A STUDY OF THE IMPACT OF CLIA '88 ON PERSONNEL NEEDS IN CLINICAL LABORATORIES OF ACUTE CARE FACILITIES IN VIRGINIA

by

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(ABSTRACT)

The purpose of this study was to determine the impact of Regulation 1 of CLIA '88 on personnel needs in clinical laboratories of acute care hospitals in Virginia, resulting from proficiency testing, complexity level of testing and personnel standards. Because the legislation was enacted and passed with the intent of improving the quality of laboratory testing in every setting, the problem of the study was to determine the effects Regulation 1 of CLIA '88 had on personnel needs for the delivery of quality clinical laboratory services in acute care hospitals of Virginia.

A survey was sent to 140 acute care hospital laboratories in Virginia. There were 107 respondents, with 75 respondents providing usable data for this study. The remainder did not provide full laboratory services. Demographic information was obtained regarding bed capacity, educational levels of current personnel serving in different capacities, test volume, and percent of tests performed by different complexity levels. Comparisons were made among small, medium, and large facilities.

The majority of respondents were representative of a facility with a bed capacity of 200 or less. The level of test complexity performed was similar regardless of the facility size. The majority of facilities did not anticipate an increase in personnel needs as a result of CLIA personnel standards. All facilities had personnel at all capacities that met required educational levels at this time.

The majority of facilities did not anticipate an increase in personnel as a result of increased proficiency testing; however, when a projected need was indicated, there was a greater need indicated for AS degree level personnel followed by BS level personnel with a decline indicated in nondegreed personnel. Staffing pattern changes related to increased proficiency testing indicated differences in the projected needs of small, medium, and large facilities.

Barriers for implementing CLIA '88 personnel standards were identified from the literature review and the pilot study. Respondents were asked to identify the barriers that were most significant; they are in order as ranked: cost, availability of qualified personnel, and CLIA not reflecting the depth of knowledge and judgment needed to make independent competent judgment. The barriers were also reviewed by hospital bed size.

It was concluded that as the number of tests being sent out increased, the number of tests being performed in-house

have increased at the moderate complexity level, a level which requires less qualified personnel. The intent of the law to improve the quality of laboratory testing has not occurred in every setting. If the intent of the law is implemented, a need exists to provide educational opportunities at the AS and BS level for experienced personnel. Respondents did not perceive criteria as established by CLIA '88 as being adequate to determine the qualifications of personnel, who are responsible for quality patient test results in all settings.

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INTRODUCTION

Conceptual Framework

The conceptual framework of this study was based on the analysis of the anticipated effects of complexity testing, proficiency testing, and personnel standards of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) on personnel needs of clinical laboratories in hospitals. These amendments were passed in an effort to improve the quality of laboratory testing and to assure patients that testing accuracy would be maintained regardless of the setting, the circumstances, or the personnel. This meant personnel standards that had been in effect for over 20 years under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) were either eliminated or greatly modified by CLIA '88. Although increased proficiency testing of personnel had been mandated in all complexity laboratory levels except physician performed microscopy (PPM), lowered personnel standards for hiring practices could affect proficiency performance.

Furthermore, risks and consequences of erroneous results should be taken into consideration in the assignment of personnel standards as mandated by the CLIA '88 statute. A major concern of educational institutions is that the lowered personnel standards to an Associate of Science (AS)

degree level for supervisors will decrease the number of four-year graduates and increase the demand for two-year graduates. Personnel standards may increase demands for technicians with an AS degree or for technologists with a Bachelor of Science (BS) degree in order to perform high complexity testing and to act as supervisors. Supervisors and personnel for high complexity testing have until 1997 to obtain an AS degree. Raising the minimum standards for testing personnel will affect those technicians/ technologists now in the field without an AS degree. Requirements may change for general supervisors if recommendations are approved to require a BS degree (McNett, 1993a).

CLIA '88 greatly expands the responsibilities of the Department of Health and Human Services (DHHS) for certification of laboratories. Virtually all laboratories that perform tests for the diagnosis, prevention, or treatment of disease or assessment of health will be affected if exemptions are not put into effect by 1996. The test complexity model covers four, and possibly five, regulatory categories: PPM; waived; moderate complexity; high complexity testing and possible accurate and precise technology (APT) (Auxter, 1994; "Capitol Hill," 1993; "CLIA '88 Final," 1992; Department of Health and Human Services [DHHS], 1993).

Inspection to enforce the mandated standards was to have begun on September 1, 1992; however, extensions have been approved with proficiency testing sanctions to apply to currently regulated laboratories by January 1, 1994 (Nash & Stine, 1993b). Because of the increase in workload on the Health Care Financing Administration (HCFA), larger, previously unregulated, and currently regulated laboratories will probably be inspected first. Laboratories in violation of the mandated federal standards may be subject to fines of up to $10,000 per day. Until now, HCFA has only been able to withdraw Medicare certification ("Latest Survey," 1992).

Regulations were published by HCFA on February 28, 1992, but a response period was given until April 28, 1992. Then the Clinical Laboratory Improvement Advisory Committee (CLIAC) of the Public Health Service (PHS) under Centers for Disease Controls (CDC) sorted through over 7,000 comments from administrators and practitioners in the field for HCFA. According to Mooney (1992), PHS and HCFA reviewed the comments to determine if any changes were needed. These responses indicated that some requirements needed further review. It was expected that updates from recommendations of CLIAC would probably be released during the spring of 1994; however, this did not occur. Any violations were to be reviewed as the regulations were written, according to revisions of the rules released in September 1992 in a

statement from the Secretary of DHHS (see Appendix A). Key changes in CLIA '88 were also made and published January 1993 (see Appendix B).

Problem Statement

Because the federal regulations were written to implement CLIA '67, technology has increased the sophistication of the testing levels and the capabilities of clinical laboratories by more user friendly equipment (Swiercz, 1994). Many more laboratories are now located out of hospitals: in physicians' offices, in reference facilities, in industrial complexes, and in private and governmental facilities. Because of these situations the quality of testing and the qualifications of the individuals performing the tests have become controversial issues for clinical laboratories. This controversy resulted in the passage of legislation known as CLIA '88. After four years of anticipation, anxiety, and disagreements over proficiency testing and personnel standards, the federal regulations to implement this legislation were released in February 1992 with updates on September 1, 1992, and January 19, 1993. There was marked disagreement among professional groups over the regulations as published by HCFA. Interested groups expressed concerns because the legislation has resulted in changes in the delivery of clinical laboratory medicine. Therefore, the problem of this study was to determine what

effects Regulation 1 of CLIA '88 has had on personnel needs for the delivery of quality clinical laboratory services in acute care hospitals of Virginia.

Purpose Statement

The purpose of the study was to identify the anticipated effects on clinical laboratory personnel needs resulting from proficiency testing, complexity level of testing, and personnel standards as mandated in Regulation 1 of CLIA '88.

Research Questions

The following general research questions were addressed in the study:

1. What were the qualifications of current personnel employed in clinical laboratories of acute care facilities performing high complexity testing?
2. How did the qualifications of current personnel employed in clinical laboratories compare with personnel requirements as mandated under CLIA '88?
3. What effect have the personnel standards of CLIA '88 had on the projected staffing patterns by education levels of clinical laboratories?
4. What was the effect of the requirement for

increased proficiency testing of CLIA '88 in the high complexity level on personnel needs of acute care facilities?

5. What perceived barriers exist for implementing CLIA '88 personnel standards?

Delimitation

The study was delimited to 140 clinical laboratories of acute care hospital facilities in Virginia. Because of complexity testing level variations and incomplete listing by the State Department of Health for the various certification levels, independent clinical laboratories located outside of acute care facilities were not included.

Background for Study

Since 1967 two federal programs have significantly influenced clinical laboratories. One program, which was under CLIA '67, affected interstate commerce. The other program, under the Social Security Act of 1965, required laboratories to meet certain minimum standards for certification for reimbursement for services provided to Medicare patients (Schaeffer, 1981). The original CLIA of 1967 became effective by rules published in the Federal Register, October 15 and December 31, 1968. The regulations included standards which were designed to assure performance

of accurate laboratory procedures and services with the issuance of licensure to confirm compliance (Department of Health, Education, and Welfare [DHEW], 1968a, 1968b).

The responsibility for administering the CLIA program was delegated to the CDC by the DHHS, which was called the Department of Health, Education, and Welfare (DHEW) in 1967 (Schaeffer, 1981). According to Schaeffer, during the first 10 years after the passage of CLIA '67, the program grew, especially for laboratories involved in interstate commerce; whereas, laboratories under the Social Security legislation remained fairly unchanged or unaffected. Schaeffer indicated that in 1978, CDC began to monitor laboratory evaluation programs of the Joint Commission on Accreditation of Hospital Organizations (JCAHO) and the American Osteopathic Association (AOA). A total reassignment of roles by CDC and the PHS placed all regulatory activities for CLIA and Medicare laboratories under HCFA, but it did not have the responsibility for evaluating each of the clinical laboratories (Schaeffer, 1981).

In spite of all these efforts to improve the performance of laboratory procedures and services, the quality and accuracy of the desired results had not taken place. After 20 years of deliberation, lobbying, and differences of opinion on how and what should be done, new

legislation was passed: CLIA '88. The purpose of CLIA '88 was to help laboratories improve performance and produce quality results ("CLIA '88 Update--AACC," 1992).

CLIA '88 Regulations

The CLIA '88 rule consisted of four separate areas of regulation for implementing the law:

1. Laboratory Standards and Complexity Model regulation, which covers quality control, quality assurance, proficiency testing, and personnel standards;
2. Enforcement Procedures regulation, which establishes sanctions and enforcement options for HCFA on laboratories that do not meet federal standards;
3. Certification and User Fees regulation, which sets mandated laboratory user fees for certification, compliance determination, inspection, and follow-up visits or compliant investigations; and
4. Deeming of Accrediting Bodies and Exemption of State Licensure Programs regulation, which will provide criteria for granting authority to nonprofit organizations or state licensure agencies to certify laboratories on behalf of the DHHS. (DHHS, 1992; Gore, 1992a)

Gore (1992a) indicated that the publicity about fatal results from wrong pap smear reports and other inaccurate test results was the reason that Congress passed these regulations to improve laboratory safety in every setting. Gore (1992a) indicated that the result was a change in the way clinical laboratory science was practiced, and according to many professionals, not necessarily for the better. Some sources maintained that patient health would be harmed; therefore, controversy continued over the regulations because many laboratories that had never been regulated were now affected, especially physician-office laboratories (POLs; Gore, 1992a).

The Laboratory Standards and Complexity Model regulation was the most controversial because of the classification of tests according to a complexity model, because of the requirements for proficiency testing, and because of personnel standards for waived, moderately complex, and/or high complexity testing (Gore, 1992a; Lang, 1992a). Since February 1992, many professional organizations have submitted numerous comments to HCFA to address changes to the CLIA standard rule. On January 19, 1993, HCFA published technical corrections in the Federal Register; one created a fourth testing category called PPM. A fifth category, APT, was proposed for laboratories performing moderate complexity tests ("Capitol Hill," 1993;

"Health Care," 1993). As of 1994, the proposal for a category of APT has been tabled by CLIAC.

On August 12, 1993, CLIAC recommended enlarging the waivered and PPM categories and also proposed to exempt over 79,000 waivered and PPM laboratories from complying with the standard. A proposal by the Clinton Administration would weaken CLIA '88 if the exemption occurred ("Health Care," 1993; Nash & Stine, 1993b). By January of 1996 the Secretary of the DHHS will issue a report on whether the regulation on laboratories performing moderate complexity tests should continue (Madigan, 1993b). Several professional organizations representative of clinical laboratory personnel were collaborating to effect preservation of personnel standards and site neutrality (Lang, 1992a). The American Society for Medical Technology (ASMT), now the American Society for Clinical Laboratory Sciences (ASCLS), American Society of Clinical Pathologists (ASCP), the Clinical Laboratory Management Association (CLMA), and the International Society for Clinical Laboratory Technology (ISCLT) have worked together to effect implementation of CLIA '88.

DHHS has delegated to CDC the authority to recommend appointments to and oversee the CLIAC, which will develop and conduct research to evaluate CLIA's impact on lab testing quality according to the Washington G-2 Reports

(Weissman, 1992). The committee's main charges were to assist DHHS in resolving test complexity issues and reevaluating criteria used to categorize tests and to recommend changes in performance requirements of personnel standards (Weissman, 1992). The committee met in May 1993 to study comments received about the regulations published in the Federal Register, February 28, 1992, to implement CLIA of 1988. Indications were that wide-ranging modifications of personnel standards would be seen ("CLIA Watch," 1993). Personnel standards were effective September 1992, with clarifications published in the Federal Register, January 19, 1993. Labs had to enroll in an approved proficiency testing program by January 1, 1994, however, sanctions will not be enforced until 1995.

The February 28, 1992, Federal Register published final rules implementing CLIA '88 to be effective September 1, 1992. Laboratories have until 1997 to fully implement all personnel standards; however, CLIAC made a recommendation to require associate degrees by September 1, 1994 but it was not acted upon by HCFA. This period of implementation of CLIA '88 could be crucial years for clinical laboratories. The final rules, which were originally intended to improve the quality of laboratory testing, may actually decrease long-standing federal personnel standards as set forth in the standards of CLIA '67. Because the personnel standards

had been reduced, the distinction between educational levels and certification were no longer as significant. Also, the personnel standards, which were already a concern in laboratories, may further affect the quality of test results for diagnostic and treatment purposes. The CLIA '88 rules essentially disavowed the value of the requirements for formal education and professional training ("CLIA '88: 30," 1992). If the value of formal education for clinical laboratory personnel was decreased, the needs of employers would be markedly changed if less prepared individuals were sought.

CLIA '67 sought to regulate the laboratory analytical process in order to assure quality standards for laboratory testing (Peddecord & Hammond, 1990). The history of controversy regarding laboratory standards will cause a lengthy, debated contest to implement and to modify regulations for CLIA '88, because of personnel standards, the federal regulatory process, public expectation of fail-safe technology, and proficiency and patient testing. With the implementation of CLIA '88 a marked increase in federal authority on the practice and quality of clinical laboratory medicine in the United States resulted.

The expectations of society produced increased scrutiny about the accuracy of laboratory data, the timeliness of performing laboratory tests, and the transmission of results

(Bianco, Froede, Siefert, & Zimmerly, 1989). The need to provide quality test results must correlate with personnel standards. CLIA '88 had either a positive or a negative effect on the delivery of clinical laboratory services, depending upon whether or not the standards were further diluted by decreasing the number of laboratories regulated.

Definitions

The following definitions refer to acronyms or terms as they were used in this study:

Acronyms

1. AACC--American Association of Clinical Chemistry
2. AMA--American Medical Association
3. AOA--American Osteopathic Association
4. APT--Accurate and Precise Technology
5. AS--Associate of Science degree
6. ASCLS-American Society for Clinical Laboratory Science
7. ASCP--American Society of Clinical Pathologists
8. ASMT--American Society for Medical Technology
9. BS--Bachelor of Science degree
10. CAHEA--Committee on Allied Health Accreditation
11. CAP--College of American Pathologists
12. CDC--Centers for Disease Control
13. CFA--Consumer Federation of America

14. CLIA '67--Clinical Laboratory Improvement Act (Public Law No. 90-174, 42, CFR, Part 74)
15. CLIA '88--Clinical Laboratory Improvement Amendments (Public Law No. 100-578)
16. CLIAC--Clinical Laboratory Improvement Advisory Committee
17. CLMA--Clinical Laboratory Management Association
18. DHEW--Department of Health, Education and Welfare
19. DHHS--Department of Health and Human Services
20. DO--Doctor of Osteopathy
21. FDA--Food and Drug Administration
22. FTEs--Full-time equivalent students
23. HCFA--Health Care Financing Administration
24. JCAHO--Joint Commission on Accreditation of Hospital Organization
25. MLO--Medical Laboratory Observer
26. MLT--medical laboratory technician who holds an associate degree from a two-year program or holds a certificate from a one-year-hospital based program.
27. MS--Master of Science Degree
28. MT--medical technologist who holds a BS degree from a college or university in medical technology or a related science
29. NIDA--National Institute on Drug Abuse

30. PhD--Doctor of Philosophy Degree
31. PHS--Public Health Service
32. POC--Point-of-Care
33. POLs--Physician Office Laboratories
34. PPM--physician performed microscopy
35. PT--Proficiency testing--tests run as quality control measures to verify reliability and validity
36. QA/QC--Quality Assurance/Quality Control
37. VA--Veterans Affairs

Terms

1. Complexity level of testing--testing categories based on training and experience required and necessity for independent judgment.
2. Deeming status--authority granted from HCFA to nonprofit organizations or state licensure agencies to certify laboratories on behalf of DHHS.
3. Laboratorian--one who works in a laboratory.
4. Personnel standards--minimum educational requirements of personnel to perform laboratory tests.
5. Site neutrality of testing -- accountability for the quality of testing without regard for the location where performed.

Significance of Study

The anticipated effects of CLIA '88 are of concern to both practitioners and educators. Many clinical facilities of acute care hospitals throughout Virginia have personnel who presently do not meet the educational standards as mandated in CLIA '88. When the standards were implemented on September 1, 1992, individuals with deficiencies were given until 1997 to meet the educational standards. Additional proficiency testing must be done in order for a laboratory to be certified to perform a procedure for patient diagnostic work or treatment. The qualifications required of personnel depend upon what procedures the laboratory performs. The changes in the delivery of clinical laboratory medical services as a result of CLIA '88 will impact on both the type of students and programs necessary to meet the demand. As CLIA '88 is implemented, the number of technologists and technicians needed with specified educational levels will be related to the level of complexity testing chosen by each clinical facility.

Chapter 2

REVIEW OF LITERATURE

This chapter presents a comprehensive review of the literature related to the CLIA '67 and CLIA '88. Their effect/impact and possible modification, projected as a result of health care reform, will be shown.

Purpose of CLIA '67

The PHS Regulations, Title 42, Code of Federal Regulation was published in the Federal Register October 15, 1968, followed by additions on December 31, 1968. The regulations known as CLIA '67 included standards designed to assure accuracy and consistency in the performance of clinical laboratory procedures and the delivery of services. CLIA '67 was directed at independent laboratories engaged in interstate commerce to which individuals were entitled to have payments made on their behalf for quality test results (DHEW, 1968a).

The responsibility for administering CLIA '67 was delegated to the CDC. The intent was to improve laboratories rather than just to evaluate their performances (Schaeffer, 1981). By 1978, CDC had begun to monitor the laboratory evaluation programs of the JCAHO and the AOA. This was a part of the implementation of CLIA with all regulatory activities for CLIA and Medicare laboratories in

HCFA (Schaeffer, 1981).

Proficiency testing, as a means of improving laboratory performance and for educating all levels of personnel, was a part of the requirements of CLIA '67 administered by CDC. Although abuses of proficiency testing occurred if it was treated as an exception instead of a routine procedure it was better than no control. According to Schaeffer, prior to CLIA '67, this had been the case for poorly performing, unregulated laboratories.

Schaeffer (1981) indicated that personnel standards of CLIA '67 were not unanimously agreed upon; Congress proposed changes to CLIA in 1971, 1975, 1976, 1977, 1978, and 1979, with no final agreed changes until 1988. The success of CLIA '67 was small because it was restricted to only 860 of the 80,000 laboratories estimated to be in operation in the United States during the 1970s. Schaeffer indicated that because 60,000 of the 80,000 laboratories were POLs not subject to regulatory controls, CLIA '67 had little effect. "The CLIA changes of 1975 came close to the ideal and most major laboratory defects would have vanished" (Schaeffer, p. 181), but the amendments did not pass Congress.

Stress in Quality Reforms Leading to Changes in CLIA '67

During the mid-80s more than 90% of primary care

physicians had access to an office laboratory, most often their own (Fischer & Addison, 1985). Only about one third of the labs had formally educated medical technologists (MTs) or medical laboratory technicians (MLTs), and the remainder of the personnel received no laboratory education other than an informal on-the-job training (Fischer & Addison, 1985). Physicians began to solicit lab work from other physicians to increase their volume; then any laboratory that accepted more than 100 referred tests per year had to comply with Medicare regulations for independent laboratories (Fischer & Addison). A new climate of accountability in the quality of testing performed in POLs was recognized in the mid-80s. This new emphasis on accountability in POLs was instrumental in site neutrality of testing being incorporated in CLIA '88.

With the shift of laboratory tests from the hospital to other settings little attention was being paid to educational issues (Fischer, Addison, Koneman, & Crowley, 1986). Some states were considering the regulation of POLs; HCFA had looked at applying the same controls to POLs that were currently applied to hospitals and independent laboratories but proficiency testing was still waived by CLIA '67 and CLIA '88. At any rate, primary care physicians should provide input into the laboratory educational programs to include POLs (Fischer et al., 1986). As the

volume of laboratory work in POLs increased, there was increased pressure at the federal and state laboratories to regulate these laboratories (Wildermann & Schneider, 1986). HCFA received the legislative authority for some control over POLs in CLIA '88. A longitudinal study of error prevalence in POLs showed that participation in a quarterly proficiency testing program for a 12- to 15-month period did not lead to a measurable increase in performances (Bloch, Cembrowski, & Lembesis, 1988). For proficiency testing to be effective; there should be fewer corrective actions required.

As a part of the quality of test results, the Board of Registry of the ASCP conducted a survey to determine the impact of the quality of laboratory staff on the accuracy of laboratory results. An accuracy score was calculated for laboratories with only ASCP-MTs and for laboratories with no ASCP-certified MTs. The mean raw score for laboratories hiring only certified MTs was 95% accuracy (SD = 4%) while the mean raw score for laboratories employing only noncertified technologists was 75% accuracy (SD = 30%) (Lunz, Castleberry, James, & Stahl, 1987). According to Lunz et al., a significant positive Spearman(rs) correlation confirmed a relationship between employing a higher proportion of certified MTs and accuracy of test results ($rs = .34$; $p<.001$). Certification was ignored in both CLIA '67 and CLIA '88; only educational

preparation was considered. One factor affecting the level of personnel hired was resource allocations. Drummond (1987) indicated that resource decisions were made on behalf of the community as a whole, and clinical decisions were made on behalf of the individual patient. The quality of life was used as a measurement to assess costs and allocation of resources in health care.

To further support the need for adequately trained personnel in a hospital laboratory or POL, a study was done to compare the reliability of results produced by trained technologists with those individuals without formal training. A Kodak DT-60 tabletop chemistry analyzer was used in this study. Special assistance was necessary for the testing even with trained personnel (Belsey, Goitein, & Baer, 1987); therefore, results were more accurately obtained by trained personnel.

