VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF HEALTH PROFESSIONS
Staff Draft 3/25/2010

Workplan for the Review of Medical Laboratory Scientists and Technician

Background & Authority

By virtue of its statutory authority in §54.1-2510 of the *Code of Virginia* to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board is reviewing the need for regulation of laboratory scientists and technicians pursuant to a request from Delegate John M. O'Bannon. Delegate O'Bannon proposed House Bill 601 during in the 2010 Session of the General Assembly (attached). The legislation was continued to the 2011.

To govern evaluative reviews, the Board has developed formal criteria and policies referenced in its publication, *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions, 1998.* Among other things, the criteria assess the degree of risk from unregulated practice, the costs and benefits of the various levels of regulation, and the advantages and disadvantages of the various alternatives to regulation that might protect the public. By adopting these criteria and application policies, the Board has endorsed a consistent standard by which to judge the need to regulate any health profession. The aim of this standard is to lead decision-makers to consider the least governmental restriction possible that is consistent with the public's protection. This standard is in keeping with regulatory principles established in Virginia law and is accepted in the national community of regulators.

Study Scope & Methodology. The general scope of this study will be to provide an evaluative review of the policy literature, pertinent state and federal laws, malpractice and disciplinary data, potential economic impact, and public comment concerning the regulation of medical laboratory scientists and medical laboratory technicians in Virginia. The aim is to better understand the scopes of practice of these practitioners and issues relating to the need for adequate safeguards for the public's protection.

The Committee will make recommendations to the full Board concerning the practitioner group(s) to be selected. With the approval of the full Board, the Committee will examine the competencies currently expected of the selected practitioner groups in other jurisdictions to the degree that they exist. The Committee will focus their efforts in determining the answers to the following key questions for each group:

- What is the potential risk for harm to the consumer?
- What specialized skills and training do practitioners possess?
- To what degree is independent judgment required in their practices?
- Is their scope of practice distinguishable from other regulated occupations or professions?
- What would be the economic impact to the public if this group were regulated?
- Are there alternatives other than state regulation of this occupation which would adequately protect the public?
- If the Committee determines that this occupation requires state regulation, what is the least restrictive level that is consistent with the protection of the public's health, safety and welfare?

To answer the key questions, the following steps are recommended:

1. Conduct a review of the general policy literature, if any, related to the regulation of the respective group.
2. Conduct a review of the current relevant states laws and regulations.
3. Review malpractice insurance coverage data (if it is found to exist) in conjunction with other data to address Criterion One - Risk of Harm to the Public.
4. Review available reimbursement data to develop an estimate of how regulating this group may affect costs to address Criterion Five – Economic Impact
5. Prepare an initial draft report to the Board for public comment.
6. Conduct a hearing on the issue of the state regulation of this occupation, including any public health and safety issues germane to current practices as well as the potential fiscal impact which may result from such regulation.
7. Review all public comment, apply the Board's criteria and policies, and consider recommendations for changes in Virginia statute.
8. Prepare a draft with recommendations to the full Board.
9. Review the report and recommendations by the Board, and publish a draft report for consideration by the Department Director and Secretary.
10. If required based on recommendations by the Department Director and Secretary, amend the report and prepare a final report for their approval.

TENTATIVE TIMETABLE

May 4, 2010 - Review and Approval of the Workplan

Jul. 1, 2010 - First Draft Report to the Regulatory Research Committee

Jul., 2010 (TBD) - Public Hearing

Mid-Jul. 2010 (TBD) - Second Report with Summary of Public Comment to the Committee for Review and Consideration of Policy Options

Aug., 2010 (TBD) - Public Comment on Resulting Report and Recommendations

Sept., 2010 (TBD) - Regulatory Research Committee Meeting to Review Final Report and Make Final Recommendations to the Full Board. Full Board to Vote on Final Report and Recommendations

Oct., 2010 (TBD) - Final Report to the Department Director and Secretary of Health and Human Resources

Nov. 2, 2010 - Final Report Due to Legislative Services

Resources Required. The resources for this review are included in the FY 2010-11 Budgets of the Board of Health Professions. It is estimated that the review will require the services of a consulting policy researcher and 1/10th of the time of the Executive Director and general support from the Senior Regulatory Analyst and Operations Manager. The total cost associated for this project, to include staff time, telephone charges, photocopying, office materials, and court reporter, is estimated to be $8,500.

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HOUSE BILL NO. 601

Offered January 13, 2010

Prefiled January 12, 2010

A BILL to amend the Code of Virginia by adding in Article 4 of Chapter 29 of Title 54.1 sections numbered 54.1-2957.14 and 54.1-2957.15, relating to registration of medical laboratory scientists and medical laboratory technicians.

Patron-- O'Bannon

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Article 4 of Chapter 29 of Title 54.1 sections numbered 54.1-2957.14 and 54.1-2957.15 as follows:

§ 54.1-2957.14. Medical laboratory scientist and medical laboratory technician; definitions.

"Medical laboratory scientist" means a person who meets the requirements for registration as a medical laboratory scientist with the Board, and who engages in the development, performance, interpretation, and evaluation of laboratory tests in such areas as hematology, clinical chemistry, immunohematology, microbiology, serology/immunology, coagulation, molecular, and other emerging diagnostics.

"Medical laboratory technician" means a person who meets the requirements for registration as a medical laboratory technician with the Board, and who performs laboratory tests in such areas as hematology, clinical chemistry, immunohematology, microbiology, serology/immunology, coagulation, molecular, and other emerging diagnostics.

§ 54.1-2957.15. Registration as medical laboratory scientist or medical laboratory technician.

A. It shall be unlawful for a person to practice or hold himself out as practicing as a medical laboratory scientist or medical laboratory technician, or to engage in activities defined as constituting the practice of a person required to be registered as a medical laboratory scientists or medical laboratory technician as provided in regulations adopted by the Board, unless he has registered with the Board.

B. Every applicant for registration as a medical laboratory scientist shall pay the required fee and shall submit written evidence that the applicant:

1. Has received a baccalaureate degree from a regionally accredited college or university;

2. Has satisfactorily completed a program of experience and training required by the American Society of Clinical Pathology Board of Certification, American Medical Technologists, or other nationally recognized certification agency; and

3. Has passed a certification examination administered by the American Society for Clinical Pathology Board of Registry, the American Medical Technologists, or other nationally recognized credentialing agency.

C. Every applicant for registration as a medical laboratory technician shall pay the required fee and shall submit written evidence that the applicant:

1. Has received an associates degree or higher from a regionally accredited college or university;

2. Has satisfactorily completed a program of experience and training required by the American Society of Clinical Pathology Board of Certification, American Medical Technologists, or other nationally recognized certification agency; and

3. Has passed a certification examination administered by the American Society for Clinical Pathology Board of Registry, the American Medical Technologists, or other nationally recognized credentialing agency.

D. The Board shall adopt regulations to implement the provisions of this section.

2. That the Board of Medicine shall waive requirements related to receipt of the required baccalaureate or associates degree, satisfactory completion of an approved program of experience and training, and successful completion of a certification examination for persons seeking registration as a medical laboratory scientist or medical laboratory technician for any person who (i) makes application for registration before July 1, 2011; (ii) otherwise complies with regulations of the Board relating to moral turpitude; and (iii) has at least three years documented work experience as a medical laboratory scientist or medical laboratory technician.

July 1, 2010 Draft

Study of the Need to Regulate Medical Laboratory Scientists and Medical Laboratory Technicians

Virginia Department of Health Professions

Virginia Board of Health Professions

Table of Contents

I. Background and Authority

A. Authority

House Bill No. 601 was introduced by Delegate John M. O'Bannon during the 2010 Session of the Virginia General Assembly. This bill proposed the registration of medical laboratory scientists and medical laboratory technicians. "By virtue of its statutory authority in §54.1-2510 of the Cod e of Virginia to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board of Health Professions is reviewing the need for regulation of laboratory scientists and technicians pursuant to the request from Delegate John M. O'Bannon."

B. Background

Medical/clinical laboratory testing is a critical part of health care in this country. More than 10 billion laboratory tests are performed annually in the U.S. (ASCP, 2010 –fast facts). It is also estimated that laboratory testing is involved in approximately 70 – 80% of the diagnostic and treatment decisions made by physicians (VSCLS, 2010 correspondence "Clinical Laboratory Science Risk Assessment"). Some tests are relatively simple and routine, but many tests are complex and sophisticated. Tests of greater complexity require properly trained medical laboratory scientists and technicians by federal mandate. Advancing technology and research in this field mean more and more complex tests are being developed which will require trained personnel to properly conduct and interpret the results. However, despite the increasing need for such professionals, the educational and training programs necessary to prepare individuals to enter this field are in decline and have been for over 35 years.

