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3000 MARINE CORPS PENTAGON
WASHINGTON, DC 20350-3000

IN REPLY REFER TO
OPNAVINST 6530.4B
MCO 6530.2
BUMED-M3/CMC-MED
13 Aug 2007

OPNAV INSTRUCTION 6530.4B
MARINE CORPS ORDER 6530.2

From: Chief of Naval Operations
Commandant of the Marine Corps

Subj: DEPARTMENT OF THE NAVY BLOOD PROGRAM

Ref: (a) DOD Directive 6000.12 of 29 Apr 1996
(b) DOD Instruction 6480.4 of 5 Aug 1996
(c) Military Blood Program (DOD Master Blood Plan) 2004 of 1992 (NOTAL)
(d) Joint Pub 4-02.1
(e) OPNAVINST 6700.2, Chapter 3
(f) OPNAVINST 6530.2D
(g) BUMEDINST 5450.165
(h) NAVMED Policy Memo 06-002 of 23 Jan 2006
(i) Title 21, Code of Federal Regulations (CFR), Parts 200 to 299, 600 to 799, and 800-899, current edition
(j) NAVMED P-5101, Technical Manual of the American Association of Blood Banks
(k) NAVMED P-5120, Standards for Blood Bank and Transfusion Services of the American Association of Blood Banks (NOTAL)
(l) NAVMED P-5123, Operational Procedures for Military Blood Donor Centers and Armed Services Whole Blood Processing Laboratories
(m) NAVMED P-6530, Armed Services Blood Program Joint Blood Program Handbook
(n) ASD(HA) Policy Memo 01-020 of 4 Dec 2001
(o) ASD(HA) Policy Memo 96-044 of 1 May 1996
(p) ASD(HA) Policy Memo 04-015 of 21 Jun 2004
(q) OASD(HA) Policy Memo of 10 May 1994
(r) OASD(HA) Policy Memo of 7 Jul 2005
(s) OPNAVINST 3710.7T, Chapter 8

Encl: (1) General Policies and Procedures for Support and Operation of the Navy Blood Program
(2) Continental United States (CONUS) Regional Blood Systems
(3) Outside the Continental United States (OCONUS) Area Blood Systems
(4) Navy Blood Program Office Responsibilities
(5) Navy Component Command Blood Program

- (6) Technical Assistant Visits Procedures and FDA Inspections
- (7) Type Commanders (TYCOMs); Commanding Officers Afloat; Commanders, Marine Corps Medical Battalion; and Commanding Officers, Medical Treatment Facility, USNS COMFORT and USNS MERCY
- (8) Navy Frozen Blood Program Technical Assist Visit (TAV) Checklist for Amphibious Assault Ships, LHA; Amphibious Assault Ship (Multi-Purpose), LHD; and Auxiliary Hospital Ship, T-AH
- (9) Navy Blood Program Donor Unit Number Blocks and FDA Registration Numbers
- (10) Navy Blood Program Abbreviations and Definitions

1. Purpose. To provide organizational and operational policies, provide procedural guidance, and fully implement the Navy's Blood Program (NPB) as required by references (a) and (b). This instruction is a complete revision and should be read in its entirety.

2. Cancellation. OPNAVINST 6530.4A.

3. Scope. Applies to all Navy and Marine Corps activities where blood (liquid or frozen) or blood components are collected, processed, stored, shipped, or transfused.

4. Background. References (a) through (e) describe the Armed Services Blood Program (ASBP) and provide general guidance for the operation and interface of the blood programs of the three uniformed services. The Secretary of the Navy is tasked with responsibility for the operation of departmental and command blood programs that ensure proper use of blood resources and enable the Navy and Marine Corps to meet mobilization and contingency requirements for blood and blood products. Overall responsibility for the NBP has been delegated to the Chief, Bureau of Medicine and Surgery (BUMED). BUMED's NBP Office, (BUMED-M3B63), is responsible for coordination and management of all NBP matters for the Chief, BUMED and the Surgeon General of the Navy (Chief of Naval Operations (CNO) (N093)).

5. Donor Support. Donor support for the NBP is addressed in reference (f). Installation commanders will, through appointed installation blood program coordinators, oversee all blood collections (military donor center operations and civilian blood agencies) on their installations or activities.

6. Organization. The NBP is a centrally managed system, coordinated to the tactical execution level via a regionalized organization. References (a) through (s) and enclosures (1) through (10) contain policies, procedures, and information for operation and support of the NBP.

a. CONUS health care facilities with blood donor centers or transfusion services are assigned into one of three regional blood systems. Enclosure (2) identifies the regional organization, area directors and components, and delineates specific command responsibilities.

b. OCONUS health care facilities with blood donor centers or transfusion services fall under a component command blood program and are assigned geographically to area joint blood systems established by the unified command's joint blood program office. Enclosure (3) identifies the regional organization and delineates specific command responsibilities regarding NBP operations.

7. Responsibilities

a. Chief, BUMED. Serves as the Responsible Head for the Navy's Food and Drug Administration (FDA) establishment license (license number 635), establishes policy and manages the collection, manufacturing, processing, distribution, transfusion or use, and disposition of all blood products within the Department of the Navy. Ensures the safety, purity, and potency of blood products through compliance with current Good Manufacturing Practices (cGMPs) of the FDA, federal regulations and guidelines, national standards, and Department of Defense (DOD) guidelines.

b. Director, Naval Blood Program Division (BUMED-M3B63). Responsible for coordination and management of all NBP matters for the Chief, BUMED and is the authorized representative to the FDA with responsibilities identified in enclosure (4). Serves as a liaison with the Armed Services Blood Program Office (ASBPO), other Service blood programs, and civilian blood banks/programs. Directs the actions of the quality assurance (QA) manager to ensure compliance with the FDA's cGMPs at all Naval medical treatment facilities (MTFs). As directed by reference (q), the QA manager is responsible for establishing a

planned, systematic approach to quality assurance to provide adequate confidence in the safety, purity, potency, and traceability of blood products, donor and patient safety, and equipment that will conform to validated requirements throughout its life cycle.

8. Action

a. Component Commands. Establish a component command blood program in support of the unified command's joint blood program. Oversee all Fleet blood bank and donor center operations OCONUS and aboard ships following enclosures (1), (3), and (5) through (8).

b. Type Commanders. Establish command blood programs per reference (f), and coordinate all blood program elements following enclosures (1) and (6) through (8).

c. Afloat Commanding Officers. Establish a command blood program per reference (f), and comply with the applicable paragraphs in enclosures (1) and (7). As required by reference (m), ensure any non-FDA licensed blood product collected or received and transfused aboard ship is documented and promptly reported to the NBP Office, following paragraph 12 of enclosure (1).

d. Shore Commands (Navy and Marine Corps). Establish a command blood program per reference (f), and comply with applicable sections of enclosures (1) through (8).

e. Regional Blood System Directors. Serve as regional blood system coordinators with responsibilities following enclosures (1), (2), (6), and (8).

f. CONUS and OCONUS Blood Donor Centers and Transfusion Services. Comply with the requirements in enclosures (1) through (3), (6), and (8).

9. Report. Per reference (r), the ASBP Blood Bank Operational Report required by enclosures (1) through (3) will be generated through the ASBP Operational Data Reporting System (ODRS). This report is exempt from reports control per SECNAV M-5214.1.

10. Forms

a. FDA 2830, Blood Establishment Registration and Product Listing, is available from BUMED-M3B63 or at:
<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2830.pdf>.

b. DD 572, Blood Donation Record, S/N 0102-LF-015-9800, can be ordered from Navy Forms Online at:
<https://forms.daps.dla.mil/>.



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GENERAL POLICIES AND PROCEDURES FOR
SUPPORT AND OPERATION OF THE NAVY BLOOD PROGRAM

1. Command Blood Program. Per reference (e), each Navy and Marine Corps command must establish an active peacetime command blood program. Commands must coordinate with the nearest Navy or Armed Services blood donor center to ensure support of routine blood product requirements for patients receiving medical care in DOD Military Health System (MHS) facilities and rapid expansion requirements of the Armed Services Blood Program (ASBP) in support of joint operating forces worldwide during mobilization or contingency. To ensure that civilian blood collections from the DOD donor pool do not reduce the DOD MHS capability, commanders and commanding officers will, through appointed command blood program coordinators, oversee all civilian blood collections on their installations, activities, and ships. To assist in managing this important MHS resource, a Memorandum of Understanding (MOU) must be established with any civilian blood collection agency authorized on base access to personnel (military and civilian). Paragraph 5e of this enclosure provides further information concerning MOUs.

2. Blood Banks (Donor Centers and Transfusion Services)

a. All fixed shore facilities must register with the FDA as required by reference (i) and will obtain and maintain accreditation by the American Association of Blood Banks (AABB). Annual verification of current activity within the facility will be verified through form FDA 2830 (7/06), Blood Establishment Registration and Product Listing.

b. A Quality assurance (QA) unit, separate (as much as possible) from operational responsibility, must be in place to ensure compliance with reference (i). A quality plan must be in place and annual reports of QA must be submitted to the NBP (BUMED-M3B63), when requested.

c. Technical and operational guidance, unless otherwise directed, must comply with references (j) and (k).

3. Blood Donor Centers

a. Navy blood donor centers (CONUS and OCONUS) must be licensed with the FDA per reference (i), and operate as

specifically outlined in enclosures (2) and (3) of this instruction. Application forms are available from BUMED NBP (BUMED-M3B63).

b. Reference (1) prescribes operational procedures for military blood donor centers and must be used in concert with references (i) through (k).

c. The following Naval medical facilities will operate peacetime blood donor centers:

NATNAVMEDCEN Bethesda, MD
NAVHOSP Camp Lejeune, NC
Naval Health Clinic Great Lakes, IL
USNAVHOSP Okinawa
NAVMEDCEN Portsmouth, VA
USNAVHOSP Guam
NAVMEDCEN San Diego, CA

d. Operational capabilities and requirements, including established blood quotas, of the blood donor centers may not be terminated or reduced in scope without prior approval from Chief, BUMED.

4. Blood Donor Center Mobilization and Emergency Response. For CONUS facilities, facility blood collection quotas are established by the NBP Office in response to Unified Command theater response requirements levied to each Service by the ASBPO. Additional blood donor center mobilization guidance is provided in enclosure (2) of this instruction. Operations and capabilities of blood donor centers, required to meet established blood quotas, may not be terminated or reduced in scope or capability without prior approval from Chief, BUMED.

5. Procurement. The life-saving nature of blood products requires strict regulations concerning their procurement; therefore, guidance given herein is described in general terms. Procurement methods for routine day-to-day MTF blood product support will be those which offer the greatest overall advantage to the Government. Emergent blood procurement source priorities and restrictions cannot be dictated. Unless doing so endangers a patient's welfare, procurement sources should be used in the following descending priority:

a. Local Volunteer Military Donors. Requirements for blood products are ordinarily met through collection of donors in the volunteer military pool by Armed Services blood donor centers. Eligible military donor pool categories are active duty (including Coast Guard) and their dependents, retirees and their dependents, drilling Reservists on active duty, and federal and DOD civilian employees. Collections are only authorized aboard military installations, federal and DOD leased installations or facilities, and naval/Coast Guard ships. Reference (f) and paragraph 1 of this enclosure provide policy and guidance for command support of the Navy and DOD Blood Program. Commanding officers of Navy MTFs must establish and maintain blood procurement programs designed to meet both routine and emergency requirements to the maximum extent possible.

b. Navy Blood Program (CONUS). Additional blood product support may be obtained through the redistribution of CONUS Navy blood product inventories as outlined in enclosure (2).

c. Navy Blood Program (OCONUS). Additional blood product support may be obtained through the redistribution of FDA-licensed unified command blood product inventories as outlined in enclosure (3). In emergencies, non-FDA licensed blood products may be obtained from local host nation blood supplies or through emergency collection of walking blood donors. Patient notification, required documentation, and follow-up counseling/testing required by reference (n) are outlined in enclosure (3).

d. Interservice Regional Support. CONUS medical facilities located near Army, Navy, or Air Force blood processing facilities are encouraged to negotiate formal support agreements. When primary blood product support is rendered by another service, Navy and Marine Corps donor populations will be made available to the supporting facility following reference (f). Support agreements must be reviewed by NBP prior to facility approvals.

e. Civilian Blood Banking Agencies. Navy and Marine Corps policy requires line commands and MTFs to establish an MOU with local civilian blood banks or blood collection agencies for blood products when no other sources exist within DOD which can be realistically applied to the task. Before completing an MOU, commands should obtain an example of an MOU from the NBP Office (BUMED-M3B63). Routine blood product support of civilian blood agencies is not a proper function for naval medical facilities.

(1) To reduce the number of MOUs in a geographical area and to ensure central management of regional blood donors and resources, line commands should allow the local Armed Services blood donor center or local MTF to write and manage an all-inclusive MOU, identifying each command participating in the MOU. For all blood support and donor access MOUs, the local Armed Services blood donor center and the nearest DOD military MTF must be active participants in developing the contents and terms of the MOU and must be signatories of the document. To ensure overall Service compliance, the Armed Services blood donor center's Service blood program officer must also review and approve all MOUs prior to BUMED approval and execution.

(2) Since the Government expends resources (loss of work-hours and utility and facility maintenance costs) when civilian blood agencies collect blood in Government facilities or federal or Government installations, MOUs must include a provision to grant credits per donor collected which can be exchanged for blood and blood products or provide an agreed upon number of blood products and/or services, at no cost to the Government, in exchange for access to donors. Blood products or services obtained through an MOU may be used within the MHS, provided to the Department of Veterans Affairs, or otherwise used in support of the ASBP following the priorities established in reference (f).

(a) MOUs must be businesslike and reciprocal and must not be used as a substitute for proper blood bank management practices. For the protection of both parties, MOUs must not involve accumulation of high exchange account balances (credit or debit). MOUs may be written to allow unused credits to be zeroed if not used within a specified time period.

(b) Routine blood product support of civilian hospitals or civilian blood agencies is not a proper function for naval medical facilities.

(c) MOUs with civilian agencies must not provide for: bartering of unexpired Navy blood resources or credits for "dollar credit;" bartering for supplies, equipment, or services; procurement of donor recruitment items or donor incentives; obtaining education or training. Credits or dollar credits must be used for obtaining blood products to include apheresis products, commercial coagulation factors, and immune globulins.

(d) MOUs must include points of contact for each organization covered under the MOU; include a termination period not longer than 2 years; and include a requirement for the civilian blood organization to notify military personnel and the local military medical facility of abnormal donor tests, except Human Immunodeficiency Virus (HIV) and Human T Lymphotropic Virus (HTLV). The civilian blood organization will not notify military personnel of abnormal HIV or HTLV tests, but will notify the military medical facility of such abnormal tests. The military medical facility will be responsible for notifying and counseling donors with abnormal HIV and HTLV tests.

(3) Active duty military or civilian employees of DOD should consult with their ethics counselor for guidance regarding compliance with the Joint Ethics Regulation (JER) and Standards for Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635) before agreeing to serve on the board of directors of a civilian blood agency, or in any other advisory capacity to such a non-federal entity, in either their personal or professional capacity.

f. When blood and blood products are required in scientific and research projects, the priorities and sources in subparagraphs 5a through 5d of this enclosure apply.

6. Donor Nourishment During Navy Blood Donor Center Operations. The provision of nourishment for blood donors is outlined in paragraph 6 of reference (f).

7. Management of Blood and Blood Products

a. Inventory Control. Blood banks must establish inventory control procedures for blood and blood products that provide maximum product coverage with minimum outdating or loss of blood products. Critical, minimum, and maximum product stocking levels must be established, made part of local standard operating procedures, and be posted for quick access and review.

b. Outdating and Loss Control. Blood banks must establish procedures that ensure minimum outdating or loss of blood and blood products. Experience in military and civilian blood banks has demonstrated that an outdating rate of 5 percent or less, is achievable through proper management techniques. Special

circumstances such as facility size or geographical location may impact outdating. The following steps should be taken to assist in reducing the outdate rate:

(1) Avoid random blood collections and meet weekly established blood quotas. Close coordination must be maintained with command blood programs providing donors to ensure that specific numbers, groups, and types are provided on request.

(2) Establish inventory levels based on historical requirements.

(3) Establish maximum time periods for holding cross-matched blood. In general, the timeframe of 24 to 72 hours is considered acceptable.

(4) Establish a transfusion review committee to review transfusion practices in the MTF.

(5) Develop and implement a maximum surgical blood order schedule (MSBOS) as a preoperative crossmatching management tool for autologous and allogeneic transfusions. Properly implemented, monitored, and updated quarterly, the MSBOS should reduce cross-matching costs, and through increased use, reduce red blood cell inventory requirements and thereby reduce product outdating.

(6) In concert with the MSBOS, adopt a "type and screen" concept as a substitute for the "type and crossmatch."

(7) In coordination with the regional blood system director, transfer blood and blood products nearing their expiration dates to other MTFs, federal medical facilities, or civilian blood agencies through the MOU. Or, where economically feasible, blood donor centers will enter into agreements for the sale of short dated blood products to the AABB National Blood Exchange (NBE). A warranted contracting officer must sign all NBE agreements. Revenue generated by such agreements may be maintained at the NBE for future procurement of blood products or legally returned to the local command operating funds and may be subsequently used to supplement the blood bank operating budget. Efforts must first be made to transfer the blood through the NBP.

8. Transfusion Policy. When contemplating hemotherapy, the dangers of transmission of disease and other undesirable side effects of transfusion must be weighed. Every consideration must be given to alternative methods of treatment. Before the transfusion of allogeneic blood products, the patient must be briefed on the risks/dangers of transfusion and on alternative transfusion methods (autologous, intra-operative, etc.) available. An informed consent form must be specifically designed for the transfusion of blood and blood products (allogeneic and autologous). Further guidance is outlined in references (j) and (k).

