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PART 58
CLINICAL LABORATORIES AND BLOOD BANKS
(Statutory authority: Public Health Law, sections 574(1), 576;
Vehicle and Traffic Law, section 1194)

Subpart 58-1 Clinical Laboratories
Subpart 58-2 Blood Banks
Subpart 58-3 Clinical Laboratory Inspection and Reference Fees
Subpart 58-4 Repealed
Subpart 58-5 Hematopoietic Progenitor Cell Banks
Subpart 58-6 Repealed
Subpart 58-7 Repealed
Subpart 58-8 Human Immunodeficiency Virus (HIV) Testing

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CLINICAL LABORATORIES

Sec.

58-1.1 Permit.
58-1.2 Laboratory director.
58-1.3 Clinical laboratory supervision.
58-1.4 Qualifications of laboratory supervisor.
58-1.5 Duties and qualifications of clinical laboratory technical personnel.
58-1.6 Physical facilities.
58-1.7 Acceptance of specimens.
58-1.8 Results of tests to be reported only to physicians or other authorized persons.
58-1.9 Testing to be done on premises except in certain instances.
58-1.10 Specimens: identification and examination.
58-1.11 Reports and records.
58-1.12 Cytopathology standards and quality assurance.
58-1.13 General requirements for performance of anatomic pathology and cytopathology procedures.

Section 58-1.1 Permit.

(a) Permit means a clinical laboratory or blood bank permit issued by the Commissioner of Health. No clinical laboratory or blood bank shall be issued a permit in a category unless:

(1) its director or assistant director holds a certificate of qualification in the category for which the permit is sought;

(2) the laboratory has been inspected and has corrected any deficiencies found; and

(3) the laboratory has successfully participated in all required proficiency examinations or remedial activities in the categories sought.

(b) A clinical laboratory or blood bank shall perform only those tests that are within the categories stated on its permit. Specimens for all other tests shall be referred to a clinical laboratory with a permit in the appropriate category. Categories of tests shall be designated according to the following procedures or specialties:

(1) one or more of the following subspecialties of microbiology: bacteriology, virology, mycology, parasitology, and mycobacteriology;
(2) hematology;

(3) blood services-diagnostic immunohematology, collection and/or transfusion;

(4) one or more of the following subspecialties of clinical biochemistry: clinical chemistry, blood pH and gases, endocrinology, and therapeutic substance monitoring/quantitative toxicology;

(5) histopathology or one or more of the following subspecialties: dermatopathology and oral pathology;

(6) cytopathology;

(7) urinalysis;

(8) one or more of the following subspecialties of toxicology: drug analysis-qualitative, blood lead and erythrocyte protoporphyrin, forensic toxicology, and chlorinated hydrocarbons;

(9) cytogenetics;

(10) human immunodeficiency virus (HIV) testing;

(11) histocompatibility;

(12) diagnostic immunology;

(13) cellular immunology;

(14) oncofetal antigens; and

(15) other specific tests or procedures as designated by the department.

(c) In performance of laboratory procedures stated on its permit, a blood bank shall meet the appropriate requirements in Subpart 58-2 and sections 58-1.2 through 58-1.6, 58-1.9, 58-1.10 and 58-1.11 of this Subpart.

(d) A provisional permit shall be available which shall be valid for a period determined by the Department to be sufficient to enable the department to assess the proficiency of the laboratory in the categories sought. The provisional permit may be renewed pending issuance or denial of a permit if initial proficiency test results are
inconclusive.

(1) A clinical laboratory or blood bank initially applying for permit may be issued a provisional permit when the laboratory meets the following conditions:

   (i) a valid and complete permit application has been filed; and
   
   (ii) application and reference fees have been paid; and

   (iii) the director or assistant director holds a Certificate of Qualification in all categories sought; and

   (iv) the laboratory has been inspected by the department and has provided satisfactory evidence of correction of any deficiencies found.

(2) Provisional permits shall not be available in the categories of cytogenetics-general, mycology, mycobacteriology, human immunodeficiency virus screening and/or confirmatory testing, or virology.

(3) A clinical laboratory or blood bank which has failed to demonstrate its proficiency in testing specimens in a category may, after successful participation in a remediation program, including proficiency testing, be granted a provisional permit.

(4) If the director or any owner of the laboratory applying for a provisional permit has ever directed or owned a laboratory which has had its permit revoked, suspended, limited or annulled, or which has an enforcement proceeding against it pending at the time of application for a provisional permit, a provisional permit shall not be issued. Owner shall include any individual, corporation, partner or other person holding a 10 percent or more interest in the laboratory.

(5) Provisional permits may be revoked, suspended, limited or annulled, or the holder thereof may be censured, reprimanded or otherwise disciplined in accordance with the Public Health Law, including section 577 thereof.

(6) A provisional permit in a category may be converted to a permit when the laboratory has demonstrated to the satisfaction of the department its proficiency in testing specimens in that category.

58-1.2 Laboratory director.

(a) The director shall serve the laboratory full time, or on a regular part-time basis. Regular part-time basis shall mean assumption of full responsibility for direction and technical operation of the laboratory, including adherence to the department's quality control standards and training of personnel performing the testing. If he serves
on a regular part-time basis, he shall not serve as director of more than two clinical laboratories, within or outside New York State, or more than one clinical laboratory and one blood bank or more than two blood banks. Where a laboratory and a blood bank are on the same premises and are under the supervision of the same director, such laboratory and blood bank shall be deemed one laboratory for the purpose of this subdivision. Notwithstanding the foregoing provisions of this subdivision, if the commissioner finds that more than two laboratories are required to serve the needs of an area and the total volume and the types of laboratory service provided by the several laboratories are not such as to require the services of more than one director, he may authorize an individual to direct more than two laboratories or blood banks or combinations thereof. Such authorization must be renewed at least every two years. The commissioner may also make an exception where the additional directorships involve only blood-holding facilities as defined in section 58-2.1(i) of this Part.

(b) Commensurate with the laboratory workload, scope and complexity of the testing procedures carried out, qualifications of on-site personnel, proximity to another laboratory under identical directorship, and availability of alternate monitoring and communication capabilities, 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. The adequacy of the amount of time a laboratory director is present and in active direction shall be determined by the department based on the factors enumerated above, results of on-site inspections and proficiency testing and documentation of the director's full responsibility for direction and technical operation. Attendance records may be required to document the adequacy of the director's presence.

(c) The director shall be responsible for performance of all tests carried out in the laboratory, adherence to the department's quality assurance standards for such tests, and accurate reporting of test results.

(d) The director shall be responsible for ensuring the employment of qualified laboratory personnel, evaluation of job performance of such personnel and their inservice training.

(e) If the director's employment terminates or he is temporarily absent, arrangements shall be made for a qualified temporary director, which arrangements must receive the prior approval of the department. An assistant director who holds a certificate of qualification to be a director of a clinical laboratory or blood bank in the appropriate category may act for the director in the director's absence, and at such time shall fully discharge the duties and responsibilities of the director.

(f) When the director's employment terminates, for whatever reason, both the
owner and the director of the laboratory, or chief executive office of the facility, shall notify the department in writing prior to the termination.

(g) In case of death or physical and/or mental incapacitation of the director, the owner or the chief executive officer must notify the department within 72 hours of such event.

58-1.3 Clinical laboratory supervision.

(a) A clinical 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 responsible for the proper performance of all laboratory procedures.

(b) A laboratory director who qualifies pursuant to the provisions of section 19-2 of this Title shall also be deemed qualified as a supervisor.

(c) Depending upon the size and functions of the laboratory, the department may authorize the laboratory director to also serve as the supervisor of the laboratory.

(d) The supervisor shall be on the laboratory premises during all hours in which tests are performed. An exception to the on-premises requirement shall be applicable with respect to the performance of procedures required for emergency purposes; provided, that the person performing the test qualifies as a medical technologist pursuant to the provisions of section 58-1.5(b) of this Subpart, the results of his work are reviewed by the supervisor or director during his or her next duty period, and a record is maintained to reflect the actual review.

(e) An individual who qualifies as a supervisor pursuant to provisions of section 58-1.4(d) of this Subpart, shall supervise technical personnel in the specialty of cytology only.

58-1.4 Qualifications of laboratory supervisor. The laboratory supervisor must meet one of the following requirements:

(a) The supervisor is a physician licensed to practice medicine or osteopathy in the State of New York or an individual who has earned a doctoral degree from an accredited institution with a chemical, physical or biological science as his major subject (accredited, as used herein, refers to accreditation by a nationally recognized accrediting agency or association, as determined by the United States Commissioner of Education). The supervisor shall, subsequent to graduation, have had at least two years' experience in one of the laboratory specialties in a clinical laboratory or blood
bank having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, a health department, university, medical research institution, or other institution which provides equivalent training.

(b) The supervisor holds a degree of master of arts or master of science from an accredited institution with a major in one of the chemical, physical or biological sciences and, subsequent to graduation, has had at least four years of pertinent laboratory experience of which not less than two years have been spent working in the designated laboratory specialty in a clinical laboratory having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, a health department, university, medical research institution, or other institution which provides equivalent training.

(c) The supervisor is qualified as a medical technologist pursuant to the provisions of section 58-1.5(b) of this Subpart and has had at least six years of pertinent clinical laboratory experience subsequent to qualifying of which at least two years have been spent working in a clinical laboratory having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, university, health department, medical research institution or other institution which provides equivalent training.

(d) The supervisor is qualified as a cytotechnologist pursuant to the provisions of section 58-1.5(c) of this Subpart and subsequent to qualifying, has had at least four years of pertinent clinical laboratory experience in cytotechnology in a laboratory having a doctoral level director qualified in cytopathology. The clinical laboratory shall be part of a hospital, health department, university, medical research institution, or other institution which provides equivalent training.

(e) With respect to individuals first qualifying prior to April 1, 1972, an exception to the requirements in subdivision (a), (b) or (c) of this section may be made if:

1. the supervisor was performing the duties of a clinical laboratory supervisor at any time between July 1, 1961 and September 1, 1971; and

2. the supervisor has had at least 15 years of pertinent clinical laboratory experience prior to September 1, 1971: provided, that a minimum of 30 semester hours of credit toward a bachelor's degree with a chemical, physical or a biological science as his major subject; or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by two years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year; and

3. he has performed the duties of a supervisor for at least two years during the qualifying 15 years in:
(i) a clinical laboratory having a director at the doctoral level, of a hospital, university, health department or medical research institution; or

(ii) in a laboratory approved under the Medicare supplementary medical insurance program, provided also, that where qualifying years in a laboratory described in subparagraph (i) of this paragraph are obtained after January 30, 1969, the laboratory meets applicable conditions under the Medicare health insurance program, or, under title 42, Code of Federal Regulations, part 74, the latter being the regulations issued pursuant to the Federal Clinical Laboratories Improvement Act of 1967.

58-1.5 Duties and qualifications of clinical laboratory technical personnel.

(a) Duties of technologist. The laboratory shall employ a sufficient number of qualified medical technologists, or where appropriate, cytotechnologists, to perform proficiently under general supervision the clinical laboratory tests which require the exercise of independent judgment as follows:

(1) The medical technologists shall perform tests which require the exercise of independent judgment and responsibility, with a minimal supervision by the director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training and experience.

(2) With respect to specialties in which the medical technologist is not qualified by education, training or experience, he shall function only under direct supervision and perform only tests which require limited technical skill and responsibility.

(3) Clinical laboratory technologists shall be sufficient in number to adequately supervise the work of technicians and trainees.

(4) An individual who qualifies as a cytotechnologist under subdivision (c) of this section may supervise technicians and trainees only in the specialty of cytology.

(b) Qualifications of medical technologist. A medical technologist must meet one of the following requirements:

(1) Successful completion of a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university.

(2) Successful completion of three academic years of study (a minimum of 90 semester hours or equivalent) in an accredited college or university which met the specific requirements for entrance into, and the successful completion of a course of training of at least 12 months in a school of medical technology approved by the Council...
on Medical Education of the American Medical Association.

(3) Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical or biological sciences and, in addition, at least one year of pertinent laboratory experience and/or training covering the specialty(ies) or subspecialty(ies) in which he performs tests, provided the combination has given the individual the equivalent in such specialty(ies) or subspecialty(ies) of the education and training described in paragraph (1) or (2) of this subdivision.

(4) Successful completion of three years (90 semester hours or equivalent) in an accredited college or university with a distribution of courses as shown below, and, in addition, successful experience and/or training covering several fields of medical laboratory work of such length (not less than one year), and of such quality that this experience or training, when combined with the education, will have provided the individual with education and training in medical technology equivalent to that described in paragraph (1) or (2) of this subdivision. Distribution of course work: (Where semester hours are stated, it is understood that the equivalent in quarter hours is equally acceptable. The specified courses must have included lecture and laboratory work. Survey courses are not acceptable.)

   (i) for those whose training was completed prior to September 15, 1963: At least 24 semester hours in chemistry and biology courses of which not less than nine semester hours must have been in chemistry and must have included at least six semester hours in inorganic chemistry, and not less than 12 semester hours must have been in biology courses pertinent to medical sciences;

   (ii) for those whose training was completed after September 15, 1963: 16 semester hours in chemistry courses, which included at least six semester hours in inorganic chemistry and are acceptable toward a major in chemistry; 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and three semester hours of mathematics.

(5) With respect to individuals first qualifying prior to April 1, 1972, an exception to the requirements in paragraphs (1), (2), (3) or (4) of this subdivision may be made if:

   (i) the technologist was performing the duties of a medical technologist at any time between July 1, 1961 and September 1, 1971;

   (ii) the technologist has had at least 10 years of pertinent clinical laboratory experience prior to September 1, 1971: provided, that a minimum of 30
semester hours credit toward a bachelor's degree from an accredited institution with a chemical, physical, or a biological science as his major subject; or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by two years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year; and

(iii) he has performed the duties of a clinical laboratory technologist for at least two years during the qualifying 10 years:

(a) in a clinical laboratory having a director at the doctoral level, of a hospital, university, health department or medical research institution; or

(b) in a laboratory approved under the supplementary medical insurance program: Provided also, that where qualifying years in a laboratory described in clause (a) of this subparagraph are obtained after January 30, 1969, the laboratory meets applicable conditions under the Federal health insurance program, or under title 42, Code of Federal Regulations, part 74, the latter being the regulations issued pursuant to the Federal Clinical Laboratories Improvement Act of 1967.

(c) Qualifications of cytotechnologists:

(1) have successfully completed two years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences; and

(i) must have received 12 months of training in a school of cytotechnology approved by the American Medical Association; or

(ii) received six months formal training in a school of cytotechnology approved by the American Medical Association and six months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal six months of training; or

(2) prior to September 1, 1971, shall have been graduated from high school, completed six months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and completed two years of full-time experience in cytotechnology.

58-1.6 Physical facilities. No specimen shall be examined unless the portion of the laboratory premises and the equipment used therein have been approved by the department as adequate for proper performance of the type of tests for which the laboratory is authorized.
58-1.7 Acceptance of specimens.

(a) No establishment other than a clinical laboratory under permit shall accept specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of a disease or the assessment of a health condition. This subdivision shall not be deemed to prohibit the acceptance of specimens solely for teaching and research purposes.

(b) Except as otherwise provided in section 58-1.9 of this Subpart, a clinical laboratory shall examine specimens only at the request of licensed physicians or other persons authorized by law to use the findings of laboratory examinations in their practice or in the performance of their official duties.

(1) If the request is oral, the physician or other authorized person shall submit a written request to the laboratory within 48 hours. If the laboratory does not receive the written request within that period, it shall note that fact in the record of daily accession.

(2) Other persons authorized by law to request the examination of specimens shall include but not be limited to:

   (i) dentists and podiatrists, provided such examination is within the scope of practice of dentistry or podiatry;

   (ii) chiropractors, provided such examination is within the scope of practice of chiropractic, as determined by the Executive Secretary of the State Board of Chiropractic, Cultural Education Center, Empire State Plaza, Albany, New York 12201;

   (iii) physician's assistants, provided such examination is authorized by the supervising physician, and licensed midwives in accordance with their written protocols;

   (iv) nurse practitioners, provided such examination is authorized under Article 139 of the State Education Law;

   (v) police officers, provided such examination is incident to arrest charges for alcohol or drug impairment; and

   (vi) judges ordering paternity tests under the Family Court Act.

(c)(1) A clinical laboratory under permit may operate one or more collecting or transfer stations, provided that it first obtains written approval from the commissioner for each proposed station.

(2) A collecting station is a facility, fixed or mobile, operated by a clinical
laboratory under permit, for the collection, drawing and/or temporary storage of materials derived from the human body, until forwarded to the clinical laboratory for testing.

(3) A transfer station is a fixed facility or a mobile courier service, operated by a clinical laboratory under permit, for the acceptance and/or temporary storage and/or transfer of materials derived from the human body, until forwarded to the clinical laboratory for testing.

(4) A temporary collecting station is a one-time, one-site facility, operated by a clinical laboratory under permit, with the prior approval of the department, which collects, draws and/or temporarily stores materials derived from the human body, as part of a health fair, health assessment or health risk reduction program, for the purpose of screening for health risk under a general order from a licensed physician-in-charge.

(5) A temporary collecting station may perform specific tests on-site with the prior approval of the department, including approval for testing, storage, transportation, record-keeping, and reporting protocols, provided that:

(i) all testing is performed under the active supervision of a clinical laboratory with a permit in the specific category of testing, provided that:

(a) such testing be limited to treatable diseases or those of public health significance and preventable by early detection; and

(b) the risks of erroneous results do not outweigh the benefits of testing.

(ii) the clinical laboratory can document that the testing method/technique is accurate, reliable, reproducible, and suitable for on-site use;

(iii) the clinical laboratory is responsible for adherence to all quality control/quality assurance procedures;

(iv) the physician-in-charge is responsible for assuring that participants with abnormal/at risk results are counseled appropriately and/or referred to a physician with pertinent materials for test interpretation;

(v) procedures exist to refer for follow-up those participants without a personal physician;

(vi) the screening is conducted to ensure an orderly flow of activities so that discussion of test results, under the direction of the physician-in-charge, takes place in an area suitable for confidential counseling without distraction; and
(vii) suitable procedures for safe collection and disposal of specimens are in place.

(6) Departmental approval to operate a collecting or transfer station must be renewed annually on July 1 in conjunction with the clinical laboratory's permit. Such application for approval must include the name and address of the permit laboratory and a protocol for operation of the station and for ensuring the security and integrity of the specimens collected. The department will conduct annual inspections of collecting stations.

(d) A collecting station or temporary collecting station shall:

(1) create and maintain a record of the daily accession of specimens containing the following information, except that a fixed station which accepts specimens from a mobile station may use a copy of the mobile station's accession record in lieu of creating its own for specimens provided by the mobile station:

(i) the name and address or other identification of the person from whom the specimen was taken;

(ii) the name and address or other identifier of the licensed physician or other authorized person who requested the test;

(iii) the date and hour when the specimen was taken;

(iv) the date and, if the test must be performed within 24 hours, the time the specimen was received in the collecting station;

(v) the type of test requested; and

(vi) the date and hour when each specimen was forwarded to the clinical laboratory for testing;

(2) forward a copy of the accession record to the clinical laboratory together with the specimens.

(e) Collecting stations, temporary collecting stations and transfer stations shall:

(1) have on their premises an operating refrigerator which:

(i) maintains a temperature range of 4 to 10 degrees Centigrade;

(ii) is equipped with an accurate thermometer; and

(iii) shall be used exclusively for the storage of patient specimens.
for clinical laboratory testing;

(2) store each specimen requiring refrigeration in the refrigerator at all times until removed for forwarding to the clinical laboratory;

(3) store each specimen so as to maintain its original condition as much as possible, and assure that it will not become unsatisfactory as a patient specimen;

(4) forward specimens only to the clinical laboratory by which they are operated;

(5) transport, or arrange for the transportation of, each specimen which requires refrigeration, in a manner that will assure that its temperature will remain at between 4 and 10 degrees Centigrade until it reaches the clinical laboratory;

(6) transport, or arrange for the transportation of, all specimens not requiring refrigeration, so as to maintain their original condition as much as possible and assure that they will not become unsatisfactory as patient specimens; and

(7) transport, or arrange for the transportation of, all specimens in a manner designed to minimize the likelihood of exposing personnel or the public to any source of infection or hazard.