With an aging population and more medical tests being developed and entering the market, the demand for medical laboratory testing in the U.S. is rapidly increasing. At the same time the number of medical/clinical laboratories is also increasing (Census, 2009), however, the number of programs to train qualified laboratory personnel is decreasing. Given these conditions of greater demand and decreasing resources, there are concerns about who will fill the laboratory personnel positions in medical and clinical laboratories in the future.

C. Potential for harm, why it should be examined

Based on the principles of occupational and professional regulation established by the Virginia General Assembly, the Board of Health Professions has adopted the following criteria to guide evaluations of the need for regulation of health occupations and professions. The first, and arguably, most important of these criteria is the risk of harm to the consumer.

In regard to the professions of medical laboratory scientists and medical laboratory technicians, there are numerous issues to consider.

- The increasing complexity and number of tests entering the market requires that qualified laboratory personnel stay continually educated. The same can be said for the rapid advancements in laboratory technology which require personnel to stay up-to-date and trained on new and sophisticated laboratory equipment.

- The field of medical laboratory science is somewhat hidden and unknown when compared to the more visible medical professions. While shortages in nurses and primary care physicians are discussed frequently in the press, little is ever heard about the shortages in medical laboratory personnel.
- The U.S. population is increasing at the same time it is aging. Both of these conditions mean that there will be a continued increase in the demand and need for medical testing.

Several studies have cited the frequency of laboratory error and indicated the potential for harm, per ASCP's 2005 policy statement on the State Licensure of Laboratory Personnel: A CMS study of waived testing laboratories indicates that incidents of failure to follow manufacturers' instructions may occur in as many as 60,000 laboratories and that this may "potentially harm patients (CMS, 2001)." Without adequate training of laboratory personnel, the likelihood of inaccurate test results increases (HCFA, 1995). A study of problems in laboratory testing in primary care estimates that more than 16 percent of incorrect test results affect patient care (Nutting et.al., 1996).

The ASCP's 2005 policy statement also outlines the importance of qualified laboratory personnel in the preparedness for bioterrorism and pandemic threats. "Laboratory professionals must provide prompt and accurate test results so that a potential outbreak can be detected, provide support for hospitals and clinics caring for affected patients and assist in the development of an integrated epidemic network. Laboratory professionals must be trained to recognize microbial pathogens likely to be used for bioterrorism; to safely collect, transport and process specimens containing biological agents associated with bioterrorist acts; to follow chain of custody and other legal requirements; and to understand the role of mass disaster support services" (Carroll et.al., 2003).

There are numerous certification and accreditation agencies that help to define the standards for medical laboratory scientists and technicians. There are also some states that regulate these professions through licensing. The federal government regulates the medical laboratory industry through its CLIA regulations. It is necessary to determine how effective these tools are in ensuring that laboratory personnel conducting tests are minimally qualified to do so.

II. The Profession/Role of Medical Laboratory Scientist and Medical Laboratory Technician

Medical laboratory professionals are a necessary and critical part of the medical professions. However, because they work behind the scenes, rarely coming into contact with the patients, their profession is not as well understood as those of doctors and nurses. However, nearly everyone who has ever seen a doctor for a medical diagnosis has benefited from their expertise.

A. Definition of Medical Laboratory Scientist (MLS) and Medical Laboratory Technician (MLT)

Medical Laboratory Scientists and Medical Laboratory Technicians are clinical laboratory professionals that most typically work in hospitals, medical offices and clinics, and independent (private) laboratories. Both professions are commonly known by other names:

- Medical Laboratory Scientists (MLS) are also known as medical technologists, clinical laboratory technologists, and clinical laboratory scientists.

- Medical Laboratory Technicians (MLT) are also known as clinical laboratory technicians, and medical technicians.

(To simplify this issue, throughout this report we will refer to these laboratory professionals as MLS and MLTs, although various professional organizations, accrediting organizations, etc. may use the other titles noted above.)

The difference between these two professional classes is found among level of education, complexity of the tests performed, and supervisory responsibilities.

B. Variance in duties and settings

Duties

Clinical laboratory testing plays a crucial role in the detection, diagnosis, and treatment of disease. MLSs and MLTs are a vital component in modern health care although their roles and responsibilities are not as well know as others in the medical professions.

The job responsibilities of clinical laboratory professionals generally include the collection, preparation, examination, and analysis of body fluids, tissues, and cells for signs of disease. They identify bacteria, parasites, infections, chemicals, and cell abnormalities; match blood for transfusions; and use technically sophisticated laboratory equipment. Some equipment is automated and must be kept properly calibrated. With the increased automation in many labs, the work has become less hands-on and more analytical. Test outcomes are evaluated for accuracy and results are relayed to the requesting physicians (BLS, 2010).

- MLSs routinely perform more complex tests that do MLTs. They also develop and modify laboratory procedures, evaluate and interpret test results, and establish and monitor programs to ensure testing accuracy. MLSs often supervise MLTs and other laboratory assistants (BLS, 2010).

- MLTs perform less complex tests and laboratory procedures than MLSs. They often prepare specimens for analysis and perform manual tests in accordance with detailed instructions. They usually work under the supervision of MLSs or laboratory managers (BLS, 2010).

A review of the National Credentialing Agency for Laboratory Personnel (NCA) examination content illustrates the differences between the MLS and the MLT professions. Throughout the content documents there are specific elements MLSs are required to know or perform that are not required of MLTs. These involve specific types of testing, as well as evaluating test results for possible additional testing. There are also laboratory management tasks included in the MLS content set such as monitoring productivity, workload, turn around time, quality control, etc. Content is categorized as "recall, application, and analysis." Both the MLS and MLT content sets include 150 total items, however the categories of this content differs (see Table 1). For a full description of the NCA examination content, see Appendix 1 (NCA Content).

Table 1 NCA Examination Content Categories by MLS and MLT				
	Recall	Application	Analysis	Total
MLS	29	72	49	150
MLT	47	87	16	150

(NCA content)

Settings

The settings in which MLSs and MLTs are employed vary widely. Hospitals, physician's offices and clinics, and private laboratories are the more standard settings. MLSs that work in smaller labs are often generalists and perform a wide variety of tests while those working in larger labs often specialize in one area. Areas of specialization include:

- Clinical chemistry technologists - prepare specimens/analyze chemical and hormonal contents of body fluids
- Cytotechnologists - prepare slides of body cells, examine cells microscopically for abnormalities
- Immunology technologists - examine elements of human immune system, its response to foreign bodies
- Immunohematology technologists - collect, type, prepare blood and its components for transfusions
- Microbiology technologists - examine/identify bacteria and other microorganisms
- Molecular biology technologists - perform complex protein and nucleic acid testing on cell samples

A review of data provided by CMS on the CLIA website for certified Virginia laboratories, also listed the following types of setting for medical/clinical laboratories:

Ambulance
Ambulatory Surgery Center
Ancillary Testing Site
Assisted Living Facility
Blood Bank
Community Clinic
Comp Outpatient Rehab Facility
End Stage Renal Disease Facility
Federally Qualified Health Center
Health Fair
Health Maintenance Organization
Home Health Agency
Hospice
Hospital
Independent
Industrial
Insurance
Intermediate Care Facility For Mentally Retarded
Mobile Laboratory
Other
Other Practitioner
Pharmacy
Physician Office
Prison
Public Health Laboratory
Rural Health Clinic
School/Student Health Service
Skilled Nursing Facility/Nursing Facility
Tissue Bank/Repositories

Advancement in the profession

Through additional education and experience MLTs may advance to become MLSs. MLSs may advance to supervisory or chief level positions, or laboratory managers in hospitals. Graduate degrees in life sciences or medical technology and professional certification may help with career advancement. Laboratory director positions usually require a doctorate. (BLS) CAP and JC standards for the position of Clinical Laboratory Director state that "the director should possess a broad knowledge of clinical medicine, basic medical sciences, clinical laboratory sciences, and operations." (See Appendix 2 for a listing of specific knowledge and performance criteria.) (CAP, 1999)

C. Bureau of Labor Statistics Information

The United States Department of Labor's Bureau of Labor Statistics (BLS) publishes an Occupational Outlook Handbook which provides information on many types of jobs. This information includes basic duties of the job, required training and education, average income, and current and projected employment prospects.

Current numbers of laboratory professionals

The number of MLSs and MLTs, as of May 2009, according to the BLS (BLS, 2010).

Table 2
Number of MLS and MLT professionals in the US and VA

	MLS	MLT	Total
United States	166,860	152,420	319,280
Virginia	4,720	3,950	8,670

Training and Education

- MLSs typically hold a bachelor's degree in a life science or in medical technology.
- MLTs typically hold an associate degree or a certificate.

