Department of Veterans Affairs **VHA DIRECTIVE 2007-038**
Veterans Health Administration
Washington, DC 20420 **November 8, 2007**

VBECS BLOOD BANK SOFTWARE

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines policy mandating the use of the Veterans Health Information Systems and Technology Architecture (VistA) Blood Establishment Computer Software (VBECS), also known as the VBECS Blood Bank module.

2. BACKGROUND

a. In 1994, the Food and Drug Administration (FDA) published a notice in the Federal Register indicating that blood bank software was considered a medical device and was, therefore, subject to the portion of the Code of Federal Regulations devoted to medical devices, i.e., Part 800, as well as to good manufacturing practices and other FDA guidelines.

b. The VBECS Blood Bank module is registered with the FDA as a medical device in accordance with the 1976, 1990, and 1992 Medical Device amendments to the Federal Food, Drug and Cosmetic Act (Public Law 75-717), and provides guidance to VHA Information Resources Management (IRM) staff regarding local modifications. The FDA Letter of Substantial Equivalence, dated October 19, 2006, requires stringent change control procedures for the Blood Bank software. ***NOTE:*** *Legacy VistA Blood Bank v5.2 software continues to provide historical data and will be administered as a medical device.*

c. The blood bank software provides significant design safeguards for safety-critical requirements related to the safety, purity, and potency of blood and a blood component transfused in VHA facilities and, therefore, is subject to strict change control procedures. Those components of a national package (routines, data dictionaries, etc.) that implement a controlled procedure, contain controlled or strictly defined interface, or report data to a database external to the local facility must not be altered.

d. The FDA considers software that has been modified locally to be a different medical device from the one submitted by VHA. The FDA could have the facility cease using the software because it is a medical device that has not been registered with the FDA. Additionally, VHA, as a manufacturer of a medical device, is required to maintain control of the composition of its device, and could be cited for failure to maintain control of the software.

b. The VHA Chief Information Officer (CIO) coordinates with the Department of Veterans Affairs (VA) Office of Information and Technology, CIO, which developed the VBECS software, in:

(1) Performing checks and system monitoring audits.

(2) Providing the National Director, Pathology and Laboratory Medicine Services, with a list of VHA facilities that are not running the prescribed version of the VBECS Blood Bank software.

(3) Identifying those components of the national Blood Bank packages (VBECS and VistA v5.2) that are impacted by this Directive (see Att. A).

(4) Evaluating all changes to the defined software to determine the impact of the change on the intended uses, the safety-critical requirements, the functional requirements, and the software requirement specifications of the VBECS and/or those of any subsequently released versions.

(5) Distributing any changes to the VBECS software.

3. POLICY: It is VHA policy that all VHA blood banks and/or transfusion services must use the VBECS Blood Bank software, inclusive of all applicable patches.

4. ACTION: Each Veterans Integrated Service Network (VISN) Director is required to ensure that all medical facilities that have a blood bank and/or transfusion service are using the VBECS Blood Bank software with all current patches installed and are not using VBECS Blood Bank software that contains any local modification or any modification not officially released by the VACIO.

5. REFERENCES

a. Public Law 75-717, and the 1976, 1990, and 1992 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

b. Title 21 United States Code, Section 360.

c. American Association of Blood Banks (AABB) 24th edition Standards for Blood Banks and Transfusion Services

d. VBECS Users Manual.

e. VHA Handbook 1106.1, Pathology and Laboratory Medicine Service Procedures.

6. FOLLOW-UP RESPONSIBILITY: The Chief Information Officer (19) and the National Director, Pathology and Laboratory Medicine Services (115) are responsible for the contents of this Directive. Questions regarding interfacing equipment with the Blood Bank software, developing ad hoc reports, modifying current reports, etc., should be referred to the Compliance Officer, Diagnostic Services SHG (115), VHA Central Office at 202-273-8420; other inquiries . may be addressed to 1-888-596-4357.

7. RESCISSIONS: None. This VHA Directive expires on November 30, 2012.

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Attachment

DISTRIBUTION: CO: E-mailed 11/9/07
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ATTACHMENT A

VETERANS HEALTH INFORMATION SYSTEMS AND TECHNOLOGY ARCHITECTURE (VISTA) COMPONENTS CONTAINING CONTROLLED SOFTWARE

1. Routines must have a statement embedded in the form of a comment that states that the routine contains controlled software, is subject to stringent change control procedures, and is not to be modified. A similar comment must be included in the file description for files subject to this policy.

2. For routines and files in Group A, modifications are not to be made to the Blood Bank software (Veterans Health Information Systems and Technology Architecture (VistA) Blood Establishment Computer Software (VBECS) (also known as the VBECS Blood Bank module) or VistA v5.2) except under the control of the Department of Veterans Affairs (VA) Office of Information and Technology, Chief Information Officer (VACIO), as change control is critical to the Food and Drug Administration (FDA) good manufacturing requirements to which the software development process must adhere.

3. GROUP A

a. **All options in the LRBL namespace**

b. **All routines in the LRBL namespace**

c. **Routines in the LRU namespace**

LRUB	LRUC	LRUCN
LRUD	LRUDIT	LRUG
LRUL	LRUMSG	LRUT
LRUTL		

d. All routines in the VBEC namespace.

e. **Files**

(1) Agglutination Strength (#62.55)

(2) Blood Inventory (#65)

(3) Blood Bank Utility (#65.4)

(4) Blood Donor (#65.5)

(5) Blood Product (#66)

(6) Blood Validation (#66.2)

(7) Operation (Maximum Surgical Blood Order Schedule (MSBOS) (#66.5))

(8) Blood Component (#66.9)

(9) All files in the 6000 through 6010 file number range.

(10) All VBEC name spaced entries in the PROTOCOL file (#101)

(11) All VBEC name spaced entries in the LOGICAL LINKS file (#870)

(12) All VBEC name spaced entries in the PARAMETERS file (#8989.5)

(13) All VBEC name spaced entries in the HL7 APPLICATION PARAMETER (# 771)

4. GROUP B. ***NOTE:*** *The majority of the routines on the "B" list are included because they relate to a patient specimen; evaluation of the acceptability of a patient specimen is a critical safety requirement and many design safeguards exist.*

a. **Routines in the LR Namespace**

LR7OB63	LR7OB630	LR7OFB0	LR7OR1
LR7OSBB1	LR7OSBR	LR7OSBR1	LR7OSUM
LR7OV3	LRAPS3	LRCENDEL	LRCKF
LRDPA	LRDPA1	LRDPA2	LROS
LRTSTJAM	LRTSTJAN	LRTSTOUT	LRU
LRUA	LRUFILE	LRUPA	LRUPACA
LRUPACT	LRUPT	LRUTW	LRUW
LRUWG	LRUWK	LRUWL	LRX
LRXREF1			

b. **Files**

(1) **Laboratory Test** (#60)

(2) **Function Field** (#61.3)

(3) **Collection Sample** (#62)

(4) **Execute Code** (#62.07)

(5) **Laboratory Data** (#63)

(6) **Laboratory Letter** (#65.9)

(7) **Accession** (#68)

(8) **Laboratory Section Print** (#69.2)

(9) **Laboratory Site** (#69.9)

NOTE: *Changes cannot be made without a formal evaluation to determine the potential impact on safety-critical requirements and to provide appropriate change control when indicated. Changes can only be made to the Blood Bank software under the control of the Department of Veterans Affairs (VA) Office of Information and Technology.*