



## DoD INSTRUCTION 6480.04

### ARMED SERVICES BLOOD PROGRAM

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<b>Originating Component:</b>	Office of the Under Secretary of Defense for Personnel and Readiness
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<b>Reissues and Cancels:</b>	DoD Instruction 6480.04, "Armed Services Blood Program Operational Procedures," August 13, 2012, as amended
<b>Incorporates and Cancels:</b>	See Paragraph 1.3.
<b>Approved by:</b>	Gilbert R. Cisneros, Jr., Under Secretary of Defense for Personnel and Readiness

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**Purpose:** In accordance with the authority in DoD Directive (DoDD) 5124.02, the Deputy Secretary of Defense approval of the May 27, 2014 Under Secretary of Defense for Personnel and Readiness (USD(P&R)) Action Memorandum, and the August 7, 2018 Assistant Secretary of Defense for Health Affairs (ASD(HA)) Memorandum, this issuance:

- Establishes policy, assigns responsibilities, and provides procedures for the provision of blood and blood products during peacetime and across the range of military operations (ROMO).
- Establishes the Defense Health Agency (DHA) as the DoD Component responsible for the operational management and support of the Armed Services Blood Program (ASBP).
- Incorporates DoD guidance regarding the use of non-U.S. Food and Drug Administration (FDA) compliant blood and blood products.
- Establishes the requirement for whole blood donor screening of Service members deploying for more than 30 days outside the United States.

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## SECTION 1: GENERAL ISSUANCE INFORMATION

### 1.1. APPLICABILITY.

This issuance applies to:

- a. OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff (CJCS) and the Joint Staff, the Combatant Commands (CCMDs), the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the “DoD Components”).
- b. The procurement of blood and blood products by the ASBP from sources outside the DoD, when expressly required for military use.
- c. Research and development programs devoted to progress and improvement in support of the ASBP, including DoD-civilian partnerships.

### 1.2. POLICY.

- a. The ASBP is comprised of the integrated blood and blood product support systems and operational elements of the DHA, Military Services, and the CCMDs.
- b. All ASBP-sponsored blood donations must take place on installations, in facilities, or aboard ships operated or leased by the DoD or Federal Government.
- c. The National Blood Exchange may be used for the transfer of blood and blood products to and from civilian facilities.
- d. Pre-deployment whole blood donor screening, as outlined in Paragraph 3.5., directly supports force health protection. Among other measures, it promotes the fielding of a healthy and fit force and improves the provision of medical care to injured Service members, including the delivery of time-sensitive walking blood bank operations supported by Service members who donate blood on a voluntary basis.
- e. The DoD will adhere to current good manufacturing practices and standards published by the FDA and the Centers for Medicare and Medicaid Services, and sustain regulatory compliance through agencies such as the Association for the Advancement of Blood and Biotherapies (AABB), the Joint Commission, and the College of American Pathologists.
- f. Transfused blood and blood products will be FDA-compliant, with the following exceptions:
  - (1) The use of blood and blood products under a force health protection program pursuant to an emergency use authorization (EUA) or investigational new drug application and in accordance with DoD Instruction (DoDI) 6200.02.

(2) In medical emergency situations, in accordance with Section 610.40(g) of Title 21, Code of Federal Regulations, permitting the release of properly labeled blood products before completion of required testing. This includes circumstances when FDA-compliant blood is not readily available (e.g., at medical treatment facilities (MTFs) located overseas) and during scenarios in which non-FDA compliant blood may be the only alternative during combat operations or mass casualty events.

g. ASBP activities will comply with Health Insurance Portability and Accountability and Privacy Act requirements as outlined in DoDI 6025.18, DoDI 5400.11, and Section 552a of Title 5, United States Code, as amended.

### **1.3. INCORPORATES AND CANCELS.**

a. Pursuant to the Deputy Secretary of Defense approval of the May 27, 2014 Under Secretary of Defense for Personnel and Readiness (USD(P&R)) Action Memorandum, DoDD 6000.12E, which designated the Secretary of the Army as the Executive Agency for the ASBP, is hereby cancelled.

b. Applicable policy and responsibilities previously in DoDD 6000.12E pertaining to the ASBP, medical manpower, military medical training, and medical logistics have been provided for in DoDD 5136.01, DoDIs 1322.24, 6000.13, 6000.19, and 6430.02, and this issuance.

## SECTION 2: RESPONSIBILITIES

### 2.1. ASD(HA).

Under the authority, direction, and control of the USD(P&R), the ASD(HA):

- a. Advises the USD(P&R) on all matters related to blood and blood products.
- b. Plans, programs, budgets, and executes the development and fielding of new technologies and programs to support this issuance.
- c. Manages and oversees all medical policies, plans, programs, and systems related to the administration of blood and blood products.
- d. Develops policy related to blood and blood products and the Armed Services Blood Program.
- e. Makes final determination of whether blood donor screening, blood collection, and manufacturing of blood products of partner nations is comparable to U.S. blood products standards.