(f)(1) A mobile collecting station shall, in addition to complying with all requirements for fixed facilities, provide the department upon request with a monthly schedule in advance.

(2) A mobile collecting station, temporary collecting station or transfer station may use an alternative system of refrigerating specimens, provided that specimen temperatures are maintained at between 4 and 10 degrees Centigrade and the system's temperature is monitored and recorded periodically whenever in use.

(g)(1) No tests on specimens, whether human, veterinary, environmental or other, shall be performed in a collecting or transfer station except for:

(i) the screening or glucose and/or ketones in a collecting station, which must be performed prior to the administration of glucose for a glucose tolerance test. If sugar or ketones are present, the physician ordering such a test must be advised and the collection of blood for the tests may not be performed without his or her approval. Such approval must be documented in the accession record; and

(ii) tests performed in temporary collecting stations pursuant to section 58-1.7(c)(4) of this Part.

(2) Processing of specimens in a collecting, temporary collecting or
transfer station shall be restricted to the preparation of specimens for transport solely to preserve their integrity and reliability. Such preparation shall include, but not be limited to, centrifugation, separation of serum, freezing, refrigeration of specimens, and air drying, fixing and/or freezing of smears.

(h) A clinical laboratory shall, at any time when a collecting station, temporary collecting station, or transfer station it operates is open, permit the inspection of said station by a representative of the department.

(i) The collecting station, temporary collecting station, or transfer station shall be identified by the name of the clinical laboratory. The collecting station, temporary collecting station, or transfer station must post conspicuously, in the waiting area or other place visible to all visitors, a sign which states:

(1) the services at the site are limited to collection of specimens and/or preparation of the specimens for transport;

(2) the name and address of the laboratory which will test the specimens;

(3) information on billing practices, including the name and address of the establishment from which bills will originate and to which billing questions can be directed.

(j) Collecting stations, temporary collecting stations, and transfer stations shall be operated in such a way that no violation of article 38 of the General Business Law takes place.

(k) The aforesaid written approval of the commissioner may be revoked, suspended, limited or annulled as to any or all of the collecting stations, temporary collecting stations or transfer stations operated by a clinical laboratory under permit on proof that any one of said stations has been operated in violation of this Subpart, the Sanitary Code contained in Chapter I of this Title, or article 38 of the General Business Law. The enforcement provisions applicable to laboratory permits in subdivisions 2, 3 and 4 of section 577 of the Public Health Law shall also apply to such proceedings. In addition, in the event of a violation, the laboratory permit of the clinical laboratory operating the collecting station, temporary collecting station, or transfer station may be revoked, suspended, limited or annulled pursuant to paragraph (g) of subdivision 1 of section 577 of the Public Health Law.

58-1.8 Results of tests to be reported only to physicians or other authorized persons. No person shall report the result of any test, examination or analysis of a specimen submitted for evidence of human disease or medical condition except to a physician, his agent, or other person authorized by law to employ the results
thereof in the conduct of his practice or in the fulfillment of his official duties. Reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person, except that information concerning blood type and Rh type factor may be provided in writing to the individual whose blood was testing without the consent of the individual's physician.

58-1.9 Testing to be done on premises except in certain instances. All specimens accepted by a laboratory for specified tests shall be tested on its premises. However, specimens for infrequently performed tests or those not included within specialties or subspecialties stated on its permit or those requiring specialized equipment and skill may be forwarded to and accepted by another laboratory under permit issued by the commissioner or to a laboratory which is operated by a government agency or a nonprofit research institution or to any other laboratory approved by the department. The reports of the results of such tests shall be sent by the testing laboratory to the forwarding laboratory, except that the forwarding laboratory may authorize the testing laboratory to send the report directly to the physician or other authorized person who requested the test, in which event the testing laboratory shall send a duplicate of the said report to the forwarding laboratory. Where the results of a test have been reported to it by the testing laboratory, the forwarding laboratory shall send a transcript of such report to the physician or other authorized person who requested the test and shall indicate thereon the name of the laboratory actually performing the test. In no event shall any report of the result of any test or transcript thereof be sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

58-1.10 Specimens: identification and examination.

(a) Every specimen received for testing shall be numbered or otherwise appropriately identified and listed in an accession book, or another system acceptable to the department.

(b) Every tissue specimen shall be examined and reported upon by a qualified pathologist who is certified or eligible for certification for pathologic anatomy by the American Board of Pathology or whose qualifications, in the opinion of the Public Health Council pursuant to Part 19 of this Title, are equivalent of such certification. Preliminary examination or "screening" of specimens for cytopathology may be made only by an individual who has had special training acceptable to the department.

(c) A clinical laboratory or blood bank shall at any time during its regular working hours permit the inspection of its premises and records by a representative of the department and shall examine and report promptly on all specimens submitted by the department for the purpose of determining the competency of the laboratory.
(d) If the component to be tested for in a specimen is perishable, labile, or otherwise subject to deterioration, such specimen shall be tested as promptly as possible after collection. If a specimen is transported or stored, it shall be properly preserved, refrigerated, frozen or otherwise appropriately treated to maintain it in as close to its original state as is possible by then current technics.

(e) A specimen received by a laboratory shall not be tested or reported on if:

1. the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested;

2. it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen;

3. it is perishable and the time lapse between the collection of the specimen and its receipt by the laboratory is of such duration that the test finding may no longer be reliable; or

4. the date and, in the case of tests specified by the department, the hour when the specimen was taken by the physician or other authorized person is not furnished with the specimen.

(f) When a specimen is not tested for any of the reasons specified in subdivision (e) of this section the laboratory shall promptly notify the sender and give the reason therefor.

(g) All technical procedures employed in a laboratory shall be of proven reliability and generally accepted by leading authorities in the specialties of laboratory medicine and/or approved by the department.

58-1.11 Reports and records.

(a) When requested, a laboratory shall submit reports containing such information and data concerning its technical operation as may be specified by the department. Such reports shall be signed both by the owner and director of the laboratory.

(b) Each clinical laboratory or blood bank shall have records indicating the daily accession of specimens and containing the following information:

1. The laboratory shall have an accession system which may be a computerized accession system. It shall include:

   i. the accession number or other identification of the specimen;
(ii) the name or other identification of the person from whom the specimen was taken;

(iii) the date the specimen was received in the laboratory;

(iv) the test or tests requested for that specimen;

(v) if the request for the test was oral and, contrary to the requirements of subdivision (b) of section 58-1.7 of this Subpart, the request was not followed by a written request, a statement to that effect, provided that, in the case of a computerized accession system, such a statement may be recorded in a separate accession log;

(vi) in the event a specimen is forwarded to another clinical laboratory for tests, the name of such other laboratory, the date upon which the specimen was forwarded, the date it was tested or the result or results were reported, and the date the report of findings was received from such laboratory, provided that, in the case of a computerized accession system, such information may be recorded in a separate accession log;

(vii) a brief description of the condition of unsatisfactory specimens when received, for example, broken, leaked, hemolyzed, turbid, etc.; provided that, in the case of a computerized accession system such information may be recorded in the laboratory report required by paragraph (2) of this subdivision;

(viii) if the specimen is not received from another laboratory either:

(a) the date the specimen was tested; or

(b) the date the result was reported, provided that the testing date or dates are available upon the request of the originating physician for the same period of time specified in subdivision (c) of this section for the retention of the report, unless the information required by clause (a) and (b) is recorded in the laboratory report required by paragraph (2) of this subdivision;

(ix) the hour, if required, when the specimen was received in the laboratory, unless such information is recorded in the laboratory report required by paragraph (2) of this subdivision;

(x) the name of the licensed physician or other authorized person or clinical laboratory or blood bank submitting the specimen, unless such information is recorded in the laboratory report required by paragraph (2) of this subdivision;
(xi) where a computerized accession system is in use, hard copy (computer generated) accession records shall be available to the laboratory staff or other authorized person in the laboratory for three months from the receipt of the specimen and shall contain all information required by paragraph (1) of this subdivision to be recorded in a computerized accession system.

(2) Each clinical laboratory or blood bank shall produce a laboratory report and shall supply the original of said report to the physician or other authorized person submitting each specimen for analysis. Each laboratory shall retain a duplicate copy of the report. Pathology reports shall utilize an accepted system of disease nomenclature. Each report shall contain the following information:

(i) patient name or other identification and the name of the person or institution referring the specimen;

(ii) the result of the laboratory test or tests;

(iii) the date, and hour if required, when the specimen was originally collected by the physician or other authorized person;

(iv) the name under which the laboratory has been issued a permit and its address;

(v) any information required to be recorded by paragraph (1) of this subdivision;

(vi) reports including numerical results shall include normal values, reference intervals, or similar method for identifying abnormal values. Alternative procedures other than reporting these values on the report may be approved by the department; and

(vii) if the specimen is received from another laboratory, either the date the specimen was tested or the date the result was reported, provided that the testing date or dates are available upon request of the originating physician or forwarding laboratory for the same period of time specified in subdivision (c) of this section.

(c) All records and reports of tests performed including the original or duplicates of original reports received from another laboratory shall be kept on the premises of both laboratories and shall be exhibited to representatives of the department on request. Records listed below shall be retained by the laboratory for at least the period specified. If other New York State or Federal regulations or statutes require retention for different periods of time, the laboratory shall retain the appropriate record for the longest period applicable. Records shall be retained in their original form for a period of
three months and may thereafter be stored on microfilm, microfiche, or other photographic record, or as magnetic tapes or other media in an electronic data processing system. Such records shall be adequately protected against destruction, either by archival storage or duplicated photographic or electronic medium or by other suitable means providing equivalent protection. Records which are required to be retained for more than two years may, after two years, be stored off the immediate laboratory premises, provided they can be available to the laboratory staff or other authorized person in the laboratory within 24 hours of a request for records.

(1) Requests for tests shall be retained for the same period of time as required for the test results or seven years, whichever is less, except that referral information for cytogenetic cases shall be retained for six years.

(2) Accession records shall be retained for seven years.

(3) Records of quality control results shall be retained for two years.

(4) Preventative maintenance, service and repair records shall be retained for as long as the instrument remains in use, except that records of monitoring of temperature-controlled spaces shall be kept for one year.

(5) The following types of laboratory reports shall be retained for at least the period specified;

   (i) tissue pathology including exfoliative cytology - 20 years;

   (ii) syphilis serology - negative report - two years;

   (iii) cytogenetics - 25 years; and

   (iv) all others - 7 years.

(6) Worksheets containing instrument readings and/or personal observations upon which the outcome is based shall be retained for one year.

(d) The following requirements shall apply to the retention and disposition of specimens:

(1) Specimens shall be retained so as to be accessible to the laboratory within 24 hours for at least the period set forth below:

   (i) blood film - other than routine - 1 year;

   (ii) blood film - routine - 6 months;

   (iii) bacteriology slide on which a diagnosis depends - 1 year;
(iv) cytology slide showing any abnormality - 7 years;

(v) cytology slide showing no abnormality - 3 years;

(vi) tissue block - 20 years;

(vii) histopathology block - 20 years;

(viii) histopathology slide - 20 years;

(ix) bone marrow biopsy - 20 years;

(x) cytogenetic slide - 6 years;

(xi) photographic slide of cytogenetic karyotype - 25 years; and

(xii) recipient blood specimens - 1 week stoppered at 6 degrees Celsius.

(2) All specimens shall be disposed of in a manner designed to minimize the likelihood of causing infection to any member of the public or laboratory staff. The laboratory shall have a written protocol which shall be available to the department for inspection, describing its procedures for the disposal of specimens.

58-1.12 Cytopathology standards and quality assurance.

(a) Definitions.

(1) Examination means the initial review or screening of cytopathology samples by a cytotechnologist to determine if the sample is negative, abnormal or questionable, and shall include the marking of potentially abnormal cells and completion of laboratory records.

(2) Re-examination means the review of slides which have been examined or screened as normal. The selection of these slides must be made based on a protocol, available in the laboratory, which includes patient history, qualifications of the examining cytotechnologist, and source of referral.

(3) Facilitating means the preparation and review of non-gynecological slides by a cytotechnologist for diagnosis by a pathologist, and shall include the marking of abnormal cells and selection of representative slides.

(4) Quality control and quality assurance means those procedures and protocols, including re-examination, in place in the laboratory to assure consistency,
reliability, documentation and accuracy of results reported, and shall include corrective actions taken in the event of laboratory error.

(5) Cytotechnologist means a clinical laboratory professional specializing in the analysis of cytopathology samples, including Pap smears, for cervical cancer and other diseases, who meets the qualifications specified by the department in section 58-1.5 of this Subpart. For purposes of the work standard in subdivision (b) below, this shall mean any person who is engaged in the initial examination of cytologic specimens. Cytopathologists who are engaged in initial examination of cytologic specimens need not register, but must maintain workload records and comply with workload standards.

(6) Cytotechnologist work standard means a limitation on the number of Pap smears (also known as gynecologic slides) and non-gynecologic slides which a cytotechnologist may examine or facilitate during a particular time period, or other limitation on the quantity, speed or manner of examination of slides by a cytotechnologist.

(7) Employ means to employ or contract with a cytotechnologist to examine cytological materials, including gynecologic and non-gynecologic slides.

(8) Part-time means working less than a seven-and-one-half or an eight-hour day for a particular employer.

(9) Clinical laboratory means a clinical laboratory licensed by the Department of Health of the City of New York or by the New York State Department of Health.

(10) Work day means a twenty-four-hour period during which a cytotechnologist examines cytological materials for a clinical laboratory.

(11) Work month means a calendar month during which a cytotechnologist examines cytological materials, including gynecologic slides, for a clinical laboratory.

(12) Non-gynecological slide means a slide containing material obtained from other than the cervical-vaginal area. For each non-gynecologic case for which up to three slides are submitted, each of the slides shall count as one toward the work standard. For each non-gynecologic case for which more than three slides are submitted, only the first three shall be counted toward the work standard.

(13) Total hours worked means the time spent during each work day at all employers examining slides and performing ancillary duties as defined in section 58-
1.12(b)(3) of this Subpart. For part-time cytotechnologists, the denominator shall be based on a seven-and-one-half or an eight-hour day adjusted as described in section 58-1.2(b)(3) and (4) of this section.

(b) Cytotechnologist work standard.

(1) No cytotechnologist shall exceed the applicable cytotechnologist work standard. No clinical laboratory shall require, authorize, encourage or permit any cytotechnologist to exceed the applicable cytotechnologist work standard. In determining whether a cytotechnologist exceeds the applicable cytotechnologist work standard, all work performed by the cytotechnologist during a given work day shall be considered, without regard to the clinical laboratory or other person for which it was performed.

(2) Unless otherwise provided, a cytotechnologist may examine no more than eighty one-slide gynecologic cases or fifty two-slide gynecologic cases per work day. If a cytotechnologist also examines non-gynecologic slides in a given work day, the cytotechnologist's workload for gynecologic slides shall be correspondingly reduced, in accordance with written guidelines prepared by the clinical laboratory and filed with the department, so that a cytotechnologist examines no more than a combined total of one-hundred gynecologic and non-gynecologic slides per work day.

(3) If a cytotechnologist spends more than one hour per day at any laboratory performing duties not directly related to examination of slides, such as assisting in fine needle aspirations, staining and preparation of slides, quality control and quality assurance activities, reporting test results, training, continuing education and routine clerical work, the laboratory director must decrease that cytotechnologist's workload and hours spent in screening.

(4) When a cytotechnologist works part-time or performs duties other than slide examination, the slide limit must be prorated using one or more of the following formulas:

   (i) screening one-slide gynecologic cases:

   \[
   \frac{\text{hours worked on slides}}{\text{total hours worked in a work day}} \times 80 \text{ (cases)}
   \]

   (ii) screening two-slide gynecologic cases:

   \[
   \frac{\text{hours worked on slides}}{\text{total hours worked in a work day}} \times 50 \text{ (cases)}
   \]
(iii) facilitating non-gynecologic cases (up to three slides):

\[
\text{hours worked on slides} \times 30 \text{ (cases)} \\
\text{total hours worked in a work day}
\]

(5) In no case shall the hourly rate of examination exceed 12.5 slides per hour per cytotechnologist, unless the laboratory has the department's approval for individual cytotechnologists to exceed this limit.

(6) The laboratory must provide rest periods and breaks as needed by the cytotechnologist.

(7) Exceptions.

(i) Each laboratory shall evaluate the performance of each cytotechnologist providing services to it, and establish an appropriate examination volume limitation based on the cytotechnologist's experience, documented accuracy and performance in proficiency testing, or on other reasons, including false-negative or false-positive interpretations. Under no circumstances shall this volume be exceeded, even if it is lower than the maximum work standard.

(ii) A cytotechnologist may exceed the work standard by twenty (20) percent, with the written approval of the department. The laboratory director may request such approval based on each cytotechnologist's experience, documented accuracy, including false-negative or false-positive interpretations, and a performance score in proficiency testing of not more than two (2) errors. Documentation of department approval shall be available in the laboratory, and may be revoked by the department with prior notice to the laboratory, based on a cytotechnologist's performance in proficiency testing or other evidence that the cytotechnologist's accuracy is other than acceptable. The laboratory director shall monitor the performance of each cytotechnologist and advise the department whenever the approval is to be revoked based on on-the-job performance.

(iii) Cytotechnologists who qualify as supervisors under section 58-1.4 of this Subpart may re-examine up to twenty (20) slides per day in addition to the workload standard, provided the combined total number of slides does not exceed one-hundred (100), as part of the quality assurance program of the laboratory, with the prior approval of the department, based on documented accuracy, including false-negative and false-positive interpretations, and performance in proficiency testing. Such approval may be revoked, with prior notice to the laboratory, based on proficiency testing performance or other evidence that the cytotechnologist's accuracy is other than acceptable. Records shall be maintained to document the examination volume and hours worked by each cytotechnologist.
(iv) The department may increase the cytotechnologist work standard beyond the level already authorized elsewhere in this section for cytotechnologists using a federal Food and Drug Administration (FDA)-approved device in the preparation or examination of cytology slides:

(a) in determining whether to increase the cytotechnologist work standard with respect to a particular device, the department shall consider the following: the FDA’s approved use of the device; studies of the accuracy, reliability and appropriate use of the device; input from clinical laboratories using the device; recommendations of experts in the field of cytology and/or cytotechnology; and other relevant information as appropriate;

(b) (1) the department may require a clinical laboratory wishing to exceed the cytotechnologist work standard set forth elsewhere in this section to request in writing the department’s approval. The department may also require the applicant laboratory to provide, in a form acceptable to the department, some or all of the following information regarding the device in use at the laboratory: the device manufacturer’s recommendations, if any, regarding the quantity (i.e., slide volume), speed or manner of slide examination, and the basis for such recommendations; documentation of training for each cytotechnologist using the device; each cytotechnologist’s experience using the device, including false-negative and false-positive interpretations, workload, and number of hours spent examining slides; each cytotechnologist’s performance on proficiency testing; as well as any other information as determined appropriate by the department to assess device capacity and user capability; and

(2) the department shall provide written notice of the authorized work standard established pursuant to this subparagraph. The department may set a work standard in writing that applies to one or more cytotechnologists.

(c) laboratories shall maintain documentation of approval pursuant to this subparagraph for a minimum of two (2) years after use of the device is discontinued;

(d) if the department determines that a cytotechnologist work standard authorized pursuant to this subparagraph increases the rate of errors or compromises the reliability of results, the department shall adjust the standard as it deems appropriate and shall notify the affected clinical laboratories in writing of such change. Clinical laboratories that find the adjustment unacceptable may only request in writing that the department reconsider its determination; and

(e) notwithstanding the foregoing, any cytotechnologist work standard authorized by the department pursuant to this subparagraph shall be at least as stringent as the federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred and eighty-eight (1988) and/or other applicable law(s).
(c) Regularly scheduled education programs, averaging two hours per month, must be provided to the cytotechnologists and records thereof maintained.

(d) Record-keeping.

(1) Each clinical laboratory shall maintain records on work standards for three years, in a form approved by the department, which set forth, for each cytotechnologist employed by the clinical laboratory:

(i) the name and registration number of the cytotechnologist;

(ii) the number of hours worked by the cytotechnologist in each work day;

(iii) the number of one-slide and two-slide gynecologic cases and non-gynecologic cases and slides examined by the cytotechnologist, as well as the total number of slides examined during each work day; and

(iv) the actual hours worked, if required by the department, for any cytotechnologist working at more than one employer.