9. Use of Expired Blood and Blood Products. Despite conscientious efforts to avoid expiration, Navy blood banks and blood donor centers will accumulate varying amounts of expired blood and blood products. Three programs recommended to achieve maximum use of expired blood products are: within-hospital use (not transfusion); research; and/or, expired blood products and plasma exchange agreements. Expired blood and blood products are not for injectable use.

a. Within-Hospital Use or Research Use. Each naval medical facility has recurring needs for blood and blood products that can be filled by use of expired products. Examples of within-hospital use are training programs, reagent manufacture, and quality control. Uses also include research and scientific activities.

b. Recovered Expired Blood Products or Plasma Exchange Agreements

(1) Depending upon the volume of expired blood products or recovered plasma, and where economically feasible, CONUS blood donor centers will enter into agreements for the sale of unusable blood products. A warranted contracting officer must sign all plasma exchange agreements. Revenue generated by such agreements may be returned to the local command.

(2) Since the FDA strictly controls expired products, the products must test negative for all FDA and AABB required tests and be correctly labeled according to FDA regulations. A letter must be obtained from the exchange vendor stating the products will be used solely for the manufacture of non-injectable products.

10. Testing of Donor Units. All donor units will undergo complete testing for tests required by the DOD, FDA, and AABB following references (i) through (k). Autologous donor units must be screened for all tests used to screen allogeneic donor units; however, autologous blood will not be crossed over for allogeneic use under any circumstances.

11. Computerization and Information Management. Transfusion services, blood donor centers, LHAs, LHDs, fleet hospitals, and TAHs will use the Defense Blood Standard System or Theater DBSS (DBSS or TDBSS), where available, to perform the functional processes for donor collections, product and component processing, transfusions, records maintenance, and lookbacks.

12. Blood Product Tracking. All commands (ashore and afloat) that collect, store, ship, or transfuse blood or blood products must use a system to track the final disposition of each unit of blood and blood product collected and received. DBSS must be used if available. Regardless of the tracking system used, it must specifically identify the donor number, identification of patient transfused, shipping facility, receiving facility, reason for destruction, method of destruction, and all applicable dates. As directed in reference (n), any non-FDA licensed blood product collected and transfused must be reported to the NBP.

13. Lookback Program. All commands (ashore and afloat) that collect, store, ship, or transfuse blood or blood products, must permanently maintain all blood product collection, transfusion, testing, shipping, and/or disposition records to support present and future transfusion transmitted disease lookback issues.

a. Records must be maintained in a manner which provides physical and environmental protection. Records must be placed on a permanent storage medium (e.g., microfilm reel or microfiche, CD-ROM, floppy disk) with a working duplicate of each cassette, sheet, or disk stored in a separate area from the master cassette, sheet, or disk.

b. Before being placed on the storage medium, records must be organized to allow for easy review and identification of specific records.

c. Regardless of the method stored (paper or electronic) Blood Donation Record forms (DD 572) must be maintained in a manner that will allow quick access by ascending donor number order.

14. Quality Assurance Program. All FDA-registered transfusion services and blood donor centers will develop and maintain a QA program. The QA unit will be responsible for the implementation of the QA program to ensure compliance with references (i) and (q). Each blood bank system must be assessed annually to ensure compliance with critical control points and key elements as established in the NBP's Quality Plan. Since the Navy Surgeon General is the Responsible Head to the FDA for all Navy blood establishments, commands will ensure QA personnel have immediate access to the Head, NBP and the blood program's QA manager.

15. Blood Donor Numbers. Navy blood donor centers will use International Society Blood Transfusion (ISBT) 128 barcode labeling technology for all units collected. This system allows for service wide recognition of the blood donor center collecting the unit of blood. Enclosure (9) lists approved ISBT-128 identification numbers and FDA registration numbers for each facility. If ISBT-128 donor unit number identification labels are not available, units with emergency blood drawing capability (i.e., ships and fleet hospitals, etc.) will identify collected units by using the lot number of the integral segment (this number will be matched to the donor on corresponding paperwork).

16. Blood Bank Operational Report. Per reference (r), each blood bank (CONUS and OCONUS), with or without a blood donor center, must submit a monthly operational report using the ODRS located at: <http://odrs.lockheedmartin.com/>. Users are required to be registered and trained before using the system. Blood Bank Operational Report data (cost, staff, and operational data) are required to be entered and verified by the officer in charge by the 10th of the following month.

CONTINENTAL UNITED STATES (CONUS) REGIONAL BLOOD SYSTEMS

1. General. CONUS Navy MTFs with blood transfusion services or blood donor centers (BDCs) are assigned into three regional blood systems. Each regional blood system has a regional director, and is comprised of regional fixed facilities and shipboard blood bank assets.

2. Objectives

a. Enhance the Navy Blood Program (NBP) readiness through the regional distribution of the Navy's weekly blood component shipping commitment to a designated Armed Services Whole Blood Processing Laboratory (ASWBPL).

b. Ensure the availability and adequate supply of high quality blood and blood products, which meet or exceed the standard of care of the DOD Military Health System (MHS) and the joint war fighter through established BDCs. BUMED-M3B63 establishes production capability for the BDCs based on the available donor population.

c. Improve the quality of blood banking practices through ensuring and monitoring compliance with FDA regulations, guidelines, current Good Manufacturing Practices (cGMPs), and American Association of Blood Bank (AABB) standards.

d. Assess and plan for implementation of advances in blood and blood component therapy (e.g., frozen products, freeze-dried products, blood substitutes, hemostatic agents) and evaluate appropriateness of use within the Navy, Marine Corps, and other Services.

e. Ensure compatibility with any future plans for a regionalized tri-service blood program.

f. Standardize procedures, equipment, and training throughout the NBP.

g. Improve blood resource management practices through resource sharing throughout the MHS.

h. Ensure best business practices are employed to align command resources with productivity on a cost per unit scale.

3. Director, Regional Blood System. Commanding officers of MTFs designated in this enclosure as coordinators of regional blood systems, automatically serve as the regional blood system directors. However, the commanding officer shall designate a medical technologist, naval officer billet code (NOBC) 0866, to carry out the daily duties and responsibilities of the regional director. The designated director is authorized direct liaison with BUMED-M3B63 on all regional blood program issues. Duties of the regional director are:

a. Coordinates and manages all Navy blood banking matters for the assigned regional blood system, for both ashore facilities and CONUS homeported ships.

b. Serves as technical advisor and consultant to the type commanders (TYCOMs) for shipboard blood programs (liquid and frozen). Per enclosure (7), conducts annual and pre-deployment technical assistance visits (TAVs) on ships with frozen blood and, upon request, on ships with liquid blood capability.

c. Coordinates regional blood shipments to an ASWBPL or to other facilities as directed by BUMED-M3B63.

d. Per enclosure (7), maintains shipboard frozen blood inventories. Upon notification by the TYCOM, coordinates relocation of shipboard frozen blood assets during ship overhaul periods or upon unanticipated loss of freezer capability. If the regional blood system cannot absorb the assets, BUMED-M3B63 shall be notified for assistance. Costs associated with relocation (removal and return) must be borne by the ship.

e. Ensures efficient use of regional blood system resources

(1) Assists MTFs with establishing minimum inventory quantities based on transfusion history. Determines quantities of blood products considered in excess of regional requirements, and directs blood product transfer to other Navy regional facilities, other DOD MTFs, federal facilities, or local civilian blood banks, as directed.

(2) Directs blood product shipments between blood banks within the region and between regional blood systems as directed by BUMED-M3B63.

(3) Per enclosure (7), supports shipboard deployment requests for liquid blood where possible.

(4) Refers to BUMED-M3B63 for appropriate action, all shipboard deployment requests or requirements that cannot be met within the region for validation and coordination of support.

f. Ensures all requirements for cryoprecipitated anti-hemophilic factor, fresh frozen plasma, and frozen blood stockpiles and capabilities, as directed within this instruction, are met at each area facility.

g. Performs TAVs and QA audits of each area blood bank, at least annually, following enclosure (6).

(1) Copies of TAVs and audits shall be forwarded to the commanding officer of the inspected blood bank and the NBP within 30 days of the visit.

(2) MTFs shall reply to TAVs and audits within 30 days of receipt of the report outlining corrective actions to findings.

h. Receives information copies, reviews, and coordinates appropriate corrective actions on all applicable blood bank inspection reports (i.e., shipboard medical readiness assessments (MRAs), NBP audits, FDA inspections, AABB accreditation assessments, etc.) from all regional blood system facilities ashore and afloat.

i. Receives information copies, reviews, and takes appropriate corrective managerial actions on the monthly Armed Services Blood Program (ASBP) operational data report into the blood bank Operational Data Report System (ODRS) report from all regional blood system facilities ashore.

j. In concert with the public affairs officers, performs public information functions for the regional blood system. Acts as the commanding officer and BUMED's representative when dealing with local community blood banks.

k. Works with local non-medical military authorities to ensure all requests from civilian blood agencies to conduct blood drives on military and federal installations are coordinated per reference (f) and enclosure (1) of this instruction.

4. All Blood Banks. Unless otherwise directed, must:

a. Comply with mission and functions requirements in appropriate Naval Supply Systems Command (NAVSUP) 5450 instructions.

b. Establish and maintain donor recruiting programs with local military commands following reference (f). Ensure flight personnel meet donation criteria following reference (s).

c. Maintain a blood donor procurement program designed to meet both routine blood product requirements for patients receiving medical care in DOD MHS facilities and rapid expansion requirements of the ASBP in support of the joint operating forces worldwide during contingency or mobilization. This program must also be capable of providing short-notice supplemental donor support to other Navy regional facilities or other Service BDCs or facilities.

d. Maintain a blood inventory control system in the Defense Blood Bank System (DBSS) enabling the regional blood system director to effectively manage regional blood resources. Advise the regional director of predicted blood product excesses or shortages.

e. Following the regional director's guidance, make arrangements for intra- or inter-area shipments of excess blood products to other DOD, federal, or civilian activities as directed.

f. As directed, collect, process, and ship quantities of blood products to the designated ASWBPL. As directed, collect, process, and ship quantities of blood to other Navy facilities for freezing in support of Navy shipboard and depot frozen blood program.

g. Per enclosure (7), support shipboard deployment requests for liquid blood where possible. Refer to regional director for appropriate action, all shipboard deployment requests or requirements that cannot be locally met.

h. Establish and maintain management controls on blood credits earned through MOUs or other agreements.

i. As directed, develop and maintain capability of freezing, processing, storing, shipping, and deglycerolizing frozen blood in support of the Navy's Frozen Blood Program. As directed, collect, process, and ship blood for freezing in support of the Navy Shipboard Frozen Blood Program and frozen blood product depot (BPD) inventory levels. Assigned frozen storage quotas will be 68 percent O positive, 17 percent O negative, 13 percent A positive, and 2 percent A negative. Storage quotas will be above those units stored as in-house supplemental inventory, autologous, rare, and/or for training.

j. Ensure appropriate donor center training and competency assessment is provided for command personnel having BDC requirements in support of external or internal donor center contingency operations. Ensure personnel officers (NOBC 0866) and technicians (NOBC 8506), with assignments to Medical Augmentation Program (MAP) platforms that carry frozen blood (fleet hospitals, LHAs, LHDs, and T-AHs) receive annual training in frozen blood deglycerolization techniques. Personnel must receive training either in-house, if frozen blood technology is available, or must be sent temporary additional duty (TAD) to the nearest facility with the technology. Annual training must include, at minimum, the deglycerolization of at least four training units. Training and competency assessment must be documented in member's mobilization file.

k. At the request of the Navy regional blood system director, assist in the establishment of a program which will administer the Navy Blood Program (liquid and frozen) aboard naval vessels homeported in their area.

l. Each transfusion service and BDC will use DBSS to perform the applicable functional processes. Continuity of Operations Plans (COOP) must be locally developed for use during DBSS downtimes.

m. Establish and maintain a Lookback Program as directed by BUMED-M3B63. Blood bank records, component preparation records, blood destruction and shipment documents, and transfusion records shall be retained following references (j) and (k) unless otherwise directed by BUMED-M3B63. Commands, who at one time maintained a peacetime BDC operation, must ensure steps are taken to meet this lookback and storage medium requirement.

n. Use standard blood bank forms, blood products labels, and standardized operating procedures as directed by BUMED-M3B63.

o. Have a mechanism in place to detect, evaluate, and correct process deviations/errors. Additionally, the facility should have a system to evaluate the effectiveness of corrective actions taken. The following applies to all facilities (registered and licensed):

(1) Process deviations discovered before a product is distributed, are to be treated as internal variances. Document the deviation, take corrective action, document the action, and file the documentation in the facility's internal variance report file.

(2) Process deviations discovered after a product is distributed (issued, transfused, or shipped), must be reported to the FDA via BUMED-M3B63QA on a BPD form, FDA 3486, with a summary of appropriate corrective action. Upon discovery, initiate an investigation and make appropriate notifications. Report the deviation by telephone or electronically to BUMED-M3B63 within 5 days of discovery. Forward an official letter from the commanding officer to Chief, BUMED (BUMED-M3B63) with the BPD report as an enclosure within 28 days of discovery. Forward a copy of the BPD with cover letter to the regional blood system director.

(3) For information obtained after donation, post donation reports (use same BPD report) are required if the product was distributed and if:

(a) The donor should have been deferred had the information been known at the time of donation and the product quality may be affected.

(b) The medical evaluation otherwise suggests that product quality may be affected; or,

(c) The information is insufficient to conclude that product quality is not compromised.

(4) Process deviations (donor center or transfusion service) resulting in the death of a donor or patient must be reported immediately to the facility's commanding officer.

Telephone communication within 24 hours is also required to the Regional Navy Medicine Command and BUMED-M3B63 (during normal working hours, call (202) 762-3434, DSN 762-3434, or after normal working hours, the officer of the day (202) 762-3211 or DSN 762-3211). BUMED is required to notify the FDA at (301) 827-6220 or Fax (301) 827-6748 within 24 hours of the incident. Forward an official letter from the commanding officer to Chief, BUMED (BUMED-M3B63) with the BPD report as an enclosure within 5 days of the incident. This letter will be reported to the FDA from BUMED. Forward a copy to the regional blood system director. Other hospital accreditation standards may also require reporting.

p. Submit monthly ODRS report via the following Web site: <http://odrs.lockheedmartin.com/>. Users are required to be registered and trained before using the system. Data are required to be entered and verified by the 10th day of the following month.

q. To ensure sufficient and recurring prime vendor demand for inventory items required to support surge requirements, use of similar BDC supply and equipment items for peacetime and expanded Armed Services Blood Bank Center (ASBBC) operations is encouraged.

5. Regional Blood Systems

a. Navy Medicine National Capital Area (NAVMED NCA)

(1) National Naval Medical Center (NATNAVMEDCEN) Bethesda, MD

(a) Serve as the Navy's executive agent for and support the operation of the ASBBC, NCR; providing primary blood product support to DOD MTFs in the Washington DC area, including NATNAVMEDCEN Bethesda, Walter Reed Army Medical Center, and Malcolm Grow Medical Center.

(b) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(c) Operate a transfusion service following references (i) through (k), relying on routine blood product support from the ASBBC, NCR.

(d) Establish and maintain the ability to store, ship, and deglycerolize red blood cells. Maintain a stockpile of 250 units of frozen red blood cells (of these 100 will be group O of known phenotypes for C, D, E, c, e, Fya, Fyb, Jka, Jkb, K, and k), stored at -65°C or colder, minimum of 2 automated frozen blood cell washers, and, 1 water bath.

(e) In support of Navy contingency clinical requirements, maintain a minimum of 100 units of fresh frozen plasma (50 group A, 25 group B, and 25 AB) and 50 units of cryoprecipitated antihemophilic factor (non group O) above normal daily patient requirements, stored at -40°C or colder.

(f) Maintain, at a minimum, FDA licensure to store, ship, and transfuse the following products: Cryoprecipitated antihemophilic factor, fresh frozen plasma, liquid platelets (random and apheresis), red blood cells, red blood cells frozen, red blood cells deglycerolized, whole blood, and autologous red blood cells and whole blood.

(g) Provide annual training per paragraph 4j of this enclosure.

(2) Armed Services Blood Bank Center, National Capital Region (ASBBC, NCR)

(a) Assumes the responsibilities as Regional Blood System Director, per paragraph 3 of this enclosure.

(b) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(c) Complies with BUMED quotas for the collection, processing, and shipment of blood components to a designated ASWBPL and other designated receivers. Upon donor center activation, quotas may be modified based on the military contingency; however, the facility should be able to collect, process, and ship up to 100 units of packed red blood cells per day. Manpower augmentation to support BDC activation may consist of hospital corpsmen (NEC 8506 or 0000) that have been trained and demonstrate competence in donor center operations. Per reference (m), the donor center augmentation team should be 24 individuals to handle full activation of donor quotas.

(d) Establishes and maintains a Center of Excellence (CE) for transfusion transmitted disease (TTD) testing; including Nucleic Acid Testing (NAT), using FDA licensed procedures and equipment.

(e) Establishes a CE for special products to support clinical services within the Navy. In addition, supports the Navy contingency programs by maintaining a minimum of 100 units of fresh frozen plasma (50 group A, 25 group B, and 25 group AB) and 50 units of cryoprecipitated antihemophilic factor above daily patient requirements, stored at -40°C or colder. Uses only blood groups A, B, and AB when manufacturing cryoprecipitated antihemophilic factor.

