Audit Report

ARMED SERVICES BLOOD PROGRAM
DEFENSE BLOOD STANDARD SYSTEM

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Abstract
This report is the second in a series regarding the Armed Services Blood Program. The mission of the Armed Services Blood Program is to provide quality blood products, blood substitutes, and services for all worldwide DoD customers in peacetime, in wartime, and during contingency operations. The Defense Blood Standard System (DBSS) is the automated information system used by Blood Program Organizations to maintain and track blood donations and blood product inventories. It provides blood product management for fresh and frozen blood products during blood collection, processing, testing, shipping, and storage. It also provides transfusion service management and system administration. DBSS is unique because it is the only automated information system within the Military Health System that is regulated by the Food and Drug Administration as a Class II Medical Device. The Class II Medical Device designation gives the Food and Drug Administration the authority to inspect the development and use of DBSS. The DBSS Project Office, under the Clinical Information Technology Program Office, Office of the Assistant Secretary of Defense (Health Affairs), is responsible for managing the system. Management and support costs for DBSS for FYs 1991 through 2000 totaled $70.1 million. Projected costs for FYs 2001 through 2007 are $43.8 million.

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Acronyms

ASBPO	Armed Services Blood Program Office
CHCS	Composite Health Care System
CITPO	Clinical Information Technology Program Office
DBSS	Defense Blood Standard System
FDA	Food and Drug Administration
JMAR	Joint Medical Asset Repository
TDBSS	Theater Defense Blood Standard System
TMSSC	Tri-Service Medical System Support Center

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October 22, 2001

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE
(HEALTH AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE
(FINANCIAL MANAGEMENT AND COMPTROLLER)
NAVAL INSPECTOR GENERAL
AUDITOR GENERAL, DEPARTMENT OF THE ARMY
DIRECTOR, ARMED SERVICES BLOOD PROGRAM
OFFICE

SUBJECT: Audit Report on the Armed Services Blood Program Defense Blood Standard System (Report No. D-2002-010)

We are providing this report for review and comment. This report is the second of two reports on the Armed Services Blood Program. We considered management comments on a draft of this report when preparing the final report.

DoD Directive 7650.3 requires that all recommendations be resolved promptly. We request that the Assistant Secretary of Defense (Health Affairs), the Armed Services Blood Program Office, the Army, the Navy, and the Air Force provide additional comments, as indicated in Table 2 (page 20) and Table 4 (page 30) of this report, by November 26, 2001.

We appreciate the courtesies extended to the audit staff. For additional information on this report, please contact Mr. Michael A. Joseph at (757) 766-9108 (mjoseph@dodig.osd.mil) or Ms. Betsy Brilliant at (703) 604-8875 (DSN 664-8875) (bbrilliant@dodig.osd.mil). See Appendix E for the report distribution. The audit team members are listed inside the back cover.

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Report No. D-2002-010 **October 22, 2001**
(Project No. D2000LF-0028.001)
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Armed Services Blood Program
Defense Blood Standard System

Executive Summary

Introduction. This report is the second in a series regarding the Armed Services Blood Program. The mission of the Armed Services Blood Program is to provide quality blood products, blood substitutes, and services for all worldwide DoD customers in peacetime, in wartime, and during contingency operations.

The Defense Blood Standard System (DBSS) is the automated information system used by Blood Program Organizations to maintain and track blood donations and blood product inventories. It provides blood product management for fresh and frozen blood products during blood collection, processing, testing, shipping, and storage. It also provides transfusion service management and system administration. DBSS is unique because it is the only automated information system within the Military Health System that is regulated by the Food and Drug Administration as a Class II Medical Device. The Class II Medical Device designation gives the Food and Drug Administration the authority to inspect the development and use of DBSS.

The DBSS Project Office, under the Clinical Information Technology Program Office, Office of the Assistant Secretary of Defense (Health Affairs), is responsible for managing the system. Management and support costs for DBSS for FYs 1991 through 2000 totaled $70.1 million. Projected costs for FYs 2001 through 2007 are $43.8 million.

Objectives. The overall objective of the audit was to determine whether the management and administration of the Armed Services Blood Program was adequate to ensure quality blood products were properly handled and controlled during peacetime and wartime. This report addresses the automated information systems supporting the Armed Services Blood Program. The previous audit addressed readiness issues. We also reviewed the adequacy of the management control programs of the TRICARE Management Activity and the offices of the Surgeons General, as they applied to the audit objective.

Results. Implementation of DBSS was not adequate to meet all user and mission needs of the Armed Services Blood Program. DBSS did not provide the elements necessary to fully support blood program operations. As a result, use of DBSS could adversely affect asset accountability, increase the workload at Blood Program Organizations, increase the risk of blood inventory errors, and could possibly result in the inappropriate release of blood products (finding A).

The deployment and use of DBSS was not consistent throughout DoD. Two different versions of DBSS were in operation simultaneously. The interface to the Composite Health Care System was only being used at 46 percent of the fixed facilities, and only 54 percent of the Theater DBSS laptops were ready for use. In addition, reporting to the Joint Medical Asset Repository through DBSS and Theater DBSS was not complete. As a result, standardized blood product management was not achieved, workload for Blood Program Offices and Organizations increased, and DoD might not achieve total asset visibility of blood products (finding B). See Appendix A for details on our review of the management control program.

Summary of Recommendations. We recommend that the Director, Armed Services Blood Program Office, establish a plan to ensure that original key functional requirements are incorporated into DBSS. We recommend that the DBSS Project Office establish management controls to ensure system requests are processed completely and timely and trouble tickets are reviewed for compliance with performance standards and trends of system problems. Further, we recommend that procedures be established to ensure tracking of system request information is complete, mobile server users are supported, trouble ticket processing information is provided, and computer-based training reflects current DBSS functionality. We also recommend that the DBSS and Joint Medical Asset Repository Project Offices modify their systems to ensure in-transit inventory is not counted twice. We recommend that the Surgeons General establish an annual competency assessment program for system administrators and develop a tri-Service system administrator training program. In addition, we recommend that the Service Blood Program Offices establish policy requiring deployment plans for future DBSS upgrades and have a DBSS reporting capability at all facilities that maintain or transfuse blood products. Additionally, we recommend that the Service Blood Program Offices establish time frames for implementing the latest DBSS software and update the blood program policies to include the requirement to use DBSS at all Blood Program Organizations. We also recommend that the Blood Program Offices jointly develop and implement plans to correct the problems with the Composite Health Care System interface and the Theater DBSS implementation.

Management Actions. The Office of the Assistant Secretary of Defense (Health Affairs) took action to correct several problems identified by our audit. In March, personnel reviewed most of the outstanding system requests. Three of the five original requirements have been funded for development beginning in FY 2002. A new contract was awarded in June 2001 to provide support services to users of Military Health Service systems, including DBSS. In addition, a survey will be prepared to identify reports that could be beneficial to all DBSS users. The DBSS Project Office modified the standard operating procedure regarding review of system requests to include the requirement for impact analyses, and readiness representation was added to the review committee. Additionally, the DBSS Project Office began preparing quarterly performance review reports of technical support.

Management Comments. The Air Force partially concurred with the findings of our report and the Office of the Assistant Secretary of Defense (Health Affairs), the Armed Services Blood Program Office, the Army, the Navy, and the Air Force generally concurred with our recommendations. The Armed Services Blood Program Office agreed to validate and prioritize the remaining original functional requirements for incorporation into DBSS. The Assistant Secretary has developed standard operating procedures for processing system requests and trouble tickets, has established quality

checks, and has developed a procedure to provide trouble ticket information to the users and system administrators. Further, the Assistant Secretary will provide computer-based training with each major release of DBSS and the next major release will contain a correction to ensure in-transit inventory is not counted twice. The Assistant Secretary nonconcurred with our recommendation to provide a spares program for mobile servers and workstations, stating that he is reviewing alternative solutions to address the issue. The Army and the Navy concurred with the recommendation to develop competency assessments for DBSS system administrators; however, the Air Force nonconcurred, stating that the DBSS computer-based training provided an adequate assessment tool. The Army and the Navy concurred with the recommendation to develop a tri-Service system administrator training program; however, neither agreed to consolidate their programs. The Air Force nonconcurred, stating that the Navy program is a defacto tri-Service training program.

The Service Blood Program Offices concurred with the recommendation to establish policy requiring deployment plans for future DBSS upgrades, to establish a time frame for implementing the latest DBSS version, and to update the blood program policies to require the use of DBSS. The Air Force nonconcurred with the recommendation to provide a DBSS reporting capability at all facilities that maintain or transfuse blood products, stating that not all facilities need to use DBSS. The Service Blood Program Offices concurred with the overall recommendation to implement a plan to correct the problems with the Composite Health Care System interface and Theater DBSS. See the Finding section for a discussion of management comments and the Management Comments section for the complete text of the comments.

Audit Response. As a result of management actions, we modified the report and deleted a recommendation to provide adequate guidance regarding the use and implementation of the Theater DBSS equipment. The number of Air Force Theater DBSS laptops readied for use has increased since issuance of the draft report and the Air Force plans to activate the remaining laptops during upcoming training exercises.

Management comments were partially responsive. We request that the Assistant Secretary of Defense (Health Affairs) provide additional information concerning an alternate solution to a spares or replacement program for mobile servers and workstations. We disagree with the Air Force that the DBSS computer-based training provides an adequate assessment tool for system administrator competency and request that the Service Blood Program Offices reconsider the establishment of a tri-Service system administrator training program. Further, we disagree with the Air Force that not every facility needs to have the capability to report blood product information to DBSS. While not every site may require a DBSS or TDBSS computer, we maintain that blood inventory data should be transmitted to an existing DBSS or TDBSS facility so that the database remains current. We request that the Assistant Secretary of Defense (Health Affairs), the Armed Services Blood Program Office, the Army, the Navy, and the Air Force provide comments, as indicated in Table 2 and Table 4, by November 26, 2001.

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Background

The Armed Services Blood Program. The Armed Services Blood Program (the Blood Program) was formally established by Presidential Order in 1952 as the Military Blood Program, part of the National Blood Program. The Blood Program's mission is to provide quality blood products, blood substitutes, and services for all worldwide DoD customers in peacetime, in wartime, and during contingency operations. The primary operational policies for the Blood Program are Army Technical Manual 8-227-11/NAVMED [Navy Medical] P-5123/Air Force Instruction 44-118, "Operational Procedures for the Armed Services Blood Program Elements" (the Operational Procedures Manual), September 1, 1995, and Army Manual 8-227-12/NAVMED P-6530/Air Force Handbook 44-152, "Joint Blood Program Handbook" (the Handbook), January 21, 1998. The Blood Program is managed by the Armed Services Blood Program Office (ASBPO) and Service and Joint Blood Program Offices (Blood Program Offices). The Blood Program includes operational components, such as blood donor centers and blood product depots (Blood Program Organizations). The Blood Program Offices and Blood Program Organizations (Blood Program Activities) are responsible for the successful collection, storage, and distribution of blood products. See Appendix C for a glossary of key terms.

The Defense Blood Standard System. The Defense Blood Standard System (DBSS) is the automated information system used by Blood Program Organizations to maintain and track blood donations and blood product inventories during peacetime and in the event of war or contingency operations. DBSS provides blood product management for fresh and frozen blood products during blood collection, processing, testing, shipping, and storage. It also provides transfusion service management and system administration. DBSS is unique because it is the only automated information system within the Military Health System that is regulated by the Food and Drug Administration (FDA) as a Class II Medical Device. The Class II Medical Device designation gives the FDA the authority to inspect the development and use of DBSS.

DBSS supports blood operations at military treatment facilities, Armed Services Whole Blood Processing Laboratories, blood product depots, blood donor centers, and mobile blood drives. A theater version of DBSS, Theater DBSS (TDBSS), supports Blood Program Organizations that primarily have wartime missions, such as blood supply units and blood transshipment centers. DBSS and TDBSS use the same software; the difference between the two systems is that DBSS is operated on a desktop personal computer and TDBSS is operated on a laptop.[1]

[1]For purposes of the report, the Blood Program Organizations operating DBSS will be referred to as "fixed facilities," and the Blood Program Organizations operating TDBSS will be referred to as TDBSS facilities.

In the late 1980s, DoD recognized the need for an automated blood system. At that time, with the increase in the number of human immunodeficiency virus cases in the United States, DoD identified a need to automate the lookback[2] and donor deferral[3] programs. The first attempt by DoD to create an automated blood system was the Defense Blood Management Information System. That system was found to be ineffective and, in the early 1990s, was replaced with DBSS. DBSS management and support costs for FY 1991 through FY 2000 totaled $70.1 million. Projected costs for FY 2001 through FY 2007 are $43.8 million.

DBSS Interface and Upward Reporting Capabilities. As of May 2001, DBSS had interface capabilities with two systems, the Composite Health Care System (CHCS) and the Automated Blood Product Labeling System, and provided input to a third system, the Joint Medical Asset Repository (JMAR). The interfaces with CHCS and the Automated Blood Product Labeling System are bi-directional; that is, each system can send data to and receive data from the other system. In contrast, the interface with JMAR is a one-way sharing of data. JMAR receives blood product inventory and shipping information from DBSS through an online upward reporting capability.

DBSS Program Management. The responsibility for managing DBSS resides with the DBSS Project Office, under the Clinical Information Technology Program Office (CITPO), Office of the Assistant Secretary of Defense (Health Affairs).[4] In addition to overall management responsibilities, the DBSS Project Office, in coordination with the user community, is responsible for identifying new requirements, resolving user complaints, and acting as the technical representative for the design and maintenance contract with Electronic Data Systems to ensure that DBSS meets Government specifications. The functional proponent of DBSS is the ASBPO. As such, the ASBPO is involved in the design and funding for DBSS.

Technical Support. Two major organizations provided technical support for DBSS, Electronic Data Systems and the Tri-Service Medical System Support Center (TMSSC). Electronic Data Systems is the contractor responsible for the integration, design, development, operation, and maintenance of DBSS. TMSSC, a DoD organization within the Office of the Assistant Secretary of Defense (Health Affairs), provided the initial technical support[5] and elevated more complex issues to Electronic Data Systems.

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[2]Lookback refers to the process of tracking blood product donations and transfusions so that former blood recipients or donors can be notified that they may have received or donated infected blood products.

[3]Blood donors can be either temporarily or permanently deferred from donating blood products, depending on their exposure or possible exposure to infectious diseases.

[4]Management of the program under the Office of the Assistant Secretary of Defense (Health Affairs) began in 1998 when the Office of the Navy Surgeon General ceased being the executive agent for the system.

[5]As of October 1, 2001, TMSSC was replaced by the International Business Machines Corporation.

DBSS Deployment. As of August 31, 2001, DBSS had been deployed to 79 fixed facilities: 78 operational facilities and 1 training facility. The initial test, or "Alpha" version, of DBSS was fielded in 1992. Since 1994, nine versions of DBSS have been deployed, as shown in Table 1. The release of the next version is planned for August 2002.

Table 1. DBSS Deployment

DBSS Version	Deployment Date
1.00	August 1994
1.01	February 1995
1.02	May 1995
1.02EM[1]	July 1995
1.03	November 1995
2.00/2.01[2]	not deployed
3.00	October 1998-February 1999
3.01	March 1999
3.02	September 2000
3.03	September 2000

[1]EM indicates an emergency maintenance release to correct system problems.
[2]Functional requirements for version 2.00/2.01 were included in version 3.00.

TDBSS Deployment. As of August 31, 2001, TDBSS equipment had been delivered to 24 of the 35 TDBSS facilities (3 Army, 6 Navy, and 15 Air Force). The Military Departments were in the process of deploying TDBSS hardware that contains at least DBSS version 3.01 software.

Objectives

The overall objective of the audit was to determine whether the management and administration of the Blood Program was adequate to ensure quality blood products were properly handled and controlled during peacetime and wartime. This audit is the second in a series of audits concerning the Blood Program. This report addresses the automated information systems supporting the Blood Program. The previous audit addressed Blood Program readiness issues. We also reviewed the adequacy of the management control programs of the TRICARE Management Activity and the offices of the Surgeons General as they applied to the audit objective. See Appendix A for a discussion of the audit scope and methodology, our review of the management control programs, and prior coverage related to the audit objectives.

Other Matters of Interest

A discussion of the accessibility to JMAR is in Appendix B. As of March 2001, there were only limited controls in place to identify and terminate unauthorized and inactive user accounts. In June 2001, additional controls were established for creating and managing user accounts. The discussion in the appendix describes the need for readiness-related controls.

