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Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

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1. Transmitted is a complete revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 5, "Immunohematology, Blood Transfusion and Transfusion Medicine," formerly entitled "Laboratory Service Responsibilities."

2. Principal changes are:

a. Paragraph 5.01: Establishes policy for operation of blood and blood component transfusions in VA medical centers.

b. Paragraph 5.02: Provides requirements for inspection, accreditation, and legislation of blood banks.

c. Paragraph 5.03: Outlines the responsibilities of the VA medical center Director, Pathology and Laboratory Medicine Service, Transfusion Officer, Chief of Pathology and Laboratory Medicine Service, Chief Blood Bank, and supervisors

d. Paragraph 5.04: Defines general practices in blood banks.

e. Paragraph 5.05: Defines conditions for storage of blood and blood products.

f. Paragraph 5.06: Defines requirements for operation of allogenic (homologous).

g. Paragraph 5.07: Defines requirements for autologous blood transfusion programs.

h. Paragraph 5.08: Defines requirements for therapeutic phlebotomy.

i. Paragraph 5.09: Outlines standard practices for blood/component transfusions.

j. Paragraph 5.10: Provides requirements for emergency blood transfusions.

k. Paragraph 5.11: Provides requirements for special blood transfusions.

l. Paragraph 5.12: Defines policy and procedures for rectifying transfusion complications.

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- m. Paragraph 5.13: Provides policy and procedures for inventory control.

- n. Paragraph 5.14: Defines policies for record keeping, retention and retrieval.

- o. Paragraph 5.15: Provides policy for acceptance of military blood program units.

- p. Paragraph 5.16: Defines computer requirements for blood transfusion services.

- q. Paragraph 5.17: Provides current references for blood transfusion services.

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3. Filing Instructions

Remove pages	Insert pages
19 through 22i	5-i through 5-ii 5-1 through 5-37 5A-1 through 5B-1

4. RESCISSION/S: M-2, Part VI, Chapter 5, dated August 21, 1987, Change 73;
and VHA Circulars: 10-63-097, 10-64-071, 10-85-181, 10-87-012, 10-87-064, 10-
87-065, 10-89-104, and 10-90-026.

S/ by Dennis Smith
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Acting Under Secretary for Health

Distribution: RPC: 1276 is assigned
FD

Printing Date: 2/94

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part VI, Chapter 5, change 73, dated August 21, 1987

2. Circulars

10-63-097
10-64-071
10-85-181
10-87-012
10-87-064
10-87-065
10-89-104
10-90-026

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CHAPTER 5. IMMUNOHEMATOLOGY, BLOOD TRANSFUSION
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5.01 GENERAL POLICY

a. The Department of Veterans Affairs (VA) shall provide suitable blood, blood components, fractions, and derivatives to meet the transfusion needs of patients under treatment in VA medical centers. The term "blood" used in this chapter will include blood, blood components and coagulation derivatives. It will not include albumin or other derivatives.

b. Essential blood bank services shall be available at all times.

c. A current manual of procedures will be maintained in the blood bank and available to the laboratory staff at all times.

(1) The Standard Operating Procedure (SOP) Manual must be comprehensive, reflect the policies of the VA medical center, and must include written procedures for all procedures performed and all services provides.

(2) The procedures shall be in conformance with the current edition of Standards for Blood Banks and Transfusion Services, published by the American Association of Blood Banks (AABB) (see subpar. 5.17a). NOTE: Helpful information may also be found in other AABB publications, including the current edition of the Accreditation Requirements Manual (see subpar. 5.17b) and the Technical Methods and Procedures (see subpar. 5.17c). These publications will be available at all VA medical centers.

(3) The procedures shall also be in conformance with the National Committee for Clinical Laboratory Standards (NCCLS) format as required by College of American Pathologist (CAP) (see subpars. 5.17d and e).

(4) Copies of the current revision of M-2, Part VI, Chapters 2 and 5, and M-2, Part I, Chapter 12, must be included for reference.

d. Only blood from voluntary donors shall be utilized. Blood and blood components shall be tested for all transfusion transmitted disease markers as required by the Bureau of Biologics, Food and Drug Administration (FDA), Department of Health and Human Services (HHS) and recommended by AABB (see subpars. 5.17f and g). NOTE: Various methods for obtaining blood for transfusions are described in M-2, Part I, Chapter 12, Blood Transfusion Service - General Administration.

e. A means shall be provided for patients to undergo autologous predeposit donation, as detailed in paragraph 5.07, whether at the medical center or at a blood center supplying other blood components to the medical center.

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f. Although VA policy discourages segregating units of blood or components (directed donations) for transfusions, the VA will ensure a means to provide such units, if requested, in accordance with M-2, Part I, Chapter 12.

g. Transfusion practices and problems will be reviewed regularly and documented in the minutes of the Transfusion Committee of the hospital. The Clinical Executive Board (CEB) will oversee the functions and will approve the minutes of the Transfusion Committee (see Chs. 1 and 12.) The Transfusion Committee will review monitors to

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track appropriateness of patient care in accordance with the requirements of Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) (see subpar. 5.17 h).

h. Use of the Blood Bank module software of the laboratory package of the Decentralized Hospital Computer Program (DHCP), or comparable software, is mandated in order to:

(1) Minimize the potential for errors, based on the variety of control functions, and

(2) Maximize the availability of management and quality assurance information which is not easily retrievable via manual means (see par. 5.16).

5.02 INSPECTION AND ACCREDITATION

a. The Director of each VA medical center is mandated to ensure current accreditation of the blood bank with AABB. VA medical centers are strongly encouraged to also apply for institutional membership in AABB, a nationally recognized professional organization which is actively engaged in improving blood banking through educational and accreditation programs. The costs of accreditation and/or membership will be borne by the medical center.

b. The Director of each VA medical center is mandated to register with FDA if the medical center is involved in drawing either autologous, or allogeneic (homologous) donors, or in preparing blood components.

c. For additional details regarding other agencies, see Chapter 2.

5.03 RESPONSIBILITIES

a. The Director, Pathology and Laboratory Medicine Service, VA Central Office, will provide oversight responsibility for ensuring current accreditation with CAP and JCAHO, in accordance with Chapter 2. The performance of each blood bank will be reviewed regularly and will be based on AABB inspection deficiencies, CAP inspection deficiencies, CAP Quality Improvement (QI) survey deficiencies and FDA deficiencies.

b. The Director of each VA medical center will appoint a Transfusion Officer, not necessarily a pathologist (in accordance with M-2, Pt. I, Ch. 12), who will be responsible for the oversight of blood usage review for the VA medical center.

(1) In large, more complex, affiliated VA medical centers, the Transfusion Officer will be a physician with knowledge and expertise in blood banking, or hematology, to ensure acceptable transfusion practices in the hospital.

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(2) In smaller, nonaffiliated VA medical centers or those in which there is no full-time Chief, Pathology and Laboratory Medicine Service, the Transfusion Officer will be a physician with medical experience in the transfusion of patients.

(3) The Chief, Pathology and Laboratory Medicine Service, should not usually be appointed as Transfusion Officer since there must be objective peer review of blood usage.

c. The Chief, Pathology and Laboratory Medicine Service, is responsible for appointing a Chief, Blood Bank Section, to oversee the collection of autologous and/or

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allogeneic (homologous) blood donors if the medical center is involved in these activities as described in paragraphs 5.06 and 5.07.

d. The Chief, Pathology and Laboratory Medicine Service, or designated Chief, Blood Bank Section, is responsible for:

(1) The clinical and administrative laboratory aspects of the medical center's blood transfusion policies and their implementation. This person may also be responsible for the technical aspects of the blood bank with appropriate functions delegated to those laboratory personnel who are competent in blood bank procedures.

(2) Appointing a Blood Bank Supervisor who will be responsible for appropriate administrative and technical supervision of the daily functions of the Blood Bank/Transfusions Service (see Ch. 12).

(3) Establishing and implementing guidelines to promote the health and safety of the laboratory personnel through controlled environment and appropriate policies and techniques in accordance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standards (see subpar. 5.17i).

e. In larger facilities, the Chief, Pathology and Laboratory Medicine Service, or Chief, Blood Bank Section, is responsible for seeking consultation from a recognized authority in the field of blood banking when complications arise in the treatment of patients what would merit such a consultation. In smaller facilities that do not have a full-time pathologist, clinically related transfusion problems will be resolved by the designated Transfusion Officer.

f. The Blood Bank will work closely with the medical staff in endeavoring to provide appropriate blood components or clotting factors to help meet patient care needs (see M-2, Pt. I, Ch. 12). The Chief, Blood Bank Section, may have to operate as a consultant on component usage under certain conditions or in planning patient therapy.

5.04 GENERAL BLOOD BANK PRACTICES

a. Quality Control

(1) The Laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, for accurate and reliable testing and for result reporting in accordance with the current edition of AABB and CAP standards (subpars. 5.17 a and e) and the 21 Code of Federal Regulations (CFR), 606 (subpar. 5.17 j). These criteria must be included in the SOP Manual of the Blood Bank.

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(2) The laboratory must perform reagent quality control as required by the current edition of AABB Standards for Blood Banks and Transfusion Services. Refer to Chapter 2, for additional specific details.

(3) The testing for ABO and D (Rho) typing, unexpected antibody detection and identification and compatibility testing must be performed in accordance with the manufacturers' direction and as applicable with 21 CFR 606 and 640.

(4) The laboratory must perform equipment quality control as required by the current editions of both the AABB Inspection Report Form and the AABB Accreditation Requirements Manual.

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(5) Remedial actions taken to correct conditions that fail to meet the criteria specified in subparagraph 5.04 a(1) must be documented and reviewed as required by the current AABB and CAP standards.

b. Patient Identification

(1) There will be positive verification of the identity of the prospective recipient prior to securing the blood specimen to be used for pretransfusion compatibility testing.

(a) This will be carried out by checking the wristband for name and Social Security Number (SSN) and, if the patient is conscious, by asking the patient to give own name.

(b) In the event that these procedures are not possible, a physician, nurse, or physician's assistant who has positive knowledge of the patient's identity will make the verification.