When CLIA '67 was passed by Congress, members were concerned with increasing reports of erroneous laboratory results that were seriously jeopardizing the health and lives of patients (Laessig & Ehrmeyer, 1988). Personnel standards were mandated, along with documented proficiency testing; but according to Laessig and Ehrmeyer, the difficulty was that "using proficiency testing for law enforcement is like using a chisel to drive a screw" (p. 330). However, even coerced proficiency testing has

improved laboratory performance. When proficiency testing is approached by supervisors appropriately, programs can provide benefits to laboratories as a mechanism for self-improvement, for continuing education, and for a fulfillment of regulatory requirements while covering the spectrum of laboratory disciplines (Rippey & Williamson, 1988).

For a comparison of results from 132 patients in New Jersey, specimens were sent to four independent laboratories to evaluate the interlaboratory and intralaboratory agreement in the performance of Lyme disease serological testing (Schwartz, Goldstein, Ribeiro, Schulze, & Shahied, 1989). The measurement of agreement employed, the Kappa statistic, ranged from .45 to .53 among the four laboratories and from .50 to .54 within the commercial laboratory. These values represented low levels of agreement (Schwartz et al., 1989). These data suggested a standardization of procedures must be done for accurate results between laboratories for patient diagnosis and treatment. In many of these cases antibiotic treatment for Lyme disease could be instituted without need.

Another study was done to determine the accuracy of portable cholesterol analyzers in public screening programs. Finger-stick values were compared with cholesterol values from venous blood samples sent to a reference laboratory from four different screenings in Minnesota. The difference

in values from the four sites could be attributed to technician training and/or experience with the portable analyzer. A systematic error of accuracy of ±5% was present in a finger-stick cholesterol and ±9.2% for random error or precision for a total error of ±14.2% (Naughton, Luepker, & Strickland, 1990). At the time of this study CLIA '88 had been passed, but regulations were still being reviewed for implementation of the law.

With the increase in sophisticated technology that is easily learned, bedside testing for the critically ill patient may be beneficial for "real-time" treatment of patients (Zaloga, 1990). According to Zaloga, bedside testing has the potential to reduce many sources of laboratory error; however, errors due to inappropriate collection and poor performance of the test are still present. Inaccuracies may be overcome with training in quality control. However, a trained technologist is required for optimal use and benefit for the patient in cost considerations and nursing time. Assuring the quality of bedside testing results is essential, and this assurance of quality is more difficult with multiple nontechnically trained users. So proper training of users, quality control for the instrument and user performance must be assessed to determine which tests are cost-effective for improved patient care for bedside testing (Zaloga, 1990).

Regulations of CLIA '88

In May 1990 the first proposed rules to implement CLIA '88 were issued by the HCFA. The standards were to apply to all laboratories, including previously unregulated POLs. The labs were to be regulated based on the complexity of tests performed rather than on the site where they were located (Kostreski, 1990). Laboratories certified by the National Institute on Drug Abuse (NIDA) to perform forensic urine drug testing and research labs that do not report patient-specific results were exempt from compliance with the regulations as proposed, published May 21,1990 in the Federal Register. A 90-day comment period until August 20, 1990, was allowed.

In the first proposed regulation, tests were divided into three categories:

1. Certificate of waiver--28 tests were identified that were simple and would pose no risk to the patient if performed incorrectly; application fee would be due every two years with unannounced inspections made to determine that only tests on the waived list were being performed;
2. Level I category--11 tests were identified that were simple to perform, but reasonable harm could be done to the patient if the tests were performed incorrectly; and

3. Level II category--these were tests not listed on waiver or level I test lists; people qualified at both level I and II would have to renew their certification every two years and would have to comply with proficiency testing, patient test management, quality control, personnel standards, and quality assurance requirements which were the same as published by HCFA in the March 14, 1990 final rule for CLIA '67. (DHHS, 1990; Kostreski, 1990, pp. 18-19)

Difficulties in Implementation of CLIA '88

Congress passed the CLIA '88 legislation in October 1988 in response to media reports and the public response over laboratory errors that led to patient misdiagnoses and deaths from inaccurate reading of screening pap smears for cancer. But there was a delay in implementing the rule because of a lack of agreement among the laboratory and scientific community. At the time of passage, the final rule was to apply to all laboratories in all settings; however, this has yet to be implemented (Kostreski, 1990; Peddecord & Hammond, 1990).

By August 20, 1990, HCFA had received tens of thousands of letters commenting on the structure of the standards to be required under CLIA '88. HCFA continued to review

comments until 1991, with a delay for implementation of a final rule projected until 1992 ("CLIA '88 Rule," 1990). The complexity model for testing was proposed by ASMT for five categories of testing levels; the personnel standards which were tied to the testing model were the most controversial aspects of CLIA '88. In October 1990 ASCP still proposed formal education for personnel to move up the career ladder; whereas, ASMT proposed that an individual could move from a level I practitioner to a level II by passing a competency exam; this removed the requirement for an academic degree ("CLIA '88 Rule," 1990). In 1991 The American Society for Microbiology, Association of State and Territorial Public Health Laboratory Directors, CLMA, and American Medical Technologists agreed on recommendations for personnel standards. The standards included the following: (1) the general supervisor would be on a minimum of one shift a day, (2) the technical supervisor for microbiology and clinical chemistry could be a medical technologist with a specialty certification, (3) the evaluation of equivalency of alternative pathways to the BS degree for MTs, and (4) a grandfather clause for certified MTs because ASCP 2 + 1 technologists would not be qualified under the proposed rule at that time ("CLIA '88 Rule," 1990). ASCP further endorsed recognition of the broad scope of expertise in testing by trained technicians since it would have a positive impact on

the shortage of MTs. ASCP also endorsed proficiency testing no less than twice yearly and changes were needed especially in the cytology final rule. These presentations were made to Congress on CLIA '88 sponsored by the National Committee on Clinical Laboratory Standards in Arlington, Virginia, August 6-8, 1990 ("Make," 1990). With professional groups in disagreement about the final rule for implementing CLIA and with the thousands of comments reviewed by HCFA, no further regulations were published. Laboratories were still operating under CLIA '67 which was updated March 14, 1990 in the Federal Register ("Surviving the 90's," 1991).

While the dispute continued regarding regulations for implementing CLIA '88, Heller, in the February 3, 1991 Parade, discussed the fact that medical tests were not infallible. Heller gave some examples, such as the following: the pap test fails to detect cervical dysplasia or cancer up to 40% of the time, nearly one half of all cholesterol test results vary by 5% or more from the correct value, and unacceptable quality mammograms were produced at 13% of x-ray labs surveyed. A patient misdiagnosed as having cancer was quoted as saying that "the inferior quality of medical personnel is the root of the problem" (Westgard, Petersen, & Wiabe, 1991). A study was done to evaluate laboratory process specifications to assure quality in the U. S. National Cholesterol Education Program. The

conclusion was that the best approach to assure quality and accuracy was skilled analysts (p. 661).

In March 1991, with an increased shortage of qualified credentialed laboratory personnel, the DHHS initiated plans to provide a proficiency examination which would lower education and training standards ("ASCP Renews," 1991). With no firm rules for CLIA '88, professional groups voiced great opposition. These groups felt it unwise to replace proper credentialing without evidence of education or training with a minimum level of competency achievement for both the technologist and technician. Harmening (1992) advocated increasing the number of qualified graduates instead of DHHS offering a proficiency exam.

In the March 25, 1991, Advance, Richard Sowers, a laboratory director of Lancaster, PA, said "CLIA '88 will have a more serious effect upon the clinical laboratory industry than any other legislation governing the laboratory, including CLIA '67" (Herb, 1991b, p. 9). With the anticipation of CLIA '88 offering more problems in the personnel shortage, Congress introduced legislation through the Rural Healthcare Coalition for increased loans and grants to recruit clinical laboratory personnel to work in a rural or underserved area with documented personnel shortage (Pailet, 1991). In 1991 nearly 50% of the grants awarded from the House Rural Healthcare Coalition and the ASCP

Laboratory Professions Education Institute had a medical laboratory profession component, and 2.8 million dollars were appropriated to fund 10 grants in 1992 (Sher, 1992). At the American Medical Technologists national conference, Anthony Tirone, director of DHHSs Office of Survey and Certification, Health Standards and Quality Bureau, indicated that he had more than 60,000 comments to review at HCFA concerning CLIA '88. In addition to there not being a consensus on any of the comments, there was no funding for CLIA activity because it was to be self-funded (Herb, 1991a). According to Herb, Mr. Tirone further indicated that personnel standards would not be finalized before 1992.

Licensure As a Way to Supercede CLIA Personnel Standards

In addition to concerns over CLIA, AIDS was on the increase so different strategies were evaluated to motivate and retain laboratory personnel. Among the strategies used were a big push for cross-training, reward innovation, participation in decision-making, and upgrading education (Moulton, 1991). Moulton indicated that with a continued increase in the shortage of quality personnel, the leaders of the medical laboratory professionals were pushing for contact with national legislators to improve the medical laboratory profession. In 1992 the Bureau of Labor

Statistics projected a 24% increase in the need for MTs and MLTs by the year 2000 (Harmening, 1992).

With the failure of personnel standards of CLIA to be implemented, the ASMT Professional and Government Affairs committee and directors pushed for states to pursue personnel licensure with strong state requirements that would supersede CLIA regulations when they were published (Kelly, 1991). According to Kelly, as a result of professional activities, in 1991 six states had licensure mandated and 26 states had some degree of licensure activity in progress. While professional groups were pushing for stricter laboratory standards, legislation was introduced in June 1991 to exempt the Department of Veterans Affairs (VA) from CLIA '88 (Lang, 1991). According to Lang, professional groups indicated that a VA exemption would set a dangerous precedent, even though Dr. Eleanor Travers, National Director of Pathology and Laboratory Medicine for the VA, did not believe that the VA mission should be controlled by another department in the executive branch because when a department is created by Congress it is meant to function independently. VA standards later developed were much more rigid than CLIA.

Modification in CLIA '88 Before Implementation

In addition to the growing shortage of quality personnel, clinical laboratories were beginning to face changing population demographics and a growing need to document quality and cost effectiveness while doing more with less (Tune, 1991). The DHHS redrafted rules, formulated by CDC and HCFA for CLIA '88, which downgraded some standards for independent and hospital laboratories. The draft dated October 4, 1991, reformulated the Test Complexity Model as follows (Weissman, 1991, p. 1):

1991 Test Complexity Model

Test Complexity	Certificate	Requirements
Simple	Certificate of waiver	Application and follow manufacturer's labels
Moderately Complex	Registration certificate, then certificate of accreditation	Application and apply all standards (QA [quality assurance], QC [quality control], PT [proficiency testing], PTM

Test Complexity	Certificate	Requirements
		[patient test management], LIS [laboratory information systems], and limited personnel requirements)
Highly Complex	Same as above	Same as above except higher personnel requirements

The restructured personnel requirements have opted for a significant easing of qualifications for most levels. The modified CLIA '88 personnel requirements were as follows:

1988 Modified Personnel Requirements

Test Complexity Level	Requirement
Waiver	None
Moderately Complex	Director--any degree plus requisite experience. Technical consultant--any appropriately degreed personnel with one-year full-time lab training or

Test Complexity Level	Requirement
	experience; may also be qualified as a director. Testing personnel--may range from director to qualified high school graduate or equivalent.
Highly Complex	Director--Board certified pathologist or doctoral scientist, or medical doctor with experience. Technical supervisor--minimum BS degree or previously qualified. Clinical consultant--same as director. General supervisor--must be accessible when testing is performed; minimum of AS degree or previously qualified. Testing personnel--2-year degree acceptable or

Test Complexity Level	Requirement
	previously qualified. Testing personnel assistant--high school graduate or equivalent and under direct supervisor of general supervisor (Lang, 1992g; Weissman, 1991, p. 6).

Widely divergent views emerged as special interest groups reacted to CLIA '88 implementation: some accused HCFA of coming up with a totally unworkable plan that would create major access problems; others complained that the agency's proposal was aimed at dodging a site-neutral requirement (Weissman, 1991). The debate continued with on-going dissension.

As a result of all the dissension, ASCP planned a conference for February 14-16, 1992 on "Blueprint for the Future of Pathology and Laboratory Medicine" to assess the delivery of quality laboratory services dependent on medical, technical, and administrative functions ("Planning," 1991).

With the passage of CLIA '88 and the implementation of rules and regulations governing an estimated 150,000 additional laboratories, more importance was attached to

proficiency testing to measure the quality of laboratory testing. A study was done to determine variables affecting performance in proficiency testing: the size of a laboratory with lower testing volumes demonstrated less accuracy than variables in personnel alone (Wilson & Lewis, 1991).

With an increased consumer emphasis on more for less, a strong push for national healthcare reform was studied. Gail Wilensky, PhD, administrator of HCFA, reviewed several factors contributing to the rising cost in healthcare; some of these were defensive medicine, third-party payment which stimulated demand, employers deducting the cost of health plans for taxes, cost-based hospital reimbursement, fee-for-service system-more services for less, and physicians wanting more money in the pocket (Gore, 1992b).

Wilensky projected managed-care plans as a means to reverse excessive treatment. Laboratory fees were a major part of the increase in fees; however, with increasing federal regulations the cost per test was increased. Federal regulatory activity in the last five years has involved all aspects of the laboratory from safety to proficiency and put it under a bureaucratic microscope with 13% of the gross national product being spent on healthcare (Lang, 1992h).

Four years after CLIA '88 was passed, rules to implement the law were finally published in the Federal

Register, February 28, 1992, with a 60-day comment period. An advisory committee (CLIAC) was appointed by CDC to assist the PHS in reviewing comments ("CLIA '88 Final," 1992). Proficiency testing enrollment was delayed until January 1, 1994 for newly regulated labs, already enrolled under March 1990 final rules, and until 1995 for previously unregulated labs ("CLIA '88 Final," 1992). Penalties for unsuccessful proficiency testing performance will be assessed until 1995 ("CLMA," 1992).

A detailed comparison of personnel standards between CLIA '67 and CLIA '88 can be found in Appendix C, used with permission, (American Association for Clinical Chemistry, Inc., [AACC], 1992). ASCP was much opposed to the new rules as written because personnel standards were diluted by devaluing formal education and training in the clinical laboratory sciences (see ASCP letter, Appendix D). Detailed personnel requirements of CLIA can be found in Appendix E.

Implementation of CLIA '88 Rules

Four types of testing were excluded from CLIA '88 rules. They were testing for forensic purposes, research testing where patient-specific rules were not reported, drug testing performed by laboratories that meet NIDA guidelines and regulations, and for health assessment of individual patients ("CLIA '88: Final Standard," 1992; "CLMA," 1992).

All regulations except the certification and user fees took effect on March 30, 1992, and became effective on September 1, 1992. The three categories of testing based on complexity of the testing method were as proposed in October 1991; however, the complexity waived level was assessed based on specified criteria:

Criteria Proposed for Waived Testing

1. employ methods that are so simple and accurate that the likelihood of erroneous results are negligible;
2. pose no reasonable harm to the patient if the test is performed incorrectly; and
3. have been cleared by the Food and Drug Administration (FDA) for home use. ("CLMA," 1992, p. 4)

Criteria used to categorize tests as moderate or high complexity were as follows:

Criteria Proposed for Moderate/High Complexity Testing

1. degree of knowledge needed to perform the tests;
2. training and experience required;
3. complexity of reagent and materials preparation;
4. characteristic of operational steps;
5. characteristics of availability of calibration, QC, and PT materials;

6. troubleshooting and maintenance required; and
7. the degree of interpretation and judgment required in the testing process.

("CLMA," p. 4)

According to the staff from CLMA, as of February 1992 eight tests met the waiver category, more than 40 general types of tests or procedures met the moderate complexity category, and more than 50 general tests or procedures were categorized as high complexity. Each laboratory performing either moderate or high complexity testing was required to enroll in an approved proficiency testing program for each of the specialties and subspecialities for which it sought certification.

With the release of rules for CLIA '88, federal regulatory authority was expanded from 13,000 to an estimated 200,000-300,000 laboratories, including POLs, (Kirk, 1992; Lang, 1992d). Lang indicated that the most controversial portion of the regulations was the personnel standards, because one person could qualify for several positions in the laboratory. In addition, Lang said in most cases, persons in all personnel categories who qualified for their position under previous federal regulations were grandfathered into the appropriate personnel category. The ASMT and other professional groups encouraged members and nonmembers to contact HCFA and their federal legislators to

express concerns about the shortcomings of the rules, especially the personnel standards (Herb & Staff, 1992). For example, DHHS has estimated that 75% of all laboratory procedures would be classified as moderate complexity, which could be performed by an individual with a minimum of a high school diploma and training appropriate for the test being performed or by an AS degree with no special training or experience (Mass, 1992; Pailet, 1992). There was great concern that lowered personnel standards would lower salaries further, thus compounding the problems in recruiting and retaining competent laboratorians (Davis, 1992).

According to Pailet (1992) the overwhelmingly negative response to the CLIA regulations centered around four recommended revisions; they were:

1. General supervisors in highly complex laboratories should be required to have a BS degree in a laboratory science.
2. The minimum educational requirement for testing personnel in a highly complex laboratory should be an AS degree in a laboratory science.
3. The final rule should retain distinctions between the scope of practice of MTs and MLTs rather than lumping both together as 'testing personnel'.
4. Technical consultants in moderately complex labs

must have documented formal laboratory training and experience, which the rule does not specify.

5. CDC and HCFA must revise the test categorizations to more accurately reflect the depth of knowledge and independent judgment needed to perform many of the moderately complex tests. (p. 308)

ASCP viewed the CLIA rules as an error in that they did not meet the mandate of the CLIA '88 law, and appeared to be inadequate to protect the public by not improving the quality of laboratory testing ("CLIA '88: 30,", 1992, Johnson, 1992). The final rule changed the emphasis from multiple employee positions to multiple roles that can be filled by a single employee (Noble, 1992b).

The multiple role is a part of the emphasis in point-of-care (POC) testing to control systematic and random errors in the laboratory (Horman, 1992). Horman indicated that the bedside testing or POC testing would reduce laboratory error and costs only if personnel become technologically proficient in test performance in acute-care settings. Given the lax personnel standards, especially for moderate complexity testing, the CLIA rules may fail to encompass the risk to the patient as required, under the statue, in an acute care setting (Albertson, 1992).

POC testing brings new challenges to quality control under CLIA '88 (Noble, 1992a). Legislators, such as John

Dingell (D-MI) and James Slaughter (D-KS), are concerned with the botched effort by HCFA to implement CLIA and noted that the losers are the American public, American industry, and the American economy (Buccino, 1992c; Mooney, 1992). According to Mooney (1992), Dr. Cynthia Needham, American Society for Microbiology secretary and head of microbiology at the Department of Laboratory Medicine at the Lahey Clinic Medical Center, Burlington, Massachusetts, believed that the final CLIA rule represented a down-grading of standards for the clinical laboratory. The rule already considerably weakened from CLIA '67, because a high school graduate with no formal clinical training or experience can continue to perform high complexity testing until 1997, at which time he/she would have to have an AS degree. This rule was altered in the update of regulations published January 1993 in the Federal Register.

Impact of Implementation

Physicians, as well as laboratory professionals, appear to be impacted by CLIA. Buccino (1992b) indicated that in a study from American Medical News, an estimated 4,000 medical doctors had to close their office laboratories or had to reduce the number of tests performed or only do waived testing, because of the CLIA costs when the federal regulations were implemented September 1, 1992. Quality

control and proficiency testing were the main causes of an increase in expenses. A study conducted over a 21 month period by Levine Associates, Inc., and Mathematica Policy Research, Inc. found no evidence that three annual proficiency testing events were more effective than one or two, according to Buccino. Buccino reviewed the overall concerns of POLs regarding CLIA '88 regulations which were cost, personnel requirements, test complexity categories, proficiency testing, documentation, inspections, and quality control/quality assurance issues.

Management and clinical medicine combined forces on May 29-30, 1992 in Baltimore, Maryland, for a seminar on "The Team Approach to Managing CLIA"; the expected impact was addressed for finances, staffing, proficiency testing, accreditation, POC/alternate site testing, and information systems/informatics (Scott, 1992). In order to prepare BS and AS graduates for the year 2000 in the clinical laboratory, educational programs must look at curricula and make adjustments for practice changes, technological changes, growth in the knowledge base, and economic pressures (McKenzie, 1992). The expenses of the clinical laboratory must be efficiently managed if rising costs are to be contained and quality maintained. Future graduates will need multiple skills to be competitive in the job market (Raichle & Harmening, 1992).

As an example of the desire for quality, the Consumer Federation of America (CFA) protested the final CLIA regulations because they violated the spirit of the law by reducing laboratory standards. The violations were expressed as follows:

1. Failure to reduce the risk to the patient is patently illegal.
2. Personnel standards are inappropriate and violate the congressional intent to extend and improve existing standards.
3. The reduction of the number of proficiency tests per year and the standard for passing does not reflect the desire of Congress to improve general industry practice.
4. HCFA proposes to categorize tests without public comment and its process for dissemination of information to the public about labs is inadequate. (Lang, 1992b; Tune, 1992).

Litigation from the CFA will probably be in the courts for months to come.

As of August 11, 1992, five major studies mandated by CLIA '88 that were to be completed by January 1, 1990, had not been finished so delay advocates argued that Congress intended all studies to be completed prior to the implementation of CLIA '88 ("CLIA '88 Update," 1992). One

of the studies was to answer questions regarding clinical laboratory testing and the relationship of current personnel standards and proficiency testing to laboratory quality; this study could take five years and proposals were not due until mid-September 1992 ("CLIA '88 Update," 1992).

A final rule, the fourth, of CLIA which was to "provide granting and withdrawal of deeming authority to private nonprofit accreditation organizations and of CLIA exemption under state laboratory programs" was published in the July 31, 1992, Federal Register. In order for the College of American Pathologists (CAP) to act as the proficiency testing agency the state must recognize CAP under its state program ("CLIA '88 Update," 1992; Lang, 1992e). CAP has now been recognized as a proficiency testing agency for CLIA.

In order to operate a clinical laboratory or to do testing anywhere in the United States after September 1, 1992, a certificate had to be obtained from HCFA (DHHS, 1992; Passey, 1992). Testing sites included POLs, nursing stations, health fairs, shopping malls, surgery suites, home nursing settings, and the traditional laboratory settings. Four types of certificates have been issued by HCFA. They are:

1. certificate of waiver--permits lab to perform only waived tests;
2. moderate complexity certificate--permits the

laboratory to perform tests of moderate complexity in addition to waived tests;

3. high complexity certificate--permits the laboratory to perform tests high complexity plus moderate and waived tests; and
4. registration certificate--an interim certificate granted until HCFA can judge the lab's suitability for a full-privilege certificate (Passey, 1992, p. 27).

