THE VIRGINIA BOARD OF HEALTH PROFESSIONS
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

Study into the Need to Regulate

Laboratory Scientists & Technicians

in the Commonwealth of Virginia

March 2012

Virginia Board of Health Professions
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ABOUT THIS DOCUMENT

The Board of Health Professions began this study in Spring of 2010. An independent contractor completed an initial report in September of 2010. The Board required additional information, including the results of a FOIA request to the Federal Centers for Medicare & Medicaid Services and a listing of policy options. Board staff completed the study after September 2010.

The initial report prepared by the contractor included several Appendices. These Appendices included thousands of pages of publicly available Federal and state statutes and regulations. We did not reproduce those Appendices here, but they are available from the Board upon request. Additionally, scanned copies of the original documents provided by CMS pursuant to our FOIA request are available upon request.

This document incorporates the four documents produced by the Board during the course of this study. Other briefings and presentations are available as attachments to the Regulatory Research Committees' meeting minutes. The documents incorporated here are:

1. Laboratory Scientists and Laboratory Technicians: Policy Options,
2. Clinical Laboratory Scientist/Technician: FOIA Request Overview,
3. A Summary of the FOIA request and the documentation provided by CMS, and,
4. The initial report produced by the contractor.

The Policy Options Document acts as an executive summary and is listed first. It includes a summary of findings and the recommendation of the Board. Other documents appear in reverse chronological order.

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(This document includes its own Table of Contents)

LABORATORY SCIENTISTS AND LABORATORY TECHNICIANS: POLICY OPTIONS

AUTHORITY

Delegate John M. O'Bannon introduced House Bill No. 601 during the 2010 Session of the Virginia General Assembly. The bill proposed registration of medical laboratory scientists and medical laboratory technicians. 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 of Health Professions is reviewing the need for regulation of laboratory scientists and technicians pursuant to the request from Delegate John M. O'Bannon.

The review was initially undertaken in summer of 2010 by an independent contractor, and the Board of Health Professions' Regulatory Research Committee (RRC) held a public hearing on July 16, 2010. The contractor submitted a document entitled *Study of the Need to Regulate Medical Laboratory Scientists and Laboratory Technicians* in September of 2010. At its September 29, 2010 meeting, the RRC recommended that some regulation of medical laboratory scientists and technicians was warranted. However, action was tabled pending further research on the proper form of regulation. Completion of the study was undertaken by Board of Health Professions staff.

On April 14, 2011, staff received documents from the Centers for Medicare & Medicaid Services (CMS) pertaining to a Freedom of Information Act (FOIA) request submitted by the independent contractor for documents related to complaints and deficiency citations in Virginia's clinical laboratories. The RRC reviewed these documents at its June 20, 2011 meeting and requested staff to prepare a description of policy options. Since the Board has experienced turnover, we have also included a summary of staff findings in this document.

SUMMARY OF FINDINGS

1. Laboratory tests are an essential part of modern medical practice, and their quality directly influences patient health.

Health and laboratory workers perform over 10 billion laboratory tests every year. Up to 80 percent of medical diagnoses are based on laboratory test results. Laboratory tests are often essential for developing treatment plans, including drug regimens and transfusions. Inaccurate laboratory results, or delays in providing results, can result in significant harm to patients, including death.

2. Clinical laboratories and tests are changing rapidly due to technological advances. Technological change is affecting clinical laboratories and tests in two ways. First, new tests are being developed at the vanguard of medical practice in areas such as genetics and molecular medicine. Performing and understanding these tests often requires new skills and updated education in these areas. Meanwhile, technological advances are making existing tests easier and more routine to perform. Tests which previously required skilled professional judgment and expensive laboratory equipment are now provided at the point of care, in nursing homes, ambulances, pharmacies or in patient's homes. They are performed by nurses, pharmacy technicians, family caregivers or patients themselves. Most labs are not centralized independent or hospital labs, but are point of care labs. (See Table, next page).

3. Clinical Laboratory Workers fall into three generalist and various specialist roles.

Generalist Roles

A. Medical Laboratory Scientists—Perform laboratory tests on tissues and fluids. Scientists perform the most complex tests, develop procedures, interpret test results and maintain quality control processes, including responsibility for automated equipment testing processes.
Training: Bachelor's in a life science or a combination of training and experience.

B. Medical Laboratory Technicians—Perform laboratory tests on tissues and fluids. Technicians perform less complex tests, prepare specimens for analysis and perform manual tests with detailed instructions. Technicians usually work under the supervision of scientists or otherwise qualified laboratory managers.
Training: Post-Secondary Certificate or Associate Degree, or a combination of training and experience.

C. Phlebotomists—Collect and process blood and other laboratory samples, usually under the supervision of a laboratory technician.
Training: On the job training or training certificate.

Examples of Specialist Roles

A. Cytotechnologists—Prepare and analyze cell samples for abnormalities indicating disease. Generally, cytotechnologists analyze Pap smear tests and other tests for cancer.
Training: Bachelor's degree in cytotechnology, or a post-graduate training certificate in cytotechnology

B. Histotechnologists—Prepare thin tissue slices for examination under a microscope by a clinical pathologist.
Training: Bachelor's degree with a science emphasis and advanced training or one year experience working with a pathologist.

C. Specialists in Blood Banking—Specialists in blood center and transfusion services operations. Collect and process blood, analyze blood types and blood abnormalities, and provide transfusion therapy services.
Training: Postgraduate certificate or master's degree

Lab Type	# Certified in Virginia	# Waived	Percent Waived
AMBULANCE	16	14	88%
AMBULATORY SURGERY CENTER	72	62	86%
ANCILLARY TEST SITE	62	28	45%
ASSISTED LIVING FACILITY	4	3	75%
BLOOD BANKS	13	4	31%
COMMUNITY CLINIC	118	44	37%
COMPREHENSIVE OUTPATIENT REHAB	5	4	80%
END STAGE RENAL DISEASE DIALYSIS	127	126	99%
FEDERALLY QUALIFIED HEALTH CENTER	27	8	30%
HEALTH FAIR	17	17	100%
HMO	24	8	33%
HOME HEALTH AGENCY	209	207	99%
HOSPICE	51	48	94%
HOSPITAL	160	32	20%
INDEPENDENT	101	25	25%
INDUSTRIAL	42	40	95%
INSURANCE	2	2	100%
INTERMEDIATE CARE FACILITY	5	5	100%
MOBILE LAB	56	44	79%
OTHER	477	326	68%
OTHER PRACTITIONER	88	55	63%
PHARMACY	200	198	99%
PHYSICIAN OFFICE	2894	1449	50%
PRISON	4	4	100%
PUBLIC HEALTH LABORATORY	4	2	50%
RURAL HEALTH CARE CLINIC	23	9	39%
SCHOOL/STUDENT HEALTH SERVICE	64	42	66%
SKILLED NURSING/NURSING FACILITY	256	252	98%
TISSUE BANK/REPOSITORIES	2	0	0%
Total (January 2010)	5123	3058	60%

4. The 1988 Federal Clinical Laboratory Improvement Amendments (CLIA) are the main regulatory apparatus ensuring the quality of clinical laboratory services.

The Centers for Medicare & Medicaid Services administers CLIA in conjunction with the Food and Drug Administration and the Centers for Disease Control and Prevention. All clinical laboratories (not just those receiving CMS reimbursement) are required to be certified through CLIA. CLIA's regulatory approach involves certifying clinical laboratories based on the type of laboratory tests performed. Certified laboratories must meet standards, including personnel standards, based on the complexity and the risk of harm of the tests performed, and their potential risk of harm. CLIA uses a combination of lab surveys, complaint investigations and proficiency testing to enforce standards. In Virginia, surveys and investigations are conducted by either the Virginia Department of Health, or a private accreditation agency "deemed" by CMS to have equivalent standards to CLIA. Proficiency testing is performed by private proficiency testing companies on behalf of CMS. Proficiency testing tests lab personnel individually as well as lab quality control measures in general. An outline of test categories, lab categories and their related standards and enforcement procedures appears below:

Test Type	Definition	CLIA Personnel Requirements
Waived	Low complexity and low risk of harm. These tests are often performed by providers at the point of care.	None
Moderate Complexity	Moderate Complexity and/or risk of harm	HS diploma and documented training
High Complexity	High complexity and/or risk of harm	Associate degree and completion of either: 1) accredited or approved clinical laboratory training program 2) three months laboratory training in specialty
Provider-Performed Microscopy Procedures (PPMP)	Moderate or High Complexity tests that must be performed at the point of care by a health care provider.	Physician, Dentist or Mid-level health care provider

CMS issues four types of certificates to labs (Figures from June, 2011):

Certificate	Definition	Requirements	National	In Virginia
Certificate of Waiver	Waived tests only	Must be certified. Subject to random, on-site inspections- about 2% of labs per year.	146,071 (66.7 %)	3,158 (60.8%)
Certificate of Compliance	Perform all tests Surveyed by State agency	Surveyed biennially. Proficiency testing quarterly.	19,319 (8.8%)	482 (8.7%)
Certificate of Accreditation	Perform all tests Surveyed by accrediting organization	Surveyed biennially. Proficiency testing quarterly.	15,787 (7.2%)	469 (9.0 %)
Certificate for Provider Performed Microscopy Procedures	Perform PPMP and waived tests only.	Subject to random, on-site inspections— about 2% of labs per year.	37,767 (17.2%)	1,086 (20.9%)
Total			218,944	5,195

5. CLIA defines roles for clinical laboratory management.

CLIA identifies certain roles that must be filled within each laboratory. In the case of small labs performing a limited number of tests, these roles may be filled by one person. In larger labs, a qualified person may fill one or more roles. CLIA qualifications are extremely detailed, and differ depending on the complexity of tests performed, the specialty area, and the individual tests. Requirements shown here are only general outlines.

A. Laboratory Director: The laboratory director is responsible for the overall operation and administration of the laboratory, including employment of competent personnel and quality control. Laboratory directors must be actively involved in operations and available to staff on an as needed basis. Laboratory directors may only oversee five non-waived labs. Tasks performed by other managing personnel are delegated by the laboratory director, and he is ultimately responsible for their activities.
Qualifications: A Board certified Clinical Pathologist, a physician with training or experience in clinical laboratory responsibilities, an experienced PhD in laboratory sciences, or a master's or bachelor's educated scientist with one or two years, respectively, of both *laboratory work experience* and *laboratory supervisory experience.*

B. Technical Consultant/Supervisor: Technical consultants/supervisors are responsible for providing technical consultation for tests in each specialty or subspecialty performed by the lab. Consultants and supervisors have the same responsibilities; however technical supervisors are required for high complexity tests and have higher qualification requirements. Technical consultants/supervisors may be generalists, providing support for all lab tests, or specialists. However, they must have the required education, training or experience to provide technical expertise for tests in their area of responsibility.
Qualifications: Equivalent to laboratory director, but training and experiential requirements must be within requisite specialty areas.