(c) The individual securing blood specimens will authenticate them by labeling the tube and by signing Standard Form (SF) 518, Blood or Blood Component Transfusion. The tube will be identified by an adhesive label bearing the:

1. Recipient's full name,
2. SSN,
3. Date, and
4. Identity of the individual drawing the blood.

NOTE: This information must be recorded on the label at the time of venipuncture to avoid confusion of specimens.

(d) In accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services and the Accreditation Requirements Manual (subpar. 5.17 b), there must be a mechanism to identify the individual who obtained the blood sample in order to establish accountability for correct patient identification.

(e) Samples deemed unsuitable for testing, in accordance with the specimen rejection criteria detailed in the SOP, shall be rejected and testing shall not be performed until a new sample is received. In no case shall a specimen which was not labeled, improperly labeled, or is otherwise unsuitable for testing, be used for pretransfusion testing.

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(2) Prior to issue of any blood components for transfusion, VA Form 10-2984, Caution Tag, properly completed and signed, will be attached securely to each unit of blood. A computer generated label may be used as an overlay.

(3) Before starting a transfusion, two qualified persons will certify that the recipient is the person named on VA Form 10-2984, which is attached to the blood container, and on SF 518 which accompanies the unit. This will be done by verifying the patient identification information on the wristband against that on the SF 518 and VA Form 10-2984 (see M-2, Pt. I, Ch. 12).

c. Pretransfusion Testing

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(1) Patient specimens used in pretransfusion compatibility testing shall comply with the age requirements of the AABB Standards for Blood Banks and Transfusion Services and the Accreditation Requirements Manual.

(2) Routinely, pretransfusion compatibility testing will not be initiated until an order is received in the Blood Bank. This order may be in hard copy or by an electronic request, and need not be submitted on the SF 518, if the SF 518 is generated in the Blood Bank. Verbal requests for blood will not constitute the proper authority, except as indicated in subparagraph 5.10b(2)(b).

(3) Pretransfusion compatibility testing, including ABO/Rh typing, antibody screening and crossmatching, will be performed in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services and the Accreditation Requirements Manual (see subpar. 5.07f for specific details regarding autologous units). If a clinical situation exists which precludes completion of routine pretransfusion compatibility testing, the situation must be handled in accordance with subparagraph 5.10b.

(a) Testing of both donor and recipient blood will be performed utilizing antisera and reagent red blood cells which are in date, and have been licensed by the FDA.

(b) Appropriate confirmation testing of donor units will be performed prior to issue of the unit for subsequent transfusion in accordance with the requirements of the current edition of the AABB Standards for blood banks and Transfusion Services.

d. Retention of Samples. Samples used in pretransfusion compatibility testing, including both the patient specimen and the sample of each of transfused blood, shall be maintained in accordance with the current editions of the AABB Standards for Blood Banks and Transfusion Services and the Accreditation Requirements Manual.

e. Competency Measurement. Assessment of an employee's ability to perform work adequately should be an ongoing practice in accordance with established VA policy found in MP-5, Part I, Chapter 430.

f. Proficiency Testing. Proficiency testing is the assessment of the medical center's laboratory testing by an external agency through use of survey material. Proficiency testing surveys for Blood Banks can be obtained from professional organizations (such as CAP, AABB, etc.) approved by Pathology and Laboratory Medicine Service, VA Central Office.

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(1) The submitted results for the medical center are evaluated with peer VA medical centers on a local basis, as well as on a nationwide VA basis by Pathology and Laboratory Medicine Service, VA Central Office. NOTE: All proficiency testing failures will be evaluated by VA Central Office.

(2) In accordance with the recommendations of the current edition of the AABB Accreditation Requirements Manual, the testing of proficiency samples should be rotated among the technical staff in order to get a representative assessment of the work being performed.

(3) Refer to Chapter 2, for the specific details of proficiency testing requirements for immunohematology.

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5.05 BLOOD AND BLOOD PRODUCTS STORAGE FACILITIES

a. Blood and blood components must be stored under appropriate conditions as detailed in the current editions of the AABB Standards for Blood Banks and Transfusion Services and the Accreditation Requirements Manual. This includes a recording thermometer and temperature alarm system which is regularly inspected, i.e., at least daily.

(1) An audible alarm system must monitor proper blood product storage 24 hours per day, including refrigerators, freezers and platelet incubators where components might be stored. The alarm may need to be located remotely from the Blood Bank if the Blood Bank staffing patterns do not provide 24 hour coverage.

(2) Inspections of the alarm system must be performed and documented as part of the ongoing equipment quality control.

(3) The refrigerators and/or freezers used for blood component storage, as well as the alarms, will be connected to the facility's emergency power.

b. Blood shall be stored ONLY in equipment which is designed to that purpose and which is continuously monitored. A few subsidiary refrigerators may be authorized, by the Chief, Pathology and Laboratory Medicine Service, or the Chief, Blood Bank Section, for use in areas outside the blood bank section of the Laboratory Service, such as the operating suite, the emergency room and critical care units. The temperature and appearance of these units will be monitored in the same manner as units within the Blood Bank.

c. If blood is stored or maintained outside of a monitored refrigerator, the medical center must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood product. Storage conditions for red blood cell products are not to exceed 6 degrees Centigrade and transport conditions must not exceed 10 degrees Centigrade. NOTE: In some VA medical centers, transportation may need to include containers designed for this purpose if there is not sufficient environmental temperature control. If the temperature exceeds the established limits, the unit shall not be used for transfusion.

d. To detect abnormalities, each unit of blood should be inspected at regular intervals and immediately prior to issue in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services.

e. Appropriate records must be maintained of the final disposition for each component, as detailed in paragraph 5.14. If the unit is not transfused, records must include information on the destruction of the unit.

5.06 OPERATION OF AN ALLOGENEIC (HOMOLOGOUS) BLOOD DONOR PROGRAM

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NOTE: For purposes of general policies and procedures, "directed donors" drawn by the medical center will also be considered "allogeneic donors" (described under paragraph 5.11a).

a. Policy

(1) If blood is to be collected from allogeneic (homologous) blood donor, all policies and procedures must meet the requirements of the FDA current good manufacturing

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procedures (CGMP) and the current edition of the AABB Standards for Blood Banks and Transfusion Services manual, regardless of the number of donors to be collected on an annual basis.

(2) Donor room activities will be performed by appropriately trained, competent personnel who have demonstrated technical competency in donor room procedures, and who are knowledgeable in the issues associated with:

- (a) Transfusion transmitted diseases, and
- (b) Behaviors which are considered high risk for transmitting pathogens.

(3) The Chief, Blood Bank Section, or designated alternate, must be on the premises during the collection of allogeneic (homologous) donors, except as detailed in the SOP Manual.

(4) Prior to each donation, a sufficiently detailed interview will be conducted with the prospective donor to determine whether the individual meets current donor requirements, as detailed, and that the donation will not be detrimental to the donor.

(a) Guidelines for donor selection, including medical history and physical examination, shall be in accordance with the current requirements of the AABB Standards for Blood Banks and Transfusion Services and the regulations of the Bureau of Biologics and Research. References giving guidance related to donor history questions include subparagraphs 5.17a, k, l, and m.

(b) Adequate space must be provided for conducting the donor interview. While visual privacy is recommended, verbal (auditory) privacy is mandatory since it allows the donor and the interviewer to discuss confidential medical history issues which could affect donor suitability.

(c) The results of the donor history and physical examination will be recorded on VA Form 10-2420, Blood Donor Registration, or preferably on a comparable DHCP generated form. Local modifications to the form or to the software, are not authorized. All requests for change must be submitted through the Director, Pathology and Laboratory Medicine Service, to Directives, Forms and Records Management (161B4), who will submit the request to OMB (Office of Management and Budget) for approval to ensure that the content is appropriate for use in the VA.

(d) The questions regarding suitability of the prospective donor which are not addressed by the SOP shall be referred to the Chief, Blood Bank Section, or the Chief, Pathology and Laboratory Medicine Service, for evaluation (see paragraph 5.03c). All deviations from the SOP, as well as explanations for

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responses which would otherwise seem to preclude donation, must be properly documented.

(5) Donor records of the medical center shall be reviewed to determine whether the prospective donor:

(a) Has previously donated at that medical center, or

(b) Has been placed in a temporary or permanent deferral status, and

(c) Whether there are any special concerns that need be addressed, e.g., previous donor reactions.

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(6) All prospective donors must be informed that to ensure a safe blood supply, required transfusion transmitted disease marker testing will be performed. The donor must sign an informed consent, for performance of this testing, which shall be incorporated into the donation record, preferably on the same donor history form. Any prospective donor not in agreement with this policy may leave the blood donor station without explanation.

(7) Each donor must be provided the opportunity to indicate in confidence, at the time of donation, that blood collected may be unsuitable for transfusion. One mechanism is known as Confidential Unit Exclusion (CUE). This allows the donor to indicate that the unit of blood which might be or has been drawn should not be used for subsequent transfusion.

(8) Release of all allogeneic (homologous) units into inventory for subsequent transfusion prior to the completion of all required testing shall be done under the strict supervision of the Chief, Blood Bank Section, and the Blood Bank Supervisor. This should only be done in an emergency situation, or if the donor has undergone recent pre-testing with the results of the pre-testing still pending.

(a) This practice shall be restricted to those situations involving a patient with documented special needs, e.g., an Histocompatibility Iocus Antigen (HLA) matched single donor apheresis product for which the predonation screening testing was acceptable.

(b) Completion of testing shall be accomplished as soon as possible.

(9) Appropriate records must be maintained of the final disposition for each unit, as detailed in paragraph 5.14. If the unit is not released to inventory, records must include information on the destruction of the unit.

b. Collection and Component Preparation Procedures

(1) Donor identification will include donor's:

(a) Full name,

(b) SSN,

(c) Age,

(d) Sex,

(e) Address, and

(f) Telephone number.

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(2) Emergency treatment must be available at all times in the event of a severe donor reaction.