A certificate of accreditation is good for two years before renewal is required. (Lang, 1992i; Passey, 1992, p. 27)

In a public statement on August 28, 1992, Louis W. Sullivan, MD, secretary of DHHS, noted that personnel standards would impose a great hardship on small rural hospitals and physicians' offices (see Appendix A). The personnel standard, requiring 24-hour supervision of all tests performed, was revised to permit individuals currently employed and performing high complexity testing to continue to work night shifts in the absence of on-site supervision, providing that the work performed was checked within 24 hours. Those testing personnel who were required to have an associate degree in order to continue testing would have five years to complete the degree in order to continue to insure quality and reliability of results (Buccino, 1992a;

Sanchez, 1992).

Sullivan called the CLIA rules "among the most complex and challenging regulations that HHS has ever had to implement" ("HHS Labels," 1992). Because of a shortage of clinical laboratory personnel, partially from the inability to implement CLIA, a survey was done to look for offerings of educational programs to retrain inactive laboratory professionals to meet needs of recruitment and retention (Bamberg, 1992). In the survey discussed by Bamberg, 57 retraining programs were identified in 30 states to meet an 11.6% shortage for staff medical technologists and an 11.1% shortage for staff medical laboratory technicians. To encourage entry into the field consensus is necessary but will not be easy.

In September 1992 CDC moved some tests from moderate to high complexity testing. A new test complexity category was proposed by physicians and nonphysician practitioners: Professional Waived, currently viewed as moderate complexity ("CLIA '88: Final Standard," 1992; Lang, 1992f).

Even before the implementation of CLIA, the final rules had sparked controversy about potential harm to patients. CLIA's main areas of interest and concern include the effect of personnel standards on health care and test complexity categories, and the costs of certification, quality control, and proficiency testing (Gore, 1992a). Gore believed that

the failure of the CLIA rules to recognize the traditional BS degree education and training for some high complexity lab testing undermined the educational system and threatens quality. Waived tests are not subject to proficiency testing and the scrutiny applied to other tests. Proficiency testing for smaller labs means more work and increased costs. Gore indicated that in all laboratory disciplines the number of specimens to be tested in each proficiency test has increased from two to five. Proficiency testing is judged on the basis of whether the lab passes, not the individual, except cytology where each individual must be enrolled in an approved proficiency testing program by January 1, 1994 (Tune, 1992).

Staffing Shortage Continues in Spite of CLIA '88

With increased emphasis on improving productivity while decreasing costs, the results of a MLO (Medical Laboratory Oberver) survey showed that the staffing shortage continued to escalate:

1. During 1992 the vacancy rate was highest in small hospitals--22%; whereas, the 1990 vacancy rate had been 8%;
2. Western labs had a vacancy rate of 19%; whereas, the 1990 vacancy rate had been 7%;
3. In 83% of labs, the current vacancy rate was the

same or higher than the yearly rate; 17% reported a lower current vacancy rate;

4. In 33% of the labs responses indicated that services and operations were adversely affected;
5. A 27% vacancy rate for cytotechnologists was reported, 16% for phlebotomists, 14% for technicians, 12% for technologists, and 30% for histotechnologists;
6. Thirty-four percent of all respondents said that every lab section had suffered, 53% said a staff shortage affected all sections, with hematology, chemistry and microbiology being hurt the most;
7. Forty-three percent of all respondents said the shortage affected all shifts, with the greatest shortage during evenings and weekends;
8. Ninety-two percent believed that the lab staffing situation would get worse or remain the same in their geographic area;
9. The average number of FTEs in all labs had declined with losses heaviest in independent and group practice laboratories and in the East;
10. MLTs versus MTs:

    -Seventy-five percent of labs employed MLTs

    -Sixty-six percent of labs said MLTs performed the same work as MTs,

-Eighty-one percent of labs hired MLTs at a lower salary grade than MTs even though 66% of those had MLTs/MTs do the same work,

-Seventy-one percent who hired MLTs never made them supervisors,

-in 1992 the MT/MLT ratio was 2.89:1; in 1990 it was 2.2:1;

11. Ninety-one percent of respondents paid overtime; in 1990 it had been 88% (shortages were supplemented with overtime work in 94% of labs);
12. During slack time unpaid time off was given in 56% of labs without losing benefits;
13. Sixty-eight percent of all respondents said that CLIA would hurt the laboratory profession generally, while 73% of those with a shortage indicated that CLIA would hurt the profession. (Jahn, 1992; Summarized by permission, see Appendix F).

Jahn reported that some professionals believed that if labs were to survive the staffing shortage, prompt attention must be given to restructuring the present academic curricula in medical technology schools.

In MLO's 1992 survey on "Lab Staffing Today," laboratories indicated that to cut costs, some MTs performing bench work should be replaced by MLTs. MTs would

be supervisors or specialists (Jahn, 1992). A concise review of the personnel qualifications under CLIA for moderate and high complexity testing can be found in Appendix E.

In the Wage and Vacancy Survey of Medical Laboratories conducted by ASCP Board of Registry for 1988, 1990 and 1992, a comparison was made of the following: positions, vacancy rates, median beginning hourly rates, and median pay rate for medical laboratory personnel in 1992 ("Latest Survey," 1992). The six highest vacancy rates in 1992 by position were: staff cytotechnologists--21.2%, supervisor cytotechnologists--20%, phlebotomists--15.4%, manager--15%, MLTs--14.6%, and staff MTs--13.8%. The survey results confirmed that during the four-year period, beginning median hourly rates and median pay rates increased only slightly ("Latest Survey," 1992). Apparently, salaries have not provided an incentive to prevent a continued increase in the shortage of laboratory personnel.

CLIA '88, with its updates of 1992, "was enacted to insure that Americans receive high-quality, reliable testing in laboratories of all types and sizes throughout the nation. Primarily administered by HCFA, it is being implemented in conjunction with the CDC and Food and Drug Administration (FDA) through the DHHS interagency clinical laboratory programs" (Aziz & Sliva, 1992, pp. 4, 8). By

November 1992 the VA had not written its CLIA equivalent standards, which were to be equal to or more stringent than CLIA '88. VA exempt status was thought to affect health care; however, the VA standards are now more strict than CLIA.

Because of the economic downtrends, student enrollment had risen somewhat in medical laboratory educational programs; however, if the shortages were to be corrected salaries must be improved to be more attractive to young people and job security must become a factor ("Latest Survey," 1992).

1993 Corrections of Rules for Implementation of CLIA '88

HCFA published CLIA correcting amendments in the January 19, 1993, Federal Register (see Appendix G), regarding a technical error in the fee schedule applicable to clinical laboratories and the test performance requirements as tests from the waived list were removed. A new category for testing of moderate complexity was established for PPM procedures; which are exempt from routine inspection and proficiency testing except pinworm preps, unless complaints are received. This testing may be performed in the future by nonphysicians as nurses and nurse-practitioners (DHHS, 1993; Lang, 1993c).

Also podiatrists were now recognized as meeting requirements for a qualified laboratory director (DHHS, 1993). The final rule, published February 28, 1992, with provisions to be effective September 1, 1992, was amended and the effective date was now January 19, 1993; this delay would give laboratories time to understand standards and not disrupt public access to laboratory services. Key changes in CLIA performance requirements condensed from final rule of January 19, 1993 are included in Appendix B (Weissman, 1993).

One aspect of implementing CLIA '88 under modified amendments was the mandated quality control program which had to relate to all aspects of the operation of a laboratory as to its precision and accuracy of results (Passey, 1993d). One of the main focuses of HCFA inspections was that the laboratory must be prepared to document method validation, performance specification, calibration verification, instrument maintenance, and documentation of facilities (Passey, 1993b; 1993c; 1993d).

Most testing personnel were temporarily allowed to work without supervision, an issue of great concern on evening and night shifts in high complexity laboratories (Lang, 1992c, 1993c). According to Lang, testing personnel (without an associate degree) in high complexity laboratories however still must earn the AS degree by 1997.

Lang (1993b, 1993c, 1993d) also indicated that personnel requirements and proficiency testing had contributed to the closing of approximately 4000 POLs rather than conforming to CLIA mandates. In February 1993, the second meeting of CLIAC, which was mandated by CLIA '88 to advise HCFA on CLIA issues, was held; personnel standards were high on the list of topics discussed. More than 20 divergent views on (a) technical consultant requirements in moderate complexity lab and (b) standards for testing personnel working without supervision in high complexity laboratories were expressed (Lang, 1993c, 1993e).

As a result of the February 1993 meeting, CLIAC recommended the following to HCFA:

1. In high complexity testing labs individuals who as of September 1, 1994 had graduated from a CAHEA/ABHES or a 50-week military training program can perform tests independently; this grants equivalency to MLT-Cs, CLAs, and military trained personnel;
2. Grandfather all individuals without formal training who were performing high complexity testing on September 1, 1992, as long as results were reviewed by a general supervisor within twenty-four hours;
3. After September 1, 1994, all new hires must have

had a minimum of an AS degree in laboratory science for high complexity testing;

4. The general supervisor in high complexity testing should have a minimum of a BS degree;
5. Regulations should recognize a BS plus four years of subspecialty experience, MS plus two years of subspeciality experience, or PhD plus one year of subspeciality experience to be a technical supervisor in immunohematology;
6. Expansion of the PPM category to include nurse practitioners, nurse midwives and physician assistants;
7. Recategorization of HDL cholesterol from high to moderate complexity;
8. Tzank and Gram Stain do not meet PPM or waived category;
9. Rapid Strep test does not meet PPM or waived category. (Madigan, 1993a, p. 7; Sanchez, 1993, p. 4)

Under CLIA'88, modified personnel standards covered all personnel who performed moderate to high complexity testing; they must all demonstrate professional competency (Gore, 1993). Gore expressed concern that laboratories had not fully defined how to document competency to inspectors. Passey (1993a) indicated ways to cope with CLIA penalties

and how to avoid them; he further indicated, as a comparison, that if CLIA '67 penalties were lethal, then CLIA'88 punishments are life-threatening.

First Lady Hillary Rodham Clinton spoke to the American Medical Association (AMA) on June 13, 1993, and indicated that changes to CLIA '88 were coming; such changes were to simplify and eliminate the burdensome regulations created by CLIA, which affected professionals in private practice and in public health departments. As a part of healthcare reform, Mrs. Clinton advocated removing micromanagement and regulations that were not cost effective or did not improve quality (Lang, 1993a). Lang also indicated that the White House confirmed that major changes were coming to CLIA '88, especially in POLs because it was too restrictive for the physician. Lang indicated that removing the restrictions would affect site neutrality of the law, which was to guarantee that quality test results were obtained regardless of the site.

The May 1993 meeting of CLIAC resulted in two major personnel changes being recommended to HCFA:

1. To expand the PPM category, to include nurse practitioners, nurse midwives and physicians' assistants; and
2. To require a BS degree and one year of experience for general supervisors in high complexity labs;

> grandfathering would apply to individuals who were supervisors prior to September 1, 1992 (Lang, 1993a). Additionally, according to Lang, CLIAC recommended that all testing personnel in high complexity labs must have an AS degree by September 1, 1994, in order to work without supervision. This recommended change in law would require all nonsupervised testing personnel to have an AS degree by September 1994; this was a drastic change from that which was published September 1, 1992, stating a five-year period or until 1997 ("CLIA Watch," 1993; "CLIAC Recommends," 1993; Nash and Stine, 1993a).

HCFA did not approve the recommendations by September 1994.

Because of continued discontent with CLIA '88, medical laboratory professional groups in several states were continuing to pursue licensure for laboratory personnel, and state licensure requirements must be equal to or more stringent than federal regulations of CLIA. States that had or were near licensure bill approvals were Montana, Rhode Island, Texas, Washington, and Florida (McNett, 1993b). The ASMT, now the ASCLS, advocated that the lobbying was the best way to fight statutory changes to CLIA, but in order to lobby, understanding the legislative process is the key to success (Buccino, 1993b). A lab coalition of professional organizations had been formed for the major focus to ensure

that site neutrality provisions of CLIA were not changed by the Clintons' administration health care reform package, so that consumers would know that quality lab results were obtained regardless of where the tests are performed (Buccino, 1993a). This coalition was much opposed to POLs not having to follow the same rules of CLIA that independent and hospital labs follow: members were especially concerned with personnel standards, quality control, and proficiency testing (McNett, 1993b). CLIAC met in August 1993 to review comments for CLIA '88 changes in 1992 and 1993. HCFA has not responded to recommendations made by CLIAC, but in the meantime clinical laboratories are attempting to meet the regulations as released in 1992 and in 1993.

Refocus of CLIA in the Clinton Health Care Reform Plan

In a Synopsis of the Health Care Reform Plan as published by Lang (1993f; 1993g), a refocus of CLIA was presented as stressed in the Clintons' health care reform plan. Regulations would continue for labs with a comprehensive menu of tests with a volume of 50,000 or greater and for labs that engage in critical thinking when testing is conducted to monitor care while it is being delivered. Major changes were proposed by exempting laboratories performing tests in the waived category,

including registration and fees, and also by expanding the tests in the waived category. Laboratories performing moderate complexity tests would be subject to less stringent inspection requirements. Personnel standards would be revised for relief in urban and rural areas. All individuals currently working as a bench tech or as a supervisor would be grandfathered in. The major target for inspections to implement the regulations would be at high-volume, high-risk, and high-complexity testing labs ("CLIA '88, 1993"; Lang, 1993g).

Because of a refocus of CLIA '88 now being proposed by health care reform plans, this study focused on high complexity testing laboratories located in acute care hospital facilities.

Chapter 3

METHODS OF RESEARCH

This chapter describes the study design, population, pilot study, instrumentation, procedures for data collection, and the methods used for analyzing the data.

Design of the Study

Design of this study was descriptive research. The design was selected to describe systematically the impact of CLIA '88 on personnel needs. Data were obtained from a mail survey sent to laboratories of acute care hospitals in Virginia. Demographic information from each facility included size, test volume, type of laboratory, number of employees in different categories, licensure of facility, and accrediting agency. The respondents were asked for the level of complexity of testing, for the qualifications of current personnel, and for projected personnel needs under recognized CLIA titles. Respondents were also asked to assess the effects on personnel needs resulting from the CLIA '88 legislation.

Personnel needs were compared among small, medium, and large facilities. The percentage of increase or decrease of personnel needs of each educational level was determined.

Population

The population of this study consisted of laboratories of acute care hospital facilities in Virginia. Two directories

were used to identify the laboratories. The first was a directory of hospitals from the Virginia Hospital Association. The second was a directory of Medicare approved acute care facilities which was obtained from the Virginia Department of Health. From these sources, a total of 144 acute care hospital laboratories were identified and surveyed.

The survey was sent to the laboratory manager or chief technologist of each laboratory. Because these individuals were actually involved in recruitment, hiring, evaluating, and scheduling employees, it was their responsibility to be acutely aware of CLIA and its impact.

Only laboratories of acute care hospital facilities were chosen. Laboratories performing only waived testing, physician performed microscopy testing, and moderate complexity testing were not selected because health care reform plans now being studied by Congress have proposed exempting these laboratories or easing the enforcement of CLIA '88 regulations on POLs. Independent laboratories outside of a hospital were not included in this study because of incomplete data from the State Department of Health for applications for certification of complexity testing level variations.

Instrumentation and Pilot Study

The research instrument used was a mail survey

developed specifically for this study after completing a comprehensive review of literature. The questionnaire was sent to five laboratory supervisors in Southwest Virginia. This pilot study allowed an appraisal of the adequacy of data being collected and provided an opportunity to receive suggestions for modifications before the actual mail survey was done. The pilot study also was an opportunity to assess content validity of the instrument. The supervisors who completed the pilot survey were very familiar with CLIA and evaluated the survey instrument for clarity, understanding, and appropriateness of information being sought in the study. Additions or corrections of items in the survey were made from information obtained from the pilot study participants. This helped contribute to reliability.

The results of the pilot study confirmed that the contents of the survey instrument was pertinent regarding the impact of CLIA '88 on personnel needs. Changes were made to the instrument after the initial pilot survey had been tested before it was sent to facilities used in the study.

The initial corrected survey and accompanying letter for the pilot study can be found in Appendix H. Under demographic information, the pilot study respondents suggested that a category should be placed in Questions 1-5 for none (0). In Questions 11 and 12, the category of bachelor's degree with training and/or experience was added.

In Questions 13 and 14, the departments of histology and cytology were added. Apparently, in some laboratories these two departments are included in the total clinical laboratory; other laboratories consider the two departments strictly as the pathology laboratory, and other facilities contract or send out all histological and cytological specimens. In Question 17, the description of CLIA test categorization was rewritten for better understanding. The respondents were very positive about the survey instrument, including the open-ended questions, 18 through 20.

Data Collection Procedures

Accompanied by a letter of explanation, the survey was mailed during the spring and early summer of 1994 to 144 acute care hospital laboratories (see Appendix H). Because of four mergers or closures only 140 facilities were available to respond. Three weeks after the initial mailing a follow-up was sent to nonrespondents. This was followed by a phone call to answer key questions and to encourage nonrespondents to complete the survey. A thank-you note was sent to all respondents.

The variables included in the study were as follows:

1. the size of the facility;
2. the educational level of present personnel;
3. three of the four categories of CLIA regulation 1;

4. perceived effects on laboratory services resulting from CLIA;
5. personnel staffing pattern changes as a result of CLIA; and
6. barriers for implementing CLIA changes.

Procedures Used to Analyze Data

A restatement of the purpose of the study and the research questions follow. The procedures used to analyze each research question are also presented. The purpose of the study was to identify the anticipated effects on personnel needs in acute care hospitals resulting from CLIA '88 regulations including proficiency testing, complexity level of testing, and personnel standards. It was anticipated that CLIA '88 regulations would have an impact on personnel needs for the delivery of quality clinical laboratory services in Virginia.

Descriptive statistics were used to describe systematically the existing laboratory arena as a result of CLIA '88, to identify the effects of problems that existed as a result of or resulting from the legislation, and to make comparisons of personnel needs resulting from CLIA '88 standards in laboratories of small, medium or large acute care hospitals in both urban and rural areas.

Restatement of Research Questions

Answers to the following questions were sought:

1. What were the qualifications of current personnel employed in clinical laboratories of acute care facilities performing high complexity testing?
2. How did the qualifications of current personnel employed in clinical laboratories compare with personnel requirements as mandated under CLIA '88?
3. What effect have the personnel standards of CLIA '88 had on the projected staffing patterns by education levels of clinical laboratories?
4. What was the effect of the requirement for increased proficiency testing of CLIA '88 in the high complexity level on personnel needs of acute care facilities?
5. What perceived barriers exist for implementing CLIA '88 personnel standards?

Specific statistical analysis related to each research question was as follows:

1. Respondents identified the educational qualifications of current personnel employed in each category. Percentages were determined for each educational level in each department for laboratory director, technical supervisor/consultant, clinical consultant, department supervisors, and high complexity

testing personnel by department.

2. Qualifications of current personnel employed in each category by department were compared with personnel requirements as mandated under CLIA '88 for high complexity testing.

3. Respondents were asked if a change in projected staffing patterns resulted from the personnel standards of CLIA '88. Facilities that responded indicating a change in projected personnel needs noted the educational level and whether the need was for an increase or decrease in staff. Percentages were determined for each level and the degree of need. The facilities which indicated a projected staffing pattern change were identified according to hospital size. The need was compared by percentage among small, medium, and large hospitals.

4. Respondents were asked to indicate projected staffing pattern changes as a result of increased proficiency testing. If a change was identified, projected changes were indicated by educational level for a BS or AS degree. Percentage of changes were compared among small, medium, and large hospitals.

5. Respondents were asked if barriers existed for

implementing CLIA '88 personnel standards. If barriers existed, they were categorized by percent among small, medium, and large facilities.

Review of Open-Ended Questions

Three open-ended questions were included in the survey. Responses were categorized and it was determined if there was any relationship to the research questions. Information from open-ended questions was included as appropriate to the research questions. The questions were as follows:

1. What do you see as the effect of CLIA '88 on the delivery and quality of clinical laboratory services?

   The relationship to CLIA '88 Regulation 1 was determined by placing responses in categories as to positive or negative and then ranking them in order of frequency of occurrence. Categories of responses were used when applicable to specific research questions.

2. What changes have occurred in your laboratory services as a result of CLIA '88? How have these changes been implemented?

   The relationship to CLIA '88 Regulation 1 was determined by categorizing changes. Changes that were implemented were identified, and categories were used as applicable to specific research questions.

3. In your opinion, which of the following should have been incorporated in the CLIA '88 personnel standards?

If respondents were not satisfied with the personnel standards as written, criteria that were considered to be important to the respondents were identified and the percent of the number of responses was determined. Recommended criteria that were considered important for personnel standards were used as related to specific research questions.

Summary

The design of this study was descriptive research, using the mail survey methodology. The population for this study consisted of laboratories from 140 acute care hospital facilities in Virginia. The instrument included demographic information, categories of present employees, projected personnel needs, and the impact of CLIA '88 on personnel needs resulting from personnel standards, level of complexity testing, and proficiency testing requirements. The survey instrument was pilot tested by five supervisors in laboratories from acute care hospitals. Data obtained from the respondent laboratories were compiled and analyzed according to the research questions. The comments received

from the open-ended questions were categorized in relationship to CLIA '88 Regulation 1 and then summarized.

Chapter 4

FINDINGS OF THE STUDY

This chapter is a report of the findings from the study regarding the impact of CLIA '88 on personnel needs of clinical laboratories in hospitals of Virginia. Details of the results and profiles of the respondents are given in response to Regulation 1 of CLIA '88 covering personnel qualifications, level of test complexity performed, increased proficiency testing, and the barriers to implementing the personnel standards.

Profile of Responding Laboratories

The survey instrument with a letter of explanation (see Appendix H) was mailed to a total of 144 institutions: 112 acute care hospitals listed by the Virginia Department of Health, and 32 other acute care psychiatric, rehabilitation, and state hospitals listed by the Virginia Hospital Association. Surveys were not sent to military and VA facilities because they are exempt from CLIA regulations. Four facilities had merged or had closed; therefore, of the existing facilities, the final number was 140.

From the first survey mailing 39 responses were received. A second mailing was sent to 101 facilities with a letter requesting participation (see Appendix H). Twenty-nine additional survey responses were received.

The next step was to make personal contact with all nonrespondents, which resulted in 72 phone calls being made. After the phone calls 17 additional surveys were mailed to respondents who indicated a survey was never received or had been discarded (see Appendix H). Thirty-nine additional survey responses were received for a total of 107 or 76.4% of the 140 facilities surveyed.

Of the 107 respondents, 32 or 29.9% of the facilities were not providing full clinical laboratory services in-house but were either sending the collected specimens to a reference laboratory, contracting with a neighboring hospital laboratory to perform the tests, or using a reference laboratory to provide the total service. The remaining 75 or 70.1% were performing in-house testing at all complexity levels. Therefore, the total number of respondents providing data used from this survey was 75.

