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**NEW JERSEY STATE
SANITARY CODE**

New Jersey State
Department of Health
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**CHAPTER IV
LABORATORIES**

(Promulgated 1978)

The Public Health Council in the Department of Health, pursuant to authority of N.J.S.A. 45:9-42.34, has adopted new rules for the operation of clinical laboratories under the New Jersey Clinical Laboratory Improvement Act. N.J.S.A. 45:9-42.26 et seq. These regulations will be cited as N.J.A.C. 8:44-2.1 et seq.

Regulation 1. Definitions

(a) All terms not defined shall have the meaning given them in the Act.

(b) Accredited. The term "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 N.J. State Board of Higher Education.

(c) Consultation. A "consultation" is 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.

(d) Personal and direct supervision. The phrase "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.

(e) In vitro Radioassay. The term "radioassay" means the analysis following the administration of a radioactive material to a patient or the addition of a radionuclide to a body fluid from a patient and the subsequent analysis of the body fluid, or excreta in order to evaluate body function. This definition excludes scanning and in vivo measurements.

(f) Subsequent to graduation. The phrase "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.

(g) Substitution of education for experience. The phrase "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.

(h) Trainee. The term "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.*

(i) True duplicate means a carbon or other mechanical copy.

(j) Physician means any person licensed to practice medicine and surgery by the N.J. Board of Medical Examiners.

Regulation 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 regulations 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.).

Regulation 3.

The Public Health Council on the advice of the Commissioner may promulgate, enforce and may amend or repeal those regulations that at any given time shall be no less stringent than the complete interim or revised national laboratory regulations in effect at that time.

Regulation 4. Laboratory Director

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

(a) Administration. 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 Director—Qualifications

The laboratory director shall hold a valid, current license as a bioanalytical laboratory director issued pursuant to P.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 (ii) is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties, or (iii) is certified by the American Society of Cytology to practice cytopathology or possesses qualifications which are equivalent to those required for such certification (under this provision the individual may qualify as a director only in the specialty of Cytology), or (iv) subsequent to graduation has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in an approved clinical laboratory;
- (3) Holds an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (i) is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the Ameri-

can Board of Bioanalysis, or other national accrediting board acceptable to the Department of Health in one of the laboratory specialties, or (ii) subsequent to graduation has had 4 or more years of full-time general clinical laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in an approved clinical laboratory; or

- (4) The requirements of b(1), (2), (3) do not apply to individuals who qualified as a bioanalytical director and were licensed pursuant to P.L. 1953, c. 420 (N.J.S.A. 45:9-42.1 et seq.) prior to adoption of these regulations.

Regulation 5. Supervision

The clinical laboratory shall be supervised by qualified personnel.

(a) Supervision. The laboratory shall have one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, are held responsible for the proper performance of all laboratory procedures. A laboratory director who qualifies under §4(b) (1), (2), (3), or (4) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor.

- (1) Required supervisors. There are two categories of required supervisors. A general supervisor—one who meets the requirements of paragraph (b) of this section—is on the laboratory premises during all hours in which tests are being performed. With respect to the specialty of diagnostic cytology, cytotechnologists do not examine slide preparations unless a supervisor who qualifies pursuant to the provisions of paragraph (b)(4) of this section or section 6(b)(8) is on the premises at all times. A technical supervisor—one who meets the pertinent requirements of section 6(b)—spends an adequate amount of time in the laboratory to supervise the technical performance of the staff in the specialty and is readily available for personal or telephone consultation. A general supervisor may also be a technical supervisor in those specialties in which the requirements of §6(b) are met.
- (2) Supervision of emergency procedures. When emergencies arise outside regularly scheduled hours of duty, an individual who qualifies as a general supervisor is not required to be on the premises provided that the technologist performing tests is qualified to perform such tests. The supervisor, who is responsible for the results of the work, reviews them during the next duty period, and a record is maintained to reflect the actual review. *Nighttime, week-end, or holiday duty hours shall be considered as Emergency Procedures.*

