Supporting Statement Outline – Enterprise Blood Management System (EBMS): Blood Donor Management System (BDMS) and Blood Management Blood Bank Transfusion Services (BMBB/TS)

SUPPORTING STATEMENT – PART A

A. JUSTIFICATION

1. Need for the Information Collection

Enterprise Blood Management System (EBMS) is composed of two separate Commercial-Off-The-Shelf (COTS) products: Blood Donor Management System (BDMS) for donor functionality and the Blood Management Blood Bank Transfusion Services (BMBB/TS) for Transfusion Services functionality. This strategic technology modernization project will enhance the Department of Defense (DoD) Blood Program capabilities for Donor Center and Blood Bank/Transfusion Services through the seamless integration of blood products inventory management, transport, availability, and most importantly blood product traceability from collection to disposition. BDMS and BMBB/TS will replace the Defense Blood Standard System (DBSS), which is the legacy system, at Garrison locations. DBSS has been unable to accommodate revised Food and Drug Administration (FDA) regulatory requirements, new information technology features, information assurance updates, and deploy software upgrades in a timely manner to meet Blood Donor Center (BDCs) and Military Treatment Facilities (MTFs) Transfusion Service department end users demands. DBSS sites are not integrated with each other and decentralized standalone servers are located at each facility which requires high maintenance costs due to the unsupportable software and aged hardware components. The patient and donor legacy records stored within the DBSS application will be transferred into the BDMS and BMBB/TS applications via automated scripts developed by a contracted vendor. DBSS will not automatically or manually push information into the BDMS and BMBB/TS systems or vice versa.

For the safety of all involved, EBMS is subject to the FDA regulations. In addition, BDCs and Transfusion Services departments follow the latest AABB (American Association of Blood Banks) standards for industry best practices. All FDA cleared medical devices must obtain minimum levels of functionality required by law. In order to attain standardization, ensure a safe blood product, and must comply with the Quality System Regulation (Title 21 Code of Federal Regulation part 820), all Military blood facilities are licensed and/or registered by the FDA and must operate according to Title 21, Code of Federal Regulations (CFR), Part 200 Series, Drug Current Good Manufacturing Practices, Part 600 series, Biologics, and Part 800 series, Medical Devices.

BDMS, an enterprise-wide automated information system (AIS) that will be deployed to 23 Blood Donor Centers (BDCs), is comprised of a group of commercial off the shelf (COTs) products: LifeTrak® Donor, LifeTrak® Lab/Distribution, and InSight® Enterprise. LifeTrak®, developed by Mediware Information Systems, Inc., is the core of the BDMS solution. BDMS is scheduled to begin an Early Assessment (EA) to evaluate system performance and identify

project risk in September to October 2014. In contrast of DBSS, BDMS reduces the time and effort associated with staff scheduling, mobile blood drive scheduling, blood donor center management, donation registration, and donor communication. BDMS functionality includes the ability to provide an end-to-end solution for Garrison blood collection through the following: improved operations and management of product inventory, blood product traceability from collection to final disposition, enterprise shipment tracking and inventory of data, automated, enterprise-wide lookback for donations and products, mobile blood drive management, and enterprise donor deferral management. Since DBSS is decentralized, the application does not provide automated donor screening, enterprise deferral management, enterprise inventory management, or enterprise lookback solution. InSight® provides innovative performance management solution that works seamlessly with LifeTrak® to automate the graphical presentation and analysis of key performance metrics (i.e. operational and clinical).