There were 33 contacts that failed to respond to the survey. Reasons given for nonrespondents' lack of participation were: the potential respondent was not available or there was not enough time to complete the survey. Some of the contacts promised that the survey would be returned. Apparently, the reason that the surveys were not returned was because individuals felt that CLIA probably would not ever be fully implemented or would be rescinded. There was also a reluctance noted in the voice of the

nonrespondents regarding how the results could be incriminating in some way.

As a part of the survey, demographic information was collected on each clinical facility. The first variable was bed size (see Figure 1 for the distribution). Because only 26.6% of responding hospitals had over 200 beds, those with over 200 beds were combined into a large category. This was done to maintain confidentiality. Hospitals with under 100 beds were classified as small, and 100-200 beds was classified as medium sized. For the remainder of the summarized results, respondents were classified in size by small, medium, or large.

Staffing data of each facility by educational background were obtained from the surveys (see Table 1). Seventy-four facilities responded with usable data. All of these facilities had at least one technologist at the BS degree level or higher with 31 facilities or 41.9% having one to five. Eight facilities or 11% did not have any AS degree or higher level technicians and 46 facilities or 63% had one to five. Twenty-two facilities or 30.6% did not have any technicians with less than an AS degree, while 41 facilities or 56.9% had one to five. Eight facilities or 11% did not have any assistants, aides, or phlebotomists, while 42 facilities or 57.5% had one to five. The highest

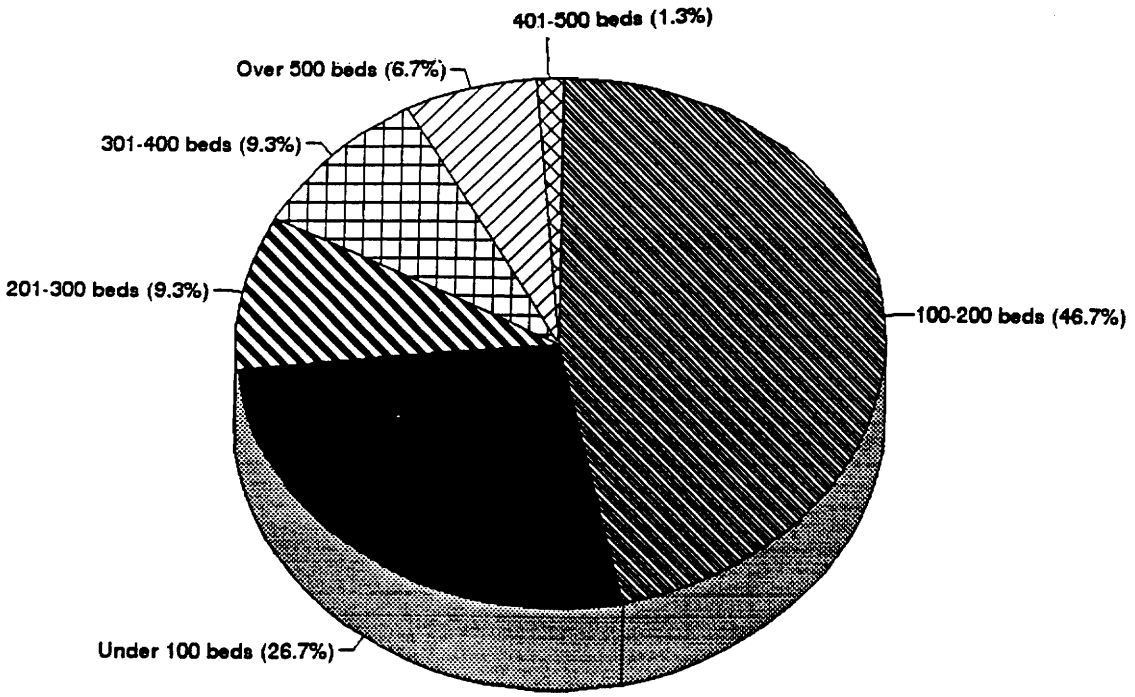

Figure 1. Distribution of survey respondents by bed size

Table 1

Personnel Staffing by Educational Level

No. of Personnel	Technologists (BS or Higher)	Technicians (AS or Higher)	Technicians (Less than AS)	Assistants/ Aides/ Phlebotomists
	Responses	Responses	Responses	Responses
0	-- --	8 (11.0)	22 (30.6)	8 (11.0)
1-5	31 (41.9)	46 (63.0)	41 (56.9)	42 (57.5)
6-10	16 (21.6)	15 (20.5)	6 (8.3)	5 (6.8)
11-15	9 (12.2)	3 (4.1)	-- --	10 (13.7)
16-20	4 (5.4)	-- --	2 (2.8)	6 (8.2)
21-25	5 (6.8)	-- --	-- --	-- --
Over 25	9 (12.2)	1 (1.4)	1 (1.4)	2 (2.7)
Total	74a (100.1)b	73a (100.0)	72a (100.0)	73a (99.9)b

Note. Total responses = 74. Percent of facilities responding is indicated in parentheses.

[a]Total responses may vary in each category of educational level.
[b]Percentage total may not equal 100% because values were rounded to 0.1.

average number of personnel at each educational level was in the one to five category.

Each facility was asked to indicate the agencies that license and accredit the facility. The responses were compiled in Table 2. Responding facilities were all licensed by an appropriate agency and 69 facilities or 92% responded that they had sought accreditation from an external agency that requires validation of quality patient testing. Accreditation by JCAHO and CAP is important because they both have deemed status from HCFA. An inspection by the JCAHO is accepted in place of a CLIA inspection. Results of proficiency testing from the CAP is accepted by HCFA.

Each facility was asked to indicate by percent the complexity level of testing performed by the laboratory according to CLIA categories of waived, moderate-complexity, and high complexity testing. Percent ranges were established in increments of 10 from 1 to 100. The number of responses received and the percent of total respondents can be noted in Table 3. As shown in Table 3, waived testing was being done by 49 respondents in a range of 1-40% of total testing with the highest percent of 57.1% in the 1-10% range. Moderate complexity testing was being done by 55 respondents in a range of 1-100% of total testing with the highest number in the 81-90% range of total testing. High

Table 2

Licensure and/or Accreditation Agency

Licensing Agency	No. of Responses	Accrediting Agency	No. of Responses
Medicare	62 (82.7)	JCAHO[d]	69 (92.0)
		CAP[e]	50 (66.7)
		AABB[f]	42 (56.0)
		COLA[g]	3 (4.0)
Other: State	2 (2.7)	CARF[h]	1 (1.3)
CLIA[a]	2 (2.7)		
FDA[b]	1 (1.3)		
VDH[c]	2 (2.7)		

Note. Total Responses = 75; however, the number of responses varied by facility. Percent of facilities responding is indicated in parentheses.

[a]Clinical Laboratory Improvement Amendment
[b]Food and Drug Administration
[c]Virginia Department of Health
[d]Joint Commission on Accreditation of Hospital Organizations
[e]College of American Pathologists
[f]American Association of Blood Banks
[g]Commission on Office Laboratory Accreditation
[h]Commission on Accreditation for Rehabilitation Facilities

Table 3

Distribution of Test Complexity Level

% Range of Tests Performed	Number of Responses		
	Waived	Moderate Complexity	High Complexity
1-10	28 (57.1)	1 (1.8)	4 (7.1)
11-20	16 (32.7)	2 (3.6)	12 (21.4)
21-30	4 (8.2)	2 (3.6)	16 (28.6)
31-40	1 (2.0)	1 (1.8)	8 (14.3)
41-50	-- --	5 (9.1)	4 (7.1)
51-60	-- --	8 (14.5)	4 (7.1)
61-70	-- --	13 (23.6)	1 (1.8)
71-80	-- --	5 (9.1)	1 (1.8)
81-90	-- --	14 (25.5)	3 (5.4)
91-100	-- --	4 (7.3)	4 (5.4)
Total	49 (100.0)	55 (99.9)a	56 (100.0)

NOTE. All facilities did not respond or data were unusable. Percent of facilities is indicated in parentheses.

[a]Percent may not equal 100 due to rounding.

complexity testing was being done by 56 respondents in a range of 1-100% of total testing with the highest numbers in the 1-30% range of total testing. Table 3 shows that the highest percent of testing was in the moderate complexity category (also see Figure 2). The averages for test complexity levels were calculated for small (less than 100 beds), medium (100-200 beds), and large (over 200 beds) hospitals. Table 4 indicates that regardless of the hospital bed size, only small differences in the averages of waived, moderate complexity, and high complexity level of testing were found. As shown in Table 4, the averages of facilities of all sizes perform a majority of testing at the moderate complexity level.

Each clinical laboratory was asked to indicate the approximate test volume range per year. As noted in Table 5, 44.4% of respondents had a test volume range of 50,000-250,000 tests per year. Test volume ranges were determined for small, medium, and large size hospitals. As shown in Figure 3, small and medium size facilities had the highest number of responses in the 50,000-250,000 test volume range, while the large size facilities had the largest number of responses in the 501,000-1,000,000 test volume range.

Data Analysis

Five research questions were explored to determine the

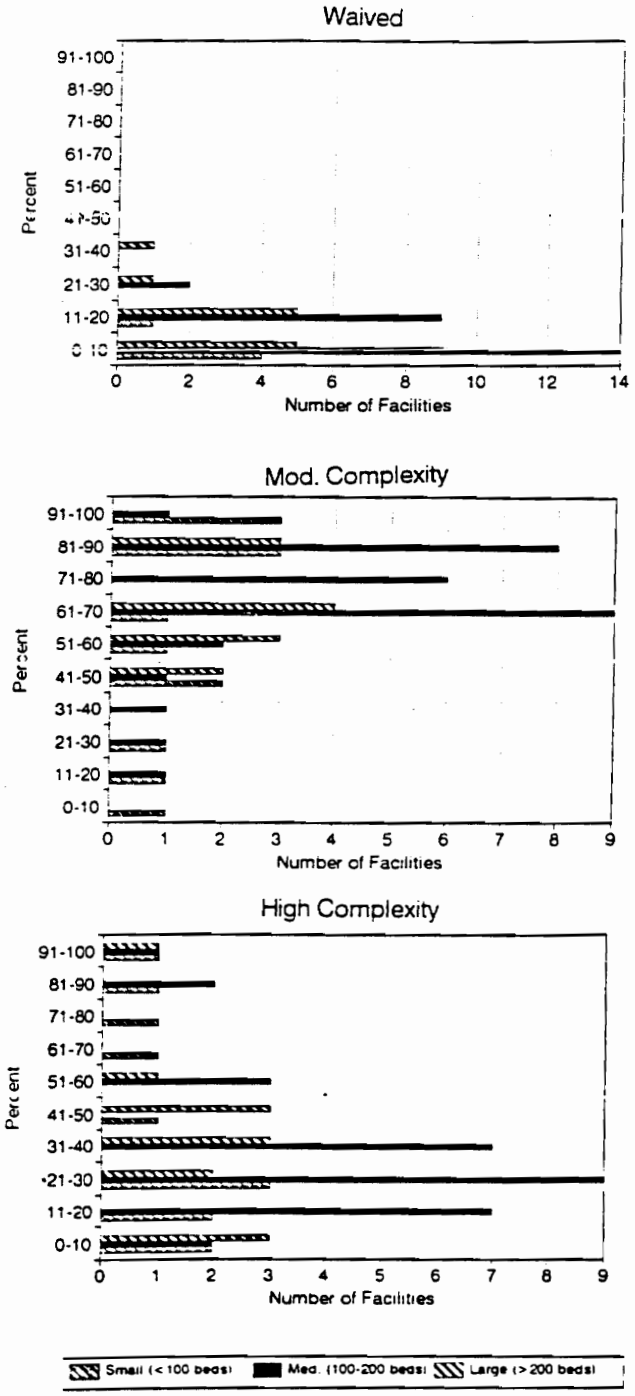

Figure 2. Distribution of test complexity level by facility size

Table 4

Test Complexity Level Averages by Hospital Size

Hospital Size	Percent of Testing by Complexity Level			
	Waived	Moderate	High	Total
Small	7.0	58.0	35.0	100.0
Medium	6.0	63.0	31.0	100.0
Large	9.0	56.0	35.0	100.0

Table 5

Annual Test Volume Range by Laboratory

Test Volume Range	No. of Responses	Percent
Less than 50,000	6	8.3
50,000-250,000	32	44.4
250,001-500,000	15	20.8
500,001-1,000,000	17	23.6
Over 1,000,000	2	2.8
Total	72[a]	99.9[b]

Note. Total Responses = 75

[a]All responses did not provide usable data.
[b]Totals may not equal 100% because results are rounded to nearest 0.1%.

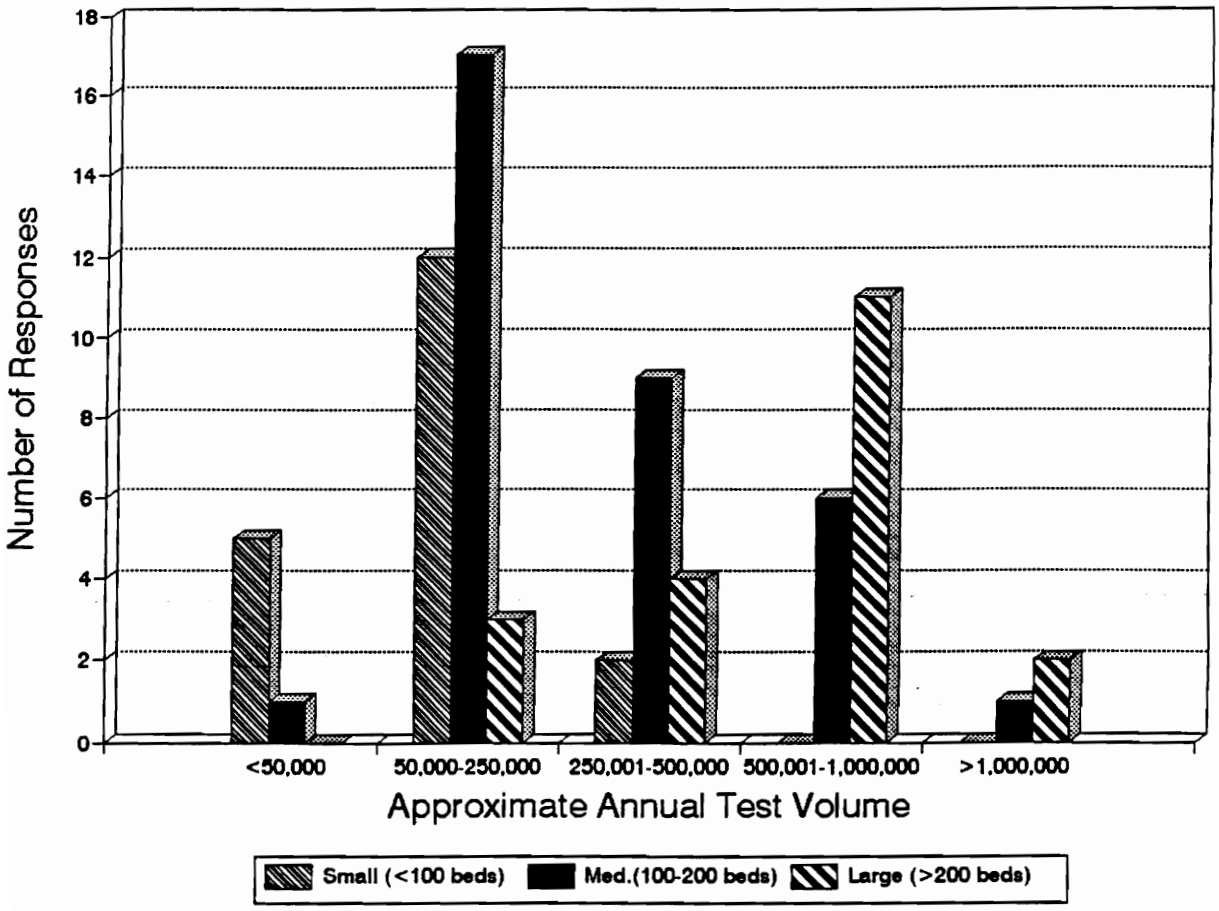

Figure 3. Approximate annual test volume by facility size

impact of CLIA '88 Regulation 1 on personnel needs of clinical laboratories in acute care facilities in Virginia.

Specifically, answers to the following questions were sought:

1. What were the qualifications of current personnel employed in clinical laboratories of acute care facilities performing high complexity testing?

Respondents were asked to identify the educational qualifications of current personnel employed in each category of the clinical laboratory as defined in Regulation 1 of CLIA '88 (see Tables 6, 7, and 8).

As Table 6 indicates, the current qualifications are given for individuals in the categories of laboratory director, technical supervisor/consultant and clinical consultant. As shown in Table 7, the highest level of qualifications attained for the general supervisor in each department is a bachelor's degree with training for an average of 63.9% except for histology and cytology. In histology, 30.0% of general supervision is performed by a nondegreed individual with prior experience as a supervisor. In cytology 34.4% of general supervision is performed by an individual qualified as a laboratory director or technical supervisor. As shown in Table 8, most of the individuals performing high complexity testing by department either have a bachelor's degree in chemical, physical, biological, or

Table 6

Current Qualifications of Director/Consultant

Educational Level	Number of Responses		
	Laboratory Director	Technical Supervisor/Consultant	Clinical Consultant
MD/DO/DOP	67 (89.3)	21 (30.0)	4 (7.0)
MD/DO Board Certified			52 (91.2)
PhD with recognized boards	1 (1.3)		
PhD with experience and/or training (non-certified)			
Master's degree with training and/or experience	2 (2.7)	12 (17.1)	
Bachelor's degree with training and/or experience	5 (6.7)	36 (51.4)	
Other		1 (1.4)	1 (1.8)
TOTAL	75 (100.0)	70[a] (99.9)[b]	57[a] (100)

Note. Percent of facilities responding is in parentheses

[a]All respondents did not provide this information.
[b]Percentages may not total 100% because results rounded to nearest 0.1%

Table 7
Qualifications of Supervisors by Department of Responding Facilities

	Hematology No. (%)	Clinical Chemistry No. (%)	Immuno-Hematology No. (%)	Immunology No. (%)	Micro-Biology No. (%)
Qualfied as a laboratory director or technical supervisor	9 (12.0%)	8 (10.7%)	8 (13.1%)	8 (11.4%)	7 (10.0%)
MD/DO/DOP	--	--	2 (3.3%)	--	--
PhD	--	--	--	--	1 (1.4%)
Master's degree	2 (2.7%)	6 (8.0%)	3 (4.9%)	2 (2.9%)	4 (5.7%)
Bachelor's degree with training	48 (64.0%)	42 (56.0%)	37 (60.7%)	48 (68.6%)	49 (70.0%)
Associate degree with two years training, experience or both	6 (8.0%)	11 (14.7%)	4 (6.6%)	5 (7.1%)	2 (2.9%)
Nondegreed with prior experience as supervisor	10 (13.3%)	8 (10.7%)	7 (11.5%)	6 (8.6%)	6 (8.6%)
Other (specify)	--	--	--	1 (1.4%)	1 (1.4%)
Total	75 (100.0%)	75 (100.0%)	61 (100.1%)	70 (100.0%)	70 (100.0%)

	Coagulation/body fluids No. (%)	Histology No. (%)	Cytology No. (%)	Other No. (%)
Qualified as a laboratory director or technical supervisor	8 (11.6%)	6 (15.0%)	11 (34.4%)	2 (25.0%)
MD/DO/DOP	1 (1.4%)	9 (22.5%)	7 (21.9%)	--
PhD	--	--	1 (3.2%)	--
Master's degree	2 (2.9%)	1 (2.5%)	9 (28.1%)	--
Bachelor's degree with training	45 (65.2%)	8 (20.0%)	1 (3.1%)	5 (62.5%)
Associate degree with two years training, experience or both	5 (7.2%)	3 (7.5%)	--	--
Nondegreed with prior experience as supervisor	8 (11.6%)	12 (30.0%)	1 (3.1%)	1 (12.5%)
Other (specify)	--	1 (2.5%)	2 (6.3%)	--
Total	69 (99.9%)	40 (100.0%)	32 (100.1%)	8 (100.0%)

Table 8
Qualifications of Personnel Performing High Complexity Testing by Department of Responding Facilities

	Hematology No. (%)	Clinical Chemistry No. (%)	Immuno-Hematology No. (%)	Immunology No. (%)	Micro-Biology No. (%)
MD/DO/DOP	--	--	--	---	--
PhD in clinical, physical biological or clinical science	--	--	--	--	--
Masters degree in clinical, physical, biological or clinical lab science	6 (0.9%)	9.5[a] (1.5%)	9 (1.9%)	4 (1.0%)	8 (1.9%)
Bachelor's degree in chemical, physical, biological, or clinical lab science	354 (55.6%)	348 (55.2%)	277.5[a] (57.6%)	245 (58.7%)	245.5[a] (59.4%)
Associate's degree in chemical, physical, biological or clinical science	178 (28.0%)	177 (28.1%)	130 (27.0%)	100 (24.0%)	112 (27.1%)
Previously qualified as technologist without AS degree	77.5[a] (12.2%)	76.5[a] (12.1%)	61.5[a] (12.8%)	58.5[a] (14.0%)	41 (9.9%)
High school graduate with documented training	21 (3.3%)	19 (3.0%)	4 (0.8%)	10 (2.4%)	7 (1.7%)
Other (specify)	--	--	--	--	--
Total	636.5[a] (100.0%)	630 (99.9%)	482 (100.1%)	417.5[a] (100.1%)	413.5[a] (100.0%)

	Coagulation/body fluids No. (%)	Histology No. (%)	Cytology No. (%)	Other No. (%)	Total
MD/DO/DOP	--	17 (18.5%)	19 (28.8%)	--	36 (1.1%)
PhD in clinical, physical biological or clinical science	--	1 (1.1%)	1 (1.5%)	--	2 (0.1)
Master's degree in clinical, physical, biological or clinical lab science	5 (0.9%)	4 (4.3%)	--	1 (1.5%)	46.5[a] (1.4%)
Bachelor's degree in chemical, physical, biological, or clinical lab science	303 (54.7%)	18 (19.6%)	36 (54.5%)	35 (51.5%)	1862 (55.4%)
Associate's degree in chemical, physical, biological or clinical science	154 (27.8%)	13 (14.1%)	1 (1.5%)	15 (22.1%)	880 (26.2%)
Previously qualified as technologist without AS degree	72.5[a] (13.1%)	15 (16.3%)	--	7 (10.3%)	409.5[a] (12.2%)
High school graduate with documented training	19 (3.4%)	23 (25.0%)	8 (12.1%)	10 (14.7%)	121 (3.6)
Other (specify)	--	1 (1.1%)	1 (1.5%)	--	2 (0.1)
Total	553.5[a] (99.9%)	92 (100.0%)	66 (99.9%)	68 (100.1%)	3359 (100.1%)

Note.
a Personnel are assigned to two departments

clinical science (55.4%); or have an associate's degree in chemical, physical, biological, or clinical laboratory science (26.2%), except in histology and cytology. Overall, 81.6% of testing personnel have either a BS or AS degree in the appropriate fields.

