

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series XXVI
(1983)

Preliminary Requirement for Approval by the
West Virginia Department of Health of a
Laboratory for a Specified Technique

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Subject: Preliminary Requirement for Approval by the West Virginia Department of Health of a Laboratory for a Specified Technique

Section 1. General

1.1. Scope - These legislative rules establish the basic layout, equipment and personnel requirement for approval of a laboratory by the West Virginia department of health for a specified technique as required by state laws.

1.2. Authority - These legislative rules are issued under the authority of Chapter 16, Article 1, Section 7 and are related to Chapter 48, Article 1, Section 6a and Chapter 16, Article 9A, Section 1 of the West Virginia Code of 1931, as amended.

1.3. Filing Date - These legislative rules were filed on the 28th day of November 1967, in the Secretary of State's office.

1.4. Effective Date - These legislative rules became effective on the 29th day of December 1967.

1.5. Refiling Date - These legislative rules were refiled pursuant to Chapter 29A, Article 2, Section 5 of the West Virginia Code of 1931, as amended on the 30th day of December 1982, in the Secretary of State's office.

Section 2. Application and Enforcement

2.1. Application - These legislative rules apply to any person seeking approval for a laboratory by the West Virginia department of health for a specified technique.

2.2. Enforcement - The enforcement of these legislative rules is vested with the director of the West Virginia department of health or his lawful designee.

Section 3. Layout

3.1. If a laboratory desires approval by the West Virginia department of health for a specified technique such as required under the Premarital, Prenatal, and Barbers and Beauticians' Law, it must first show that it meets the following basic requirements relative to location, floor space, lighting, ventilation, water and sewage disposal, equipment, apparatus and personnel:

3.1.1. Location - Suitably located and sufficiently isolated in any well lighted, well ventilated and well heated space which will be free from excessive traffic.

3.1.2. Floor Space - Adequate space for apparatus and equipment; in addition, adequate space for working, storage, reporting and record keeping, and for compilation and periodic evaluation, by the director and others interested in the productivity of the laboratory, of summary reports on volume and variety of work. A minimum of 100 square feet is recommended.

3.1.3. Lighting - Adequate daylight or artificial light, approximating 50 foot-candle illumination at actual working surfaces where detailed work is carried out. Generalized lighting in order to reduce glare and contrast should be provided at approximately 20 foot-candles.

3.1.4. Adequate Ventilation

3.1.5. Water and Sewage Disposal - Hot and cold running water and sanitary sewage disposal systems in the laboratory.

Section 4. Equipment

4.1. The following basic items are required to be in good condition in any laboratory desiring approval:

- (a) Laboratory sink;
- (b) Cabinets for reagents, small equipment, etc.;
- (c) Microscope and lamp;
- (d) Refrigerator of at least 6 cu. ft. capacity;
- (e) Adequate gas and electric outlets;
- (f) Adequate centrifuge;
- (g) Adequate glassware and reagents;
- (h) Adequate working tables;
- (i) Adequate filing system;
- (j) Current laboratory reference tests.

4.2. The following equipment maintained in good condition is also required for approval in syphilis serology:

- (a) Serologic shaker and/or rotator; speed should be regularly checked;
- (b) Adequate water bath facilities, with constant temperature control.

4.3. The following equipment should be readily available and maintained in good condition, for use by the laboratory:

- (a) Hot air sterilizer of at least 18' x 14" x 14" i. d. or equivalent;
- (b) Autoclave;
- (c) Balance and weights of suitable accuracy;
- (d) Still or demineralizer, properly operated.

Section 5. Personnel and Qualifications

5.1. Actual Direction and Supervision - Either the director or an authorized and capable assistant to the director of the laboratory must in actuality be regularly available to direct, supervise, and actively participate in the work of the laboratory. If the director is not in reality full time in, or readily available to the laboratory, there must be in the laboratory at all other times during its working hours a capable assistant to the director (or more if desired) who has (or who share) full authority and the responsibility for the activities of the laboratory in the absence of the director.

5.2. The Director - It is desirable that the director of a hospital laboratory be a qualified clinical pathologist who is a licensed physician. A Clinical Pathologist is defined as a physician who devotes the majority of his time to the practice of clinical pathology, who has had post-graduate training in and is qualified in the fields of bacteriology, bio-chemistry, blood banking, clinical microscopy, hematology, parasitology and serology. It is desirable that the director of a public health or an independent clinical, bacteriological or biochemical laboratory hold a doctorate, or equivalent training, in one or more of the associated fields of science.

5.3. The director must have minimum qualifications as follows:

5.3.1. He must be at least a college graduate with major work for his degree in one or more of the biological or chemical sciences commonly employed in clinical laboratories.

5.3.2. OR, if not a college graduate, he must have had at least 60 semester hours or equivalent study in an accredited college, and in addition must have had 3 years of appropriate laboratory experience. The required 60 hours of study must have included not less than 6 semester hours of

bacteriology, 10 semester hours of chemistry, and 3 semester hours of physics.

5.3.3. OR, a high school graduate is permissible, provided he had had 5 (five) years of satisfactory experience under a qualified clinical pathologist, immunologist or serologist. Two years of this experience must have occurred within the five years immediately preceding such employment. In such case, a licensed physician connected with the employing institution must accept full responsibility for the accuracy of the laboratory's work.

5.3.4. He must also have had at least 3 years experience performing clinical or public health laboratory analyses in two or more of the various fields of clinical laboratory activity in a clinical or public health laboratory acceptable to the West Virginia department of health. Each year of resident post-graduate study in fundamental medical sciences which has been satisfactorily completed in a college or university accredited for granting a post-graduate degree in one or more of these sciences, or in an institution accredited for such post-graduate training by the Council on Medical Education and Hospitals of the American Medical Association, may be substituted year for year of the required experience, up to a maximum to two years.

5.4. Assistant to the Director - Must have the requirements specified in 5.3.1 and must have had at least one year's experience as described in 5.3.4.

5.5. Qualifications for Additional Technical Workers - Must be at least high school graduates with a minimum of one year of technical training in one or more of the sciences or procedures commonly employed in a clinical laboratory. Such training must have been received in an accredited college

or university, or in a laboratory approved for such training by the Council on Medical Education and Hospitals of the American Medical Association, or in a laboratory directed by a qualified clinical pathologist, or in a nationally recognized public health laboratory.

5.6. Personnel Exempt for these Requirements - Sections 5.2, 5.3, 5.4 and 5.5 do not apply to a person in a given laboratory in which he is employed at the time these regulations become effective.

Section 6. Approval for Proficiency not Granted Hereunder - Neither this rule, nor any part thereof, may be construed as the sole basis for granting approval by the West Virginia department of health for proficiency in a specific test.