Headquarters
United States Forces Korea
Unit #15237
APO AP 96271-5237

United States Forces Korea
Regulation 40-31

16 June 2020

Medical Services

KOREA AREA EMERGENCY BLOOD PROGRAM

***This regulation is a new edition.**

FOR THE COMMANDER:

STEPHEN C. WILLIAMS
Major General, USAF
Chief of Staff

OFFICIAL:

ROCKSON M. ROSARIO
Chief of Publications and
Records Management

Summary. This regulation implements the United States (U.S.) Military Emergency Blood Program (EBP) in Korea as outlined in Department of Defense Assistant Secretary of Defense (Health Affairs) Policy 10-002 and Joint Trauma System (JTS) Clinical Practice Guidelines (CPG) ID: 21. This regulation prescribes the responsibilities, policies, and procedures for the operation and management of the Korea Area EBP in meeting contingency requirements for the United States Forces Korea (USFK).

Applicability. This regulation applies to all USFK elements in Korea and installations or garrisons in the Republic of Korea (ROK).

Supplementation. Further supplements to this regulation by subordinate commands are authorized so long as these minimum requirements are maintained. Prior review is encouraged from Korean Area Joint Blood Program Officer (KAJBPO), Headquarters (HQ) USFK, (FKSG), Unit #15237, APO AP 96271-5237, email: indopacom.humphreys.usfk.list.fksg@mail.mil.

Forms. The forms associated with this program can be found in the JTS CPG #21.

Records Management. Records created as a result of processes prescribed by this regulation must be maintained and disposed of according to the Armed Service Blood Program Division current guidance. At time of this publication, that is use of Theater Medical Data Store-Blood Tabs for maintaining Donor screening and Patient Transfusion records; and AHLTA-T for general medical care in a Theater of Operations. Contact the KAJBPO to ensure most current version of this document and its appendices.

Suggested Improvements. The proponent of this regulation is Office of the Command Surgeon, HQ USFK (FKSG). Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to HQ USFK (FKSG), Unit #15237, APO AP 96271-5237, email: indopacom.humphreys.usfk.list.fksg@mail.mil.

Distribution. Electronic Media Only.

CONTENTS

Chapter 1
General

1-1. Purpose
For contingency operations it has been estimated that US Forces on the Korean Peninsula will need thousands of units of blood to support trauma victims in contingency operations or war. This regulation prescribes policies and establish responsibilities, tasks, and procedures for the operation and management of the Korea Area Emergency Blood Program (EBP) which will be needed to sustain contingency operations. This will provide for pretesting of potential Donors to be used for non- Food and Drug Administration (FDA) blood product collection (to include whole blood or apheresis platelets).

1-2. References

a. ASD(HA) Policy #10-002, *Policy on the Use of Non-FDA Licensed Blood Products.*

b. Code of Federal Regulations (CFR), Title 21, Series 200 (Drug Manufacture), 600 (Blood and Blood Components) and 800 (Equipment Procedure Validation).

c. Joint Trauma System (JTS) Clinical Practice Guidelines (CPG), *Whole Blood Transfusion* (CPG ID: 21).

d. USFK Regulation 40-3, Korea Area Joint Blood Program.

e. AABB (formerly American Association of Blood Banks), *Standards for Blood Banks and Transfusion Services*.

f. USFK PAM 40-31, Korean Area Emergency Blood Program (EBP) Procedures.

1-3. Explanation of Abbreviations and Terms
Abbreviations and terms used in this regulation are explained in the glossary.

1-4. Commander's intent
To further expand and provide continuity for the Korea Area EBP, delineate responsibilities, and provide guidance and procedures in order to ensure readiness around United States Forces Korea (USFK) area of responsibility (AOR).

Chapter 2
Policy and Responsibilities

2-1. Policy

a. Examples for users of this program can be found in USFK PAM 40-31, Korean Area EBP. USFK Command Surgeon is the proponent and exception authority delegated from the USFK Chief of Staff with the responsibility to author, approve, and publish updates to the USFK PAM 40-3. USFK Command Surgeon has been delegated the responsibility to ensure timely updates in accordance with latest Department of Defense (DoD) instructions, policies, and procedures and approve exceptions or waivers to this regulation that are consistent with controlling law and regulations.

b. Routine blood requirements will be met through deglycerolization of tested frozen blood cells

or tested blood product shipments from US FDA licensed facilities and coordinated through the Korean Area Joint Blood Program Officer (KAJBPO) with the USINDOPACOM Joint Blood Program Officer (JBPO).

c. When emergency needs exceed capability of routine blood supply or whole blood would be the better choice for a patient, as determined by the facility/location senior medical person, the use of emergency non-FDA whole blood collection and transfusion is authorized as outlined in ASD (HA) Policy #10-002, *Policy on the Use of Non-FDA Licensed Blood Products* and Joint Trauma System (JTS) Clinical Practice Guidelines (CPG), *Whole Blood Transfusion* (CPG ID: 21).

