complexity laboratories under the federal CLIA standards.

Items C and D allow medical technologists and other health care professionals (e.g., nurses and physician assistants) to serve as directors of moderate-complexity testing provided they have the requisite degree in science and can meet the laboratory training, experience and supervisory requirements.

4. What are the responsibilities of a laboratory director?

Generally, the director is responsible for the overall operation and administration of the laboratory, including employment of personnel who are competent to perform test procedures and to record and report test results promptly, accurately, and proficiently. The laboratory director must be accessible during testing. Each individual director can *direct no more than five laboratories*. Specifically, the laboratory director must:

A. Ensure that the testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of the test performance;
B. Ensure that the physical plant and the environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected;
C. Ensure that the testing methods selected have the capability of

providing the quality of results required for patient care. Ensure that verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method. Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results;

D. Ensure that the laboratory is enrolled in an approved PT program and that all the requirements for participation in PT are met;
E. Ensure that the QC and QA programs are established and maintained;
F. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
G. Ensure that all remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified;
H. Ensure that reports of test results include pertinent information required for interpretation;
I. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of testing;
J. Employ a sufficient number of laboratory personnel who are appropriately qualified to provide consultation, supervise and perform tests and report test results prior to testing patient specimens;
K. Ensure that policies and procedures are established to monitor individuals who conduct pre-analytical, analytical, and post-analytical phases of testing, and whenever necessary identify need for remedial training or continuing education;
L. Ensure that an approved procedural manual is available to all personnel; and
M. Specify in writing, the responsibilities and duties of each consultant and each person engaged in the testing process—including an identification of which procedures and examinations each individual is authorized to perform, whether supervision is necessary, and whether consultant or director review is needed prior to reporting patient results.

5. Must the laboratory director be onsite during all testing?

There is no provision in the CLIA law that requires the lab director be onsite during all laboratory testing. CLIA regulations state that the lab director must be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed

6. Who can serve as a technical consultant?

The following individuals qualify to fill the role of technical consultant in a moderate-complexity laboratory:

A. Pathologists.
B. Individuals who hold a doctoral or master's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution with at least one year of

laboratory training or experience in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

C. Individuals who have earned a bachelor's degree in chemical, physical, biological or medical technology from an accredited institution and have at least two years laboratory training or experience in the designated specialty or subspecialty area of service for which the technical consultant is responsible.
D. Physicians who have at least one year of laboratory training or one year of experience or both, in the specialty or subspecialty areas for which the technical consultant is responsible. The training or experience may be acquired simultaneously in more than one specialty or subspecialty. For example, those physicians who have obtained laboratory training or experience during their medical residency training programs qualify as technical consultants of any specialty or subspecialty area related to their training or experience (e.g., board-certified hematologists would be qualified as technical consultants of all examinations and test procedures in the specialty of hematology).
E. The technical consultant requirements for laboratory training or experience in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual, who has at least a bachelor's degree in biology and additionally has documented two years of work experience performing tests of moderate complexity in all the specialties and subspecialties of service would be qualified as a technical consultant in a laboratory that performs moderate-complexity testing in all specialties and subspecialties of service.

7. What are the responsibilities of the technical consultant?

Generally, the technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant does not have to be on site but must be accessible to the laboratory to provide on site and telephone consultation as needed. Specifically, the technical consultant is responsible for:

A. Selecting test methods;
B. Verifying the test procedures and the establishment of the laboratory's test performance characteristics;
C. Enrolling and participating in an approved PT program;
D. Establishing a QC program (See Chapter 6);
E. Resolving technical problems and ensuring that remedial actions are taken when needed whenever test systems deviate from the laboratory's established performance specifications;
F. Ensuring that patient test results are not reported until corrective actions are taken and the test system is functioning properly;
G. Identifying training needs and assuring that each individual performing

tests receives regular in-service training and education appropriate for the laboratory and testing being performed;

H. Evaluating the competency of all testing personnel and assuring that all staff maintain their competency to perform the test procedures and report patient test results promptly, accurately and proficiently. The procedures for evaluation of competency must include, but are not limited to:
   - ❖ Direct observation of routine patient test performance;
   - ❖ Monitoring the recording and reporting of test results;
   - ❖ Review of intermediate test results and worksheets, QC records, PT results and preventive maintenance and function checks;
   - ❖ Direct observation of performance of instrument maintenance and function checks;
   - ❖ Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples; and
   - ❖ Assessment of problem solving skills.

I. Evaluating and documenting the performance of individuals responsible for moderate-complexity testing at least semi-annually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless that methodology or instrumentation changes, in which case, before reporting patient results, the individual's performance must be re-evaluated to include the new methodology or instrumentation.

8. Who can be a clinical consultant?

The following individuals qualify to fill the role of clinical consultant in a laboratory performing moderate complexity testing:

A. Pathologists.
B. A physician licensed to practice medicine in the state where the laboratory is located.

9. What are the responsibilities of the clinical consultant?

Generally, the clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. Specifically, the clinical consultant must:

A. Be available to provide clinical consultation to the laboratory's clients;
B. Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;
C. Ensure the reports of the test results include pertinent information required for specific patient interpretation of test results; and
D. Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of test results reported and their interpretation concerning specific patient conditions.

10. Who qualifies as testing personnel?

Specifically, the following individuals qualify to fill the role of testing personnel in a laboratory performing moderate-complexity testing:

- A physician (medicine or osteopathy) who is licensed to practice in the state where the laboratory is located.
- Individuals who have earned a doctoral, master's, or bachelor's degree in chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution.
- Individuals who have earned an associate's degree in chemical, physical, biological or medical technology from an accredited institution.
- High school graduates or equivalents who have successfully completed an official, military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of medical laboratory specialist (laboratory technician).
- Individuals who have earned an academic high school diploma or equivalent; and have documented training "appropriate" for the testing performed prior to their performance. The director must certify that laboratory personnel have the following skills:
    - Understanding proper specimen collection, including applicable patient preparation, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens
    - Able to implement all standard laboratory procedures
    - Able to perform each test method and operate each instrument properly
    - Able to perform instrument maintenance, troubleshooting, and calibration as required
    - Has a working knowledge of reagent storage and stability
    - Understanding and ability to implement all quality control policies and procedures
    - Awareness of factors that can influence test results
    - Able to assess and verify the validity of patient test results through the evaluation of quality control values prior to reporting test results

11. Would a nurse in a physician office laboratory be able to perform patient testing?

Yes. In most cases, a nurse, as well as other qualified individuals would be able to perform the laboratory testing in a physician office laboratory.