(2) Every cytopathology laboratory shall maintain, and make available to the department upon request, a calendar year workload report containing the following information for every cytotechnologist employed for any period of time during that calendar year:

i) name of cytotechnologist;

ii) registration number of cytotechnologist;

iii) number of days worked and, for part-time cytotechnologists, full-day equivalent number calculated;

iv) number of one-slide gynecologic cases read by the cytotechnologist;

v) number of two-slide gynecologic cases read by the cytotechnologist; and

vi) number of non-gynecologic cases read by the cytotechnologist.

(3) Every cytotechnologist shall maintain, and make available to the department upon request, a calendar year workload report containing the following
information for every cytopathology laboratory in which the cytotechnologist performed screening and/or facilitating during that calendar year:

i) name of laboratory;

ii) identification number of laboratory;

iii) number of days worked and, for part-time cytotechnologists, full-day equivalent number calculated;

iv) number of one-slide gynecologic cases read by the cytotechnologist;

v) number of two-slide gynecologic cases read by the cytotechnologist; and

vi) number of non-gynecologic cases read by the cytotechnologist.

(4) Each cytotechnologist shall maintain records on work standards for three years, in a form approved by the department, which set forth:

(i) the number of hours worked by the cytotechnologist in each work day;

(ii) the number of one-slide and two-slide gynecologic cases and non-gynecologic cases and slides examined, as well as the total number of slides examined during each work day;

(iii) the name and address of the clinical laboratory(ies) or other person(s) for whom the slides were examined;

(iv) the cytotechnologist registration number assigned by the department; and

(v) the actual hours worked at each employer, if required by the department.

(5) Records required to be maintained by clinical laboratories and cytotechnologists shall be made available for inspection and copying by the department upon request.

(6) Multiple employers. Whenever a cytotechnologist is employed by more than one clinical laboratory or other person during a work day, the cytotechnologist shall advise each clinical laboratory or person of any previous employment during the work day and the amount of work performed, to ensure that the
applicable cytotechnologist work standard is not exceeded.

(e) Standards for gynecologic slides.

(1) Each laboratory must establish a written protocol defining the standards to be used for determining if a slide is inadequate to test. These standards must be available in the laboratory and must be provided to each ordering physician or other practitioner.

(2) A gynecologic slide or a Pap smear shall not result in a diagnostic report if:

   (i) the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested;
   (ii) it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen;
   (iii) the slide is broken to such extent that it cannot be repaired adequately so that cells are not obscured or lost; and
   (iv) it contains insufficient cells or the cells are obscured by inflammation, blood, or lubricating ointment, so that an accurate diagnosis cannot be made.

(3) The laboratory shall note in the laboratory record and in the report to the physician the reason for the unsatisfactory evaluation. Such records must be available for inspection by the department. The total number of unsatisfactory smears should be reported to the department at least annually.

(4) If a slide is unsatisfactory under this subdivision, the clinical laboratory shall have an affirmative duty to advise the collecting physician or other practitioner that the slide or specimen is unsatisfactory and request the submission of a new slide. If the inadequacy is due to collection and preservation technique, the laboratory shall offer assistance to the practitioner in collection of adequate samples, free of contamination and foreign material.

(5) As minimum clinical information, the laboratory order form must request the patient’s date of onset of last menstrual period, age, previous abnormal cytology, and previous significant history.

(6) If the minimum required clinical information is not included on the order form or is otherwise unavailable, the laboratory must request this information. If the clinical information is not received, the laboratory record must be so noted and the report to the physician must state that the minimum required information was not provided.
(7) Slides from negative cases must be retained for at least five years and slides from cases with abnormalities must be retained for at least 10 years.

(8) Laboratory reports must identify the cytotechnologist and/or cytopathologist who diagnosed the case.

(f) Re-examination of slides.

(1) Each laboratory must establish a system for targeted re-examination of at least 10 percent of gynecologic slides determined to be not abnormal or questionable. Documentation of this system must be available in the laboratory for inspection by the department and to ordering physicians or other practitioners.

(2) Re-examination shall be based on prior cancer and other history of the patient, results of previous examinations, patient risk status as determined by the clinical physician, source of referral (i.e., practices and/or clinics with high-risk patients or high incidence or from geographical areas with high risk of disease). Re-examination shall also be performed on slides examined by new or inexperienced cytotechnologists and those determined to be in need of remediation based on proficiency testing performance. Records of this rescreening must be maintained for three years.

(3) In addition, laboratories employing more than one cytotechnologist must establish a system, which may be part of re-examination, to ensure the laboratory’s consistency in examination of slides by two or more individuals or by the same individual on different occasions. Copies of the results must be maintained for three years and be available for inspection and copying by the department.

(4) All gynecologic cases which have been interpreted by a cytotechnologist as dysplasia, cervical intraepithelial neoplasia (CIN), carcinoma in situ (CIS) or malignancy and all non-gynecologic cases must be reviewed by a pathologist.

(5) Cases with abnormal findings as described in (4) above must be tracked by the laboratory and follow-up information, including results of subsequent biopsies, must be documented and available in the laboratory for twenty years.

(6) Records of recognized false-positive and false-negative cases must be maintained, including copies of subsequent biopsy reports, for twenty years, and be available to the department.

(g) Registration of cytotechnologists. All cytotechnologists, as defined in this Subpart, who are employed by a clinical laboratory must register with the department on the form provided by the department.
(2) The registration application must include the name and home address of the cytotechnologist; the name and address of all locations at which the cytotechnologist is employed as a cytotechnologist, regardless of whether the site or facility is under New York State or New York City permit; the cytotechnologist's working days and hours at each facility or site; the cytotechnologist's education and experience; the cytotechnologist's Social Security number as required under section 5 of the New York State Tax Law; and other information the department may require for enforcement of this Subpart.

(3) Within 30 days of a change in home address, employer or employer address, the cytotechnologist must notify the department on the form provided by the department.

(4) The department shall advise each cytotechnologist of the assigned registration number and provide an identification card to each cytotechnologist. The registration number must be used on all records, as required by the department. The registration card must be kept by the cytotechnologist and a copy must be maintained by each employing laboratory.

(5) No clinical laboratory shall employ a cytotechnologist unless the cytotechnologist is registered under this section. If the cytotechnologist is not registered at the time of hiring, an application for registration must be made within one week of commencing employment. When a cytotechnologist is hired, resigns or otherwise is separated from the laboratory, the laboratory director must so advise the department.

(6) A cytotechnologist's registration may be revoked, denied, suspended, or annulled upon falsification of information on the registration application, falsification of laboratory workload records, termination from a laboratory for cause, or other violation of the law, rules and regulations.

58-1.13 General requirements for performance of anatomic pathology and cytopathology procedures.

(a) Facilities.

(1) Laboratory space.

    (i) Work areas must be clean, well-lighted and well-ventilated;

    (ii) utilities (water, gas, suction, electricity) must be available, as
needed; (iii) microscopic work area, including space and furniture, must be conducive to high-quality performance;

(iv) cytopreparation area(s) must be separate from screening and clerical/secretarial area(s) so that personnel are protected from hazardous fumes and screening areas are free from distractions;

(v) there must be sufficient space for quality control, administrative, and clerical functions; and

(vi) storage of records and specimens must be in compliance with section 58-1.11 (c) and (d) of this Subpart.

(2) Safety precautions.

(i) Health and safety precautions comparable to those required in hospital laboratories must be maintained; and

(ii) universal precautions must be enforced when liquid specimens are handled.

(3) Equipment and reference resources.

(i) There must be an adequate number of high-quality, well-maintained binocular microscopes;

(ii) preventive maintenance of microscopes and other equipment must be performed, as recommended by the manufacturer, and documented in a log book; and

(iii) a core reference library should be conveniently available on the laboratory premises.

(4) Support personnel. There should be adequate clerical and laboratory assistance personnel, whose number and type are dependent on the volume of work.

(5) Salaries. The method of compensation should not adversely affect the quality of performance. Cytotechnologists should be free from quota or other pressures that limit appropriate slide review time.

(b) Laboratory operation.

(1) Specimens must be identified properly and must be accompanied by a complete test requisition containing minimal clinical information.
(2) A laboratory procedure manual describing the handling and storage of specimens from origination to final report, including collection, preservation, transportation, rescreening protocol and standards for specimens or slides, must be available in the work area.

(3) Solutions and stains.

(i) Solutions and stains must be labelled to indicate concentration, expiration date, and storage requirements;

(ii) Stains must be monitored daily and written records thereon maintained;

(iii) Cross-contamination of specimens must be avoided. Non-gynecologic specimens must be stained separately from gynecologic specimens. Solutions must be filtered or replaced daily; particular care must be taken to filter solutions after processing body fluid specimens; and

(iv) Solutions and stains must be kept covered when not in use and stored at appropriate temperatures.

(4) Microscopy.

(i) All microscopy must be performed on the laboratory premises; and

(ii) Cytotechnologist functions should include evaluation of the adequacy of specimens, marking of areas appropriate for further review, and rendering of a provisional interpretation.

(c) Special requirements for histopathology, oral pathology and dermatopathology.

(1) All special stains shall be controlled for intended reactivity by the use of positive tissue sections, processed at the same time as the unknown tissue sections. Acid-fast staining procedures must include both a positive and a negative control slide.

(2) All unprocessed remnants of tissue specimens shall be retained in a fixative solution until the portions submitted for microscopy have been examined and diagnosed by a pathologist.

(3) Stained slides and paraffin blocks shall be retained for a minimum of 20 years from the date of examination.
(4) It is recommended that copies of reports be kept in numeric and alphabetic cross files. A numerical accession record satisfies the numeric file recommendation.

(5) Records must indicate the total number of blocks taken and the name of the pathologist who diagnosed the case.

(6) A duplicate copy of all reports, or the capability to reproduce the same, must be retained by the laboratory for 20 years.

(7) All slides referred for consultation must have the patient's name and other identifiers written on the label.
SUBPART 58-2
Blood Banks

(Statutory authority: Public Health Law, Sec. 3121(5))

Sec.

58-2.1 Definitions
58-2.2 Qualification of donors
58-2.3 Required laboratory tests for donated blood
58-2.4 Collection of blood
58-2.5 Sterilization of instruments
58-2.6 Collection and handling of blood for subsequent allogeneic or autogeneic transfusion
58-2.7 Immunohematology testing
58-2.8 Standard operating procedures
58-2.9 Issuance of blood, blood components and derivatives
58-2.10 Required records and confidentiality
58-2.11 Records to be kept when blood is collected for autogeneic or allogeneic transfusion
58-2.12 Records to be kept when blood, blood components or derivatives are issued for allogeneic or autogeneic transfusion
58-2.13 Blood donation centers
58-2.14 Plasmapheresis
58-2.15 Cytapheresis
58-2.16 Required standards for transfusions
58-2.17 Laboratory tests to be performed prior to allogeneic or autogeneic transfusion
58-2.18 Records to be kept when blood or blood component transfusions are performed
58-2.19 Records to be kept when plasma derivatives are infused
58-2.20 Neonatal transfusions
58-2.21 Limited transfusion services
58-2.22 Holding facilities
58-2.23 HIV-1 and HIV-2 antibody testing results
58-2.24 Disposal of untransfused and expired blood units
58-2.25 Intraoperative and postoperative blood recovery and normovolemic hemodilution
58-2.26 Exceptions
58-2.27 Reinfusion procedures

Section 58-2.1 – Definitions

(a) Blood bank means a facility for the collection, processing, storage or distribution of human blood, human blood components or blood derivatives, or the performance of reinfusion procedures. A blood bank shall employ a qualified director for administrative purposes and, if blood collection is performed, a qualified medical director.
(b) **Blood donation center** means a facility, fixed or mobile, that is operated by a blood bank and used for the collection of blood, plasma or cytapheresis products, or separation of whole blood into components.

(c) **Donor or blood donor** means a person who provides his/her blood or plasma for transfusion of whole blood, blood components or derivatives.

(d) **Blood components** means those preparations separated from a single donation of whole blood, or collected by apheresis, intended for direct use in transfusion, including but not limited to plasma, fresh frozen plasma, red blood cells, washed red blood cells, leukocyte-reduced red blood cells, platelets, granulocytes and cryoprecipitate.

(e) **Derivatives** means those preparations separated from plasma derived from multiple donors, including but not limited to albumin, immune globulin, plasma protein fraction and clotting factor concentrates.

(f) **Blood products** means whole blood, blood components or derivatives.

(g) **Plasmapheresis** means the withdrawal of blood to obtain plasma with subsequent or simultaneous reinfusion into the donor of his/her own red blood cells.

(h) **Serial plasmapheresis program** means a program of individual donor donations on a regular basis by plasmapheresis yielding three liters or more of plasma per consecutive four-week period.

(i) **Cytapheresis** means the separation and collection of blood cells or other formed elements by hemapheresis for the purpose of obtaining a transfusable blood component.

(j) **Intraoperative blood recovery** means recovery of blood from a surgical field and processing of recovered blood for direct reinfusion, storage or infusion into a cardiopulmonary bypass pump. Intraoperative blood recovery does not include performance of perioperative normovolemic hemodilution procedures. Postoperative blood recovery means recovery of blood from a wound following surgery, and processing of recovered blood for direct reinfusion or storage. Intraoperative blood recovery was formerly termed intraoperative blood salvage.

(k) **F.D.A.** means the Food and Drug Administration of the United States Department of Health and Human Services.

(l) **Limited transfusion service** means a facility, home care services agency, physician's office, or other entity which administers blood or blood components, and may temporarily store blood or blood components, and distribute them within its own organization, but relies on a blood bank holding a permit in blood services-transfusion to perform laboratory tests required under section 58-2.17 of this Subpart.

(m) **Holding facility** means a facility at which blood is temporarily stored but which does not offer any other blood banking services.
(n) **Transfusion service** means a service which issues blood, blood components or blood derivatives for administration into a person, but does not include a limited transfusion service.

(o) **Institution** means a hospital or other facility operating a transfusion service under a permit issued by the department.

(p) **Allogeneic collection** means the removal and storage of blood or blood components from a donor for transfusion into another person, and includes blood donated for directed donation to another person, or donated for autogeneic use and subsequently crossed-over in whole or in part for use by others. Allogeneic collection was formerly termed homologous collection.

(q) **Autogeneic collection** means the removal and storage of blood or blood components from a donor for subsequent reinfusion into that same person, and includes preoperative hemodilution procedures if at any time the blood leaves the operating room in which surgery is performed. Autogeneic collection was formerly termed autologous collection.

(r) **Directed donation** means an allogeneic collection in which blood from a particular donor is designated for use by a specified recipient.

(s) **Medical director** means a qualified physician who is employed by a blood bank, and is responsible for donor selection and safety.

(t) **Department** means the New York State Department of Health.

(u) **Reinfusion procedure** means the withdrawal of a small amount of blood or a component thereof from a patient, its processing by addition of substances or by culturing, and administration of the product so obtained, in whole or in part, into the same patient for diagnostic or therapeutic purposes. Reinfusion procedures shall include, but not be limited to, radioisotopic tagging, and genetic and immunologic manipulation, but shall not include processing of whole blood units into components for autogeneic reinfusion, such as platelet concentrates, packed red blood cells and plasma.

(v) **Normovolemic hemodilution** means the collection of blood prior to surgery, and includes fluid replacement and reinfusion during or after surgery for purpose of reducing red cell loss during surgery.

(w) **Limited reinfusion** service means a facility, home care services agency, physician's office or other non-hospital entity that performs reinfusion procedures.

(x) **Clinical laboratory technician** means a clinical laboratory practitioner who performs clinical laboratory procedures and examinations, pursuant to established and approved protocols of the department, which require limited exercise of independent judgment, and are performed under the supervision of a clinical laboratory technologist, laboratory supervisor, or director of a clinical laboratory.
(y) **Clinical laboratory technologist** means a clinical laboratory practitioner who, pursuant to established and approved protocols of the department, performs clinical laboratory procedures and examinations and any other tests or procedures conducted by a clinical laboratory, including maintaining equipment and records, and performing quality assurance activities related to examination performance, which require the exercise of independent judgment and responsibility.

(z) **Health care provider**, for the purposes of this Subpart, means a physician, physician assistant or nurse practitioner.

(aa) **Nurse practitioner** means a registered professional nurse licensed and currently registered, under the Laws of the State of New York, to diagnose illness and physical conditions, and perform therapeutic and corrective measures, in accordance with a collaborative agreement with a physician qualified to collaborate in the specialty involved.

(ab) **Physician** means an allopathic or osteopathic physician licensed and currently registered, under the Laws of the State of New York or in the state of practice, to practice medicine.

(ac) **Physician assistant** means a person licensed and currently registered, under the Laws of the State of New York, to practice medicine under the supervision of a physician.

(ad) **Physician designee** means a physician designated by the medical director to be responsible for one or more routine or special tasks.

**Section 58-2.2 - Qualifications of donors**

(a) The medical director shall be responsible for the determination that blood may be collected safely from a donor and that the donor's blood is acceptable for collection. This determination shall be made by the medical director or trained staff members under the medical director's supervision on the day of collection of the blood. In addition, autogeneic collections prior to anticipated surgery or other medical procedure shall require the written authorization of the donor's health care provider and written consent of the donor. If autogeneic blood is to be subsequently used for allogeneic transfusion, all requirements in subdivision (f) of this section must be met.

(b) Only those persons may be accepted as donors of blood for allogeneic use who are in good health as indicated by:

1. freedom from acute respiratory diseases;
2. freedom from infectious skin lesions at the phlebotomy site and from any infectious skin disease generalized to an extent that creates a risk of contamination of the blood;
3. freedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examinations required in this Subpart;
4. freedom from active tuberculosis. A person with a history of tuberculosis may be accepted as a blood donor following completion of drug therapy;
(5) freedom from syphilis. However, blood for plasma fractionation into heat-treated or pathogen-inactivated derivatives may be accepted;

(6) freedom from a history of viral hepatitis for a duration specified by the United States Public Health Service;

(7) freedom from a history of malaria or travel to or residence in malarially endemic areas for periods of time considered to increase risks for malaria exposure, as determined by the United States Public Health Service. However, plasma for transfusion fractionation may be accepted from donors with a history of malaria or travel to a malarially endemic area;

(8) freedom from signs and symptoms of human immunodeficiency virus (HIV) infection; and

(9) freedom from other medical contraindications.

c) For allogeneic collections, a person may not be accepted as a blood donor:
   (1) whose health may be affected adversely by the bleeding;

   (2) who has received a transfusion of blood or blood components within the past year, with the exception of autogeneic transfusion;

   (3) who is under 17 years of age, except that donors who are 16 years of age may be accepted, if they have presented written permission specific to the occasion from a parent or guardian;

   (4) who is more than 75 years of age, except that donors over 75 may be accepted after satisfactory case-by-case review by the medical director or physician designee;

   (5) who is known to use or presents indications of having used illegal injectable drugs;

   (6) whose oral temperature exceeds 37.5 degrees Celsius (99.5 degrees Fahrenheit);

   (7) whose pulse after resting is faster than 110 or slower than 45 beats per minute, except if the donor is an athlete with high exercise tolerance; or whose pulse exhibits pathologic irregularities;

   (8) whose systolic blood pressure exceeds 180 millimeters of mercury, or whose diastolic pressure exceeds 100 millimeters;

   (9) whose weight is less than 50 kilograms (110 pounds), except that a donor whose weight is between 40 kilograms (88 pounds) and 50 kilograms (110 pounds) may donate a volume proportionate to the donor's weight, provided that the anticoagulant is proportionately reduced and the container is appropriately labeled;
(10) whose hemoglobin content is less than 12.5 grams per deciliter or whose hematocrit is less than 38%, as determined by techniques found by the department to meet medical standards generally accepted in New York State;

(11) who is known ever to have received pituitary-derived human growth hormone; or

(12) who falls into a category of individuals determined by the United States Public Health Service to be unsuitable for blood donation.

(d) For allogeneic collection:
   (1) All donors shall be given educational materials on risk activities for HIV infection and shall be advised that persons at risk for HIV infection should refrain from donating blood.

   (2) Each donor shall be provided the opportunity to indicate confidentially that blood collected is unsuitable for transfusion.

(e) For autogeneic collection only:
   (1) There are no age limits.

   (2) The hemoglobin concentration of the donor-patient should be no less than 11 grams per deciliter, or the hematocrit, if substituted, should be no less than 33 percent, unless otherwise approved in writing by the medical director of the blood bank or other physician designated by such medical director.

