Final Report

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Study of the Need to Regulate Clinical Laboratory Personnel

Virginia Department of Health Professions
The Board of Health Professions

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I. BACKGROUND:

The Virginia Society for Clinical Laboratory Science petitioned the Board of Health Professions to review the need for state licensure of clinical laboratory personnel. Known by a variety of titles, clinical laboratory personnel conduct diagnostic tests on human specimens in diverse settings such as hospitals, physician office laboratories, reference laboratories, pharmaceutical companies, and research facilities. Physicians and other health care providers and researchers rely heavily upon the accuracy of the results of the laboratory tests performed by these personnel. Given the potential dangers to the public health of inaccurate or inappropriate testing, the current study was undertaken in an effort to determine if state regulation of these personnel would measurably affect testing outcomes in the laboratories.

The report that follows outlines issues pertaining to the nature of the profession of clinical laboratory science, academic preparation, availability of educational programs, voluntary certification, present and proposed federal regulation, issues related to test accuracy, laboratory survey deficiencies and public hearing findings. The information contained in this report is intended to provide policy-makers with a complete view of the profession as it exists in the present healthcare market in Virginia.

II. THE PROFESSION:

The Bureau of Labor Statistics (BLS) provides a detailed description of the practice engaged in by clinical laboratory scientists / medical technologists (CLS/MT) and clinical laboratory technicians / medical laboratory technicians (CLT/MLT) (BLS Occupational Outlook Handbook, 1998-1999).

- CLS/MTs perform complex chemical, biological, hematological, immunologic, microscopic, and bacteriological tests. They microscopically examine blood, tissue, and other body substances. They make cultures of body fluid or tissue samples to determine the presence of bacteria, fungi, parasites, or other micro-organisms. They analyze samples for chemical content or reaction and determine blood glucose or cholesterol levels. They also type and cross-match blood samples for transfusions. Additionally, medical and clinical laboratory technologists may evaluate test results, develop and modify procedures, and establish and monitor programs to insure the accuracy of tests. CLS/MTs may advance to supervisory positions in laboratory work or become chief medical or clinical laboratory technologists or laboratory managers in hospitals. Manufacturers of home diagnostic testing kits and laboratory equipment and supplies seek experienced technologists to work in product development, marketing, and sales. Opportunities are also available in academia. Graduate education in medical technology, one of the biological sciences, chemistry, management, or education usually speeds

advancement. A doctorate is sometimes needed to become a laboratory director. However, federal regulation allows directors of moderate complexity laboratories to have either a master's degree or a bachelor's degree combined with the appropriate amount of training and experience. Section VI of this report contains information pertaining to test complexity.

- The usual requirement for an entry-level position as a CLS/MT is a bachelor's degree with a major in medical technology or in one of the life sciences. Universities and hospitals offer medical technology programs. It is also possible to qualify through a combination of on-the-job and specialized training. Masters degrees in medical technology and related clinical laboratory sciences provide training for specialized areas of laboratory work or teaching, administration, or research.

- Technologists in small laboratories perform many types of tests, while those in large laboratories generally specialize. Technologists who prepare specimens and analyze the chemical and hormonal contents of body fluids are clinical chemistry technologists. Those who examine and identify bacteria and other micro-organisms are microbiology technologists. Blood bank technologists collect, type, and prepare blood and its components for transfusions. Immunology technologists examine elements and responses of the human immune system to foreign bodies. Cytotechnologists, prepare slides of body cells and microscopically examine these cells for abnormalities which may signal the beginning of a cancerous growth.

- CLT/MLTs often perform less complex tests and laboratory procedures than technologists. Technicians may prepare specimens and operate automatic analyzers, for example, or they may perform manual tests following detailed instructions. Like technologists, they may work in several areas of the clinical laboratory or specialize in just one. They usually work under the supervision of medical and clinical laboratory technologists or laboratory managers. Medical and clinical laboratory technicians generally have either an associate's degree from a community or junior college, or a certificate from a hospital, vocational or technical school, or from one of the Armed Forces. A few technicians have a high school diploma or GED with on-the-job training.

- Clinical laboratory personnel need analytical judgment and the ability to work under pressure. Problem solving skills are also desirable. Close attention to detail is essential because small differences or changes in test substances or numerical readouts can be crucial for patient care. Manual dexterity and normal color vision are highly desirable. With the widespread use of automated laboratory equipment, computer skills are important.

III. ACADEMIC TRAINING:

The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) is a nonprofit organization that independently accredits education programs in the following areas: clinical laboratory scientist/medical technologist (CLS/MT), clinical laboratory technician/medical laboratory technician (CLT/MLT)(associate degree and certificate), histotechnologist (HTL), histologic technician (HT) (associate degree and certificate) and pathologists' assistant (Path Asst). NAACLS also independently approves phlebotomist, cytogenetic technologist and clinical assistant educational programs. NAACLS is an autonomous, nonprofit organization established in 1973. NAACLS is recognized by the United States Department of Education and the Council for Higher Education Accreditation (CHEA) (NAACLS Guide to Accreditation).

The following chart indicates the status of the educational programs that presently exist in the field of clinical laboratory sciences as of 1998:

TYPE OF PROGRAM	ACCREDITED	APPROVED
CLS/MT (technologist)	288	n/a
CLT/MLT (technician)	249	n/a
HT/HTL	32	n/a
Pathologist Assistant	6	n/a
Phlebotomy	n/a	66
Cytogenetic Technology	n/a	6

Information furnished by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS)

NAACLS accredited CLS/MT programs in Virginia include Fairfax Hospital, Augusta Medical Center, Rockingham Memorial Hospital, Norfolk State University, Old Dominion University, Virginia Commonwealth University and Roanoke Memorial Hospital/Carilion Health Systems. Accredited CLT/MLT programs include Northern Virginia Community College, Thomas Nelson Community College, J. Sargeant Reynolds Community College, Wytheville Community College and Centra Health Systems of Lynchburg (NAACLS Program Search).

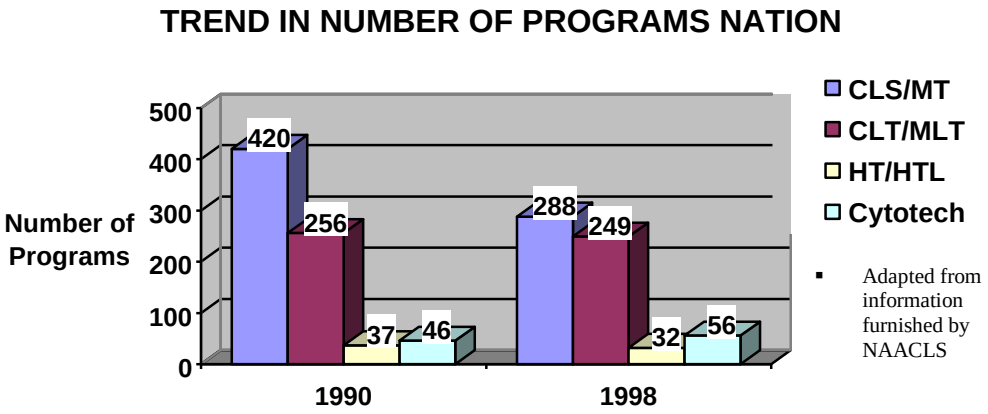
Additionally, the Accrediting Bureau of Health Education Schools (ABHES) is recognized by the U.S. Department of Education and the Council for Higher Education Accreditation to accredit training institutions and programs in medical assisting and medical laboratory technology. There are ten medical laboratory technician schools accredited by ABHES (Email communication with AHBES, September 1999).