12. What are the responsibilities of testing personnel who perform moderate-complexity testing?

Generally, testing personnel perform the actual testing process.

Specifically, testing personnel must:

A. Follow the laboratory's procedures for handling specimens, processing tests, analyzing tests, and reporting and maintaining records of patient results;

B. Maintain records that demonstrate that PT samples are tested in the same manner as patient samples;
C. Adhere to the laboratory's QC policies, and document all QC activities, instrument and procedural calibrations, and maintenance performed;
D. Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;
E. Be capable of identifying problems that may adversely affect test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and
F. Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

Section 7.C
Personnel Standards for High-Complexity Testing

1. What are the personnel standards for high-complexity laboratories?

The personnel standards for high-complexity laboratories are appropriately more stringent than the requirements for moderate-complexity facilities. There are five functions that must be fulfilled in high-complexity labs:

A. Director;
B. Technical supervisor;
C. General supervisor;
D. Clinical consultant, and
E. Testing personnel.

Like the moderate-complexity testing sites, many individuals or a single individual with the appropriate training or experience could fill all five personnel roles required in a high-complexity laboratory.

2. Who may qualify as the director of a laboratory performing high-complexity testing?

The following individuals would be qualified to serve as a director in a laboratory performing high-complexity testing:

A. Pathologists.
B. Physicians with at least one year of laboratory training during residency (e.g., physicians certified either in hematology or both hematology and medical oncology) or at least two years of experience directing or supervising high-complexity testing.
C. Individuals who hold a doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution **and** are certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology or other Boards deemed acceptable by the Department of Health and Human Services.
D. Individuals who hold a doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution, but who are **not** board certified can qualify **if** they served as a director of a high complexity laboratory prior to February 24, 2003 and have two years of laboratory training or experience and two years directing or supervising a high complexity laboratory.
E. Individuals who served or could have qualified as a laboratory director under CLIA ’67 prior to February 28, 1992.
F. Individuals who qualify under state law as a laboratory director—provided they qualified by February 28, 1992.
G. Dentists certified by the American Board of Oral Pathology or who have equivalent qualifications.

3. What are the responsibilities of a laboratory director for high-complexity testing?

The director's responsibilities for a high-complexity facility are the same as for the moderate-complexity testing sites (see Section 7.B, Question 4) with one additional responsibility: The director must ensure that the general supervisor provides onsite supervision for high school graduates, trained in non-degree training programs, performing high-complexity testing. The director of a high-complexity laboratory may delegate these activities to qualified personnel but still is responsible for the proper performance of all duties. The director is responsible for the overall operation and administration of the laboratory, including hiring personnel to perform test procedures and track test results promptly, accurately and proficiently. The laboratory director must be accessible during testing. Each director can direct no more than five laboratories.

4. Who qualifies as a technical consultant of a high-complexity laboratory?

Individuals who have a bachelor's degree and four years of laboratory training or experience in the specialty or subspecialty of testing are permitted to provide technical supervision of high-complexity testing in the specialties and subspecialties of hematology, radiobioassay, microbiology, immunology and chemistry. Individuals with a master's degree in science must have two years of laboratory training and experience to fill the role of technical supervisor. A physician without certification in the specialty of pathology will be allowed to serve as the technical supervisor in all specialty and subspecialty areas—except cytology and histopathology—provided the physician has one year of training or experience in the specialty or subspecialty of testing being supervised. Those physicians who are not pathologists but who have medical laboratory residency training and experience acquired during their training programs for specialty certification will be qualified as technical supervisors of any specialty or subspecialty related to their residency training or experience. Specifically, the following individuals would be qualified to serve as a technical supervisor in a laboratory performing high-complexity testing:

A. Pathologists.
B. Someone with a medical degree, an osteopathy degree or a doctoral degree in science with one year of laboratory training or experience for the specialty (i.e., chemistry), at least six months of which are in the subspeciality.
C. Someone with a master's in science with two years of laboratory experience or training in the specialty with a minimum of six months spent acquiring proficiency in the subspecialty.
D. Someone with a bachelor's degree in science with four years of training or experience, with six months spent acquiring proficiency in the subspecialty.

5. Who may qualify as a technical supervisor?

The qualifications for this position depend on the specialties or subspecialties being supervised. Individuals with a doctoral, master's, or bachelor's degree and

the appropriate experience qualify. The amount of time required for appropriate experience varies according to the academic credentials of the individual. A non-physician with a doctoral degree needs one year of experience, the master's level requires two years, and the bachelor's level requires four years. With the exception of the following, all specialties and subspecialties require a combination of academic degree, laboratory experience and subspecialty experience: cytology, pathology, histocompatibility, clinical cytogenetics and immunohematology.

6. What are the responsibilities of the technical supervisor?

Generally, the technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical consultant does not have to be onsite but must be accessible to provide onsite and telephone consultation as needed. Specifically, the technical supervisor is responsible for:

A. Selecting test methods;
B. Verifying the test procedures and the establishment of the laboratory's test performance characteristics;
C. Enrolling and participating in an approved PT program;
D. Establishing a QC program (See Chapter 6);
E. Resolving technical problems and ensuring that necessary remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;
F. Ensuring that patient test results are not reported until corrective actions are taken and the test system is functioning properly;
G. Identifying training needs and assuring that each individual performing tests receives regular, in-service training and education appropriate for the laboratory and testing being performed;
H. Evaluating the competency of all testing personnel and assuring that all staff maintain their competency to perform the test procedures and report patient test results promptly, accurately and proficiently. The procedures for evaluation of competency must include, but are not limited to:
   - ❖ Direct observation of routine patient test performance;
   - ❖ Monitoring the recording and reporting of test results;
   - ❖ Review of intermediate test results and worksheets, QC records, PT results and preventive maintenance and function checks;
   - ❖ Direct observation of performance of instrument maintenance and function checks;
   - ❖ Assessment of test performance by testing previously analyzed specimens, internal blind testing samples or external PT samples; and . Assessment of problem-solving skills.
I. Evaluating and documenting the performance of individuals responsible for moderate-complexity testing at least semi-annually during their first year. Thereafter, evaluations must be performed at least annually unless the methodology or instrumentation changes, in which case the individual's performance must be reevaluated—before

reporting patient results—to include the new methodology or instrumentation.

