N.J.A.C. 8:8-1 et seq.

COLLECTION, PROCESSING, STORAGE AND DISTRIBUTION OF BLOOD BLOOD BANK INSPECTION CHECKLIST

REGULATIONS				
	LICENSURE	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-1.3 (a)	Is the facility currently licensed to conduct a blood bank in NJ as required under the provisions of N.J.S.A. 26:2A-2 et seq.?			
N.J.A.C. 8:8-1.3 (b)	Is a blood bank license obtained whenever any function related to the collection, processing, storage, distribution or the administration of blood and blood components is performed?			
N.J.A.C. 8:8-1.3 (c)	Is a separate blood bank license obtained for each permanent location?			
N.J.A.C. 8:8-1.3 (c)	Are the SOPs of the licensed outside provider which performs additional services within the facility reviewed and approved by the blood bank director?			
N.J.A.C. 8:8-1.3 (f)	Does the blood bank perform only those services, related to this chapter for which they have specifically requested and received licensure?			
N.J.A.C. 8:8-1.3 (g)	Does the blood bank distribute blood and blood components for therapeutic purposes only to New Jersey licensed blood banks, unless a non-surgical situation exists which could not be anticipated?			
	PROFICIENCY TESTING	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-1.5 (b)	Are records of all proficiency testing results, including interpretations, maintained?			
N.J.A.C. 8:8-1.5 (c)	Are proficiency testing results periodically reviewed and evaluated by the blood bank director?			
	PERSONNEL/ TRAINING	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-2.2 (b) 1.	Is the blood bank director responsible and have authority for all blood bank SOPs? Are the SOP(s) for the administration of blood and blood components established			

	in consultation with the blood bank director?			
N.J.A.C. 8:8-2.2 (b) 6.	Does the director delegate his or her responsibilities for administering the blood bank to a properly qualified and trained designee and are the designee's duties outlined in the SOPs?			
N.J.A.C. 8:8-2.2 (c)	**Is the blood bank director qualified by:** 1. Education/licensure; 2. Training; and 3. Appropriate experience?			
N.J.A.C. 8:8-2.3 (a)	Does the blood bank have one or more qualified supervisors who supervise all blood banking functions and who are responsible in the absence of the blood bank director?			
N.J.A.C. 8:8-2.3 (b) 1.	Does the blood bank have a responsible individual on the premises who is qualified to provide emergency care during the collection or transfusion of blood in accordance with N.J.A.C. 8:8-2.3 (d)?			
N.J.A.C. 8:8-2.3 (b) 2.	Does the blood bank have an adequate number of personnel?			
N.J.A.C. 8:8-2.3 (b) 3.	Are personnel associated with donor or transfusion related functions suitably trained through a documented formal training program and supervised in the performance of their prescribed tasks?			
N.J.A.C. 8:8-2.3 (c)	Are personnel's job descriptions current and are job qualifications defined for each job position/title?			
N.J.A.C. 8:8-2.3 (d) 1. i.	Is the donor or transfusion emergency care personnel a physician licensed in the State or a registered nurse (R.N.) holding a current certificate of registration and has taken an eight hour course in cardiopulmonary resuscitation (CPR) for health care providers and holds a current CPR certification?			
N.J.A.C. 8:8-2.3 (g)	Does the blood bank have a process for identifying and monitoring the training needs of personnel who are performing activities which affect the quality of blood and blood components?			
N.J.A.C. 8:8-2.3 (h)	Does the blood bank evaluate the			

	competency of personnel at specified intervals? Is there a process for initial and ongoing competence assessment of personnel?			
	FACILITIES, EQUIPMENT AND CONTAMINATED MATERIAL	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-3.1(a)	Does the blood bank have adequate quarters, environment, and equipment to maintain safe and acceptable standards for handling of human blood and blood components?			
N.J.A.C. 8:8-3.1 (c) 3.	Does the blood bank uniquely identify all equipment critical to the provision of blood and blood components? Is there a schedule for monitoring and maintaining the equipment as required by the manufacturer and in accordance with this chapter?			
	QUALITY MANAGEMENT	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-4.1 (a)	Does the blood bank have quality control and quality assurance programs which are in compliance with the rules to ensure that blood and blood components, reagents and equipment perform as expected?			
N.J.A.C. 8:8-4.1 (b) 1.	Do the SOP manuals contain all policies and procedures developed for use?			
N.J.A.C. 8:8-4.1(b) 2.	Is there evidence of validation of all methods used by the blood bank?			
N.J.A.C. 8:8-4.1(b) 2.	Does the blood bank have a process for qualifying critical equipment prior to initial use? Is there evidence of qualification and validation for all critical equipment including the FDA-cleared devices?			
N.J.A.C. 8:8-4.1(b) 2.	Are new or changed SOPs validated before implementation?			
N.J.A.C. 8:8-4.1(b) 3.	Is there evidence of periodic evaluation of reagents and equipment including the date of performance?			
N.J.A.C. 8:8-4.1(b) 3.	Are QC results for reagents and equipment reviewed and documented?			
N.J.A.C. 8:8-4.1(b) 3.	Are equipment problems documented, investigated and resolved? Is there a process for removing equipment from service and reporting to manufacturer			

	when indicated?			
N.J.A.C. 8:8-4.1(b) 3.	Does the blood bank have a process for scheduled monitoring and preventive maintenance for equipment which includes: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results?			
N.J.A.C. 8:8-4.1(b) 4.	Is there evidence of periodic evaluation of blood and blood components in accordance with, whichever is more stringent, the current Code of Federal Regulations and/or current Standards of the American Association of Blood Banks?			
N.J.A.C. 8:8-4.1 (b) 5.	Is there evidence of periodic evaluation to determine that policies and procedures are appropriate and are followed?			
N.J.A.C. 8:8-4.1 (b) 5.	Does the blood bank have a process for reviewing and approving new and revised SOPs?			
N.J.A.C. 8:8-4.1 (b) 5.	Does the blood bank use only current SOPs, forms and valid documents?			
N.J.A.C. 8:8-4.1(b) 6.	Is there evidence that the blood bank director or supervisor perform a daily review of computer maintained error correction records?			
N.J.A.C. 8:8-4.1(b) 7.	Is there evidence of adequate and timely corrective action for malfunctions, failures or adverse events?			
N.J.A.C. 8:8-4.1 (b) 8.	Is there evidence of a QA & QC review by the supervisor or the director?			
N.J.A.C. 8:8-4.1 (b) 9.	Is there an evidence of self-evaluation of the clinical appropriateness of licensed activities?			
	STANDARD OPERATING PROCEDURES	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-4.2 (a)	Are policies and procedures developed for use in the blood bank and required by this chapter detailed in a manual(s) of SOP? Does the blood bank have a master list of SOPs, labels and forms?			
N.J.A.C. 8:8-4.2 (a)	Does the blood bank have a process to develop new SOPs and change existing ones?			

