APPENDIX – E UPDATED MARCH 2001

BLOOD BANK USER MANUAL
CHANGE CONTROL PROCEDURES

VALIDATION GUIDELINES

BLOOD BANK SOFTWARE FREQUENTLY ASKED QUESTIONS

PLEASE NOTE:

This updated Laboratory V 5.2 Blood Bank User Manual Appendix E is intended to REPLACE the previously published Lab Multidivisional Patch LR*5.2*72 Blood Bank User Manual Appendix E dated JULY 1996

The purpose of this document is to both provide guidance for sites to establish a total validation testing plan of the VistA Blood Bank Software v 5.2 and also give guidance when re-validation needs to occur—such as when patches to the software are issued, changes are made in site-definable fields in specific files that can affect functionality within the Blood Bank and/or new entries are created in the BLOOD PRODUCT File (#66)

Also included at the end of this appendix is a Frequently Asked Questions (FAQ) section. Within this section are questions and answers to many commonly asked questions about the VistA Blood Bank Software v 5.2.

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Change Control for Blood Bank Files

Purpose

To provide a mechanism for controlling changes made to files which have control over the functionality of the blood bank software. This includes:

- FUNCTION FIELD file (#61.3)
- BLOOD BANK UTILITY file (#65.4)
- BLOOD PRODUCT file (#66)
- LABORATORY SITE file (#69.9)

Once the initial system validation is performed and the software has been implemented in production, file changes may be necessary for a variety of reasons. Some of these include:

- VistA software patch/new versions
- Change in standard operating procedure
- Addition of new blood products to BLOOD PRODUCT file (#66)
- Addition of new supplier to an existing blood product in BLOOD PRODUCT file (#66)
- Change in characteristic/property for supplier information for blood product in BLOOD PRODUCT file (#66), e.g. cost
- Change in donor history questions in BLOOD BANK UTILITY file (#65.4)

In order to ensure appropriate process control for file changes, a series of request forms are provided. At the end of each form is an area entitled Change Control Summary which should be used for documentation.

For each file, a table is also included which details the validation requirements for file changes.

Policies

1. In general, file changes are requested and made by the Blood Bank supervisory staff who have the required security access; however, if specific changes are needed for fields which do not have software control, these changes can be made by the Laboratory Information Manager if necessary. For example, units of blood/blood components might be received from a supplier not previously entered for that particular component. Since the units cannot be logged in until this is resolved, the changes should be made and documented using the designated form. A few changes require a higher level of security and file access. These are specifically noted on the request forms.

2. Editing of the blood bank files should always be done using the appropriate blood bank options, unless otherwise designated. These options are locked with a specific key to provide an additional level of security. Access to these options is controlled both by Kernel security, which requires the appropriate security key, and by menu management which controls access to the menu options.

3. Impact analysis is part of documenting the change control process. This involves studying/assessing the system to determine the impact of the change. This might include effects on related functionality or system output. The information provided in the tables for each file indicates the purpose of the field and options/functionality which are affected by that specific field. Additional details are also provided is the Blood Bank User Manual for the specific option referenced. According to the AABB guidelines, "Changes may not be made until the impact or risk to the system has been evaluated, a controlled process has been executed, the results have been obtained and analyzed, and the output has been found acceptable." This analysis can be documented on the series of forms provided entitled "Requests for File Changes.." Areas have been provided on these forms to assess and document training, procedure revisions and validation outcomes.

4. Validation is required when changes are made in the files which perform some type of software control function. Once the system validation has been completed, each change made to the file needs to be evaluated to determine whether the change requires validation. This should be done on a field by field basis using the tables of validation requirements included on for each file.

    a. In some cases, the changes are cosmetic and are only being made to fields which involve a characteristic/property change. In these cases, the change must be documented; however, the extent of validation can be limited to an assessment of whether the change is reflected in the software function. For example, the addition of a new supplier to the BLOOD PRODUCT FILE (#66) only requires that the supplier be available as a choice in the "Log-in regular (invoices) [LRBLILR]" option.
    This can be documented using the forms included in this procedure which include the date the change was made, the person making the change and the fact that the test case yielded acceptable results.

    b. In other cases, the change will involve a field which performs some type of software control. In these case, it is necessary to perform sufficient validation to be able to conclude that the product to which the change is being is substantially equivalent to one which has already undergone validation. For example, if a decision has been made to no longer allow a specific blood product to be requested because of a policy change and another blood product already exists in the BLOOD PRODUCT file (#66) which has the CAN BE REQUESTED field set to NO and this has already been validated, the extent of validation for the change can be limited to an assessment of whether the change is reflected in the software function. For example, that particular product should no longer be accessible using the "Blood component requests [LRBLPCS]" option in the Patient [LRBLP] menu. This can be documented using the forms included in this procedure

which include the date the change was made, the person making the change and the fact that the test case yielded acceptable results.

c. When new products are added to the file, it is necessary to document that the new entry functions as intended. Validation cases need to be developed which include the areas which require validation when changes are made.
d. For tracking purposes, the results of validation performed for file changes should be entered into the BLOOD BANK VALIDATION file (#66.2) using the Blood Bank Software Validation Documentation [LRBLVAL] option in the Supervisor [LRBLS] menu.

5. Communication of the change will vary based on the impact analysis. In some cases, training will be required, as will revisions in standard operating procedures (SOP). In other cases, training and/or SOP changes will not be necessary; however, the personnel who may be performing a particular task may need to be informed of the change and an electronic mail message may be adequate. In still other cases, such as the addition of a new supplier to an existing blood product, communication is probably unnecessary as the software either accepts or rejects the choice and on-line help allows display of all available choices.

6. Printouts of the files should be requested once the changes have been made to ensure that the entries are accurate and that all changes have been adequately documented. The Laboratory Information Manager can generate these printouts upon request.

7. At a minimum, the change control records should include:

    a. a description of the change,
    b. the date of the change,
    c. the person making the change,
    d. equipment or other functions that are affected by the change,
    e. an authorization signature,
    f. the validation risk assessment, and
    g. the documentation of approval and acceptance.

Procedure

A. Planning

1. VistA Patch/Version Update

a. Review the information provided with the patch/new version to determine the scope of the changes.
b. Determine the potential impact of this specific change on your individual division/ facility.
c. Determine what the training needs are, i.e., who will require training and what type of training is necessary.
d. Have the patch/new version loaded in a mirrored test account so that the functionality and the impact of the patch can be assessed.
e. Coordinate the training needs, the validation and the implementation of the patch/new version so that it has the least amount of impact on normal operations of the facility.

2. Addition of new products to the BLOOD PRODUCT file (#66)

a. Complete the form entitled "Request for File Changes to the BLOOD PRODUCT file (#66)". Indicate the information to be entered for each field.
b. Make the necessary changes in the procedure manual and any other places that listings of the products are detailed.

3. Changes to existing entries in BLOOD PRODUCT file (#66)

Complete the form entitled "Request for File Changes to the BLOOD PRODUCT file (#66)". Indicate the information to be entered for each field.