(b) General supervisor—qualifications. The laboratory supervisor shall meet one of the following requirements:

- (1)(i) Is a physician, or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and (ii) subsequent to graduation has had at least

- 2 years of experience in one of the laboratory specialties in an approved clinical laboratory;
- (2)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and (ii) subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in an approved clinical laboratory;
 - (3)(i) Is qualified as a clinical laboratory technologist pursuant to the provisions of §7(b)(1), (2), (3), (4), or (6) and (ii) subsequent to the date of qualifying as a clinical laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in an approved clinical laboratory;
 - (4) With respect to the specialty of diagnostic cytology, qualifies as a supervisory cytotechnologist because he: (i) is qualified as a cytotechnologist pursuant to the provisions of §7(c) and (ii) has within the preceding 10 years had 4 years of full-time experience as a cytotechnologist in a laboratory directed or supervised by a pathologist or other physician certified as a specialist in diagnostic cytology or;
 - (5) With respect to individuals first qualifying prior to July 1, 1971, has had at least 15 years of pertinent full-time clinical laboratory experience prior to January 1, 1968; this required experience may be met by the substitution of education for experience.

Regulation 6. Tests Performed

The clinical laboratory shall perform only those laboratory tests and procedures that are within the specialties or subspecialties for which the laboratory is licensed.

(a) Proficiency testing. All clinical laboratories must successfully participate in a proficiency testing program covering all clinical laboratory specialties and subspecialties as made available in which the laboratory is approved to perform tests. Laboratories shall: (1) receive and examine and/or analyze specimens delivered by mail or messenger at such times as designated by the proficiency testing service; and (2) maintain records of all proficiency testing results in programs in which it is a participant and make such records, including results and interpretations routinely available to the Department of Health. An exception to the requirements of this paragraph may be made provided the Department of Health determines that an appropriate proficiency testing program is not readily available.

(b) Procedures and tests—competency. The laboratory shall perform only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director or supervisors are qualified.

(1) If the laboratory director or supervisor 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 certification (board eligible), the laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties.

- (2) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, virology, mycology, and parasitology, the director or a supervisor (i) holds an earned doctoral or master's degree in microbiology from an accredited institution or is a physician, and (ii) subsequent to graduation has had at least 4 years of experience in clinical microbiology.
- (3) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of serology, the director or a supervisor (i) holds an earned doctoral or master's degree in biology, chemistry, immunology, or microbiology from an accredited institution or is a physician and, (ii) subsequent to graduation has had at least 4 years experience in serology.
- (4) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of hematology, including gross and microscopic examination of the blood, the director or a supervisor (i) holds a master's or a bachelor's degree in biology, immunology, microbiology, or chemistry, or medical technology from an accredited institution, and (ii) subsequent to graduation has had at least 4 years of experience in hematology.
- (5) If the requirements of paragraph (b)(1) of this section are not met and (i) the laboratory performs tests in the specialty of immunohematology, the director or a supervisor is a physician with at least 2 years of experience in immunohematology subsequent to graduation; or (ii) within the specialty of immunohematology, the laboratory performs tests in the subspecialties of ABO grouping and Rh typing, antibody detection, identification, and titrating only, the director or a supervisor holds a master's or bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution and subsequent to graduation has had at least 4 years of experience in immunohematology.
- (6) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of clinical chemistry, the director or a supervisor (i) holds an earned doctoral or master's degree in chemistry from an accredited institution or is a physician, and (ii) subsequent to graduation has had at least 4 years of experience in clinical chemistry.
- (7) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of radioassay, the director or a supervisor (i) holds an earned doctoral, master's or bachelor's degree in chemistry, physics, biology, or medical technology from an accredited institution or is a physician, and (ii) subsequent to graduation has had at least 4 years of experience in radioassay.
- (8) If the requirements of paragraph (b)(1)(i) of this section are not met and the laboratory performs tests in the specialty of diagnostic cytology, the director or a supervisor, (i) is a physician who is certified by the American Society of Cytology to practice cytopathology or possesses qualifications which are