A. Implementation of the Defense Blood Standard System

Implementation of DBSS was not adequate to meet all user and mission needs of the Blood Program. DBSS did not provide the elements necessary to fully support Blood Program operations. The inability to meet user and mission needs occurred because DoD did not incorporate key original requirements into the system design, did not ensure DBSS provided all necessary data for total asset visibility, and did not provide adequate system support to users. Further, the DBSS Project Office did not provide complete or up-to-date user training, and the Service Blood Program Offices did not establish required competency assessments for key functional personnel. As a result, use of DBSS could adversely affect asset accountability, increase the workload at Blood Program Organizations, increase the risk of blood inventory errors, and possibly result in the inappropriate release of blood products.

User and Mission Needs

DBSS implementation was not adequate to meet user and mission needs of the Blood Program. Specifically, DBSS implementation did not provide the following elements necessary to fully support Blood Program operations.

- Five original design requirements (global donor deferral; global lookback; laboratory testing equipment interface; accurate, timely, and readily available reports; and cryovial shipment and storage management).
- Total asset visibility.
- Adequate system support.
- Adequate user training.

Original Design Requirements

The inadequacies of DBSS in supporting user and mission requirements occurred in part because the implemented system did not include key original requirements. The initial system included functions that captured blood donor information, provided blood product management, identified site-specific lookback information, recorded transfusion information, and supported system administration. However, five functions that were identified as user requirements for the initial versions of DBSS (versions 1.00 and 2.00), and were used as justification for automating the blood system, had still not been included in DBSS—almost 7 years after the first version was deployed. The five functions are global donor deferral; global lookback; an interface with

laboratory testing equipment; accurate, timely, and readily available reports; and cryovial shipment and storage management. See Appendix D for a detailed description of the key functional requirements.

We identified the key original design requirements by reviewing studies and other planning documents because the DBSS Project Office could not provide a mission needs statement, an operational requirements document, or some other formal document that outlined the initial validated user requirements for DBSS. Documents reviewed included the following.

- "Defense Blood Management Information System, Functional Description," September 23, 1987, National Data Corporation, San Antonio, Texas.
- "Corporate Information Management for the MHSS [Military Health Services System]-Blood Management, High Level Functional Situation Analysis," August 12, 1991, Corporate Information Management Medical Functional Group.
- "Corporate Information Management, Medical, Defense Blood Standard System, Functional Economic Analysis," undated, Vector Research, Incorporated, Arlington, Virginia.
- "DBSS Apache Study, Process Analysis and Models," April 1992.
- User group meeting minutes from a May 11, 1992, Functional User Group Workshop, that addressed the design of DBSS versions 1.00 and 2.00.
- "Medical Readiness Strategic Plan 1998-2004," August 1998.

To ensure DBSS incorporates the functionality required by the users, DoD must provide the funding necessary to implement the five key functions identified by users as critical requirements. The first three functions—global donor deferral, global lookback, and an interface with laboratory testing equipment—are funded for development in FY 2002 and FY 2003. However, the remaining two functions are not funded.

The fourth function, an improved reporting capability, was being partially addressed. As a result of this audit, the DBSS Project Office will survey the user community for reports created at individual Blood Program Organizations that could have universal benefit. Reports that are approved for widespread distribution will be posted on the DBSS Internet site. However, that action does not solve the problems associated with the accurate generation of DD Form 2555, "Blood Bank Operational Report."

System changes needed to incorporate the fifth function, cryovial management, had been approved but assigned a low priority. ASBPO should ensure the five original key functional requirements are incorporated into DBSS.

Total Asset Visibility

The DBSS and JMAR Project Offices did not ensure that upward reporting from DBSS to JMAR provided all critical blood product data necessary for total asset visibility. Specifically, data reported from DBSS to JMAR did not reflect that a blood product shipment was received by a Blood Program Organization, which could potentially result in a temporary double counting of blood assets. JMAR contains 12 query reports used by Blood Program Offices for planning purposes. The reports provide on-hand blood product inventory data for each Blood Program Organization or group of organizations and data for blood products in transit between Blood Program Organizations. DBSS updates on-hand inventory data for Blood Program Organizations on a daily basis. The inventory data for in-transit blood products are posted to JMAR as soon as a shipment is annotated as "closed" in DBSS; however, the inventory data are maintained in JMAR for 7 days. To determine the total number of blood products within a unified command, a JMAR user would need to run query reports for both on-hand and in-transit inventory. Because the in-transit inventory data remain in JMAR regardless of whether the inventory was received, blood products could be included in both the in-transit and on-hand inventory data for the receiving facility. To obtain the correct inventory information, the unified command would have to contact the sites showing in-transit inventory to determine its receipt status, partially defeating the purpose of having an automated reporting capability. The problem could be significant during wartime or a contingency operation, when the shipping of blood products will increase substantially. The DBSS and JMAR Project Offices should modify their systems, as needed, to ensure in-transit inventory is not counted twice.

System Support

DoD did not provide adequate system support to users. System support is composed of two processes—system request processing and trouble ticket processing. The DBSS Project Office and the Blood Program Offices did not adequately process user-initiated system requests. TMSSC did not adequately provide technical support for trouble ticket processing, as required by its support agreement with CITPO. In addition, the DBSS Project Office did not provide adequate oversight of the trouble ticket process.

Initially, the two system support processes operated independently. Before January 2001, users submitted system requests to the Blood Program Offices, DBSS Project Office, TMSSC, or Electronic Data Systems and submitted trouble tickets to TMSSC. To improve management of the system support process, both system requests and trouble tickets were submitted only through TMSSC. TMSSC forwarded the system requests to Electronic Data Systems, which entered the information into the tracking system.

System Request Processing. The DBSS Project Office and the Blood Program Offices did not adequately process user-initiated system requests. We identified four concerns with the handling of system requests by the DBSS Project Office and the Blood Program Offices:

- outstanding system requests,
- approved system requests lacked documentation,
- impact studies for changes were not conducted, and
- readiness-related representation was not included in the review process.

System requests are formally submitted by users and handled through the system request process. That process is outlined in the "DBSS Configuration Management Plan," January 2001, which updated the August 1998 Configuration Management Plan. The Configuration Management Plan includes procedures for the review, prioritization, and documentation for incorporating user requirements into the system's design. Specifically, the process for handling system requests includes two types of reviews. The first type is a functional review, which is performed by Blood Program Office, DBSS Project Office, and Electronic Data Systems personnel. The second type is a technical review, which is performed by DBSS Project Office and Electronic Data Systems personnel. Each review group makes recommendations and prioritizes the system requests until they are closed out as a nonessential functionality, approved as a funded requirement for DBSS, or approved as an unfunded requirement for DBSS. Further, the Configuration Management Plan requires that the status of each system request be maintained in an automated tracking system and that the entire process for the validation, approval, review, and prioritization of system requests be completed on at least a quarterly basis.

There are two types of system requests—system change requests and system incident reports. System change requests are requests for functional changes and enhancements to existing DBSS requirements. Examples of system change requests include adding a global lookback capability, maintaining additional donor and transfusion data, computing blood types, and providing expiration schedules for all blood products. System incident reports are requests for a correction to DBSS when the system does not operate properly. System incident reports are temporarily resolved through system workarounds.[6] Users have submitted system incident reports for problems associated with the accuracy of blood reports, the dating of blood products, the scanning of blood product information into DBSS, and the entry of donor information.

Outstanding System Requests. Before March 2001, DoD had not adequately processed 729 system requests that had been submitted between May 1994 and October 2000. The 729 outstanding system requests were composed of 480 system change requests and 249 system incident reports. Although required by the Configuration Management Plan to process the system

[6]A workaround is a method of accomplishing a task, despite inadequacy in software or hardware, without correcting the underlying problem.

requests on a quarterly basis, DoD failed to meet the standard, resulting in the incomplete processing of 480 system change requests. Further, although required, the system change requests were not adequately maintained in the automated tracking system. The 249 system incident reports also had not been adequately processed, resulting in 133 system workarounds that must be managed by the Blood Program Organizations until a corrective change is incorporated into DBSS. According to the DBSS Project Office, an initial review of the 480 outstanding system change requests was completed in March 2001, resulting in 218 being closed, 11 funded for a future release, 5 had already been fielded, and the remaining 246 were in various stages of review. We commend the DBSS Project Office for taking action to reduce the backlog of system change requests. However, as of May 2001, 116 outstanding system incident reports still needed to be reviewed and 131 of the 133 workarounds had not been resolved with permanent changes.

Documentation of Approved System Requests. System requests approved for inclusion in versions 3.02 and 3.03 and future versions of DBSS had not been adequately documented, as required by the Configuration Management Plan. We reviewed the postings in the automated tracking system for 22 system requests included in DBSS versions 3.02 and 3.03 and for 7 that had been approved for the next DBSS version release. Of the 29 postings reviewed, only 2 contained all of the data, validations, and approvals required. Examples of omissions included indication of potential patient safety impacts, DBSS Project Office validation, and technical and functional approval.

Impact Studies for Changes. The system request functional review process did not require an impact study for changes to determine the effect of a proposed change on all Blood Program Organizations. Because Blood Program Organizations perform different functions—some organizations collect blood, some transfuse blood, and others only store and ship blood products—a change that could improve the processing at one organization could negatively affect the performance of another. That situation occurred when DBSS version 3.00 was implemented. A change that improved processing at the blood donor centers negatively impacted the ability of the Armed Services Whole Blood Processing Laboratories to process blood products. The blood processing laboratories indicated that although they could accommodate the extra work required during peacetime, in the event of a wartime situation or a contingency operation, they would not be able to adequately meet their mission. The blood processing laboratories submitted a system request to correct the problem. If an impact study had been completed before incorporating the system change, the additional expense needed to correct the resulting problem could have been avoided.

As a result of our audit, in June 2001, the DBSS Project Office revised its "User Focus Group Standard Operating Procedure" to include the requirement to perform a functional impact assessment. The purpose of the assessment is to determine the impact of an approved system request on other Blood Program Organizations.

Readiness-Related Representation in the Review Process. The DBSS Project Office did not ensure that the functional review process included personnel representing all possible users of DBSS. There were no representatives from TDBSS facilities included in the functional review process to ensure that readiness requirements were considered. It is imperative to have input from all types of users, including users familiar with TDBSS, so that all operational aspects of the Blood Program are considered when system requests are reviewed. As a result of our audit, in June 2001, the DBSS Project Office revised its "User Focus Group Standard Operating Procedure" to include a Service-designated TDBSS user as a voting member of the user focus group.

Enhancements to the System Request Process. Although the DBSS Project Office had worked diligently to define and implement new procedures for system request processing, the following changes would improve the process.

- Completely process all outstanding system requests.
- Establish management controls to ensure all future system requests are processed in accordance with the Configuration Management Plan.
- Establish procedures to ensure all required data, validations, and approvals are entered into the tracking system.

Trouble Ticket Processing. TMSSC did not adequately provide technical support, as required by the support agreement with CITPO. That support agreement outlined the requirements for both the DBSS Project Office and TMSSC. Technical support began with a user submitting a trouble ticket to TMSSC through a telephone call, facsimile, or e-mail. If the trouble ticket could not be resolved by TMSSC, it was elevated to Electronic Data Systems. Electronic Data Systems could resolve the problem directly, return the trouble ticket to TMSSC for resolution, or elevate the problem as a system request.

Under the support agreement, TMSSC was required to meet monthly performance standards and to report trouble ticket and performance information on a monthly basis to CITPO. Specifically, TMSSC was required each month to resolve 50 percent of trouble tickets within 48 hours of submission and 80 percent within 144 hours. During calendar year 2000, TMSSC met its standard to submit monthly reports. However, TMSSC met the 48-hour performance standard in only 2 out of 11[7] months and did not meet the 144-hour standard at all. Figure 1 shows TMSSC compliance with the 48-hour time standard; Figure 2 shows TMSSC compliance with the 144-hour time standard.

[7]TMSSC did not produce metrics for December 2000 because the automated system used to track the metric data was being updated.

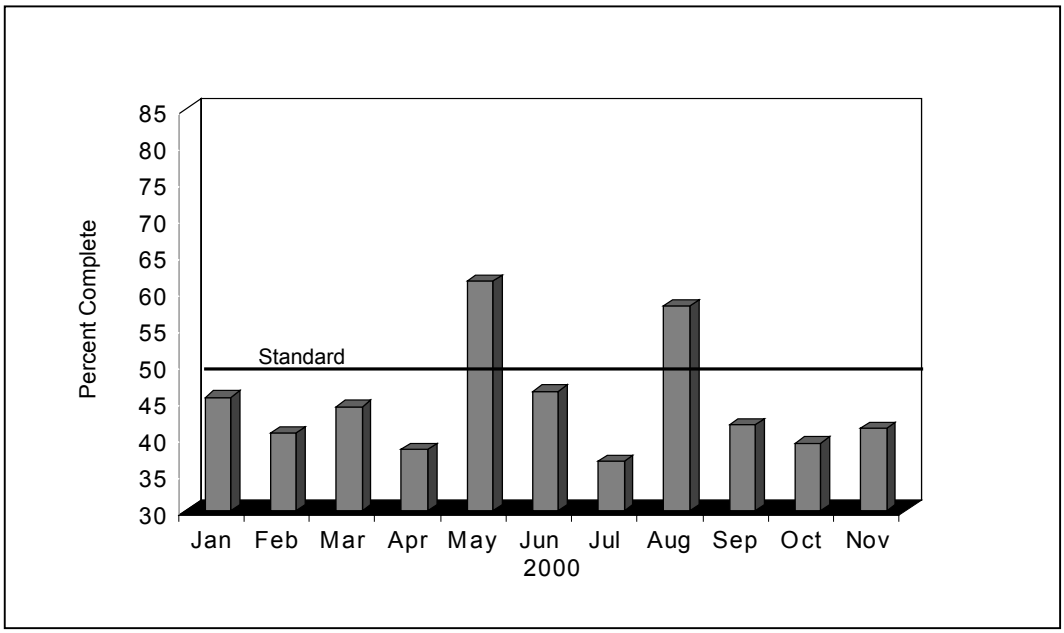

Figure 1. Percent of Trouble Tickets Resolved by TMSSC Within 48 Hours During Calendar Year 2000

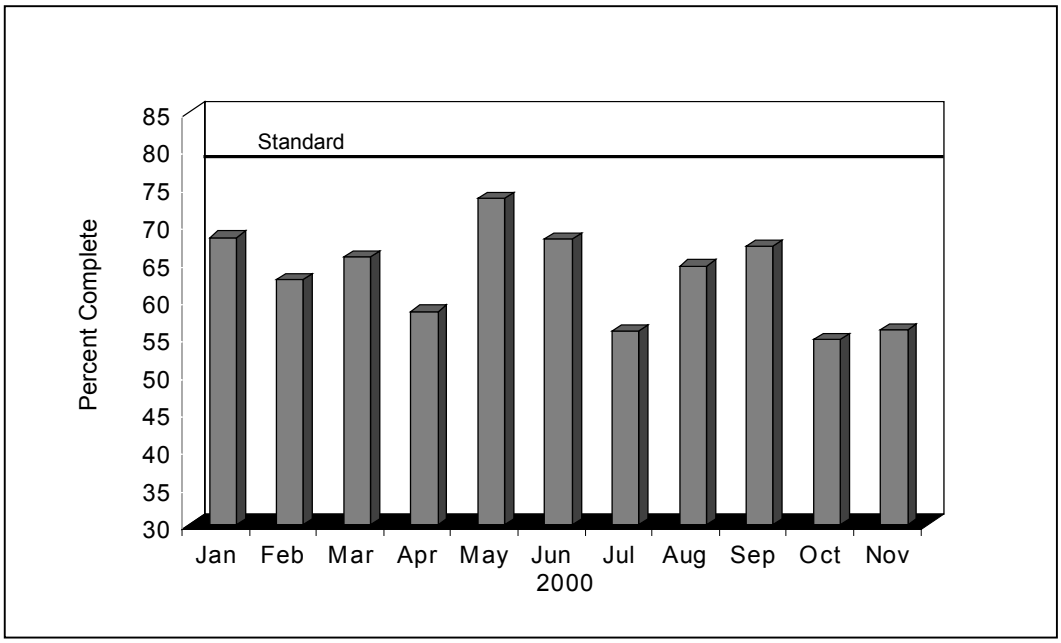

Figure 2. Percent of Trouble Tickets Resolved by TMSSC Within 144 Hours During Calendar Year 2000

On June 8, 2001, the Office of the Assistant Secretary of Defense (Health Affairs) awarded a support services contract to the International Business Machines Corporation to perform the services being handled by TMSSC. The contract requires compliance with incentivized performance metrics, which allows for both positive and negative financial incentives based on established performance criteria. The contract was effective October 1, 2001; TMSSC no longer provides support services.