Examples:

- addition of new supplier to existing blood product
- change in the cost in the supplier information for a blood product

4. Changes to existing entries in FUNCTION FIELD file (#61.3)

Complete the form entitled "Request for File Changes to the FUNCTION FIELD file (#61.3)". Indicate the information to be added or changed for each field.

Examples:

- Change in the clinical significance of antibody, i.e. requiring units to be typed and antigen negative for corresponding antigen
- Change in wording of the information on the Blood Bank Consultation Report
- Addition of new journal reference to the Blood Bank Consultation Report

5. Changes to existing entries in BLOOD BANK UTILITY file (# 65.4)

a. If the changes do not involve donor history questions or the blood donor consent, complete the form entitled "Request for File Changes to the BLOOD BANK UTILITY file (#65.4)". Indicate the information to be entered for each field.
b. If the change involves donor history questions, complete the form entitled "Request for File Changes to the BLOOD BANK UTILITY file (#65.4)-DONOR HISTORY QUESTIONS." Indicate the information to be entered/changed.
c. If the change involves the donor consent, complete the form entitled "Request for File Changes to the BLOOD BANK UTILITY file (#65.4)-DONOR CONSENT." Indicate the information to be entered/changed.

Examples:

- Change in donor reaction code
- Change in donor history questions
- Change in the wording of the donor consent

6. Changes to existing entries in LABORATORY SITE file (#69.9)

Complete the form entitled "Request for File Changes to the LABORATORY SITE file (#69.9)". Indicate the information to be added or changed for each field.

Examples:

- Exclusion of the fields for direct antiglobulin testing in the LRBLSCREEN template used to enter Type and screen test results
- Elimination of the requirement to include ALT testing on blood donors

B. Training

Training can be accomplished in a variety of manners and should be tailored to the scope and application of the file change. In some cases, the change may be transparent to the user and no training may be required. In other cases, the change may be transparent to the user, but may involve changes in control functions of which the user needs to be cognizant and communication of the change via a mail message may be sufficient. In still other cases, the user may encounter changes in functionality for which hands-on training might be appropriate in conjunction with some type of competency assessment.

1. VistA Patch/Version Update

Training needs will vary based on the scope of the patch and will need to be determined on a patch by patch basis.

2. Addition of new products to the BLOOD PRODUCT file (#66)

No specific computer training is necessary for additions to the BLOOD PRODUCT file (#66) unless:

a. there are changes in processes or in standard operating procedures which might be associated with these file changes may require training, or
b. the entries for the new product involve software control for which training has not previously been provided.
c. the site is initially defining new blood products that are being labeled using the ISBT 128 system.

3. Changes to existing entries in BLOOD PRODUCT file (#66)

a. No specific computer training is necessary for additions of new suppliers to an existing blood product in File (#66).
b. Change in fields which do not involve software control require no specific computer training. For example, changes in the cost subfield for supplier information represents a characteristic/property which does not require training.

4. Changes to existing entries in BLOOD BANK UTILITY file (#65.4)

No specific computer training is necessary for additions to the BLOOD BANK UTILITY file (#65.4) unless:

a. there are changes in processes or in standard operating procedures which might be associated with these file changes may require training, such as changes in donor history questions, or
b. the entries for the new entry involve software control for which training has not previously been provided.

5. Changes to existing entries in FUNCTION FIELD file (#61.3)

No specific computer training is necessary for additions to an existing BLOOD GROUP ANTIGEN or BLOOD GROUP ANTIBODY in File 61.3.

6. Changes to existing entries in the LABORATORY SITE file (#69.9)

Specific computer training is probably necessary for the majority of changes in this file, if not all, will also involve a change in standard operating procedures.

C. Implementation

1. VistA Patch/Version Update

Proceed as indicated in the information provided with the patch when it is released. In some cases which involve complex patches, extended documentation will be provided in the form of Release Notes and Implementation Guide. Although suggested validation scenarios are exported along with each Patch/Version Update, sites are encouraged to be creative and develop any additional scenarios to fully test the software at their site. The validation test plan must reflect the actual procedures and workflow of the individual VA Medical Center. Suggested validation scenarios exported along with a patch assume that a site has previously performed full validation of the software. The suggested scenarios exported along with a patch are in actuality re-validation scenarios designed to verify that changes exported in the patch have not had any adverse affect on blood bank functionality.

2. Addition/Changes to the BLOOD PRODUCT file (#66)

a. Use the Edit blood products file [LRBLSEB] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.
b. Once the changes have been completed, request a full printout of the BLOOD PRODUCT file (#66) to ensure that the entries are accurate and that all changes have been adequately documented.
c. Communicate the changes to all personnel directly or indirectly affected by the change IF the change involves knowledge needed to perform their assigned duties. If training is not required, but information needs to be disseminated, use of electronic mail is the method of choice whenever possible as this provides a built-in tracking mechanism to document whether the recipient has received/read the information.

3. Changes to existing entries in BLOOD BANK UTILITY file (#65.4)

a. Use the Edit blood bank utility [LRBLSEU] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.
b. If editing is limited to changes in field 2 DONOR HISTORY, use the Edit donor history questions [LRBLSEH] option in the Blood donor edit options [LRBLSD] submenu of the Supervisor [LRBLS] menu.
c. If editing is limited to changes in field 3 COMMENT which controls the wording of the donor consent which appears at the end of the donor history, consent and physical form, use the Edit donor consent[LRBLDCX] option in the Blood donor edit options..[LRBLSD] submenu of the Supervisor [LRBLS] menu.
d. Once the changes have been completed, request a full printout of the BLOOD BANK UTILITY File (#65.4) to ensure that the entries are accurate and that all changes have been adequately documented.
e. Communicate the changes to all personnel directly or indirectly affected by the change IF the change involves knowledge needed to perform their assigned duties. If training is not required, but information needs to be disseminated, use of electronic mail is the method of choice whenever possible as this provides a built-in tracking mechanism to document whether the recipient has received/read the information.

4. Changes to existing entries in FUNCTION FIELD file (#61.3)

> **NOTE:** This file is also used for anatomic pathology and microbiology. This procedure applies only to the limited specific fields in the table.

a. Use the Edit Corresponding Antigen/Antibody [LRBLSNO] option in the Supervisor menu [LRBLS]. This option will limit access to only those specific fields which can be edited without a higher level of security.
b. Do NOT request a full printout of the FUNCTION FIELD file (#61.3) in an attempt to ensure that the entries are accurate and that all changes have been adequately documented. This file includes many entries other than those designated as BLOOD GROUP ANTIGEN or BLOOD GROUP ANTIBODY. Instead, requesting a printout based on a search where the IDENTIFIER = BLOOD GROUP ANTIGEN or IDENTIFIER = BLOOD GROUP ANTIBODY in combination with the print template LRBL ANTIBODY LISTING will provide a report which includes the relevant fields.

5. Changes to LABORATORY SITE file (#69.9)

> **NOTE:** Only one entry exists in this file, i.e. HOSPITAL. Additions to the file cannot be made.