2. How did the qualifications of current personnel employed in clinical laboratories of acute care facilities performing high complexity testing compare with personnel requirements as mandated under CLIA '88?

The qualifications of current personnel were compared with the criteria listed in the CLIA '88 update published in January 1993.

(a) The director of high-complexity testing may be:

(1) MD/DO, if not board certified then must have one year of laboratory training during residency, or two years of experience directing or supervising high-complexity testing,

(2) a PhD with HHS-recognized boards, or

(3) a PhD, until September 1, 1994, with two years of training or experience or both. (DHHS, 1993)

Seven individuals had less than the educational level required but were directors prior to passage of CLIA '88. If the law is fully implemented as written then these seven

directors would no longer be qualified.

(b) The technical supervisor/consultant of high-complexity testing:

(1) the same individual functioning as the director,

(2) certified in specialties or subspecialties and be qualified with a MD/DO, PhD, master's, or bachelor's degree with one to four years of training and/or experience and at least six months of experience in many subspecialties. (DHHS, 1993)

All technical supervisors met one of the above educational levels except one individual. This individual would no longer be qualified if CLIA was fully implemented.

(c) Clinical consultants of high-complexity testing must be:

(1) a MD/DO and be board certified,

(2) a PhD qualified as a director and having HHS-approved national boards, or

(3) MD/DO with training and/or experience. (DHHS, 1993)

All respondents indicated that the clinical consultant was an MD except one facility. This individual would not be qualified if the law becomes strictly enforced.

(d) The general supervisor of high-complexity testing

> may be qualified as a laboratory director, a technical consultant/supervisor, or as a clinical consultant. Education qualifications may be MD/DO; PhD; master's degree; bachelor's degree with one year of training, experience, or both in high-complexity testing; or an associate's degree with two years of training, experience, or both in high-complexity testing; or may be previously qualified under CLIA '67. (DHHS, 1993)

All of the supervisors met one of the above criteria except five individuals. With strict enforcement of the law these five supervisors would not be eligible unless they were qualified under CLIA '67.

> (e) The qualifications of personnel performing high-complexity testing may:
>
> (1) be qualified as a director, consultant, or supervisor,
>
> (2) previously be qualified or could have been qualified prior to March 14, 1990, or
>
> (3) have a high school diploma and have until September 1, 1997, to earn an AS degree, in the meantime these individuals must have work reviewed within 24 hours unless a graduate of an accredited certificate or military training program. (DHHS, 1993)

There were 530 individuals who had previously qualified as technologists without an AS degree or were high school graduates with documented training. If the directive to obtain an AS degree by 1997 is actually implemented, then these individuals will no longer be qualified to perform high complexity testing.

Response to an open-ended question regarding the effects of CLIA '88 on the delivery and quality of laboratory services indicated that personnel standards were unrealistic and they had created recruiting difficulties in rural areas, had eliminated those qualified by experience, had lessened the professionalism of the field, and had resulted in personnel with neither the education nor the experience performing the tests. Because these responses were from an open-ended question, no numerical values were assigned.

3. What effect have the personnel standards of CLIA '88 had on the projected staffing patterns by educational levels of clinical laboratories?

Respondents were asked to evaluate the effect of the personnel standards of CLIA '88 on the projected staffing patterns of clinical laboratory positions by educational levels. Of the 68 facilities that responded to the question, 44 facilities (64.6%) indicated a projected change in personnel needs. As shown in Table 9 for facilities

indicating a change, 43.1% indicated the greatest increase in projected personnel needs was at the associate degree level followed by 35.3% indicating the greatest need at the bachelor's degree level. A decreased need for nondegreed technical personnel was projected by 37.1% of the facilities. If a change was indicated, Table 10 shows projected staffing pattern changes as identified according to hospital size. Small- and medium-sized hospitals that indicated a need for staffing pattern changes showed a similar need for an increase in both the bachelor's and associate degree level. All hospitals noting staffing pattern changes indicated a decrease in the need for nondegreed personnel. Of the large hospitals indicating projected staffing changes, 42.1% showed a greater need for associate degree personnel than for other educational levels.

An open-ended question regarding changes that have occurred as a result of CLIA '88 indicated that personnel who do not meet educational requirements are being encouraged to seek either an AS or BS degree, depending on the need to meet personnel standards. In other cases where an individual left a position, a higher educational level person was sought with at least an AS degree. Because information was obtained from an open-ended question, no numerical values were assigned.

Table 9

Projected Staffing Pattern Changes by Educational Levels

Educational Levels	Institutions Projecting An Increased Need		Institutions Projecting A Decreased Need		Institutions Projecting No Change in Need	
	No. of Responses	%	No. of Responses	%	No. of Responses	%
MD/DO	4	6.5	1	1.6	57	91.6
PhD	--	--	6	11.1	48	88.9
Master's degree	5	8.3	2	3.3	53	88.3
Bachelor's degree	24	35.3	3	4.4	41	60.3
Associate degree	28	43.1	4	6.2	33	50.8
Nondegreed technical personnel	7	11.3	23	37.1	32	51.6

Note. Total responses = 68; totals not given because facilities may have responded to more than one category or not at all.

Table 10

Projected Staffing Pattern Changes by Hospital Size

	Small (Under 100 beds)			Medium (100-200 beds)			Large (201 beds and larger)		
	Inc.	Dec.	Unch.	Inc.	Dec.	Unch.	Inc.	Dec.	Unch.
MD/DO	--	--	14 (100.0)	2 (6.7)	--	28 (93.3)	2 (11.1)	--	15
PhD	--	1 (10.0)	9 (90.0)	--	4 (14.3)	24 (85.7)	--	1 (6.3)	15 (93.8)
Masters	1 (7.1)	--	13 (92.9)	3 (10.0)	2 (6.7)	23 (83.3)	1 (7.7)	1 (6.3)	15 (93.8)
Bachelors	8 (44.4)	--	10 (55.6)	14 (45.2)	1 (3.2)	16 (51.6)	2 (10.5)	2 (10.5)	13 (78.9)
Associate	7 (43.8)	2 (12.5)	7 (43.8)	13 (43.3)	1 (3.3)	16 (53.3)	8 (42.1)	1 (5.3)	10 (52.6)
Non-degreed	1 (6.7)	7 (46.7)	7 (46.7)	3 (10.0)	11 (36.7)	16 (53.3)	3 (17.6)	5 (29.4)	9 (52.9)

Note. Inc. = Increased; Dec. = Decreased; Unch. = Unchanged; No totals given because of variable responses to categories. Percent of facilities responding is in parentheses.

4. What was the effect of increased proficiency testing requirements of CLIA '88 in the high complexity level on personnel needs of acute care facilities?

One of the mandates in Regulation 1 of CLIA '88 is increased proficiency testing. Respondents were asked to indicate projected personnel staffing pattern changes as a result of increased proficiency testing; if the increased testing would result in an increase, decrease or no change in personnel needs; and to indicate the number of projected individuals involved. As indicated in Table 11, the majority (62.2%) of laboratories did not see a need for a change in their staffing pattern in order to perform increased proficiency testing. Of those laboratories indicating an increased need (37.8%), a larger proportion (23%) indicated an increased need at the associate degee level than those indicating an increased need at the bachelor's degree level (14.9%). The laboratories indicating a staffing pattern increase as a result of increased proficiency testing is shown in Table 12 according to facility sizes.

Of the laboratories indicating a change in staffing patterns (37.8%) in Table 11, the numbers would be very small when compared to the total number of testing personnel from Table 8. The total number of current BS qualified

Table 11

Projected Changes in Personnel Staffing as a Result of Increased Proficiency Testing

Personnel Staffing Patterns	Total No. of Responding Laboratories
Change - No	46 (62.2%)
- Yes	28 (37.8%)
If yes, projected change indicated:	
Bachelor's degree[a]	11 (14.9%)
Associate degree[b]	17 (23.0%)
Total responses	**74**

Note. Only BS and AS degree levels were assessed.

[a]Projected number of BS personnel needed: increased = 22, decreased = 0.
[b]Projected number of AS personnel needed: increased = 58, decreased = 0.

Table 12

Projected Increases in Personnel Needs by Facility Size as a Result of Proficiency Testing

	Hospital Bed Size			
Educational Level Needed	Small	Medium	Large	Total
BS Level[a]	3 (10.7)	7 (25)	1 (3.6)	11 (39.3)
AS Level[b]	2 (7.1)	4 (14.3)	11 (39.3)	17 (60.7)
TOTAL	5 (17.8)	11 (39.3)	12 (42.9)	28 (100)

Note. Total responses projecting an increased need in personnel as a result of proficiency testing = 28. Percentage of facilities (expressing an increased need) is in parenthesis.

[a]Facilities indicating a need for BS level = 11
[b]Facilities indicating a need for AS level = 17

personnel performing high complexity testing is 1862; and the total number of AS qualified personnel is 880. With the projected number of BS qualified personnel needed as seen in Table 11, the percent increase was 1.2%. With the projected number of AS qualified personnel needed as seen in Table 11, the percent increase was 6.2%.

Responses to an open-ended question indicated that increased proficiency testing had resulted in increased documentation and personnel training on new instrumentation and procedures in the laboratory and at alternate sites. These changes have resulted in increased personnel time, so that current staff members either have assumed an increased workload, or low volume tests have been discontinued or have been sent to a reference laboratory.

5. What perceived barriers existed for implementing CLIA '88 standards?

Respondents were asked to identify barriers that exist in their laboratories for implementing CLIA '88 personnel standards. Five common barriers identified in the literature review and in the pilot study were listed and the responses can be found in Table 13. Cost seems to be the largest barrier and was identified by 48.6% of the laboratories.

The barriers to implement CLIA personnel standards were reviewed according to the bed size of the hospital. Table

Table 13

Perceived Barriers for Implementing Personnel Standards

Barriers	No. of Responses[a]	Percent of Facilities Responding
Cost	35	48.6
Availability of qualified personnel	29	40.3
CLIA test categorization does not reflect the depth of knowledge and independent judgment needed to demonstrate competency	24	33.3
Present staff meeting standards	26	36.1
Support by hospital administration	15	20.8

Note. Total number of facilities responding = 72.

[a]Multiple responses per facility

14 demonstrates that cost was a concern for facilities of all sizes. A higher proportion of facilities with less than 100 beds were more concerned about the availability of qualified personnel. Large-size facilities were more concerned about the categorization of tests by complexity level and the cost for implementing CLIA personnel standards. As shown in Table 14, facilities of all sizes identified multiple barriers for implementing CLIA personnel standards.

In an open-ended question, respondents were asked about the effect of CLIA '88 on the delivery and quality of laboratory services. Cost was identified by 50-60% of the facilities as being a perceived barrier for implementing personnel standards and it was identified as having the most significant effect on the delivery and quality of laboratory services. Availability of qualified personnel was especially a concern for small hospitals (65%) and this factor also was identified as creating recruitment difficulties to provide quality test results. A further result of the availability of qualified personnel was that tests were being done by less qualified personnel and that qualifications were not followed for the test complexity level performed. These comments indicated that CLIA '88 Regulation 1 was not followed according to the letter of the law.

Table 14

Perceived Barriers for Implementing Personnel Standards by Hospital Size

	Response by Hospital Size		
Barriers Existed	Small	Medium	Large
No	0%	8.6%	20.0%
Yes	100.0%	91.4%	80.0%
(If yes, categorized by %):			
Cost	60.0%	50.0%	50.0%
Availability of qualified personnel	65.0%	37.5%	25.0%
Present staff meeting standards	30.0%	40.6%	37.5%
Support by hospital administrtaion	30.0%	18.8%	18.5%
CLIA test categorization does not reflect the depth of knowledge and independent judgment needed to demonstrate competency	30.0%	37.5%	50.0%

Note. Total Responses = 72.

Because of the resistance to the personnel standards as written, respondents were asked in an open-ended question what criteria should have been incorporated in the CLIA '88 personnel standards. All respondents answered the question with 1.3% indicating none or otherwise the standards were adequate as written. The remaining 98.7% indicated that additional factors should have been included as shown in Table 15.

Criteria that were considered to be very important by the majority of respondents for inclusion in CLIA personnel standards were certification, experience, education, and mandated continuing education. Although several states have achieved or are actively pursuing state licensure in lieu of strict personnel standards by CLIA, only about one-third of respondents in Virginia hospital laboratories considered licensure important.

Criteria listed under Other in Table 15, included grandfathering all qualified technologists/technicians, requiring a minimum entry level of an AS degree and BS degree, requiring supervisory experience for all general supervisors, and requiring individual proficiency testing. Responses were in agreement among laboratories from hospitals of different bed sizes.

Table 15

Additional Criteria for Inclusion in CLIA '88 Personnel Standards

Additional Criteria	No. Responding[a]	% of Total Respondents[b]
Experience	53	71.6
Certification	58	78.4
Education	52	70.3
State Licensure	23	31.1
Mandated Continuing Education	49	66.2
Other	7	9.5

Note. Total number of facilities responding = 74.

[a]Number responding will not total 74 because of multiple responses.

[b]Total percent will not equal 100% because of multiple responses.

Summary of Results

The summary is organized to present data related to the demographics of the respondents and the findings to assess the impact of CLIA '88 Regulation 1 on the personnel needs of clinical laboratories in acute care facilities of Virginia. The major emphasis of Regulation 1 is proficiency testing, complexity level of testing, and personnel standards.

Demographic Data

The survey instrument was sent to 140 active acute care facilities. The number of responses received was 107, with 33 facilities not responding. Of the 107 respondents, 32 facilities were not providing full clinical laboratory services; therefore, data were used from 75 facilities or (70.1%). However, some respondents did not answer all questions or data were incomplete; therefore, the number of total responses varied.

The hospitals were placed into three categories by bed size: small (less than 100 beds), medium (100-200 beds), and large (over 200 beds). Responses received by bed size were: small--26.7%, medium--46.7%, and large--26.6%.

Current staffing by educational level was related to

facility size. All agencies were licensed by an appropriate agency, and most were accredited by an agency approved by CLIA with deeming status. The majority of complexity level of testing in all facilities, regardless of bed size, was in the moderate category. The test volume by facility size was as expected for the size of facility, although there was a great difference in the annual test volume between small and medium facilities.

The current qualifications of director(s)/ consultant(s), supervisor(s), and testing personnel met the CLIA '88 personnel standards as extended in the statute by the Secretary of DHHS, on September 1, 1992 (Appendix A) with few exceptions. If the original intent of the statute is implemented and the extension is made void, some personnel in all categories would no longer meet the standard.

Data Analysis

When respondents were asked to evaluate the effect of the personnel standards on the projected staffing patterns, 64.6% of the facilities indicated a change would result. For facilities indicating a change, the greatest need was at the AS degree level with 43.1% of the institutions needing an increase, while 35.3% of the institutions needed an increase at the BS degree level. Furthermore, 31.7% of the institutions projected a decreased need for nondegreed

technical personnel. The need for AS degree personnel is greater for large facilities than for small or medium-sized facilities. Small and medium-sized facilities indicate a need for both BS and AS degree level personnel.

When respondents were asked to evaluate the projected changes in personnel staffing as a result of increased proficiency testing, 62.2% indicated that no change was necessary. The remaining 37.8% indicated a need for AS degree level followed by BS degree level personnel.

The majority of respondents from facilities of all sizes indicated that barriers existed for the implementation of CLIA '88 personnel standards. Cost was a common concern for all sized facilities; whereas, facilities with less than 100 beds were most concerned about the availability of qualified personnel, and facilities with more than 200 beds were equally concerned about the categorization of tests by complexity level disregarding judgment needed by the tester. Barriers for the implementation of personnel standards were also identified as effects on the delivery and quality of services.

Most of the changes that have been made are related to Regulation 1, which includes quality assurance and quality control, proficiency testing, and test complexity level.

As a means of improving the personnel standards, 98.7% of respondents indicated that additional factors should have

been included. A majority of respondents listed experience, certification, education, and mandated continuing education as criteria that should have been included to provide quality care.

Chapter 5

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

This chapter reviews the purpose of the study, summarizes the findings, presents the conclusions, and gives recommendations drawn from the findings regarding the impact of CLIA '88 on personnel needs in clinical laboratories of hospitals in Virginia.

Summary of Study

Purpose of Study

This study was conducted to identify the anticipated effects of Regulation 1 of CLIA '88 on personnel needs in clinical laboratories of acute care hospitals in Virginia. Regulation 1 is the Laboratory Standards and Complexity Model Regulation, which covers quality control, quality assurance, proficiency testing, and personnel standards. This legislation was passed with the intent of improving the quality of laboratory testing in every setting to assure accuracy of patients' tests results. Full implementation of the law as passed in 1988 has yet to be completed in 1994; in fact, controversy continues to postpone implementation of certain provisions of the law.

Demographics

A survey was mailed to 140 clinical laboratories of acute care facilities. A total of 107 responses was

received; of that number 32 (29.9%) facilities were not providing full laboratory services in-house. The remaining 75 (70.1%) of the clinical laboratories provided data for this study. The largest representative of the population was 100-200 beds at 46.7%, followed by under 100 beds at 26.7%.

All facilities were licensed by an appropriate agency and 92% had sought accreditation from an external agency that required validation of quality patient testing. The JCAHO and CAP have both received deemed status by HCFA for inspections and proficiency testing, respectively. Most respondents were accredited by JCAHO, CAP, and/or AABB.

Regardless of the bed size of the facility the majority of tests performed were at the moderate complexity level. The majority of facilities had the most personnel at the BS and AS degree educational levels. The greatest number of small and medium size facilities had an approximate annual test volume within the 50,000-250,000 range and large size facilities in the 500,001-1,000,000 range.

Research Questions and Review of Findings

The research questions were used as the framework for summarizing the findings.

1. What were the qualifications of current personnel employed in clinical laboratories of acute care facilities performing high complexity testing?

The qualifications of current personnel by categories were as follows:

-- Of the laboratory directors, 89.3% were MD/DO/DOP, while the remaining directors had a variety of education and experience;

-- Of the technical supervisor/consultants, 51.4% had a bachelor's degree with training and/or experience and the remaining had a variety of education and experience;

-- Of the clinical consultants, 91.2% were MD/DO Board certified;

-- Of general supervisors, a range of 56%-70% had a bachelor's degree with training in all departments except in histology and cytology. In histology 20% of general supervision was performed by a BS degreed individual and 30% was performed by a nondegreed individual with prior experience as a supervisor. In cytology 34.4% of general supervision was performed by an individual qualified as a laboratory director or technical supervisor; and 3.1% was performed by an individual with a BS degree;

-- Of the personnel performing high complexity testing, 81.6% had a BS degree or an AS degree in chemical, physical, biological or clinical

sciences; of the remaining personnel, 18.4% had varying educational preparation and experience.

2. How did the qualifications of current personnel employed in clinical laboratories of acute care facilities performing high complexity testing compare with personnel requirements as mandated under CLIA '88?

Almost all of the laboratory directors, technical supervisors, and clinical consultants met the personnel standards as revised in January 1993, except those in histology and cytology. Approximately 10% of the supervisors were nondegreed with prior experience as a supervisor; these individuals would not be qualified if the personnel standards were implemented as intended by the law. The number of testing personnel who did not have an AS degree varied by department from 14-25%. This percent represents a total of 532 individuals.

3. What effect have the personnel standards of CLIA '88 had on the projected staffing patterns of clinical laboratories by educational levels?

Of the facilities responding to the question, 44 (64.6%) indicated that the personnel standards had resulted in projected staffing pattern changes. For the facilities indicating an increased need in personnel, 43.1% indicated the greatest need at the AS degree level. Twenty-four (35.3%) of the facilities

indicated an increased need at the BS degree level. For the facilities projecting a decreased need in personnel, 23 (37.1%) of them indicated the decrease would be greatest for nondegreed technical personnel. For the hospitals indicating an increase in personnel needs, small and medium sized hospitals indicated a similar need for personnel at the BS and AS degree levels; whereas, large hospitals indicated a greater need for AS degreed personnel.

4. What were the projected effects of increased proficiency testing requirements of CLIA '88 in the high complexity level on personnel needs of acute care facilities?

Of the facilities that responded, 46 (62.2%) indicated that no change was projected in personnel staffing as a result of increased proficiency testing. The remainder (28 or 37.8%) indicated a projected change in personnel needs; the projected need was greater at the AS degree level followed by the BS degree level.

5. What perceived barriers exist for implementing CLIA '88 personnel standards?

Cost was very important for hospitals of all sizes (50-60% of respondents). The availability of qualified personnel was a very important barrier (65% of

respondents) for small hospitals. The categorization of tests by complexity level was equally important as cost for the large hospitals (50% of respondents). All small hospitals, 91.4% of medium-sized hospitals, and 80% of large hospitals identified that barriers existed.

Conclusions

The findings of this study with the review of current literature were used to formulate the following conclusions:

1. It is concluded that if CLIA '88 stands as corrected in January 1993, a substantial number of individuals currently employed in clinical laboratories must complete educational requirements by 1997 to be qualified to be supervisors and to perform tests at the high complexity level.

According to the corrections published in the Federal Register, January 1993, testing personnel with a high school diploma and documented training and who were not qualified or eligible to qualify as a technologist by March 14, 1990, must have an AS degree by September 1, 1997 to perform high complexity testing. The results of this study showed that 530.5 out of 3359 testing personnel (15.8%) did not have an AS degree; of this number 123 out of 3359 (3.7%) were not

previously qualified as a technologist without a degree.

If the recommendations made by CLIAC to HCFA in 1993 are approved for supervisors to have a BS degree, the need for personnel for supervisors will be increased with 95 out of 500 (19%) requiring a BS degree.

2. It is concluded that CLIA '88 has had an effect on the projected need for clinical personnel by educational levels.

A greater need for AS degreed individuals than for BS levels, and a decrease in the need for nondegreed personnel is indicated. Some 43.1% of respondents proposed a need for AS degreed personnel followed by 35.3% projecting a need for BS degreed individuals with almost 40% (37.1%) proposing a decreased need for nondegreed personnel. Overall, the need to increase total numbers is not indicated, but rather a shifting in the distribution of educational levels of personnel. Proficiency testing was not perceived as producing a major need to increase the number of personnel. In the comparison of total numbers now with projected numbers, the percent increase for BS qualified personnel was 1.2% and for AS qualified personnel was 6.2%.

