
Deployment and Readiness Systems Program Management Office

Post-Implementation Review Plan for Enterprise Blood Management System Increment 1, Blood Donor Management System



Prepared by:

Force Health Protection and Readiness

Support Milestone: Fielding Decision

Version 1.0

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DOCUMENT APPROVAL

Enterprise Blood Management System Increment 1
Post Implementation Review Plan
Version 1.0

Signature Page

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ENTERPRISE BLOOD MANAGEMENT SYSTEM INCREMENT 1, BLOOD DONOR MANAGEMENT SYSTEM POST IMPLEMENTATION REVIEW PLAN

1 INTRODUCTION

The Enterprise Blood Management System (EBMS) is an Acquisition Category III program consisting of two Increments: EBMS Increment 1, Blood Donor Management System (BDMS) and EBMS Increment 2, Blood Management Blood Bank Transfusion Service (BMBB/TS). The program management responsibility of EBMS falls under the Deployment and Readiness Systems (D&RS) Program Management Office (PMO) under the executive management of the Program Executive Officer (PEO)¹, Defense Health Clinical Systems (DHCS). The Defense Health Agency (DHA) Component Acquisition Executive (CAE) serves as the Milestone Decision Authority (MDA).

Both EBMS Increments are needed to replace the legacy Defense Blood Standard System (DBSS). EBMS Increment 1, BDMS will replace the donor portion of the Defense Blood Standard System (DBSS) by providing the ability to manage donor registration, donor deferral, blood products test results, inventory shipment, enterprise reporting, and donor application user accreditation/ training. The scope includes implementation within the Blood Donor Centers (BDCs) – Continental United States (CONUS) and Outside CONUS (OCONUS).

1.1 Purpose

The post implementation review (PIR) will report the degree to which doctrine, organization, training, materiel, leadership and education, personnel, facilities, and policy changes have achieved the established measures of effectiveness for the desired capability; evaluate systems to ensure positive return on investment and decide whether continuation, modification, or termination of the systems is necessary to meet mission requirements; and document lessons learned from the PIR.

The purpose of this PIR plan is to support the EBMS Increment 1, BDMS Fielding Decision in accordance with the Interim DoD Instruction 5000.02, Enclosure 11, and the Defense Acquisition Guidebook (DAG). This document will provide the necessary framework, but the actual evaluation is the responsibility of the designated functional sponsor. The outcome of the PIR will be a detailed report that will:

- Verify the established Measures of Effectiveness (MOEs) from the BDMS Test Plan
- Delineate the differences between estimated and actual investment costs and the benefits and possible ramifications for unplanned funding needs in the future

¹ Defense Health Information Management Systems PMO no longer exists following reorganization approved by Assistant Secretary of Defense Health Affairs TRICARE Management Activity Memorandum, Subject: “Reorganization of the Joint Medical Information Systems Program Executive Office”, June 5, 2013.

- List the investment, selection and control processes “lessons learned” that can be used as the basis for management improvements
- Determine whether the delivered product meets the business need and how shortfalls may be mitigated

If there are subsequent releases, each release will require an update to the PIR.

1.2 Background

According to the DAG, the Government Performance and Results Act (GPRA)² requires Federal Agencies to compare actual program results with established performance objectives. In addition, the Clinger Cohen Act (Title 40/CCA)³ requires that Federal Agencies ensure that outcome-based performance measurements are prescribed for the Information Technology (IT) to be acquired and that these performance measurements measure how well the IT supports the programs of the Agency⁴.

This information requirement is referred to in the Interim DoD 5000.02⁵ as a PIR. DoD component will plan, conduct and document the required review for IT systems post Fielding Decision. Specifically, the plan for conducting the PIR is due at the Fielding Decision.

The Office of Management and Budget (OMB) Circular A-130⁶ has prescribed specific PIR performance measurements of how well the acquired IT supports Federal Agency programs and the DAG provides details of the expected information (to comply with statute) for this PIR. The procedures for measuring a PIR are listed below:

- Conduct post-implementation reviews of information systems and information resource management processes to validate estimated benefits and costs, and document effective management practices for broader use.
- Evaluate systems to ensure positive return on investment and decide whether continuation, modification, or termination of the systems is necessary to meet business/agency mission requirements.
- Document lessons learned from the post-implementation reviews. Redesign oversight mechanisms and performance levels to incorporate acquired knowledge.
- Re-assess an investment's business case, technical compliance, and compliance against the Economic Analysis (EA).
- Update the EA and Automated Information Technology (AIT) capital planning processes as needed.

The PIR will assess actual system performance against program expectations. The DAG provides the guidance necessary for this review after Initial Operational Capability (IOC) and

² Government Performance and Results Act (GPRA) Modernization Act of 2010

³ Section 11313 of Subtitle III of title 40 of the United States Code (formerly known as Division E of the Clinger-Cohen Act (CCA) (hereinafter referred to as "Title 40/CCA")

⁴ DAG (Defense Acquisition Guidebook, Chapter 7.9 - Post Implementation Review)

⁵ Interim DoD Instruction 5000.02, Table 2, Milestone and Phase Information Requirements

⁶ OMB Circular A-130, Chapter 8, “Policy”, section b.(1)(d)

after Full Deployment. The DAG further states that the review must verify the fielded system meets or exceeds thresholds and objectives for cost, performance, and support parameters approved at full-rate production. The PIR will be conducted following completion of Fielding Decision to the end users⁷.

This PIR will be conducted by the functional sponsor's designee, with support and cooperation from the D&RS PMO as necessary. Working in conjunction with the stakeholders, the functional sponsor shall select the parameters for evaluations based on their relevance to future modifications or upgrades for performance, sustainability, and affordability improvements, or when there is a high level of risk that a Critical Success Factor (CSF) will not be sustained over the life of the system. The proposed format for the final evaluation is located in Appendix A of this document. This format may be tailored to fit the findings of the PIR Team.

An appropriately conducted PIR will satisfy both GPRA and Title 40/CCA requirements for a post deployment evaluation.