**Table 1: BDMS Functionality Comparison with DBSS**

| Functionality | BDMS | DBSS |
|---|---|---|
| Donor Registration/ Information Collected | Donor will provide the BDC staff member a government issued identification card to obtain as much personal demographic information as possible. The BDC enters the data 'real-time' into the BDMS during the registration process. Information provided includes Name, Age, Sex, Date of Birth, Address, Family Member Prefix (FMP), Military Sponsor's Social Security Number (SSN), and government issued identification and state information. | Donor will provide the BDC staff member a government issued identification card to obtain as much personal demographic information for verification. Personal demographics are completed on DD Form 572 and provided to the BDC for processing. Information provided includes Name, Age, Sex, Date of Birth, Address, Family Member Prefix (FMP), Military Sponsor's Social Security Number (SSN), and donor's SSN. The information is not entered into the DBSS application until completion of the donation. |
| Donor Screening | Donor accesses the BDMS application with the BDC personnel to complete the automated medical history Uniform Donor Health Questionnaire (UDHQ) electronically. The responses are stored in the BDMS application, | Donor is provided a manual DD Form 572 and responds to the medical history questionnaire on paper. The responses are kept on a physical form and maintained. |
| Deferral | Enterprise deferral allows for all 23 BDCs to access donor medical history and indelibility information to donate. | Decentralized servers, so there is no enterprise deferral capability across the BDCs to share information. |
| Enterprise Reporting | BDMS provides enterprise reporting | Each BDC runs a report from the |

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|---|---|---|
| | capability via InSight® which automatically communicates with the LifeTrak® Application server to transmit data and convert the information into a graphical representation for upper leadership review and analysis. | DBSS application and manually transcribes the information into the Operational Data Reporting System on a monthly basis to provide blood product collection, manufacturing, testing, shipping inventory, as well as staffing, supply, and other operational data. |

Basis for donor screening information collection: BDCs that collect blood components (whole blood, plasma, platelets, etc..) intended for transfusion consisting of the implementation of a standardized full-length donor history questionnaire (DHQ) are required to comply with the donor screening/qualification requirements in accordance with the FDA regulatory requirements Title 21 Code of Federal Regulations (CFR) §§ 610.41, 640.3, and 640.63. In addition, AABB Standards for Blood Banks and Transfusion Services, 29th ed, provide details of the latest standards of practice in donor management and blood banking/transfusion medicine.

Blood Management Blood Bank Transfusion Services (BMBB/TS) is scheduled to Go-Live at select MTFs beginning 8 September 2014. BMBB/TS, an enterprise-wide AIS will be deployed to 60 MTF blood banks/transfusion services facilities, is comprised of a group of COTS products: HCLL™, InSight® Enterprise, and KnowledgeTrak™. HCLL, developed by Mediware Information Systems, Inc. is the the core of the BMBB/TS solution. BMBB/TS will automate transfusion services operation and provides necessary control to manage specimens, orders, and blood products, routine and electronic cross-matching. KnowledgeTrak® Learning Management System (LMS) will provide a powerful tool for compliance, learning and document management that allows facilities to closely monitor competencies of staff and control access to HCLL™ based on competency assessment. InSight® will provide innovative performance management solution that works seamlessly with HCLL™ to automate the graphical presentation and analysis of key performance metrics (i.e. operational and clinical) across the Enterprise. BMBB/TS application will manage blood component inventory levels and availability; patient and blood component compatibility testing. In comparison with DBSS, the BMBB/TS application provides an enterprise-wide transfusion service traceability solution improving the ability to lookback through the entire patient and blood product's life cycle ensuring compliance with regulatory requirements; access to blood inventory that will improve the ability to efficiently determine the status/potential enterprise needs; allow the MTFs to share blood management data to external agencies when required in support of national emergency management and enterprise-wide surveillance; and provide training to BDC and MTF Transfusion Service department users on blood management/blood banking transfusion service functionality consistent with changes as they are implemented.

