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Medical

THE AIR FORCE BLOOD PROGRAM



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This Air Force Instruction (AFI) implements Air Force Policy Directive 44-1, Medical Operations, and Department of Defense (DoD) Instruction 6480.4, Armed Services Blood Program Operational Procedures and is consistent with Air Force Manual (AFMAN) 41-111_IP, Standards for Blood Banks and Transfusion Services. This publication provides the standardized procedures for management and operation of the Air Force Blood Program (AFBP) in alignment with requirements set forth by the AABB, the Armed Services Blood Program, the College of American Pathologists, Assistant Secretary of Defense for Health Affairs (ASD(HA)), and the Food and Drug Administration (FDA). It applies to all individuals assigned to Air Force (AF) blood missions, including Air Force Reserve and Air National Guard personnel upon mobilization. This instruction may be supplemented at any level, but all supplements must be routed to the Air Force Medical Operations Agency (AFMOA) Air Force Blood Program Division for coordination prior to certification and approval. Refer recommended changes and questions about this publication to the AFBP using AF Form 847, Recommendation for Change of Publication. Route AF Forms 847 from the field through the appropriate functional chain of command. Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with AFMAN 33-363, Management of Records, and disposed of in accordance with the AF Records Disposition Schedule located in the AF Records Information Management System. This Instruction requires the collection and or maintenance of information protected by the Privacy Act of 1974 authorized by 5 U.S.C. 552a, 42 U.S.C. 290dd-2, and DoD Health Information Privacy Regulation (DoD 6025.18-R). The applicable System of Records Notice (SORN), EDHA 07,

Military Health Information System (November 18, 2013, 78 FR 69076) is available at: <http://dpclo.defense.gov/Privacy/SORNs.aspx>. The authorities to waive wing/unit level requirements in this publication are identified with a Tier number (T-0, T-1, T-2, T-3) following the compliance statement. See Air Force Instruction (AFI) 33-360, Publications and Forms Management, for a description of the authorities associated with the Tier numbers. Submit requests for waivers through the chain of command to the appropriate Tier waiver approval authority, or alternately, to the requestors commander for non-tiered compliance items. The use of the name or mark of any specific manufacturer, commercial product, commodity, or service in this publication does not imply endorsement by the AF.

SUMMARY OF CHANGES

The revision of this publication updates the new AF Surgeon General (AF/SG) signature block; removes uncommon and underutilized acronyms; removes the requirement for the Base Blood Program Officer to establish a donor recognition program; removes the limit to 500 credits for blood products from civilian collections; and clarifies additional expectations of civilian Memoranda of Understanding for credits. Attachment 2 was updated as follows: the 366th Medical Group at Mountain Home Air Force Base (AFB) was deleted and 39th Medical Group at Incirlik Air Base, Armed Services Blood Banking Center-San Antonio at Joint Base San Antonio and Air Force Special Operations Command were added.

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Chapter 1

PROGRAM OVERVIEW, ROLES, AND RESPONSIBILITIES

1.1. Overview. This publication provides the standardized procedures for management and operation of the AFBP in alignment with requirements set forth by the AABB, the Armed Services Blood Program, the College of American Pathologists, Assistant Secretary of Defense for Health Affairs, and the FDA. The AFBP provides safe, cost-effective, quality blood products and services in support of the Department of Defense's wartime and peacetime medical missions. The AFBP ensures that collection, manufacturing, storage, distribution and transfusion of blood products to military personnel adhere to the FDA Current Good Manufacturing Practices and regulations published by the FDA in Title 21 of the Code of Federal Regulations, Parts 200-299 and Parts 600-680 and to the standards of national accrediting agencies. The AFBP operates per direction of the Air Force Surgeon General by authority granted under Biologics License Number 610, issued by the FDA.

1.2. Program Organization. The primary focus of the AFBP is to provide leadership, direction and guidance for all elements of the AFBP in support of expeditionary and peacetime medical missions. The AFBP is an integral part of the Armed Services Blood Program. The Armed Services Blood Program is under the responsibility of the Assistant Secretary of Defense for Health Affairs. The Secretary of the Army is the Department of Defense Executive Agent for the Armed Services Blood Program. The Armed Services Blood Program is an integrated blood products system composed of the Military Services' and Combatant Commands' blood programs, and is coordinated by the Armed Services Blood Program Office. This program provides blood products to Department of Defense military treatment facilities for both peacetime and wartime use. The readiness posture of the program is maintained through an active voluntary donor program, blood collection, blood product manufacturing, quality assurance (QA), logistics, and transfusion training programs. The program also actively participates in joint exercises and responds to homeland defense contingencies and public health emergencies when directed by government authorities.

1.3. Air Force Blood Program Elements. The AFBP is composed of various operational, manufacturing and shipping elements including Blood Donor Centers, Transfusion Services, Armed Services Whole Blood Processing Laboratories, Expeditionary Blood Transshipment Centers, Expeditionary Blood Support Centers, and Frozen Blood Product Teams. Each element contributes to a tri-service blood distribution system that supports military treatment facilities in the Continental United States (CONUS) and outside the Continental United States (OCONUS) during peacetime and wartime. All the CONUS military treatment facilities and blood donor centers are registered or licensed with the FDA and maintain accreditation by the AABB. All OCONUS military treatment facilities, with the exception of the 673d Medical Group, must be registered with the FDA and are highly encouraged to follow AABB standards. The 673d Medical Group at Joint Base Elmendorf-Richardson, Alaska, will maintain AABB accreditation and FDA registration.

1.4. Responsibilities.

1.4.1. The Assistant Secretary of the Air Force for Manpower and Reserve Affairs (SAF/MR) serves as an agent of the Secretary of the Air Force and provides guidance, direction, and

oversight for all matters pertaining to the formulation, review, and execution of plans, policies, programs, and budgets addressing the AFBP. SAF/MR will:

1.4.1.1. Provide funds, facilities, and support personnel, as required, to maintain the Blood Donor Centers and the Armed Services Whole Blood Processing Laboratories.

1.4.1.2. Fund transportation of AF-collected and processed blood products and incidental expenses associated with their delivery to the first CONUS destination.

1.4.1.3. Provide, as the DoD Executive Agent for the Armed Services Whole Blood Processing Laboratories, Expeditionary Blood Transshipment Centers, Expeditionary Blood Support Centers, and Frozen Blood Product Teams appropriate support personnel, facilities, and budgetary resources, as required to maintain at least two Armed Services Whole Blood Processing Laboratories in active status.

1.4.2. The Air Force Surgeon General will:

1.4.2.1. Serve as the authorized agent for the Air Force Biologics License Number 610, issued by the FDA. This authority may be delegated to the Chief and/or Deputy Chief, AFBP.

1.4.2.2. Exercise control over all matters relating to compliance with FDA requirements as detailed in 21 CFR Parts 200-299 and 600-680. Ensure all AFBP elements gain FDA registration or licensure, as appropriate, and comply with FDA regulations.

1.4.2.3. Ensure appropriate action is taken to correct and prevent recurrence if the FDA issues a Form FDA 483, Inspectional Observations, to an AFBP element.

1.4.2.4. Ensure the FDA's Director, Office of Compliance, Center for Biologics Evaluation and Research, receives notification within 24 hours in the event of a transfusion-related fatality or when the post-transfusion cause of death is unknown and could possibly be related to transfusion.