### 2.2. DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT (DASD(HRP&O)).

Under the authority, direction, and control of the ASD(HA), the DASD(HRP&O):

- a. Provides oversight for the implementation of this issuance.
- b. Identifies the capability gaps of current blood technologies and programs and, through the Defense Health Program (DHP), supports research, development, testing, and evaluation programs to support DoD blood and blood products policy.
- c. Specifies key force health protection elements, reporting frequency, and measures of success for ASBP quality assurance (QA) and policy compliance in accordance with DoDI 6200.05.
- d. Coordinates on DoD Component requests for:
  - (1) The EUA of unapproved blood and blood products to the FDA in accordance with DoDI 6200.02.
  - (2) The use of blood products and donor testing services classified as investigational new drugs and when required by the FDA.
  - (3) The designation of partner nation blood and blood products as comparable to U.S. products, as outlined in Paragraph 3.3.k.

e. Coordinates ASBP support for homeland defense contingencies and public health emergencies pursuant to DoDD 3025.18 and DoDI 3025.24.

f. Develops and updates guidance based upon reporting summaries received from the ASBP, as necessary.

### **2.3. DIRECTOR, DHA**

Under the authority, direction, and control of the USD(P&R), through the ASD(HA), the Director, DHA:

a. Manages the ASBP in accordance with:

(1) Policies developed by the ASD(HA).

(2) Plans, programs, standards, and procedures developed by the ASBP Division (ASBPD).

b. Monitors and submits ASBP quality performance metrics to the DASD(HRP&O).

c. Must update current policy and procedures of the ASBP as follows:

(1) Develops and publishes a DHA-publication within 6 months of this issuance's effective date with guidance for implementing the ASBP policy outlined in this issuance, to include direction on implementing standardized, pre-deployment whole blood donor screening for all Service members, both Active and Reserve Component, as specified in Paragraph 2.3.m.

(2) In coordination with the Secretaries of the Military Departments, revises the current editions of ASBP technical manuals (TMs) as DHA multi-Service regulations.

d. Pursuant to the November 13, 2020 ASD(HA) Memorandum and in coordination with the Military Department Surgeons General, ensures FDA compliance (as the designated FDA authorizing official) for all ASBP activities.

(1) Maintains three separate FDA licenses or registrations for all DoD blood collection and transfusion facilities. Each FDA license or registration applies to a group of Military Department-aligned facilities that the Service blood program officers (SBPOs) support as outlined in Paragraph 2.4.e.

(2) Communicates with the FDA on matters pertaining to licensed and registered facilities.

e. Develops and publishes ASBP blood policy letters and DHA publications, in collaboration with the other DoD Components, for implementing this issuance and related ASBP policies.

f. Ensures blood donor centers (BDCs) meet or exceed the ASBP assigned blood product quotas and provide those blood products to the Armed Services Whole Blood Processing Laboratory (ASWBPL) on a scheduled basis, as coordinated by the SBPOs.

g. Maintains and implements a lookback program in accordance with regulatory and DHA guidance that provides the capability to notify former blood recipients or donors that they may have received or donated blood or blood products that have been compromised.

h. In coordination with the Office of the Joint Staff Surgeon (OJSS) and the Command Surgeons of CCMDs with geographic areas of responsibility (AORs), the United States Special Operations Command (USSOCOM), and the Military Departments, develops guidance for:

(1) The use of newly approved blood and blood products.

(2) The use of blood and blood products under an EUA following a Declaration of Emergency by the Secretary of Health and Human Services, in accordance with DoDI 6200.02.

(3) The collection, transfusion, reporting, and follow-up of non-FDA compliant blood and blood products collected during contingency operations.

i. Appoints the ASBPD Chief to serve a 4-year tour based on nominations from the Military Departments. The position will rotate sequentially among the Military Departments when there is a qualified candidate, as determined by the Director, DHA. Qualified candidates will have a diverse background in military blood programs and medical planning operations, and should be in the grade of O-5 or O-6 (O-6 recommended), with nominations of other highly qualified candidates considered on an individual basis.

j. Provides support personnel, facilities, and budgetary resources for the ASBPD, and manages Service members assigned to the organization in accordance with DoDD 5136.13.

k. Prepares and submits to the ASD(HA), through appropriate MHS governance processes and in accordance with DoDD 7045.14, resource requirements for ASBP activities funded through the DHP appropriation. This includes, but is not limited to, DHP funding for:

(1) The procurement of blood from U.S. civilian sources, including transportation and incidental expenses directly related to transportation, to either final continental United States (CONUS) destination or ASWBPL when overall military requirements exceed the capability of the DoD.

(2) The procurement of blood from host nation sources, including transportation and incidental expenses directly related to transportation, for use in DHA-administered MTFs located outside the United States.

