

November 10, 1999

## VISTA BLOOD BANK SOFTWARE

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive informs facilities that the Veterans Health Information Systems and Technology Architecture (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 Food and Drug Administration (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 to provide guidance to VHA Information Resources Management (IRM) staff regarding local modifications. The FDA Letter of Substantial Equivalence, dated April 23, 1999, requires stringent change control procedures for the blood bank software.

**2. BACKGROUND:** In 1994, 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.

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

a. The blood bank software provides significant design safeguards for safety 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, contains 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 the Chief Information Officer (OCIO).

b. All VHA blood banks and/or transfusion services must use the Blood Bank Module or the laboratory package of VISTA. VISTA v 5.2 inclusive of patches LR\*5.2\*72, 90, 92, 139,147, 194, 203 and 212 is the current version of the blood bank software that will be used by all blood banks and/or transfusion services.

c. All changes to this defined software must be thoroughly evaluated to determine the impact of the change on the intended uses, the safety critical requirements, the functional requirements and the software requirements specifications of the VISTA Blood Bank Software V5.2. Any changes to the blood bank software will be distributed by the OCIO.

d. According to the FDA, if a facility makes local modifications in the blood bank software and intends to further distribute those modifications, that site must register as a device manufacturer and must provide a separate 510(k) for that version of the software. Therefore,

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facilities will not use local modifications to the VISTA blood bank software regardless of when these modifications were made.

e. The FDA will consider software that has been modified locally to be a different medical device from the one submitted by VHA. Therefore, at the time of inspection, the FDA could have the facility cease using the software because it is a medical device that has not been registered with the FDA. In addition, because VHA, as a manufacturer of a medical device, is required to maintain control of the composition of its device, VHA could be cited by the FDA for failure to maintain control of the software.

### **4. ACTION**

a. Veterans Integrated Service Network (VISN) Directors and VA medical center Directors are required to ensure that all medical facilities that have a blood bank and/or transfusion service are using the VISTA blood bank software v 5.2 with patches LR\*5.2\*72, 90, 92, 139,147, 194, 203 and 212.

b. VISN Directors and VA medical center Directors are required to ensure that all medical facilities that have a blood bank and/or transfusion service are not using the VISTA blood bank software that contains any local or any modification not officially released by OCIO modifications.

c. The OCIO, which is responsible for the development of this software, will perform a checksums audit and will provide the Chief Consultant, Diagnostic Services Strategic Health Group (SHG), with a list of VHA facilities that are not running the prescribed version of the VISTA blood bank software.

d. The OCIO has identified all of those components of the national Laboratory package which are impacted by this policy. Attachment A provides this listing. Routines shall 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 should not be modified. A similar comment must be included in the file description for files which are subject to this policy.

e. For routines and files in Group A of the listing in Attachment A, local modifications are not to be made to the VISTA Blood Bank Software V5.2 except under the control of the Development OCIO as change control is critical to the FDA good manufacturing requirements to which the software development process must adhere. Questions regarding interfacing equipment with the blood bank software, developing ad hoc reports, modifying current reports, etc., should be referred to the VISTA Blood Bank Software Compliance Officer, Diagnostic Services SHG (115), VHA Headquarters.

### **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. Draft Reviewer Guidance for Premarket Notification Submission for Blood Establishment Computer Software, April 1996.

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

**6. FOLLOW-UP RESPONSIBILITY:** The Chief Information Officer (19) and the Chief, Diagnostic Services SHG (115) are responsible for the content of this Directive.

**7. RESCISSIONS:** This VHA Directive expires on November 30, 2004.

S/ by Frances Murphy, M.D. for  
Thomas L. Garthwaite, M.D.  
Acting Under Secretary for Health

Attachment

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ATTACHMENT A

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

1. **GROUP A.** Changes should not be made to the Blood Bank software except under the control of the Development Chief Information Officer Field Office.

- a. All options in the LRBL namespace
- b. All routines in the LRBL namespace
- c. Routines in the LRU namespace

LRUB	LRUD	LRUL	LRUT
LRUCN	LRUDIT		LRUMSG

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.** 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.

*NOTE: The majority of the routines on the B list have been included because they relate to a patient specimen and 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**

LRCENDEL	LRU	LRUPA	LRUTW
LROS	LRUA	LRUPACA	LRUW
LRTSTJAM	LRUC	LRUPACT	LRUWG
LRTSTJAN	LRUFILE	LRUPT	LRUWK
LRTSTOUT	LRUG	LRUTL	LRUWL

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)**