C. Clinical Consultant: Assists clients with interpretations of laboratory test results and their meaning for diagnosis, treatment plans and patient care.
Qualifications: The laboratory director or a physician.

D. Testing Personnel: Perform tests. There must be a sufficient number of testing personnel to perform the volume of tests performed at the lab.
Qualifications: Generally, as noted in the chart in Section 4. Training and qualifications are specified according to the specific test(s) performed or to specialties and subspecialties. On-the-job, military or formal training at an educational institution are acceptable.

6. CLIA-style regulation has advantages unique to clinical laboratories.

A. Markets for laboratory tests are national: Lab specimens are often sent across state borders for testing. State regulations will not affect tests sent across borders, or may prove onerous if they do so. State regulations that prove costly or burdensome may result in tests for Virginia's patients being sent out of state.

B. Lab work lends itself to output/error testing: Laboratories do not provide assessments, treatment plans, patient counseling or direct patient care. They provide analyses, the results of which may be objectively tested. Proficiency testing provides an objective test of competency.

C. Technology is changing the nature of lab work: More lab tests are becoming automated and less complex to perform. FDA classification of lab tests assimilate technological changes into regulations and personnel requirements. This allows tests that become routine to be performed at the point of care by health providers, while more complex or risky tests are subject to greater restrictions.

D. Errors tend to be process-oriented: Studies suggest that the majority of laboratory errors occur in the pre- and post-analytical phases of the testing process. Poor communication, breakdowns in specimen processing and other managerial/data issues influence these errors much more than the specialized skills associated with medical laboratory analyses. CLIA's process accounts for improvements in data processing, quality control, communication and other management issues that improve lab quality as well as the quality of staff.

7. There are some notable criticisms of CLIA.

A. Over 80% of labs are not subject to enforcement measures: Waived labs and PMPP labs are not subject to surveys or proficiency testing. Additionally, a greater number and breadth of tests are being categorized as waived tests. In 2002, CMS initiated random on-site surveys of waived and PMPP labs after finding deficiencies in over 50 percent of these labs during a review. CMS is currently reviewing its process for regulating waived tests and laboratories.

B. Sanctions are rare: CLIA's goal is to improve quality in labs. Regulators view the survey process as educational as well as regulatory, and often allow labs to correct deficiencies before imposing sanctions unless there is a risk to patients or there are repeated deficiencies.

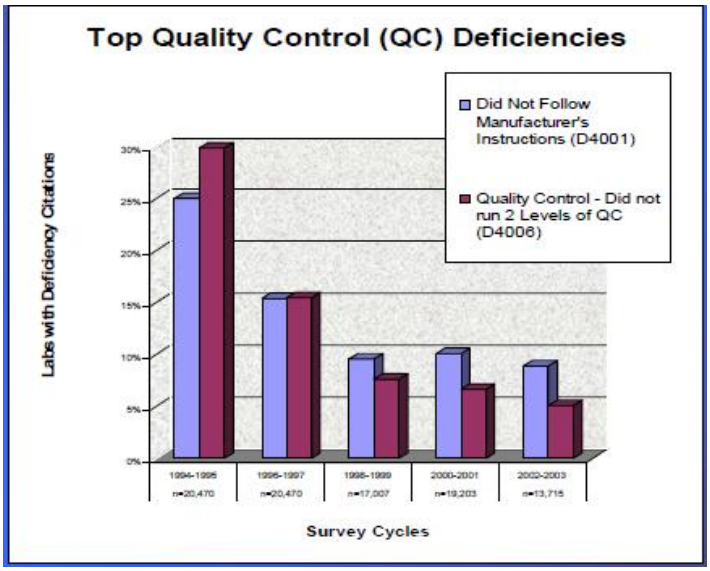
C. Survey process is fragmented: Survey and complaint investigations are conducted by agencies in each state and by six deemed accrediting organizations. Although all labs must meet CLIA or CLIA-equivalent standards, the ability of the survey organizations and their processes to identify deficiencies varies.

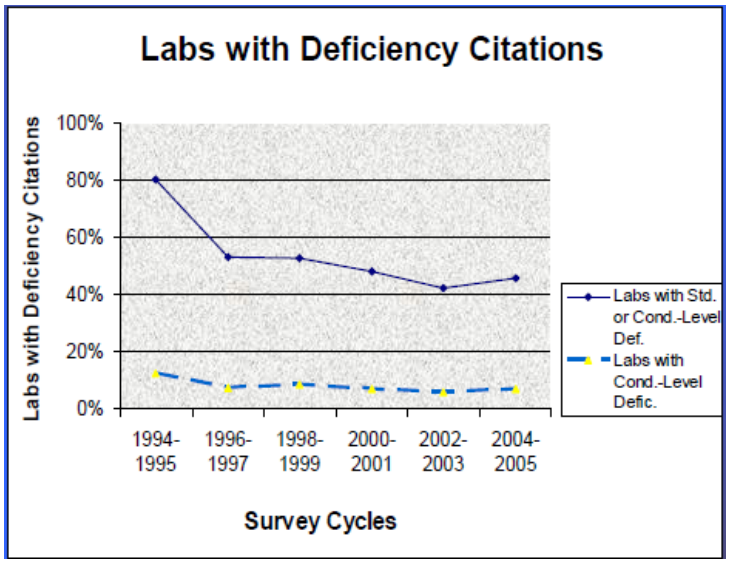
D. It is unclear if CLIA has improved lab quality: The lack of standardization of enforcement and data reporting makes it difficult to assess the efficacy of CLIA regulations at improving lab quality. Additionally, improvements in existing quality measures may be due to the growth of waived labs, which are not subject to CLIA surveys or proficiency tests, rather than real improvements in lab quality.

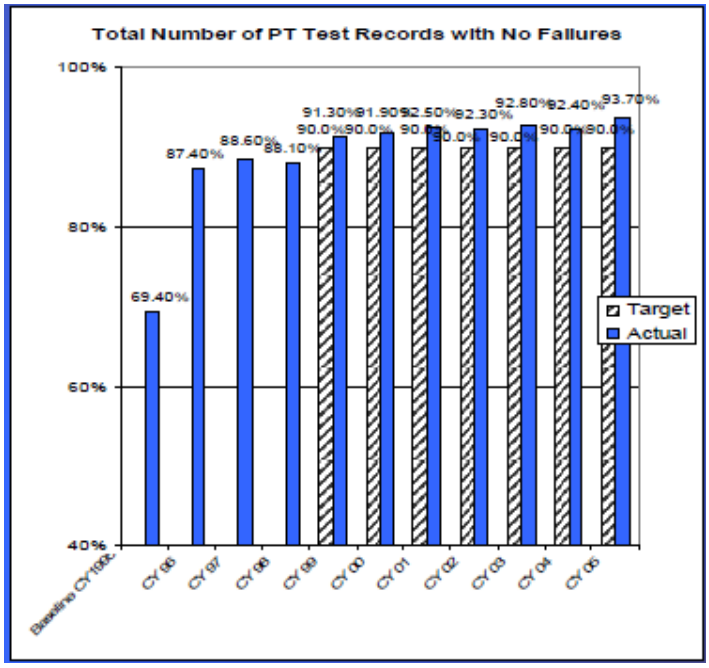
8. CMS measures show an increase in lab quality since CLIA was enacted.

CMS reports that on key measures, lab quality has improved since the introduction of CLIA. The following charts are from a presentation by Judith A. Yost, Director of CMS Laboratory Services, to the Clinical Laboratory Improvement Amendments Advisory Committee (CLIAC), a part of the CDC, in September 2006, available in the CLIAC minutes of the same date as Addendum E: http://wwwn.cdc.gov/cliac/cliac0906.aspx.

Deficiency citations for labs that did not have at least two levels of quality control and that did not follow manufacturer's instructions in lab procedures declined from about 20 percent and 30percent, respectively, from the mid-90's to about five percent and eight percent in 2003. The proportion of non-waived labs with minor and major deficiencies has declined as well. Proficiency test pass rates for all tests increased from about 70 percent in 1996 to over 90 percent in 2006.







A 2006 GAO report outlined many of the criticisms of CLIA implementation. CMS undertook a series of changes as a result. CMS is currently examining changes in enforcement policies for Certificate of Waiver labs, including legislative changes to improve the level of oversight.[1]

9. States must meet CLIA minimal requirements, but may also initiate more stringent requirements.

State surveying agencies may impose additional requirements on CLIA labs, including personnel requirements, by adopting their own facility certification or licensing standards. Additionally, states that have standards and regulatory procedures deemed at least equivalent to CLIA requirements may apply to be exempt from CLIA processes and run their own laboratory regulatory programs. Currently, New York and Washington are CLIA exempt.

10. Eleven states regulate clinical laboratory personnel, 39 states and the District of Columbia do not regulate clinical laboratory personnel (See Appendix): Most of regulating states regulate both laboratory scientists and laboratory technicians, and grant licenses to generalists and limited licenses to specialists. Generally, scientists are able to perform any test in their specialty areas, and technicians are limited to performing tests that do not require independent judgment and work under supervision. Several states regulate CLIA-defined roles specifically, as well as testing personnel-- particularly the laboratory director, but also technical consultants/supervisors. Most states exempt CLIA-defined waived tests, however, Nevada creates its own list of exempt tests.

11. From 2005 to 2010, CMS cited 37 Virginia labs for deficiencies directly related to insufficient numbers of testing personnel for the volume and complexity of tests performed, four of which involved immediate jeopardy citations: The particular deficiency cited may include administrative/recordkeeping problems as well as actual deficiencies of testing personnel, so it is unclear if unqualified persons were performing tests in all cases. At least one complaint investigation revealed that unqualified staff performed tests, while another revealed that a person who failed proficiency tests performed tests without supervision. Laboratory directors and technical supervisors were also cited, as it is their responsibility to ensure that enough qualified staff is available, that they are competent, that they enroll in PT and that tests and quality control is performed properly. No evidence of harm directly linked to inadequately qualified personnel was found.

[1] See Judith Yost's presentation to CLIAC at its February2010 meeting, Addendum C: http://wwwn.cdc.gov/cliac/cliac0210.aspx, and the September 2006 meeting, Addendum E: http://wwwn.cdc.gov/cliac/cliac0906.aspx.

