

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

Form #3

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AUG 1 3 31 PM '97

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code § 16-5J-10

AMENDMENT TO AN EXISTING RULE: YES NO

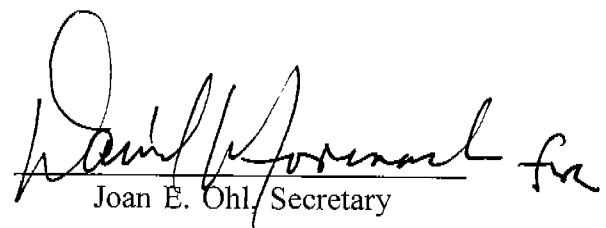
IF YES, SERIES NUMBER OF RULE BEING AMENDED: 57

TITLE OF RULE BEING AMENDED: Clinical Laboratory Technician and Technologist Licensure
and Certification

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.


Joan E. Ohl, Secretary

\$13.30

Date: July 28, 1997
To: Legislative Rule-Making Review Committee
From: Kay Howard, Director
Regulatory Development
Department of Health and Human Resources
Re: Clinical Laboratory Technician and Technologist Licensure and
Certification 64 CSR 57

1. Authorizing statute(s) citation: § 16-5J-10
2.
 - a. Date filed in State Register with Notice of Hearing: June 27, 1997
 - b. Other notice, including advertising, given of the hearing: The Department sent copies of the proposed rule to a number of professional groups, to affected health care facilities, to local health departments, and to various individuals known to be interested in the rule.
 - c. Date public comment period ended: July 28, 1997
 - d. List of persons who commented, amendments, reasons for amendments.
Attached X No comments received _____
 - e. Date of filing in State Register the Agency-Approved proposed Legislative Rule following public hearing: August 1, 1997
 - f. Name and phone number of agency contact person: Kay Howard, 558-3223
3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:
 - a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.
 - b. Date of hearing:
 - c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?
 - d. Attach findings and determinations and reasons:

**Discussion of Public Comments Received
Concerning the Proposed Rule
Clinical Laboratory Technician and Technologist
Licensure and Certification, 64 CSR 57
August 1, 1997**

The Clinical Laboratory Technician and Technologist Licensure and Certification Rule was approved as a new rule by the 1997 Legislature. The Legislature, however, stipulated an expiration date for the new rule of July 1, 1998, with the understanding that the Department would revise the rule by adding specific requirements for education and training, and would also attempt to clarify the rule. The promulgation authority for this rule is in W. Va. Code § 16-5J-10.

The Department attempted to meet both these expectations in the rule as proposed for public comment. In order to set educational requirements which both upgrade and recognize the current status of the profession within West Virginia, the Department adopted the use of the term clinical laboratory practitioner, and established four (4) categories of clinical laboratory practitioner licenses. The proposed amendments also simplified the rule by deleting the usage of a separate process for certification and exemption from certification; and added specific educational and/or training requirements for each of the four (4) categories. Certification is handled by definition. Other definitions were revised as needed.

The Department received numerous comments from sixteen (16) individuals and groups. Summaries of the comments received, the Department's responses to comments and descriptions of modifications to the rule appear below.

GENERAL COMMENTS

1. Comment: Many commenters stated that the proposed revisions represented significant improvement in the rule, while offering suggestions for additional revisions.

Response: The Department appreciates the comments.

2. Comment: One commenter said there should be a state licensure board to enforce this rule.

Response: The Department does not disagree with this comment. However, the law does not provide for a separate board to administer the law. The law assigns the responsibility for licensure to the Department.

3. Comment: Will licensure be issued specifically for a specialty or subspecialty or will the licensure be general for all areas of lab work? If by specialty, can the individual perform testing in other areas of the laboratory without having these added to their license? (This is in reference to individuals who cross-train in other areas of the laboratory but who may not participate in the proficiency testing for that area.)

Response: The Department does plan to issue a license by specialty or subspecialty. An individual who cross-trains in another area of the laboratory would be in a clinical practitioner trainee status for that specialty or subspecialty. The Department believes individuals should participate in proficiency testing whether it be College of American Pathologists or other approved proficiency testing program or an in-house proficiency testing of unknown specimens prepared by the supervisor.

4. Comment: As the rule is stated, we do not see what licensure that a CLA (clinical laboratory assistant) or military trained personnel could apply for other than CLP-POCT which would restrict them to performing only moderate complexity testing. Does part 5.5.b cover letting these employees perform high complexity testing?

Response: A point-of-care-technician is limited in 2.16 to moderate complexity testing. They also may do “waived” testing. A CLA or military trained individual could be licensed as a clinical laboratory practitioner (CLP-MLT) or (CLP-MT), if he/she meets the requirements in 2.1.c or 2.1.d.

5. Comment: One commenter suggested the use of an advisory board for point-of-care testing.

Response: The Department believes that other changes discussed below are sufficient to assure appropriate utilization of point of care technicians. Additionally, the board would need to be established by rule or law. To add such a board to the rule would require opportunity for additional public comment and delay the current revision effort.

6. Comment: One commenter was concerned that the rule did not fully address due process issues, and asked if these were addressed in the cited Code and procedural rule.

Response: Yes, they are.

7. Comment: The missing severability clause is important and should not be deleted unless other authority makes it clear that this provision still applies.

Response: Under the provisions of W. Va. Code § 2-2-10(cc), severability is assumed. It is not necessary to have a severability provision in the rule.

COMMENTS RELATED TO SPECIFIC ITEMS

§ 1.7. Comment: Although this item states that the rule applies to clinical laboratory consultants, directors, and supervisors, no provision is made for special licenses for these categories.

Response: The definition of clinical laboratory practitioner (2.6) does not include clinical laboratory directors, consultants, or supervisors whose job tasks do not include processing

specimens, or performing or reporting laboratory tests. If one of these individuals processes specimens or performs tests or reports results, he or she would have to be licensed.

§ 2.1. Comments: Section 2.1 received numerous comments. One (1) commenter asked for the American Academy for Microbiology be added as an accrediting agency. Another commenter asked for COLT Certification to be added as an alternative qualification for point-of-care technicians. Another commenter suggested adding a general provision to giving the Department the authority to recognition certification by agencies not specified in the rule.

Response: The Department agrees and has added both some specific accrediting agencies and also a new item, 2.1.e, giving the Department the authority to accept other national accrediting groups.

§ 2.1.b. Comment: The designation “clinical laboratory scientist” is not used by the International Society for Clinical Laboratory Technology (ISCLT). Request change to read: after medical laboratory personnel “is certified as a medical technologist (RMT) or a laboratory technician (RLT) by the Credentialing Commission of the International Society for Clinical Laboratory Technology (ISCLT.)”

Response: The Department agrees and has accordingly modified 2.1.b.

§ 2.1.c. Comments: One commenter suggested that “certification” is generally used in connection with private, not governmental agencies, and recommended the item be changed to read: “Is qualified as a laboratory technician or laboratory technologist under the Medicare/CLIA requirements in effect prior to March 14, 1990. Another commenter asked whether the Department intends this section to refer specifically to individuals who have passed the HHS/HEW proficiency exam, or to all individuals who qualified as technologists or technicians under Medicare conditions of participation (or the CLIA 67 regulations) that were in effect prior to March 1990.

Response: The Department uses the term “certified” in this section to be consistent with the wording in W. Va. Code § 16-5J-10. The Medicare requirements published in the Federal Register March 14, 1990 include qualifications for medical technologists, medical technicians and cytotechnologists, as well as those who passed the HHS/HEW examination. The Department intends this section to include all individuals who qualified under this regulation. To clarify the rule, 2.1.c has been reworded.

§ 2.1.d. Comment: Section 2.1.d appears to require that the laboratorian was working in West Virginia prior to July 1, 1989.

Response: The commenter evidently is misinterpreting 2.1.d as a requirement for licensure. Rather, this item is a “grandfather clause.” Although the law is silent on whether the grandfather clause refers specifically to individuals employed in West Virginia July 1, 1989, it would be too difficult for the Department to document employment in another state. There are other options available to qualify for licensure. Thus, the “grandfathering” is restricted to individuals employed

in West Virginia.

§ 2.5.b.3. Comment: Two (2) commenters recommended deleting Section 2.5.b.3 because the CLIA-88 does not define or require a laboratory director of waived testing.

Response: The Department believes the CLIA-88 does require that a waived laboratory have a laboratory director. However, since this rule does not apply to individuals performing only waived testing, the Department agrees to deleting this section.

§ 2.7. Comments: Commenters suggested that there should be a limit to the amount of time an individual could continue to function as a trainee.

Response: The Department agrees, and has added subsection 4.3 to limit the time for which an individual may perform laboratory tests as a trainee.

§ 2.13 & 2.14. Comment: Several commenters recommend changes in 2.13 and 2.14. One commenter asks that a generalist category be added to the list of specialties listed in these two (2) sections. Another commenter recommended that technicians be limited to waived, PPM, and moderately complex tests as defined by CLIA-88 and laboratory technologists be permitted to perform all of these procedures plus highly complex procedures. Still another commenter suggested the following additional wording: 2.13”The tasks assigned should require limited exercise of independent judgement and be performed under the supervision of a clinical laboratory consultant as defined at 2.4, a clinical laboratory director as defined at 2.5.b, or a clinical laboratory supervisor as defined at 2.8; and 2.14. . . and the tasks require broad exercise of independent judgement and responsibility with little or no direct technical supervision.

Response: The Department agrees that a generalist category is acceptable, but believes that this can be accomplished by deleting the language relating to areas of concentration in both items. The Department does not agree that the changes recommended by the other two (2) commenters are needed. The amount of supervision and the tests the individual is permitted to perform is the responsibility of the clinical laboratory director as noted in 7.1. It would be difficult, if not impossible, for the Department to monitor each licensee as to the daily supervision and tests they perform. The definitions in 2.13 and 2.14 are adequate to define the laboratory technician and laboratory technologist classification. Both have been reworded for purposes of clarification.

§ 2.16. Comment: Eight (8) commenters recommended changes to the definition of point-of-care-technician.

Response: The Department agrees that this definition should be changed and has adopted a combination of the language suggested by ASCP and AMT.

§ 3. The Department has simplified the cite for adoption of relevant federal standards, and has eliminated certain cites to be consistent with modifications.

§ 4.2. Comment: Does the trainee have to be directly supervised by a CLP licensed in the specialty that the trainee is performing testing? One (1) commenter recommended that the trainee of a trainee be restricted to a licensed clinical laboratory practitioner who is a laboratory technologist.

