below); rechecks must be conducted using two levels of calibrators, controls, standards, or a combination of these materials.

(4) Limits for standards and reference samples shall be recorded and shall include the course of action to be instituted when the results are outside the acceptable limits for each lot number of controls. Manufacturer's limits may be used only if they are verified by the laboratory.

(5) For urinalysis, the laboratory shall use a positive control each day of patient testing, which checks the reactivity of each constituent for which qualitative tests are reported.

(6) Counting equipment used for in vitro radioassay determination shall be checked for stability at least once each day of use with radioactive standards or reference sources. Records which document the routine precision of each method, automated or manual, and its recalibration scheduled, shall be maintained. At least one standard and one reference sample (control) shall be included with each run (ad defined by guidelines) of unknown specimens.

(7) For blood gas analysis, a two point calibration must be performed and documented each shift; a third point verification must be run using a separate material from that used in the two point check; for blood gas analyzers which include other chemistries (electrolytes, glucose, bun, etc.) the quality control requirements are outlined under Rule 290-9-8-.09 and .09(5).

(8) For co-oximetry, preventive maintenance shall follow manufacturer's guidelines except where regulations are more stringent; a hemoglobin control shall be performed each day of testing. The calibration of the instrument shall be checked weekly unless required more frequently by the manufacturer.

(9) Drug screens for medical purposes must contain a standard which contains all drugs to be identified by the method used, or for which the laboratory reports, per each plate or run. The control must go through all phases of testing including extraction, unless technology that is more current has been approved by the Department. Positive qualitative tests must be confirmed by a quantitative method, if required or recommended by the manufacturer.

Authority O.C.G.A. Sec. 31-22-1 et seq. **History.** Original Rule entitled "Quality Control for Clinical Chemistry" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-8-.13 Quality Control for Immunohematology.

Those clinical laboratories which provide for the collection, processing or storage of human blood and its components shall provide methods for the selection of blood and component donors as well as for the collection, storage, processing and transfusion of blood and its components, and shall ensure that the blood and component donation will not be detrimental to the donor and also protect, as far as possible, the recipient of the human blood or any of its components from infectious disease known to be transmissible by blood. The methods used shall conform to the following:

(a) **Selection of donor:**
1. On the day of donation, the donor shall be evaluated in order to protect the donor and the recipient of the donation. At a minimum, the following shall be used in the evaluation of the donor and records shall be retained.
2. The minimum age for donation is seventeen (17) years; the maximum age for a donor is left to the discretion of the director of the facility providing the donor is in good health.

3. Minimum weight for routine donation shall not be less than 110 lbs. (50 kg) with a maximum of 525 ml. of blood removed per donation; individuals weighing less than 110 lb. (50 kg) may donate relative to the volume collected; in this event, the volume of anticoagulant must be considered. Any recent unexplained weight loss (e.g., more than 4.5 gk. or 10 lbs) should be evaluated by the donor's physician.

4. The volume of donation shall not exceed 545 ml in an eight week period; donation of whole blood must be deferred for at least 48 hours after apheresis.

5. The systolic blood pressure shall be no higher than 180mm of mercury, and the diastolic blood pressure must be no higher than 90 mm of mercury.

6. Pulse rate shall be between 50 and 100 beats per minute. Prospective donors with pathogenic cardiac irregularities must be deferred.

7. Donor hemogoblin or hematocrit must be determined prior to donation by a method acceptable to the Department; donors with a hemoglobin less than 12,5g/dL or a hematocrit less than 38% must not be considered for donation.

8. Prospective donors with chronic or acute illness must be evaluated by a physician prior to donation.

9. Routine donation must be deferred for six months after the conclusion of a pregnancy.

10. Prospective donors on therapeutic drugs must be evaluated by a physician prior to donation to protect the donor and the recipient.

11. The donor temperature (oral) shall not exceed 37.5 degrees C. (99.6 degrees F.).

(b) **Donor deferral:**
1. Abnormal behavior: a prospective donor shall not appear to be under the influence of alcohol or any illegal substance.

2. The site of venipuncture shall be free of lesions; evidence of drug abuse shall indefinitely exclude the potential donor. At a minimum, both arms shall be inspected for parenteral drug use.

3. A history of syphilis or gonorrhea shall exclude the potential donor for a period of not less than six months after treatment of the disease.