(a) All personnel working in the donor area must be adequately trained and proven competent in handling potential donor reactions.

(b) Donor collection should be located in close proximity to areas where emergency medical care is available. If the donor room is not located in such areas, personnel must be trained and certified in cardiopulmonary resuscitation (CPR) techniques. The donor room must be equipped with an emergency crash cart.

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(c) In the event that the collections are being done off site from the medical center, arrangements must be made, in advance, for emergency medical care.

(3) If the review of previous records provides information which needs to be addressed, i.e., donor is temporarily, or permanently deferred, or otherwise requires special attention, the person conducting the interview will take the appropriate action according to the SOP prior to the collection of the unit. Appropriate actions include review of the information, or intervention, by either the Blood Bank Supervisor or the Chief, Blood Bank Section. NOTE: In the event that the donor's previous records are not reviewed until after the donation, such as on a blood mobile where the donation is not occurring in the main donor center, the unit shall be placed in quarantine until review of the records has been completed.

(4) Policies to ensure positive identification of a unit of blood component must be established, documented and strictly followed. An alphanumeric system will be used to relate the donor history form to each donor unit and all samples. This identification will ensure that blood may be traced back to the original donor record, or to its final disposition.

(5) Non-therapeutic plateletpheresis, leukapheresis and plasmapheresis procedure require specialized equipment and involve significant additional risks. This procedure must be restricted to those medical centers which can support the existence of such programs.

(a) Written policies of these procedures must meet the requirements of the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and the current regulations of the FDA.

(b) Additional significant hazards, over and above those associated with whole blood donation, exist for donors undergoing apheresis.

1. A unique informed consent is required for apheresis procedures; the donor must be apprised of all relevant aspects of the procedure in advance.

2. A physician trained in handling adverse donor reactions must be on the premises and immediately accessible.

(6) Dating periods for blood and blood components must conform to the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and to 21 CFR 610.53.

c. Disease Marker Testing, Labeling, and Distribution

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(1) Blood and blood product processing and distribution must comply with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual. In addition, specific details are provided in 21 CFR 211, 640 and 606 for products licensed by the Bureau of Biologics and Research.

(2) Testing for transfusion transmitted disease markers can be performed at another laboratory, providing the laboratory performing the testing is either currently accredited by CAP, or holds a current certification of accreditation under the Clinical Laboratory Improvement Act of 1988 (see Ch. 11).

(3) A mechanism must exist to prevent release of a unit, which is positive for any of the transfusion transmitted disease markers, into available inventory for subsequent

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transfusion, i.e., the unit shall be placed in a quarantine status until such time as the testing is repeated and the unit deemed acceptable for release according to established AABB and FDA algorithms.

(4) If the unit is released into available inventory for subsequent transfusion on an emergency basis, prior to the completion of testing (see par. 5.06a(8)), a mechanism must exist to identify that information to appropriate supervisory personnel. This is necessary in the event that the testing is deemed unacceptable and subsequent release of the unit would not be appropriate.

(5) Labeling of blood and blood components must conform to the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual. Specific details are provided in 21 CFR part 606, subpart G (subpar. 5.17j).

(6) When appropriate, records of temporary and permanent deferral information must be updated to reflect current disease marker testing results prior to the time when that donor would otherwise be eligible for a subsequent donation.

(a) Donors shall be notified of positive disease marker test results, in accordance with the provisions of the informed consent.

(b) Once appropriate release of information consent has been received, results of disease marker testing will be forwarded to the donor's designated physician. In accordance with the Privacy Act of 1974 and 38 U.S.C. (United States Code) 5701 and 7332 confidentiality of the test results will be strictly maintained.

(7) Appropriate records must be maintained of the final disposition for each unit, as detailed in paragraph 5.14. If the unit is not released to inventory, records must include information on the destruction of the unit, including all components which may have been prepared.

d. Recipient and Donor Tracking ("Look Back"). Identification of persons who may have received blood components containing transfusion transmitted disease agents, e.g., HIV (Human Immunodeficiency Virus), is generally referred to as "look back". In order to identify individuals who might have been exposed via a previous blood transfusion and who may be infectious to others, it is necessary to identify all recipients of blood components from previous donations when current testing is confirmed positive.

(1) All recipients of blood components from previous donations identified as part of the "look back" process should be identified and tested in accordance with the specific recommendations of the AABB for that specific disease marker.

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In general terms, "look back" is appropriate for some markers, including anti-HIV, but is not recommended for others such as anti-HCV.

(2) See specific details in paragraph 5.12 c(2) regarding contact of recipients.

5.07 AUTOLOGOUS BLOOD TRANSFUSION

Autologous donation is the removal of blood or blood components from a donor-patient for subsequent reinfusion. There are several types of autologous donations, including predeposit, intraoperative salvage, apheresis, and hemodilution. NOTE: This policy will address only predeposit donations. Intraoperative blood salvage, apheresis, and hemodilution are addressed in M-2, part I, chapter 12.

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NOTE: Although it is understood that some patients receiving autologous units may also require the transfusion of allogeneic units in addition to the autologous units, the Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic (para. 5.17o) recommended that health care medical centers implement all reasonable strategies, including predeposit autologous transfusion, to avoid homologous (allogeneic) transfusion.

a. Statement of Policy

(1) A means will be provided for patients to undergo autologous predeposit donation, as detailed in paragraph 5.07, whether at that medical center or at the blood center supplying other blood components to the medical center.

(2) Though the use of allogeneic (homologous) blood has been proven to be safe, it does carry certain risks, including the possibility of transfusion transmitted diseases and other rare complications. Autologous transfusion obviates many of these risks; therefore, the Blood Bank shall provide the means for patients to undergo autologous donation if the procedure is deemed to be warranted and feasible by the patient's treating physician and the blood bank physician where the actual donation is to occur.

(a) This service may be provided at the VA medical center or arrangements may be made with the local blood center supplying the medical center to have the autologous units drawn at the blood center.

1. Depending on the patient's clinical condition, autologous donation may not be safe in a setting other than a hospital.

2. Regardless of the drawing site, the VA medical center will bear the cost of the procedure.

NOTE: For patients who undergo elective surgery, donation is recommended 1, or 2, weeks before the surgical procedure.

(b) If the patient predeposits a unit at the VA medical center, the donor room must meet the requirements of FDA, AABB, and CAP (regardless of the number of units collected on an annual basis), including having appropriately trained personnel and a comprehensive procedure manual in the appropriate format. (See subpars. 5.17 a, e, and p.)

(c) If a patient predeposits a unit at the VA medical center, the facility is strongly encouraged to register with HHS. Once registered, the Blood Bank will be inspected voluntarily by the FDA on an annual basis.

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(d) If units cannot be collected at the VA medical center and are predeposited at the blood center supplying the medical center, transportation of the units must meet Federal and state regulations.

1. Units which are transported from one site to another must undergo disease marker testing for transfusion transmitted disease by the drawing/shipping facility (see subpar. 5.07d).

2. The receiving VA medical center must express, in writing, it's willingness to receive units which tested positively for the transfusion transmitted disease markers, or units which are incompletely tested, i.e., results pending, at the time shipped.

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(e) Autologous units not utilized by the patient must be destroyed. Although FDA and AABB clearly permit autologous units to be used for homologous transfusion, i.e., "crossed over", provided they meet all of the necessary requirements, this practice is not acceptable to VA. NOTE: Most patients in VA hospitals would not meet routine AABB donor standards and the savings in blood costs has been found to be negligible.

b. Donor Requirements (if the VA medical center functions as the drawing site)

(1) Because of the special circumstances surrounding autologous donation, rigid criteria for donor selection are not applicable. Suitable guidelines must be detailed in the SOP Manual and must be in accordance with the current edition of the AABB Standards. Individuals presenting for autologous donations are to be considered patients, and personnel must follow the OSHA Bloodborne Pathogen Standard guidelines regarding personal protective equipment, the specifics of which must be contained in the facility's SOP.

(a) Units shall not be drawn from septic patients, or from patients exhibiting skin infections, at venipuncture sites.

(b) Based on current scientific literature, most otherwise healthy patients tolerate surgery with a hematocrit of 20 percent if intravascular volume and oxygenation are adequate. Patients who are anemic, i.e., hemoglobin levels below 110 g/L (11 g/dL) or hematocrit levels below 33 percent shall be excluded.

(c) Patients with cardiovascular disease are usually rejected, depending on the local policy and evaluation of the Chief, Blood Bank Section.

(d) The donation interval for the patient-donor is determined by both the patient's physician and the Chief, Blood Bank Section. In selected cases, donation can be as frequent as every 3 days. Donors donating frequently may require iron supplementation and/or erythropoietin.

(e) Donations are discouraged within 72 hours prior to surgery since restoration of blood volume to predonation levels takes 24 to 48 hours in most donors. The Chief, Blood Bank Section must approve any intervals less than 72 hours.

(2) A modified donor questionnaire must be completed to ensure that the procedure is safe for the patient-donor, and that the documentation is adequate.

(3) In the event than an autologous donation which does not meet the established guidelines, is approved by the Chief, Blood Bank Section, the

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deviation must be adequately documented. Either the Chief, Blood Bank Section, or the patient's physician, must be present to oversee the procedure.

c. Procedure

(1) A signed informed consent must be secured from the patient-donor. In this form, the patient shall be notified if the patient's blood will be tested for any and/or all transfusion transmitted disease markers.

(2) A mechanism must exist to notify the patient-donor of the results if clinically significant according to the algorithms detailed in subparagraph 5.06d for allogeneic (homologous) donors.

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(3) The volume to be drawn must be in accordance with the current edition of the AABB Standards, i.e., 450 ± 45 ml if the donor weighs at least 110 pounds (50 kg). If the donor weighs less, the volume of blood drawn and the anticoagulant must be adjusted accordingly such that the blood volume drawn shall not exceed 12 percent of the patient-donor's estimated blood volume (see the 14th edition of AABB's Technical Manual, page 8 for formula).