d. Special consideration must be given on the use of this program. Donors who have had more than 200mLs of blood collected are unable to donate again for up to 56 days without special medical consideration.

e. All organizations conducting blood collection and transfusion will have SOPs/Operating Instructions (OIs) that outline conduct of their program. These SOP/OIs will meet minimum criteria established in JTS CPG ID:21 and be approved by the USFK Surgeon. Periodic routine audits will be conducted by the KAJBPO to ensure requirements are met or as needed to correct deficiencies. Audit checklist can be found in USFK PAM 40-31, Chapter 9. Sample SOP/OIs can be found in USFK PAM 40-31, chapters 3-5 or JTS CPG ID:21.

f. All personnel conducting EBP collections and transfusions will be trained by a verified instructor, competency assessed, and verified by their first line Surgeon's Office for EBP processes and procedures IAW their approved SOP/OIs. A roster with current and competency assessment documentation will be maintained at all times for inspection purposes and will be submitted to the USFK Surgeon Office upon request. This training may include the Medical Skill Training Center EBP training program, but must also include local unit training to ensure SOP/OIs are understood and how unit level operations are to be conducted.

g. At minimum, all confirmed type O Neg service members will receive ABO/Rh blood type confirmation, antibody screen, anti-A IgM titer, and anti-B IgM titer testing. If determined to be low titer O Neg (having titer of <1:256 for both Anti-A and Anti-B) infectious disease testing as outlined in USFK PAM 40-31, Chapter 6 will be done. Upon confirmation of non-deferred status, all low titer O Neg donors will be issued a green, low titer O identification (ID) card. This will be an inspectable item. Numbers of screened low titer O Neg donors will be reported monthly to the KAJBPO, no later than the 15th of the next month.

h. Use of all other blood types service members is authorized, but not directed to the service components. Separate funding and/or testing will be required and procured by the unit; and approved through the USFK Surgeon Office. The KAJBPO may advise on other blood type possible testing courses of action at the direction of the USFK Surgeon. Further clarification: O Positive service members may also be tested to be a low-titer O donor using same criteria as the O Neg donor. A, B, and AB Positive and Negative donors may also be used for type specific only blood donations and must meet all of testing requirements identified in this policy in USFK PAM 40-31, chapter 6.

i. All prescreened Donors will be tested at least annually for the tests outlined in USFK PAM 40-31, chapter 6 by a Clinical Lab Improvement Act (CLIA) approved or equivalent lab for testing of allogeneic blood collection to be considered fully prescreened:

j. All prescreened Donors will be issued a USFK Donor ID device that will have at minimum:

(1) USFK Logo

(2) Picture of Donor

(3) Date samples collected

(4) Donor Blood Type and be colored red for non low-titer O Blood or green for low titer O Blood

(5) Unique 13 digit Donor Identification Number or barcode that will be used for Theater Medical Data Stores (TMDS)-B entry

NOTE: An ID device is defined as a command or Medical Treatment Facility (MTF) issued item that is highly durable and has the above information on it and be green for low-titer O donors and red (type specific) for all other types. These items are to be considered controlled devices to ensure duplication is difficult and to ensure erroneous data is not placed on the Donor ID device. Example IDs will be provided upon request from the USFK Surgeon Office. All ID devices will be approved by the USFK Surgeon or the KAJBPO prior to use.

k. All organizations conducting any tactical blood operations, to include EBP collection or transfusion, will use TMDS-B as their system of record. Instructions for use for all emergency blood functions can be found in USFK PAM 40-31, chapter 8. A request for new site establishment will be completed and submitted to the KAJBPO who will review and forward to the USINDOPACOM Joint Blood Program Office for approval, as applicable. An example is located in USFK PAM 40-31, chapter 10.

l. All conducting tactical blood operations will establish a donor notification program for all deferred donors with supporting public health organization. This program will include donor notification letters for abnormal test results, counseling, follow up testing, and process for deferring in TMDS-B. Example letters can be found in USFK PAM 40-31, chapter 7. Instructions for entry into TMDS-B can be found in USFK PAM 40-31, chapter 8.

m. The number one cause of fatality due to blood transfusion is ABO mismatch between Donor and Recipient. **Except where medical or tactical situation prevents, an ABO blood type of the Patient and Donor and compatibility test will be conducted prior to transfusion to verify compatibility prior to transfusion to prevent potentially fatal hemolytic transfusion reactions. This includes when using low titer O Donors.**

n. All transfusion of non-FDA blood products to include theater collected whole blood will be communicated to the KAJBPO as soon as mission situation allows, but not later than 7 days post transfusion. Transfusion will be entered into TMDS-B by the site who executes the transfusion or their supporting Role 3. Instructions for TMDS-B transfusion entry are located in USFK PAM 40-31, chapter 8. Blood products created through the donation process are automatically created as non-FDA in TMDS-B. In accordance with USFK Reg 40-3, all DoD healthcare beneficiary transfusion recipients of non-US FDA Licensed Blood products, to include transfusions within a USFK MTF or at a Host Nation MTF will participate in a follow-up program.

n. Elements of the program will include at minimum:

(1) Appropriate documentation in the medical record detailing pre-transfusion informed consent (when applicable), post-transfusion notification, and counseling.