Basis for Transfusion Services information collection: The initial point of collection of the patient demographics and personal health information is captured by the ordering physician and/or inpatient/outpatient clinics. As required by AABB Standards for Blood Banks and

Transfusion Services, all patients must be identified by two independent and unique identifiers. The patient's identification is not provided to the Transfusion Services department.

| Functionality | BMBB/TS | DBSS |
|---|---|---|
| Patient Registration/ Information Collected | Physician request Transfusion Request on the Standard Form (SF) 518 for a patient. The initial point of collection of the patient information (Name, Sex, Date of Birth, and FMP/SSN) is captured by the outpatient laboratory/clinic section and/or the inpatient ward. The SF 518 is provided to the Transfusion Services department for processing. Transfusion Services registers and admits the patient into the BMBB/TS to begin processing the transfusion request by ordering testing and the blood products required. | Physician request Transfusion Request on the Standard Form (SF) 518 for a patient. The initial point of collection of the patient information (Name, Sex, Date of Birth, and FMP/SSN) is captured by the outpatient laboratory/clinic section and/or the inpatient ward. The SF 518 is provided to the Transfusion Services department for processing. Transfusion Services registers the patient into DBSS and processes the transfusion request by ordering testing and the blood products required. |
| Patient and Unit Testing | Transfusion Services department conducts compatibility testing with the patient sample and blood unit. The reactions of the results (1+, 2+, and 3+ to include blood type i.e. O Positive) are recorded in the application real-time. BMBB/TS capability provides electronic crossmatching which presents eligible units for transfusion to the patient. | Transfusion Services department conducts compatibility testing and records the results on a manual log (i.e reactions). The only information that is transcribed into the application is the blood type result (i.e. O Positive). Electronic crossmatching is not a current capability of the DBSS application. |
| Learning Management System (LMS) | BMBB/TS provides an enterprise learning management system that allows documents to be uploaded and shared across multiple facilities; allows computer based training (CBT) modules, and tracks user training. | DBSS provides a training database to allow new users to be trained on the application. The training record is not enterprise and can only be accessed at each facility. |

| | | |
|---|---|---|
| Enterprise Reporting | BMBB/TS provides enterprise reporting capability via InSight® which automatically communicates with the HCLL™Application server to transmit data and convert the information into a graphical representation for upper leadership review and analysis. | Each Transfusion Services department runs a report from the DBSS application and manually transcribes the information into the Operational Data Reporting System on a monthly basis to provide, testing, shipping inventory, as well as staffing, supply, and other operational data. |

**Table 2: BMBB/TS Functionality Comparison with DBSS**

2. Use of the Information

The universe of data collection respondents will include the following:

- End User: BDC and MTF Transfusion Services staff members who could be Active Duty, Federal employees, and/or contractors.
- EBMS Product Team: Contract Support Staff and Development vendor who designed and configured the collection techniques.
- Respondents: Referred to as the donor and patient who provide their personal demographics and/or medical health information for donor collection and/or transfusion related treatment.

BDMS and BMBB/TS are both enterprise-wide AIS used to organize the management of donor, blood bank /Transfusion Services for BDCs and MTFs Transfusion Services across the Military Health System (MHS). BMBB/TS and BDMS will be used by approximately 1,200 Blood Donor Center and Transfusion Services department end users. For BDMS, the Blood Donor Center personnel will use the system for the majority of the blood donor processing tasks. The donor is presented a series of questions regarding the donor's medical history via the Uniform Donor Health Questionnaire (UDHQ) within the BDMS application.

- From collection to disposition of the blood product lifecycle: Donor (respondent) volunteers to donate blood and/or blood component
- Donor performs donor screening and collects donor demographics (name, address, SSN, date of birth, sex, phone number) and personal health information on the UDHQ.
- BDC personnel conduct the phlebotomy (i.e. collect whole blood) from the donor
- BDC conduct testing on the blood to identify blood type and infectious diseases (i.e. HIV, Hepatitis, etc.).

- If the blood unit is free from infectious diseases, the BDC personnel process the whole blood product into components (Plasma, Red Blood Cell, Platelets, etc...) If the unit test positive for infectious diseases, the unit will be quarantined and not distributed for transfusions.

- The blood components are labeled by the BDC personnel with blood type (i.e. O Positive), expiration date, and donation identification number information.