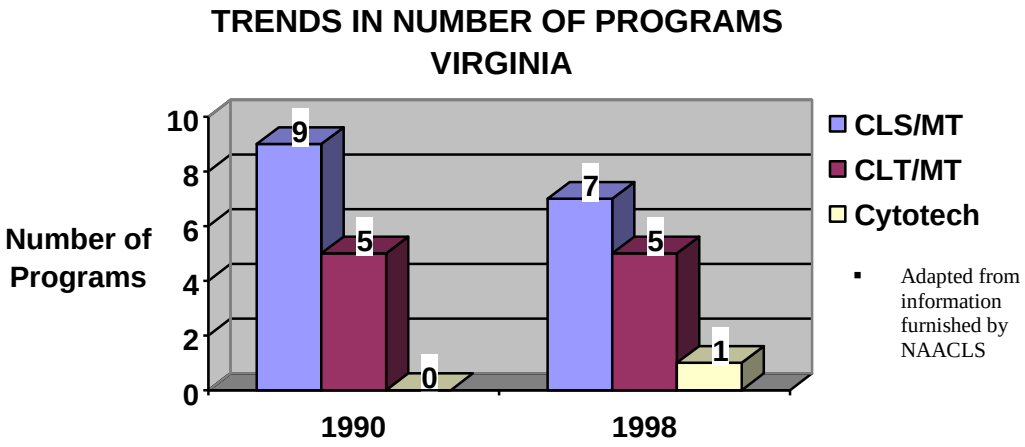
Trends in Educational Programs:

There appears to be a downward trend in the number of programs offered in the area of the clinical laboratory sciences. On a national level, in 1990, there were 420 CLS/MT programs accredited by NAACLS. In 1998, that number had decreased to 288. This has resulted in a slow decline in the number of graduates. In 1990, there

were 3,024 graduates from CLS/MT program. In 1998, there were 2,667 (Kimball, 1999).

In Virginia, in 1990, there were nine CLS/MT programs. In 1998, that number had declined to seven. Interestingly, the number of graduates from CLS/MT programs has increased from 68 to 78 despite the closure of programs (Kimball, 1999). The following chart depicts nationwide trends in the numbers of programs and graduates in the area of clinical laboratory science:





TRENDS IN NUMBER OF GRADUATES

Type of Program	NATION		VIRGINIA	
	1990	1998	1990	1998
CLS/MT	3024	2667	68	78
CLT/MLT	2292	2412	36	41
HT & HTL	104	120	0	0
CYTOTECH	210	299	0	9

Adapted from information furnished by NAACLS

Both at the national and state level, as can be seen from the graphic representations above, there has been a decrease in the number of CLS/MT programs and fairly steady existence of CLT/MLT programs over the past eight years. This may reflect a shift in employment patterns that may be occurring, in part, because of the increased automation in the clinical laboratory science field. In addition, there may be a greater need for specialized skills in a field that is becoming technologically advanced. This may be an explanation for the slow growth among the programs in the area of cytogenetic technology.

Nationwide, in the past eight years, there has been a decline in the number of graduates in the CLS/MT category. The degree of decline may not be as large as expected due to the fact that the majority of declining programs are hospital-based. Compared to academic programs, these programs typically have small numbers of students (Kimball, 1999). Thus, closure does not cause the widespread supply issues that might be realized if the closures were occurring in academia.

According to the executive director of NAACLS, accredited hospital programs often close because of lack of support for education on the part of the institution. Lack of resources and understaffing make it difficult to support quality educational programs. In regards to programs in academic settings, closures occur due to an inability to attract students. Factors that negatively impact enrollment include a rigorous curriculum with requirements similar to those in a pre-medicine track and low entry-level salaries offered to new graduates holding a baccalaureate degree (Kimball, 1999).

This trend of declining graduates has not been realized in Virginia. Despite a closure of two programs in the state, the number of CLS/MT graduates has fluctuated between 71 and 78 between 1995 and 1998. In regards to CLTs/MLTs, HT & HTLs and cytotechnologists, there has been a slow increase in the number of graduates nationwide over the past eight years. This same trend has been noted in Virginia (except with HT & HTL for which there are no programs in Virginia) (Kimball, 1999).

The following is a chart depicting the level of educational attainment of clinical laboratory personnel, in Virginia, as derived from the 1990 United States Census Data:

EDUCATIONAL ATTAINMENT	FULL-TIME (n=5358)	OTHER (n=2188)
< High School Diploma	136	63
High School Graduate	771	226
Some College (no degree); Associates Degree	1,958	869
Bachelors Degree	2,077	824
Graduate or Professional Degree	416	206

Adapted from information obtained at http://govinfo.library.orst.edu/cgi-bin/sstf22-list?rloc=x050&table=1&rjob=B37.

IV. CERTIFICATION:

At some laboratory facilities, voluntary certification is a prerequisite for employment for clinical laboratory personnel. In regards to CLS/MT's and CLT/MLT's, there are four primary agencies that provide voluntary credentialing. These are the National Certification Agency (NCA), the American Medical Technologists (AMT), the American Society of Clinical Pathologists Board of Registry (ASCP-BOR) and the American Association of Bioanalysts (AAB). AAB was known previously as the International Society for Clinical Laboratory Technology (ISCLT).

The following chart indicates the levels at which the four agencies voluntary certify testing personnel:

AGENCY	Clinical Laboratory Technologist / Clinical Laboratory Scientist / Medical Technologist	Clinical Laboratory Technician / Medical Laboratory Technician	Histotechnologists	Cytogenetic Technicians
NCA	YES	YES	NO	NO
AMT	YES	YES	NO	NO
ASCP-BOR	YES	YES	YES	Certifies cytotechnologists and specialists in cytotechnology
AAB	YES	YES	NO	NO

Adapted from information provided by the NCA, AMT, ASCP-BOR and AAB.

The requirements for voluntary certification vary from organization to organization. Details of the specific requirements to sit for the certification examinations can be found in Appendix 1.

V. EMPLOYMENT AND WAGES:

According to the BLS, CLS/MT's and CLT/MLT's held about 285,000 jobs in 1996. The majority of these professionals were employed in the hospital setting. Most others worked in medical laboratories and offices and clinics of physicians. Some were employed in blood banks, research and testing laboratories, and in the Federal Government (Department of Veterans Affairs, U.S. Public Health Service facilities) (BLS Occupational Outlook Handbook, 1998-1999). The following charts provide comparative data between Virginia, the nation and selected regulated states in regard to employment numbers and salary patterns:

1997 Employment & Wage Estimates – Nation, Virginia & Selected Regulated States
Clinical Laboratory Scientists / Medical Technologists (CLS/MT) &
Clinical Laboratory Technicians / Medical Laboratory Technicians (CLT/MLT)

LOCATION	# OF CLS/MT	# OF CLT/MLT	MEAN HOURLY WAGE CLS/MT	MEAN HOURLY WAGE CLT/MLT	MEAN SALARY CLS/MT	MEAN SALARY CLT/MLT
Nation	157,530	136,380	$18.44	$12.93	$38,350	$26,900
Virginia	3,220	2,310	$15.10	$13.10	$31,420	$27,060
Tennessee **	2,960	3,230	$16.84	$11.55	$35,030	$24,020
W. Virginia **	970	1,060	$15.77	$11.53	$32,800	$23,980
Montana **	500	300	$17.59	$11.51	$36,590	$23,940

**States in which regulation of clinical laboratory personnel is in place.
Adapted from information obtained at http://stats.bls.gov/oes/state/oessrch2.htm

In regards to voluntary certification of CLS/MT's and CLT/MLT's in Virginia, the following chart depicts the number of certified personnel in Virginia:

Total Personnel vs. Certified Personnel in Virginia

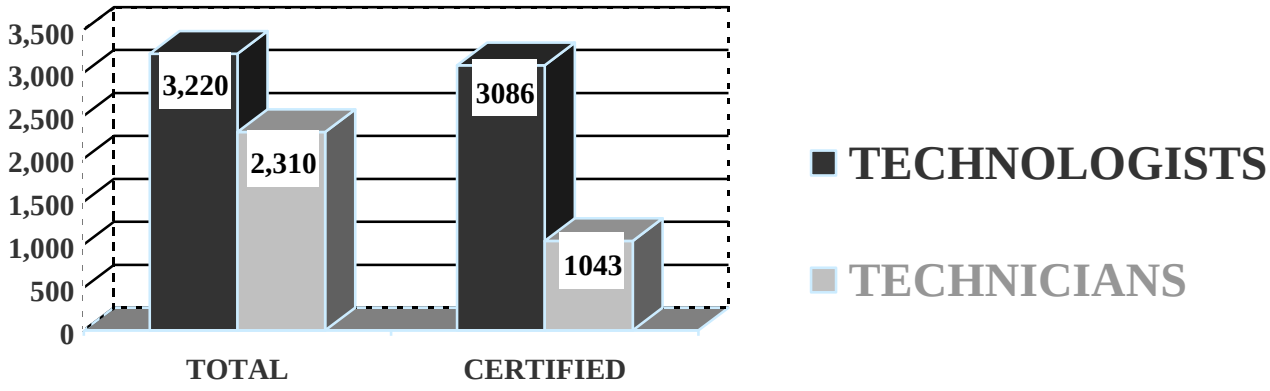


Chart derived from data from Bureau of Labor Statistics and information provided by national voluntary certifying agencies (ASCP-BOR, AMT, NCA, AAB).

In light of information provided by the Health Care Financing Administration (HCFA), it is unclear how accurate the BLS estimates are regarding the numbers of clinical laboratory technologists and technicians in Virginia. Based on data from the HCFA, there are 9,805 persons identified as testing personnel in laboratories that hold certificates of waiver, provider performed microscopy procedures (PPMP), compliance and accreditation. In addition, another 43,095 persons are identified as "waived individuals" (HCFA Information, 1999). These are persons who are performing waived tests. Since CLIA does not mandate any educational requirements for those performing waived testing, these persons can have training ranging from a high school diploma with on-the-job training to nurses to clinical laboratory scientists to physicians.

Employment Outlook

Employment of clinical laboratory personnel is expected to grow at about the same rate as the average for all occupations (increase 10-20%) through the year 2006 as the volume of laboratory tests increases with population growth and the development of new types of tests. Hospitals and independent laboratories have recently undergone considerable consolidation and restructuring that has boosted productivity and allowed the same number of personnel to perform more tests than previously possible (BLS Occupational Outlook Handbook, 1998-1999). As a result, competition for jobs has increased and individuals may now have to look longer to find employment than in the past.

Technological advances are expected to continue to have two opposing effects on employment through 2006. New, more powerful diagnostic tests will encourage more testing and spur employment. However, advances in laboratory automation and simpler tests, which make it possible for each worker to perform more tests, should slow growth. Research and development efforts are targeted at simplifying routine testing procedures so that non-laboratory personnel, physicians and patients in particular, can perform tests now done in laboratories (BLS Occupational Outlook Handbook, 1998-1999).

Clinical laboratory technologists and technicians sorted by numeric change in employment, 1996-2006 – Nine Selected Industries

Industry	1996 employment		Projected 2006 employment		Change, 1996-2006	
	Number	Percent distribution	Number	Percent distribution	Number	Percent
Total, all industries	285,100	100.00	327,581	100.00	42,481	14.9
Offices of physicians including osteopaths	46,034	16.15	71,193	21.73	25,159	54.7
Medical and dental laboratories	39,663	13.91	49,099	14.99	9,436	23.8
Health and allied services, nec	11,024	3.87	16,503	5.04	5,480	49.7
Offices of other health practitioners	1,030	0.36	1,784	0.54	755	73.3
Nursing and personal care facilities	744	0.26	1,049	0.32	305	41.0
Home health care services	306	0.11	577	0.18	271	88.7
Offices and clinics of dentists	413	0.15	561	0.17	147	35.6
Hospitals, public and private	151,647	53.19	146,543	44.73	-5,105	-3.4
Research and testing services	•	•	•	•	•	•

- Data are suppressed because of confidentiality or because there are less than 50 workers.

http://stats.bls.gov/asp/oep/nioem/empior.asp?MultipleSelect=000000&Sort=nchg&StartItem=1&Base=1996&Proj=2006&SingleSelect=329100220&Type=Occupation&number=10

VI. FEDERAL REGULATION – CLIA '88:

The Clinical Laboratory Improvement Act (CLIA) of 1988 established quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in 1992 (CLIA General Program Description). A copy of the regulations can be found in Appendix 2.

The regulations are based on the complexity of the test method. The more complicated the test, the more stringent the requirements. Tests are classified as follows, from least complex to most complex: waived complexity, moderate complexity (including provider performed microscopy) and high complexity. CLIA provides specific guidelines in regards to proficiency testing standards, patient test management, quality control, personnel qualifications and quality assurance (CLIA General Program Description).

The United States Department of Health and Human Services' Health Care Financing Administration (HCFA) is responsible for the implementation of CLIA nationally. The Department of Health is the state agency that is responsible for oversite of the CLIA program in Virginia. HCFA is responsible for laboratory registration, fee collection, surveyor guidelines and training, enforcement, approval of proficiency testing (PT) providers, accrediting organizations and exempt states. The Virginia Department of Health serves as the state HCFA surveyor for the CLIA

program. Test categorization is done through the Centers for Disease Control and Prevention (CDC) (CLIA General Program Description).

On-site surveys for laboratories conducting moderate or high complexity tests are done every two years. The laboratories that meet CLIA requirements, as determined by a successful on-site survey, have the option of participating in the Alternate Quality Assessment Survey (AQAS). AQAS is a self-survey document that allows laboratories to go longer than two years without an on-site survey (HCFA – AQAS, 1999). In Virginia, there are approximately 80 laboratories in the AQAS program (HCFA, 1999). A listing of these laboratories can be found in Appendix 3.

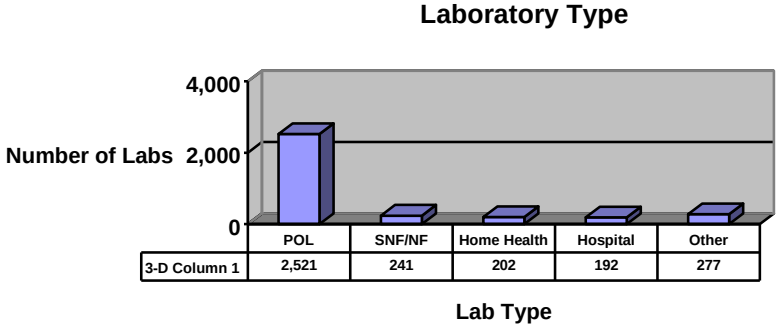
There are various approved accrediting organizations under CLIA. They are the American Association of Blood Banks (AABB), American Osteopathic Association (AOA), American Society of Histocompatibility and Immunogenetics (ASHI), College of American Pathologists (CAP), Commission on Office Laboratory Accreditation (COLA) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Ten percent all laboratories registered with CLIA have been accredited by one or more of these organizations (CLIA Update, 1999).

A certificate of accreditation is awarded when the laboratory is in compliance with standards set forth by one of these HCFA approved accreditation organizations. This means that the laboratory is deemed to have met applicable CLIA requirements (CLIA General Program Description). Specific information regarding the number of laboratory types, certification levels and accrediting organizations can be found in Appendix 4.