7. Who may serve as a general supervisor of a high-complexity testing site?

The following individuals can fill the role of general supervisor in a laboratory performing high-complexity testing:

A. Physicians are qualified to function as general supervisors if they have at least one year of laboratory training or experience during medical residency training programs for specialty certification.

B. Individuals who are qualified as directors or technical supervisors of high-complexity testing are qualified to function as general supervisors.

C. Individuals with a doctorate, master's or bachelor's degree and one year of experience in laboratory training can qualify as general supervisors. This will permit nurses and other allied health care professionals to qualify as general supervisors.

D. Individuals with an associate's degree in laboratory science or medical technology also are qualified to be general supervisors provided they have at least two years experience in high-complexity testing.

E. Individuals who qualify under the Medicare/CLIA '67 regulations or under applicable state law as general supervisors for high-complexity testing, provided they qualified by the date of publication of these regulations.

F. Individuals with a bachelor's degree in respiratory therapy and one year of training or experience in blood gas analysis and those individuals who have an associate's degree related to pulmonary function and two years of training or experience in blood-gas analysis can serve as general supervisors in a blood gas laboratory.

G. Someone with a high school degree or the equivalent who began serving as a general supervisor on or before Sept. 1, 1992—provided the individual has at least 10 years of training or experience in high complexity testing, or six years of supervisory experience between Sept. 1, 1982 and Sept. 1, 1992.

H. Individuals who have graduated from an accredited laboratory training program (Accrediting Bureau of Health Education Schools, Commission on Allied Health Education Accreditation, etc.).

I. Individuals who successfully have completed a 50-week U.S. military medical laboratory training program and hold the military enlisted occupational specialty of medical laboratory specialist (laboratory technician).

8. What are the responsibilities of the general supervisor?

The general supervisor must provide day-to-day, but not necessarily onsite, supervision of testing personnel. However, direct onsite supervision will be

required for high-complexity testing performed by a high school graduate who does not meet the qualification requirements for testing personnel. In other cases, the general supervisor must be accessible to the laboratory to provide onsite, telephone or electronic consultation, as needed. Specifically, the general supervisor:

A. Is responsible for monitoring test analysis and specimen examinations to ensure that acceptable levels of analytic performance are maintained; and
B. Is responsible for the day-to-day supervision of personnel providing high-complexity testing. Additionally, the director or technical consultant may delegate to the general supervisor the responsibility for:
   - ❖ Assuring that all remedial actions are taken whenever test systems deviate from performance specifications;
   - ❖ Ensuring that patient results are not reported until all corrective actions have been taken and the test system is functioning properly;
   - ❖ Providing orientation to all testing personnel; and
   - ❖ Annually evaluating and documenting the performance of all testing personnel.

9. Who qualifies as a clinical consultant?

The following individuals may fill the role of clinical consultant in a high-complexity laboratory:

A. Any physician who meets the training or experience requirements for directing a high-complexity laboratory.
B. A physician licensed to practice medicine in the state where the laboratory is located.

10. What are the responsibilities of the clinical consultant?

Generally, the clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. Specifically, the clinical consultant must:

A. Be available to provide clinical consultation to the laboratory's clients;
B. Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;
C. Ensure that the reports of the test results include pertinent information required for patient-specific interpretation of test results; and
D. Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality and interpretation of test results.

11. Who qualifies as testing personnel?

CLIA '88 eliminates the delineation of "medical technologist,""clinical laboratory scientist,""medical laboratory technician," and "clinical laboratory technician," and instead refers to all non-management personnel as "testing personnel." The

following individuals can fill the role of testing personnel in a laboratory performing high-complexity testing:

A. Any individual qualified as a laboratory director, clinical consultant, technical supervisor or general supervisor;
B. A physician or an individual with a doctoral or master's degree in science is qualified to perform high complexity testing in specialty areas other than pathology;
C. An individual with an associate degree in science can perform high-complexity testing without direct, onsite supervision by a general supervisor;
D. Until Sept. 1, 1997, CMS allowed high school graduates to perform high-complexity testing under the onsite, direct supervision of a general supervisor. CMS expects that these individuals will complete the course work necessary to obtain an associate's degree in laboratory science or medical technology to continue to qualify to perform high-complexity testing.
E. Individuals hired after April 24, 1995, but before Sept. 1, 1997, must have obtained an associate's degree by Sept. 1, 1997.
F. Individuals who graduated from an accredited laboratory training program (i.e., Accrediting Bureau of Health Education Schools, Commission on Allied Health Education Accreditation, or another program approved by HHS);
G. Individuals who have successfully completed a 50-week U.S. military medical laboratory training program and hold the military enlisted occupational specialty of medical laboratory specialist (laboratory technician); and
H. Non-degreed individuals who have completed 90 semester hours in medical laboratory technology or laboratory science (including either 24 hours of medical technology, or six hours of chemistry, six hours of biology and 12 hours of courses in chemistry, biology or medical laboratory technology in any combination). In addition, individuals must have completed either an approved or accredited clinical laboratory training program or three months of documented training in each specialty in which the individual performs high complexity testing.
I. Respiratory therapy personnel with bachelor's or associate's degrees can perform blood-gas analysis in a blood gas laboratory.