1.4.2.4.1. Ensure FDA / Center for Biologics Evaluation and Research receives notification of reportable biological product deviations.

1.4.2.4.2. Provide continuing education programs for clinical laboratory officers and QA staff to ensure they are current in current Good Manufacturing Practices and matters of FDA compliance and regulation.

1.4.2.5. Appoint the Chief, AFBP, from candidates provided by the Chief Consultant to the Surgeon General for Medical Laboratory.

1.4.3. Air Force Medical Operations Agency will:

1.4.3.1. Support the AFBP and ensure adequate resources are available to meet blood missions.

1.4.3.2. Provide consultation to Major Commands (MAJCOMs) for any blood-related matters via the AFBP.

1.4.3.3. Ensure blood program funds received from the Armed Services Blood Program are distributed according to requirements and budget plan. Ensure that military treatment facilities with blood services funding requirements identify and request appropriate source funding.

1.4.4. The Chief, Air Force Blood Program will:

1.4.4.1. On behalf of the AF/SG, manage the AF Biologics License Number 610, issued by the FDA. Coordinate AF policies to ensure compliance with AABB, Armed Services Blood Program, FDA, Assistant Secretary of Defense for Health Affairs and other regulatory or accrediting agencies, to include fatality reporting, deviation reporting and coordination of the infectious disease lookback program.

1.4.4.2. Serve as authorized agent to the FDA and appoint AFBP staff as authorized agents, as appropriate.

1.4.4.3. Coordinate and manage all AF blood matters, including operational, research, training and QA issues. Provide operational guidance to MAJCOMS, military treatment facilities and readiness sections. Assist in determining training and manning requirements for enlisted laboratory technicians and laboratory officers serving in operational blood missions.

1.4.4.4. Serve as liaison between military treatment facilities and the FDA. The AFBP is the only agency authorized to interact with the FDA (except when the military treatment facility is undergoing on-site FDA inspections). All FDA license/registration applications and biological product deviations must be coordinated through, approved by and submitted by the AFBP. **(T-2)**.

1.4.4.5. Serve as the consultant to the Manpower and Equipment Force Packaging Responsible Agencies for blood-related Unit Type Codes, Allowance Standards and pilot units. Ensure readiness functions are appropriately identified, staffed and funded.

1.4.4.6. Perform regulatory evaluations of the AF FDA–licensed and registered facilities to provide guidance and ensure compliance with all applicable regulations and standards. **(T-2)**.

1.4.4.7. Direct the actions of the QA managers to ensure compliance with regulations and accreditation standards. Guide military treatment facilities in appropriate investigation, corrective action and submission of all FDA–reportable deviations.

1.4.4.8. Monitor any reports of suspected transfusion-transmitted diseases submitted to the AFBP as required by the FDA reporting system and lookback regulations.

1.4.4.9. Establish AF blood product quotas for Department of Defense contingencies and identify blood mobilization requirements.

1.4.4.10. Coordinate the activities of AF Blood Donor Centers to meet the Armed Services Blood Program Office quota requirements and monitor blood distribution network effectiveness during peacetime and wartime.

1.4.4.11. Ensure AFBP elements appropriately fund the peacetime component of their blood missions using the Program Objective Memorandum (POM) process at their attached military treatment facility.

1.4.4.12. Contact the Armed Services Blood Program Office to identify and obtain appropriate funding when the AFBP mission is expanded due to war, contingency or emergency.

1.4.4.13. Provide the Armed Services Blood Program Office with accurate requirements for forecasting and sourcing the types and quantities of blood products to be procured for peacetime use, homeland defense, wartime and contingencies.

1.4.4.14. Compile AFBP QA statistics for process improvement initiatives, and coordinate with the Armed Services Blood Program Office to establish program performance metrics and standards.

1.4.4.15. Assist in the development, deployment and maintenance of information technology initiatives in support of the AFBP and Armed Services Blood Program.

1.4.4.16. Supervise the Directors of the Armed Services Whole Blood Processing Laboratories and Air Force-led Armed Services Blood Banking Centers.

1.4.5. The Medical Consultant, AFBP, will:

1.4.5.1. Serve in a consultative role to the Armed Services Blood Program Office and AFBP on donor acceptability, review of FDA reports, updating deferral lists and readiness issues. May also serve as medical advisor on DoD committees and other Federal Committees.

1.4.5.2. Be a transfusion medicine trained pathologist, preferably board certified in transfusion medicine.

1.4.6. Installation Commanders will:

1.4.6.1. Encourage donors at the frequency and in the quantity necessary to enable AF Blood Donor Centers to meet peacetime and contingency needs for blood products. **(T-2)**.

1.4.6.2. Encourage cooperation between subordinate commanders to support the AFBP mission and to minimize interruption of work and training schedules while soliciting blood donors during normal duty hours. **(T-2)**.

1.4.6.3. Ensure DoD-affiliated Blood Donor Centers, where available, have priority access to donors over civilian blood collecting organizations in order to meet DoD healthcare requirements. **(T-1)**.

1.4.6.4. Establish Memoranda of Understanding (MOU) with all civilian blood collection agencies that are granted access to DoD donors on military installations in accordance with (IAW) ASD(HA) Policy 04-015, Revised Policy Regarding Standardization of Infectious Disease Reporting Requirements for Civilian Blood Agencies Collecting Blood on Military Installations, at Military Leased Facilities or Aboard Ships; ASD(HA) Policy 04-019, Revised Policy Regarding Civilian Blood Collections on Military Installations, Leased Facilities, and Aboard Ships; and this instruction. **(T-1)**.

1.4.6.5. Provide necessary support to enable the Armed Services Blood Program, Blood Donor Centers, and/or civilian blood collection agencies with MOUs to perform blood drives. **(T-1)**.

1.4.6.6. Ensure the Military Personnel Section (MPS) provides the requesting military Blood Donor Center with a base personnel roster of active component members by unit and ABO group and Rh blood type. Refer to Paragraph 2.1.3 for further information. **(T-2)**.

1.4.6.7. Appoint in writing, an officer, senior NCO, or civilian employee (GS-7 or higher) who will be able to dedicate sufficient time to serve as the Base Blood Program Officer. For bases with AF Blood Donor Centers, the Blood Donor Center recruiter will serve as the Base Blood Program Officer. The Blood Donor Center recruiter does not require appointment. **(T-2)**.

1.4.7. The Base Blood Program Officer:

1.4.7.1. May develop a program of continuing donor education and motivation to recognize people for their donations.

1.4.7.2. Develops a system with points-of-contact for each installation unit to provide donors for installation-sponsored blood drives. **(T-3)**.

1.4.7.3. Updates the installation commander, at least annually, on donor program activities and unit blood collection statistics. **(T-3)**.

1.4.7.4. Ensures that MOUs are accomplished with each civilian agency collecting donors on the installation. **(T-3)**.

1.4.7.5. Works in consultation with the AFBP and local military treatment facility's laboratory when developing an MOU. **(T-3)**.

1.4.8. The Military Treatment Facility Commander or Director:

1.4.8.1. Ensures compliance with AABB, Armed Services Blood Program, FDA, ASD(HA) and other accrediting agency standards, to include fatality reporting, deviation reporting and the infectious disease lookback program. **(T-0)**.