- BDCs ship the blood components to MTFs

- MTFs receive the blood products and perform unit testing to confirm the blood type and place into inventory

- Physician request transfusion of specific blood products for a patient and communicates to nurse

- Patient blood sample is collected from laboratory phlebotomy section, outpatient clinic, and/or inpatient ward.

- Blood sample and associated Transfusion Request form (Standard Form 518) which contains the patient demographic information and the physician request for blood products. This information is brought to the Transfusion Services department for processing.

- Transfusion Services department conducts verification of the patient demographics and request by reviewing the information in the Composite Health Clinical System (CHCS).

- Transfusion Services conducts the patient and blood product compatibility testing.

- Blood Product is labeled with the Unit Toe Tag that contains the recipient (patient) of the blood transfusion, blood compatibility testing results, and blood product information.

- Transfusion Services issue the blood product to the Inpatient/Outpatient nurse.

- Nurse/Physician transfuse the blood product to the patient

- Completed transfusion record is returned back to Transfusion Services for data entry and disposition of the blood product.

The main functions of the BDMS include the ability to support the full spectrum of donor screening, registration functions, and all blood manufacturing functions. Donor eligibility is determined via a standardized screening process as required by the 21 Code of Federal Regulations (CFR) §§ 610.41, 640.3, and 640.63 and the AABB (American Association of Blood Banks) Standards for Blood Banks and Transfusion Services, 29th edition. Regulations require careful screening of the donor immediately prior to the donation. The screening process employs

a comprehensive health history interview and a limited physical exam. This protects the donor by ensuring that the donation of blood does not exacerbate any preexisting medical condition in the donor. This also protects the recipient(s), patient, by minimizing the risk of transmitting infectious agents from the donor. Within the DBSS application, donor screening is performed using a manual form (DD Form 572, Blood Donation Record), that must be manually reviewed and frequently updated. In view of the ever increasing litany of questions to be included on the DD Form 572 Blood Donor Record, a manual screening process is no longer viable.

The Blood Donor Centers (BDCs) will use the BDMS application to administer an automated UDHQ to collect donor screening information and capture the donor's health history. The health history questionnaire serves as the first step in the collection process for protecting the blood supply and potential donor. The information obtained from the questionnaire is inputted into the Blood Donor Management System (BDMS). The information is used to ensure a safe blood supply for military beneficiaries during wartime, peacetime, and contingency times of operations. The information assists in reducing the risk of transfusion-transmitted infectious diseases by automatically identifying ineligible donors before their blood is collected. The use of donor's name, date of birth, address, sex, phone number, and personal health information will inextricably link patients and donors with blood products and donations. There is no interface between the BDMS and BMBB/TS application.

The main purpose of BMBB/TS is to manage Military Treatment Facility (MTF) inpatient and outpatient blood test results for transfusion compatibility. BMBB/TS will provide the following high-level functionality: Automate operations while giving MTF staff the control needed to manage specimens, orders, blood products, , and routine and electronic cross-matching. Transfusion Services personnel will collect the following personally identifiable information (PII) / protected health information (PHI) and perform data entry into the BMBB/TS application: name, other names used (Alias), address, sex, date of birth, truncated social security number (SSN), gender, race / ethnicity, and medical information. In comparison with DBSS, the physician Transfusion Request form will still be submitted on the Standard Form 518. Upon completion of the patient and blood product compatibility testing, the Unit Toe Tag is attached to the blood product which contains the results of the patient and blood product transfusion compatibility testing, blood product expiration information, special patient instructions, donation identification number, and patient and blood product blood type information. The nursing staff will verify this information with the Transfusion Services personnel before the blood product is issued to the nurse. The Transfusion Services will enter the results of the crossmatch compatibility testing within the BMBB/TS to correspond with the blood unit component. This information is printed on the unit toe tag for identification and tracking purposes.