12. What are the responsibilities of testing personnel performing high-complexity testing?

Generally, testing personnel perform the actual testing process. Specifically, testing personnel must:

A. Follow the laboratory's procedures for handling specimens, processing tests, analyzing tests, and reporting and maintaining records of patient results;
B. Maintain records that demonstrate that PT samples are tested in the

same manner as patient samples;

C. Adhere to the laboratory's QC policies, and document all QC activities, instrument and procedural calibrations, and maintenance performed;
D. Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;
E. Be capable of identifying problems that may affect test results adversely, and either correct the problems or immediately notify the technical consultant, clinical consultant or director; and
F. Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.
G. Earn an associate's degree by Sept. 1, 1997, if hired after April 24, 1995.

Chapter 8
The Inspection Process

1. As a waived laboratory, will I be inspected by CMS?

You are required, at the time of application for a certificate of waiver, to agree to permit CMS to conduct an inspection when the agency has substantial reason to believe that your laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; in response to complaints from the public; or on a random basis to determine whether your laboratory is performing nonwaived tests, and following manufacturer's instructions.

CMS is randomly inspecting 2% of all Waived and PPM laboratories each year. A pilot study with 10 states has shown that there is significant non-compliance with manufacturer instructions in Waived category laboratories. As a result, CMS decided to expand its random surveys of these laboratories to all states. The results nationally have been essentially the same as shown on the pilot. Through 2002, approximately 60% of these laboratories surveyed either did not have manufacturer instructions available or were not performing the Quality Control required by the manufacturer's instructions. Nearly a quarter of the laboratories had certificate issues. There were other categories of deficiencies as well. This is a significant issue being examined by the CLIAC (CLIA technical advisory committee.)

2. As a PPM laboratory, will I be inspected by CMS?

PPM laboratories are subject to the same random inspections as waived laboratories. (See above.) PPM laboratories are subject to Moderate Complexity regulations, since these laboratories are only exempt from the personnel regulations included in CLIA, but are subject to all other requirements. These laboratories showed problems in the following areas: 38% did not perform Proficiency testing (or otherwise did outside evaluations of the procedures they were performing at least twice per year); 36% had no centrifuge or microscope maintenance; 28% had no director approved procedure manual; 25% did not document personnel competency; and 23% had certificate issues.

3. Are laboratories that perform moderate- and high-complexity testing subject to inspection?

Yes. Laboratories performing moderate- (not PPM) and high-complexity testing are subject to a regular inspection every two years to ensure compliance with CLIA standards.

4. Is it possible to avoid an onsite survey inspection?

Yes. Laboratories that received an exceptional rating during their last onsite inspections are eligible to complete the Alternative Quality Assessment Survey form in lieu of participating in an onsite inspection. CMS mails the survey form to eligible laboratories, which are expected to complete and return the form within 15 days. Laboratories not meeting this deadline will be scheduled for an onsite

inspection. Unfortunately, the cost of the paper survey is the same as the cost of an onsite inspection. Laboratories performing cytology (Pap smear) testing are not eligible for this paper survey.

5. Who performs the inspections?

Inspections are usually performed by state agency surveyors under contract to CMS. Most of the surveyors worked as laboratory technologists before working for the state agency. Each state maintains its own CLIA implementation program through which these surveyors work. Laboratories registered by private accrediting organizations are inspected by one of the program's full-time or volunteer (depending on the organization) surveyors. These surveyors have laboratory backgrounds as well.

6. What will inspectors look for?

CMS has developed guidelines for inspectors to help them to determine whether or not a laboratory is in compliance with all of the CLIA requirements. These guidelines were developed with a greater emphasis on outcomes. As a result, quality and PT components will receive the greatest degree of review. The guidelines are expected to place a greater emphasis on outcomes. COLA already has provided its participants with suggestions on how to prepare for an inspection and a list of items for which inspectors will be looking. The CMS guidelines can be found online at: www.cms.hhs.gov/clia/appendc.asp.

HELPFUL HINTS:

- Don't forget that one of the advantages of participating in the COLA program is that you will be given an opportunity to self-inspect your laboratory before a COLA inspection. COLA will provide you with an evaluation and report of your deficiencies which you will be able to correct prior to the official inspection.
- Procedure manuals are necessary and are likely to be one of the first things the inspectors ask to see.
- Advance preparation will ensure that the survey process goes smoothly and quickly. Surveys last from two hours to three days.
- Laboratories that have all materials well-organized and easily accessible tend to find the survey less cumbersome.

7. Other than the biennial inspection, will CMS further inspect my laboratory?

CMS or its designee can inspect all laboratories that have been issued a CMS certificate or a certificate of accreditation, or state-exempt laboratories at any time as part of a complaint investigation. Additionally, CMS conducts random, sample validation inspections of privately accredited laboratories and laboratories in states with approved licensure programs (see Chapter 3).

8. How is the biennial inspection with CMS scheduled?

CMS inspections are announced except when following up on a complaint. Accreditation agencies may set their own policies but their surveys are almost always announced as well.

9. Do I have to pay for the biennial, and/or unannounced inspection?

Yes. Laboratories are required to pay for this biennial inspection as well as for the costs of investigations resulting from complaints if a problem is found. Please note that the actual inspection fee will depend on the number of specialties your laboratory performs and the volume of testing. Contact your state agency (Appendix A) for specific fee information.

10. How do these inspection fees compare to the fees of private and state accrediting programs?

The CMS fee schedule and the fee schedule for private state accrediting programs often is comparable. COLA's standard fee is competitive with CMS's fees.

11. When must I pay the biennial inspection fee?

CMS bills laboratories for the survey that will take place during the next two-year survey cycle halfway through the current cycle. For example, a laboratory that paid for its current inspection in Jan. 2007 will be billed in Jan. 2008 for the inspection that will take place sometime between Jan. 2009 and Jan. 2011.

Chapter 9
The Enforcement of CLIA ’88

1. What is the purpose of the enforcement standards?

The purpose of the regulations detailing the enforcement procedures of CLIA ’88 is to protect all individuals served by laboratories and to motivate laboratories to comply with the Medicare and CLIA ’88 standards, which promote accurate and reliable laboratory test results. The level of deficiencies within the lab determines sanctions that result from noncompliance. For this purpose, CMS has defined what constitutes a deficiency and has identified three levels of deficiency.

