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**NEW JERSEY STATE
SANITARY CODE**

New Jersey (State)
Department of Health,
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**CHAPTER IV
LABORATORIES**

(Promulgated 1953, latest revision 1964)

CHAPTERS OF THE NEW JERSEY STATE SANITARY CODE

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| I Local Boards of Health and Personnel | VI Boarding Homes for Children |
| II Reportable Diseases | VII Production, Distribution and Sale of Certified Milk, Cream and Skim Milk |
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FOREWORD

The New Jersey State Sanitary Code is composed of regulations organized into appropriate chapters. The chapters have been promulgated by the Public Health Council of the State Department of Health after public hearing, pursuant to statute. (New Jersey Statutes Annotated 26:1A-7).

The provisions of the State Sanitary Code have the force and effect of law. They are enforceable by the State Department of Health, local boards of health, local police authorities, and other enforcement agencies.

New Jersey Statutes Annotated 26:1A-10 provide that each violation of any provision of the State Sanitary Code shall constitute a separate offense and each such violation shall be punishable by a penalty of not less than twenty-five dollars (\$25.00) nor more than one hundred dollars (\$100.00).

The names of persons on the Public Health Council will be given to any person on request. Members of the Council receive no remuneration for their services.

Many persons have primary need for specific chapters of the Code rather than the Code in its entirety. Separate chapters of the Code have been printed to meet such requests and to preclude the necessity of reprinting the entire Code when individual chapters are revised.

Regulation 1 - Laboratory inspection, standards and reports

(a) Laboratories required by statute and those regulations of Chapter II and VII of the State Sanitary Code to be approved by the State Department of Health shall comply with all provisions of this chapter. (R.S. 37:1-23; 26:4-49:2)

(b) All laboratories shall comply with Regulations 9a, 10 and 11 of this chapter.

(c) All laboratory premises, equipment, supplies and records shall be made available to inspection and reinspection by authorized representatives of the State Department of Health.

(d) Reports of laboratories other than those referred to in (a) above which perform bacteriological or other sanitary tests associated with potable water, milk or other foods, for a health officer or a local board of health shall be based upon and confined to laboratory examinations performed in accordance with methods and techniques acceptable to the State Department of Health.

Regulation 2 - Certification of certain laboratories

The laboratories designated by Regulation 1 (a) of this chapter shall make application for and obtain a certificate of approval from the Department. This certificate shall be posted in a conspicuous place at the entrance to the laboratory. Certificates of approval shall be subject to revocation for cause.

Notice of issuance of certificates of approval to laboratories and disapproval of laboratories shall be forwarded to the board of health of the municipality or district wherein the laboratory is located within 10 days of such approval or disapproval.

Regulation 3 - Application for certification generally; certain exceptions

(a) Application for certification shall be made on a form supplied by the Department. Certificates of approval expire at the end of each calendar year. Application for renewal of certificates shall be submitted to the Department on or before November first. Initial requests for a certificate or requests for a certificate following invalidation of a previous certificate may be submitted at any time.

(b) Laboratories other than those conducted by a board of health shall not be eligible to apply for a

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certificate until they have been established for at least one year.

(c) A laboratory other than that conducted by a board of health shall not be eligible to apply for an initial certificate until it shall have obtained the signed endorsement of at least ten physicians attesting to the fact that they desire the facilities of such laboratory and other evidence as may be desired by the State Department of Health.

Regulation 4 - Personnel requirements; change in personnel

(a) A supervisor who may be designated as "Director," "Bacteriologist-in Charge," "Serologist-in-Charge," or "Chemist-in-Charge" shall be in charge of the laboratory applying for a certificate.

(b) The supervisor shall meet the following minimum qualifications:

He shall possess a doctorate degree in philosophy, science, public health or medicine, or be licensed to practice medicine in the State of New Jersey, with adequate experience in laboratory procedures, or

He shall have graduated from a college or university of recognized standing with at least a Bachelor's degree in bacteriology, biology, or allied sciences, shall possess a public health laboratory technician license issued by this Department, and shall have had four years acceptable laboratory experience, two of which shall have been spent in a public health laboratory, or its equivalent, preferably having served as assistant bacteriologist or assistant serologist.

He shall be a person of known integrity and professional ability who shall be capable of conducting a laboratory in which satisfactory standards of work are maintained at all times and he shall possess such personal qualifications as: ability to exercise meticulous care in technique, good judgment, sense of responsibility, ability to cooperate with and supervise the work of others.