However, the problems identified with TMSSC performance could continue to occur under the new contract. According to the DBSS Project Office, "There is no question that the DBSS medical device [designation] had an impact on TMSSC's inability to meet established standards." The DBSS Project Office stated that TMSSC was working with them to develop alternative metrics. However, the new support services contract has the same performance metrics for handling DBSS issues as any other automated system in the Military Health System. If DBSS support is more complex because of the Class II Medical Device designation, then the contract should include separate metrics for DBSS.

Oversight of the Trouble Ticket Process. The DBSS Project Office did not provide adequate oversight of the trouble ticket process. The DBSS Project Office did not comply with a requirement to prepare quarterly performance review reports of TMSSC technical support to ensure it performed adequately. In addition, the DBSS Project Office did not review monthly reports submitted by TMSSC to proactively identify possible problem areas associated with DBSS. Further, the DBSS Project Office did not ensure that users were provided complete guidance concerning trouble ticket processing.

DBSS Project Office Performance and Requirements. The DBSS Project Office did not prepare quarterly performance review reports of TMSSC technical support, as required by the support agreement. Further, the DBSS Project Office did not proactively review TMSSC-provided reports to identify potential problem areas associated with DBSS. TMSSC was required by the support agreement to report trouble ticket and performance information to CITPO each month. The reporting was to cover trouble tickets submitted during the current month plus the preceding 11 months and identify the status of trouble tickets by Military Department, priority, subject, and TRICARE region. The DBSS Project Office was required to prepare a quarterly report on its review of the monthly reports submitted by TMSSC.

The DBSS Project Office did not ensure that TMSSC provided adequate technical support to users because it was not completing its quarterly performance reviews of TMSSC performance, as required. Had the DBSS Project Office performed the reviews and prepared the reports, it would have identified that TMSSC performance was not acceptable and that users were not being adequately supported.

As a result of our audit, in June 2001, the DBSS Project Office issued a quarterly performance review report covering the second quarter of FY 2001. The report identified the need for revised metrics and that TMSSC did not meet its standard for the quarter.

Reviewing the trouble ticket submission reports would also have provided the DBSS Project Office with the opportunity to proactively identify problems reported by the users. For example, a systematic review of TMSSC reports by the DBSS Project Office would have shown that there was a widespread problem with mobile DBSS systems.[8] The mobile systems are used on blood drives to record DBSS data for downloading into the fixed facility DBSS database. Without the mobile systems, the DBSS data has to be manually collected for entry into DBSS at a later time, resulting in both extra work and the possibility of a data input error. Of the 18 Blood Program Organizations contacted, 6 conducted mobile blood drives and 4 of those 6 reported problems with their mobile DBSS system. Those four organizations conducted up to four mobile blood drives a week. Three organizations were without a mobile server for between 12 days and 6 weeks, and the fourth was without a mobile server for 6 out of 8 months. Although CITPO established a spares or replacement program for other hardware components, it did not have a spares or replacement program for the mobile servers or workstations. Had a review been conducted, the DBSS Project Office could have identified the problem and established a spares or replacement program to assist the Blood Program Organizations.

The DBSS Project Office needs to establish controls to ensure quarterly performance reviews of the system support services contractor are conducted and required reports are prepared. In addition, the DBSS Project Office needs to establish procedures to review the monthly trouble ticket reports to identify possible DBSS problems.

User Understanding of the Trouble Ticket Process. The DBSS Project Office did not ensure that users were provided complete guidance concerning the trouble ticket process. There was insufficient information available to users in the "DBSS User's Guide Version 3.03," August 2000, and the "System Administrator Guide Version 3.03," September 2000. The guides do not contain the TMSSC time standards for the resolution of trouble tickets or the criteria that users should consider when requesting a priority for their trouble tickets.[9] In addition, the guides contain no information concerning the TMSSC trouble ticket tracking system, Remedy, which was specifically designed to allow users to follow the status of their trouble tickets. Remedy was accessed by authorized users through Infonet, a TMSSC Internet site.[10] Out of 18 Blood Program Organizations, only 4 were aware of the time standards for resolving trouble tickets. In addition, only 7 were aware of how priorities were assigned or had been asked to assign a priority. Only 10 had Infonet accounts.

As a result of our audit, the DBSS Project Office started to address the problem of user understanding of the trouble ticket process. On April 25, 2001, the DBSS Project Office issued a memorandum to the Service Blood Program

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[8]Mobile DBSS systems include both servers and workstations.

[9]Each trouble ticket was assigned a priority of low, moderate, or high, based on the severity of the problem. According to TMSSC, the user assigned the initial priority, which might be changed after evaluation by TMSSC. The priority dictated the order in which the trouble tickets were to be resolved.

[10]Effective October 1, 2001, a similar trouble ticket tracking system was made available to DBSS users and system administrators by International Business Machines Corporation.

Offices that provided criteria for establishing trouble ticket priorities. That is an excellent first step; however, the information needs to be included in a primary information source, such as the User and System Administrator Guides. In addition, the information needs to be expanded to include trouble ticket time standards and tracking procedures.

User Training

The DBSS Project Office did not provide users with complete and current training. Additionally, the Service Blood Program Offices did not establish standardized competency assessments to measure the skills of system administrators, as required by the FDA, and did not train them to meet those standards.

Computer-Based Training. Computer-based training provided by the DBSS Project Office for DBSS users and its system administrators was not updated to reflect the system functionality added with the September 2000 releases of DBSS. Generally, the Blood Program Organizations required their new staff to complete the computer-based training before they could access DBSS and they required current staff to complete the training annually. Out of 18 Blood Program Organizations, 14 were using the computer-based training; however, 8 of those organizations did not find it useful. At the four organizations not using the training, three were TDBSS facilities and one was a fixed facility that had created its own training program.

The computer-based training consists of five user modules and one system administrator module. However, the training is not adequate to fully meet user training needs because it was not updated to reflect new functionality incorporated in the September 2000 releases of DBSS. The computer-based training available to Blood Program Organizations was issued in February 1999 and does not reflect the updated functionality. The training modules do not include instructions on scanning blood product information into and out of inventory or the interface with the new automatic labeling capability. Further, new drop-down menus used to expedite the processing of blood products are not included in the training, forcing the student to enter data that is not required by the latest DBSS versions. In addition, the training does not address upward reporting to JMAR, a key system administrator responsibility.

As of May 2001, there were no plans to update the computer-based training nor was there a mechanism in the DBSS contract to ensure the computer-based training is updated with each major release. The computer-based training is the primary training tool for DBSS users. If it is to remain so, it should include all key DBSS functions and be updated as part of future major releases.

System Administrator Competency Assessments. The Service Blood Program Offices did not establish standardized competency assessments for system administrators, as required by the FDA, and did not train them to meet those standards. Compliance with FDA requirements is critical to meeting mission needs. When inspecting computer systems, the FDA evaluates all processes to determine if an overall computer system is acceptable. As part of that

inspection, the FDA evaluates the competency of individuals engaged in manufacturing blood products and determines whether Blood Program Organizations have procedures for assessing the adequacy of their training programs. Because the system administration of DBSS is a major part of the computer system process, the system administrator responsibilities fall within the scope of the FDA compliance program. However, the Military Departments did not establish standardized competency assessments for its system administrators, and very few of the Blood Program Organizations had developed such standards. Out of 18 Blood Program Organizations, only 2 had published competency assessments for their system administrators and only 1 (Walter Reed Army Medical Center) had a comprehensive assessment checklist.

The Military Departments recognized the need to have competent system administrators and that the computer-based training was not sufficient for that purpose. The Army and the Navy independently developed system administrator training courses. Those training courses are conducted at the Army Medical Department Center and School in San Antonio, Texas.

Training Enhancements. DBSS training could be improved in three ways.

- Update the DBSS computer-based training to reflect current functionality.
- Establish a method to ensure updated computer-based training is provided with each major release.
- Establish annual competency assessment requirements for system administrators and develop a tri-Service system administrator training program to train system administrators to meet those requirements.

Effect of Not Meeting User and Mission Needs

DBSS does not provide key functionality required by DBSS users, which could adversely affect asset accountability, increase the workload at Blood Program Organizations and technical support offices, increase the risk of blood inventory errors, and possibly result in the inappropriate release of blood products. The lack of the functionality limits the ability of DBSS to be a complete blood management system.

Users cannot rely on DBSS to provide accurate blood product inventory or operational data on a global or local level. Local inventory reports continue to be compiled manually because DBSS lacks the functionality to generate all the data needed for inventory reporting. When functions are performed manually instead of using DBSS, the workload for Blood Program Activities increases.

The use of manual records and the independent recording of data into multiple systems can increase the chance of data input error or the release of inappropriate blood products. The lack of a global donor deferral function creates opportunities for personnel to donate at blood donor centers within the Military Health System after having been temporarily or permanently deferred

by another facility. The lack of a global lookback capability increases the risk of not identifying all blood recipients or blood products that may have been exposed to an infectious disease, because Blood Program Organizations must rely on the independent check of records at multiple facilities. The lack of an interface between DBSS and laboratory testing equipment requires the manual input of more than one million infectious disease test results into DBSS on an annual basis. We realize that local controls are in place to prevent input errors and to prevent the inappropriate release of blood products; however, automating those functions can improve the process and reduce overall risk.

Management Comments on the Finding and Audit Response

Air Force Comments. The Air Force partially concurred with the finding. It did not agree that the Service Blood Program Offices should establish competency assessments for key functional personnel. It stated that competency assessment was provided for the DBSS functional system administrator as a component of the computer-based training program. The Air Force also stated that the Army and the Navy have established system administrator training courses and that several Air Force members have attended. Further, the Air Force stated that increased risk of blood inventory errors are related to the use of JMAR. It stated that when only DBSS is used, local inventory data is not counted twice. The Air Force requested that the report clearly state that it is the JMAR blood inventory data that is at risk of being in error, not the DBSS inventory data. The Air Force also stated that the finding does not support that the use of DBSS could possibly result in the inappropriate release of blood products. Last, the Air Force disagreed with our statement to include representatives from TDBSS facilities in the functional review process.

Audit Response. The audit responses to Recommendation A.3.a. and Recommendation A.3.b. address system administrator competency assessments and training.

The duplicate counting problem is a result of the upload from DBSS to JMAR. The link needs to be modified whether within the JMAR system or DBSS. We still believe the use of DBSS could result in an inappropriate release of blood products, as discussed in Appendix D.

Regarding the Air Force comment on the requirement for TDBSS representation in the functional review process, the DBSS Project Office has already revised its policy to require Service-designated TDBSS users as voting members of the user focus group.

Recommendations, Management Comments, and Audit Response

A.1. We recommend that the Director, Armed Services Blood Program Office, in coordination with the Service Blood Program Offices and the Defense Blood Standard System Project Office, establish a plan for ensuring the original key functional requirements that were identified by system users as critical are incorporated into the Defense Blood Standard System.

Armed Services Blood Program Office Comments. ASBPO concurred, stating that it will coordinate with the Services to validate original functional requirements previously identified by system users and, if valid, prioritize those requirements for incorporation into DBSS.

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred and stated that he will support the Director of the Armed Services Blood Program, as appropriate.

Army Comments. The Army concurred and agreed to work with ASBPO and the Service Blood Program Offices to validate and prioritize the original functional requirements.

Navy Comments. The Navy concurred and agreed to work with ASBPO and the Service Blood Program Offices to validate and prioritize the original functional requirements.

A.2. We recommend that the Defense Blood Standard System Project Office:

a. Establish management controls to ensure:

(1) System requests are processed completely and timely, and that all required data, validations, and approvals are entered into the tracking system.

(2) A review of trouble ticket submissions is completed, as required, to determine compliance with trouble ticket performance standards by both current and future contractors.

(3) Trend analyses are completed on trouble ticket reports to identify opportunities for system improvements.

b. Establish procedures to ensure that spare or replacement Defense Blood Standard System mobile servers and workstations are available when users experience hardware problems.

c. Establish a method to inform users and system administrators about the trouble ticket process, including, at a minimum, an explanation of priority assignments, trouble ticket processing time standards, and trouble ticket tracking procedures.

d. Provide updated computer-based training with each major software release that reflects current functionality.

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred with Recommendations A.2.a., A.2.c., and A.2.d. The Assistant Secretary has developed standard operating procedures to address the complete and timely processing of system requests, complaint handling, trouble tickets, and trend analysis. In addition, performance reviews and quality checks are being conducted for the first level of trouble ticket processing and quality checks are being conducted to ensure that all required data is entered into the system request tracking system. To ensure users and system administrators are informed about the trouble ticket process, a DBSS technical bulletin procedure has been established. Further, the Assistant Secretary stated that computer-based training will be provided with each major release beginning with the next major release scheduled for the fourth quarter of FY 2002. The Assistant Secretary nonconcurred with Recommendation A.2.b., which requested he establish procedures to ensure spare or replacement DBSS mobile servers and workstations are available. Instead, he stated that a "root cause analysis" of the mobile system trouble tickets is being performed to determine the best solution to address the issue.

Armed Services Blood Program Office Comments. ASBPO concurred.

Army Comments. The Army concurred.

Navy Comments. The Navy concurred.

Audit Response. Assistant Secretary of Defense (Health Affairs) comments on Recommendations A.2.a., A.2.c., and A.2.d. are fully responsive. The Assistant Secretary's response to Recommendation A.2.b. is partially responsive. We will consider his alternative proposal to the establishment of a spares or replacement program for mobile servers and workstations after we have received more details. We request that in response to the final report, the Assistant Secretary provide specific details concerning the alternative solution so that we can evaluate whether it meets the intent of the recommendation.

A.3. We recommend that the Surgeons General of the Military Departments:

a. Establish annual competency assessment requirements for system administrators.

b. Develop a tri-Service system administrator training program.

Army Comments. The Army concurred and agreed to work with ASBPO and the other Service Blood Program Offices to develop a standardized competency assessment tool for DBSS system administrators. The estimated time frame for

completion is October 31, 2001. The Army stated that it has established a DBSS System Administrators/Users Course at the Army Medical Department Center and School (the School), and the training is based on DBSS version 3.02/3.03. The Army also stated that the Navy offers essentially the same training at the School. The Air Force has been invited to send representatives to those courses for training on a space-available basis. The Army had not solicited the Air Force for funding for the training.

Navy Comments. The Navy concurred and agreed to work with ASBPO and the other Service Blood Program Offices to develop a standardized competency assessment tool for system administrators. The estimated time frame for completion is October 31, 2001. The Navy stated that it offers system administrator training at the School and the Air Force may send personnel on a space-available basis. The Navy, like the Army, had not solicited funds from the Air Force for the training.

Air Force Comments. The Air Force nonconcurred, stating that competency assessment tools are provided as part of the computer-based training and that annual competency assessment of system administrators is already required. The Air Force also stated that the Navy has contracted for a DBSS training program that is open to all Services and is a de facto tri-Service training program.

Armed Services Blood Program Office Comments. ASBPO concurred, stating that training is currently offered by the Army and the Navy.

Audit Response. Army and Navy comments on Recommendation A.3.a. are fully responsive. Army and Navy comments on Recommendation A.3.b. are partially responsive. The Army and the Navy concurred with the recommendation to establish a tri-Service training program; however, neither Military Department agreed to consolidate its program into a tri-Service training program for DBSS system administrators. The Army and the Navy offer essentially the same training, developed under separate contracts with the same contractor. A single training contract would be more efficient than having separate contracts and would eliminate the potential for DoD paying twice for any changes necessary to incorporate DBSS updates. We request that in response to the final report, the Army and the Navy indicate how and when they will develop a single tri-Service training program to meet the training needs for all DBSS system administrators.

Air Force comments are not responsive. The Service Blood Program Offices have not established annual competency assessment requirements for system administrators, as indicated by the Air Force. We found the current computer-based training insufficient, as it does not address all current system administrator functions, including the responsibilities of the technical system administrator. The Army and the Navy concurred with our recommendation and agreed to establish competency assessment requirements by October 31, 2001. Further, the system administrator training currently provided by the Army and the Navy only provides training to Air Force personnel on a space-available basis. With the Air Force supporting a tri-Service training program, the training would be available to all appropriate Air Force personnel instead of solely on a space-available basis. In response to the final report, we

request that the Air Force reconsider its position concerning the establishment of annual competency assessment requirements for system administrators and the development of a tri-Service system administrator training program.

A.4. We recommend that the Joint Medical Asset Repository and Defense Blood Standard System Project Offices modify their systems, as necessary, to ensure in-transit inventory is not counted twice.

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred, stating that appropriate action has been initiated to ensure in-transit inventory is not counted twice in JMAR. Further, corrective changes in DBSS will be in the release scheduled for the second quarter of FY 2003.

Armed Services Blood Program Office Comments. ASBPO concurred.

Army Comments. The Army concurred.

Navy Comments. The Navy concurred.

Management Comments Required

Management is requested to comment on the items indicated with an X in Table 2.