4. Potential donors who have received blood, blood components, derivatives, or other human tissue known to be a possible source of blood borne pathogens shall be excluded as donors for a period of not less than 12 months.

5. Potential donors who have taken medication known to alter platelet function within the previous three days, shall be evaluated as to the impact on the patient who is to receive the platelets from this donor and that such donor is to be the sole source of the platelets.

6. Immunizations and vaccinations: Donors shall be evaluated for the impact of the immunizations and vaccinations on the donation in accordance with general accepted standards of practice. At a minimum the following actions shall be taken:

(i) Potential donors who have received toxoids and killed viral, bacterial, and rickettsial immunizations and/or vaccinations may be considered as a donor if symptom-free and afebrile.
(ii) Potential donors who received human diploid cell rabies shots may be considered if symptom-free and afebrile, unless the vaccine was given following an animal bite; the exclusion period for this event shall be no less than one year.
(iii) Potential donors shall be deferred after receiving the following vaccinations:
(I) Live attenuated viruses such as measles, rubella(a), mumps (oral), or yellow fever shall be deferred for a period of not less than two weeks.
(II) German measles (rubella) shall be deferred for a period of not less than four weeks.
(III) Hepatitis B Immune Globulin (HBIG) shall be deferred for a period of not less than twelve months.

7. Infectious diseases requiring indefinite deferral:

(i) Those potential donors with a history of hepatitis B after the age of eleven, or those who have been confirmed positive for hepatitis B surface antigen (HBsAg) or those who have had a repeatedly reactive test for antibodies to hepatitis B core (anti-HCc) on more than one occurrence.

(ii) Those potential donors with a present or past clinical history of infection with hepatitis C virus (HCV), human T-cell lymphatic virus (HTLV) or human immunodeficiency virus (HIV);

(iii) Those potential donors (male) who have had sex with another male since 1977;

(iv) Those potential donors who have had sex for money;

(v) Those potential donors who were born or emigrated from a country where heterosexual activity is thought to play a major role in the transmission of HIV-2 infection.

8. Deferral of potential donors having had contact with potential viral pathogens, application of a tattoo, mucus membrane exposure to blood, exposure to blood or other body fluid through non-sterile skin penetration, non-casual contact with another person

positive for hepatitis B surface antigen (HGsAg) or HIV, or being incarcerated in a correctional institution for more than 72 hours, shall be not less than twelve months.

9. Malaria:

(i) Potential donors diagnosed as having malaria must be excluded for a period of not less than 3 years after becoming asymptomatic;
(ii) A potential donor coming from a country considered endemic for malaria must be excluded for a period of not less than 3 years;
(iii) Potential donors who are permanent residents of a country in which malaria is not considered endemic, but who has traveled to a malaria endemic country must be excluded for a period of not less than 12 months, and they must be asymptomatic at the time of donation;
(iv) Malaria restrictions may not apply, if the donor is only donating plasma and the red cells are not used for transfusion purposes.

10. Other protozoan diseases: Potential donors with a history of Babesiosis or Chagas' disease shall be deferred indefinitely.

(c) **Donor Information.** Potential donors must be informed and sign a consent form. This information/form must contain, at least, information relative to the potential danger of donation, the significance of blood-borne pathogens, and post-phlebotomy care. The donor must be given the opportunity to confidentially request that his/ her donation not be used for transfusion. A physician associated with the collecting facility must establish a means to notify donors of any significant abnormality detected during predonation evaluation or laboratory test results.

(d) **Autologous donor blood.** If a donation is only for autologous purposes, the donor requirements may be reduced, however, no donation shall be collected for an individual with a systemic infection. The unit must be labeled "autologous use only". Autologous units must be stored under the same requirements as banked blood. However, the autologous units must be segregated from the regular banked blood and blood components. The facility must be licensed by the FDA for the collection and storage of autologous donations.

1. The facility must have policies and procedures for the selection of donors, the collection, processing (testing), storage and disposition of autologous donations.

2. The ABO group and Rh type on these units to be transfused must be determined.

3. Test for HBsAg, HIV-1, anti-HIV-1, anti-HIV-2, anti-HCV, anti- Hbc and a serological test for syphilis must be performed by the collecting facility prior to being transfused in another facility. The unit must be labeled positive for any positive test results.