12. Staff received comment from clinical laboratory personnel, their professional organizations and the American Society of Clinical Pathologists supporting regulation. No patients, providers, facilities or other consumers of laboratory services provided comment supporting regulation. The Virginia Hospital and Healthcare Association provided comment opposing regulation.

13. The Regulatory Research Committee has previously recommended regulation of clinical laboratory personnel: From the minutes of the Sept. 29, 2010 Regulatory Research Committee meeting: "On properly seconded motion by Mr. Boehm, the Committee recommended that regulation of medical laboratory scientists and technicians was warranted. They further recommended continuance of the study to enable them to determine the appropriate form of regulation and under which agency or board that regulation should be overseen."

POLICY OPTIONS REVIEWED

Several policy options are presented here with a bullet point list outlining the rationale for each. Waived tests and waived laboratories are exempt in all options.

1. No professional regulation, with recommendation to license or certify laboratory facilities: The committee examined the need to regulate laboratory personnel as a regulated health profession, and the licensure provisions in H.B. 601 in particular. We did not, however, look into regulation of clinical laboratories or clinical testing in general. However, if the Committee believes that CLIA regulations are not sufficient to ensure quality in clinical laboratories, the committee may recommend facility regulation as an alternative to professional regulation. The Office of Licensure and Certification (OLC) of the Virginia Department of Health licenses, regulates and inspects healthcare facilities and the Virginia Board of Health provides oversight and regulatory guidance in this area.

- Evidence of harm related to substandard regulation of testing personnel was not found.
- Clinical laboratories and laboratory personnel are already regulated through CLIA. CLIA has improved lab quality and proficiency test pass rates of non-waived labs.
- Deficiencies related to personnel were cited, indicating that CLIA enforces personnel standards.
- The Board's criteria for regulating a new profession require that there be no alternatives to professional regulation that adequately protect the public, including strengthening existing consumer protection laws and regulations.
- While states must meet CLIA requirements, they may set additional requirements above CLIA's requirements.
- If Virginia's laboratories require additional regulation, regulating laboratory facilities provides an avenue of regulation that does not create an additional regulatory structure. VDH already surveys laboratories under CLIA.
- About 7.2 percent of Virginia's CLIA registered labs are accredited and surveyed by private "deemed" organizations. Laboratory regulation would provide additional state oversight of these laboratories.
- Facility regulation may provide more flexibility in addressing quality issues, including raising personnel standards.
- Most errors occur in the pre- and post-analytical phases of the testing process, related to communication, data and specimen management and other administrative processes. Regulation of workers may pull resources from investments that may have a greater impact on lab and testing quality.
- Proficiency testing and laboratory inspections may provide a better means of ensuring quality, since outputs may be measured objectively and laboratory personnel do not provide direct patient care.
- Consumers of laboratory services are not seeking additional regulation of clinical laboratory personnel.

2: Voluntary certification for testing personnel: Creates title protection for laboratory scientists and laboratory technicians certified by national certification organizations. This would prevent uncertified persons from referring to themselves as clinical/medical laboratory scientists and technologists or clinical/medical technicians or other protected titles. Voluntary certification is generally intended for practitioners specifically selected by the patient. It provides information to patients so they may better select their own practitioners without limiting the diversity of available practitioners. Voluntary certification for some personnel could be combined with licensure at higher levels (See "Policy Options in Combination," pg.11).

- Laboratory personnel generally do not interact with patients in a manner that allows them to choose the personnel performing tests. Additionally, many of the point of care tests are waived tests. However, many non-waived laboratories are in physician's offices, pharmacies and ambulatory health clinics. A few are associated with mobile labs, HMOs, home health agencies and other community-based health providers. Patients who use these services may benefit from official information on the qualifications of persons providing the tests in community-based laboratories.

3. Licensure for management personnel: Requires lab directors and/or technical supervisors to obtain a license as a laboratory director and/or technical supervisor. This usually includes an additional license for physician directors and supervisors.

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- Evidence of harm related to substandard performance of testing personnel was not found.
- Through CLIA, management is responsible for ensuring proper staffing. Citations for inadequate staffing are directed towards technical supervisors and laboratory personnel.
- CLIA only requires bachelor's training with two years' experience to fill the role of the lab director and the technical supervisor. Certification or membership in a professional group is not required.
- Regulation would add professional standards and ethics to lab management practice.
- Management is responsible for ensuring quality and best practices throughout the lab. Regulation of management would affect the quality of the pre- and post- analytical phases as well as the analytical phase.
- Continuing education would ensure lab directors and technical supervisors are up to date on technology, equipment and best practices in the laboratory sciences, including physician directors and supervisors.
- Through discipline, licensure of management personnel ensures that incompetent or unethical persons cannot operate or manage laboratories despite meeting minimal qualifications (i.e., it ensures those who are in charge of ensuring the competence of lab personnel meet laboratory competency standards themselves, cannot lab-hop, or open fly-by-night operations).

4. Licensure for laboratory scientists: Requires non-physicians performing tests that require independent judgment and responsibility, and non-physician technical supervisors and laboratory directors, to obtain a license.

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- The Board's criteria for regulating a new profession at the licensure level require that practice be independent with a high degree of autonomy and little or no direct supervision. Laboratory scientists perform tests that require independent judgment and responsibility and thus may meet this criterion.
- Laboratory technicians do not perform tests that require independent judgment or responsibility. They are supervised by laboratory scientists, and thus may not meet the requirement for licensure.
- Licensure would add professional standards and ethics to persons performing the most complex tests, developing and interpreting tests and to persons supervising laboratory technicians and other laboratory personnel.
- Licensure for laboratory scientists ensures that non-physician laboratory management personnel are also licensed. Physician directors and supervisors would maintain standards under their physician license.

5. Licensure for all testing personnel: Requires licensure for laboratory technicians as well as laboratory scientists.

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- Although laboratory technicians do not perform tests that require independent judgment or responsibility, they perform tests of moderate to high complexity that can pose a risk of harm to patients.
- CLIA allows those with high school and on-the job training to perform these tests. Licensure as a laboratory technician would require formal certification and a post-secondary certificate or associate degree.
- Licensure for testing personnel ensures that non-physician laboratory management personnel are licensed as well.

POLICY OPTIONS IN COMBINATION

The previous policy options may be used alone or in combination. The following chart provides an overview of all the options available.

Professional Level	Laboratory Management	Laboratory Scientist	Laboratory Technician	Rationale
Option 1	Not Regulated	Not Regulated	Not Regulated	• See Option 1
Option 2	Not regulated	Voluntary Certification	Voluntary Certification	• CLIA is effectively regulating laboratories • Patients at community-based labs may benefit from information on the qualifications of laboratory personnel
Option 2a	Not regulated	Voluntary Certification	Not regulated	• CLIA is effectively regulating laboratories • Patients at community-based labs may benefit from information on the qualifications of those supervising lab personnel
Option 2b	Licensure	Voluntary Certification	Not Regulated	• The Board determines management requires licensure • Patients at community-based labs may benefit from information on the qualifications of those supervising lab personnel
Option 2c	Licensure	Voluntary Certification	Voluntary Certification	• The Board determines management requires licensure • Patients at community-based labs may benefit from information on the qualifications of laboratory personnel
Option 2d	Licensure	Licensure	Voluntary Certification	• The Board determines management and laboratory scientists require licensure. • Patients at community-based labs may benefit from information on the qualifications of laboratory personnel.
Option 3	Licensure	Not Regulated	Not Regulated	• See Option 3
Option 4	Not regulated	Licensure	Not regulated	• See Option 4
Option 4a	Licensure	Licensure	Not regulated	• Option 4 and • All those using independent judgment and providing supervision of laboratory workers require licensure • Laboratory management, including physicians, require licensure specific to their management role beyond that of laboratory scientists
Option 5	Not regulated	Licensure	Licensure	• See Option 5
Option 5a	Licensure	Licensure	Licensure	• Option 5 and • All those performing non-waived tests require licensure • Laboratory management, including physicians, require licensure specific to their management role beyond that of laboratory scientists

RECOMMENDATION

At its February 14, 2012 meeting, the Regulatory Research Committee recommended licensure for both clinical laboratory scientists and clinical laboratory technicians, citing the following rationale:

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- Although laboratory technicians do not perform tests that require independent judgment or responsibility, they perform tests of moderate to high complexity that can pose a risk of harm to patients.
- CLIA allows those with high school and on-the job training to perform these tests. Licensure as a laboratory technician would require formal certification and a post-secondary certificate or associate degree.
- Licensure for testing personnel ensures that non-physician laboratory management personnel are licensed as well.

In particular, the Committee noted public comment related to Laboratory Technicians' independent assessment of tests flagged for review by automated quality control equipment.

APPENDIX: STATE LICENSURE REQUIREMENTS

California: California's Laboratory Field Services, a division of the Department of Public Health, licenses both laboratory facilities and laboratory personnel. California licenses Clinical Laboratory Scientists, Cytotechnologists, Medical Laboratory Technicians, Laboratory Directors and Phlebotomists. Clinical Laboratory Scientists may seek licensure as generalists, or in one of eight specialty areas. Laboratory directors are licensed in one of seven specialty areas.

Florida: Laboratory Scientists, Laboratory Technicians, Laboratory Directors and Laboratory Supervisors are licensed in one of 14 specialty areas. All licensed personnel are able to collect, process, store and ship specimens and perform tests within their specialty area. Laboratory scientists, supervisors and directors may interpret test results.

Georgia: Until July 2010, Georgia facility licensure requirements had additional personnel requirements. Testing personnel had to have a national certification as a Laboratory Scientist or Laboratory Technician. In 2010, Georgia repealed its clinical laboratory licensure law, reverting to CLIA standards.

Hawaii: Hawaii licenses Laboratory Directors, Clinical Laboratory Specialists, Cytotechnologists, Medical Technologists (Laboratory Scientists) and Medical Laboratory Technicians (Laboratory Technicians). Medical Technologists are Bachelor trained Laboratory Scientists; Clinical Laboratory Specialists are Bachelor trained Scientists in one of six specialties.

Louisiana: Louisiana licenses Clinical Laboratory Scientists: Generalist, Clinical Laboratory Scientist: Technician, Clinical Laboratory Scientist: Specialist, Cytotechnologists and Laboratory Assistants. Phlebotomists must be certified if they are not employed or supervised by a physician, clinic, or other licensed health care facility. Clinical Laboratory Generalists may perform all tests. Clinical Laboratory Specialists may perform all tests within a specialty area. Clinical Laboratory Technicians may only perform tests that do not require "independent judgment or responsibility" and may only perform high complexity tests under supervision. Laboratory assistants may only

perform tests that do not require "independent judgment or responsibility" under supervision of a licensed health care provider or laboratory director, or may perform high complexity tests under supervision as required in CLIA.