According to the BLS:

"Most entry-level medical laboratory scientist positions require a bachelor's degree with a major in one of the following sciences: medical technology/clinical laboratory, chemical, physical, or biological. "However, it is possible to qualify for some jobs with a combination of education and on-the-job and specialized training. Some universities and hospitals offer medical technology programs.

Bachelor's degree programs in medical technology/clinical laboratory "include courses in chemistry, biological sciences, microbiology, mathematics, and statistics, as well as specialized courses devoted to knowledge and skills used in the clinical laboratory. Many programs also offer or require courses in management, business, and computer applications. The Clinical Laboratory Improvement Act (CLIA) requires technologists who perform highly complex tests to have at least an associate degree.

Medical laboratory technicians typically have an associate degree from a community or a certificate from a technical school, hospital training program, or the U.S. Military (BLS).

Income

Medical laboratory scientist (MLS):

As of May 2008,

- Median annual wages = $53,500.
- The middle 50 percent earned between $44,560 and $63,420.
- The lowest 10 percent earned < $36,180, and the highest 10 percent earned > $74,680. (BLS)

Median annual wages in the industries employing the largest numbers of medical laboratory scientists were:

Table 3 Industries and Median Wages of Medical Laboratory Scientists	
Federal Executive Branch	$59,800
General medical and surgical hospitals	$54,220
Medical and diagnostic laboratories	$53,360
Offices of physicians	$49,080
Colleges, universities, and professional schools	$47,890

Medical laboratory technician (MLT):

As of May 2008,

- Median annual wages = $35,380
- The middle 50 percent earned between $28,420 and $44,310
- The lowest 10 percent earned < $23,480, and the highest 10 percent earned > $53,520 (BLS)

Median annual wages in the industries employing the largest numbers of medical laboratory technicians were:

Table 4 Industries and Median Wages of Medical Laboratory Technicians	
General medical and surgical hospitals	$36,840
Colleges, universities, and professional schools	$36,290
Offices of physicians	$33,980
Medical and diagnostic laboratories	$32,630
Other ambulatory health care services	$31,320

Hourly wages and specialties

For purposes of comparisons, the table below shows where MLSs and MLTs fall on the hourly wage scale when compared with other medical laboratory professions. The median hourly wages of laboratory technologists and technicians, in various specialties and laboratory types, in 2007 were (ASCP):

Table 5 2007Median Hourly Wages of Clinical Laboratory Professionals By Specialty and Laboratory Type			
Specialty	**Hospital**	**Private Clinic**	**Physician Office Laboratory**
Cytotechnologist	$27.55	$28.75	$26.24
Histotechnologist	$22.93	$23.35	$25.00
Medical laboratory scientist	**$23.45**	**$23.00**	**$20.00**
Histotechnician	$20.00	$20.00	$21.00
Medical laboratory technician	**$18.54**	**$17.00**	**$16.96**
Phlebotomist	$12.50	$12.50	$13.00

D. Current/projected employment outlook

According to the BLS, medical laboratory scientists and technicians held about 328,100 jobs in 2008. More than half of these jobs were in hospitals, the rest were primarily in physicians' offices and in medical/diagnostic laboratories.

"Employment of medical laboratory workers is expected to grow by 14 percent between 2008 and 2018, faster than the average for all other occupations (BLS)."

Testing volume is also expected to increase due to an aging population, population growth, and advances in new types of tests.

Projected trends in medical/clinical laboratory positions:

Table 7
Projected Data from the National Employment Matrix (BLS)

Occupational Title	Employment 2008	Projected Employment 2018	Change 2008 - 2018	
			Number	Percent
Medical/Clinical laboratory technologist	172,400	193,000	20,500	+12%
Medical/Clinical laboratory technician	155,600	180,700	25,000	+16%
Combined total	**328,100**	**373,600**	**45,600**	**+14%**

NOTE: Data in this table are rounded. See the discussion of the employment projections table in the *Handbook* introductory chapter on *Occupational Information Included in the Handbook*.

Recent trends in the number of medical laboratories:

Table 8
Change in Number of Establishments* for Medical Laboratories (Census)

	1997	2007 (preliminary)	Change 1997 - 2007	
			Number	Percent
Number of establishments*	4,655	6,253	1,598	+34%

*Establishment – single physical location, classified by its major activity (if 2 or more are conducted at a single location).

E. Other laboratory professionals

For purposes of context, other laboratory professions were examined; one medical laboratory, one medical and sometimes employed in laboratories and one scientific laboratory but non-medical.

Laboratory Director

Laboratory directors are responsible for the overall operation and administration of the laboratory including managing a staff of qualified personnel. Depending on the qualifications of the laboratory staff, some of the director's responsibilities may be delegated but must follow CLIA regulations based on the complexity level of the lab's testing. Ultimately, laboratory directors are responsible to ensure that their laboratory provides accurate, reliable and timely patient test results.

Generally, the responsibilities of a laboratory director include:

- oversight of the physical and environmental conditions of the laboratory are adequate for the types of testing conducted and that it is a safe work environment for employees;
- ensuring use of appropriate and quality testing procedures throughout all phases of testing (pre-analytic, analytic, post-analytic);
- maintaining appropriate personnel levels to provide necessary supervision of personnel, testing, consulting and reporting and to ensure quality performance;
- regularly reviewing results of lab proficiency testing, policies and procedure manuals, staff performance, and quality control programs, to promote excellence through continuous improvement (CMS, 2010 – lab director).

Laboratory directors must have specific educational background and work experience. Generally, these requirement are a doctoral degree from an accredited institution in chemical, physical or biological science, a minimum of 4 years of clinical laboratory experience, and passing the certification organization's specified examination.

Under CLIA regulations, CMS specifies the necessary qualifications for laboratory directors in their regulations at 42 CFR 493.1405(b)(2)(ii)(B). Certification agencies also have specific requirements for laboratory directors seeking voluntary certification; the current approved certification boards for directors of high complexity testing are:

ABB – American Board of Bioanalysis
ABB public health microbiology certification
ABCC – American Board of Clinical Chemistry
ABCC 24-month Commission on Accreditation in Clinical Chemistry (COMACC) accredited program
ABFT – American Board of Forensic Toxicology
ABHI – American Board of Histocompatibility and Immunogenetics
ABMG – American Board of Medical Genetics
ABMLI – American Board of Medical Laboratory Immunology
ABMM – American Board of Medical Microbiology
NRCC – National Registry of Certified Chemists (CMS, 2010 lab directors).

Medical Assistant

Depending on the setting of employment, medical assistants may perform administrative or clinical tasks, or both. In smaller practices medical assistants are typically generalists performing various administrative tasks under the supervision of an office manager as well as clinical tasks under the supervision of a physician and other medical staff. In larger practices and settings, medical assistants may specialize in one area or department. Among the more clinical-focused tasks, state laws may dictate what a medical assistant is permitted to do. Generally, the responsibilities of a medical assistant may include:

- preparing patients for examinations by taking their medical histories and recording vital signs;
- assisting physicians during examinations;
- collecting/preparing laboratory specimens and performing basic laboratory tests;
- disposing of contaminated supplies and sterilizing medical instruments;
- purchasing and maintaining supplies and equipment;
- preparing waiting and examining rooms areas, and maintaining room instruments and equipment.

Additionally, under the direction of a physician, they may: prepare and administer medications; authorize drug refills and telephone prescriptions to a pharmacy; instruct patients about medications and special diets, explain treatment procedures; draw blood, remove sutures, change dressings; prepare patients for x rays, and take electrocardiograms (BLS, 2010 – med asst).

According to the BLS, in 2008 there were 483,600 medical assistants employed in the U.S. Of these, the majority (62%) worked in physicians' offices, 13% in hospitals, 11% in the offices of other health practitioners and the rest in other healthcare industries, such as outpatient care centers and nursing and residential care facilities. Median annual wages ranged from about $25,000 - $30,000. Growth in this profession (from 2008 to 2018) is estimated at 34%.

There are no formal education or training requirements for medical assistants. Some complete one or two year programs and most have a high school diploma. Training programs are offered in a variety of settings including on-the-job training, vocational high schools and postsecondary schools, community colleges and junior colleges. Postsecondary programs offer certificates and/or diplomas and some offer associate degrees. Course work generally includes: anatomy, physiology, and medical terminology, laboratory techniques, clinical and diagnostic procedures, pharmaceutical principles, the administration of medications, first aid, office practices, patient relations, medical law, ethics, keyboarding, transcription, recordkeeping, accounting, and insurance processing. There are two accrediting bodies that accredited medical assistant programs:

- ABHES: Accrediting Bureau of Health Education Schools
- CAAHEP: Commission on Accreditation of Allied Health Education Programs

In Virginia, accredited medical assistant programs are offered through ECPI, Act College, Bryant and Stratton College, and National College, as well as through numerous smaller institutions. Accredited programs often include an internship that provides practical experience in physicians' offices or other healthcare facilities (BLS, 2010 – med asst).