Response: Section 4.2 indicates that the trainee must work under the personnel and direct supervision of: a licensed clinical laboratory practitioner (CLP), or a clinical laboratory director, consultant or supervisor. The clinical laboratory practitioner must be licensed under the specialty or subspecialty he/she is training a trainee. The Department believes it is appropriate for any clinical laboratory practitioner, i.e. a laboratory technician (CLP-MLT), a point-of-care-technician (CLP-POCT), or a cytotechnologist (CLP-CT), to train a trainee as long as the trainer is licensed in the specialty or subspecialty in which he/she is providing the training.

§ § 5.1.b & 5.1.c. Comment: Both 5.1.b and 5.1.c should be deleted. Both are required in 5.2, 5.3, 5.4 and 5.5 through the documentation requirements. Documentation of certification, education and/or training are necessary for licensure. Employment should not be a condition for obtaining a license.

Response: The Department believes 5.1.b and 5.1.c are needed because they set forth the requirements for documentation of the specialties or subspecialties of laboratory tests for which the applicant has been trained and is currently competent to perform. They permit/require different types of documentation, depending on whether the applicant is currently employed or unemployed. Therefore, employment is not a condition for obtaining a license. The Department has revised these items somewhat for purposes of clarification, however, and has merged 5.1.c into 5.1.b.

§ § 5.2.b & 5.3.b. Comment: In 5.2.b and 5.3.b subsection 2.1 should be required. To allow a person to go to school, receive a degree and not pass an examination to provide evidence of competency is not appropriate. Certification is passing a standardized test offered by one (1) of several certifying agencies. Once certified, the certification is lifetime.

Response: The Department agrees, and has modified the item accordingly.

§ § 5.2.c & 5.3.c. Comment: One (1) commenter recommended that “specialties” be changed to “testing” in 5.2.c and 5.3.c. Another commenter stated that there needs to be a limit to the number of tests an individual can perform in 5.2.c and 5.3.c.

Response: The Department has chosen to require the laboratory director to certify the specialty or specialties of laboratory tests for which the applicant has been trained and is currently competent to perform (see 5.1.b). There are literally thousands of tests approved by the FDA for clinical laboratory testing, and the list grows daily. The specialties and subspecialties do not change frequently. The final decision on what tests within a specialty or subspecialty an individual is currently competent to perform is most appropriately left to the clinical laboratory director.

§ 5.3.b. Comment: One commenter suggested adding an “or” following 5.3.b in order to

make 5.3.b comparable to 5.2. Another commenter recommends adding “meets one (1) of the following qualifications.”

Response: The item is confusing because it is grammatically incorrect. It has been clarified.

§ 5.3.d. Comment: Delete. The minimum requirements are covered in 5.3.a, 5.3.b and 5.3.c.

Response: The Department believes that 5.3.d must be retained to cover those individuals working as laboratory technicians who have an associate degree which includes chemistry and biology. Deleting this provision may prevent individuals with laboratory experience now working in rural laboratories from being licensed.

§ 5.4.b. Comment: Two (2) commenters suggested changing the name of the accrediting agency noted in 5.4.b because of a change in its name.

Response: The Department agrees.

§ 5.5. Comment: Point-of-care-technicians requirements in 5.5 must have their practice limited to the tests they will perform for point of care testing and not to the entire specialty. Training and competency should be the minimum requirements.

Response: The Department believes this issue is covered adequately in 5.5.a.3 which requires a signed statement from the laboratory director that the applicant has had the training to provide him or her with the skills to perform the specific tests he or she will perform.

§ 5.5.a.2. Comment: Delete. Employment should not be a condition for licensure.

Response: The Department believes employment is necessary for point-of-care technicians to be licensed. Additionally, 5.5.a.2 is included in this rule to document that the person seeking licensure is not working in a laboratory which holds a CLIA certificate of waiver. This rule does not apply to individuals who perform only waived tests.

§ 5.5.a.3. Comment: Change 5.5.a.3. Documentation to establish that he or she is competent and has been trained for a limited number of tests.

Response: The Department believes the language of 5.5.a.3 accomplishes this comment. It requires the laboratory director to specify which tests the applicant is trained and has the skills to perform.

§ 5.5.b. Comment: Section 5.5.b should be clarified if the Department intends “additional tests” to mean tests in addition to those previously identified by the laboratory director in connection with the technicians initial application for licensure.

Response: This is the intention of the Department, and the item has been clarified.

§ 7.1. Comment: The possession of a license of any type in West Virginia does not “authorize” any performance of any service. Change 7.1.

Response: The Department intends 7.1 to indicate that the final decision on what laboratory tests a person performs in the clinical laboratory rests with the clinical laboratory director. The Department agrees with the commenter’s statement, but does not see the need for a change in the wording of this section.

COMMENTERS

Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57

American Medical Technologists, WV State Society, Kimberly Chevront, President
American Society of Clinical Pathologists, Washington, D.C.
Boyd, Craig E., Charleston, WV
Cabell Huntington Hospital, Judy Blevins, Assistant Administrative Director Laboratory
International Society for Clinical Laboratory Technology, St. Louis, Missouri
Jackson General Hospital, 9 staff: Maggie Clark MT(ASCP); John Frank MLT(ASCP), MT;
Chester Hess MLT(ASCP); Melissa Holsinger MLT(ASCP); Peggy S. Manuel
MT(ASCP); Cheryl Marnhout MLT; David Ruble MLT(ASCP); Karen Shuler
MLT(ASCP); Jean Starcher MLR(ASCP)
Miller, Irvin A., Clarksburg, WV
Minnich, M.S., SM (AAM), Linda, Clinical Virologist, Charleston Area Medical Center
West Virginia Society for Clinical Laboratories Scientists, Judy McDaniel, Government Affairs



American Medical Technologists

WEST VIRGINIA STATE SOCIETY
Kimberly A. Chevront, MT, MBA, President
Laboratory Administrator
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1325 Locust Avenue
Fairmont, WV 26554
(304) 367-7488

July 25, 1997

RECEIVED

JUL 28 1997

REGULATORY DEVELOPMENT

Ms. Kay Howard, Director
Regulatory Development
Department of Health and Human Resources
Capitol Complex -- Building 3, Room 265
Charleston, WV 25305

RE: Proposed Amended Rule for Licensure of
Clinical Laboratory Practitioners (64 CSR 57)

Dear Ms. Howard:

The following comments are submitted on behalf of American Medical Technologists (AMT) and the West Virginia State Society of AMT (WVSSAMT). These comments pertain to the Proposed Amended Rule for licensure of clinical laboratory practitioners (64 CSR 57) dated June 27, 1997.

AMT is a national credentialing organization and registry for clinical laboratory professionals and medical assistants. AMT has approximately 30,000 members in good standing, including a sizable and active state society in West Virginia. AMT was founded in 1939 and is the largest independent (member-owned) certifying organization for non-physician medical laboratory personnel. As you know, the West Virginia statute requiring licensure of laboratory personnel expressly recognizes AMT's certifications for medical technologists and laboratory technicians (W.Va. Code § 16-5J-10).

AMT realizes that the Department has faced a difficult task in crafting regulations which balance the need to insure testing quality and patient safety with the need to maintain access to services, particularly in rural areas. Nevertheless, AMT was disappointed with certain aspects of the regulations that were adopted by the Department and approved by the Legislative Rulemaking Review Committee last fall. Those regulations established personnel standards that essentially duplicated the minimal federal standards already in place under CLIA, and did little to implement the legislature's obvious intent (as evidenced by its passing the licensure law a year after CLIA's enactment) that standards more stringent than CLIA's be implemented in West Virginia.

"Pride of the Profession"

Incorporated in 1939

We were pleased that the 1997 Legislature directed the Department to add specific requirements for education and training of lab practitioners. The proposed amended rule is a significant improvement over the version currently in effect. In addition to the upgraded education standards, we are especially supportive of the Department's proposal to eliminate the separate provisions for obtaining certification by the State and for exemptions from certification. AMT is also pleased that the Department has retained the present requirement for continuing education credits in connection with license renewals.

While AMT generally supports the proposal, we have several comments on specific provisions which we believe need clarification or modification:

1. **§ 64-57-2.1.c.** -- This subsection includes in the definition of "Certified" an individual who is "certified by the federal government as a laboratory technician or laboratory technologist under the federal certification requirements in effect prior to March 14, 1990." It is our understanding, however, that the only persons who were "certified" by the federal government prior to March 14, 1990, were those who had passed the proficiency examination for clinical laboratory technologists administered by the U.S. Department of Health and Human Services (HHS) or its predecessor, the Department of Health, Education and Welfare (HEW). It is not clear whether the Department intended this subsection to refer specifically to individuals who have passed the HHS/HEW proficiency exam, or to all individuals who qualified as technologists or technicians under the Medicare Conditions of Participation (or the CLIA '67 regulations) that were in effect prior to March 1990. The subsection should be modified to clarify the Department's intent.

2. **§ 2.5.b.3.** -- We recommend that paragraph 2.5.b.3 be deleted from the definition of "Clinical Laboratory Director," since "waived" labs are not required to have a Director under the federal CLIA regulations.

3. **§§ 2.13 and 2.14** -- The definitions of "Laboratory Technician" and "Laboratory Technologist" imply that all such practitioners specialize in "a category such as blood banking, chemistry, hematology, microbiology and immunology." These provisions should be clarified to recognize that technicians and technologists "may concentrate their activities or specialize . . . ," but also may be generalists.

4. **§ 2.16** -- The newly proposed definition of "Point of Care Technician" inadequately distinguishes these technicians from other "laboratory technicians" who have greater levels of responsibility and higher education requirements. The definition also mistakenly recites the definition of waived testing to describe moderate complexity testing. AMT recommends that section 2.16 be modified as follows:

2.16. Point of Care Technician -- A type of laboratory technician whose job tasks include specimen processing, laboratory test performance, and laboratory test reporting directly to a physician for review and evaluation. These technicians may perform only tests that have been categorized as "waived" or "moderately complex" under CLIA. These individuals must perform testing under the personal and direct supervision of a clinical laboratory consultant as defined in Section 2.4, a clinical laboratory director as defined in Section 2.5.b, or a clinical laboratory supervisor as defined in Section 2.8.

5. § 5.3. -- For the sake of consistency and clarity, we suggest inserting at the end of the first paragraph in this section the following underlined text: ". . . submit documentation sufficient to establish that he or she meets one (1) of the following qualifications:"

6. § 5.4.b -- Because the named accrediting agency (CAHEA) no longer exists, this subsection should be modified to state: "Has graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (or its predecessor, the Committee on Allied Health Education and Accreditation)."

