CHAPTER 44

CHAPTER IV OF THE STATE SANITARY CODE

Authority

N.J.S.A. 26:1A-33 and 45:9-42.30; and
Reorganization Plan No. 003-2005.

Source and Effective Date

R.2007 d.48, effective January 9, 2007.
See: 38 N.J.R. 2560(a), 39 N.J.R. 447(a).

Chapter Expiration Date

Chapter 44, Chapter IV of the State Sanitary Code, expires on January 9, 2012.

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Subchapter 3, Limited Purpose Laboratories, was repealed by R.1993 d.200, effective May 17, 1993.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 October 21, 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: 32 N.J.R. 1369(a), 32 N.J.R. 3462(a).

Subchapter 3, Limited Purpose Laboratory, was adopted as emergency new rules by R.2004 d.219, effective May 19, 2004 (to expire July 18, 2004). See: 36 N.J.R. 2926(a). Subchapter 3 was subsequently adopted as concurrent new rules by R.2004 d.311, effective July 15, 2004. See: 36 N.J.R. 3877(a).

In accordance with N.J.S.A. 52:14B-5.1d, the expiration date of Chapter 44, Chapter IV of the State Sanitary Code, was extended by gubernatorial directive from September 18, 2005 to September 18, 2006. See: 37 N.J.R. 4020(a).

Chapter 44, Chapter IV of the State Sanitary Code, was readopted as R.2007 d.48, effective January 9, 2007. See: Source and Effective Date.

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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 regulations 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.

(b) Laboratory supervisors shall report to the State Department of Health and Senior Services, within 48 hours of the completion of the analysis, the results of laboratory examinations for hazardous substances in blood and urine, as follows:

1. Lead:

i. All blood lead test results;

ii. Urine lead levels equal to or greater than 80 µg/dL in individuals greater than 16 years of age.

2. Mercury:

i. Blood mercury levels equal to or greater than 2.8 µg/dL;

ii. Urine mercury levels equal to or greater than 20 µg/L.

3. Arsenic:

i. Blood arsenic levels equal to or greater than .07 µg/ml;

ii. Urine arsenic levels equal to or greater than 100 µg/L.

4. Cadmium:

i. Blood cadmium levels equal to or greater than five µg/L of whole blood;

ii. Urine cadmium levels equal to or greater than three µg/gram creatinine.

(c) The reports required by (b) above shall contain the result of the laboratory examination, including units; the type of specimen tested; the sample number and date the sample was collected and analyzed; the name, address, telephone number, sex, and date of birth or age of the patient; if the patient is over 16 years old, the name, address, and telephone number of the employer; the patient's occupation; the name, address, telephone number, and name of the medical facility of the requesting physician; and the name, address, telephone number of testing laboratory.

Amended by R.1985 d.518, effective October 21, 1985.
See: 17 N.J.R. 1831(a), 17 N.J.R. 2554(b).
(d) added.
Amended by R.1994 d.36, effective January 18, 1994.
See: 25 N.J.R. 3751(a), 26 N.J.R. 362(a).
Amended by R.1994 d.275, effective June 6, 1994.
See: 26 N.J.R. 294(b), 26 N.J.R. 1190(a), 26 N.J.R. 2270(a).
Amended by R.1998 d.175, effective April 6, 1998.
See: 29 N.J.R. 4227(a), 30 N.J.R. 1310(c).
In (b), rewrote the introductory paragraph and 1.

8:44-2.12 Inspection and registration concerning handling of live microorganisms or viruses pathogenic for humans, or birds

(a) Laboratories or other places where live microorganisms or viruses pathogenic for humans, animals, or birds are handled, cultivated or kept shall be subject to inspection and reinspection at any time by authorized representatives of the Department of Health.

(b) The director of a laboratory or person in charge of any other place where live microorganisms or viruses pathogenic for humans, animals, or birds are handled, cultivated or kept shall, on forms provided by the Department of Health, register such laboratory or place with the Department between the dates of March 1, 1954 and April 1, 1954. Such laboratories or other places established on or after April 1, 1954 shall register with the Department prior to handling, cultivating, keeping, selling, transporting or otherwise disposing of live microorganisms or viruses covered by this Section.

1. Laboratories or other places required to be registered under the provisions of this Chapter shall promptly forward all information requested by the Department.

(c) Registration requirements do not apply to laboratories maintained by official governmental agencies, voluntary general hospitals, those physicians licensed to practice medicine and surgery in this State, those veterinarians licensed to practice veterinary medicine in this State, manufacturers of biologics licensed by the United States government.