1.4.8.2. Ensures the necessary corrective actions are taken to ensure compliance with FDA regulations and notifies the AFBP of any unresolved problems. **(T-0)**.

1.4.8.3. Appoints a qualified Medical Director to direct the local Transfusion Service and/or Blood Donor Center. **(T-1)**.

1.4.8.3.1. Ensures the QA Officer is for the local Blood Donor Center is separate from operational responsibility and will not be supervised by the Blood Donor Center management. **(T-1)**.

1.4.8.3.2. Ensures the QA Officer is for the local Transfusion Service is separate from operational responsibility, as much as possible. **(T-1)**.

1.4.9. The Air Force Blood Program Elements: (See paragraph 1.3.)

1.4.9.1. Comply with directives, regulations and standards of AABB, Armed Services Blood Program, FDA, ASD(HA) and other accrediting agencies to include fatality reporting, deviation reporting and the infectious disease lookback program. **(T-0)**.

1.4.9.2. Develop and maintain a QA program. **(T-3)**.

1.4.9.3. Contact the AFBP to route questions to the FDA. **(T-0)**.

1.4.9.4. Ensure the AFBP receives notification in the event of a transfusion-related fatality or when the post-transfusion cause of death is unknown and could possibly be related to transfusion; notification must occur no later than 24 hours after discovery. **(T-0)**.

1.4.9.5. Initiate all infectious disease lookback functions as required by the FDA. Possible, suspected and confirmed cases of transfusion-transmitted disease requiring lookback investigation will be reported to the AFBP as a biological product deviation. **(T-0)**.

1.4.9.6. Initiate peacetime funding requests through the supporting Resource Management Office of the local military treatment facility with the POM process in alignment with the AF POM schedule.

1.4.9.7. Coordinate funding for expanded missions due to contingency or emergency through the AFBP.

1.4.9.8. Prepare for continuous operation at the maximum tasking noted in AFI 44-118, Operational Procedures for the Armed Services Blood Program Elements. **(T-3)**.

1.4.9.9. Ship, as directed, existing stock from Blood Donor Center inventory in support of contingencies within 24 hours of notification. **(T-3)**.

1.4.9.10. Participate in the Armed Services Blood Program frozen blood program as directed and funded.

1.4.9.11. Establish minimum, target and maximum blood product inventory levels. **(T-3)**.

1.4.10. The Inventory Manager:

1.4.10.1. Monitors blood inventory levels to keep inventory near established target level. **(T-3)**.

1.4.10.2. Maintains account with the DoD CONUS Blood Management Tool. **(T-3)**.

1.4.10.3. Procures and distributes excess blood products for routine day-to-day military treatment facility use via methods that offer the greatest overall advantage to the AF (refer to paragraph 3.4). **(T-3)**.

1.4.11. The Quality Assurance unit will:

1.4.11.1. Be responsible for the QA program to ensure compliance with AABB, Armed Services Blood Program, FDA, ASD(HA) and other accrediting agencies, to include fatality reporting, deviation reporting and the infectious disease lookback program. **(T-3)**.

1.4.11.2. Retain authority to cease production of blood products if problems with Current Good Manufacturing Practices (cGMP) are identified.

1.4.11.3. Submit data to the AFBP for inclusion in the annual FDA report. **(T-2)**.

1.4.12. The Armed Services Whole Blood Processing Laboratories (ASWBPLs) will:

1.4.12.1. Receive and maintain a contingency reserve of blood products and act as a central repository for forward shipment of blood products to operational units. **(T-2)**.

1.4.12.2. Perform ABO and Rh confirmation testing on Red Blood Cell units. **(T-2)**.

1.4.12.3. Pack, ice and prepare blood products for shipment to the theater. **(T-2)**.

1.4.12.4. Prepare for continuous operation at the maximum tasking noted in AFI 44-118. **(T-2)**.

1.4.12.5. Distribute excess blood products to the Service Blood Programs, to Veterans Affairs (VA) facilities or other locations as directed by Armed Services Blood Program Office via the Chief, AFBP. **(T-2)**.

1.4.12.6. Provide support to exercises (real-world blood support and simulated blood), as directed by the Armed Services Blood Program Office via the AFBP. **(T-2)**.

1.4.12.7. When directed and funded by the AFBP, maintain equipment, supplies and an adequate number of trained personnel for freezing, deglycerolization and training purposes in support of the Armed Services Blood Program frozen blood program. **(T-2)**.

1.4.12.8. Provide daily inventory reports, weekly compliance reports and other reports as directed to the AFBP. **(T-2)**.

Chapter 2

BLOOD DONOR CENTER OPERATIONS

2.1. Overview. Blood Donor Centers are FDA-licensed CONUS-based facilities that serve vital peacetime and wartime missions supporting the Military Health Service with blood products in the CONUS and worldwide. The three AF Blood Donor Centers are located at Keesler AFB, Mississippi; Joint Base San Antonio, Texas; and Wright-Patterson AFB, Ohio. Blood will only be collected from United States citizens, to include military members, DoD civilians or contractors, or beneficiaries.

2.1.1. Voluntary Donations. All blood donations will be voluntary (per FDA Compliance Policy Guide Sec. 230.150, Blood Donor Classification Statement, Paid or Volunteer Donor) and will comply with FDA and AABB requirements. **(T-0)**. The AF encourages its employees to volunteer as blood donors. A civilian employee may be excused for a maximum time of four hours to support volunteer blood donation IAW AFI 36-815, Absence and Leave. Military commanders may authorize time-off incentive (special pass) for active duty personnel. Terms of a contract outline how contractor time is accounted for when donating blood.

2.1.2. Donor Nourishment. Refreshments (such as cookies, water and fruit juice) should be provided as a provision of medical care to donors to minimize adverse reactions to blood donation. Subsistence items should be purchased through Medical Logistics using Operation and Maintenance (O&M) funds at sites with attached AF Blood Donor Centers. Note: Civilian organizations operating blood drives on base will furnish their own nourishment items for donors.

2.1.3. Donor Recruitment. Recruiting should target specific blood types and products to meet local and contingency requirements. Indiscriminate collections of unrequested blood types should be avoided in order to reduce outdate rates and avoid waste of government resources for collection, testing and distribution. Close coordination with installation command personnel is critical to the provision of adequate donors to ensure that specific numbers and blood types are provided on request. Blood Donor Centers should request active duty alpha rosters from the Military Personnel Flight as needed.

2.1.4. Donor Motivation. Reasonable incentives and recognition, such as T-shirts, coffee mugs, or pens, may be offered for recruitment and retention of donors to encourage continued donations, ensuring support and success of the AFBP mission IAW AFI 65-601V1, Budget Guidance and Procedures. Note: Civilian organizations will furnish their own donor incentive items.

2.1.5. Aircrew. Aircrew and Special Operational Duty members who donate blood (200 mL or more) may be disqualified from flying up to 72 hours IAW AFI 48-123, Medical Examinations and Standards. This restriction includes donation of whole blood, plasmapheresis and plateletpheresis.

2.2. Product Distribution. Products manufactured by AF Blood Donor Centers will be distributed in the following descending priority: **(T-1)**

2.2.1. Contingency requirements, including support of Armed Services Blood Program Office –levied quotas.

- 2.2.2. Military Health Systems requirements at AF military treatment facilities.
- 2.2.3. Military Health Systems requirements at other DoD military treatment facilities.
- 2.2.4. Requests from other institutions such as Veteran's Affairs or Public Health Services.
- 2.2.5. Other civilian exchange programs.