CLIA AND VIRGINIA:

As part of this study, the Board of Health Professions solicited input from HCFA at both the state and federal level. Information regarding number of laboratories, type of laboratories, certificate type, number and nature of conditional level and standard level deficiencies and proficiency test failures was obtained.

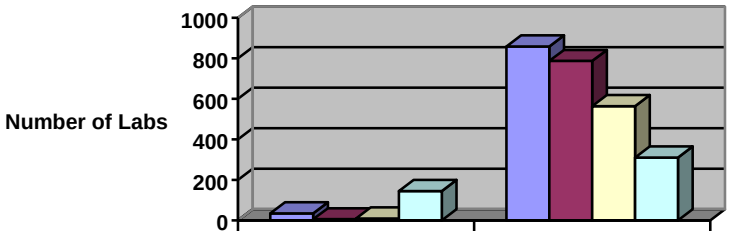
There are 4,062 laboratories registered in Virginia (HCFA Information, 1999). The top five laboratory types are indicated in the following chart:



There are less that one hundred laboratories located at each of the other locations such as ambulatory surgery centers, blood banks, mobile units and community clinics. A complete breakdown of laboratory type by location can be found in appendix 5.

There are approximately 574 laboratories in Virginia that have certificates of accreditation from CLIA. As mentioned previously, this means that the laboratory is in compliance with standards set forth by a HCFA approved accreditation organization. Of these 574 laboratories, 141 are hospital laboratories and 294 are physician office laboratories. Thus, hospital and POLs account for 435, or 75%, of the laboratories holding certificates of accreditation (HCFA, 1999). A full listing of accredited laboratories and their respective accrediting organizations can be found in Appendix 6.

Certificate Type by Lab Type



	Hospital	POL
Waiver	34	859
PPM	5	787
Compliance	9	564
Accreditation	144	310

*Information provided by the HCFA

Proficiency Test Performance in Virginia:

Proficiency testing is required of all laboratories performing moderate or high complexity testing. As mentioned previously, there are approximately 4,062 laboratories in Virginia. Of these laboratories, approximately 1,801 possess certificates of waiver. These laboratories are not required to participate in a proficiency testing program. Approximately 2,261 laboratories possess certificates of

provider performed microscopy procedures (PPMP), certificates of compliance or certificates of accreditation (HCFA Information, 1999). These laboratories are required to participate in proficiency testing.

In 1998, there were 161 laboratories in Virginia cited for failure in proficiency testing. This involved the testing of 434 analytes. In 1999, there were 80 laboratories cited for deficiencies in proficiency testing. This involved the testing of 162 analytes**.** Of the 80 laboratories cited in 1999, 39 failed the previous year. These 39 laboratories accounted for 66 of the 162 total analyte failures. Of these 66 failures, 35 involved the same analyte types that were failed the previous year (HCFA Information, 1999). A complete listing of laboratories with PT failures in 1998 and 1999 can be found in Appendix 7.

The proficiency test score needs to be considered when interpreting the meaning of the failure rate of laboratories. Scores of zero are given for any of the three circumstances:

1. The laboratory participates in HCFA approved PT company but fails to report PT scores.
2. The laboratory has ceased testing of a particular analyte but fails to notify the PT company.
3. The laboratory fails testing all five samples of a particular analyte.

In the data provided by the HCFA for 1998 and 1999, there were 596 total analytes tested for which there were unsuccessful test results. Scoring on 308 of the analytes was zero (HCFA Information, 1999). This could mean that all samples of the particular analyte resulted in erroneous scores or that the laboratory failed to report PT scores for that analyte.

Location of Laboratories with PT Failures (1998,1999)

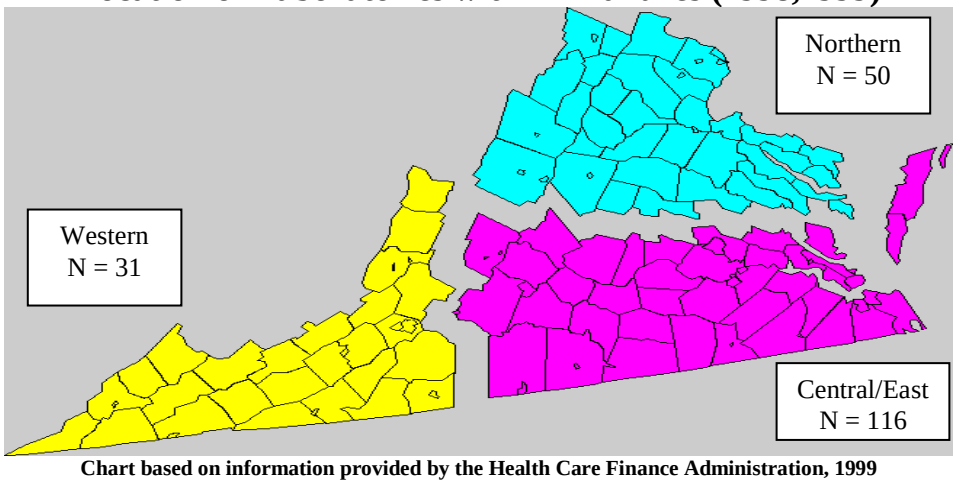


Chart based on information provided by the Health Care Finance Administration, 1999

On the following page, there is a comparative assessment of proficiency tests failure in Virginia versus selected regulated states in 1998. The findings are based on information provided by the HCFA. Unfortunately, the total number of proficiency test reports is unavailable for each state. Also, information regarding laboratory type was unavailable. Finally, level of personnel training is unknown when PT scores are reported. This makes it difficult to make definitive conclusions based on these findings.

VIRGINIA AND SELECTED REGULATED STATES
[Information provided by the HCFA (1999)]

STATE	# of Laboratories – PPMP, Compliance & Accreditation	Number of Laboratories with Proficiency Test Failures	Number of Analytes	Number of Events	Events with Zero Score
Virginia **Total = 4,062**	2,261	161 (7.1%)	354	434	247 (56.9%)
Florida** **Total = 10,888**	4,285	320 (7.5%)	933	1352	987 (73.0%)
Tennessee** **Total = 3,715**	2,091	154 (7.4%)	358	440	246 (55.9%)
West Virginia** **Total = 1,499**	677	51 (7.5%)	101	138	87 (63.0%)

** Regulation of clinical laboratory personnel in place.

Surveys and Conditional and Standard Level Deficiencies:

The Virginia Department of Health surveys laboratories that possess a CLIA certificate of compliance every two years. The one exception is laboratories that participate in the AQAS program. Based on data provided by the HCFA, there are a total of 741 laboratories in this category. Since the implementation of CLIA in 1992, there have been 906 laboratories surveyed in Virginia. Of the 906 laboratories surveyed, 333 were cited for a total of 912 deficiencies. In regard to the nature of the deficiency, 106 were at the conditional level and 806 were at the standard level (HCFA Information, 1999).

Conditional level deficiencies are those that present an immediate and serious danger to the public. The laboratory is required to submit a written plan of correction within ten days of the identification of the deficiency. Corrective action must occur within 90 days. In addition, laboratories cited for conditional level deficiencies are subject to unannounced inspections by the Virginia Department of Health (Morris, 1999). The most common conditional level deficiencies were related to PT enrollment and/or successful PT participation (HCFA Information, 1999). Standard level deficiencies require corrective action within one year of its identification. A complete listing of laboratories receiving standard and/or conditional level deficiencies among the 906 surveyed can be found in Appendix 8.

The Laboratory Registry:

The Laboratory Registry is a listing of laboratories that have failed to comply with the CLIA requirements over a certain time period making it necessary for HCFA to take adverse action against them. Actions may include certificate revocation, certificate suspension, certificate limitation, termination and suspension of Medicare payments and directed plans of correction (HCFA Laboratory Registry, 1996-1998). The Registry listing for 1996, 1997 and 1998 is available via a link from the HCFA web site. According to a HCFA representative, the Registry listing consists of all final CLIA enforcement actions taken as reported by each regional office for the states under their jurisdiction (Cometa, 1999).