(4) Until such time as disease marker testing has been completed, the unit(s) shall be segregated and stored in a quarantined area away from all other units and shall be labelled with a BIOHAZARD sticker in order to prevent inadvertent issue and/or transfusion of the unit to a different patient.

(5) Until such time as disease marker testing has been completed, separation into components is discouraged unless there is a specific reason to do so, approved by the Chief, Blood Bank Section.

d. Disease Marker Testing and Labeling

(1) All units shall be tested in accordance with the current edition of the AABB Standards. Testing should also meet the current FDA requirements.

(a) In the case of autologous blood, or components thereof, that will be transfused outside the collecting medical center, the first unit from a given patient-donor during a 30 day period must be tested for all FDA required tests. These tests must be performed at:

1. The time of collection, prior to labeling and distribution of the blood; and

2. A laboratory holding a Certificate of Accreditation under the Clinical Laboratory Improvement Act of 1988, or a CAP approved laboratory.

(b) In the case of autologous blood, or components thereof, that will be transfused within the collecting medical center, disease marker testing is not required provided the product is restricted for autologous use only and that the products which are not used by the patient-donor are destroyed.

1. If the units are not tested, they shall be segregated and stored in a quarantined area away from all other units, and must be labelled with a BIOHAZARD sticker in order to prevent inadvertent issue/transfusion of the unit to a different patient.

2. If the units are not tested, separation into components is discouraged unless there is a specific reason to do so, and the Chief, Blood Bank Section, has approved.

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(2) If a test for any disease marker is repeatedly reactive and/or confirmed positive, prior to issue for transfusion, the unit shall be destroyed in order to reduce the known biohazardous risk, except as detailed in the following subparagraphs.

(a) If the unit is positive for anti-HIV or HBsAg, the unit shall be destroyed unless the patient cannot be provided with compatible blood other than the patient's own.

1. In the event that the unit is not destroyed, the unit shall be marked with a BIOHAZARD label and must be stored in a quarantine area away from all other units available for routine use.

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2. Under no circumstances are components to be prepared from such units because of the safety hazard to the personnel.

(b) If the unit is positive for disease markers other than anti-HIV, or HBsAg, and the Chief, Blood Bank Section, agrees to allow subsequent transfusion of that unit, a biohazard label must be applied to each donor unit, and the patient's physician must sign a release form before release of the unit.

(c) If the unit is positive for disease markers other than anti-HIV, or HBsAg, blood components must be prepared in accordance with practices which provide adequate protection from a potential biosafety hazard (Biosafety Level 2), e.g., frozen blood preparation or washed cells, which utilize methodologies where there is a risk of unit breakage, should be done using personal protective equipment which includes a laboratory coat, gloves and some type of face shield. NOTE: If manual centrifugation is done, double overwraps must be used.

(3) If a test for anti-HIV-1 (or anti-HIV-1/2), or HBsAg, is repeatedly reactive, but additional, more specific confirmatory tests are negative, the unit must be labeled "For Autologous Use Only." Products do not require the special precautions applicable to positive units.

(4) Units shall be labeled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and 21 CFR 606.121(i)(4) and 21 CFR 640.4(g)(2). The "For Autologous Use Only" Label is to appear in place of the blood group label to ensure that autologous blood is not mistaken for blood intended for routine allogeneic (homologous) transfusion.

(5) If units have not been completely tested or the unit is positive for disease markers other than anti-HIV, or HBsAg, the patient's physician must sign a release form indicating this decision to accept the unit in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and the current FDA requirements.

e. Identification of Autologous Units

(1) All units shall be labeled "For Autologous Use Only" in accordance with the labeling requirements described.

(2) Procedures need to be in place to ensure that:

(a) The patient receives all units of autologous blood prior to the transfusion of allogeneic (homologous) units.

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(b) Autologous products cannot be inadvertently converted to products which might be released to a patient other than the patient-donor.

(c) Autologous units not utilized by the patient, must be destroyed, rather than being crossed-over and made available for homologous inventory.

f. Pretransfusion Compatibility Testing

(1) Prior to issue of the unit for transfusion, the ABO and Rh typing must be confirmed in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

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(2) A pretransfusion sample of patient's blood is required for performance pretransfusion compatibility testing before the issue of the autologous unit(s). For units not collected at the transfusing medical center, the usual compatibility testing is required to avoid inadvertent reactions.

g. Autologous Blood Utilization. A mechanism should be in place to evaluate the Autologous Program, specifically whether the program is being underutilized or overutilized (see details in Ch. 2 and in M-2, Pt. I, Ch. 12).

5.08 THERAPEUTIC PHLEBOTOMY

Therapeutic phlebotomy involves the withdrawal of a specified amount of blood from a patient, usually undertaken for the treatment of polycythemia or hemachromatosis. NOTE: Other indications may warrant this procedure.

a. General Principles

(1) All policies and procedures must conform to the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and the current CAP requirements.

(2) Since therapeutic phlebotomy procedures are not performed on normal blood donors, the requirements and guidelines that constitute good medical practice are somewhat different than those for allogeneic (homologous) donors. Although the procedure must be ordered by the patient's treating physician, the Chief, Blood Bank Section, must decide whether to accept responsibility for this procedure.

(a) This can be done on a case by case basis, or in accordance with the SOP, provided any deviations are referred to the Chief, Blood Bank Section, prior to the donation.

(b) The informed consent of the patient must be obtained prior to the performance of the procedure.

b. Procedures

(1) Therapeutic phlebotomies must be performed in areas which are adequately equipped and staffed for the procedure. Emergency treatment must be available at all times in the event of a severe reaction.

(a) In VA facilities with adequate accommodations within the Blood Bank, the therapeutic phlebotomy should be done in this area.

(b) In smaller VA facilities without adequate accommodations within the Blood Bank, the therapeutic phlebotomy will be performed at the patient's

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bedside for inpatients and in a designated area for outpatients, such as in the emergency area, or Ambulatory Care Service.

(2) Since individuals presenting for therapeutic phlebotomies are to be considered patients, rather than allogeneic (homologous) blood donors, personnel must follow the OSHA Bloodborne pathogen standard guidelines regarding personal protective equipment, the specifics of which must be contained in the facility's SOP.

(3) Blood withdrawn for therapeutic phlebotomy must be so labeled. Since this blood is not suitable for allogeneic transfusion and must be considered potentially biohazardous, it

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should be quarantined, or immediately destroyed, in accordance with the SOP.

5.09 STANDARD PRACTICES FOR BLOOD/COMPONENT TRANSFUSION

NOTE: Pretransfusion compatibility testing issues are addressed under paragraph 5.04.

Since HIV was first reported, homologous blood utilization practices have changed. The decision to transfuse blood has become much more conservative. It has also been brought to light that patients can safely tolerate hemoglobin levels as low as 7.0 g/dL. With current testing, the risk of HIV transmission is low, 1:40,000 to 1:100,000.

a. General Principles

(1) Blood represents a scarce national resource and every effort must be expended to ensure it's judicious use. Blood components will be utilized unless there is a written justification by the physician ordering 'Whole Blood', in which case it will be reviewed by the Blood Bank physician prior to the transfusion. The consensus of nationally recognized experts in blood transfusion therapy is that nearly all of the needs of patients treated in VA facilities can be met through the use of component therapy.

(2) Policies authorizing persons to start blood and blood component transfusions can be found in M-2, Part I, Chapter 12.

(3) Units will be selected for transfusion in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

(a) All allogeneic (homologous) units must be from volunteer blood donors, and must have been tested and found negative for all transfusion transmitted disease markers required by FDA and any additional markers required and/or recommended by AABB.

(b) See paragraph 5.07 for details on autologous unit requirements.

(c) Although the ABO/Rh of the units must be confirmed (see subpar. 5.04d) prior to issue, testing for irregular antibodies and transfusion transmitted disease markers should not be repeated.

(d) A system must be in place to:

1. Ensure selection of the appropriate component for transfusion that accommodates the special transfusion needs of a given patient, e.g., only irradiated products, only (cytomegalovirus (CMV) negative products, etc.;

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2. Ensure selection of autologous units when appropriate, as detailed in subparagraph 5.07f; and

3. Identify Rh negative individuals who might be potential recipients of Rh Immune Globulin (RhIG) in the event of transfusion of an Rh positive blood component. NOTE: Whether these individuals actually receive RhIG shall be based on the decision of the Chief, Blood Bank Section, or designee. The decision shall be properly documented.

(e) Selection of compatible, group specific, or group compatible red blood cells is required (see App. 5A).

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1. If selection of group compatible platelets, or cryoprecipitate, is not possible due to inventory restrictions, the patient's direct antiglobulin test should be monitored.

2. In the case of platelets or cellular apheresis products, consideration should be given to reducing the volume of the product in accordance with the recommendations in the current edition of the AABB Technical Manual.

(4) Labeling of each unit will be in accordance with the requirements of the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual. NOTE: Labeling responsibilities will vary according to the functions being carried out by the medical center personnel.

(a) In the event that the unit was prepared from other components, e.g., a pooled product, a mechanism must exist to trace the individual unit numbers which went into the final product. Only one unique number must be visible on the product.

(b) If a new number is assigned by the medical center, a system must exist to clearly identify to the transfusionist which number is to be utilized. The original number assigned by the collection facility must not be obscured.

(5) Blood must not be warmed toward body temperature except through certified equipment designed for this purpose, which may only be used in explicit situations such as rapid or massive transfusions. The equipment utilized, the procedures utilized, and the equipment quality control will be in accord with the AABB Standards for Blood Banks and Transfusion Services Manual.

(a) Pathology and Laboratory Medicine Service will ensure that all devices utilized for warming blood undergo appropriate quality control, regardless of the location of the equipment, and the service to which the equipment is assigned.

(b) The use of blood warming coils immersed in water is prohibited due to difficulties in regulating the temperature of the water, and the potentially adverse effects of overheating.

(6) No drugs, or solutions, will be added to the blood units, injected or infused through the same intravenous administration sets as the blood. The practice of using a "Y" infusion set and isotonic sodium chloride solution (saline, suitable for intravenous use) to start the transfusion is acceptable.