(2) Patients shall have a pre-transfusion blood sample collected and submitted for base-line serologic testing, whenever possible.

(3) Patients must be tested at intervals prescribed by Armed Services Blood Program Division (ASBPD), or applicable service component prescribed intervals, at 3, 6, and 12 months from transfusion of non-FDA licensed blood products. All testing will be completed after evacuation and documented in the patient's medical record.

(4) Report non-FDA transfusions to the KAJBPO to include Patient name, DoD ID or Social Security Number, as applicable, date of birth, type and number of blood product(s) transfused, and origin of blood if not from US Citizen. Include notification date and any follow-up testing.

o. Collection, receipt, processing, storage, and distribution of all blood products to include emergency collected whole blood throughout USFK are to be under the technical control of the KAJBPO.

p. All exceptions to this policy will be approved in writing by the USFK Surgeon. Application for exception will be requested through the KAJBPO.

2-2. Commanding General, Eighth Army (8A) will:

a. Operate and maintain an EBP to include development of USFK Surgeon approved Standard Operating Procedures (SOPs) at the end user level, generally the Medical Treatment Facility (MTF). An example of process flow for emergency whole blood can be found in CPG:21 or in USFK PAM 40-31, chapter 2. Example SOPs can be found in USFK PAM 40-31, chapters 3-5.

b. Establish an in-processing procedure where all service members have blood type checked in medical record. All type O Negative (O Neg) service members will receive: ABO/Rh type confirmation, antibody screen, anti-A IgM titer, and anti-B IgM titer testing. If determined to be low titer O Neg (having titer of <1:256 for both Anti-A and Anti-B) infectious disease testing as outlined in USFK PAM 40-31, chapter 6 will be done. Upon confirmation of non-deferred status, all low titer O Neg donors will be issued a green, low titer O identification card. This will be an inspectable item. Numbers of screened low titer O Neg donors will be reported monthly to the KAJBPO, no later than the 15th of the next month.

c. Establish a donor notification program for all deferred donors with supporting public health organization. This program will include donor notification letters for abnormal test results, counseling, follow up testing, and process for deferring in TMDS-B. Example donor notification letters can be found in USFK PAM 40-31, chapter 7. Entry of deferred donors into TMDS-B can be found in USFK PAM 40-31, chapter 8.

d. As needed, develop a USFK Surgeon approved program for screening all other potential donors. This can include use of O Positive donors in the low-titer program and/or all other donors for type specific transfusion. This program will include titer for O Positive donors, prescreen testing as outlined in this policy, and prescreened donors will be given a standardized green, low-titer card. Cutoff for low-titer is still defined as having a titer of <1:256 for both Anti-A and Anti-B on IgM antibody test. All other blood types, to include: high titer O donors, A donors, B donors, and AB donors, will be for type specific only at MTFs that have sufficient personnel to confirm donors on donor lists and conduct applicable lab testing (type and screens). These donors may also be used for apheresis collection programs at blood support detachments and blood supply units.

e. Establish a training program and provide a designated training team that will serve as the primary point of contact for “train the trainer” training needs and prescreen coordination for testing. This program will be USFK Surgeon approved and cover all aspects of emergency blood collection to include at minimum: prescreening process, deferred donor notification process and public health points of contact, whole blood collection process, signs of donor reactions and treatment, whole blood storage criteria, whole blood transfusion process, signs and symptoms of transfusion reactions and treatment, TMDS-B entry process for prescreen, deferral, collection, and transfusion.

f. Establish and maintain a prescreen collection program and at least one emergency whole blood collection teams at all 8A MTFs. These sites will be used for conducting annual re-screening of screened personnel who remain in Korea more than 12 months and O Neg donors who may have missed screening at in-processing stations. These sites will also be prepared to collect emergency whole blood from organic, local, and directed donors during contingency operations. Blood may be used by the MTF or may be directed for distribution by the KAJBPO.

g. Provide testing capability for all EBP for ABO/Rh confirmation, antibody screening, and titer testing for Anti-A and Anti-B IgM testing.

h. Ensure blood donation by USFK personnel is strictly voluntary.

i. Ensure EBP personnel are capable of conducting and sustaining blood program operations in accordance with applicable Food and Drug Administration (FDA), Armed Services Blood Program Division (ASBPD), AABB (formerly the American Association of Blood Banks), and Service guidance and regulations. Current version of USFK PAM 40-31, chapter 9 will be used to ensure compliance with this policy and applicable standards.