7. § 5.5.b. -- The term "additional tests" in this subsection requires clarification. We assume the Department intends "additional tests" to mean tests in addition to those previously identified by the laboratory director in connection with the technician's initial application for license under subsection 5.5.a.3. If so, this should be clarified in subsection 5.5.b.

8. **COLT Certification** -- AMT recently developed and is now offering a new certification examination designed to test for the knowledge and competencies required to perform moderately complex laboratory testing in a physician office or clinic setting. This exam, passage of which leads to the Certified Office Laboratory Technician (COLT) certification, may be useful in qualifying individuals for licensure in the Point of Care Technician category under the proposed amended rule. A copy of the COLT exam outline is enclosed for the Department's reference. AMT suggests that the Department consider adding the COLT certification as an alternative qualification route for point of care technicians under section 5.5.a. of the proposal.

9. **Severability** -- The severability provision contained in the current rule (§ 64-57-14) is missing from the proposed amended rule. This is an important provision and should be included, unless other authority makes clear that severability is to be assumed in connection with any such regulation.

Thank you for the opportunity to comment on the proposal. Please contact me if you desire additional information about AMT, WVSSAMT, or these comments.

Sincerely,



Kimberly A. Chevront, MT, MBA
President
West Virginia State Society of
American Medical Technologists

cc: Bobby Stewart, MT, President, AMT
Gerard P. Boe, Ph.D., AMT Executive Director
Kay Ferguson, MT, Chair, State Legislative Committee
Michael N. McCarty, AMT Legal Counsel

AMERICAN MEDICAL TECHNOLOGISTS



***Overview of American Medical Technologists
Certified Office Laboratory Technician (COLT)
Certification Examination Characteristics***

AMERICAN MEDICAL TECHNOLOGISTS
710 Higgins Road
Park Ridge, Illinois
60068-5765

(847) 823-5169
FAX: (847) 823-0458



American Medical Technologists

AMERICAN MEDICAL TECHNOLOGISTS CERTIFIED OFFICE LABORATORY TECHNICIAN (COLT) CERTIFICATION EXAMINATION SPECIFICATIONS

Number
of items
in category

Content Area, Sub-area, and Competency

18

CHEMISTRY

A. General Knowledge

1. Know terminology related to clinical chemistry including:

supernatant	precision	linearity	confidence limit
decant	reliability	enzymes	standard deviation
precipitate	shift	isoenzymes	coefficient of variation
accuracy	trend	electrolytes	mean value

2. Know designations and abbreviations used for weights and measures

3. Collect and handle blood specimens for analysis

a. Know differences between serum, plasma, and whole blood

b. Understand precautions used in collecting blood samples

- Know how to prevent hemolysis

- Collect blood in collecting tubes for analysis (clotted and anticoagulated blood)

- Use proper anticoagulants for each analysis

- Know effects of improper anticoagulant use

4. Know how to handle and preserve body fluids for chemical analysis

a. Know the types and uses of urine preservatives

b. Know how to handle and process all body fluids

5. Understand Beer's (Beer-Lambert) Law

6. Perform all necessary quality control in the clinical laboratory

a. Know daily quality control and use of results

b. Know proficiency testing

7. Know glassware and pipettes used in the clinical laboratory, and the cleaning and maintenance of instruments

B. Instrumentation

1. Know automated instrumentation

a. Know continuous flow analysis, and its parts and function

b. Know discrete analysis and the instruments utilizing this procedure

c. Know the random access analyzer

2. Perform daily, weekly, and monthly maintenance on chemical analyzers

3. Know the operation and principles of special analyzers commonly used in the physician's office laboratory

4. Know use and maintenance of other laboratory instruments including automatic pipette and meters (pH meter and refractometer)

C. Liver and Hepatic Function Tests

1. Know the clinical symptoms associated with liver disease, and obstructive and hemolytic jaundice

D. Carbohydrate Metabolism Tests

1. Know terminology related to carbohydrate metabolism tests including: ketone, insulin, and carbohydrate
2. Know the body's uses of carbohydrates
3. Know types of glucose analysis tests
 - a. Know true glucose tests (glucose-specific)
 - b. Perform tests for glucose (blood and urine)

E. Endocrinology

1. Know thyroid testing and recognize related symptoms

F. Electrolytes

1. Know what are electrolytes, their role in disease, and their normal values

G. Special Chemistry Procedures

1. Know special tests and specimen requirements
 - a. Know therapeutic drug tests
 - b. Know HDL, LDL, VLDL, cholesterol, triglycerides, and other lipids
2. Know that uric acid is employed in the test for gout

H. Quality Improvement

1. Employ quality control/quality assurance (QC/QA)
 - a. Know and recognize the difference between QC and QA
 - b. Know proficiency testing
2. Employ proper safety precautions
3. Know quality improvement regulations

HEMATOLOGY**A. General Knowledge****1. Know terminology related to hematology including:**

hematology	thrombocytes	microcytic	
cells	leukocytes	normocytic	hematocrit
blood	reticulocytes	normochromic	hemoglobin
serum	erythrocytes	hypochromia	anisocytosis
plasma	macrocytic	hyperchromia	poikilocytosis

2. Know functions of the blood
3. Know the life cycle and life span of erythrocytes
4. Know the significance of thrombocytes (platelets)
5. Know the significance of all granulocytes, lymphocytes, and monocytes

B. Erythrocyte Procedures

1. Know the tests used in red blood cell (erythrocyte) indices
 - a. Know mean corpuscular volume (MCV)
 - b. Know corpuscular hemoglobin (MCH)
 - c. Know corpuscular hemoglobin concentration (MCHC)
2. Know the principles, types (Wintrobe and Westergren) and uses of an erythrocyte sedimentation rate (ESR), and perform each
3. Perform macro- and microhematocrit determinations

C. Special Cellular Procedures

1. Perform semen examination for motility

D. Instrumentation

1. Know automated cell counters and their cell-counting parameters
2. Know use and maintenance of laboratory instruments including: the microscope, centrifuge, glassware, and pipettes

E. Coagulation and Hemostasis

1. Know the clinical significance of coagulation
2. Know the importance of proper specimen collection
 - a. Know the effect of short draw
 - b. Know the effect of a hemolyzed specimen
 - c. Know the limit of time plasma can set on the cells
3. Know how to perform the prothrombin time (PT) and what medication it monitors

F. Quality Improvement

1. Employ quality control/quality assurance (QC/QA)
 - a. Know and recognize the difference between QC and QA
 - b. Know proficiency testing
2. Employ proper safety precautions
3. Know quality improvement regulations

IMMUNOLOGY AND SEROLOGY**A. General Knowledge**

1. Know terminology related to immunology and serology including:

antigen	hemolysis	RPR
antibody	VDRL	blood serum versus plasma

2. Know the principles of antigen-antibody reaction
3. Know that RPR is a test for syphilis and the process for confirming a reactive result
4. Know what diseases cause false reactive RPRs

B. Serological Tests for Syphilis

1. Know the types of serological tests for syphilis
2. Perform qualitative RPR
3. Know how to test RPR delivery needles for accuracy
4. Know quality control procedures for RPR

C. Analytic Procedures

1. Perform heterophile agglutination (mono spot test)
 - quantitative with sheep cells, guinea pig, and horse serum absorption
 - qualitative with latex agglutination or blood cell agglutination tests
2. Perform rheumatoid arthritis tests (latex agglutination)
3. Perform qualitative pregnancy tests

D. Special Procedures

1. Know acquired immune deficiency syndrome (AIDS)

E. Immunohematology

1. Know that there are blood groups, blood types, and Rhs, and the significance of each

F. Quality Improvement

1. Employ quality control/quality assurance (QC/QA)
 - a. Know and recognize the difference between QC and QA
 - b. Know proficiency testing
2. Employ proper safety precautions
3. Know quality improvement regulations

BACTERIOLOGY**A. General Knowledge**

1. Know terminology related to bacteriology including: bacteria, aerobic, pathogenic, and anaerobic
2. Know basic types and shapes of bacteria
 - a. Gram's stain
 - b. KOH
 - c. Wet preps
3. Prepare and use Gram's stain and know the theory underlying staining

B. Media Preparation, Techniques, and Cultures

1. Prepare bacterial smears and stain with Gram's stain
2. Know uses of culture media including: blood agar, SSA agar, chocolate agar, Thayer-Martin chocolate agar, eosin methylene blue (EMB), thioglycollate broth, and MacConkey agar
3. Culture urine and throat specimens and know the proper collection and transportation of all other specimens

C. Bacterial Identification

1. Perform colony counts
2. Perform presumptive identifications
3. Perform differentiating tests including: oxidase, catalase, optochin disk (P disk), and bacitracin disk (A disk)

D. Special Tests

1. Perform special tests, including group A streptococci
 - rapid enzyme immunoassay test (or other antigen detection kits) from throat swabs
 - cultures for beta hemolysis screening

E. Quality Improvement

1. Employ quality control/quality assurance (QC/QA)
 - a. Know and recognize the difference between QC and QA
 - b. Know proficiency testing
2. Employ proper safety precautions
3. Know quality improvement regulations

URINALYSIS**A. General Knowledge**

1. Know terminology related to urinalysis
2. Collect random, midstream, catheterized, and timed (2, 12, 24-hour) urine specimens

B. Anatomy and Physiology

1. Know the physical properties of urine
2. Know the chemical properties of urine
3. Know the microscopic structures found in urine
4. Know the casts found in urine

C. Analytic Procedures

1. Perform urinalysis to obtain physical, chemical, and microscopic findings
2. Know and perform individual chemical tests on urine including: pH, protein, glucose, ketones, nitrate, bilirubin, urobilinogen, occult blood, specific gravity, and leukocyte esterase
3. Perform special tests including: Ictotest® (Ames) for bilirubin and sulfosalicylic acid test for protein

D. Microscopic Techniques

1. Know names and descriptions of blood cells found in urine
2. Know names, descriptions, and types of epithelial cells found in urine
3. Know descriptions and definitions of casts found in urine
4. Identify and know descriptions of parasites found in urine

E. Pathophysiology

1. Relate abnormal urinary findings to disease states
2. Know causes of each type of cell and cast found in urine
3. Know types of crystals found in urine
4. Know descriptions of pathological crystals found in urine
5. Know amorphous and its significance in urine
6. Know mucus and its significance in urine
7. Know descriptions of spermatozoa and their significance in urine
8. Know descriptions of bacteria and their significance in urine

F. Quality Improvement

1. Employ quality control/quality assurance (QC/QA)
 - a. Know and recognize the difference between QC and QA
 - b. Know proficiency testing
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3. Know quality improvement regulations