(7) Following completion of all transfusions, the completed duplicate SF 518, will be returned to the Blood Bank. Section III should have been

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completed to include all required information on the administration of the unit (see Ch. 12).

b. Blood Components and Derivatives. Issues regarding administration of blood components and appropriateness of clinical indications are addressed in M-2, Part I, Chapter 12.

(1) The use of whole blood in the vast majority of VA hospital clinical settings is not warranted and should be monitored by the Blood Usage Review Committee. Most units drawn are converted into a variety of blood components for better utilization of resources.

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(a) Depending on the nature of patients being treated at the medical center, e.g., the acuteness of the clinical setting and disease mix, the types of components will vary significantly.

1. Whether the medical center is involved in component preparation, or not, will depend on the proximity and adequacy of the services offered by the local supplying blood center.

2. In the event that blood components are prepared by the VA medical center, the medical center must be inspected and accredited for those functions in accordance with paragraph 5.02.

(b) All component preparation, storage and labeling, regardless of the number of units prepared on an annual basis, shall be done in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and 21 CFR 640.

(2) In general, blood components are used for specific types of clinical conditions, according to the following general guidelines. See the current edition of the Circular of Information (subpar. 5.17q) for additional details.

(a) Occasionally, whole blood may be needed for the treatment of massive acute blood loss.

(b) Red blood cell products are used for the treatment of anemia not treatable pharmacologically either due to etiology, or time constraints. Specific types of red blood cell components, including leukocyte poor, frozen deglycerolized, and irradiated may be indicated in specific situations.

(c) Fresh frozen plasma must not be used as a volume expander instead of crystalloid solutions. It should be used for the treatment of significant multiple coagulation factor deficiencies or congenital factor deficiencies not treatable by cryoprecipitate. These coagulation deficiencies may be associated with:

1. Massive transfusion,
2. Severe liver disease,
3. Disseminated intravascular coagulation,
4. Hemolytic uremic syndrome, or
5. Thrombotic thrombocytopenia purpura.

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(d) Cryoprecipitate is used for the treatment of specific coagulation factor deficiencies, including:

1. Factor VIII deficiency,
2. Von Willebrand's disease,
3. Hypofibrinogenemia,
4. Uremic thrombocytopeny not responsive to desmopressin acetate (DDAVP),
and

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5. Disseminated intravascular coagulation.

(e) Platelets are used for the treatment of thrombocytopenia or thrombocytopeny associated with a variety of other clinical conditions, including active bleeding, massive transfusion, disseminated intravascular coagulation, and scheduled invasive procedures.

(f) Granulocytes are used for the treatment of life-threatening neutropenia, or granulocyte dysfunction, with specific coexisting clinical conditions. Orders for granulocytes must be approved by the Chief, Blood Bank Section, or designee, and must be reviewed by the Transfusion Committee.

(3) If patients have experienced repeated febrile nonhemolytic transfusion reactions, they should receive leukocyte reduced red blood cell products. In these cases, consideration should be given to the use of the "spin and filter" process using microaggregate filters, which can utilize bedside filtration, rather than the other technologies which require sophisticated equipment, or manipulation of the donor unit on the donation date.

(4) Plateletpheresis units are indicated in clinical conditions where a specific donor is more appropriate, e.g., HLA matching, or minimizing donor exposures to prevent the patient from becoming refractory, or in which random platelets are not available. Prior to ordering of HLA matched platelets, attempts should be made to select donors based on performance of platelet crossmatches.

(5) If irradiation of blood, or blood components, is appropriate in order to reduce the risk of graft-versus-host disease, such as in selected immunosuppressed patients, or in recipients of directed donor units from first degree relatives, irradiation procedures must be in compliance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

(6) Use of cytomegalovirus (CMV) negative blood components are indicated in patients who are undergoing transplantation or are otherwise severely immunocompromised.

(7) Massive transfusion, i.e., transfusion volume equivalent to the recipient's blood volume within a short period of time, may be accompanied by significant clinical complications which may include coagulation defects. The Chief, Blood Bank Section, in conjunction with the patient's physician should assess the patient's laboratory values and clinical conditions in determining the appropriate component replacement therapy.

(8) Albumin and plasma protein fraction are considered derivatives rather than blood components. They are usually dispensed by Pharmacy Service rather

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than by the Blood Bank. Albumin has very limited indications and should be monitored in a process similar to that of the blood components. This oversight function can be provided by the Pharmacy and Therapeutics Committee rather than by the Blood Transfusion Committee, if that is deemed more appropriate by the medical center.

(9) Coagulation derivatives, such as Factor VIII concentrates, Factor IX concentrates, Konyne^R, Proplex^R or FEIBA Immune Complex^R, are therapeutic derivatives which should usually be dispensed by the Blood Bank, and reviewed as part of Blood Usage Review in order to effectively manage the patient's treatment for coagulation disorders. NOTE: If these derivatives are dispensed by Pharmacy Service, the patient's transfusion history and laboratory results may be difficult to interpret (see subpar. 5.11b).

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c. Issue of Blood

(1) Emergency need for blood, or blood components, rarely precludes routine pretransfusion testing, as detailed in paragraph 5.04c. In extreme emergencies, e.g., massive hemorrhaging, the requesting VA Form 10-2984, a properly completed and signed Caution Tag will be attached securely to each unit of blood and Section I and Section II of the SF 518 will be completed.

(4) Procedures for the issue of blood will be in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

(a) In order to minimize the chance for error, blood can only be issued by laboratory service staff who have been fully trained and are authorized to perform this function. In those medical centers where non-laboratory personnel perform this function during the off hours, those individuals must be properly trained and their ongoing competency documented.

(b) Blood will only be issued to personnel who present a written and signed request which contains the intended recipient's full name and SSN. All significant information, including the identification of the intended recipient and the unit information, i.e., unit identification (ID), ABO/Rh and expiration date, will be co-checked by the issuing personnel and the person to whom the unit is being issued.

(c) Blood will be inspected immediately prior to issue, in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual. Blood showing any abnormality as to color, or appearance, shall not be issued for transfusion as it might result in life threatening complications.

(d) All units must be transfused through a filter designed for that purpose. Although not indicated for routine use, microfiltration using specialized filters may be warranted in certain situations to help prevent febrile nonhemolytic transfusion reactions.

(5) Use of the Blood Bank module software of the DHCP Laboratory package is mandated since it provides a variety of control functions to prevent inappropriate issue of units.

(6) Blood should not be issued for transfusion until the necessary preparation is complete. This will prevent inadvertent delays in starting the infusion which might result in inappropriate storage of the unit outside of a monitored environment. As detailed in paragraphs 5.05b and 5.05c, units that exceed the acceptable storage requirements may not be used for transfusion and must be discarded.

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(7) Transportation of blood will be in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual. NOTE: Since the units issued for transfusion have been tested and found negative for transfusion transmitted diseases, with the possible exception of autologous units, units of blood do not need to be transported in accordance with the provisions of the OSHA Bloodborne Pathogen standard for handling biohazardous materials.

(8) All unused blood units, or portions thereof, shall be returned to the blood bank, regardless of whether the unit was entered or not.

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5.10 EMERGENCY BLOOD TRANSFUSION PROCEDURES

Rarely, medical emergencies requiring transfusion may call for deviations from standard blood banking procedures. Such deviations carry definite medical and legal risks. The potentially deleterious effects of transfusing incompletely tested units must be carefully weighed against the therapeutic benefits required by the clinical situation at hand. The decision to transfuse such units is ultimately the responsibility of the attending physician directly in charge of the patient's care.

a. General Principles

(1) Any clinical scenario in which all of the immunohematological procedures considered essential to good transfusion therapy cannot be completed to the satisfaction of the Transfusion Officer must be considered as an emergency. See paragraph 5.04 for details of essential pretransfusion testing.

(2) Emergency situations may involve:

(a) Those circumstances in which the need for transfusion is so urgent that one, or more, units must be released before the recipient's ABO/Rh has been determined, or the compatibility testing has been completed; and/or

(b) Those circumstances in which there is enough time to determine the ABO/Rh of the recipient, but the compatibility testing, routinely done in accordance with the SOP, has not been completed.

(3) Massive transfusion of blood in an emergency, i.e., transfusion volume equal to, or greater than, the patient's blood volume administered within a short period, may be accompanied by significant clinical complications. The patient's physician in concert with the Chief, Blood Bank Section, or a clinical hematologist, must plan appropriate transfusion therapy to address any coagulation deficiencies which may develop.

b. Procedures

(1) All procedures for emergency issue of blood will be in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

(2) In any case involving an emergency, as defined in subparagraph 5.10a(1), the treating physician, or designate physician, will provide a statement which includes the justification for deviation from the usual practice, and will sign the statement. This transfers the responsibility of the decision to transfuse

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blood that has not undergone routine pretransfusion compatibility testing at the time of the transfusion, to the physician making the clinical judgment.

(a) This statement can be included either on the SF 518 in the Remarks section, or on a separate form approved by the Medical Records Committee of the medical center.

(b) Under extreme circumstances, verbal orders which are countersigned by specified designees, such as a Registered Nurse, or another physician, may be accepted, providing the documentation is completed as soon as possible. This documentation must be retained in the Blood Bank.

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(3) Selection of units to be issued should be based on the nature of the emergency, the valuable inventory and the patient's current test results.

(a) If the patient's ABO/Rh has not been determined from a current sample, group O red blood cells should be used. Previous records may not be used for the issue of group specific blood.

(b) If the patient's ABO/Rh has been determined, but the remainder of the compatibility testing has not been completed, group specific red blood cells should be selected.

(4) Routine pretransfusion compatibility testing should be completed as soon as possible. If any incompatibilities, or problems, are encountered, the patient's physician should be notified immediately.

(5) Occasionally, patient transfusion requirements cannot be met with group and type specific blood. In these cases, ONLY compatible components must be selected as shown in appendix 5A.