Forensic scientist

Like other laboratory scientists, forensic scientists evaluate and analyze evidence and interpret the results of those analyses. However, unlike the medical laboratory professionals, forensic scientists work in the arena of law instead of health, and are a key part of the justice and regulatory systems. The work of forensic scientists serves both criminal and civil justice and their conclusions may be used by either the defense or prosecution. Ultimately, the work that they do serves to help find the truth of a given set of circumstances (AAFS, 2010)

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Forensic scientists often work in a government setting. Federal government and many state and local governments operate their own forensic laboratories independently or through medical examiners'/coroners' offices, police departments, and universities (BLS, 2010 - forensic). Occasionally governments may contract with an independent forensic lab because they do not have their own lab, or because their labs is unequipped for more specialized analyses. Independent forensic labs also may provide testing for cases of civil litigation (DFS conversation, 6-29-10). This is an expanding area of forensic science that may address varying issues such as product liability, validity of signatures, compliance with environmental laws (AAFS, 2010). With the expansion of private forensic labs, there is a good deal of competition in the field for qualified forensic scientists. State and local labs struggle to compete with the higher wages that federal and independent forensic labs may offer (DFS conversation, 6-29-10).

There are numerous areas of specialization within the forensic science discipline, some of the more common include:

- Archeology
- Criminalistics (which encompasses biological, trace, impression evidence; ballistics, etc.)

- Digital & Multimedia
- DNA
- Engineering Sciences
- Entomology
- Jurisprudence
- Odontology
- Pathology/Biology
- Physical Anthropology
- Psychiatry & Behavioral Science
- Questioned Documents
- Toxicology

(AAFS, 2010; Wikipedia, 2010)

Depending on the area of specialization and employment setting, the specific tasks of a forensic scientist will vary. Generally, their duties include: preparing and analyzing physical evidence; conducting tests on substances or body fluids; identifying and classifying substances, materials, and other evidence; ensuring proper collection and storage methods of evidence; documenting chain-of-custody; recording analyses performed and findings; maintaining strict quality control; data management; reporting findings; and providing court testimony as an expert witness. (BLS 2010; AAFS, 2010)

According to the BLS, in 2008, there were 12,800 forensic science technicians employed nationally, and 430 in Virginia. It is projected that this profession will grow about 20% between 2008 and 2018 (BLS, 2010 – forensic).

In Virginia, a forensic scientist is required to hold a bachelor's degree in chemistry, biology, physics, molecular biology, or a related science. In the future, a master's degree may be required (jobs/VA, 2010). There are a few colleges and universities that offer degrees in forensic science; only 15 are master's level programs (DFS, 2010- website). With or without a forensic degree program, course work is important for those that would like to specialize in a particular area of forensic science. For example, extensive studies in chemistry are important for drug analysts, molecular biology is necessary for DNA analysts. Although graduate degrees are not always required in most disciplines, they are useful in career advancement (ASCLD, 2010 – website).

Currently, there are no mandatory licensing or certification requirements for forensic scientists. Many, however, earn certification from one of the many professional organizations that support forensic scientists and the various areas of forensic specialization:

- American Academy of Forensic Psychology
- American Academy of Forensic Sciences
- American Academy of Psychiatry and Law
- American Board of Criminalistics
- American Board of Forensic Anthropology
- American Board of Forensic Document Examiners, Inc.
- American Board of Forensic Odontology
- American Board of Forensic Psychology
- American Board of Forensic Toxicology
- American Society of Crime Lab Directors
- American Society of Forensic Odontology

- American Society of Questioned Document Examiners
- California Association of Criminalists
- California Association of Toxicologists
- Canadian Society of Forensic Science
- Forensic Sciences Foundation
- International Association for Identification
- International Association of Forensic Nurses
- International Association of Forensic Toxicologists
- Royal Society of Medicine
- Society of Forensic Toxicologists
- Southern Association of Forensic Scientists
- Southwestern Association of Forensic Scientists
- Southwestern Association of Toxicologists
- Young Forensic Scientists Forum

(ASCLS, 2010 – forensic)

In an extensive and congressionally mandated report from the National Research Council (NRC) in 2009, one of the recommendations stated that "laboratory accreditation and individual certification of forensic science professionals should be mandatory, and all forensic science professionals should have access to a certification process (NRC, 2009)." The report's overall findings cited a lack of standardization across the forensic science system and a critical lack of resources to support it.

III. Education and Training

A. Educational requirements

Typically,

- MLSs have a bachelor's degree in a life science,
- MLTs have an associate's degree in a science, clinical, or medical-related course of study.

MLS programs

The usual requirement for an entry-level position as a medical laboratory scientist is a bachelor's degree with a major in a life science or medical technology. Bachelor's degree programs in medical technology include courses in the life sciences, mathematics, statistics, and also include courses that detail the knowledge and skills specific to working in a clinical laboratory. Some also include courses in management, business, and computer applications (BLS, 2010). In some states, it is possible to qualify for some MLS positions without a bachelor's degree by having a combination of education and specialized on-the-job and training (BLS, 2010).

MLT programs

The usual requirement for an entry-level position as a medical laboratory technician is an associate's degree from a community or junior college or a certificate/diploma from a program offered through a hospital, a vocational or technical school, or the Armed Forces. In some states, technicians may be trained on the job (BLS, 2010).

B. Accrediting agencies for MLS/MLT education programs

Nationally, there are three accrediting agencies that offer either MLS and/or MLT educational programs:

- NAACLS National Accrediting Agency for Clinical Laboratory Science
- CAAHEP Commission on Accreditation of Allied Health Education Programs
- ABHES Accrediting Bureau of Health Education Schools

NAACLS accredits approximately 479 programs for medical laboratory scientists, medical laboratory technicians, as well as histotechnologists and histotechnicians, cytogenetic technologists, and diagnostic molecular scientists (BLS, 2010).

C. Accredited programs in Virginia

In Virginia, there are two accrediting agencies that offer either MLS and/or MLT educational programs (ABHES does not accredit any MLS or MLT programs in Virginia.):

- NAACLS accredits 7 MLS programs and 4 MLT programs in Virginia
- CAAHEP accredits 0 MLS programs and 1 MLT program in Virginia

Table 8
MLS Programs in Virginia,
by Location and Accrediting Organization

MLS Program	Location	Accrediting Org
Inova Fairfax Hospital	Falls Church	NAACLS
Augusta Health School of Clinical Laboratory Science	Fisherville	NAACLS
Rockingham Memorial Hospital	Harrisonburg	NAACLS
Norfolk State University	Norfolk	NAACLS
Old Dominion University	Norfolk	NAACLS
Virginia Commonwealth University	Richmond	NAACLS
Carilion Medical Center	Roanoke	NAACLS

Table 9
MLT Programs in Virginia,
by Location and Accrediting Organization

MLT Program	Location	Accrediting Org
Centra Health Systems, Inc.	Lynchburg	NAACLS
J. Sargeant Reynolds Community College	Richmond	NAACLS
Miller-Motte Technical College	Lynchburg	CAAHEP
Northern Virginia Community College	Springfield	NAACLS
Wytheville Community College	Wytheville	NAACLS

CAAHEP and ABHES also accredit numerous "Medical Assistant" programs throughout Virginia. These programs are often described as including some "clinical laboratory training." CAAHEP accredits 12 "Medical Assistant" programs and ABHES accredits 9 "Medical Assistant" programs across the Commonwealth.