(f) In support of the Navy's Frozen Blood Program, establishes and maintains the ability to store, ship, and deglycerolize red blood cells. Maintains a minimum inventory of 1,000 units of frozen blood stored at -40°C or colder, minimum of 2 automated frozen blood cell washers, and 1 water bath. Documents when frozen red cell units are outdated, destroyed, used for transfusion, or other, and are no longer in the available inventory.

(g) Supports blood bank requirements of USNS Comfort (T-AH 20) including frozen blood inventory maintenance, print-on-demand labels, physical control, and maintenance of the Theater Defense Blood Standard System (TDBSS), and technical assist visits (TAVs) following enclosures (7) and (8) of this instruction.

(h) FDA Licensure. Maintains, at a minimum, FDA licensure for the following products: Cryoprecipitated antihemophilic factor, fresh frozen plasma, platelets (random and apheresis), red blood cells AS-5, red blood cells deglycerolized, red blood cells frozen, whole blood CPD, whole blood CPDA-1, and autologous red blood cells AS-5 and whole blood CPD.

(i) Provides annual frozen blood training per paragraph 4j of this enclosure.

b. NAVMED East

(1) Naval Medical Center (NAVMEDCEN), Portsmouth, VA

(a) Assumes the responsibilities as the Regional Blood System Director, NAVMED East, per paragraph 3 of this enclosure.

(b) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(c) Complies with BUMED quotas for the collection, processing, and shipment of blood components to a designated ASWBPL and other designated receivers. Upon donor center activation, quotas may be modified based on the military contingency; however, the facility should be able to collect, process, and ship up to 110 units of packed red blood cells per day. Manpower augmentation to support BDC activation may consist of hospital corpsmen (NEC 8506 or 0000) that have been trained and demonstrate competence in donor center operations. Per reference (m), the donor center augmentation team should be 25 individuals to handle full activation of donor quotas.

(d) Establishes a CE for blood collection with Naval Hospital, Camp Lejeune, NC, and Naval Health Clinic Great Lakes, IL.

(e) Establishes and maintains a CE for special products to support clinical services within the Navy. In addition, supports the Navy contingency programs by maintaining a minimum of 100 units of fresh frozen plasma (50 group A, 25 group B, and 25 group AB) and 50 units of cryoprecipitated antihemophilic factor above daily patient requirements, stored at -40°C or colder. Uses only blood group A, B, and AB when manufacturing cryoprecipitated antihemophilic factor.

(f) Maintains a minimum of 1,000 units of frozen red blood cells (of these 100 will be group O units of known phenotypes for C, D, E, c, e, Fya, Fyb, Jka, Jkb, K, and k) stored at -65°C or colder, 4 frozen blood cell washers, and 2 water baths. Documents when frozen red cell units are transfused, outdated, destroyed, used for transfusion, or other, and are no longer in the available inventory.

(g) Support blood bank requirements of Naval ships home ported in the Norfolk shipyard (LHAs and LHDs) including frozen blood inventory maintenance, print-on-demand labels, physical control, and maintenance of the TDBSS and TAVs following enclosures (7) and (8) of this instruction.

(h) Serves as primary contact point for technical and administrative blood banking matters for NAVHOSPs Camp Lejeune; Pensacola; Jacksonville; Cherry Point; Charleston; Beaufort; Naval Health Clinic Great Lakes; and USNAVHOSP Guantanamo Bay.

(i) Serves as an NBP reserve storage center by maintaining 50 bags of cryoprecipitated antihemophilic factor above daily patient requirements. Uses only blood groups A, B, and AB when manufacturing cryoprecipitated antihemophilic factor.

(j) FDA Licensure. Maintains, at a minimum, FDA licensure for the following products: Cryoprecipitated antihemophilic factor, fresh frozen plasma, platelets, red blood cells, red blood cells deglycerolized, red blood cells frozen, whole blood CPD, whole blood CPDA-1, and autologous red blood cells and whole blood.

(k) Provides annual frozen blood training per paragraph 4j of this enclosure.

(2) Naval Hospital (NAVHOSP), Camp Lejeune, NC

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Complies with BUMED quotas for the collection, processing, and shipment of blood components to a designated ASWBPL and other designated receivers. Upon donor center activation, quotas may be modified based on the military contingency; however, the facility should be able to collect, process, and ship up to 100 units of packed red blood cells per day. Manpower augmentation to support BDC activation may consist of hospital corpsmen (NEC 8506 or 0000) that have been trained and demonstrate competence in donor center operations. Per reference (m), the donor center augmentation team should be 25 individuals to handle full activation of donor quotas.

(c) Establishes and maintains a CE for blood collection and component processing, including but not limited to: whole blood, red blood cells, fresh frozen plasma (FFP), cryoprecipitated antihemophilic factor, and plasma.

(d) Establishes and maintains a CE to support the Navy's Frozen Blood Program by maintaining the capability to collect, process, freeze, ship, and deglycerolize blood. Maintains a minimum of 600 units of frozen blood at -65°C or colder, five frozen blood cell washers, and one frozen blood water bath.

1. Obtains and ships plasma (not serum) cryogenic vials from donors of blood frozen at its facility to the designated location (Fort Knox, KY). If additional testing is required for new disease markers, the designated location will perform required testing. Local standard operating procedures must include notification of Fort Knox of final disposition, so cryogenic vials may be discarded.

2. Documents when frozen red cell units are transfused, outdated, destroyed, used for transfusion, or other, and are no longer in the available inventory.

3. Upon notification by another facility or ship, annotates the final disposition of frozen red blood cell units and notifies the designated storage location so the cryovials can be destroyed.

(e) Provides primary blood product support to NAVHOSP, Cherry Point and secondary support to other MTFs as directed by the Regional Blood System Director.

(f) Supports Navy contingency programs by maintaining a minimum of 50 units of fresh frozen plasma (50 group A, 25 group B, and 25 group AB) stored at -40°C or colder.

(g) Serves as a NBP reserve storage center by maintaining 50 bags of cryoprecipitated antihemophilic factor above daily patient requirements. Uses only blood groups A, B, and AB when manufacturing cryoprecipitated antihemophilic factor.

(h) Supports II Marine Expeditionary Force (MEF) with blood bank operational planning, training, and contingency blood products if directed.

(i) FDA Licensure. Maintains, at a minimum, FDA licensure for the following products: Cryoprecipitated antihemophilic factor, FFP, platelets, red blood cells, red blood cells deglycerolized, red blood cells frozen, whole blood CPD, whole blood CPDA-1, and autologous red blood cells and whole blood.

(j) Provides annual frozen blood training per paragraph 4j of this enclosure.

(3) Naval Health Clinic, Great Lakes, IL

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Complies with BUMED quotas for the collection, processing, and shipment of blood components to a designated ASWBPL and other designated receivers. Upon donor center activation, quotas may be modified based on the military contingency; however, the facility should be able to collect, process, and ship up to 100 units of packed red blood cells per day. Manpower augmentation to support BDC activation may consist of hospital corpsmen (NEC 8506 or 0000) that have been trained and demonstrate competence in donor center operations. Per reference (m), the donor center augmentation team should be 25 individuals to handle full activation of donor quotas.

(c) Establishes and maintains a CE for blood collection and component processing, including but not limited to: whole blood, red blood cells, FFP, cryoprecipitated antihemophilic factor, and plasma.

(d) Establishes and maintains a CE to support the Navy's Frozen Blood Program by maintaining the capability to collect, process, freeze, ship, and deglycerolize blood. Maintains a minimum of 600 units of frozen blood at -65°C or colder, 5 frozen blood cell washers, and 1 frozen blood water bath.

1. Obtains and ships plasma (not serum) cryogenic vials from donors of blood frozen at its facility to the designated location (Fort Knox, KY). If additional testing is required for new disease markers, the designated location will

perform required testing. Local standard operating procedures must include notification of Fort Knox of final disposition, so cryogenic vials may be discarded.

2. Documents when frozen red cell units are transfused, outdated, destroyed, used for transfusion, or other, and are no longer in the available inventory.

3. Upon notification by another facility or ship, annotates the final disposition of frozen red blood cell units and notifies the designated storage location so the cryovials can be destroyed.

(e) Provides secondary support to other MTFs as directed by the Regional Blood System Director.

(f) Supports Navy contingency programs by maintaining a minimum of 100 units of fresh frozen plasma (50 group A, 25 group B, and 25 group AB) stored at -40°C or colder.

(g) Serves as a NBP reserve storage center by maintaining 50 bags of cryoprecipitated antihemophilic factor above daily patient requirements. Uses only blood groups A, B, and AB when manufacturing cryoprecipitated antihemophilic factor.

(h) FDA Licensure. Maintains, at a minimum, FDA licensure for the following products: cryoprecipitated antihemophilic factor, FFP, platelets, red blood cells, red blood cells deglycerolized, red blood cells frozen, whole blood CPD, whole blood CPDA-1, and autologous red blood cells and whole blood.

(i) Provides annual frozen blood training per paragraph 4j of this enclosure.

(4) Naval Hospital (NAVHOSP), Pensacola, FL

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a transfusion service relying on routine blood product support and rotates products with civilian blood bank or as directed by the Regional Blood System Director.

(c) Stores fresh frozen plasma at -40°C or colder.

(d) FDA Licensure. Registered as a transfusion service.

(e) Makes donor population available to ASBP BDC and helps in the collection of blood from such donors.

(5) Naval Hospital (NAVHOSP), Jacksonville, FL

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a transfusion service relying on routine blood product support and rotates products with civilian blood bank or as directed by the Regional Director.

(c) Stores fresh frozen plasma at -40°C or colder.

(d) Supports Navy contingency programs by maintaining a minimum of 50 units of fresh frozen plasma (25 group A, 10 group B, and 15 group AB) stored at -40°C or colder.

(e) FDA Licensure. Registered as a transfusion service.

(f) Makes donor population available to ASBP BDC and helps in the collection of blood from such donors.

(6) Naval Hospital (NAVHOSP), Cherry Point, NC

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a transfusion service relying on routine blood product support from NAVHOSP Camp Lejeune. Rotates blood products with NAVHOSP Camp Lejeune or as directed by the Regional Blood System Director.

(c) Stores fresh frozen plasma at -40°C or colder.

(d) FDA Licensure. Maintains Registered as a transfusion service.

(e) Makes a donor population available to ASBP BDC and helps in the collection of blood from such donors.

(7) Naval Hospital (NAVHOSP), Charleston, SC

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a transfusion service relying on routine blood product support and rotate products with civilian blood bank or as directed by the Regional Blood System Director.

(c) Stores fresh frozen plasma at -40°C or colder.

(d) FDA Licensure. Registered as a transfusion service.

(e) Makes a donor population available to ASBP BDC and helps in the collection of blood from such donors.

(8) Naval Hospital (NAVHOSP), Beaufort, SC

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a transfusion service relying on routine blood product support and rotates products with civilian blood bank or as directed by the Regional Director.

(c) Stores fresh frozen plasma at -40°C or colder.

(d) Supports Navy contingency programs by maintaining a minimum of 50 units of fresh frozen plasma (25 group A, 15 group B, and 10 group AB) stored at -40°C or colder.

(e) Serves as a NBP reserve storage center by maintaining 25 bags of cryoprecipitated antihemophilic factor above daily patient requirements. Uses only blood groups A, B, and AB when manufacturing cryoprecipitated antihemophilic factor.

(f) FDA Licensure. Registered as a transfusion service.

(g) Makes a donor population available to ASBP BDC and helps in the collection of blood from such donors.

c. NAVMED West

(1) Naval Medical Center (NAVMEDCEN), San Diego, CA

(a) Assumes the responsibilities as Navy Component Regional Director, NAVMED West, per paragraph 3 of this enclosure.

(b) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(c) Complies with BUMED quotas for the collection, processing, and shipment of blood components to a designated ASWBPL and other designated receivers. Upon donor center activation, quotas may be modified based on the military contingency; however, the facility should be able to collect, process, and ship up to 110 units of packed red blood cells per day. Manpower augmentation to support BDC activation may consist of hospital corpsmen (NEC 8506 or 0000) that have been trained and demonstrated competence in donor center operations. Per reference (m), the donor center augmentation team should be 25 individuals to handle full activation of donor quotas.

(d) Establishes and maintains a CE for TTD testing.

(e) Establishes and maintains a CE for special products to support clinical services within the Navy. In addition, supports the Navy contingency programs by maintaining a minimum of 100 units of fresh frozen plasma (50 group A, 25 group B, and 25 group AB) and 50 units of cryoprecipitated antihemophilic factor above daily patient requirements, stored at -40°C or colder. Uses only blood groups A, B, and AB when manufacturing cryoprecipitated antihemophilic factor.

(f) Maintains minimum of 1,000 units of frozen red blood cells at -65°C or colder, 4 frozen blood cell washers, and 2 frozen blood water baths. Documents when frozen red cell units are transfused, outdated, destroyed, used for transfusion, or other, and are no longer in the available inventory. Maintains a stockpile of 100 group O frozen red blood units of known phenotypes for C, D, E, c, e, Fya, Fyb, Jka, Jkb, K, and k. Establishes a CE for frozen blood to support the Navy's Frozen Blood Program by maintaining the capability to collect, process, freeze, ship, and deglycerolize blood.

(g) Supports blood bank requirements of Naval ships homeported in the San Diego shipyard (USNS Mercy [T-AH 19], LHAs, and LHDs) including frozen blood inventory maintenance, print-on-demand labels, physical control and maintenance of the TDBSS, and TAVs following enclosures (7) and (8) of this instruction.

(h) Serves as primary contact point for technical and administrative blood banking matters at NAVHOSPs Camp Pendleton, Lemoore, Twentynine Palms, Bremerton, and Oak Harbor.

(i) Supports I Marine Expeditionary Force (MEF) with blood bank operational planning, training, and contingency blood products if directed.

(j) FDA Licensure. Maintains, at a minimum, FDA licensure for the following products: cryoprecipitated antihemophilic factor, fresh frozen plasma, platelets, red blood cells, red blood cells deglycerolized, red blood cells frozen, whole blood CPD, whole blood CPDA-1 and autologous red blood cells AS-5 and whole blood CPD.

(k) Provides annual frozen blood training per paragraph 4j of this enclosure.

(2) Naval Hospital (NAVHOSP) Camp Pendleton, CA

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a transfusion service relying on routine blood product support and rotates products with NAVMEDCEN San Diego.

(c) Supports Navy contingency programs by maintaining a minimum of 40 units of fresh frozen plasma (20 group A, 10 group B, and 10 group AB) stored at -40°C or colder.

(d) Serves as a NBP reserve storage center by maintaining 25 bags of cryoprecipitated antihemophilic factor above daily patient requirements.

(e) FDA Licensure. Registered as a transfusion service.

(f) Makes a donor population available to the ASBP BDC at NAVMEDCEN San Diego and helps in the collection of blood from such donors.

(3) Naval Hospital (NAVHOSP), Lemoore, CA

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a blood transfusion service relying on the local civilian blood agency for routine blood product support.

(c) Stores fresh frozen Plasma at -40°C or colder.

(d) FDA Licensure. Registered as a transfusion service.

(e) Makes a donor population available to ASBP BDC and helps in the collection of blood from such donors.

(4) Naval Hospital (NAVHOSP, Marine Corps Base), Twentynine Palms, CA

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a blood transfusion service relying on the local civilian blood agency for routine blood product support.

(c) Stores fresh frozen plasma at -40°C or colder.

(d) FDA Licensure. Registered as a transfusion service.

(e) Makes a donor population available to ASBP BDC and helps in the collection of blood from such donors.

(5) Naval Hospital (NAVHOSP), Bremerton, WA

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a transfusion service relying on routine blood product support and rotates products with the ASBBC, Ft Lewis as directed by the Regional Blood Director.

(c) Stores fresh frozen plasma at -40°C or Colder.

(d) Serves as initial contact point for technical and administrative blood banking matters at NAVHOSP Oak Harbor, WA.

(e) FDA Licensure. Registered as a transfusion service.

(f) Makes a donor population available to ASBP ASBBC and helps in the collection of blood from such donors.

(6) Naval Hospital (NAVHOSP), Oak Harbor, WA

(a) Ensures compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Operates a blood transfusion service relying on routine blood product support from the ASBBC, Ft Lewis.

(c) Stores fresh frozen plasma at -40°C or colder.

(d) FDA Licensure. Registered as a transfusion service.

(e) Makes a donor population available to ASBP ASBBC and helps in the collection of blood from such donors.

OUTSIDE THE CONTINENTAL UNITED STATES (OCONUS)
AREA BLOOD SYSTEMS

1. General. OCONUS Navy MTFs with blood transfusion services or BDCs are responsible to the Navy component command for the service blood programs and integrate into the unified command for the theater joint blood program. The unified command assigns blood banks and BDCs to geographical AJBP. Each Service component blood program manager and AJBPO reports to the unified command Joint Blood Program Office (JBPO). Each AJBP has an area blood program manager, and is comprised of fixed facilities, field medical units, and/or shipboard blood bank assets.

2. Objectives

a. Ensure the availability and adequate supply of high quality blood and blood products, which meets the standard of care, to the DOD MHS and joint operating forces during peacetime, and periods of contingency and mobilization.

b. Increase theater contingency and readiness posture.

c. Increase the quality of blood banking practices by ensuring and monitoring compliance with FDA regulations, guidelines, and cGMPs, and AABB standards.

d. Standardize procedures, equipment, and training throughout the Navy Blood Program.

e. Assess and plan for implementation of advances in blood and blood component therapy (e.g., frozen products, freeze dried products, blood substitutes, hemostatic agents) and evaluate their appropriateness for use within the Navy and Marine Corps with respect to contingency planning.

f. Improve blood resource management practices.

g. Exchange information on availability of excess blood bank equipment.