equivalent to those required for certification (under this provision the laboratory is qualified to perform such tests only on that anatomic site for which the director or supervisor is certified); or (ii) is an individual who, pursuant to a request to establish his qualifications filed prior to January 1, 1971, has demonstrated competency (A) through at least 7 years of accumulative experience in a position of diagnostic responsibility in the field of clinical cytology, or through 5 years of full-time training in diagnostic clinical cytology with suitable endorsement by a physician who has been supervisor in such activity; (B) by the publishing of treatises, texts, or other publications on the subject of diagnostic cytology which are generally acknowledged and recognized by the medical profession as authoritative in the field; (C) by appointment to and service in pertinent teaching and research positions in recognized schools of medicine; (D) by acceptance into or award of membership and office in professional societies in this field; and (E) by receipt of other professional honors for excellence in the use of procedures in exfoliative cytology for the diagnosis of a pathological condition (under this provision the laboratory is qualified to perform such tests only on that anatomic site with respect to which such competency is so established). An individual who qualified under this paragraph (b) (8)(ii) is deemed also to meet the requirements of §4(b)(2)(iii).

- (9) An exception to the requirements in paragraphs (b)(2), (3), (4), (5)(ii), (6), and (7) of this section is made with respect to an individual who qualifies as a director under §4(b)(4). The laboratory such individual directs may perform tests in:
- (i) Microbiology: If the director has a bachelor's degree in a biological science and subsequent to graduation has had at least 6 years of experience in microbiology;
 - (ii) Hematology: If the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of clinical laboratory experience of which at least 4 years of experience are in hematology;
 - (iii) Serology: If the director has a bachelor's degree in biology, chemistry, immunology, or microbiology and subsequent to graduation has had at least 6 years of experience in serology;
 - (iv) In vitro Radioassay: If the director has a bachelor's degree in a chemical, physical, or biological science and subsequent to graduation has had at least 6 years of laboratory experience, at least 1 year of which is in radioassay;
 - (v) Blood grouping and Rh typing, antibody detection, identification, and titring: If the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of clinical laboratory experience of which at least 4 years of experience are in immunohematology;
 - (vi) Clinical chemistry: If the director has a

bachelor's degree in a chemical science or its equivalent and subsequent to graduation has had at least 6 years of experience in clinical chemistry;

- (vii) Any of the above specialties: If the director has a bachelor's degree in medical technology and subsequent to graduation has had at least the designated years of specialized experience.

Regulation 7. Technical Personnel

The clinical laboratory shall have a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.

(a) Technologist—duties. The laboratory shall employ a sufficient number of clinical laboratory technologists and/or cytotechnologists to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment.

(b) Technologists—qualifications. Each clinical laboratory technologist shall:

- (1) Have earned a bachelor's degree in medical technology from an accredited college or university; or
- (2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary of the United States Department of Health, Education and Welfare, and have successfully completed a course of training of at least 12 months in such a school; or
- (3) Have earned a bachelor's degree in one of the chemical, physical or biological sciences and, in addition, have at least 1 year of pertinent full-time laboratory experience and/or training in the specialty or subspecialty in which the individual performs tests; or
- (4) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses:
 - (i) For those whose training was completed prior to September 15, 1963. At least 24 semester hours in chemistry and biology courses of which:
 - (A) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses, and
 - (B) At least 12 semester hours in biology courses pertinent to the medical sciences, or
 - (ii) For those whose training was completed after September 14, 1963.
 - (A) 16 semester hours in chemistry courses which included at least 6 semester hours in inorganic chemistry and which are acceptable toward a major in chemistry; and
 - (B) 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and
 - (C) 3 semester hours of mathematics; and

- (iii) Have experience and/or training covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or
- (5) With respect to individuals first qualifying prior to July 1, 1971; the technologist:
 - (i) Was performing the duties of a clinical laboratory technologist at any time between July 1, 1961, and January 1, 1968, and
 - (ii) Has had at least 10 years of pertinent clinical laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience) *or*
- (6) Have achieved a satisfactory grade in a proficiency examination approved by the Secretary of the United States, Department of Health, Education and Welfare.
 - (c) Cytotechnologists—qualifications. Each laboratory cytotechnologist shall:
 - (1) Have successfully completed 2 years in a accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and (i) have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by the Secretary of the United States Department of Health, Education and Welfare, or (ii) have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by the Secretary and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal 6 months of training; or
 - (2) Prior to January 1, 1969, have (i) been graduated from high school, (ii) completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and (iii) completed 2 years of full-time supervised experience in cytotechnology; or
 - (3) Have achieved a satisfactory grade in a proficiency examination approved by the Secretary of the United States Department of Health, Education and Welfare.
 - (d) Technician—duties. Clinical laboratory technicians shall be employed in sufficient number to meet the workload demands of the laboratory and shall function only under direct supervision of a clinical laboratory technologist.
 - (1) Each technician shall perform only those clinical laboratory procedures which require a degree of skill commensurate with the education, training, and technical abilities and which involve limited exercise of independent judgment.
 - (2) No clinical laboratory technician shall perform procedures in the absence of a qualified clinical laboratory technologist, supervisor, or director.
 - (3) A technician trainee shall perform only those procedures under the personal and direct supervision of a qualified supervisor or technologist for which the trainee has received formal instruction and has demonstrated competency.
 - (e) Technician—qualifications. Each clinical laboratory technician shall meet one of the following requirements:
 - (1) Has successfully completed 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or have an associate degree based on a course of study including those subjects from an accredited institution;
 - (2) Is a high school graduate or equivalent and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by the Secretary of the United States, Department of Health, Education and Welfare; and/or the N.J. State Board of Higher Education;
 - (3) Is a high school graduate or equivalent and has 2 years of pertinent full-time laboratory experience as a technician trainee in an approved clinical laboratory;
 - (4) Is a high school graduate or equivalent and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).
 - (f) Personnel policies. There shall be written personnel policies, practices, and procedures that adequately support sound laboratory practice.
 - (1) Current employee records shall be maintained and include a resume of each employee's training, experience, duties, and date or dates of employment.
 - (2) Files shall contain evidence of adequate health supervision of employees, such as results of preemployment physical examinations, including P.P.D. tuberculin test followed by chest X-rays when indicated, immunization records, and records of all illnesses and accidents occurring on duty.
 - (3) Work assignments shall be consistent with qualifications.

Regulation 8. Management

The clinical laboratory shall maintain records and facilities which are adequate and appropriate for the services offered.

(a) Workrecords. Workrecords of quantitative tests must be maintained and these records must indicate final results together with all corresponding instrument readings and calculations. Where instrumentation produces tracings or printouts of results, these tracings or printouts must be retained and may serve as the workrecord.

(b) Laboratory procedure manual. A compilation shall be kept of all automated and manual methods for tests which are performed in or offered by the laboratory. Each procedure shall be reviewed and dated by the technical supervisor at least annually. For those tests which are normally performed on automated test equipment, provision shall be made and documented for performing such tests by alternate methods, or for storing the test specimens, in the event this equipment becomes inoperable.

(c) Laboratory management. Space and facilities shall be adequate to properly perform the services which are performed in or offered by the laboratory.