Table 10 Medical Assistant/Assisting Programs* in Virginia, by Location and Accrediting Organization		
Medical Assistant/Assisting Program	**Location**	**Accrediting Org**
ACT College	Alexandria	ABHES
ACT College	Arlington	ABHES
ACT College	Manassas	ABHES
Bryant and Stratton College	Richmond	CAAHEP
Bryant and Stratton College	Virginia Beach	CAAHEP
ECPI College of Technology	Manassas	ABHES
ECPI Technical College	Roanoke	ABHES
Medical Careers Institute	Newport News	ABHES
Medical Careers Institute	Virginia Beach	ABHES
Medical Careers Institute	Richmond	ABHES
Medical Careers Institute	Richmond	ABHES
Medical Careers Institute	Newport News	CAAHEP
Miller-Motte Technical College	Lynchburg	CAAHEP
National College	Bluefield	CAAHEP
National College	Charlottesville	CAAHEP
National College	Danville	CAAHEP
National College	Harrisonburg	CAAHEP
National College	Lynchburg	CAAHEP
National College	Martinsville	CAAHEP
National College	Roanoke	CAAHEP
Tidewater Community College	Norfolk	CAAHEP

*Some are diploma programs; some are associate's degree programs

(CAAHEP, 2010; ABHES, 2010; NAACLS, 2010)

D. Body of knowledge

In order to help define and explain the medical laboratory professions, a record of the knowledge necessary to that profession is documented in a body of knowledge (BOK). It includes what is commonly accepted as the essential knowledge base for what is recognized and practiced in a given profession (ASCLS, 2004). As outlined by the ASCLS, its purpose is to

- "Emphasize knowledge unique to the profession (i.e., knowledge not contained in other professional domains), thus defining the identity of clinical laboratory professionals in their relationships to other professional, to administrators, to patients, and to the public
- Serve as a basis for: (1) Differentiating various levels of practice. (2) Creating or revision curricula and educational resources, (3) Developing assessment and certification examination, and (4) Designing job descriptions.
- Serve as a basis for defining career mobility and the required educational content to achieve a higher level of practice
- Serve as a source document that, through periodic revisions, will reflect scientific and technical advances in the profession" (ASCLS, 2004).

For both the MLS and MLT, (CLS and CLT are used by ASCLS) the BOK contains the following sections:

- Professional Description
- Administration/Management
- Clinical Chemistry

- Clinical Hematology & Coagulation
- Clinical Immunology
- Clinical Microbiology
- Education
- General Laboratory Practice
- Immunohematology
- Phlebotomy
- Renal Function & Urinalysis

In the BOK for MLS, there is an additional section not included in the BOK for MLT:

- Technical Consultant

(To view the full Body of Knowledge for MLS and MLT, see Appendix 3.)

E. National trends

Due to the aging workforce employed in these professions, the aging population of the country, and the medical and clinical research which results in increased and more sophisticated clinical tests, there is a current and projected need for greater numbers of MTs and MLTs. Despite the need for more medical laboratory scientists and technicians, the number of educational and training programs for these professionals is in decline.

> "In 1999, when the first NAACLS Strategies for Program Revitalization Task Force wrote its report, it stated that in the previous 25 years, over 40 percent of NAACLS accredited Clinical Laboratory Science/Medical Technology (CLS/MT) programs had closed, resulting in approximately 50 percent fewer graduates. Ten years have passed since that time, but the statistics now look even grimmer. In the past 25 years (1983-2008), the number of NAACLS accredited CLS/MT programs has decreased over 65%, which continues to result in approximately 50% fewer graduates, (NAACLS document, Program Revitalization – strategies for survival)"

Table 11
NAACLS Accredited Programs

Type of Program	2000	2010	Change 2000 - 2010	
			Number	Percent
MLS (technologist)	288	226	-62	-22%
MLT (technician)	249	205	-44	-18%

Examining the past decade, it seems the trend in the declining number of programs for MLSs and MLTs continues.

IV. Certification/Regulation

Ensuring that medical laboratory personnel possess the necessary knowledge, skills, and abilities is critical to quality patient care. This is managed in various ways. Some states require licensure, which sets minimum standards for personnel working in clinical labs, others don't. Some facilities require personnel to be certified by a professional organization, which also sets minimum standards. There are

federal requirements that specify which laboratory professionals are permitted to perform which types of tests or functions.

This section will review the various methods by which personnel are licensed, certified, and regulated and will review which states have passed laws concerning the licensure/certification of MLSs and MLTs.

A. Voluntary certification

Certification by a professional organization is a voluntary process and is a less restrictive form of regulation than licensure. Professional organizations will grant certification to persons who have met predetermined qualifications such as education, training, and experience, and who have passed a certifying exam. Fees are charged for the application and examination (ASCP, 2005).

Professional organizations that provide voluntary certification for MLSs and MLTs, as well as other types of clinical laboratory personnel are listed below. ASCLS and NCA no longer offer certification as they have recently or are currently in the process of merging with ASCP-BOC.

AAB	American Association of Bioanalysts
AMT	American Medical Technologists
ASCP-BOC	American Society for Clinical Pathology-Board of Certification
ASCLS	American Society for Clinical Laboratory Science (working on merging w ASCP-BOC)
NCA	National Credentialing Agency for Laboratory Personnel (now merged with ASCP-BOC)

In order to qualify for certification, one must meet the specific criteria set forth by the certifying organization for the specific discipline of their choosing. The criteria for each of the agencies offering certification for MLS and MLT professionals are available on their websites, noted below.

MT (ABB) - www.aab.org/aab/MT.asp?SnID=969574188
MLT (ABB) - www.aab.org/aab/MLT.asp?SnID=969574188
MT (AMT) - www.amt1.com/page.asp?i=168
MLT (AMT) - www.amt1.com/page.asp?i=185
MLS (ASCP) -
www.ascp.org/FunctionalNavigation/certification/GetCertified/TechnologistCertification.aspx#mt
MLT (ASCP) -
www.ascp.org/FunctionalNavigation/certification/GetCertified/TechnicianCertification.aspx#mlt

(In this listing, MT is the equivalent of MLS.)

B. State licensure and laws

Typically, licensure is awarded by a state government agency or body to those who have met the necessary qualifications and minimum competencies in a given and legally defined occupational scope of practice. A licensure requirement bans non-licensed persons from performing certain services and can also provide a universal standard for entry-level personnel. (ASCP, 2005). Licensure is more restrictive than certification, and sometimes requires the licensed person to maintain and keep current their skills through continuing education.

Certification, as described previously, is less restrictive than licensure, voluntary, and often included among the requirements for MLS and MLT licensure. By requiring professional certification, states are

assured that licensed personnel maintain certain minimum qualifications of continuing education and skills training (ASCP, 2005).

Despite the expense and bureaucracy involved in requiring MLSs and MLTs to be licensed, some who believe that state licensure provides an opportunity to increase professional recognition and as a result it may increase the recruitment of new and retention of current laboratory professionals. They argue that licensure helps to promote a professional image and educate the medical field, the public, and legislators about the importance of integrity and high standards in the medical laboratory professions (ASCP, 2005).

In Virginia

Currently Virginia has no state requirements that MLSs or MLTs be licensed, however many laboratories in Virginia may require MLSs and MLTs to be certified by one of the professional certification organizations.

In other states

There are currently twelve states and one U.S. territory with laboratory personnel licensure requirements for Medical Laboratory Scientist and Medical Laboratory Technician personnel:

- California
- Florida
- Georgia
- Hawaii
- Louisiana
- Montana
- Nevada
- New York
- North Dakota
- Rhode Island
- Tennessee
- West Virginia
- Puerto Rico

The components of the laws vary state-to-state, but usually include an annual licensing fee (some are bi- or tri-annual), a provision for continuing education, a minimum education and professional competency requirements. Most states (except California) require documentation of certification from an acceptable certification agency. Other requirements that may be expected are fingerprinting (Louisiana, other states currently considering adding this provision), documentation of certification, and documentation of education, training, and competency. Some states require documentation of a defined number of contact hours prior to issuing a license. California does not recognize any certification or any other state license. Most states give reciprocity for another state license as stringent as or more stringent than that state.

(See Appendix 4 for a list of the states with laboratory personnel licensure, their requirements, and contact information.)

Fees charged by the states for licensure cover a wide range. Amounts depend on the specific type of laboratory personnel seeking licensure and whether it is for an annual/initial licensure or a license renewal. By converting bi and tri-annual fees to reflect an annual fee, we can compare the fees charged across states. These comparisons show that annual/initial licensure costs range from $16 to $345. Licensure renewal fees range from $3 to $97.

- The average annual/initial fees for MLS is $90, for MLT is $77.

- The average renewal fee for MLS is $50, for MLT is $45.

For those states that did not indicate a different fee structure for MLT, the MLS fee structure is assumed (and is noted in the table in light gray text).

Table 12
Fees For Medical Laboratory Scientist and Medical Laboratory Technical Personnel Licensure
(Per Regulating States)

State	Annual/Initial fee		Renewal Fee	
	MLS	MLT	MLS	MLT
CA	$97.00	$97.00	$97.00	$97.00
FL	(initial) $105.00	(initial) $105.00	(every 2 yrs) $136.00	(every 2 yrs) $136.00
GA	?	?	?	?
HI	(initial) $10.00	(initial) $10.00	$3.00	$3.00
LA	$50.00	$50.00		
MT	(initial) $100.00	(initial) $100.00	$45.00	$45.00
NV	(initial) $50.00	(initial) $50.00	$25.00	$25.00
NY	(initial) $345.00	(initial) $245.00	(every 3 yrs) $170.00	(every 3 yrs) $120.00
ND	$90.00	$70.00	$80.00	$60.00
PR	(every 3 yrs) $50.00	(every 3 yrs) $50.00		
RI	$62.50	$31.25		
TN	$125.00	$125.00		
WV	$25.00	$25.00	$25.00	$25.00

	MLS	MLT	MLS	MLT
Mean	$90	$77	$50	$45
Range	$16.67(PR) - $345(NY)	$16.67(PR) - $245(NY)	$3(HI) - $97(CA)	$3(HI) - $97(CA)

State Licensure Issues

In the ASCP's 2005 policy statement on the state licensure of laboratory personnel, they cited a number of issues concerning state licensure that are worth mentioning.