3. Navy Component Blood Program Officer (CBPO). Must be a medical technologist, NOBC 0866, with certification as a Specialist in Blood Banking (SBB) or possess the appropriate experience in organization and management of the ASBP

(Additional Qualifier Designator (AQD) 60V) to carry out the duties and responsibilities of the component blood program manager. The Navy component blood program manager must be appointed, in writing, by the component command surgeon; Pacific Fleet (PACFLT); Commander United States Fleet Forces Command (CUSFFC); and United States Navy Europe (USNAVEUR), and is authorized direct liaison with BUMED's Naval Blood Program Division (BUMED-M3B63) on all Navy component blood program issues to perform the duties as outlined below:

a. Establishes and operates a component command blood program to support the peacetime and wartime blood requirements within the theater area of responsibility and ensure integration into the unified command and AJBPs.

b. Serves as a special assistant to the Component Command Surgeon to coordinate and manage on all blood bank matters for both ashore facilities and component shipboard activities. Is responsible to the component commander for the NBP and to the JBPO for the theater component blood program.

c. Serves as technical advisor and consultant to the TYCOMs for shipboard blood programs (liquid and frozen). Per enclosure (7) and (8), conducts annual and pre-deployment TAVs on ships with frozen blood and, upon request, on ships with liquid blood capability.

d. Maintains shipboard frozen blood inventories. Upon notification by the TYCOMs, coordinates with the unified command JBPO for relocation of shipboard frozen blood assets during ship overhaul periods or upon unanticipated loss of freezer capability. If the theater blood program cannot absorb the assets, notifies BUMED-M3B63 for assistance.

(1) Costs associated with relocation (removal and return) must be borne by the ship.

(2) Cryogenic vials must remain at the designated repository and should not be placed aboard ship.

e. Refers all shipboard deployment blood requests or requirements that cannot be met with theater assets for validation and coordination of support to BUMED-M3B63 for appropriate action.

f. Serves as the primary liaison between the unified command JBPO, the component command, component blood program activities and facilities, and BUMED-M3B63 for:

(1) Coordination and management of peacetime blood banking matters for the component command.

(2) Coordination and implementation of theater joint blood program peacetime initiatives at component blood program activities and facilities to meet theater wartime blood program requirements and operations.

g. Serves as the primary liaison between the JBPO, the component command, and component blood program activities and facilities to ensure tri-service cooperation and integration of the component blood program into the Joint Blood Program and implementation of unified command and NBP initiatives, programs, policies, and procedures.

h. Coordinates with the unified command JBPO and theater AJBPOs to ensure the availability and adequate supply of quality blood and blood products during peacetime and contingency, to ensure implementation of peacetime initiatives to meet theater Wartime Blood Program requirements, and to ensure maintenance of contingency and readiness posture of component blood program activities.

i. Exchanges information between the component command, BUMED-M3B63, component blood program activities, and the JBPO on changes in component and joint blood programs policies, regulations, modernization, and availability of excess blood bank equipment and supplies.

j. Assesses and plans for implementation of advances in blood and blood component therapy (e.g., frozen products, platelet apheresis, freeze-dried products, blood substitutes, hemostatic agents) and evaluates appropriateness of use with respect to contingency planning.

k. Increases and maintains the quality of blood banking practices of the component command through monitoring component blood program facility compliance with FDA regulations and guidelines, AABB standards, and DOD and NBP directives and guidelines.

1. Receives information copies, reviews, and coordinates implementation of appropriate corrective actions on deficiencies identified in applicable inspection reports (i.e., shipboard medical readiness assessments (MRAs), NBP audits, FDA inspections, AABB accreditation assessments, etc.) from all component blood program facilities ashore and afloat.

4. All Blood Banks/Transfusion Services. Unless otherwise directed, must:

a. Comply with mission and function requirements following the appropriate Naval Supply Systems Command (NAVSUP) instructions.

b. Establish and maintain donor marketing and recruiting programs with local command activities as per reference (f). Ensure flight personnel meet donation criteria per reference (s).

c. Maintain a blood donor procurement program designed to meet both routine and emergency blood product requirements for patients receiving medical care in DOD MHS facilities and rapid expansion requirements of the Unified Command Joint Blood Program in support of the joint operating forces during contingency or mobilization. This program must also be capable of providing short-notice supplemental donor support to other service BDCs.

d. Utilize the Unified Command Joint Blood Program as a source of blood if unable to meet local requirements. For those facilities that do not routinely collect blood (e.g., USNAVHOSP Guantanamo Bay; USNAVHOSP Rota; USNAVHOSP Naples; USNAVHOSP Sigonella; USNAVHOSP Yokosuka; NAVMEDCL Diego Garcia), maintain a list of acceptable emergency donors based on blood group and type, previous TTDs, and answers to questions concerning the donor medical history located on the DD 572, Blood Donation Record, for an emergency blood donor program. Will ensure adequate supplies for such are maintained.

(1) Previous TTD testing gives no assurance of the lack of infectivity on the day of donation. Reliance on accurate and complete medical screening on the day of donation provides the safest blood product when concurrent testing is not available.

(2) As directed in reference (n), if blood donor units are collected and transfused before TTD testing is completed, a plasma sample must be collected from the donor, properly labeled, frozen, and tested as soon as possible for the battery of blood donor tests required by FDA and the NBP. If TTD testing is not performed in-house, forward the frozen donor sample to the nearest military medical facility capable of testing the sample for the current battery of blood donor tests.

(3) As directed in reference (n), if emergency non-FDA licensed blood products are used (including products from host nation blood collection agencies), transfusion recipients must be notified, counseled, and subsequently tested for possible TTD at 3-month, 6-month, and 12-month intervals. Documentation in the patient medical record must be accomplished following guidance provided in reference (n).

(4) As directed in reference (n), any transfusion of a non-FDA licensed blood product (e.g., aboard ship, fixed MTF, host nation facility) must be reported to BUMED NBP (BUMED-M3B63), via official message, within 30 days of occurrence. BUMED will maintain a database for potential infectious disease lookback cases.

e. Advise the AJBPO of predicted blood product excesses or shortages. As directed, make arrangements for intra-theater shipments of excess blood products to other theater blood program activities.

f. As directed, develop and maintain the capability to store, ship, and deglycerolize frozen blood in support of theater blood requirements. Storage quotas will be above those units stored for in-house supplemental inventory, autologous use, rare blood product inventory, and/or training use.

g. Per enclosure (7), support shipboard deployment requests for liquid blood where possible. Refer to the unified command JBPO for appropriate action, all shipboard deployment requests or requirements for validation and coordination of support.

h. Ensure appropriate training is provided for command personnel (officers (NOBC 0866) and technicians (NEC 8506)) with assignments to Component unit identification code (UIC) platforms

in support of internal or external BDC operations, BPD operations, shipboard frozen blood operations (casualty receiving and treatment ship (CRTS), TAH), or medical units with blood transfusion capabilities (CRTS, TAH, FH, Marine Corps field units).

(1) Ensure personnel with assignments to mobilization platforms with frozen blood capabilities receive annual training in frozen red blood cell deglycerolization techniques. Annual frozen blood training must include, at a minimum, the deglycerolization of at least four frozen red cell units.

(2) Personnel must receive training either in-house, if available, or must be authorized temporary additional duty (TAD) at the nearest MTF with the available capability.

(3) Annual training and competency assessment must be documented in the member's mobilization training record.

i. Maintain a blood inventory control system capable of tracking the disposition of all blood products. Utilize the DBSS, where available, to perform the applicable functional blood bank processes. Continuity of Operations Plans (COOP) must be locally developed and updated for use during DBSS downtimes. The COOP should be tested semi-annually at a minimum and documentation kept following FDA regulations and AABB standards.

j. Establish and maintain an infectious disease Lookback Program as directed by BUMED NBP (BUMED-M3B63). Permanently retain all blood bank records as per paragraphs 11 through 13 of enclosure (1). Commands, who previously operated a peacetime BDC, must ensure steps are taken to meet lookback and record storage requirements.

k. Use standard blood bank forms, blood products labels, and standardized operating procedures as directed by BUMED-M3B63.

l. Have a mechanism in place to detect, evaluate and, correct process deviations/errors. Additionally, the facility should have a system to evaluate the effectiveness of corrective actions taken. The following applies to all facilities (registered and licensed):

(1) Process deviations discovered before a product is distributed, are to be treated as internal variances. Document the deviation, take corrective action, document the action, and file the documentation in the facility's internal variance report file.

(2) Process deviations discovered after a product is distributed (transfused or shipped), must be reported to the FDA via BUMED-M3B63QA on a BPD form, FDA 3486, with a summary of appropriate corrective action. Upon discovery, initiate an investigation and make appropriate notifications. Report the deviation by telephone or electronically to BUMED-M3B63 within 5 days of discovery. Forward an official letter from the commanding officer to Chief, BUMED (BUMED-M3B63) with the BPD report as an enclosure within 28 days of discovery. Forward a copy of the BPD with cover letter to the regional blood system director.

(3) For information obtained after donation, post donation reports (use same BPD report) are required if the product was distributed and if:

(a) The donor should have been deferred had the information been known at the time of donation and the product quality may be affected.

(b) The medical evaluation otherwise suggests that product quality may be affected; or,

(c) The information is insufficient to conclude that product quality is not compromised.

(4) Process deviations (donor center or transfusion service) resulting in the death of a donor or patient must be reported immediately to the facility's commanding officer. Telephone communication within 24 hours is also required to the Regional Navy Medicine Command and BUMED-M3B63 (during normal working hours, call (202) 762-3434, DSN 762-3434, or after normal working hours, the officer of the day (202) 762-3211 or DSN 762-3211). BUMED is required to notify the FDA at (301) 827-6220 or Fax (301) 827-6748 within 24 hours of the incident. Forward an official letter from the commanding officer to Chief, BUMED (BUMED-M3B63) with the BPD report as an enclosure within 5 days of the incident. This letter will be reported to the FDA

from BUMED. Forward a copy to the regional blood system director. Other hospital accreditation standards may also require reporting.

m. Submit monthly ODRS report by Web site at: <http://odrs.lockheedmartin.com/>. Users are required to be registered and trained before using the system. Data are required to be entered and verified by the 10th day of the following month.

5. Navy Component Command Blood Programs

a. CUSFFC. Designates in writing a CBPO to perform duties outlined in paragraph 4 of this enclosure.

(1) U.S. Naval Hospital (USNAVHOSP), Guantanamo Bay, Cuba

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and area joint blood program offices and the component command blood program office for development of contingency and mobilization requirements in support of operational plans (OPLANS).

(c) Maintain the capability, as directed, to function as a Blood Supply Unit.

(d) Operate a transfusion service following references (i) through (k), relying on routine blood product support from NAVMEDCEN Portsmouth. Obtain secondary blood support through the use of deglycerolized/thawed frozen blood products.

(e) In support of the Navy's Frozen Blood Program, establish and maintain capability to store, ship, and deglycerolize red blood cells. Maintain a minimum inventory of 50 units of frozen blood stored at -65°C or colder, 2 automated frozen blood cell washers, and 1 water bath. To facilitate inventory management of stored frozen plasma specimens, ensure local standard operating procedures include timely notification of NAVMEDCEN Portsmouth when frozen red blood cell units are transfused, outdated, destroyed, or used.

(f) Maintain a contingency donor collection program such that technician proficiency and regular contact with command blood program coordinators is maintained. FDA licensure for the manufacturer of blood products is not required. Comply with requirements for non-FDA licensed blood products as directed in reference (n).

(g) Provide annual training per paragraph 4h of this enclosure.

(h) In support of Navy contingency clinical requirements, maintain a minimum of 25 units of fresh frozen plasma (10 group A, 5 group B, and 10 AB) above normal daily patient requirements, at -40°C or colder.

(i) FDA Licensure. Registered as a transfusion service.

b. PACFLT. Designates in writing a CBPO to perform duties outlined in paragraph 4 of this enclosure.

(1) U.S. Naval Hospital (USNAVHOSP), Okinawa, JA

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and area joint blood program offices and the component command blood program office for development of contingency and mobilization requirements in support of OPLANS.

(c) Serve as the Navy's executive agent for and support the operation of the U.S. Pacific Command, Armed Services Blood Bank Center (USPACOM ASBBC) and the USPACOM frozen Blood Product Depot (BPD), providing primary blood product support to theater DOD MTFs following references (f) and (i) through (m).

(d) Ensure readiness capability of the ASBBC and BPD are adequately maintained to meet the expanded frozen blood and donor collection missions and assigned contingency red blood cell quota requirements of the unified command. Operation of the BDC and the BPD in peacetime is critical to maintain personnel competency and training for immediate activation and expansion of the ASBBC and BPD.

1. Ensure that component UIC mobilization assignments of ASBBC and BPD staff and augmentation personnel are maintained.

2. Ensure that ASBBC and BPD staff and augmentation personnel are trained.

3. Ensure that ASBBC and BPD equipment and facilities are maintained and are functional.

4. Establish and maintain ASBBC and BPD activation and mobilization plans to ensure blood collection and deglycerolization quotas are met.

(e) Operate a transfusion service following references (i) through (k), relying on routine blood product support from the ASBBC PACOM. Obtain secondary blood support through the use of deglycerolized/thawed frozen blood products. Obtain emergency blood product support from host nation civilian agencies. Comply with requirements for the emergency use of non-FDA licensed blood products as directed in reference (n).

(f) Provide annual training per paragraph 4h of this enclosure.

(g) FDA Licensure. Cryoprecipitated antihemophilic factor, fresh frozen plasma, liquid platelets (random), red blood cells, red blood cells frozen, red blood cells deglycerolized, whole blood, and autologous red blood cells and whole blood.

(2) ASBBC, U.S. Pacific Command (USPACOM), Okinawa, JA

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and area joint blood program offices and the component command blood program office for development of contingency and mobilization requirements in support of OPLANS. Assume the responsibilities as Okinawa AJBPO.

(c) Operate the ASBBC, U.S. Pacific Command (ASBBC PACOM) and the PACOM BPD as directed in references (f) and (i) through (m). Provide primary blood product support to DOD MTFs in the Pacific theater as directed by the unified command JBPO.

(d) Ensure readiness capability of the ASBBC and BPD are adequately maintained to meet the expanded frozen blood and donor collection mission and assigned contingency red blood cell quota requirements. Operation of the ASBBC and the BPD in peacetime is critical to maintain personnel competency and training for immediate activation and expansion of the ASBBC and the BPD.

(e) Serve as primary contact point for technical and administrative blood banking matters for USNAVHOSP Okinawa transfusion service. Perform annual TAVs to USNAVHOSP Okinawa transfusion service as directed in enclosure (6).

(f) Comply with unified command directed daily, weekly, and monthly quotas for the collection, processing, and/or shipment of blood components to theater medical units in support of unified command operational plans (OPLANS) or to other designated receivers. Upon activation, quotas may be modified based on the specific contingency requirements. Maintain the capability, as directed, to function as a theater Blood Supply Unit.

(g) Establish and maintain capability to perform in-house TTD testing, including NAT, using FDA licensed procedures and equipment.

(h) Establish and maintain capability to collect and prepare random platelets, using licensed procedures and equipment.

(i) In support of the Navy's Frozen Blood Program, establish and maintain capability to store, ship, and deglycerolize frozen red blood cells. Maintain a minimum inventory of 3,500 units of frozen blood stored at -65°C or colder, 10 automated frozen blood cell washers, and 5 water baths. One automated frozen red blood cell washer, capability to store 350 units of frozen red blood cells at -65°C or colder, and associated materials will be maintained as a contingency at the 18th Marine Group, Kadena AB, Japan.

1. To facilitate inventory management of stored frozen plasma specimens, ensure local standard operating procedures include timely notification of the ASWBPL West when frozen units are transfused, outdated, destroyed, or used.

2. Maintain a stockpile of 50 group O frozen red blood units of known phenotypes for C, D, E, c, e, Fya, Fyb, Jka, Jkb, K, and k, stored at -65°C or colder.

(j) In support of Navy contingency clinical requirements, maintain a minimum of 500 units of fresh frozen plasma (125 group A, 125 group B, and 250 AB) and 150 units of cryoprecipitated antihemophilic factor (non group O), stored at -40°C or colder.

(k) Support blood bank requirements of theater homeported ships including maintenance of frozen blood inventory, availability of print-on-demand blood product labels, and maintenance of and personnel training for the Theater Defense Blood Standard System (TDBSS).

(l) Provide annual training per paragraph 4h of this enclosure.

(m) FDA Licensure. Cryoprecipitated antihemophilic factor, fresh frozen plasma, random platelets, red blood cells, red blood cells frozen, red blood cells deglycerolized, whole blood, and autologous red blood cells and whole blood.

(3) U.S. Naval Hospital (NAVHOSP), Yokosuka, JA

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and area joint blood program offices and the component command blood program office for development of contingency and mobilization requirements in support of OPLANS.

(c) Maintain the capability, as directed, to function as a Blood Supply Unit.

(d) Operate a transfusion service following references (f) and (i) through (m), relying on routine blood product support

from the ASBBC PACOM. Obtain secondary blood support through the use of deglycerolized/thawed frozen blood products. Obtain emergency blood product support from host nation civilian agencies through a local MOU(s). Comply with requirements for the emergency use of non-FDA licensed blood products as directed in reference (n).

(e) Maintain a contingency donor collection program such that technician proficiency and regular contact with command blood program coordinators is maintained. FDA licensure for the manufacturer of blood products is not required. Comply with requirements for non-FDA licensed blood products following reference (n).

(f) In support of the Navy's Frozen Blood Program, establish and maintain capability to store, ship, and deglycerolize red blood cells.

1. Maintain a minimum inventory of 500 units of frozen blood stored at -65°C or colder, 4 automated frozen blood cell washers, and 2 water baths.