j. Ensure 8A medical personnel establish local policy, responsibility, and written guidance on the use of Non-US FDA Licensed Blood Products to include transfusions within MTFs.

k. Ensure all prescreened individuals within 8A are entered into the TMDS-B.

l. Ensure TMDS-B is updated by subordinate MTFs for all blood products collected or received (to include those from CONUS). Training Lessons for TMDS-B for Emergency Blood can be found in USFK PAM 40-31, chapter 8.

m. Provide at minimum monthly reports of training status of clinical personnel for EBP (required to be trained and number trained) number of donors screened by blood type and titer result for O donors, number of pending screening results, supplies available as number of donors that can be collected with current on hand supplies to the KAJBPO, and identify the target for EBP collectors and/or transfusionists. All medical personnel with a clinical background will be able to collect and transfuse under the direction of a licensed Healthcare Provider. Non-medical personnel may also be trained at discretion of applicable component surgeon.

n. Be prepared to execute emergency blood drive collection, within 8 hours of receipt of order, of all verified low-titer O Neg donors and store at 1-6°C for up to 21 days at all collecting stations. Blood may be used by 8A MTF or directed shipped to another MTF at direction of USFK Surgeon or KAJBPO.

2-3. Commander, Seventh Air Force (7th AF) will:

a. Operate and maintain an EBP to include development of USFK Surgeon approved Standard Operating Procedures (SOPs) at the end user level, generally the MTF. An example of process

flow for emergency whole blood can be found in CPG: 21 or in USFK PAM 40-31, chapter 2. Example SOPs can be found in USFK PAM 40-31, chapters 3-5.

b. Establish an in-processing procedure where all service members have blood type checked in medical record. All O Neg service members will receive: ABO/Rh type confirmation, antibody screen, anti-A IgM titer, and anti-B IgM titer testing. If determined to be low titer O Neg (having titer of <1:256 for both Anti-A and Anti-B) infectious disease testing as outlined in USFK PAM 40-31, chapter 6 will be done. Upon confirmation of non-deferred status, all low titer O Neg donors will be issued a green, low titer O identification card. This will be an inspectable item. Numbers of screened low titer O Neg donors will be reported monthly to the KAJBPO, no later than the 15th of the next month.

c. Establish a donor notification program for all deferred donors with supporting public health organization. This program will include donor notification letters for abnormal test results, counseling, follow up testing, and process for deferring in TMDS-B. Example donor notification letters can be found in USFK PAM 40-31, chapter 7. Entry of deferred donors into TMDS-B can be found in USFK PAM 40-31, chapter 3.

d. As needed, develop a USFK Surgeon approved program for screening all other potential donors. This can include use of O Positive donors in the low-titer program and/or all other donors for type specific transfusion. This program will include titer for O Positive donors, prescreen testing as outlined in this policy, and prescreened donors will be given a standardized green, low-titer card. Cutoff for low-titer is still defined as having a titer of <1:256 for both Anti-A and Anti-B on IgM antibody test. All other blood types, to include: high titer O donors, A donors, B donors, and AB donors, will be for type specific only at MTFs that have sufficient personnel to confirm donors on donor lists and conduct applicable lab testing (type and screens). These donors may also be used for apheresis collection programs at blood support detachments and blood supply units.

e. Establish and maintain a prescreen collection program and at least one emergency whole blood collection teams at all 7th AF MTFs. These sites will be used for conducting annual re-screening of screened personnel who remain in Korea more than 12 months and O Neg donors who may have missed screening at in-processing stations. These sites will also be prepared to collect emergency whole blood from organic, local, and directed donors during contingency operations. Blood may be used at the MTF or may be directed for distribution by the KAJBPO.

f. Ensure blood donation by USFK personnel is strictly voluntary.

g. Ensure EBP personnel are capable of conducting and sustaining blood program operations in accordance with applicable FDA, ASBPD, AABB, and Service guidance and regulations. Current version of USFK PAM 40-31, chapter 9 will be used to ensure compliance with this policy and applicable standards.

h. Ensure 7th AF medical personnel establish local policy, responsibility and written guidance on the use of Non-US FDA Licensed Blood Products to include transfusions within MTFs.

i. Ensure all prescreened individuals within 7th AF are entered into TMDS-B, the overseas blood system of record.

j. Ensure TMDS-B is updated by subordinate MTFs for all blood products collected or received (to include those from CONUS). Training Lessons for TMDS-B for Emergency Blood can be found in USFK PAM 40-31, chapter 8.

k. Provide at minimum monthly reports of training status of clinical personnel for EBP, number of donors screened by blood type and titer result for O donors, number of pending screening results, supplies available as number of donors that can be collected with current on hand supplies to the USFK KAJBPO, and identify the target for EBP collectors and/or transfusionists. All medical personnel with a clinical background will be able to collect and transfuse under the direction of a licensed Healthcare Provider. Non-medical personnel may also be trained at discretion of applicable component surgeon.

l. Be prepared to execute emergency blood drive collection, within 8 hours of receipt of order, of all verified low titer O donors and store at 1-6°C for up to 21 days at all reporting stations. Blood may be used by 7th AF MTF or directed shipped to another MTF at direction of USFK Surgeon or KAJBPO.

