

CHAPTER 44**CHAPTER IV OF THE STATE SANITARY CODE****Authority**

N.J.S.A. 26:1A-7 and 45:9-42.34.

Source and Effective Date

R.2000 d.377, effective September 18, 2000.
See: 32 N.J.R. 1369(a), 32 N.J.R. 3462(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 44, Chapter IV of the State Sanitary Code, expires on March 17, 2007. See: 38 N.J.R. 2560(a).

Chapter Historical Note

Chapter 44, Chapter IV of the State Sanitary Code, was adopted as R.1978 d.336, effective September 18, 1978. See: 10 N.J.R. 147(c), 10 N.J.R. 430(a).

Pursuant to Executive Order 66(1978), Chapter 44, Chapter IV of the State Sanitary Code, was readopted as R.1983 d.498, effective November 7, 1983. See: 15 N.J.R. 995(a), 15 N.J.R. 1862(a).

Pursuant to Executive Order 66(1978), Chapter 44, Chapter IV of the State Sanitary Code, was readopted as R.1988 d.561, effective November 2, 1988. See: 20 N.J.R. 2222(a), 20 N.J.R. 3017(a).

Subchapter 3, Limited Purpose Laboratories, was adopted as R.1990 d.512, effective October 15, 1990. See: 22 N.J.R. 1323(a), 22 N.J.R. 3232(a).

Subchapter 3, Limited Purpose Laboratories, was repealed by R.1993 d.200, effective May 17, 1993. See: 25 N.J.R. 668(a), 25 N.J.R. 1969(b).

Pursuant to Executive Order No. 66(1978), Chapter 44, Chapter IV of the State Sanitary Code, was readopted as R.1993 d.595, effective April 12, 1993. See: 25 N.J.R. 3904(a), 25 N.J.R. 5164(a).

Pursuant to Executive Order No. 66(1978), Chapter 44, Chapter IV of the State Sanitary Code, was readopted as R.1995 d.239, effective April 12, 1995. See: 27 N.J.R. 626(a), 27 N.J.R. 1985(a). Pursuant to Executive Order No. 66(1978), Chapter 44 expired on April 12, 2000.

Chapter 44, Chapter IV of the State Sanitary Code, was adopted as new rules by R.2000 d.377, effective September 18, 2000. See: Source and Effective Date.

CHAPTER TABLE OF CONTENTS**SUBCHAPTER 1. (RESERVED)****SUBCHAPTER 2. OPERATION OF CLINICAL LABORATORIES**

- 8:44-2.1 Definitions
- 8:44-2.2 Applicability of regulations
- 8:44-2.3 Laboratory director
- 8:44-2.4 Supervision
- 8:44-2.5 Tests performed
- 8:44-2.6 Technical personnel
- 8:44-2.7 Management
- 8:44-2.8 Quality control
- 8:44-2.9 Amendments
- 8:44-2.10 Public Health Council
- 8:44-2.11 Reporting by laboratory supervisors

- 8:44-2.12 Inspection and registration concerning handling of live microorganisms or viruses pathogenic for humans, or birds
- 8:44-2.13 Sale, transportation or other disposal of live microorganisms or viruses pathogenic for humans, animals, or birds

SUBCHAPTER 3. LIMITED PURPOSE LABORATORY

- 8:44-3.1 Limited purpose laboratory; definition and minimum protocols
- 8:44-3.2 Applicability of subchapter
- 8:44-3.3 Director
- 8:44-3.4 Supervision
- 8:44-3.5 Screening tests performed
- 8:44-3.6 Management of a limited purpose laboratory
- 8:44-3.7 Procedure manual
- 8:44-3.8 Facilities
- 8:44-3.9 Collection of specimens
- 8:44-3.10 Disposable equipment
- 8:44-3.11 Records of specimens
- 8:44-3.12 Examinations and reports
- 8:44-3.13 Report records
- 8:44-3.14 Quality control and quality assurance
- 8:44-3.15 Initial and renewal licensure fees
- 8:44-3.16 Compliance

SUBCHAPTER 1. (RESERVED)**SUBCHAPTER 2. OPERATION OF CLINICAL LABORATORIES****8:44-2.1 Definitions**

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise. All terms not defined herein shall have the meaning given them in the New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26 et seq.

"Accredited" means having the approval conferred upon schools, institutions, or programs where appropriate by a nationally recognized accrediting agency or association as determined by the U.S. Commissioner of Education and/or New Jersey State Board of Higher Education.