   (3) The frequency of phlebotomy for autogeneic transfusion shall be determined by the medical director of the blood bank and the donor-patient's physician. Phlebotomy of the donor-patient within 72 hours of the time of the anticipated surgery or transfusion must be authorized in writing by the medical director or other physician designated by the medical director.

   (4) Donation for autogeneic transfusion should not be undertaken if medically contraindicated.

(f) Blood withdrawn for autogeneic transfusion may not be used for allogeneic transfusion unless the donor meets all the criteria set forth in subdivision (b), and paragraphs (c)(2), (5) and (6) of this section, and the unit meets the requirements set forth in section 58-2.3(a) of this Subpart. The minimum hemoglobin concentration for such a unit shall be 12.5 grams per 100 milliliters or a hematocrit of 38 percent, and the minimum volume for such a unit shall be 405 milliliters.

(g) Blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of this section shall not be used for transfusion unless the container label indicates the donor's disease that necessitated withdrawal of blood, except that, in the case of a donor with hemochromatosis, blood without such labeling may be used for transfusion, provided that the blood bank has demonstrated that therapeutic phlebotomy is available free of charge to hemochromatosis patients and that all other requirements of this Subpart have been met.
58-2.3 Required laboratory tests for donated blood.

(a) For allogeneic collections under New York State permit, approved tests for syphilis; hepatitis B surface antigen (HBsAg); HIV-1 and hepatitis C virus (HCV) nucleic acid; and antibodies to hepatitis B core antigen (anti-HBc), HCV, HIV-1, HIV-2, and human T-lymphotropic virus types I and II (HTLV-I/II) shall be performed in a New York State-permitted laboratory. For autogeneic collections, such testing shall be performed unless the blood is intended for transfusion at the same facility where it is collected and a system is in place to ensure correct disposition of each blood unit, but the testing need not be performed again if already performed within the previous 30 days or if performed on a specimen collected subsequently. Results of a given test run shall not be accepted and reported if results of test kit controls are outside of the predetermined acceptable range. A written report shall be received thereon prior to the release of blood or blood components for transfusion and, if serologic tests are positive, shall preclude release for allogeneic transfusion except as described in section 58-2.9(b) of this Subpart. Until such testing is completed, all blood and blood components shall be stored in a separate refrigerator or prominently labeled separate area of the refrigerator reserved for quarantined units. However, in an emergency requiring release for transfusion prior to receipt of such report, the results shall be recorded subsequently on the recipient’s chart. Any unacceptable blood unit identified, as well as all of its components, shall be removed immediately from the quarantine area and disposed of or moved to a separate area reserved for such units. Units unacceptable for transfusion, which are retained for other purposes, shall be labeled with pertinent test results.

(b) All test runs for required tests for infectious disease markers that generate numeric readings shall include a weakly reactive control. If the results of this weakly reactive control or any other control do not fall within the predetermined acceptable range, results from that run shall not be reported until the run is repeated. Results of all tests shall be verified by a second staff member to preclude errors in transcription or interpretation. In a manual system, examination of the original instrument tape shall be conducted by the second staff member. Except for results of tests performed on samples from autogeneic donors, as specified in section 58-2.23 of this Subpart, incomplete test results shall not be reported to donors, including any initially reactive test results not yet repeated in duplicate. Release of blood units from quarantine shall be based on examination of a signed and verified hard copy, or electronic equivalent, of all test results. The director of the laboratory conducting the testing shall be responsible for ensuring that testing is performed in accordance with this Subpart. The blood bank director shall be responsible for development of algorithms for test result interpretation and shall approve, in writing, the laboratory procedures to be used.

(c) Plasma collected for fractionation purposes only need not be tested for HTLV-I.

(d) If platelets are donated by the infant's mother to an infant with alloimmune neonatal thrombocytopenia, the donor's blood need not be tested as required in subdivision (a) of this section. In such case, the donor requirements specified in section 58-2.2 of this Subpart may also be waived with the written authorization of the medical director of the blood bank or physician designee.
(e) If multiple patient-dedicated blood components are donated by a single donor to support a particular patient, that donor's blood may be screened for all analytes specified in subdivision (a) of this section every 30 days, rather than at each donation.

(f) For both allogeneic and autogeneic collection, the ABO and Rh groups of every donor shall be determined in accordance with procedures approved by the department. The determination shall be made by:

1) testing the blood cells with anti-A and anti-B grouping sera; testing the serum or plasma from the blood with known group A and group B red blood cells; and

2) testing the blood with anti-Rh(o) (anti-D) grouping serum, including, in the case of initially negative testing with anti-Rho (anti-D), a method designed to detect weak D.

(g) For allogeneic collection, required tests for detecting unexpected alloantibodies:

1) All donor blood shall be tested for unexpected alloantibodies using reagent red blood cells that meet F.D.A. standards and are intended for this purpose.

2) Methods of testing for alloantibodies shall be those that demonstrate sensitizing and hemolytic antibodies.

(h) Errors or accidents in collecting, testing or processing of donor blood that may affect the safety or purity of any product or health of the donor or recipient shall be reported to the department's Wadsworth Center within seven (7) calendar days of such an error or its discovery.

58-2.4 Collection of blood.

(a) Prior to collection of blood for testing, a signed form must be obtained from the donor or person legally authorized to consent on behalf of such donor, in which the donor or the person legally authorized to consent acknowledges that he/she has been provided with written materials stating that HIV testing for donor screening purposes shall be performed in conjunction with all donations.

(b) Quantity limitations. Allogeneic and autogeneic donors may give a maximum of 550 milliliters of whole blood in addition to pilot samples of up to 30 milliliters.

(c) Frequency limitations. No allogeneic blood donor may donate more than 550 milliliters of whole blood within an eight-week period, unless approved to do so by a physician who examines the potential donor at the time of the proposed second donation. In no event may an allogeneic blood donor donate more than twice within a 16-week period. The foregoing prohibition on donations does not apply to allogeneic blood donors diagnosed with hemochromatosis. For autogeneic collections, the frequency of donation shall be as specified in section 58-2.2(e)(3) of this Subpart.
58-2.5 Sterilization of instruments.

For both allogeneic and autogeneic transfusions, syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another, shall either be licensed by the F.D.A. for single use or be heat-sterilized prior to each use. Heat sterilization shall be by autoclaving at 121.5 degrees Celsius for 15 minutes after the chamber of the autoclave has been evacuated and has reached that temperature, or by dry heat for two hours at 170 degrees Celsius or by such other procedure as may be approved by the department.

58-2.6 Collection and handling of blood for subsequent allogeneic or autogeneic transfusion.

(a) Every blood donation shall be obtained under the direction of the medical director. Medical services for emergency care of the donor shall be available. Collection of blood for transfusion may be conducted only at blood banks with a permit in blood services-collection and at blood donation centers approved by the department.

(b) Phlebotomy apparatus and blood containers shall be clean, pyrogen-free and sterile. Anticoagulants shall be placed in containers prior to sterilization.

(c) Phlebotomy sites shall be prepared by a procedure found by the department to meet medical standards generally accepted in New York State.

(d) Blood collection systems shall meet the following minimum requirements:
   (1) Blood shall be collected under aseptic conditions using an approved closed system or a vented system if adequately protected against contamination.
   (2) Anticoagulant solutions shall be sterile and pyrogen-free. F.D.A.-approved formulae such as anticoagulant citrate dextrose (ACD) (21-day storage), citrate phosphate dextrose (CPD) (21-day storage), trisodium citrate (48-hour storage), heparin (48-hour storage), citrate phosphate dextrose adenine-1 (CPDA-1) (35-day storage), and other safe and effective formulae and storage periods, of such length as to assure the blood's continued effectiveness for transfusion and retention of its safety, purity and potency, as approved by the department, may be employed.
   (3) Labeling requirements.
      (i) For allogeneic collection, the container and the attached pilot blood specimens shall be legibly labeled at the time of collection with the associated unit's identification code. The container label shall indicate the date of expiration. As soon as available, the results of ABO and Rh grouping tests shall be affixed to component containers.
      (ii) With the exception of units collected in an operating room which never leave the immediate proximity of the patient, for autogeneic collection, the following information shall appear on a label or tag attached to the blood container:
         (a) the identification of the collecting facility;
(b) the patient's name and if available, the name of the hospital where the patient is to be transfused and the patient's hospital registration number or, if unavailable, social security number, birth date or similar identifying information. This tag shall be removed if the unit is subsequently used for allogeneic transfusion;

(c) ABO and Rh group;

(d) date of expiration;

(e) if the unit does not qualify for allogeneic transfusion, a prominent label to read "For autologous use only" or similar wording;

(f) an autogeneic unit from a donor who has tested positive or reactive on any of the tests required in section 58-2.3(a) of this Subpart within the previous 30 days shall be labeled as a biohazard unless confirmatory testing has been negative. The exterior of the shipping container shall not contain any information identifying the donor; and

(g) a label bearing the donor classification statement "Autologous donor" shall be permanently affixed to the unit.

(e) For allogeneic and autogeneic collections, adequate specimens of blood sufficient for all testing to be performed shall be taken.

(f) The blood shall be collected in the manner appropriate for the container employed. Following collection, the container shall be sealed securely. If a container is opened or entered in any way, the blood component must be transfused within 24 hours or discarded, unless a sterile connecting device which maintains a functionally closed system has been utilized for entry. After deglycerolizing, frozen red blood cells shall be transfused or refrozen within 24 hours, or shall be discarded. If a refrozen unit is subsequently rethawed and deglycerolized, a notation indicating such previous thawing and deglycerolizing shall be made on a label or tag attached to the blood unit, or on accompanying paperwork. After thawing of fresh frozen plasma, its blood component shall be transfused immediately or stored at between one and six degrees Celsius. Plasma stored in the liquid state for more than 24 hours shall be released only for medical indications other than replacement of labile coagulation factors. Cryoprecipitate intended for factor VIII replacement must be transfused within six hours after thawing.

(g) Until issued, whole blood and red cell components shall be stored continuously in a refrigerator either with a fan for circulating air, or of a capacity and design to ensure that the proper temperature is maintained throughout, and equipped with automatic temperature recording and an audible alarm. Storage shall be at a temperature of not less than one degree Celsius nor more than six degrees Celsius. No items other than specimens, tissue, or reagents shall be stored in a refrigerator in which whole blood and red blood cell components are stored. Temperature records shall be available for inspection for at least five years. Blood in transit shall be refrigerated at a temperature between one degree Celsius and 10 degrees Celsius, preferably between four degrees Celsius and six degrees Celsius, with the exception of units from which platelets will be separated. Units which will be used as a source of platelets shall be stored at room temperature,
preferably at 20 to 24 degrees Celsius, until platelets are separated, but for no more than eight hours. Autogeneic units shall be stored in a separate, specifically designated portion of the refrigerator.

(h) Until issued, cryoprecipitate, fresh frozen plasma and cryoprecipitate-poor plasma shall be stored continuously at a temperature not higher than minus 18 degrees Celsius in a freezer equipped with automatic temperature recording and an audible alarm. Storage time shall not exceed one year. Such components shall not be relabeled as different components and released for transfusion, but may be used for fractionation into derivatives. Freezer temperature records shall be available for inspection for at least five years.

(i) Until issued, platelets shall be stored at 20 to 24 degrees Celsius and shall be continuously rotated on a rotator designed for such use. Temperature records shall be available for inspection for at least five years.

(j) Until issued, frozen red blood cells shall be stored at a temperature no higher than minus 65 degrees Celsius in a freezer equipped with automatic temperature recording and audible alarm, or in liquid nitrogen. Liquid nitrogen levels must be mechanically or visually monitored daily. Storage time shall not exceed ten years. Freezer temperature or liquid nitrogen level records shall be available for inspection for at least five years. After thawing, blood shall be transfused within 24 hours or discarded.

(k) Whenever blood is irradiated, a protocol for such irradiation, approved by the director of transfusion services or the director of the blood bank, must be followed. Maintenance and operation of blood irradiators must conform to the manufacturer's instructions. Whenever irradiation of blood is medically indicated because of a blood relationship between donor and recipient, such irradiation shall be performed by the blood bank collecting the blood unless the hospital notifies in writing the facility collecting the blood that the hospital will be responsible for irradiation, in which case such blood shall be identified as requiring irradiation on a tag or paperwork accompanying the units. Blood that has been irradiated shall be identified as "Irradiated" on label or tag attached to the unit.

(l) Fresh frozen plasma, cryoprecipitate and frozen red blood cells shall be thawed only in a water bath at a temperature not exceeding 38 degrees Celsius or in another device specially designed for such thawing. If a water bath is used for thawing, its temperature shall be recorded each day of such use. Temperature records shall be available for inspection for at least five years. Maintenance and operation of all equipment for processing or preparation of blood components shall conform to the manufacturer's instructions and shall follow a protocol approved by the director of transfusion services.

(m) Except for blood recovered intraoperatively or postoperatively, or collected for use in a reinfusion procedure, all blood intended for transfusion shall upon collection become the responsibility of the blood collection service. Disposition of blood collected by phlebotomy shall be at the discretion of the director of the collection service until the blood is transferred to a transfusion service, at which time its disposition shall be at the discretion of the director of transfusion services. The director of the blood bank shall ensure that during any transport blood is
packed and handled appropriately and only by authorized individuals. No directed or autogeneic blood unit or component shall be transported to a transfusion service unless the director of the receiving transfusion service or his/her designee has authorized such transport. A transfusion service which has granted standing authorization for receipt of blood shall be given specific notice prior to each shipment. Disposition of blood recovered intraoperatively or postoperatively shall be at the discretion of the intraoperative or postoperative blood collection service, unless the blood is transferred to the hospital blood bank for storage, at which time its disposition shall be at the discretion of the director of transfusion services. Blood banks shall not release blood components or blood intended for transfusion to any site in New York State not permitted as a collection service or transfusion service, or approved as a limited transfusion service.

(n) The premises, equipment, procedure manuals, records, circulars of information, and all blood, blood components and derivatives shall be available for inspection, review and approval by the department during normal business hours.

58-2.7 Immunohematology testing.

(a) Labeling of specimens intended for pre-transfusion testing shall include the patient’s name, patient’s identification number, and date of collection. Identification of the person collecting the specimen shall be recorded.

(b) All tests, including, but not limited to, ABO and Rho(D) grouping, antibody detection and identification, and compatibility testing, shall employ methods, techniques or procedures which have been approved or recommended for the particular reagent in use by the F.D.A. or the American Association of Blood Banks, and which have been demonstrated to be effective in a manner acceptable to the department in conformance with generally accepted laboratory principles. All grouping antisera, reagents, devices, methods, and procedures for blood unit processing or transfusion-related testing shall be approved by the F.D.A. or conform to the recommended minimum requirements of the F.D.A.

(c) All reagents shall be stored in labeled containers under conditions appropriate for each reagent as directed by the manufacturer and shall be removed from use after their expiration date. The reactivity and specificity of each reagent shall be determined whenever a new lot is employed. All methods shall conform to manufacturers’ instructions unless otherwise approved by the department.

(d) Negative controls run on each day of use are not required for anti-human globulin and antibody screening cells, provided manufacturers’ instructions are followed. New lots of reagents shall be thoroughly evaluated, but antibody identification cell panels need not be tested with a known antibody. All test procedures to be used shall be determined by the blood bank director and shall be documented in the standard operating procedure manual. If no negative reactions are observed on a given test run, an investigation shall be performed and controls run. Such quality control records shall be accessible to laboratory personnel engaged in immunohematology testing and to the department.
(e) Centrifuges used for testing of red blood cell agglutination shall undergo revolutions per minute (RPM) and timer checks quarterly. Functional calibration that determines optimal centrifugation conditions shall be performed prior to initial use, after adjustments or repairs, and at least annually thereafter, and shall be documented. The procedure shall specify the speed and duration of centrifugation to be used. A microscope shall be located in the work area designated for immunohematology testing, if use of a microscope is specified by the facility’s standard operating procedure manual or by a test kit manufacturer’s package insert. Microscopic examination shall be performed for red blood cell agglutination tests whenever indicated for the procedure in use.

58-2.8 Standard operating procedures.

(a) Current standard operating procedure manuals or other procedural guides specific to the facility shall be available at all times in the immediate work area of personnel engaged in the collection, processing, testing, storage, distribution and administration of blood, blood components or derivatives for autogeneic or allogeneic use, and for therapeutic, prophylactic or diagnostic purposes. There shall be a written protocol for all procedures performed at the facility. Manuals shall contain a protocol for writing, maintaining and periodic review of standard operating procedures by user personnel and management staff. Procedure manuals shall have the following features:

1. a standardized format;

2. a system of numbering and/or entitling individual procedures;

3. a clearly written description of purpose for each procedure;

4. a reference section listing appropriate scientific literature;

5. clearly defined areas of personnel responsibility by title;

6. documented approval of procedures and procedural modifications by the director, and annual review by the director or authorized supervisor;

7. instructions for the completion of reports and forms, including examples;

8. effective date and date of review for each procedure; and

9. a system of archiving earlier versions of procedures and forms.

(b) The procedure manual shall include a written procedure for documenting errors or accidents in collection, testing, processing, storage or distribution that may affect the safety or purity of any product, or health of the donor or recipient. If the error or accident is not detected prior to issuance of the blood, blood components or derivatives, the error or accident shall be reported immediately to the receiving facility. All such errors and accidents shall also be reported to the department's Wadsworth Center within seven (7) calendar days of discovery.
The procedure manual shall include written policies and protocols regarding the following, for activities performed at the site:

1. use and maintenance of blood warming devices;
2. type of infusion sets and filters for all components;
3. inspection of components prior to issuance;
4. type of personnel who may remove components;
5. for collecting facilities, obtaining blood or components from other institutions during emergency situations;
6. prenatal and neonatal testing;
7. evaluation of reported transfusion reactions;
8. emergency release of uncrossmatched blood;
9. method validation requirements;
10. professional qualifications of personnel who may collect blood specimens for pretransfusion testing; and
11. specimen and labeling requirements for pretransfusion samples.

The policies and procedures specified in the procedure manual shall be followed at all times. If deviations are identified, appropriate corrective action shall be taken and documented.

The blood bank director or the director of transfusion services shall establish and maintain a planned and periodic internal review program for monitoring and evaluating the quality and appropriateness of standard operating procedures in the performance of blood bank and transfusion service activities. Included in the program shall be a system for designing and implementing corrective action for any problems identified. Quality assurance deficiencies shall be documented, and evidence shall be available that problems are reported to the appropriate individuals in a timely manner and that corrective action is implemented and subsequently followed-up.

58-2.9 Issuance of blood, blood components and derivatives.

Unless they are needed to meet a medical emergency, blood and blood components shall be transported in a leak-resistant, crush-resistant and puncture-resistant container featuring a prominent label which:

1. identifies the contents as "human blood" or "biomedical product";
(2) describes the contents, the packing agent, if any, and any special precautions necessary in handling such blood; and

(3) contains the name, address and twenty-four hour telephone number of the person or entity to be contacted in the event that the container is found to be leaking or damaged, or to have been misdirected.

(b) Except in an emergency or except as indicated in section 58-2.3(c) or (d) of this Subpart, blood and blood components shall not be made available for allogeneic transfusion, unless a donor blood sample reacts negatively to tests required in section 58-2.3(a) of this Subpart, and testing specified in section 58-2.3(f) of this Subpart has been completed. Untested or incompletely tested blood, including blood from directed donations and cytapheresis collections, shall not be issued if a fully tested blood component is available, except in the case of autogeneic donations, as specified in section 58-2.3(a) of this Subpart. Cytapheresis units for which testing has not been completed may be distributed to a hospital by the facility collecting the units, but such components may not be issued by a transfusion service until testing is complete, except in the case of a life-threatening emergency. The release of cytapheresis components from a donor found to have a positive result for anti-HBc may be permitted upon the authorization of the health care provider ordering the transfusion and the written authorization of the medical director or physician designee, provided that such authorization documents the indication and justification for such release. Such components shall be labeled with all positive test results. Blood from a donor whose blood specimen reacts positively in a test for syphilis and is nonreactive in confirmatory testing shall be appropriately labeled and may be used for plasma fractionation. Blood from a donor whose blood specimen reacts positively in tests for HBsAg, HIV or HCV nucleic acid, or antibodies to HCV, HIV-1, HIV-2, or HTLV-I/II shall be appropriately labeled and may not be used for allogeneic transfusion or for fractionation. Blood from a donor whose blood sample reacts positively in tests for HBsAg or antibodies to HIV-1 and/or HIV-2 may not be used for autogeneic transfusion without the written authorization of the patient’s physician and, if drawn by another facility, the director of the transfusion service receiving the unit.