2-4. Commander, Naval Forces Korea (CNFK) will:

a. Operate and maintain an EBP to include development of USFK Surgeon approved Standard Operating Procedures (SOPs) at the end user level, generally the MTF. An example of process flow for emergency whole blood can be found in CPG:21 or in USFK PAM 40-31, chapter 2. Example SOPs can be found in Appendices 3-5.

b. Establish an in-processing procedure where all service members have blood type checked in medical record. All O Neg service members will receive: ABO/Rh type confirmation, antibody screen, anti-A IgM titer, and anti-B IgM titer testing. If determined to be low titer O Neg (having titer of <1:256 for both Anti-A and Anti-B) infectious disease testing as outlined in USFK PAM 40-31, chapter 5 will be done. Upon confirmation of non-deferred status, all low titer O Neg donors will be issued a green, low titer O identification card. This will be an inspectable item. Numbers of screened low titer O Neg donors will be reported monthly to the KAJBPO, no later than the 15th of the next month.

c. Establish a donor notification program for all deferred donors with supporting public health organization. This program will include donor notification letters for abnormal test results, counseling, follow up testing, and process for deferring in TMDS-B. Example donor notification letters can be found in USFK PAM 40-31, chapter 7. Entry of deferred donors into TMDS-B can be found in USFK PAM 40-31, chapter 8.

d. As needed, develop a USFK Surgeon approved program for screening all other potential donors. This can include use of O Positive donors in the low-titer program and/or all other donors for type specific transfusion. This program will include titer for O Positive donors, prescreen testing as outlined in this policy, and prescreened donors will be given a standardized green, low-titer card. Cutoff for low-titer is still defined as having a titer of <1:256 for both Anti-A and Anti-B on IgM antibody test. All other blood types, to include: high titer O donors, A donors, B donors, and AB donors, will be for type specific only at MTFs that have sufficient personnel to confirm donors on donor lists and conduct applicable lab testing (type and screens). These donors may also be used for apheresis collection programs at blood support detachments and blood supply units.

e. Establish and maintain a prescreen collection program and at least one emergency whole blood collection team at all CNFK MTFs. These sites will be used for conducting annual re-screening of screened personnel who remain in Korea more than 12 months and O Neg donors who may have missed screening at in-processing stations. These sites will also be prepared to collect emergency whole blood from organic, local, and directed donors during contingency operations. Blood may be used by the MTF or may be directed for distribution by the KAJBPO.

f. Establish a donor notification program for all deferred donors with supporting public health organization. This program will include donor notification letters for abnormal test results, counseling, follow up testing, and process for deferring in TMDS-B.

g. As needed, develop a USFK Surgeon approved program for screening non-low titer O donors for type specific transfusion at Role III facilities. This program will include all prescreen testing as outlined in this policy and prescreened donors will be given a standardized type specific only donor card. These donors may also be used for apheresis collection programs at blood support detachments and blood supply units.

h. Ensure blood donation by USFK personnel is strictly voluntary.

i. Ensure EBP personnel are capable of conducting and sustaining blood program operations in accordance with applicable FDA, ASBPD, AABB, and Service guidance and regulations. Current version of USFK PAM 40-31, chapter 9 will be used to ensure compliance with this policy and applicable standards.

j. Ensure CNFK medical personnel establish local policy, responsibility and written guidance on the use of Non-US FDA Licensed Blood Products to include transfusions within MTFs.

k. Ensure all prescreened individuals within CNFK are entered into TMDS-B, the overseas blood system of record. TMDS-B training slides can be found in USFK PAM 40-31, chapter 8.

l. Ensure TMDS-B is updated by subordinate MTFs for all blood products collected or received (to include those from CONUS).

m. Provide at minimum monthly reports of training status of clinical personnel for EBP, number of donors screened by blood type and titer result for O donors, number of pending screening results, supplies available as number of donors that can be collected with current on hand supplies to the USFK KAJBPO, and identify the target for EBP collectors and/or transfusionists. All medical personnel with a clinical background will be able to collect and transfuse under the direction of a licensed Healthcare Provider. Non-medical personnel may also be trained at discretion of applicable component surgeon.

n. Be prepared to execute emergency blood drive collection, within 8 hours of receipt of order, of all verified low titer O donors and store at 1-6°C for up to 21 days at all reporting stations. Blood may be used by CNFK MTF or directed shipped to another MTF at direction of USFK Surgeon or KAJBPO.