Table 2. Management Comments Required on Finding A

Recommendation Number	Organization	Concur/ Nonconcur	Proposed Action	Completion Date
A.2.b.	Health Affairs		X	X
A.3.a.	Air Force	X	X	X
A.3.b.	Army		X	X
A.3.b.	Navy		X	X
A.3.b.	Air Force	X	X	X

B. Deployment and Use of the Defense Blood Standard System

The deployment and use of DBSS was not consistent throughout DoD. Two different versions of DBSS were in operation simultaneously. Additionally, only 46 percent of fixed facilities used the CHCS interface, and only 54 percent of the TDBSS laptops were ready for use. In addition, reporting to JMAR through DBSS was not complete. The inconsistent deployment and use of DBSS occurred because the Service Blood Program Offices did not provide adequate oversight of DBSS implementation. In addition, Blood Program policy published by the Military Departments does not require the use of DBSS at all Blood Program Organizations. As a result, standardized blood product management was not achieved, workload for Blood Program Activities increased, and DoD might not achieve total asset visibility of blood products.

DBSS Versions in Use

As of August 31, 2001, two different versions of DBSS were operational at the same time by Blood Program Organizations within DoD—3.01 and 3.03.[11] Version 3.03 included enhancements that added readiness reporting through JMAR, added an automated labeling capability, and corrected some deficiencies identified in previous versions of DBSS. The Blood Program Organizations that had not implemented version 3.03 were either not performing the functions or were performing them manually. Table 3 shows, by Military Department, the implementation of DBSS versions 3.01 and 3.03 at fixed facilities.

Table 3. DBSS Versions Implemented as of August 31, 2001

Military Department	Number of Fixed Facilities Using Version	
	Version 3.01	Version 3.03
Army	15	17
Navy	5	19
Air Force	1	20
Total	**21**	**56**

[11]One facility was using version 3.00; however, that facility was scheduled to close and did not have plans to upgrade prior to closure. Version 3.02 was released with version 3.03. All facilities that implemented 3.03 also implemented 3.02.

Although version 3.03 was released in September 2000, 27 percent of the fixed facilities with DBSS still had not implemented it a year later. Specifically, version 3.01 was still operational at 47 percent of the Army facilities, 21 percent of the Navy facilities, and 5 percent of the Air Force facilities. In addition, only 4 of the 24 TDBSS facilities had laptops loaded with DBSS version 3.03.

CHCS Interface

Although the CHCS interface has been available since the deployment of DBSS version 3.00 in February 1999, all facilities that could be linked to CHCS were not. As of August 31, 2001, only 46 percent of the fixed facilities that could use the interface[12] had turned on the capability. Specifically, 39 percent of Army, 42 percent of Navy, and 63 percent of Air Force facilities had turned on the interface capability. The interface allows medical staff to use CHCS to automatically submit a request for blood products to DBSS. DBSS processes the request and provides CHCS with test results and blood availability information. The purpose of the interface is to increase productivity and reduce clerical errors because data would only need to be entered once. Without the interface, data must be independently entered into both systems, increasing workload and possibility of error.

TDBSS Deployment

Although each Service Blood Program Office had taken some action to deploy the new TDBSS laptop computers, as of August 31, 2001, TDBSS had not been fully implemented. Ultimately, 52 TDBSS laptops will be deployed to 35 TDBSS facilities—21 at 13 Army facilities, 6 at 6 Navy facilities, and 25 at 16 Air Force facilities. As of August 31, 2001, 32 laptops had been delivered to 24 TDBSS facilities. However, only 28, or 54 percent, of the 52 laptops designated for TDBSS were ready for use: 3 Army, 4 Navy, and 21 Air Force.

JMAR Reporting Capability

JMAR upward reporting through DBSS was not complete. The Service Blood Program Offices did not require all Blood Program Organizations that store or use blood products to have either a DBSS or TDBSS capability. Some Navy ships and some Military Department health care providers outside fixed and deployable military treatment facilities will not have TDBSS laptops. To achieve total asset visibility of blood product inventory, all organizations storing or using blood products must have the capability to upward report blood product data from DBSS to JMAR.

[12]Not all Blood Program Organizations will use the CHCS interface. Generally, only blood donor centers and blood transfusion service centers generate data applicable to both DBSS and CHCS.

The inconsistent deployment and use of DBSS occurred because the Blood Program Offices did not provide adequate oversight of system implementation. Additionally, Blood Program policy published by the Military Departments does not require the use of DBSS at all Blood Program Organizations.

Oversight of DBSS Implementation

The Blood Program Offices did not adequately oversee the implementation of DBSS. They did not ensure that the latest version of DBSS was installed within a reasonable time frame, and they did not ensure that the CHCS interface was used at all applicable Blood Program Organizations. In addition, the Blood Program Offices did not ensure that the implementation of TDBSS was standardized throughout DoD and did not provide a DBSS capability at all Blood Program Organizations that store or use blood products.

Implementation of New DBSS Versions. The Service Blood Program Offices did not ensure that the latest version of DBSS was installed within a reasonable time frame. Although released in September 2000, 27 percent of the fixed facilities were still using version 3.01 as of August 31, 2001. The Military Departments, as holders of separate FDA blood manufacturing licenses, independently oversee the implementation of system upgrades. The Air Force Blood Program Office was the most aggressive in requiring implementation of the version 3.03 upgrade by setting an implementation suspense date of December 15, 2000, for its fixed facilities. As of August 31, 2001, 95 percent of Air Force facilities had implemented the latest version of DBSS. The Navy Blood Program Office directed its facilities to implement version 3.03 by March 31, 2001. As of August 31, 2001, 21 percent of Navy facilities had still not implemented the latest version of DBSS. The Army Blood Program Office did not set an implementation suspense date for its fixed facilities and that lack of direction is reflected in the fact that 47 percent of the facilities had not implemented the upgrade as of August 31, 2001. The Military Departments need to establish a time frame for full implementation of DBSS version 3.03.

CHCS Interface. The Blood Program Offices and the DBSS Project Office did not adequately oversee the implementation of the CHCS interface in DBSS. They did not require their fixed facilities to use the CHCS interface. Consequently, only 46 percent of fixed facilities had turned on the CHCS interface capability as of August 31, 2001. We understand the reluctance of some of the facilities to use the interface, given operational problems experienced by some users. Problems reported to us include having to re-enter data that was deleted when DBSS abruptly shut down or the creation of duplicate records caused by the merger of the databases of the two systems. However, the shortfalls must be weighed against the benefit of ultimately having a single entry for blood product data. A CHCS interface working group was addressing the interface problems and DBSS users may attend the working group meetings.

TDBSS Implementation. The Blood Program Offices and the DBSS Project Office did not adequately oversee the implementation of the TDBSS hardware and software. Although the DBSS Project Office provided the Military

Departments with the specifications for the TDBSS laptop hardware and provided DBSS software, the Military Departments were responsible for the purchase and deployment of the TDBSS laptops. The Military Departments independently began deploying the TDBSS laptops in August 1999.

The Assistant Secretary of Defense (Health Affairs) developed TDBSS to provide the unified commands with a blood management capability. TDBSS is an interim solution pending the release of the Theater Medical Information Program. The Theater Medical Information Program will provide theater commanders with an integrated health decision support system that will provide, among other capabilities, medical logistics information. However, until the Theater Medical Information Program is operational, TDBSS is the preferred method for providing a readiness-related blood management capability and that method is not functioning correctly.

The Military Departments identified hardware and software problems with the deployment of TDBSS. First, the TDBSS laptops needed to be tested for compliance with FDA requirements. As a result of a 1999 FDA inspection, the DBSS Project Office determined that compliance testing was necessary. Because each Military Department purchased different laptops, a laptop from each Military Department had to be provided to Electronic Data Systems for testing. The DBSS Project Office could not provide a date for completion of the testing. As a result of the testing requirement, the Army delayed full deployment of its TDBSS laptops until approval of the hardware is obtained. The Navy and the Air Force deployed their equipment before it was known that FDA standards applied to the TDBSS laptops, so further action is dependent on the results of the compliance testing. However, the DBSS Project Office and the Military Departments expect the TDBSS laptops to be approved.

Second, the Service Blood Program Offices reported that DBSS versions 3.02 and 3.03 do not operate properly on the TDBSS laptops. Several facilities reported to TMSSC that they could not upgrade to versions 3.02 and 3.03. TDBSS users were told to continue to use version 3.01 and that there was not a mandate to upgrade to versions 3.02 and 3.03. The trouble tickets were closed and TDBSS users were informed to postpone the upgrade until a configuration to support the upgrade was available. If TDBSS is to be used, its software should be current. The problems associated with the upgrade should be resolved.

Third, the Military Departments did not plan to provide a TDBSS capability at all of its readiness-related facilities that handle blood products. Specifically, the Military Departments did not plan to provide TDBSS laptops to health care providers outside fixed and deployable military treatment facilities and the Navy did not plan to provide TDBSS laptops to 10 of its ships that maintain frozen blood inventories.[13] Instead, the Military Departments will collect blood product inventory and use information through a current DBSS or TDBSS user. For example, the Navy Blood Program Office indicated that the inventory for

[13]The 10 ships are landing helicopter-amphibious and landing helicopter-dock ships that maintain frozen blood inventories and could transfuse blood during wartime or contingency operation. The two hospital ships, USNS *Mercy* and USNS *Comfort*, are equipped with TDBSS.

the ships would be managed through DBSS at the fixed facilities responsible for the ships' inventory. Further, the Military Departments indicated that the lack of TDBSS laptops would be resolved with the eventual deployment of the Theater Medical Information Program. Until the Theater Medical Information Program is deployed, the Military Departments need to establish procedures to ensure that all inventory and use of blood products is reported through a DBSS or TDBSS capability.

Until TDBSS is fully implemented, readiness-related Blood Program Organizations will not be able to provide inventory data for total asset visibility. Additionally, without a TDBSS capability, TDBSS facilities will not be able to train to perform their mobility tasks and, in the event of a war or contingency operation, they will be forced to use manual records for inventory and shipping data and will not be able to upward report that data to JMAR.

Blood Program Policy

The Military Departments did not update published Blood Program policies to require DBSS or TDBSS use at all Blood Program Organizations. Specifically, the tri-Service Operational Procedures Manual and Handbook, the primary policies outlining peacetime and wartime blood processing procedures, do not require the use of DBSS or TDBSS, except at blood donor centers. Additionally, the Operational Procedures Manual directs the blood product depots to use an obsolete Navy automated system to maintain and manage frozen blood inventories. The Air Force Surgeon General issued Notice to Airmen 99-003, "Selection, Testing, and Release of Blood Components," April 16, 1999, that directed the use of DBSS. However, that notice does not replace the need to update the tri-Service policies.

Effect of Inconsistent Deployment and Use

As a result of the inconsistent deployment and use of DBSS, standardized blood product management was not achieved, workload was increased for Blood Program Activities, and DoD might not achieve total asset visibility of blood products. The workload of the DBSS Project Office increased because it had to maintain multiple versions of DBSS. Further, the workload increased at fixed facilities that had not implemented the CHCS interface, because medical staff had to enter data into both CHCS and DBSS independently. That not only increased the workload at those facilities but also increased the possibility of data input errors. Further, without TDBSS laptops deployed to all readiness-related Blood Program Organizations, DoD might not be able to adequately manage its supply of blood products or identify its blood inventory in the event of a contingency. Additionally, without updated Blood Program policy requiring the use of DBSS for all blood product management and inventory reporting, Blood Program Organizations independently and inconsistently determine how to manage their inventory and report inventory information.

Management Comments on the Finding and Audit Response

Air Force Comments. The Air Force did not concur with the finding. It did not agree with the number of sites reported that had installed the various DBSS versions, turned on the CHCS interface capability, or deployed TDBSS laptop computers. Further, the Air Force did not agree with our statements that Service Blood Program Offices had not adequately overseen the implementation of DBSS or the implementation of the CHCS interface capability. The Air Force also stated that it had been actively involved and that the statements should be modified to indicate that "some" of the Service Blood Program Offices did not adequately oversee the implementation of DBSS or the interface with CHCS. The Air Force stated that CHCS would not be used at the two Armed Services Whole Blood Processing Laboratories and that four additional facilities were instructed to delay the use of the capability. Accordingly, the Air Force felt that those facilities should not be used to determine the percentage of its facilities without the CHCS interface capability. In addition, the Air Force did not agree with our statement that it provided "little" guidance on the use and implementation of the TDBSS laptop computers.

Audit Response. The numbers reported in the draft report were valid as of March 21, 2001. Data for the versions of DBSS in use, the number of facilities using the CHCS interface, and the number of TDBSS laptop computers deployed have been updated in the report to reflect the status as of August 31, 2001. With regard to the CHCS interface, we noted in the report that not all Blood Program Organizations will use the interface and we did not include those facilities, such as the Armed Services Whole Blood Processing Laboratories, in our computations. However, we continued to include all other facilities in the computation regardless of the reason for the delay because, as was stated in the report, the capability had been present since February 1999 and was not being used. Because of problems identified during the audit, oversight was not adequate by all the Service Blood Program Offices, not just some. We deleted our statement that the Air Force provided little guidance on the implementation and use of TDBSS because the number of Air Force TDBSS laptops readied for use has increased since issuance of the draft report. The Air Force plans to activate the remaining laptops during upcoming training exercises.

Recommendations, Management Comments, and Audit Response

Deleted Recommendation. As a result of management comments, we deleted draft Recommendation B.1.c. and updated the report accordingly.

B.1. We recommend that the Service Blood Program Offices, in coordination with the Armed Services Blood Program Office and the Defense Blood Standard System Project Office:

a. Establish policy requiring a deployment execution plan for all future Defense Blood Standard System upgrades that includes implementation time frames.

b. Establish procedures to ensure all Blood Program Organizations that either maintain blood product inventory or perform transfusions have a capability to report blood product information and inventories to the Defense Blood Standard System or Theater Defense Blood Standard System.

Army Comments. The Army concurred and agreed to work with ASBPO and the other Service Blood Program Offices to establish execution plans and time frames for implementation of subsequent versions of DBSS. The Army stated that delays in the deployment of TDBSS were directly attributable to the failure of the Theater Medical Information Program to meet timelines, which required the Service Blood Program Offices to deploy TDBSS as an interim solution. TDBSS has had numerous technical and software problems that are currently being addressed and the corrections funded. The Army stated that when the problems with the TDBSS laptops are resolved, the laptops will be deployed, and that the prospective users will receive DBSS user and system administrator training.

Navy Comments. The Navy concurred and agreed to work with ASBPO and the other Service Blood Program Offices to establish execution plans and time frames for implementation of subsequent versions of DBSS. The Navy stated that it plans to deploy TDBSS to the casualty receiving and treatment ships and fleet hospitals as part of the Theater Medical Information Program, not as a "stand-alone" package as TDBSS is currently designed. In addition, it stated that if TDBSS capabilities are required at fleet hospitals in a contingency prior to the implementation of the Theater Management Information Program, it will purchase additional TDBSS laptops for those facilities. The Navy stated that if the Theater Medical Information Program is not deployed, DBSS will not be required or practical at the echelon 2 level of care,[14] even though blood will be stored and transfused at that level.

Air Force Comments. The Air Force concurred with Recommendation B.1.a.; however, it nonconcurred with Recommendation B.1.b. The Air Force stated that it disagrees that a DBSS reporting capability is necessary at all facilities that maintain or transfuse blood products. The Air Force also stated that many of the facilities are remotely located and maintain small quantities of blood and, therefore, do not require the use of DBSS.

Armed Services Blood Program Office Comments. ASBPO concurred and stated that it would work with the Services to establish execution plans and time frames for implementation of subsequent versions of DBSS. ASBPO also stated that TDBSS was deployed only as an interim measure to provide a year 2000-compliant system to the field until the Theater Medical Information

[14]Echelon 2 care is administered by a team of physicians or physician assistants who apply emergency procedures to prevent death or loss of limbs.

Program was deployed. Further, ASBPO stated that the Services had given their best effort to deploy TDBSS in light of the numerous technical and software problems associated with the laptops.

Audit Response. Army, Navy, and Air Force comments on Recommendation B.1.a. are fully responsive. The Army and the Navy are partially responsive and the Air Force is not responsive on Recommendation B.1.b. Although the Army and the Navy concurred with the recommendation, they did not address how they would provide a capability to report blood inventory and transfusion information at facilities not equipped with DBSS or TDBSS. The Army statement that the delayed deployment of the Theater Medical Information Program affected the deployment of TDBSS does not address the reporting of inventory information. Although we agree with the Navy statement that DBSS or TDBSS may not be required or practical at the echelon 2 facilities, it did not state how blood inventory data at those facilities would be transmitted to DBSS. We disagree with the Air Force statement that all facilities that maintain or transfuse blood products do not need a DBSS reporting capability. While we agree that all facilities may not require a DBSS or TDBSS computer, we maintain that the inventory and transfusion information must be transmitted to an existing DBSS or TDBSS facility so that the database remains current. We request that in response to the final report, the Army, the Navy, and the Air Force indicate how they will provide the capability to report blood product inventory information for those facilities not equipped with DBSS or TDBSS computers.