3. Use of Information Technology

BDMS and BMBB/TS will provide a more cost effective and manageable solution that adapts to sudden changes in requirements, meets the needs of the Military Health System (MHS) community, and maintains compliance with regulatory bodies without incurring unexpected costs that must go through the acquisition process to develop and implement. BDMS and BMBB/TS applications improve the ability to look back through the entire donor blood product

and patient lifecycle, allowing the BDCs and MTFs to more consistently comply with regulatory requirements in a safe, cost effective manner.

BDMS will use the automated UDHQ as a collection method for donor eligibility and suitability and it is included in this OMB submission. During the donation, the respondent's demographics are provided to the blood donor center staff personnel for data entry into the BDMS application. The donor is allowed to access the BDMS application and presented the BDMS Disclosure Statement and Privacy Act Statement (PAS) and requested to click "ok" in agreement with the policies. The user is then presented with a series of questions depending on the specific donation type: Allogeneic (Questions 1-48); Autologous (Questions 101-114); or Therapeutic (Questions 201-206) – included in this submission. Each donor respondent is only allowed to donate one unit of blood per donation. After the donor respondent answers the questions within the application with either a Yes (positive) or No (negative) response, the blood donor center personnel insert the UDHQ form into a printer to print the results of the questionnaire. Not all screening questions will print on the UDHQ form, only questions with a 'positive' response will generate the question being printed on the form. The 'negative' responses are informational only and will be stored within the BDMS application and never will be generated on the UDHQ. The respondent is requested to review their 'positive' responses on the printed out form and provide signature of consent to move forward with the blood donation process. The respondent blood is collected and provided a resting area for 15 minutes to ensure the respondent is feeling well before leaving the donation collection facility.

BMBB/TS will use the Unit Toe Tag, included in this submission, as an output report for patient compatibility testing. The patient demographics (first/last name, date of birth, blood products requested) are provided from the hospital physicians or nursing staff to the Transfusion Services department. The patient information is verified within the Composite Health Care System (CHCS) and entered into the BMBB/TS. There is no interaction with the BMBB/TS application and patient respondents. There are no current or planned interfaces to transfer information from BDMS and BMBB/TS. All work performed in the application is conducted by the Transfusion Services personnel. Once the patient demographic information is entered into the BMBB/TS application, patient and blood product crossmatch is conducted to determine compatibility with blood product components. After testing is completed, the results are printed on the Unit Toe Tag as an output which is attached to the blood component that is issued to the nursing staff

With the implementation of BDMS, the manual paper collection DD Form 572 donor screening collection will be replaced by the automated UDHQ data collection method. In contrast with DBSS, the information collected manually had to be entered back into the DBSS application by the Blood Donor Center personnel. Since the BDMS functionality provides the ability to automate the donor screening, registration, blood product testing, and distribution of the blood product inventory, there is reduced burden on the Blood Donor Center (BDC) personnel for performing data entry.

With the implementation of BMBB/TS, the manual SF 518 Transfusion Request form will still be utilized in comparison with DBSS. The method on how the patient demographic

information is collected will still be conducted by laboratory phlebotomy department, outpatient clinic, and/or inpatient ward. In turn, the information provided to the Transfusion Services will be entered into the BMBB/TS application by department staff. There is no additional burden on the Transfusion Services personnel for performing data entry because the process is similar to the legacy system. When the interface between CHCS and BMBB/TS is deployed, the burden will be reduced because the patient information will be automatically transferred to BMBB/TS.

4. Non-duplication

BDMS donor screening process requires that during each blood donation the donor is required to be rescreened and answer the donor questionnaire each time. Therefore, the donor information collected is duplicated but it relevant and critical for the safe blood supply.