2-5. Commander, Marine Forces Korea (MARFORK) will:

a. Designate at least one emergency blood program coordinator and coordinate a prescreen collection program through supporting USFK MTFs. This coordinator will be trained in the use of TMDS-B and responsible for TMDS-B entry for prescreened donors, scheduling annual re-screening of screened personnel who remain in Korea more than 12 months, and follow up for O Neg donors who may have missed screening at in-processing stations. The coordinator will also ensure issuance of standardized donor cards, verifying the correct card goes to the correct donor. The coordinator will also be prepared to support collection of emergency whole blood at supporting MTFs during contingency operations.

b. Operate and maintain an EBP as coordinated through supporting USFK MTFs.

c. Establish an in-processing procedure where all service members have blood type checked in medical record. Coordinate through supporting USFK MTF for all O Neg service members will receive: ABO/Rh type confirmation, antibody screen, anti-A IgM titer, and anti-B IgM titer testing. If determined to be low titer O Neg (having titer of <1:256 for both Anti-A and Anti-B) infectious disease testing as outlined in USFK PAM 40-31, chapter 6 will be done. Upon confirmation of non-deferred status, all low titer O Neg donors will be issued a green, low titer O identification card. This will be an inspectable item. Numbers of screened low titer O Neg donors will be reported monthly to the KAJBPO, no later than the 15th of the next month.

d. Establish through supporting USFK MTFs, a donor notification program for all deferred donors with supporting public health organization. This program will include donor notification letters for abnormal test results, counseling, follow up testing, and process for deferring in TMDS-B. Example donor notification letters can be found in USFK PAM 40-31, chapter 7. Entry of deferred donors into TMDS-B can be found in USFK PAM 40-31, chapter 8.

e. As needed, coordinate with USFK MTFs to participate in a USFK Surgeon approved program for screening all other potential donors. This can include use of O Positive donors in the low-titer program and/or all other donors for type specific transfusion. This program will include titer for O Positive donors, prescreen testing as outlined in this policy, and prescreened donors will be given a standardized green, low-titer card. Cutoff for low-titer is still defined as having a titer of <1:256 for both Anti-A and Anti-B on IgM antibody test. All other blood types, to include: high titer O donors, A donors, B donors, and AB donors, will be for type specific only at MTFs that have sufficient personnel to confirm donors on donor lists and conduct applicable lab testing (type and screens). These donors may also be used for apheresis collection programs at blood support detachments and blood supply units.

f. Ensure blood donation by USFK personnel is strictly voluntary.

g. Ensure TMDS-B is updated for all blood products collected from MARFORK donors. TMDS-B training slides can be found in USFK PAM 40-31, chapter 8.

h. Provide at minimum monthly reports of training status of personnel for EBP, number of donors screened by blood type and titer result for O donors, number of pending screening results, supplies available as number of donors that can be collected with current on hand supplies to the USFK KAJBPO, and identify the target for EBP collectors and/or transfusionists. All medical personnel with a clinical background will be able to collect and transfuse under the direction of a licensed Healthcare Provider. Non-medical personnel may also be trained at discretion of applicable component surgeon.

i. Be prepared to support emergency blood drive collection at supporting MTFs, within 8 hours of receipt of order, of all verified low titer O donors and type specific donors as applicable.

2-6. Commander, Special Operations Command Korea (SOCKOR) will:

a. Operate and maintain an EBP to include development of USFK Surgeon approved Standard Operating Procedures (SOPs) at the end user level, generally the MTF. An example of process flow for emergency whole blood can be found in CPG:21 or in USFK PAM 40-31, chapter 2. Example SOPs can be found in Appendices 3-5.

b. Establish an in-processing procedure where all service members have blood type checked in medical record. All O Neg service members will receive: ABO/Rh type confirmation, antibody screen, anti-A IgM titer, and anti-B IgM titer testing. If determined to be low titer O Neg (having titer

of <1:256 for both Anti-A and Anti-B) infectious disease testing as outlined in USFK PAM 40-31, chapter 6 will be done. Upon confirmation of non-deferred status, all low titer O Neg donors will be issued a green, low titer O identification card. This will be an inspectable item. Numbers of screened low titer O Neg donors will be reported monthly to the KAJBPO, no later than the 15th of the next month.

c. Establish a donor notification program for all deferred donors with supporting public health organization. This program will include donor notification letters for abnormal test results, counseling, follow up testing, and process for deferring in TMDS-B. Example donor notification letters can be found in USFK PAM 40-31, chapter 7. Entry of deferred donors into TMDS-B can be found in USFK PAM 40-31, chapter 8.

d. As needed, develop a USFK Surgeon approved program for screening all other potential donors. This can include use of O Positive donors in the low-titer program and/or all other donors for type specific transfusion. This program will include titer for O Positive donors, prescreen testing as outlined in this policy, and prescreened donors will be given a standardized green, low-titer card. Cutoff for low-titer is still defined as having a titer of <1:256 for both Anti-A and Anti-B on IgM antibody test. All other blood types, to include: high titer O donors, A donors, B donors, and AB donors, will be for type specific only at MTFs that have sufficient personnel to confirm donors on donor lists and conduct applicable lab testing (type and screens). These donors may also be used for apheresis collection programs at blood support detachments and blood supply units.