N.J.A.C. 8:8-4.2 (b)	Does each procedure have a current pertinent literature reference?			
N.J.A.C. 8:8-4.2 (c)	Do the actual test procedures coincide with the manufacturers' current product insert or written documentation from the manufacturer?			
N.J.A.C. 8:8-4.2 (c)	Are all materials, containers and reagents for collection, preservation, storage and testing of blood and components used in accordance with the manufacturer's written instructions and meet specified requirements?			
N.J.A.C. 8:8-4.2 (d)	Is the most current edition of the manufacturer's product inserts available?			
N.J.A.C. 8:8-4.2 (e)	Does the blood bank director review the SOPs annually and is this review documented by date and the blood bank director's signature?			
N.J.A.C. 8:8-4.2 (f)	Are significant changes to procedures reviewed, dated and signed by the blood bank director?			
	DOCUMENTED REVIEW			
N.J.A.C. 8:8-4.3 (a)	When blood or blood components are collected and/or prepared, does a key individual in the operation of the blood bank conduct a documented review prior to the release and final labeling of blood and blood components to ensure that blood from unsuitable donors is not distributed for transfusion or further manufacture?			
N.J.A.C. 8:8-4.3 (a) 1.	Are the sequence of the numbers of the blood and blood components drawn verified and donor numbers for which no donations are available accounted for?			
N.J.A.C. 8:8-4.3 (a) 2.	Are all required tests, as outlined in N.J.A.C. 8:8-7.2 performed on all blood and blood components, with specimens drawn from the donor at the time of collection and before release for transfusion, and for granulocytes, drawn up to 10 days prior to collection?			
N.J.A.C. 8:8-4.3 (a) 3.	Are blood or blood components with positive or questionable test results not released for allogeneic transfusions?			
N.J.A.C. 8:8-4.3 (a) 4.	Are blood or blood components collected			

	from donors that shall be deferred not released for allogeneic transfusion or for further manufacture?			
N.J.A.C. 8:8-4.3 (a) 5.	**Are required tests performed correctly and properly interpreted as determined by at least the following criteria:** i. Personnel are following the blood bank's established procedures for the test; ii. Equipment is correctly set-up for test method specific adjustments; iii. Test results on the machine printout can be traced to the worklist; iv. Test runs, that are unacceptable by the criteria specified by the manufacturers' product insert, are repeated; v. Appropriate repeat testing is performed; and vi. Review of the interpretation of all final test results to assure that the interpretation complies with state requirements, when applicable, or the manufacturers' product insert?			
N.J.A.C. 8:8-4.3 (a) 7.	Are all blood and blood components from donations that have positive or questionable test results quarantined until their final disposition is determined?			
N.J.A.C. 8:8-4.3 (b)	Are final disposition/destruction records completed at the time of disposition/ destruction and are there documented review to verify that records accurately reflect that disposition/destruction?			
	ERRORS AND ACCIDENTS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-4.4 (a)	When components are improperly tested, not tested, or tested properly but improperly interpreted for ABO or infectious diseases, is there evidence of immediate effort to locate and quarantine all components that is labeled and released for transfusion, fractionation, reagent production, research or other use until satisfactory resolution?			
N.J.A.C. 8:8-4.4 (b)	When an accident occurs, is there an immediate effort to locate and destroy all unsuitable components that have been released for transfusion, fractionation, reagent production, research or other use?			

N.J.A.C. 8:8-4.4 (c)	Is the notification procedure for error or accident occurrences resulting in a blood transfusion that could result in infectious disease or other harmful consequences in accordance with 8:8-4.4 (c), and are these actions documented completely?			
	RECORDS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-5.1 (a)	Are suitable legible records prepared with indelible material maintained for a period of not less than five years and records to trace a unit of blood or blood component from its source to final disposition kept for at least 10 years after transfusion or five years after the latest expiration date for the individual product?			
N.J.A.C. 8:8-5.1 (a)	Is there SOP which ensures that documents and records are stored and archived in accordance with the rules and record retention policies?			
N.J.A.C. 8:8-5.1 (a) 1.	Does the blood bank have a policy which addresses the confidentiality of donor and recipient records?			
N.J.A.C. 8:8-5.1 (b)	**Are corrections to errors made in this manner:** 1. Not conceal the original entry; 2. Document the reason for the correction; and 3. Include the date the change was made and the initials of the person making the change?			
N.J.A.C. 8:8-5.1 (c)	Are workload lists for the testing sequence of specimens prepared prior to testing?			
N.J.A.C. 8:8-5.1 (d)	Are corresponding instrument readings, calculations and applicable tracings or printouts maintained with the final test results?			
N.J.A.C. 8:8-5.1 (e) 1. i.	Does the blood bank perform validation of all computer programs prior to use, and/or if modification is made to determine if software consistently performs as required and within pre-established limits?			
N.J.A.C. 8:8-5.1 (e) 1. ii.	Does the blood bank validation include review of confidentiality of donor information, security of data and system documentation?			
N.J.A.C. 8:8-5.1 (e) 2.	Are there adequate provisions to			