4. The transfusing facility and the physician must be informed of any abnormal test results. Prior to autotranfusion, the ABO group and Rh type of the donor and recipient must be confirmed.

5. Autologous units must be labeled "autologous donor" and "for autologous use only."

(e) **Therapeutic donations:**
1. Therapeutic bleeding, to include hemapheresis, can only be performed with the written approval of the patient's physician and must be approved by the director of the laboratory.

2. There shall be written policies and procedures for performing the phlebotomy.

3. Records must be retained to document patient identification, diagnosis, and type of therapeutic procedure performed, extracorporeal blood volume, nature and volume of component removed, quality control of measuring device, any occurrence of adverse reactions to medication, disposition of the blood, and the unit shall be labeled "not for transfusion".

(f) **Reagent quality control.** All reagents must conform to FDA regulations and manufacturer's instructions must be followed.

1. ABO antisera must be quality controlled with a positive control each day of use.

2. Rh antisera and reagent cells must be quality controlled with a negative control each day of use; the negative control may be deleted if indicated by the manufacturer.

3. Other antisera must be quality controlled with a positive and negative control each day of use.

4. Anti human globulin sera must be quality controlled with a positive and negative control each day of use.

5. Antibody screening cells must be quality controlled with a positive control each day of use.

6. Each bottle of reagents used in testing must be evaluated in the quality control program on the day of use.

(g) **Transfusion services.** It is the responsibility of the laboratory director to assure that the needs of the physicians responsible for the diagnosis, management, and treatment of patients are met in reference to blood, blood components, blood products and blood bank testing services.

(h) **Preparation of blood components.** The process of component preparation must be sterile and a closed system is preferred.

1. If a closed system is not employed or the seal is broken, components stored between 1–6° C shall have an expiration date of 24 hours.

2. All components must be traceable through identification numbers and lot numbers.

3. For red blood cells, the unit must contain the type of anticoagulant/ preservative used in the collection.

(i) Red blood cells and deglycerolized red cells designated for freezing, must be frozen within six days of collection.

(ii) Rejuvenated red blood cells: following rejuvenation, the cells may be washed and transfused within 24 hours or deglycerolized and frozen; the label on the unit of blood after rejuvenation must indicate the rejuvenating solutions.

(iii) Irradiated red blood cells: for red blood cells which have received at least 500 cGy irradiation, the dose shall be a minimum of 2,500 cGy targeted to the midpoint of the canister; if free-standing irradiation is used, or to the center midplane of an irradiation field if a respiratory instrument is used; the method used for irradiation must be monitored at least annually to verify the delivered cGy.

4. Plasma components. Fresh frozed plasma – removed from a single donor must be stored at –18° C; if collected in CPD, CPD.2, OR CPDA-1, the plasma must be frozen within 8 hours of collection; if colleted in ACD, the plasma must be frozen within 6 hours of collection. The freezing process must protect the plasma from chemical alteration.

(i) Cryoprecipated antihemophilic factor (AHF) must be thawed at 1–6° C, separated from the plasma and stored frozen within one hour; there must be a method to monitor the amount of AHF and fibrinogen harvested. For platelets and platelet pheresis, a method to determine the concentration of platelets must be established and followed. When leukocyte reduction is a consideration, there shall be a method to determine the leukocyte contamination.

(ii) For granulocyte pheresis, a method shall be established and followed to monitor the concentration of the component.

(iii) When any blood components are mixed/pooled, any plasma alloantibodies must be compatible with red cell antigens.

(i) **Testing of donor blood.** Prior to transfusion, the testing laboratory must perform, at a minimum, the following tests on donor blood:

1. ABO group must be performed by testing the red cells with anti-A and anti-B, and by testing the serum or plasma for expected antibodies to A1 and B red blood cells.

2. Rh type must be determined with anti-D; if the anti-D is negative, a test for weak D must be performed; both tests must be negative in order for the unit to be labeled D negative; the donor's previous record must be checked relative to ABO and Rh, and any discrepancy must be resolved.

3. Testing for unexpected red cell antibodies: serum or plasma from donors with a history of transfusion or pregnancy must be tested for the presence of clinically significant antibodies; if any such antibody(s) is detected, it must be identified, if the blood is to be transfused, and the blood and its components labeled with the identity of the antibody(s).