5.11 SPECIAL TRANSFUSION PROCEDURES

a. Directed Blood Donations. Directed donations are provided by friends, or family of patients, earmarked exclusively for a specific patient, and are generally not considered safer than routinely donated units. Although VA policy discourages directed donations, there may be instances where the patient stipulates that directed blood be used to meet transfusion needs. Under these circumstances, an option available to the treating physician is the provision of alternative care modalities, e.g., autologous predeposit or intraoperative blood salvage, within the limits of the patient's consent.

(1) If after consultation with the patient's physician, the Chief, Pathology and Laboratory Medicine Service, and/or the Chief, Blood Bank Section, and the Chief of Staff, determine that directed donations are the best course of action for meeting the transfusion needs of that patient, such units may be drawn, or requested, from the blood center which supplies the blood for the medical center.

(2) Proper disclosure will be made to the patient of the risks involved in the event that the patient's blood need exceeds the number of directed units available, requiring supplementation of allogeneic (homologous) units from stock. If the patient refuses to consent to the use of blood other than that of the directed donor units, careful documentation of the patient's refusal will be maintained. Under these circumstances, the patient's physician should consider whether to provide alternative care within the limits of the patient's consent.

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(3) Requests for directed donor units are generally considered to be limited to red blood cells unless specific arrangements are made for additional components.

b. Coagulation Derivatives. Coagulation derivatives are obtained by the biochemical fractionation of plasma pools which cannot be subjected to heat treatment for inactivation of viruses which may cause transfusion transmitted diseases. Recombinant technologies which obviate these complications are available for some specific products. In some VA medical centers, the Blood Bank is involved in the storage and issue of these derivatives. The Chief, Blood Bank Section, and the clinical hematologist must be involved in determining the appropriateness and the dosage of these derivatives.

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(1) Factor VIII concentrates may be indicated in situations where large amounts of Factor VIII are needed, such as in trauma, or scheduled invasive procedures.

(a) The concentration, i.e., units of Antihemophilic Factor (AHF) activity, is indicated on each vial and will vary significantly from lot to lot; therefore, the dosage will need to be determined based on the actual concentration.

1. The dosage of Factor VIII concentrate should be based on the following formula:

$$PV (.05 \times BW) \times DI = \text{units of AHF,}$$

Where: PV = plasma volume, BW = body weight in grams, and DI = desired increase.

2. Therapy schedules and protocols vary and require close coordination between the Blood Bank, the hematologist, and the patient's primary care physician, particularly if the patient requires an invasive procedure.

(b) Factor VIII concentrates do NOT contain the von Willebrand's portion of the Factor VIII molecule and will NOT provide effective therapy for this disorder. Patients with von Willebrand's disease must be treated with cryoprecipitate.

(c) The isoagglutinin titer (anti-A, anti-B, and anti-A,B) may be very high in these concentrates and may produce a transient hemolytic episode in group A patients. This does not occur as frequently in group B patients.

(d) Although testing has improved significantly, the risk of complications, such as hepatitis or Acquired Immunodeficiency Syndrome (AIDS), are significant, attributable to the manner of preparation in which large pools of plasma are utilized.

(2) Factor IX concentrates may be indicated in situations where large amounts of Factors II, VII, IX, and X are needed, or in patients who have developed inhibitors to Factor VIII.

(a) The concentration, i.e., units of Factor IX activity, is indicated on each vial and will vary significantly from lot to lot; therefore, the dosage will need to be determined based on the actual concentration.

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(b) Use of Factor IX concentrates is contraindicated in patients with hepatic damage, or vascular disease, because of the associated risk of hypercoagulability with subsequent thrombosis associated with this derivative.

(c) Although testing has improved significantly, the risk of complications such as hepatitis or AIDS, are significant, attributable to the manner of preparation in which large pools of plasma are utilized.

c. Therapeutic Apheresis Procedures. Therapeutic cytopheresis and plasmapheresis are indicated for treatment of certain clinical conditions. Current literature should be consulted to determine the appropriate frequency, volume, and replacement fluids for the specific diagnosis.

NOTE: Pathology and Laboratory Medicine Service will be involved in providing, or

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helping to provide in the case that these services are performed by Medical or Surgical Service, apheresis procedures and in assessing the appropriateness of care in these procedures.

(1) Therapeutic cytapheresis and therapeutic plasmapheresis require specialized equipment and involve significant additional risks.

(a) Performance of manual plasmapheresis may be acceptable in specific clinical conditions, such as Waldenstrom's macroglobulinemia. It is less efficient than plasmapheresis which utilizes automated or semi-automated instrumentation.

(b) Performance of automated or semi-automated plasmapheresis, and/or cytapheresis shall be restricted to those facilities which can fully support the existence of such services.

(2) Therapeutic apheresis procedures may be performed by contract with the local blood center, providing the blood center maintains a current FDA licensure and AABB accreditation.

(3) All procedures must be done in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and the current FDA regulations.

(a) Emergency treatment must be available at all times in the event of severe reactions. Personnel performing apheresis must be adequately trained and proven competent in handling potential reactions. NOTE: Consideration should be given to having the personnel maintain certification in CPR techniques.

(b) Depending on the patient's clinical condition and the nature of the procedure, the procedure may need to be performed in an area separate from that being used for whole blood donation, or non-therapeutic procedures, preferably on the ward.

5.12 TRANSFUSION COMPLICATIONS

a. General Principles

(1) All suspected transfusion reactions occurring in medical centers for which the VA has investigational responsibility, including home transfusions or transfusions in extended care centers, must be promptly investigated by the Chief, Blood Bank Section, or the Chief, Pathology and Laboratory Medicine.

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(2) The Blood Bank must be notified immediately in the event of a suspected transfusion reaction. The specific testing and procedures to be addressed by the investigation must include at least those required by the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

(3) All necessary remedial actions taken to prevent recurrences of transfusion reactions shall be documented in the patient's chart, in the VA medical center blood bank, and in the minutes of the VA medical center Transfusion Committee.

(4) Procedures to prevent recurrent reactions shall be in place in the Blood Bank Procedure Manual, in the VA medical center Quality Management Policy Manual and the Nursing Service Policy Manual.

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(5) Policies and procedures shall be reviewed at least annually to ensure that they adequately provide for the safety of individuals being transfused within the VA medical center.

(6) Reports of the findings, conclusions, and actions taken regarding the investigation of suspected transfusion reactions will be included in the Blood Usage Review activities of the medical center (see M-2, Pt. I, Ch. 12).

b. Immediate Reactions

(1) If suspected complications occur during a transfusion, the procedure must be discontinued immediately. The medical center must promptly investigate all transfusion reactions in accordance with the facility's established regulations. The extent of the investigation shall be determined by the Transfusion Officer and the Chief, Pathology and Laboratory Medicine Service, or the Chief, Blood Bank Section.

(a) The patient's physician shall be notified immediately.

(b) Appropriate samples of blood must be obtained and Section III of the SF 518 must be completed.

(c) A separate form for reporting transfusion reactions should be developed for local use in recording the findings of the investigation.

(d) The unit of blood or the empty bag, the administration set, and the SF 518 shall be returned to the Blood Bank immediately.

(2) If the findings of the investigation confirm that the patient is experiencing an acute hemolytic reaction, the patient's physician and the Chief, Laboratory Service, or designated Chief, Blood Bank Section, must be notified immediately (see App. 5B for information on the management of major ABO incompatible transfusion reactions.)

(3) The findings and conclusions of the investigation will be documented promptly in the patient's clinical record. In addition, VA form 10-2633, Report of Special Incident Involving a Beneficiary, must be initiated in accordance with M-2, Part I, Chapter 35.

c. Delayed Reactions

(1) Delayed hemolytic reactions should be investigated to the extent necessary to elucidate the cause and in accordance with the requirements of the current edition of the AABB Standards for Blood Banks and Transfusion Service. If the findings of the investigation reveal that the patient is experiencing a

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delayed hemolytic reaction, the patient's physician must be notified immediately.

(2) If the findings of the investigation reveal that the patient is experiencing a delayed hemolytic reaction, the Blood Bank records shall be immediately updated to reflect the fact that the patient has an irregular antibody, and must receive only red blood cells which lack the corresponding antigen. NOTE: If the data is properly entered, the DHCP software will control the issue of inappropriate units in the future.

d. Transfusion Transmitted Diseases

(1) Cases of actual or suspected hepatitis should be investigated to determine whether the case might involve posttransfusion hepatitis. If the patient has received blood

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products within 2 weeks to 6 months, the investigation should be handled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Service.

(2) A system must be in place to identify recipients of blood from donors subsequently found to have infection with HIV-1 or HTLV-I/II. This is commonly referred to as the "Look Back" Program. NOTE: Preliminary meetings of the FDA Blood Products Advisory Committee indicate this will be done for HCV.

(a) These patients will be contacted by the VA medical center to inform them of the test findings, and for counseling. A note should be placed in the medical chart of all patients recalled as to the reason for the recall. Counseling should be done by a knowledgeable and a compassionate physician who can define the risk and interpret the results for the patient, preferably a physician affiliated with the Infectious Disease Section of Medical Service.

(b) Testing will be provided to each patient, free of charge, following a documented informed consent. The results of the testing will be documented in the patient's chart and will be conveyed to the patient by the counseling physician. Confidentiality of the test results will be strictly maintained and the test results will be disclosed only as authorized by the Privacy Act of 1974 and 38 United States Code (U.S.C.) 5701 and 7332.

(c) VA medical center personnel will comply fully with requests from blood collection agencies in the "Look Back" Program, but only to the extent authorized by the Privacy Act of 1974 and 38 U.S.C. 5701 and 7332. These statutes permit the VA to make nonconsensual disclosure to blood collection agencies of the results of testing for HIV antibody in the recipients of donated blood, provided the format in which such information is disclosed prevents such recipients from being identified by name or address. VA may not make nonconsensual disclosure of such HIV results to any other persons or organizations. The recipients of donated blood may, of course, consent to the disclosure of their names and addresses with the results of such testing to any non-VA person or organization. Questions on authority to disclose information on HIV testing during the "Look Back" Program should be referred to Chief, Medical Administration Service, or VA District Counsel at the local medical center.