2. What are the three levels of deficiency?

CMS has created the following three types of deficiencies (defined as noncompliance with any of the conditions that a laboratory must meet to obtain a CLIA certificate):

A. Condition-level deficiencies with an immediate jeopardy;
B. Condition-level deficiencies without an immediate jeopardy; and
C. Deficiencies below the condition level without an immediate jeopardy, which are referred to as “standard deficiencies.”

3. What kinds of sanctions may be imposed on my laboratory?

A. *Principal sanctions:* The HHS Secretary may suspend, limit or revoke a laboratory’s certificate. When CMS suspends or revokes any type of CLIA certificate, it concurrently cancels the laboratory’s approval to receive Medicare payment for its services. When CMS limits the laboratory’s certificate, it concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory’s limited certificate. This type of sanctioning is likely to be imposed on a laboratory that poses immediate jeopardy to patients. In 2006, CLIA certificates of 73 laboratories were suspended, limited, or revoked.
B. *Alternative sanctions:* The HHS Secretary may decide an alternative sanction is appropriate. If so, a laboratory would be subject to a directed plan of correction, onsite monitoring, and/or a civil monetary penalty, typically $3,000 or $10,000 per day of infraction. This type of sanctioning is likely to be imposed on a laboratory that does not pose immediate jeopardy to patients. This is the type of sanctioning most often imposed on POLs. The purpose of the alternative sanctions is to give CMS some flexibility in penalizing laboratories prior to suspending, limiting or revoking a lab’s certificate issued under CLIA (defined as “principle sanctions”)—which cancels the laboratory’s approval to receive Medicare payment for its services. In 2006, alternative sanctions were imposed on 89 laboratories.
C. *Civil suit*: CMS also may bring suit to enjoin continuation of any laboratory activity that would constitute a significant hazard to public health.

D. *Criminal sanctions:* Any individual who is convicted of intentionally violating the CLIA standards may be subject to criminal sanctions. Five laboratories were convicted under federal or state laws relating to fraud and abuse, false billing, or kickbacks in 2004. One lab owner was sentenced to 60 months in prison and ordered to pay restitution of more than $2.5 million.

4. What factors will CMS consider when imposing a sanction?

CMS has developed a procedure for implementing sanctions that consider:

A. The nature, incidence, duration and severity of the deficiencies;
B. Whether the same condition-level deficiency has been identified repeatedly;
C. The relationship of one deficiency to another or others;
D. The overall compliance history of the laboratory;
E. The corrective and long-term compliance outcomes that CMS hopes to achieve through the application of the sanction; and
F. Whether the laboratory has made any progress toward compliance.

5. Will I be notified before a sanction is imposed?

If CMS identifies a laboratory that has a condition-level deficiency, the laboratory will receive written notice stating:

A. The condition-level noncompliance that has been identified;
B. The sanction or sanctions that CMS proposes to impose on the laboratory;
C. The rationale for the proposed sanction or sanctions;
D. The projected effective date and duration of the sanctions;
E. The authority for imposition of the proposed sanctions; and
F. The time allowed for the laboratory to respond to the notice.

6. How many days in advance will I be notified of a pending sanction?

Laboratories cited for deficiencies that do not pose immediate jeopardy will receive notification *15 days* prior to the imposition of the sanction. Those laboratories cited for deficiencies that do pose immediate jeopardy will be given five days notification prior to the imposition of the sanction. Laboratories may respond to the notice of a deficiency and the applicable sanction during this notification period.

Additionally, at the end of an inspection, the inspector should conduct an "exit interview," at which time the laboratory director will be given information about any deficiencies for which the laboratory is likely to be cited.

7. How long do the alternative sanctions remain in place?

Alternative sanctions continue until either the laboratory corrects all condition-level deficiencies, or CMS suspends, limits or revokes a laboratory's CLIA certificate. Alternative sanctions are not lifted until a laboratory's compliance with all condition-level requirements is verified. When a laboratory submits a credible allegation of compliance, CMS determines whether to certify compliance

on the basis of the information presented or to revisit the laboratory to verify compliance.

8. How long do I have to correct deficiencies once CMS imposes an alternative sanction?

Twelve months from the last day of inspection.

9. What happens if I am unable to correct the deficiency within 12 months?

If the laboratory does not correct the deficiencies once CMS imposes an intermediate alternative sanction within *12 months* of the last day of inspection, CMS may:

A. Cancel the laboratory's approval to receive Medicare payments, and discontinue Medicare payments as of the day the cancellation takes effect;
B. Following a revisit that indicates that the laboratory has not corrected deficiencies, CMS can notify the laboratory that it intends to suspend, revoke or limit the CLIA certificate (it also should notify the laboratory of its right to a hearing); and
C. Impose another alternative sanction that does not pertain to Medicare.

10. What sanctions can CMS impose when deficiencies are below the condition level?

Technically, if the laboratory has minimal deficiencies (e.g., lacks a current procedural manual), then the laboratory could be cited and would be responsible for submitting an acceptable plan of correction. If the laboratory does not correct the deficiency within *12 months*, CMS could cancel the laboratory's approval for Medicare payment, notify the laboratory of its intent to cancel the CLIA certificate and of the laboratory's right to a hearing or both. However, CMS surveyors are being encouraged to cite only deficiencies that have a direct negative effect on the quality outcome of patient care. If a deficiency that does not directly affect the outcome of patient care is discovered, surveyors are encouraged to alert the laboratory personnel of the problems and teach them how to resolve it. If you experience a survey in which you believe the surveyor has cited several areas that do not directly affect the outcome of patient care, you are encouraged to notify ACP staff.

11. Can an inspector visit my laboratory during the time allowed for correction of deficiencies?

Yes. The state survey agency or another CMS agent may visit the laboratory to evaluate progress during the period covered by the facility's plan of correction, and at the end of the period to determine whether the deficiencies have been corrected. If, during a visit, the laboratory provides credible evidence that it has achieved compliance before the visit, the sanctions are lifted as of the earlier date. If, during a revisit, the laboratory has not corrected its deficiencies, CMS may propose to suspend, limit or revoke the laboratory's certificate. If, at the end of the plan of correction, all condition-level deficiencies have been corrected, but

deficiencies still exist that are less than the condition level, CMS may request a revised plan of correction. The revised plan of correction may not exceed *12 months* from the date of the inspection that originally identified the cited deficiencies. If, at the end of the period covered by the plan of correction, the laboratory still has deficiencies, additional alternative or principle sanctions may be imposed.