"Consultation" means a communication between two or more physicians concerning the diagnosis or treatment in a given case. Consultation would, when indicated, include history taking, examination of the patient, and rendering to the attending physician an opinion concerning diagnosis and/or treatment.

"Personal and direct supervision" means that a qualified general supervisor or supervisory cytotechnologist, where applicable, is present in the immediate bench area when laboratory procedures are being performed.

"Physician" means any person licensed to practice medicine and surgery by the New Jersey Board of Medical Examiners.

"Radioassay" means the analysis following the administration of a radioactive material to a patient and the subsequent

analysis of the body fluid, or excreta in order to evaluate body function. This definition includes scanning and in vivo measurements.

"Subsequent to graduation" means laboratory training and experience acquired after receipt of the degree specified. However, experience as a technologist in a licensed clinical laboratory, which was gained prior to acquiring such degree, may be substituted on an equivalency basis of 1.5 years of such experience for every 1 year of postdegree training and experience; and experience as a general supervisor in a licensed clinical laboratory, which was gained prior to acquiring such degree, may be substituted on a 1 for 1 basis.

"Substitution of education for experience" means that a minimum of 30 semester hours of credit from an approved school of medical technology, or towards a bachelor's degree from an accredited institution with a chemical, physical, or biological science as the major subject is considered equivalent to 2 years of experience. Additional education is equated at the rate of 15 semester hours of credit for 1 year of experience.

"Trainee" means an individual who is gaining the required years of clinical laboratory on-the-job experience to qualify as a technician and/or technologist and is participating in a structured training program approved by the Department of Health, designed to provide the trainee with a broad range of laboratory procedures of progressive technical difficulty. A training program compatible with that of a nationally recognized accrediting society, board or organization is acceptable.

"True duplicate" means a carbon or other mechanical copy.

8:44-2.2 Applicability of regulations

(a) Except as otherwise provided herein, the regulations shall apply to clinical laboratories engaged in the performance of chemical, bacteriologic, virologic, parasitologic, serologic, mycologic, hematologic, immunohematologic, biophysical, cytologic, radiobioassay or other examinations of materials derived from the human body for the purpose of yielding information for the diagnosis, prevention or treatment of disease or the assessment of medical condition.

(b) The rules do not apply to the following:

1. Anatomic pathology, which is defined as the gross or microscopic examination of tissues by a physician specifically trained to interpret and diagnose disease by such examination;

2. Clinical laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health services, whatsoever;

3. Clinical laboratories operated by the United States Government;

4. Blood banks licensed under P.L.1963, c.33 (N.J.S.A. 26:2A-2 et seq.);

5. Clinical laboratories possessing a Federal Certificate of Waiver as defined by Federal Clinical Laboratory Amendments of 1988 (CLIA '88) (P.L. 100-578) and regu-

lations adopted thereunder (42 CFR Part 493, published in the Federal Register, February 28, 1992); and

6. Clinical laboratories which are operated by the Department of Corrections, any county jail, any county probation department, or any drug or alcohol treatment center providing services to persons under the jurisdiction of any of these agencies or in a program of supervisory treatment pursuant to the provisions of N.J.S. 2C:43-13 and which perform only urinalysis for screening purposes to detect the presence of alcohol or illegal substances. The Attorney General shall approve procedures, methods and devices used by these agencies or centers in screening for alcohol or illegal substances.

Amended by R.1993 d.200, effective May 17, 1993.

See: 25 N.J.R. 668(a), 25 N.J.R. 1969(b).

Added exception at (b)5.

Amended by R.1993 d.595, effective November 15, 1993.

See: 25 N.J.R. 3904(a), 25 N.J.R. 5164(a).

8:44-2.3 Laboratory director

(a) The clinical laboratory shall be under the direction of a qualified person.

(b) The director shall administer the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests.

1. The director shall serve the laboratory full time, or on a regular part-time basis. The director shall not individually serve as director or Co-director of more than three laboratories.

2. Commensurate with the laboratory workload, the director shall spend an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and shall be readily available for personal or telephone consultation.

3. The director is responsible for the proper performance of all tests made in the laboratory.

4. The director is responsible for the employment of qualified laboratory personnel and their inservice training.

5. If the director is to be absent, the director must arrange for a qualified substitute director.

(c) The laboratory director shall hold a valid, current license as a bioanalytical laboratory director issued pursuant to L.1953, c.420 (N.J.S.A. 45:9-42.1 et seq.), and, in addition, shall meet one of the following requirements:

1. Is a physician certified in anatomical and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for such certification (board eligible);

2. Is a physician who:

- i. Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or