This file is also used by the main laboratory package and by other packages such as CPRS. This procedure applies only to limited specific fields applicable to the Blood Bank..

a. Use the Edit blood bank site parameters [LRBLSSP] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu. This option restricts access to only specific fields applicable to the Blood Bank software.
b. If the change involves a change to multidivisional functionality, the change requires a higher level of security access and cannot be made using the Edit blood bank site parameters [LRBLSSP] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu. This change must be done by either the Laboratory Information Manager or IRM staff who have a higher level of security access, as indicated on the form for requesting changes and in the table of validation requirements for this file.
c. Once the changes have been completed, request a full printout of the LABORATORY SITE file (#69.9) to ensure that the entries for the edited fields are accurate and that all changes have been adequately documented.

D. Validation Requirements

Consult Appendix D of the Blood Bank User Manual dated July 1996 for details on the performance of validation testing, development of a Validation Plan, evaluation of the testing and procedures to follow in the event that the software does not perform as expected. Detailed information for these areas is not included in this procedure.

1. VistA Patch/Version Update

In the majority of cases, patches are released with detailed descriptions and test scenarios; however, a revised listing of the control functions and a revised set of test case tracking worksheets are not provided. These are only provided for version updates and patches which involve extensive changes to multiple files, options or functionality.

The extent of the Validation Plan would depend on the scope of the validation to be performed. For example, the plan for a version update or a patch involving extensive routine and/or data dictionary changes would be significantly different than that for a patch involving a single option and 1-2 routines.

The suggested validation test scenarios exported with a patch assume that a full validation has previously been performed on the Blood Bank software at the site. The suggested scenarios exported with a patch are designed to only RE-VALIDATE specific options and specific test conditions based on the coding changes exported in the patch. It should also be noted that they are in fact SUGGESTED validation test scenarios. Actual scenarios must reflect the actual procedures and workflow of the individual VA Medical Center. An example of this is, if a patch contains changes reflected only in an option that is not in use at a facility, such as a change to the donor module and donors are not processed at the site, then the suggested validation scenario for that option does not need to be incorporated into the validation test plan at the site.

2. Additions/Changes to Files unrelated to patches/version updates

a. For each file, a table has been included which provides details about the specific fields for the file. This table includes:

   (1) Field number and name
   (2) Type of data, e.g., free text, number, set
   (3) Purpose of the field, e.g., software control function, characteristic/ property, algorithm function
   (4) Validation requirements if change is made

      (a) Not applicable - used primarily for fields that are not currently in use or that involve some characteristic/property that does not involve the safety, purity or potency of a unit of blood/blood component
      (b) Not needed - used to indicate that no additional validation is necessary once it has been demonstrated that other comparable file entries have been validated and found to be acceptable. For example, the field entries for AS-1 Red Blood Cells and CPDA-1 Red Blood Cells would probably be nearly identical and each would not need to be separately validated for those which were identical.

(c) Required - used to indicate that validation is required. Brief additional information is provided to indicate which option should be used to validate the functionality. Further details should be obtained from the Blood Bank User Manual documentation for that specific option and from previous validation test cases involving that specific option.

b. If the various forms entitled "Request for File Changes to the ..." are used, no elaborate validation plan is needed as this form provides for the necessary documentation.

(1) Training needs, including dates of completion and comments if appropriate
(2) Procedure needs, including the name of the standard operating procedure and the date the change was made if appropriate
(3) Validation testing summary, including the risk assessment (validation needed or not needed), the date and person performing the testing if it was needed, whether the results were acceptable and comments if appropriate
(4) Supervisory review summary, including the person(s) authorizing the change

E. Change Control Summary

1. Specific procedures must be followed if a problem is identified in which the software does not function as intended or as detailed in the documentation. In general, the problem/error should first be reported to the Laboratory Information Manager, followed by the IRM staff at the facility, then to a member of the CLIN2 National VistA Support team. Reporting to the CLIN2 team can be done either by telephone to the National Help Desk or by initiating a NOIS call on FORUM.

    a. If a problem is identified and the nature of the problem indicates that there is a system deficiency which can be handled by an alteration in the workflow processes until the situation is corrected, the Blood Bank Supervisor may decide to continue implementation of the change, provided the alternative procedures are implemented and the problem is reported.
    b. If the nature of the problem indicates that there is a system deficiency which cannot be handled by an alteration in the workflow processes, the Blood Bank Supervisor should not continue with implementation of the change until the problems are satisfactorily resolved.

2. Make sure that the change control records include at least:

    a. a description of the change,
    b. the date of the change,
    c. the name of the person making the change,
    d. any equipment or other functions that are affected by the change,
    e. an authorization signature,
    f. a validation risk assessment, and
    g. documentation of approval and acceptance.

If the forms provided in this appendix are utilized, an area is provided at the end of each request form to document this information.

Forms for Requesting File Changes and Validation Requirements for File Changes

Request for File Changes to the BLOOD PRODUCT file (#66)

TYPE OF REQUEST:
[ ] Additional (new) blood product
[ ] Change in blood product entry
[ ] (Specify: _____)

REASON FOR REQUEST:
[ ] VistA Software Patch (Patch #: _____)
[ ] Change in standard operating procedure
[ ] Change in scope of services provided
[ ] Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the Edit blood products file [LRBLSEB] option in the "Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.

Consult the table detailing Validation Requirements for File Changes for the BLOOD PRODUCT file (#66) which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the BLOOD PRODUCT File (#66)

Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.01 NAME identifies product		(free text, 2-40 characters)	Accept. Unaccept.
.02 ABBREVIATION characteristic used to access/identify this specific component		(free text, 1-4 characters)	Accept. Unaccept.
.03 CAN BE MODIFIED determines whether this product can be modified into other products		(set) YES NO	Not needed Accept. Unaccept.
.04 IDENTIFIER determines whether this file entry can be accessed (only component/derivatives with IDENTIFIER = BB should be accessible at any prompt which references component		(set) BB AB T	Not needed Accept. Unaccept.
.05 PRODUCT CODE characteristic used to by bar code reader or by manual entry to access this specific component. 5 characters for Codabar labeled components, 8 characters for ISBT 128 labeled components.		(free text, 1-8 characters)	Not needed Accept. Unaccept.
.055 DOD CODE used by the Department of Defense		(free text, 2-5 characters) NA for VA use	Not needed Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.06 MODIFICATION CRITERIA determines the edit template used when this product is selected during modification of another product		(set) DIVIDED POOLED WASHED/ FROZEN LEUKOCYTE POOR REJUVENATED DEGLYCEROLIZED IRRADIATED SEPARATED	Accept. Unaccept.
.07 PATIENT/PRODUCT ABO determines whether units selected for a patient must be identical or must be red cell compatible		(set) MUST MATCH MUST BE COMPATIBLE	Not needed Accept. Unaccept.
.08 PATIENT/PRODUCT RH determines whether units selected for a patient must be identical or must be red cell compatible		(set) MUST MATCH MUST BE COMPATIBLE	Not needed Accept. Unaccept.
.09 PATIENT/PRODUCT REQUIREMENT determines whether units must be crossmatched or if the product contains large volumes of plasma which should be compatible with the patient's red cells		(set) CROSSMATCH PLASMA/ PATIENT COMPATIBILITY	Not needed Accept. Unaccept.
.1 VOLUME (ml) characteristic		(number, 0 decimals, 1-1000)	Not needed
.11 DAYS LEFT calculates the new expiration date required if this product is prepared from another product present in inventory		(number, 2 decimals, .16-2557)	Accept. Unaccept.
.12 ANTICOAGULANT/ ADDITIVE prevents mixing of components during modifications (e.g., a product which has CPDA-1 cannot be modified to a product which has CPD as the anticoagulant)		(set) CPD ACD CPDA-1 ADSOL	Not needed Accept. Unaccept.
.13 COLLECTION/PREP HOURS in the donor module options only, i.e., indicates the maximum time allowable between the DATE/TIME COLLECTION STARTED (65.54,4.2) and the DATE/TIME STORED (65.66,.03)		(number, 0 decimals, 1-144)	Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.135 MAXIMUM STORAGE DAYS in the donor module option, calculates the default shown for the EXPIRATION DATE (65.66,.04); in the inventory module option, screens the entry for the EXPIRATION DATE/TIME (65,.06) for potential data entry errors		number, .16-3652 (4 hr to 10 years)	Accept. Unaccept.
.14 MODIFIED BEFORE RELEASE prevents issue/relocation of products which must be modified such as Frozen Red Blood Cells which must be deglycerolized before issue		(set) YES NO	Accept. Unaccept.
.15 CAN BE REQUESTED prevents selection of products which should not be accessed/selected		(set) YES NO	Not needed Accept. Unaccept.
.16 PATIENT SPECIMEN AGE ALLOWED prevents selection of units of this product for specimens IF the difference between the current time and the BLOOD SAMPLE DATE/TIME exceeds the entry in this field for this product		number in hours, 24-240 (1 to 10 days)	Not needed Accept. Unaccept.
.18 RETYPE AFTER PREPARATION determines whether units of this product must be retyped before issue/release. If YES, units which are created using the [LRBLIDN] option will appear on the Inventory testing worksheet generated by [LRBLIW].		(set) YES NO	Not needed Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.19 CONTAINS RED BLOOD CELLS (1) determines whether units of this product must be retyped before issue/release. If YES, units will not be able to be released using [LRBLIDR] until required recheck results are entered. (2) used for sorting purposes on some reports		(set) YES NO	Not needed Accept. Unaccept.
.21 MAX AGE FOR PEDIATRIC USE determines whether units of this product can be modified into pediatric units		(number in days, 0 decimals, 1-1827)	Accept. Unaccept.
.22 PEDIATRIC PRODUCT determines which products can be accessed when modifying a unit in inventory using the [LRBLPED] option; (both must also have same entry in the ANTICOAGULANT/ ADDITIVE field)		pointer to another entry in File 66	Accept. Unaccept.
.23 SPECIFIC GRAVITY in the [LRBLPED] option, i.e., used to convert the volume of the unit in mls. into an equivalent wt. in gms.		(set) 1.06 (whole blood) 1.08 (red cells) 1.03 (plasma)	Not needed Accept. Unaccept.
.24 MAXIMUM INFUSION TIME(MIN) used to determine which units should be included in the Prolonged transfusion times report generated by the [LRBLPIT] option		number, 0 decimals, 1-999 (minutes)	Not needed Accept. Unaccept.
.25 AUTOLOGOUS/ DIRECTED COMPONENT determines whether additional data is needed to restrict selection of the unit for the intended patient (RESTRICTED FOR field)		(set) AUTOLOGOUS DIRECTED NEITHER	Not needed Accept. Unaccept.
.26 ADMINISTRATIVE CATEGORY used to determine which units should be included in several different reports, e.g. Phenotyped units available [LRBLIPH] and Blood Bank Administrative Data [LRBLA]		(set) WHOLE BLOOD RBC FROZEN RBC DEGLYC RBC LEUCODEPLETED RBC WASHED RBC FFP	Not needed Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.27 POOLED PRODUCT determines whether a unit of that specific product can be accessed thorough the Edit pooled blood product [LRBLJM] option; used by the integrity check routine in the [LRBLII] option to determine which fields may have missing data		(set) YES NO	Not needed Accept. Unaccept.
.28 ASK BAG LOT # determines whether the BAG LOT # field (65,1.1) should be included in the edit template used by the [LRBLIDN] option when modifying units		(set) YES NO	Accept. Unaccept.
.29 IS ISBT128 Required field. Indicates whether the component type is labeled as CODABAR or ISBT 128. Entry here is used by the MODIFY TO field to restrict modification of a component to only others of the same labeling type.		(set) YES NO	Accept. Unaccept.
1 DESCRIPTION (Subfile 66.09) .01 DESCRIPTION intended for use for display purposes in future		(word processing; 1-50 characters)	Not Applicable
2 SYNONYM (Subfile 66.021) .01 SYNONYM used for look-up access purposes only		(free text; 2-50 characters)	Accept. Unaccept.
3 MODIFY TO (Subfile 66.03) .01 MODIFY TO determines which products can be accessed when modifying a unit in inventory using the [LRBLIDN] option. Is screened to only allow existing entries in the BLOOD PRODUCT File that have matching entries in the IS ISBT128 field.		(pointer to File 66-enter name.)	Accept. Unaccept.
3 MODIFY TO (Subfile 66.03) .02 NOT ONLY ONE ALLOWED determines whether more than one product may be created when modifying a unit in inventory using the [LRBLIDN] option		(set) YES NO	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .01 SUPPLIER name of supplier - determines characteristics based on subfields detailed below		(free text; 1-30 characters)	Accept. Unaccept.

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
4 SUPPLIER (Subfile 66.01) used for look-up and information purposes only .03 ADDRESS LINE 1 .04 ADDRESS LINE 2 .05 ADDRESS LINE 3 .06 CITY .07 STATE .08 ZIP CODE .09 PHONE		.03 ADDRESS LINE 1 (free text; 1-30 charac.) .04 ADDRESS LINE 2 (free text; 1-30 charac.) .05 ADDRESS LINE 3 (free text; 1-30 charac.) .06 CITY (free text; 1-30 charac.) .07 STATE (pointer to State File(#5)) .08 ZIP CODE (free text; 5-9 characters) .09 PHONE (free text; 4-30 charac.)	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .02 COST calculates expenses for reports		(number, 0-9999)	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .1 SUPPLIER PREFIX NUMBER determines the prefix to be added to the unit ID scanned by the bar code reader when entering a unit in inventory in the [LRBLILR] option		(free text, 1-3 characters)	Accept. Unaccept.
4 SUPPLIER (Subfile 66.01) .11 REGISTRATION NUMBER used for reference/information only		(free text, 7-9 digits)	Not applicable