In 1996, there were two laboratories in Virginia that received sanctions from HCFA. One laboratory in Martinsville was not in compliance with CLIA conditions in regards to cytology, laboratory director, laboratory technical supervisor and quality assurance. A plan of correction was not submitted. The sanctions included cancellation of approval to receive Medicare payments, suspension of CLIA certificate and proposed revocation of CLIA certificate. The second laboratory, located in a family practice setting in Chesapeake, was not enrolled in a PT program for bacteriology and general immunology. In addition, there was a failure to submit a plan of correction and other necessary documentation. The sanctions included cancellation

of approval to receive Medicare payment and limitation of their CLIA certificate (HCFA Laboratory Registry, 1996).

In 1997, there was one listing pertaining to Virginia in the Laboratory Registry. A laboratory in a Health South facility in Richmond had their CLIA accreditation denied due to a failure to adhere to the accreditation organization's required improvements (HCFA Laboratory Registry, 1997). There were no sanctions taken by the HCFA against laboratories in Virginia in 1998. The 1996-1998 Laboratory Registry can be found in Appendix 9.

Recent Regulatory Efforts:

There have been recent efforts to enact federal legislation that would serve to exempt physician office laboratories from the regulations as set forth by CLIA '88. In 1995, during the 104th Congress, bills were brought forth by Representative Bill Archer in the House (H.R 1386) and Senator Kay Bailey Hutchinson in the Senate (S.877) that addressed exemption of physician office laboratories from section 353 of the Public Service Health Act (Archer, 1995; Hutchinson, 1995). The exemption of the POLs would not pertain to those laboratories that perform Papanicolaous (Pap) smears. The House bill was referred to the Committee on Commerce (Archer, 1995). The Senate bill was referred to the Committee on Labor and Human Resources (Hutchinson, 1995).

Similar bills were introduced in the House (H.R. 2250) and the Senate (S. 1068) during the 105th Congress by the same patrons (Archer, 1996; Hutchinson, 1996). H.R 2250 was referred to the Committee on Commerce and then to the Subcommittee on Health and Environment (Archer, 1996). S.1068 was referred to the Committee on Labor and Human Resources (Hutchinson, 1996). A final bill was introduced to the 106th Congress by Representative Archer (H.R. 528) (Archer, 1997). To date, none of these bills have been enacted.

Both Representative Archer and Senator Hutchinson cited similar reasons for their respective bills. They indicated that the CLIA '88 has resulted in minimal improvements in testing quality. In addition, they cited that CLIA '88 has resulted in substantially increased paperwork and has hindered the provision of high quality patient care. Senator Hutchinson indicated that 27% of Texas laboratories have ceased offering testing services due to the CLIA '88 mandates. In addition, another 31% have reduced the number of testing services they provide. Reduction of elimination of POL testing has the potential to create barrier to both access and treatment compliance (Archer 1995-1997; Hutchinson, 1995-1996). However, the contention that CLIA will serve as a catalyst for POL laboratory closure is contradictory to the BLS predictions for the employment of clinical laboratory technologists and technicians in this setting in 2006. The BLS projects an increase of approximately 25,000 employees in this area in the ten-year interval from 1996 to 2006 (BLS Occupational Outlook Handbook, 1998-1999).

Interestingly, the American Society for Microbiology (ASM) wrote a position statement opposing H.R. 2250. They cited that the result of the legislation would be the exemption of approximately 90,000 physician office laboratories from any type of oversight in regards to quality or accuracy. ASM reference studies that have been done since CLIA '88s inception that demonstrate an improvement in testing accuracy in the POL setting. The coalition members that supported this statement included many of the large organizations in the clinical laboratory science field. Included were the following: The American Association for Clinical Chemistry, the American Association of Bioanalysts, the American Clinical Laboratory Association, American Medical Technologists and the American Society for Clinical Laboratory Science (ASM, 1998).

Conversely, the American Medical Association supported H.R. 528 citing that it would provide relief from the "excessive and unworkable CLIA requirements." This bill was essentially identical to H.R. 2250 that was introduced the previous year. The AMA argues that CLIA has resulted in higher costs for the POL and this, in turn, has resulted in many physicians ceasing in-office laboratory testing. Thus, patients are inconvenienced by having to seek laboratory services at a location geographically apart from their physician's office. According to the AMA, this often times comes at an additional cost to the patient (AMA, 1999).

Perceived Inadequacy of CLIA '88:

Critics of the CLIA regulations have focused on the varying degrees of personnel requirements for the different levels of testing. The testing personnel requirements for the various levels of testing range from high school education with on-the-job training to an associate degree. Specifics can be located in Appendix 10 in regards to training requirements of testing personnel.

In addition, proficiency testing has been cited as a problematic area. Proficiency testing is the mechanism used to insure ongoing test accuracy in laboratories participating in the CLIA program. In the 1995 Institute "Frontiers in Laboratory Practice Research" a report of panel findings indicate that proficiency testing is "a flawed proxy for directly measuring the quality of daily laboratory testing within the context of the total testing process." Further, they indicate that proficiency testing focuses only on the analytical component of the test procedure and neglects to address the pre- and post-analytical portions of the testing process (Barr, 1995). This makes interpretations of studies reporting variations in proficiency testing based on level of personnel training difficult to interpret.

VII. ACCURACY OF TESTING:

Reilly et al. (1999), in their article entitled "Evaluation of mycology laboratory proficiency testing", investigated the difference in proficiency testing outcomes in both overt (unblinded) and covert (blinded) conditions. The hypothesis was that

proficiency testing that is done in an overt fashion results in findings that are associated with optimal rather than typical laboratory performance. The authors found that higher error rates in the identification of common fungi occurred in the covert proficiency test condition.

Plebani and Carraro (1997) investigated the types and frequency of mistakes occurring in the hospital laboratory setting in an effort to determine the most critical phases in the testing process. Their findings support the notion that errors are not limited to the analytical phase. Among 40,490 analyses, 189 mistakes were identified. Of these mistakes, the majority occurred in the preanalytical phase (68.2%). There was a lower frequency of occurrence in the analytical (13.3%) and the post-analytical phase (18.5%). The following is a chart indicating the nature of the mistakes that occurred in the various phases of laboratory testing in this study:

Preanalytical (n=129)	Analytical (n=25)	Post-Analytical (n=35)
• Wrong name of patient (n=5) • Error in hospital unit identification (n=36) • Physicians order missed (n=34) • Order misinterpreted (n=6) • Inappropriate container used (n=5) • Specimen collection incorrect (n=4) • Specimen collected from infusion route (n=39)	• Isolated malfunctioning of instrument (n=5) • Lack of specificity of the method (n=4) • Unacceptable performance (n=16)	• Correction of erroneous finding overlooked (n=9) • Keyboard entry error (n=5) • Turnaround time exceeded (n=6) • Physician not notified of problem (n=6)

Adapted from Plebano and Carraro, 1997.

Plebani and Carraro (1997) indicated that 74% of the 189 mistakes had "no effect" on patients' outcome. The remainder of the mistakes resulted in outcomes such as inappropriate transfusions (n=4), inappropriate modification of heparin infusion or digoxin therapy (n=6), inappropriate infusion of electrolyte solution (n=2) and inappropriate follow-up studies (n=37). It should be noted that this study was conducted in Italy. However, despite an inability to directly generalize the findings to the United States, it provides insight into the nature of laboratory errors at different phases of testing. Furthermore, it is one of the few studies that attempt to address the issue of testing errors and patient outcomes.