2.3. Walking Donor Program. Walking Donor Programs are intended for OCONUS facilities where the local blood supply may not be equivalent to FDA standards, or where the local supplier may not be able to provide enough blood products during contingency situations. These involve the emergent collection of non-FDA compliant blood products in support of disaster and contingency demand. All OCONUS military treatment facilities should incorporate the demand for blood into their contingency response plans and determine when a Walking Donor Program may be required. The use of blood collected under emergency conditions may be required to save life or limb during mass casualty events or combat operations.

2.3.1. Military treatment facilities that identify a need to establish a Walking Donor Program should coordinate with their respective MAJCOM/SG and Area Blood Program Officer for approval and guidance.

2.3.2. The military treatment facility is responsible for funding the Walking Donor Program.

2.3.3. To the greatest extent possible, military treatment facilities with Walking Donor Programs will establish and maintain rosters of pre-infectious disease tested donors (HBsAg, Anti-HBc, Anti-HCV, HCV RNA, Anti-HIV 1/2, HIV-1 RNA, Anti-HTLV I/II, WNV RNA, Syphilis, Chagas and Zika virus) and will repeat prescreening at regular intervals not to exceed 90 days. **(T-3)**.

2.3.4. When emergency blood collections are required, donors will be selected in the following descending priority:

2.3.4.1. Donors who have been prescreened within the last 90 days with the full panel of FDA –licensed donor infectious disease tests and found to be negative for all tests. Note: Any donor with a positive test result will not be listed as an approved, prescreened donor and must not be collected.

2.3.4.2. Donors who report donating in the past and have not been deferred for transfusion-transmitted disease.

2.3.4.3. Donors who have not been prescreened with FDA –licensed tests, nor have been blood donors in the past.

2.3.5. On the day of donation, prospective donors will be screened for eligibility using approved donor history screening protocols and be tested for infectious diseases using Armed Services Blood Program Office –approved rapid screening tests. As much as possible, rapid screening tests should be performed before issuing the product.

2.3.6. When emergency blood units are collected:

2.3.6.1. Each unit and its corresponding infectious disease samples will be labeled with a unique donor identification number. The identification number should be International Society of Blood Transfusion-compliant, if possible. Products must be labeled “For Emergency Use Only” IAW 21 CFR Part 610.40(g). **(T-3)**.

2.3.6.2. The blood samples will be sent to an FDA –licensed donor testing laboratory for retrospective testing.

2.3.6.3. All collection information and the results of all rapid screening and retrospective sample testing will be maintained locally and entered into the operational blood management system. **(T-3)**.

2.3.6.4. Follow-up notification and counseling will be provided to any donor who tests positive/reactive on either a prescreen, rapid or retrospective infectious disease test. Appropriate medical treatment referrals will be accomplished. **(T-1)**.

Chapter 3

TRANSFUSION SERVICE OPERATIONS

3.1. Overview. Transfusion of human blood products carries a small, but genuine risk of adverse events and transmission of infectious agents. Alternative interventions, such as the transfusion of synthetic factor concentrates or products that have undergone viral-inactivation procedures (e.g. albumin, other plasma derivatives and substitutes) should be considered for use in lieu of blood products when possible.

3.1.1. Informed Consent. Clinicians will accomplish and document informed consent IAW AFI 44-102, Medical Care Management. **(T-3)**.

3.1.2. Blood Component Requests. Standard Form 518, Blood or Blood Component Transfusion (SF 518), suitable Enterprise Blood Management System –Transfusion form or local form shall be completed for each component request. **(T-3)**. Note: The SF 518 does not represent the physician’s order to transfuse a blood product, but may be used to document the transfusion event within the recipient’s medical record.

3.1.3. Military Treatment Facility Instruction. Each military treatment facility that operates a Transfusion Service shall have a military treatment facility instruction that establishes and governs the transfusion-related activities in the facility. **(T-3)**.

3.1.3.1. The military treatment facility policy will address blood component administration to include the use of infusion devices, compatible fluids, ancillary equipment, transfusion and blood utilization monitoring; blood administration shall be consistent with the AABB Circular of Information for the Use of Human Blood and Blood Components, AABB standards and FDA regulations. **(T-0)**.

3.1.3.2. Patients may refuse transfusion of blood products for religious reasons. The military treatment facility instruction should address how the provider will obtain patient consent in this situation and how the facility manages these patients’ blood requirements.

3.1.4. Transfusion Reaction. Investigation of suspected transfusion reactions should use AF Form 1224, Blood Transfusion Reaction Investigation or an equivalent locally developed form.

3.1.5. Transfusion-Related Fatality. The AFBP (DSN 969-9941 or 9928; Commercial 210-395-9941 or 9928) must be notified within 24 hours of a transfusion-related fatality or when the post-transfusion cause of death is unknown and could possibly be related to transfusion. **(T-2)**. The military treatment facility is required to begin a root cause analysis and forward a report to the AFBP within five calendar days of the event. **(T-2)**. The military treatment facility will ensure they inform their chain of command to include the MAJCOM/SG office. **(T-3)**. The AFBP will inform the AF/SG and submit the final report within seven days of the event to the FDA at the address in Table 3.1. **(T-0)**.

Table 3.1. Air Force Blood Program Notification to the Food and Drug Administration.

Method	Contact Details
E-mail	Fatalities2@fda.hhs.gov
Telephone/voice-mail	240-402-9160

Fax	301-827-0333, Attn: CBER Fatality Program Manager
Express mail	US Food & Drug Administration Center for Biologics Evaluation and Research, c/o Document Control Center 10903 New Hampshire Ave W071, G112 Silver Spring, MD 20993-0002

3.2. Inventory Management . Effective management of blood resources is vital to maintaining sufficient blood products to meet all requirements. The Transfusion Service must efficiently manage and monitor several key areas of control. **(T-3)**.

3.2.1. Establish minimum, target and maximum levels of each blood product by blood type and maintain stock levels near the target threshold to ensure maximum coverage with minimum outdating. **(T-3)**.

3.2.2. Monitor the inventory levels and expiration dates of all blood products to ensure minimal outdating and minimal loss of blood products. **(T-3)**.

3.2.3. Avoid maintaining stock levels above the established target level.

3.2.4. Monitor and evaluate blood ordering and usage practices in the military treatment facility blood utilization committee or function. **(T-3)**.

3.2.5. Establish maximum time periods for holding cross-matched blood. **(T-3)**. Consider enacting policy to return cross-matched blood units to the general inventory prior to the three-day expiration if it appears the patient will not need the blood.

3.2.6. Establish a maximum surgical blood ordering schedule to identify which surgical procedures require only a type and screen and which procedures warrant a type and crossmatch. **(T-3)**. The maximum surgical blood ordering schedule should be developed based on historical records of blood use and in coordination with surgical subject matter experts.

3.2.7. Use the type and screen in lieu of type and crossmatch in concert with the maximum surgical blood ordering schedule and whenever the likelihood for blood usage is low. **(T-3)**.