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
4 SUPPLIER (Subfile 66.01) .12 UNIT LABEL NON-STANDARD controls the translation of the unit ID scanned by the bar code reader when entering a unit in inventory using the [LRBLILR] option		(set) YES Non-Standard= numeric NO Standard=alphanumeric	Accept. Unaccept.
1 LOT # (Subfile 66.02) .01 LOT # .02 EXPIRATION DATE not currently used by the software		not currently used by the software	Not applicable
5 CRITERIA FOR USE (Subfile 66.05) .01 CRITERIA FOR USE intended for use for display purposes in future		(word processing)	Not applicable
6 TESTS TO CHECK (Subfile 66.08) used to identify/flag non pre-op component requests which exceed the audit criteria (may enter more than one) .01 TESTS TO CHECK .02 SPECIMEN .03 > OR < TEST VALUE		.01 TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	Accept. Unaccept.
7 REQUISITION INSTRUCTIONS (Subfile 66.07) .01 REQUISITION INSTRUCTIONS intended for use for display purposes in future		(word processing) Not applicable	Not applicable

Additions/Change to the BLOOD PRODUCT File (#66) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8 PRE-OP TESTS TO CHECK (Subfile 66.08) used to identify/flag non pre-op component requests which exceed the audit criteria (may enter more than one) .01 PRE-OP TESTS TO CHECK .02 SPECIMEN .03 > OR < TEST VALUE		.01 TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	Accept. Unaccept.
9 EQUIVALENT PRODUCT The purpose of this field is to associate a CODABAR labeled component as entered in the BLOOD PRODUCT File to an equivalent ISBT 128 labeled component as entered in the BLOOD PRODUCT File. Currently field has no associated control function but may be useful in a future database conversion to a future product.		pointer to another entry in File 66. Screened to allow only File 66 entries with entries in the IS ISBT1128 field that do NOT match	
10 ASSOCIATED DIVISION (Subfile 66.1) .01 ASSOCIATED DIVISION limits access to products based the division of the user at a given point in time with the products attempt-ing to be requested; allows multiple entries for multidivisional facility		(pointer to INSTITUTION File (#4))	Not needed Accept. Unaccept.
500 WKLD CODE (Subfile 66.06) .01 WKLD CODE used for workload capture by the [LRBLIDN] option and the [LRBLDCP] option		(pointer to WKLD CODE File (#64)) 86183 Irradiation 86269 Cryo prep (≥4) 86271 Cryo prep 86272 Cryo thaw/pooling 86275 Frozen Bld Prep 86276 Deglyc. Froz. Bld 86277 Rejuvenation 86390 Plt prep (≥4) 86392 Plt prep 86393 Platelet pooling 86670 Washed RBC 86795 RBC prep 86796 RBC prep (≥4) 86800 FFP 86801 FFP prep (≥4) 86805 FFP thawing 86810 Divided/separated	Not needed Accept. Unaccept.

Change Control Summary for Additions/Changes to the BLOOD PRODUCT File (#66)

Training

[ ] None needed [ ] Completed/documented (Date _____ by _____)

Comments: _____

Documentation

[ ] New printout of file obtained

[ ] Procedure change needed

[ ] Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

[ ] None needed [ ] Acceptable* [ ] Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to BLOOD PRODUCT file (#66)

BLOOD PRODUCT File (#66)		
NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit blood products file [LRBLSEB]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu.		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.01 NAME free text, 2-40 characters	identifies product, i.e., blood/blood component	Not Applicable
.02 ABBREVIATION free text, 1-4 characters	characteristic/property; used to access this specific component and to identify the components on displays and/or reports	Not Applicable
.03 CAN BE MODIFIED set; yes/no	software control function, i.e., determines whether this product can be modified into other products	Required- use the [LRBLIDN] option
.04 IDENTIFIER set; BB AB T	software control function, i.e., determines whether this file entry can be accessed (only component/derivatives with IDENTIFIER = BB should be accessible at any prompt which references component)	No additional validation necessary once it has been demonstrated that file entries with an identifier of T or AB cannot be accessed.
.05 PRODUCT CODE free text, 1-8 characters	characteristic/property; used by bar code reader or by manual entry to access this specific component	Required - need to make sure that it is accurate & accesses the correct product
.055 DOD CODE free text, 2-5 characters	characteristic/property; free text used by the Department of Defense	Not Applicable for VA use
.06 MODIFICATION CRITERIA set; DIVIDED POOLED WASHED FROZEN LEUKOCYTE POOR REJUVENATED DEGLYCEROLIZED IRRADIATED SEPARATED	software control function, i.e., determines the edit template used when this product is selected during modification of another product.	Required- use the [LRBLIDN] option

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.07 PATIENT/PRODUCT ABO set; MUST MATCH MUST BE COMPATIBLE	software control function, i.e., determines whether units selected for a patient must be identical or must be red cell compatible	No additional validation necessary once it has been demonstrated that other file entries function appropriately
.08 PATIENT/PRODUCT RH set; MUST MATCH MUST BE COMPATIBLE	software control function, i.e., determines whether units selected for a patient must be identical (MUST MATCH) or must be red cell compatible (MUST BE COMPATIBLE)	No additional validation necessary once it has been demonstrated that other file entries function appropriately
.09 PATIENT/PRODUCT REQUIREMENT set; CROSSMATCH/ PLASMA/ PATIENT COMPATIBILITY	software control function, i.e., determines whether units must be crossmatched or if the product contains large volumes of plasma which should be compatible with the patient's red cells	No additional validation necessary once it has been demonstrated that other file entries function appropriately
.1 VOLUME (ml) number, 0 decimals, 1-1000	characteristic/property;	Not Needed
.11 DAYS LEFT number, 2 decimals, .16-2557	software control function, i.e., calculates the new expiration date required if this product is prepared from another product present in inventory.	Required- use the [LRBLIDN] option
.12 ANTICOAGULANT/ ADDITIVE set; CPD ACD CPDA-1 ADSOL	software control function, i.e., prevents mixing of components during modifications (e.g., a product which has CPDA-1 cannot be modified to a product which has CPD as the anticoagulant)	No additional validation necessary once it has been demonstrated that other file entries function appropriately

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.13 COLLECTION/PREP HOURS number, 0 decimals, 1-144	software control function in the donor module options only, i.e., indicates the maximum time allowable between the DATE/TIME COLLECTION STARTED (65.54,4.2) and the DATE/TIME STORED (65.66,.03)	Required- use the [LRBLDC] option
.135 MAXIMUM STORAGE DAYS number, .16-3652 (4 hr to 10 years)	software control function in the donor module option, i.e., calculates the default shown for the EXPIRATION DATE (65.66,.04) software control function in the inventory module option, i.e., screens the entry for the EXPIRATION DATE/TIME (65,.06) for potential data entry errors	Required- use the [LRBLDC] option Required- use the [LRBLILR] option
.14 MODIFIED BEFORE RELEASE set; YES NO	software control function, i.e., prevents issue/relocation of products which must be modified such as Frozen Red Blood Cells which must be deglycerolized before issue	Required- use the [LRBLIDR] option
.15 CAN BE REQUESTED set; YES NO	software control function, i.e., prevents selection of products which should not be accessed/selected	No additional validation necessary once it has been demonstrated that other file entries function appropriately
.16 PATIENT SPECIMEN AGE ALLOWED number, 24-240 (1 to 10 days)	software control function, i.e., prevents selection of units of this product for specimens if the difference between the current time and the BLOOD SAMPLE DATE/TIME (??) exceeds the entry in this field for this product	No additional validation necessary once it has been demonstrated that other file entries with the same time entry function appropriately