4. Testing to prevent disease transmission: All blood for transfusion must be tested for HBsAg, anti-HBC, anti-HTLV, HIV-1-Ag, anti-HIV-1, anti-HIV-2, anti-HCV, and with a
serological test for syphilis; blood should not be transfused prior to completion of testing; in the event of prior transfusion, follow up investigation must be documented and the recipient's physician must be notified if the unit was found to be positive for any or all of those markers.

(i) **Blood labeling.** The label on a unit of blood or blood component must identify the original unit and any component, or component modification; the label must be clear, eye-readable, and may be machine readable; handwritten labels must be legible and in permanent ink; prior to labeling, a review to reveal units not to be issued shall be completed; the labeling process must include a second check to determine if an error has occurred in the labeling; this check must verify ABO, expiration date, and other appropriate labels on the unit as well as components. An appropriate label must be affixed, should modification be made to the component.

1. Unit identification. A unique identifier must be assigned to each unit by the collection facility; such identification may not be removed or altered by subsequent facilities; other facilities may affix another unique identifier which must identify the facility; no more than two unit identifications may appear on the unit at a given time.

2. Labeling at collection or preparation. At the time of collection for whole blood, and at the time of preparation for components, the unit must be labeled as to whether it is whole blood, a component, or an intended component, unique identification, type of anticoagulant (not required for frozen, deglycerolized, rejuvenated, or washed blood cells); for platelets, low volume red blood cells, fresh frozen plasma, pooled components, or components prepared by apheresis, the approximate volume must appear on the container, sedimenting agent (if any), and the identification of any facility collecting or modifying the blood component.

3. Labeling prior to use. The final container label must indicate at least the following information:

(i) Temperature of storage, expiration date/time, if appropriate, identification of the facility preparing the final component, ABO group, Rh type and interpretation of unexpected antibody test, when positive, and instructions for the transfusionist, at a minimum; to properly identify intended recipient, the statement "This product may transmit infectious agents. Caution: Federal law prohibits dispensing without a prescription."

(ii) The type of donor: i.e., volunteer, paid or autologous.

(iii) Name of anticoagulant, except for components, prepared by hemapheresis, and type of cells, i.e., frozen, deglycerolized, rejuvenated or washed red cells.

4. Irradiated blood and components must be labeled as such, along with the name of the facility performing the irradiation.

5. CMV negative red blood cells or cellular components to be issued to a CMV negative recipient must be labeled CMV-negative.

6. Labeling for pooled components: In addition to the labeling requirements under "labeling at collection or preparation" and "prior to use," the label for pooled components must contain the following: name of pooled component, final volume of pooled component, name of facility preparing the pooled component, and unique identification of pooled component. The following information must appear either on the label or on the attached tag:

(i) Number of units in the pool.
(ii) ABO group and Rh type in the pool (–Rh is not required for cryoprecipitate).
(iii) The record must contain the unique identification for each unit in the pool as well as the collecting facility.

7. Labeling of blood bags must meet FDA regulations (21 CFR 606 Subpart G).

(k) **Storage.** Refrigerators in which blood and blood components are stored must provide a uniform temperature. Blood and blood components must be stored within an acceptable temperature range.

1. Refrigerators, freezers, incubators, and other storage areas must have a continuously monitored record of the temperature; in those areas not continuously monitored, the temperature must be monitored and documented each four hours of storage.

2. Refrigerators and freezers used for the storage of blood and blood components must be equipped with an audible alarm, set to activate at a temperature to allow proper action to be taken before the blood and components reach unacceptable temperatures.

3. The alarm system used with liquid nitrogen storage must be set in such a manner as to alert personnel of an unsafe level of liquid nitrogen.

1. Blood and red blood cells must be transported in a manner to ensure a temperature of 1–10° C.

2. Components stored at 20–24° C must be transported at 20–24° C.

3. Components stored in a frozen state must be transported to assure that they remain in the frozen state.

(m) **Expiration of blood and blood components.** Provided that FDA approved collection methods, solutions, labeling practices, storage, transportation and equipment

are used, the expiration date that appears on the label must be followed under ordinary situations. In order to consider this the expiration date, the closed system under which the unit was collected must not have been compromised; dating periods must follow FDA regulations (21 CFR 610.5B).