12. Can CMS suspend part of the Medicare payments for laboratory tests rather than all Medicare payments for laboratory testing when a deficiency in my laboratory has not been corrected?

Yes. CMS may suspend part of Medicare payments if a laboratory is found to have condition-level deficiencies (i.e., inadequate PT results or lack of a procedural manual) with respect to one or more specialties, rather than all laboratory payments if the laboratory agrees not to charge Medicare beneficiaries or their private insurance carriers for those specialties and subspecialties. Before imposing this sanction, CMS must notify the laboratory and provide an opportunity to respond. This sanction continues until the laboratory corrects the deficiency, but no longer than 12 months.

13. When can CMS suspend all Medicare payments for laboratory tests if a condition-level deficiency is present?

CMS can suspend payments for all laboratory services if the laboratory has condition-level deficiencies when the following conditions are met:

A. The laboratory has not corrected its condition-level deficiencies included in the plan within three months from the last inspection; or
B. The laboratory has been found to repeat condition-level deficiencies during three consecutive inspections; and
C. The laboratory has chosen (in return for not having its Medicare approval immediately canceled) not to charge Medicare beneficiaries or their private insurance carriers for those services for which Medicare payment is suspended.

Before imposing this sanction, CMS must notify the laboratory and provide an opportunity to respond. This sanction continues until the laboratory corrects the deficiency, but will not exceed 12 months. If all deficiencies are not corrected within 12 months, CMS may cancel the laboratory's approval to receive Medicare payments.

14. What happens if I am issued a directed plan of correction?

When imposing a directed plan of correction, CMS must give the laboratory an opportunity to respond. CMS directs the laboratory to take specific, corrective action within a specified time period and directs the laboratory to submit the names of laboratory clients for notification purposes within ten calendar days. The laboratory clients must be notified of the sanction within 30 days of when the state agency receives the information.

If CMS imposes a principle sanction following the imposition of an alternative sanction, and CMS already has obtained a list of the laboratory clients, the agency

may use this list to notify clients that a principle sanction has been imposed. If CMS imposes a directed plan of correction, and on the revisit it finds that the laboratory has not corrected its deficiencies within 12 months of the last day of the inspection, the following rules apply:

A. CMS cancels the laboratory's approval for Medicare payments, and notifies the laboratory of its intent to suspend, limit or revoke the CLIA certificate.
B. The directed plan of correction continues in effect until the day of suspension, limitation or revocation of the certificate.

15. What will CMS consider when determining a civil monetary penalty?

CMS may impose a civil monetary penalty against any laboratory it determines has deficiencies, regardless of whether those deficiencies pose a serious risk. Factors CMS would consider in determining the amount of the penalty include:

A. The nature, scope, duration and severity of the deficiency;
B. The existence of repeat deficiencies;
C. The laboratory's overall compliance history including, but not limited to, any period of noncompliance that occurred between certifications of compliance;
D. Intent or reason for noncompliance; and
E. The accuracy and extent of laboratory records.

16. What are the ranges of civil monetary penalties that may be imposed?

A. For a condition-level deficiency that poses an immediate danger or jeopardy, the range is $3,050 to $10,000 per day of noncompliance or per violation.
B. For a condition-level deficiency that *does not pose an immediate jeopardy*, the range is $50 to $3,000 per day of noncompliance or per violation.

If immediate danger is removed (within five days) but the deficiency continues, CMS will shift the penalty amount to the lower civil penalty range. The final rule provides conditions under which CMS can increase or decrease penalty amounts. For example, if a laboratory does not request a hearing, CMS may decrease the penalty amount by 35 percent.

17. If a civil monetary penalty is imposed, does a laboratory have the opportunity to appeal?

The laboratory has 60 days to appeal the civil monetary penalty to an administrative law judge. CMS also has the ability to settle any case at any time.

18. Can CMS impose onsite monitoring?

Yes. CMS may require continuous onsite monitoring as a plan of correction to make sure the laboratory makes the corrections. The laboratory would pay the cost of the onsite monitoring—which would be computed by multiplying the number of hours by the hourly rate negotiated by CMS and the state. Before imposing this sanction, CMS will notify the laboratory and give the laboratory an

opportunity to respond. Once imposed, onsite monitoring will continue until CMS determines that the laboratory has the capability to ensure compliance with all condition-level requirements. If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, CMS may cancel the laboratory's approval for Medicare payment for its services and notify the laboratory of the agency's intent to suspend, limit or revoke the laboratory's certificate.

19. If I fail to perform PT successfully, can CMS impose training and technical assistance?

Yes. If the laboratory fails to perform PT acceptably on any specialty tests, CMS may require the laboratory to train its personnel and to obtain technical assistance, if necessary, to meet the requirements of PT.

20. When would CMS likely suspend, revoke or limit my CLIA certificate?

CMS may initiate adverse action to suspend, limit or revoke a laboratory's CLIA certificate if it finds that a laboratory owner or operator or one of its employees has:

A. Been guilty of misrepresentation in obtaining a CLIA certificate;
B. Performed—or represented the laboratory as entitled to perform—a test for which it is not certified;
C. Failed to comply with certificate requirements and performance standards;
D. Failed to comply with reasonable requests for information that CMS concludes is necessary to determine the laboratory's continued eligibility;
E. Refused a reasonable request for inspection;
F. Violated or abetted in the violation of any provision of CLIA;
G. Failed to comply with an alternative sanction; and/or
H. Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

21. Can CMS suspend, limit or revoke a CLIA certificate without a hearing?

No. Except in the following circumstances:

A. If the laboratory's deficiencies pose an immediate jeopardy;
B. If the laboratory has refused to respond to a reasonable request for information; and
C. If the laboratory refuses to allow an inspection.