- (1) Workbench space shall be ample, well-lighted, and convenient to sink, water, gas, and suction and electrical outlets as necessary.
 - (2) Work areas shall be arranged so as to minimize problems in transportation and communication.
 - (3) The laboratory shall be properly ventilated.
 - (4) Volatile chemicals and inflammable solvents shall be properly stored as specified by O.S.H.A.
 - (5) Temperature and humidity shall be controlled within limits required for proper performance of tests and operation of instruments affected by these variations.
 - (6) Voltage levels at electrical sources to which automated equipment is connected shall be monitored and recorded.
 - (7) Adequate fire precautions and occupational safety and health laws shall be known, posted, and observed insuring that there is freedom from physical, chemical, and biological hazards.
- (d) Collection of specimens. No persons other than a licensed physician, or one otherwise authorized by law, shall manipulate a patient for the collection of specimens except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction, or upon the written request of a licensed physician.
- (e) Sterilization. Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall not be reused unless they are properly sterilized prior to each use and wrapped in a manner which will insure that they remain sterile until used. Appropriate sterilization and disinfection techniques shall be utilized, as required, for tests performed on potentially contaminated material and for the protection of laboratory personnel. Disposable syringes, needles, pipettes, Petri dishes, and other disposable items shall be destroyed immediately after use as stipulated in N.J.S.A. 2A:170-25.17. Each sterilizing cycle shall contain a device which indicates proper sterilization and a record kept of time, temperature, pressure and type of indicator. Proper operation of the autoclave shall be checked monthly with viable spores.
- (f) Examination and reports. The laboratory shall examine specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and shall report only to those authorized by law to receive such results.
- (1) If the patient is sent to the laboratory, a written request for the desired laboratory procedures must be obtained from a person authorized by law to use findings of laboratory examination.
 - (2) If only a specimen is sent, it must be accompanied by a written request.
 - (3) If the laboratory receives reference specimens from another laboratory, it shall report back to the laboratory submitting the specimens.
- (g) Specimens—records. The laboratory shall maintain a record indicating the daily accession of specimens, each of which is numbered or otherwise appropriately identified. Records shall contain the following information:
- (1) The laboratory number or other identification of the specimen.
 - (2) The name and other identification of the person from which the specimen was taken.
 - (3) The name of the licensed physician or other authorized person or clinical laboratory which submitted the specimen.
 - (4) The date the specimen was collected by the physician or other authorized person.
 - (5) The date the specimen was received in the laboratory.
 - (6) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed, or turbid, etc.).
 - (7) The type of test performed.
 - (8) The date that test was performed.
 - (9) The results of the laboratory test or cross-reference to results and the date of reporting.
 - (10) The name and address of the laboratory to which forwarded if the procedure is not performed at this laboratory.
- (h) Laboratory report and record. The original or true duplicate of the laboratory report shall be sent promptly to the licensed physician or other authorized person who requested the test and all reports shall be preserved by the laboratory for a period of at least 2 years after the date of submittal of the report. Laboratory reports of fully automated, multicomponent testing must consist of, *or have attached*, instrument tracings or true duplicates of such tracings *or computer printout of test results*.
- (1) The laboratory director is responsible for the laboratory report.
 - (2) True duplicate copies or a suitable record of laboratory reports shall be filed in the laboratory in a manner which permits ready identification and accessibility.
 - (3) The results of laboratory tests or procedures or transcripts thereof shall be sent to the *licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations*. *The patient may request a copy of such reports*. The laboratory may charge a reasonable fee for copying.
 - (4) Pertinent “normal” ranges as determined by the laboratory performing the tests shall be available to the physician requesting such tests.
 - (5) A list of analytical methods employed by the laboratory and a basis for the listed “normal” range shall be maintained in the laboratory. The list shall be made available to any physician ordering an examination upon request.
 - (6) If the laboratory refers specimens to another laboratory, the physician ordering an examination shall receive the original reference laboratory report or a true duplicate of that report. The reference laboratory must report its findings on report forms of the reference laboratory. If the physician so requests, the referring laboratory may authorize the testing laboratory to report directly to the physician or other authorized person who requested the test, in which event the testing laboratory must send a duplicate of the report to the referring laboratory.