e. Establish and maintain a prescreen collection program and at least one emergency whole blood collection team for SOCKOR. This team will be used for conducting annual re-screening of screened personnel who remain in Korea more than 12 months and O Neg donors who may have missed screening at in-processing stations. This team will also be prepared to collect emergency whole blood from organic, local, and directed donors during contingency operations. Blood may be used by SOCKOR Medical or may be directed for distribution by the KAJBPO.

f. Ensure blood donation by USFK personnel is strictly voluntary.

g. Ensure EBP personnel are capable of conducting and sustaining blood program operations in accordance with applicable FDA, ASBPD, AABB, and Service guidance and regulations. Current version of USFK PAM 40-31, chapter 9 will be used to ensure compliance with this policy and applicable standards.

h. Ensure all prescreened individuals within SOCKOR are entered into TMDS-B, the overseas blood system of record. Training slides for TMDS-B can be found in USFK PAM 40-31, chapter 8.

i. Ensure TMDS-B is updated for all MTFs for blood products collected or received (to include those from CONUS).

j. Provide at minimum monthly reports of training status of clinical personnel for EBP, number of donors screened by blood type and titer result for O donors, number of pending screening results, supplies available as number of donors that can be collected with current on hand supplies to the USFK KAJBPO, and identify the target for EBP collectors and/or transfusionists. All medical personnel with a clinical background will be able to collect and transfuse under the direction of a licensed Healthcare Provider. Non-medical personnel may also be trained at discretion of applicable component surgeon.

2-7. USFK Command Surgeon (FKSG) will:

a. Operate and maintain an EBP to include review and approval of component developed Standard Operating Procedures. Example SOPs can be found in Appendices 2-4.

b. Budget and allocate funding to support the Korean Area Joint Blood Program Officer with travel and per diem allowances to support planning, execution, and audits of this program. Audits will use current version of USFK PAM 40-31, chapter 9 to ensure compliance with this policy and applicable standards.

c. Facilitate the planning and execution of joint blood support on the Korean peninsula, in order to assist the U.S. Indo-Pacific Command (USINDOPACOM) Joint Blood Program Office (JBPO) in meeting theater blood requirements.

d. Ensure Theater Medical Data Stores (TMDS) is used by supported MTFs to ensure post transfusion follow-up tracking program is established as directed by ASD (HA) Policy #10-002, *Policy on the Use of Non-FDA Licensed Blood Products*. TMDS flags all theater collected blood products as non-FDA allowing for easy tracking using transfusion report functions in TMDS.

e. Ensure audits of EBP programs occur every two years or more frequently when major issues arise to ensure the greatest degree of safety and efficacy for Donors and Recipients. Current version of USFK PAM 40-31, chapter 9 will be used in conducting audits.

2-8. Korea Area Joint Blood Program Officer (KAJBPO) will:

a. Advise the USFK Command Surgeon on all matters concerning the EBP.

b. Provide managerial and technical oversight of all DoD military blood activities on the Korea peninsula, and evaluate Class VIIIb program items and staff training.

c. Coordinate EBP for all medical elements in the USFK AOR and assist by providing technical expertise and guidance to medical elements in USFK.

d. Develop and maintain minimum requirements and acceptable Standards (evaluation criteria and checklists) in accordance with JTS and Blood Program Office(s) guidance. Ensure this list is provided and followed by the end user. Current version of this is located in USFK PAM 40-31, chapter 9.

e. Develop and maintain minimum supply requirements lists for collection and transfusion of emergency whole blood (prepackaged kits and bulk class VIIIa). Ensure this information is provided and followed by the end user.

f. Oversee the development of Standards, SOPs, and Job Aids for use by the end users of the EBP in order to ensure intent of applicable regulations and guidelines are met.

g. Evaluate EBPs periodically, but not less than once every two years, or as directed by USFK Surgeon to ensure compliance with applicable regulations and guidelines.

h. When fully functioning, integrate EBP into the MEDCOP and applicable OPLANs.

i. Ensure follow-ups are conducted on all DoD healthcare beneficiary transfusion recipients of non-US FDA approved Blood products per ASD(HA)/ASBPD Policy on Use of non-US FDA Licensed Blood and Blood Products.

j. Serve as a conduit between non-DoD blood collection agencies and DoD blood collection agencies from outside of the Korean peninsula to facilitate and coordinate the hosting of blood drives as appropriate.

k. Provide the USINDOPACOM JBPO with copies of this regulation and supplements to include reports as required and updates.

l. Conduct periodic audits of TMDS-B to ensure data is being updated, is current, and is accurate. The recommended rate is review each unit monthly and provide feedback to the TMDS-B site manager.