(3) The transportation, and incidental expenses directly related to transportation, of blood and blood products collected or processed at DHA-administered BDCs and laboratories to other DHA-administered facilities and the ASWBPLs.

l. Authorizes the ASBPD Chief to liaise directly with U.S. government and civilian agencies regarding blood and blood products and to conduct in-kind exchange of these products with government and civilian agencies to support daily operations.

m. Establishes a standardized pre-deployment whole blood donor screening program for use across the DoD that includes a donor health history questionnaire and screens for transfusion transmitted diseases, blood type and, for Service members with group O blood, current anti-A and anti-B titer levels. See Paragraph 3.5. for details on pre-deployment whole blood donor screening.

n. Develops and updates clinical practice guidelines for the use of blood and blood products, including but not limited to product definitions, indications, collection, storage, testing, transfusion, and documentation.

o. Provides administrative guidance on:

(1) Planning and resource oversight of information systems supporting all ASBP elements.

(2) Collection of blood by civilian collections agencies that helps minimize the impact on the DoD military blood program in meeting its operational requirements.

(3) Donation of blood and blood products by non-DoD affiliated individuals.

(4) Use of non-FDA compliant blood and blood products transfused overseas in support of medical emergency situations, such as those encountered during combat operations and mass casualty events, or when FDA compliant blood products are not readily available.

p. Coordinates the ASBP response to homeland defense contingencies and public health emergencies pursuant to DoDD 3025.18 and DoDI 3025.24.

q. In coordination with the Military Department Surgeons General, designates a blood program officer to support the Combatant Commanders with geographic AORs (GCCs) who do not have an assigned joint blood program officer (JBPO). DHA-designated blood program officers provide support to GCCs as an additional duty.

r. Coordinates the ASBP response for the ROMO outside of the CONUS using Combatant Commander (CCDR) requirements for operational plans, contingency plans, campaign plans, and execution orders.

## **2.4. SECRETARIES OF THE MILITARY DEPARTMENTS.**

The Secretaries of the Military Departments:

a. In accordance with this issuance, establish and sustain a blood program that provides blood and blood products to MTFs under the jurisdiction of the Department of Defense, in peacetime, in deployed locations, and in support of the ROMO, to the maximum extent possible.

b. Prepare and submit program and budget requirements in support of the ASBP in accordance with DoDD 7045.14. This includes, but is not limited to:



(1) Requirements for DHP-funded activities not prepared by the Director, DHA. These requirements are coordinated with the Director, DHA, and submitted through appropriate MHS governance processes to the ASD(HA).

(2) Requirements for expeditionary capabilities, such as those identified in Paragraphs 2.5. through 2.7., that support ASBP activities in the deployed environment and are fully or partially funded by the respective Military Departments using non-DHP funds.

c. Collectively provide a minimum of three officers to staff the ASBPD. In addition to the nominative ASBPD Chief position, the Military Departments will assign another two officers serving in the Medical Service Corps (Army and Navy) or Biomedical Sciences Corps (Air Force) in the recommended grade of O-4 or O-5, with certification as blood bank specialists. All ASBP members carry out their ASBPD assignments as their primary duty.

d. Provide personnel and training to establish standardized pre-deployment whole blood donor screening programs in accordance with Paragraph 3.5. and applicable DHA guidance.

e. Appoint an SBPO, assigned to the respective Military Department, who:

(1) Serves as an FDA alternate authorizing official, accountable to the Director, DHA, for maintaining the FDA licensure or registration of blood collection and transfusion activities for designated facilities.

(2) Is authorized to communicate with the FDA and civilian blood agencies regarding these designated facilities.

## **2.5. SECRETARY OF THE ARMY.**

In addition to the responsibilities in Paragraph 2.4., the Secretary of the Army:

a. Provides appropriate support personnel, facilities, and budgetary resources to support dedicated Army medical detachment blood support (MDBS) and blood product depot (BPD) units.

b. Activates the Army MDBSs and BPDs in response to CCMD requirements validated by the Joint Staff. Coordinates activation with the requesting CCDR and notifies the Director, DHA.

c. Obtains the concurrence of the respective GCC or designated representative before closing, transferring, or deactivating an operational Army MDBS or BPD.

## **2.6. SECRETARY OF THE AIR FORCE.**

In addition to the responsibilities in Paragraph 2.4., the Secretary of the Air Force:

a. Provides appropriate support personnel, facilities, and budgetary resources to support ASWBPLs, expeditionary blood transshipment centers (EBTCs), and expeditionary blood support centers (EBSCs).

(1) Maintains at least two ASWBPLs in active status and at appropriate CONUS air terminals to process and ship blood products to CONUS and outside of the CONUS locations in support of CCMD requirements, in coordination with the CJCS and the Director, DHA.

(2) Coordinates staffing of the designated ASWBPLs by medical personnel from the Army, Navy, and Air Force, in accordance with joint staffing criteria outlined in TM 8-227-11/NAVMED P-5123/AFI 44-118.

b. Activates the EBTCs and EBSCs in response to CCMD requirements validated by the Joint Staff. Coordinates activation with the requesting CCDR and notifies the Director, DHA.

c. Obtains concurrence of the respective CCDR or designated representative before closing, deactivating, or transferring an EBTC or EBSC.

d. Coordinates with the CJCS and Director, DHA, before closing, transferring, or deactivating an ASWBPL.