Grandfather Provisions

> "To prevent disruption of the medical laboratory workforce, laboratory personnel licensure bills should include "grandfathering provisions" to allow individuals who have established careers as laboratory personnel to continue working at their current professional level. Typically, state licensure laws for laboratory personnel spell out certain criteria allowing an established laboratory practitioner to be licensed. At a minimum, grandfather provisions would need to conform to the requirements specified by CLIA for high complexity testing. This would generally require laboratory personnel to possess an Associate degree and appropriate clinical laboratory training, but could involve lesser qualifications depending on CLIA's requirements and the amount of work experience possessed by the laboratory practitioner. Individuals licensed via grandfathering provisions should be certified, provided they are eligible for a state-approved certification examination (ASCP, 2005)."

Continuing Education

"A continuing education requirement should be included in state licensure laws. Continuing education can help maintain the skill level of licensed laboratory personnel (especially as it relates to bioterrorism and new technologies) and is therefore a useful mechanism to ensure patient health and welfare (ASCP, 2005)."

Scope of Practice

"State licensure laws must define the scope of practice for laboratory professionals. The passage of a state licensure law is an opportunity to reaffirm the scope of practice for laboratory professionals and to ensure adequate personnel standards and protection of patient safety and health (ASCP, 2005)."

C. Federal regulation – Clinical Laboratory Improvement Amendments (CLIA)

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 which established quality standards for all laboratory testing, its objective being "*to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed* (CMS, 2010 – CLIA program description). The final CLIA regulations were published in February 1992.

The Centers for Medicare & Medicaid Services (CMS) regulates all clinical laboratory testing (excluding research) in the U.S. through its CLIA program. In total, CLIA covers approximately 200,000 laboratory entities. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities (CMS, 2010 – CLIA overview).

As defined by CLIA,a laboratory is

"... any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health," (CMS, 2010 – CLIA program description).

The types of laboratories regulated by CLIA include:

- Laboratories in hospitals, numerous types of clinics, home health agencies, prisons, ambulatory sites and physician offices
- Intermediate and long term care facilities, hospice
- Blood banks, tissue banks/repositories,
- Laboratories in federal facilities, industrial labs
- Point-of-care test sites in emergency rooms, surgical suites, ambulances, cardiac catheterization labs
- Outpatient facilities
- Independent labs, mobile labs, insurance companies/HMOs
- Health fairs, pharmacies
- Public health laboratories

(CMS, 2010 - CLIA lab demographics)

<u>Test Complexity</u>

Three categories of tests were established based on the complexity of the test method; requirements are more stringent for tests of greater complexity. The three categories of tests (listed from least complex to most complex) are:

- waived complexity,
- moderate complexity*
- high complexity.

[*Moderate complexity also includes a subcategory of provider-performed microscopy (PPM)].

Laboratories are surveyed (inspected) based on the complexity of tests performed. Surveys are performed in accordance with CLIA regulations by each state's surveying agency in order to determine the lab's regulatory compliance, improve its overall test performance, and assess the lab's ability to monitor itself. The survey process includes:

- observation of the laboratory's (past and current) practices,
- interviews with the laboratory's personnel,
- review of the laboratory's relevant documented records, and
- assessment of whether the laboratory is meeting the requirements of the CLIA regulations to produce accurate, reliable and timely (quality) test results (CMS, 2010 – CLIA outcome oriented survey process).

To enroll in the CLIA program, laboratories must first register by completing an application, pay fees, be surveyed (if applicable), and become certified. CLIA fees are based on the type of certificate requested by the laboratory (see Table 13) and, for moderate and high complexity laboratories, the annual volume and types of testing performed. Waived and PPM laboratories may apply directly for their certificate since they are not subject to routine surveys. Laboratories performing moderate and/or high complexity testing must be surveyed routinely and can choose whether they wish to be surveyed by CMS or by a private accrediting organization (CMS 2010 - CLIA program description).

Table 13
Types of CLIA Certificates and Conditions of Certificate

Certificate Type	Conditions of certificate
Certificate of Waiver	Lab may perform only waived tests
Certificate for PPMP*	Lab may perform only microscopy procedures and waived tests
Certificate of Registration	Lab may conduct moderate or high complexity testing (or both) until determined by survey to be in compliance with CLIA regulations
Certificate of Compliance	Lab is in compliance with all applicable CLIA requirements
Certificate of Accreditation	Lab is accredited by a CMS-approved accreditation organization

*Provider-Performed Microscopy Procedures (CLIA,2010 – types of certificates)

Types of CLIA Laboratories in Virginia

In Virginia, surveys of clinical laboratories participating in the CLIA program are conducted by The Acute Care Division of The Office of Licensure and Certification, Virginia Department of Health. There are currently 5,007 participating laboratories in Virginia. Approximately 80% of these are labs with Certificates of Waiver or PPM, meaning they are not routinely surveyed. (See Appendix 5 for a list of all labs in Virginia.)

Table 14 All CLIA Virginia Labs, by Type of Certificate	
Certificate Type	**Percent of Labs**
Waiver	59%
PPM	21%
Accredited	9%
Compliance	9%
Registration	1%

(CMS, 2010 - CLIA lab demographics)

Test Complexity and Personnel Requirements

CLIA regulations require that laboratory personnel have specific minimum qualifications depending on the testing complexity being performed in their facility. Table 15 displays the minimum personnel qualifications for each testing complexity level.

Table 15 CLIA Personnel Requirements, by Test Complexity Level	
Test complexity	**Minimum personnel qualifications**
Waived	None
Moderate Complexity	HS diploma or (equivalent)and documented training for the testing performed
High Complexity	Associate degree (including 24 semester hours in science) and completion of either: (1) accredited or approved clinical laboratory training program (2) three months laboratory training in the specialty(ies) in which the individual performs high complexity testing

(ASCP, 2005)

Federal agencies responsible for CLIA

CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of PT providers, accrediting organizations and exempt states. The Centers for Disease Control and Prevention (CDC) is responsible for the CLIA studies, convening the Clinical Laboratory Improvement Amendments Committee (CLIAC) and providing scientific and technical support/consultation to DHHS/CMS, and the Food and Drug Administration (FDA) is responsible for test categorization (CMS, 2010 - CLIA program description).

Certificate of Waiver Project

Since 1992, the types of tests waived under CLIA have increased from 8 to approximately 100 tests and the number of laboratories issued a certificate of waiver has increased from 20% to 65% of the estimated 214,000 laboratories enrolled in CLIA (CLS 2010 Legislative Symposium, 2010).De spite the enormous growth in these tests and the labs that use them, laboratories with certificates of waiver are not routinely inspected by the state surveyors. (See Appendix 6 for a list of Waived Tests or link to http://www.cms.gov/CLIA/downloads/waivetbl.pdf)

In April 2002, CMS began a program of educational on-site visits to those laboratories that have been issued a certificate of waiver under CLIA. State agency surveyors now conduct announced visits to 2% of these labs annually. This initiative is

> "designed to help educate the laboratories on sound laboratory practices. The State agency surveyors will ensure that personnel conduct quality testing in a manner which protects patient safety, determine each laboratory's regulatory compliance, and make certain that each laboratory is only conducting the more simple tests that are appropriate for a certificate of waiver facility. If

problems are uncovered, the surveyors will provide education and assistance to the laboratories to help them achieve more accurate, reliable and timely test results," (CMS,2010 – CLIA waived lab project).

ASCP cites a 2001 CMS study of facilities that performed waived testing and PPM which found widespread problems as proof of the need for greater oversight. Most of the testing at these facilities was performed by registered nurses, licensed practical nurses, practicing physicians, and medical assistants, not by medical laboratory professionals. Problems cited in the study included failure to have and/or follow current manufacturer's instructions for proper test performance, failure to perform quality control as required by the manufacturer or the CDC, and failure to perform required calibration according to the manufacturer's recommendations. Further, of the waived testing labs surveyed

- 23% did not have valid or appropriate CLIA certificates,
- 19% had inadequately trained or evaluated personnel,
- 9% did not follow the manufacturer's storage and handling instructions, and
- 6% used expired reagents/test kits.