There will be a duplication of some of the patient transfusion request data collected, since the initial entry point for inpatient/outpatient transfusion related activities are collected within CHCS. CHCS is the MTFs electronic health information system that captures and stores patient demographic information, personal health information to include physician orders, patient test samples, and patient test results. The Blood Bank/Transfusion Services department personnel have to conduct manual verification of the patient demographic information from CHCS. BMBB/TS' is not the initial point of collection of information from individuals; therefore, individuals do not have the opportunity to object to the collection of their Personally Identifiable Information (PII) / Protected Health Information (PHI). The initial point of PII collection is CHCS which is collected from the phlebotomy department, inpatient ward, and/or outpatient clinics. The blood bank personnel do not have any interaction with patients. An automated interface between the CHCS and BMBB/TS application would avoid duplication of the patient information collected. The CHCS interface is planned for Fiscal Year (FY) 2016/2017 and deployed to the MTFs.

5. Burden on Small Business

There is no impact to small businesses.

6. Less Frequent Collection

Less frequent collections are anticipated after the initial input and the previous stored donor and patient can be verified in the BDMS and BMBB/TS applications. For blood donor collections, donors are required to conduct the donor screening process and update their information during each blood donor collection to ensure a safe effective blood supply is obtained from donors. For those patients requiring the administration/transfusion of blood, they will be required to update their information as needed with the transfusion request form (i.e. changes in their work or home addresses, phone numbers, marriage, etc.).

7. Paperwork Reduction Act Guidelines

There are no special circumstances related to this collection.

8. Consultation and Public Comments

a. The 60-day Federal Register Notice for this collection of information was published on November 29, 2012, Vol. 77 No. 230, page, 71,713. No public comments were received.

The delay in getting the package submitted to OMB past the 12month time limit of the 60-day FRN is due primarily to the preparation of the web-based application, however, the contents of the Information Collection have not changed since the closing of the public comment and the time the package was submitted for OMB review. No public comments were received in response to either the 60-day FRN or the 30-day FRN.

The 30-day FRN Federal Register Notice was published on April 18, 2014, Vol 79. No. 75, page 21,902.

b. Weekly meetings are held with each respective Service Blood Program Service Blood Program Offices to consult with the service functional representatives on the validity of the requirements to collect information and the frequency of the collection. In addition, Joint Configuration Working Group (JCWG) is conducted with the Air Force, Army, and Navy functional representatives and the Information Management representatives to review current requirements, federal regulations, and industry standards.

9. Gifts or Payment

There was no payment or gifts provided to the respondents.

10. Confidentiality

The donor and patient information stored in the BDMS and BMBB/TS applications contain sensitive information; therefore, it contains built-in safeguards to limit access and visibility of Personally identifiable information (PII) and Personal health information (PHI). EBMS uses role-based security, so a user can only view the information for which permission has been granted by the BDC and Blood Bank Department Site Supervisor. Both system applications, BDMS and BMBB/TS, have been Defense Health Agency (DHA) certified and accredited (C&A) and passed thorough security testing and evaluation by Defense Health Clinical Systems (DHCS) Information Assurance and DHA Cybersecurity Division. It meets safeguards specified by the Privacy Act of 1974 in that it maintains a published Department of Defense (DoD) Privacy Impact Assessment (PIA) and System of Record Notice (SORN) covering Active Duty Military, Reserve, National Guard, and government civilian employees, to include non-appropriated fund employees, foreign nationals, DoD contractors, and volunteers. EBMS is hosted in a secure facility managed by the MHS Enterprise Operations Center (MESOC) datacenter in San Antonio, TX and Aurora, CO. As a blood management automated system, BDMS and BMBB/TS will collect and store PHI/PII. Although BDMS and BMBB/TS issues each donor and patient a distinctive medical record number, continued collection of the SSN is required donor eligibility and suitability for successful continuity of operations within

DoD and interoperability with federal organizations external to DoD. As the DoD and other federal organizations migrate from the use of the SSN as a primary means of identification in accordance with executive guidelines, BDMS and BMBB/TS will reduce usage. Protection of personally identifiable information (PII) is required by federal statues and policy and DoD guidelines and regulations.