Nutting et al. (1996) supports the contention that laboratory errors frequently occur in the pre- and post-analytical phases of testing. One hundred and twenty four clinicians in forty-nine practices reported laboratory problems that occurred over a six-month time period. There were 180 laboratory problems reported. Forty-five occurred in POLs and 135 occurred in reference laboratories. Of the 180 laboratory problems reported, 55.6% of the problems occurred in the pre-analytical phase, 13.3% in the analytical phase and 27.8% in the post-analytical phase. Of the 180 problems reported, 27% were determined to have had effects on patient care. Effects included delays in treatment and/or diagnosis and repetitive testing. These findings must be

balanced with the inherent limitations of studies that rely on self-report. In addition, the total number of laboratory tests completed in the six-month period was unreported.

As part of this study, the Board of Health Professions obtained information about specimen rejection from a large, metropolitan hospital in Virginia. The information shared is relevant to the issue of pre-analytical errors. In January and February of 1997, there were 26,587 specimens collected from patients by phlebotomists. Of these, 104 specimens (.4%) were rejected due to improper collection (n=12), improper labeling (n=36), specimen quantity not sufficient (n=26) or exceeding delivery time (n=8). According to a source at the hospital, non-phlebotomy personnel collect approximately 85% of all specimens. This would mean that non-phlebotomy personnel collected approximately 150,659 specimens in this two-month period. Of these, 1,268 specimens (.8%) were rejected due to improper collection (n=155), improper labeling (n=435), specimen quantity not sufficient (n=215) or exceeding delivery time (n=76). A hospital source indicated that trained laboratory personnel enhanced the laboratory's ability to identify, and if possible correct, errors that occurred during the pre-analytical phase.

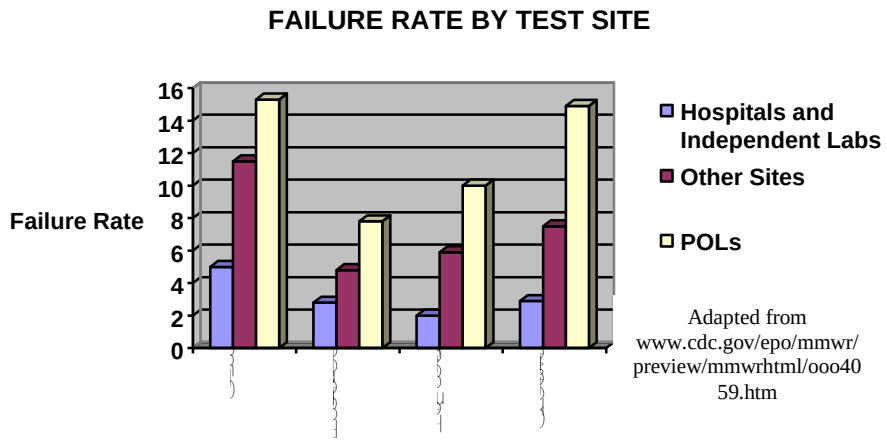
The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has implemented a Sentinel Event policy that is designed to encourage health care organizations to self-report medical errors. A sentinel event is "any unexpected occurrence involving death or serious physical or psychological injury, or risk thereof" (JCAHO, 1999). The self-reports are analyzed and occurrence frequency and root causes are determined in order to reduce the risk of future events.

In the August 30, 1999 Sentinel Event Alert, JCAHO reported on 12 of the 15 blood transfusion error events that had been reported in the past three years. Ten of the twelve cases resulted in death. Eleven of the twelve cases occurred in high-risk areas of hospitals. These areas included emergency rooms, intensive care units and operating rooms. None of the sentinel events related to blood transfusion occurred in Virginia (Hellquist, 1999). The root causes of these sentinel events related to blood transfusion included patient identification, staffing levels, orientation and training of staff, supervision of staff, communication among staff members, availability of information and physical environments.

There have been multiple articles written about quality of clinical laboratory performance in relation to personnel qualifications and laboratory type. Hurst et al (1998) in their article entitled "Are Physicians' Office Laboratory Results of Comparable Quality to those Produced in other Laboratory Settings?" found significant differences in proficiency testing performance between POLs not using licensed medical technologists, POLs using licensed medical technologists and non-POLs that performed moderate to high complexity testing. Unsatisfactory performance for the POLs without licensed medical technologists was almost three times (21.5% vs. 8.1%) as great as for the non-POLS and one-and-a-half times (21.5% vs. 14%) as great as that of POLs that utilized licensed medical technologists as testing or supervisory personnel ($p<.001$). Despite these incidences of unsatisfactory performance, POLs without licensed medical technologists, POLS using licensed

medical technologists and non-POLs demonstrated adequate PT outcomes 95.6, 98.2 and 99.1 percent of the time respectively (Hurst et al., 1998). The meaningfulness of these findings is difficult to interpret because of the unequal sample size of each test site and the discrepant number of analyte challenges per test site. In addition, the demographics in regards to testing site location, size and annual volume and testing personnel are not provided.

In the March 8, 1996 edition of the Morbidity and Mortality Weekly Report, the level of proficiency testing performance for 17, 058 laboratories was reported. The laboratories settings were as follows: physician office laboratories (POLs), hospital and independent laboratories (HIs) and "other sites" (e.g., community clinics, comprehensive outpatient rehabilitation centers, dialysis settings). Satisfactory proficiency testing performance was noted as follows: 89% for POLs, 97% for HIs and 94% for "other sites". For four of the most common laboratory tests, the following chart indicates the percent "failure rate" (<80% correct in test set) by test site:



Adapted from www.cdc.gov/epo/mmwr/preview/mmwrhtml/ooo4059.htm

Lunz et al (1992) in their study entitled "Laboratory Staff Qualifications and Accuracy of Proficiency Test Results" hypothesized that laboratories that employ a high percentage of ASCP-BOR certified medical technologists produce more accurate test results than laboratories that do not employ ASCP-BOR certified technologists. The findings of the study indicate that laboratories that employ 100% ASCP-BOR certified medical technologists produce results yielding 80% or greater accuracy (4 out of 5 analytes correct) 98.3% of the time for basic tests and 98.6% of the time for comprehensive tests. In laboratories that employ no ASCP-BOR certified MTs, the 80% accuracy rate was realized 91.4% of the time for basic tests and 95.1% of the time

for comprehensive tests. The authors concluded that utilization of ASCP-BOR certified MTs resulted in greater test result accuracy.

The findings reported by Luntz et al. (1992) must be considered along with the limitations in the research design. First, there was a significant difference in the number of laboratories categorized as "100% ASCP-BOR" and those categorized "0% ASCP-BOR". For example, in the area of basic laboratory testing, there were 878 labs in the former group and only 320 in the latter. This discrepancy in sample size, when not corrected for statistically, may yield spurious results. Secondly, generalization of these findings is difficult because the researchers do not provide information regarding laboratory type or training and educational level of personnel in testing sites not employing ASCP-BOR certified personnel. These are confounding variables that may influence the findings sited in the report. Finally, this study was reported in 1992. However, it was actually conducted in 1988. The proposed CLIA '88 regulation was not implemented until 1992. Thus, the results may be different than what would be realized if the study was repeated in 1999 with CLIA regulations in place.

VIII. PROFESSIONAL REGULATION:

Twelve states have enacted their own regulations pertaining to the practice of clinical laboratory science. States that regulate above and beyond CLIA '88 are Florida, California, Georgia, Hawaii, Louisiana, Montana, Nevada, North Dakota, Rhode Island, Tennessee and West Virginia (ASCP, 1999). Each state was surveyed to determine the impetus behind regulation, the number of licensed personnel, requirements for licensures and complaints and disciplinary actions since 1993. The findings are depicted in the charts located in Appendix 11.