(c) Supervisors shall be present and direct the activities of the laboratory during its operating hours. In the absence of the supervisor, the person next in charge shall meet the full qualifications of the office of supervisor.

(d) Loss of services of a supervisor in charge of a laboratory shall automatically invalidate a certificate of approval of the Department and shall immediately be reported to the State Department of Health. Upon invalidation of a certificate of approval under such circumstances the Department, upon application therefor, may grant permission to a laboratory to perform services for a local board of health or a health officer for such period of time and under such conditions as it may prescribe.

Regulation 5 - Laboratory quarters, location and equipment

(a) The laboratory shall be housed in well lighted, properly ventilated and adequately spaced quarters, to provide for the type of work for which a certificate is requested. Laboratories shall not be located in living quarters unless there are provisions for separate entrance, and plumbing fixtures and other facilities used for laboratory purposes are separate from those for household purposes.

(b) The laboratory shall be equipped with gas, electricity, and hot and cold running water. The minimum equipment shall consist of the following apparatus, meeting the requirements for the tests to be conducted: Autoclave, dry air sterilizer, constant temperature 37° incubator, microscope, centrifuge, constant temperature water bath and refrigerator. All necessary glassware, lamps, burners, reagents, stains, antigens and sera must be of recognized standard and good quality and available at all times for the various tests for which a certificate is requested.

(c) The laboratory shall be equipped with an adequate reference library.

(d) Laboratory animals shall be kept in adequate sanitary quarters maintained separate from the rooms in which laboratory tests are conducted.

Regulation 6 - Laboratory methods

(a) Serologic tests for syphilis shall be performed in the manner as prescribed by the latest recommendation of their authors and approved by the State Department of Health.

(b) Serologic evaluation shall be: Specificity: Standard of specificity (percent of negative sera reported as negative) shall be at least 99 percent as obtained by the control laboratory.

Sensitivity: Standard of sensitivity (percent of positive sera reported as positive) shall not be more than 10 percent below that obtained by the control laboratory.

(c) Modification of existing methods or new methods must be approved by the State Department of Health before they may be applied. The test for such approval is their ability to produce results the equivalent of standard tests now approved by the Department.

(d) The laboratory shall obtain a high degree of accuracy, 80-90%, in identification of bacteriological specimens submitted for examination in any diseases for which the laboratory is to receive or has received a certificate.

(e) Animal brains examined for rabies and found to be Negri-negative shall have a suitable portion thereof inoculated into mice in those instances where there is

a record of a bite or intimate human or animal contact.

Regulation 7 - Records

(a) Laboratories applying for a certificate must show facilities for keeping complete laboratory results. All such records (except negative serology records) shall be kept on file for at least one year. Positive slides referable to communicable diseases shall be retained for at least three months.

(b) Records shall be kept up to date and open to inspection by authorized representatives of the State Department of Health.

Regulation 8 - Ethical considerations

(a) The laboratory shall conform to ethical professional practice. Public announcements of the laboratory shall be strictly limited to cover only tests for which a certificate is granted and shall be so worded as not to give the impression of general coverage of procedures not listed on the certificate.

(b) Reports shall be confined to laboratory findings; pertinent data may be added when required to interpret properly the examination results.

Regulation 9 - Reporting by laboratory supervisors

Laboratory supervisors shall:

(a) immediately report results of laboratory examinations of specimens of humans, animals, or birds indicating or suggesting the existence of communicable diseases to the State Department of Health, to the physician or veterinarian submitting the specimen and, excepting results pertaining to venereal diseases, simultaneously forward a copy thereof to the health officer having jurisdiction where the patient is located.

(b) immediately report results of laboratory examinations of specimens of persons being considered for release from isolation or quarantine from any disease listed in Chapter II, Regulation I of the State Sanitary Code, whether said report be positive or negative, to the physician submitting the specimen and simultaneously forward a copy thereof to the health officer having jurisdiction where the patient is located.

(c) promptly report to the State Department of Health the results of comparative and evaluation examinations made of specimens which may be sent to the laboratory by the Department.

Regulation 10 - Inspection and registration concerning handling of live microorganisms or viruses pathogenic for humans, animals, 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 State 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 State 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 Regulation.

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.

Regulation 11 - Sale, transportation or other disposal of live microorganisms or viruses pathogenic for humans, animals, or birds

Live microorganisms or viruses pathogenic for humans, animals, or birds shall not be sold, knowingly transported or otherwise disposed of in viable form without written permission of the State 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.