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.18 RETYPE AFTER PREPARATION set; YES NO	software control function, i.e., determines whether units of this product must be retyped before issue/release. If YES, units which are created using the [LRBLIDN] option will appear on the Inventory testing worksheet generated by [LRBLIW].	No additional validation necessary once it has been demonstrated that other file entries functions appropriately
.19 CONTAINS RED BLOOD CELLS set; YES NO	software control function, i.e., (1) determines whether units of this product must be retyped before issue/release. If YES, units will not be able to be released using [LRBLIDR] until required recheck results are entered. (2) used for sorting purposes on some reports	No additional validation necessary once it has been demonstrated that other file entries function appropriately
.21 MAX AGE FOR PEDIATRIC USE number, 0 decimals, 1-1827 (days)	software control function, i.e., determines whether units of this product can be modified into pediatric units	Required- use the [LRBLPED] option
.22 PEDIATRIC PRODUCT pointer to another entry in File 66	software control function, i.e., determines which products can be accessed when modifying a unit in inventory using the [LRBLPED] option; however, both must also have the same entry in the ANTICOAGULANT/ ADDITIVE field	Required- use the [LRBLPED] option
.23 SPECIFIC GRAVITY set; 1.06 1.08 1.03	algorithm function in the inventory module [LRBLPED] option, i.e., used to convert the volume of the unit in mls. into an equivalent wt. in gms.	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.24 MAXIMUM INFUSION TIME(MIN) number, 0 decimals, 1-999 (minutes)	algorithm function used to determine which units should be included in the Prolonged transfusion times report generated by the [LRBLPIT] option	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.25 AUTOLOGOUS/ DIRECTED COMPONENT set; AUTOLOGOUS DIRECTED NEITHER	software control function, i.e., determines whether additional data is needed to restrict selection of the unit for the intended patient (RESTRICTED FOR field)	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.26 ADMINISTRATIVE CATEGORY set; WHOLE BLOOD RBC FROZEN RBC DEGLYCRBC LEUCODEPLETED RBC WASHED RBC FFP CRYO RANDOM PLAT APHERESIS PLAT GRANULOCYTES	algorithm function used to determine which units should be included in several different reports, e.g. Phenotyped units available [LRBLIPH] and Blood Bank Administrative Data [LRBLA]	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.27 POOLED PRODUCT set; YES NO	algorithm function used by the integrity check routine in the [LRBLII] option to determine which fields may have missing data software control function, i.e., determines whether a unit of that specific product can be accessed thorough the Edit pooled blood product [LRBLJM] option	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately Required-use the [LRBLJM] option
.28 ASK BAG LOT # set; YES NO	software control function, i.e., determines whether the BAG LOT # field (65,1.1) should be included in the edit template used by the [LRBLIDN] option when modifying units	Required-use the [LRBLIDN] option

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.29 IS ISBT128 set; YES NO	Indicates whether product type belongs to ISBT128 or to CODABAR	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
1 DESCRIPTION (Subfile 66.09) .01 DESCRIPTION word processing; 1-50 characters	characteristic/property; intended for use for display purposes in future	Not applicable
2 SYNONYM (Subfile 66.021) .01 SYNONYM free text; 2-50 characters	characteristic/property; used for look-up access purposes only	Required - need to make sure that it is accurate
3 MODIFY TO (Subfile 66.03) .01 MODIFY TO pointer to File 66	software control function, i.e., determines which products can be accessed when modifying a unit in inventory using the [LRBLIDN] option. Screened to only allow existing entries in the BLOOD PRODUCT File that have matching entries in the IS ISBT128 field.	Required- use the [LRBLIDN] option
3 MODIFY TO (Subfile 66.03) .02 NOT ONLY ONE ALLOWED set;YES NO	software control function, i.e., determines whether more than one product may be created when modifying a unit in inventory using the [LRBLIDN] option	Required- use the [LRBLIDN] option
4 SUPPLIER (Subfile 66.01) .01 SUPPLIER free text; 1-30 characters	software control, i.e. determines characteristics based on subfields detailed below	Required - need to make sure that it is accurate- use the [LRBLILR] option

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
4 SUPPLIER (Subfile 66.01) .03 ADDRESS LINE 1 free text; 1-30 characters .04 ADDRESS LINE 2 free text; 1-30 characters .05 ADDRESS LINE 3 free text; 1-30 characters .06 CITY free text; 1-30 characters .07 STATE pointer to State File (#5) .08 ZIP CODE free text; 5-9 characters .09 PHONE free text; 4-30 characters	characteristic/property; used for look-up and information purposes only	Required - need to make sure that it is accurate
4 SUPPLIER (Subfile 66.01) .02 COST number, 0-9999	characteristic/property; used for calculating expenses on various transaction reports	Required - need to make sure that it is accurate-use the [LRBLRIT] option
4 SUPPLIER (Subfile 66.01) .1 SUPPLIER PREFIX NUMBER free text, 1-3 characters	software control function, i.e., determines the prefix to be added to the unit ID which is scanned by the bar code reader when entering a unit in inventory using the [LRBLILR] option	Required - need to make sure that it is accurate-use the [LRBLILR] option
4 SUPPLIER (Subfile 66.01) .11 REGISTRATION NUMBER free text, 7-9 digits	characteristic/property; used for reference/information only	Not applicable

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
4 SUPPLIER (Subfile 66.01) .12 UNIT LABEL NON-STANDARD set; YES NO	software control function, i.e., controls the translation of the unit ID which is scanned by the bar code reader when entering a unit in inventory using the [LRBLILR] option NOTE: Standard=alphanumeric (NO) Non-Standard=numeric (YES)	Required - need to make sure that it is accurate-use the [LRBLILR] option
1 LOT # (Subfile 66.02) .01 LOT # free text, 1-30 characters .02 EXPIRATION DATE date	not currently used by the software	Not applicable
5 CRITERIA FOR USE (Subfile 66.05) .01 CRITERIA FOR USE word processing	characteristic/property; intended for use for display purposes in future	Not applicable
6 TESTS TO CHECK (Subfile 66.08) .01 TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	algorithm function used to identify/flag non pre-op component requests which exceed the audit criteria entered which evaluates the most recent data in File 63 for the tests identified	Required-use either the [LRBLPCS] option or the [LRBLPLOGIN] option
7 REQUISITION INSTRUCTIONS (Subfile 66.07) .01 REQUISITION INSTRUCTIONS word processing	characteristic/property; intended for use for display purposes in future	Not applicable