Glossary

Section I. Acronyms

7th AF	Seventh Air Force
8A	Eighth Army
AABB	American Association of Blood Banks
ABO/Rh	Blood type designation for type A, B, AB, or O and D
AOR	Area of Responsibility
ASBPD	Armed Services Blood Program Office
ASBP	Armed Services Blood Program
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASWBPL	Armed Services Whole Blood Processing Laboratory
BLDREP	Blood Report
BMC	Branch Medical Clinic
BPD	Blood Products Depot
BSD	Blood Support Detachment
CFC	Combined Forces Command
CFR	Code of Federal Regulations
CNFK	Commander, Naval Forces Korea
DoD	Department of Defense
EBP	Emergency Blood Program
EBTS	Expeditionary Blood Transshipment System
FDA	Food and Drug Administration
FKSG	Office of the Command Surgeon, USFK
HQ	Headquarters
ID	Identification
JBPO	Joint Blood Program Office
KAJBPO	Korea Area Joint Blood Program Officer

MARFORK	Marine Forces Korea
MDG	Medical Group
MTF	Medical Treatment Facility
OPLAN	Operation Plans
RBCs	Red Blood Cells
ROK	Republic of Korea
SBPO	Service Blood Program Office
TS	Transfusion Service
US	United States
USFK	United States Forces Korea
USPACOM	United States Pacific Command
WBB	Walking Blood Program

Section II. Terms

AABB (formerly American Association of Blood Banks). A Blood Bank accrediting agency which establishes policy and standardized Blood Bank procedures.

ABO/Rh. Universally accepted primary blood type designation for blood. Represents the phenotypic antigen presences of either the A, B, AB, or lack of these designated as O and the presence or absence of D antigen identified as positive (+) or negative (- or =). Example A Positive (A Pos) blood type.

Area Joint Blood Program Office (AJBPO). A tri-service staffed office responsible for overall blood product management in a specific geographic area within a unified command theater of operations.

Armed Services Blood Program Division (ASBPD). A tri-service staffed DoD field operating agency responsible for ensuring implementation and coordination of ASD(HA)-established blood program policies and management of blood resources

Armed Services Whole Blood Processing Laboratory (ASWBPL). A tri-service staffed organization responsible for central receipt and processing of blood products from Blood Banks in the Continental United States, and shipment of those products to designated unified command Expeditionary Blood Transshipment Systems (EBTSs).

Blood Products. Blood and blood product components to include whole blood, red blood cells, frozen red blood cells, deglycerolized red blood cells, fresh frozen plasma, liquid plasma, cryoprecipitate and platelets.

Blood Products Depot (BPD). Component staffed; responsible for strategic storage of frozen blood products. Upon activation, may thaw, wash and distribute red blood cells, or may distribute frozen products. Maybe a component-designated medical treatment element.

Blood Report (BLDREP). Report used for requesting and providing blood product capabilities and status at various blood program activities.

Blood Support Detachment (BSD). The U.S. Army's Blood Supply Unit responsible for the receipt of blood products from the expeditionary blood transshipment systems or blood product depots (BPD); blood storage, distribution, whole blood and platelet (Apheresis) collection and issuing those products to medical treatment elements on an assigned geographical area as directed by an Area Joint Blood Program Office.

Expeditionary Blood Transshipment System (EBTS). A U.S. Air Force staffed unit responsible for receiving blood products from an Armed Services Whole Blood Processing Laboratory (ASWBPL), blood products depot (BPD) or another EBTS, re-icing those products, and issuing the products to blood supply units (BSU) or medical treatment elements at the direction of the Area Joint Blood Program Office.

Emergency Blood Program. A program for using prescreened donors, donors that are tested for infectious disease ahead of actual blood donation, for blood product collection and distribution in emergency situations only.

Food and Drug Administration (FDA). Blood Bank regulating and licensing agency which establishes regulations and requirements for use by Blood Banks involved in interstate commerce (shipping blood across State lines).

Joint Blood Program Office (JBPO). A tri-service staffed office responsible for overall blood products management in a unified command theater of operations.

Red Blood Cells (RBC). Separated from whole blood by removal of plasma. If drawn in the anticoagulant CPDA1, red blood cells must be transfused within 35 days of the date the blood was drawn. If frozen within six days of being drawn, they can be frozen and stored for ten years. They also may be chemically rejuvenated up to three days after expiration (38 days) and then frozen and stored for up to ten years. In Korea, the shelf-life of frozen red cells has been extended by the Armed Service Blood Program Office to 21 years.

Service Blood Program Office (SBPO). The organization responsible for the coordination, direction, and management of the Service's blood program in peacetime, military contingencies, wartime, and national/natural disasters.

EBP (WBB). A pretested Donor pool to be used for collection of whole blood (to include Emergency Whole Blood or Stored Whole Blood) or apheresis platelets for emergency use with intent to transfuse in time of contingency without full FDA infectious disease testing.