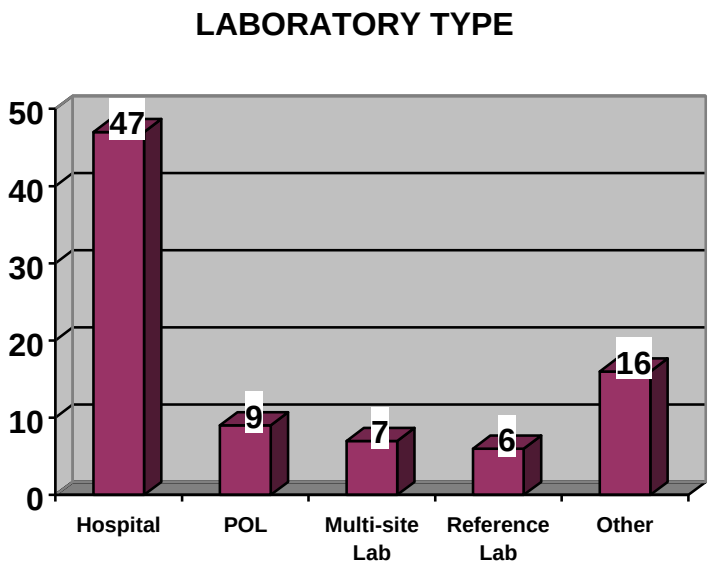
In conducting this study, the Board of Health Professions worked with the Department of Health Professions finance department to determine the estimated cost of regulation of clinical laboratory personnel in Virginia. If the clinical laboratory profession were placed within the Board of Medicine as an occupation, the total projected biennium budget would be $245,665. Based on the Bureau of Labor Statistics number regarding clinical laboratory technologists and technicians in Virginia, this would impose a cost of approximately $45 dollars per licensee per biennium. The budget projection, along with the assumptions thereof, can be found in Appendix 12.

IX. SURVEY RESULTS:

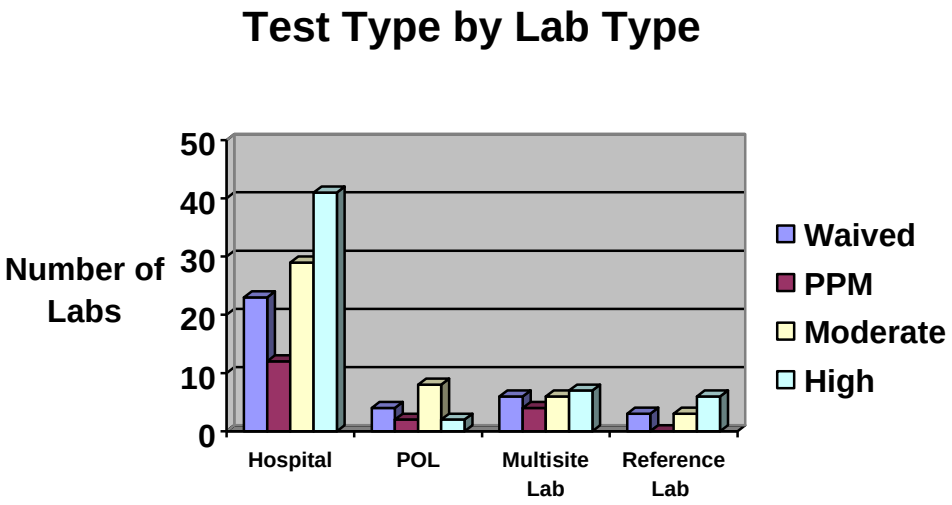
The Board of Health Professions conducted a survey of laboratories in Virginia accredited by the CAP and JCAHO. A copy of the survey can be found in Appendix 13. CAP and JCAHO were selected based on the availability of laboratory addresses at the web sites for these organizations. Survey questions pertaining to laboratory type, testing level, personnel training and voluntary certification were asked. Two hundred and thirty eight surveys were mailed. Ninety-seven surveys were returned

yielding a response rate of 40.7 percent. Of the ninety-seven surveys returned, eighty-five were usable yielding a valid response rate of 35.8%.

Of the eighty-five respondents, the following chart depicts the extent to which various laboratory types were represented:

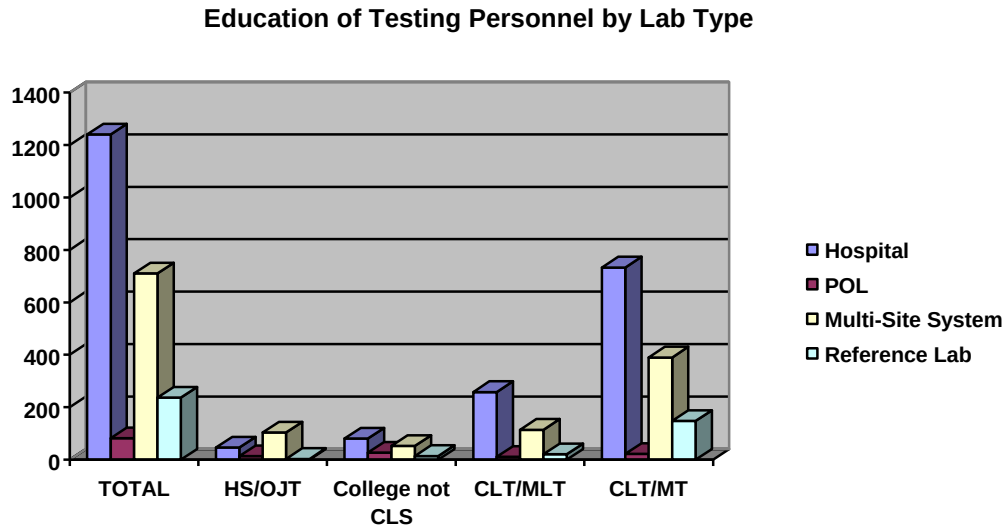


Laboratory type was coded as multi-site system if the respondent checked more than one laboratory type on the survey. The following chart depicts the test type by laboratory type:

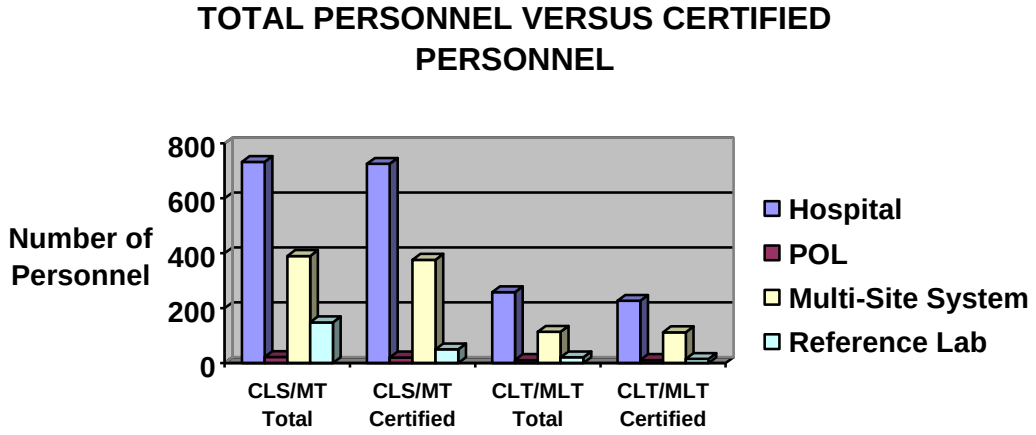


Based on the survey results, there were 2,586 individuals identified as testing personnel. Of these, approximately six percent (n=175) were identified as having a high school education with on-the-job training. Approximately eight percent (n=214) were identified as having had some college (full or partial) but not in the clinical laboratory sciences. Nineteen percent (n=486) of the testing personnel were identified as clinical laboratory technicians/medical laboratory technicians. Of these, seventy-nine percent (n=385) were certified through one of the national, voluntary certifying agencies. Approximately fifty-two percent (n=1,343) of the respondents were identified as clinical laboratory technologists/medical technologists. Of these, ninety percent (n=1,215) were certified through one of the national, voluntary certifying agencies.