## **2.7. SECRETARY OF THE NAVY.**

In addition to the responsibilities in Paragraph 2.4., the Secretary of the Navy:

a. Provides appropriate support personnel, facilities, and budgetary resources to support dedicated Navy BPDs.

b. Activates the Navy BPDs in response to CCMD requirements validated by the Joint Staff. Coordinates activation with the requesting CCDR and notifies the Director, DHA.

c. Obtains the concurrence of the respective GCC or designated representative before closing, transferring, or deactivating an operational Navy BPD.

## **2.8. CJCS.**

The CJCS:

a. In coordination with the Director, DHA, provides guidance to the CCDRs on all matters of blood support in joint operations both for planning and execution, in accordance with CJCS Manual 3122.03.

b. Through the OJSS, and on behalf of the CCDRs concerned, coordinates with and advises the ASD(HA) on the activation of ASBP capabilities that provide blood and blood products support.

## 2.9. GCCS.

The GCCs:

- a. Direct their respective subordinate commands to proactively forecast the blood and blood product requirements of medical elements within their area of responsibility, and manage and order blood products as needed.
- b. Ensure blood program policies are followed and joint doctrine is used in accordance with joint guidance (e.g., Joint Publication 4-02).
- c. If assigned, appoint the JBPO to serve as the single integrated medical logistics manager for joint blood operations. The JBPO advises the CCMD Command Surgeon on all matters concerning theater blood operations and exercises responsibility for managing, with assistance from the ASBPD, the GCC's blood program. For GCCs without an assigned JBPO, designated blood program officers provide support for theater blood operations as outlined in Paragraph 2.3.q.
- d. Implement theater lookback policies in accordance with the most current ASBP blood program letters. Lookback procedures provide the capability to notify blood recipients or donors, while in theater, that they may have received or donated blood or blood products that have been compromised.
- e. Maintain a robust blood program throughout the area of responsibility, as demonstrated by involvement in exercises, support for contingency operations, and participation in ASBPD sponsored programs and activities.
- f. Establish blood and blood product requirements for inclusion in GCC operational plans by applying current casualty rates for forces at risk and appropriate planning factors outlined in Paragraph 3.7.
- g. Establish agreements with partner nations for blood and blood product acquisition in coordination with the CJCS and the Director, DHA.
- h. Use the DoD's designated, centralized repository for operational health records (e.g., Theater Medical Data Store) for blood and blood product management, including pre-screening results, inventory, donor, and transfusion tracking.
- i. Develop supporting policy on the management and administration of blood and blood products within their respective areas of responsibility.
- j. Establish procedures, as required, for the use of partner nation blood and blood products when FDA compliant blood and blood products are not readily available. Procedures will be coordinated with the Director, DHA and the CJCS.

## **2.10. COMMANDER, UNITED STATES TRANSPORTATION COMMAND.**

The Commander, United States Transportation Command:

- a. Coordinates transportation of blood and blood products from the ASWBPLs to the CCMD-designated aerial ports of debarkation.
- b. Provides sufficient airlift in the quantity and frequency to meet the blood and blood product delivery requirements of the GCC concerned.

## **2.11. COMMANDER, USSOCOM.**

The Commander, USSOCOM:

- a. Establishes procedures, as required, for the use of partner nation blood and blood products when FDA compliant blood and blood products are not readily available. Coordinates procedures with the Director, DHA; CJCS; and the GCCs concerned.
- b. Establishes agreements with partner nations for blood and blood product acquisition in coordination with the CJCS; Director, DHA; and GCCs concerned.
- c. In coordination with the Director, DHA, maintains contingency blood support at designated MTFs in support of rapid deployment requirements.
- d. Establishes procedures for the Low-Titer O Whole Blood Program in coordination with the Director, DHA.

## SECTION 3: ASBP ACTIVITIES

### 3.1. GENERAL PROVISIONS.

a. In accordance with regulatory guidance, all blood collection and transfusion facilities will be licensed or registered by the FDA.

b. The ASBPD, with the support of the SBPOs, maintains oversight of civilian blood agency collections on military installations.

c. Blood collection and transfusion facilities will maintain AABB accreditation.

d. The DHA maintains a comprehensive, enterprise-level blood QA program in accordance with FDA regulations, current good manufacturing practices, and accreditation requirements. Supported by QA officers assigned to the DHA and Military Departments, the QA program outlines the responsibilities for the overall quality of the finished product and the authority to control the processes that may affect this product.

e. The readiness posture of the ASBP will be maintained through:

(1) A robust voluntary donor program.

(2) Collection, manufacture, and testing of the essential range of blood products.

(3) Blood product manufacturing.

(4) QA.

(5) Logistics.

(6) Transfusion training programs.

(7) An FDA-approved information management system that meets functional and regulatory requirements for FDA-registered facilities.

(8) An information management system to support joint force operational units.

(9) Dedicated support of a blood and materiel research and development program, and active involvement in joint exercises.