3.2.8. Utilize outdated blood products and waste byproducts of blood collection (e.g. Recovered Plasma) for training and research or recover through Recovered Blood Product agreements before discarding opting to discard. **(T-3)**. Refer to Paragraph 5.3 of this instruction for requirements related to Recovered Blood Product programs.

3.3. Procurement of Blood Products . Procurement methods for routine day-to-day military treatment facility blood product support will be those which offer the greatest overall advantage to the AF.

3.3.1. Procurement sources should be used in the following descending priority unless doing so hinders patient care activities:

3.3.1.1. AF Blood Donor Center or military treatment facility sources.

3.3.1.2. Armed Services Blood Program suppliers via the Blood Management Tool or direct contact.

3.3.1.3. Resource sharing with the VA.

3.3.1.4. MOUs with civilian exchange programs or regional blood centers with which military treatment facilities have established credit balances.

3.3.1.5. When above mechanisms are exhausted, purchase products from community sources.

3.3.1.6. ASWBPLs may be contacted to determine availability of excess products prior to requesting approval to procure the products through the Armed Services Blood Program Office. Blood products maintained by the ASWBPLs are considered a DoD joint blood inventory for contingency or emergency operations, and military treatment facilities should not routinely depend on these inventories as a primary source of blood product support.

3.3.2. Emergent blood procurement is not governed by the above procurement sourcing rules. The life-saving nature of blood products necessitates that there will be times when products will need to be purchased due to urgent needs or special blood attributes.

3.3.3. Inter-facility shipments may be made by commercial transportation with associated expenses charged to the receiving military treatment facility's O&M account.

3.4. Distribution of Excess Blood Products. Excess blood products will be distributed according to the following descending priority: **(T-2)**

3.4.1. Establishes support arrangements with other AF Transfusion Services.

3.4.2. Posts excess inventory to the Blood Management Tool for AF disbursement for one day.

3.4.3. Posts excess inventory to the Blood Management Tool for DoD disbursement for one subsequent day.

3.4.4. Makes available any remaining excess not distributed via above methods to the other Federal, State and local agencies or through blood exchange systems with which appropriate MOUs/Memoranda of Agreement (MOA) have been established.

3.4.5. Provides blood support to civilian treatment facilities pursuant to a request for AF logistical support IAW DoD 5500.07-R, The Joint Ethics Regulation section 3-211. Such assistance should be provided on a no impact to AF mission, minimal expense to government basis. Accordingly, the civilian facility must arrange for transportation of blood products.

3.4.6. Due to the short shelf-life of platelets, these products may be distributed outside of the above priority list if necessary.

3.4.7. Note: If a facility has a MOA whereby blood products are provided in exchange for human resources, excess inventory may be distributed to the facility providing human resources at a higher priority if necessary to meet the terms of the MOA.

Chapter 4

REGULATORY AND ADMINISTRATIVE PROCESSES FOR BLOOD PROGRAM OPERATIONS

4.1. Inventory Accountability.

4.1.1. Inventory management processes shall include frequent, documented determinations that all blood components have a proper disposition and that there are no misplaced blood products. **(T-3)**.

4.1.2. Facilities maintaining an inventory of blood products shall have a policy to reconcile every blood product listed in the Enterprise Blood Management System current inventory, line-by-line, with the blood products in physical inventory. **(T-3)**. Transfusion Services and Blood Donor Centers must accomplish this reconciliation on a monthly basis at a minimum. **(T-3)**. ASWBPLs must establish inventory control practices and a periodic reconciliation schedule that allows for accurate tracking of products and must perform a 100% reconciliation no less than annually. **(T-3)**.

4.1.3. AFBP elements will also perform a reconciliation of all products in a status of “Expired,” “Issued,” or “Quarantined” on a weekly basis at a minimum. **(T-3)**.

4.1.4. Sites shall utilize reports generated from the Enterprise Blood Management System when reconciling blood product inventory. **(T-3)**.

4.1.5. Discrepancies shall be resolved and documented in a timely manner. Discrepancies that cannot be resolved will be reported to the AFBP. **(T-3)**.

4.2. Quality Assurance (QA) Program.

4.2.1. The QA program will address each AABB Quality System Essential as defined in regulatory standards and will include tracking of metrics where possible and applicable. **(T-1)**.

4.2.2. The QA unit will conduct assessments through surveys, audits and review of FDA deviation and inspection reports. **(T-3)**. The QA unit will recommend quality improvements to the AFBP element management. **(T-3)**. The QA unit is responsible for review of all FDA reportable deviations and inspection responses before submission to the AFBP and will ensure corrective actions are appropriate. **(T-3)**.

4.2.3. The QA unit is responsible for suspending blood product production if problems with cGMPs are identified. The QA unit will notify senior management at any point that a patient safety concern is evidenced. **(T-3)**.

4.3. Infectious Disease Lookback Program.

4.3.1. Previously donated blood from donors who currently test positive for infectious diseases (e.g. Human Immunodeficiency Virus, Hepatitis B, Hepatitis C, Human T-cell Lymphotropic Virus) must be tracked to inform those recipients of the increased risk of disease. Notify the AFBP of any suspected transfusion-transmitted disease lookback cases within 72 hours of discovery.

4.3.2. All facilities that collect, store, ship or transfuse blood products must maintain all blood product collection, transfusion, testing, shipping and/or disposition records to support present

and future transfusion transmitted disease lookback issues as required by regulatory agencies. **(T-3)**.

4.3.3. Records must be maintained in a manner which provides physical and environmental protection. **(T-3)**.

4.3.4. AFBP elements will use the approved Enterprise Blood Management System to determine disposition of suspect units of blood. **(T-3)**.

4.4. Non- Food and Drug Administration Compliant Blood Products.

4.4.1. The transfusion of non- FDA compliant blood products may be required to save life or limb. Examples of non- FDA compliant blood products include products collected by a foreign country or products collected under emergency conditions during mass casualty events or combat operations (e.g. using Walking Donor Programs) and transfused before FDA – approved blood donor tests are completed.

4.4.2. Military treatment facilities that engage in the transfusion of non- FDA compliant blood products will have policies in place to comply with recipient notification and follow-up requirements as outlined in ASD(HA) Policy 10-002, Policy On the Use of Non-U.S. FDA Compliant Blood Products. **(T-0)**.

4.4.3. Military treatment facilities will track all patients who receive non-FDA compliant blood products so they may be tested for evidence of transfusion-transmitted diseases, ideally prior to transfusion and at three, six, and 12 months post-transfusion. **(T-3)**. Note: Recipients of blood products from Armed Services Blood Program Office –determined equivalent countries are exempt from this requirement. Contact the AFBP for a list of countries currently designated for exemption.

4.5. Food and Drug Administration Licensure and Registration Program.

4.5.1. An MOU between the DoD and the FDA requires each military department, through its SG, to operate its own blood program in accordance with FDA requirements. The MOU requires FDA registration of all military sites maintaining blood products in inventory.

4.5.2. All active Blood Donor Centers must be licensed by the FDA for each product that is manufactured and shipped interstate. **(T-0)**.

4.5.3. The FDA, at their discretion, inspects licensed and registered facilities to monitor compliance with regulations. Facility FDA inspections generally occur every 2-3 years.

4.5.4. Compliance with FDA regulations is required by civil law and provides recognition that AFBP elements operate under nationally accepted standards of blood product quality and safety. FDA licensure allows the AF to freely exchange licensed blood products with military and civilian blood banks across state lines as necessary.