22. When can CMS cancel a laboratory's Medicare approval?

CMS can cancel a laboratory's approval for Medicare payments under any of these circumstances:

A. When the laboratory is out of compliance with a condition-level requirement;

B. If the laboratory fails to submit a plan of correction; or
C. If the laboratory fails to correct its deficiencies within the specified time period.

The laboratory must be notified and given an opportunity to submit evidence against cancellation before the effective date of cancellation but is not necessarily given a hearing before that time.

23. Is my laboratory entitled to a hearing?

Laboratories are entitled to only one hearing.

A. The following actions (as initial determinations) would be subject to appeal:
   - ❖ The suspension, limitation or revocation of a certificate by CMS because of noncompliance, or by the OIG because of fraud and abuse, or for conviction of crimes related to CLIA certification;
   - ❖ The denial of a CLIA certificate;
   - ❖ The imposition of alternative sanctions (but not the determination as to what sanctions to impose); and
   - ❖ The denial or cancellation of the laboratory's Medicare approval.

B. The following actions are not initial determinations and therefore are not subject to appeal:
   - ❖ The finding that a laboratory accredited by a CMS-approved accreditation program or state licensing agency is no longer deemed to meet CLIA standards;
   - ❖ The finding that a laboratory has below condition-level deficiencies;
   - ❖ The determination not to reinstate a suspended CLIA certificate because the reason for the suspension remains and is likely to be a problem again;
   - ❖ The determination as to which alternative sanctions to impose, including the amount of civil monetary penalty to impose per day or per violation;
   - ❖ The denial of approval for Medicare payment for the services for which the laboratory does not have a certificate;
   - ❖ The determination that the deficiency poses an immediate jeopardy; and
   - ❖ The amount of the civil monetary penalty assessed per day or for each violation.

Out of 12 actions appealed in 2003, 10 cases were found in favor of CMS and 2 cases were dismissed.

C. Except for laboratories with continued operation that would pose an immediate jeopardy, the suspension, limitation or revocation is not effective until after a hearing decision has been issued. However, the effective date of discontinued Medicare payment would not be delayed just because a laboratory has appealed under this section and is waiting for a decision to become final. The administrative law judge's decision would be final unless a laboratory or affiliated party requests

an Appeals Council review within 60 days. Laboratories may request reconsideration of the judge's decision.

24. Can CMS initiate a civil action against a laboratory?

Yes. If CMS has reason to believe that continuation of any of a laboratory's activities would constitute a significant hazard to public health, the agency may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is posing harm. Upon proper showing, the court would issue a temporary injunction or restraining order, without bond, against continuation of the activity.

25. Will CMS be making information available to the public about laboratories that have been cited for deficiencies?

Yes. Once a year CMS will print information in its registry that is useful in evaluating the performance of laboratories. CMS must send an advance copy of the draft registry to its regional offices for verification of the information contained in the registry before making it available to the public. The information in the registry includes:

A. A list of laboratories convicted in fraud and abuse activities;
B. A list of laboratories that have had their CLIA certificate suspended, limited or revoked;
C. A list of people (laboratory owners, operators or employees) convicted of violating CLIA requirements;
D. A list of laboratories on which alternative sanctions have been imposed, showing corrective action taken by the laboratory and the date the laboratory achieved compliance;
E. A list of laboratories whose approval by private accreditors has been revoked and the reasons for revocation;
F. All appeals and hearing decisions; and
G. A list of laboratories that have been excluded from Medicare and Medicaid and the reason for the exclusion.

This registry can be found at www.cms.hhs.gov/clia.

26. Does CMS have to grant a laboratory a hearing before imposing a sanction?

No. CMS does not have to offer a laboratory the right to a hearing before imposing an alternative sanction; however, the agency is required to provide a reasonable opportunity for the laboratory to respond. This is not the case for civil penalties or principle sanctions which grant laboratories an opportunity to a hearing prior to the effective date of the sanctions (except laboratories that have deficiencies posing immediate jeopardy).

GLOSSARY

Accuracy: How close a determination is to the actual or true value.

Analyte: A substance or constituent for which the laboratory conducts testing.

Authorized Person: An individual authorized under state law to order tests or receive test results, or both.

Automated: An instrument or test system in which all analytical processes—including sample and reagent uptake, sample/reagent interaction, chemical/biological analysis, result calculation and result readout—are mechanized.

Batch: A specific quantity of a sample that has uniform character and quality within specified limits; it is produced according to a single manufacturing order during the same cycle of manufacture.

Calibration: The process of testing and adjusting an instrument, kit or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.

Calibration Materials: A solution with a known amount weighed in; this wording is used to replace the terms "standards" and "calibrators" because some are used interchangeably.

Challenge: For quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, the determination of the presence or the absence of an analyte, organism or substance in a sample.

CLIA: The Clinical Laboratory Improvement Amendments of 1988.

Condition-Level Deficiency: Noncompliance with any of the conditions of the regulations. A condition-level deficiency is more severe than a deficiency and thus carries greater sanctions.

Control: A substance that is used to determine whether the test results on unknown substances are valid.

Deficiency: Noncompliance with any of the standard level requirements that are below condition level ("lower level" requirements).

Event (PT): Each testing period during the year provided by proficiency testing providers. Each regulated analyte must be tested 3 times per year with a minimum of 5 challenges each cycle.

Exact Duplicates: Wording used to replace "records" or "copies" of an original report.

Function Checks: Activities performed regularly to ensure that an instrument, device or test system is performing properly. These activities usually are described by the manufacturer and may include such things as evaluating electrical levels, optical alignment, background counts, etc.

HHS: The Department of Health and Human Services, or its designee.

Interference: Occurrence of substances within a specimen—other than the one under study—that adversely influence the result.

Kit: All components of a test, which are packaged together.

Laboratory: A facility for the examination of materials derived from the human body for the purpose of providing diagnosis, prevention or treatment of any disease, or the assessment of the health of human beings.

Levey-Jennings Chart: A daily quality control chart with a calendar format.

Linear Range: The working range for each procedure, which is designed to produce accurate results.

Lot: May be an entire batch or a portion of a batch.