B.2. We recommend that the Service Blood Program Offices establish a time frame for their Blood Program Organizations to implement the latest version of the Defense Blood Standard System.

Army Comments. The Army concurred, stating that it did not direct implementation of DBSS versions 3.02 and 3.03 until standard operating procedures were completed and validated, and a test case was completed for JMAR. The Army stated that subsequent to DBSS standard operating procedures being released in May 2001 it issued a directive to load, validate, and implement DBSS version 3.03 no later than August 1, 2001. The Army stated that because of technical and hardware problems, the deadline for full implementation had been extended to October 1, 2001.

Navy Comments. The Navy concurred, stating that it directed that DBSS version 3.03 be implemented by March 31, 2001. The Navy stated that it established October 1, 2001, as a revised implementation date for its facilities because of technical and hardware problems.

Air Force Comments. The Air Force concurred, stating that it will ensure that an implementation time frame is established with every version release.

Armed Services Blood Program Office Comments. ASBPO concurred.

B.3. We recommend that the Service Blood Program Offices, the Armed Services Blood Program Office, and the Defense Blood Standard System Project Office jointly:

a. Develop and implement a plan to correct the software deficiencies identified with the interface between the Composite Health Care System and the Defense Blood Standard System and establish a time frame for the Military Departments to implement the interface at military treatment facilities.

b. Develop and implement a plan to correct the hardware and software deficiencies identified with the Theater Defense Blood Standard System, or find another means to meet the needs of the unified commands for a blood management capability.

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred and stated that the organizations are planning actions in concert with the recommendation.

Armed Services Blood Program Office Comments. ASBPO concurred and stated that the Services and the DBSS Project Office will work with ASBPO to evaluate the deficiencies identified with the CHCS interface, obtain concurrence on patient safety issues, determine priority for correcting deficiencies, and establish a time frame for implementation of the interface at Service facilities.

Army Comments. The Army concurred and agreed to work with ASBPO, the other Service Blood Program Offices, and the DBSS Project Office to evaluate the deficiencies identified with the CHCS interface, obtain concurrence as to the patient safety issues identified, prioritize the corrections, and establish a time frame for implementing the interface.

Navy Comments. The Navy concurred and agreed to work with ASBPO, the other Service Blood Program Offices, and the DBSS Project Office to evaluate the deficiencies identified with the CHCS interface, obtain concurrence as to the patient safety issues identified, prioritize the corrections, and establish a time frame for implementing the interface.

Air Force Comments. The Air Force concurred, stating that it will coordinate with the other Service Blood Program Offices, ASBPO, and the DBSS Project Office to develop corrective actions.

Audit Response. Assistant Secretary of Defense (Health Affairs), ASBPO, Army, Navy, and Air Force comments are fully responsive on Recommendation B.3.a., and partially responsive on Recommendation B.3.b. Although they concurred with the overall recommendation, they did not specifically concur with Recommendation B.3.b. to develop a plan to correct TDBSS or to provide another suitable method of blood inventory management to meet the needs of the unified commands. The Army, in its response to Recommendations B.1.a. and B.1.b., stated that it was in the process of correcting the numerous technical and software problems of TDBSS. However, the Army did not address how it will work jointly with the other Blood Program Offices to correct TDBSS or establish an alternative method of blood inventory management within the unified commands. As we stated in the report and as the Army, the Navy, and ASBPO noted in their responses to Recommendations B.1.a. and B.1.b., TDBSS was developed as an interim measure to the Theater Medical Information Program. However, they did not include in their responses

how the needs of the unified commands will be met prior to the full deployment of the Theater Medical Information Program. We request that in response to the final report, the Assistant Secretary, ASBPO, the Army, the Navy, and the Air Force indicate how they will work jointly to correct TDBSS or establish an alternative method of blood inventory management within the unified commands.

B.4. We recommend that the Military Department Surgeons General, in coordination with the Armed Services Blood Program Office, update Army Technical Manual 8-227-11/NAVMED P-5123/Air Force Instruction 44-118, "Operational Procedures for the Armed Services Blood Program Elements," and Army Manual 8-227-12/NAVMED P-6530/Air Force Handbook 44-152, "Joint Blood Program Handbook," to require the use of the Defense Blood Standard System or the Theater Defense Blood Standard System at all Blood Program Organizations.

Army Comments. The Army concurred and agreed to coordinate with ASBPO and the other Service Blood Program Offices to update the reference documents.

Navy Comments. The Navy concurred and agreed to coordinate with ASBPO and the other Services to update the reference documents.

Air Force Comments. The Air Force concurred and will coordinate with ASBPO, the other Service Blood Program Offices, and the DBSS Project Office to develop corrective actions.

Armed Services Blood Program Office Comments. ASBPO concurred, stating that it will coordinate with the Services to update the referenced documents.

Management Comments Required

Management is requested to comment on the items indicated with an X in Table 4.

Table 4. Management Comments Required on Finding B

Recommendation Number	Organization	Concur/ Nonconcur	Proposed Action	Completion Date
B.1.b.	Army		X	X
B.1.b.	Navy		X	X
B.1.b.	Air Force	X	X	X
B.3.b.	Health Affairs		X	X
B.3.b.	ASBPO		X	X
B.3.b.	Army		X	X
B.3.b.	Navy		X	X
B.3.b.	Air Force		X	X

Appendix A. Audit Process

Scope and Methodology

Work Performed. We reviewed the implementation and use of DBSS and TDBSS at the Joint Staff, 6 Blood Program Offices, 18 Blood Program Organizations (13 fixed facilities and 5 TDBSS facilities), the DBSS Project Office, Electronic Data Systems, TMSSC, and the JMAR Project Office. We reviewed management and operational aspects of the Blood Program Activities to determine the adequacy of DBSS in supporting the Blood Program. We evaluated the functionality of DBSS and its ability to meet user needs and regulatory requirements, the system infrastructure necessary to support DBSS, and the operational support and maintenance process. In addition, we examined the wartime use of DBSS and whether DBSS had standardized the inventory management of blood products throughout DoD. Because this was not an acquisition audit, we did not examine the acquisition process or acquisition-related documentation. Instead, the focus was on system sustainment issues.

We reviewed DoD, Military Department, and unified command Blood Program policies and procedures and DBSS program documents. We reviewed FDA regulations, policies, and inspection reports. We also reviewed User and System Administrator Guides, validation plans, and minutes of configuration control board and user working group meetings. We met with DBSS users and system administrators and obtained standard operating procedures, training plans, and user concerns regarding DBSS functionality. We did not review the costs incurred to develop or maintain the system administrator training programs. For 12 of the 24 Blood Program Activities contacted, we issued questionnaires to supplement information about DBSS collected during the first phase of the audit. Using the Internet, we accessed the TMSSC trouble ticket database for October 2000 to validate TMSSC trouble ticket metrics reported to the DBSS Project Office. We compiled FY 1991 through FY 2005 actual and estimated life-cycle-cost data for the design, development, and support of DBSS from spreadsheets provided by the DBSS Project Office. We did not validate the cost data. Based on management comments on the draft report, we updated the number of DBSS versions in use, the number of facilities using the CHCS interface, and the number of TDBSS laptop computers deployed to reflect the status as of August 31, 2001. The data was verified by reconciling information provided by the DBSS Project Office with data provided by the Blood Program Offices. The documents we reviewed were dated from September 1987 through October 2001.

High-Risk Area. The General Accounting Office has identified several high-risk areas in DoD. This report provides coverage of the DoD Systems Modernization and DoD Inventory Management high-risk areas.

Use of Computer-Processed Data. We relied on computer-processed data from the TMSSC trouble ticket database to determine whether TMSSC met monthly timeliness requirements for the processing of trouble tickets. We performed

limited tests on the reliability of the data by testing the record counts and categorization of the trouble tickets for 1 of the 11 months reported. We also relied on computer-processed data from the system request tracking system to determine whether system requests included in DBSS versions 3.02 and 3.03 were appropriately documented. We verified that the system requests posted in the tracking system for those versions matched the system requests included in the DBSS version release documents. We did not find errors in either system that would preclude our use of the computer-processed data to meet audit objectives or that would change the conclusions in this report.

Universe and Sample. Our sample included 6 of the 21 Blood Program Offices and 18 of the 102 Blood Program Organizations that had been provided with DBSS or TDBSS. The 21 Blood Program Offices are ASBPO, the 3 Service Blood Program Offices, 5 Joint Blood Program Offices, and 12 Area Joint Blood Program Offices. We selected ASBPO, the three Service Blood Program Offices, and two of the Joint Blood Program Offices for this audit. The Joint Blood Program Offices were from the U.S. European Command and the U.S. Pacific Command and were selected because 91 percent of the DBSS and TDBSS computers deployed to the unified commands were deployed to those commands.

Of the 102 Blood Program Organizations—78 fixed facilities and 24 TDBSS facilities—we selected 13 and 5 facilities, respectively. The judgmental selection of fixed facilities was designed to ensure representation of all the Military Departments and all types of Blood Program Organizations. Accordingly, we selected 10 blood donor centers, both Armed Services Whole Blood Processing Laboratories, and 1 blood product depot. The 10 blood donor centers were located at military treatment facilities that also provide transfusion services; 3 were Army facilities, 4 Navy, and 3 Air Force. We also considered the size of the blood donor center and included at least one relatively large facility and one small facility. Both Armed Services Whole Blood Processing Laboratories were selected because one primarily serviced the U.S. European Command and the other serviced the U.S. Pacific Command. The Army and the Navy operate the blood product depots. We originally selected two blood product depots—one Army facility that used TDBSS and one Navy facility that used DBSS. The Army blood product depot had just received its TDBSS computer and the personnel did not have the experience with TDBSS to comment on its operation; therefore, we did not include that facility in our sample. The selection of TDBSS facilities was based on the type of Blood Program Organization. Of five facilities, three were blood transshipment centers and two were transportable blood transshipment centers.

Audit Type, Dates, and Standards. We performed this program audit from September 2000 through October 2001 in accordance with generally accepted Government auditing standards except that we were unable to obtain an opinion on our system of quality control. The most recent external quality control review was withdrawn on March 15, 2001, and we will undergo a new review.

Contacts During the Audit. We visited or contacted individuals and organizations within DoD, the FDA, the Veterans Health Administration, the American Red Cross, and Electronic Data Systems. Further details are available on request.

Management Control Program Review

DoD Directive 5010.38, "Management Control (MC) Program," August 26, 1996, and DoD Instruction 5010.40, "Management Control (MC) Program Procedures," August 28, 1996, require DoD organizations to implement a comprehensive system of management controls that provides reasonable assurance that programs are operating as intended and to evaluate the adequacy of the controls.

Scope of the Review of the Management Control Program. We reviewed the adequacy of the management control programs for the deployment and implementation of DBSS and TDBSS and for DBSS training at the TRICARE Management Activity* and the offices of the Surgeons General. We reviewed management's self-evaluation applicable to those controls.

Adequacy of Management Controls. We identified material management control weaknesses for the TRICARE Management Activity and the offices of the Surgeons General, as defined by DoD Instruction 5010.40. Their management controls for DBSS implementation, deployment, and training were not adequate to ensure that DBSS was properly managed to meet requirements. However, in response to the FDA findings identified during its September 1999 inspection of the DBSS Project Office, CITPO and the DBSS Project Office developed the "Defense Blood Standard System (DBSS) Quality Policy and Manual" (the Quality Manual), December 2000. The Quality Manual establishes management controls for DBSS in the following areas.

- Purchasing and Acceptance
- Records, Documents, and Change Controls
- Design Control
- Production and Process Controls
- Corrective and Preventive Action
- Standards and Regulations

The controls established in the Quality Manual and Recommendations A.2., A.3., B.1., B.2., B.3., and B.4., will improve management of DBSS. A copy of the report will be provided to the senior official responsible for management controls in the TRICARE Management Activity and the Military Department Surgeons General.

*The TRICARE Management Activity, part of the Office of the Assistant Secretary of Defense (Health Affairs), oversees the management control program.

Adequacy of Management's Self-Evaluation. TRICARE Management Activity, Army, Navy, and Air Force officials did not identify the control weaknesses identified by the audit because they did not identify DBSS or the Blood Program as an assessable unit in their management control plans.

Prior Coverage

During the last 5 years, the Inspector General, DoD, issued one report and the Naval Inspector General issued one report discussing the Armed Services Blood Program. In addition, the FDA issued one report specifically addressing the Defense Blood Standard System. Unrestricted Inspector General, DoD, reports can be accessed at http://www.dodig.osd.mil/audit/reports.

Inspector General, DoD

Inspector General, DoD, Report No. D-2001-059, "Armed Services Blood Program Readiness," February 23, 2001

Navy

Naval Inspector General Report, "Investigation of Blood Banking Procedures at National Naval Medical Center, Bethesda, Maryland, and the Navy Blood Program," October 8, 1998

Food and Drug Administration

FDA Report Number 1119523, "FDA Inspection Report of Defense Blood Standard System Project Office," September 13, 1999

Appendix B. Other Matters of Interest

Access to the JMAR Database. Access to the JMAR database is granted by the JMAR Project Manager or Deputy Project Manager based on a requestor's "need-to-know." However, we identified during our meeting with the JMAR Project Office that immediate access to JMAR was granted to any requestor with a ".mil" e-mail address and that need-to-know was applied only to other requestors. Further, the JMAR Project Office did not have a formal process to maintain its user list. A limited review of the JMAR user account database showed that several user accounts should have been deleted or changed. Two user accounts belonged to personnel who had retired from DoD and should no longer have had access to JMAR; three accounts belonged to personnel who had transferred and changed e-mail addresses but still had accounts under their old e-mail addresses; and one user had two accounts. There may be other personnel who should no longer have access to JMAR; however, we could only identify those Blood Program personnel with whom we were familiar.

Actions Taken by the JMAR Project Office. As a result of our meeting with the JMAR Project Office about our concerns, the JMAR Project Office took some corrective action. The JMAR Project Office developed a draft policy, "Joint Medical Asset Repository Standard Operating Procedures User Account Management," updated on June 21, 2001, that outlines the procedures for creating and managing user accounts. The policy includes the following requirements:

- All potential users must submit a need-to-know justification for access to JMAR to be reviewed by a JMAR Account Administrator.
- Users must review their account information every 90 days, to include an updated need-to-know justification.
- JMAR will periodically review account information to identify users whose account has not been used or updated, or whose password has not changed within a given period.

Controls Over the JMAR Database. We commend the JMAR Project Office for its prompt response to our concerns. However, additional controls by the JMAR Project Office would further improve the management of JMAR user accounts. Joint Publication 4-02, "Doctrine for Health Services Support in Joint Operations," April 26, 1995, states that although medical information in itself is not classified, medical information can become an operations security indicator in the context of a particular military operation. JMAR will be a very important database during a contingency, and access to JMAR should be strictly managed.

The JMAR Project Office should consider implementing controls to ensure that during wartime or contingency operations, further limitations are established to restrict JMAR access to only personnel with valid, military need-to-know.

Appendix C. Glossary

Armed Services Blood Program. The combined military blood programs of the ASBPO, the individual Military Departments, and the unified commands, in an integrated blood program support system for peacetime, contingency, and war.

Armed Services Blood Program Office. A tri-Service-staffed, joint field operating agency, with the Army as the DoD Executive Agent, responsible for coordination of the Armed Services Blood Program. Program office responsibilities include ensuring implementation of blood program policies, as established by the Assistant Secretary of Defense (Health Affairs), and standardization of policies, procedures, and equipment. The ASBPO is the overall DoD manager for blood products for the Chairman of the Joint Chiefs of Staff during military contingencies and, when directed by appropriate governmental authorities, for civilian relief efforts.

Armed Services Whole Blood Processing Laboratory. A tri-Service-staffed organization, with the Air Force as the DoD Executive Agent, responsible for the central receipt and confirmation of blood products from the continental United States blood banks. The organization is also responsible for the shipment of those products to designated unified commands' blood transshipment centers and transportable blood transshipment centers.

Automated Blood Product Labeling System. A microcomputer and thermal printer-based "print-on-demand" blood product labeling system. It is a commercial-off-the-shelf system, which produces bar-coded and eye-readable full-face blood product labels, donor identification set labels, and donor identification cards in FDA format.

Blood Donor Center. Military Department-staffed Blood Program Organization responsible for the collection and processing of blood products. The blood donor center may be collocated with a blood bank in a military treatment facility. In a unified command, a blood donor center may serve as a blood supply unit.