(10) Blood donor testing capability, supported by Armed Services Blood Bank Centers (ASBBCs) or civilian contracted donor testing services.

f. ASBP operational procedures are described in detail in TM 8-227-11/NAVMED P-5123/AFI 44-118 and supporting DHA publications.

### **3.2. BLOOD COLLECTION, DISTRIBUTION, STORAGE, AND TRANSFUSION.**

a. ASBP BDCs and ASBBCs collect whole blood and blood products worldwide.

b. All civilian blood collections on installations, in leased facilities, or aboard ships as specified in Paragraph 1.2.b. will be managed through memoranda of agreement developed between the civilian blood collection agency and the commander or commanding officer allowing the civilian blood collection agency to operate in their area of responsibility. Memoranda of agreement must be reviewed and approved by the ASBPD or designated SBPO.

c. Blood and blood products manufactured by BDCs must be distributed in the following priority order:

(1) ASWBPLs in support of military or contingency operations.

(2) Special operations and rapid deployment blood support to MTFs.

(3) DoD MTFs to support patient transfusion requirements.

(4) Veterans Affairs, local government, or civilian hospitals, through either the National Blood Exchange or memoranda of agreement, when excess products are available and specific needs are identified.

d. When a BDC is unable to meet the assigned blood product quota, SBPOs coordinate with the BDC to procure needed blood products, if available, from other BDCs or civilian agencies such as the National Blood Exchange, administered by the AABB, or other U.S. blood centers, such as the American Red Cross or America's Blood Centers.

e. In support of blood collections, BDCs may use appropriated funds to purchase:

(1) Light refreshments and beverages for the express purpose of preventing adverse donor reactions.

(2) Low-cost incentive items (e.g., t-shirts, coffee mugs, pens, water bottles) to encourage voluntary donations and help maintain adequate military blood supply. Items purchased must convey an appropriate promotional message intended to compel blood donations. Items may not be personalized.

f. Blood and blood products are pre-positioned at various locations worldwide including specified Navy ships in accordance with current blood program letter.

g. Medical logistics support of the blood mission is implemented pursuant to DoDI 6430.02. All relevant organizations will provide logistics support (e.g., transportation, medical and non-medical supply, equipment, maintenance support) to the ASBP in accordance with applicable logistics policy and as required by the mission.

h. In accordance with Volume 12, Chapter 23 of DoD 7000.14-R and applicable guidance, DoD Components will document all applicable blood program costs incurred in support of the

ROMO, from peacetime civil emergencies occurring within the United States to contingency operations outside the United States, in their accounting systems for the purpose of differentiating between baseline blood program costs and costs attributable to civil emergencies and contingency operations.

i. In support of ASBP operations, the Military Departments:

(1) Provide personnel for the ASWBPLs, in accordance with staffing requirements outlined in TM 8-227-11/NAVMED P-5123/AFI 44-118.

(2) Provide personnel for ASBBCs, through Service memorandums of understanding or applicable DHA publications.

(3) Provide resources for training enlisted medical providers to draw whole blood and administer blood and blood products in accordance with the standardized tactical combat casualty care curriculum approved by the DHA, Joint Trauma System, and located on the deployed medicine website at <https://deployedmedicine.com/>.

(4) Coordinate with the ASBPD, through their respective SBPOs, to report blood inventory and data elements of blood management, including blood transfusions and blood donation.

j. BDCs may enter into written agreements with civilian vendors for the purpose of selling salvaged blood products (e.g., recovered plasma). The supporting DoD contract attorney and DoD Component comptroller concerned must review agreements before they are executed.

(1) Agreements must clearly state that proceeds from the sale of blood products to the civilian vendor will be credited to the supporting MTF's operations and maintenance appropriation.

(2) To encourage increased numbers of blood donor volunteers, proceeds from the sale of salvaged blood products will be credited to the BDC's cost center and applied to the purchase of low cost incentive items.

### **3.3. ASBPD FUNCTIONS.**

The ASBPD:

a. Functions as the DoD direct liaison for coordination and policy recommendations with the organizations listed in Paragraphs 3.3.b.(1) through 3.3.b.(4).

b. Serves as the DoD's designated office of primary responsibility for blood program support matters for U.S., DoD, North Atlantic Treaty Organization, Federal, and non-Federal civilian agencies including, but not limited to:

(1) The CCMDs.

(2) The FDA Center for Biologics Evaluation and Research, and the FDA Office of Regulatory Affairs, Office of Biological Products Operations.

(3) The U.S. Department of Health and Human Services Office of Emergency Preparedness; the National Disaster Medical System; and the Health and Human Services Advisory Committee on Blood, Organ, and Tissue Safety and Availability.

(4) The North Atlantic Treaty Organization Blood Panel.

(5) The Defense Logistics Agency for activation of contingency contracts for both medical equipment and medical supply consumables that support the ASBP.