(3) Patients with signs or symptoms of AIDS should be investigated to determine whether the case might have been acquired as a result of having been transfused with blood since the spring of 1985, when testing for HIV became available. All donors should be investigated in accordance with the recommendations of the current editions of the AABB Standards for Blood Banks and Transfusion Services Manual and the Accreditation Requirements Manual.

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e. FDA Reporting Requirements. When a complication of blood transfusion is confirmed to be fatal, the Director, Office of Compliance, Center for Drugs and Biologics, shall be notified in accordance with the provisions of 21 CFR 606.170 (subpar. 5.17s).

5.13 INVENTORY CONTROL

Blood from volunteer donors is a precious resource which should be utilized efficiently and effectively. Proper inventory control is an important element in quality resource management.

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a. Policies and procedures should be in place to ensure an appropriate balance between outdating and blood shortages and to prevent delays in providing appropriate blood components for transfusion. For example, in a hospital with low transfusion activity, maintaining a larger number of units in inventory would have an adverse effect on the outdating. Conversely, if only a few units are kept in inventory, shortages may occur which may necessitate emergency deliveries by the blood center and may adversely affect patient care by causing delays in transfusion.

(1) Realistic inventory quotas, by component and by ABO/Rh within component, must be established, and must be monitored on a daily basis.

(2) Outdating of allogeneic (homologous) red blood cells should be below 5 percent. Outdating is affected by several factors besides inventory level, including:

- (a) The size of the hospital,
- (b) The acuity of care provided,
- (c) The distance between the hospital and the blood center,
- (d) The policy regarding the use of older blood first,
- (e) The average dating remaining on units when received from the blood center,
- (f) The number of personnel involved in ordering blood,
- (g) Whether the medical center is a teaching medical center, and
- (h) The crossmatch-to-transfusion (C:T) ratio.

(3) Outdating of platelets is difficult to manage since the usage is episodic and the shelf life is only 5 days. Efforts should be made to anticipate and coordinate assessment of clinical needs.

(4) Outdating of fresh frozen plasma and cryoprecipitate is not generally a problem since the shelf life is 1 year. Inventories should be determined by the patient population and review of the usage patterns.

(5) As detailed in paragraph 5.07g, data should be evaluated separately for autologous units.

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b. Records of units drawn, units received and final dispositions of units must be maintained in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

c. Units may be shipped to other facilities under the auspices of the local blood center or they may be shipped to other VA medical centers. If units are shipped to other non-VA facilities in other states, this must be done in accordance with FDA regulations for interstate commerce, i.e., unless the medical center is licensed for interstate shipment. NOTE: This type of shipment, including shipment to non-VA facilities, should only be done in emergencies.

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5.14 BLOOD BANK RECORDS

Blood bank records are an important and integral part of the transfusion service and blood donor activities. All personnel are responsible for ensuring that the policies are understood, and that the records are properly maintained.

a. General Principles

(1) Previous patient records must be immediately available in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual in order for current results to be compared to, and confirmed by previous testing, including:

(a) ABO/Rh testing records for a minimum of 12 months, and

(b) Records for those patients known to have significant unexpected antibodies, previous transfusion reactions or special transfusion needs.

(2) Records from previous donations must be available for comparison, in accordance with subparagraph 5.06a(5) and with the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual.

(3) A comprehensive record system must be in place in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Service.

(a) An alphanumeric system will be used to identify a unique unit of blood. This identification will ensure that blood may be traced back to the original donor record, or to its final disposition. The system must prevent duplicate unit numbers for the same component.

(b) The system must allow any unit to be traced from donation to final disposition, or from final disposition to donor and will include all associated records. Periodic audits of the system should be conducted.

(c) The system must include a variety of associated records, including personnel information and previous superseded procedures.

(4) Records may be retained on-line on a computer system, or be stored manually, on microfilm, or on microfiche. If records are computerized, there must be provisions for those times when the computer is not accessible.

(5) One copy of the SF 518 shall be retained by the Blood Bank, in addition to the original copy which is designated as the patient record copy.

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b. Retention Period. Records will be maintained in accordance with the current Records Control Schedule 10-1, the current edition of the AABB Standards for Blood Banks and Transfusion Services Manual and in accordance with 21 CFR 606, subpart I, and 21 CFR 600.12(b) (subpar. 5.15 j).

5.15 MILITARY BLOOD COLLECTION AND POST-TRANSFUSION FOLLOW-UP

The U.S. Navy Blood Program has sharing agreements with the VA to supply blood and blood products to specific VA medical centers.

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(1) As detailed in paragraph 5.12d, patients with signs, or symptoms, of AIDS should be investigated to determine whether the case might have been acquired as a result of having been transfused with blood since the spring of 1985, when testing for HIV became available.

(a) Investigation of donors of units received from the U.S. Navy Program will be done, in accordance with the recommendations of the current editions of the AABB Requirements Manual.

(b) The contact office for communication is:

U.S. Navy Blood Program
MED 213
Bureau of Medicine and Surgery
Contingency and Mobilization Division
Washington, DC 20372-5120

(2) The VA medical center personnel will comply fully with requests from the U.S. Navy in the "Look Back" Program, but only to the extent authorized by the Privacy Act of 1974 and 38 U.S.C. 5701 and 7332.

(a) These statutes permit the VA to make nonconsensual disclosure to blood collection agencies of the results of testing for HIV antibody in the recipients of donated blood, provided the format in which such information is disclosed prevents such recipients from being identified by name or address. VA may not make nonconsensual disclosure of such HIV results to any other persons, or organizations. The recipients of donated blood may, of course, consent to the disclosure of their names and addresses with the results of such testing to any non-VA person or organization.

(b) Questions on authority to disclose information on HIV testing during the "Look Back" Program should be referred to Chief, Medical Administration Service, or VA District Counsel, at the local medical center.

5.16 COMPUTER REQUIREMENTS FOR BLOOD/BLOOD COMPONENT TRANSFUSION

Blood banking involves many sophisticated analyses which without automation and/or computerization can only be performed by highly skilled persons. The human ability to "look for things" is more flexible than the computer's, but the ability to flexibly and intelligently search for and analyze information starts to break down as the quantity of information becomes larger. Computers can handle vast amounts of information without suffering any deleterious effects. A sophisticated computer system allows the highly trained technical staff to devote more time and energy to those problems and sophisticated analyses not within the realm of a computer. NOTE: In order to provide

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appropriate quality assurance of the computer system, there are specific detailed requirements from AABB, CAP and FDA. See subparagraphs 5.17 a, e, and t through v for specific references.

a. Goals. The goals of the Blood Bank module DHCP software are to:

(1) Improve the safety of blood/blood component transfusion by:

(a) Decreasing the number and severity of errors,

(b) Retrieval of previous records,

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- (c) Verification of present results,
- (d) Detection of inconsistencies in data, bar code entry of unit ID, ABO/Rh, etc., and
- (e) Computer assisted donor labeling.
- (2) Improve the quality of patient care through:
 - (a) Evaluation of transfusion appropriateness,
 - (b) Flags for specific components, and
 - (c) Evaluation of transfusion increments, i.e., changes in the posttransfusion laboratory values when compared to the pretransfusion values.
- (3) Decrease the clerical workload through:
 - (a) Bar code entry of unit information,
 - (b) Printing of transfusion requests,
 - (c) Transfer of information to multiple records (unit records, patient records, etc.), and
 - (d) Preparation of labels for specimens, and unit tags.
- (4) Improve resource management through:
 - (a) Statistics by location, physician, and/or treating specialty,
 - (b) Access of information by other medical staff, and
 - (c) Optimizing inventory control.
- b. Responsibilities
 - (1) The Veterans Health Administration (VHA) developers and/or commercial vendors of laboratory software are responsible for:
 - (a) Identifying potential control functions,
 - (b) Providing a listing of error and warning messages, and

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- (c) Informing the user of override capabilities.
- (2) The medical center is responsible for providing:
 - (a) Resources to Information Resources Management (IRM) for appropriate operator support,
 - (b) Appropriate hardware,
 - (c) Appropriate backup procedures for computer downtime,

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(d) Detailed information regarding design specifications and testing prior to release, and

(e) Sample test plans and worksheets for use in validation.

(3) IRM is responsible for using the verified, released version of the software unless there are documented testing agreements to use unverified software in a structured setting. Local modifications are the responsibility of the medical center and must meet all external accreditation requirements, including those set forth by FDA, CAP, and AABB.

(4) The Chief, Pathology and Laboratory Medicine Service, or designee, in conjunction with the Transfusion Officer and/or the Chief, Blood Bank Section, is responsible for:

(a) Approval of overall functionality,

(b) Review of the validation testing results, and

(c) Collaboration with the Chief, IRM, as appropriate.

(5) The Blood Bank Supervisor, in conjunction with the Laboratory Application Coordinator(s), is responsible for:

(a) Ensuring appropriate procedures are in place (including a validation test plan),

(b) Maintaining required documentation,

(c) Ensuring adequate training of personnel,

(d) Identifying control functions for options and routines used at that medical center,

(e) Understanding the documentation provided by the vendor, and

(f) Assessing the spectrum of control for the control functions.

(6) The Blood Bank staff is responsible for referring to and following established procedures in the procedure manual(s) and maintaining appropriate information security according to VHA and Federal government policy and procedure.

c. Minimum Standard Operating Procedures for the Computer Functions

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(1) The procedures must contain information on how the computer functions are integrated into the daily operations. The information must reflect the current version of the laboratory software and whether it is a DHCP, or commercial, product.

(2) Written procedures must exist which detail the manual and backup system to be used during computer downtimes. The ability to immediately activate this procedure must be in place at all times.

(3) Written procedures must exist that:

(a) Describe the procedure for correction of data entry errors. The system must include a mechanism to:

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1. Identify who corrected the data,
 2. Control access of who can correct data, and
 3. Monitor the number of changes for both reportable and nonreportable data.
- NOTE: If it is a reportable result, the results must be identified as "corrected."