20 QUALITY CONTROL

[Quality control competencies are delineated under specific, content-related sections of the examination specifications]

6 PRACTITIONER-PERFORMED MICROSCOPY (PPM)

A. General knowledge

1. Know who can perform PPM procedures under regulations
2. Know the tests outlined under the PPM category: wet preps, KOH, fungal scrapings, semen examination for motility, nasal smears for eosinophils, and fecal examination for WBCs

20 OBTAINING BLOOD SAMPLES

A. Identify correct patient properly

B. Select appropriate containers for specimens and know requirements for container identification

C. Know physiological aspects of blood collection

D. Prepare patient for various tests

E. Select proper venipuncture site

F. Perform venipuncture

G. Collect specimen in proper tube-draw sequence

H. Perform finger punctures

I. Perform heel punctures on infants

J. Provide proper post care of venous puncture sites

K. Handle blood samples to maintain specimen integrity

20 SPECIMEN COLLECTION AND PROCESSING

A. Perform proper blood film preparation

B. Properly collect and handle specimens with time/temperature requirements

C. Process specimens for shipping

D. Instruct patient in the collection of urine specimens

E. Instruct patient in the collection of other specimens

- 20 SAFETY STANDARDS AND PROCEDURES**
- A. Identify appropriate regulatory and standard-setting agencies*
 - B. Know the use of material safety data sheets*
 - C. Employ universal precautions*
 - D. Employ infection control and isolation techniques*
 - E. Recognize patient problems related to syncope (fainting), nausea, and other complications*
- 16 TERMINOLOGY, ANATOMY, AND PHYSIOLOGY**
- A. Employ basic terminology*
 - B. Know basic anatomy*
 - C. Know basic physiological systems*
- 12 LEGAL, ETHICAL, AND PROFESSIONAL CONSIDERATIONS**
- A. Know principles of liability regarding the practice of phlebotomy*
 - B. Perform duties professionally and ethically*
 - C. Employ professional conduct and appearance in the performance of duties*
- 10 CLERICAL SKILLS AND DUTIES**
- A. Chart or file laboratory-generated reports properly*
 - a. Know what constitutes a complete and final report*
 - b. Know reporting and documentation of abnormal results*
 - B. Enter, retrieve, and verify patient collection data and special notations using appropriate sources*
 - C. Maintain inventory levels, order and restock supplies*
- 8 PROFESSIONAL COMMUNICATION AND INTERPERSONAL RELATIONS**
- A. Develop and use proper and professional communication skills with staff, patients, and families*
 - B. Communicate with patient units regarding special scheduling and special situations*
 - C. Inform patients of special test requirements*
 - D. Use proper technique and etiquette for answering the telephone and providing information*



AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

1225 New York Avenue, N.W. • Suite 250 • Washington, D.C. 20005-6156
(202) 347-4450 • Fax (202) 347-4453

WASHINGTON OFFICE

RECEIVED

JUL 25 1997

July 24, 1997

REGULATORY DEVELOPMENT

Ms. Kay Howard
Director, Office of Regulatory Development
Department of Health and Human Services
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

Dear Ms. Howard:

Thank you for the opportunity to comment on the West Virginia revised rule for Clinical Laboratory Technician and Technologist Licensure [64 CSR 57]. The American Society of Clinical Pathologists (ASCP) appreciates many of the changes made to the rule. We hope that our suggestions below will assist in clarifying the rule further, and help in assuring that the essential education, clinical training and national certification components are included in this licensure effort.

Positive Changes

ASCP is pleased with many of the proposed changes to the rule. Specifically, the recognition in the revised licensure requirements of the need for a baccalaureate degree and training for a medical technologist and an associate degree for a medical laboratory technician is an essential element needed to license qualified professionals.

We are pleased that the definition of "certified" under §64-57-2 includes national certification and that §64-57-7 through §64-57-9 has been eliminated, thus removing certification from the duty of the state.

Also, the inclusion of continuing education for all levels of practitioners is a positive provision that will help to ensure continued competence of the state's laboratory professionals.

Ms. Kay Howard
July 24, 1997
Page Two

Page Three

We suggest deleting paragraph 2.5.b.3 since there is currently no definition or criteria for a laboratory director of waived testing. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) do not outline qualifications for a laboratory director of waived testing, instead the federal rule cited applies to obtaining a certificate of waiver and the conditions for such a waiver.

Page Four

Part 2.13, Laboratory Technician, should be clarified to state: A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory. The tasks assigned should require limited exercise of independent judgment and be performed under the supervision of a clinical laboratory consultant as defined at 2.4, a clinical laboratory director as defined at 2.5.b, or a clinical laboratory supervisor as defined at 2.8.

Part 2.14, Laboratory Technologist, should be changed to state: A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory, and the tasks require broad exercise of independent judgment and responsibility with little or no direct technical supervision.

Part 2.16, Point of Care Technician, as written, incorporates the definition of waived testing instead of moderately complex testing. To bring the section in line with the definition, it should be changed to state: A type of laboratory technician whose job tasks include specimen processing, laboratory test performance, and laboratory test reporting directly to a physician for review and evaluation. These individuals may perform only tests that have been categorized as "moderately complex" under CLIA. These individuals must perform testing under the personal and direct supervision of a clinical laboratory consultant as defined at 2.4, a clinical laboratory director as defined at 2.5.b, or a clinical laboratory supervisor as defined at 2.8. The supervisor must be on the premises and available to the point of care technician at all times when testing is being performed.

Page Six

Please clarify part 4.2 by adding the following underlined phrase: A clinical laboratory practitioner trainee may perform tasks related to laboratory tests only under the personal and direct supervision of: a licensed clinical laboratory practitioner who is a laboratory technologist or a clinical laboratory director....

Ms. Kay Howard
July 24, 1997
Page Three

Page Seven

Under part 5.3, it appears there is a phrase missing from the end of the paragraph. It may be helpful to add: ... submit documentation sufficient to establish that he or she meets one (1) of the following qualifications:

Page Eight

Part 5.4.b should state the Commission on Accreditation of Allied Health Education Programs.

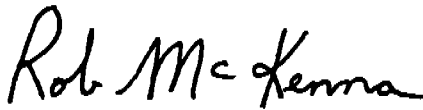
Page 13

We noticed that the severability clause was removed from this version of the rule. Is it mentioned elsewhere in the statute? We believe this is an important provision to include in the revised rule.

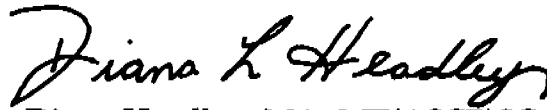
Also, §64-57-9, Hearings, while an important provision, does not fully address due process procedures. Are these due process procedures addressed in West Virginia Code §29A-5-1 et. seq., and Rules of Procedure for Contested Case Hearings and Declaratory Rulings?

Again, on behalf of the over 1300 ASCP members in West Virginia, thank you for the opportunity to comment on the revised rule. If you have questions regarding our comments, please give us a call or contact Robin Stompler, Director of the ASCP Washington Office, at (202) 347-4450.

Sincerely,



Robert McKenna, MD
President



Diana Headley, MA, MT(ASCP)SC
Chair, ASCP Associate Member Section

July 25, 1997
Regulatory Development
Department of Health and Human Resources
Capitol Complex – Building 3, Room 265
Charleston, WV 25305
Attn: Kay Howard

Dear Ms. Howard:

This letter is to inform you that some changes need to be made to the Clinical Laboratory Technician and Technologist Licensure and Certification 64 CSR 57.

1. 2.7 Clinical Laboratory Practitioner Trainee. There needs to be a time limit on how long someone may be a trainee. I would recommend up to a one-year limit.
2. 2.16. Point of Care Technician. Moderate Complexity needs to be removed as allowable testing for a Point of Care Technician.
3. 5.5.a.3.A-H. As long as the testing is changed to only allow fingerstick methodologies, only A,C,G,H are applicable.

I agree that we need to license the Laboratory personnel in West Virginia, but caution must be used to protect and preserve the quality of care provided by Medical Technologists, Medical Laboratory Technicians, and HEW Technologists (formally trained personnel).

I thank you for your consideration in this matter.

Sincerely,



Craig E. Boyd, MT(ASCP)
538 South Fort Drive
Charleston, WV 25314
304-345-3595



CABELL HUNTINGTON HOSPITAL

1340 Hal Greer Boulevard, Huntington, West Virginia 25701

RECEIVED

JUL 28 1997

~~REGULATORY DEVELOPMENT~~

To: Joan E. Ohl
Secretary
Department of Health and Human Resources

From: Judy Blevins *JB*
Assistant Administrative Director Laboratory

Subject: Clinical Laboratory Technician and Technologist Licensure and
Certification Rule 64 CSR

Date: July 25, 1997

Listed below are comments from the supervisory staff at Cabell Huntington Hospital Laboratory concerning the Licensure law for Clinical Laboratory Practitioners:

- 1) We feel that there should be state licensure Board to enforce this rule.
- 2) Part 2.16— We disagree with the terminology of “moderate complexity” testing being referred to testing procedures that are so simple and accurate as to render the likelihood of erroneous results negligible and pose no reasonable risk of harm to the patient. This is the description used for the waived testing usually and not moderate complexity testing procedures.
- 3) Under Part 5.2 a CLP-MT must meet one of two requirements to be licensed as such--either they met 5.2a and 5.2b OR they meet part 5.2c(5.2.c.1-5.2.c.8). For the CLP-MLT Part 5.3 as written, an applicant for this Licensure must meet all of the subpart requirements. This seems to be a discrepancy between the two types of Licensure. An ”or” needs to be placed at the end of part 5.3.b.
- 5) As the rule is stated we do not see what Licensure that a CLA or military trained personnel could apply for other than the CLP-POCT which would restrict them to performing only moderate complexity testing. Does part 5.5.b. cover

letting these employees perform high complexity testing?

6) In part 1.7.a about applicability it is stated that this rule applies to supervisors, laboratory directors and consultants, but under part 5.6 for initial Licensure there is no provision for licensure of these categories. The rule is unclear as to whether these individuals require a license and how they would be licensed.

7) Regarding Part 5.1b: Will licensure be issued specifically for a speciality or subspeciality or will the licensure be general for all areas of lab work? If by speciality, can the individual perform testing in other areas of the laboratory without having these added to their license? (This is in reference to individuals who crosstrain in other areas of the lab but who may not participate in the proficiency testing for that area.) The issue of speciality areas is unclear as written.