2. To facilitate inventory management of stored frozen plasma specimens, ensure that local standard operating procedures include timely notification of the ASWBPL West when frozen units are transfused, outdated, destroyed, or used.

(g) Provide annual training per paragraph 4h of this enclosure.

(h) In support of Navy contingency clinical requirements, maintain a minimum of 25 units of fresh frozen plasma (10 group A, 5 group B, and 10 AB) above normal daily patient requirements, stored at -40°C or colder.

(i) FDA Licensure. Registered as a transfusion service.

(4) U.S. Naval Hospital (USNAVHOSP), Guam

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and area joint blood program offices and the component command blood program office for development of contingency and mobilization requirements in support of OPLANS. Assume the responsibilities as Guam Area Joint Blood Program Office.

(c) Operate a transfusion service and blood donor center as directed in references (f) and (i) through (m), relying on routine blood product support from the ASBBC PACOM. Obtain secondary blood support through the use of deglycerolized/thawed frozen blood products. Obtain emergency blood product support from local civilian agencies through a local MOU(s). Comply with requirements for the emergency use of non-FDA licensed blood products as directed in reference (n).

(d) Maintain a donor collection program such that technician proficiency and regular contact with command blood program coordinators is maintained. FDA licensure for the manufacturer of blood products is required.

(e) Establish and maintain capability to perform in-house TTD testing, using FDA licensed procedures and equipment.

(f) Establish and maintain capability to collect and prepare apheresis platelets, using licensed procedures and equipment.

(g) In support of the Navy's Frozen Blood Program, establish and maintain capability to store, ship, and deglycerolize red blood cells.

1. Maintain a minimum inventory of 100 units of frozen blood stored at -65°C or colder, 2 automated frozen blood cell washers, and 1 water bath.

2. To facilitate inventory management of stored frozen plasma specimens, ensure local standard operating procedures include timely notification of the ASWBPL West when frozen units are transfused, outdated, destroyed, or used.

(h) Provide annual training per paragraph 4h of this enclosure.

(i) In support of Navy contingency clinical requirements, maintain a minimum of 25 units of fresh frozen plasma (10 group A, 5 group B, and 10 AB) above normal daily patient requirements, stored at -40°C or colder.

(j) FDA Licensure. Cryoprecipitated antihemophilic factor, fresh frozen plasma, liquid platelets (random and apheresis), red blood cells, red blood cells frozen, red blood cells deglycerolized, whole blood, and autologous red blood cells and whole blood.

(5) U.S. Branch Health Clinic, Diego Garcia

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and AJBPOs and the Component Command Blood Program Office for development of contingency and mobilization requirements in support of OPLANS.

(c) Operate a transfusion service as directed in references (f) through (h), relying on routine blood product support from the ASBBC PACOM. Comply with requirements for the emergency use of non-FDA licensed blood products as directed in reference (n).

(d) Operate a contingency donor collection program such that technician proficiency and regular contact with command blood program coordinators is maintained. FDA licensure for the manufacturer of blood products is not required. Comply with requirements for non-FDA licensed blood products as directed in reference (n).

c. NAVEUR. Designates in writing a component command blood program manager to perform duties outlined in paragraph 4 of this enclosure.

(1) U.S. Naval Hospital (USNAVHOSP), Naples, IT

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and AJBPOs and the Component Command Blood Program Office for development of contingency and mobilization requirements in support of OPLANS.

(c) Operate a transfusion service as directed in references (f) and (i) through (m), relying on routine blood product support from the ASWBPL East and/or the U.S. European Command, Armed Services Blood Bank Center (ASBBC EUCOM) when established. Obtain secondary blood support through the use of deglycerolized/thawed frozen blood products. Obtain emergency blood product support from host nation civilian agencies through a local MOU(s). Comply with requirements for the emergency use of non-FDA licensed blood products as directed in reference (n).

(d) Operate a contingency donor collection program such that technician proficiency and regular contact with command blood program coordinators is maintained. FDA licensure for the manufacturer of blood products is not required. Comply with requirements for non-FDA licensed blood products as directed in reference (n).

(e) In support of the Navy's Frozen Blood Program, establish and maintain capability to store, ship, and deglycerolize red blood cells.

1. Maintain a minimum inventory of 100 units of frozen blood stored at -65°C or colder, 2 automated frozen blood cell washers, and 1 water bath.

2. To facilitate inventory management of stored frozen plasma specimens, ensure local standard operating procedures include timely notification of the ASWBPL East when frozen units are transfused, outdated, destroyed, or used.

(f) Provide annual training per paragraph 4j of this enclosure.

(g) In support of Navy contingency clinical requirements, maintain a minimum of 25 units of fresh frozen plasma (10 group A, 5 group B, and 10 AB) above normal daily patient requirements, stored at -40°C or colder.

(h) FDA Licensure. Registered as a transfusion service.

(2) U.S. Naval Hospital (USNAVHOSP), Rota, SP

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and AJBPOs and the Component Command Blood Program Office for development of contingency and mobilization requirements in support of OPLANS.

(c) Operate a transfusion service as directed in references (f) and (i) through (m), relying on routine blood product support from the ASWBPL East and/or the ASBBC EUCOM when established. Obtain secondary blood support through the use of deglycerolized/thawed frozen blood products. Obtain emergency blood product support from host nation civilian agencies through a local MOU(s). Comply with requirements for the emergency use of non-FDA licensed blood products as directed in reference (n).

(d) Operate a contingency donor collection program such that technician proficiency and regular contact with command blood program coordinators is maintained. FDA licensure for the manufacturer of blood products is not required. Comply with requirements for non-FDA licensed blood products as directed in reference (n).

(e) In support of the Navy's Frozen Blood Program, establish and maintain capability to store, ship, and deglycerolize red blood cells.

1. Maintain a minimum inventory of 100 units of frozen blood stored at -65°C or colder, 2 automated frozen blood cell washers, and 1 water bath.

2. To facilitate inventory management of stored frozen plasma specimens, ensure local standard operating procedures include timely notification of the ASWBPL East when frozen units are transfused, outdated, destroyed, or used.

(f) Provide annual training per paragraph 4h of this enclosure.

(g) In support of Navy contingency clinical requirements, maintain a minimum of 25 units of fresh frozen plasma (10 group A, 5 group B, and 10 AB) above normal daily patient requirements, at -40°C or colder.

(h) FDA Licensure. Registered as a transfusion service.

(3) U.S. Naval Hospital (USNAVHOSP), Sigonella, IT

(a) Ensure compliance with enclosure (1) of this instruction and paragraph 4 of this enclosure.

(b) Coordinate with the unified command and AJBPOs and the Component Command Blood Program Office for development of contingency and mobilization requirements in support of OPLANS.

(c) Operate a transfusion service as directed in references (f) and (i) through (m), relying on routine blood product support from the ASWBPL East and/or the ASBBC EUCOM when established. Obtain secondary blood support through the use of deglycerolized/thawed frozen blood products. Obtain emergency blood product support from host nation civilian agencies through a local MOU(s). Comply with requirements for the emergency use of non-FDA licensed blood products as directed in reference (n).

(d) Operate a contingency donor collection program such that technician proficiency and regular contact with command blood program coordinators is maintained. FDA licensure for the manufacturer of blood products is not required. Comply with requirements for non-FDA licensed blood products as directed in reference (n).

(e) Serve as the Navy's executive agent for and support the operation of the EUCOM frozen Blood Product Depot (BPD), as directed in references (f) and (i) through (m). Provide frozen blood product support to theater DOD MTFs, when directed by the unified command joint blood program.

(f) Ensure readiness capability of the BPD is adequately maintained to meet the expanded frozen blood mission and assigned contingency red blood cell requirements. Operation of the BPD in peacetime is critical to maintain personnel competency and training for immediate activation and expansion of the BPD.

1. Ensure component UIC mobilization assignments of BPD staff and augmentation personnel are maintained.

2. Ensure BPD staff and augmentation personnel are trained.

3. Ensure BPD equipment and facilities are maintained and are functional.

4. Establish and maintain BPD activation and mobilization plans to ensure frozen blood deglycerolization requirements are met.

5. To ensure sufficient and recurring prime vendor demand for inventory items required to support surge requirements, use of similar BPD supply and equipment items for peacetime and expanded BPD operations is encouraged.

(g) In support of the Navy's Frozen Blood Program, establish and maintain capability to store, ship, and deglycerolize red blood cells.

1. Maintain a minimum inventory of 2,500 units of frozen blood stored at -65°C or colder, 10 automated frozen blood cell washers, and 4 water baths. Additionally, as an alternate frozen blood storage facility for East Coast homeported ships, maintain the capability to store a total of 4,000 units of frozen blood stored at -65°C or colder.

2. Maintain the capability, as directed, to function as a theater Blood Supply Unit (total 6,500 units).

3. To facilitate inventory management of stored frozen plasma specimens, ensure local standard operating procedures include timely notification of the ASWBPL West when frozen units are transfused, outdated, destroyed, or used.

(h) Provide annual training per paragraph 4h of this enclosure.

(i) Support blood bank requirements of theater homeported ships including maintenance of frozen blood inventory, availability of print-on-demand blood product labels, and maintenance of and personnel training for the TDBSS.

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(j) In support of Navy contingency clinical requirements, maintain a minimum of 200 units of fresh frozen plasma (75 group A, 50 group B, and 75 AB) and 50 units of cryoprecipitated antihemophilic factor (non group O) above normal daily patient requirements, stored at -40°C or colder.

(k) FDA Licensure. Registered as a transfusion service.

NAVY BLOOD PROGRAM (NBP) OFFICE RESPONSIBILITIES

1. General. The Director, BUMED Navy Blood Program (BUMED-M3B632), must be a medical technologist (NOBC 0866), certified as a specialist in blood banking (60V AQD), and possess significant experience in organization and management of the Armed Services Blood Program (ASBP).

2. Objectives

a. Ensure the availability and adequate supply of high quality blood and blood products, which meet and exceed the standard of care, to DOD MHS and joint operating forces during peacetime, and periods of contingency and mobilization.

b. Increase the readiness posture of the NBP.

c. Increase the quality of blood banking practices by ensuring and monitoring compliance with FDA regulations, guidelines, and cGMP, and AABB standards.

d. Standardize procedures, equipment, and training throughout the NBP.

e. Assess and plan for implementation of advances in blood and blood component therapy (e.g., frozen products, freeze dried products, blood substitutes, hemostatic agents) and evaluate their appropriateness for use within the Navy and Marine Corps with respect to contingency planning.

f. Exchange information on availability of excess blood bank equipment.

g. Improve blood resource management practices through consolidation and resource sharing.

3. Responsibilities

a. Manages the Navy's FDA establishment license (#635) for the Navy Surgeon General. Coordinates Navy blood bank policies to ensure compliance with the CFRs for the manufacture of blood products under the Department of Health and Human Services licensure program.

b. Serves as executive agent for coordination and management of all Navy blood banking matters including operational and QA issues. Centrally develops and distributes directives, policies, and procedures for the NBP.

c. Establishes QA management as a distinct unit from operations to ensure compliance with the principles of cGMPs. The QA unit conducts assessments through surveys, audits, review of FDA variance/deviation reports, and FDA inspections, and, recommends quality improvements to the NBP. The QA unit is responsible for review of all FDA reportable variances/deviations and inspection responses before submission to FDA, and will ensure corrective actions are appropriate.

d. Works with component commands to ensure adequate blood support for emergency, mobilization, and contingency requirements; integration of CONUS blood program into the ASBP; and Fleet support for the frozen blood program.

e. Directs the distribution of Navy blood resources and establishes quotas to support local emergencies, and mobilization and contingency requirements levied by the ASBPO.

f. Collects and maintains data on blood bank operations and takes action, as indicated, for proper allocation of Navy blood resources to ensure their effective and efficient use.

g. Serves as control center for all correspondence relative to Navy blood banking matters. Serves as central repository for all Navy Transfusion Transmitted Disease Lookback cases (e.g., HIV, HTLV, and hepatitis).

h. Initiates and coordinates issues relative to special blood projects and studies. Serves as a member of the Armed Services Blood Program Office, Blood Coordinating Committee (ABCC). and the Defense Blood Standard System Committee.

i. Acts as advisor to the professional consultant in the technical review of blood bank equipment and research. Serves as referral agent and coordinator for technical blood bank matters. Ensures the dissemination of information on developments in preparation and use of blood components.

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j. Conducts periodic assistance visits to the blood banks established as Centers of Excellence.

k. Performs public information functions for Navy blood banking.

NAVY COMPONENT COMMAND BLOOD PROGRAM

1. General. A Navy component command blood program should be established with responsibility for both the Fleet and the Marine Corps blood requirements. Each component command will designate a separate blood program manager for the Fleet/Marine Corps. To ensure the TYCOMs maintain a program that assures compliance with this instruction, the Fleet and Marine Corps component blood program is responsible to the unified commander for the operation of a component command blood program as outlined in enclosures (1) and (3).

2. Objectives

a. Support the peacetime and wartime blood requirements within component command areas and allow for program integration into the unified command's blood program.

b. In conjunction with the unified command, identify requirements for Navy or Marine Corps component Blood Supply Units.

3. Responsibilities

a. In support of the Navy's Lookback Programs, ensure deployable medical systems (DEPMEDS) and vessels capable of collecting or storing liquid or frozen blood maintain procedures that will identify and trace all blood products to final disposition of the product (destroyed, transfused, or transported from the DEPMEDS or off the ship). Forward copies of all DEPMEDS and shipboard transfusion records (including copies of DD 518s), collection records (to include copies of completed DD 572s), and DD 573s (Shipping Inventory of Blood Products) to the Bureau of Medicine and Surgery, Navy Blood Program Office, (BUMED-M3B63), 2300 E Street NW, Washington, DC 20372-5300.

b. Ensures the Navy's shipboard blood program (liquid and frozen) is properly administered as outlined in enclosure (7).

c. If equipped, ensures LHAs, LHDs, FH, and TAHs use DBSS to perform the functional processes for donor collections, product and component processing, transfusions, record maintenance, and lookbacks.

TECHNICAL ASSISTANCE VISIT PROCEDURES AND FDA INSPECTIONS

1. The Centers of Excellence and area blood directors will receive a technical assistance visit (TAV) every 2 years from the Navy Blood Program Branch, BUMED-M3B63.

2. The director of each Center of Excellence, or a qualified representative appointed by the director, annually inspects all satellite blood banks under their assigned Region to ensure compliance with FDA regulations and applicable DOD and Navy directives. Each director must budget for this mission-essential travel.

a. Use the current Navy Blood Program Quality Assurance Plan, American Association of Blood Banks Standards, and, FDA current Good Manufacturing Practice (cGMP) and guidelines for all inspections. The inspections should be conducted as an audit of all applicable blood bank systems and should address each applicable critical control point and key element. The inspection report must include an itemized list of discrepancies, recommendations, and comments on actions that will improve the effectiveness and efficiency of the Navy Blood Program.

b. Within 30 days of the Navy inspection, the inspected facility must provide the area director with written documentation (including standard operating procedures, forms, etc.) of actions taken to correct the noted deficiencies.

c. Upon receipt and acceptance of the deficiency correction report, the director must forward a formal acceptance letter to the inspected facility. Forward a copy of the formal inspection report and the facilities corrective action report to BUMED-M3B63. The inspected facility and the regional blood system director shall maintain copies of the inspection results/documentation. Address areas of concern in the formal response to the inspected facility.

3. In addition to those items addressed in system audits, the director's inspection report must contain specific comments relating to the evaluation of:

a. Training records for blood donor center personnel and augmentation staff.

b. Mobilization platform assignments to ensure personnel assigned to LHAs, LHDs, and T-AHs are receiving annual refresher training in deglycerolization procedures for frozen blood.

c. Donor center operations to:

(1) Ascertain if the facility is meeting BUMED collection quotas in support of the ASWBPL and the Navy Frozen Blood Program.

(2) Ascertain the status in meeting the blood product stocking requirements in enclosure (2) outlined for contingency frozen blood, contingency fresh frozen plasma, contingency cryoprecipitated antihemophilic factor, and known frozen blood phenotypes.

d. Blood bank and donor center records to ensure all donor cards with related Acquired Immunodeficiency Syndrome (AIDS) sheets, component logs, transfusion logs, and patient crossmatch cards are periodically microfilmed.

e. Adequacy of blood resource management.

f. HIV Lookback Program to ascertain if case files are maintained on each donor or recipient lookback request.

g. Participation in recovered expired red blood cells and plasma contracts.

h. Degree of adherence to applicable rules, regulations, standards, and directives.

4. All facilities (transfusion services and blood donor centers) will receive an annual unannounced inspection by an FDA inspector. Within 30 days of completion of the FDA inspection, the commanding officer must forward to Chief, BUMED (BUMED-M3B63) written documentation (including standard operating procedures (SOPs), forms, etc.) of actions taken to correct any discrepancies. The Navy Surgeon General will forward the command's inspection response formally to the FDA.

TYPE COMMANDERS (TYCOMs); COMMANDING OFFICERS AFLOAT;
COMMANDERS, MARINE CORPS MEDICAL BATTALION; AND
COMMANDING OFFICERS, MEDICAL TREATMENT FACILITY,
USNS COMFORT AND USNS MERCY

1. Type Commanders (TYCOMs)

a. Are responsible to the component command for developing, implementing, and maintaining a program to fully comply with this instruction.

b. Ensure standard operating procedures in enclosure (8) are developed, maintained, and reviewed annually.

c. Track informal annual or pre-deployment technical assist visits (TAVs) for LHAs and LHDs. Depending upon the situation, TAVs may be requested for any class of ship with blood collection or storage capability. Since pre-positioned frozen blood and blood products are strictly controlled by the FDA and are of congressional interest, it is absolutely imperative that LHAs and LHDs receive and document TAVs.