(b) Describe methods for maintaining data integrity, including:

1. An audit trail for changes in verified data,
2. Periodic checks on data integrity following both scheduled and unscheduled downtimes, and
3. The mechanism for reconstructing lost data.

(c) Describe maintenance procedures for hardware and software. Maintenance must be regularly scheduled to have minimum impact on operations.

(4) Define information security procedures, developed by the laboratory staff with concurrence from the facility Information Security Officer. These procedures must detail who has access to:

- (a) View data,
- (b) Enter data,
- (c) Edit data, and
- (d) Modify software.

NOTE: If the procedure contains general statements by position, there must be a detailed listing with the names of individuals and their level of access.

(5) Procedures for requesting official software modifications should include:

- (a) The details of the request submission, including the rationale for changes/modifications,
- (b) The local approval process, i.e., authorizations of changes, and
- (c) The mechanism for submitted requests for change to the verified software.

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d. Validation Testing. Prior to the release of Laboratory software, DHCP developers and/or commercial software vendors are required to subject the software to intensive testing and review as part of the development and verification process. A great deal of the functionality of software is affected by the operating system, interaction with other software packages in the same database and files which accommodate local modification. This 'verification' is not equivalent to 'validation testing', as detailed following, nor can it be substituted for mandatory 'validation testing'. NOTE: Additional details and a sample plan are included in the Laboratory Quality Management Handbook; see subparagraph 5.17n, and the Blood Bank User Manual Appendix provided with the DHCP software.

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(1) In order to confirm that the computer software logic functions as desired, using the local database, operating system and hardware configuration, validation testing must be performed in accordance with the current requirements of the various accrediting and regulatory agencies and the provisions of subparagraph 5.16b(5) (see subpar. 5.17a, e, and t through v for additional references).

(a) A 'Validation Test Plan' must exist which details the individual responsible for:

1. Developing, executing and reviewing results of test cases;
2. Evaluating the validation process;
3. Determining the acceptance criteria; and
4. Determining acceptability of testing.

(b) The 'Validation Test Plan' must address a variety of issues, including:

1. The physical description of the computer hardware;
2. The manufacturer and model;
3. The number and location of terminals;
4. The list of modems and authorized access to modems;
5. The identity of any instrument interfaces;
6. The environmental conditions;
7. The operating system and version;
8. The application software and version;
9. A listing of options/programs to which blood bank personnel have access;
10. a summary of the implementation process, including action to be taken if deviations from expected performance occur; and
11. The full variety of test cases.

(c) The 'Validation Test Plan' must define the acceptance criteria for the validation testing. The criteria should include:

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1. Definitions for successful completion of the test cases, as well as for when the user requirements will be met; and

2. The process for evaluation of unaccepted occurrences to determine whether the occurrence is critical or noncritical.

(2) Validation testing must include testing of all control functions and routine operations under a variety of test conditions:

(a) A control function is a system function that causes an activity to occur, or that influences the behavior of the user of the system. Control functions may exist even when

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competent human intervention occurs. Examples include functions in which labels are created, records are created, modified retrieved, deleted and/or archived, data is compared to a standard or a warning message is generated.

(b) For each control function, the spectrum of control must be indicated, i.e., process control or decision support.

1. Process control involves functions in which the system software actually makes a decision using available information and algorithms.

2. Decision support functions are those in which an individual bases a decision on information obtained from the system.

(c) Routine operations are those used in the daily operations of the blood bank in that medical center. Options, routines or functions which are not utilized in that medical center need not be tested. These operations should include:

1. Data entry methods,
2. Information security procedures,
3. Program overrides,
4. Data storage, and
5. Retrieval and trace ability of results.

(d) A variety of test conditions must be addressed, including:

1. Normal data;
2. Exceptional data which provides an unusual twist for the program to force the program to react to data, or a situation that might be unexpected;
3. Boundary situations to force the evaluation of conditions that are of borderline validity;
4. Invalid data to force a program to prove that it can detect invalid input; and
5. Stress conditions to determine whether system has acceptable performance limits.

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(3) Validation testing must be performed in an environment which must be a duplicate of the operating system file structure, programs, site specific options, etc., of those found in production. Although performance of this testing in a test account is preferable, this may not be possible if the test account is not complete, or well maintained. If the final testing must be done in production, there must be strict controls to ensure that it does not adversely affect daily operations and that testing data is not confused with actual patient, donor, or inventory data.

(4) Validation testing must be performed according to specified time frames in accordance with the requirements of the various regulatory agencies (see subpars. 5.17 t through v):

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(a) Retrospective validation is required for current systems and/or software in operation before the FDA memorandum of September 1989. This validation testing must include the full scope of testing detailed in subparagraph 5.16d(2).

(b) Prospective validation testing must be performed before software is put into use for daily operations. This testing must be completed before parallel, manual systems are discontinued and the computer is no longer redundant. This validation testing must include the full scope of testing detailed in subparagraph 5.16d(2).

(c) Prospective change control validation testing must be performed before revisions, or modifications, in software are put into use for daily operations. This validation testing may encompass a more limited scope depending on the nature of the change and the interaction of that specific routine on other functions. This is particularly crucial for any local modifications made since these modifications do not go through the usual regimented verification process.

(5) Validation testing must be documented in a comprehensive manner.

(a) Testing documentation must include observations from testing. This may be in the form of:

1. Work sheets,
2. Screen prints,
3. Logging files,
4. Printed reports,
5. Written transcriptions,
6. Data tapes, or
7. Data disks.

(b) Testing documentation must include proof of review of the test cases, whether testing met the acceptance criteria or required any correction action, the signature and date of approval by the Chief, Blood Bank Section and the implementation date.

e. Tracking of Errors

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- (1) A record, or log, must exist to detail:
 - (a) Unusual occurrences and errors ("bugs"),
 - (b) Clinical significance of errors,
 - (c) Corrective action taken to resolve the problem, and
 - (d) Final resolution.

(2) Unusual occurrences and errors shall be evaluated by the Laboratory Application Coordinator (LAC) and/or the VA medical center IRM Service to determine whether the problem is local, or whether it involves the released version of the software.

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(a) All errors related to the released version of the software shall be immediately reported to the laboratory DHCP software developers using the Electronic Error and Enhancement Reporting (E3R) system.

(b) Errors related to local database problems or local modifications shall be resolved by the LAC, the VA medical center IRM Service, or the supporting Information System Center (ISC) staff.

(3) In the event that an error exists, or the software does not perform a necessary control function, immediate action must be taken to provide backup procedures until the problem is resolved. This includes any error which allows the inappropriate release and distribution of unsuitable blood and blood components.

f. Training of Personnel

(1) All persons utilizing the computer shall undergo appropriate training prior to performance of duties involving the DHCP, or comparable computer software.

(2) Ongoing assessment of personnel competency, as detailed in Chapter 2, shall include the use of the computer software.

(3) Prior to the implementation of software changes and/or modifications, all users of the Blood Bank software shall be trained as part of the validation testing.

g. Documentation

(1) There must be a written record of unscheduled downtimes, including the reason for failure and any corrective action taken. NOTE: This need not necessarily be maintained in the Blood Bank.

(2) In accordance with the provisions of subparagraphs 5.16d(6) and 5.16e(1), there must be documentation of validation testing and of errors which occur either during validation testing, or after implementation.

(3) Documentation of training must be maintained.

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p. Circular of Information, AABB, August 1, 1991.

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r. "Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood & Blood Components," Memorandum from the Acting Director, Center for Biologics Evaluation and Research, FDA, HHS; March 20, 1991.

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v. Steane, S., "User Validation Guidelines (DRAFT)," AABB Letter, November 25, 1991.

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SELECTION OF NON GROUP SPECIFIC BLOOD COMPONENTS

1. RED BLOOD CELL COMPONENTS

<u>Blood Group of Recipient</u>		<u>Alternate Compatible Groups</u>
None	Group O	
	Group A	
O	Group B	
O	Group AB	A, B, or O

2. PLASMA COMPONENTS (Fresh Frozen Plasma, Platelets, Cryoprecipitate) - when used in quantities greater than 250 cc

<u>Blood Group of Recipient</u>		<u>Alternate Compatible Groups</u>
A, B, or AB	Group O	
	Group A	
AB	Group B	
AB	Group AB	None

MANAGEMENT OF MAJOR ABH INCOMPATIBLE TRANSFUSION REACTIONS

1. Approach. There is no standard approach to the medical management of transfusion reactions resulting from ABH incompatibility, because of the variety of clinical presentations that results from these accidents. Consultation with hematologists, nephrologists, the Chief, Blood Bank Section, and the transfusion officer must take place to ensure an expeditious and effective treatment.

2. Diagnosis and Therapy. Diagnosis and therapy must be geared at the following goals:

a. Preventing further addition of incompatible red blood cells into the blood circulation by stopping the transfusion immediately and removing any improperly designated units for the recipient from the active inventory.

b. Identifying the presence of disseminated intravascular coagulation (DIC) by securing adequate samples for appropriate laboratory testing and diagnosis.

c. Controlling DIC. The mainstay of treatment is to control DIC. Cryoprecipitate and heparin therapy may be necessary. This treatment is associated with risks and should only be undertaken with proper subspecialty hematology consultation.

d. Removal. Removing the circulating incompatible red blood cells to avoid further DIC and further immune complex formation. This could be achieved by exchange transfusion and/or plasmapheresis; however, these protocols carry very serious risks. This type of treatment must be carefully evaluated by the treating physician, and a clinical hematologist.

e. Correctly Handling Incompatible Transfusion Reactions. All ABH incompatible transfusion reactions constitute an emergency and cases must be handled with the greatest attention to detail. Their management requires involvement by the Chief, Blood Bank Section, and must follow the recommendations of the American Association of Blood Banks (AABB). The cornerstone of therapy is the treatment of DIC which may cause renal cortical damage with renal shutdown. Renal cortical flow, which controls DIC, should be improved by the use of diuretics that have an effect on cortical flow, i.e., Furosemide, with the goal of maintaining an output of 1 to 2 ml/kg/hr. Prolonged hypotension and shock must be treated aggressively to avoid further renal damage.