1.3 Program Summary

The aging Military Health System (MHS) legacy blood management system – the DBSS, has been unable to accommodate new features and certify software for deployment in a timely manner to meet user and regulatory demands. DBSS capabilities are not to standard, require high maintenance costs due to Food and Drug Administration (FDA) certification, and need to be implemented enterprise-wide. DBSS received a Denial of Authority To Operate (DATO) on June 24, 2010 and is currently disconnected from all MHS/Service networks. The health of MHS beneficiaries donating and receiving blood, blood components, and derivatives is at risk due to the inability to adequately manage the aforementioned items throughout the continuum of care.

The solution – the EBMS – is a strategic technology modernization project that will enhance the DoD Blood Program capabilities for Blood Donor Management through the seamless integration of blood products inventory management, transport, and availability. Per Acquisition Decision Memorandum (ADM) dated July 9, 2013, EBMS is an Acquisition Category III (ACAT III) program consisting of two increments: the BDMS (Increment 1) and the BMBB/TS (Increment 2). Both increments are needed to replace DBSS.

BDMS, an enterprise-wide automated information system (AIS) for the 23 DoD blood donor facilities, is comprised of a group of Commercial Off the Shelf (COTS) products: LifeTrak® and InSight®. LifeTrak®, developed by Mediware® Information Systems, Inc. is the core of the BDMS solution. InSight® is utilized for enterprise performance monitoring and metrics and KnowledgeTrak™ is the learning management system. BDMS will be hosted at the MHS Enterprise Service Operations Center (MESOC) in San Antonio, Texas; and the BDMS system fail-over/ Continuity of Operations (COOP) site is the MESOC in Aurora, CO. The central LifeTrak® application is a web-based application that will be accessed via laptops or desktops at local facilities. BDMS manages:

- Collection processes and donor records
- Testing and manufacturing of products

⁷ Government Performance and Results Act (GPRA) Modernization Act of 2010

- Distribution for managing inventory
- Enterprise Donor service metrics (enterprise reporting), down to a specific product

BDMS is a stand-alone system with no dependencies on other systems. Donor and deferral information will be accessible enterprise-wide. BDMS laptops support mobile blood drives using laptops capable of collecting data during the drives that synchronize upon connection with the network. An automated donor-screening tool will screen donors, both military and civilian. Blood label printing capability is supported in addition to the ability to create detailed inventory and management reports. BDMS supports the ability to securely import and export shipping and receiving data. BDMS file and table build out – the COTS Product MHS “tailoring” process – has been completed by the vendor/Joint Configuration Working Group (using the Planned Systems International, Incorporated (PSI) prototype environment) and endorsed by the D&RS PMO/Services.

The LifeTrak® Central Server and web-based InSight® application both utilize the DHSS Identity Authentication Service (iAS) to authenticate users using Single Sign On with a DoD Common Access Card (CAC).

The Enterprise Integration Engine provides the ability to ingest data from external systems (i.e. laboratory instrument data) and transfers it to the LifeTrak® database.

BDMS implementation spans MHS facilities located CONUS and OCONUS. BDMS will conduct an Operational \Assessment (OA) at three Service sites prior to seeking a Fielding Decision Q1FY16.

BDMS meets regulatory compliance at the time of implementation and can adapt to regulatory changes within the regulatory compliance period. BDMS is subject to the exacting regulations of the FDA and the standards of use by AABB (formerly the American Association of Blood Banks). The FDA regulates the manufacturing, marketing, and use of blood establishment computer systems (BECS). To obtain pre-market “510K clearance” from the FDA, BECS products must obtain minimum levels of functionality, attain standardization, ensure a safe blood product, and comply with federal law. The FDA has issued blood establishment licenses to the Service Blood Programs of the Air Force (License – 610); Army (License – 611); and Navy (License – 635). All military blood facilities are registered by the FDA and accredited by AABB; they must operate according to Title 21, Code of Federal Regulations, Part 200 Series, Drug Current Good Manufacturing Practices, Part 600 series, Biologics, and Part 800 series, Medical Devices.

1.4 PIR Description

The PIR should be carried out according to the PIR plan that will be reviewed and approved at Fielding Decision. Care should be given to ensuring that accurate raw data is captured, so it can be later used for analysis. In accordance with the PIR plan, the PIR will address:

- **Business/Customer Satisfaction:** Address whether the user is satisfied with the IT investment and determine if the investment meets their needs.
- **Mission/Program Impact:** Address if the implemented system achieves its intended impact. A comparison is conducted of the expectations contained in the original Business Case versus any subsequent release.

- **Solicit Feedback:** The most important measures of the success of a project are whether the product was developed and delivered successfully and how well the needs of the customers have been met. The most effective way to determine these measures is to solicit feedback.
- **Conduct Project Assessment:** The goal of this task is for the functional proponent representative to meet with select members of the project team and stakeholder community to present the summarized results of the feedback surveys, discuss all other aspects of the completed project, gain consensus on what was successful and what was not, and derive best practices and lessons learned.
- **Prepare Post Implementation Report:** After the assessment, the Project Manager prepares a Post Implementation Report. In the report, the Project Manager distills information gleaned from the discussion and organizes it according to the feedback categories described, adding information on key project metrics. The report documents the effectiveness of the product in meeting the needs of the Customer.
- **Return On Investment Calculations:** Compare actual project costs, benefits, risks, and return information against earlier projections. Determine the causes of any differences between planned and actual results.

1.5 Resources

The BDMS PIR will be conducted by the personnel already assigned to the initiative. Additionally, the PIR will not incur any additional costs for travel or facilities if required. There will be no compensation associated with the survey or respondents. The survey tool will be supplied by the Program Office for the analysis of feedback results.