(1) TAVs must be conducted approximately 90-120 days before deployment as part of the pre-deployment checklist or annually, at a minimum.

(2) The regional blood system director (or representative) must use enclosure (8) throughout the inspection and must outbrief the commanding officer (or his or her representative) before leaving the ship. Forward a written report of the TAV to the commanding officer within 15 working days of the TAV.

d. Ensure frozen blood training is received for support of LHAs and LHDs. Assistance will be provided by the regional blood system director.

e. Ensure afloat blood product needs or excesses are provided to the applicable servicing area blood system director before the deployment of LHAs and LHDs (see enclosure 2, paragraph 5).

f. Ensure all ships capable of collecting or storing liquid or frozen blood maintain procedures which will allow for the

identification and tracking of all products (received from off the ship or from collected shipboard) to final disposition of the products (destroyed, transfused, or transported off the ship). Ensure receiving and shipping documents, blood donor records, and transfusion records are permanently maintained.

g. Coordinate with the ship (LHA, LHD, and TAH) commanding officer and regional blood system director for the relocation of shipboard frozen blood assets during periods of ship overhaul or the unanticipated loss of freezer capability. Costs incurred during the removal and replenishment (shipping boxes, dry ice, and transportation) must be the responsibility of the ship.

h. If equipped, ensures LHAs, LHDs, FH, and TAHs use TDBSS to perform the functional processes for donor collections, product and component processing, transfusions, record maintenance, and lookbacks.

2. Commanding Officers Afloat

a. All ships capable of collecting blood (AFS, AGF, AOE, CGN, LCC, LKA, LPD, LHD, LHA, AD, AR, and T-AH):

(1) Comply with paragraph 1 of this enclosure.

(2) Maintain a list of acceptable emergency donors based on individuals' blood group and answers to questions concerning the donor medical history located on the DD 572, Blood Donation Record. See Figure 1 for a recommended flow chart for a emergency donor program.

(a) Based on the windows of infectivity, pre-deployment testing of individuals for infectious diseases (hepatitis, HIV, etc.) is not required. Volunteer contingency donors should be recruited to donate in conjunction with a pre-deployment blood drive with the local MTF and subsequently designated as the emergency donor pool.

(b) If emergency blood donor units are collected and transfused the donor must have been medically qualified and questioned, using the DD 572, on the day of collection. In addition, a plasma sample must be collected from the donor, properly labeled and frozen. Upon arrival at the nearest military medical facility with a blood donor center, submit the sample for the current battery of blood donor tests.

(c) Ships without donor unit number blocks assigned per enclosure (9) must use the segment number from the blood collection set bag (from the tubing attached to the needle that the blood flows through) as the donor identification number.

(3) Ensure procedures are in place, which allows for the identification and tracking of all blood products (received from off the ship or from emergency onboard collections), to final disposition of the product (destroyed, transfused, or transported off the ship). Ensure receiving and shipping documents, blood donation records, and transfusion records are permanently maintained. Forward copies of all shipboard transfusion records (including copies of DD 518s), collection records (to include copies of completed DD 572s), and DD 573s (Shipping Inventory of Blood Products) to the Bureau of Medicine and Surgery, Navy Blood Program Office (BUMED-M3B63), 2300 E Street NW, Washington, DC 20372-5300.

(4) As needed, coordinate peacetime deployment liquid blood requests with local CONUS blood donor center 15-30 days before deployment. Coordinate (with unified and component commands) OCONUS resupply requests to the closest U.S. Naval Hospital 10-15 days before arrival or close transit. Common request is for 5-8 units of red blood cells (75 percent O positive, 25 percent O negative). Ships must have an approved, temperature monitored, blood bank refrigerator.

b. LHAs and LHDs

(1) Comply with paragraph 1 of this enclosure.

(2) Maintain references in enclosure (8). Use enclosure (8) as a reference to maintain the frozen blood program.

(3) Ensure informal annual or pre-deployment TAVs are scheduled per enclosure (2). Since pre-positioned frozen blood and blood products are strictly controlled by the FDA, it is absolutely imperative that LHAs and LHDs receive and document TAVs.

(a) TAVs are conducted approximately 90-120 days before deployment as part of the pre-deployment checklist or annually, at a minimum. This allows sufficient time to correct discrepancies or procure supplies required to provide maximum frozen blood deglycerolization capability.

(b) The area blood system director (or representative) must use enclosure (8) throughout the inspection and must outbrief the commanding officer (or his or her representative) before leaving the ship. Forward a written report of the TAV to the commanding officer within 15 working days of the TAV.

(4) Order, maintain, and ship blood products (liquid and frozen) as directed.

(5) As needed, coordinate peacetime deployment liquid blood requests with local CONUS blood donor center 15-30 days before deployment. Coordinate OCONUS re-supply requests to the closest U.S. naval hospital 10-15 days before arrival or close transit. Common request is for 5 units of red blood cells (75 percent O positive, 25 percent O negative).

(6) Ensure deglycerolized frozen blood is used as the product of choice for transfusion in all situations, which permit. It is extremely important that when frozen red cell units are transfused, outdated, destroyed, used for training, or other, and are no longer in the available inventory, the final disposition of the units will be documented. Report the final disposition and donor number to the homeport regional blood system director. All cryovials/plasma preparation tube (PPT) are stored at the designated repository and the regional blood system director must report the final status to the designated repository.

(7) Ensure frozen blood training has been received for permanent staff and Medical Augmentation Program (MAP) laboratory personnel assigned to the platform. Assistance will be provided by the regional blood system director.

(8) Maintain a list of acceptable emergency donors based on individuals' blood group and answers to questions concerning the donor medical history located on the DD 572, Blood Donation Record.

(a) Based on the windows of infectivity, predeployment testing of individuals for infectious diseases (hepatitis, HIV, etc.) is not required. Volunteer contingency donors should be recruited to donate in conjunction with a pre-deployment blood drive with the local MTF and subsequently designated as the emergency donor pool.

(b) If emergency blood donor units are collected and transfused, the donor must have been medically qualified and questioned, using the DD 572, on the day of collection. In addition, two PPT samples must be collected from the donor, properly labeled, spun down and frozen. Upon arrival at the nearest MTF with a BDC, submit the tubes for the current battery of required blood donor tests.

(c) Ships without donor unit number blocks assigned per enclosure (9) must use the segment number from the blood collection set bag (from the tubing attached to the needle that the blood flows through) as the donor identification number.

(9) Ensure procedures are in place that will allow for the identification and tracking of all blood products (received from off the ship or from emergency onboard collections) to final disposition of the product (destroyed, transfused, or transported off the ship). Ensure receiving and shipping documents, blood donation records, and transfusion records are permanently maintained. Forward copies of all shipboard transfusion records (including copies of DD 518s), collection records (to include copies of completed DD 572s), and DD 573s (Shipping Inventory of Blood Products) to the Bureau of Medicine and Surgery, Navy Blood Program Office (BUMED-M3B63), 2300 E Street NW, Washington, DC 20372-5300.

(10) As available from NBP, maintain maximum inventory of frozen blood products outlined in paragraph 4 and maintain the capability to deglycerolize all frozen blood held in inventory. Ensure supply procedures are in place that allow for pre-deployment procurement and receipt of non-depot stocked items that support the frozen blood program. Maintain frozen blood and fresh frozen plasma at -65°C or colder.

(11) Procure print-on-demand blood product labels from the regional blood system director for whole blood, red blood cells, red blood cells deglycerolized, and whole blood number sets. Provide funding for labels with Medical Interdepartmental Purchase Request (MIPR) document.

(12) If equipped, ensure use of DBSS to perform the functional processes for donor collections, product and component processing, transfusions, record maintenance, and lookbacks.

(13) Provide blood support ashore, as directed by the Joint Task Force Surgeon.

3. Commanders, Marine Corps Medical Battalion

a. Comply with paragraph 1 of this enclosure.

b. Maintain a list of acceptable contingency donors based on individuals' blood group and answers to questions concerning the donor medical history located on the DD 572, Blood Donation Record.

(1) Based on the windows of infectivity, pre-deployment testing of individuals for infectious diseases (hepatitis, HIV, etc.) is not required. Volunteer contingency donors should be recruited to donate in conjunction with a pre-deployment blood drive with the local MTF and subsequently designated as the emergency donor pool.

(2) If emergency blood donor units are collected and transfused, the donor must have been medically qualified and questioned, using the DD 572, on the day of collection. In addition, a plasma sample must be collected from the donor, properly labeled and frozen. Upon arrival at the nearest military medical facility with a BDC, submit the sample for the current battery of blood donor tests.

(3) Marine Corps collections must use the segment number from the blood collection set bag (from the tubing attached to the needle that the blood flows through) as the donor identification number.

c. Ensure procedures are in place that will allow for the identification and tracking of all blood products to final disposition of the product (destroyed, transfused, or shipped). Ensure receiving and shipping documents, blood donation records, and transfusion records are permanently maintained. Upon return from deployment, forward copies of all transfusion records (including copies of DD 518s), collection records (to include copies of completed DD 572s), and DD 573s (Shipping Inventory of Blood Products) to the Bureau of Medicine and Surgery, Navy Blood Program Office (BUMED-M3B63), 2300 E Street NW, Washington, DC 20372-5300.

4. Commanding Officers, Medical Treatment Facility, USNS COMFORT and USNS MERCY

a. Comply with paragraph 1 of this enclosure.

b. Ensure the standard operating procedures (SOPs) in enclosure (8) are developed, maintained, and reviewed annually.

c. Maintain references in enclosure (8). Use enclosure (8) as a reference to maintain the frozen blood program.

d. Ensure informal annual or pre-deployment TAVs are scheduled per enclosure (2). Since pre-positioned frozen blood and blood products are strictly controlled by the FDA, it is absolutely imperative that T-AHs receive and document TAVs.

(1) TAVs are conducted approximately 90-120 days before deployment as part of the pre-deployment checklist or annually, at a minimum. This allows sufficient time to correct discrepancies or procure supplies required to provide maximum frozen blood deglycerolization capability.

(2) The regional blood system director (or representative) must use enclosure (8) throughout the inspection and must out brief the commanding officer (or his or her representative) before leaving the ship. Forward a written report of the TAV to the commanding officer within 15 working days of the TAV.

e. Ensure frozen blood training has been received for laboratory personnel assigned to the platform. The area blood system director will provide assistance.

f. Advise component command of predicted blood product excesses or deficiencies. Order, maintain, and ship blood products (liquid and frozen) as directed by the component command.

g. As needed, coordinate peacetime deployment liquid blood requests with local CONUS BDC 15-30 days before deployment. Coordinate OCONUS resupply requests via message to the closest U.S. naval hospital 5-10 days before arrival or close transit. Common request is for 8-10 units of red blood cells (75 percent O positive, 25 percent O negative).

h. As available from NBP, maintain maximum inventory of frozen blood products outlined in paragraph 4 and maintain the capability to deglycerolize all frozen blood held in inventory. Ensure supply procedures are in place that allow for pre-deployment procurement and receipt of non-depot stocked items that support the frozen blood program. Maintain frozen blood at -65°C or colder and fresh frozen plasma at -40°C or colder.

i. Ensure deglycerolized frozen blood is used as the product of choice for transfusion in all situations that permit. It is extremely important that when frozen red cell units are transfused, outdated, destroyed, used for transfusion, used for training, or other, and are no longer in the available inventory, the final disposition of the units will be documented. Report the final disposition and donor number to the regional blood system director. All cryovials/PPT are stored at the designated repository and the regional blood system director must report the final status to designated repository.

j. Coordinate with the regional blood system director for the relocation of shipboard frozen blood assets during periods of ship overhaul or the unanticipated loss of freezer capability. Costs incurred during the removal and replenishment (shipping boxes, dry ice, and transportation) must be the responsibility of the ship's MTF.

k. Maintain a list of acceptable contingency donors based on individuals' blood group and answers to questions concerning the donor medical history located on the DD 572, Blood Donation Record.

(1) Based on the windows of infectivity, pre-deployment testing of individuals for infectious diseases (hepatitis, HIV, etc.) is not required. It is recommended however, that volunteer contingency donors be recruited to donate in conjunction with a pre-deployment blood drive with the local MTF.

(2) If contingency blood donor units are collected and transfused in an emergency situation, the donor must have been medically qualified and questioned, using the DD 572, on the day of collection. In addition, two PPTs must be collected from the

donor, properly labeled, spun down and frozen. Upon arrival at the nearest MTF with a BDC, submit the PPTs for the current battery of required blood donor tests.

(3) Ships without donor unit number blocks assigned per enclosure (9) must use the segment number from the blood collection set bag (from the tubing attached to the needle that the blood flows through) as the donor identification number.

l. Ensure procedures are in place that will allow for the identification and tracking of all blood products (received from off the ship or from emergency onboard collections) to final disposition of the product (destroyed, transfused, or transported off the ship). Ensure receiving and shipping documents, blood donation records, and transfusion records are permanently maintained. Forward copies of all shipboard transfusion records (including copies of DD 518s), collection records (to include copies of completed DD 572s), and DD 573s (Shipping Inventory of Blood Products) to the Bureau of Medicine and Surgery, Navy Blood Program Office (BUMED-M3B63), 2300 E Street NW, Washington, DC 20372-5300.

m. Procure print-on-demand blood product labels from the regional blood system director for whole blood, red blood cells, platelets, platelets pheresis, red blood cells deglycerolized, and whole blood number sets.

n. Ensure the use of TDBSS to perform the functional processes for donor collections, product and component processing, transfusions, records maintenance, and lookbacks. Manual procedures will be developed for use during TDBSS downtimes.

5. Storage of Frozen Blood Products. Table 1 outlines shipboard requirements for two deployment types: Contingency (routine) and mobilization (wartime).

TABLE 1

FROZEN BLOOD SHIPBOARD REQUIREMENTS		
SHIP	FROZEN RED CELLS	FRESH FROZEN PLASMA
LHA	400	40
LHD	400	40
T-AH	1,400	110

6. Joint Blood Program. Deploying medical forces (FS, AGF, AOE, CGN, LCC, LKA, LPD, AD, AR, LPH, LHA, LHD, T-AH, FH, and Marine Corps Medical Battalions) which use blood and blood products to meet their mission must write standard operating procedures which will allow them to contact and integrate into the Armed Services Blood Distribution System.

a. Unified Command and Joint Blood Program Office (JBPO). Each unified command has a JBPO located within the Unified Command Surgeon's Office. The JBPO is responsible for establishing and maintaining the theater blood distribution system. The JBPO cross-levels blood products between areas within the unified command and submits daily consolidated Blood Reports (BLDREP) to the ASBPO. Deploying forces should use Table 2 to obtain the pertinent JBPO information prior to or upon arriving in the unified command's area of responsibility. The JBPO can provide information on the blood distribution system's infrastructure, points of contacts, telephone/voice numbers, and Plain Language Addresses (PLAD) for the daily BLDREP requirements. PLADs for the unified commands' JBPO are as follows:

- (1) U.S. European Command: USEUCOM VAIHINGEN GM//ECMD//.
- (2) U.S. Southern Command: USSOCOM QUARRY HEIGHTS PM//SCSG//.
- (3) U.S. Pacific Command: USPACOM CP SMITH HI//J07// with "info" to USPACOM JBPO OKINAWA JA//00K//.
- (4) U.S. Joint Forces Command: USJFCOM NORFOLK VA//JJJ//.
- (5) U.S. Central Command: USCENTCOM MACDILL AFB FL//CCSG//.

b. Area Joint Blood Program Office (AJBPO). Depending upon the unified command size or type of operation being supported, the JBPO may designate and establish AJBPOs. AJBPOs are used quite often with Joint Task Forces (JTF) and work for the JTF Surgeon. AJBPOs monitor blood requirements for Blood Transshipment Centers (BTCs), Transportable Blood Transshipment Centers (TBTCs), Blood Supply Units (BSUs), and MTFs within their designated area. They also cross-level blood products between component BSUs and submit a daily blood report (BLDREP)

to the JBPO. Deploying forces should use Table 3 to obtain the pertinent AJBPO information prior to or upon arriving in the unified command's area of responsibility.

c. Blood Transshipment Centers/Transportable Blood Transshipment Centers. BTCs or TBTCs are designated in the operation's plans or orders. They are Air Force operated and designed to store and distribute blood products to BSUs or other users. Deploying forces should use Table 4 to obtain the pertinent BTC/TBTC information prior to or upon arriving in the unified command's area of responsibility. They submit a daily BLDREP to the JBPO and Blood Shipment Reports (BLDSHIPPREPS) to receiving facilities.

d. Blood Supply Units. BSUs are designated in the operation's plans or orders. They can be an Army blood platoon, a Marine unit, a fixed MTF, a ship (T-AH), or a field MTF. They are designed to store and distribute blood products to MTFs and are the primary blood supply source within the Armed Services Blood Distribution System for all MTFs. Deploying forces should use Table 5 to obtain the pertinent BSU information prior to or upon arriving in the unified command's area of responsibility. They submit a daily consolidated BLDREP to the AJBPO or JBPO and BLDSHIPPREPS to receiving facilities.

e. Blood Product Depots (BPDs). BPDs are managed by their respective unified commands (PACOM, EUCOM, and CENTCOM) and located strategically in order to maintain large quantities of frozen blood products for use during armed conflicts or emergencies. Deploying forces should use Table 6 to obtain the pertinent BPD information prior to or upon arriving in the unified command's area of responsibility. They submit a daily BLDREP to the JBPO and BLDSHIPREP to receiving facilities.

f. Communications. Communications can be by either standardized "voice template" or use of standardized BLDREP and BLDSHIPREP messages using the Department of Defense's (DOD's) Message Text Format computer program. Each MTF is required to submit a daily BLDREP to its BSU. This report can be sent by the fastest means of communication. The BLDREP provides the MTF's current blood inventory, the amount of blood products required within the next 12 to 48 hours, the amount of blood expiring in the next 7 days, and the estimated blood products

required in the next 7 days. The BLDSHIPREP provides information on designated shipments of blood products to include transportation data and blood product amounts by blood groups.