Montana: Montana licenses Clinical Laboratory Scientists, Clinical Laboratory Specialists and Clinical Laboratory Technicians. Scientists may perform all tests. Specialists may perform all tests within a specialty area, and Technicians may perform tests that require limited independent judgment and are performed under the supervision of a laboratory scientist, supervisor or director.

Nevada: Nevada licenses lab directors, general supervisors, clinical laboratory technologists (scientists), medical technicians, and laboratory assistants. Nevada also licenses both technologists (scientists) and technicians in several specialties. The general supervisor has a role similar to the technical supervisor/consultant. Technologists may perform all tests, while technicians are limited to waived or moderate complexity tests, or high complexity tests which have results read from an instrument and do not require interpretation or intervention by the operator during the analytical phase. Laboratory Assistants may assist with tests under direct supervision with specific exceptions.

New York: New York licenses Clinical Laboratory Technologists (scientists), Certified Clinical Laboratory Technicians, Cytotechnologists and Certified Histological Technicians. Technologists may pursue a full license, or a restricted license that limits practice to one of six specialty areas. Technologists may perform all tests pursuant to a full license or limited specialty area. Technicians may only perform tests that require limited judgment.

North Dakota: North Dakota licenses Laboratory Scientists, Laboratory Technicians and Specialists.

Rhode Island: Rhode Island regulates Clinical Laboratory Scientists, Clinical Laboratory Technicians, Cytotechnologists, Histologic Technicians and MOHS (micrographic surgery) Technicians. Laboratory scientists may be licensed as generalists, or in one of eight specialties. Scientists may perform all tests within their license area. Technicians may perform tests which do not require independent judgment under supervision of a laboratory scientist, supervisor or director.

Tennessee: Tennessee licenses Laboratory Directors, Supervisors, Technologists (scientist), Technicians and special analysts. Laboratory supervisors fulfill roles similar to the technical supervisor role; technologists may perform any test laboratory. Special analysts may perform tests within a specific specialty. Technicians may only perform tests which require limited skill, responsibility or independent judgment under the supervision of a technologist, supervisor or director.

West Virginia: West Virginia requires licenses for laboratory directors, consultants, scientists, and technicians and point of care technicians in eleven specialties based on positions and functions held in a laboratory. Scientists perform all tests within approved specialty areas, while technicians may only perform tests requiring limited exercise of independent judgment under supervision of a laboratory director or supervisor. Point of Care Technicians may only perform point of care tests of moderate complexity when reporting directly to a physician and under the supervision of a laboratory director and supervisor. The consultants and directors fulfill roles equivalent to those in CLIA, and must meet the same requirements.

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Background & Authority

At its October 24th, 2011 meeting, the Regulatory Research Committee considered an ongoing study to regulate clinical laboratory scientists (hereafter "scientists") and clinical laboratory technicians (hereafter "technicians").[2] Since most members of the RRC and the Board of Health Professions were new at the time of this meeting, the RRC and Board requested more time to review the issue. Members of the RRC also expressed a desire for more information about the potential economic impacts of regulation.

Workforce Shortage

The literature on clinical laboratories abounds with articles and journals about a national workforce shortage in clinical laboratories (see bibliography). Shortages are widespread, including shortages of qualified scientists, technicians and their various specialties. The US Bureau of Labor Statistics projects clinical laboratories will add an additional 42,900 scientist and technician jobs by 2020, on top of the current workforce of 330,600. Over this period, the US will need an additional 107,300 new scientists and technicians to fill new positions and to replace retirees. Estimates of the number of current vacancies range up to 100,000.[3]

These shortages trace their roots to lab consolidations over the last few decades. Large, consolidated labs achieved economies of scale and needed fewer workers than smaller local or hospital laboratories. While some workers left the profession, the most dramatic outcome was the shrinking number of educational programs. From 1975 to 2005, the number of accredited technician programs declined from 709 to 232, and the number of graduates declined from 6,121 per year to 2,070.[4] Scientist programs saw similar declines. As of 2010, the average age of the laboratory workforce was 50 years old, compared to 42 years old for the entire civilian labor force.[5]

The American Society for Clinical Pathology concluded a summary of its 2008 Wage and Vacancy Survey by warning that "demand for all laboratory professionals far outstrips supply." The survey found that 43 percent of labs reported difficulties hiring personnel, including 65 percent of hospital labs and 42 percent of labs located in the South Central Atlantic region. The vacancy rate for staff level scientists was 10.4 percent, while the rate for staff level technicians was 6.4 percent. Two-thirds of labs reported increased competition for qualified staff as their chief hiring challenge.[6]

Response to the Workforce Shortage

Professional associations, educational institutions and laboratories have many tools at their disposal to deal with the shortage of professionals. The first and most basic is the simple economics of supply and demand. As competition for a diminished number of professionals heats up, laboratories will have to raise wages to attract qualified professionals. Over time, raised wages should draw more persons into the profession. Raising wages, however, may be difficult in a health industry marked by regulated reimbursement rates and increasing pressure to lower costs.

Professional associations and educators are also working to increase the supply of laboratory professionals. According the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) the number of graduates from accredited scientist programs has increased from 1,923 in 2003 to 2,934 in 2009. The number of technician

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[2]Clinical Laboratory Scientists and Technicians use a variety of terms to describe themselves and may practice in a variety of specialties. For our purposes, we use "scientist" to describe laboratory scientists and technologists, regardless of specialty, that usually have bachelor level education but may have an equivalent amount of education, training and experience and "technician" to describe technicians and assistants with less education and qualifications. "Clinical/Medical" and "Laboratory" descriptors are implied.

[3]See Maddox, 2011 & Medical Laboratory Observer, 2011.

[4]Kaplan & Burgess, 2010. Pg. 141.

[5]Ibid.

[6]Bennett, et al. 2009.

graduates grew from 2,143 to 2,583 over the same period.[7] Professional associations are also increasing efforts to advertise the profession to new students.

Laboratories, already feeling the effects of the workforce shortage, are also responding to the shortage. In some cases labs may substitute less educated or indirectly educated staff for certified personnel. Generally, these are persons with a life sciences, chemistry or healthcare background that do not have the applied laboratory science training that comes with a degree or certification in clinical laboratory science or technology. CLIA regulations allow for persons with diverse backgrounds to fill scientist and technician roles. However, CLIA often requires test-specific, documented training for these workers.

Labs are also responding by investing in automated testing equipment and information systems, squeezing more productivity from the existing workforce. Automated lab equipment is already having an impact on the number and qualifications of personnel needed to perform tests. In some cases, previously complex lab tests are now performed by health workers at the patient's bedside. Labs may also benefit from increased use of information systems and electronic health records. Information systems may better integrate laboratories with health providers and improve process times and quality control.

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Coordinating Council on the Clinical Laboratory Workforce. www.ccclw.org.
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Clinical Laboratory Scientist/Technician
FOIA Request Overview

Overview

The Board of Health Professions' Contractor requested the following information involving Virginia medical/clinical laboratories:

1. Complaint Investigations, Jan. 1, 2005 to Dec. 31, 2010.
2. The five most frequently cited conditional deficiencies in Virginia, Jan 1, 2005 to Dec. 31, 2010.
3. The number of times Immediate Jeopardy cased, Jan. 1, 2005 to Dec. 31 2010.

The responses for item number one appear below. In response to item number two, CMS reported that data was only available from Dec. 2006. The five most commonly cited deficiencies were:

1. §493.1403 "Laboratory Director",
2. §493.1250 "Analytic Systems",
3. §493.1421 "Testing Personnel",
4. §493.803 "PT Participation",
5. §493.803 "PT Enrollment".

CMS called immediate jeopardy on CLIA labs in Virginia a total of 23 times from 2005 to 2010. The deficiencies related to immediate jeopardy were:

1. §493.1403 "Laboratory Director",
2. §493.1250 "Analytic Systems",
3. §493.1421 "Testing Personnel",
4. §493.803 "PT Participation",
5. §493.1290 "Post Analytic Systems"

Times Cited- Top Five	Times Cited- Immediate Jeopardy	Deficiency Overview
74	**8**	**Laboratory Director** Laboratories Performing Moderate Complexity Testing §493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart. *Interpretive Guidelines §493.1403:* *The Condition: laboratory director is not met when the laboratory director:* • *Position is not filled;* • *Is not qualified; or* • *Does not fulfill the laboratory director's responsibilities.* *An individual qualified as laboratory director may not qualify as a technical consultant in a particular specialty or subspecialty unless he or she has the required testing experience.*
39	**5**	**Analytic Systems**

		§493.1250 Condition: Analytic Systems. Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual #7, that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed. *NOTE: Throughout the analytic systems section, the regulations require laboratories to follow test system manufacturer's instruction for performing the testing. This means the laboratory must perform and follow the manufacturer's package insert as approved or cleared by the FDA.* *Interpretive Guidelines §493.1250* *Significant deficiencies cited under this condition may indicate deficiencies under* *personnel. Use D5400 when deficiencies are identified that are significant and have the potential to, or adversely affect patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.* *Refer to §§493.1261 - 493.1278 for additional requirements for Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Routine Chemistry, Hematology, Immunohematology, Histopathology, Cytology, Clinical Cytogenetics, and Histocompatibility.*
37	**4**	**Testing Personnel** §493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel. The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed. *Interpretive Guidelines §493.1421* *The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, and ensuring that these responsibilities are specified in writing by the director, and that the responsibilities are appropriate to ensure compliance with the requirements concerning reporting and recordkeeping, quality control monitoring, quality assurance activities and proficiency testing participation. Cite this deficiency only when compliance problems are found in these areas that can be directly related to insufficient numbers of testing personnel. (Use D6028, which relates the finding of insufficient personnel to director responsibilities.)*
33	**3**	**PT Participation** §493.803 Condition: Successful participation. (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty,

		subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. *Interpretive Guidelines §493.803* *Only the PT program has the capability to correct scores. These corrections will be noted in the PT monitoring system as "non-routine" scores.* *No single PT enforcement protocol is universally applicable for all situations. Unique circumstances may require special considerations or actions that may not conform to the general approach outlined below. The laboratory's compliance history, its willingness to take remedial actions, and the professional judgment of surveyors, RO CLIA laboratory consultants and enforcement personnel may be factors in determining an appropriate PT enforcement plan.* *Careful review of PT performance reports and other available information should always be performed to determine whether the PT results truly represent failed PT. The potential of a PT program data input error or other factors beyond the laboratory's control should be considered. If the laboratory has made a transcription error(s), it is considered erroneous PT result(s). Absent any special circumstances (which must be documented in the case file), consider verified unsuccessful PT performance to represent unsuccessful PT participation and cite as a condition-level deficiency (use D2016 on the CMS-2567).* *NOTE: The CMS PT monitoring system may NOT be used alone to determine* *unsuccessful participation. Surveyors must verify any unsuccessful participation indicated in the PT monitoring system. This may be done by reviewing PT results* *supplied by the approved PT program (they will send copies to the surveyor if requested) or from results sent to the laboratory by the PT program.* *If the unsuccessful PT participation is the first occurrence for the laboratory, and there is no immediate jeopardy to patient health or safety, notify the laboratory and require that it seek training of its personnel, obtain the necessary technical assistance to correct the problem causing the unsuccessful participation, or both. SAs may initiate training and/or technical assistance after first obtaining RO concurrence. No onsite review is required to initiate this action.* *The laboratory will submit an acceptable plan of remedial action, listing projected* *completion dates and other pertinent information, for its training and/or technical* *assistance efforts. Follow-up is necessary to verify that the laboratory has carried out its plan. Satisfactory participation in the next PT event would*

		provide verification that the laboratory's remedial action, training and/or technical assistance were successful. The remedial action plan should demonstrate that the laboratory will correct its problems within 3 months, although special circumstances may be considered. When a laboratory refuses to take acceptable training and/or technical assistance actions (including failure to submit an acceptable plan of remedial action, or failure to complete its plan), sanction *action will be initiated.* *When the unsuccessful PT participation is not the first such occurrence for the laboratory, and there is no issue of immediate jeopardy, cite as a condition-level deficiency and take appropriate enforcement action. For immediate jeopardy cases the procedures in Subpart R apply. For non-immediate jeopardy situations, enforcement procedures should be completed within 90 days from the date that the unsuccessful PT was first identified. In immediate jeopardy situations, enforcement procedures should be completed within 23 days from the date unsuccessful participation of PT is first identified.* *Example:* *A laboratory scores 60% on a testing event in mycobacteriology. On the next testing event, the laboratory fails to participate in mycobacteriology. The citations are §§493.825(b), 493.825(e), and 493.803.* *Example:* *A laboratory scores 60% on uric acid PT samples. On the next testing event, the* *laboratory score 40% on the same analyte. The citations are §§493.841(a), 493.841(f), and 493.803. When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent to or received by the laboratory concerning its PT performance.* *When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any* *correspondence sent or received by the laboratory concerning its PT performance.*
33	**-**	**PT Enrollement** §493.803—Same as Above
-	**3**	**Post Analytic Systems** Postanalytic Systems §493.1290 Condition: Postanalytic systems. Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed. *Interpretive Guidelines §493.1290:* *Significant deficiencies cited under this condition may indicate deficiencies under* *personnel responsibilities. Use D5800 when deficiencies are identified that are:*

		significant and have the potential to, or adversely affect, patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

CMS provided extensive documentation in relation to item number one, complaint investigations. BHP staff has created a summary in two sections. The first section summarizes complaints with deficiencies cited. The second section summarizes unsubstantiated claims related to personnel issues.

Complaints with deficiencies cited:

Intake ID: VA00016633

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
    - No certificate of waiver/CLIA registration

Intake ID: VA00016196

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
    - No certificate of waiver/CLIA registration

Intake No. VA00016197

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
    - No certificate of waiver/CLIA registration

Intake No. VA00012755

Lab did not inform surgical center (in Texas) of lost/missing bladder tissue specimen in mailed sample packet. Patient had to repeat painful, invasive biopsy procedure. Deficiencies cited:

- D5207 Communications
    - Laboratory must have a system to identify and document communication breakdowns between lab and test orderer
- D5391 Preanalystic Systems Quality Assessment
    - Ongoing mechanism to monitor, assess and correct identified problems in preanalytic phase, including test request, specimen submission, handling and referral
- D5300 Preanalytic systems
    - Laboratories that perform non-waived tests must meet preanalytic testing requirements. Code D5300 is used when deficiencies have the potential to adversely affect patient testing, are systemic and pervasive and are not limited to any one specialty.
- D5393 Preanalytic systems quality assessment
    - Assessment must include review of corrective actions, revision of policies, and disucssions with appropriate staff. Lab must document all assessment activities
- D6118 Technical Supervisor Responsibilities
    - Resolving technical problems and ensuring remedial actions are taken when test systems deviate from performance specifications

Intake No. VA00011563

Lab at large hospital system not dispersing test results in a time efficient manner. Lab results only available on computer system, which is time consuming. Problem discussed with hospital president, but no improvement, so physicians filed complaint. CMS conducted 45-day onsite survey. The following deficiency was cited:

- D5805 Test Report
  - Lists information required on test report records

Intake ID: VA00016199

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
  - No certificate of waiver/CLIA registration

Intake ID: VA00018875

Complaint regarding discrepancy in lab tests was unsubtantiated due to insufficient evidence. During the investigation/survey, the following deficiencies were cited:

- D5411 Test Systems, Equipment, Instruments, Reagent
  - Test systems must be selected by laboratory. Testing must be performed following manufacturers instructions in a manner that meets the lab's stated performance specifications
- D5805 Test Report
  - Lists information required on test report records

Intake ID: VA00015006 and VA00015007

Both complaints relate to the laboratory director/physician owner of multiple labs. The physician/director had his license to practice medicine suspended by the Board of medicine. The labs did not report a new lab director, and the physician's labs continued to send out histopathology results, but without a physician's signature. It is unclear who was reviewing histopathology slides and if that person was qualified, and who was supervising an on-site Physician Assistant. One of the physician's individual offices did not have a CLIA certificate, yet was found to be conducting laboratory tests. The labs were cited for multiple deficiencies.

- D5805 Test Report
  - Lists information required on test report records
- D5891 Postanalytic Systems Quality Assurance
  - Ongoing mechanism to monitor, assess and correct identified problems in postanalytic phase, including quality of test reports, turn around times, and procedures for notification of test results
- D6076 Laboratory Director
  - Laboratory director is not qualified, failed to fulfil duties, or position is not filled
- D6078 Laboratory Director Qualifications
  - Must be a physician or hold a clinical doctorate and Board certification, or meet grandfathering requirements, and meet other qualifications
- D6079 Laboratory Director Responsibilities
  - Responsible for overall operations and administration, including employment of competent personnel and assuring regulatory compliance; if qualified, the laboratory director may act as the technical supervisor, clinical consultant, general supervisor and testing personnel, or may delegate these tasks to qualified personnel; director remains responsible for all tasks
- D5607 Histopathology
  - Tissue pathology reports must be signed by an individual qualified to examine the slides
- D5800 Postanalytic systems
  - Postanalytic systems must meet statutory requirements, and must be monitored and evaluated for quality

- D5787 Test Records
    - Records must include specimen identification, date of receipt, disposition of specimen and test record including identity of personnel performing tests

Intake ID: VA00014563

Physician office did not receive results of test. Computer system labeled specimen with wrong physician ID number. Patient Service Technician retrained and computer system replaced.

- D5805 Test Report
    - Lists information required on test report records

Intake ID: VA00014564

Lab received a urine sample in an expired tube, but failed to inform physician that it did not run the lab test. Once the lab ran the test, six days after the initial test request, it revealed that the patient had a prostate infection resistant to the antibiotic.

- D5805 Test Report
    - Lists information required on test report records

Intake ID: VA00016624

CMS redacted most of this document due to privacy concerns. The original complaint was unsubstantiated but the investigation revealed the following deficiencies:

- D5413 Test Systems, Equipment, Instruments, Reagent
    - Criteria and conditions for storage of reagents
- D5431 Manitenance and Function Checks
    - Function checks must be performed as specified in manufacturer's instructions. Function checks must be within manufacturers limits before patient testing is conducted
- D5791 Anayltic Systems Quality Assessment
    - Ongoing mechanism to monitor, assess and correct identified problems in analytic phase, including test procedures, test systems, specimen and reagent storage, function checks, calibration, control, test records and comparison of test results.

Intake ID VA00015720

Lab reported erroneous results for a patient, or results for the wrong patient, and refused to correct the medical record.

- D5205 Complaint Investigations
    - Must have system for documenting all complaints and problems reported to the laboratory. The laboratory must conduct investigations when appropriate.

Intake ID: VA00014431

CMS redacted much of this document due to privacy concerns. A problem with a blood transfusion contributed to a patient death. The hospital lab was cited for multiple deficiences. Of note are the technical supervisor responsibilities. The technical supervisor may be a physician, or a scientist trained at the bachelor's level or higher with experience in laboratory science.

- D5291 General laboratory systems quality assessment
    - The ongoing review process that encompasses all factes of the laboratory's technical and non-technical functions
- D5429 Maintenance and function checks

    - Maintence performed (or service contract) on laboratory information systems.
- D5559 Innunohematology
    - Procedures for investigating, documenting transfusion reactions and remidial measures
- D6076 Laboratory Director
    - The laboratory director is not qualified, does not fulfill responsibilities or the position is not filled
- D6094 Laboratory Director Responsibilites
    - Responsibility to maintain quality assessment program and identify failures when they occur
- D6121 Technical Supervisor Responsibilities
    - Procedures for evaluation of competency of staff
- D6124 Technical Supervisor Responsibilites
    - Direct observation of performance of instrument maintenance and function checks

Intake ID: VA00015523

Much of this document was redactd for privacy reasons. Provider signed out Cytologic preparations after failing a 2nd retest (CLIA proficiency testing). These codes relate to gynecological examinations. Individuals must successfully pass an annual proficiency test. If they fail the 1st test, they must go through training, and have two more chances to pass. All tests must be reexamined by another tester in the interim. It appears that an individual at this lab failed the gynocological proficiency test three times, but continued to perform tests. It also appears that this site was not licensed or certified to provide cytology tests.

- D2148 Cytology-gynecologic exams
    - An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set
- D2150 Cytology-gynecologic exams
    - After failing the third test, individuals may not resume examining gynecologic slides untile the individual obtains at leas 35 hours of documented, formal, continuing education and is retested
- D3009 Facilities
    - The laboratory must comply with Federal, state and local requirements (i.e. it must be licensed)
- D5613 Cytology
    - All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in cytology
- D6076 Laboratory Director
    - Laboratory director is not qualified, failed to fulfil duties, or position is not filled
- D6079 Laboratory Director Responsibilities
    - Responsible for overall operations and administration, including employment of competent personnel and assuring regulatory compliance; if qualified, the laboratory director may act as the technical supervisor, clinical consultant, general supervisor and testing personnel, or may delegate these tasks to qualified personnel; director remains responsible for all tasks
- D6108-Laboratory Technical Supervisor
    - The laboratory technical supervisor is not qualified, failed to fulfill duties, or the postiion is not filled.
- D6111-Technical Supervisor Qualifications
    - Must be a physician, or must have a bachelor, master, or doctoral degree with a complementary level of experience within the specialty area.