8) Under Part 4.2 — does the trainee have to be directly supervised by a CLP licensed in the speciality that the trainee is performing testing?

We feel that the licensure law is a positive step toward assuring that qualified individuals are performing laboratory testing.

THE CREDENTIALING COMMISSION

International Society for Clinical Laboratory Technology

917 Locust Street • Suite 1100 • St. Louis, Missouri 63101-1413 • Phone (314) 241-1445 • Fax (314) 241-1449

July 16, 1997

Regulatory Development
Dept. Of Health & Human Resources
Capitol Complex - Bldg. 3, Room 265
Charleston, WV 25305

Attn: Kay Howard

Dear Ms. Howard:

Following are the comments of the Credentialing Commission of the International Society for Clinical Laboratory Technology (ISCLT) concerning the proposed amendments to the Clinical Laboratory Technician and Technologist Licensure and Certification regulations:

Section 2.1.b. The designation "clinical laboratory scientist" is not used by the International Society for Clinical Laboratory Technology (ISCLT). ISCLT uses the designation Registered Medical Technologist (RMT) and Registered Laboratory Technician (RLT).

Therefore, change this section to read:

Is certified as a clinical laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel, or is certified as a medical technologist (RMT) or a laboratory technician (RLT) by the Credentialing Commission of the International Society for Clinical Laboratory Technology (ISCLT).

Sections 2.13 and 2.14. It is difficult to distinguish the procedures that require the "limited exercise of independent judgment" from those that require the "broad exercise of judgment and responsibility," especially if the Department does not specify which procedures fall into which category.

We suggest limiting technicians to waived, PPM, and moderately complex tests as defined by CLIA. Laboratory technologists should be permitted to perform all of these procedures plus highly complex procedures.

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JUL 22 1997

REGULATORY DEVELOPMENT

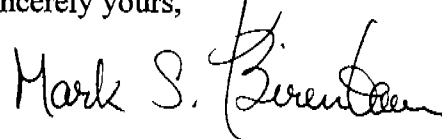
Section 2.16. Change “moderate complexity” to “waived”. HCFA determines the complexity, not FDA, unless you are referring to home test kits.

Section 2.1.c. The term “certification” is generally used in connection with private, not governmental, agencies.

Change to read:

Is qualified as a laboratory technician or laboratory technologist under the Medicare/CLIA requirements in effect prior to March 14, 1990.

Sincerely yours,

A handwritten signature in black ink that reads "Mark S. Birenbaum". The signature is written in a cursive style with a large, stylized initial "B".

Mark S. Birenbaum, Ph.D.
Administrator

P.S. Please note our new address: 917 Locust Street, Suite 1100, St. Louis, MO 63101-1413.

cc: Credentialing Commission
 ISCLT Board of Directors

RECEIVED

JUL 25 1997

REGULATORY DEVELOPMENT

July 11, 1997

Jackson General Hospital
Pinnell Street P.O. Box 720
Ripley, WV 25271
Phone: 1-304-372-2731 ext. 245

Regulatory Development
Department of Health and Human Resources
Capitol Complex - Building 3, Room 265
Charleston, WV 25305
ATTN: Kay Howard

Dear Ms. Howard:

This letter is to inform you that some changes need to be made to the Clinical Laboratory Technician and Technologist Licensure and Certification 64 CSR 57.

1. 2.7. Clinical Laboratory Practitioner Trainee. There needs to be time limit on how long someone may be a trainee. I would recommend up to a one year limit.
2. 2.16. Point of Care Technician. Moderate Complexity needs to be removed as allowable testing for a Point of Care Technician. Possibly fingerstick methodologies for non-waived testing could be allowed as long as follow-up confirmatory testing would be done by qualified personnel. To indicate that "... methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient,..." is acceptable patient care from on-the-job-trained personnel for moderately complex testing is lowering the standards to a dangerous level. This section needs removed.
3. 5.5.a.3. A - H. As long as the testing is changed to only allow fingerstick methodologies, only A, C, G, H are applicable.

I agree that we need to license the Laboratory personnel in West Virginia, but caution must be used to protect and preserve the quality of care provided by Medical Technologists, Medical Laboratory Technicians, and HEW (formally trained personnel).

Thank you for your consideration in this matter.

Sincerely,

Maggie Clark MT(ASCP)

Maggie Clark MT(ASCP)

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July 11, 1997

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Thank you for your consideration in this matter.

Sincerely,

John Frank MLT(ASCP),MT

John Frank MLT(ASCP),MT

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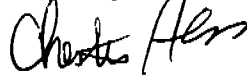
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Thank you for your consideration in this matter.

Sincerely,



Chester Hess MLT(ASCP)

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JUL 25 1997

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July 11, 1997

Jackson General Hospital
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ATTN: Kay Howard

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Thank you for your consideration in this matter.

Sincerely,

 MLT(ASCP)

Melissa Holsinger MLT(ASCP)

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JUL 25 1997

REGULATORY DEVELOPMENT

July 11, 1997

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Thank you for your consideration in this matter.

Sincerely,



Peggy S. Manuel MT(ASCP)

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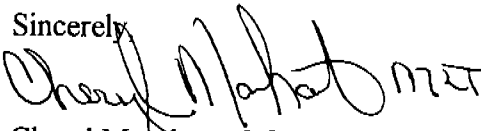
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Thank you for your consideration in this matter.

Sincerely,

Cheryl Markout MLT

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Thank you for your consideration in this matter.

Sincerely,

David Ruble MLT(ASCP)

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July 11, 1997

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I agree that we need to license the Laboratory personnel in West Virginia, but caution must be used to protect and preserve the quality of care provided by Medical Technologists, Medical Laboratory Technicians, and HEW (formally trained personnel).

Thank you for your consideration in this matter.

Sincerely,

Karen Shuler MLT(ASCP)

Karen Shuler MLT(ASCP)

RECEIVED

JUL 25 1997

July 11, 1997

REGULATORY DEVELOPMENT

Jackson General Hospital
Pinnell Street P.O. Box 720
Ripley, WV 25271
Phone: 1-304-372-2731 ext. 245

Regulatory Development
Department of Health and Human Resources
Capitol Complex - Building 3, Room 265
Charleston, WV 25305
ATTN: Kay Howard

Dear Ms. Howard:

This letter is to inform you that some changes need to be made to the Clinical Laboratory Technician and Technologist Licensure and Certification 64 CSR 57.

1. 2.7. Clinical Laboratory Practitioner Trainee. There needs to be time limit on how long someone may be a trainee. I would recommend up to a one year limit.
2. 2.16. Point of Care Technician. Moderate Complexity needs to be removed as allowable testing for a Point of Care Technician. Possibly fingerstick methodologies for non-waived testing could be allowed as long as follow-up confirmatory testing would be done by qualified personnel. To indicate that "... methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient,..." is acceptable patient care from on-the-job-trained personnel for moderately complex testing is lowering the standards to a dangerous level. This section needs removed.
3. 5.5.a.3. A - H. As long as the testing is changed to only allow fingerstick methodologies, only A, C, G, H are applicable.

I agree that we need to license the Laboratory personnel in West Virginia, but caution must be used to protect and preserve the quality of care provided by Medical Technologists, Medical Laboratory Technicians, and HEW (formally trained personnel).

Thank you for your consideration in this matter.

Sincerely,



Jean Starcher, MLT(ASCP)

Irvin A. Miller
701 Milford Street
Clarksburg, WV 26301

RECEIVED

JUL 21 1997

REGULATORY DEVELOPMENT

July 25, 1997

Regulatory Development
Department of Health & Human Resources
Capitol Complex - Building 3, Room 265
Charleston, WV 25305

Re: WV Division of Health Legislative Rules
Title 64, series 57
Clinical Laboratory Technician and Technologist Licensure

Dear Ms. Howard,

The proposed rules are a significant improvement over those to be placed into effect this year. However, I do have several major concerns.

2.16 Point of Care Technician. "Moderate complexity" must be removed. This definition of a POCT allows this person without proper training to perform over 90% of the testing in most laboratories in the state. In addition, "moderate complexity" testing does not employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient, if properly evaluated by the attending physician. The latter description is applied to "waived" testing procedures. One might replace "moderate complexity" with those procedures that can be performed with whole blood obtained by the fingerstick method and that has been approved by the Department or an advisory board for point of care testing. One must realize that it is not uncommon for the ordering physician to look to laboratory personnel for interpretation of "moderate complexity" testing results. To leave 2.16 as proposed would definitely make these licensure rules less effective than CLIA'88. The citizens of West Virginia would definitely not be protected from bad laboratory results, which is the prime reason for licensure.

2.7 Clinical Laboratory Practitioner - An individual should be limited to one(1) year as a trainee.

5.2.b and 5.3.b. Subsection 2.1 should be required. To allow a person to go to school, receive a degree and not pass an examination to provide evidence of competency is not appropriate. If an individual graduates from a law school, that individual

must pass the bar examination before he/she can practice. Why should it be any different for a CLP-MLT, CLP-MT, and CLP-CT. These individuals perform testing that could mean life or death.

Certification is passing a standardized test offered by one of several certifying agencies. Once certified, the certification is life time. I mention this because there has been a misunderstanding that one must belong to an organization and pay annual dues to maintain their certification. This is not true. There are professional organizations, some of which do offer certification exams, to which one can belong for professional enhancement, but this is not required. Those wishing to take a certification exam can do so by paying a fee for test administration. No further financial obligation is required.

5.2.c and 5.3.c. There needs to be a limit to the number of tests one can perform under this exemption from certification. A limit would allow for licensure for highly specialized individuals i.e., individuals working in the State Health Lab performing lead testing. A limit of 3 tests per licensed individual would allow for this accommodation without overly jeopardizing the intent of the licensure law.

Respectfully,



Irvin A. Miller, M.S., M.P.H., MT(ASCP)

11 July, 1997

Regulatory Development
Department of Health and Human Resources
Capitol Complex Building 3 Room 265
Charleston, WV 25305

Dear Ms Howard:

Subject: Clinical Laboratory Technician and Technologist
Licensure and Certification

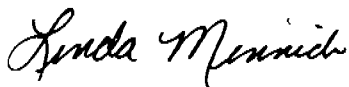
Under section 64-57-2.1.a., it is indicated that only the American Medical Technologists and American Society of Clinical Pathologists can serve as certifying agencies. The American Academy for Microbiologists is a nationally recognized certifying agency for those of us who work in the microbiology field. They have the only doctoral diplomacy certification and specialty certification programs. It is essential that this agency be added to the list. One way to include the specialty certification agencies is to use the term "nationally-acknowledges certification agencies" or "accrediting agencies for special laboratories such as microbiology, blood bank, and toxicology". There is a list of accrediting agencies in Advance.