(c) Blood components and derivatives shall be issued only if ordered by a licensed physician or other person authorized by law. Recipients shall receive whole blood of the same ABO group or compatible red blood cells. Rh(o) (D)-negative recipients shall receive Rh(o) (D)-negative blood except for reasonable exempting circumstances as determined by the director of transfusion services. Rh(o) (D)-positive recipients may receive Rh(o) (D)-positive or Rh(o) (D)-negative whole blood or red blood cells. In an emergency, appropriately documented in the records, blood may be released for transfusion prior to the completion of compatibility tests. Any transfusion service which issues blood for transfusion at a limited transfusion service shall perform the required tests on its own premises unless the limited transfusion service holds the required permit issued by the department to perform such tests.

(d) Whole blood, red blood cells, plasma or other blood components and derivatives shall be inspected visually immediately prior to issuance. If the color or physical appearance is abnormal
or there is indication or suspicion of microbial contamination, the unit or units of whole blood, blood components or derivatives shall not be issued for transfusion.

(e) Blood, blood components or derivatives may not be made available for transfusion beyond the designated expiration date, except that whole blood may be used to prepare plasma within nine days after the designated expiration date, provided that it meets the inspection standards required in subdivision (d) of this section.

(f) An established protocol for processing or pooling of blood components prior to issuance must be in place.

(g) Except in emergency situations, or in cases in which the patient has multiple vascular access lines and more than one unit will be transfused simultaneously, or in case of release to an operating room with a monitored refrigerator, only one unit of red cells at a time may be issued within a hospital for a particular patient, unless otherwise authorized in writing by the director of transfusion services.

(h) If an unused, unopened unit is returned to the blood bank, the time, date and condition of the unit must be recorded.

(i) A sample of red cells or whole blood from each red cell product issued for transfusion shall be retained for a minimum of seven days after the transfusion for further testing in the event of an adverse reaction.

(j) After issuance, red blood cells may be stored at room temperature for up to one hour or by refrigerating at between one and six degrees Celsius. Red blood cells kept at room temperature for more than one hour may not be returned to the blood bank and later reissued for transfusion unless the temperature of the component is documented not to have risen above ten degrees Celsius. If refrigerated, red blood cells shall be stored in a refrigerator designed for the purpose of storing blood, except that a cooler with suitable coolant may be used for refrigeration, provided that the temperature of the blood is maintained at between one and ten degrees Celsius.

(k) Blood or blood components shall not be identified or labeled or preferentially distributed according to the donor's membership in a category based on age, race, color, creed, national origin, sex, marital status or social organization, except for purposes of phenotyping of blood units. The sequence of issuance by a transfusion service of blood donated for designated recipients shall not be based on factors other than medical considerations.

(l) Blood or blood components from a donor who had been determined in the past to be unsuitable for subsequent donation shall not be released for transfusion unless the donor has been approved for reentry into the donor pool by the director of the blood bank.
58-2.10 Required records and confidentiality.

(a) Complete and accurate records of blood, blood components and derivatives released for allogeneic or autogeneic transfusion shall be kept for seven years or six months after the expiration date of the individual product, whichever is later, by the blood bank preparing the product and by the institution using the product. Such records shall be open to inspection by the department and shall include the information specified in sections 58-2.11 and 58-2.12 of this Subpart. For all collected or distributed blood, blood components and derivatives, the donor's name, address, telephone number, social security number and any other information which would directly or indirectly identify the blood donor of any specific unit shall not be disclosed by the blood bank to any person or entity except upon the written consent of the donor or except to the department and other agencies which issue clinical laboratory and/or blood bank permits to the facility whose records are requested.

(c) Records shall be maintained of all tests, controls, reagents and current procedures, in a manner acceptable to the department in conformance with generally accepted laboratory principles.

58-2.11 Records to be kept when blood is collected for autogeneic or allogeneic transfusion.

(a) Every blood bank shall maintain a record of each container of blood or blood components collected or prepared therein. The record shall contain the following information:

(1) donor's full name, address, age, sex and identifying code;

(2) date and amount of blood collected;

(3) any adverse reaction of the donor;

(4) signature of the phlebotomist;

(5) results of all tests performed on a sample from the donor or a unit;

(6) disposition of the blood or blood components;

(7) for autogeneic donation, documentation of written or verbal consent of the donor-patient's health care provider if donation takes place prior to anticipated surgery or medical procedure, of the physician responsible for collection or his/her designee, and of the donor-patient. If the blood is to be considered for allogeneic use, the donor shall sign a consent form giving consent for such use, specifying procedures for release of the unit by the health care provider, and stating that to the best of the donor's knowledge, the blood is safe for use by others; and

(8) if a donor is determined to be unsuitable for donation based on donor history, laboratory test results or implication in a case of transfusion-transmitted disease according to the protocol of the blood collection service, a record of the donor's name and identifying information. Blood from such a donor shall not be released, even if results of testing on subsequent donations are negative,
unless the donor has been approved for reentry into the donor pool by the director of the blood bank.

58-2.12 Records to be kept when blood, blood components or derivatives are issued for allogeneic or autogeneic transfusion.

(a) For blood and blood components, logbook records of the following information, where relevant, shall be kept in the blood bank and made available to the department for inspection:
   (1) source;
   (2) donor identification code;
   (3) ABO and Rh groups;
   (4) expiration date;
   (5) results of compatibility tests;
   (6) disposition of the unit, including recipient's name if administered;
   (7) signature or initials of the person removing the unit;
   (8) date and time of issue; and
   (9) results of all tests associated with the investigation of all transfusion reactions, with the conclusions reached and the report signed, or approved by electronic equivalent, by the director of the blood bank or a qualified physician designated by the director of the blood bank.

(b) For coagulation factor concentrates, logbook records of the following information shall be kept and made available to the department for inspection:
   (1) manufacturer;
   (2) lot number;
   (3) expiration date;
   (4) disposition, including recipient's name if administered; and
   (5) date of issue.

(c) For all derivatives, records associated with the investigation of all by electronic equivalent, by the director of the blood bank or a qualified physician designated by the director of the blood bank, shall be kept and made available to the department for inspection.
(d) These recordkeeping requirements shall also apply to blood issued to limited transfusion services.


(a) A blood bank may maintain blood donation centers at fixed sites provided written approval is obtained from the department for the establishment of each such center.

(b) Each blood donation center shall be under the supervision of the director of the blood bank, and shall be adequately lighted and ventilated, and equipped and operated in a manner satisfactory to the department.

(c) Other activities, including preparation of components, storage, distribution and donor qualification laboratory testing shall not be performed at blood donation centers without prior written approval of the department.

(d) The blood bank shall inform the department, upon request, of the number and type of mobile units active under its direction, and the provisions made for the handling of medical emergencies.


(a) The standards that apply to whole blood collection and processing shall apply to serial plasmapheresis except as otherwise specified. Whenever the plasma is not intended for transfusion, or for the preparation of fractions for transfusion, the criteria for donor selection may be limited to those designed for the safety of the donor. In such instances, the plasma unit shall be prominently labeled, "NOT FOR TRANSFUSION", or similar language.

(b) Direction. The director of a serial plasmapheresis program shall be a physician who must demonstrate satisfactory training in all aspects of hemapheresis, including a minimum of two years' experience.

(c) Informed consent. The consent of a prospective serial plasmapheresis donor shall be obtained in writing after a licensed physician explains the hazards of the procedure to the donor in such a manner that he/she is offered an opportunity to refuse consent. The donor shall be told of the risks of serial plasmapheresis, including the possibility of a hemolytic transfusion reaction if he/she is given someone else's red cells, risk of any medications or sedimenting agents to be used, and, if he/she is to be immunized or hyperimmunized, of the hazards involved. For example, in the case of immunization with human blood components, the donor shall be told specifically about the risk of viral hepatitis, as well as about the increased risk of receiving incompatible blood if he/she ever needs a transfusion. A prospective donor who is to be deliberately exposed to an antigen shall also be given a general description of the immunization program, including the nature of the material to be injected. All of this information shall also be given to each prospective donor in written form, and the donor's consent shall be signed and witnessed on a form approved by the department.
(d) **Donor qualification.** A donor may not be accepted for serial plasmapheresis unless the criteria in section 58-2.2(b) and (c) of this Subpart, with the exception of sections 58-2.2(b)(5) and (7), and 58-2.2(c)(10) and (11), are met.

(e) **Care of serial plasmapheresis donors.** A qualified, licensed physician shall be available within fifteen minutes' travel time of the premises, at which serial plasmapheresis is performed, immediately available for personal or telephone consultation in the treatment of a donor who manifests an adverse reaction, and responsible for all phases of plasmapheresis conducted. A physician or a registered nurse designated by the medical director shall be available on the premises at all times. The floor supervisor shall be a registered nurse, physician assistant, or person with at least two years' experience performing plasmapheresis procedures, and shall have completed a plasmapheresis training program that includes documented satisfactory performance of donor plasmapheresis procedures. Persons performing manual plasmapheresis procedures shall be licensed practical nurses, registered nurses, clinical laboratory technologists, physician assistants, or persons with at least two years' experience performing manual plasmapheresis procedures. Persons performing automated plasmapheresis procedures shall be licensed practical nurses, registered nurses, clinical laboratory technologists, clinical laboratory technicians or physician assistants, or persons with at least six months' experience in collecting whole blood for transfusion. All persons performing plasmapheresis procedures shall have one year's experience performing plasmapheresis procedures or shall have completed a training program in plasmapheresis procedure technique. The training program must include training in donor screening, venipuncture techniques, instrument operation, prevention of an initially addressing donor reactions, and proper documentation of all completed procedures. At the end of the training program, each plasmapheresis operator must be able to:

1. safely and effectively operate the cell separator systems in use at the facility;

2. harvest plasma which meets quality standards;

3. manage fluid volumes safely;

4. prevent, and when necessary, initially address adverse reactions;

5. develop the ability to work independently, utilizing the floor supervisor as a resource when necessary; and

6. provide support to the donor while maintaining control of the operation of the instrument.

The director shall establish an agreement with an accredited hospital in the vicinity of the plasmapheresis center for the admission of donors who sustain adverse reactions and require hospital care.

(f) **Laboratory testing.** A serologic test for syphilis shall be performed within 24 hours on a specimen collected at the time of the first donation and at four-month intervals thereafter. A donor with a reactive serologic test for syphilis shall not be plasmapheresed again until the donor's serum is nonreactive in confirmatory testing, except that donors with reactive tests for syphilis may be plasmapheresed to obtain plasma to be used for manufacturing control serum for serologic
tests for syphilis. Approved tests for HBsAg and antibodies to HCV, HIV-1 and HIV-2 shall be performed on the retained plasma or on a specimen obtained from the donor at the time of donation. If the plasma is intended for transfusion, all tests required in section 58-2.3(a) of this Subpart shall be performed.

(g) Return of red blood cells to donor. If it is not possible to return red blood cells to a plasmapheresis donor, or if whole blood is donated, the donor shall not be plasmapheresed again for eight weeks, unless the donor's extracorporeal red blood cell volume during the procedure is not expected to exceed 100 milliliters.

(h) Manual plasmapheresis procedures. Containers and anticoagulants shall meet the standards for whole blood. Before the blood container is separated from the donor for processing, it shall bear two separate and independent means of identification to enable both the donor and the phlebotomist to determine without doubt that the contents originate from the donor. Plasmapheresis shall be performed aseptically under conditions that avoid air embolism. During their separation, the red blood cells shall be maintained at a temperature not exceeding 37 degrees Celsius and under conditions known to assure the sterility and viability of these cells upon their return to the donor. The identity of the donor and the container shall be confirmed by at least two technical staff members prior to reinfusion of the red blood cells. Red blood cells shall be returned to the donor within two hours of the phlebotomy. If plasmapheresis is to be performed using equipment dissimilar to blood bags used for the collection of blood so that the standards for containers and anticoagulants for whole blood do not apply, specific approval from the department is required.

(i) Automated plasmapheresis procedures. Plasmapheresis shall be performed aseptically under conditions that avoid air embolism and maintain sterile technique. If plasmapheresis is to be performed using equipment dissimilar to blood bags used for the collection of blood so that the standards for containers and anticoagulants for whole blood do not apply, specific approval from the department is required.

(j) Records. All institutions performing plasmapheresis shall maintain records of all plasmaphereses performed, and the clinical and laboratory information pertinent thereto. These records shall include complete information on each donor, signed consent of the donor, his/her identification code, and the amount of plasma removed. When immunizations are performed, the antigen and the procedures employed shall be identified and recorded, and the donor shall give specific consent for the immunization. These records shall be available for inspection for at least seven years after each plasmapheresis.

58-2.15 Collection of blood components by apheresis.

(a) Selection of donors. The standards that apply to whole blood donation shall apply in the selection and care of the donor for apheresis, unless otherwise specified.

(b) Informed consent. The consent of a prospective donor shall be obtained in writing after a qualified and specially trained individual explains the hazards of the procedure in such a manner
that the donor is offered an opportunity to refuse consent. The donor shall be informed of the risks of apheresis and the risks of any sedimenting agents or medications to be used.

(c) Qualifications and care of the donor.
(1) Only those persons may be accepted as blood donors for apheresis who are in good health as indicated by the qualifications of a whole blood donor specified in section 58-2.2 of this Subpart, with the following exceptions:
   (i) Ingestion of aspirin-containing medications within three days of donation shall preclude donation of platelets.
   
   (ii) Cytapheresis of donors who do not meet the requirements of this subsection shall be performed only if the harvested cells are expected to be of particular value to an intended recipient, and only if the supervising physician has confirmed in writing the particular value of these cells and has certified that the donor's health permits cytapheresis.
   
   (iii) Medications or sedimenting agents to facilitate cytapheresis shall not be used in donors whose medical history suggests that these may exacerbate previous or intercurrent disease. Guidelines for use of such agents shall be established by the medical director.

(2) The medical director, who must demonstrate satisfactory training in all aspects of apheresis, including one year of experience, shall be responsible for all phases of apheresis conducted. Persons performing apheresis procedures shall be registered nurses, licensed practical nurses, clinical laboratory technologists, clinical laboratory technicians or physician assistants, or persons with at least six months’ experience collecting blood for transfusion. All persons performing apheresis procedures shall have at least one year’s experience performing apheresis procedures or shall have completed a training program in apheresis procedure technique. The training program must include training in donor screening, venipuncture techniques, instrument operation, prevention of an initially addressing donor reactions, and proper documentation of all completed procedures. At the end of the training program, each apheresis operator must be able to:
   (i) safely and effectively operate the cell separator systems in use at the facility;
   
   (ii) harvest blood components which meet quality standards;
   
   (iii) manage fluid volumes safely;
   
   (iv) prevent, and when necessary, initially address adverse reactions;
   
   (v) develop the ability to work independently, utilizing the floor supervisor as a resource when necessary; and
   
   (vi) provide support to the donor while maintaining control of the operation of the instrument.

(3) The floor supervisor shall be a:
   (i) registered nurse;
(ii) physician assistant;

(iii) person with at least two years' experience performing apheresis procedures; or

(iv) person with at least one year of experience supervising allogeneic blood collection.

(4) The floor supervisor shall have completed an apheresis training program that includes documented satisfactory performance of donor apheresis procedures.

(5) A person specifically trained in recognizing and addressing reactions that may occur in association with the procedures being performed shall be immediately available on the premises at all times during an apheresis procedure. A qualified licensed physician shall be immediately available, at least for telephone consultation, during all procedures.

(d) Volume and frequency of apheresis. Extracorporeal blood volume shall not exceed 15 percent of the donor's estimated blood volume. No more than 12.0 liters of plasma shall be removed per year from a donor weighing 175 pounds or less, and no more than 14.4 liters shall be removed per year from a donor weighing more than 175 pounds. The interval between procedures shall be at least 48 hours. The above volume and frequency requirements may be waived upon written authorization of the supervising physician, provided the donor meets all other eligibility requirements. Red blood cells shall not exceed 300 milliliters per eight weeks, unless the following requirements are met:

(1) for male donors, the donor's weight is at least 130 pounds;

(2) for female allogeneic donors, the donor's weight is at least 150 pounds;

(3) for female autogeneic donors, the donor's weight is at least 130 pounds;

(4) the allogeneic donor's hemoglobin content is 13.3 grams per deciliter or greater or hematocrit is 40 percent or greater;

(5) the autogeneic donor's hemoglobin content is 12.0 grams per deciliter or greater or hematocrit is 36 percent or greater;

(6) the volume of packed red blood cells removed does not exceed 550 milliliters; and

(7) the volume removed is replaced with at least 225 milliliters of normal saline. Following a red cell apheresis procedure in which red blood cell loss exceeds 300 milliliters, the allogeneic donor shall not donate whole blood or undergo another apheresis procedure for a minimum of 16 weeks. For autogeneic donors, frequency and volume to be removed shall be determined by the medical director of the blood bank in conformance with recommendations of the manufacturer of the apheresis device.
(e) **Return of red blood cells to donor.** If it is not possible to return red blood cells to a donor, or if whole blood is donated, the donor shall not undergo apheresis again for eight weeks, unless the donor’s extracorporeal red blood cells volume during the procedure will not exceed 100 milliliters.

(f) **Procedures for collection of blood components by apheresis and their processing.** Such procedures shall follow a written protocol approved by the medical director. Containers and anticoagulants shall meet the standards for whole blood. Apheresis shall be performed aseptically under conditions that prevent air embolism, and assure sterility and viability of cells returned to the donor.

(g) **Required records.** All facilities performing apheresis shall maintain records of all such procedures performed, and the clinical and laboratory information pertinent thereto. These records shall include complete information on the donor, volume of blood removed, anticoagulants used, duration of the procedure, volume of components obtained, medications and sedimenting agents used, including manufacturer, lot number, expiration date and amount administered, and any adverse reactions and their management. These records shall be available to the department for inspection for at least seven years after each procedure.

### 58-2.16 Required standards for transfusions.

(a) **Transfusion services.** Every institution which performs transfusions or supplies blood to limited transfusion services shall designate a physician who is a member of the staff as director of transfusion services. Such physician must be licensed and currently registered in New York State. The director of the blood bank, if a physician, may be so designated. The premises, equipment, procedure manuals, records, and all blood, blood components and derivatives shall be available for inspection by the department.

(1) It shall be the responsibility of the chief executive officer or other person in charge of each institution and of the director of transfusion services to determine that:

   (i) the rules and regulations of the Council on Human Blood and Transfusion Services and the Administrative Rules and Regulations of the department and related requirements are complied with;

   (ii) attending and other staff members and nurses are properly instructed regarding all required procedures;

   (iii) records required by the aforesaid rules and regulations are maintained;

   (iv) serious unexpected reactions and incidents involving transfusions are reported to the department’s Wadsworth Center, with sufficient detail to facilitate evaluation and investigation, within seven (7) calendar days of the reaction or incident or its discovery; and

   (v) a written policy exists regarding use of blood components negative for cytomegalovirus antibody, irradiated components, leukocyte-reduced components and other specialty components. Such a policy shall include recommended indications for component use and
a protocol for component processing and issuance. There shall also be a written policy on recommended indications for transfusion of whole blood, fresh frozen plasma and platelets.

(2) The institution shall report annually to the department the name(s) of the physician(s) in charge of the transfusion service.

(3) If blood is issued to a limited transfusion service, the director of transfusion services of the issuing facility and the director of the limited transfusion service performing the transfusion shall ensure compliance with all requirements of this Part.

(b) Each facility which transfuses blood or supplies blood to limited transfusion services shall have a transfusion committee which meets at least quarterly or more frequently as required by the department. The committee shall:
   (1) be composed of at least five members, a majority of whom are present at each meeting;

   (2) include members with expertise in transfusion medicine and qualified to review the appropriateness and technical aspects of a transfusion, such as, but not limited to, the director of transfusion services, blood bank supervisor or pathologist; and

   (3) review transfusions of all blood and blood products issued by the facility for all sites at which transfusions are performed, including all intraoperative and postoperative recovery procedures.