Intake ID: VA00014799

Personnel conducting analyisis not trained. Trained personnel left, and analysis performed by persons without training. The following deficiencies were cited:

- D5787 Test Records
    - Maintain records to include identification of specimen, date/time of receipt, condition and dispostion of specimen, records and dates of all tests, including personnel who performed the test
- D6000 Laboratory Director
    - Must have qualified laboratory director, director must fulfill responsibilities
- D6029 Director Responsibilities
    - Ensure all personnel have the appropriate education, experience and training

- D6063 Laboratory Testing Personnel
    - The laboratory must have sufficient number of qualified individuals to handle the volume and complexity of tests performed
- D6065 Testing Personnel Qualifications-moderately complex tests
    - Must have an associate degree or higher from an accredited institution or have military training in an appropriate specialty, (personnel may also have a high school diploma and have documented training appropriate for the test performed, however violations of this trianing requirement invovle another deficiency code).

Complaints related to clinical laboratory technicians/scientists, no deficiencies cited:

Intake ID: VA00017413

A complainant lodged two complaints. The first regarded physician incentives to use the lab. The second was a general statement that the lab uses unqualified staff and that "lab assistants are in charge of processing instead of people with more experience, college degrees or certified. The most important is left to unqualified technicians" and that this created poor outcomes. The complainant did not provide further information on follow up and the office did not investigate as a result.

Intake ID: VA00010486

Concerns about the manner in which "staff persons" treated a patient.

Intake ID: VA00009785

Complainant claimed there were no written procedures for employees, that the lab asks employees to perform procedures beyond their competence level, and uncredentialed staff performed moderately complex procedures. The claims were not substantiated.

Intake ID: VA00018147

Complainant claimed unqualified personnel were processing tissues from Mohs procedures and that the lab did not have personnel trained to operate the Cryostat machine, to evaluate equipment or to keep proper records. No deficiencies were cited.

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THE VIRGINIA BOARD OF HEALTH PROFESSIONS
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

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

September 2010

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Table of Contents

Executive Summary

This study into the need to regulate medical laboratory scientists (MLS) and medical laboratory technicians (MLTs) began pursuant to a request from Delegate John O'Bannon, patron of House Bill 601 (2010) and in keeping with standard evaluative methodologies and based on the principles of occupational and professional regulation established by the Virginia General Assembly. The research is guided by seven criteria ("the Criteria")[8] addressed through review of the relevant policy literature, private professional credentialing, educational program accreditation, state and federal laws and regulations, disciplinary data, fiscal impact analysis, and public comment. MLS and MLT professional certification and educational program accreditation exists through a host of credentialing organizations. Twelve states and one U.S. territory currently regulate these professions. Although the U.S. Bureau of Labor Statistics predicts a strong demand for these laboratory practitioners, graduates and educational programs have been diminishing in recent years.

In 2010, it is estimated that over 10 billion laboratory tests are performed in the U.S. annually, and 70-80% of medical diagnoses and treatments are based in the results of laboratory testing. Projected increases in the overall population and the proportion of elderly patients and anticipated new tests all point to even greater testing in the future according to the U.S. Bureau of Labor Statistics. While some medical testing has become routine and simple enough for even the consumer to conduct, recent advances in medical technology and research has engendered increasingly complex testing that requires appropriate expertise to adequately perform and to accurately advise physicians of the results.

Unlike much of health care where practitioners are easily observed by the public and other practitioners, laboratory testing is performed largely behind the scenes. The existing state oversight of practice in Virginia is through facility surveys (inspections) conducted by the Virginia Department of Health to enforce federal requirements from the Centers for Medicare and Medicaid (CMS) pursuant to Clinical Laboratory Improvement Amendments(CLIA). Laboratory directors are held accountable for ensuring facilities meet survey requirements. Surveying requirements are based on the relative complexity of the tests performed at a facility: high, moderate, or waived. Laboratories performing high or moderate complexity testing may opt to be certified by either CMS or a CMS-approved accrediting agency, such as the Joint Commission but must meet standards at or above CLIA's, and there are minimum standards for personnel education and training at these levels. But laboratories performing waived testing are *not* routinely inspected and there is no specified minimum personnel education or training requirements. In Virginia, there are currently 5,007 CLIA participating laboratories, and of these, approximately 80% have waived status.

The Board has determined that there is a reasonable potential for harm posed by unregulated practice of personnel conducting laboratory testing. They noted research reports of error in all three phases of laboratory testing: pre-analytic, analytic and post-analytic. A CMS (2001) 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. The Healthcare Financing Administration (1995) noted that without adequate training of laboratory personnel, the likelihood of inaccurate test results increases. A study of problems in laboratory testing in primary care estimates that more than 27 percent of incorrect test results affect patient care (Nutting et al., 1996). Some believe that 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). This risk posed to the public bears continued review to guide policy.

After due consideration, the Board's Regulatory Research Committee concluded at its September 29, 2010 meeting, and the full Board concurred, that Virginia should regulate MLSs and MLTs. The current system of laboratory facility oversight was viewed as insufficient to ensure the public's health, safety, and welfare. MLSs and MLT should be held accountable as practitioners. The Committee further recommended that the study be continued to afford them adequate opportunity to get the information needed to ascertain the appropriate degree and form regulation. Although requested under the U.S. Freedom of Information Act, the independent CMS survey data on activities occurring in Virginia's laboratories has not yet been received. This information can be instrumental in advising on the types of deficiencies actually occurring in Virginia's labs as well as

[8] Details are provided in the Guidance Document **75-2** Appropriate Criteria in Determining the Need for Regulation of Any Health Care Occupation or Professions, revised February 1998. The seven Criteria (in hierarchical order) are: Risk of Harm to the Consumer, Specialized Skills and Training, Autonomous Practice, Distinguishable Scope of Practice, Economic Impact, Alternatives to Regulation, and Least Restrictive Regulation.

during the pre-analytic and post-analytic phases. Because the patient's wellbeing can be affected by errors in any and all phases, the Committee seeks to gain a better understanding of the potential for harm that can occur throughout the testing process.

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 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 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. (American Society for Clinical Pathology (ASCP), 2010). It is also estimated that laboratory testing is involved in approximately 70 – 80% of the diagnostic and treatment decisions made by physicians (Virginia Society for Clinical Laboratory Science (VSCLS), n.d.). 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 (U.S. Census Bureau, 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.

Criterion One: Risk for Harm to the Consumer
The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.

Criterion Two: Specialized Skills and Training
The practice of the health occupation requires specialized education and training, and the public needs to have benefits by assurance of initial and continuing occupational competence.

Criterion Three: Autonomous Practice
The functions and responsibilities of the practitioner require independent judgment and the members of the occupational group practice autonomously.

Criterion Four: Scope of Practice
The scope of practice is distinguishable from other licensed, certified and registered occupations, in spite of possible overlapping of professional duties, methods of examination, instrumentation, or therapeutic modalities.

Criterion Five: Economic Impact
The economic costs to the public of regulating the occupational group are justified. These costs result from restriction of the supply of practitioner, and the cost of operation of regulatory boards and agencies.

Criterion Six: Alternatives to Regulation
There are no alternatives to State regulation of the occupation which adequately protect the public. Inspections and injunctions, disclosure requirements, and the strengthening of consumer protection laws and regulations are examples of methods of addressing the risk for public harm that do not require regulation of the occupation or profession.

Criterion Seven: Least Restrictive Regulation
When it is determined that the State regulation of the occupation or profession is necessary, the least restrictive level of occupational regulation consistent with public protection will be recommended to the Governor, the General Assembly and the Director of the Department of Health Professions (DHP, 1998).

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 have opportunity to participate in continuing education. 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 practiced behind-the-scenes and is relatively 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. This means 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 Centers for Medicare and Medicaid Services (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 (Healthcare Financing Administration (now CMS), 1995). A study of problems in laboratory testing in primary care estimates that more than 27 percent of incorrect test results affect patient care (Nutting et al., 1996).

The ASCP's 2005 policy statement also outlined 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 Clinical Laboratory Improvement Amendments (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

<u>Duties</u>

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 known 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, 2009).

- 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, 2009).

- 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, 2009).

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, 2007)

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
- Cytogenetic technologists – analyze and correlate chromosome number and/or genetic structure to inherited or acquired genetic disease from many tissue sources
- 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 (CMS/CLIA/Laboratory Demographic Look Up, 2010):

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 (U.S. Bureau of Labor Statistics (BLS), 2009). The College of American Pathologists (CAP) policy on the criteria for the position of Clinical Laboratory Director states that "the director should possess a broad knowledge of clinical medicine, basic medical sciences, clinical laboratory sciences, and operations," (CAP, 1999). (See Appendix 2 for the CAP policy which includes a listing of specific knowledge and performance criteria.)

C. Bureau of Labor Statistics Information

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, 2009).

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. Universities and hospitals offer medical technology programs."

"Bachelor's degree programs in medical technology 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 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, 2009).

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, 2009)

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, 2009)

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 (BLS, 2009):

Table 5
2007 Median 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, 2009)."

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 (BLS, 2009):

Table 6
Projected Data from the National Employment Matrix

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 (U.S. Census Bureau, 2009):

Table 7 Change in Number of Establishments* for Medical Laboratories				
	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/CLIA/Laboratory Director Responsibilities, n.d.).

Laboratory directors must have specific educational background and work experience. Generally, these requirements 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/CLIA/Laboratory Director Responsibilities, n.d.).

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, 2009).

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 educational 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, 2009).

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 (American Academy of Forensic Sciences (AAFS, n.d.)

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). Occasionally governments may contract with an independent forensic lab because they do not have their own lab, or because their lab is unequipped for more specialized analyses. Independent forensic labs also may provide testing for cases of civil litigation (Virginia Department of Forensic Science (DFS), 2010). 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, n.d.). 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, 2010).

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).

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 (Commonwealth

of Virginia's Employment and Resource Center, n.d.). There are a few colleges and universities that offer degrees in forensic science; only 15 are master's level programs (DFS, 2005). 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 (American Society of Crime Lab Directors (ASCLD), n.d.).

Currently, there is 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, 1/2007)

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, 2009). 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, 2009).

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, 2009).

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, 2009).

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 (NAACLS, n.d.)
- CAAHEP accredits 0 MLS programs and 1 MLT program in Virginia (CAAHEP, n.d.)

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	Fishersville	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 (CAAHEP, n.d.; ABHES, n.d.).

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, n.d.; ABHES, n.d.; NAACLS, n.d.)