Blood Products. A generic name for blood and blood components, including red blood cells (liquid or frozen), plasma (liquid or frozen), and platelet concentrates.

Blood Product Depot. A Military Department-staffed organization responsible for the strategic storage of frozen blood products in a unified command.

Blood Program Activities. The Blood Program Offices and Organizations responsible for the successful collection, storage, and distribution of blood products.

Blood Program Offices. The offices responsible for managing the Blood Program: the ASBPO, the Service Blood Program Offices, and the unified command Joint Blood Program Offices.

Blood Program Organizations. The Blood Program operational components, including the Armed Services Whole Blood Processing Laboratories, blood donor centers, blood product depots, blood supply units, and blood transshipment centers.

Blood Supply Unit. A Military Department-staffed unit responsible for the receipt and storage of blood products (liquid and frozen) from blood transshipment centers, transportable blood transshipment centers, or blood product depots. It is also responsible for issuing blood products to military treatment facilities in an assigned geographic area. A blood supply unit may be any type unit or facility designated by a Military Department.

Blood Transshipment Center. An Air Force-staffed unit responsible for receiving blood products from an Armed Services Whole Blood Processing Laboratory, a blood product depot, another blood transshipment center, or a transportable blood transshipment center; re-icing the blood products; storing the products; and issuing the products to blood supply units or military treatment facilities.

Class II Medical Device. The designation given by the FDA for medical devices whose safety and effectiveness requires both general and special controls. FDA considers "blood establishment software" as a medical device.

Clinical Information Technology Program Office. CITPO is the office within the Office of the Assistant Secretary of Defense (Health Affairs) that is responsible for the management of DBSS.

Composite Health Care System. The worldwide, automated medical information system supporting all military treatment facilities in providing comprehensive, high-quality health care to Uniformed Services personnel, retirees, and dependents. CHCS provides patient facility data management and communication capabilities, including patient administration, reporting, scheduling and coordination, laboratory orders, drug and laboratory test interaction, quality control, radiology orders and test results, and medication processing.

Cryovials. Small quantities of frozen blood that are maintained for each frozen red blood cell unit in storage so that additional infectious disease testing can be performed if required by the FDA.

Defense Blood Standard System Project Office. The office within the Office of the Assistant Secretary of Defense (Health Affairs) responsible for DBSS technical and functional management and deployment of DBSS.

Food and Drug Administration. The Government agency that establishes blood banking regulations and requirements for use by blood banks involved in interstate commerce and grants licenses to blood banks complying with those standards. The organization within the FDA that specifically handles blood banking regulations is the Division of Blood and Blood Products in the Center for Biologics Evaluation and Research. The Military Departments comply with those standards and each Military Department Surgeon General holds a license for its respective blood banks.

Joint Blood Program Office. The organization within the unified command surgeon's office responsible for the overall management of blood products in a command theater of operations.

Joint Medical Asset Repository. The DoD source for joint medical logistics information. It is a data repository designed to integrate information from various medical logistics systems throughout DoD into a centrally managed data warehouse that gives users the ability to see the location and status of medical supplies and equipment whether in storage, in transit, or in theater.

Service Blood Program Office. The organization within a Military Department responsible for the coordination and management of the Military Department's blood program.

System Administrator. The person(s) responsible for observing proper security policies and procedures that are critical to maintaining DBSS. At large facilities, those duties may be assigned to several individuals; at smaller facilities, the duties may be assigned to one individual. The system administrator responsibilities are split into the following four major categories.

- **DBSS In-House Application Administrator.** Responsible for managing user rights within the DBSS application.

- **DBSS In-House Server Administrator.** Responsible for maintaining the DBSS server and administering the database, performing the Microsoft Windows NT backup, and managing the Microsoft Windows NT event and audit logs.

- **DBSS Mobile System Administrator.** Responsible for managing the DBSS mobile server during mobile blood drives.

- **Microsoft Windows NT Domain System Administrator.** Responsible for maintaining the Microsoft Windows NT domain and has the authority to add users to the Microsoft Windows NT domain and global domain user groups.

Theater Defense Blood Standard System. A self-contained laptop platform for DBSS that provides all the functional capabilities of DBSS in a theater environment.

Tri-Service Medical System Support Center. A fee-for-service operation, located at Brooks Air Force Base, Texas, whose mission was to provide consulting, prototyping, integration, implementation, training, and sustainment of medical and non-medical information systems to enhance the global capability of DoD warfighters. With regard to DBSS, TMSSC initially handled user-identified problems (trouble tickets). Trouble tickets handled by TMSSC included problems with system configuration setup, minor software application problems, and errors that did not affect the operational or mission-essential functions of DBSS.

Trouble Ticket. A record of a problem identified to TMSSC by an end-user, including software application errors, hardware problems, database errors, and "table build" problems.

Appendix D. Original Functional Requirements

Based on our review of the requirement documents for DBSS, we identified five functions included in the initial system design for DBSS versions 1.00 or 2.00 that still had not been incorporated into DBSS by version 3.03 (the latest version released in September 2000).

Global Donor Deferral. A global donor deferral capability would allow DoD blood donor centers to determine whether potential blood donors had been permanently or temporarily deferred from donating blood at any DoD Blood Program Organization. DBSS will identify and flag deferred donors, but the capability is limited to each individual facility. That limitation is significant for DoD because the DoD population is transient and could donate or receive blood products at many different locations. The advantages to having a global donor deferral capability is that it could reduce the time necessary to identify deferred donors, reduce unnecessary infectious disease testing, and save time spent by technicians in collecting and processing blood products that may ultimately have to be destroyed. In addition, the capability could decrease the possibility of the release of an inappropriate blood product. A global donor deferral capability was identified as an initial requirement for inclusion in DBSS version 2.00 and the required completion date was September 1999 in the "Medical Readiness Strategic Plan 1998-2004" (the Strategic Plan), August 1998. The global donor deferral function has been funded for development in FY 2002 and FY 2003.

Global Lookback. A global lookback capability would allow the tracking of blood product disposition, blood donors, and blood recipients from a centralized location. The FDA requires a lookback capability to identify all donors and recipients of possibly infectious blood and any blood products that may have been donated by those individuals. It is performed for blood products that have tested positive for the human immunodeficiency virus, the hepatitis C virus, or the human T-lymphotrophic virus type-1. Currently, if a lookback must be performed, DBSS must be searched at every applicable facility to determine the source and recipients of the infectious blood products to ensure that the spread of the disease is contained and the recipients are treated. The advantages to having a global lookback capability are that it reduces the time necessary to search for blood products, donors, and recipients and could decrease the possibility of the release of an inappropriate blood product. A global lookback capability was identified as an initial requirement for inclusion in DBSS version 2.00 and the required completion date in the Strategic Plan was September 1999. The global lookback function has been funded for development in FY 2002 and FY 2003.

Interface With Laboratory Testing Equipment. The capability to record laboratory test results in DBSS through the use of an interface with the laboratory testing equipment would reduce the need for the manual entry of more than one million infectious disease test results annually. Some of the blood donor centers perform their own testing; however, most infectious disease testing is performed at centralized DoD or contractor testing sites that transmit

the test results back to the blood donor center by facsimile. DBSS requires the test results to be entered twice and if there are any discrepancies between the data entered they must be reconciled. An automated interface with the testing equipment, whether the testing is performed at the blood donor center or at another site, would reduce the possibility of manual entry errors and reduce the risk of releasing inappropriate blood products. In addition, since a blood product cannot be released until test results are entered, the interface could allow for faster release of blood products for transfusion or shipment. The laboratory testing interface was identified as an initial requirement for inclusion in DBSS version 1.00 and the required completion date in the Strategic Plan was March 1999. The function has been funded for development in FY 2002 and FY 2003.

Accurate, Timely, and Readily Available Reports. Accurate, timely, and readily available reports would reduce the need to manually create reports for internal and external uses. The 13 fixed facilities we contacted during this audit all reported problems with DBSS reports. Users stated that the DBSS reports did not provide sufficient information for inventory management or planning purposes. In addition, only 1 of 13 fixed facilities contacted had successfully generated an accurate feeder report for the DD Form 2555, "Blood Bank Operational Report," the quarterly report that contains all blood inventory and operations data for a Blood Program Organization. The Blood Bank Operational Report is the primary operational report for the Blood Program; the report data is consolidated by the Service Blood Program Offices and forwarded to the ASBPO. The ability for DBSS users and Blood Program management to obtain accurate and timely reports from DBSS would reduce the time necessary to compile report data and reduce possible reporting errors due to the manual recording of data or manual calculations. The need for accurate, timely, and readily available reports was identified as an initial requirement for inclusion in DBSS version 1.00 and, although past system updates contained changes to reports, the problems had not been completely resolved by version 3.03. Of the 729 outstanding system requests, 90 concern DBSS reporting. However, as of May 2001, there were no report-related system requests approved for development or funding. The DBSS Project Office plans instead to survey the user community for reports created at individual Blood Program Organizations that could have universal benefit to all users.

Cryovial Shipment and Storage Management. A cryovial shipment and storage management capability in DBSS would ensure that a cryovial can be easily identified and traced to its corresponding frozen red blood cell unit. Currently, cryovial inventories are maintained on various database programs, not DBSS, while frozen red blood cell inventories are maintained on DBSS. The cryovial inventory reports and DBSS frozen red blood cell inventory reports do not contain identical data, which makes it difficult to reconcile the two reports. A reconciliation of the reports is necessary to update the cryovial inventory when frozen red blood cell units are destroyed, used for training purposes, or shipped to another location. A cryovial shipment and storage management function in DBSS would ensure that the data reported for a frozen red blood cell unit and its cryovial are identical and would expedite the process of identifying cryovials for testing or for destruction. Cryovial shipment and storage management was identified as an initial requirement for inclusion in

DBSS version 1.00 and, in November 1994, subsequent to the deployment of DBSS version 1.00, a system request was submitted for the function. As of June 2001, the system request had been approved, but was assigned a low priority.

Appendix E. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense (Comptroller)
  Deputy Chief Financial Officer
  Deputy Comptroller (Program/Budget)
Assistant Secretary of Defense (Health Affairs)
  Director, TRICARE Management Activity
  Director, Armed Services Blood Program Office

Department of the Army

Assistant Secretary of the Army (Financial Management and Comptroller)
Surgeon General, Department of the Army
Auditor General, Department of the Army

Department of the Navy

Assistant Secretary of the Navy (Financial Management and Comptroller)
Assistant Secretary of the Navy (Manpower and Reserve Affairs)
Naval Inspector General
Surgeon General, Department of the Navy
Auditor General, Department of the Navy

Department of the Air Force

Assistant Secretary of the Air Force (Financial Management and Comptroller)
Surgeon General, Department of the Air Force
Auditor General, Department of the Air Force

Non-Defense Federal Organizations

Office of Management and Budget
General Accounting Office

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services
House Committee on Government Reform
House Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform

Assistant Secretary of Defense (Health Affairs) Comments

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 25 2001

Shelton R. Young
Director, Readiness and Logistic Support Directorate
Inspector General
Department of Defense

Dear Mr. Young:

This is the Department of Defense (DoD) response to the Department of Defense Inspector General draft of the proposed Audit Report, "Armed Services Blood Program, Defense Blood Standard System" dated June 29, 2001 (Project No. D2000LF-0028.001).

DoD acknowledges receipt of the Inspector General's proposed audit report and generally concurs with the overall report, findings and recommendations. DoD agrees that there should be individual and coordinated blood program efforts to ensure that management and administration of the Defense Blood Standard System (DBSS) is adequate to ensure quality blood products during times of peace and conflict.

The Armed Services Blood Program Office, Military Department Blood Program Offices and the DBSS Project Office will continue to assess long-term strategies in concert with implementation of identified near- and mid-term solutions.

Specific DoD responses to the Inspector General's proposed draft audit report and its recommendations are attached. Please feel free to direct any questions to my project officer on this matter, Lieutenant Colonel Marie-Jocelyne Charles at (703) 681-8789.

Sincerely,

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

Enclosure:
As stated

IG Draft Audit Report – Dated 29 June 2001
(D2000LF-0028.001)

Inspector General (IG) Draft Audit Report
"Armed Services Blood Program Defense Blood Standard System"

Department of Defense Comments to the Recommendations

RECOMMENDATION A.1: We recommend that the Director, Armed Services Blood Program Office, in coordination with the Service Blood Program Offices and the Defense Blood Standard System Project Office, establish a plan for ensuring the original key functional requirements that were identified by system users as critical are incorporated into the Defense Blood Standard System.

DoD RESPONSE: Concur. We are ready to support the Director of the Armed Services Blood Program Office as appropriate.

RECOMMENDATION A.2.a: We recommend that the Defense Blood Standard System Project Office:

a) Establish management controls to ensure:

(1) System requests are processed completely and timely, and that all required data, validations, and approvals are entered into the tracking system.

(2) A review of trouble ticket submissions is complete, as required, to determine compliance with trouble ticket performance standards by both current and future contractors.

(3) Trend analyses are completed on trouble ticket reports to identify opportunities for system improvements.

DoD RESPONSE: Concur. Standard operating procedures (SOP) have been developed to address system requests, complaint handling, trouble tickets, and trend analyses. Quarterly Tier 1 performance reviews are currently being conducted. Quality audit protocols include checks to ensure that all required data is entered into the tracking system. Coordination and validation are in progress and expected to be finalized by 1st quarter, FY 02.

RECOMMENDATION A.2.b: Establish procedures to ensure that spare or replacement Defense Blood Standard System mobile servers and workstations are available when users experience hardware problems.

DoD RESPONSE: Non-concur. Procedures have been developed to resolve issues affecting medical devices such as mobile servers and workstations. A root cause analysis of the mobile system tickets currently is being performed to determine the best solution to address this issue. Coordination of a proposed solution is to be completed by 1st quarter FY 02.

RECOMMENDATION A.2.c: Establish a method to inform users and system administrators about the trouble ticket process including, at a minimum, an explanation of priority assignments, trouble ticket processing time standards, and trouble ticket tracking procedures.

DoD RESPONSE: Concur. A DBSS Technical Bulletin procedure has been established to inform users and system administrators of global issues. Coordination and validation are expected to be completed by 1st quarter FY 02. Technical Bulletins have been sent to the users describing trouble ticket prioritization, processing time standards and tracking procedures. The DBSS Technical Bulletins are also available on the DBSS web page.

RECOMMENDATION A.2.d: Provide updated computer-based training with each major software release that reflects current functionality.

DoD RESPONSE : Concur. Computer-based training will be provided with each major release. Our next major release is scheduled to be deployed in the 4th quarter FY 02.

RECOMMENDATION A.4: We recommend that the Joint Medical Asset Repository and Defense Blood Standard System Project Offices modify their systems, as necessary, to ensure in-transit inventory is not counted twice.

DoD RESPONSE : Concur. Appropriate action has been initiated to ensure in-transit inventory is not counted twice in JMAR. The corrective changes in DBSS will be in the release scheduled for 2nd quarter FY 03.

RECOMMENDATION B.3: We recommend that the Service Blood Program Offices, the Armed Services Blood Program Office, and the DBSS Project Office Jointly develop and implement a plan to correct the software deficiencies identified with the interface between the Composite Health Care System and the DBSS and establish a time frame for the Military Departments to implement at military treatment facilities.

DoD RESPONSE : Concur. These organizations are planning actions in concert with this recommendation.

Armed Services Blood Program Office Comments

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

REPLY TO
ATTENTION OF

MCIR

05 SEP 2001

John P. McLaurin III
DASA(MPP), OASA(M&RA)

MEMORANDUM THRU ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS)

FOR DOD INSPECTOR GENERAL, ATTN: DIRECTOR, LOGISTICS SUPPORT DIRECTORATE, 400 ARMY NAVY DRIVE, ARLINGTON, VA 22202

SUBJECT: Reply to Draft Audit Report on the Armed Services Blood Program Defense Blood Standard System (Project D2000LF-0028.001)

1. We appreciate the opportunity to comment on your report. Our comments are enclosed.

2. Our point of contact is COL G. Michael Fitzpatrick, Director, Armed Services Blood Program, DSN 761-8024 or commercial (703) 681-8024 or Mr. deWayne Beers, Internal Review and Audit Compliance Office, DSN 471-8148 or commercial (210) 221-8148.

FOR THE SURGEON GENERAL:

Encl

PATRICK D. SCULLEY
Major General
Deputy Surgeon General

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ARMED SERVICES BLOOD PROGRAM
DRAFT OF A PROPOSED DOD IG AUDIT REPORT

Armed Services Blood Program
Defense Blood Standard System (DBSS)
Project No. D2000LF-0028.001 dtd 29 June 2001

A: FINDING: IMPLEMENTATION OF THE DEFENSE BLOOD STANDARD SYSTEM

AUDIT RECOMMENDATION A.1. We recommend that the Director, Armed Services Blood Program Office, in coordination with the Service Blood Program Offices and the DBSS Project Office, establish a plan for ensuring the original key functional requirements that were identified by system users as critical are incorporated into the Defense Blood Standard System.