8:44-2.13 Sale, transportation or other disposal of live microorganisms or viruses pathogenic for humans, animals, or birds

Live microorganisms or viruses pathogenic for humans or birds shall not be sold, knowingly transported or otherwise disposed of in viable form without written permission of the Department of Health, excepting:

(a) Such products manufactured and clearly identified, as required by law, by manufacturers of biologics licensed by the United States government and in compliance with Federal postal and other regulations; or

(b) Diseased tissue, exudate, or other specimens which are enroute to laboratories for the sole purpose of laboratory examination as an aid in diagnosis or control of disease and which are transported in compliance with Federal postal regulations or under conditions as may be prescribed by the Department and sent by physicians licensed to practice medicine and surgery in this State, by veterinarians licensed to practice veterinary medicine in this State or by licensed health officers of this State in the performance of their official duties.

SUBCHAPTER 3. LIMITED PURPOSE LABORATORY

8:44-3.1 Limited purpose laboratory; definition and minimum protocols

(a) "Limited purpose laboratory" means a facility operated by a not-for-profit organization receiving grant funds from the Department of Health and Senior Services, hereinafter known as the Department, to operate a counseling and testing site to conduct rapid FDA licensed point-of-care tests for Human Immunodeficiency Virus (HIV).

(b) A limited purpose laboratory shall establish the following protocols at a minimum:

1. Follow-up protocols to ensure that Food and Drug Administration (FDA) approved confirmatory testing is performed;

2. A protocol for the review of test results by the laboratory director and general supervisor;

3. Protocols to ensure that individuals with abnormal results are referred to an appropriate source of medical care and prevention services; and

4. Personnel policies, practices and procedures that adequately support sound rapid FDA licensed point-of-care testing practices.

8:44-3.2 Applicability of subchapter

(a) The subchapter applies to limited purpose laboratories as defined in N.J.A.C. 8:44-3.1(a).

(b) If a limited purpose laboratory is operated at more than one site, each site shall require a separate license.

8:44-3.3 Director

(a) A limited purpose laboratory shall be under the direction of a laboratory director as specified in N.J.A.C. 8:44-2.3(b)2, 3, 4, and 5, and 2.3(c).

(b) The laboratory director can direct multiple limited purpose laboratories which share a quality assurance program and laboratory policies and these shall count as one clinical laboratory for the purpose of N.J.A.C. 8:44-2.3(b) 1. The laboratory director can direct no more than five limited purpose laboratories whose quality assurance program and laboratory policies are not identical and these shall count as one clinical laboratory for the purpose of N.J.A.C. 8:44-2.3(b)1.

(c) The laboratory director shall, at a minimum, serve the limited purpose laboratory on a regular part-time basis to ensure that the provisions of this subchapter are met.

(d) The laboratory director shall be readily available for personal or telephone consultation with staff.

(e) The laboratory director shall be responsible for the proper performance of all testing procedures and for ensuring the competency of all persons performing point of care testing.

(f) The laboratory director shall arrange for a qualified substitute director, prior to the director's absence.

8:44-3.4 Supervision

(a) A limited purpose laboratory shall be supervised by a person, designated as the general supervisor, who can be, but is not limited to being, a physician, professional registered nurse, counseling and testing site coordinator, or health educator, approved by the laboratory director, who, under the general direction of the laboratory director, supervises testing personnel and the report of findings, and in the absence of the laboratory director, is responsible for the proper performance of all laboratory procedures.

1. Limited purpose laboratory records including, but not limited to, patient accession, testing, test results, quality control and temperature monitoring, shall be reviewed at least monthly by the laboratory director, general supervisor, or qualified designee of the laboratory director.

(b) The rapid FDA licensed point-of-care test for Human Immunodeficiency Virus (HIV) shall be performed by personnel, such as professional registered nurses, technicians or non-professionals, who have been trained in accordance with the provisions of the Centers for Disease Control and Prevention (CDC) Quality Assurance Guidelines for Testing using the OraQuick Rapid HIV-1 Antibody Test, hereinafter known as the CDC Quality Assurance Guidelines, which are incorporated herein by reference, as amended and supplemented, and available at http://www.cdc.gov/hiv/rapidtesting/materials/QA-Guide.htm. The laboratory director shall develop testing and operational protocols, which meet or exceed those issued by the CDC.

(c) The laboratory director shall revise quality assurance, testing, and operational protocols and provide training of testing personnel and supervisors, for any new additional point of care rapid HIV test authorized by the Department for use in limited purpose laboratories subsequent to the adoption of these regulations.

8:44-3.5 Screening tests performed

(a) A limited purpose laboratory shall perform only those tests and procedures that are expressly approved by the Department pursuant to N.J.A.C. 8:44-3.1(a).