Non-regulated analyte: An analyte not listed in Subpart I of the CLIA regulations. Proficiency testing is not required by CMS, but some method of external evaluation must be done at least twice per year. If proficiency testing is available, this is the simplest method of meeting this requirement.

Operator Variance: The variance between individuals performing a test; this is a significant factor in test systems that are dependent on technique and therefore must be considered when determining frequency of quality control checks.

Performance Characteristics: A property of a test that is used to describe its quality—e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance Specifications: A value or range of values for a performance characteristic—established or verified by the laboratory—that is used to describe the quality of patient test results.

Precision: The degree to which repeated analysis of the same materials approximate each other.

Quality System: An ongoing process for monitoring and evaluating every step of a laboratory's testing operation.

Random Error: A determination error that may occur that is not inherent to the procedure itself.

Recalibration: The repeat performance of the calibration procedure after a certain time period or when an event has occurred that may have caused a shift in test values.

Rechecking: Involves using another group of samples of known concentration or activity to verify that the procedure is operating properly.

Regulated Analyte: An analyte listed in Subpart I of the CLIA regulations for which proficiency testing is required by CMS.

Referee Laboratory: A laboratory, currently in compliance with applicable CLIA requirements, that has a record of satisfactory proficiency testing performance and has been designated by an HHS-approved proficiency testing program for the purpose of determining the correct response for the specimens in a proficiency testing event.

Reference Range: The range of test values expected for a designated population of individuals—e.g., 95 percent of individuals presumed to be healthy (normal).

Reliability: A measure of the ability to achieve accuracy and precision over a period of time.

Reportable Range: The range of test values over which the relationship between the instrument, kit or system's measurement response is shown to be valid.

Run: An interval within which the accuracy and precision of a testing system is expected to be stable; it must not exceed a period of 24 hours and must not be less frequent than the manufacturer's specifications of including controls and calibration materials.

Sample: Material contained in a vial, on a slide or in another unit that is to be tested by proficiency testing participants.

Semi-Automated: An instrument or system in which some of the steps in the analytical process are mechanized but others require operator intervention.

Shift: Values distributing themselves above or below the mean on six or more consecutive days without either a consistent rise or fall.

Specificity: How well a method distinguishes the substance being tested for from other substances present within the specimen.

Standard: Refers to a primary reference material that is of fixed or known composition; it is capable of being prepared in essentially pure form and can be used to establish a reference point for all measurements.

Standard Deviation: The difference between an individual value and the arithmetic mean.

Trend: An increase or decrease in values occurring over six or more consecutive days.

Unsatisfactory Proficiency Testing: Failure to attain the minimum satisfactory score for an analyte, test, subspecialty or specialty for a testing event.

Unsuccessful Proficiency Testing: Failure to attain the minimum satisfactory score for an analyte, test, subspecialty or specialty for two consecutive—or two of three consecutive—testing events.

Verification of Reference Range: Necessary before reporting patient results; accomplished by testing a random sample of (normal) patient specimens and comparing the results with the reference range established by the manufacturer or documented in the literature.

Waived test: A test determined by the Food and Drug Administration to meet the criteria established for exemption from most CLIA regulations. These are not entirely unregulated. Following of manufacturer's instructions, including quality control performance/frequency, is mandatory. Two percent of all Waived category laboratories will be randomly inspected each year by CMS.

APPENDIX A – CMS Regional & State Offices (CLIA Contact List)

For the most recent state and regional office contact information, visit
www.cms.hhs.gov/CLIA

APPENDIX B – CLIA Approved Proficiency Testing Programs – 2008

AMERICAN ASSOCIATION OF BIOANALYSTS
205 West Levee Street
Brownsville, TX 78520-5596
(800)234-5315

AMERICAN ACADEMY OF FAMILY PHYSICIANS
11400 Tomahawk Creek Parkway
Leawood, Kansas 66211-2672
(800)274-7911

ACCUTEST
P.O. Box 999
Westford, MA 01886
(800) 665-2575

AMERICAN PROFICIENCY INSTITUTE
1159 Business Park Drive
Traverse City, MI 49686
(800) 333-0958

MEDICAL LABORATORY EVALUATION (MLE) PROGRAM
Suite 700
25 Massachusetts Ave., NW
Washington, DC 20001-7401
(800) 338-2746, (202) 261-4500

THE COLLEGE OF AMERICAN PATHOLOGISTS - SURVEYS
325 Waukegan Road
Northfield, IL 60093-2750
(800) 832-7000

CALIFORNIA THORACIC SOCIETY
202 Fashion Lane, Suite 219
Tustin, CA 92680-3320
(714) 730-1944

EXTERNAL COMPARATIVE EVALUATION FOR LABORATORIES–EXCEL
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
(800) 323-4040

MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENE
Office of health Care Quality – Laboratory Care
Spring Grove Hospital Center
Bland Bryant Building
55 Wade Avenue
Catonsville, MD 21228
(410) 402-8029

NEW YORK STATE 4321DEPARTMENT OF HEALTH
State of New York
Department of Health
The Governor Nelson A. Rockefeller State Plaza
P.O. Box 509
Albany, NY 12201-0509
(518) 474-8739

COMMONWEALTH OF PENNSYLVANIA
Department of Health
Bureau of Laboratories
P.O. Box 500
Exton, PA 19341-0500
(610) 280-3464

PUERTO RICO PROFICIENCY TESTING SERVICE
Public Health Laboratories of Puerto Rico
PO Box 70184
San Juan, PR 00936-8184
(878) 274-6827

WISCONSIN STATE
LABORATORY OF HYGIENE
Proficiency Testing Program
465 Henry Mall
Madison, WI 53706-1578
(800) 462-5261

CMS updates this list annually. For the most recent listing of approved PT programs, contact your CMS regional office. (See Appendix A.)

APPENDIX C

Internet Browser

The FDA has made a searchable database available to the public. This can be found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

This database is searchable by Test System Name, Analyte Name and a number of other variables. It is recommended that the "drop down" box be selected rather than entering free text as the system finds things only entered exactly as listed in the database. For instance, if ESR or SedRate is entered as the analyte, rather than Erythrocyte Sedimentation Rate, no records will be found.