1.6 Schedule

Table 1: Program Events

| END DATE | EVENT |
|----------|---|
| Q2FY15 | BECS Validation/Early Assessment (EA) |
| Q1FY15 | Acquisition Decision Memorandum/Milestone C |
| Q4FY15 | Operational Assessment (OA) |
| Q1FY16 | Fielding Decision |
| Q4FY16 | Full Deployment (FD) |

2 AREAS OF ASSESSMENT

In essence, the PIR report is a summation of the successes and challenges of the BDMS program. The assessment of success supports future decision-making, while the assessment of challenges can be used to prevent recurrence of problems. Future deployments of BDMS can benefit from this knowledge, with the potential to save time, decrease cost, improve system performance, and improve organizational processes. The PIR team will utilize an online, government-procured Survey Monkey account, which will result in a decreased burden on the respondent and the collectors as compared to a paper-based survey. Survey responses will be stored in the D&RS

PMO-managed secured Survey Monkey account, and data will be taken offline and stored on a secure DHA network. There will be no hard copies of raw survey data. Refer to Appendix B for the proposed BDMS user satisfaction survey questions.

2.1 Customer Satisfaction

Customer satisfaction information will be acquired from BDMS end users located in various settings. All survey respondents will receive the survey electronically. The results will be captured, consolidated and analyzed by the D&RS PMO. D&RS PMO will develop a report of findings to be included in the PIR report and distribute to the product stakeholders for review. The responses received from BDMS end users will be anonymous and used to aid future program-level decision making.

The survey is designed to gather demographic and role-specific data on the users of BDMS and their satisfaction with the system itself. The survey collects data on six satisfaction variables which will be used to categorize the results received from the end-users, these variables include:

- System Speed
- System Reliability
- System Availability
- BDMS Training
- Overall Ease of Use
- Overall Rating of BDMS

Each of the satisfaction variables listed above will provide the Program Office with data to conduct a comprehensive review. The following is an example of a User Satisfaction Ratings Table that will be used to develop metrics associated to the variables listed above:

Table 2: Example User Satisfaction Ratings*

| Review Group | Far Below Expectations | Below Expectations | Meets Expectations | Above Expectations | Far Above Expectations |
|-----------------------------|------------------------|--------------------|--------------------|--------------------|------------------------|
| BDMS | 15 | 16 | 67 | 8 | 4 |
| Documentation Groups | 12 | 17 | 65 | 7 | 3 |

**Numbers shown in table above denote responses that agree with that category heading*

Based on user rating / user feedback, the BDMS team will make an effort towards tailoring further development to alleviating pain points, or other possible enhancement areas.

2.2 Mission/Program Impact

The Top-Level Evaluation Framework matrix, in Appendix C, shows the correlation between decisions, the primary capabilities, test methodologies, and other key test measures. The primary test event is the operational test and documentation reviews used to support the BDMS Fielding Decision.

The test and evaluation community uses MOEs and Measures of Suitability (MOSs) to provide feedback to the functional community and to the EBMS Project Office on the completeness and coverage of the requirements necessary to support the T&E of the system under test. MOEs measure the mission accomplishment that comes from the use of the system under test and all interrelated systems. Similarly, MOSs measure an item's ability to be supported in its intended operational environment. MOSs typically relate to readiness or operational availability, reliability, maintainability, and the support structure.

Note: When the BDMS PIR Plan is executed, OA results and associated user feedback will be available to PIR members for reference purposes.

2.3 Return on Investment

The costs and benefits of BDMS will be examined against the economic analysis present in the BDMS business case. Operational benefits, which reflect non-financial improvements to mission and administrative processes, will also be examined. Variance from the estimates in actual program costs and benefits data may lead to a reassessment of the BDMS economic analysis.

3 PLAN OF ACTION

3.1 Schedule the PIR

The PIR should take place once the operating environment has been established and stabilized. The typical timeframe is 6 to 12 months after BDMS Full Deployment. BDMS Full Deployment is scheduled for Q4FY16. The PMO and deployment team will field, train, and sustain the software at all designated locations. The PIR schedule should be reviewed to determine planned versus actual completion dates.

3.2 Assemble a PIR Team

PIR Teams should be comprised of individuals not directly involved in the acquisition. This PIR Team will be established as a Working-level Integrated Product Team (WIPT) within the guidelines of the BDMS Integrated Product Team (IPT) with the same voting membership.

The Team should include the following representatives:

- Functional experts with detailed knowledge of the capability or business area and its processes
- User representatives, including Combatant Command users
- Services
- Chief Information Officer (CIO) representative
- Functional Sponsors
- Domain Owners
- Joint Staff
- Test and Evaluation members
- Program Offices

- Infrastructure

3.3 Assemble and Review Available Information Sources

Sources to consider are:

- Economic calculations to establish the payback period and Return on Investment (ROI) of business systems
- Qualitative assessments related to expected benefits
- Information Assurance assessments
- Annual Chief Financial Officer (CFO) Reporting of IT investment measured performance
- Stakeholder satisfaction surveys
- Operational Test Event reports

Factors to be considered include:

Customer/User Satisfaction:

- Partnership/involvement
- Business process support
- Investment performance
- Usage

Strategic Impact and Effectiveness:

- System impact and effectiveness
- Alignment with mission goals
- Portfolio analysis and management
- Cost savings

Internal Business:

- Project performance
- Infrastructure availability
- Standards and compliance
- Maintenance
- Evaluations (accuracy, timeliness, program quality, information adequacy)
- Employee satisfaction/retention

Innovation:

- Workforce competency
- Advanced technology use
- Methodology expertise

To ensure that each asset is evaluated consistently, the functional sponsor should have a documented methodology for conducting these reviews. The methodology chosen must be in alignment with the program offices. The program office should determine whether there may be better cost, benefit, and risk measures that could be established that would improve the monitoring of future projects. In addition, a mechanism should also be in place that takes the lessons learned through the PIR and uses the lessons to update the Planning and Budgeting Phase decision criteria as well as the Acquisition Process.