4.5.5. All communication between sites and the FDA must be coordinated through the AFBP. Sites are not authorized to directly communicate with the FDA.

4.6. AABB Inspections.

4.6.1. The AABB accreditation program is a peer review and educational program motivating its members to strive for the highest level of performance in all aspects of donor collection, component manufacturing and transfusion medicine.

4.6.2. AABB accreditation is mandatory for all AF Blood Donor Centers and the CONUS Transfusion Services.

4.6.3. AABB accreditation is highly encouraged for all OCONUS Transfusion Services. OCONUS Transfusion Services should follow AABB standards as closely as possible even if not AABB-accredited.

4.7. Computerization and Information Management.

4.7.1. AFBP elements will use the approved standard Enterprise Blood Management System real-time as the system of record to perform all operational processes. **(T-3)**.

4.7.2. Utilizing the Enterprise Blood Management System real-time maximizes critical safety checks and allows facilities to promptly and accurately track each blood unit and product from creation to final disposition as required by the AABB and FDA.

4.7.3. Each facility must publish a Continuity of Operations Plan to be followed whenever the approved Enterprise Blood Management System is not available for use. **(T-3)**. If the approved Enterprise Blood Management System is expected to be unavailable for an extended time, the facility should notify the AFBP.

4.7.4. Electronic and manual records must be maintained for the time periods established by the AABB and FDA in an environment that provides physical and privacy protection and allows records to be retrieved within one week. **(T-0)**.

4.8. Required Reports.

4.8.1. Each FDA-registered facility must submit data for the annual FDA report to the AFBP. **(T-3)**.

4.8.2. Each FDA-registered facility must review and submit updates to its FDA registration to the AFBP annually. **(T-0)**.

4.8.3. When requested, each Transfusion Service and blood donor center must submit operational data to the AFBP. **(T-3)**.

4.8.4. Annual Armed Services Blood Program funding requests and accountability reports must be submitted to the AFBP. **(T-3)**.

Chapter 5

SHARING AGREEMENTS AND CONTRACT REQUIREMENTS

5.1. Overview. The main purposes for entering into MOUs are: (1) to earn credits for civilian Blood Donor Center collections on military installations, (2) to exchange excess or expired blood products and (3) to formalize blood support agreements with other DoD Blood Donor Centers. Facilities may also establish contracts for blood product purchasing and donor infectious disease testing.

5.2. Civilian Blood Donor Centers Collecting Blood on Military Installations.

5.2.1. Since the government expends resources (e.g. work-hours and utility/maintenance costs) when civilian blood agencies collect blood in AF facilities or on federal installations, MOUs must include a provision requiring the civilian agency to grant credits per donor collected. The credits can be exchanged for blood products or services, at no cost to the AF, in exchange for access to donors and facilities. Blood products or services obtained through a MOU may be used within the Military Health Service or provided to the VA IAW Paragraph 1.4.10.

5.2.2. Each civilian blood agency must have a MOU in order to collect blood donors on an AF installation. MOUs for civilian blood drives will be coordinated through and approved by the Installation Commander, the Base Blood Program Officer, and the AFBP. (T-1). The civilian collection agency must be registered with the FDA as a legal blood collecting organization.

5.2.3. The Base Blood Program Officer should contact the AFBP early in the MOU process so that guidance, standardized template and a checklist may be provided.

5.2.4. If more than one civilian blood collecting agency requests access to a military base, the civilian agencies will be granted equal access.

5.2.5. When multiple civilian agencies and/or military Blood Donor Centers are performing blood drives at an installation, the blood drive schedules must be de-conflicted and priority must be given to the military Blood Donor Center.

5.2.6. MOUs must include the requirements from ASD(HA) Revised Policy Letters 04-015 and 04-019. The MOUs do not need to include components of these policies that are already addressed in FDA regulations.

5.2.7. The MOU must be reviewed, approved and signed by the AFBP. The MOU should be sent to the AFBP for review prior to routing for official signature.

5.2.8. MOUs should be reviewed and negotiated to obtain the best return rate for the AF. The desired accumulation rate for credit-based MOUs is a ratio of no greater than one credit for every five donors collected. Facilities may develop other agreements (e.g. standing blood product shipment or other arrangements) as long as the value to the AF approximates the desired one-to-five ratio.

5.2.9. If MOUs are established on a credit basis:

5.2.9.1. MOUs should address credit management so as to avoid high credit balances.

5.2.9.2. The MOU should attempt to establish mutually agreeable credit balances and define outlets for credit use to keep the credit balances at or below the established level. Refer to Paragraph 3.4 of this instruction for distribution priorities.

5.2.9.3. The MOU should address annual carry-over of credits, specifying the balance permitted to carry-over.

5.2.9.4. Credits will only be used to obtain blood products, blood bank reference laboratory services or autologous/therapeutic collection services.

5.2.9.5. Terms of the MOU will allow one year expiration of outstanding credits following termination or expiration of the MOU.

5.2.10. These MOUs will not be used to barter for equipment, donor recruitment incentives nor education or training expenses.

5.2.11. The military treatment facility will track civilian collection numbers, credits earned, credits used and/or appropriate delivery of standing shipments IAW the agreement and local policy for accountability.

5.2.12. MOUs will be reviewed annually by the Base Blood Program Officer and the civilian agencies to ensure terms remain acceptable. Documentation of the review should be performed in accordance with local base policy and maintained locally.

5.3. Recovered Blood Product Programs.

5.3.1. Recovered Blood Product programs must be operated under a Memorandum of Agreement (MOA) with the military treatment facility commander or director and the AFBP as signatories.

5.3.1.1. The MOA must include a statement that the facility is not obligated to ship recovered blood products to the vendor.

5.3.1.2. The MOA should be reviewed periodically to compare the reimbursement rate to industry standard to ensure best value.

5.3.2. The facility will establish and maintain a documented system to track all recovered blood product shipments and appropriate vendor reimbursement.

5.3.3. Vendor payments will be mailed to the Blood Donor Center or Transfusion Service. The Blood Donor Center or Transfusion Service will deliver the check to the military treatment facility budget office for deposit in the Responsibility Center/Cost Center that generated the funds.

5.3.3.1. When funds are generated by a Blood Donor Center, the first priority for expenditure should be to support the mission of the Blood Donor Center through purchase of blood donor incentive items (e.g. T-shirts, coffee mugs, pens).

5.3.3.2. Procurement of donor incentive items is authorized in AFI 41-209, Medical Logistics Support.

5.4. Other DoD Blood Donor Centers Collecting Blood on AF installations.

5.4.1. Army or Navy Blood Donor Centers should request permission to collect donors on AF installations where regional AF Blood Donor Centers are not able to collect donors. The

request should go through the AFBP first to ensure the Blood Donor Center is not adversely competing with a regional AF Blood Donor Center. Installation commanders must allow DoD-affiliated Blood Donor Centers to have priority over civilian blood collecting organizations to meet DoD healthcare requirements. DoD Blood Donor Centers should coordinate with the local Base Blood Program Officer to de-conflict blood donation schedules.

5.4.2. The CONUS military treatment facilities located near Army, Navy or Air Force Blood Donor Centers are encouraged to negotiate formal agreements for blood inventory support. When primary blood product support is rendered by another service, the AF base donor population should be made available to the supporting facility. Support agreements must be reviewed and signed by the AFBP.