EDHA 25 DoD, entitled "Enterprise Blood Management System (EBMS)" is assigned for the BDMS and BMBB/TS applications.

http://dpclo.defense.gov/Privacy/SORNsIndex/tabid/5915/Article/9995/edha-25-dod.aspx

In accordance with DoDI 5400.16, DoD Privacy Impact Assessment (PIA) Guidance, Sections 1 and 2 of the most current BDMS and BMBB/TS PIAs are posted to the Defense Health Agency (DHA) Privacy Office web site and the links are provided below as well:

http://www.tricare.mil/tma/privacy/PIA-summary.aspx.

BDMS: http://www.tricare.mil/tma/privacy/downloads/Blood%20Donor%20Management%20System%20(BDMS)%20Privacy%20Impact%20Assesment%20(PIA)_2011%2005%2017_Sections%201%20and%202.pdf

BMBB/TS:

http://www.tricare.mil/tma/privacy/downloads/Blood%20Management%20Blood%20Bank%20Transfusion%20System%20(BMBB-TS)%20Privacy%20Impact%20Assessment%20(PIA)_2011%2012%2002_Sections%201%20and%202.pdf

11. Sensitive Questions

Personally identifiable information collected by the system includes the following: Name, Social Security Number (SSN), Sponsor's SSN, date of birth, age, gender, ethnic origin, address, phone number, and personal health information. The donor screening information collection is voluntary and the donor has to provide their personal information to complete the blood donation. If the donor objects to completing the donor screening process, the donor would be ineligible for that specific donation but each time the donor volunteers to donate a new donor screen is conducted. The Transfusion Request data collection is mandatory for the patient to be transfused blood and/or blood components in order to ensure traceability of the blood product through disposition.

12. Respondent Burden, and its Labor Costs

a. Estimation of Respondent Burden

EBMS Product Team estimates an average hourly respondent labor cost of $21.73 for blood donor volunteers and $ 22.99 for Medical Laboratory Technicians/Blood Donor Center

personnel. To arrive at these estimates, the EBMS Product Team referenced the median wage earnings from the Bureau of Labor and Statistics annual 2013 wages report.

**Table 3: Annual Respondent Burden and Cost**

| Information Collection Activity | Respondent | End User Tech | Labor Cost/ Respondent | Capital/ Startup | O&M | Total No. of Respondents | Total Hrs/Yr |
|---|---|---|---|---|---|---|---|
| Donor Registration/Interview | 0.10 | 0.10 | $2.17/$2.30 | N/A | N/A | 1200 | 240 |
| Donor will read the questionnaire instructions | 0.05 | 0.00 | $1.09 | N/A | N/A | 1600 | 80 |
| Donor Response to Uniform Donor Health Questionnaire (UDHQ) | 0.10 | 0.00 | $2.17 | N/A | N/A | 1600 | 160 |
| Complete Donor Interview to review UDHQ responses | 0.05 | 0.05 | $1.09/$1.15 | N/A | N/A | 1200 | 120 |
| Perform data entry | 0.00 | 0.10 | $2.30 | N/A | N/A | 1200 | 120 |
| Print the questionnaire and donor signs the form | 0.02 | 0.02 | $0.44/$0.46 | N/A | N/A | 1200 | 48 |
| **Total** | **0.32** | **0.27** | **Varies** | **N/A** | **N/A** | **Varies** | **766** |

EBMS Product Team estimates that BDCs and MTFs complying with FDA 21 Code of Federal Regulations (CFR) and AABB standards for donor screening and processing transfusion related request will incur annual labor costs associated with the EBMS information collection activities. EBMS estimates that to interview donors for registration, review donor questionnaire responses, and processing the transfusion related request information collected for data entry into the BDMS and BMBB/TS applications. Using the total burden hours estimated below, Table 3 illustrates the respondent costs associated with all of the information collection activities covered in this ICR. As shown in Table 3, EBMS Product Team estimates that the total annual respondent burden for all activities covered in this ICR is approximately 766 hours, at an annual cost of $1402.80

b. Labor Cost of Respondent Burden

The Bureau of Labor Statistics (BLS) annual hourly wages from May 2013was reviewed and analyzed to obtain the average median hourly range for the blood donors who are mainly Active duty personnel, dependent beneficiaries and/or civilians and the medical laboratory technicians/Blood donor center personnel processing information collected to estimate the labor cost of the respondent burden. That hourly rate was determined to be $21.73. Table 3 illustrates the respondent's labor cost with regard to the information collection activity.