(c) Each institution, through its transfusion committee, shall establish guidelines for reservation (compatibility or crossmatching) of blood for each elective surgical procedure which has been performed there more than five times in the preceding calendar year and shall set the maximum number of hours that crossmatched blood will be held on reserve.

(d) Whole blood, red blood cells, plasma, or other components and derivatives shall be prepared and administered by methods generally accepted by the F.D.A. or American Association of Blood Banks and/or by other methods approved by the department as in conformance with generally accepted laboratory principles. For blood and blood components, the person initiating the transfusion shall be a physician, registered nurse, physician assistant, nurse practitioner, licensed practical nurse or board-certified cardiovascular perfusionist (intraoperatively). A licensed practical nurse shall initiate transfusions only following satisfactory completion of a transfusion training program meeting criteria specified by the department and by the New York State Education Department and only when a registered nurse, physician assistant, or a physician is immediately available on site. A filter meeting F.D.A. requirements shall be incorporated into the intravenous administration set to be used for blood or blood component transfusions.

(e) No medications except physiologic saline for intravenous use shall be added to or mixed with blood for transfusion unless they have been approved for this use by FDA and there is documentation available to show that the addition is safe and does not adversely affect the blood component.
(f) In a health care setting, following comparison of the blood product label with all accompanying information, the person initiating the transfusion shall, at the patient’s side, immediately prior to initiating the transfusion, positively identify the recipient and the blood product to be transfused or infused, using the patient’s name and a unique numerical or alphanumerical identifier. For administration of a blood component, one additional person, who must be a physician, registered nurse, physician assistant, nurse practitioner, licensed practical nurse, or board-certified cardiovascular perfusionist (intraoperatively), shall also so identify the recipient and the blood component, unless another procedure to ensure accurate identification is used, in which case a single identification is sufficient. At least one person identifying the patient and blood component at the patient’s side shall be a physician, registered nurse, physician assistant, nurse practitioner, or board-certified cardiovascular perfusionist (intraoperatively). Each identification procedure shall be documented in writing by each participant. Two persons authorized to initiate blood transfusions shall be immediately available during a blood component transfusion and for 30 minutes afterward, except for transfusion of a patient enrolled in a chronic transfusion program who has no history of adverse reactions. A blood component recipient’s vital signs shall be serially recorded, in accordance with written policies and procedures. If the person recording the vital signs is a licensed practical nurse, all measurements outside of established parameters shall be reported to a registered nurse, physician, physician assistant, or nurse practitioner for assessment and action. Such notification shall be documented.

(g) For transfusions outside a health care setting, including in patient homes, the person initiating the transfusion and monitoring the patient shall be a physician, registered nurse, physician assistant, or nurse practitioner. Following comparison of the blood product label with all accompanying information, this person shall, at the patient’s side, immediately prior to initiating the transfusion, positively identify the recipient and the blood product to be transfused or infused, using the patient’s name and a unique numerical or alphanumerical identifier. Such identification procedure shall be documented in writing. The person administering the transfusion and another competent adult, other than the recipient, shall be immediately available at all times during a transfusion. Both persons shall be available for 30 minutes afterwards, except for transfusions of patients enrolled in a chronic transfusion program who have no history of adverse reactions. The recipient’s vital signs shall be monitored and documented, in accordance with written policies and procedures.

(h) Every facility or limited transfusion service performing transfusions shall provide 24-hour-a-day post-transfusion patient coverage by telephone as necessary.

(i) Each institution, through its transfusion committee, shall develop and implement procedures to encourage the use of autogeneic blood whenever medically indicated. These procedures shall include a mechanism for informing staff physicians of the risks and benefits of autogeneic blood and the options for autogeneic blood transfusion available at the institution. These procedures shall also include a mechanism to encourage physicians to inform their patients of such options whenever medically indicated.

(j) If blood is warmed prior to transfusion, the warming system shall be equipped with a visible thermometer and an alarm to ensure that the blood is not warmed above the temperature specified by the director of the blood bank, in conformance with the system manufacturer’s
instructions. Blood warmer temperature shall be monitored and recorded on each day of use, and such records shall be available for inspection for at least five years. Maintenance and operation of blood warmers must conform to the manufacturer’s instructions.

58-2.17 Laboratory tests to be performed prior to allogeneic or autogeneic transfusion.

(a) Tests shall be performed to determine the ABO and Rh(o) (D) groups of each recipient and each unit to be transfused in accordance with procedures approved by the department pursuant to this Subpart. ABO grouping tests shall include both forward and reverse grouping except in the case of hospital transfusion services verifying a blood group determination performed elsewhere, in which case forward grouping alone may be performed. Prior to transfusion, the ABO group of all units of whole blood and red blood cell components, as well as the Rh group of all such units labeled as Rh-negative, shall be confirmed using a sample obtained from an attached segment or using a validated computer system. Any discrepancies shall be reported in writing to the collecting facility and resolved prior to issuance of the blood for transfusion purposes.

(b) All recipient blood shall be tested for unexpected alloantibodies using reagent red blood cells that meet F.D.A. standards, are intended for this purpose and are not pooled. Methods of testing for unexpected alloantibodies shall demonstrate sensitizing and hemolytic antibodies.

(c) Except in cases necessitating emergency release of group-compatible blood or except in the case of transfusion of a volume of blood or blood components exceeding the recipient's expected normal blood volume in a 24-hour period, compatibility between recipient and donor blood shall be determined. If a clinically significant antibody has been detected, or if there is a history of presence of such an antibody, the compatibility test shall include an antiglobulin phase crossmatch. If no clinically significant antibody has been detected, and there is no known history or presence of such an antibody, the procedure to be used may be determined by the director of transfusion services, but shall, at minimum, consist of an immediate spin test or verification of the blood group of the recipient, and of the blood or blood component to be transfused.

(d) In the case of patients requiring repeated blood transfusions, or those pregnant or transfused with allogeneic red blood cell-containing components within the previous three months, fresh blood specimens shall be drawn for compatibility testing and antibody screening at intervals of not more than three days prior to the day of transfusion, except for neonates, to whom no time limits apply.

(e) The procedure to be used for compatibility testing shall be determined by the blood bank director, but shall, at minimum, consist of an immediate spin, or verification of the blood group of the recipient and of the blood or blood component to be transfused. Antiglobulin phase compatibility testing is required if a clinically significant antibody is detected during the antibody screen or if there is a history of presence of such an antibody. Laboratory procedure manuals shall be revised to reflect any changes in such procedures.

(f) A pre-transfusion sample of recipient blood, including serum or plasma, shall be retained for seven days after each transfusion for further testing in the event of an adverse reaction.
58-2.18 Records to be kept when blood or blood component transfusions are performed.

The following information shall be included on the recipient's chart or in records maintained in the blood bank:

(a) donor's identification code;

(b) donor's ABO and Rh groups;

(c) date of the transfusion and quantity of material transfused;

(d) time of starting and time of completing the transfusion;

(e) description of the blood product;

(f) description of any adverse reaction and the results of investigations related to this reaction;

(g) name(s) of the person(s) who performed the transfusion and who attended the recipient during the transfusion; and

(h) in the case of emergency issuance of uncrossmatched blood, the signature of the physician authorizing such emergency release.

58-2.19 Records to be kept when plasma derivatives are infused.

The following information shall be included on the recipient's chart or in records maintained in the blood bank or pharmacy:

(a) product name, lot number, and expiration date;

(b) date of infusion and quantity of material infused; and

(c) description of any adverse reaction and the results of investigations related to this reaction.

58-2.20 Neonatal transfusions.

(a) Transfusions of neonates shall comply with the provisions in this Part governing transfusions in general.

(b) Donor qualifications shall meet the standards required in section 58-2.2 of this Subpart, and donations shall be documented as indicated in section 58-2.11 of this Subpart.

(c) Taking and handling of blood for neonatal transfusions shall meet the requirements established by sections 58-2.4 to 58-2.6 of this Subpart.
(d) Each neonatal transfusion shall require laboratory tests specified in sections 58-2.3 and 58-2.17 of this Subpart. Compatibility tests may utilize serum from the neonate's mother, provided that donor red cells are of a group expected to be compatible with the serum of both the mother and the child.

(e) Records to be kept when blood is collected and when blood, blood components or derivatives are released for transfusion to neonates shall meet the requirements of section 58-2.11 and 58-2.12 of this Subpart.

58-2.21 Limited transfusion services.

(a) Limited transfusion services shall comply with the provisions in this Part governing transfusions in general.

(b) Limited transfusion services shall have a written agreement with an issuing facility holding a permit in blood services-transfusion. The agreement shall specify the division of responsibilities for assuring conformity with the provisions of this Part. The agreement shall be subject to the prior approval of the department. An inspection may be conducted prior to departmental approval. The agreement must include:

(1) the written approval of the issuing facility's director of transfusion services and the director of the limited transfusion service;

(2) the procedures for transport and storage of blood and means to assure compliance with such procedures;

(3) a description of the transfusion committee of the issuing facility, its responsibilities and composition;

(4) procedures for training of personnel at the limited transfusion service;

(5) requirements for handling adverse reactions, including training of personnel, availability of a physician, 24-hour coverage, and reporting and investigation of such reactions;

(6) procedures for administration of transfusions, including staffing requirements; and

(7) recordkeeping procedures as required in sections 58-2.12, 58-2.18 and 58-2.19 of this Subpart, clearly describing responsibility for maintenance of records and their location.

(c) Transfusions may be performed outside of hospitals only if the patient is cooperative, is able to respond to verbal commands and give informed consent and does not have a history of hemolytic or anaphylactic reactions. The initial transfusion for a given patient shall not be performed in the home setting, and subsequent transfusions may be performed in a patient's home only if physician limitations or hardships exist which would impede transportation to or transfusion in a hospital or ambulatory care setting.
(d) A qualified licensed physician must supervise personnel administering transfusions by limited transfusion services and must be responsible for ensuring that such personnel have adequate training and experience.

(e) A licensed physician, physician assistant, or nurse practitioner must be immediately available for personal or telephone consultation during the transfusion and for 30 minutes afterward.

(f) Any site at which a transfusion is performed by a limited transfusion service must have available an accessible working telephone to allow communication in case of an adverse reaction. All medications, equipment and supplies necessary for the management of adverse reactions must be immediately available on the premises. Infectious waste disposal must be undertaken using containers and procedures found acceptable by the department pursuant to Part 70 of this Title.

(g) Referral of a patient for out-of-hospital transfusion therapy must be approved by the director of the limited transfusion service or his/her designee. Each such transfusion must be ordered by a licensed physician, physician assistant, or nurse practitioner, and a copy of the order must be provided to both the limited transfusion service and the facility issuing the blood.

58-2.22 Holding facilities.

Issuance of a permit to a facility which holds blood for forwarding to a transfusion service, but does not perform any laboratory tests itself, shall be conditional upon filing of the annual statistical report required under Public Health Law, section 3124.

58-2.23 HIV-1 and HIV-2 antibody testing results.

No blood bank shall inform any blood or plasma donor or his/her health care provider of the results of HIV-1, HIV-2 or HIV-1/HIV-2 combination antibody screening tests unless such results are negative, with the exception of autogeneic donors, whose health care provider may be informed of screening test results if there is insufficient time prior to surgery for completion of supplemental testing, provided that such health care provider is instructed that the donor may not be informed that he or she is positive for HIV-1 or HIV-2 antibodies based based on the incomplete results. Initial reactive screening tests shall be repeated in duplicate. If two of three screening tests are reactive, the sample shall be considered repeatedly reactive, and supplemental testing shall be performed. Notification that a donor is positive shall be made only if the results have been reactive for more than one screening test, and the supplemental HIV antibody test result has been unequivocally positive. Appropriate counseling of donors regarding the significance of all test results must be available. HIV results must be reported to donors if the results are substantiated as positive, or upon supplemental testing show an increased likelihood of representing seroconversion to positive, as determined by the director of the laboratory performing the supplemental testing. This report must be made in person unless repeated efforts to encourage a donor to come in have failed, in which case notification may be made by certified restricted delivery mail. HIV results that are substantiated as negative, or upon
supplemental testing are indeterminate but do not show an increased likelihood of representing seroconversion to positive, as determined by the director of the laboratory performing the supplemental testing, may be reported to donors by mail, provided that such donors are not informed that they are seropositive. Any notification of HIV results to donors who were repeatedly reactive on initial screening tests, regardless of the results of supplemental testing, must include an offer of appropriate counseling.

58-2.24 Disposal of untransfused and expired blood units.

Units deemed unsuitable for transfusion, those not transfused for any reason, and those designated for disposal for any reason, shall be disposed of by an appropriate method in accordance with all applicable regulations and requirements. All expired blood components shall be transferred to a separate storage location within 24 hours of expiration. All such components shall be destroyed, discarded, or removed for non-transfusion purposes within 72 hours of expiration, or returned to the collection facility within one week of expiration.

58-2.25 Intraoperative and postoperative blood recovery and normovolemic hemodilution.

(a) Blood recovered intraoperatively or postoperatively from a person or collected for normovolemic hemodilution shall not be transfused into another person.

(b) Methods for intraoperative or postoperative recovery of blood and for normovolemic hemodilution shall be safe and aseptic and shall ensure accurate identification of all blood collected. The equipment used shall be operated according to the manufacturer's instructions, shall be pyrogen-free, shall include a filter capable of retaining particles potentially harmful to the recipient, and shall prevent air embolism. If the blood is warmed prior to reinfusion, the warming system shall be equipped with a visible thermometer and an alarm to ensure that the blood is not warmed above the temperature specified in a written protocol, in conformance with the system manufacturer's instructions.

(c) A complete written protocol for collection and processing of recovered blood and for normovolemic hemodilution, approved by the director of transfusion services, shall be maintained and followed. The protocol shall include criteria for selection of suitable patients and determination of dosage of ancillary agents used, as well as procedures for prevention and management of adverse reactions.

(d) If recovered blood or blood collected for normovolemic hemodilution is removed from the immediate premises for processing or storage, identification procedures shall be in place to ensure its transfusion into the intended recipient.

(e) If not immediately transfused, recovered blood shall be stored under one of the following conditions:

   (1) at one to 24 degrees Celsius for up to six hours after initiating the collection; or
(2) at one to six degrees Celsius under monitored conditions for up to 24 hours, provided storage at one to six degrees Celsius is begun within six hours of initiating the collection and the blood is washed under sterile conditions.

(f) Blood collected for normovolemic hemodilution shall be stored under one of the following conditions prior to initiation of transfusion:
   (1) at one to 24 degrees Celsius for up to eight hours after initiating the collection; or
   (2) at one to six degrees Celsius under monitored conditions for up to 24 hours, provided that storage at one to six degrees Celsius is begun within eight hours of initiating the collection.

(g) Untested recovered blood and blood collected for normovolemic hemodilution which are kept in the blood bank shall be stored in a specially designated area separate from other units and prominently labeled with the patient's name and a label "Caution: Untested Blood" or similar wording.

(h) Transfusion of blood recovered postoperatively or from post-traumatic patients shall commence within six hours of the initiation of the collection, or if not, the blood shall be discarded.

(i) All records of transfusions of blood recovered intraoperatively or postoperatively shall be available to the department for inspection for at least seven years after each transfusion. Summary records, listing the patient's name, the medical record number and procedures performed, shall be kept of all such procedures, separate from the patient's chart.

58-2.26 Exceptions.

(a) When, for indications generally accepted by the medical community, an allogeneic donor who would not otherwise qualify to donate blood or blood components is found to be uniquely suited to meet a given patient's needs, exceptions may be made to the requirements in sections 58-2.2(b) and (c), 58-2.3(a), 58-2.4(c), and 58-2.15(c), (d) and (e) of this Subpart. Such exceptions shall be approved in writing by both the medical director of the blood bank collecting the blood or his/her physician designee, and the director of the transfusion service transfusing the blood or his/her physician designee. If donation under such circumstances presents an increased risk to the donor's health or safety, the donor shall be informed of the risk and must consent in writing to such donation. If the donation presents an increased risk to the recipient's health or safety, the written authorizations of the recipient's health care provider and the recipient or person legally authorized to consent on behalf of the recipient are also required. All such exceptions granted shall be reported to the department annually in a format designated by the department.

(b) Exceptions to the requirements of this Subpart, other than the exception specified in subdivision (a) of this section, may be granted by the department on a case-by-case basis and for a limited time only, if necessitated by a medical emergency or special medical conditions. Persons seeking an exception shall apply to the department as soon as possible and shall describe the nature of the emergency or special medical conditions and the exception requested. All such emergencies or special medical conditions must be documented in the medical record, and any
action taken in response which is contrary to the requirements of this Subpart must be approved by the director of transfusion services. If it is not possible to request an exception in advance or if the department has not responded before an action contrary to the requirements of this Subpart had to be taken, the director of transfusion services must report the action taken to the department as soon as possible thereafter but not later than the end of the next business day after the action was taken.

58-2.27 Reinfusion procedures.

(a) All reinfusion procedures shall comply with written protocols approved by the director of transfusion services and the transfusion committee of the facility where the reinfusion is to be performed, the director of the hospital department where the product is reinfused, and the hospital department or facility where processing for the reinfusion procedure is performed, if different. These protocols shall include procedures for collection, labeling, handling, processing and reinfusion of the product.

(b) All reinfusion procedures performed in hospitals shall be reviewed by the hospital transfusion committee. Out-of-hospital reinfusion procedures shall be performed only by a limited reinfusion service which meets the standards in this Subpart and has been approved by the department.

(c) The syringe, tube, bag, or other container into which the blood or component thereof is collected for reinfusion, shall be labeled at the time of collection with two forms of identification, one of which shall be the patient's name. The person drawing the blood or component shall initial or sign the records pertaining to the collection and certify that the identification on the blood or component and on the pertinent records is correct.

(d) During shipment, processing and storage, reinfusion products shall be maintained at a temperature between one and 38 degrees Celsius, except as otherwise required in a protocol approved by the director of the service performing the reinfusion. Red cell reinfusion products shall not be exposed to a temperature above six degrees Celsius for more than six hours. While in transit, the container and shipping box for such products shall be appropriately labeled as containing human blood products.

(e) Any container into which the blood or component is transferred from another container during reinfusion processing shall be labeled prior to the transfer with two forms of identification, one of which shall be the patient's name or identification code. The person performing the transfer shall initial or sign the records pertaining to reinfusion processing of the blood or component and shall certify that the container identification was transcribed correctly. All final containers shall be labeled with the patient's name, description of the contents, expiration date and dosage, if applicable.

(f) All facilities preparing reinfusion products shall hold a valid department permit in the category of blood services - transfusion. Such facilities shall be open for inspection by the department during normal business hours and shall allow representatives of the department access to all protocols and records pertinent to reinfusion procedures performed in New York State.
(g) No reinfusion of a processed product shall be performed unless two individuals other than the patient have confirmed the identity of the recipient and the product to be reinfused as matching in name and in at least one additional identifier. This confirmation shall be documented in writing.

(h) All errors or accidents during processing or reinfusion procedures, which may pose a substantial risk to the patient, shall be reported to the department's Wadsworth Center, with sufficient detail to facilitate evaluation and investigation, within seven (7) calendar days of the error or accident, or its discovery.

(i) All records pertaining to reinfusion procedures shall be retained for a minimum of seven years.
SUBPART 58-3
CLINICAL LABORATORY INSPECTION AND REFERENCE FEES

(Statutory authority: Public Health Law, Section 576(4))

Sec.

58-3.1 Definitions
58-3.2 Laboratory inspection and reference fee
58-3.3 Reporting
58-3.4 Quarterly payments
58-3.5 Suspension or nonrenewal of laboratory permit
58-3.6 Fees
58-3.7 Gross annual receipts
58-3.8 Out-of-state laboratory seeking permit
58-3.9 Effective dates

Section 58-3.1 Definitions.

(a) Gross annual receipts for clinical laboratories able to segregate income. For independent laboratories or laboratories operated within facilities which can segregate their laboratory income from total facility income, gross annual receipts shall mean the total income of the laboratory from all sources for all clinical laboratory tests performed pursuant to its permit, less any amounts paid to reference laboratories for such tests which are referred.

(b) Gross annual receipts for clinical laboratories unable to segregate laboratory income.