(6) The DHA Medical Logistics Division on the development of essential characteristics of equipment, supplies, policies, and procedures associated with military blood programs.

c. Coordinates the preparation of guidelines for policy and procedural instructions to be used as minimum standards by the Military Services.

d. Coordinates the development of technical aspects of blood research programs, conveying requirements through the Research and Development Directorate, DHA to the Armed Services Biomedical Research Evaluation and Management Community of Interest, in accordance with DoDI 3216.02.

e. In consultation with the CCMDs, determines DoD emergency and mobilization blood product requirements and directs that plans are in place to meet those requirements.

f. In consultation with the CCMDs, establishes contingency blood product quotas to be maintained at the ASWBPLs and coordinates with SBPOs to meet those quotas.

g. Coordinates with the OJSS and oversees operations of the ASBP during contingencies.

h. Coordinates theater blood program issues with the appropriate CCMD Command Surgeons and the OJSS to include:

(1) Operations plan and contingency plan blood support reviews, to include sourcing of blood requirements.

(2) Pre-positioning of blood and blood products to meet contingency theater blood product requirements.

(3) Liaison initiatives with partner nation blood programs.

i. Develops guidance used by DoD facilities involved in the collection, manufacture, testing, storage, distribution, and transfusion of blood products. Such guidance is distributed by the ASBPD as blood program letters.

j. Provides public affairs and marketing support for each BDC, maintaining a program of donor motivation and education in support of the ASBP.



k. Maintains a program to evaluate partner nations' blood supplies and recommends, as necessary, to the ASD(HA) the acceptability of such partner nations' blood supplies whose blood product regulations are comparable to the FDA's.

(1) When transfused to DoD beneficiaries at non-U.S facilities, recipients of blood products manufactured in countries deemed comparable by the ASD(HA) will be exempt from the required follow-up and tracking. However, changes in a country's testing or practice that degrade or put into question whether blood products are FDA comparable will trigger a re-evaluation of deemed status.

(2) The current or potential volume of blood products transfused to U.S. personnel from countries deemed comparable should be great enough to warrant a waiver and ease the administrative burden associated with tracking. In circumstances where blood products from these countries are used before being fully tested, according to the manufacturing nation's prescribed regulations and guidelines, all recipient follow-up requirements remain mandatory.

l. Maintains a blood management tool to assist DoD blood activities (e.g., BDCs and transfusion facilities) in moving surplus blood and blood products.

m. Maintains a blood establishment computer system for transfusion services and BDCs (e.g., Enterprise Blood Management System Transfusion, Military Health System GENESIS PathNet-Blood Bank Transfusion, and Enterprise Blood Management System-Donor).

### **3.4. SBPO FUNCTIONS.**

Each SBPO:

a. Serves as the principal advisor to the respective Military Department Surgeon General on all matters related to the Service-specific blood program. Recommends, develops, and maintains Service-specific policies related to the blood program, blood, and blood products, in accordance with DoD, DHA, Service, and FDA policies.

b. Supports their respective Military Department on policies and procedures involving deployability, assignability, and employability for all blood bank activities in the deployed setting.

c. Coordinates with the ASBPD Chief, JBPOs, Area JBPOs, and counterpart SBPOs to maintain the readiness posture of the ASBP during peacetime and contingency operations and ensure the availability and supply of quality blood and blood products.

d. Serves as the FDA alternate authorizing official, accountable to the Director, DHA, for maintaining the FDA licensure or registration of blood collection and transfusion activities for designated facilities. SBPO duties as an FDA alternate authorizing official will be outlined in a support agreement between the DHA and Military Departments, prepared in accordance with DoDI 4000.19.

(1) Supports the ASBPD in maintaining an enterprise-level blood QA program in accordance with Paragraph 3.1.d.

(2) Supports lookback program activities.

e. Coordinates with the ASBPD to assign blood product quotas, based upon operational requirements, and to provide blood products to the ASWBPLs on a continuous basis to meet worldwide contingencies.

f. Coordinates BDC and transfusion service responses to accreditation and inspection agencies.

g. Implements ASBP blood program letters.

h. Serves as a participant on committees related to blood and blood products as requested by the ASBPD Chief.

### **3.5. WHOLE BLOOD DONOR SCREENING.**

a. Pre-deployment whole blood donor screening facilitates safe, time-sensitive walking blood bank activities in support of contingency operations and are sustained by Service members donating blood on a voluntary basis. DoD-wide implementation of pre-deployment whole blood donor screening will be initiated not later than 18 months after the DHA issues standardized procedural guidance pursuant to Paragraph 2.3.b.(1).

b. Pre-deployment whole blood donor screening will be required for all deployments greater than 30 days outside the United States. This requirement is specific to Service members only, in both the Active and Reserve Components. For deployments of 30 days or less outside the United States, and for operations of all durations within the United States, the requirement for whole blood donor screening will be based on health risk and the decisions of the CCDR, Service Component commander, or commander exercising operational control in consultation with the Director, DHA.

c. In accordance with standardized procedures established by the Director, DHA:

(1) Whole blood donor screening will be conducted within 120 days of deployment. For Service members who deploy more than once during a 4-month period, screening results collected within the previous 120 days will be considered current for their upcoming deployment.

