

ABSTRACT - PROPOSED AMENDED RULE

**DIVISION OF HEALTH
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION
64 CSR 57**

Summary: The proposed amended legislative rule 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 in 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 realistically set educational requirements which upgrade the professional and 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.

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6/27/97

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.

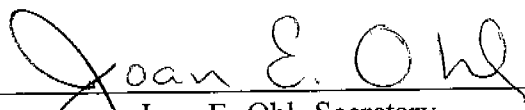
None. The Department anticipates that most of the individuals now performing laboratory procedures are already in compliance with the specified education and training requirements.

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

For Public Comment

June 27, 1997 - July 28, 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

JUN 27 3 53 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.~~

1.6. Supersession 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~~ 1.7. ~~Application~~ Applicability. -- Except as otherwise provided in this rule, this legislative rule applies to:

~~2.1.a~~ 1.7.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~~ 1.7.b. Clinical laboratory consultants, directors, and supervisors in West Virginia.

~~2.2~~ 1.8. This rule does not apply to:

~~2.2.a~~ 1.8.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;

~~2.2.b~~ 1.8.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~~ 1.8.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~~ 1.8.c.1. Any individual who performs laboratory tests only on himself or herself or members of his or her family.

~~2.3~~ 1.9. 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 by the International Society for Clinical Laboratory Technology;

2.1.c. 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; or

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

~~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;

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

~~3.4.b.3~~ 2.5.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-c~~ 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 who concentrate their activities in categories such as blood banking, chemistry, hematology, microbiology and immunology.

~~3-12~~ 2.14. Laboratory Technologist. -- A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory, which tasks require the broad exercise of judgement and responsibility with little or no direct technical supervision, who perform a broad range of laboratory tests and concentrate their activities or specialize in a category such as blood banking, chemistry, hematology, microbiology and immunology.

~~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 to a physician to review and evaluate the results obtained. These individuals can perform only tests that have been deemed "moderate complexity" by FDA since they 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.

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

The following provisions of the October 1, 1994, 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~~ 3.1. 42 CFR § 493.7;
- ~~4.2~~ 3.2. 42 CFR § 493.17;
- ~~4.3~~ 3.3. 42 CFR § 493.19 (a) - (d);
- ~~4.4~~ 3.4. 42 CFR § 493.35;
- ~~4.5.~~ ~~42 CFR § 493.1363;~~
- ~~4.6~~ 3.5. 42 CFR § 493.1405;
- ~~4.7~~ 3.6. 42 CFR § 493.1411;
- ~~4.8~~ 3.7. 42 CFR § 493.1417;
- ~~4.9~~ ~~42 CFR § 493.1423;~~
- ~~4.10~~ 3.8. 42 CFR § 493.1443;
- ~~4.11~~ 3.9. 42 CFR § 493.1449;
- ~~4.12~~ 3.10. 42 CFR § 493.1455;
- ~~4.13~~ 3.11. 42 CFR § 493.1461; and
- ~~4.14~~ 3.12. 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.

~~§ 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; 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;~~

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

~~6.1.d.~~ 5.1.d. 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; 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 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. He or she is certified as defined in Subsection 2.1 of this rule;

5.3.b. Has earned an associate degree in medical technology;

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 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 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:

5.5.a.1. Documentation to establish 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;

5.5.a.2. Documentation to establish that he or she is employed in a clinical labo-

ratory which holds a CLIA certificate other than a certificate of waiver; and

5.5.a.3. 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.3.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.3.B. The skills required for implementing all standard laboratory procedures;

5.5.a.3.C. The skills required for performing each test method and for proper instrument use;

5.5.a.3.D. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

5.5.a.3.E. A working knowledge of reagent stability and storage;

5.5.a.3.F. The skills required to implement the quality control policies and procedures of the laboratory;

5.5.a.3.G. An awareness of the factors that influence test results; and

5.5.a.3.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 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 Subparagraphs 5.5.a.3.A through 5.5.a.3.H 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.e. 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:

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~~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.