3.4 Conduct the PIR

A project is considered complete when it has been successfully implemented and transitioned to the performing organization and approved by the Project Sponsor. At this point in the project management lifecycle, the responsibilities of the Project Manager are to assess how closely the project met Customer needs, highlight what worked well, learn from mistakes made during the project, identify patterns and trends, derive ways to improve upon processes executed throughout the project, and, most importantly, communicate results. The purpose of the PIR is to gather the information required to meet those responsibilities, and to present the information in a PIR report.

3.5 Conduct the Analysis

The analysis portion of the PIR should answer the questions, “Did we get what we needed?” This provides a contrast to the test and evaluation measurements of MOEs which answer the question, “Did we get what we asked for?” This would imply that the PIR should assess the extent to which the DoD's investment decision-making processes were able to capture the user's initial intent. The PIR should also address whether the user's needs changed during the time the system was being acquired. The outputs of the analysis become the PIR findings. The findings should clearly identify the extent to which the user received what they needed.

3.6 Prepare a Report and Provide Recommendations

Once PIR results have been consolidated, the PIR Team will prepare a report and make recommendations that can be leveraged to mature the capabilities and business needs processes. The primary recipient of the PIR report should be the Sponsor/Domain Owner who is responsible for articulating the original objectives and outcome-based performance measures on which the program or investment was based. The results of the PIR can aid in refining requirements for subsequent increments. Recommendations may be made to correct errors, improve user satisfaction, or improve system performance to better match user/business needs. The PIR Team will also determine whether different or more appropriate outcome-based performance measures can be developed to enhance the assessment of future spirals or similar IT investment projects. This review will look at the strategic impact and effectiveness of the system and address whether the system is in alignment with the mission and goals as outlined in the requirements documentation. The high-level functional requirements include a list of the CSFs along with a Requirements Traceability Matrix. Refer to Appendix D for a list of BDMS CSFs. A thorough review of these areas will help determine the impact of the deployed system. The Team will evaluate these requirements to see how successful the program has been at meeting the thresholds and objectives. The Team will also develop a requirements review process and use it to:

- Demonstrate achievements against the projected costs, benefits, and timeliness

- Isolate areas that do not meet required standards of performance and provide recommendations for corrective actions, based on CSFs and other customer feedback
- Identify opportunities to enhance the system
- Identify program strengths and weaknesses for future reference and corrective action
- Provide lessons learned to help in developing future systems/programs

Factors to be evaluated might include qualitative benefits, quantitative benefits, system performance, and schedule benefits such as:

- Improved facility management of personnel/workload
- Enhanced health and fitness of the force
- Improved inventory management
- Reduction in duplicative efforts

At a minimum, system performance will be evaluated against the Joint and Service Concepts of Employment/Operations relative to acceptable thresholds for data synchronization to determine how effectively BDMS supports the needs of users. The final PIR report will be produced once all appropriate data have been collected and analyzed. As the domain owner, the Deputy Assistant Secretary of Defense for Health Affairs, Force Health Protection and Readiness, will receive the final PIR report from the PIR team. A copy will also be provided to the DHCS PEO, as well as the lead Operational Test Agency and the DHA Defense Health Cost Analysis and Program Evaluation.

4 NEXT PIR REVIEW DATES

Supplementary PIRs may be required if there are subsequent BDMS releases. (Presently no additional releases are scheduled). Each new release will require an update to the PIR.

APPENDIX A: DRAFT POST IMPLEMENTATION REVIEW REPORT FORMAT

1. Executive Summary

The executive summary should reference the major findings and recommendations of the review.

2. Background

Provide a brief description of BDMS and the circumstances leading to implementation.

3. Methodology

Describe the approach used to conduct the review, interviews, team members, duration of the review, survey instruments, etc.

4. Review Findings

Each item identified in the methodology section should be included in the review of findings. The following areas should be investigated individually and as a group:

Program Management:

- Discuss the project management approach used. Identify positive and negative aspects of that approach. Determine ways to enhance or change the approach for future use on this program and other Military Health Service IT programs.
- Compare the functionality to be delivered to what was actually delivered. Assess user perceptions of the value/worth of the functionality implemented. All exceptions and/or differences should be highlighted and the impact of the omitted/added functionality explained.
- Compare the actual timetable for BDMS against the approved timeline. Reasons for any differences should be explained. Evaluate the effect of any changes to the planned development/implementation.
- Compare the benefits accrued to date with the benefits expected to be accrued as stated in applicable acquisition documentation. A statement is required on the expected achievement of any outstanding benefits. Reasons for any differences should be explained. At a minimum, CSFs and MOEs benefits should be measured.
- The Event Design Plan (EDP) for the Operational Assessment of BDMS will serve as the source document MOEs.
- Describe the implementation and training component, noting strategies, difficulties, deficiencies, and eventual success or failure.
- Address program audit issues. Describe existing controls and security measures and assess their adequacy.

Benefits:

- Determine the impact of the deployed system.
- Review CSFs and compare them to the fielded system.

Cost of Maintenance and Development:

- Compare the actual project costs against the estimated costs in the Business Case. Reasons for any differences should be explained.

Cybersecurity:

- D&RS PMO/DHA Infrastructure and Operations are responsible for monitoring the security for the BDMS program. During the PIR, the D&RS PMO security point of contact will be responsible for providing the Team with an evaluation of all applicable Cybersecurity artifacts.

System Interfaces:

- Software metrics – The goal is to track, analyze, forecast, and thereby improve the present and future software development process and its associated standards taking into account that BDMS is a COTS product and a Medical Device thus limiting software development to change requests submitted to the medical device manufacturer. Measure performance against requirements at all levels of BDMS infrastructure.
- Availability – Measure the mean time between: failure, downtime, and maintenance.
- Software Integration Lessons Learned - The goal is to capture modifications to integration effort and process for present and future software integration and its associated standards. Collect and record major lessons learned throughout the deployment process and disseminate appropriately.

User Satisfaction:

- Discuss survey techniques and instruments used to determine user satisfaction.
- Explain the results of user service surveys. Identify deficiencies and develop a course of action to support recommendations.
- Determine usage rates.
- Evaluate training and help desk support.