> **ASBP RESPONSE: Concur. The ASBPO will coordinate with the Services to validate original functional requirements previously identified by system users. If valid, they will be prioritized for incorporation into DBSS.**

AUDIT RECOMMENDATION: A.2. We recommend that the DBSS Project Office:

> a) Establish management controls to ensure: (1) System requests are processed completely and timely, and that all required data, validations, and approvals are entered into the tracking system. (2) A review of trouble ticket performance standards by both current and future contractors. (3) Trend analyses are completed on trouble ticket reports to identify opportunities for system improvements.
>
> b) Establish procedures to ensure that spare or replacement DBSS mobile servers and workstations are available when users experience hardware problems.
>
> c) Establish a method to inform users and system administrators about the trouble ticket process, including, at a minimum, an explanation of priority assignments, trouble ticket processing time standards, and trouble ticket tracking procedures.
>
> d) Provide updated computer-based training with each major software release that reflects current functionality.
>
> **ASBP RESPONSE: Concur. The DBSS Project Office is the lead on this issue.**

AUDIT RECOMMENDATION: A.3. We recommend that the Surgeons General of the Military Departments: a.) Establish annual competency assessment requirements for system administrators. b.) Develop a tri-Service systems administrator training program.

> **ASBP RESPONSE: Concur. The Services will work with the ASBPO to establish a standardized competency assessment tool for system administrators. Estimated time frame for completion is 31 October 2001. The Navy and Army currently have a DBSS systems administrator training program in place at Ft Sam Houston, Texas. The Air Force has been invited to send personnel to these courses for training on a**

Final Report Reference

space available basis. **The Army and Navy have not solicited the Air Force for additional funding for this training opportunity.**

AUDIT RECOMMENDATION: A.4. We recommend that the Joint Medical Asset Repository and DBSS Project Office modify their systems, as necessary, to ensure in-transit inventory is not counted twice.

ASBP RESPONSE: Concur. The DBSS Project Office has the lead on this issue.

B: FINDING: DEPLOYMENT/USE OF THE DEFENSE BLOOD STANDARD SYSTEM

AUDIT RECOMMENDATION: B.1. We recommend that the Service Blood Program Offices, in coordination with the Armed Services Blood Program Office and the DBSS Project Office:

a) Establish policy requiring a deployment execution plan for all future Defense Blood Standard System upgrades that includes implementation time frames.

b) Establish procedures to ensure all Blood Program Organizations that either maintain blood product inventory or perform transfusions have a capability to report blood product information and inventories to the Defense Blood Standard System or Theater Defense Blood Standard System.

Deleted

c) Establish procedures to ensure all Blood Program Organizations that receive TDBSS laptops are provided with adequate guidance regarding the use and implementation.

ASBP RESPONSE: Concur. It should be noted that the delays in TMIP deployment of TDBSS created the need to establish TDBSS as an interim, stopgap measure to provide year 2000 compliant systems in the field until TMIP is deployed. Furthermore, a number of technical and software problems and difficulties with the validation of the TDBSS hardware using DBSS software have delayed fielding of TDBSS. The Services have performed heroic efforts to put an interim bridge to TDBSS out in the field when the responsibility for the final product is TMIP's. The Services should be applauded for their best effort to get TDBSS out in the field. The Services will work with the ASBPO to establish execution plans and time frames for implementation of subsequent versions of DBSS and to establish guidance regarding the use and implementation of TDBSS laptops.

AUDIT RECOMMENDATION: B.2. We recommend that the Service Blood Program Offices establish a time frame for their Blood Program Organizations to implement the latest version of the Defense Blood Standard System.

ASBP RESPONSE: Concur.

AUDIT RECOMMENDATION: B.3. We recommend that the Service Blood Program Offices, the Armed Services Blood Program Office, and the DBSS Project Office Jointly:

a.) Develop and implement a plan to correct the software deficiencies identified with the interface between the Composite Health Care System and the DBSS and establish a time frame for the Military Departments to implement at military treatment facilities.

b.) Develop and implement a plan to correct the hardware and software deficiencies identified with the Theater Defense Blood Standard System, or find another means to meet the needs of the unified commands for a blood management capability.

> **ASBP RESPONSE: Concur. The Services and the DBSS Project Office will work with the ASBPO to evaluate the deficiencies identified with the CHCS interface, obtain concurrence on patient safety related issues, determine priority for correcting deficiencies, and establish a time frame for implementation of the interface at Service facilities.**

AUDIT RECOMMENDATION: B.4. We recommend that the Military Department Surgeons General, in coordination with the Armed Services Blood Program Office, update Army Technical Manual 8-227-11/NAVMED P-5123/Air Force Instruction 44-118, "Operational Procedures for the Armed Services Blood Program Elements," and Army Manual 8-227-12/NAVMED P-6530/Air Force Handbook 44-152, "Joint Blood Program Handbook," to require the use of the Defense Blood Standard System or the Theater Defense Blood Standard System at all Blood Program Organizations.

> **ASBP RESPONSE: Concur. The ASBPO will coordinate with the Services to update the reference documents.**

Department of the Army Comments

DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000

REPLY TO ATTENTION OF

MCHO-CL-R

24 August 2001

MEMORANDUM FOR Department of Defense, ATTN: Office of the Inspector General, 400 Army Navy Drive, Arlington, VA 22202

SUBJECT: Audit Report on the Armed Services Blood Program Defense Blood Standard System (DBSS) Project Number D2000LF-0028.001

1. The U.S. Army Blood Program Office (BPO) provides the following responses to the Draft of the Proposed DoD Inspector General Audit Report on the DBSS:

a. Finding: Implementation of the DBSS.

(1) **AUDIT RECOMMENDATION A.1.**: We recommend that the Director, Armed Services Blood Program Office in coordination with the Service Blood Program Offices and the DBSS Project Office, establish a plan for ensuring the original key functional requirements that were +identified by system users as critical are incorporated into the Defense Blood Standard System.

- **ARMY BPO RESPONSE**: Concur with this recommendation. The Army BPO will work with the ASBPO and the other Services Blood Program Offices to validate original functional requirements previously identified by system users. If valid, they will be prioritized for incorporation into DBSS.

(2) **AUDIT RECOMMENDATION A.2.**: We recommend that the DBSS Project Office: (a.) Establish management controls to ensure: 1.) System requests are processed completely and timely, and that all required data, validations, and approvals are entered into the tracking system; 2.) A review of trouble ticket performance standards by both current and future contractors; and 3.) Trend analyses are completed on trouble ticket reports to identify opportunities for system improvements.

(b.) Establish procedures to ensure that spare or replacement DBSS mobile servers and workstations are available when users experience hardware problems.

(c.) Establish a method to inform users and system administrators about the trouble ticket process, including, at a minimum, an explanation of priority assignments, trouble ticket processing time standards, and trouble ticket tracking procedures.

(d.) Provide updated computer-based training with each major software release that reflects current functionality.

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- **ARMY BPO RESPONSE**: Concur with all recommendations.

(3) **AUDIT RECOMMENDATION A.3.**: We recommend that the Surgeons General of the Military Departments:

(a.) Establish annual competency assessment requirements for system administrators.

(b.) Develop a tri-Service systems administrator-training program.

- **ARMY BPO RESPONSE**: Concur with these findings. The Army BPO will work with the ASBPO and the other Service Blood Program Offices to develop a standardized competency assessment tool for DBSS System Administrators. Estimated time frame for completion is 31 October 2001. The Army BPO established a DBSS Systems Administrator/Users Course at the Army Medical Department Center and School (AMEDDC&S) at Fort Sam Houston, Texas for Army laboratory and information management office personnel with deployment of the Windows 3.0 version of DBSS. The AMEDDC&S is currently training on DBSS version 3.02/3.03. The Navy offers essentially the same DBSS System Administrator/User Course for Navy personnel at the AMEDDC&S. The Air Force has been invited to send personnel to these courses for training on a space available basis. The Army and Navy have not solicited the Air Force for additional funding for this training opportunity.

(4) **AUDIT RECOMMENDATION A.4.**: We recommend that the Joint Medical Asset Repository and DBSS Project Office modify their systems, as necessary, to ensure in-transit inventory is not counted twice.

- **ARMY BPO RESPONSE**: Concur with this recommendation.

b. Deployment/Use of the DBSS.

(1) **AUDIT RECOMMENDATION B.1.**: We recommend that the Service Blood Program Offices, in coordination with the Armed Services Blood Program Office and the DBSS Project Office:

(a.) Establish policy requiring a deployment execution plan for all future Defense Blood Standard System upgrades that includes implementation time frames.

Final Report Reference

MCHO-CL-R
SUBJECT: Audit report on the Armed Services Blood Program Office (ASBPO) Defense Blood Standard System (DBSS) Project Number D2000LF-0028.001

(b.) Establish procedures to ensure all Blood Program Organizations that either maintain blood product inventory or perform transfusions have a capability to report blood product information and inventories to the Defense Blood Standard System or Theater Defense Blood Standard System.

Deleted

(c.) Establish procedures to ensure all Blood Program Organizations that receive TDBSS laptops are provided with adequate guidance regarding the use and implementation.

- **ARMY BPO RESPONSE**: Concur with these recommendations. The Army BPO will work with the ASBPO and the other Service Blood Program Offices to establish execution plans and time frames for implementation of subsequent versions of DBSS and to establish guidance regarding the use and implementation of Theater DBSS (TDBSS) laptops. However, it should be pointed out that delays in deploying TDBSS can be directly attributed to the failure of the Theater Medical Information Program (TMIP) to meet its timeline, creating the need to establish TDBSS as an interim, stopgap measure to provide year 2000 compliant systems in the field until TMIP is deployed. Furthermore, a number of technical and software problems and difficulties with the validation of the TDBSS hardware using DBSS software have delayed fielding of TDBSS to Army sites. On 9 March 2001, the DBSS Project Office and the DBSS software developer, Electronic Data Systems (EDS), performed a Hazard Analysis on an Army TDBSS laptop computer to identify the configuration differences between the Army TDBSS wartime system and the DBSS peacetime system and to document the impact of these differences. Eleven hazards were identified following the hazard analysis and a mitigation plan was devised to identify actions that need to be accomplished to resolve the identified hazards. Following the Hazard Analysis, EDS also recommended a full regression test be performed to determine if the configuration of the Army TDBSS laptops adversely affect the DBSS application or the intended use of the system. Although the three items that failed following regression analysis have been resolved, none of the eleven hazards identified have been addressed, due primarily to issues with funding to contract EDS to resolve the hazards and development of the Statement of Work for EDS to perform the work. EDS recently developed a White Paper that will be used to create a Statement of Work. Following receipt of the White Paper from EDS, the Army BPO has recently agreed to provide the funds that the White Paper determined are necessary for EDS to resolve the eleven hazards identified during Hazard Analysis. Upon receipt of funds, EDS estimates that resolution of all hazards may take up to six weeks. When these hazards have been resolved, the Army BPO will pre-position the TDBSS laptops at the AMEDDC&S where the prospective recipient's of the TDBSS laptops will receive DBSS System Administrator/User training on their TDBSS laptop computer.

3

(2) **AUDIT RECOMMENDATION B.2.**: We recommend that the Service Blood Program Offices establish a time frame for their Blood Program Organizations to implement the latest version of the Defense Blood Standard System.

- **ARMY BPO RESPONSE**: Concur with this recommendation. Following the release of DBSS version 3.02/3.03, standardized Standard Operating Procedures (SOPs) for their use were under development and pending release from the ASBPO. Due to concerns regarding regulatory compliance, the Army BPO decided not to direct implementation of DBSS version 3.02/3.03 until after the standardized SOPs were completed and validations were completed on these SOPs. Additionally, deployment of DBSS version 3.02/3.03 was delayed pending resolution of a test case issue involving JMAR. Although DBSS version 3.02/3.03 SOPs for Transfusion Services was released in February 2001, DBSS SOPs for Blood Donor Centers were not released until May 2001. The Army BPO subsequently issued a directive to Army sites on 15 May 2001 to load, validate, and implement DBSS version 3.02/3.03 not later than 1 August 2001. Due to technical and hardware problems, full implementation at all Army sites has been extended to 1 October 2001. As of 20 August 2001, approximately 28 Army sites have either validated or are in the process of validating DBSS version 3.02/3.03.

(3) **AUDIT RECOMMENDATION B3.**: We recommend that the Service Blood Program Offices, the Armed Services Blood Program Office, and the DBSS Project Office Jointly:

(a.) Develop and implement a plan to correct the software deficiencies identified with the interface between the Composite Health Care System and the DBSS and establish a time frame for the Military Departments to implement at military treatment facilities.

(b.) Develop and implement a plan to correct the hardware and software deficiencies identified with the Theater Defense Blood Standard System, or find another means to meet the needs of the unified commands for a blood management capability.

- **ARMY BPO RESPONSE**: Concur with these recommendations. The Army BPO will work with the ASBPO, the other Service Blood Program Offices, and the DBSS Project Office to evaluate the deficiencies identified with the CHCS interface, obtain concurrence on patient safety related issues, determine priority for correcting deficiencies, and establish a time frame for implementation of the interface at Service facilities.

MCHO-CL-R
SUBJECT: Audit report on the Armed Services Blood Program Office (ASBPO) Defense Blood Standard System (DBSS) Project Number D2000LF-0028.001

(4) **AUDIT RECOMMENDATION B.4.**: We recommend that the Military Department Surgeons General, in coordination with the Armed Services Blood Program Office, update Army Technical Manual 8-227-11/NAVMED P-5123/Air Force Instruction 44-118, "Operational Procedures for the Armed Services Blood Program Elements," and Army Manual 8-227-12/NAVMED P-6530/Air Force Handbook 44-152, "Joint Blood Program Handbook," to require the use of the Defense Blood Standard System or the Theater Defense Blood Standard System at all Blood Program Organizations.

- **ARMY BPO RESPONSE**: Concur with this recommendation. The Army BPO will coordinate with the ASBPO and the other Service Blood Program Offices to update the reference documents.

2. Our point of contact is LTC Gary C. Norris, Director, Army Blood Program, Office of the Assistant Chief of Staff for Health Policy and Services, Headquarters, U.S. Army Medical Command, DSN 761-0360 or Commercial (703) 681-0360.

FOR THE COMMANDER:

ELDER GRANGER
COL, MC
Assistant Chief of Staff for
Health Policy and Services

5

Department of the Navy Comments

DEPARTMENT OF THE NAVY
OFFICE OF THE ASSISTANT SECRETARY
(MANPOWER AND RESERVE AFFAIRS)
1000 NAVY PENTAGON
WASHINGTON, D.C. 20350-1000

AUG 28 2001

MEMORANDUM FOR THE DEPARTMENT OF DEFENSE INSPECTOR GENERAL

SUBJECT: Armed Services Blood Program Defense Blood Standard System (DBSS) - ACTION MEMORANDUM

Thank you for the opportunity to review your findings and recommendations concerning the subject report in Attachment 1. As requested, additional comments are provided in Attachment 2 for your review and consideration.

My point of contact is Commander Terry Moulton,MSC, USN who can be reached at (703) 693-0238.

Thomas V. Colella

Thomas V. Colella
Principal Deputy
Assistant Secretary of the Navy
(Manpower and Reserve Affairs)

Attachments:
1. DoDIG Draft Report: Armed Services Blood Program
2. Department of the Navy comments

DEPARTMENT OF THE NAVY COMMENTS

Armed Services Blood Program
Defense Blood Standard System (DBSS)
Project No. D2000LF-0028.001 of 29 June 2001

A: FINDING: IMPLEMENTATION OF THE DEFENSE BLOOD STANDARD SYSTEM

AUDIT RECOMMENDATION A.1. We recommend the Director, Armed Services Blood Program Office, in coordination with the Service Blood Program Offices and the DBSS Project Office, establish a plan for ensuring the original key functional requirements that were identified by system users as critical are incorporated into the Defense Blood Standard System.

NAVY RESPONSE: Concur. The ASBPO has been assigned as the lead on the issue. The Navy will work with the ASBPO and the other Services to validate original functional requirements previously identified by system users. If valid, they will be prioritized for incorporation.

AUDIT RECOMMENDATION: A.2. We recommend the DBSS Project Office:

a.) Establish management controls to ensure: (1) System requests are processed completely and timely, and all required data, validations, and approvals are entered into the tracking system. (2) A review of trouble ticket performance standards by both current and future contractors. (3) Trend analyses are completed on trouble ticket reports to identify opportunities for system improvements.

b.) Establish procedures to ensure spare or replacement DBSS mobile servers and workstations are available when users experience hardware problems.

c.) Establish a method to inform users and system administrators about the trouble ticket process, including, at a minimum, an explanation of priority assignments, trouble ticket processing time standards, and trouble ticket tracking procedures.

d.) Provide updated computer-based training with each major software release that reflects current functionality.