Regulation 9. Quality Control

- (a) General. Quality controls imposed and practiced by

the laboratory must provide for and include written records to assure:

- (1) Preventative maintenance, periodic inspection, and testing for proper operation of equipment and instruments as may be appropriate; validation of methods; evaluation of reagents and volumetric equipment; surveillance of results; and remedial action to be taken in response to detected defects.
 - (2) Adequacy of facilities, equipment, instruments, and methods for performance of the procedures or categories of procedures for which licensure is approved; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature-controlled spaces and equipment, including water baths, incubators, sterilizers, and refrigerators, to assure proper performance; evaluation of analytical measuring devices, such as photometers and radioactivity counting equipment, with respect to all critical operating characteristics. Records must reflect actual readings obtained both before and after any adjustments have been made.
 - (3) Labeling of all reagents and solutions to indicate identity, and when significant, titer, strength, or concentration, recommended storage requirements, preparation or expiration date, and other pertinent information. Materials of substandard reactivity and deteriorated materials may not be used. All outdated material must be discarded immediately.
 - (4) The availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category (e.g., clinical chemistry, hematology), of current laboratory manuals or other complete written descriptions and instructions relating to (i) the analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews, (ii) reagents, (iii) control and calibration procedures, and (iv) pertinent current literature references. Textbooks may be used as supplements to such written descriptions but may not be used in lieu thereof.
 - (5) Written approval by the director or supervisor of all changes in laboratory procedures.
 - (6) Maintenance and availability to laboratory personnel and to the Department of Health of records reflecting dates and, where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, and changes and dates of changes in laboratory procedures.
 - (7) A laboratory shall accept only specimens which have been properly collected, labeled, processed, stored and transported in such a manner as to assure identity and the stability of the specimen with respect to the requested tests or analyses; or if a specimen's stability has not been assured the laboratory report shall clearly state that the results may be invalid due to an unsatisfactory sample.
- (b) Quality Control System Methodologies. Provision shall be made for an acceptable quality control program covering all types of analysis performed by the laboratory for verification and assessment of accuracy, measurement of precision, and detection of error.
- (1) Microbiology. Chemical and biological solutions, reagents, media, antibiotic discs and antisera shall be tested and inspected each day of use for reactivity and deterioration, and the results of such tests and inspections shall be recorded.
 - (i) Bacteriology and mycology. Staining materials shall be tested for intended reactivity by concurrent application to smears of microorganisms with predictable staining characteristics. Each batch of medium shall be tested and results recorded before or concurrently with use with selected organisms to confirm required growth characteristics, selectivity, enrichment, biochemical response, and sensitivity.
 - (ii) Parasitology. A reference collection of slides, photographs, or gross specimens of identified parasites shall be available and used in the laboratory for appropriate comparison with diagnostic specimens. A calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor.
 - (iii) Virology. Systems for the isolation of viruses and reagents for the identification of viruses shall be available to cover the entire range of viruses which are etiologically related to clinical diseases for which services are offered. Records shall be maintained which reflect the systems used and the reactions observed. In tests for the identification of viruses, controls shall be employed which will identify erroneous results. If serodiagnostic tests for virus diseases are performed, requirements for quality control as specified for serology shall apply.
 - (2) Serology
 - (i) Serologic tests on unknown specimens shall be run concurrently with a positive control serum of known titer or controls of graded reactivity plus a negative control in order to detect variations in reactivity levels. Controls for all test components (antigens, complement, erythrocyte indicator systems, etc.), shall be employed to insure reactivity and uniform dosage. Tests results shall not be reported unless the predetermined reactivity pattern of the controls is obtained.
 - (ii) Each new lot of reagent shall be tested concurrently with one of known acceptable reactivity before the new reagent is placed in routine use.
 - (iii) Equipment, glassware, reagents, controls, and techniques for tests for syphilis shall conform to those recommended in the "Manual of Tests for Syphilis 1969," U.S. Public Health Service Publication No. 411, January 1969.
 - (3) Clinical Chemistry
 - (i) Each instrument or other device shall be recalibrated or rechecked at least once on each day of use. Records which document the routine precision of each method, automated or manual, and its recalibration schedule shall be maintained and be available to laboratory personnel and the Department of Health. At least one standard and one reference sample (control) or two controls shall be included with each