	safeguard against the eventuality of unexpected electronic loss of data from the computer storage medium?			
N.J.A.C. 8:8-5.1 (e) 3.	Does the computer system maintain duplicate records on electronic storage media, update these duplicates continuously and/or transfer electronically stored data to hard copy?			
N.J.A.C. 8:8-5.1 (e) 4.	Do the computer system SOPs describe each of the blood bank's methods for performing requirements in (e) 1 through 3 above?			
N.J.A.C. 8:8-5.1 (e) 5.	Does the computer automatically note, at the time of correction, when corrections are made to verified results?			
N.J.A.C. 8:8-5.1 (e) 6.	Does the computer maintain the original verified entry, including the date, time and the identity of the person performing the test?			
N.J.A.C. 8:8-5.1 (e) 6.	When corrections to verified results are made in the computer, do the original and corrected entries show the date, time and identity of the person performing the original and corrected records?			
N.J.A.C. 8:8-5.1 (e) 7.	Are records maintained in the computer in compliance with all requirements of this chapter?			
N.J.A.C. 8:8-5.1 (e) 8.	Does the computer list donor collection records by sequential donor numeric or alphanumeric identifier?			
N.J.A.C. 8:8-5.1 (f) 1.	Do records include all data secured and developed by blood banks concerning donor and/or recipient testing, donor identification, medical qualifications, registration as well as the processing, storage, distribution and final disposition of blood and blood components?			
N.J.A.C. 8:8-5.1 (f) 2.	Do records make it possible to trace a unit of blood or blood component by a sequential numeric or alphanumeric identifier from source to final disposition?			
N.J.A.C. 8:8-5.1 (f) 3.	Are records readily available for review?			
N.J.A.C. 8:8-5.1 (f) 4.	Are data reported using the Department form by January 31 of each year for the State's Statistical Summary of Blood Use			

	Report?			
N.J.A.C. 8:8-5.1 (f) 5.	Are actual results of each test observed recorded immediately and is the final interpretation recorded upon completion of testing?			
N.J.A.C. 8:8-5.1 (f) 6.	Do records include all the significant steps of the process and who performed them?			
N.J.A.C. 8:8-5.1 (f) 7.	Do records include written documentation of any verbal instructions including the identity of all involved individuals?			
N.J.A.C. 8:8-5.1 (g)	**Before blood is issued for transfusion, are test results for each recipient sample compared with:** 1. Records of previous ABO and Rh typing results for the past 12 months; and 2. Past records of all patients known to have significant unexpected antibodies; severe adverse reactions to transfusion, and/or difficulty in blood typing?			
N.J.A.C. 8:8-5.1 (h)	If computer system is used, is there an alternate method available to allow access to the information required in **8:8-5.1 (g)** in case of computer failure?			
	Do donor records include at least the following:			
N.J.A.C. 8:8-5.1(i) 1. i.	An annual record of each unit of blood and blood component, listed by sequential numeric or alphanumeric identifier, as to its source bank and final disposition?			
N.J.A.C. 8:8-5.1 (i) 1. ii.	Donor history, examination, consent, deferral, reactions and also the result of required laboratory tests performed on all blood donors?			
N.J.A.C. 8:8-5.1 (i) 1. iii.	An annual alphabetical file of donor registration cards (manual or computerized) or a cross index system?			
N.J.A.C. 8:8-5.1 (i) 1. iv.	Blood and component labeling, including initials of person responsible for such labeling?			
N.J.A.C. 8:8-5.1 (i) 1. v.	Storage temperatures of components, including dated and initialed temperature recording charts?			
N.J.A.C. 8:8-5.1 (i) 1. vi.	Results of visual inspection of blood?			
N.J.A.C. 8:8-5.1 (i) 1. vii.	Results of blood processing, including test results and interpretation of all tests and			

	retests?			
N.J.A.C. 8:8-5.1 (i) 1. viii.	Component preparation, including all relevant dates and times?			
N.J.A.C. 8:8-5.1 (i) 1. ix.	Documentation of separation and pooling of recovered plasma?			
N.J.A.C. 8:8-5.1 (i) 1. x.	Documentation of units included in pooled products?			
N.J.A.C. 8:8-5.1 (i) 1. xi.	Reissue records, including records of proper temperature maintenance; and			
N.J.A.C. 8:8-5.1 (i) 1. xii.	A system that relates a donor with each previous donation?			
	Do recipient records include at least the following:			
N.J.A.C. 8:8-5.1(i) 2. i.	An alphabetical file of the recipient and all units administered?			
N.J.A.C. 8:8-5.1 (i) 2. ii	Each recipient's ABO and Rh type available for immediate reference for at least the past 12 months?			
N.J.A.C. 8:8-5.1 (i) 2. iii.	History of significant unexpected antibodies, adverse reactions to transfusion and/or difficulty in blood grouping and typing available for immediate reference for at least the past five years?			
N.J.A.C. 8:8-5.1 (i) 2. iv.	Transfusion request records?			
N.J.A.C. 8:8-5.1 (i) 2. v.	Test results, interpretations and release or issue date for compatibility testing?			
N.J.A.C. 8:8-5.1 (i) 2. vi.	Emergency release of blood including written or validated electronic signature of the requesting physician and the type of blood and/or blood component?			
N.J.A.C. 8:8-5.1 (i) 3.	List of therapeutic bleedings, including a signed request by physician, donor's disease and disposition of units?			
N.J.A.C. 8:8-5.1 (i) 4.	Detailed procedure manual including all policies and procedures developed for use in the blood bank and required by this chapter?			
N.J.A.C. 8:8-5.1 (i) 5.	Evidence of annual review of the procedure manual by the blood bank director?			
N.J.A.C. 8:8-5.1 (i) 6.	A data sheet for each cytapheresis procedure with records of: volume of blood processed; anticoagulants given;			

	duration of procedure; volume of product; drugs given; identity of the donor; any reactions that occurred and how they were treated and any other information necessary to ensure the proper preparation of the component and the safety of the donor?			
N.J.A.C. 8:8-5.1 (i) 7.	Quality control and quality assurance records, including, but not limited to: periodic evaluation of personnel, blood and blood components, reagents, equipment, including dates of performance; tests performed; observed results; interpretations; identification of personnel performing the tests; any appropriate corrective action taken; and review by the supervisor and/or director?			
N.J.A.C. 8:8-5.1 (i) 8.	Antibody identification records?			
N.J.A.C. 8:8-5.1 (i) 9.	Reports of suspected adverse reactions to transfusions and laboratory investigations?			
N.J.A.C. 8:8-5.1 (i) 10.	Are lot numbers of supplies and reagents documented?			
N.J.A.C. 8:8-5.1(i) 11.	Is there a method to identify persons performing each significant step in collecting, processing, compatibility testing and distributing blood or blood components?			
N.J.A.C. 8:8-5.1(i) 12.	Are shipping records from the blood distributor verified and documented at the time of blood and blood component receipt?			
	REPORTING REQUIREMENTS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-5.2 (a) 1.	Is any hemolytic or delayed hemolytic and other known or suspected life-threatening transfusion reaction reported to the Department on required forms within 10 days of occurrence?			
N.J.A.C. 8:8-5.2 (a) 2.	Is any known or suspected fatal transfusion reaction reported by telephone by the next working day and a written follow-up sent using the form provided by the Department within 10 days of occurrence?			
N.J.A.C. 8:8-5.2 (b) 1.	Is any known or presumed case of transfusion associated AIDS reported to			