5.5. Contracts for Blood Product Purchasing.

5.5.1. Blood product costs specified in the contract should be no greater than the prevailing rates charged in the local community.

5.5.2. When a military treatment facility has a MOU whereby blood credits are accrued for donations by military members, those credits should be expended prior to purchasing blood products from civilian facilities.

5.5.3. Facilities remain accountable to the procurement priorities outlined in Paragraph 3.3 of this instruction.

5.6. Contracts for Donor Infectious Disease Testing.

5.6.1. To support increased economies of scale and overall decreased cost to the AF, before a Blood Donor Center enters a contract with a civilian laboratory for donor infectious disease marker testing, the contracted cost-per-donor should be compared to the AF donor testing reference laboratory's cost-per-donor (per current published cost-per-donor charge) and also to other civilian laboratories to ensure best value for the AF.

5.6.2. The contracted testing laboratory must be FDA-licensed and AABB-accredited.

5.6.3. The contract should specify the maximum result turnaround time to ensure that collected blood will be available for priority shipment to Armed Services Whole Blood Processing Laboratories or immediate local use.

5.7. Wartime Contract Restrictions . It is not permitted to use contractual or any other arrangements made by individual facilities with civilian sector organizations to provide blood products in support of the emergency, mobilization and wartime blood program unless approved by the AFBP and supported by a signed MOU.

Chapter 6

AIR FORCE BLOOD PROGRAM READINESS FUNCTIONS

6.1. Overview. The AFBP supports war and contingency blood product requirements. The AFBP also responds to homeland defense contingencies and public health emergencies by supporting civilian authorities when directed by authorized government authorities within the DoD chain of command.

6.1.1. Detailed information related to AFBP readiness operations can be found in DoDD 6480.4 and AFI 44-118.

6.1.2. The Federal Emergency Management Agency created the National Blood Program to meet the nation's need for blood, blood components, derivatives and plasma expanders in the event of mobilization or national emergency. The AFBP will coordinate AF Blood Donor Centers support of the National Blood Program and national emergencies when directed by the Armed Services Blood Program Office.

6.1.3. The Armed Services Blood Program Office is responsible for activation of contingency blood product, equipment and supply procurement contracts when necessary to support increased mission requirements or when the need for blood products exceeds DoD's ability to supply required products.

6.2. Blood Readiness Elements/Functions . Additional details for these functions can be found in AF Tactics, Techniques and Procedures 3-42.711, Blood Support Operations

6.2.1. Blood Donor Centers provide blood and blood products in support of peacetime and wartime contingencies. Blood Donor Centers can collect, manufacture, and ship red blood cells; Fresh Frozen Plasma; Cryoprecipitate; Plasma Frozen within 24 hours of phlebotomy; Apheresis Platelets; Apheresis Fresh Frozen Plasma; and Red Blood Cells destined for freezing. The Blood Donor Center is typically a fixed facility under the operational control of the military treatment facility commander or director at the installation where the Blood Donor Center is located.

6.2.2. Armed Services Whole Blood Processing Laboratories (ASWBPLs). The ASWBPLs serve as the central receiving and shipment points in the CONUS for blood shipments from the Blood Donor Centers. There are two: one located at Joint Base McGuire-Dix-Lakehurst, New Jersey (ASWBPL –East), and one at Travis AFB, California (ASWBPL –West), to facilitate blood shipments to military treatment facilities in CONUS and around the world. They are operationally controlled by the AFBP and are capable of expanding operations to meet blood support requirements as necessary.

6.2.3. Expeditionary Blood Support Centers. The Expeditionary Blood Support Center is a deployable laboratory team that must be co-located with an AF Theater Hospital or equivalent Joint Deployed Medical Facility. The Expeditionary Blood Support Center cannot operate in a stand-alone environment. The Expeditionary Blood Support Center team expands blood support capabilities for emergency trauma situations by manufacturing apheresis platelets and fresh whole blood units. The team is operationally controlled by the AF Theater Hospital /Joint Deployed Medical Facility commander.

6.2.4. Expeditionary Blood Transshipment Centers. The Expeditionary Blood Transshipment Center provides the capability to receive, store and ship blood products in a theater of operation. They are normally located at major airfields, with one or more assigned within a Combatant Command. Expeditionary Blood Transshipment Centers are operationally controlled by the Combatant Command Joint Blood Program Officer.

6.2.5. Frozen Blood Product Teams. The Frozen Blood Product Team provides coverage to support the processing of pre-positioned frozen blood stocks. When liquid red blood cells are unavailable or below minimum advisable inventory levels, the team thaws and deglycerolizes stockpiled frozen red blood cells for mass casualty, disaster relief or humanitarian assistance operations. The deglycerolized liquid red blood cells produced are suitable for transfusion for 14 days and provide the blood units needed to sustain patient care until the liquid pipeline is fully operational.

6.2.6. Transfusion Services. Transfusion Services are part of the military treatment facility's Laboratory operations. During times of disaster or contingencies, Transfusion Services should follow guidelines outlined in their local medical contingency response plan.

DOROTHY A. HOGG
Lieutenant General, USAF, NC
Surgeon General

Attachment 1**GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION*****References***

AFI 36-815, *Absence and Leave*, 8 July 2015

AFI 41-209, *Medical Logistics Support*, 6 October 2014

AFI 44-102, *Medical Care Management*, 17 March 2015

AFI 44-118, *Operational Procedures for the Armed Services Blood Program Elements*, 1 September 2007

AFI 48-123, *Medical Examinations and Standards*, 5 November 2013

AFI 65-601V1, *Budget Guidance and Procedures*, 16 August 2012

AFMAN 41-111_IP, *Standards for Blood Banks and Transfusion Services – 31st Edition*, 1 April 2018

AFPD 44-1, *Medical Operations*, 9 June 2016

AFTTP 3-42.711, *Blood Support Operations*, 19 April 2013

DoD 5500.07-R, *The Joint Ethics Regulation, Logistical Support of Non-Federal Entity Events*, 30 October 2012

DoD Instruction 6480.4, *Armed Services Blood Program Operational Procedures*, 13 August 2012

FDA Compliance Policy Guide, *Blood Donor Classification Statement, Paid, or Volunteer Donor Sec. 230.150*, 1 November 2011

ASD(HA) Revised Policy 04-015, *Standardization of Infectious Disease Reporting Requirements for Civilian Blood Agencies Collecting Blood on Military Installations, at Military Leased Facilities or Aboard Ships*, 21 June 2004

ASD(HA) Revised Policy 04-019, *Regarding Civilian Blood Collections on Military Installations, Leased Facilities and Aboard Ships*, 10 August 2004

ASD(HA) Policy 10-002, *On the Use of Non-U.S. Food and Drug Administration Compliant Blood Products*, 19 March 2010