   (1) For laboratories operated by health maintenance organizations, facilities with operating certificates issued pursuant to section 2805 of the Public Health Law, and other similar facilities which are reimbursed by third-party payors for laboratory services as part of an all inclusive facility per diem rate and which cannot segregate laboratory income from total facility income, gross annual receipts shall mean the amount computed by multiplying the total annual cost of the laboratory, by a fraction, the numerator of which is the gross revenue of the facility and the denominator of which is the gross cost of operating the facility. This amount must be further adjusted by subtracting any amounts paid to reference laboratories for such tests which are referred. Laboratories must obtain prior department approval to use this method by documenting that they are unable to segregate income.

   (2) For all other clinical laboratories unable to segregate their annual income from tests performed pursuant to their New York State permit, gross annual receipts shall mean the amount the laboratory would have received had it billed the prevailing rate for these services. The prevailing rate shall mean the fee
schedule for clinical laboratory services as listed on pages 5-1 through 5-14 of the Medicaid Management Information System Provider Manual for Laboratories, March 1982 edition, as published by the New York State Department of Social Services. Copies of this publication are available from the Department of Social Services, 40 North Pearl Street, Albany, NY 12243, and a copy is available for inspection and copying from the records access officer of the Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237. Laboratories must obtain prior department approval to use this method by documenting that they are unable to identify laboratory income.

(c) Inspection and reference fee shall mean the fee charged to a clinical laboratory calculated by multiplying the total operating expenses of the clinical laboratory evaluation program of the Department of Health by a fraction, the numerator of which is the gross annual receipts of such laboratory and the denominator of which is the total gross annual receipts of all laboratories issued permits.

(d) Permit year shall mean July 1st to June 30th.

58-3.2 Laboratory inspection and reference fee.

Each laboratory issued a permit by the department pursuant to section 575 of the Public Health Law shall be charged an annual laboratory inspection and reference fee.

58-3.3 Reporting.

(a) On or before May 1st of each State fiscal year (April 1st to March 31st), the department will advise each laboratory of the total estimated cost of the clinical laboratory improvement program for the previous State fiscal year.

(b) On or before May 15th, each laboratory will certify and report its gross annual receipts for the previous calendar year on forms to be provided by the department. If requested by the laboratory, this report shall be deemed confidential and exempt from disclosure under the Freedom of Information Law (article 6 of the Public Officers Law), pursuant to the authority in section 89(5) of the Public Officers Law. Knowing and/or willful failure to report or inaccurate reporting shall result in nonrenewal of the laboratory permit.

(c) On or before June 1st, the department shall bill each laboratory for its inspection and reference fee and shall advise each laboratory of the total gross receipts reported by all laboratories.

58-3.4 Quarterly payments.
At least quarterly payments must be made. If the laboratory elects to make quarterly payments, equal quarterly payments must be made by June 30th, September 30th, December 31st and March 10th of the State fiscal year to which the billing relates. Nothing herein precludes full payment from being made before these dates.

58-3.5 Suspension or nonrenewal of laboratory permit.

Knowing and/or willful failure to meet the quarterly payment requirement will result in suspension or nonrenewal of the laboratory permit.

58-3.6 Fees.

On or before September 15th, the department will review the annual cost of the clinical laboratory inspection program as initially estimated. Fees will be adjusted when any change results in an increase or decrease in fees of more than $100 per laboratory. If an adjustment is required, the department shall notify the laboratories of any additional fees or credits by October 15th. Any additional fees are payable not later than 30 days after the date of the notification statement. Credits shall be applied to the next regular payment.

58-3.7 Gross annual receipts.

(a) A laboratory which has no gross annual receipts because it did not operate in New York State the previous permit year shall pay a first year accreditation fee of $1,000 regardless of the number of months remaining in the permit year. When applying for renewal of that permit, the laboratory shall report its gross receipts for the calendar months in which it operated and these receipts shall be projected to a 12-month basis for the purpose of computing gross annual receipts.

(b) A laboratory which has no permit, but accepted business which required it to have a New York State permit, had gross annual receipts in the previous permit year, and applies for a permit after commencement of the permit year shall pay a fee computed as an annual fee but prorated for the months remaining in the permit year, or $1,000, whichever is greater.

58-3.8 Out-of-state laboratory seeking permit.

(a) Prior to any onsite inspection, an out-of-state laboratory possessing or seeking a New York State permit shall pay to the department, by certified check, bank check, teller’s check or money order, a fee calculated by the department and consisting of the following components:
(1) a transportation expense, which shall be either the actual travel expense if travel is by common carrier, or a mileage expense at the rate negotiated between the State and the union representing the employees scheduled to conduct the inspection; and

(2) a per diem expense as specified by the New York State Comptroller for the inspecting employees, multiplied by the number of additional days estimated by the department to be necessary for travel and the actual inspection.

(b) In calculating this fee, the department shall estimate the total cost of the components specified in paragraph (a)(1) of this section and divide it equally among the laboratories inspected on any trip.

(c) In the event the department underestimates any of the above expenses, the laboratory shall pay any difference between the estimate and the actual expense.

(d) Fees collected shall be credited to the Clinical Laboratory Reference Fee Account. In the event the department overestimates any of the above expenses, the laboratory shall be notified of the difference between the estimate and the actual expense, and its account shall be credited that amount unless a refund is requested.

(e) Failure to pay the fee for out-of-state inspection will result in suspension or nonrenewal of the laboratory permit.

58-3.9 Effective dates.

(a) Until March 31, 1986, the following dates shall have the following meanings:

(1) In section 58-3.3(a), May 1st shall mean the effective date of this regulation.

(2) In section 58-3.3(b), May 15th shall mean a date 10 days after the effective date of this regulation.

(3) In section 58-3.3(c), June 1st shall mean a date 45 days after the effective date of this regulation.

(4) In section 58-3.4, June 30th, September 30th, December 31st and March 10th shall mean dates to be negotiated by the department and each laboratory for the payment of quarterly installments of the 1985-86 fee; provided, however, that full payment must be made by March 10, 1986.

(b) The provisions of this section shall expire on March 31, 1986.
SUBPART 58-5
Hematopoietic Progenitor Cell Banks

(Statutory Authority: Public Health Law, section 3121(5))

Sec.

58-5.1 Definitions
58-5.2 General requirements
58-5.3 Hematopoietic progenitor cell procurement
58-5.4 Donor qualifications
58-5.5 Sterilization of instruments
58-5.6 Collection and handling of hematopoietic progenitor cells
58-5.7 Hematopoietic progenitor cell processing facilities
58-5.8 Required records
58-5.9 Quality assurance and safety requirements
58-5.10 Compliance with standards
58-5.11 Licensure
58-5.12 Special circumstances

58-5.1 Definitions.

As used in this Part:
(a) Bone marrow means the human tissue filling cavities of bone, consisting of fully mature and precursor hematopoietic cells intended for transplantation.

(b) Hematopoietic progenitor cells means human precursor hematopoietic cells derived from bone marrow, peripheral blood or other tissue sources, such as cord blood obtained from the placenta or umbilical cord.

(c) Hematopoietic progenitor cell bank means hematopoietic progenitor cell procurement service, hematopoietic progenitor cell processing facility or hematopoietic progenitor cell transplantation facility.

(d) Hematopoietic progenitor cell procurement service means a facility which performs donor selection and bone marrow aspiration or other hematopoietic progenitor cell collection, and preprocessing storage of hematopoietic progenitor cells from autogeneic and/or allogeneic donors.

(e) Hematopoietic progenitor cell processing facility means a facility which processes bone marrow or other hematopoietic progenitor cell samples, including purging, storage, and distribution of hematopoietic progenitor cells from autogeneic and/or allogeneic donors.

(f) Hematopoietic progenitor cell transplantation facility means a facility which temporarily stores and transplants hematopoietic progenitor cells, and includes facilities which infuse autogeneic
hematopoietic progenitor cells and bone marrow transplantation services approved by the commissioner pursuant to section 709.8 of this Title.

(g) Hematopoietic progenitor cell transplantation service means a specific unit conducting hematopoietic progenitor cell transplantation within a hematopoietic progenitor cell transplantation facility. Such a service shall be independently supervised by a qualified director.

(h) Department means the New York State Department of Health.

(i) Commissioner means the Commissioner of the New York State Department of Health.

58-5.2 General requirements.

(a) A hematopoietic progenitor cell procurement service shall possess a license issued under Subpart 52-2 of this Title in the category of either limited tissue procurement service or comprehensive tissue procurement service, and operate under standards established by this Subpart, Subpart 52-2 except section 52-2.9, and one or more licensed hematopoietic progenitor cell transplantation facilities. Unless the procurement service and the transplantation facility are operated by the same institution, a hematopoietic progenitor cell procurement service shall have a written agreement with the transplantation facility, which specifies that hematopoietic progenitor cells collected and stored by the hematopoietic progenitor cell collection procurement service are acceptable for transplantation by the hematopoietic progenitor cell transplantation facility. Collection of hematopoietic progenitor cells performed at facilities outside New York State shall follow policies and procedures consistent with this Subpart. Documentation of such policies and procedures shall be maintained by each associated hematopoietic progenitor cell transplantation facility. Hematoietic progenitor cells collected outside New York State shall be approved for use in New York State, in writing, by the director of the hematopoietic progenitor cell transplantation facility or by a physician designated by the director.

(b) A hematopoietic progenitor cell processing facility shall possess a license issued under Subpart 52-2 of this Title in the category of tissue processing facility, and be associated with and operating under standards established by one or more hematopoietic progenitor cell transplantation services.

(c) Hematopoietic progenitor cell transplantation facility shall possess a license under Subpart 52-2 of this Title in the category of tissue transplantation facility.

(d) Hematopoietic progenitor cell procurement services, hematopoietic progenitor cell processing facilities and hematopoietic progenitor cell transplantation facilities may operate independently, or together as part of the same organization.

(e) The director of a hematopoietic progenitor cell procurement service and/or processing facility shall ensure the development and implementation of policies and procedures consistent with this Subpart for the operation of the service and the appointment of the medical director and a medical advisory committee.
(1) The director of a hematopoietic progenitor cell procurement service collecting hematopoietic cells from peripheral blood shall be a physician and have at least one year's experience in apheresis, including or supplemented by experience in the performance or supervision of at least twenty-five (25) peripheral blood hematopoietic progenitor cell collection procedures. The director of a hematopoietic progenitor cell procurement service collecting bone marrow shall be a physician and have at least one year's experience in bone marrow collection, including or supplemented by experience in the performance or supervision of at least twelve (12) bone marrow collection procedures. The director of a hematopoietic progenitor cell procurement service collecting cord blood only shall be a physician and have at least one year's experience in hematopoietic progenitor cell collection, including or supplemented by experience in the performance or supervision of at least twenty-five (25) hematopoietic progenitor cell collection procedures. Such director shall also demonstrate satisfactory knowledge in the area of hematopoietic cell collection, with particular emphasis on the unique characteristics of cord blood collection. A person who has been approved by the department to direct a hematopoietic progenitor cell procurement service as of the effective date of these amendments shall be deemed to qualify as director.

(2) The director of a hematopoietic progenitor cell processing facility shall possess a doctoral degree in the biological sciences and have at least three (3) years' laboratory experience, including at least six (6) months' experience in a clinical laboratory or blood bank. In addition, the director of a hematopoietic progenitor cell processing facility shall have one year's experience in hematopoietic progenitor cell processing, including or supplemented by experience in the performance or supervision of at least twenty-five (25) hematopoietic progenitor cell processing procedures. A person who has been approved by the department to direct a hematopoietic progenitor cell processing facility as of the effective date of these amendments shall be deemed to qualify as director.

(f) Medical direction of a hematopoietic progenitor cell procurement service and/or processing facility shall be provided by a physician in consultation with the medical advisory committee. Such physician shall be licensed and currently registered with the New York State Education Department or in the state or jurisdiction of practice. The medical director of a hematopoietic progenitor cell procurement service shall have two (2) years’ experience or training in clinical hematology/oncology that includes experience in bone marrow transplantation or two (2) years’ experience in transfusion medicine, in addition to either one year's experience in hematopoietic progenitor cell collection, or performance or supervision of at least twenty-five (25) hematopoietic progenitor cell collection procedures for each anatomic site (bone marrow, peripheral blood, cord blood or other site) to be used as a source of hematopoietic progenitor cells. The medical director of a hematopoietic progenitor cell processing facility shall have two (2) years' experience in clinical hematology/oncology that includes bone marrow transplantation experience, or two (2) years' experience in training in laboratory medicine or transfusion medicine, in addition to either one year's experience in hematopoietic progenitor cell processing, or experience in the performance or supervision of at least twenty-five (25) hematopoietic progenitor cell processing procedures. A person who has been approved by the department as medical director of a hematopoietic progenitor cell bank as of the effective date of these amendments shall be deemed to qualify as medical director.
(g) The hematopoietic progenitor cell transplantation service director shall be a physician who shall be responsible for compliance with section 52-2.8 of this Title, and shall monitor the medical efficacy of the hematopoietic progenitor cell transplantation program.

(h) The medical advisory committee, which may be the in-house transfusion committee or transplantation committee, shall include experts in the areas of infectious disease, hematology, oncology, histocompatibility and transfusion medicine, as well as physicians representing associated hematopoietic progenitor cell transplantation facilities. The committee shall meet at least annually.

(i) The medical director of a hematopoietic progenitor cell procurement service, in consultation with the medical advisory committee shall monitor the medical efficacy of the program, and in conjunction with the associated hematopoietic progenitor cell transplantation facility shall, as a minimum, develop medical criteria for donor participation.

(j) The medical director of a hematopoietic progenitor cell procurement service shall be responsible for all aspects of donor qualification, as described in section 58-5.4 of this Subpart.

(k) The director of a hematopoietic progenitor cell procurement service and/or processing facility shall be responsible for the technical and scientific operation of the facility, and shall develop quality standards for hematopoietic progenitor cells.

58-5.3 Hematopoietic progenitor cell procurement.

(a) Facilities where allogeneic or autogeneic hematopoietic progenitor cells are collected shall be adequately lighted, ventilated and equipped, and be operated in a manner which conforms to current medical standards generally accepted by leading authorities in transplantation medicine.

(b) Each hematopoietic progenitor cell procurement service, except for such facilities collecting cord blood only, shall document association with a hematopoietic progenitor cell transplantation facility and compliance with the procedures, protocols and recordkeeping requirements for collection as established by the transplantation facility, as well as all requirements of this Subpart.

(c) All required clinical laboratory testing shall meet the standards of Article 5 Title V of the Public Health Law.

(d) For bone marrow harvesting procedures, adequate facilities shall be available for the administration of anesthesia and for emergency resuscitation. A qualified anesthesiologist shall be on the premises at all times during harvesting procedures.

(e) Emergency services shall be immediately available to any donor who manifests an adverse reaction.

(f) A physician shall explain the hazards of the donation procedure to the donor in such a manner that the donor is offered an opportunity to refuse consent. The donor shall be advised of the risks.
of hematopoietic progenitor cell donation and of the anesthesia method to be used, the potential need for transfusional support and possible side effects of each procedure, and options for disposition of hematopoietic progenitor cells no longer needed by the intended recipient. All this information shall be provided to each prospective donor in written form. The written informed consent of the prospective donor shall then be obtained. Autogeneic donors shall also be informed of the risks associated with hematopoietic progenitor cell collection.

(g) Informed consent for collection of cord blood shall be obtained from the donor's mother before stem cells are placed in inventory. In all cases of in utero cord blood collection, consent shall be obtained prior to collection.

(h) Hematopoietic progenitor cells from autogeneic donors shall not be destroyed or released for purposes other than infusion into the intended patient without written authorization from the director of the facility storing the hematopoietic progenitor cells and;
   (1) if the donor/patient is deceased, written documentation of death; or
   (2) if the donor/patient is living, written authorization from the physician currently responsible for treating the patient for the underlying disorder for which the hematopoietic progenitor cells were collected; and documented informed consent from the donor/patient or donor/patient's guardian, unless it is documented that no response was received within sixty (60) days to at least two (2) written requests for such consent sent at least thirty (30) days apart. Documentation of such written requests shall be maintained.

(i) Hematopoietic progenitor cells from allogeneic donors shall not be destroyed or released for purposes other than transplantation into the originally intended recipient without the written authorization of the intended recipient's physician and documentation that the intended recipient, if living, has been notified that the cells will not be available.

58-5.4 Donor qualifications.

(a) Except in the case of an autogeneic donation, a complete donor history shall be obtained prior to hematopoietic progenitor cell donation. A summary of the donor history obtained by a hematopoietic progenitor cell procurement service shall be provided to the physician performing the transplant for a determination of the cell's suitability for transplantation. The donor history, or in the case of cord blood donation, the history of the donor's biologic mother and, if available, the donor's biologic father, shall include, but not be limited to, information concerning:
   (1) any acute respiratory disease;
   (2) any infectious skin disease that creates a risk of contamination of the hematopoietic progenitor cells;
   (3) any disease transmissible by hematopoietic progenitor cells insofar as can be determined by donor history;
   (4) active tuberculosis or history of therapy therefor;
(5) history of malaria or travel to or residence in malarially endemic areas for periods of time considered to bear increased risks for malaria exposure, as determined by criteria established by the procurement or collection facility, consistent with criteria developed by the United States Public Health Service;

(6) known coagulation or platelet disorders;

(7) any medical condition which may be affected adversely by the collection procedure;

(8) any medical condition, including a malignancy, that would adversely affect the quality of the hematopoietic progenitor cells collected;

(9) receipt of an organ transplant or a transfusion of blood or blood components within the past twelve (12) months;

(10) indications of drug or alcohol abuse; and

(11) other medical conditions or circumstances as determined by the medical advisory committee and medical director of the procurement service.

(b) Except in the case of an autogeneic donation or cord blood donation, a complete physical examination of the donor shall be performed by the medical director of the procurement service or another qualified physician.

(c) For autogeneic donations, testing for syphilis, hepatitis B surface antigen (HBsAg), antibody to human immunodeficiency virus type 1 (anti-HIV-1) and antibody to human immunodeficiency virus type 2 (anti-HIV-2) shall be performed, unless already performed within the previous thirty (30) days, or unless the hematopoietic progenitor cells are collected, processed and transfused at the same facility and a system is in place to ensure disposition to the intended recipient.

(d) For allogeneic hematopoietic progenitor cell donations in New York State, specimens of blood shall be collected from the donor, or in the case of umbilical cord blood, from the donor’s mother, and the following tests shall be performed in a clinical laboratory under permit by the department. For out-of-state donations, all required clinical laboratory testing shall be performed by a laboratory which is approved by the regulatory authority in the state or jurisdiction where the laboratory is located, or by the department:

(1) within thirty (30) days prior to or seventy-two (72) hours after donation, and prior to initiation of the transplant conditioning regimen in the recipient:
   (i) direct tests for indicators of infection with syphilis and cytomegalovirus CMV);

   (ii) HBsAg;

   (iii) antibody to hepatitis B core antigen (anti-HBc), antibody to hepatitis C virus (anti-HCV), anti-HIV-1, anti-HIV-2 and antibody to human T-cell lymphotropic virus type 1 (anti-HTLV-I; and
(iv) except for cord blood donation, peripheral blood cell enumeration (red, white and platelet) and differential blood smear evaluation.

(2) prior to ablation of the recipient, major histocompatibility antigens (HLA-A, B and DR and other minor histocompatibility antigens, including mixed lymphocyte culture or DNA typing, as indicated.

(e) Except for allogeneic donors confirmed positive for any indicator of HIV infection, the decision as to the acceptability of hematopoietic progenitor cells shall be made by the hematopoietic progenitor cell transplantation service director. Hematopoietic progenitor cells from allogeneic donors confirmed positive for any indicator of HIV infection may not be used in any case.

58-5.5 Sterilization of instruments.

Syringes, needles, lancets, or other phlebotomy or hematopoietic progenitor cell collection devices capable of transmitting infection from one person to another and licensed for single use by the Food and Drug Administration shall be appropriately discarded after such use. Reusable devices shall be heat-sterilized prior to each use. Heat sterilization shall be by autoclaving at 121.5 degrees Celsius for fifteen (15) minutes after the chamber of the autoclave has been evacuated and has reached that temperature, or by dry heat for two (2) hours at 170 degrees Celsius, or by such other similarly acceptable procedure in accordance with current medical standards generally accepted by leading authorities in transplantation medicine.

58-5.6 Collection and handling of hematopoietic progenitor cells.