3. It is concluded that laboratories of acute care hospitals are performing a majority of testing at the moderate complexity level.

This level requires personnel at lower educational

levels and less complicated instrumentation which reduces costs. Laboratories in hospitals of all sizes were performing a majority of testing at the moderate complexity level (56-63%).

These survey results parallel a national survey completed in May 1994. Jahn showed that 64% of all laboratories began sending out tests previously done in-house as a direct result of CLIA. This was supported by Swiercz (1994) who discussed mechanical medical technology, which includes much of moderate complexity testing. This type of technology is intended to replace educated professionals who have knowledge, skills, and abilities.

Recommendations

The review of pertinent literature, findings of this study, and the analysis of the results served as the basis for the following recommendations:

Professional Groups

1. It is recommended that clinical educators in Virginia establish a formal line of communication with clinical laboratory managers to determine the extent of regionalization of laboratories, to evaluate future personnel needs, and to aid in recruitment and

placement of graduates.

2. It is recommended that the clinical educators in Virginia work together to evaluate curricular changes for the BS and AS degree level. This evaluation should be done at the Clinical Educators Forum and at the discipline meetings sponsored by the Virginia Community College System to determine if educational programs are prepared to meet the future personnel needs at the appropriate educational level.

3. It is recommended that clinical educators and practitioners maintain formal communication to determine the extent of downsizing, POC testing, and the effects on personnel needs in laboratories of acute care facilities in Virginia.

4. It is recommended that the clinical educators and practitioners of Virginia establish contact with the appropriate members of congress, senators, and members of CLIAC to identify appropriate criteria that should be included in the personnel standards of Regulation 1 of CLIA '88.

Further Studies/Research

1. It is recommended that studies be done to determine if laboratories are achieving cost containment at the expense of quality by increasing testing at the moderate complexity level, by sending out high

complexity testing, and by hiring personnel at a lower educational level.

2. It is recommended that the clinical educators of Virginia compare results of graduates and employment rates and locations from 1992, the date that CLIA '88 personnel standards were implemented, until 1997 or at such time that CLIA '88 personnel standards may be modified or corrected.

3. It is recommended that a study be done to determine the status of quality patient care as a result of CLIA '88.

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APPENDIX A

PUBLIC STATEMENT BY LOUIS W. SULLIVAN, MD SECRETARY OF DHHS, AUGUST 28, 1992

STATEMENT BY SECRETARY LOUIS W. SULLIVAN, M.D.

A number of small rural hospitals have commented that the February 28 CLIA regulations would impose a great hardship on their laboratories. Specifically, the hospitals say that the personnel requirements for individuals performing highly complex tests and the requirement for 24-hour supervision of the personnel would mean that many of the individuals who have been performing tests in these facilities for many years would not be able to continue to perform the tests, primarily because there would be no supervision for night shifts in the labs.

In recognition of this problem, we are revising the regulations to permit individuals currently employed and performing highly complex tests to continue, until we issue further regulations, to work night shifts in the absence of on-site supervision, provided the work performed during those times is checked within 24 hours.

This will give us time to reevaluate this requirements, and at the same time will prevent disruption of laboratories, especially those in rural areas.

An existing CLIA requirement that provides some relief to small rural hospitals, as well as other laboratories, is the provision that those testing personnel who are required to have an associate degree in order to continue to perform testing will have five years to obtain the degree. This provision as well was designed to blend requirements for quality with a concern for minimizing the disruption in the laboratory community, particularly in the rural community.

U. S. Department of Health and Human Services
August 28, 1992

STATEMENT BY SECRETARY LOUIS W. SULLIVAN, M.D.
Regarding CLIA Implementation for Physicians

The Clinical Laboratory Improvement Amendments of 1988 are among the most complex and challenging regulations which the Department of Health and Human Services has ever had to implement. The intention of the CLIA law is one that is shared strongly by the Administration, Congress and health care professionals: to ensure the quality and reliability of medical tests performed by clinical laboratories throughout the nation. However, this law mandates a significant increase in federal regulatory oversight, and all of those involved in implementing the status recognize the potential for unintended consequences which could actually hinder rather than improve patient care.

The Department is committed to implementing CLIA and achieving its desired affects with a minimum of disruption to health care professionals and without negative impact on patients. Over the past months and years, we have consulted carefully with physicians, laboratory professionals and others to achieve a proper balance in our regulations. In particular, we have sought approaches that would ensure the reliability of tests without reducing patient access to tests.

The development of CLIA regulations has been an evolving process. Problems in the initial proposals were recognized and extensive changes were made, especially in response to comments by physicians. Final regulations were published February 28, but because the Department recognized that there were still concerns about the regulation, it included an additional comment period to solicit further public input. Based on these comments, the Department will be making further changes to the rules. I have sought to make clear, and I reemphasize today, that we will continue to learn more as we phase in the new CLIA structure. The Department o Health and Human Services is committed to making the changes and adjustments to the current rule that prove necessary to achieve the desirable goals of CLIA without imposing unnecessary burden on health care professionals and without impacting negatively on patient care.

As CLIA provisions go into effect today, it is important for physicians and others to keep in mind the evolving nature of this regulatory structure. The Department will continue to accept and analyze comments on the impacts and effects of CLIA provisions. It is our hope that CLIA implementation will involve an ongoing partnership with the physician community.

In particular, the Department is reviewing comments on the classifications of specific tests. Some 10,000 test procedures were assigned complexity ratings, and some of these classifications are being reviewed based on information made available during the comment period. We anticipate that when the finalized complexity list is published this fall, there will be some changes in classifications based on information received.

In addition, we are especially concerned that further modification of the CLIA regulation may be necessary for some microscopy tests. It is not clear that CLIA oversight will add to reliability of this work when performed by the physician, and further modification of the regulations may well be necessary. If necessary, we will invite comment for this area specifically. Necessary changes to the final regulations will be published with responses to comments on the regulations later this year. In the meantime, existing physician practices and patient care will not be affected.

With regard to the mechanics of CLIA implementation, several

points are of importance for the physician who will be affected by CLIA over the next two years:

- The process of surveying clinical laboratories will begin with the largest facilities. Thus most of the surveys this year will involve those commercial and hospital laboratories which were already subject to federal oversight. The first biannual inspections of physicians' facilities will take place in 1993 and 1994.

- The purpose of the initial inspection of physician facilities will be primarily educational. If inspectors find that a physician's office laboratory does not meet certain CLIA standards at the time of the inspection, the lab will be asked to come into compliance with the standards and will be provided technical assistance in explaining options for meeting the standards. Sanctions would only be applied if conditions posed immediate jeopardy to patient health. Sanctions will not be applied due to a failure to meet technical CLIA standards as of September 1. The purpose is to assist physicians in meeting CLIA standards and assuring accurate test results.

- Laboratories located in physicians' offices, where unannounced inspections could disrupt patient care, will be surveyed on an announced basis, so that doctors can schedule time for meeting with inspectors. (Currently regulated commercial laboratories will continue to be inspected on an unannounced basis, as will inspections arising from unusual suspected problems or complaints.)

- Even though laboratories should have registered with HCFA under CLIA by Sept. 1, HCFA will continue to pay laboratory claims without regard to CLIA registration until Dec. 1. During this phase-in period, laboratories (including physicians' offices) filing claims will be notified of the need to register, if they have not already done so.

In addition, CLIA quality standards have been developed taking into account the special circumstances of physicians' offices. These provisions as well will be phased in over a reasonable time period:

- Requirement to participate in proficiency testing programs begins in 1994, allowing time to scale up these programs and enroll physician facilities. Sanctions for failing proficiency testing begin in 1995.

- Almost all physicians will qualify automatically as a lab director by virtue of their experience in running their own lab or their training in residency. For the few doctors who do not fall into these categories, a year will be allowed to obtain continuing medical education in these areas.

- All physician labs, including those doing the most complex tests, can continue using their current testing personnel as long as the personnel have at least a high school degree and training for the lab test work they perform, and are appropriately supervised. At the end of five years, personnel doing the most complex tests would be expected to complete an associate degree in medical technology.

Today's patient benefits significantly from the availability of high quality laboratory testing, made possible especially due to advancing technology. An increasing number and variety of laboratory

tests are accessible today, with increasing convenience and often at lower costs, through the performance of testing and analysis in physicians' offices. Because of the growth of such testing, the CLIA statute has extended federal regulations to laboratory facilities of all sizes. However, in implementing this law, the Department of Health and Human Services seeks to avoid unnecessary regulations which would discourage physicians from offering the testing in the setting of their offices or otherwise impeded good patient care. We pledge to work with physicians, laboratory professionals, patient groups and others to achieve the goals of CLIA without inflicting unanticipated and unnecessary negative impacts on health care professionals or their patients.

Department of Health and Human Services
September 1, 1992

APPENDIX B

KEY CHANGES IN CLIA PERFORMANCE REQUIREMENTS FROM JANUARY 1993

KEY CHANGES IN CLIA PERFORMANCE REQUIREMENTS
Final Rule of January 19, 1993

Allows personnel employed and performing high complexity tests as of 9/1/92 to continue in the absence of on-site supervision as long as work is checked by a general supervisor within 24 hours

Recognizes individuals who qualified or could have qualified as general supervisors under previous 3/14/90 Medicare rules

Modifies definition of "physician" to include state-licensed podiatrists and allows qualified dentists to serve as lab directors or technical supervisors in oral pathology

Creates new certificate category of physician-performed microscopic procedures not subject to routine inspection

Adds another test (e.g., HemoCue) to waived category

Delays application of CLIA to workplace drug testing pending study

Permits hospital labs in contiguous buildings on the same campus and under common direction to qualify for a single certificate

Provides that non-for-profit, federal, state, or local government labs which limit testing to a combination of not more than 15 moderately complex or waived tests file for single certificate

Clarifies that labs not at fixed location (e.g., health fairs, blood mobiles. etc.) may be covered under primary site or home base certificate

Specifies that cytology slide preparations need not be evaluated on-site but can be referred to lab certified for cytology testing

Prescribes that a lab won't be penalized if, through no fault of its own, it has failed to obtain written authorization for testing

Allows blood gas analysis by individuals having a bachelor's degree in cardiovascular technology or respiratory therapy

Source: CLIA Implementation: Major Developments Update, May 1993; G-2 Reports; Washington, D.C.

APPENDIX C

COMPARISON OF PERSONNEL STANDARDS BETWEEN CLIA '67 AND CLIA '88

PERSONNEL STANDARDS

A COMPARISON BETWEEN CLIA '67 AND CLIA '88

MARCH 14, 1990 FINAL RULE GOVERNING MEDICARE, MEDICAID AND CLIA '67 LABORATORIES	FEBRUARY 28, 1992 FINAL RULE IMPLEMENTING CLIA '88	FEBRUARY 28, 1992 FINAL RULE IMPLEMENTING CLIA '88
Independent Laboratories	**Moderately Complex Laboratories**	**Highly Complex Laboratories**
Laboratory Director	**Laboratory Director**	**Laboratory Director**
(a)The laboratory director must possess a current license issued by the state, if such licensing exists; and	(a) The laboratory director must possess a current license by the state in which the laboratory is located, if such licensing is required; and	(a) The laboratory director must possess a current license as a laboratory director issued by the state in which the laboratory is located, if such licensing is required; and
(b) The laboratory director must:	(b) The laboratory director must--	(b) The laboratory director must--
(1) Be a physician certified in anatomical or clinical pathology (or both) by the ABP or AOBP or possess qualifications that are equivalent to those required for such certification; or	(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; and	(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; and

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Laboratory Director	**Laboratory Director**	Laboratory Director
(2) Be a physician who: (i) Is certified by ABP or AOBP in at least one of the laboratory specialties, or (ii) is certified by the ABMB, the ABCC, the ABB or (iii) is certified by ASC to practice cytopathology or possesses qualifications that are equivalent to those required for such certification or (iv) subsequent to graduation has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; or	(ii) Be certified in anatomic or clinical pathology, or both, by the ABP or the AOBP or possess qualifications that are equivalent to those required for such certification; or	(ii) Be certified in anatomic or clinical pathology, or both, by the ABP or the AOBP or possess qualifications that are equivalent to those required for such certification; or
(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;	(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; and	(2) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; and
	(ii) Have had laboratory training or experience consisting of:	(i) Have at least one year of laboratory training during medical residency; or
	(A) At least one year directing or supervising non-waived laboratory testing; or	(ii) Have at least 2 years of experience directing or supervising high complexity testing; or
	(B) Effective (August 2, 1993) have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or	
	(C) Laboratory training equivalent to paragraph (b) (2) (ii) (B) of this section obtained during medical residency; or	

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Laboratory Director	**Laboratory Director**	**Laboratory Director**
(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical or biological science as a major subject and (i) is certified by ABMM, the ABCC, the ABB or other national accrediting board acceptable to HHS in one of the laboratory specialties or (ii) subsequent to graduation has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; or	(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and	(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution--
	(i) Be certified by the ABMM, the ABCC, the ABB, or the ABMLI; or	(i) Be certified by the ABMM, the ABCC, the ABB, the ABMLI or other board deemed comparable by HHS; or
	(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;	(ii) Until September 1, 1994, must have at least--
(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and in addition, either:	(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;	(A) Two years of laboratory training or experience, or both;
		(B) Two years of experience directing or supervising high complexity testing; and
(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;	(ii) Have at least one year of laboratory training or experience, or both; and	(C) On September 1, 1994, individuals must meet the qualifications specified in paragraph (b) (3) (i) of this section;

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Laboratory Director	Laboratory Director	Laboratory Director
(ii) Held a master's degree from an accredited institution with a chemical, physical or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience.	(iii) In addition, have at least one year of supervisory laboratory experience; or	(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or
(iii) Held a bachelor's degree from an accredited institution with a chemical, physical or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience;	(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; (ii) Have at least 2 years of laboratory training or experience, or both; and (iii) In addition, have at least 2 years of supervisory laboratory experience;	(5) On or before February 28, 1992, be qualified under state law to direct a laboratory in the state in which the laboratory is located.
(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or	(6) Have previously qualified or could have qualified as a laboratory director under 42 CFR 493.1415 published March 14, 1990, on or before February 28, 1992.; or	
(6) Qualify under state law to direct the laboratory in the state in which the laboratory is located.	(7) On or before February 28, 1992, qualified under state law to direct a laboratory in the state in which the laboratory is located.	

3/90 Final Rule
Current Law

Technical Supervisor

Specific qualifications are required for the individual providing technical supervision for each of the specialties and subspecialties in which the laboratory performs tests or procedures.

(a) The laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the technical supervisor is a physician; and

(1) Is certified in both anatomical and clinical pathology by the ABP or the AOBP; or

(2) Possesses qualifications that are equivalent to those required for certification.

2/28 Final Rule
Moderately Complex

Technical Consultant

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of services in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

(a) The technical consultant must possess a current license issued by the state in which the laboratory is located, if such licensing is required.

(b) The technical consultant must--

2/28 Final Rule
Highly Complex

Technical Supervisor

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of services in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the state in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor--

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Technical Supervisor	**Technical Consultant**	**Technical Supervisor**
(b) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology, the testing must be performed under the supervision of an individual who—	(1)(i) Be a doctor of medicine or doctor of osteopathy in the state in which the laboratory is located; and	(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; and
(1) Is a physician and–	(ii) Be certified in anatomic or clinical pathology, or both, by the ABP or the AOBP or possess qualifications that are equivalent to those required for such certification; or	(2) Is certified in both anatomic and clinical pathology by the ABP or the AOBP or possesses qualifications that are equivalent to those required for such certification.
(i) Is certified in clinical pathology by the ABP or the AOBP; or		(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must--
(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i); or	(2)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; and	(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; and
(2)(i) Holds an earned doctoral or masters's degree in microbiology from an accredited institution or is a physician, and (ii) Subsequent to graduation has had at least 4 years of experience in clinical microbiology.		

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Technical Supervisor	**Technical Consultant**	**Technical Supervisor**
(c) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the testing must be performed under the supervision of an individual who--	(ii) Have at least one year of laboratory training or experience, or both, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or	(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or
(1) Is a physician and--	(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and	(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and
(i) Is certified in clinical pathology by the ABP or the AOBP; or	(ii) Have at least one year of laboratory training or experience, or both, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or	(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or
(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or		
(2)(i) Holds an earned doctoral or master's degree in biology, chemistry, immunology or microbiology from an accredited institution or is a physician, and		(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and
(ii) Subsequent to graduation has had at least 4 years of experience in immunology.		

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Technical Supervisor	**Technical Consultant**	**Technical Supervisor**
(d) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of chemistry, the testing must be performed under the supervision of an individual who--		(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or
(1) Is a physician and--	(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and	(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and
(i) Is certified in clinical pathology by the ABP or AOBP; or		
(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or	(ii) Have at least 2 years of laboratory training or experience, or both, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.	(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (There are similar requirements for other specialties in the rule).
(2)(i) Holds an earned doctoral or master's degree in chemistry from an accredited institution or is a physician; and		
(ii) Subsequent to graduation has had at least 4 years of experience in clinical chemistry.		
Other specialties have their own specific requirements.		

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
No comparable position.	**Clinical Consultant**	**Clinical Consultant**
	The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must–	The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must–
	(a) Be available to provide clinical consultation to the laboratory's clients;	(a) Be available to provide clinical consultation to the laboratory's clients;
	(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;	(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;
	(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and	(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and
	(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.	(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

3/90 Final Rule
Current Law

General Supervisor

The laboratory has one or more supervisors who, under the direction of the laboratory director, supervise technical personnel and reporting of test results, perform tests requiring special scientific skills, and, in the absence of the director and technical supervisor, are held responsible for the proper performance of all laboratory procedures.

(a) Each supervisor possesses a current license as a laboratory supervisor issued by the state, if such licensing exists; and

(b) The laboratory supervisor–

(1) Who qualifies as a laboratory director under 493.1415(b)(1),(2),(4) or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor.

2/28 Final Rule
Moderately Complex

No comparable position.

2/28 Final Rule
Highly Complex

General Supervisor

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test requirements.

(a) The general supervisor must possess a current license issued by the state in which the laboratory is located, if such licensing is required; and

(b) The general supervisor must be qualified as a--

(1) Laboratory director under 493.1443; or

(2) Technical supervisor under 493.1449.

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
General Supervisor		**General Supervisor**
(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory.		(3) Have previously qualified or could have qualified as a general supervisor under 42 CFR 493.1427 of the federal regulations published March 14, 1990 on or before February 28, 1992. There are separate requirements for certain specialties.
Technologist	**Testing Personnel**	**Testing Personnel**
Each technologist must--	Each individual performing moderate complexity testing must--	Each individual performing high complexity testing must--
(a) Possess a current license as a laboratory technologist issued by the state, if such licensing exists; and	(a) Possess a current license issued by the state in which the laboratory is located, if such licensing is required; and	(a) Possess a current license issued by the state in which the laboratory is located, if such licensing is required; and
(b)(1) Have a earned bachelor's degree in a medical technology from an accredited university;	(b) Meet one of the following requirements:	(b) Meet one of the following requirements:

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Technologist	Testing Personnel	Testing Personnel
	(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or	(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or
(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school;	(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or	(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or
	(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist; or	(3) Have previously qualified or could have qualified as a technologist under 42 CFR 493.1433 published in March 14, 1990 (55 FR 9538), on or before February 28, 1992;
	(4)(i) Have earned an academic high school diploma or equivalent; and	(4) Until September 1, 1997-- (i) Have earned an academic high school diploma or equivalent; and

3/90 Final Rule
Current Law

Technologist

(3) Have earned a bachelor's degree in one of the chemical, physical or biological sciences and in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests;

(4) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with specified courses.

(i) For those whose training was completed before September 15, 1963. At least 24 semester hours in chemistry and biology courses of which--

(A) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(B) At least 12 semester hours in biology courses pertinent to the medical sciences; or

2/28 Final Rule
Moderately Complex

Testing Personnel

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has--

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

2/28 Final Rule
Highly Complex

Testing Personnel

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has--

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Technologist	**Testing Personnel**	**Testing Personnel**
(ii) For those whose training was completed after September 14, 1963.	(F) The skills required to implement the quality control policies and procedures of the laboratory;	(F) The skills required to implement the quality control policies and procedures of the laboratory;
(A) 16 semester hours in chemistry courses that included at least 6 semester hours in organic chemistry and that are acceptable toward a major in chemistry;	(G) An awareness of the factors that influence test results; and	(G) An awareness of the factors that influence test results; and
(B) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and	(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.	(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.
(C) 3 semester hours of mathematics;		
(iii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or (5) With respect to individuals first qualifying before July 1, 1971, the technologist--		

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Technologist		
(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and		
(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or		
(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.		
Technician		
Each laboratory technician--		
(a) Possesses a current license as a technician, issued by the State if such licensing exists; and		

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule Highly Complex
Technician		
(b)(1) Has successfully completed 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or has an associate degree based on a course of study including those subjects from an accredited institution;	Testing Personnel role combines functions from Technologist and Technician positions.	Testing Personnel role combines functions from Technologist and Technician positions.
(2) Is a high school graduate or equivalent and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by HHS;		
(3) Is a high school graduate or equivalent and has two years of pertinent full-time laboratory experience as a technician trainee in a laboratory;		

3/90 Final Rule Current Law	2/28 Final Rule Moderately Complex	2/28 Final Rule High Complexity
Technician		
(4) Is a high school graduate or equivalent and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist;		
(5) With respect to a technician not meeting the training and experience requirements defined in paragraph (b) (1), (2), (3), or (4) of this section--		
(i) Was performing the duties of a clinical laboratory technician any time between July 1, 1961 and January 1, 1968, and		
(ii) Has had at least 5 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience.); or		

3/90 Final Rule Current Law	2/28 Final Rule Moderate Complexity	2/28 Final Rule High Complexity
Technician (6) Achieves a satisfactory grade in a proficiency examination approved by HHS. However, after December 31, 1977, initial certification as a technician must be accordance with paragraph (b)(1), (2), (3), or (4) of this section.		

Source: The nuts and bolts of CLIA '88 by American Association for Clinical Chemistry, Inc., 1992, Washington DC.

December 19, 1994

Ms. Rosemary O'Brien
American Association for Clinical Chemistry, Inc.
2101 L Street, Suite 202
Washington, DC 20037

Dear Ms. O'Brien:

I am doing research on the "Impact of CLIA '88 on Personnel Needs in Acute Care Hospitals of Virginia", for dissertation studies at Virginia Tech, Blacksburg, Virginia. I would like to quote some material from the publication of Nuts and Bolts of CLIA '88 from program #150-01 of March 23-24, 1992. The comparison between CLIA '67 and CLIA '88 would be very helpful in supporting my literature review covering personnel changes from CLIA '67 to CLIA '88.