(n) **Apheresis.** At a minimum, the following policies and procedures must be available and followed when blood or a blood component is to be returned to the donor in a timely manner to assure that only the donor's blood or blood component is reinfused to the donor:

1. Only 0.9% USE injectable sodium chloride may be mixed with the blood as a diluent.

2. Donor must provide an informed consent.

3. A licensed physician must be responsible for the apheresis procedure and must assure donor care.

4. Only sterile, pyrogen-free, non-toxic containers and additives which are compatible with the contents may be employed (those approved by the FDA).

5. For apheresis performed for the purpose of transfusion (i.e., platelet, AHF, granulocytes), there must be policies and procedures to evaluate the recovery with the recipient's needs considered; those products not meeting the established criteria must not be transfused without additional evaluation.

6. The procedures employed must assure the safe reinfusion of blood and avoid possible air embolism.

7. Any adverse reactions must be documented and medical advice must be rendered.

(o) **Plasmapheresis.** The donor criteria for an occasional (not to exceed one donation in a four-week period) donation shall be the same as those for a whole blood donor.

1. When plasmapheresis occurs more frequently than once every four weeks, FDA regulations 21 CFR 600-660 must be followed; for those donations not following this regulation, the donor must have a physical on the day of donation and a physician must request the donation and take responsibility for any undesirable outcome.

2. Cells shall be returned to the donor before collecting a second unit or within 2 hours of the initial phlebotomy; no more than 500 ml. of whole blood shall be removed at one time, or 1000 ml. for transfusion (or within 24 hours), unless, the donor's weight exceeds 176 lbs., in which case the amount shall be 600 ml. or 1200 ml. respectively.

3. If the pheresis is performed using an automated instrument, the amount of plasma collected shall not exceed the amount approved by the FDA for the instrument in use.

(p) **Compatibility Testing.** Requests for transfusion and samples from the recipient must contain sufficient information for positive identification of the recipient; the facility must establish policies to determine minimum criteria for recipient identification; these policies and procedures must contain provisions for emergency situations; the minimum acceptable information must be the patient's name (first and last) and an identification number, if not addressed in the emergency policy; any discrepancy must be resolved prior to testing. The facility must do the following as appropriate:

1. Recipient specimen labeling policies and procedures must be established by the facility. These policies and procedures must provide a method of positive recipient identification on the specimen, a unique identification between the recipient, the specimen(s), and the blood or components to be prepared for the patient, assure that the specimen is labeled at the time of collection in the presence of the recipient, and assure a method to identify and document the specific identity of the individual collecting the specimen. Should there by any discrepancy in the specific identification system, it must be resolved prior to testing.

2. The transfusion service must confirm the ABO group of all whole blood and red blood cells as well as the Rh type using a sample obtained from the attached segment. Any discrepancy in group and/or type must be reported to the collecting facility and the unit must be quarantined until notification from the collecting agency. This verification must be completed prior to release for transfusion. A label must be affixed to the unit indicating group and type confirmation.

3. Each blood specimen consisting of one or more tubes to be used in testing for the transfusion of whole blood and/or red blood cells must be tested for ABO group and Rh type. A screen for unexpected antibodies to red blood cell antigens must be performed. If the transfusion is to take place more than three days in the future, the specimen must be recollected and re-screened for antibodies to red blood cell antigens if:

(i) The patient has been transfused in the preceding three months with blood or components containing red blood cells;
(ii) The patient has been pregnant in the preceding three months or;
(iii) The patient history is not certain or unavailable.

4. ABO group must be determined using the red cells with anti-A and anti-B reagents. The serum or plasma must be tested using known A1 and B cells to determine the presence of expected antibodies to A1 and B cells. Any discrepancy must be resolved.

5. Rh typing must be determined using anti-D reagents. A control system must be employed, if indicated by the manufacturer of the anti-D reagent.

6. Screening for unexpected antibodies in the recipient's specimen must be conducted. This screen must be capable of detecting clinically significant antibodies and must include a 37° C incubation preceding an antiglobulin test using red blood cell reagents that are not pooled. With documentation of equivalent sensitivity, an alternative screening method may be employed. A control system using red blood cells sensitized with IgG must be applied to each test interpreted as negative. When a licensed test system

is employed that does not allow the addition of IgG-sensitized cells, controls shall be used as recommended by the manufacturer.

7. Prior to release for transfusion of whole blood or red blood cells, the transfusion history or the patient must be reviewed in order to detect a possible error.