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 professionals, 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 is 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 MLSs 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, 2009).

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. NCA no longer offer certification as they have recently merged with ASCP-BOC.

AAB	American Association of Bioanalysts
AMT	American Medical Technologists
ASCP-BOC	American Society for Clinical Pathology-Board of Certification
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 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. 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 fee 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 Table 12 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	N/A	N/A	N/A	N/A
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)

Regulating states' survey results

States that currently regulate MLSs and MLTs were contacted for this report in an effort to find out more about the impetus behind their state's regulation, how many MLSs and MLTs are currently licensed, and what, if any, credentialing exam is required for state licensure eligibility. Four states provided some of this information to us. Three of the four states began regulating these professions in the late 1980s – early 1990s. NY began regulating more recently in 2006. Following is a summary of information received to these specific questions:

What was the impetus behind the regulation of medical/clinical laboratory personnel in your State?
Responses were public safety, professionalism and accountability. New York noted that it was the professional organizations that sought licensure which was a 20 year effort.

How many currently licensed/certified medical/clinical laboratory personnel are in your State?
MT reported 764 MLS, and 113 MLT.
RI reported 927 MLS, and 248 MLT.
NY reported 12,951 MLS, and 2,174 MLT.

Do you require applicants to have successfully passed a national voluntary credentialing exam to be eligible for state licensure/certification? If so, which credentialing agencies are accepted in your State?
Three of the four states do require applicants to pass an exam; NY does not have this requirement, but is contracted with ASCP to conduct exams. Of the three states that require applicants to pass an exam, all accepted ASCP-BOC, AMT, and NCA. Two of the three states accepted ABB, AACC, ASM, and ISCLT. One state also accepted ABMG, and another also accepted ASHI-HLA.

Additionally, the regulating states were asked to share information on the number and nature of complaints and/or disciplinary actions over a 5 year period. Only one state provided us with this information. In this state for the years from 2005 to 2009, the number of complaints received each year ranged from 3 in 2008 to 23 in 2006. The nature of the complaints over this five year period was most frequently "misrepresentation of training" (41 complaints) and occasionally "unlicensed practice: (5 complaints). The number of disciplinary actions ranged from 0 (in 2006 and 2008) to 4 (in 2009) and complete information on their nature were not available.

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/CLIA/Program Descriptions/Projects, 2010). 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/CLIA/overview, 2010).

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/CLIA/Program Descriptions/Projects, 2010).

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/CLIA/Laboratory Demographic Look Up, 2010)

<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/Outcome Oriented Survey Process, n.d.).

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/CLIA/Program Descriptions/Projects, 2010).

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 (CMS/Types of CLIA Certificates, n.d.)

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 CLIA 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/CLIA/Laboratory Demographic Look Up, 2010)

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 16 displays the minimum personnel qualifications for each testing complexity level.

Table 16
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/CLIA/Program Descriptions/Projects, 2010).

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). Despite 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. (For a list of Waived Tests see Appendix 6 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/CLIA/Certificate of Waiver Laboratory Project, 2010).

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 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/CLIA/Proficiency Testing, n.d.).

As of 3/16/2010, there were 13 CMS approved proficiency testing programs. (For a list CMS-approved PT providers see Appendix 7 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/Partners in Laboratory Oversight, n.d.).

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/Partners in Laboratory Oversight, n.d.)

As in any regulatory discussion, there are a number of terms used in regard to the survey process that require definition (CMS/Partners in Laboratory Oversight, n.d.):

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?

The CMS regional office was again contacted after the July 16th hearing and asked for the above information to be forwarded. CMS instructed us to request the information through a Freedom of Information request. This was done, and as of this writing, the requested documentation has not been received.

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/Partners in Laboratory Oversight, n.d.)

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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/Alternate Quality Assessment Survey, n.d.)

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/CLIA/Laboratory Registry, 2010). 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/CLIA/Accreditation Organizations, n.d.)

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 contacted these organizations again after the July 16th hearing and asked for this information to be forwarded; most suggested that we contact CMS for this type of information. CMS was contacted (the regional CLIA office that oversees Virginia specifically) and we were instructed to request the information through a Freedom of Information request. We did so and are waiting for the requested documentation to be forwarded.

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). 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, n.d.).

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 and Handy, 2009).

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 and 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 and colleagues 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 and Handy, 2009). 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 and Handy, 2009).

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 and 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 and Jackson-Tarentino, 2000). Other quality assessment programs and proficiency testing help identify analytical errors and prevent further errors (Cembrowski and 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 and 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).

Some believe that 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).

VI. Summary of the Public Hearing

A public hearing was conducted on July 16, 2010 in Board Room 3 at 1:00 PM at the Department of Health Professions, 69960 Mayland Drive, Richmond, Virginia. The purpose of the hearing was to receive public comment on the need to regulate medical laboratory scientists and medical laboratory technicians in Virginia.

Approximately 22 persons attended the hearing representing related professional organizations, hospital organizations, universities, as well as individuals previously and currently employed in these and related professions. Comment on the need for regulation was provided by some of the individuals in attendance and some comments were received in writing at the offices of the Board of Health Professions. A majority of the comments received were in support of regulation. A transcript of the comments from the public hearing and copies of comments received via correspondence are included in this report (see Appendix 8).

In support:

Overall, those in support of regulating MLSs and MLTs emphasized that above all the health, safety, and welfare of the public must be protected. More specifically, they discussed the following points:

Increased automation and volume of testing

> Although a much greater percentage of laboratory testing is automated, it doesn't mean that lesser qualified personnel should conduct the testing. Accurate interpretation of testing values is critical. Laboratory personnel must be adept at assessing the validity of test results and this requires a full understanding of the scientific processes as they relate to medical laboratory science. It is

important to ensure quality and safety standards as the complexity and quantity of testing increases. The rapidly increasing volume of laboratory testing has created trends toward treating labs as a business rather than a public health service. Although many laboratories require their staff to be certified, some do not in order to save on costs.

Scope of practice for MLS/MLT

These laboratory professionals integrate the day-to-day processes of the various phases of laboratory testing. This requires background and context in laboratory sciences to understand how these phases interrelate as these phases are a continuous flow and not separate processes. The pre-analytical phase requires the identification of specimen quality and how it may impact test results. Samples must be correct and handled accordingly. Variables must be recognized. Transport and storage conditions as well as turnaround time must be considered. Recognizing the appropriateness of tests ordered is part of this phase. The analytical phase includes the production of test data, monitoring for accuracy and utility, correlation and interpretation of the test data, and methodology and implementation of new testing methods. It is critical in this phase that the laboratory professional be able to monitor the quality of the results from both the instrument and the testing methods, and be able to troubleshoot causes of possible erroneous results. The post-analytical phase includes the design and verification of processes that assist in the receipt and interpretation of test results. Accuracy and timeliness in communication is critical, being sure that results are received in a timely manner and that the results are clearly understood.

Risk for harm

Documented examples of harm can be difficult to obtain, however, it doesn't mean that harm does not occur. Some harm takes the form of laboratory testing errors that are eventually corrected, but which caused delays in the patient receiving an accurate diagnosis and treatment. Harm sometimes takes the form of medical complications that are caused by but never attributed to testing errors. Testing errors may also contribute to a "chain of errors" which results in repeated or unnecessary testing, and this contributes to greater costs for patients and consumers. Additionally it was noted that regulation of the medical laboratory professions at the state level will provide more accurate and reliable mechanisms to identify, collect data on, and provide access to Virginia's laboratory workforce. These data will be necessary to access and mobilize qualified medical laboratory professionals to effectively respond to bioterrorism or other public safety threats.

CLIA regulations are not stringent enough

CLIA regulations are not standards and were never intended to be – they are merely a regulation, and are very minimal. They were put into place in response to increases in deaths in nursing homes and deaths that resulted due to pap smear testing errors. However, over time the CLIA regulations have been accepted by some states as a sufficient regulation of the clinical laboratory profession. More recently, CMS presented information from their Certificate of Waiver Project indicating that the risk of harm is present in (low complexity) waived testing laboratories. Contributing factors cited include high staff turnover, lack of formal laboratory education and limited training in test performance and quality assurance.

As the practice of laboratory science evolves and expands at an ever-increasing pace, it is left to the states to ensure that their laboratory personnel are appropriately qualified. Federal regulations are difficult and slow to change, and as previously noted were never intended to represent the ideal qualifications.

Importance of education and training

Educational and training standards will help ensure that laboratory personnel possess appropriate academic and clinical training, are able to pass competency-based exams conducted by an approved national certifying organization and participate in continuing education programs. The role of MLS/MLTs is very complex and it is important that these personnel have scientific degrees in their background. Additionally, higher education and training standards may actually help reduce the current shortage of medical laboratory personnel. It was noted that higher educational and certification standards in the MLS/MLT field often increase the number of qualified applicants, perhaps due to increased awareness of the professions and the perception of improved professionalism. It was also noted that it takes less time to train and there is less turnover among laboratory professionals with training in clinical laboratory science.

As laboratory practices continue to evolve in quantity and complexity, it is important that the practitioners expand their level knowledge as their responsibilities change over time. Given the increasing demands on physicians, these responsibilities have grown to more often include consulting with and advising physicians about the types of tests needed in a given case and accurate interpretation of test results.

Point-of-care testing by non-laboratory personnel

Some concerns were voiced about the potential for harm with point-of-care testing being performed by personnel who are not specifically trained or certified in medical laboratory testing. It was noted that some physician office personnel who are trained on-the-job to perform point-of-care testing, such as RNs or MAs, do not always understand the tests they are performing or the significance of quality control and may not employ good laboratory practices. Their training and their focus is rightly on patient care, and that is a very different focus from that of a laboratory technician. Additionally, automated or waived testing requires analytical and critical thinking skills in order to properly evaluate and assess the accuracy and validity of test results. Doctors often rely on medical laboratory scientists to interpret and provide guidance on test results.

Suggestions about/benefits of regulation

Regulation/licensure of MLS/MLTs will assist in identifying state manpower issues such as shortages of laboratory personnel and the distribution of personnel statewide. If regulation is approved, it should specify education and training requirements for MLS/MLTs and require certification by a nationally recognized certification agency. Additionally, the regulation language should include the specialty of cytogenetics where other specialties are listed, and at minimum, if this bill becomes law, the implementation should recognize the different laboratory professionals that are medical laboratory scientists in the broadest sense of the definition.

Additionally it was noted that, among the general public, many people believe that the laboratory personnel that conduct their medical tests are somehow minimally qualified and certified. Most of the rest of the professionals in the medical fields already are.