Because the document is copyrighted, it was recommended that I contact you to seek permission to use this quoted material. I would greatly appreciate your response.

Yours truly,

Betty V. Craft, Professor
Medical Laboratory Technology

gjs

AACC AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY, INC.

2101 L Street, N.W., Suite 202, Washington, D.C. 20037-1526 • Phone 202-857-0717 • Toll Free 1-800-892-1400 • Fax 202-887-5093

December 22, 1994

Betty V. Craft, Professor
Medical Laboratory Technology
Wytheville Community College
1000 East Main Street
Wytheville, VA 24382

Dear Ms. Craft:

Thank you for your interest in our Nuts and Bolts of CLIA '88 manual; I'm glad you find it useful.

On behalf of the American Association for Clinical Chemistry, Inc., I give permission for you to quote material from the manual, as long as you give AACC full credit.

If possible, we would like to receive a copy of your dissertation when it is finished. We might be interested in your material for a future manual. Good luck with your research!

Sincerely,

Donna Plante
Manager, Regulatory Affairs

APPENDIX D

ASCP LETTER IN OPPOSITION TO CLIA

AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
1101 Vermont Avenue, N. W. • Suite 604 • Washington, D.C. 20005 • (202) 371-0515

WASHINGTON OFFICE

Dear ASCP Member:

The Clinical Laboratory Improvement Amendments of 1988 was passed in an effort to improve the quality of laboratory testing and to assure patients that testing accuracy would be maintained regardless of setting. The Final rules, published February 28, 1992, however, eliminate strong personnel standards that have been in effect for over 20 years under Medicare and CLIA '67. This letter is to ask for your assistance in affecting a change in this policy.

The new personnel standards at all levels devalue formal training and education in the laboratory sciences. This revision to long-standing education and training requirements decreases quality in hospitals and independent laboratories (which perform the majority of testing today) and increases the risk to the public rather than reducing it as mandated under CLIA '88. The Department of Health and Human Services (HHS), however, responded to the overwhelming majority of commentors who opposed CLIA '88 personnel standards first proposed in May of 1990 (which were similar to Medicare and CLIA '67 standards). Laboratory professionals need to be heard on this radical change in direction.

ASCP urges you to write to the Health Care Financing Administration (HCFA) and your Member of Congress with your concern about the CLIA '88 Final rules. A 60-day comment period ends April 28, 1992. Please use 2 to 4 of the attached "Points to Make" to guide you in your personal letter. In addition, call on your colleagues to write letters.

Be sure to send a copy of your letter to the ASCP Washington Office so that they can follow up, particularly with Congressional offices.

Thank you for your prompt action on this important issue.

Sincerely,

Ernest S. Tucker, III, MD

Ernest S. Tucker III, MD
President

Marilyn S. Held, SpM, MT(ASCP)

Marilyn S. Held, SpM, MT(ASCP)
Chairman, Associate Member Section

APPENDIX E

PERSONNEL REQUIREMENTS OF CLIA '88 FOR MODERATE AND HIGH COMPLEXITY LABS

PERSONNEL REQUIREMENTS CLIA '88

MODERATE COMPLEXITY LABS

DIRECTOR

1. Laboratory director licence if required by State AND
2. Licensed MD, DO AND
   - Certified in anatomic or clinical pathology OR
   - Lab training or experience consisting of: 1 year directing or supervising non-waived lab OR
   - 20 CME credits in lab practice about director responsibilities (effective in Feb 93) OR
   - Training equivalent to 20 CME credits during medical residency
3. Doctoral degree in laboratory science AND
   - Board certified OR
   - 1 year experience directing or supervising non-waived lab
4. Master's degree in lab science AND
   - 1 year lab training or experience AND
   - 1 year of supervisory experience
5. Bachelor's degree in lab science AND
   - 2 years lab training or experience AND
   - 2 years of supervisory experience

TECHNICAL CONSULTANT

1. License, if required by State AND
2. Licensed MD, DO AND
   - Certified in anatomic orclinical pathology OR
   - Lab training or experience consisting of: 1 year laboratory training or experience in designated specialty/subspecialty in areas of service
3. Doctoral or Master's degree in laboratory science AND
   - 1 year laboratory training or experience in designated specialty/subspecialty in areas of service
4. Bachelor's degree in lab science AND
   - 2 years laboratory training or experience in designated specialty/subspecialty in areas of service

NOTE: "Training or experience" can be acquired concurrently in specialties and subspecialties

CLINICAL CONSULTANT

1. Licensed MD or DO OR
2. Qualified laboratory director (see Director's column)

TESTING PERSONNEL

1. Licensed by State, if required
2. Licensed MD or DO
3. Doctorate, masters, Bachelor, or Associate degree in laboratory science
4. High School graduate or equivalent AND
   - 50 week military training as Medical Lab Specialist OR
   - Documentation of training appropriate to testing performed,TO INCLUDE:
     - Specimen collection, labeling, preparation, etc...
     - implement laboratory procedures
     - perform tests assigned
     - conduct preventive maintenance, troubleshooting, calibration
     - knowledge of reagent stability and storage
     - implement quality control procedures
     - knowledge of factors influencing test results
     - validate patient test results with QC before reporting

HIGH COMPLEXITY LABS

DIRECTOR

1. Laboratory director license if required by state AND
2. Licensed MD, DO AND
   - Certified in anatomic or clinical pathology OR
   - 1 year of laboratory training during medical residency OR
   - 2 years of experience directing or supervising high complexity lab
3. Doctoral degree in laboratory science AND
   - Board certified OR (until Feb '94)
   - 2 years laboratory training/experience AND
   - 2 years experience directing or supervising high complexity lab

TECHNICAL SUPERVISOR

Specific qualifications are required for each specialty or subspecialty.

FOR ALL SPECIALTIES/SUBSPECIALTIES EXCEPT FOR HISTOCOMPATIBILITY AND CYTOGENETICS:

1. Licensed MD or DO AND
   - Certified in anatomic AND clinical pathology

FOR SUBSPECIALTIES OF BACTERIOLOGY, MYCOBACTERIOLOGY, MYCOLOGY, VIROLOGY, PARASITOLOGY:

1. Licensed MD, DO AND
   - Certified in clinical pathology OR
   - 1 year training or experience in high complexity microbiology with a minimum of 6 months in the appropriate subspecialty
2. Doctoral degree in laboratory science AND
   - 1 year training or experience in high complexity microbiology with a minimum of 6 months in the appropriate subspecialty
3. Master's degree in laboratory science AND
   - 2 years training or experience in high complexity microbiology with a minimum of 6 months in the appropriate subspecialty
4. Bachelor's degree in laboratory science AND
   - 4 years training or experience in high complexity microbiology with a minimum of 6 months in the appropriate subspecialty

FOR DIAGNOSTIC IMMUNOLOGY, CHEMISTRY, HEMATOLOGY,RADIOBIOASSAY: Same educational/experiential requirements EXCEPT no 6 month subspecialty requirement.

FOR PATHOLOGY AND ITS SUBSPECIALTIES, CYTOLOGY, HISTOPATHOLOGY,

CLINICAL CONSULTANT

1. Licensed MD or DO OR
2. Qualified laboratory director

GENERAL SUPERVISOR

1. Licensed by State, if required
2. Qualified Director OR
3. Qualified Technical Supervisor OR
4. MD, DO, Doctorate, master's, or bachelor's degree in lab science AND
   - 1 year lab training/experience in high complexity testing OR
4. Associate's degree AND
   - 2 years lab training or experience

FOR BLOOD GASES:

If not qualified above,

5. Bachelor's or Associate's degree in respiratory therapy AND 1 or 2 years of training or *experience*

FOR CYTOLOGY, SEE REGULATION

TESTING PERSONNEL

1. Licensed MD or DO
2. Doctor, Master, Bachelor, or Associate degree in laboratory science
3. Previously qualified as technologist
4. [Until Feb '97]: Same as moderate complexity

FOR BLOOD GASES:

4. Bachelor or associate degree in respiratory therapy.

PERSONNEL QUALIFICATIONS UNDER CLIA '88

For Moderate-Complexity Testing

Director(1)

M.D./D.O.(2): If not board certified in anatomic or clinical pathology; one year directing or supervising nonwaived testing, or by Aug. 2, 1993, have 20 hours of continuing education (for laboratory directors, consistent with 493.1407); or residency training equivalent to the 20 hours specified above, or

Ph.D.(3): HHS-recognized boards; or one year of training or experience or both directing or supervising nonwaived testing, or Master's degree(4) with one year of training or experience or both plus one year's experience as a supervisor, or Bachelor's degree(4) with two years of training or experience or both plus two years as a supervisor; or previously qualified under 493.1415 (March 14, 1990) before Feb. 28, 1992; or, before Feb. 28, 1992, qualified under state law to direct a laboratory in the state.

Technical consultant(1)

M.D./D.O.(2): If not board certified in anatomic or clinical pathology, having one year of training or experience or both in the designated specialty or subspecialty of service, or

Ph.D.(3) or master's degree(3) with one year of training or experience or both in the designated specialty or subspecialty of service, or

Bachelor's degree(4) with two years of training or experience or both in the designated specialty or subspecialty of service.

Clinical consultant(1)

Qualified as a director (M.D./D.O.(2) or board-certified Ph.D.(3), or

M.D./D.O.(2)

Testing personnel(1)

M.D./D.O.(2), Ph.D.(4), master's degree(4), bachelor's degree(4), associate's degree(5), or high school diploma or equivalent(6).

Must have successfully completed a military lab procedures course of at least 50 weeks and held an enlisted occupational specialty of medical lab specialist or high school diploma (or equivalent) with documented training in eight specified areas.

FOR HIGH-COMPLEXITY TESTING

Director(1)

M.D./D.O.(2): If not board certified in anatomic or clinical pathology; one year of laboratory training during residency; or two years of experience directing or supervising high-complexity testing, or

Ph.D.(3) with HHS-recognized boards, or

Ph.D.(3) until Sept. 1, 1994, with two years of training or experience or both; and two years of experience directing or supervising high-complexity testing; by Sept. 1, 1994, be certified by national boards or be serving as laboratory director and previously qualified or could have qualified [that is, was eligible to qualify] as director under 42 CFR 493.1415 (published March 14, 1990) on or before Feb. 28, 1992; or on or before Feb. 28, 1992, be qualified under state law as a laboratory director for the state.

Technical supervisor(1)

The director may function as technical supervisor, or

the laboratory may perform anatomic and clinical laboratory procedures if the director qualifies as an M.D./D.O.(2).

The laboratory may perform tests in the specialties/subspecialties in which the technical supervisor is specifically qualified as follows: M.D./D.O.(2), Ph.D.(3), master's degree(3), or bachelor's degree(4) with one to four years of training and/or experience and at least six months of experience in many subspecialties.

Special qualifications are required in 493.1449 for cytology, histopathology, dermatopathology, ophthalmic pathology, oral pathology, histocompatibility, cytogenetics, and immunohematology.

Clinical consultant(1)

M.D./D.O.(2) (board certified), or

Ph.D.(3) qualified as a director and having HHS-approved national boards, or

M.D./D.O.(2)

General supervisor(1)

Qualified as a laboratory director or technical supervisor for high-complexity testing, or

M.D./D.O.(2), or

Ph.D.(3), or

Master's degree(3), or

Bachelor's degree(4) with one year of training, experience, or both

in high complexity testing, or

Associate's degree(5) with two years of training, experience, or both in high-complexity testing; or previously qualified under 42 CFR 493.1427 (March 14, 1990).

For blood gas analysis:

Qualified as a laboratory director or technical supervisor, or

Bachelor's degree(4) with degree in respiratory therapy, plus one year of laboratory training, experience, or both in blood gas analysis, or

Associate's degree(5) with a degree related to pulmonary function, plus two years of training, experience, or both in blood gas analysis.

The requirements for a general supervisor in histopathology, oral pathology, dermatopathology, or ophthalmic pathology are met because the test is done by a director or technical supervisor.

Testing personnel(1)

M.D./D.O.(2), Ph.D.(3), master's degree(3), or bachelor's degree(4), or associate's degree(5), or have previously qualified or could have qualified [that is, was eligible to qualify] as a technologist under 42 CFR 493.1433 (March 14,1990).

High school diploma(6): Until Sept. 1, 1997, have a high school diploma and documented training prior to performing testing on any patient's specimens that includes eight specific items [See 493.1423(b)(4)Iii), 493.1489(b)(4)Iii).

For blood gas analysis:

Bachelor's degree(4) in respiratory therapy, or

Associate's degree(5) in respiratory therapy.

Special qualifications for cytotechnologists and anyone examining histopathology specimens have been established in 493.1489(b)(6).

For the next five years, a high school graduate may continue to perform tests of high complexity. As of Sept. 1, 1997, all personnel performing high-complexity testing must hold at least an associate's degree.

HHS: Department of Health and Human Services.

Source: Clinical Laboratory Improvement Amendments of 1988; Final Rule. 42 CFR Subpart M--Personnel for Moderate and High Complexity Testing, 493.1401-493.1495, pp. 7172-7183. Feb. 28, 1992.

Key to circled numbers

(1) Currently licensed to perform the duties of the position by the state in which the laboratory is located

(2) Licensed to practice medicine or osteopathy in the state in which the laboratory is located

(3) Holding a degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution*

(4) Holding a degree in a chemical, physical, biological, or clinical laboratory science, or in medical-technology from an accredited institution.* "...'laboratory training or experience, or both' in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests." (---Note to Standard; Technical consultant qualifications 493.1411, p. 7174, and repeated except for the last three words in Note Standard; Technical supervisor qualifications 493.1449, p. 7180, Federal Register, Feb. 28, 1992

(5) Holding an associate's degree in a chemical, physical, or biological science or in medical laboratory technology from an accredited institution*

(6) Holding a high school diploma or equivalent, such as a G.E.D. (generated equivalency diploma). A technical school diploma is not considered an equivalent

*An accredited institution, defined in 493.2, is one that is acceptable to the Health Care Financing Administration as specified in HCFA's State Operations Manual.

APPENDIX F

REQUEST AND PERMISSION LETTERS FROM MLO EDITOR, ROBERT FITZGIBBON

August 3, 1994

Mr. Robert J. Fitzgibbon, Editor
MLO
Five Paragon Drive
Montvale, NJ 07645

Dear Mr. Fitzgibbon:

I am a candidate for a doctoral degree from Virginia Tech, Blacksburg, Virginia. My research studies are on the impact of CLIA '88 on personnel needs in clinical laboratories of acute care facilities in Virginia. I would like permission in writing to use statistical information from surveys conducted by the editors of MLO in collaboration with the Medical Economics research department. The editions of the articles are as follows:

1. M. Jahn. (Sept. 1992). MLO, 24 (9), pp. 24-29; 31-34.

2. M. Jahn. (May 1994). MLO, 22 (5), pp. 20-26.

The data compiled by these research projects support my findings.

It will be helpful if you would respond soon. I am completing my final chapters and expect to defend in September. Thank you for this consideration.

Sincerely yours,

Betty V. Craft

gjs

MLO

Five Paragon Drive
Montvale, NJ 07645-1742
201 358 7200

August 9, 1994

Betty V. Craft
Wytheville Community College
1000 East Main Street
Wytheville, VA 24382

Dear Ms. Craft:

We are pleased to grant you permission to use statistical information from the MLO articles you cited in your letter.

We grant this permission with the understanding that the statistics will only be used for your research and not for any other purpose.

I thank you for your interest in MLO.

Sincerely,

Robert J. Fitzgibbon
Editor

APPENDIX G

CLIA CORRECTING AMENDMENTS FROM JANUARY 1993

493.1265 (Amended)

63. Section 493.1265 is amended as follows:

a. In paragraph (b)(1), "cultures" is revised to read "cultures,".

b. In paragraph (b)(2), "Bone marrow transplantation and living transplants," is revised to read "Bone marrow transplantation,"

c. In paragraph (c), "or parentage testing" is removed.

64. Section 493.1271 is revised to read as follows:

493.1271 Condition: Transfusion services and bloodbanking.

If a facility provides services for the transfusion of blood and blood products,the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart M for technical supervision in immunohematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients. The facility meets this condition by complying with the standards in 493.1273 through 493.1285.

65. In 493.1405, the introductory text of paragraph (b) is republished and paragraphs (b)(2) through (6) are revised to read as follows:

493.1405 Standard: Laboratory director qualifications.

(b) The laboratory director must ---

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least one year directing or supervising non-waived laboratory testing; or

(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or

(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and

(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or

(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing;

(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;

(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or

65a. A new 493.1406 is added to read as follows:

493.1406 Standard; Laboratory director qualifications on or before February 24, 1992.

The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.

(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and

(b) The laboratory director must:

(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(2) Be a physician who:

(i) Is certified by the American Board of Pathology or the American Osteopathetic Board of Pathology in at least one of the laboratory specialties; or

(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or

(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or

(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties.

(3) For the subspecialty of oral pathology only be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;

(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and

(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or

(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either:

(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or

(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970, or

(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

Note: The January 7, 1968 date for meeting the 12 months' laboratory direction requirements in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State Law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21,1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

66. In 493.1411, the Introductory text of paragraph (b) is republished and paragraphs (b)(2) through (4) are revised to read as follows:

493.1411 Standard; Technical consultant qualifications.

(b) The technical consultant must---

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

Note: The technical consultant requirements for "laboratory training or experience, or both " in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

67. Section 493.1417 is amended by revising paragraph (b) to read as follows:

493.1417 Standard; Clinical consultant qualifications.

(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

493.1423 (Amended)

68. In 493.1423 (b)(4)(i), "Have earned an academic high school diploma" is revised to read "Have earned a high school diploma">

69. In 493.1443, the introductory text of paragraph (b) is republished, paragraphs (b)(2) and (b)(5) are revised, and paragraph (b)(6) is added to read as follows:

493.1443 Standard; Laboratory director qualifications.

(b) The laboratory director must---

(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and

(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

* * * * * *

(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

70. Section 493.1449 is amended by revising paragraphs (c)(2)(i), (d)(2)(i), (e)(2)(i), (f)(2)(i), (g)(2)(i), (h)(2)(i), (i)(2)(i), (j)(2)(i), (l)(3), (m), (n)(2)(i), (o)(1)(i), (p)(1)(i), (Q)(2)(i) to read as follows. The introductory text in paragraph (1) is republished.

493.1449 Standard. Technical supervisor qualifications.

* * * * * *

(c) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(d) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(e) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(f) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(g) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(h) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(i) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(j) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must---

* * * * * *

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and---

(B) Must meet one of the following requirements:

(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and---

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or

(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(o) * * *

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(p) * * *

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

* * * * * *

(q) * * *

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

493.1451 (Amended)

71. In 493.1451(b)(4), "parameter" is revised to read "parameters".

72. Section 493.1455 is amended by revising paragraphs (a) and (b) to read as follows:

493.1455 Standard; Clinical consultant qualifications.

* * * * * *

(a) Be qualified as a laboratory director under 493.1443 (b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443 (b)(6); or

(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

73. Section 493.1461 is amended by revising paragraphs (c)(1) and (d)(2) to read as follows. The introductory text of paragraph (d) is republished.

493.1461 Standard: General supervisor qualifications.

* * * * * *

(c) * * *

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

* * * * * *

(d) For blood gas analysis, the individual providing general supervision must---

* * * * * *

(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

* * * * * *

74. In 493.1463, the introductory test of this section is republished, paragraph (a) is revised, and a new paragraph (c) is added to read as follows.

493.1463 Standard. General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(a) The general supervisor--(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under 493.1489;

(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under 493.1489(b)(4); and

(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

* * * * * *

(c) Exception: For individuals qualified under 493.1489(b)(4), who were performing high complexity testing on or before January 19,1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under 493.1461.

75. In 493.1489, paragraphs (b)(1), (b)(4)(i), and (b)(5) are revised to read as follows:

493.1489 Standard; Testing personnel qualifications.

* * * * * *

(b) * * *

(1) Be a doctor of medicine, doctor of osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

* * * * * *

(4) * * *

(i) Have earned a high school diploma or equivalent; and

* * * * * *

(5) For blood gas analysis, the individual must---

(i) Be qualified under 493.1489(b)(1), (2), (3), or (4);

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

* * * * * *

76. Section 493.1495 is amended by revising paragraph (b)(7) and adding new paragraph (c) to read as follows:

493.1495 Standard; Testing personnel responsibilities.

* * * * * *

(b) * * *

(7) Except as specified in paragraph (c) of this section, if qualified under 493.1489(b)(4), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under 493.1461.

(c) Exception. For individuals qualified under 493.1489(b)(4), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under 493.1461.

493.1701 (Amended)

77. In 493.1701, "complexity of testing performed and reported," is revised to read "complexity of testing performed, and test results reported,".

78. Section 493.1709 is revised to read as follows:

493.1709 Standard; Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) If a laboratory performs tests that are not included under subpart 1 of this part, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.

79. Section 493.1715 is revised to read as follows:

493.1715 Standard; Communications.

The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions must be taken, as necessary, to resolve the problems and minimize communication breakdowns.

80. Section 493.1721 is revised to read as follows:

493.1721 Standard; Quality assurance records.

The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken. All quality assurance records must be available to HHS and maintained for a period of 2 years.

81. Section 493.1775 is amended by revising paragraph (a) to read as follows:

493.1775 Condition: Inspection of laboratories issued a certificate of waiver.

(a) HHS or its designee may conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to assess compliance with the applicable requirements of part 493.

* * * * * *

82. A new 493.1776 is added to read as follows:

493.1776 Condition: Inspection of physician-performed microscopy procedures.

(a) HHS or its designee will conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to--(1) Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health;

(2) Evaluate complaints from the public;

(3) Determine whether the laboratory is performing tests in addition to procedures listed in 493.16 that are not included on the laboratory's certificate; and

(4) Collect information to determine the addition, deletion, or continued inclusion of tests listed in 493.16. Applicable requirements for the purpose of this section are located in subpart C, registration certificate, certificate for physician-performed microscopy procedures, and certificate, or if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; and subpart P, quality assurance of this part, as well as 493.16(e).

(b) The laboratory may be required, as part of this inspection, to---(1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493 as noted in paragraph (e) of this section;

(2) Permit HHS or its designee access to all areas of the facility including--

(i) Specimen processing areas;
(ii) Storage facilities for specimens, requests, supplies, records, and reports; and
(iii) Testing and reporting areas.

(3) Permit physicians to be observed performing tests and reporting results;

(4) Permit HHS or its designee upon request to review all information and data necessary to---

(i) Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health;
(ii) Evaluate complaints from the public;
(iii) Determine whether the laboratory is performing tests in addition to procedures listed in 493.16 that are not included on the laboratory's certificate;
(iv) Collect information to determine the addition, deletion, or continued inclusion of tests listed in 493.16; and

(5) Provide copies to HHS or its designee of all records and data that the agency requires under these regulations.