In light of the 2001 study's findings, ASCP suggests these problems can be addressed through state licensure by requiring adequate training and certification of laboratory personnel in all laboratories (ASCP, 2005).

Proficiency testing

Proficiency testing (PT) is required for certain types of tests by CLIA regulations. Laboratories that perform these tests (referred to as "regulated analytes") are required to enroll in a CMS approved PT program for each of these tests. PT is used to verify the accuracy and reliability of a lab's testing and provides laboratory directors and staff with measurable indicators of their performance.

The way PT works is sets of proficiency testing samples are sent to a participating laboratory by a CMS-approved PT program about three times per year. After testing the PT samples in the same manner as it does patient specimens, the lab reports its sample results back to their PT program. The program grades the results using CLIA grading criteria then sends the laboratory its scores indicating how accurately it performed the testing. CMS and AOs routinely monitor their the performance of member laboratories. Although PT is not required for waived tests, it is encouraged as a method of monitoring and maintaining accuracy (CMS, 2010 – PT).

As of 3/16/2010, there are currently 13 CMS approved proficiency testing programs. (See Appendix 7 for a list of PT providers from CLIA or link to:
http://www.cms.gov/CLIA/14_Proficiency_Testing_Providers.asp#TopOfPage)

The survey process

The survey process through which medical/clinical laboratories are regulated is essentially an inspection. It involves a number of different agencies and organizations at the federal, regional, and state level, and may involve accreditation organizations, depending on the type of certificate the laboratory holds (waiver, PPM, accredited, compliance, or registration). Protocols are followed to ensure safety of patients, the public, and laboratory personnel. Labs with waiver or PPM certificates are not regularly surveyed, but may undergo a site visit as part of the Certificate of Waiver Project. Labs with accredited, compliance or registration certificates that conduct moderate or high complexity testing are surveyed. When conditions are discovered that might jeopardize safety, whether through the survey program or by a complaint, coordination of the various regulating agencies and organization is essential.

The survey process consists of certain critical elements which are included in the survey protocol:

A. Pre-Survey Preparation
    1. Initiate initial contact, as applicable (clarifying application information, scheduling survey if announced)
    2. Request proficiency testing history
    3. Review general laboratory history (changes since last survey, complaints, previous survey findings and corrective actions, laboratory staffing)
B. Entrance Conference
    1. State the overall survey goals and objectives (who, what, why?)
    2. Provide an overview of survey process (what will happen during this survey?)
    3. Tour the laboratory (may include the specimen workflow path)
C. Sample Selection Criteria
    1. Include new personnel, tests, equipment, laboratory information system, location
    2. Select proficiency testing data
    3. Identify number of testing sites, services offered, patient population served
    4. Observe critical activities (e.g., blood banking)
    5. Request critical values, laboratory's policy for such and actions taken
    6. Review prior compliance and complaint history
D. Information Gathering/Interviews/Record Review/Investigational Techniques
    1. Become interactive—show me
    2. Evaluate laboratory practice against written policy and procedures
    3. Observe and evaluate laboratory output (all testing steps, proficiency testing data, comparative data, QC and maintenance,)
    4. Examine quality Assessment program
    5. Balance records review and staff interaction (achieving the right balance is a surveyor skill learned through training and experience)
E. Exit Conference
    1. Provide a summary of findings: for deficiencies, include the standard, severity, and examples or data
    2. Afford an opportunity for laboratory to provide additional information
    3. Outline process for submitting plan of correction
    4. Indicate authority to remove copies of documents
    5. Solicit a Root Cause Analysis
        a. State this is a laboratory responsibility
        b. Look for and offer patterns and indicators
        c. Include corrective and preventive actions
        d. Offer guidance to the laboratory; however, laboratory must perform analysis
F. Plan of Correction
    1. Must demonstrate sustained compliance
    2. Ensure communication and collaboration among affected parties on serious issues Surveyor
G. Selection/Training/Oversight
    1. Qualifications: Medical technology training, laboratory experience, communication skills, auditing skills
    2. Training: teamwork skills, standards, mentoring and evaluation, documenting meaningful findings from observations, knowing and understanding the survey process, auditing techniques, flexibility, confidentiality, conflict of interest, professional conduct, sensitivity, continuing education in technical and soft skills, ongoing monitoring for effectiveness (CMS, 2010 – partners)

When particular situations of concern are found via survey or complaint, the surveying body (state or accrediting organization) notifies CMS through the appropriate regional office. CLIA regulations specify that this information must be communicated in writing or through the appropriate CMS data mechanism within a specific time frame and must contain the laboratory name, CLIA number, deficiencies identified, if applicable, and dates of identification or of any actions taken. These situations include:

- Immediate jeopardy situations (within 10 days)
- Newly accredited or licensed laboratories, including specialty, subspecialty and test volume information (within 30 days)
- Data related to unsuccessful PT performance and actions taken (within 30 days)
- Any adverse actions taken by the AO or the State, e.g., denial, withdrawal or revocation of accreditation or State licensure, limitation of specialty/subspecialty, etc (within 30 days)
- Revisions in specialty/subspecialty testing (additions or deletions) in existing accredited or CLIA exempt laboratories (within 30 days of receipt from the laboratory) (CMS, 2010 – partners)

As in any regulatory discussion, there are a number of terms used in regard to the survey process that require definition (CMS, 2010 – partners):

Immediate jeopardy	means a situation in which prompt corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury, or harm, or death, to individuals served by the laboratory, or to the health and safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.
Complaint investigation	includes any activity or follow up conducted by the SA, RO, approved State program, State licensure program or AO concerning a complaint received from any source. The investigation may or may not result in an on-site survey. A complaint is any information received by any of the above that causes doubt or concern regarding CLIA compliance of a regulated entity.
Validation Survey	is an on-site inspection of an accredited or state exempt laboratory by CMS or its agent, up to 90 days after the accrediting organization's (AO) or State Laboratory program's inspection, to assess compliance with CLIA requirements and ultimately, the results of these validation surveys reflect the performance of the AO or State program.
Expanded survey	is a focused survey that has been enlarged to include all condition and standard level requirements applicable to the laboratory operations because the focused survey findings resulted in a condition level deficiency or other findings or information warrant it.
Focused survey	is an on-site survey that addresses the deficient condition and requirements alleged by the complaint.
Unsatisfactory PT performance	means a failure to attain a minimum satisfactory score for an analyte, test, specialty or subspecialty for a testing event.
Unsuccessful PT Performance	means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for 2 consecutive or 2 of 3 testing events with a rolling time frame.
Unsuccessful participation in PT	means one of the following: (1) Unsatisfactory performance for the same analyte for 2 consecutive or 2 out of 3 testing events; Repeated unsatisfactory overall testing event scores for 2 consecutive or 2 out of 3 testing events for the same specialty or subspecialty; (2) An unsatisfactory testing event score for those subspecialties not graded by analyte, that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology for the same

> subspecialty for 2 consecutive or 2 out of 3 testing events; or (3) Failure of the laboratory performing gynecologic cytology to meet the requirements at 42 CFR 493.855.

Pending questions: The CMS regional office was contacted in June 2010 in hopes that they could assist us in answering the following questions pertaining to the CLIA program in Virginia:

- What are the five most frequently cited conditional deficiencies? Are any of these a result of PT? What were the conditions that made PT fail? Among these what are the five chief areas of potential harm?
- How many times was immediate jeopardy found in Virginia labs? What were the standards most frequently cited in a determination of immediate jeopardy?
- How many complaint investigations were undertaken in Virginia?

We hope to have this information available for the next draft of this report

Rapid Response Protocol (RRP)

The CMS central office is ultimately responsible for the effective administration of the CLIA program. It is involved when situations require a coordinated and rapid response to ensure safety. A Rapid Response Protocol (RRP) was developed to promote quick communication and essential coordination among the partners when survey findings or complaints have the probability of resulting in a significant impact to the public health or for other concerns such as media coverage, political concerns, legal/public interest issues, involvement of CMS central office staff, involvement of other Federal/State agencies/entities, coordinated response in cases of immediate jeopardy, or other situations where CMS central office coordination and handling may be necessary (CMS, 2010 – partners).

Alternate Quality Assessment Survey (AQAS)

AQAS is a program which allows moderate and high complexity labs that qualify to extend the period between onsite surveys by one certification cycle. It is designed to reward labs in good standing and used as a tool to educate and recertify labs. AQAS will provide a self-survey document consistent with the onsite survey process to interested and eligible laboratories that:

- Have been surveyed onsite during the certification period prior to being considered for receipt of the AQAS;
- Have zero or few minor deficiencies cited during the previous certification period; and
- Have participated satisfactorily in proficiency testing; i.e., attained a minimum satisfactory score for each analyte, test, subspecialty or specialty for each testing event since the last onsite survey.