5. Identify Lessons Learned

Lessons learned should include, but are not limited to:

- The project management process
- The systems development process
- The contracting methodology used
- The training received/provided
- The technology that was used

- The software that was used

6. Recommendations

Document the recommendations resulting from the PIR and the action plans to implement the recommendations. All recommendations must be prioritized and it is important to evaluate each recommended change as to their impact on all areas of BDMS. Costs and benefits related to implementing the recommendations should be included. The completed report will be coordinated among the stakeholders prior to submission to the domain owner.

APPENDIX B: DRAFT USER SURVEY QUESTIONS

Privacy Advisory

The information collected from you in this survey is completely voluntary and will be used to evaluate the Enterprise Blood Management System Increment 1, Blood Donor Management System (BDMS) end user satisfaction and system usability. Future BDMS deployments can benefit from this knowledge, with the potential to save time, decrease cost, and improve system performance. Neither the Department of Defense (DoD) nor Deployment and Readiness Systems Program Management Office, under the executive management of the Program Executive Office Defense Health Clinical Systems, will collect personal information that can be used to identify you when you visit this Web site. If, for some reason, you supply us with personal information, it will be treated as confidential. No Internet Protocol addresses, cookies, browser data, operating system information, or the number of bytes sent and received by your computer will be collected or stored. Therefore our organization will not be able to link any survey response data to your computer. It will reside in a data collection database. The results may be shared with DoD Components for the use of validating and improving end user satisfaction and system usability. None of this information will be revealed publicly or used to identify you.

1. Are you a Contractor?

- Yes – *[survey will end at this point]*
- No

2. How frequently do you use BDMS?

- I have never used BDMS – *[survey will end at this point]*
- I no longer use BDMS (former user who has stopped using the system)
- Infrequent user (does not use the system everyday)
- Frequent user (usually uses the system a few times every day)
- Very frequent user (consistently uses the system throughout the day)

3. How long have you been using BDMS?

- Less than 3 months
- 3 to 6 months
- 6 to 12 months
- 1 or more years

4. What is the name of the facility where you work?

- Camp Lejeune, NC
- Fort Benning, GA
- Fort Bliss, TX
- Fort Bragg, NC
- Fort Gordon, GA
- Fort Hood, TX
- Fort Leonardwood, MO
- Fort Sam Houston, TX
- Great Lakes, IL
- Joint Base Lewis-McChord
- Keesler AFB, MS
- Lackland AFB, TX
- Landstuhl, Germany
- McGuire AFB, NJ ASWBPL - East
- Naval Hospital Guam, Guam
- Okinawa, Japan
- Pentagon, VA
- Portsmouth, VA
- San Diego NMC, CA
- Travis AFB, CA ASWBPL – West
- Tripler, Hawaii
- WRNMMC, MD
- Wright Patterson AFB, OH

5. What branch of service do you belong to or support?

- Air Force
- Army
- Marine Corps
- Navy
- Other:

6. Which of the following describes your PRIMARY functional area at this facility?

- Blood Donor Center Operations
- Laboratory (Unit Testing)
- Distribution (Shipping/Receiving)
- Other Role:

7. How satisfied are you with: (Scale: Very Satisfied/ Satisfied/ Neither Satisfied nor Dissatisfied/ Dissatisfied/ Very Dissatisfied)

- System speed
- System reliability
- System availability
- Application connectivity
- Helpdesk process

- BDMS training
- BDMS training materials
- Overall ease of using the system
- Overall rating of BDMS

8. Has your organization changed its workflow or business processes to make it easier for you to use BDMS?

- Yes
- No
- Comments (if yes, please explain):

9. How satisfied are you with the following BDMS functions: (Scale: Very Satisfied/ Satisfied/ Neither Satisfied nor Dissatisfied/ Dissatisfied/ Very Dissatisfied)

- Donor Registration
- Recording Donor Health History Responses/Physical Findings
- Managing Donors – Donor Merge, Donor Interdictions
- Shipping products
- Recording donor comments
- Inventory Management
- Testing
- Manufacturing/Modifying Products
- Product Labeling
- Product QC Functions
- Comments:

10. Comments:

APPENDIX C: BDMS MEASURES OF EFFECTIVENESS, SUITABILITY, AND SURVIVABILITY

The Army Test and Evaluation Command (ATEC) will conduct an operational assessment (OA). The OA is a field test of a system or item to examine its operational effectiveness, suitability, and survivability. OA is conducted under realistic operational conditions with users who represent those expected to operate and maintain the system when it is fielded or deployed. An OA is conducted using production or production representative units.

The system is assessed for overall system effectiveness, suitability, and survivability utilizing a framework of ten critical operational issues (COI). A COI is a key operational effectiveness, suitability, or survivability issue that must be evaluated to determine the system's capability to perform its mission.

A COI is normally phrased as a question that must be answered in order to properly evaluate operational effectiveness, suitability, and survivability.

| Critical Operational Issue (COI) / Criteria | Measures | Threshold | Test Methodologies/ Key Resources |
|---|---|--|---|
| COI 1. Business Process Support Criterion 1. Does BDMS support the business process in a timely and accurate manner? | MOE 1-1. Percent of Essential Business Functions (EBF) successfully completed to support the User's Business Process | 99.5% for EBFs linked to High Level Business Outcomes 85% for all other EBFs | Primary: OA Scenario Execution Secondary: EA and BECS Scenario Execution; Functional SIT |
| | MOE 1-2. Percent of users indicating they were able to successfully complete their Business Process Support EBFs | 70% or greater of surveyed users indicate through the UOS that BDMS meets MOE. | Primary: OA User Opinion Surveys Secondary: EA and BECS User Opinion Surveys |
| COI 2. Interoperability Criterion 2. Does BDMS support the Net-Ready CSF requirements? | MOE 2-1. Interoperability Assessment of Net-Ready CSF | Must operate on each Service's infrastructure and must fully demonstrate that the critical system data exchanges can be accomplished to support military operations in net-centric operations. System can be installed, configured, and managed on each Service's platforms and communications infrastructure to support its net-centric military operations. | Primary: OA JITC Over-the-shoulder Observations and End User Surveys/Interviews Secondary: SIT and EA JITC Over-the-shoulder Observations and Database migration verification |