My specialty certification is in Public Health and Medical Laboratory Microbiology. It required 5 years of supervisory experience before I could even take the written examination. At that time (several years ago), ASCP did not have specialty programs in this field and there is still no categorical examination for clinical virology. I understand that ASCP is evaluating this and may offer one in the future.

I request that the American Academy for Microbiologists be included as an accrediting agency.

Section 2.1.d. appears to require that the laboratorian was working in a laboratory in West Virginia prior to July 7, 1989. Many of us had to go out of state to find work during that period. Could this be modified to include individuals working in accredited laboratories or under a certified laboratory director? Thank you for the opportunity to comment on this regulation.

Sincerely,



Linda Minnich, M.S., SM(AAM)
Clinical Virologist
Virology - Serology Laboratory
Charleston Area Medical Center

July 25, 1997

West Virginia Society for Clinical Laboratories Scientists
Judy McDaniel
WVSCLS Government Affairs
541 West Virginia Avenue
Morgantown, WV 26505

RECEIVED

JUL 28 1997

REGULATORY DEVELOPMENT

Regulatory Development
ATTN: Kay Howard
Department of Health and Human Resources
Capital Complex - Building 3, Room 265
Charleston, WV 25305

Dear Sir,

The West Virginia Society for Clinical Laboratory Scientists (WVSCLS) offer the following comments on the Clinical Laboratory Technician and Technologist Licensure and Certification:

- ADDITION 2.1e** **Is certified by another agency recognized by the West Virginia Department of Health and Human Resources.**
- CHANGE 2.16** **Point of Care Technician.--A type of laboratory technician whose job tasks include specimen processing, laboratory test performance and laboratory test reporting to a physician to review and evaluate the results obtained. These individuals can perform only tests that have been deemed "moderate complexity" by the FDA. Their practice is limited to tests for Point of Care service only.**

Both 5.1.b and 5.1.c are required in 5.2, 5.3, 5.4 and 5.5 through the documentation requirements. Documentation of certification, education and/or training are necessary for licensure. Employment should not be a condition for obtaining a license.

- DELETE 5.1.b** **If employed as a clinical laboratory practitioner, a statement obtained from and signed by the applicant's laboratory director which identifies the specialty or specialties of laboratory tests for which the applicant has been trained and is currently competent to perform. The evaluation of competency shall include consideration of the applicant's performance in any proficiency testing programs:**
- DELETE 5.1.c** **If not currently employed as a clinical laboratory practitioner, documentation to identify the specialty or specialties of laboratory tests for which the applicant has been trained and has previously performed:
and**

CHANGE 5.2.c Change specialties to **testing**.
CHANGE 5.3.c Change specialties to **testing**.
DELETE 5.3.d We believe that the minimum requirements are covered in 5.3.a, 5.3.b, and 5.3.c.

5.5 Point of Care Technician:
This whole section needs revised to include language for individuals who do not meet the certification or educational minimums. These individuals must have their practice limited to the tests they will perform for point of care testing and not to an entire specialty. Training and competency should be the minimum requirements.

DELETE 5.5.a.2 Employment should not be a condition for licensure.
CHANGE 5.5.a.3 Documentation to establish that he or she is competent and has been trained for a limited number of tests.
CHANGE 7.1 The possession of a license of any type in WV does not "authorize" any performance of any service.

Sincerely,



Judy McDaniel
WVSCLS

ABSTRACT - PROPOSED AMENDED RULE
DIVISION OF HEALTH
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION
64 CSR 57

Summary: The proposed amended agency-approved legislative rule, Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57, sets forth standards and procedures for licensing laboratory technicians, including point of care technicians, and laboratory technologists, including cytotechnologists, as clinical laboratory practitioners. The rule, in general, sets forth application and enforcement procedures; defines terms; adopts certain federal standards relating to laboratory personnel; specifies permitted activities and supervision; and establishes reciprocity with other jurisdictions. The rule also establishes that no license shall be issued to a health care facility in West Virginia as long as it uses an unlicensed clinical laboratory practitioner and includes procedures for contested case hearings. The promulgation authority for this rule is W. Va. Code § 16-5J-10.

The Clinical Laboratory Technician and Technologist Licensure and Certification Rule was approved as a new rule by the 1997 Legislature. The Legislature, however, stipulated an expiration date for the new rule of July 1, 1998, with the understanding that the Department would revise the rule by adding specific requirements for education and training, and would also attempt to clarify the rule.

The Department has attempted to meet both these expectations. In order to set realistic educational requirements which upgrade the professional and yet recognize the current status of the profession within West Virginia, the Department has adopted the use of the term clinical laboratory practitioner, and has established four (4) categories of clinical laboratory practitioner licenses. The proposed amendments also simplify the rule by deleting the usage of a separate process for certification and exemption from certification; and add specific educational and/or training requirements for each of the four (4) categories. Certification is handled by definition. Other definitions are revised as needed.

For further information contact: Frank W. Lambert, Jr., Dr. P.H., Director, Office of Laboratory Services, telephone (304) 558-3530, Bureau for Public Health, Department of Health and Human Resources, State Capitol Complex, Building 3, Room 518, Charleston, West Virginia, 25305; or the Office of Regulatory Development, Bureau of Operations, Department of Health and Human Resources, State Capitol Complex, Building 3, Room 265, Charleston, West Virginia, 25305, telephone (304) 558-3223.

Rev. 7/31/97

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR
57

Type of Rule: Legislative Interpretive Procedural

Agency: Bureau for Public Health (For the Division of Health)
Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$	\$
Personal Services					
Current Expense					
Repairs & Alterations					
Equipment					
Other					
Revenue					

2. Explanation of above estimates.

The proposed amendments are not projected to have any impact on either the cost of the licensure program or the revenue produced at the statutory fee of \$25 per license.

3. Objectives of this rule:

Generally, the proposed amended legislative rule sets forth standards and procedures for licensing laboratory technicians, including point of care technicians, and laboratory technologists, including cytologists, as clinical laboratory practitioners. The purpose of the proposed amendments is to add specific requirements for education and training, and to clarify the rule.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

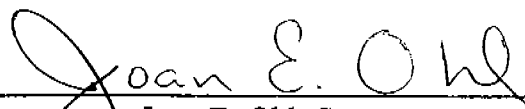
None. The Department anticipates that most of the individuals now performing laboratory procedures are already in compliance with the specified education and training requirements.

C. Economic Impact on Citizens/Public at Large.

None.

Date: June 27, 1997

Signature of Agency Head or Authorized Representative



Joan E. Ohl, Secretary
Department of Health and Human Resources

WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULES

TITLE 64, SERIES 57

CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE

**Agency-Approved Rule
For Filing with the
Legislative Rule-Making Review Committee**

August 1, 1997

**WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULES
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION**

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FILED

TITLE 64
WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULES
SERIES 57
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE

AUG 1 3 31 PM '97
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§ 64-57-1. General.

1.1. Scope. -- This legislative rule sets forth standards and procedures for the ~~certification~~ and licensing of laboratory technicians and laboratory technologists as clinical laboratory practitioners and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory practitioners by health care facilities.

1.2. Authority. -- W. Va. Code § 16-5J-10.

1.3. Filing Date. --

1.4. Effective Date. --

~~1.5. Expiration Date. -- July 1, 1998.~~

1.5. Supercession of Former Rule. -- This rule amends and reenacts Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57, effective August 1, 1997.

~~§ 64-57-2. Application and Enforcement.~~

~~2.1~~ 1.6. Application Applicability. -- Except as otherwise provided in this rule, this legislative rule applies to:

~~2.1.a~~ 1.6.a. Clinical laboratory practitioners employed as such in West Virginia, including individuals employed as clinical laboratory practitioners in agencies or organizations exempted from licensure as a laboratory under the provisions of W. Va. Code § 16-5J-7, i.e., county health departments organized under W. Va. Code § 16-2-1 et seq. or § 16-2A-1 et seq.; primary health care centers having tax exempt status and receiving contributions which are deductible to the contributor under provisions of federal law; or any laboratory operated solely for research or teaching purposes; and

~~2.1.b~~ 1.6.b. Clinical laboratory consultants, directors, and supervisors in West Virginia.

~~2.2~~ 1.7. This rule does not apply to:

~~2.2.a~~ 1.7.a. Any individual who performs only laboratory tests published in the Federal Register as waived under CLIA by the Centers for Disease Control under the provisions of § 42 CFR ~~493.7~~ 493.17;

~~2.2.b~~ 1.7.b. Any physician, dentist, nurse practitioner, nurse midwife or physician assistant, licensed within this State working within the scope of his or her professional license,

who performs only provider-performed microscopy procedures as found at § 42 CFR 493.19 (a) - (d);

~~2.2.e~~ 1.7.c. Any respiratory care provider licensed within the state providing diagnostic testing within the scope of his or her professional license who performs moderate complexity testing as defined by CLIA, pursuant to 42 CFR 493.17; or

~~2.2.d~~ 1.7.c.1. Any individual who performs laboratory tests only on himself or herself or members of his or her family.

~~2.3~~ 1.8. Enforcement. -- This rule is enforced by the secretary of the West Virginia department of health and human resources.

§ 64-57-3 2. Definitions.

2.1. Certified. -- As applied to an individual means that he or she:

2.1.a. Is certified as a medical laboratory technician or medical technologist by the American Medical Technologists or the American Society of Clinical Pathologists;

2.1.b. Is certified as a clinical laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel or is certified as a medical technologist or as a laboratory technician by Credentialing Commission of the International Society for Clinical Laboratory Technology;

2.1.c. Is certified as a laboratory technician or laboratory technologist under the Medicare/CLIA certification requirements in effect prior to March 14, 1990;

2.1.d. Was performing laboratory technologist or laboratory technician tasks in a clinical laboratory in West Virginia on or before July 7, 1989; or

2.1.e. Is certified by another national medical laboratory personnel credentialing agency recognized by the Department.

~~3.1~~ 2.2. CLIA. -- Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public Health Service Act (Title 42 United States Code Section 263a).

~~3.2~~ 2.3. Clinical Laboratory. -- Any facility or place, however named, for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease, or the impairment of, or the assessment of the health of human beings.