(2) Whole blood donor screening will include a health history questionnaire and screen for transfusion transmitted diseases, blood type and, for Service members with group O blood, current anti-A and anti-B titer levels.

d. Whole blood donor screening results will be documented within:

(1) The ASBP-designated information system, as applicable.

(2) Theater Medical Data Store or its successor.

(3) The Service electronic tracking system for individual medical readiness requirements, the deployment health record, and the DoD health record, as appropriate, in accordance with DoDIs 6490.03 and 6040.45.

### **3.6. BLOOD REPORTING.**

#### **a. Contingency Blood Reports.**

Service operational units within a CCMD with a geographic AOR, including USSOCOM units, will report blood program operations during deployments, contingencies, or wartime. The units will use an information management system (e.g., Theater Medical Data Store), or alternatively, U.S. message text formats, or format prescribed by the ASBPD or CCMD JBPO, as appropriate.

#### **b. ASWBPL Daily Inventory Report.**

Unless notified otherwise, each ASWBPL will submit a daily inventory report to the ASBPD on Monday through Friday of each week, excluding Federal holidays.

#### **c. ASWBPL Weekly Compliance Report.**

The ASWBPLs will submit a weekly compliance report via the Air Force SBPO. This report provides information on quota compliance for each Military Service, amount of products received from civilian sources, age of blood, and frozen product breakage data.

#### **d. DoD Reportable Events (DoD REs).**

Volume 2 of DHA-Procedural Manual 6025.13 provides guidance for the implementation of the DoD Patient Safety Program (PSP), including procedures for DoD REs.

(1) All DoD REs involving blood transfusions require mandatory reporting through respective DHA Market/Intermediate Headquarters to DHA and ASD(HA) leadership in accordance with the DoD PSP.

(2) Upon notification of a DoD RE involving a blood transfusion, the DHA Market/Intermediate Headquarters will notify the DHA PSP within 24 hours of the RE. In turn, the DHA PSP will notify the ASBPD, DHA within 24 hours of their notification and provide an executive summary of the incident.

(3) When required, the ASBPD, DHA will coordinate with the designated SBPO to notify the FDA of the DoD RE and coordinate responses within the DoD and with other Federal and civilian departments and agencies, as necessary.

### **3.7. MOBILIZATION PLANNING.**

Based on medical planning factors (e.g., number of wounded in action, non-battle injury, and MTFs), CCMDs will estimate the type and numbers of blood products required using blood planning factors outlined in TM 8-227-12/NAVMED P-6530/AFH 44-152 or the most current multi-service joint blood program handbook.

## GLOSSARY

### G.1. ACRONYMS.

ACRONYM	MEANING
AABB	Association for the Advancement of Blood and Biotherapies
AFI	Air Force instruction
AOR	area of responsibility
ASBBC	Armed Services Blood Bank Center
ASBP	Armed Services Blood Program
ASBPD	Armed Services Blood Program Division
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASWBPL	Armed Services Whole Blood Processing Laboratory
BDC	blood donor center
BPD	blood product depot
CCDR	Combatant Commander
CCMD	Combatant Command
CJCS	Chairman of the Joint Chiefs of Staff
CONUS	continental United States
DASD(HRP&O)	Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight
DHA	Defense Health Agency
DHP	Defense Health Program
DoDD	DoD directive
DoDI	DoD instruction
EBSC	expeditionary blood support center
EBTC	expeditionary blood transshipment center
EUA	emergency use authorization
FDA	Food and Drug Administration
GCC	Combatant Commander with a geographic area of responsibility
JBPO	joint blood program officer
MDBS	medical detachment blood support
MTF	medical treatment facility
NAVMED	Navy medical publication

<b>ACRONYM</b>	<b>MEANING</b>
OJSS	Office of the Joint Staff Surgeon
PSP	Patient Safety Program
QA	quality assurance
RBC	red blood cell
RE	reportable event
ROMO	range of military operations
SBPO	Service blood program officer
TM	technical manual
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USSOCOM	United States Special Operations Command

## **G.2. DEFINITIONS.**

Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

<b>TERM</b>	<b>DEFINITION</b>
<b>AABB</b>	A civilian blood banking association that establishes international standards for blood banks. The AABB also publishes the “Standards for Blood Banks and Transfusion Services,” the “Technical Manual,” and the “Accreditation Manual.” These publications have been adopted for use by the DoD.
<b>anti-A and anti-B titer levels</b>	The amount of anti-A and anti-B present in the blood, as detected and measured in a blood test, and expressed as a ratio (e.g., <1:256).
<b>ASBBC</b>	A Tri-Service staffed BDC under the operational control of the designated SBPO.
<b>ASBP</b>	The combined military blood programs of the ASBPD, the individual Military Services, and the CCMDs in a single integrated blood and blood products support system for peacetime and across the ROMO.