| Critical Operational Issue (COI) / Criteria | Measures | Threshold | Test Methodologies/ Key Resources |
|---|---|--|--|
| | | EBMS components must demonstrate the end-to-end information exchange requirements with its critical and external systems/ applications/ interfaces, as defined in the Business Case. | |
| <p>COI 3. Database Management</p> <p>Criterion 3. Is data available in a timely, complete, and accurate manner?</p> | <p>MOE 3-1. Database Migration</p> | <p>Pass/Fail</p> | <p>Database Migration SIT</p> |
| | <p>MOE 3-2. High Level Outcome Data Completeness</p> | <p>99.5%</p> | <p>Primary: OA scenarios execution database queries and verification SIT database migration queries and verification</p> <p>Secondary: EA scenario execution database query/verification</p> |
| | <p>MOE 3-3: High Level Outcome Data Accuracy</p> | <p>99.9%</p> | <p>Primary: OA scenarios execution database queries and verification SIT database migration queries and verification</p> <p>Secondary: EA scenario execution database query/verification</p> |
| | <p>MOE 3-4. Accessibility Query CSFs, database timeliness and load</p> | <p>15 seconds for up to 100 requests per second for both system and network</p> | <p>Primary: Capacity Analysis OA Instrumentation</p> <p>Secondary: EA instrumentation</p> |

| Critical Operational Issue (COI) / Criteria | Measures | Threshold | Test Methodologies/ Key Resources |
|---|--|---|--|
| <p>COI 4. Network System Management</p> <p>Criterion 4. Mission accomplished by managing and utilizing intended network infrastructure.</p> | <p>MOE 4-1. Accessibility Query CSFs, network timeliness and load</p> | <p>15 seconds for up to 100 requests per second for both system and network</p> | <p>Primary: Capacity Analysis OA Instrumentation</p> <p>Secondary: EA instrumentation</p> |
| <p>COI 5. Training</p> <p>Criterion 5. Does BDMS training prepare users to operate the system as expected?</p> | <p>MOS 5-1. Percent of users indicating through the UOS that the training prepared them to operate the system in a timely and accurate manner.</p> | <p>80% or greater of surveyed users indicate through the UOS that BDMS meets MOS</p> | <p>Primary: OA User Opinion Surveys</p> <p>Secondary: EA User Opinion Surveys</p> |
| | <p>MOS 5-2. Percent of users indicating through the UOS that training documentation is adequate to support task completion and deployment.</p> | <p>80% or greater of surveyed users indicate through the UOS that BDMS meets MOS</p> | <p>Primary: OA User Opinion Surveys</p> <p>Secondary: EA User Opinion Surveys</p> |
| | <p>MOS 5-3. Percent of users indicating through the UOS that formal and informal change management efforts facilitated an efficient transition from the legacy system to the BDMS system.</p> | <p>80% or greater of surveyed users indicate through the UOS that BDMS meets MOS</p> | <p>Primary: OA User Opinion Surveys</p> <p>Secondary: EA User Opinion Surveys</p> |
| | <p>MOS 5-4. Formal training (based on the new SOPs) must be developed and provided to each site.</p> | <p>Pass/Fail</p> | <p>AMEDDC&S Training Readiness Statement</p> |
| | <p>MOE 5-5. SOPs are FDA and AABB compliant.</p> | <p>Pass/Fail</p> | <p>Primary: BECS validation results. Secondary: OA scenario execution</p> |
| <p>COI 6. User Friendliness</p> <p>Criterion 6. Does BDMS provide features and characteristics that enable users to operate the system in a timely and accurate manner?</p> | <p>MOS 6-1. BDMS’ data entry, data displays, interactive controls, and error management functions are adequate and easy to use to facilitate mission performance in a timely and accurate manner.</p> | <p>80% or greater of surveyed users indicate through the UOS that BDMS meets MOS.</p> | <p>Primary: OA User Opinion Surveys</p> <p>Secondary: EA User Opinion Surveys</p> |
| <p>COI 7. Supportability</p> <p>Criterion 7. Does BDMS provide the capability to support users in accomplishing their mission by insuring a reliable, available, and maintainable system?</p> | <p>MOS 7-1. There are adequate manpower and personnel to support users in documenting and tracking issues so as to facilitate issue resolution in a timely manner.</p> | <p>80% or greater of surveyed users indicate through the UOS that BDMS meets MOS.</p> <p>Staffing levels in accordance with Life Cycle Sustainment Plan</p> | <p>Primary: OA User Opinion Surveys Life Cycle Sustainment Plan SME review</p> <p>Secondary: EA User Opinion Surveys</p> |
| | <p>MOS 7-2. BDMS must</p> | <p>MTBx where x are the</p> | <p>Primary:</p> |