BLOOD PRODUCT File (#66) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8 PRE-OP TESTS TO CHECK (Subfile 66.08) .01 PRE-OP TESTS TO CHECK pointer to Laboratory Test File (#60) .02 SPECIMEN pointer to Topography Field File (#61) .03 > OR < TEST VALUE free text	algorithm function used to identify/flag pre-op component requests which exceed the audit criteria entered which evaluates the most recent data in File 63 for the tests identified	Required-use either the [LRBLPCS] option or the [LRBLPLOGIN] option
9 EQUIVALENT PRODUCT	The purpose of this field is to associate a CODABAR labeled component as entered in the BLOOD PRODUCT File to an equivalent ISBT 128 labeled component as entered in the BLOOD PRODUCT File. Currently field has no associated control function but may be useful in a future database conversion to a future product.	Not Applicable
10 ASSOCIATED DIVISION (Subfile 66.1) .01 ASSOCIATED DIVISION pointer to INSTITUTION File (#4)	software control which limits access to products based on a comparison of the division of the user at a given point in time with the products attempting to be requested.	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
500 WKLD CODE (Subfile 66.06) .01 WKLD CODE pointer to WKLD CODE File (#64)	characteristic/property used for workload capture by the [LRBLIDN] option and the [LRBLDCP] option	No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately

Request for File Changes to the FUNCTION FIELD file (#61.3)

TYPE OF REQUEST:
[ ] Additional blood group antigen/antibody
[ ] Change in blood group antigen/antibody entry
[ ] (Specify: _____)

REASON FOR REQUEST:
[ ] VistA Software Patch (Patch #: _____)
[ ] Change in standard operating procedure
[ ] Change in scope of services provided
[ ] Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit Corresponding Antigen/Antibody [LRBLSNO]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. Use of this option will restrict file access to the fields shown below.

Consult the table on Validation Requirements for File Changes to the FUNCTION FIELD file (#61.3) which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the FUNCTION FIELD File (#61.3)

Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.01 NAME identifies antigen/antibody		(free text, 1-30 characters)	
.04 CORRESPONDING ANTIGEN/ANTIBODY compares entries in the ANTIBODIES IDENTIFIED field (#63,.075) for a specific patient with entries in the RBC ANTIGEN S ABSENT field (#65,70) for the unit.		(pointer to File 61.3)	Accept. Unaccept.
.06 COMPATIBILITY FACTOR used to calculate the percentage of compatible units for inclusion on the Blood Bank Consultation Report generated for patients with clinically significant antibodies		(number, 3 decimals, 0-1)	Accept. Unaccept.

Additions/Change to the FUNCTION FIELD File (#61.3) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Valida-tion**
5 JOURNAL REFERENCE (Subfile 61.32) .01 TITLE OF ARTICLE 1 AUTHOR 2 MEDICAL JOURNAL 3 VOLUME 4 STARTING PAGE 5 DATE characteristics/properties which print on the Blood Bank Consultation Report generated for patients with clinically significant antibodies if field 61.32,6 is set to YES		.01 TITLE OF ARTICLE free text, 1-80 characters 1 AUTHOR free text, 1-80 characters 2 MEDICAL JOURNAL pointer to LAB JOURNAL file (#95) 3 VOLUME free text, 1-6 characters 4 STARTING PAGE free text, 1-6 characters 5 DATE date	Accept. Unaccept.
5 JOURNAL REFERENCE (Subfile 61.32) continued 6 LIST ON PATIENT RECORD determines which journal references to include on the Blood Bank Consultation Report generated for patients with clinically significant antibodies		(set) YES NO	Accept. Unaccept.
7 COMMENT prints on the Blood Bank Consultation Report generated for patients with clinically significant antibodies		(free text)	Accept. Unaccept.

Change Control Summary for Additions/Changes to the FUNCTION FIELD file (#61.3)

Training

[ ] None needed [ ] Completed/documented (Date _____ by _____)

Comments: _____

Documentation

[ ] New printout of file obtained

[ ] No procedure change needed

[ ] Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

[ ] None needed [ ] Acceptable* [ ] Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to FUNCTION FIELD file (#61.3)

FUNCTION FIELD File (#61.3)		
NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit Corresponding Antigen/Antibody [LRBLSNO]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. Use of this option will restrict file access to the fields shown below.		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.01 NAME free text, 1-30 characters	identifies antigen/antibody	
.04 CORRESPONDING ANTIGEN/ANTIBODY pointer to File 61.3	software control, i.e., compares entries in the ANTIBODIES IDENTIFIED field (#63,.075) for a specific patient with entries in the RBC ANTIGENS ABSENT field (#65,70) for the unit. For example, since anti-K is a clinically significant antibody, if you selected "51810 ANTI K", you would expect to find an entry of "50500 K" in the CORRESPONDING ANTIGEN/ANTIBODY field.	Required - use the [LRBLPX] and the [LRBLIDR] options
.06 COMPATIBILITY FACTOR number, 3 decimals, 0-1	characteristic/property which is used to calculate the percentage of compatible units for inclusion on the Blood Bank Consultation Report generated for patients with clinically significant antibodies	Required - use the [LRUCN] option

FUNCTION FIELD File (#61.3) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
5 JOURNAL REFERENCE (Subfile 61.32) .01 TITLE OF ARTICLE free text, 1-80 characters 1 AUTHOR free text, 1-80 characters 2 MEDICAL JOURNAL pointer to LAB JOURNAL file (#95) 3 VOLUME free text, 1-6 characters 4 STARTING PAGE free text, 1-6 characters 5 DATE date	characteristics/properties which print on the Blood Bank Consultation Report generated for patients with clinically significant antibodies if field 61.32,6 is set to YES	Required- check for accuracy - use the [LRUCN] option
5 JOURNAL REFERENCE (Subfile 61.32) 6 LIST ON PATIENT RECORD set; YES NO	software control, i.e., determines which journal references to include on the Blood Bank Consultation Report generated for patients with clinically significant antibodies if field 61.32,6 is set to YES	Required - use the [LRUCN] option
7 COMMENT	characteristic/property which prints on the Blood Bank Consultation Report generated for patients with clinically significant antibodies	Required - use the [LRUCN] option

Request for File Changes to BLOOD BANK UTILITY file (#65.4)
Canned Comments/Transfusion Reactions

This file serves two purposes, one in the donor module and the other in providing choices for types of transfusion reactions.

TYPE OF REQUEST:
[ ] Additional entry (e.g. donor group/transfusion reaction)
[ ] Change in entry
(Specify: _____)

REASON FOR REQUEST:
[ ] VistA Software Patch (Patch #: _____)
[ ] Change in standard operating procedure
[ ] Change in scope of services provided
[ ] Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit blood bank utility [LRBLSEU]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu.

Consult the table on Validation Requirements for File Changes to the BLOOD BANK UTILITY File (#65.4) which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation

Additions/Change to the BLOOD BANK UTILITY File (#65.4)

Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.01 NAME identifies entry, i.e., name of the collection site, donor group affiliation, code related to the donor history or type of transfusion reaction		(free text, 1-30 characters)	Not Applicable
.02 SCREEN determines which entries in the file are accessible during specific data entry options		(set) GROUP AFFILIATION DEFERRAL CODE COLLECTION SITE GR0UP AFFILIATION& COLLECTION SITE DONOR REACTION TRANSFUSION REACTION	Not needed Accept. Unaccept.

