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

As amended, R.1983 d.498, effective November 7, 1983.
See: 15 N.J.R. 846(a), 15 N.J.R. 1862(b).

8:44–2.4 Supervision

(a) The clinical laboratory shall be supervised by qualified personnel.

(b) The laboratory shall have one or more supervisors who, under the general discussion of the laboratory director, supervise technical personnel and report 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 subsection (c) of this section 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 subsection (c) 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 side preparations unless a supervisor who qualifies pursuant to the provisions of paragraph 4 of subsection (c) of this section or N.J.A.C. 8:44–1.5(c)8 is on the premises at all times. A technical supervisor—one who meets the pertinent requirements of N.J.A.C. 8:44–1.5(c)—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 N.J.A.C. 8:44–1.5(c) 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. Night time, week-end, or holiday duty hours shall be considered as Emergency Procedures.

(c) The laboratory supervisor shall meet one of the following requirements:

1. 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 subsequent to graduation has had at least 2 years of experience in one of the laboratory specialties in an approved clinical laboratory;

2. Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in an approved clinical laboratory;

3. Is qualified as a clinical laboratory technologist pursuant to the provisions of section 6 of this subchapter and 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 section 6 of this subchapter and

ii. Has within the preceding 10 years has 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 individual 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.

8:44–2.5 Tests performed

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

(b) All clinical laboratories shall enroll and successfully participate in either the Department of Health proficiency testing (PT) program, or specifically designated surveys in the College of American Pathologists' CAP Surveys Program or the American Association of Bioanalysts (AAB) PT Program. Enrollment in the CAP Surveys or AAB PT Programs must cover all clinical laboratory specialties, analytes and/or subspecialties for which a given laboratory is approved to perform tests which have been designated by the Department as requiring proficiency testing. Laboratories shall: enroll and participate in proficiency testing surveys appropriate to their level of service; receive and examine and/or analyze specimens delivered by mail or messenger, at such times as designated by the proficiency testing provider; and maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health. The Department of Health shall reserve authority to regrade data from the CAP Surveys Program or the AAB PT Program (that is, survey scores and cumulative performance interpretations) through the Clinical Laboratory Improvement Service according to its own licensing standards. Any report issued by the CAP Surveys Program or the AAB PT Program by itself shall not be construed as determinative of compliance with the New Jersey licensing standards. An exception to the enrollment requirements of this subsection may be made, provided the Department of Health determines that an appropriate proficiency testing survey is not readily available.

(c) 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 1 of this subsection 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 doctorate 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 1 of this subsection 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 1 of this subsection 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 1 of this subsection 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 titering 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 1 of this subsection 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 1 of this subsection 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 1 of this subsection 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 qualified filed prior to January 1, 1971, has demonstrated competency:

(1) 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;

(2) 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;

(3) By appointment to and service in pertinent teaching and research positions in recognized schools of medicine;

(4) By acceptance into or award of membership and office in professional societies in this field; and

(5) 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 is deemed also to meet the requirements of paragraph 1 of this subsection.

9. An exception to the requirements in paragraphs 2 through 7 of this subsection is made with respect to an individual who qualifies as a director under paragraph 3 of this subsection. The laboratory such individual directs may perform tests in the following:

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 titering: 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.

Amended by R.1995 d. 239, effective May 15, 1995.
See: 27 N.J.R. 626(a), 27 N.J.R. 1985(a).

8:44–2.6 Technical personnel

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

(b) 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.

(c) 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:

(1) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(2) 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:

(1) 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

(2) 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(3) Three 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 1 and 2 of this subsection; 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. Achieved a satisfactory grade in a proficiency examination approved by the Secretary of the United States, Department of Health, Education and Welfare.

(d) Each laboratory cytotechnologist shall:

1. Have successfully completed 2 years in an 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. Achieved a satisfactory grade in a proficiency examination approved by the Secretary of the United States, Department of Health, Education and Welfare.

(e) 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.

(f) Each clinical laboratory technician shall meet one of the following requirements:

1. Have 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;