Final Report Reference

NAVY RESPONSE: Concur. The DBSS Project Office is lead on this issue.

AUDIT RECOMMENDATION: A.3. We recommend the Surgeons General of the Military Departments: a.) Establish annual competency assessment requirements for system administrators. b.) Develop a tri-service systems administrator training program.

NAVY RESPONSE: Concur. The Navy will work with the ASBPO and the other Services to establish a standardized competency assessment tool for system administrators. Estimated time frame for completion is 31 October 2001. The Navy and Army currently have a DBSS systems administrator training program in place at Ft Sam Houston, Texas. The Air Force has been invited to send personnel to these courses for training on a space available basis. The Army and Navy have not solicited the Air Force for additional funding for this training opportunity.

AUDIT RECOMMENDATION: A.4. We recommend the Joint Medical Asset Repository and DBSS Project Office modify their systems, as necessary, to ensure in-transit inventory is not counted twice.

NAVY RESPONSE: Concur. The DBSS Project Office has lead on this issue.

B: FINDING: DEPLOYMENT/USE OF THE DEFENSE BLOOD STANDARD SYSTEM

AUDIT RECOMMENDATION: B.1. We recommend that the Service Blood Program Offices, in coordination with the Armed Services Blood Program Office and the DBSS Project Office:

a.) Establish policy requiring a deployment execution plan for all future Defense Blood Standard System upgrades that includes implementation timeframes.

b.) Establish procedures to ensure all blood program organizations that either maintain blood product inventory or perform transfusions have a capability to report blood product information and inventories to the Defense Blood Standard System or Theater Defense Blood Standard System.

c.) Establish procedures to ensure all blood program organizations that receive TDBSS laptops are provided with adequate guidance regarding the use and implementation.

Deleted

2

NAVY RESPONSE: Concur. The Navy will work with the ASBPO and the other Services to establish execution plans and timeframes for implementation of subsequent versions of DBSS and to establish guidance regarding the use and implementation of TDBSS laptops. The Naval Medical Information Management Center plans to deploy TDBSS to Navy casualty receiving and treatment ships and fleet hospitals as part of the Theater Medical Information Program (TMIP) package when it is deployed to these platforms, not as a current stand alone laptop system that is currently used for the TDBSS platform. This will ensure standardized hardware and software platforms and standardized requirements for training and system administration. This will also ensure approval and support by the Navy line community. If TDBSS capabilities are required at fleet hospitals in a contingency prior to TMIP implementation, the Navy will purchase additional TDBSS laptop units and have them configured and shipped as needed. However, unless TMIP is deployed, the use of DBSS will not be required at the Level II echelons of care, even though they store and transfuse blood products because its use is not practical at that level of care.

AUDIT RECOMMENDATION: B.2. We recommend the Service Blood Program Offices establish a timeframe for their Blood Program Organizations to implement the latest version of the Defense Blood Standard System.

NAVY RESPONSE: Concur. In November 2000, Navy facilities were originally directed to implement v3.03 by 31 March 2001. The Navy Blood Program is tracking the validation status and implementation of the Navy sites and is monitoring their progress. As of 30 July 2001, more than 50% of the Navy fixed facilities have completed validation of 3.03. However, technical and hardware problems have prevented full implementation to date by all sites. The Navy Blood Program has established 1 October 2001 as a revised implementation date for its facilities.

AUDIT RECOMMENDATION: B.3. We recommend the Service Blood Program Offices, the Armed Services Blood Program Office, and the DBSS Project Office jointly:

a.) Develop and implement a plan to correct the software deficiencies identified with the interface between the Composite Health Care System and the DBSS and establish a timeframe for

the military departments to implement at military treatment facilities.

b.) Develop and implement a plan to correct the hardware and software deficiencies identified with the Theater Defense Blood Standard System, or find another means to meet the needs of the unified commands for a blood management capability.

NAVY RESPONSE: Concur. The Navy will work with the ASBPO, the other Services, and the DBSS Project Office to evaluate the deficiencies identified with the CHCS interface, obtain concurrence on patient safety related issues, determine priority for correcting deficiencies, and establish a timeframe for implementation of the interface at Service facilities.

AUDIT RECOMMENDATION: B.4. We recommend the military department Surgeons General, in coordination with the Armed Services Blood Program Office, update Army Technical Manual 8-227-11/NAVMED P-5123/Air Force Instruction 44-118, "Operational Procedures for the Armed Services Blood Program Elements," and Army Manual 8-227-12/NAVMED P-6530/Air Force Handbook 44-152, "Joint Blood Program Handbook," to require the use of the Defense Blood Standard System or the Theater Defense Blood Standard System at all Blood Program Organizations.

NAVY RESPONSE: Concur. The ASBPO has been assigned as the lead on this issue. Navy will coordinate with the ASBPO and the other Services to update the reference documents.

Department of the Air Force Comments

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON, DC

AUG 27 2001

MEMORANDUM FOR ASSISTANT INSPECTOR GENERAL FOR AUDITING
OFFICE OF THE INSPECTOR GENERAL
DEPARTMENT OF DEFENSE

FROM: HQ USAF/SG
110 Luke Avenue, Room 400
Bolling AFB DC 20332-7050

SUBJECT: Audit Report on Armed Services Blood Program Defense Blood Standard System (DBSS) (Project No D2000LF-0028.001)

This is in reply to your memorandum requesting the Assistant Secretary of the Air Force (Financial Management and Comptroller) provide Air Force comments on the subject report.

We **do not concur,** with the findings of this draft report as it is currently written. We are withholding our concurrence until the final report has incorporated the comments below.

USAF-1. Major. Page i, para 5, lines 3-6. **Change to read:** "As a result, use of DBSS could adversely affect asset accountability, increase the workload at blood program organizations, and, when used with JMAR, increase the risk of blood inventory errors~~, and could possibly result in the inappropriate release of blood products~~ (finding A)." **RATIONALE:** This statement as written, in the Executive Summary, is misleading, inaccurate and contradicts findings in this report. The findings of the report do not support the assumption that use of DBSS could possibly result in the inappropriate release of blood products. On page 16, para 4, lines 13-15 this report acknowledges that local controls are in place to prevent input errors and to prevent the inappropriate release of blood products. Use of DBSS has reduced errors in inappropriate release of blood products as documented through measured reduction in FDA reportable errors. The findings of increased risk of blood inventory errors relate to use of JMAR for total asset visibility. When only DBSS is used, local inventory is not counted twice. Therefore, this report must be clear that it is the JMAR blood inventory data that is at risk of being in error, not the DBSS blood inventory data.

USAF-2. Major. Page ii, para 2, lines 11-21. **Change to read:** "We recommend that the Surgeons General ~~establish an annual competency assessment program for system administrators and~~ develop a ~~t~~Tri-Service administrator training program. In addition, we recommend that the Service Blood Program Offices establish a policy requiring deployment plans for future DBSS upgrades ~~and have a DBSS reporting capability at all facilities that maintain or transfuse blood products~~. Additionally, we recommend that the Service Blood Program Offices establish time frames for implementing the latest DBSS software and update the

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blood program policies to include the requirement to use DBSS at all blood program organizations that have DBSS. We also recommend that the blood program offices jointly develop and implement plans to correct the problems with the Composite Health Care System interface and the Theater DBSS implementation." **RATIONALE:** Annual competency assessment for system administrators is already included in the Computer Based Training module. This competency assessment was developed for all DBSS facilities, regardless of size or functions. Therefore, individual facilities may need to tailor it to better suit their individual requirements. The statement as it reads indicates that no competency assessment tools were provided for system administrators. We do not concur that DBSS reporting capability is necessary at all facilities that maintain or transfuse blood products. Many of these facilities are remotely located and maintain small quantities of blood products for emergencies where blood may not arrive in the time needed. The inventory maintained by these facilities would not be available for distribution to other facilities. With the small quantity these facilities maintain, and the infrequency that blood is transfused at these facilities, there is no benefit to the added cost and workload needed to maintain DBSS at these facilities.

USAF-3. Major. Page 5, para 1, lines 8-13. **Change to read:** "Further, the DBSS Project Office did not provide complete or up-to-date user training~~, and the Service Blood Program Offices did not establish required competency assessments for key functional personnel~~. As a result, use of DBSS could adversely affect asset accountability, increase the workload at blood program organizations, and when used with JMAR, increase the risk of blood inventory errors.~~, and could possibly result in the inappropriate release of blood products.~~" **RATIONALE:** Competency assessment was provided for the DBSS Functional System Administrator as a component of the Computer Based Training program. See rationale for USAF-1 and USAF-2.

USAF-4. Major. Page 10, para 3, lines 3-5. **Change to read:** "~~There were no representatives from TDBSS facilities included in the functional review process to ensure that readiness requirements were considered.~~" **RATIONALE:** The Air Force representative to the User Focus Group had been assigned to a readiness that would use TDBSS. Although not currently assigned to a TDBSS facility, her experience and knowledge are well suited to representing both fixed and deployable units. Additionally, the Air Force Blood Program Officer represents the Directorate of Medical Readiness and is a voting member of the User Review Board.

USAF-5. Major. Page 15, para 3, lines 1-4. **Change to read:** "~~The Service Blood Program Offices did not establish standardized competency assessments for system administrators, as required by the FDA, and did not train them to meet those standards.~~" **RATIONALE:** Competency assessment was provided for the DBSS Functional System Administrator as a component of the Computer Based Training (CBT) program. See rationale for USAF-1 and USAF-2. Furthermore, the Army and the Navy established system administrator courses to enhance the training provided by the CBT. Both Services have opened their training classes to the Air Force and several Air Force members have attended.

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USAF-6. Major. Page 18, Table 2. **Change to read:** As of March 21, 2001, there were 3 Air Force sites on Version 3.01 and 18 on Version 3.03. **RATIONALE:** These are the correct

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numbers as of 21 March 2001. As of 1 August 2001, there are 20 Air Force sites on Version 3.03 and 1 on Version 3.01.

[1]Revised Page 22

USAF-7. Major. Page 19, para 2, line 5-6. **Change to read:** "... and ~~57~~ 93 percent of Air Force facilities had turned on the interface capability." **RATIONALE:** Not all the Air Force facilities with DBSS 3.03 could turn on the CHCS interface. The two Armed Services Whole Blood Processing Laboratories (ASWBPL) do not have CHCS. Also, three Air Force facilities share their CHCS server with another Service, and are unable to turn on the CHCS interface until the other Service is prepared to do so. Additionally, the DBSS project office instructed the AF facility in the National Capital Area not to turn on the CHCS interface until the consolidation of the National Capital Area CHCS database was completed. Therefore, of the 21 Air Force DBSS facilities, 15 have the capability of using the CHCS interface. Of those, 14 had turned it on (93 percent).

[2]Revised Page 22

USAF-8. Major. Page 19, para 3, line 7. **Change to read:** "... and ~~seven~~ twenty Air Force." **RATIONALE:** Currently there are twenty Air Force TDBSS laptops ready for use.

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USAF-9. Major. Page 20, para 3, line 1-2. **Change to read:** "Some of the ~~The~~ Blood Program Offices did not adequately oversee the implementation of DBSS." **RATIONALE:** As stated in the report "The Air Force Blood Program Office [AFBPO] was the most aggressive in requiring implementation of the version 3.03 upgrade by setting an implementation suspense date of December 15, 2000, for its fixed facilities." Although only 67 percent (14 of 21) sites met this deadline, the remaining sites had technical problems that the AFBPO was aware of and worked with the DBSS Project Office to ensure timely resolution. Currently, 20 sites are active with DBSS 3.03, the remaining site having severe technical problems.

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USAF-10. Major. Page 20, para 5, line 1-3. **Change to read:** "Some of the ~~The~~ Blood Program Offices did not adequately oversee the implementation of the CHCS interface in DBSS. They did not require their fixed facilities to use the DBSS interface." **RATIONALE:** The AFBPO did direct that the CHCS interface be turned on at numerous Air Force Blood Program monthly teleconferences. As interfaces were turned on, problems were identified, such as incomplete installation of previous versions, which had gone undetected. Resolution of these problems, in many instances, resolved other long-standing problems and improved the performance of DBSS. This was used by the AFBPO as further justification to turn on the CHCS. Today, 93 percent of the Air Force sites capable of turning on the interface have done so.

Deleted

USAF-11. Major. Page 22, para 2. **Change to read:** "Fourth, while the Air Force Blood Program Office provided ~~little~~ guidance regarding the use and implementation of TDBSS equipment,~~.~~ ~~As a result, as of March 2001, all~~ of the 25 laptops that had been deployed to the TDBSS facilities, ~~but~~ only ~~7~~ 20 were ready for use. One U.S. European Command organization contacted during the audit still had three of its four laptops packed in the original shipping boxes because personnel were unsure of what action to take." **RATIONALE:** Based upon the number of laptops currently ready for use, there is little justification for judging the adequacy of the guidance issued by the AFBPO. The numbers cited in this draft do not accurately reflect the correct TDBSS status. The U.S. European Command organization mentioned in the report is the last to activate their TDBSS units, and have 4 of the 5 that are yet to be activated. They are

[1]An Air Force update provided October 9, 2001, changed 93 percent to 63 percent, which is reflected in the report.

[2]An Air Force update provided September 18, 2001, changed 20 to 21, which is reflected in the report.

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currently in the process of training their personnel and activating their units in preparation for a Blood Transhipment Center exercise in response to the findings from the previous audit of the Blood Program. The remaining laptop, also in USEUCOM, will be activated during the annual training of the Transportable Blood Transhipment Center personnel that will be coming from CONUS in October 2001.

Comments regarding the recommendations and proposed plan of action are as follows:

USAF-12. Non-Concur. Page 17, Recommendation A.3.a. "We recommend that the Surgeons General of the Military Departments establish annual competency assessment requirements for system administrators." **RATIONALE:** Competency assessment tools are provided as part of the Computer Based Training System Administrator module. Additionally, annual competency of system administrators is already required. See USAF-2. Page 18

USAF-13. Non-Concur. Page 17, Recommendation A.3.b. "We recommend that the Surgeons General of the Military Departments develop a ~~t~~Tri-Service system administrator training program." **RATIONALE:** The Navy has contracted for a DBSS training program that is open to all Service. This is already in place and is a defacto Tri-Service training program. See USAF-3. Page 18

USAF-14. Concur. Page 23, Recommendation B.1.a. "We recommend that the Service Blood Program Offices, in coordination with the Armed Services Blood Program Office and the Defense Blood Standard System Project Office establish policy requiring a deployment execution plan for all future Defense Blood Standard System upgrades that includes implementation time frames." **Corrective Actions:** We will coordinate with the other blood program offices in establishing deployment execution plans to include implementation time frames for subsequent versions of DBSS. Page 27

USAF-15. Non-Concur. Page 23, Recommendation B.1.b. "We recommend that the Service Blood Program Offices, in coordination with the Armed Services Blood Program Office and the Defense Blood Standard System Project Office establish procedures to ensure all Blood Program Organizations that either maintain blood product inventory or perform transfusions have a capability to report blood product information and inventories to the Defense Blood Standard System or Theater Defense Blood Standard System." **RATIONALE:** There are many Air Force facilities that are remotely located and maintain small quantities of blood products for emergencies where blood may not arrive in the time needed. The inventory maintained by these facilities would not be available for distribution to other facilities. With the small quantity these facilities maintain and the infrequency that blood is transfused at these facilities, there is no benefit to the added cost and workload needed to maintain DBSS at these facilities. Page 27

USAF-16. Concur. Page 23, Recommendation B.1.c. "We recommend that the Service Blood Program Offices, in coordination with the Armed Services Blood Program Office and the Defense Blood Standard System Project Office establish procedures to ensure all Blood Program Organizations that receive TDBSS laptops are provided with adequate guidance regarding the use and implementation of the equipment." **Corrective Actions:** We will provide adequate guidance with all future deployments of TDBSS laptops. Deleted

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USAF-17. Concur. Page 23, Recommendation B.2. "We recommend that the Service Blood Program Offices establish a time frame for their Blood Program Organizations to implement the latest version of the Defense Blood Standard System." **Corrective Actions:** We will ensure that an implementation time frame is established with every version release.

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USAF-18. Concur. Page 23, Recommendations B.3.a., B.3.b., and B.4. **Corrective Actions:** We will coordinate with the other Service Blood Program Offices, the Armed Services Blood Program Office and the Defense Blood Standard System Project Office to develop corrective actions.

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JAMES G. ROUDEBUSH
Major General, USAF, MC, CFS
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