(1) Voice BLDREP and BLDSHIPREP. Use Tables #7 and #8 respectively. Complete the required information prior to calling.

(2) BLDREP Message. This standardized message format is found in DOD's Message Text Format computer software program. To use this standardized format:

(a) Enter the program, assign the message a name, and press ENTER.

(b) Highlight "USMTF" (not Genadmin) and press ENTER.

(c) Press "F10" to view the menu.

(d) Highlight BLDREP and press ENTER.

(e) Type the message. Codes for completing this report are explained in Table 9.

(3) BLDSHIPREP Message. This standardized message format is found in DOD's Message Text Format computer software program. To use this standardized format:

(a) Enter the program, assign the message a name, and press ENTER.

(b) Highlight "USMTF" (not Genadmin) and press ENTER.

(c) Press "F10" to view the menu.

(d) Highlight BLDSHIPREP and press ENTER.

(e) Type the message. Codes for completing this report are explained in Table 9.

TABLE 2

JOINT BLOOD PROGRAM OFFICE

THE JBPO IS: _____

LOCATION: _____

COMMERCIAL: _____

DSN: _____

INMARSAT: _____

DNVT: _____

STU III (SECURE): _____

TACTICAL FAX: _____

COMMERCIAL FAX: _____

SECURE FAX: _____

MESSAGE PLA: _____

ROUTING INDICATOR: _____

TABLE 3

AREA JOINT BLOOD PROGRAM OFFICE

THE AJBPO IS: _____

LOCATION: _____

COMMERCIAL: _____

DSN: _____

INMARSAT: _____

DNVT: _____

STU III (SECURE): _____

TACTICAL FAX: _____

COMMERCIAL FAX: _____

SECURE FAX: _____

MESSAGE PLA: _____

ROUTING INDICATOR: _____

TABLE 4

BLOOD TRANSSHIPMENT CENTER/TRANSPORTABLE BLOOD
TRANSSHIPMENT CENTER

THE BTC/TBTC IS: _____

THE POC IS: _____

LOCATION: _____

COMMERCIAL: _____

DSN: _____

DNVT: _____

INMARSAT: _____

STU III (SECURE): _____

TACTICAL FAX: _____

COMMERCIAL FAX: _____

SECURE FAX: _____

MESSAGE PLA: _____

ROUTING INDICATOR: _____

TABLE 5

BLOOD SUPPLY UNIT

THE BSU IS: _____

THE POC: _____

LOCATION: _____

COMMERCIAL: _____

DSN: _____

INMARSAT: _____

DNVT: _____

STU III (SECURE): _____

TACTICAL FAX: _____

COMMERCIAL FAX: _____

SECURE FAX: _____

MESSAGE PLA: _____

ROUTING INDICATOR: _____

TABLE 6

BLOOD PRODUCT DEPOT

THE BPD IS: _____

THE POC IS: _____

LOCATION: _____

COMMERCIAL: _____

DSN: _____

INMARSAT: _____

DNVT: _____

STU III (SECURE): _____

TACTICAL FAX: _____

COMMERCIAL FAX: _____

SECURE FAX: _____

MESSAGE PLA: _____

ROUTING INDICATOR: _____

TABLE 7

BLDREP VOICE TEMPLATE

Addressee _____: When Addressee answers, the Originator responds: This is _____, Blood Report, please inform me when you are ready to receive a voice BLDREP-----"OVER"

This message is: FLASH IMMEDIATE PRIORITY ROUTINE
(circle one)

This message is: TOP SECRET SECRET CONFIDENTIAL UNCLASSIFIED
(circle one)

BLOOD REPORT

1. As of: _____ (Day-time-zone of this report)
2. Unit: _____ (Your unit's name or designator code)
3. Activity: _____ (Your unit's activity brevity letter)
4. Location: _____ (Your Lat/Long, UTM or place name)
5. Rendezvous: _____ (Naval ships only: Projected Lat/Long or place name for delivery)
6. Arrival: _____ (Naval ships only: Estimated arrival time-day, time zone, month, and year--at projected location)
7. Status of: _____ (Name or designator code of the unit or activity reporting the status other than originator)
8. Activity: _____ (Reporting unit's activity brevity code letter other than originator)
9. On Hand: _____ (Number and code of each blood product on hand)
10. Needed: _____ (Number and code of each blood product requested)
11. Expiration: _____ (Estimate of total number of blood product by group and type to expire in next 7 days)
12. Resupply: _____ (Estimate of total number of blood products by group and type required for resupply in the next 7 days)

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BLDREP VOICE TEMPLATE
CONTINUED

13. Narrative:_____

14. Time:_____ (Message hour-minute-zone)

15. Authentication:_____ (Message authentication
IAW JTF procedures)

"OVER"

TABLE 8

BLDSHIPREP VOICE TEMPLATE

Addressee _____: When Addressee answers, the Originator responds: This is _____, Blood Report, please inform me when you are ready to receive a voice BLDSHIPREP-----"OVER"

This message is: FLASH IMMEDIATE PRIORITY ROUTINE
(circle one)

This message is: TOP SECRET SECRET CONFIDENTIAL UNCLASSIFIED
circle one)

BLOOD SHIPMENT REPORT

1. As of: _____ (Day-time-zone of this report)
2. Unit: _____ (Your unit's name or designator code)
3. Activity: _____ (Your unit's activity brevity letter)
4. Location: _____ (Your Lat/Long, UTM or place name)
5. Rendezvous: _____ (Naval ships only: Projected Lat/Long or place name for delivery)
6. Arrival: _____ (Naval ships only: ETA in the projected location's time zone, month, day, year) the next 7 days)
7. Product: _____ (Brevity code of blood product being shipped)
8. O Positive: _____ (Number of units)
9. O Negative: _____ (Number of units)
10. A Positive: _____ (Number of units)
11. A Negative: _____ (Number of units)
12. B Positive: _____ (Number of units)
13. B Negative: _____ (Number of units)
14. AB Positive: _____ (Number of units)
15. AB Negative: _____ (Number of units)

BLDSHIPREP VOICE TEMPLATE
(CONTINUED)

16. Total: _____ (Total number of units of products being shipped)
17. Control: _____ (Airbill # or transportation control #-TCN)
18. Mission: _____ (Airline/flt #/ACC-mission #)
19. Arrival: _____ (ETA of that time zone, month, year)
20. Boxes: _____ (Number of boxes in shipment)
21. Contact: _____ (Name of shipper's point of contact (POC))
22. Telephone: _____ (24 hour telephone number of shipper's POC)
23. Narrative: _____
24. Time: _____ (Message hour-minute-zone)
25. Authentication: _____ (Message authentication IAW JTF procedures)

Say "OVER"

TABLE 9

BLDREP/BLDSHIPREP MESSAGE CODES

1. MANAGEMENT
 - A JBPO
 - B AJBPO

2. FACILITIES
 - C ASWBPL
 - D BDC
 - E BPD
 - F BTC
 - G BSU
 - H MTF
 - I NV (NAVAL VESSEL)

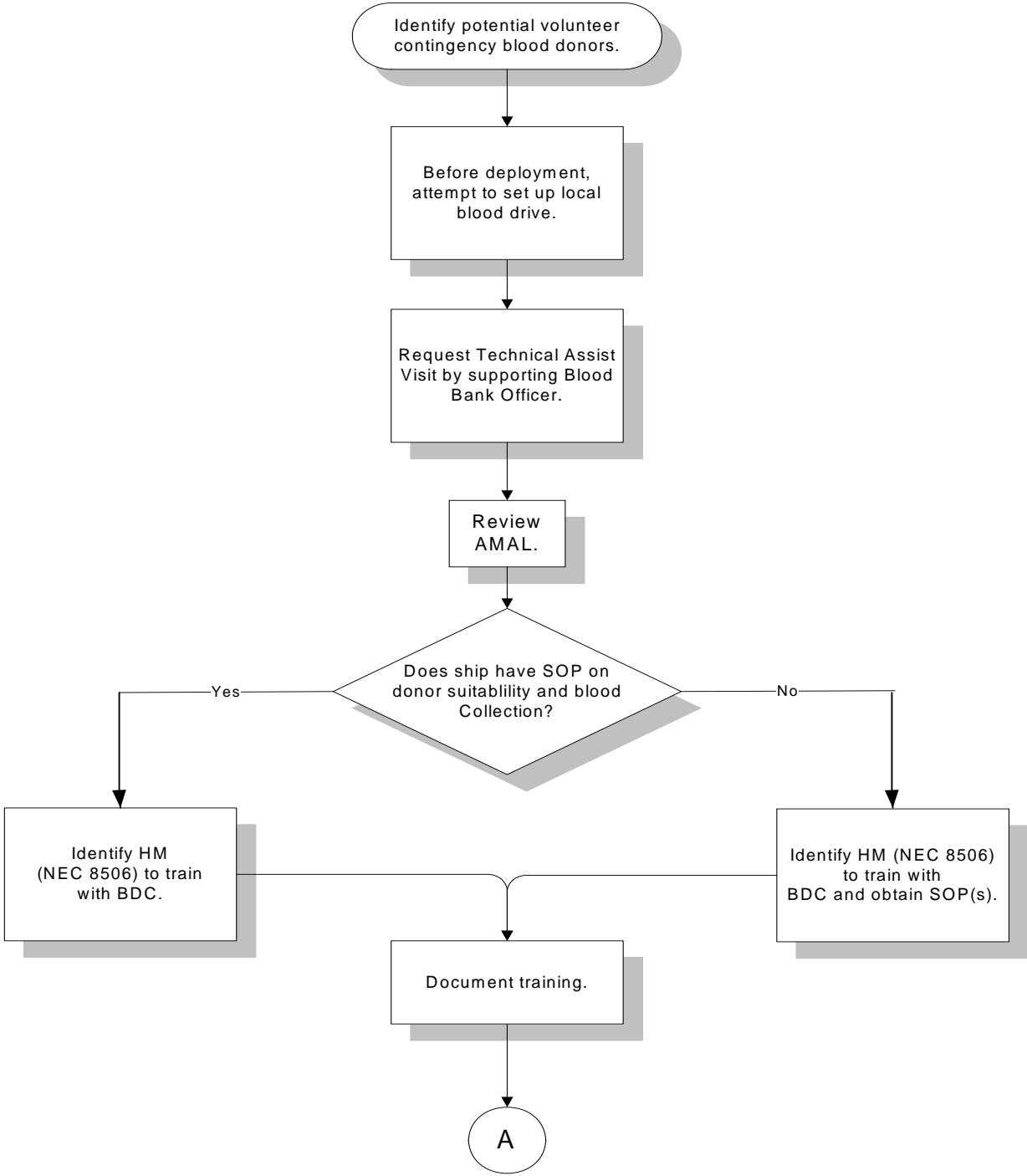
3. PRODUCTS
 - J RCZ (RED BLOOD CELLS)
 - K WBZ (WHOLE BLOOD)
 - L RCF (FROZEN RED CELLS)
 - M PFF (FRESH FROZEN PLASMA)
 - N PCF (FROZEN PLATELETS)

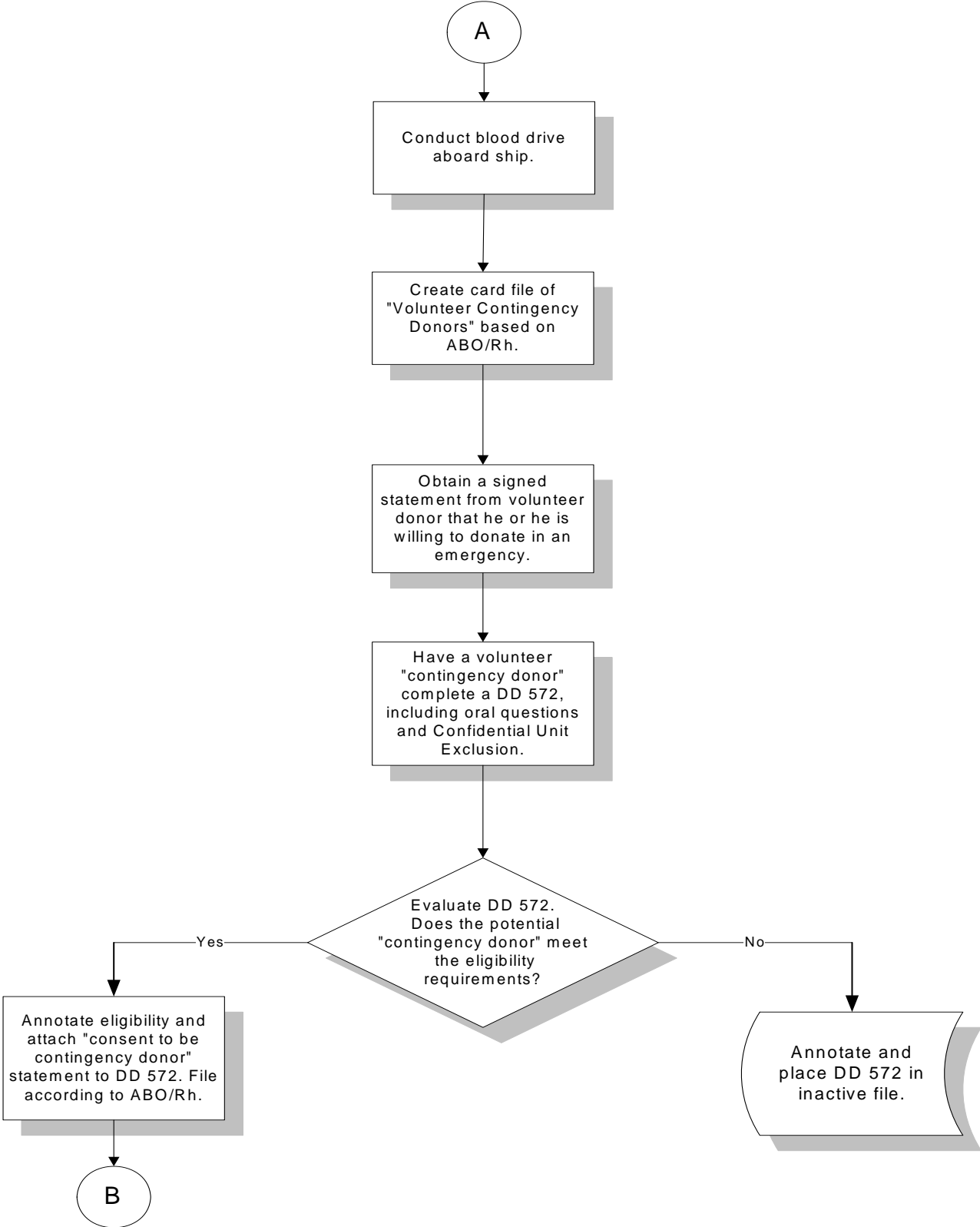
4. BLOOD GROUPS
 - Q RANDOM GROUP O/A/B
 - R RANDOM GROUP O/A
 - S RANDOM GROUP O
 - T RANDOM GROUP A
 - U RANDOM GROUP B
 - V RANDOM GROUP AB

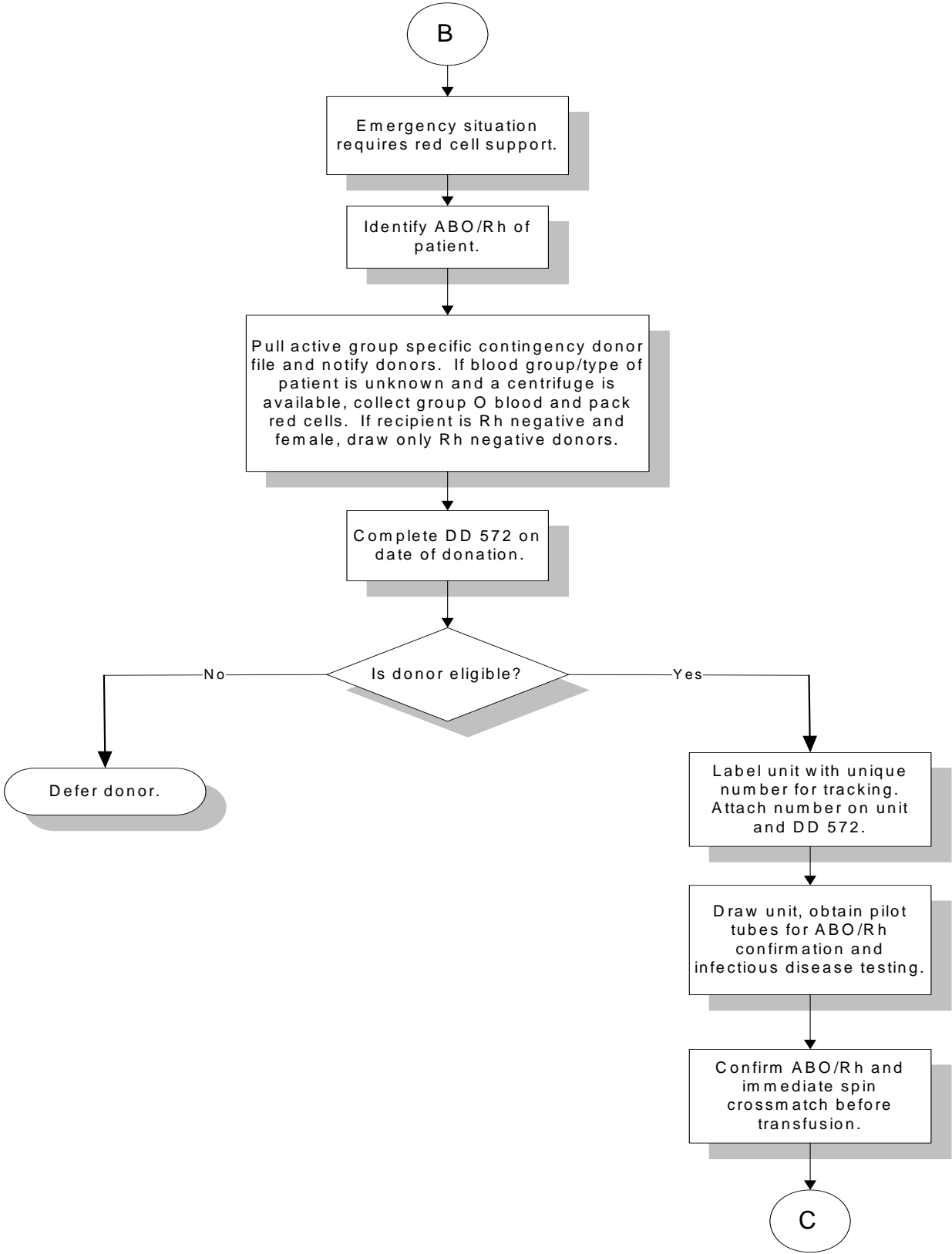
5. TIME FRAME
 - W REQUIRED WITHIN 12 HOURS
 - X REQUIRED WITHIN 24 HOURS
 - Y REQUIRED WITHIN 48 HOURS

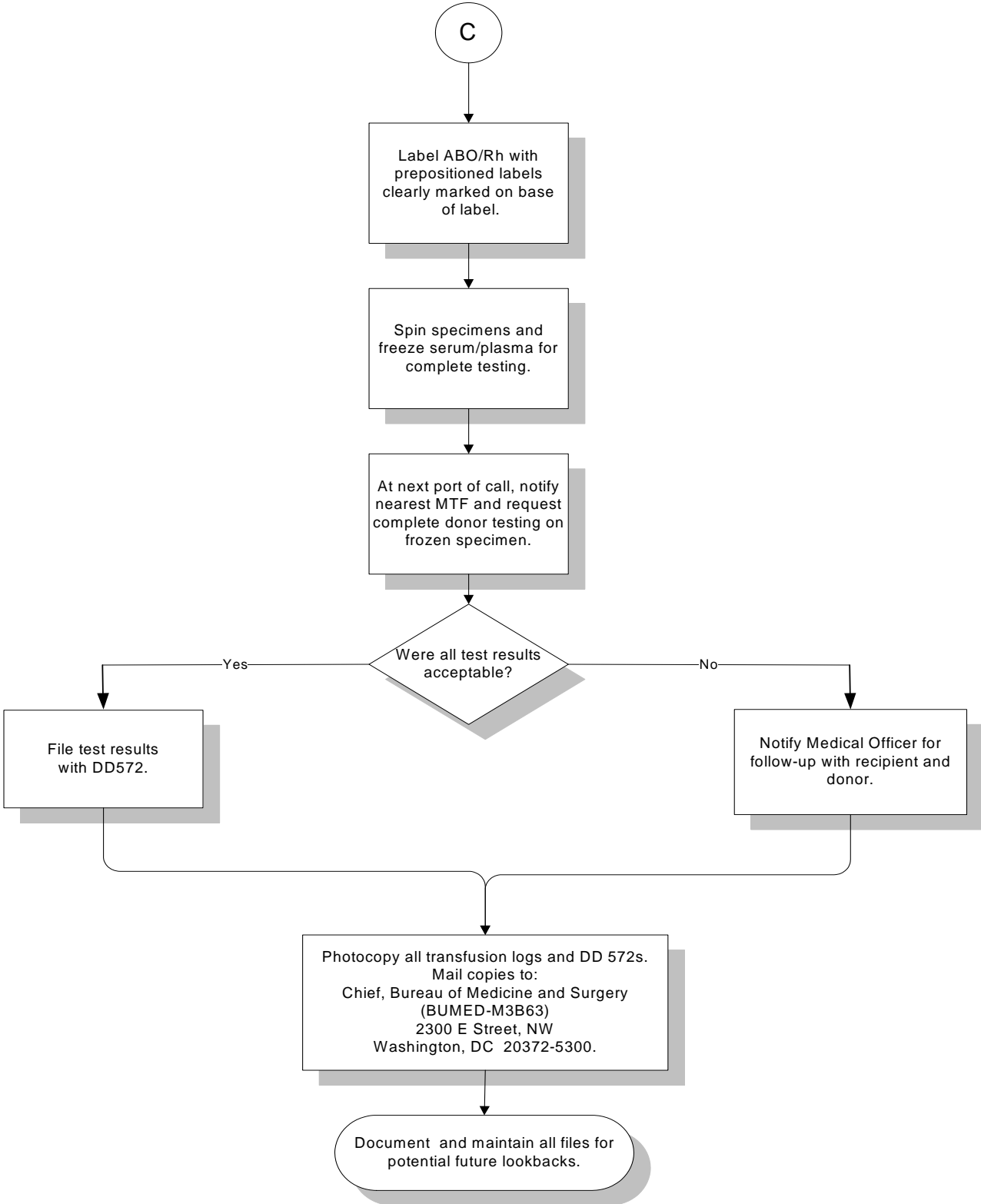
6. MISC
 - Z NOT APPLICABLE

Figure 1: Contingency Donor Program









NAVY FROZEN BLOOD PROGRAM
TECHNICAL ASSIST VISIT (TAV) CHECKLIST FOR
AMPHIBIOUS ASSAULT SHIPS, LHA;
AMPHIBIOUS ASSAULT SHIP (MULTI-PURPOSE), LHD;
AND AUXILIARY HOSPITAL SHIP, T-AH

Date:
Name of ship:
Homeport:
Responsible Line Commander:
Type Commander:
Component Command:
Ship's Medical Department Representative:
TAV Representative:
Last MRA Date:
Last MRA Results/Conducted by:

REQUIRED REFERENCES ABOARD	YES	NO
OPNAVINST 6530.2D (Donor Support for DON Blood Program)		
OPNAVINST 6530.4B (DON Blood Program)		
NAVMED P-5101 (AABB Technical Manual)		
NAVMED P-6530 (Joint Blood Program Handbook)		
NAVMED P-5123 (Operations of Donor Center/Shipping)		
COMNAVSURFORINST 6000.1, Chapter 8		

REQUIRED STANDARD OPERATING PROCEDURES	YES	NO
Shipboard donor screening, collection, and processing. How to handle an emergency blood drive.		
Deglycerolization of frozen red blood cells.		
Notification of cryovial/PPT repository once frozen units have been deglycerolized.		
Immediate spin crossmatching of red blood cells or frozen red blood cells.		
Patient and donor record tracking for all products. Includes expiring, breakage, transfusing, shipping, and destruction.		
Donor trip scale quality control.		
Reagent quality control.		
Deglycerolization quality control.		
Equipment maintenance and quality control.		
Plan and provisions in case of refrigerator/freezer failure.		

REQUIRED STANDARD OPERATING PROCEDURES (Continued)	YES	NO
Storage requirements for Frozen products. **Critical Temp must be below -65 degrees Celsius (FRBC) and -40 degrees Celsius (FFP and/or CRYO)		
Storage requirements for Liquid products/reagents. **Critical Temp must be between 1 to 6 degrees Celsius		
Rotation of inventory for maximum shelf-life.		
Procedure for requesting blood products, emergency, and in-theater operations, etc.		
Procedure for record retention and notification of transfusions to BUMED.		
Have the laboratory technicians (in donor operations) received training in frozen blood procedures?		

TRAINING	YES	NO
Have the laboratory technicians received an annual refresher course conducted by the local naval hospital?		
Are at least two personnel trained in cell washing procedures?		
Is all training documented in the medical department's training log?		
Have BIOMED repair technicians (if available) or machinist mates been trained in refrigerator/freezer maintenance or repair?		

GENERAL QUESTIONS	YES	NO
Are the refrigerator and freezer temperature control logs and graphs maintained?		
Are the freezers and refrigerators connected to emergency power?		
Are units of frozen blood products rotated to shore medical treatment facilities at least 3 months before end of shelf-life?		
Are the standard operating procedures being followed?		
Are the CO ² tanks used for the freezer backup system liquid siphon tanks? "Siphon" or "Dip Tube" will be stenciled on the side of tank by vendor. (Not required if freezers have dual cascade systems.)		
Do freezer and refrigerators have adequate and functional remote alarm systems installed for both power and temperature that are appropriately and periodically checked?		

OPNAVINST 6530.4B
MCO 6530.2
13 Aug 2007

FROZEN BLOOD PRODUCT STATUS			
	Products		
	Red Blood Cells	Plasma	Platelets
Number Authorized			
Number On-Board			
Earliest Expiration Date			

AMMAL

DESCRIPTION

7211	TAH Blood Bank (1000 bed)
7212	TAH Blood Bank (500 bed)
7213	TAH Blood Bank (250 bed)
7214	TAH Blood Bank (ROS)
1018	LHA/LHD Level Three Lab Core
1019	LHA/LHD Level Three Lab Supplemental
1020	LHD Blood Bank Supplemental
1021	LHA/LHD Core AMMAL
1022	LHA/LHD Supplemental AMMAL

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NAVY BLOOD PROGRAM
DONOR UNIT NUMBER BLOCKS
AND
FDA REGISTRATION NUMBERS

<u>COLLECTION CENTER</u>	<u>ICCBBA NUMBER</u>	<u>FDA REG NUMBER</u>
NAVMEDCEN San Diego CA	W0216	2076443
NAVHOSP Bremerton WA	W0203	3076829
NAVHOSP Camp Pendleton CA	W0205	2076574
NATNAVMEDCEN Bethesda MD	W0200	1176560
NAVHC ¹ Great Lakes IL	W0209	1476899
NAVMEDCEN Portsmouth VA	W0215	1176859
NAVHOSP Beaufort	W0202	1076931
NAVHOSP Camp Lejeune NC	W0204	1076942
NAVHOSP Charleston SC	W0206	1076900
NAVHOSP Guantanamo Bay CU	W0218	9611746
NAVHOSP Jacksonville FL	W0211	1076576
NAVHOSP Pensacola FL	W0214	1076561
NAVHOSP Okinawa JA (PACOM)	W0221	9611673
NAVHOSP Guam	W0217	9611740
NAVHOSP Yokosuka JA	W0225	9611679
NAVHOSP Naples IT	W0220	9611160
NAVHOSP Rota SP	W0223	9611702
NAVHOSP Sigonella IT	W0224	9612480

¹ Naval Health Clinic

NAVY BLOOD PROGRAM ABBREVIATIONS OR DEFINITIONS

AABB American Association of Blood Banks.
Organization that establishes blood banking policies and practices considered to be standards of care.

ABO/Rh The blood groupings (A, B, AB, or O associated with Positive or Negative).

AFB Air Force Base.

AHG Antihuman Globulin. Blood bank reagent used to detect human globulins coating red blood cells.

AIDS Acquired immunodeficiency syndrome.

AJBPO Area Joint Blood Program Office. A geographical area established by the Joint Blood Program Office to handle blood distribution for that specific area. The Joint Blood Program Office can establish multiple ASBPOs within the unified command.

AMC Air Mobility Command. Air Force Specified Command. Responsible for moving blood from the ASWBPL to the theater of operations.

ASBP Armed Services Blood Program.

ASBPO Armed Services Blood Program Office.
Coordinates the operation of the Armed Services Blood Program. Executive agent is the Army. Offices located with the Army Surgeon General. Triservice, consisting of director and two deputy directors (Operations and Modernization). Director's position rotates between services.

ASWBPL Armed Service Whole Blood Processing Laboratory. Operated by the Air Force but tri-service staffed. During mobilization, responsible for receiving blood from the military or civilian blood programs and transporting overseas. ASWBPL EAST is located at McGuire AFB, New Jersey. ASWBPL WEST is located at Travis AFB, California.

BLDREP Blood Report. A standardized message text format message developed by the Armed Services Blood Program used daily by theater blood units to report status of blood inventories and requirements. The template is located in the "USMTF" portion of the Message Text Format Program.

BLDSHIPREP Blood Shipment Report. A standardized message text format message developed by the Armed Services Blood Program use by all blood program entities to notify consignees that blood has been shipped and to provide shipment information. The template is located in the "USMTF" portion of the Message Text Format Program.

BPD Blood Product Depot. A fixed service component operated facility used to store pre-positioned frozen blood products for future theater use. Can also refer to Biological Product Deviation, a report submitted to the FDA; check the context used.

BRMEDCLINIC Branch Medical Clinic.

BSU Blood Supply Unit. A service component entity used to store and distribute blood from blood transshipment centers/transportable blood transshipment centers to medical treatment facilities or to receive and ship blood from medical treatment facilities to blood transshipment centers/transportable blood transshipment centers.

BTC Blood Transshipment Center. A stationary Air Force distribution center within a unified commands' theater used to receive and distribute blood to Blood Supply Units and medical treatment facilities.

BUMED Bureau of Medicine and Surgery.

COMSC Commander, Military Sealift Command.

CONUS Continental United States. The 48 contiguous States.

cGMP Current Good Manufacturing Practices. Laws that govern the production of a biological product as referenced in 21 CFR.

CFR Code of Federal Regulations.

CPD Citrate Phosphate Dextrose. Anticoagulant used in the collection of whole blood. The FDA has approved CPD blood for 21-day storage.

CPDA-1 Citrate Phosphate Dextrose Adenine-Formula 1. Anticoagulant used in the collection of whole blood. The FDA has approved CPDA-1 blood for 35-day storage.

DBSS Defense Blood Standard System. Blood bank computer management information system.

DEPMEDS Deployable medical systems.

DOD Department of Defense.

DON Department of the Navy.

DNVT Digital Non-secure Voice Terminal

FDA Food and Drug Administration. Department under the Secretary of Health and Human Services which licenses the collection and manufacture of blood and blood products.

GBL Government bill of lading.

GROUP O Blood group O.

GROUP A Blood group A.

GROUP B Blood group B.

GROUP AB Blood group AB.

HCT Hematocrit. The percent of red blood cells per volume of blood.

HIV Human Immunodeficiency Virus. Virus which causes Acquired Immune Deficiency Syndrome. Two types, Type 1 (HIV-1) and Type 2 (HIV-2).

HTLV Human T-Lymphotropic Virus. A retrovirus which has been etiologically linked to adult T-cell leukemia/lymphoma and associated with a progressive demyelinating myelopathy (tropic spastic paraparesis--TSP/HAM).

INMARSAT International Maritime Satellite.

JBPO Joint Blood Program Office. Unified commands' office that establishes and maintains the theater blood distribution system.

JTF Joint Task Force. A command made up of different Service components (e.g., Army, Navy, Air Force, Marine Corps, Coast Guard) to handle a specific mission.

LHA Amphibious Assault Ship (General Purpose). Class of ship carrying liquid and frozen blood. Includes USS TARAWA, USS SAIPAN, USS BELLEAU WOOD, USS PELELIU, and USS NASSAU.

LHD Amphibious Assault Ship (Multi-purpose). Class of ship carrying liquid and frozen blood. Includes USS WASP, USS ESSEX, USS KEARSARGE, and USS BOXER.

BUMED-M3B63 Code assigned to the Head, Navy Blood Program Management Office, Bureau of Medicine and Surgery. Responsible for the operation of the Navy Blood Program.

MAP Medical Augmentation Program. Program used to identify and deploy medical personnel to mobilization platforms.

MCB Marine Corps Base.

MIPR Medical Interdepartmental Purchase Request. Use to transfer funds from one command to another.

mL Milliliter. A unit of volume equal to one-thousandth of a liter.

MOU Memorandum of Understanding.

MSBOS Maximum Surgical Blood Order Schedule. Cumulative database of surgical procedures, the probability of blood utilization, actual blood utilization, and crossmatch requirements.

MTF Medical Treatment Facility.

NACL Sodium chloride.

NATNAVMEDCEN
(NNMC) National Naval Medical Center, Bethesda, MD.

NAVHOSP Naval Hospital. Naval hospitals located in the continental United States.

NAVMED NCA Navy Medicine National Capital Area

NAVMEDCEN
(NMC) Naval Medical Center.

NMF Navy Management Fund.

NOBC Navy Officer Billet Code. Numerical code used to identify officers' professional expertise.

OCONUS Outside the Continental United States. Outside the 48 contiguous states.

OPLANS Operational Plans. Plans developed by the unified commands for defense of either the entire theater of operations or a specific area.

PLAD Plain Language Addresses. Message Text Format addresses used to forward DOD messages.

PWRMS Pre-position War Reserve Materiel Stocks. Critical supplies which are pre-positioned to preclude loss of capability due to failure of the industrial base.

SOL Solution. A liquid.

SOP Standard Operating Procedures.

STU Secure Telephone Unit.

T-AH (TAH) Auxiliary Hospital Ship. Includes USNS MERCY
and USNS COMFORT.

TAV Technical Assist Visit. An annual or pre-
deployment visit by an area blood system
director to LHAs and LHDs.

TBTC Transportable Blood Transshipment Center. A
portable Air Force distribution center within a
unified commands' theater used to receive
and distribute blood to Blood Supply Units and
medical treatment facilities.

USMTF United States Message Text Format. The message
type section within DOD's Message Text Format
Program that contains standardized templates.

USNAVHOSP United States Naval Hospital. Naval hospital
located outside the continental United States.