<b>TERM</b>	<b>DEFINITION</b>
<b>ASBPD</b>	A division within the DHA responsible for coordination of the ASBP. Functions include implementation of blood program policies established by the ASD(HA), and standardization of policies, procedures, and equipment. The ASBPD provides guidance for the full array of blood and blood products (e.g., red blood cells (RBCs), platelets, fresh frozen plasma, plasma frozen within 24-hours, cryoprecipitate) collected in support of peacetime activities and across the ROMO. Formerly known as the Armed Services Blood Program Office.
<b>ASWBPL</b>	A tri-Service-staffed organization, led by the Secretary of the Air Force, responsible for central receipt and confirmation of blood products from CONUS blood banks and the further shipment of those products to designated CCMDs with geographic AORs and other MTFs.
<b>BDC</b>	May be Service (Army, Navy, Air Force) or tri-Service operated. Responsibilities include collection, processing, manufacturing, testing, and distribution of blood products. BDCs may be collocated with a blood bank in an MTF.
<b>blood policy letter</b>	A policy directive from the DHA, ASBPD to the functional blood banking community (i.e., BDCs, transfusion service activities and JBPOs) addressing regulatory or ASD(HA) requirements and the necessary steps for implementation of directives across the Military Health System.
<b>blood product</b>	Any therapeutic substance prepared from human blood, blood components, and plasma derivatives (e.g., whole blood, RBCs, fresh frozen plasma/ plasma frozen within 24 hours of phlebotomy, platelets, and cryoprecipitate).
<b>blood product planning factors</b>	Factors used in computing mobilization requirements for blood products (e.g., RBCs, fresh frozen plasma, plasma frozen within 24 hours of phlebotomy, platelets, and cryoprecipitate).
<b>blood type</b>	Any of the four main groups into which human blood is divided (A, B, AB, or O) and includes Rhesus factor, a positive or negative indicator of the presence or absence of an inherited protein on the surface of RBCs.

<b>TERM</b>	<b>DEFINITION</b>
<b>BPD</b>	A medical unit responsible for strategic storage of frozen blood products in a CCMD with a geographic AOR. Frozen blood products are provided to each CCMD component based on joint blood program instructions.
<b>Center for Biologics Evaluation and Research</b>	The FDA division responsible for establishing blood banking regulations and requirements and grants licenses and approvals to products complying with those standards.
<b>compromised blood or blood products</b>	Blood or blood components from donors subsequently found to have, or be at risk for, relevant transmissible diseases or other problems with purity, potency, or safety.
<b>deployment</b>	Defined in the DoD Dictionary of Military and Associated Terms.
<b>DoD RE</b>	Defined in Volume 2 of DHA-Procedural Manual 6025.13.
<b>EBSC</b>	An Air Force-directed element that expands blood support capabilities in-theater by providing advanced capabilities in the collection and preparation of blood components. EBSCs are not standalone and must be co-located with an Air Force theater hospital or equivalent joint MTF.
<b>EBTC</b>	An Air Force-directed blood element that provides the capability to receive, store, inventory, and ship blood products. EBTCs are normally located at major airfields, with one or more EBTCs located in an area of responsibility.
<b>enlisted medical providers</b>	U.S. Army Combat Medics, U.S. Navy Hospital and Independent Duty Corpsmen, and U.S. Air Force Aerospace Medicine and Independent Duty Medical Technicians.
<b>force health protection</b>	Defined in DoDD 6200.04.
<b>JBPO</b>	A Service-nominated field grade officer assigned to a CCMD Command Surgeon's staff and responsible as the single integrated medical logistics manager for joint blood product management in support of CCMD operations.



<b>TERM</b>	<b>DEFINITION</b>
<b>lookback</b>	A process where a BDC or transfusion service investigates and/or notifies consignees of blood or blood components from donors subsequently found to have, or be at risk for, relevant transmissible diseases or identify products that should be recalled for problems in purity, potency, or safety.
<b>medical logistics</b>	A function of the Military Health System that provides the ability to organize and provide life-cycle management of specialized medical products and logistics services required to support health readiness requirements across the ROMO. Medical logistics functions include management of medical materiel (supplies, gases, equipment, and assemblages), medical equipment and its maintenance (including medical repair parts), blood distribution, optical fabrication, medical facilities management, medical logistics services, and medical contracting.
<b>MTF</b>	Defined in the DoD Dictionary of Military and Associated Terms.
<b>National Blood Exchange</b>	A nation-wide program administered by the AABB for sharing blood and blood products within the United States.
<b>partner nation</b>	Defined in the DoD Dictionary of Military and Associated Terms.
<b>research</b>	Defined in DoDI 3216.02.
<b>ROMO</b>	Any military operation supporting DoD objectives, both inside and outside the CONUS, resulting in Service members and DoD Expeditionary Civilian personnel placed on contingency, deployment, or contingency deployment orders, including but not limited to noncombatant evacuation; homeland defense; defense support of civil authorities; foreign humanitarian assistance; disaster response; and stability operations.
<b>SBPO</b>	A Military Department-designated blood program officer responsible for coordination and management of a respective Military Service's blood program.
<b>walking blood bank</b>	The process of obtaining warm fresh whole blood (non-FDA compliant) from screened donors for emergency transfusion.
<b>wounded in action</b>	Defined in DoDI 1300.18.

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