(c) The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the requirements of part 493.

(d) Failure to permit an inspection under this subsection may result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate in accordance with subpart R of this part.

83. Section 493.1777 is amended by revising the section heading and paragraph (a) to read as follows:

493.1777 Condition: Inspection of all laboratories not issued a certificate of waiver, certificate for physician-performed microscopy procedures, or a certificate of accreditation.

(a) HHS or its designee may conduct unannounced or announced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. To assess compliance with the requirements of part 493, HHS will inspect a laboratory possessing a registration certificate before issuance of a certificate.

* * * * * *

84. Section 493.1780 is amended by revising the section heading, paragraphs (a), (b), and (e) to read as follows:

493.1780 Condition: Inspection of accredited and CLIA-exempt laboratories.

(a) HHS or its designees may conduct unannounced or announced, random validation inspections of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) HHS or its designee will conduct unannounced complaint inspections of an accredited or CLIA-exempt laboratory at any time during its hours of operation upon receiving a complaint about that laboratory.

* * * * * *

(e) The laboratory must retain:

(1) Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR part 606, subpart I;

(2) Records of blood and blood product testing for a period of not less than 5 years after processing records have been completed, or 6 months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d);

(3) Pathology test reports for at least 10 years after the date of reporting, as required in 493.1109; and

(4) All other laboratory records for at least 3 years unless otherwise specified in part 493.

* * * * * *

493.1806 (Amended)

85. In 493.1806(d), "State-exempt" is revised to read "CLIA-exempt".

86. Section 493.1814 is amended by revising paragraph (b)(3) to read as follows:

493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

* * * * * *

(b) * * *

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, (while a hearing on the proposed suspension, limitation, or revocation of the certificate, registration certificate, certificate of accreditation, or certificate for physician-performed microscopy procedures is pending.)

87. Section 493.1834 is amended by revising paragraphs (b) and (f)(2)(iii) to read as follows:

493.1834 Civil money penalty.

* * * * * *

(b) Scope. This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of, or in addition to suspending, limiting, or revoking the certificate, registration certificate, certificate of accreditation, or certificate for physician-performed microscopy procedures of a laboratory that is found to have condition level deficiencies.

* * * * * *

(f) * * *

(2) * * *

(iii) HCFA suspends, limits, or revokes the laboratory's certificate, registration certificate, certificate of accreditation, or certificate for physician-performed microscopy procedures.

* * * * * *

88. Section 493.1836 is amended by revising paragraphs (c)(2) and (c)(3) to read as follows:

493.1836 State onsite monitoring.

* * * * * *

(c) * * *

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate, registration certificate, certificate of accreditation, or certificate for physician-performed microscopy procedures.

(3) If the laboratory still does not correct the deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate, registration certificate, certificate of accreditation, or certificate for physician-performed microscopy procedures is effective.

89. Section 493.2001 is amended by revising paragraph (e) to read as follows:

493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

* * * * * *

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS will review and make recommendations concerning:

(1) Criteria for categorizing tests and examinations of moderate and high complexity;
(2) Determination of waived tests;
(3) Personnel standards;
(4) Patient test management, quality control, quality assurance standards;

(5) Proficiency testing standards;
(6) Applicability to the standards of new technology; and
(7) Other issues relevant to part 493, if requested by HHS.

Source: Catalog of Federal Domestic Assistance, Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program. Dated October 1,1992.

James O. Mason, Assistant Secretary for Health; Dated: September 18, 1992.

William Toby, Jr., Acting Deputy Administrator, Health Car Financing Administration. Approved: December 11, 1992.

Louis W. Sullivan, Secretary, [FR Doc. 93-1169 Filed 1-15-93; 8:45 am]

APPENDIX H

LETTERS AND SURVEY INSTRUMENTS

1. LETTER ACCOMPANYING PILOT STUDY SURVEY

2. PILOT STUDY SURVEY INSTRUMENT

3. LETTERS AND MEMO SENT WITH FIRST, SECOND, AND THIRD SURVEY MAILINGS

4. SURVEY INSTRUMENT

April 12, 1994

Dear Laboratory Supervisor:

Since September 1992, CLIA '88 has produced changes in the operation and delivery of clinical laboratory services. As a part of my research studies at Virginia Tech, I am planning to conduct a survey to assess the anticipated impact of personnel standards, proficiency testing and the complexity level of testing of CLIA '88 on personnel needs for the delivery of quality clinical laboratory services in acute care facilities of Virginia. Prior to conducting the survey, I am required by my graduate committee to pilot test the survey instrument and have it critiqued by experts in the field; therefore, I would greatly appreciate your assistance.

If you believe questions are inappropriate in assessing personnel needs, please indicate such. If additional information would be beneficial in assessing future personnel needs for your facility, I would appreciate your suggestions.

Thank you for both your time and expertise in assessing this survey instrument. Please return it with comments in the enclosed stamped envelope by April 15. I would be happy to share the results at a later date.

Sincerely,

Betty V. Craft, MT(ASCP)
MLT Program Director

gjs

Impact of CLIA '88

(PILOT) SURVEY INSTRUMENT

Congress united to improve the quality and reliability of laboratory testing in every setting by the passage of Public Law 100-578, Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

This survey is being conducted to assess the anticipated impact of personnel standards, proficiency testing and the complexity level of testing of CLIA '88 on personnel needs for the delivery of quality clinical laboratory services in acute care facilities of Virginia. Your opinions regarding CLIA are very important. Please respond to all of the following survey items as related to your laboratory.

PART I. DEMOGRAPHIC INFORMATION

Directions: Please provide the following demographic information about your facility by checking the appropriate response.

1. Size of Facility

____(1) 0
____(2) under 100 beds
____(3) 100-200 beds
____(4) 201-300 beds
____(5) 301-400 beds
____(6) 401-500 beds
____(7) over 500 beds

2. Number of Full-Time Equivalent Technologists with an appropriate B.S. degree or higher.

____(1) 0
____(2) 1-5
____(3) 6-10
____(4) 11-15
____(5) 16-20
____(6) 21-25
____(7) over 25

3. Number of Full-Time Equivalent Technicians with an appropriate A.S. degree.

____(1) 0
____(2) 1-5
____(3) 6-10
____(4) 11-15
____(5) 16-20
____(6) 21-25
____(7) over 25

5. Number of Full-Time Equivalent Aides/Assistants/Phlebotomists

____(1) 1-5
____(2) 6-10
____(3) 11-15
____(4) 16-20
____(5) 21-25
____(6) over 25

6. Facility licensed by: (check all that apply)

____(1) Medicare
____(2) JCAHO
____(3) AOA
____(4) Other_____

7. Facility accredited by: (check all that apply)

____(1) CAP
____(2) AABB
____(3) POAA
____(4) COLA
____(5) Other_____

8. According to CLIA categories, indicate the complexity level of testing by percent. (All responses should total 100%).

____(1) Waived
____(2) Moderate-Complexity
____(3) High Complexity Test

9. Indicate the approximate annual Test Volume for your laboratory.

____(1) less than 50,000
____(2) 50,000-250,000
____(3) 250,000-500,000
____(4) 500,000-1,000,000
____(5) if over 1,000,000 please specify approximate number
_____

PART II. CURRENT PERSONNEL QUALIFICATIONS

Directions: Please check the highest qualifications that describe the individual(s) employed in each of the following positions.

10. Laboratory Director

____(1) M.D./D.O./D.O.P.
____(2) Ph.D. with recognized boards
____(3) Ph.D. with experience and/or training (non-certified)
____(4) Master's degree with training and/or experience
____(5) Bachelor's degree with training and/or experience
____(6) Other (please specify)_____

11. Technical supervisor/consultant

_____(1) M.D./D.O./D.O.P.
_____(2) Ph.D. with training and/or experience
_____(3) Master's degree with training and/or experience
_____(4) Other (please specify)

12. Clinical consultant

_____(1) M.D./D.O. board certified
_____(2) M.D./D.O./D.O.P.
_____(3) Ph.D. board-certified, and/or having HHS-approved boards
_____(4) Other (please specify)

13. For the general supervisor in each department listed, check the highest level of qualifications attained:

	Hematology	Clinical Chemistry	Immuno-hematology	Immunology	Microbiology	Coagulation Body Fluids	Other
1. Qualified as a laboratory director or technical supervisor							
2. MD/DO/DOP							
3. Ph.D.							
4. Master's degree							
5. Bachelor's degree with training							
6. Associate degree with two years of training, experience, or both							
7. Non-degreed with prior experience as supervisor							
8. Other (specify) _____							

14. Please indicate the number of individuals performing high complexity testing in each of the following departments according to their educational qualifications.

	Hematology	Clinical Chemistry	Immuno-hematology	Immunology	Microbiology	Coagulation /Body Fluids	Other
1. MD/DO/DOP							
2. Ph.D. in clinical, physical, biological, or clinical science							
3. Master's Degree in chemical, physical, biological, or clinical lab science							
4. Bachelor's degree in chemical, physical, biological, or clin lab science or in Med Tech							
5. Associate's degree in chemical, physical, biological, or clinical lab science							
6. Previously qualified as technologist without A.S. degree							
7. High school graduate with documented training							

Other (specify)_____

15. If the overall projected personnel needs indicate a staffing pattern change, indicate (I) for increased, (U) for unchanged, and (D) for decreased needs for each of the following educational levels:

(1) M.D./D.O._____
(2) Ph.D._____
(3) Master's degree_____
(4) Bachelor's degree_____
(5) Associate degree_____
(6) Non-degreed technical personnel_____

16. Check one or more of the following items to indicate projected personnel staffing pattern changes necessitated by increased proficiency testing as mandated by CLIA '88. If a change is needed, give the actual number of projected individuals.

____(1) no change
____(2) Bachelor's degree
a. increased need (#_____)
b. decreased need (#_____)
____(3) Associate degree
a. increased need (#_____)
b. decreased need (#_____)

17. Which of the following exist as barriers in your laboratory for implementing CLIA '88 personnel standards?

____ cost
____ availability of qualified personnel
____ present staff meeting standards
____ support by hospital administration
____ test categorization does not reflect the depth of knowledge and independent judgment needed to demonstrate professional competency

Others (please list)

_____

_____

PART III. IMPACT ON LABORATORY SERVICES - OPINION

18. In your opinion, what do you see as the effect of CLIA '88 on the delivery and quality of clinical laboratory services?

19. What changes have occurred in your laboratory services as a result of CLIA '88? How have these changes been implemented?

20. In your opinion which of the following should have been incorporated in the CLIA '88 personnel standards: (check all that apply)

____ Experience
____ Certification
____ Education
____ State licensure
____ Mandated continuing education
____ Other (please specify)_____

April 18, 1994

Dear Laboratory Manager/Chief Technologist:

Since the passage of Clinical Laboratory Improvement Act Amendments (CLIA) of 1988, clinical laboratory practitioners and educators have been concerned about how these regulations will affect the professions involved. The most controversial issue seems to be the Lab Standards and Complexity Model Regulation, which includes personnel standards, quality control, quality assurance, and proficiency testing. The educational levels required of personnel may still vary depending on the final regulations which are proposed for release later in 1994.

As a part of my doctoral dissertation at Virginia Tech, I am studying the potential impact of CLIA '88 on clinical laboratory personnel needs in acute care facilities of Virginia. Therefore, I need your assistance. Please complete the enclosed survey which is numerically coded for follow-up purposes only. All results will be kept confidential and no mention will be made of any specific facility. Data will be classified by bed capacity and test volume.

If you would like a copy of the results, please place your name and address on the back of the return envelope. Please do not put this information on the survey so that when results are tallied each facility will remain anonymous. Enclosed is a stamped, self-addressed envelope to return your completed survey by **May 16, 1994.** If you have any questions, please call me at (703) 228-5541.

Thank you for your time and contribution in assessing the impact of CLIA '88 on personnel needs of clinical laboratories in acute care facilities of Virginia.

Sincerely,

Betty V. Craft
M.A., MT(ASCP), CLS (NCA)

enclosure

May 26, 1994

Dear Laboratory Manager/Chief Technologist:

I sincerely need your assistance. A few weeks ago, a survey was mailed to you which requested information on your facility concerning the potential impact of CLIA '88 on clinical laboratory personnel needs in acute care facilities of Virginia. Both practitioners and educators have been concerned about how the regulations will affect the professions involved.

As of today, I have not received your completed survey. Each survey is significant so that the result will accurately represent clinical personnel needs in Virginia. In case your survey has been misplaced or destroyed, a replacement is enclosed. Please take a few minutes to complete the survey and return it in the enclosed postage-paid envelope no later than June 10, 1994.

As previously stated, all results for each facility will be tallied anonymously. If you would like a summary of the survey results, please place your name and address on the back of the return envelope. Your cooperation will be greatly appreciated.

Sincerely,

Betty Craft

Betty Craft

gjs

enclosures

MEMORANDUM

TO:

FROM: Betty Craft

DATE:

RE: Completion of survey to study impact of CLIA'88 on clinical laboratory personnel needs

I appreciate you taking time to review the enclosed survey, completing it, and returning it as soon as possible. I am enclosing a copy of the letter of explanation sent with the second mailing of the survey. Thank you for contributing to this study.

db

Impact of CLIA '88

SURVEY INSTRUMENT

Congress united to improve the quality and reliability of laboratory testing in every setting by the passage of Public Law 100-578, Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

This survey is being conducted to assess the anticipated impact of personnel standards, proficiency testing and the complexity level of testing of CLIA '88 on personnel needs for the delivery of quality clinical laboratory services in acute care facilities of Virginia. Your opinions regarding CLIA are very important. Please respond to all of the following survey items as related to your laboratory.

PART I. DEMOGRAPHIC INFORMATION

Directions: Please provide the following demographic information about your facility by checking the appropriate response.

1. Size of Facility

_____ (1) under 100 beds
_____ (2) 100-200 beds
_____ (3) 201-300 beds
_____ (4) 301-400 beds
_____ (5) 401-500 beds
_____ (6) over 500 beds

2. Number of Full-Time Equivalent Technologists with an appropriate B.S. degree or higher.

_____ (1) 0
_____ (2) 1-5
_____ (3) 6-10
_____ (4) 11-15
_____ (5) 16-20
_____ (6) 21-25
_____ (7) over 25

3. Number of Full-time Equivalent Technicians with an appropriate A.S. degree.

_____ (1) 0
_____ (2) 1-5
_____ (3) 6-10
_____ (4) 11-15
_____ (5) 16-20
_____ (6) 21-25
_____ (7) over 25

4. Number of Full-Time Equivalent Technicians with less than an A.S. degree.

_____ (1) 0
_____ (2) 1-5
_____ (3) 6-10
_____ (4) 11-15
_____ (5) 16-20
_____ (6) 21-25
_____ (7) over 25

5. Number of Full-Time Equivalent Aides/Assistants/Phlebotomists.

_____ (1) 0
_____ (2) 1-5
_____ (3) 6-10
_____ (4) 11-15
_____ (5) 16-20
_____ (6) 21-25
_____ (7) over 25

6. Facility licensed by: (check all that apply).

_____ (1) Medicare
_____ (2) JCAHO
_____ (3) AOA
_____ (4) Other _____

7. Facility accredited by: (check all that apply).

_____ (1) CAP
_____ (2) AABB
_____ (3) POAA
_____ (4) COLA
_____ (5) Other _____

8. According to CLIA categories, indicate the complexity level of testing by percent for your laboratory. (All responses should total 100%).

_____ (1) Waived
_____ (2) Moderate-Complexity
_____ (3) High Complexity Testing

9. Indicate the approximate annual Test Volume for your laboratory.

(1) less than 50,000 ... (4) 500,000-1,000,000

PART II. CURRENT PERSONNAL QUALIFICATIONS

Directions: Please check the highest qualifications that describe the individual(s) employed in each of the following positions.

10. Laboratory Director

_____ (1) M.D. / D.O. / D.O.P.
_____ (2) Ph.D. with recognized boards
_____ (3) Ph.D. with experience and/or training (non-certified)
_____ (4) Master's degree with training and/or experience
_____ (5) Bachelor's degree with training and/or experience
_____ (6) Other (please specify) _____

11. Technical supervisor/consultant

_____ (1) M.D. / D.O. / D.O.P.
_____ (2) Ph.D. with training and/or experience
_____ (3) Master's degree with training and/or experience
_____ (4) Bachelor's degree with training and/or experience
_____ (5) Other (please specify) _____

12. Clinical consultant

_____ (1) M.D. / D.O. board certified
_____ (2) M.D. / D.O. / D.O.P.
_____ (3) Ph.D. board-certified, and/or having HHS-approved boards
_____ (4) Other (please specify) _____

13. For the general supervisor in each department listed, check the highest level of qualifications attained:

HIGHEST QUALIFICATION	DEPARTMENT								
	HEMATOLOGY	CLINICAL CHEMISTRY	IMMUNO-HEMATOLOGY	IMMUNOLOGY	MICROBIOLOGY	COAGULATION/ BODY FLUIDS	HISTOLOGY	CYTOLOGY	OTHER
1. Qualified as a laboratory director or technical supervisor									
2. MD/DO/DOP									
3. Ph.D.									
4. Master's degree									
5. Bachelor's degree with training									
6. Associate degree with two years training, experience, or both									
7. Non-degreed with prior experience as supervisor									
8. Other (specify) _____									

14. Please indicate the number of individuals performing high complexity testing in each of the following departments according to their educational qualifications.

HIGHEST QUALIFICATION	DEPARTMENT								
	HEMATOLOGY	CLINICAL CHEMISTRY	IMMUNO-HEMATOLOGY	IMMUNOLOGY	MICROBIOLOGY	COAGULATION/ BODY FLUIDS	HISTOLOGY	CYTOLOGY	OTHER
1. MD/DO/DOP									
2. Ph.D. in clinical, physical, biological, or clinical science									
3. Master's degree in chemical, physical, biological, or clinical lab science									
4. Bachelor's degree in chemical, physical, biological, or clinical lab science									
5. Associate's degree in chemical, physical, biological, or clinical lab science									
6. Previously qualified as technologist without A.S. degree									
7. High School graduate with documented training									

15. If the overall projected personnel needs indicate a staffing pattern change, indicate (I) for increased, (U) for unchanged, and (D) for decreased needs for each of the following educational levels:

(1) M.D. / D.O. _____ (4) Bachelor's degree _____
(2) Ph.D. _____ (5) Associate degree _____
(3) Master's degree _____ (6) Non-degreed technical personnel _____

16. Check one or more of the following items to indicate projected personnel staffing pattern changes necessitated by increased proficiency testing as mandated by CLIA '88. If a change is needed, give the actual number of projected individuals.

_____ (1) no change
_____ (2) Bachelor's degree
a. increased need (#_____)
b. decreased need (#_____)
_____ (3) Associate degree
a. increased need (#_____)
b. decreased need (#_____)

17. Which of the following do you see as barriers in your laboratory for implementing CLIA '88 personnel standards?

_____ cost
_____ availability of qualified personnel
_____ present staff meeting standards
_____ support by hospital administration
_____ CLIA test categorization does no reflect the depth of knowledge and independent judgement needed to demonstrate professional competency
Others (please list)

_____
_____

PART III. IMPACT ON LABORATORY SERVICES - OPINION

18. What do you see as the effect of CLIA '88 on the delivery and quality of clinical laboratory services?

19. What changes have occurred in your laboratory services as a result of CLIA '88? How have these changes been implemented?

20. In your opinion, which of the following should have been incorporated in the CLIA '88 personnel standards: (check all that apply)

_____ Experience
_____ Certification
_____ Education
_____ State licensure
_____ Mandated continuing education
_____ Other (please specify) _____

VITA
Betty Vance Craft

EDUCATION

1994	Candidate for Ed.D. in Vocational Technical Education, Virginia Tech, Blacksburg, Virginia
1975	M.A. in Business Administration with a concentration in Health Care Administration, Central MIchigan University, Mt. Pleasant, Michigan
1968-75	Other Graduate studies - University of Virginia, Charlottesville, Virginia and Virginia Tech, Blacksburg, Virginia; Central Michigan University, Mt. Pleasants, Michigan in Health Care Education
1959	B.S. in Medical Technology, Concord College, Athens, West Virginia
	Certificate in Medical Technology, Beckley Memorial Hospital (Appalachian Regional Hospital), Beckley, West Virginia

EXPERIENCE

1973-Present	MLT-(AD) Program Director/Education Coordinator; Promotions from Instructor to Professor; Wytheville Community College, Wytheville, Virginia
1973-1981	MLT-(C) Program Director Wytheville Community College, Wytheville, Virginia
1970-1973	Program Director/Education Coordinator of CLA Program, Wytheville Community College, Wytheville, Virginia
1968-1970	Secondary teacher in General, Physical, and Biological Sciences and Chemistry; Wythe County Public Schools, Wytheville, Virginia
1968	Substitute teacher in Junior and Senior High Schools, Mercer County Board of Education, Princeton, West Virginia
1962-1967	Chief Technologist of Clinical Laboratory Greenbrier Valley Hospital, Ronceverte, West Virginia

1961-1962 Secondary teacher in General, Physical, and Biological Sciences; Physics, and Math; Greenbrier County Board of Education, Lewisburg, West Virginia

1959-1961 Medical Technologist in Clinical Laboratory Beckley Memorial Hospital, Beckley, West Virginia

PROFESSIONAL MEMBERSHIPS

Wytheville Community College

Faculty Government Association
WCC/Virginia Community College Association
Clinical Laboratory Educators Consortia of Virginia
Virginia Society Clinical Laboratory Sciences
American Society Clinical Laboratory Sciences
Mid-Atlantic Blood Bank Association
American Association for Clinical Chemistry, Inc.
American Society for Clinical Pathologists (Assoc.)
American Association of University Women
Delta Kappa Gamma, Honorary Organization for Women Educators

(RECENT)
SPECIAL APPOINTMENTS/REPRESENTATION/AWARDS

Appointment - Virginia Area Health Education Centers State Task Force for Allied Health Force - 1991-Present

Representative - Virginia Community College System Chancellor's Faculty Advisory Committee - 1989-1994

Delegate from Wytheville Community College to Virginia Association of Allied Health Professions, Vice-President 1993-1995; Coordinator of 1994 Spring Meeting

Member - Steering Committee of Wytheville Community College for SACS Self-Study Process - 1993-1995

Appointment - Clinical Laboratory Science Program Review Committee, National Accrediting Agency for Clinical Laboratory Sciences, Chicago, Illinois - 1994-1998

Teaching Excellence Award from NISOD, Austin, Texas - 1989

Improvement of Instruction Award from Wytheville Community College, 1986

Selected for Instructional Leadership Workshop, VCCS, Richmond, Virginia - 1991

Signed Betty J. Craft