In opposition:

The Virginia Hospital and Healthcare Association (VHHA) spoke in opposition to the regulation of medical laboratory scientists and technicians in Virginia. The Association noted that federal health care reform will bring significant changes system-wide including emerging regulations which will add greatly to providers' administrative and regulatory burdens, requiring additional human and financial resources. Additionally, VHHA noted that CLIA regulations, Virginia Department of Health's Office of Licensure and Certification,

and The Joint Commission accreditation represent significant oversight of Virginia's hospitals and may mean no additional regulation is required in the hospital setting.

VII. Review of the Virginia Board of Health Professions Criteria for Evaluating the Need for Regulation

Based on the findings of this report, each of the seven criteria used to evaluate the need for regulation were reviewed.

Criterion One: Risk for Harm to the Consumer

> *The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.*

The findings of this study noted some areas of concern when considering the risk of harm:

CLIA regulations
Laboratories are regulated by CLIA, but laboratory personnel are not. However, CLIA regulations do require that laboratory personnel have specific minimum qualifications depending on the testing complexity being performed in their facility. Many consider these minimum qualifications to be insufficient given the scope of practice for MLS and MLT personnel.

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). Despite 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.

A CMS study of facilities that performed waived testing and PPM found widespread problems and concluded there was need for greater oversight. 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.

Point-of-Care testing
Point-of-Care testing is an area of some concern regarding the potential for harm. Such testing is often performed by personnel who are not specifically trained or certified in medical laboratory testing. These personnel (often RNs or MAs) may receive on-the-job training to perform point-of-care testing, but may not understand the tests they are performing or the significance of quality control. Their training and focus is on direct patient care, which is a very different focus from that of laboratory best practice.

Ability to detect harm

Due to the nature of proper test selection and laboratory testing generally, it can often be difficult to detect harm with certainty. When the wrong test is administered a correct diagnosis may be missed, if a test is conducted without adherence to best laboratory practice, results of that test may not relay the most accurate results. These sorts of missteps could result in a patient receiving the wrong treatment, receiving treatment that is too aggressive or not aggressive enough, having to endure further or unnecessary testing, or in not receiving any treatment at all. Not all laboratory error results in obvious and immediately recognizable harm.

Criterion Two: Specialized Skills and Training

> *The practice of the health occupation requires specialized education and training, and the public needs to have benefits by assurance of initial and continuing occupational competence.*

While the case can be made that MLS and MLTs need specialized education and training to perform the tasks required of their profession, there is currently no training mandated for these professionals in Virginia beyond the minimum standards set by CLIA laboratory requirements. This study found the following information relative to specialized skills and training:

Bureau of Labor Statistics information

According to the BLS, typically MLSs have a bachelor's degree in a life science and MLTs have an associate's degree in a science, clinical, or medical-related course of study. 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, 2009). 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 (BLS, 2009).

CLIA requirements

As previously mentioned, CLIA regulations require that laboratory personnel have specific minimum qualifications depending on the testing complexity being performed in their facility. For laboratories that conduct tests of moderate complexity, a high school diploma or (equivalent) and documented training for the testing performed are required. For laboratories that conduct tests of high complexity, an associate degree (including 24 semester hours in science) and completion of either (1) accredited or approved clinical laboratory training program or (2) three months laboratory training in the specialty(ies) in which the individual performs high complexity testing are required.

Need for continuing education

The increasing complexity and number of medical tests entering the market requires that qualified laboratory personnel participate in continuing education. Additionally, rapid advancements in laboratory technology require personnel to stay up-to-date and trained on how to operate and maintain new and sophisticated laboratory equipment. There are currently no continuing education requirements for MLS and MLTs unless required by the specific laboratory in which they are employed.

Importance of basic education in a life science or medical technology

Due to the increasing reliance on automated testing, it is important that MLT and MLS professionals have grounding in a life science or medical technology. This type of educational background provides the

laboratory professional with context necessary to more fully understand the types of tests they are conducting, when those tests are most appropriate, and how to interpret the results given a set of specific variables.

Criterion Three: Autonomous Practice

> *The functions and responsibilities of the practitioner require independent judgment and the members of the occupational group practice autonomously.*

*D*epending on the setting and complexity of testing conducted by a given laboratory, MLS and MLTs may work with varying levels of autonomy and requirements for independent judgment. Under CLIA, all laboratories are required to be headed by a Laboratory Director; however, a director may oversee up to five labs. There are also requirements under CLIA that moderate and high complexity testing laboratories include required personnel positions, although if qualified, more than one position can he held by one individual. These requirements are in place to provide proper oversight of testing personnel, but is can be expected that due to the high volume of testing conducted by many labs, the ability of a director or their designate to provide the necessary direct supervision to protect the public from harm may be compromised at times.

While waived testing may not require a great deal of independent judgment for conducting the actual test, it is required to assess how variables such as transport, storage, and timeliness might affect a given test's results. It is critical that all laboratory professionals have the ability to recognize the conditions and practices that may compromise samples and thereby test results.

Further it was cited that due to the increased demands on physicians, there is more reliance on MLSs particularly to be able to communicate an accurate assessment and interpretation of a test's results to the physician.

Criterion Four: Scope of Practice

> *The scope of practice is distinguishable from other licensed, certified and registered occupations, in spite of possible overlapping of professional duties, methods of examination, instrumentation, or therapeutic modalities.*

The scope of practice of MLS/MLTs is distinguishable from other licensed, certified and registered occupations with which they often work, such as laboratory directors, physicians and nurses. Under CLIA, laboratory directors must have specific educational background and work experience. Generally, these requirements 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. Physicians and nurses are both licensed occupations, but their focus is on direct patient care whereas the medical laboratory occupations' focus is on laboratory practice in support of direct patient care.

Criterion Five: Economic Impact

> *The economic costs to the public of regulating the occupational group are justified. These costs result from restriction of the supply of practitioner, and the cost of operation of regulatory boards and agencies.*

The economic impact of regulating MLS and MLTs is difficult to estimate. The intent of regulation in the medical professions is to decrease the risk of harm to the public, and certainly the most serious harm would be that of physical harm. However, increased costs to the public are also considered harm and should be mitigated where possible.

Cost of regulation

If costs increase for the industry it can be safely assumed that costs will eventually increase for the public. Regulation could impact costs on the industry for various reasons: If increased educational requirements are part of the regulation of these professions, then costs to those seeking employment in these professions will certainly increase. Further, continuing education requirements would increase costs to either the individual or their employer. Licensing fees would also increase costs for the persons employed as MLS or MLTs.

BLS data from May 2009 indicate that the average annual salary for MLS and MLTs in states that regulate these professions is only slightly higher (MLS = $56,662, MLT = $38,338) than the national average annual salaries (MLS = $55,620, MLT = $37,860). Currently in Virginia the salaries for MLS and MLTs are slightly below the national average, more so for MLSs (MLS = $53,380, MLT = $37,440). It is possible that increased regulation of these professions could increase their average annual salary in Virginia if higher incomes result from regulation.

Criterion Six: Alternatives to Regulation

> *There are no alternatives to State regulation of the occupation which adequately protect the public. Inspections and injunctions, disclosure requirements, and the strengthening of consumer protection laws and regulations are examples of methods of addressing the risk for public harm that do not require regulation of the occupation or profession.*

There are a few alternatives to state regulation that could increase protection of the public and which are based on issues cited as reasons to consider the regulation of MLS and MLTs. Pre-requisites to employment could be established and which would set out specific minimum educational requirements and/or work experience that are more stringent than currently required by CLIA. Due to the rapidly evolving nature of these technical professions, continuing education requirements could keep the medical laboratory workforce up-to-date on new testing methods, equipment, and best practices. A disclosure requirement could be established for these professions in order to make future employers aware of any disciplinary actions taken against MLS and MLTs seeking employment with their firms.

Criterion Seven: Least Restrictive Regulation

> *When it is determined that the State regulation of the occupation or profession is necessary, the least restrictive level of occupational regulation consistent with public protection will be recommended to the Governor, the General Assembly and the Director of the Department of Health Professions (DHP, 1998).*

Registration would be the least restrictive and could be used to track MLS and MLTs. This would assist in understanding workforce levels statewide and could be used to assist in identifying individuals with pending or serious disciplinary actions against them. But it wouldn't address the concerns related to educational foundation or the need for continuing education. Certification would be more restrictive than registration, but could be constructed in order to address the educational concerns.

Recommendations

After due consideration, the Board of Health Professions' Regulatory Research Committee concluded at its September 29, 2010 meeting that Virginia should regulate medical laboratory scientists and technicians. The current system of laboratory facility oversight was viewed as insufficient to adequately ensure the public's health, safety, and welfare and medical laboratory scientists and technicians should be held accountable for their individual practices. The full Board concurred.

Medical laboratory testing affects the vast majority of diagnoses and treatments. Testing volume can be expected to increase along with Virginia's growing and aging population and the increased demand for health care services due to the recent federal health reform legislation. Although simple tests are prevalent, the ever evolving and complex nature of medical science and technologies requires the Commonwealth's assurance of competence in Virginia's medical laboratory scientists and technicians to safeguard accurate results and appropriate interpretations.

The Committee recommended continuation of the study to afford them adequate opportunity to obtain the information needed for them to recommend the appropriate degree and form regulation. Although requested under the U.S. Freedom of Information Act, the independent CMS survey data on activities occurring in Virginia's laboratories has not yet been received. This information can be instrumental in advising on the types of deficiencies actually occurring in Virginia's labs as well as during the pre-analytic and post-analytic phases. Because the patient's wellbeing can be affected by errors in any and all phases, the Committee seeks to gain a better understanding of the potential for harm that can occur throughout the testing process.

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IX. Appendices[1]

Appendix 1: National Credentialing Agency for Clinical Laboratory Scientists Examination Content for Clinical Laboratory Scientists (NCA Content CLS)

Appendix 2: College of American Pathologists Criteria for the Clinical Laboratory Director

Appendix 3: American Society for Clinical Laboratory Science Body of Knowledge for Clinical Laboratory Scientists (ASCLS BOK CLS)

Appendix 3A: American Society for Clinical Laboratory Science Body of Knowledge for Clinical Laboratory Technicians (ASCLS BOK CLT)

Appendix 4: Laboratory Scientist and Laboratory Technical Personnel Licensure in Other States

Appendix 5: CLIA (Clinical Laboratory Status for Virginia Laboratories

Appendix 6: Tests Granted Waiver Status under Clinical Laboratory Improvement Amendments (CLIA)

Appendix 7: Transcript of the Public Hearing Held on July 16, 2010

[1] Due to the volume of the appendices, they are available from the Board office or for viewing and/or downloading from the Board of Health Professions website: www.bhp.virginia.gov under the title of this report.