batch of twenty or a fraction thereof of unknown specimens where such standards and reference samples are available. Control limits for standards and reference samples shall be recorded and displayed and shall include the course of action to be instituted when the results are outside the acceptable limits.

- (ii) Screening or qualitative chemical urinalysis shall be checked daily by use of suitable reference samples.
- (4) Immunohematology
- (i) ABO grouping shall be performed by testing unknown red cells with anti-A and anti-B grouping serums licensed under Part 73, Title 42, Code of Federal Regulations, or possessing equivalent potency, using the technique for which the serum is specifically designed to be effective. For confirmation of ABO grouping, the unknown serum shall be tested with known A1 and B red cells.
 - (ii) The Rho (D) type shall be determined by testing unknown red cells with anti-Rho (anti-D) typing serum licensed under 42 CFR Part 73, or possessing equivalent potency, using the technique for which the serum is specifically designed to be effective. Anti-Rho' (CD), anti-Rho'' (DE), and anti-Rho rh'rh'' (CDE) serums licensed pursuant to 42 CFR Part 73, or possessing an equivalent potency may be used for typing blood. All Rho negative cells shall be tested for the Rho variant (Du). A control system of patient's cells suspended in his own serum or in albumin shall be employed when the test is performed in a protein medium.
 - (iii) The potency and reliability of reagents (antisera, known test cells, and antiglobulin-Coombs serum) which are used for ABO grouping, Rh typing, antibody detection and compatibility determinations must be tested for reactivity on each day of use and when a new lot of reagents is first used.
- (5) Hematology. Instruments and other devices used in hematological examination of specimens shall be recalibrated, retested or reinspected, as may be appropriate, each day of use. Each procedure for which standards and controls are available shall be rechecked each day of use with standards or controls covering the entire range of expected values. Tests such as the one-stage prothrombin time test shall be run in duplicate concurrently with both normal and abnormal controls and results recorded. Reference materials, such as hemoglobin pools and stabilized cells shall be tested at least once for each 8-hour shift of each day of use to insure accuracy of results. Standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by random replicate testing of specimens. The accuracy and precision of blood cell counts, hematocrit and hemoglobin measurements shall be tested each day of use.
- (6) Exfoliative cytology. The laboratory director or supervisor qualified in cytology or cytotechnologist shall rescreen for proper staining and correct in-

terpretation at least a 10-percent random sample of gynecological smears which have been interpreted to be in one of the benign categories by personnel not possessing director or supervisor qualifications. All gynecological smears interpreted to be in the "suspicious" or positive categories by screeners shall be confirmed by the laboratory director or qualified supervisor and the report shall be signed by a physician qualified in pathology or cytology. All nongynecological cytological preparations, positive and negative, shall be reviewed by a director or supervisor qualified in cytology. Nonmanual methods shall provide quality control similar to that provided in other nonmanual laboratory procedures. All benign smears shall be retained for not less than two years from the date of examination. All other smears shall be retained indefinitely.

- (7) Radioassay. The counting equipment shall be checked for stability at least once on each day of use, with radioactive standards or reference sources similar in energy activity to those isotopes used for clinical assay to be processed daily. At least one standard and one reference sample (control) or two controls shall be included with each batch of twenty or fraction thereof of unknown specimens where such standards and reference samples are available. For each method, records which document the routine precision and the recalibration schedule shall be maintained and be available to the staff and to the Department of Health.

Regulation 10. 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 1 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 11. 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 of 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 12. 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.