| Critical Operational Issue (COI) / Criteria | Measures | Threshold | Test Methodologies/ Key Resources |
|---|---|---|---|
| | provide a reliable system to support the Users in accomplishing their mission in a timely and accurate manner. | reliability failure categories in the Failure Definition/Scoring Criteria (FD/SC) | <p>OA Scenario Execution data and failure information (help desk tickets and/or test incident reports)</p> <p>Secondary: OA Scenario Execution data and failure information (help desk tickets and/or test incident reports)</p> |
| | MOS 7-3. BDMS is consistently available to support the users in accomplishing their mission in a timely and accurate manner | <p>99% Operational Availability (A_o)</p> <p>This requirement applies to enterprise instances of this system as well as client systems. A_o is calculated from the formula $Up\ time/Total\ Time$ or $Up\ Time/(Up\ Time + Downtime) = MTBSA / (MTBSA+MTTR + ALDT)$.</p> <p>MTBSA: Mean Time Before System Abort MTTR: Mean Time To Repair ALDT: Average Logistics Delay Time</p> | <p>Primary: OA Scenario Execution data and failure information (help desk tickets and/or test incident reports)</p> <p>Secondary: OA Scenario Execution data and failure information (help desk tickets and/or test incident reports)</p> |
| | MOS 7-4. Percent of Users indicating that the BDMS online help text, data field names and, error messages and icons help Users to enter data into BDMS Documentation Tool. | 80% or greater of surveyed users indicate through the UOS that BDMS meets MOS | <p>Primary: OA User Opinion Surveys</p> <p>Secondary: EA User Opinion Surveys</p> |
| | MOS 7-5. Percent of Users indicating that the BDMS User manual and/or quick reference guides are adequate to assist in resolving questions concerning how BDMS usage. | 80% or greater of surveyed users indicate through the UOS that BDMS meets MOS | <p>Primary: OA User Opinion Surveys</p> <p>Secondary: EA User Opinion Surveys</p> |
| | MOS 7-6. The Percent of Users indicating help desk provides adequate service to enable issue resolution. | 80% or greater of surveyed users indicate through the UOS that BDMS meets MOS | <p>Primary: OA User Opinion Surveys</p> <p>Secondary: EA User Opinion Surveys</p> |
| | MOS 7-7. BDMS shall be | Successful development | Life Cycle Sustainment Plan |

| Critical Operational Issue (COI) / Criteria | Measures | Threshold | Test Methodologies/ Key Resources |
|--|---|--|--|
| | compliant with a lifecycle sustainment plan | of a lifecycle sustainment plan | Completion |
| | MOS 7-8. Number, severity, and response times of help desk tickets. | In accordance with service level agreement in BDMS Life Cycle Sustainment Plan | Primary: OA Scenario Execution data and failure information (help desk tickets and/or test incident reports) Secondary: OA Scenario Execution data and failure information (help desk tickets and/or test incident reports) |
| COI 8. Cyber Security Criterion 8: Does BDMS comply with the MHS’s comprehensive security program (see DODI 8510.01) and have processes and procedures to prevent unauthorized individuals from degrading, manipulating, or interrupting system performance or data availability? | MOS 8-1. All required security certifications and accreditations verified in accordance with DODI 8510.01 | Successful issuance of an Authority to Operate (ATO) or Interim Authority to Operate (IATO). | Signed ATO or IATO |
| | MOS 8-2. The system has controls to prevent unauthorized individuals from degrading, manipulating, or interrupting system performance or data availability | No high risk (Category 1 or 2) vulnerabilities in the Plan of Actions and Milestones (POA&M). | Copy of the DIACAP package containing DIACAP Scorecard, Plan of Actions and Milestones (POA&M), signed ATO or IATO, and DHA IA led security test and evaluation reports |
| COI 9. Continuity of Operations Criterion 9: Are BDMS’s COOP features and capabilities, along with user practices and processes, adequate to sustain the system as required for the mission, including backup, restoration, archiving, and scheduled shut down for maintenance or movement? | MOS 9-1. COOP features, capabilities, practices, and processes are adequate to sustain the system. | An adequate Continuity of Operations Plan must exist at both the enterprise and MTF levels. Successful demonstration of alternate site functionality. | COOP plans and interviews with appropriate system administrators. Demonstration of alternate site functionality. |

APPENDIX D: BDMS CRITICAL SUCCESS FACTORS

| Requirement | | |
|--|---|-----------------------------|
| Critical Success Factors | Production Threshold | Production Objective |
| <p>Net-Ready (NR)</p> <p>Fully support execution of joint critical operational activities and information exchanges identified in the DoD Enterprise as well as be IAW solution architectures based on integrated Department of Defense Architecture Framework (DoDAF) content, and must satisfy the technical requirements for transition to Net-Centric operations.</p> | <ul style="list-style-type: none"> • 1) Solution architecture products compliant with DoD Enterprise Architecture based on an integrated DoDAF content, including specified operationally effective information exchanges. • 2) Compliant with Net - Centric Data Strategy and Net-Centric Services Strategy, and the principles and rules identified in the DoD Information Enterprise Architecture (DoD IEA). • 3) Compliant with GIG Technical Guidance to include the implementation guidance of GIG Enterprise Service Profiles (GESPs) necessary to meet all operational requirements specified in the DoD Enterprise Architecture. • 4) Information assurance requirements including availability, integrity, authentication, confidentiality, and non-repudiation, and issuance of an Interim | <p>[T=O].</p> |

| | | |
|---|---|---|
| | <p>Authority to Operate (IATO) or Authority To Operate (ATO) by the Designated Accrediting Authority (DAA).</p> | |
| <p>System Operational Availability</p> | <p>Must provide a 99% Operational Availability (A_o). This requirement applies to enterprise instances of this system as well as client systems. A_o is calculated from the formula Up time/Total Time or Up Time/ (Up Time + Downtime) = MTBSA / (MTBSA+MTTR + ALDT).</p> <p>MTBSA: Mean Time Before System Abort</p> <p>MTTR: Mean Time To Repair</p> <p>ALDT: Average Logistics Delay Time</p> | <p>Must provide a 100% operational availability</p> |
| <p>System Operational Availability</p> | <p>Must provide a 99% Operational Availability (A_o). This requirement applies to enterprise instances of this system as well as client systems. A_o is calculated from the formula Up time/Total Time or Up Time/ (Up Time + Downtime) = MTBSA / (MTBSA+MTTR + ALDT).</p> <p>MTBSA: Mean Time Before</p> | <p>Must provide a 100% operational availability</p> |

