

October 14, 2004

SOFTWARE FOR VISTA BLOOD BANK

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines responsibilities associated with the Veterans Health Information Systems and Technology Architecture (VistA) Blood Bank Software v5.2.

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 subject to good manufacturing practices and other FDA guidelines.

b. The VistA Blood Bank Software v5.2, also known as the Blood Bank module of the Decentralized Hospital Computer Program (DHCP) Laboratory package, has been 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). The FDA Letter of Substantial Equivalence, dated April 23, 1999, requires stringent change control procedures for the blood bank software.

c. The FDA considers software that has been modified locally to be a different medical device from the one submitted by VHA for 510(k) approval. 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 VHA could be cited by the FDA for failure to maintain control of the software.

d. The VistA blood bank software provides significant design safeguards for critical requirements related to the safety, purity and potency of blood and blood components drawn and/or 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 a controlled or strictly defined interface, or report data to a database external to the local facility, must not be altered except by the Office of Information Chief Health Information Officer (CHIO). The CHIO has identified all of those components of the national Laboratory package which are impacted by this policy (see Attachment A).

3. POLICY: It is VHA policy that all facilities must adhere to the stringent procedures regarding the use of blood bank software.

THIS VHA DIRECTIVE EXPIRES OCTOBER 31, 2009

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4. ACTION

a. **Veterans Integrated Service Network (VISN) Directors and Medical Center Directors.** VISN Directors and Medical Center Directors are required to ensure that all medical facilities that have a blood bank and/or transfusion service:

(1) Are using use the Blood Bank Module of the laboratory package of VistA. The current version of the blood bank software is VistA v5.2 (inclusive of all applicable LR*5.2 patches).

(2) Are not using the VistA blood bank software that contains any local modifications or any changes or enhancements not officially released or approved by CHIO.

b. **CHIO.** The CHIO, is responsible for:

(1) The development, enhancement, and modification of this software.

(2) Routinely performing checksums audit and providing the National Director, Pathology and Laboratory Medicine Services (P&LMS), with a list of VHA facilities that are not running the prescribed version of the VistA blood bank software.

(3) Providing guidance to VHA Information Resources Management (IRM) staff regarding local modifications to the software defined in Attachment A.

(4) Evaluating all changes to this defined software to determine the impact of the change on the intended use, the safety-critical requirements, the functional requirements, and the software specifications requirements of the VistA Blood Bank Software v5.2. **NOTE:** *Only the CHIO makes or distributes changes to the blood bank software.*

(5) Ensuring routines have a statement embedded in the form of a comment which states that the routine contains controlled software, is subject to stringent change control procedures, and is not to be modified. **NOTE:** *A similar comment must be included in the file description for files that are subject to this policy.*

(6) Thoroughly evaluating, assessing the risk to the blood bank application, and testing prior to deployment of any changes to any of modules and/or files listed in Attachment A. Changes must be coordinated with the blood bank software development team prior to implementation.

5. REFERENCES

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

b. Title 21 United States Code, Section 360.

c. FDA, Center for Biologics Evaluation and Research. "Reviewer Guidance for Premarket Notification Submission for Blood Establishment Computer Software," January 13, 1997.

d. Blood Bank Users Manual, VistA Blood Bank software, V. 5.2.

6. FOLLOW-UP RESPONSIBILITY: The Chief Health Information Officer (19) and the National Director, Pathology and Laboratory Medicine Service (115), are responsible for the content of this Directive. Questions regarding interfacing equipment with the blood bank software, developing ad hoc reports, modifying current reports, etc., need to be referred to the VistA Blood Bank Software Compliance Officer, Diagnostic Services SHG (115), VHA Central Office, at 202-273-8420.

7. RESCISSIONS: VHA Directive 99-053 is rescinded. This VHA Directive expires on October 31, 2009.

S/ Arthur S. Hamerschlag for
Jonathan B. Perlin, MD, PhD, MSHA, FACP
Acting Under Secretary for Health

Attachment

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ATTACHMENT A

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

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 Chief Health Information Officer.

1. 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. 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** (MSBOS) (#66.5).
- (8) **Blood Component** (#66.9).

2. 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.*

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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) **Lab Letter (#65.9).**
- (7) **Accession (#68).**
- (8) **Lab Section Print (#69.2).**
- (9) **Laboratory Site (#69.9).**