~~3.3~~ 2.4. Clinical Laboratory Consultant. -- A person who ~~3.3.a.~~ meets the qualifications for:

~~3.3.a.1~~ 2.4.a. Moderate complexity testing technical consultant found at 42 CFR § 493.1411;

~~3.3.a.2~~ 2.4.b. Moderate complexity testing clinical consultant found at 42 CFR § 493.1417; or

~~3.3.a.3~~ 2.4.c. High complexity testing clinical consultant found at 42 CFR § 493.1455.

~~3.4~~ 2.5. Clinical Laboratory Director. -- A person who:

~~3.4.a~~ 2.5.a. Provides overall management and direction of a clinical laboratory; and

~~3.4.b~~ 2.5.b. Meets the qualifications for directors of:

~~3.4.b.1~~ 2.5.b.1. Moderate complexity testing laboratories found at 42 CFR § 493.1405; or

~~3.4.b.2~~ 2.5.b.2. High complexity testing laboratories found at 42 CFR § 493.1443.

~~or~~

~~3.4.b.3.~~ ~~Waived clinical laboratories found at 42 CFR § 493.35.~~

~~3.5~~ 2.6. Clinical Laboratory Practitioner. -- A laboratory technician or a laboratory technologist. The term "clinical laboratory practitioner" includes laboratory technicians (CLP-MLT), point of care technicians (CLP-POCT), cytotechnologists (CLP-CT), and laboratory technologists (CLP-MT), but does not include: clinical laboratory practitioner trainees; clinical laboratory directors, consultants, or supervisors whose job tasks do not include processing specimens, or performing or reporting laboratory tests; or physicians licensed under W. Va. Code § 30-3-1 et seq. or § 30-14-1 et seq. who perform laboratory tests only on their own patients.

~~3.6~~ 2.7. Clinical Laboratory Practitioner Trainee. -- A person who is in a training program designed for his or her qualification as a clinical laboratory practitioner or who has successfully completed such a training program and has applied for, but not yet received a clinical laboratory practitioner license.

~~3.7~~ 2.8. Clinical Laboratory Supervisor. -- A person who meets the qualifications for:

~~3.7.a~~ 2.8.a. A high complexity testing technical supervisor found at 42 CFR § 493.1449;

~~3.7.b~~ 2.8.b. A high complexity testing general supervisor found at 42 CFR § 493.1461;

~~or~~

~~3.7.c~~ 2.8.c. A high complexity testing cytology general supervisor found at 42 CFR § 493.1469.

~~3.8~~ 2.9. Contact Hours. -- The actual number of hours an individual participates in continuing education. Ten (10) contact hours equal one (1) continuing education unit.

2.10. Cytotechnologist. -- A type of laboratory technologist whose job tasks include specimen processing, test performance and reporting of cytological examinations supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology.

~~3-9~~ 2.11. Department. -- The West Virginia department of health and human resources.

~~3-10~~ 2.12. Health Care Facility. -- An entity subject to licensure as a:

~~3-10-a~~ 2.12.a. Birthing center under W. Va. Code § 16-2E-1 et seq.;

~~3-10-b~~ 2.12.b. Hospital or extended care facility operated in connection with a hospital, or an ambulatory surgical facility, or an ambulatory health care facility, including a medical adult day care center under W. Va. Code § 16-5B-1 et seq.;

~~3-10-e~~ 2.12.c. Nursing home or personal care home under W. Va. Code § 16-5C-1 et seq.;

~~3-10-d~~ 2.12.d. Residential board and care home under W. Va. Code § 16-5C-1 et seq. and § 16-5H-1 et seq.;

~~3-10-e~~ 2.12.e. Hospice under W. Va. Code § 16-5I-1 et seq.;

~~3-10-f~~ 2.12.f. Clinical laboratory under W. Va. Code § 16-5J-1 et seq.;

~~3-10-g~~ 2.12.g. Hospital, center or facility for the care and treatment of the mentally ill or mentally retarded, or for the prevention of such disorders under W. Va. Code § 27-9-1 et seq. or

~~3-10-h~~ 2.12.h. Group residential facility for the developmentally disabled or behaviorally disabled under W. Va. Code § 27-17-1 et seq.

~~3-11~~ 2.13. Laboratory Technician. -- A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory which tasks require limited exercise of independent judgement and be performed under the supervision of a clinical laboratory directory or a clinical laboratory supervisor.

~~3-12~~ 2.14. Laboratory Technologist. -- A person ~~whose who~~ performs a broad range of laboratory tests ~~job tasks include specimen processing, laboratory test performance, or laboratory test reporting~~ in a clinical laboratory. Job tasks may include specimen processing, laboratory test performance, or laboratory test reporting and other tasks requiring the broad exercise of judgement and responsibility with little or no direct technical supervision.

~~3-13~~ 2.15. Laboratory Test. -- The biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

2.16. Point of Care Technician. -- A type of laboratory technician whose job tasks include specimen processing, laboratory test performance and laboratory test reporting directly to a

physician to review and evaluate the results obtained. These technicians shall perform only tests that have been categorized as “moderately complex” under CLIA, and shall perform testing under the personal supervision of a clinical laboratory director or a clinical laboratory supervisor. This supervision shall be available to the point-of-care-technician at all times when testing is being performed.

§ 64-57-4 3. Incorporation by Reference.

The following provisions of the October 1, 1994 ~~1996~~, edition of 42 CFR Part 493, Laboratory Requirements, ~~as amended in the April 24, 1995 edition of the Federal Register (60 FR 20035), and as further amended and published by January 1, 1997,~~ are hereby incorporated by reference:

- ~~4.1. 42 CFR § 493.7;~~
- ~~4.2~~ 3.1. 42 CFR § 493.17;
- ~~4.3~~ 3.2. 42 CFR § 493.19 (a) - (d);
- ~~4.4. 42 CFR § 493.35;~~
- ~~4.5. 42 CFR § 493.1363;~~
- ~~4.6~~ 3.3. 42 CFR § 493.1405;
- ~~4.7~~ 3.4. 42 CFR § 493.1411;
- ~~4.8~~ 3.5. 42 CFR § 493.1417;
- ~~4.9 42 CFR § 493.1423;~~
- ~~4.10~~ 3.6. 42 CFR § 493.1443;
- ~~4.11~~ 3.7. 42 CFR § 493.1449;
- ~~4.12~~ 3.8. 42 CFR § 493.1455;
- ~~4.13~~ 3.9. 42 CFR § 493.1461; and
- ~~4.14~~ 3.10. 42 CFR § 493.1469.
- ~~4.15. 42 CFR § 493.1483; and~~
- ~~4.16 42 CFR § 493.1489.~~

§ 64-57-5 4. Prohibition; Persons Subject to Licensure; Clinical Laboratory Practitioner Trainees.

~~5.1~~ 4.1. No person shall perform any clinical laboratory practitioner tasks in West Virginia, except as specified in this rule, unless the person is licensed by the secretary as a clinical laboratory practitioner.

~~5.2~~ 4.2. A clinical laboratory practitioner trainee may perform tasks related to laboratory tests only under the personal and direct supervision of: a licensed clinical laboratory practitioner; or a clinical laboratory director, consultant or supervisor.

4.3. A clinical laboratory practitioner trainee may not perform laboratory testing as a trainee for more than one (1) year.

§ ~~64-57-6~~ 5. Licensure Requirements, Duration, Renewal.

~~6.1~~ 5.1. General. -- Applicants for a ~~clinical laboratory practitioner license~~ licensure as a clinical laboratory practitioner - laboratory technologist, a clinical laboratory practitioner - laboratory technician, a clinical laboratory practitioner - cytotechnologist, or a clinical laboratory practitioner - point of care technician shall submit to the secretary:

~~6.1.a~~ 5.1.a. A completed application form supplied by the secretary with the documentation of ~~qualifications~~ required by this rule;

~~6.1.b~~ 5.1.b. ~~If employed in a clinical laboratory, a current job description and a statement identifying the specialty or specialties of laboratory tests for which the applicant has been trained and is currently competent to perform, except as specified in this rule. The required job description and statement of competency shall be signed and provided to the applicant by the applicant's clinical laboratory director. The attestation shall be partially based on the applicant's performance, if any, in proficiency testing programs; Documentation of the applicant's competency in the specialties or subspecialties of laboratory tests for which the applicant has been trained and is currently competent to perform. If the applicant is currently employed as a clinical laboratory practitioner, the documentation shall consist of a statement obtained from and signed by the applicant's laboratory director which identifies these specialties or subspecialties of laboratory tests. The evaluation of competency shall include consideration of the applicant's performance in any proficiency testing programs. If the applicant is not currently employed as a clinical laboratory practitioner, the documentation shall be adequate to identify and verify the specialty or specialties of laboratory tests for which the applicant has been trained and has previously performed; and~~

~~6.1.d~~ 5.1.c. The licensure fee shown on the application as authorized by W. Va. Code.

~~6.2.~~ The secretary shall ~~grant a clinical laboratory practitioner license to applicants who:~~

~~6.2.a.~~ ~~Are certified as a clinical laboratory practitioner under Section 7 of this rule or are exempt from certification under Section 8 of this rule; and~~

~~6.2.b.~~ ~~Comply with the requirements of Section 6.1 of this rule.~~

5.2. Clinical Laboratory Practitioner - Laboratory Technologist (CLP-MT). -- A person

seeking licensure as a clinical laboratory practitioner - laboratory technologist shall, at the time of application for initial licensure as a clinical laboratory practitioner - laboratory technologist, apply for a license on the form provided by the secretary and submit documentation to establish that he or she meets one (1) of the following qualifications:

5.2.a. He or she is certified as defined in Subsection 2.1 of this rule;

5.2.b. He or she has earned a bachelor's degree in medical technology, and has passed a national certification examination administered by a certifying agency recognized under subsection 2.1 of this rule; or

5.2.c. He or she has earned a bachelor's degree in a chemical, physical, or biological science other than medical technology, and, in addition, has at least one (1) year of pertinent full-time experience or training, or both, designed to provide him or her the following with respect to the specialties or subspecialties he or she will perform:

5.2.c.1. 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;

5.2.c.2. The skills required for implementing all standard laboratory procedures;

5.2.c.3. The skills required for performing each test method and for proper instrument use;

5.2.c.4. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

5.2.c.5. A working knowledge of reagent stability and storage;

5.2.c.6. The skills required to implement the quality control policies and procedures of the laboratory;

5.2.c.7. An awareness of the factors that influence test results; and

5.2.c.8. 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.