| | | |
|--|--|--|
| | <p>System Abort</p> <p>MTTR: Mean Time To Repair</p> <p>ALDT: Average Logistics Delay Time</p> | |
| <p><u>Accessibility</u></p> <p>BDMS when connected to the network instances, the following information access capabilities are visible & understandable to authorized users:</p> <ul style="list-style-type: none"> • 1. Donor Management - management of Donor information as it relates to donations, test results and Donor data to include: • Donor consolidated donation history • Alerts for unsuitable donors • 2. Blood/Blood Product Management - tracking, documentation & management of blood/blood products to include: • Manufacturing data • Accurate Barcode labeling • Blood Component Information <p>IAW FDA & AABB regulations.</p> | <p>NIPRNET Access</p> <p>Per hour - 100 users.</p> <ul style="list-style-type: none"> • 1. Donor Management - <p>Query Response Time</p> <ul style="list-style-type: none"> • Content - 15seconds for up to 100 requests per second <ul style="list-style-type: none"> • 2. Blood/Blood Product Management - <p>Query Response Time</p> <ul style="list-style-type: none"> • Content -15 seconds for up to 100 requests per second | <p>NIPRNET Access</p> <p>Per hour - 350 users.</p> <ul style="list-style-type: none"> • 1. Donor Management - <p>Query Response Time</p> <ul style="list-style-type: none"> • Content - 5 seconds for up to 350 requests per second <ul style="list-style-type: none"> • 2. Blood/Blood Product Management - <p>Query Response Time</p> <ul style="list-style-type: none"> • Content - 5 seconds for up to 350 requests per second |

| | | |
|---|--|--|
| <ul style="list-style-type: none"> • 3. Inventory Management - track data associated with storage, disposition & shipment of blood products to include: • Blood/Blood Product traceability from Donation to destruction • Donation Identification Number (DIN) • Potential blood product needs for the enterprise • 4. Look Back - retrieval capability for Donor Services from input to final disposition in compliance with regulatory guidelines: | <p>3. Inventory Management -</p> <p>Query Response Time</p> <ul style="list-style-type: none"> • Content - 15 seconds for up to 100 requests per second <p>4. Look Back -</p> <p>Query Response Time</p> <ul style="list-style-type: none"> • Content - 15 seconds for up to 100 requests per second | <p>3. Inventory Management -</p> <p>Query Response Time</p> <ul style="list-style-type: none"> • Content - 5 seconds for up to 350 requests per second <p>4. Look Back -</p> <p>Query Response Time</p> <ul style="list-style-type: none"> • Content - 5 seconds for up to 350 requests per second |
|---|--|--|

APPENDIX E: ACRONYMS

| Acronym | Definition |
|--------------------------|---|
| A_o | Operational Availability |
| AABB | formerly the American Association of Blood Banks |
| ACAT | Acquisition Category |
| AIT | Automated Information Technology |
| ALDT | Average Logistics Delay Time |
| AMEDD C&S | Army Medical Department Board Center and School |
| APBC | Automated Patient Backup Card |
| ATO | Authority to Operate |
| BDMS | Blood Donor Management System |
| BMBB/TS | Blood Management Blood Bank Transfusion Service |
| CAC | Common Access Card |
| CCA | Clinger Cohen Act |
| CFO | Chief Financial Officer |
| CIO | Chief Information Officer |
| COI | Critical Operational Issue |
| CONUS | Continental United States |
| COOP | Continuity of Operations Plan |
| CSF | Critical Success Factor |
| DBSS | Defense Blood Standard System |
| D&RS PMO | Deployment and Readiness Systems Program Management Office |
| DAA | Designated Accrediting Authority |
| DIACAP | DoD Information Assurance Certification and Accreditation Process |
| DIN | Donation Identification Number |
| DoD | Department of Defense |
| DoDAF | Department of Defense Architecture Framework |
| DoD EA | Department of Defense Enterprise Architecture |
| DoDI | Department of Defense Instruction |
| EA | Economic Analysis |

| Acronym | Definition |
|----------------|---|
| EBF | Essential Business Functions |
| EBMS | Enterprise Blood Management System |
| EHR | Electronic Health Record |
| FD/SC | Failure Definition/Scoring Criteria |
| FDA | Food and Drug Administration |
| FD | Full Deployment |
| GESP | Global Information Grid Enterprise Service Profiles |
| GIG | Global Information Grid |
| GPRA | Government Performance and Results Act (GPRA) |
| IA | Information Assurance |
| iAS | identity Authentication Services |
| IATO | Interim Authority to Operate |
| IAW | In Accordance With |
| IOC | Initial Operational Capability |
| IPT | Integrated Product Team |
| JITC | Joint Interoperability Test Command |
| KPP | Key Performance Parameter |
| MESOC | MHS Enterprise Service Operations Center |
| MHS | Military Health System |
| MOE | Measure of Effectiveness |
| MOP | Measure of Performance |
| MOS | Measure of Suitability |
| MTBSA | Mean Time Before System Abort |
| MTTR | Mean Time To Repair |
| NIPRNET | Non-secure Internet Protocol router Network |
| NR | Net-Ready |
| OA | Operational Assessment |
| OCONUS | Outside the Continental United States |
| OMB | Office of Management and Budget |
| PEO | Program Executive Officer |

| Acronym | Definition |
|------------------|---------------------------------------|
| PIR | Post-Implementation Review |
| PMO | Program Management Office |
| POA&M | Plan of Actions and Milestones |
| ROI | Return on Investment |
| SIT | System Integration Testing |
| SME | Subject Matter Expert |
| SOP | Standard Operating Procedure |
| T=O | Threshold equals Objective |
| T&E | Test and Evaluation |
| UOS | User Opinion Surveys |
| WIPT | Working-level Integrated Product Team |

APPENDIX F: REFERENCES

Defense Acquisition Guidebook (DAG), <https://dag.dau.mil/Pages/Default.aspx>

DoD Instruction 5000.02, “Operation of the Defense Acquisition System,” dated November 25, 2013 (interim guidance)

Office of Management and Budget (OMB) Circular A-130, Chapter 8

Clinger-Cohen Compliance Guidance Clinger-Cohen Act (Title 40/CCA)

Government Performance and Results Act (GPRA) Modernization Act of 2010

Enterprise Blood Management System Acquisition Decision Memorandum, July 9, 2013

Blood Donor Management System Business Case v1.0, July 30, 2014