8. Except in cases of emergency, a sample of the recipient's serum or plasma must be crossmatched against a sample from the donor cells from a specimen attached to the unit of whole blood or red blood cells. The crossmatch must have the ability to demonstrate ABO incompatibility and clinically significant antibodies to red blood cell antigens and must include an antiglobulin test. If no clinically significant antibodies to red blood cell antigens are detected and the patient's history does not indicate a clinically significant antibody, then only serologic testing to detect ABO incompatibility is required.

9. A computer system that has been validated by the facility to prevent the release of ABO incompatible blood and blood components, may be used in place of a serologic crossmatch, provided that the system contains donor information to include the donor number, the component name, ABO group, and Rh type of the component and the interpretation of the ABO confirmatory test. The system must contain the recipient's ABO group and Rh type.

(i) There must be a method to verify correct entry of data prior to release of blood or components. The system must alert the user to discrepancies between the donor unit labeling and the blood group confirmatory test interpretation and to ABO incompatibilities between the recipient and the donor unit.

(ii) There must be documentation of initial training for those individuals using the system, and of annual training thereafter. After initial training, annual training may be limited to upgrades and/or changes in the computerized system. The facility must maintain a back-up program to implement in the event of failure or malfunction of the computerized system to assure uninterrupted service.

(q) **Selection of blood and blood components for transfusion:**
1. Recipients should receive ABO group specific whole blood of ABO group compatible red blood cells.

2. Whole blood and red blood cells must lack the red blood cell antigen when the recipient demonstrates the presence of a clinically significant, unexpected antibody(s) to a specific red blood cell antigen(s). In addition, the donor unit must lack the red blood cell antigen(s) when the recipient's history indicates the presence of a clinically significant antibody(s) directed toward a specific antigen.

3. Fresh frozen plasma should be ABO compatible, whenever possible.

4. The donor plasma in platelet preparations must be ABO compatible when the recipient is an infant. Red blood cells and granulocytes shall be ABO compatible with the recipient's plasma.

5. Each facility must have written and utilized policies and procedures for the release of blood and blood components for transfusion purposes.

6. When a recipient has received a volume of blood approximating his/her total blood volume in a 24-hour period, the compatibility testing procedure may be abbreviated. This is at the discretion of the director of the laboratory. There must be written policies and procedures for the laboratory personnel to follow.

7. Where recipients are under four months of age, the ABO group, using anti-A, anti-B, and the Rh type, using anti-D must be performed on the infant. For the antibody screen, serum or plasma from the infant or infant's mother may be used. If the initial red blood cell antibody screen is negative, it is not required to crossmatch donor red blood cells for the initial or subsequent transfusions for the duration of that hospitalization. If the initial antibody screen is positive for clinically significant red blood cell antibodies, the infant must be transfused with red blood cells that are negative for the corresponding antigen or are compatible by antiglobulin crossmatch.

8. In the case of massive or exchange transfusion, only blood drawn to be hemoglobin S negative should be transfused.

(r) **Issuance and transfusion of blood and blood components.** At the time of release for transfusion, the donor unit must be labeled as specified in the facility's policy. The information must include, at a minimum, the recipient's name (first and last), identification number, donor unit number, and compatibility test interpretation, if performed. There must be a mechanism to identify the intended recipient and requested blood component at the time of issue. The transfusion record for each unit of blood, blood component or pooled component must contain the intended recipient's name, identification number, ABO group, and if required, the Rh type, the interpretation of the compatibility tests, if performed, and the date of transfusion. Following the transfusion, the record must be made part of the patient's medical record. A sealed specimen from the recipient and the donor must be maintained at 1–6° C for a period of seven days post transfusion.

1. Blood must be inspected immediately before issuance. If it appears abnormal, the unit must not be transfused.

2. Blood that has been returned to the blood bank must not be reissued unless the container closure has not been disturbed, and blood has not been allowed to warm above 10° C or cool below 1° C during storage or transportation. There must be policies in place and followed to assure that temperature ranges are not exceeded. The record must indicate that the blood has been reissued, and that it has been inspected prior to being reissued.

3. At least one sealed segment of integral donor tubing must remain attached to the container. Those segments removed may be reattached, if the identification number on them are identical to the segment(s) that remain attached.