Laboratories that are not eligible include labs performing cytology, histocompatibility and cytogenetics; and labs with substantiated complaints. These labs will be surveyed onsite. No laboratory will receive the AQAS for two consecutive certification cycles (CMS, 2010 – AQAS)

The Laboratory Registry

CMS makes available specific information useful in evaluating the performance of laboratories. CLIA and implementing regulations at 42 CFR 493.1850 require that this listing include the following:

> (1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.
> (2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reasons for the adverse actions.
> (3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the Public Health Service Act (PHS Act), together with circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing—
(i) the effective date of the sanctions;
(ii) the reason for imposing them;
(iii) any corrective action taken by the laboratory;
(iv) if the laboratory has achieved compliance, the verified date of compliance.
(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.
(6) All appeals and hearing decisions.
(7) A list of laboratories against which CMS has brought suit under Section 493.1846 and the reasons for those actions.
(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for exclusion.

Civil settlements reached with clinical laboratories are also noted (CMS, 2010 – registry). The Laboratory Registry may be accessed online at: http://www.cms.gov/CLIA/18_Laboratory_Registry.asp#TopOfPage

D. Laboratory accreditation

Accredited Labs

Laboratories performing moderate or high complexity testing can opt to be certified by either CMS or by one of the CMS-approved national accrediting organizations. Laboratories accredited by an accrediting organization (AO) are exempt from routine surveys by their state survey agency (this is referred to as deemed status) and are instead surveyed by the AO. However, labs with deemed status are required to meet, at minimum, the same conditions as required by CMS/CLIA and are sometimes required to meet additional, more stringent standards per the AO (CMS, 2010 - survey and certification).

CMS Approved Accrediting Organizations

- AABB
- American Osteopathic Association
- American Society for Histocompatibility and Immunogenetics
- College of American Pathologists
- COLA
- Joint Commission

(CMS, 2010 – AO)

The CMS approved accrediting organizations were contacted in June 2010 for information about their Virginia membership and asked to provide data that might help the BHP assess the risk of harm. As accrediting bodies, they were asked to provide information about complaints they have received about Virginia clinical labs, the nature of these complaints, and the types of labs against which these complaints were made. We hope to have this information available for the next draft of this report.

V. Literature Review

In the late 19th century, epidemics such as cholera and tuberculosis led to the development of tests able to detect their presence. These advancements brought the laboratory into the forefront of what was then considered modern medicine (Delwiche, 2003).

By more modern albeit bureaucratic standards, a clinical laboratory is defined as:

"...a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories," (CLIA, 1988).

The modern clinical laboratory is outfitted with an array of complex testing equipment and technical manuals. The demands of the current U.S. health care system require billions of laboratory tests be performed each year (ASCP, 2010 –fast facts). Laboratory errors are to be expected. A laboratory error is defined as "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these," (Bonini et.al., 2002), and "any error made by the personnel in a clinical laboratory in performing a test, interpreting data, or reporting or recording the results. Laboratory error must always be considered a possible explanation for findings that are at variance with the composite clinical condition of the patient or are widely divergent from previous laboratory tests. The general procedure is to repeat the test when an abnormal result is found," (thefreedictionary.com).

Error and phase of analysis

The total testing process (TTP) is defined by the activities in three related clinical workflow phases both outside and inside the laboratory:

- Pre-analytic activities: clinician test selection, test ordering, patient preparation, specimen collection, patient and specimen identification and specimen transport;
- Analytic activities: specimen processing and preparation, testing of the specimen, results review and verification and quality control (QC) checks;
- Post-analytic activities: turnaround time (TAT), critical value reporting, report formatting, general results reporting, clinician interpretation and follow-up, lab interpretive consultation services, specimen storage (Iancu, 2010)..

Numerous studies have examined the issue of laboratory error, many of which examined it from the perspective of in which phase of analysis the error took place. Although there is general agreement among these studies that most errors are found in the pre-analytic phase and the least are found in the analytic phase, the wide variance among the studies' designs make comparison difficult. Bonini et.al noted these comparability issues as the use of different data collection methods, different periods of study (from 3 months to 10 years), in different laboratory sectors, and differences in the reporting and measuring of the errors made. However at the same time it was found that, even when different study designs, population sizes, and error discovery methods were used, the distribution of errors across the three different phases of the testing process was very similar (Bonini et.al, 2002).

Plebani and Corraro examined errors in the hospital laboratory setting, including identifying most common types of errors. Among 40,490 analyses, 189 mistakes were found; 68% were in the pre-analytical phase, 13% occurred in the analytical phase, and 19% happened in the post-analytical phase. It was also found that 74% of the 189 errors had no effect on patient outcomes. Of the 26% that did affect patient outcomes, the error resulted in unnecessary investigation or inappropriate patient care. The specific type of error in each phases are listed in the table below (Plebani & Carraro, 1997).

Pre analytical (129 total errors)		Analytical (25 total errors)		Post analytical (35 total errors)	
39	Specimen collected from infusion route	16	Unacceptable performance	9	Correction of erroneous finding overlooked
36	Error in hospital unit identification	5	Isolated malfunctioning of instrument	5	Keyboard entry error
34	Physician's orders missed	4	Lack of specificity of the method	6	Turnaround time
6	Order misinterpreted			6	Physician not notified of problem
5	Inappropriate container used				
5	Wrong name of patient				
4	Specimen collection incorrect				

Supporting this general pattern, Nutting et.al. also found that lab errors occurred primarily in the pre and post analysis phases: 56% were pre analytical, 13% were analytical, and 28% were post analytical. They also noted that of the 180 problems reported, 45 were in physician's office laboratories and 135 in reference laboratories. Additionally, 27% of the errors were reported to have negative effects on patient care, such as delays in treatment and/or diagnosis, and repeat testing (Nutting et.al., 1996).

Iancu also looked at errors in the various phases of the testing process among recent studies and found that, indeed, most errors are due to pre-analytical factors (46% to 68% of total errors), and the post-analytical phase has the second highest error rate (19% to 47% of total errors), (Iancu, 2010). Similar ranges were estimated by The Laboratory Medicine National Status Report with pre-analytic phase errors of 32% to 75%, analytical phase errors of 13% to 32%, and post-analytical errors of 9% to 31% (CDC, 2008).

Advances in technology and quality controls developed for the analytical phase corrected most of the errors for this phase, and errors due to analytical problems were significantly reduced over time. There is evidence, however, that interference and interruption may have a serious impact on patient care in that the majority of errors occur in pre-analytical testing, especially in manually intensive processes (Iancu, 2010).

The difference in error rates between in- and outpatients is noteworthy: In Bonini and Plebani's 2002 study there were a total of 15,503 errors among 2,583,850 test results (0.60%) for inpatients vs. 792 errors among 2,032,133 tests results (0.039%) for outpatients. They cited multiple reasons for this difference: in an outpatient setting there is greater control of sample drawing when compared with hospital personnel who had a high degree of turnover and lower skills in the inpatient setting, and inpatients had higher complexity examinations performed and multiple blood drawings. (Bonini & Plebani, 2002)

Bonini and Plebani (2002) also provided further insights on the analytic and post-analytic phases of the testing process: there is evidence that the analytical error rate has improved significantly over time (Witte et.al., 1997) which is likely the result of the improved training and qualifications of testing personnel (Hurst et.al., 1998) (Stull et.al., 1998) and improvements in defining the allowable errors in internal quality-control practice (Jenny & Jackson-Tarentino, 2000). Other quality assessment programs and proficiency testing help identify analytical errors and prevent further errors (Cembrowski & Carey, 2000).

Regarding the post-analytical phase, a few studies have examined how laboratory results are managed. Technology plays a role, i.e., an online connection between the lab and the wards, that without proper organization, made communication between the two worse (Kilpatrick & Holding, 2001) which could result in harm when results involve a critical value. In addition to prompt communication, the quality of communication is also important. Kanagasabapathy (2010) noted that the quality of the comments on test results made by senior laboratory personnel can provide value, especially when an interpretation is offered on the more complex tests, and can help or influence patient management. However, some comments found in the study reflected incorrect or misleading interpretation and advice (Kanagasabapathy, 2010).

Part of the problem with laboratory error is that no one is responsible to see a test through from pre-analysis all the way through post-analysis (Graban, 2009). Or as Novis (2008) put it the "problem is not the personnel, it's the process" (Novis, 2008). This suggests a patient-centered approach to delivery of health care services, without regard to which analytical phase is more concerned with seriousness of error. "Elimination of patient misidentification and better communication of results should be the main goals for quality improvement," (Plebani, 2010).

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