	the Department within 10 days on forms provided for this purpose?			
N.J.A.C. 8:8-5.2 (c)	Are all prospective donors who tested positive for hepatitis B surface antigen and antibody to hepatitis C virus reported to the Department within 10 days on forms provided for this purpose?			
N.J.A.C. 8:8-5.2 (d)	Are errors, as outlined in N.J.A.C. 8:8-4.4 (a), that result in the availability of unsuitable blood and blood components for transfusion or distribution, reported on forms provided by the Department within 15 working days of the recognition of the error?			
N.J.A.C. 8:8-5.2 (e)	Are errors that result in the wrong blood or blood component being transfused, regardless of harm to the recipient, reported on forms provided by the Department within 15 working days of the recognition of the error?			
	DONOR IDENTIFICATION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-6.1 (a)	Are blood donors identified by an identification card or another form of authorized identification?			
N.J.A.C. 8:8-6.1 (b)	Is the type of identification used written on the donor registration card at the time of each blood donation?			
	MEDICAL HISTORY; PHYSICAL EXAMINATIONS, BLEEDING LIMITATIONS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-6.2	Are procedures used for performing donor medical history, physical examinations, and bleeding limitations consistent with, whichever is more stringent, the most recent Code of Federal Regulations or the most recent Standards of the American Association of Blood Banks?			
	DONOR SELECTION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-6.3 (a)	Is the prospective donor's history evaluated on the day of the donation and the donor examined by trained and qualified blood bank personnel?			
N.J.A.C. 8:8-6.3 (b)	Are donors excluded from donating blood for transfusion while their names appear in the latest revision of publications (i.e.			

	Hepatitis Registry) supplied to the blood bank by the Department?			
N.J.A.C. 8:8-6.3 (c)	Prior to issue for distribution, are permanent deferral records, which include reason for deferral for donor past medical history and all required laboratory tests reviewed to determine if the blood and blood components meet all the requirements for allogeneic use?			
	INFORMATION PROVIDED TO DONOR	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-6.4 (a)	Is donor consent obtained in writing and is the procedure adequately explained to the prospective donor and gives the donor an opportunity to ask questions and refuse consent?			
N.J.A.C. 8:8-6.4 (b)	Is the donor instructed in post phlebotomy care and cautioned as to possible adverse reactions?			
N.J.A.C. 8:8-6.4 (c)	Is the blood bank director responsible for notifying the donors of the cause of rejection?			
	AIDS SCREENING REQUIREMENTS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-6.5 (b)	Is educational material given to the blood donors to allow donors to determine whether or not they have engaged in high risk behavior prior to the collection of blood?			
N.J.A.C. 8:8-6.5 (e)	Are blood and blood components that are positive to serologic tests for HIV or collected from a donor known to be HIV positive discarded or used for research purposes only?			
N.J.A.C. 8:8-6.5 (f) 1.	If not included in the informed consent, is a written statement, notifying the donor that the blood or blood components collected will be tested for AIDS, signed, prior to donation?			
N.J.A.C. 8:8-6.5 (h)	Are reactive donors notified and counseled in person?			
N.J.A.C. 8:8-6.5 (i)	Does the blood bank maintain records pertaining to all HIV requirements and test results in a confidential manner?			
	GENERAL CRITERIA	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-7.1 (a)	Does the procedure for the collection, processing, storage, and distribution of			

	blood and blood components meet the requirements of this chapter?			
N.J.A.C. 8:8-7.1 (d)	**Does blood bank distributing blood and blood components:** 1. Provide information circular with each product; 2. Provide accurate expiration dates and hours on the container label; and 3. Meet licensed expiration dates for the product?			
N.J.A.C. 8:8-7.1 (e)	Are the preparation and processing procedures for all blood and blood components consistent with, whichever is more stringent, the Code of Federal Regulations or the Standards of American Association of Blood Banks, as amended or supplemented?			
	TESTING	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-7.2 (a)	Are laboratory tests performed on specimens of blood taken from the donor at the time of phlebotomy or up to 10 days prior to granulocytes collection?			
N.J.A.C. 8:8-7.2 (b)	Are available FDA licensed reagents used for screening tests?			
N.J.A.C. 8:8-7.2 (c)	Is all required infectious disease testing performed before distributing blood for transfusion?			
N.J.A.C. 8:8-7.2 (d)	Is all testing required in N.J.A.C. 8:8-7.2 performed in accordance with FDA regulations?			
N.J.A.C. 8:8-7.2 (f)	Does the attending physician attest in writing the existence of an emergency if untested units are transfused, and is the recipient's physician notified if the test is subsequently positive?			
N.J.A.C. 8:8-7.2 (g)	1. Is each container of blood properly identified and labeled as to its blood group? 2. Is the ABO group of each blood donation determined using known Anti-A and Anti-B reagents, and using known A_1 and B red blood cells? 3. Do all Anti-A and Anti-B reagents meet the Code of Federal Regulations minimum requirements, and are procedures used in accordance the manufacturer's directions? 4. Are new determinations of the ABO group made for each collection?			
N.J.A.C. 8:8-7.2 (h)	1. Is the Rh type of each container of			

	donor blood determined with Anti-D reagent? 2. If Rh negative, is blood tested using a technique designed to detect weak D?			
N.J.A.C. 8:8-7.2 (i)	1. Is each container of blood tested for unexpected antibodies to red cell antigens using a screening cell suspension which meets the CFR minimum requirements? 2. Are the methods of testing capable of demonstrating clinically significant antibodies and include the antiglobulin test? 3. Does the blood bank have a policy concerning transfusion of components containing significant amount of incompatible ABO or unexpected red cell antibodies?			
N.J.A.C. 8:8-7.2 (j)	Does the facility at which the transfusion is administered confirm the ABO group and Rh type of all Rh negative units on a sample obtained from the integral attached segment, of all units of whole blood and red blood cells?			
	DONOR'S EMERGENCY CARE	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.2 (a)	Is blood drawn from donors only when a physician or RN are available on the premises for emergency care?			
N.J.A.C. 8:8-8.2 (b)	Does the blood bank have an SOP which allows the blood bank director to determine on a case-by-case basis, to exempt the emergency care personnel requirement to allow alternative donor emergency care personnel?			
N.J.A.C. 8:8-8.2 (c) 1.	Does the blood bank SOP outline the requirements for granting an exemption from the emergency care personnel requirement?			
N.J.A.C. 8:8-8.2 (c) 3.	Does alternative emergency care personnel present at the site of the blood collection drive meet training, education and experience requirements established by the blood bank director and who, at a minimum, possess current CPR and standard first aid certifications, and have readily available access to either land line or cell phone communications to			

	immediately call 9-1-1 for assistance in the event of a medical emergency?			
N.J.A.C. 8:8-8.2 (c) 4.	Does the blood bank maintain accurate records documenting all occurrences when the blood bank director has authorized an exemption under (b) above, including the date and location of the blood collection drive, the name and signature of the blood bank director who authorized the exemption and the rationale for the blood bank director's determination to exempt the emergency care personnel requirement?			
	MEDICAL CONTINGENCY PLAN	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.3 (a)	**Does each location for collection or the transfusion of blood and blood components have a current medical contingency plan which includes:** 1. Immediate access to an identified land line telephone for notification of 9-1-1 or other emergency care services; and 2. A detailed SOP outlining the circumstances to immediately notify 9-1-1 or other emergency care services?			
N.J.A.C. 8:8-8.3 (b)	Does each location maintain a copy of the medical contingency plan on the premises of each licensed blood bank for a period of not less than five years?			
	DONOR PROTECTION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.4 (a)	Is the donor adequately prepared prior to phlebotomy to protect donor and recipient from infection?			
N.J.A.C. 8:8-8.4 (b)	Is all equipment used in the collection of blood, such as syringes, needles, lancets or other blood letting devices sterile and pyrogen free?			
N.J.A.C. 8:8-8.4 (d)	Are all personnel concerned with the collection of blood instructed in appropriate first aid procedures in the event of donor reaction?			
	METHOD OF BLOOD COLLECTION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.5 (a)	Is a unique sequential numeric or alphanumeric identification placed on all material related to that donation			

	immediately prior to collection of the blood or blood component?			
N.J.A.C. 8:8-8.5 (b)	Is the method employed for the removal of blood from the donor conforming to accepted standards of asepsis?			
N.J.A.C. 8:8-8.5 (c)	Are blood containers and donor sets sterile and pyrogen-free?			
N.J.A.C. 8:8-8.5 (g)	Are the anticoagulant solution and the blood thoroughly mixed during bleeding?			
N.J.A.C. 8:8-8.5 (i)	Immediately after bleeding, is the blood placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward a range between one to six degrees Centigrade unless platelets are to be harvested?			
N.J.A.C. 8:8-8.5 (j)	Is the volume of blood collected from the donor in accordance with FDA regulations and AABB Standards?			
	PILOT SAMPLES	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.6 (c)	At the time of collection, if additional blood for laboratory tests is needed, are the containers properly labeled before or at the time of collection, and are re-identified with the blood container immediately after filling?			
	BLOOD CONTAINERS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.7 (a)	Are containers for whole blood and blood components used for collection identified by recording the manufacturer's lot numbers and are they sterile and pyrogen-free?			
N.J.A.C. 8:8-8.7 (b)	Are the containers sufficiently colorless and transparent to permit visual inspection of blood?			
	LABELING	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.8 (a)	Is the labeling procedure consistent with the most recent Code of Federal Regulations?			
N.J.A.C. 8:8-8.8 (b)	Are blood and blood components labeled conspicuously with notation of incomplete testing and when applicable positive or abnormal test results?			
N.J.A.C. 8:8-8.8 (c)	**Is untested autologous blood collected from a donor/recipient, who has been tested in the last 30 days labeled with**: 1. A statement that the blood was collected			

	from a donor known to be tested for FDA-required tests; and 2. The date that the donor recipient was tested?			
	AUTOLOGOUS COLLECTION/TRANSFUSION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.10 (a)	Are SOPs submitted to the Department and written approval received prior to initiation of the service?			
N.J.A.C. 8:8-8.10 (c)	Are autologous collections/transfusions done only at the written request of the physician or clinical practitioner?			
N.J.A.C. 8:8-8.10 (c)	Is a telephone request for autologous collection followed by written confirmation within seven calendar days?			
N.J.A.C. 8:8-8.10 (d)	Are the testing and labeling requirements for autologous donations consistent with, whichever is more stringent, this chapter or the Code of Federal Regulations?			
N.J.A.C. 8:8-8.10 (e) 2.	Are "For Autologous Use Only" units segregated, and used solely for this purpose if the patient-donor and/or donated unit do not meet the criteria for donor selection?			
N.J.A.C. 8:8-8.10 (e) 4.	Are "For Autologous Use Only" units that test positive or abnormal and are transfused to the donor/recipient labeled with a Biohazard label?			
	DIRECTED DONATION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.11 (a)	Are SOPs submitted to the Department and written approval received prior to initiation of the service?			
N.J.A.C. 8:8-8.11 (d)	Are directed donations initiated only at the written request of the intended recipient's clinical practitioner or a transfusion facility?			
N.J.A.C. 8:8-8.11 (d)	Is the telephone request followed by written confirmation within seven calendar days?			
	PERIOPERATIVE AUTOLOGOUS BLOOD COLLECTION AND ADMINISTRATION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.12 (a)	Is the perioperative autologous blood collection and administration facility licensed to operate in New Jersey?			
N.J.A.C. 8:8-8.12 (b)	Are SOPs submitted to the Department			

	and written approval received prior to initiation of the service?			
N.J.A.C. 8:8-8.12 (c)	Is the perioperative autologous transfusion procedures performed in accordance with the Standards of the American Association of Blood Banks, as amended or supplemented?			
	THERAPEUTIC PHLEBOTOMY	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.13 (a)	Is the facility licensed to offer therapeutic phlebotomy service in NJ?			
N.J.A.C. 8:8-8.13 (b)	Is therapeutic phlebotomy done at the written request of the patient's physician or clinical practitioner?			
N.J.A.C. 8:8-8.13 (c)	Is there a written procedure describing the therapeutic phlebotomy technique used?			
N.J.A.C. 8:8-8.13 (d)	Are records of patient identification, diagnosis, therapeutic procedure, volume of plasma and cells removed, volume replaced, nature of the replacement fluids, any adverse reactions, and a record of the administered medications maintained?			
N.J.A.C. 8:8-8.13 (e)	Is an informed consent of the patient obtained before therapeutic phlebotomy?			
N.J.A.C. 8:8-8.13 (f)	Are there provisions for the management of reactions?			
N.J.A.C. 8:8-8.13 (g)	Is there a written agreement specifying the division of responsibilities for assuring compliance if therapeutic phlebotomy procedures and recordkeeping are not entirely performed by blood bank personnel?			
N.J.A.C. 8:8-8.13 (h)	Is the blood or blood component withdrawn from a patient for therapeutic purposes clearly indicated as such on the blood label?			
N.J.A.C. 8:8-8.13 (i)	**Is blood or blood components obtained from therapeutic phlebotomy for allogeneic transfusion following these criteria:** 1. Received a waiver from the FDA; 2. Procedure performed at no expense to the donor; 3. Donor diagnosis is hereditary hemochromatosis; 4. Donor meets all the allogeneic donation criteria except for donation interval and hematocrit?			

	PLASMAPHERESIS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.14 (a)	Is the facility licensed to perform plasmapheresis procedures in NJ?			
N.J.A.C. 8:8-8.14 (b)	Are SOPs submitted and written approval received from the Department prior to initiation of the service?			
N.J.A.C. 8:8-8.14 (c) 9.	Is the amount of plasma withdrawn consistent with the current Code of Federal Regulations?			
N.J.A.C. 8:8-8.14 (d)	Is plasmapheresis performed in accordance with the AABB Standards, as amended and supplemented?			
	CYTAPHERESIS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-8.15 (a)	Is the facility licensed to perform cytapheresis procedures in NJ?			
N.J.A.C. 8:8-8.15 (b)	Are SOPs submitted and written approval received from the Department prior to initiation of the service?			
N.J.A.C. 8:8-8.15 (d)	Is the interval between procedures at least 48 hours, and the amount of plasma collected follows the amount cleared by the FDA for the device?			
N.J.A.C. 8:8-8.15 (e)	Does cytapheresis donor after donating whole blood wait at least eight weeks before a subsequent cytapheresis procedure unless the extracorporeal red cell volume of the apheresis machine does not exceed 100 ml?			
N.J.A.C. 8:8-8.15 (f)	Does cytapheresis donor wait at least eight weeks before a subsequent apheresis procedure if it becomes technically impossible to return the donor's red blood cells during apheresis unless the red cell loss was less than 200 ml?			
N.J.A.C. 8:8-8.15 (g)	Does the blood bank have a mechanism to ensure that donor red cell losses during any eight-week period, as well as the preceding 12 months, do not exceed the loss of red cells permitted for whole blood collections?			
N.J.A.C. 8:8-8.15 (i)	Does the donor wait for 16 weeks to donate after a two-unit red cell collection?			
N.J.A.C. 8:8-8.15 (j)	Do volume limits of red cells and plasma removed from the donor follow the FDA-cleared device criteria in the case of			

	multiple concurrent apheresis collections?			
	RECIPIENT BLOOD TESTING	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-9.1 (b)	Do forms and request for blood and blood components and forms accompanying recipient blood samples have sufficient information for the positive identification of the recipient?			
N.J.A.C. 8:8-9.1 (c)	Do forms and request for blood and blood components include the recipient's full name, as it appears on the identification band, and a traceable identification number? If more than one traceable identification numbers are needed to positively identify the recipient, are they documented on all blood bank documents used for recipient testing?			
N.J.A.C. 8:8-9.1 (d)	Are incomplete or illegible forms accepted?			
N.J.A.C. 8:8-9.1 (e)	Are intended recipient and the blood sample identified at the time of collection by a mechanism which positively identifies the recipient? If other method of identification than the armband is used, is the alternative method approved by the Department prior to use?			
N.J.A.C. 8:8-9.1 (f)	**Are samples for compatibility testing:**			
N.J.A.C. 8:8-9.1 (f) 1.	Identified by a label firmly attached to the sample before leaving the side of the recipient?			
N.J.A.C. 8:8-9.1 (f) 2.	Labeled at the time of the collection with at least the recipient's full name, as it appears on the identification band, traceable identification number, the identity of the person drawing the sample and the date the sample was drawn?			
N.J.A.C. 8:8-9.1 (f) 3.	Obtained within three days of the scheduled transfusion when the recipient has been transfused or pregnant in the preceding three months or if this information is not known?			
N.J.A.C. 8:8-9.1 (f) 4.	Examined by a qualified person, before specimens are used for typing or compatibility testing, to confirm that all information on the request form is in agreement with that on the specimen label? In the case of a discrepancy or			

	doubt, is another specimen obtained and used for these procedures?			
N.J.A.C. 8:8-9.1 (f) 5.	Is the secondary compatibility testing sample label affixed in a manner that it could be peeled off so that personnel performing the compatibility testing can verify the full name and the traceable identification number of the recipient on the original and secondary labels and the full name and the traceable identification number of the recipient are not obscured?			
N.J.A.C. 8:8-9.1 (g) 1.	Does testing of the recipient's blood include: determination of ABO group?			
N.J.A.C. 8:8-9.1 (g) 2. iii.	Is an appropriate control system required for the Anti-D reagent used?			
N.J.A.C. 8:8-9.1 (g) 4.	**Is the performance of compatibility testing:** i. Consistent with the most recent Code of Federal Regulations and does it include a method to verify the ABO group of the donor unit and the recipient?			
N.J.A.C. 8:8-9.1 (g) 4. iii.	**If a computer system is used to detect ABO incompatibility, are the following requirements met:** (1) On-site validation to ensure that only ABO compatible whole blood and red blood cells components are selected for transfusion; (2) Performance of two determinations of the recipient's ABO group; (3) Computer system contain the donor unit number, component name; ABO group and Rh type of the component, the confirmed ABO group, the two unique recipient identifiers, recipient ABO group, Rh type, and antibody screening results; (4) Contain logic to alert the user to discrepancies between the donor ABO group and Rh type on the unit label and those determined by blood group confirmatory tests, and ABO incompatibility between the recipient and the donor unit; (5) Method to verify correct entry of data before release of blood and blood components for transfusion.			
N.J.A.C. 8:8-9.1 (g) 5.	Is a control system using red blood cells sensitized with IgG used to confirm			

	negative autoglobulin testing?			
N.J.A.C. 8:8-9.1 (h)	**Does the policy for selection of compatible blood and blood components for transfusion for special circumstances in accordance with AABB Standards, as amended and supplemented, include:** 1. Mechanism which ensures that patients with special transfusion requirements receive the correct component as clinically indicated 2. Policy regarding transfusion of cellular components selected or processed to reduce Cytomegalovirus (CMV) transmission and irradiated components for patients at risk for transfusion-associated graft-vs.-host disease?			
	SUSPECTED TRANSFUSION REACTIONS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-9.2 (a)	Does the blood bank and transfusion service have a system for detecting and evaluating suspected adverse reactions to transfusion?			
N.J.A.C. 8:8-9.2 (b)	Are suspected transfusion reactions evaluated promptly once physician determines them as possible transfusion reaction?			
N.J.A.C. 8:8-9.2 (c)	**In the event of a suspected transfusion reaction, does the staff attending the patient** 1. Notify the blood bank and the responsible clinical practitioner immediately and document all instructions for the evaluation of the suspected reaction? 2. Note the reaction in the patient's medical record and on the blood transfusion documentation?			
N.J.A.C. 8:8-9.2 (d)	**If an acute hemolytic transfusion reaction is suspected, is the transfusion discontinued and does the blood bank staff:** 1. Check labels on the blood container and all other records associated with the transfusion to detect clerical errors in identification; 2. Retype the post transfusion reaction sample for ABO group and Rh typing and compare the results to the pretransfusion results; 3. Inspect the post reaction plasma or serum			

	for evidence of hemolysis 4. Perform Direct Antiglobulin Test (DAT); 5. Notify the blood bank director immediately if discrepancies or adverse results are identified in (d) 1 through 4 above.			
N.J.A.C. 8:8-9.2 (e)	Does the blood bank have a written procedure that specifies the additional tests that need to be performed when discrepancies or adverse results exist?			
N.J.A.C. 8:8-9.2 (f)	Does the blood bank ensure that blood is not released for transfusion while the suspected transfusion reaction investigation is in progress unless documented approval is received from the blood bank director?			
	URGENT REQUIREMENT OF BLOOD	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-9.4 (b) 1.	If the ABO group and Rh type have been determined by the transfusing facility, are recipients transfused with type-specific blood?			
N.J.A.C. 8:8-9.4 (b) 2.	If the ABO group and Rh type have not been determined by the transfusing facility, are recipients transfused with O red blood cells?			
N.J.A.C. 8:8-9.4 (b) 3.	Does the record contain a statement of the requesting physician indicating that there is an urgent clinical situation requiring the release of blood before completion of required testing? Does the record contain a written or validated electronic signature of the requesting physician?			
N.J.A.C. 8:8-9.4 (b) 4.	Does the tag or label indicate in a conspicuous fashion that required testing had not been completed at the time of issue?			
N.J.A.C. 8:8-9.4 (b) 5.	Are required tests completed promptly?			
	ISSUE OF BLOOD	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-10.1 (a)	Are the issue and administration of blood and blood components performed at the request of a clinical practitioner?			
N.J.A.C. 8:8-10.1 (b)	Does the blood transfusion request or claim form include the recipient's full name, as it appears on the identification band, traceable identification number and			

	the type and quantity of component?			
N.J.A.C. 8:8-10.1 (c)	Before the blood container is released from the blood bank for transfusion, does it contain an attached label or tag to positively identify the unit with the intended recipient?			
N.J.A.C. 8:8-10.1 (d)	Does the person receiving the blood present a written request with sufficient information for the positive identification of the recipient at the time the blood or blood component is released from the blood bank for transfusion?			
N.J.A.C. 8:8-10.1 (e)	Does the technologist who issues the blood perform an active identification check along with the person picking up the blood which includes the recipient's full name, as it appears on the identification band, traceable identification number, the type and quantity of component and the date of the transfusion?			
N.J.A.C. 8:8-10.1 (f)	Does the blood bank staff record the unit number and the type of component issued on the issue slip or claim form?			
N.J.A.C. 8:8-10.1 (g) 1.	Are blood samples retained and stored at 1 to 6 degree C for at least seven days after transfusion?			
	ADMINISTRATION OF BLOOD	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-10.2 (a)	Are blood or blood components for transfusion prescribed by a clinical practitioner?			
N.J.A.C. 8:8-10.2 (b)	**Are recipient and the blood container identified as follows:**			
N.J.A.C. 8:8-10.2 (b) 1.	Does the transfusion service have a written procedure for the positive identification of the recipient and the blood container?			
N.J.A.C. 8:8-10.2 (b) 2.	Are two qualified individuals simultaneously checking and matching all information identifying the container with the identifying information on the person of the intended recipient and the compatibility testing request slip at the bedside, immediately prior to transfusion?			
N.J.A.C. 8:8-10.2 (b) 3.	Are the two qualified individuals who checked this information signing the			

	transfusion form to attest that this information was checked and that it matched at the bedside?			
N.J.A.C. 8:8-10.2 (b) 4.	Does all identification attached to the container remain attached at least until the transfusion has been completed?			
N.J.A.C. 8:8-10.2 (c) 1.	Are blood and components transfused through a sterile, pyrogen-free transfusion set equipped with a filter appropriate to the component?			
N.J.A.C. 8:8-10.2 (c) 2.	Is the procedure for warming of blood consistent with AABB Standards and FDA regulations?			
N.J.A.C. 8:8-10.2 (c) 3.	Is irradiation of blood consistent with current acceptable standards of the American Association of Blood Banks or current guidelines issued by the Food and Drug Administration, whichever is more stringent?			
N.J.A.C. 8:8-10.2 (c) 4.	Is the recipient observed periodically during the transfusion and for an appropriate time thereafter for potential adverse reactions? Are there documentation of pretransfusion, 15 minute, and the post transfusion vital signs on transfusion records?			
	REISSUE OF BLOOD	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-10.3 (a)	**Does the procedure for returning and reissuing blood or blood components include the following conditions?**			
N.J.A.C. 8:8-10.3 (a) 1.	The container closure or seal has not been punctured or tampered with;			
N.J.A.C. 8:8-10.3 (a) 2.	The blood has been continuously stored and shipped under controlled conditions or returned to the blood bank within a pre-determined time, set by the blood bank, which is acceptable to the Department;			
N.J.A.C. 8:8-10.3 (a) 3.	Blood has not been allowed to warm above 10 degrees Centigrade or cool below one degree Centigrade;			
N.J.A.C. 8:8-10.3 (a) 4.	Original identification labels and tags are attached and unaltered;			
N.J.A.C. 8:8-10.3 (a) 5.	The original pilot sample has not been removed or tampered with and at least one sealed segment of the integral donor tubing remains attached to the container;			