4. When the requesting physician indicated with a signed statement, that a delay in transfusion could be detrimental to the patient, the blood may be released prior to the completion of the tests that are performed to reduce the transmission of infectious diseases as well as the compatibility testing. In that event, recipients whose ABO group can be determined (excluding the recipients' history) may receive ABO group specific or ABO group compatible red blood cells or whole blood. The unit must be labeled in a conspicuous manner to indicate that the compatibility testing was not performed at the time of release. Standard compatibility tests should be completed promptly on those units signed out as "uncrossmatched". All requirements relative to the labeling of specimens to assure positive identification must not be ignored during the collection, release, or the transfusion of blood during an emergency. After completion of required testing, the laboratory must notify the recipient's physician and the laboratory director, if a test result could effect the health and safety of the recipient.

(s) **Transfusion complications.** The facility must establish policies and procedures to assure that any transfusion complication is investigated. These policies and procedures must have a mechanism to detect errors in reporting, and evaluation of suspected complications of transfusion. All such investigations must be evaluated with a written interpretation by the laboratory director. The collection facility must be notified, if the complication appears to be attributed to the donor or the processing of the unit. Fatal transfusion reactions must be reported to the FDA, the collecting facility, and the Department.

Authority O.C.G.A. Sec. 31-22-1 et seq. History. Original Rule entitled "Quality Control for Immunohematology" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-8-.14 Quality Control for Hematology.

Instruments used in hematological examination of specimens shall be recalibrated, retested or reinspected, as appropriate, each day of use. Each procedure shall be recalibrated or rechecked each shift of use with standards or controls covering the entire range of expected values, unless required more frequently by the manufacturer or federal laboratory regulations. Tests such as the hematocrit and one-stage prothrombin time test shall be run in duplicate except as specified in published guidelines. Standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by the laboratory. All control materials used to satisfy the control requirement must have documented established limits.

Authority O.C.G.A. Sec. 31-22-1 et seq. History. Original Rule entitled "Quality Control for Hematology" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-8-.15 Quality Control for Exfoliative Cytology; Histopathology; and Oral Pathology.

(1) **Exfoliative Cytology.**

(a) The laboratory must establish and document an annual evaluation of the number of cytology cases examined, the number of specimens processed by type, the number of

cases reported by diagnosis, including the number of cases reported as unsatisfactory for diagnosis, the number of gynecologic cases where cytology and available histology are discrepant, and the number of cases where histology results were unavailable for comparison. The evaluation must also include the number of gynecologic cases where the rescreen of a negative or normal test results in a reclassification to a premalignant or malignant diagnosis.

(b) The laboratory must evaluate the case reviews of each person examining slides against the overall statistical values, document the reasons for deviations, and corrective actions taken, if needed.

(c) The laboratory must develop and implement procedures to detect inadequately prepared slides, assuring no diagnosis is reported on such cases. Such procedures must include a plan for promptly notifying referring physicians of inadequately prepared slides. The report must clearly distinguish specimens, or smears, or both, that are unsatisfactory for diagnosis interpretation. Documentation of unsatisfactory specimens and notifications
must be retained by the laboratory for a minimum of five years.

(d) The laboratory director or supervisor qualified in cytology or cytotechnology shall rescreen for proper staining and correct interpretation at least a ten percent random sample of gynecological smears which have been interpreted to be in one of the benign categories by personnel not processing director or supervisor qualifications. The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information. Records of initial examination and rescreening must be available. Rescreening must be performed prior to reporting.

(e) No laboratory shall assign or permit an individual engaged in the evaluation of cytology preparations by non-automated microscopic technique to examine more than one hundred (one patient per slide, gynecologic or non-gynecologic, or both) slides in a twenty-four hour period. This limit represents an absolute maximum number of slides in any twenty-four hour period, unless slide preparations are made using automated, semi-automated, or other liquid-based slide preparatory techniques resulting in cell
dispersion over one-half or less of the slide area, in which case the slide counts as one-half slide, if examined by nonautomated microscopic technique. The maximum number of one hundred slides shall be examined in not less than an eight-hour period.
Recognizing individual differences in abilities, the laboratory must establish the maximum number of slides (not to exceed the 100 slide limit) each individual may screen in a twenty-four hour period, and records must be available to document that each
individual's workload limit is reassessed at least every six months and adjusted, when necessary. For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an eight hour workday basis,
a period of eight hours must be used to prorate the number of slides that may be examined by using the following formula: