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 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) 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 micro-organisms 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. Test results shall not be reported unless the predetermined reactivity pattern of the controls is obtained.

ii. Each new lot of reagant shall be tested concurrently with one of known acceptable reactivity before the new reagent is placed in routine use.

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. Immuno-hematology:

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 BO 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 examinations 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 interpretation 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 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.

Amended by R.1993 d.498, effective November 7, 1983.
See: 15 N.J.R. 995(a), 15 N.J.R. 1862(a).
In (b)2, deleted old iii. concerning tests for syphilis.

8:44–2.9 Amendments

The Public Health Council on the advice of the Commissioner may promulgate, enforce and may amend or repeal these 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.

8:44–2.10 Public Health Council

The Public Health Council on the advice of the Commissioner may promulgate, enforce and may amend or repeal these 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.

8:44–2.11 Reporting by laboratory supervisors

(a) Laboratory supervisors shall:

1. Immediately report results of laboratory examinations of specimens of humans, animals, or birds indicating or suggesting the existence of communicable diseases to the 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;

2. Immediately report results of laboratory examinations of specimens of persons being considered for release from isolation or quarantine from any disease listed, 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;

3. Promptly report to the Department of Health the results of comparative and evaluation examinations made of specimens which may be sent to the laboratory by the Department.

(b) Laboratory supervisors shall immediately report to the State Department of Health, results of laboratory examinations indicating levels of hazardous substances in blood and urine equal to or greater than the following:

1. Lead:

i. Blood lead levels equal to or greater than 25 μg/dL in individuals greater than 16 years of age;

ii. Blood lead levels equal to or greater than 20 μg/dL in children up to and including 16 years of age;

iii. 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).

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. (RESERVED)