(a) All hematopoietic progenitor cell specimens obtained by bone marrow aspiration shall be collected by the medical director of the procurement service or other qualified physician, physician’s assistant, or a nurse practitioner under the supervision of the medical director. Hematopoietic progenitor cells obtained by peripheral blood apheresis shall be collected by an individual trained in pheresis in accordance with the requirements of section 58-2.15 of this Part. Cord blood collection shall be performed by staff with documented training, experience and proficiency in the techniques utilized.

(b) Hematopoietic progenitor cell collection apparatus and containers shall be clean, pyrogen-free and sterile.

(c) Phlebotomy and bone marrow aspiration puncture sites shall be prepared by a procedure which conforms to current medical standards generally accepted by leading authorities in transplantation medicine.

(d) Hematopoietic progenitor cell collection systems shall meet the following minimum requirements:
(1) hematopoietic progenitor cells shall be collected under aseptic conditions using an approved system adequately protected against contamination;

(2) additives shall be used as required to ensure the continued suitability of hematopoietic progenitor cells for transplantation and retention of viability. All changes in additives shall be validated on-site, and such validation shall be documented;

(3) each container shall be legibly labeled or tagged at the time of collection with:
   (i) the donor's identification code and date of collection; and
   (ii) if known, the recipient/patient's name, the name of the hospital where the patient is to be transplanted, and the patient's hospital registration number or, if unavailable, Social Security number, birthdate, or similar identifying information;

(4) each final container shall be legibly labeled or tagged at the time of issuance with:
   (i) if performed, the results of laboratory tests for syphilis, HBsAg, and antibodies to HBV, HCV, HIV-1, HIV-2, HTLV-I and CMV, unless the results were forwarded to the hematopoietic progenitor cell transplantation service in advance or included in records accompanying the hematopoietic progenitor cells; and
   (ii) a biohazard label, if the donor has tested reactive or positive for any of the tests required in section 58-5.4(c) or (d)(1) of this Subpart; and

(5) if microbial culturing is performed, suspected contamination shall be reported to the transplantation service.

(e) Prior to collection of cord blood, an access agreement/acknowledgment shall be consummated between the administration of the hospital or other collection site and the licensed cord blood bank

58-5.7 Hematopoietic progenitor cell processing facilities.

(a) If hematopoietic progenitor cells are to be frozen, the following requirements apply:
   (1) unless otherwise specifically authorized in writing by the director of the hematopoietic progenitor cell processing facility, hematopoietic progenitor cells shall be frozen within forty-eight (48) hours of collection, using cryopreservation techniques generally accepted by experts in transplantation medicine and meeting the requirements of this Subpart;

   (2) until used, hematopoietic progenitor cells shall be stored continuously within a temperature range of minus 196 degrees Celsius to minus 80 degrees Celsius, under one of the following conditions:
      (i) in a mechanical freezer reserved for hematopoietic progenitor cells, equipped with an automatic temperature recording device, an audible alarm and a back-up system in the event of unexpected mechanical failure; or
(ii) in a liquid nitrogen freezer reserved for hematopoietic progenitor cells, equipped with an automatic liquid nitrogen level monitor, an audible alarm and a back-up system in the event of unexpected liquid nitrogen loss;

(3) frozen hematopoietic progenitor cells in transit from a processing facility to a transplantation facility or other facility shall be:
   (i) maintained, at a minimum, on dry ice or in a liquid nitrogen dry shipper. Storage/transport procedures for the frozen hematopoietic progenitor cells shall be validated, and such validation shall be documented;

   (ii) transported as fast as reasonably possible and without any unnecessary delay; and

   (iii) used immediately upon arrival or stored as required in paragraph (2) of this subdivision until thawed for use; and

(4) hematopoietic progenitor cell specimens shall be inspected visually at the time of freezing and thawing. If the color or physical appearance is abnormal or there is indication or suspicion of microbial contamination, the cells shall not be released for transplantation unless authorized, in writing, by the transplantation service director.

(b) Hematopoietic progenitor cells stored in the liquid state shall be maintained at a temperature and for a period of time specified in a protocol approved by the director of the hematopoietic progenitor cell procurement service and/or processing facility.

(c) Storage temperature records for hematopoietic progenitor cells shall be maintained as required in section 58-5.8(c) and (d) of this Subpart, and be made available for inspection by the department for the entire period of storage and for one year afterward.

(d) Unless needed to meet a medical emergency, hematopoietic progenitor cells shall be transported in a leak-resistant, crush-resistant and puncture-resistant container featuring a prominent label which:
   (1) identifies the contents as "human blood", "human hematopoietic progenitor cells" or "human bone marrow";

   (2) describes the contents, the packing agent, if any, and any special precautions necessary in handling such contents; and

   (3) contains the name, address and twenty-four (24) hour telephone number of the person or entity to be contacted in the event that the container is found leaking or damaged, or is misdirected.

58-5.8 Required records.

(a) Complete and accurate records of hematopoietic progenitor cells released for transplantation shall be kept for seven (7) years by the hematopoietic progenitor cell procurement service,
processing facility and transplantation service using the sample. Such records shall be open to inspection by the department. For all donated hematopoietic progenitor cells, the donor's name, address, and any other information that would directly or indirectly identify the donor shall not be disclosed or released by the bank to any person or entity, except upon the written consent of the donor or the person authorized by law to make the donation, or to authorized employees of the department, or as permitted by law. The recipient's name, address, and any other information that would directly or indirectly identify the recipient shall not be disclosed or released by the hematopoietic progenitor cell bank to any person or entity, except upon the written consent of the recipient, or except to authorized employees of the department, or as permitted by law.

(b) Records to be kept by the hematopoietic progenitor cell procurement service shall include, but not be limited to, the following information:
   (1) donor's full name, address, age, sex, and identification code, as well as documentation of donor or donor's mother informed consent;
   (2) date and volume of hematopoietic progenitor cells collected;
   (3) any adverse reaction of the donor and its outcome;
   (4) medical history and results of all required clinical laboratory tests and of the physical examination performed;
   (5) disposition of hematopoietic progenitor cells;
   (6) documentation of sterility testing, and viability and recovery checks, if performed; and
   (7) medical director's authorization for the collection.

(c) Records to be kept by the hematopoietic progenitor cell processing facility shall include, but not be limited to, the following information:
   (1) donor's identification code, date and amount of cells collected;
   (2) results of all clinical laboratory tests performed;
   (3) methods used for processing, preserving storage and transport of the hematopoietic progenitor cells, including manufacturer's name and lot numbers of all reagents used in processing or preserving the cells;
   (4) temperature records of the storage chamber;
   (5) records of visual inspection of the hematopoietic progenitor cell specimens at the time of freezing and thawing;
   (6) specimen location in the storage chamber;
   (7) methods used for hematopoietic progenitor cell preservation, storage and transport; and
(8) disposition of the cells.

(d) Whenever hematopoietic progenitor cells are released for transplantation, the following records shall be maintained by the hematopoietic progenitor cell transplantation facility:
   
   (1) name of the hematopoietic progenitor cell bank providing the cells, description of the specimen, and condition of the cells and shipping container upon receipt, including any loss noted of liquid nitrogen, dry ice or other coolant;

   (2) if applicable, any extenuating circumstances that warrant acceptance of hematopoietic progenitor cells from donors who test positive;

   (3) medical history and results of all tests, and of the physical examination performed on the donor, if applicable;

   (4) disposition of the hematopoietic progenitor cells, including date and time released, and name of recipient;

   (5) outcome of the transplantation procedure, including, but not limited to, any adverse outcome or infectious disease in the recipient; and

   (6) if applicable, records documenting storage and temperature monitoring of hematopoietic progenitor cells, in accordance with the requirements in section 58-5.7 of this Subpart.

58-5.9 Quality assurance and safety requirements.

(a) Quality assurance.

(1) The hematopoietic progenitor cell procurement service and hematopoietic progenitor cell processing facility shall keep records which indicate that a quality assurance program is maintained in the following areas:

   (i) preventive maintenance, periodic inspections and testing for proper operation of equipment;

   (ii) monitoring of all temperature-controlled spaces and equipment to ensure proper performance;

   (iii) validation of microprocessor-controlled equipment and associated software, including test plan protocols, results of parallel testing and supervisory review; and

   (iv) validation of hematopoietic progenitor cell processing and testing methodologies.

(2) Hematopoietic progenitor cell processing, laboratory and storage facilities shall be maintained in a clean and orderly manner, and shall be of suitable size, construction and location to assure product and personnel safety.
(3) All reagents and solutions shall be in-date, stored properly and labeled to indicate identity and, as appropriate, titer, strength or concentration, recommended storage requirements, preparation and/or expiration date, and other pertinent information. All such materials shall be removed from use on the expiration date. Materials of substandard reactivity and deteriorated materials shall be discarded regardless of expiration date.

(4) All specimens accompanying the collected hematopoietic progenitor cells shall be sufficiently stable to provide accurate and precise test results suitable for clinical interpretation. The hematopoietic progenitor cell procurement service shall ensure that specimens are collected, preserved and transported to the laboratory in such a manner as to meet this requirement. Specimens for analysis shall be identified fully and accessioned in a log book. The accessioning system shall be designed to allow tracing of the hematopoietic progenitor cells to a specific donor, and to identify the date and, if applicable, the time of retrieval.

(5) Current standard operating procedure manuals specific to the facility shall be available at all times in the immediate work area of personnel engaged in retrieval, processing, testing, storage, distribution or other hematopoietic progenitor cell procurement activity. There shall be a written protocol for all procedures performed. Manuals shall contain a protocol for development, maintenance and periodic review of standard operating procedures by facility personnel and management staff. Procedure manuals shall have the following features:
   (i) a standardized format for procedures;
   (ii) a system of numbering and/or titling individual procedures;
   (iii) a clearly written description of purpose for each procedure;
   (iv) a reference section listing appropriate scientific literature and industry and/or corporate standards espoused by the hematopoietic progenitor cell procurement service and/or processing facility;
   (v) clearly defined areas of employee or technical staff responsibility by position/title;
   (vi) documented approval of procedures and procedural modifications, including annual review by the director of the hematopoietic cell procurement service and/or processing facility, or authorized supervisor;
   (vii) instructions for the completion of reports and forms, including examples;
   (viii) effective date and date of review for each procedure; and
   (ix) a system for archiving earlier versions of procedures and forms.

(6) The policies and procedures specified in the procedure manual shall be followed at all times. If deviations or deficiencies are identified, appropriate corrective action shall be taken and documented.
(7) The director of the hematopoietic progenitor cell procurement service and/or processing facility shall establish and maintain a planned and periodic internal review program for monitoring and evaluating the quality and appropriateness of the hematopoietic progenitor cell banking services. Included in the program shall be systems for evaluating errors, and designing, implementing and documenting corrective action for any deficiencies identified. Quality assurance deficiencies shall be documented, and evidence shall be available that any operational or procedural problems are reported to supervisory personnel in a timely manner, and that corrective action is implemented, documented and subsequently followed-up.

(8) The director of the hematopoietic progenitor cell procurement service and/or hematopoietic progenitor cell processing facility shall be responsible for developing policies, procedures and/or standards for the qualifications, training, certification and continuing education of technical staff. Documentation of compliance with this requirement and with the policies developed shall be maintained.

(b) Safety.

(1) The hematopoietic progenitor cell procurement service and/or processing facility shall implement written safety and infection control policies and procedures to ensure protection from unnecessary physical, chemical and biological hazards, as follows:

(i) Decontamination and disposal techniques for regulated medical waste shall be utilized. All hazardous and regulated medical waste materials shall be handled, stored and discarded pursuant to Part 70 of this Title.

(ii) If sterilization equipment is used, the pressure, temperature and duration of each cycle shall be recorded and such records maintained for one year. For each run, these parameters shall be within the manufacturer's recommended operating standards. If any one or more of these parameters fall(s) outside the manufacturer's standards, all material shall be resterilized. Chemical, biological and physical detection systems should be used in conjunction with these other measurements of performance.

(iii) Eating, drinking, smoking or the application of cosmetics or contact lenses shall not be permitted in the work areas. Refrigerators or freezers used for storing specimens or reagents shall not be used for any other purpose.

(iv) Gloves and laboratory coats, gowns or other protective clothing shall be worn as necessary while handling blood specimens or hematopoietic progenitor cell tissue. Such protective clothing shall not be worn outside the work area and shall be disposed of in an appropriate receptacle.

(2) The hematopoietic progenitor cell procurement service and/or processing facility shall have written policies and procedures in the following areas:

(i) Infection control;

(ii) Biosafety;

(iii) Chemical and radiological safety;
(iv) emergency response to worksite accidents; and

(v) medical waste disposal.

(3) The safe collection of peripheral blood hematopoietic progenitor cells by apheresis shall be the responsibility of the medical director of the apheresis service. Collection shall be performed in full compliance with section 58-2.15 of this Part.

(4) Hematopoietic progenitor cell transplantation facilities shall report suspected cases of infectious disease transmission in recipients to the hematopoietic progenitor cell bank providing the tissue.

(5) The hematopoietic progenitor cell bank shall have a written procedure for documenting any errors or accidents in retrieval, testing, processing, storage or disposition of hematopoietic progenitor cells that may affect the safety of the cells, and for reporting such errors or accidents to the medical advisory committee of the bank. If the error or accident is detected after issuance of the cells, the error or accident shall be reported to the receiving facility immediately upon detection by the distributing facility. All errors with the potential for serious adverse effects on the recipient shall also be reported to the department's Wadsworth Center within seven (7) calendar days of discovery.

58-5.10 Compliance with standards.

(a) Hematopoietic progenitor cell procurement services and/or processing facilities shall allow admission to representatives of the department for the purpose of inspecting the premises and evaluating operating procedures, equipment and records, including financial records and lists of physicians or facilities to whom or to which hematopoietic progenitor cells are released, to determine compliance with the standards in this Subpart. If the commissioner determines that a significant likelihood exists that adequate safeguards are not implemented, the department may require that cells not be released pending a hearing. Such hearing shall commence within fifteen (15) days of any suspension pursuant to this section.

(b) Whenever requested, a hematopoietic progenitor cell bank shall submit to the department reports containing such information and data concerning the bank's activities as may be required by this Subpart. Such reports shall be signed by the director of the hematopoietic progenitor cell bank.

58-5.11 Licensure.

No person shall own or operate a hematopoietic progenitor cell procurement service, processing facility or transplantation facility in New York State unless licensed by the department under Subpart 52-2 of this Title. All provisions of Subpart 52-2 of this Title shall apply to a hematopoietic progenitor
58-5.12 Special circumstances.

(a) The department may exempt a hematopoietic progenitor cell bank from a specific standard contained in this Subpart, provided:

(1) the hematopoietic progenitor cell bank has requested an exemption under limited circumstances prior to the noncompliance with the standard; and

(2) the hematopoietic progenitor cell bank has demonstrated to the department that application of the standard to such bank under the limited circumstances for which the exemption is sought:

(i) is inconsistent with the provision of the particular service, as documented in properly conducted current medical or scientific research, or current scientific literature;

(ii) is incompatible with a requirement imposed by a federal or other state's government unit which is similar to the standard for which the exemption is sought, and the department determines that the requirement imposed by the federal or other state's governmental unit adequately protects the public health, safety and welfare, based upon commonly accepted medical standards, properly conducted medical or scientific research, or current scientific literature; or

(iii) would prevent or impair the provision of services necessitated by a medical emergency or special medical condition. Hematopoietic progenitor cell banks seeking an exemption pursuant to this subparagraph shall describe the nature of the emergency or special medical condition and the exemption requested, for review on a case-by-case basis by the department. All such emergencies or special medical conditions shall be documented in the medical record, and any action taken in response which is contrary to the requirements of this Subpart shall be approved by the director of the hematopoietic progenitor cell transplantation service.

(b) A copy of the department's approval for an exemption shall be maintained by the hematopoietic progenitor cell transplantation facility and the hematopoietic progenitor cell bank releasing the cells.
SUBPART 58-8
Human Immunodeficiency Virus (HIV) Testing

(Statutory Authority: Public Health Law, section 576)

SEC.

58-8.1 Definitions
58-8.2 HIV testing and record keeping requirements
58-8.3 Confidentiality
58-8.4 HIV result reporting requirements

Section 58-8.1 Definitions.

For the purposes of this Subpart, unless the context indicates otherwise, the terms below shall have the following meanings:
   (a) Department means the New York State Department of Health.
   (b) Donor means a human being, living or dead, who is the source or potential source of a body, organ, tissue or fluid for transfusion, transplantation, transfer, artificial insemination or implantation.
   (c) FDA means the Food and Drug Administration of the United States Department of Health and Human Services.
   (d) HIV antibody screening means the performance of tests to detect HIV antibodies, which tests are not sufficiently specific to ensure definitive evidence of HIV infection.
   (e) HIV identification testing means the performance of tests to detect or characterize HIV or HIV viral components, including, but not limited to, HIV protein and HIV nucleic acid. HIV identification testing shall also include cultivation of the infectious virus.
   (f) HIV confirmatory testing means the performance of one or more supplemental tests to substantiate or refute results of HIV testing procedures that are not sufficiently specific to ensure definitive evidence of HIV infection.
   (g) HIV diagnostic testing means the performance of HIV tests for purposes of diagnosing, assessing or monitoring HIV infection in persons who may have been exposed to HIV, are at risk of exposure to HIV, or are known to be HIV infected, but shall not include testing of donors. HIV testing of individuals in conjunction with an application for insurance shall be considered HIV diagnostic testing whenever test results are communicated to the applicant or his/her medical provider by the insurance company's medical director or a consulting physician or a physician under the medical director's supervision.
   (h) Preliminary finding of HIV infection means results of antibody screening that have been neither substantiated nor refuted by HIV confirmatory testing.
58-8.2 HIV testing and record keeping requirements.

In addition to other applicable requirements in this Part, and Parts 52 and 63 of this Title, clinical laboratories, blood banks and tissue banks with a New York State clinical laboratory permit to perform HIV testing shall meet the following requirements:

(a) Specimens for testing patients, donors and insurance applicants shall be only of the type approved by the FDA or acceptable to the department for use with the particular method or test kit.

(b) All tests shall employ reagents, methods, techniques and procedures approved by the FDA or acceptable to the department in conformance with generally accepted laboratory principles.

(c) If the test result is to be communicated to the test subject or other person legally authorized to receive the result, results for specimens found reactive in accordance with the test manufacturer’s interpretation of HIV antibody screening test results shall be confirmed with HIV confirmatory testing.

(d) Confirmatory testing shall be performed as soon as practicable in all cases when notification of a preliminary finding of HIV infection is made.

(e) A standard operating procedure manual (SOPM) shall be developed and maintained current, and shall include, in addition to documentation required elsewhere in this Part and Part 52 of this Title, algorithms for use of each HIV test method or test kit, and policies and processes for accepting specimens, reporting results, and ensuring compliance with confidentiality requirements and, as applicable, reporting requirements of Article 21, Title III and Article 27-F of the Public Health Law and New York State Insurance Law section 2611(c).

58-8.3 Confidentiality.

Each clinical laboratory, blood bank, tissue bank or organ procurement organization performing, or causing the performance or receiving the results of HIV testing shall establish and implement procedures for confidentiality, disclosure and re-disclosure consistent with applicable federal and state law and regulations, including Article 27-F of the Public Health Law and New York State Insurance Law section 2611(c). No bill, claim for reimbursement or invoice issued by a clinical laboratory, blood or tissue bank or its agent shall disclose the nature of the service rendered to a named individual by using the acronym HIV, or the words human immunodeficiency virus or similar identifying words, unless disclosure is authorized by law and the intended recipient of the bill, claim or invoice is an entity subject to New York State or federal confidentiality, disclosure and re-disclosure requirements.
58-8.4 HIV result reporting requirements.

(a) No clinical laboratory shall notify a physician or other person legally authorized to receive the result that an HIV test is positive solely on the basis of HIV antibody screening, except that a clinical laboratory may report a preliminary finding of HIV infection pursuant to the written request of a physician or other person legally authorized to receive the test results. Results for specimens found non-reactive by HIV antibody screening may be reported to the physician who ordered the testing or other person legally authorized to receive the result.

(b) For HIV diagnostic testing, a report of preliminary finding of HIV infection shall prominently and clearly state that the finding is preliminary, that results of confirmatory testing will follow, and that such confirmatory results must be considered in making a diagnosis related to HIV infection.

(c) No blood, tissue or organ donor, or consenting next of kin shall be notified that an HIV test result is positive solely on the basis of HIV antibody screening.