5.3. Clinical Laboratory Practitioner - Laboratory Technician (CLP-MLT). -- A person seeking licensure as a clinical laboratory practitioner - laboratory technician shall, at the time of application for initial licensure as a clinical laboratory practitioner - laboratory technician apply on the form provided by the secretary, and submit documentation sufficient to establish that he or she:

5.3.a. Is certified as defined in subsection 2.1 of this rule;

5.3.b. Has earned an associate degree in medical technology, and has passed a national

certification examination administered by a certifying agency recognized under subsection 2.1 of this rule;

5.3.c. Has successfully completed sixty (60) semester hours of academic credit at an accredited institution, including chemistry, biology, and a structured curriculum in medical laboratory techniques, and has at least one (1) year of pertinent full-time experience or training, or both, designed to provide him or her the following with respect to the specialties or subspecialties he or she will perform:

5.3.c.1. 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;

5.3.c.2. The skills required for implementing all standard laboratory procedures;

5.3.c.3. The skills required for performing each test method and for proper instrument use;

5.3.c.4. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

5.3.c.5. A working knowledge of reagent stability and storage;

5.3.c.6. The skills required to implement the quality control policies and procedures of the laboratory;

5.3.c.7. An awareness of the factors that influence test results; and

5.3.c.8. 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; or

5.3.d. Has an associate degree from an accredited institution based on a course of study including chemistry and biology, and has at least one (1) year of pertinent full-time experience, or training, or both, designed to comply with the requirements of Paragraphs 5.3.c.1 through 5.3.c.8 of this rule.

5.4. Clinical Laboratory Practitioner - Cytotechnologist (CLP-CT). -- A person seeking licensure as a clinical laboratory practitioner - cytotechnologist shall, at the time of application for initial licensure as a clinical laboratory practitioner - cytotechnologist, apply for licensure on the form provided by the secretary and submit documentation to establish that he or she:

5.4.a. Is certified as defined in Subsection 2.1 of this rule;

5.4.b. Has graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs, or its predecessor, the Committee on Allied Health Education and Accreditation; or

5.4.c. Has been certified in cytotechnology by a certifying agency approved by United States Department of Health and Human Services.

5.5. Clinical Laboratory Practitioner - Point of Care Technician (CLP-POCT). --

5.5.a. A person seeking licensure as a clinical laboratory practitioner - point of care technician shall, at the time of application for initial licensure as a clinical laboratory practitioner - point of care technician, apply on the form provided by the secretary, and submit documentation to establish that he or she:

5.5.a.1. Is certified as defined in Subsection 2.1 of this rule; or

5.5.a.2. Has at least a high school diploma, a general education development certificate (GED), or an equivalent approved by the State department of education;

5.5.a.3. Is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and

5.5.a.4. Submits with the application a statement obtained from and signed by his or her laboratory director which states that the applicant has had training designed to provide him or her the following with respect to the specific tests he or she will perform:

5.5.a.4.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;

5.5.a.4.B. The skills required for implementing all standard laboratory procedures;

5.5.a.4.C. The skills required for performing each test method and for proper instrument use;

5.5.a.4.D. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

5.5.a.4.E. A working knowledge of reagent stability and storage;

5.5.a.4.F. The skills required to implement the quality control policies and procedures of the laboratory;

5.5.a.4.G. An awareness of the factors that influence test results; and

5.5.a.4.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.

5.5.b. In the event that a person licensed as a clinical laboratory practitioner - point of

care technician is to perform tests in addition to those which he or she is licensed to perform, he or she shall submit to the secretary documentation of training related to the additional tests in the skills, knowledge, and awareness as required by paragraphs 5.5.a.4.A through 5.5.a.4.G of this rule.

5.6. Initial License. -- If an applicant complies with Subsection 5.1 of this rule, the secretary shall grant licensure as follows:

5.6.a. A clinical laboratory practitioner - technologist license to an applicant who complies with the requirements of Subsection 5.2 of this rule;

5.6.b. A clinical laboratory practitioner - technician license to an applicant who complies with the requirements of Subsection 5.3 of this rule;

5.6.c. A clinical laboratory practitioner - cytotechnologist license to an applicant who complies with the requirements of Subsection 5.4 of this rule; or

5.6.d. A clinical laboratory practitioner - point of care technician license to an applicant who complies with the requirements of Subsection 5.5 of this rule.

~~6.3~~ 5.7. Renewal License.

5.7.a. An applicant for renewal of either a current or an expired license shall submit the application, information and licensure fee required by Subsection 5.1 of this rule and evidence that the applicant has completed at least ten (10) contact hours (one (1) continuing education unit) of educational activities commensurate with the level of complexity of testing the individual performs from a program or programs approved by the secretary, since the issuance of his or her current or expired license, as applicable. Acceptable continuing educational activities include, but are not limited to, activities such as: lectures, seminars, workshops, formal classes, in-service programs or correspondence courses.

~~6.4.~~ 5.7.b. The secretary shall renew a license if the applicant ~~complies~~ submits the licensure fee, a completed application form and otherwise is in compliance with the requirements of Section ~~6.3~~ of this rule.

~~6.5.~~ 5.8. Term of License. -- A clinical laboratory practitioner license expires ~~the earlier of:~~ one (1) year after issuance; ~~or~~ the date it was issued.

~~6.5.b. The expiration of the individual's certification or exemption from certification as a clinical laboratory practitioner.~~

~~§ 64-57-7. Certification.~~

~~A person seeking certification as a clinical laboratory practitioner shall, at the time of application for initial licensure as a clinical laboratory practitioner, also apply for certification on the form provided by the secretary and submit documentation sufficient to establish that he or she meets one (1) of the following qualifications for certification:~~

~~7.1. He or she is certified as a medical laboratory technician or technologist by the American Medical Technologists or the American Society of Clinical Pathologists;~~

~~7.2. He or she is certified as a clinical laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel or by the International Society for Clinical Laboratory Technology;~~

~~7.3. He or she was performing clinical laboratory practitioner tasks in a clinical laboratory in West Virginia on July 7, 1989; or~~

~~7.4. He or she meets the qualifications, except for State licensure, for:~~

~~7.4.a. Testing personnel found at 42 CFR § 493.1423, for persons performing moderate complexity tests;~~

~~7.4.b. Testing personnel found at 42 CFR § 493.1489, for persons performing high complexity tests;~~

~~7.4.c. Cytotechnologists found at 42 CFR § 493.1483, for persons performing cytological examinations; or~~

~~7.5. He or she is certified under any other applicable federal program.~~

~~**§64-57-8. Exemption from Certification.**~~

~~8.1. A person seeking an exemption from certification as a clinical laboratory practitioner shall submit a request for exemption from certification on a form provided by the secretary. The request shall include a statement signed by the director of the clinical laboratory in which the applicant is employed of: the type and number of the laboratory's CLIA certificate, and which of the qualifications for exemption established by this rule the applicant meets.~~

~~The request shall include a document which identifies the type and number of CLIA certificate of the laboratory in which the person is employed and states the exemption qualification found in Section 8.2 of this rule which applies to the person seeking the exemption. The document shall be signed by the clinical director of the laboratory.~~

~~8.2. The secretary shall exempt a person from certification as a clinical laboratory practitioner if:~~

~~8.2.a. He or she is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and~~

~~8.2.b. His or her laboratory director states that the person applying for exemption from certification meets the qualifications, except for State licensure, for:~~

~~8.2.b.1. Testing personnel found at 42 CFR § 493.1423: Provided, That the applicant shall submit with his or her application documentation that he or she has at least a high~~

school diploma, a general education development certificate (GED), or an equivalent approved by the State department of education, and has had training designed to provide him or her the following with respect to the specific tests he or she will perform:

~~8.2.b.1.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;~~

~~8.2.b.1.B. The skills required for implementing all standard laboratory procedures;~~

~~8.2.b.1.C. The skills required for performing each test method and for proper instrument use;~~

~~8.2.b.1.D. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;~~

~~8.2.b.1.E. A working knowledge of reagent stability and storage;~~

~~8.2.b.1.F. The skills required to implement the quality control policies and procedures of the laboratory;~~

~~8.2.b.1.G. An awareness of the factors that influence test results; and~~

~~8.2.b.1.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, and Provided further: That, in the event that the individual is to perform additional tests, he or she shall submit to the secretary documentation of training related to the additional tests in the skills, knowledge, and awareness as required by Sections 8.2.b.1.A through 8.2.b.1.H of this rule; or~~

~~8.2.b.2. For persons performing cytotechnological examinations, the qualifications for cytotechnologists found at 42 CFR § 493.1483.~~

~~§64-57-9. Expiration of Certification and Exemption.~~

~~An individual's certification or exemption from certification as a clinical laboratory practitioner expires when the person holding the certification or the exemption no longer meets the qualifications stated in this rule for certification or for exemption from certification.~~

~~§ 64-57-10 6. Reciprocity.~~

~~The secretary may issue a clinical laboratory practitioner license or certification to a person who holds a license or certification from another jurisdiction which has licensure or and certification requirements at least as stringent as the requirements of this rule. Applicants for reciprocity shall submit with their application the license application fee and a statement from their licensing or certifying jurisdiction that they are in good standing. with their application.~~

§ 64-57-~~11~~ 7. Limitations on License and Use of Titles by Health Care Facilities.

~~11.1.~~ 7.1. Licensure ~~or certification~~ as a clinical laboratory practitioner does not authorize the person to perform laboratory tests unless his or her clinical laboratory director has determined that the person is qualified by education, training or experience to perform such tests.

~~11.2.~~ 7.2. Health care facilities shall not use the terms clinical laboratory practitioner, laboratory or medical technician, cytotechnologist, point of care technician, or laboratory or medical technologist, or abbreviations thereof, to refer to a person who is not licensed as a clinical laboratory practitioner.

§ 64-57-~~12~~ 8. Revocation and Non-issuance of Clinical Laboratory Practitioner Licenses.

A clinical laboratory practitioner license, ~~certification, or exemption from certification,~~ shall not be issued or shall be revoked if the applicant for or holder thereof:

~~12.1.~~ 8.1. Has misrepresented material facts in an application or has assisted another person in doing so;

~~12.2.~~ 8.2. Does not meet the requirements for licensure, ~~certification, or exemption from certification;~~ or

~~12.3.~~ 8.3. Has been convicted of a felony involving laboratory practices.

§ 64-57-~~13~~ 9. Hearings.

~~13.1.~~ 9.1. A request for a hearing may be made to the secretary by an applicant for a clinical laboratory practitioner ~~certification or~~ license, by a holder thereof or by a health care facility. The request shall specify the grounds relied upon as a basis for the relief requested.

~~13.2.~~ 9.2. Hearings shall be conducted in accordance with the provisions of W. Va. Code § 29A-5-1 et seq., and Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West Virginia Administrative Rules, 64 CSR 1.