Title 21, Code of Federal Regulations, Parts 200-299 and Parts 600-680

Prescribed Forms

Standard Form 518, *Blood or Blood Component Transfusion Request*, Sep 92

AF Form 1224, *Blood Transfusion Reaction Investigation*, 20040819 V1

Adopted Forms

AF Form 847, *Recommendation for Change of Publication*

Abbreviations and Acronyms

AF—Air Force

AFB—Air Force Base

AFI—Air Force Instruction

AFBP—Air Force Blood Program

AFMAN—Air Force Manual

AFPD—Air Force Policy Directive

AF/SG—Air Force Surgeon General

AFTTP—Air Force Tactics, Techniques and Procedures

ASD(HA)—Assistant Secretary of Defense for Health Affairs

ASWBPL—Armed Services Whole Blood Processing Laboratory

CFR—Code of Federal Regulations

cGMP—Current Good Manufacturing Practices

CONUS—Continental United States

DoD—Department of Defense

DoDD—Department of Defense Directive

FDA—Food and Drug Administration

IAW—In Accordance With

MAJCOM—Major Command

MOU—Memorandum of Understanding

MPS—Military Personnel Section

O&M—Operational and Management

POM—Program Objective Memorandum

QA—Quality Assurance

SAF/MR—Secretary of the Air Force for Manpower and Reserve Affairs

SF—Standard Form

SG—Surgeon General

VA—Department of Veterans Affairs

Terms

AABB—A scientific and technical group, formerly named the American Association of Blood Banks, that establishes policy and standardizes procedures for the field of blood banking, including donor collections and transfusion services. Membership and inspections recognize high technical

and administrative competence. AABB represents the “gold standard” of quality patient care and customer service.

Air Force Blood Program (AFBP)—The Blood Program operated for the Air Force Surgeon General. This function is located within the Air Force Medical Operations Agency. The Chief, Air Force Blood Program directs the peacetime and wartime operation of the program worldwide.

Area Blood Program Office—A tri-service staffed office responsible for joint blood product management in an assigned geographic area within a unified command.

Armed Services Blood Banking Center—A tri-service staffed facility responsible for collecting and processing blood products. The Air Force is the executive agent for the Armed Services Blood Banking Center located at Joint Base San Antonio.

Armed Services Blood Program—The combined military blood programs of the individual services including unified and specified commands in an integrated blood products support system.

Armed Services Blood Program Office—A tri-service staffed DoD field operating agency responsible for coordinating the military blood programs and related blood activities of the military departments, the unified and specified commands, various federal, civilian, and allied military agencies. Armed Services Blood Program Office is chartered by the DoD to monitor the policies established by the Assistant Secretary of Defense for Health Affairs.

Armed Services Whole Blood Processing Laboratory (ASWBPL)—A tri-service staffed facility that is responsible for receipt and reprocessing of blood products from the CONUS blood donor centers, and shipment of these products to designated unified command blood transshipment centers. The Air Force is the executive agent for all ASWBPLs.

Blood Donor Center—Component staffed the CONUS agencies responsible for collecting and processing of blood products. Processed blood will be shipped from the Blood Donor Center to the ASWBPL. Blood Donor Centers may be collocated within a blood bank.

Food and Drug Administration—The FDA Division of Blood and Blood Products establishes blood banking regulations and requirements for use by blood banks involved in interstate commerce (shipping blood and blood products across state lines), and grants licenses to blood banks that comply with those standards. The FDA considers blood as a manufactured drug. The military departments comply with these standards and each service Surgeon General holds an FDA license for the respective service’s blood banks.

FDA-Biological Product Deviation—Reportable errors occur when an event takes place during the collection, processing, testing and/or labeling of blood products that affect the safety, purity or potency of the blood product and the blood product was distributed (“distributed” is further defined as “the biological product has left the control of the licensed manufacturer or unlicensed blood establishment”).

Fresh Frozen Plasma—Plasma is the straw colored liquid obtained when separating red blood cells from whole blood. In peacetime, blood banks freeze and store this product for no more than one year at -18C or colder. For contingencies, military blood banks extend the shelf life to three years.

Joint Blood Program Office—A tri-service staffed office responsible for overall joint blood product management in a unified command theater of operations.

Maximum Surgical Blood Ordering Schedule—A hospital approved list of recommended blood ordering practices by procedure based on national blood use averages. Adherence to the Maximum Surgical Blood Ordering Schedule prevents over utilization of limited blood bank resources and better manages blood inventory for when it is truly is needed.

Medical Treatment Facility—A facility established for the purpose of furnishing medical and/or dental care to eligible individuals.

Memorandum of Agreement (MOA)—A type of intra-service, intra-agency, or inter-agency agreement between two or more parties, which includes specific terms that are agreed to, and commitment by at least one party to engage in action. It includes either a commitment of resources or binds a party to a specific action.

Memorandum of Understanding (MOU)—A type of intra-service, intra-agency, or inter-agency agreement between two or more parties, which includes only a general understanding between the parties. It neither includes commitment of resources nor binds a party to a specific action.

Platelet Concentrates—Platelets are cellular fragments in the blood that assist in blood clotting. Platelet concentrates are separated from whole blood by centrifugation and are stored at room temperature for up to five days with gentle agitation, or at -80C for two years.

Red Blood Cells—Red Blood Cells are the oxygen carrying component of whole blood. Red Blood Cells are separated from whole blood by centrifugation or sedimentation and removal of residual plasma.

Type and Crossmatch—A blood bank procedure to determine the ABO and Rh groups of a patient and the serologic compatibility test with a donor unit of red cells to ensure safe transfusion. A Type and Crossmatch procedure is used when the probability of actual blood usage is high.

Type and Screen—A blood bank procedure to determine ABO and Rh groups of a patient and the antibody screen to determine if the patient has any unusual antibodies that might complicate finding a compatible unit of red blood cells. A Type and Screen procedure is used when the probability of actual blood usage is low.

Attachment 2—FACILITY FDA REGISTRATION AND LICENSE NUMBERS

Table A2.1—Facility FDA Registration and License Numbers. Refer to this information to determine the manufacturer of a specific blood product or the site specific FDA registration number. The Air Force Blood Program FDA license number is 610.

Facility or Unit Name	International Society of Blood Transfusion-128 Facility Code	Food and Drug Administration Registration Number
81st Medical Group Keesler AF, MS	W0017	1077548
Armed Services Blood Banking Center-San Antonio Joint Base San Antonio TX	W0013	1677552
88th Medical Group Wright Patterson AFB OH	W0016	1577551

ASWBPL-East Joint Base McGuire-Dix-Lakehurst NJ	W0001	2277553
ASWBPL-West Douglas B. Kendrick Blood Processing Laboratory Travis AFB CA	W0002	2951520
Air Force Special Operations Command (For Low Titer Whole Blood Program)	W0029	N/A
59th Medical Wing Joint Base San Antonio TX	N/A	3012374081
779th Medical Group Joint Base Andrews MD	N/A	1177549
673d Medical Group Joint Base Elmendorf-Richardson AK	N/A	3020816
60th Medical Group Travis AFB CA	N/A	2977555
99th Medical Group Nellis AFB NV	N/A	2951185
96th Medical Group Eglin AFB FL	N/A	1052138
633d Medical Group Langley AFB VA	N/A	1177774
432nd Medical Group Misawa AB, JA	N/A	9612293
51st Medical Group Osan AB ROK	N/A	9613030
48th Medical Group RAF Lakenheath UK	N/A	9612214
374th Medical Grp Yokota AB JA	N/A	9612177
31st Medical Grp Aviano AB Italy	N/A	9614827
39th Medical Group Incirlik AB Turkey	N/A	3012251962