N.J.A.C. 8:8-10.3 (a) 6.	The blood has been allowed to settle long enough to permit reinspection of the plasma if applicable; and			
N.J.A.C. 8:8-10.3 (a) 7.	Records indicate the blood was reissued with documentation of the time it was returned and reissued.			
	STORAGE OF BLOOD	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-11.1 (a)	Is the equipment used for the storage of blood or blood components kept clean and are the individual compartments used only for the storage of blood and blood components, blood bank reagents, pilot and patient samples?			
N.J.A.C. 8:8-11.1 (b)	Are food or potentially contaminated material stored in the equipment used for storage of blood or blood components?			
N.J.A.C. 8:8-11.1 (c)	Are there written procedures containing directions on how to maintain blood and blood components within permissible temperatures and instructions to be followed in the event of power failure or other disruption of refrigeration available?			
	STORAGE REFRIGERATORS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-11.2 (a)	Are refrigerators used for the storage of blood and blood components capable or maintaining the blood at a temperature between 1-6 degree Centigrade?			
N.J.A.C. 8:8-11.2 (b)	Are refrigerators for blood or blood component storage provided with a fan for circulating air or of a design to ensure that the proper temperature is maintained throughout?			
N.J.A.C. 8:8-11.2 (c)	Is liquid temperature for the storage refrigerator monitored?			
N.J.A.C. 8:8-11.2 (d)	Does the liquid medium used reflect the actual temperature of blood in storage?			
	FREEZERS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-11.3 (a)	Does the freezer maintain the products at a temperature below -18 degrees Centigrade?			
N.J.A.C. 8:8-11.3 (b)	Does the liquid nitrogen freezer maintain the products at a gas phase temperature below -120 degrees Centigrade?			
	ROOM TEMPERATURE	**YES**	**NO**	**N/A**

N.J.A.C. 8:8-11.4 (a)	Is the room temperature storage for components maintained at a temperature of 20 to 24 degrees Centigrade?			
N.J.A.C. 8:8-11.4 (b)	Is the ambient temperature recorded every four hours during storage if components are stored in an open storage area?			
	TEMPERATURE MONITORING SYSTEM	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-11.5 (a)	Does the equipment used to store blood and blood components have a system to record temperature continuously? In the event of equipment failure, are the storage temperatures recorded at least every four hours?			
N.J.A.C. 8:8-11.5 (b)	Is the temperature recording device calibrated periodically, inspected at least daily and are written records of the temperatures kept on file?			
N.J.A.C. 8:8-11.5 (c)	**Are alarms attached to the blood and blood component storage equipment?** 1. Visual and audible alarm systems to indicate whenever the temperature is outside acceptable ranges. 2. Alarms installed in location which provides 24 hour coverage by night personnel or switchboard operators. 3. Alarms set to activate at a temperature which shall allow proper action to be taken before the blood or blood components reach undesirable temperatures.			
N.J.A.C. 8:8-11.5 (c) 4.	When the alarm is activated, does the licensee initiate a process for immediate investigation and is there documentation of appropriate corrective action?			
N.J.A.C. 8:8-11.5 (d)	Is there a written procedure posted prominently for staff to follow in case of electrical or equipment failure?			
	INSPECTION OF BLOOD AND BLOOD COMPONENT	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-11.6 (a)	Are stored blood and/or blood components inspected daily and are records maintained during the entire period of storage and immediately prior to issue or use?			
N.J.A.C. 8:8-11.6 (b)	Is the unit of blood or blood components			

	not issued for transfusion purposes if the color or physical appearance is abnormal or if there is any indication or suspicion of contamination?			
N.J.A.C. 8:8-11.6 (c)	Are methods to limit and detect bacterial contamination in all platelet components in accordance with AABB Standards?			
	EXPIRATION DATES	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-11.7 (b)	Are expiration dates assigned to blood and blood components in accordance with the Code of Federal Regulations, as amended or supplemented?			
	PACKAGING AND TRANSPORTATION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-11.8 (a)	Are processed whole blood, modified whole blood and all liquid red blood cell components transported in a manner that will maintain temperatures of one to 10 degrees Centigrade?			
N.J.A.C. 8:8-11.8 (b)	Are components ordinarily stored at 20 to 24 degrees Centigrade transported at this temperature?			
N.J.A.C. 8:8-11.8 (c)	Are components ordinarily stored frozen transported in a manner designed to keep them frozen?			
N.J.A.C. 8:8-11.8 (d)	Does the receiving facility transfer the blood immediately upon arrival to temperature controlled equipment for further storage?			
	General Provisions	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-12.1 (a)	Do facilities that perform out-of-hospital transfusion possess a blood bank license to offer the service in New Jersey?			
N.J.A.C. 8:8-12.1 (c)	Does the OOHT service and the New Jersey licensed "Transfusion Service" have written agreement that specifies the division of responsibilities for assuring compliance with this chapter? Does the New Jersey licensed transfusion service agree in this written document to perform recipient testing and provide technical consultation when necessary?			
N.J.A.C. 8:8-12.1 (d)	Are SOPs submitted and written approval received from the Department prior to initiation of the service?			

	OUT-OF-HOSPITAL TRANSFUSIONS	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-12.2 (a)	Are out-of-hospital transfusions (OOHT) done under medical supervision, and is the patient observed during the transfusion for an appropriate time thereafter for suspected adverse reactions? Are specific instructions concerning possible adverse reactions provided in writing for the patient?			
N.J.A.C. 8:8-12.2 (d)	Is recipient safety assured by at least the following: 1. If a physician is not present, is the transfusionist an RN who is able to administer emergency care and has taken an eight hour course in cardiopulmonary resuscitation within three years and successfully passed a practical and written exam on the subject matter? 2. Is a second responsible person available on the premises to help with emergency situations and provide the second check required in N.J.A.C. 8:8-10.2?			
	OOHT IN EMERGENCY SITUATION	**YES**	**NO**	**N/A**
N.J.A.C. 8:8-12.3 (a)	Are facilities not routinely using blood for transfusion, but may use it in an emergency to treat a life-threatening situation, licensed?			