The following chart indicates the employment numbers by lab type based on the survey responses:



The following chart indicates certification status of CLS/MTs and CLT/MLT in various laboratory settings:



Survey Findings:

Based on the low response rate to the survey and the large variation in the types of laboratories responding as compared to known laboratory types in Virginia, the data can only be used to help identify potential trends in the field of clinical laboratory science. Based on the data, it appears that hospitals primarily utilize CLS/MTs and CLT/MLTs that are certified through a national certifying agency. This trend is noticed for multi-site systems and POLs as well. In reference laboratories, the majority of CLT/MLTs appear to be certified through a national certifying organization. However, of the 148 CLS/MTs working in reference laboratories, only fifty were voluntarily certified. This may reflect a greater reliance on technician level support in these settings. Further investigation is needed in this area.

X. SUMMARY OF PUBLIC HEARING:

A hearing was conducted on January 7, 2000 to received public comment on the need to regulate clinical laboratory personnel in Virginia. Approximately a dozen persons attended the hearing representing hospital organizations, academic settings, professional organizations and state agencies. A complete record of the public hearing, as well as public comment received via mail can be found in Appendix 14. The following is a summary of the key points that evolved during the hearing:

1. If regulation is deemed necessary, there would need to be a "grandfather clause" to allow existing clinical laboratory personnel, who hold various voluntary national certifications, to be able to continue to practice. However, some felt that this clause would create an immediate shortage in laboratory personnel because of the perceived high number of personnel who have received on-the-job training in settings such as POLs and urgent care centers. A related point is that the majority of hospitals seem to employ laboratory personnel who are voluntarily certified by one of the national certifying agencies. However, many POLs and urgent care centers do not seem to employ these types of personnel. On-the-job training is more prevalent in these settings.

2. The participants voiced a strong need for mandatory, ongoing continuing education within the clinical laboratory science field. This is particularly important in settings such as POLs and urgent care centers whereby there is limited programs which are focused on insuring ongoing competence of clinicians. It appears that adequate means are available to obtain CE. These include conferences, journal quizzes and teleconferences. It was noted that some voluntary certification agencies require that laboratory personnel

obtain continuing education credits as a means to maintain their certification.

3. Testing occurs in three phases – pre-analytical, analytical and post-analytical. Participants indicated that there would need to be regulatory oversight in all three phases of testing. In many circumstances, the clinical laboratory practitioner has little control over the pre-analytical phase of testing. Unlicensed assistive personnel, CNAs, nurses and/or phlebotomists may collect specimens. In general, more errors occur with samples collected by non-phlebotomy personnel than by phlebotomy personnel. Additionally, many people doing waived tests and point-of-care testing are already licensed in the state of Virginia as RNs, LPNs,CNAs or medical assistants. However, this does not insure competence in conducting laboratory tests.

4. Representatives from various academic settings indicated that finding employment has not been problematic for recent graduates. However, with the increased focused on productivity, cost-containment and group mergers, there have been difficulties finding clinical sites for training students in educational programs.

5. The Virginia Department of Health is responsible for implementing CLIA in the state. It is anticipated that regulation, if deemed necessary, would have little impact on the Virginia Department of Health in regard to money or time in the present-day survey system.

6. The Virginia Hospital and Healthcare Association opposed regulation of clinical laboratory personnel in Virginia. The Association states that "CLIA 88 establishes broad and thorough regulation of laboratory practices and personnel, looking at professional credentials and competence in the broader context of all laboratory services provided to hospital patients." In addition, the VHHA contends that regulation would result in a restricted labor pool resulting in increased human resource cost absorbed by hospitals. (Written correspondence in Appendix 14)

XI. POLICY OPTIONS:

1. At the April 20, 1999 BHP meeting, the Board members voted unanimously to focus on clinical laboratory technologists and technicians as well as histotechnologists and cytogenetic technicians during the course of this study. **OPTION 1:** The Board could decide to study the practice of histotechnologists and cytogenetic technicians prior to making any recommendations regarding regulatory action.

2. The findings of this study suggest that many of the laboratory errors that occur are initiated in the pre-analytical phase. Thus, skilled practitioners are needed in the analytical and post-analytical phases to detect erroneous test values that are a result of actions such as use of an incorrect collection tube, poor collection technique or inappropriate specimen storage or transport. The result of pre-analytical errors is typically a need to re-collect patient specimens. This inconveniences patients and may result in the delay of much needed medical interventions and/or prolonged time spent in the healthcare system. In addition, healthcare organizations need to address the financial ramifications of repeated testing due to avoidable pre-analytical errors. **OPTION 2:** Shift study focus to issues related to pre-analytical specimen collection. This may include research into the qualifications and practice patterns of unlicensed assistive personnel, phlebotomists and nursing personnel in the area of pre-analytical specimen collection.

3. The focus of this study was on CLS/MTs and CLT/MLTs. At the outset of this study, the long-term focus was to investigate the practice of histotechnologists and cytogenetic technicians as well. Through the process of this research, it appears that the information for these two groups would likely be similar to that already obtained for CLS/MTs and CLT/MLTs due to the nature of information available based on federal CLIA regulations. For example, proficiency test scores are not available at the personnel level. In addition, limited information is available about the employment of these types of practitioners in public or private healthcare settings. For example, while the Bureau of Labor Statistics has data pertaining to CLS/MTs and CLT/MLTs, they do not classify histotechnologists or cytogenetic technicians. During the course of this study, a survey of CAP accredited laboratories was conducted. The low response rate by facilities and the low number of histotechnologists (n=111) and cytology personnel (n=89) identified on the surveys indicates that these will likely be difficult populations to access. **OPTION 3**: The Board of Health Professions could decide that there is no compelling evidence to support a study of histotechnologists and cytogenetic technicians at this time. There is a high probability, due to the limitations inherent in available data sources, that the information obtained will be similar to that contained in this report.

4. It appears that there is a potential for patient harm to occur if one views laboratory activities as extending from the pre-analytical to post-analytical phases. However, based on the literature and the comments received during the public hearing, laboratory personnel appear to have limited participation in many facilities in the pre-analytical phase of testing. Thus, regulation of the CLS/MT or CLT/MLT may not have the intended effect of reducing testing error and increasing quality patient care. **OPTION 4:** The Board of Health Professions could decide to conclude their

study on CLS/MTs and CLT/MLTs with a recommendation that no action be taken due to a lack of compelling evidence that suggests that regulation will address the root cause of many of the testing errors.

5. Through the course of this study, an instrument was developed to assess the risk of harm of clinical laboratory practice in a regulated versus unregulated scenario. The instrument focused on all phases of testing. Given the research results, the instrument may need to be refined to focus more distinctly on the pre-analytical phase. **OPTION 5:** The Board of Health Professions could decide to refine the instrument to focus on test phase rather than overall laboratory practice. The findings may provide empirical support for a shift in focus to those practitioners involved in the pre-analytical phase of testing.

XII. Board of Health Professions Vote:

The findings of this study were presented to the Regulatory Research Committee on February 16, 2000. The Board of Health Professions unanimously voted in favor of the recommendation of the Regulatory Research Committee that no action be taken in regard to regulating CLS/MTs and CLT/MLTs due to a lack of compelling evidence that suggests that regulation will address the root cause of many of the testing errors.

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