13. Respondent Costs Other Than Burden Hour Costs

a. Beyond the labor cost for the Respondent's time, there is no additional operational start up or maintenance costs.

14. Cost to the Federal Government

EBMS Product Team estimates an average hourly respondent labor cost of $22.99 for medical laboratory technologist/technicians and $38.31 for EBMS Product Team Computer System Analyst support staff. To arrive at these estimates, the EBMS Product Team referenced the median wage earnings from the Bureau of Labor and Statistics annual 2013 wages report.

EBMS Product Team estimates that the EBMS Product Team complying with FDA 21 Code of Federal Regulations (CFR) and AABB standards will incur annual labor costs associated with development of the collection techniques, specific information collection activities such as configuring the collection technique into the BDMS application, and the functional end users verifying the regulatory requirements in the questionnaire have been implemented correctly. Using the total burden hours estimated below, Table 4 illustrates the Federal Government costs associated with all of the information collection activities covered in this ICR. As shown in Table 4, EBMS Product Team estimates that the total annual Federal Government burden for all activities covered in this ICR is approximately 3410 hours, at an annual cost of $118.228. To arrive at these estimates, EBMS Product Team consulted with Blood Donor Center and Transfusion Services end users of the regulated community to include the EBMS Product Line Manager.

**Table 4: Federal Government Labor and Cost Burden**

| Information Collection Activity | Contractor Support | Medical Lab Tech | Labor Cost/ Respondent | Capital/ Startup | O&M | Total No. of Respondents | Total Hours/ Yr |
|---|---|---|---|---|---|---|---|
| Develop questionnaire | 320.0 | 0.00 | $0.00 | $38.31 | N/A | 3 | 960 |
| Conduct Demo of questionnaire to End Users | 8.0 | 8.0 | $22.99 | N/A | $38.31 | 20 | 320 |
| Provide additional questions | 0.00 | 5.0 | $22.99 | N/A | N/A | 5 | 250 |
| Perform Fix cycle and correct defects in questionnaire | 240.0 | 0.00 | $0.00 | N/A | $38.31 | 3 | 720 |
| Review revised | 40.0 | 40.0 | $22.99 | N/A | $38.31 | 10 | 800 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| questionnaire | | | | | | | |
| Configure the questionnaire into the BDMS application | 160.0 | 0.00 | $0.00 | N/A | $38.31 | 5 | 360 |
| **Total** | **768.00** | **53.00** | **Varies** | $38.31 | $38.31 | **Varies** | **3410** |

15. Reasons for Change in Burden

This is a program change due to a new collection for the BDMS and BMBB/TS applications. The new applications will only require the BDC and MTF Transfusion Services personnel to perform data entry into the BDMS and BMBB/TS.

In comparison with the DBSS application; there will be a decrease in the labor burden due to the discontinuation of performing manual data entry and inputting the information collection into the BDMS and BMBB/TS applications. For BDMS, donor/donation test results are recorded in DBSS by manual data entry which is time consuming and tedious task for the end user which can result in an increase of data entry error. With the new BDMS system, there is an automated upload feature for end users to upload donor/donation test results into BDMS with minimal steps to initiate this process.

16. Publication of Results

This collection does not use any statistical methods, nor will results of any type be published.

17. Non-Display of OMB Expiration Date

This submission is not seeking an exception to displaying the expiration date of this information collection.

18. Exceptions to "Certification for Paperwork Reduction Submissions"

There are no exceptions to the certification statement.