Additions/Change to the BLOOD BANK UTILITY File (#65.4) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.03 FULL NAME characteristic/property		(free text, 1-80 charac.)	Not Applicable
1.1 ADDRESS LINE 1 characteristic/property **		(free text, 1-30 charac.)	Not Applicable
1.2 ADDRESS LINE 2 characteristic/property **		(free text, 1-30 charac.)	Not Applicable
1.3 ADDRESS LINE 3 characteristic/property **		(free text, 1-30 charac.)	Not Applicable
1.4 CITY characteristic/property**		(free text, 1-30 charac.)	Not Applicable
1.5 STATE characteristic/property **		(pointer to State File(#5))	Not Applicable
1.6 ZIP CODE characteristic/property**		(free text, 5-9 charac.)	Not Applicable
1.7 PHONE 1 characteristic/property**		(free text, 3-15 charac.)	Not Applicable
1.8 PHONE 2 characteristic/property**		(free text, 3-15 charac.)	Not Applicable
1.9 GROUP LEADER characteristic/property**		(free text, 3-30 charac.)	Not Applicable

**not used for entries for which the SCREEN =DONOR REACTION or TRANSFUSION REACTION

Change Control Summary for Additions/Changes to the BLOOD BANK UTILITY file (#65.4)
Canned Comments/Transfusion Reactions

Training

[ ] None needed [ ] Completed/documented (Date _____ by _____)

Comments: _____

Documentation

[ ] New printout of file obtained

[ ] No procedure change needed

[ ] Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

[ ] None needed [ ] Acceptable* [ ] Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Request for File Changes to the BLOOD BANK UTILITY file (#65.4) Donor History Questions

TYPE OF REQUEST:
[ ] Additional donor question
[ ] Change in existing donor history question
[ ] (Specify: _____)

REASON FOR REQUEST:
[ ] Change in accrediting/regulatory requirement
[ ] Change in standard operating procedure
[ ] Change in scope of services provided
[ ] Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. If editing is limited to changes in field 2 DONOR HISTORY, use the "Edit donor history questions [LRBLSEH] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu.

Consult the table Validation Requirements for File Changes to the BLOOD BANK UTILITY FILE (#65.4) which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the DONOR HISTORY QUESTIONS in the BLOOD BANK UTILITY File (#65.4) Field 2 DONOR HISTORY (word processing)		
Current Entry* *if applicable	**New Entry** (word processing)	**Validation**
		Accept. Unaccept.
		Accept. Unaccept.
		Accept. Unaccept.
		Accept. Unaccept.

Change Control Summary for Additions/Changes to the Donor History Questions in the BLOOD BANK UTILITY file (#65.4) Field 2 Donor History (word processing)

Training

[ ] None needed [ ] Completed/documented (Date _____ by _____)

Comments: _____

Documentation

[ ] New printout of file obtained

[ ] No procedure change needed

[ ] Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

[ ] None needed [ ] Acceptable* [ ] Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Request for File Changes to the BLOOD BANK UTILITY file (#65.4) Donor Consent

TYPE OF REQUEST: [ ] Change in wording of donor consent
(Specify: _____)

REASON FOR REQUEST:
[ ] Change in accrediting/regulatory requirement
[ ] Change in standard operating procedure
[ ] Change in scope of services provided
[ ] Other (Specify: _____)

NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. If editing is limited to changes in field 3 COMMENT, use the "Edit donor consent [LRBLDCX] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu.

Consult the table Validation Requirements for File Changes to the BLOOD BANK UTILITY FILE (#65.4) which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the DONOR HISTORY QUESTIONS in the BLOOD BANK UTILITY File (#65.4) Field 3 COMMENT (word processing)		
Current Entry* *if applicable	**New Entry** (word processing)	**Validation**
		Accept. Unaccept.

Change Control Summary for Additions/Changes to Donor Consent in the BLOOD BANK UTILITY file (#65.4)
Field 3 Comment (word processing)

Training

[ ] None needed [ ] Completed/documented (Date _____ by _____)

Comments: _____

Documentation

[ ] New printout of file obtained

[ ] No procedure change needed

[ ] Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

[ ] None needed [ ] Acceptable* [ ] Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to the BLOOD BANK UTILITY file (#65.4)

BLOOD BANK UTILITY File (#65.4)		
NOTE: Additions to the file can be made; however, no entries should be deleted as this is a file which has extensive pointer relationships. Editing of the file entries can be done using the "Edit blood bank utility [LRBLSEU]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. This file serves two purposes, one in the donor module and the other in providing choices for types of transfusion reactions. If editing is limited to changes in field 2 DONOR HISTORY, use the "Edit donor history questions [LRBLSEH] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu. If editing is limited to changes in field 3 COMMENT, use the "Edit donor consent[LRBLDCX] option in the "Blood donor edit options..[LRBLSD]" submenu of the "Supervisor [LRBLS]" menu.		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.01 NAME free text, 2-30 characters	identifies entry, e.g. the name of the collection site, donor group affiliation, coded item related to the donor history or type of transfusion reaction	
.02 SCREEN set; GROUP AFFILIATION DEFERRAL CODE COLLECTION SITE GROUP AFFILIATION & COLLECTION SITE DONOR REACTION TRANSFUSION REACTION	software control, i.e. determines which entries in the file are accessible during data entry options	Yes only if the specific screen has not been validated previously No additional validation necessary once it has been demonstrated that other comparable file entries function appropriately
.03 FULL NAME free text, 1-80 characters	characteristic/property	Yes - need to make sure that it is accurate and accesses the correct file entry
1.1 ADDRESS LINE 1 free text, 1-30 characters	characteristic/property	Not Applicable
1.2 ADDRESS LINE 2 free text, 1-30 characters	characteristic/property	Not Applicable

BLOOD BANK UTILITY File (#65.4) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
1.3 ADDRESS LINE 3 free text, 1-30 characters	characteristic/property	Not Applicable
1.4 CITY free text, 1-30 characters	characteristic/property	Not Applicable
1.5 STATE pointer to State File (#5)	characteristic/property	Not Applicable
1.6 ZIP CODE free text, 5-9 characters	characteristic/property	Not Applicable
1.7 PHONE 1 free text, 3-15 characters	characteristic/property	Not Applicable
1.8 PHONE 2 free text, 3-15 characters	characteristic/property	Not Applicable
1.9 GROUP LEADER free text, 3-30 characters	characteristic/property	Not Applicable
2 DONOR HISTORY word processing	software control, i.e. entries on the donor history questionaire	Yes- use the [LRBLDR] option
3 COMMENT word processing	software control, i.e. entries on the donor consent paragraph	Yes- use the [LRBLDR] option

Request for File Changes to the LABORATORY SITE file (#69.9)

TYPE OF REQUEST:
[ ] Additional entry
[ ] Change in entry
[ ] (Specify: _____)

REASON FOR REQUEST:
[ ] VA Software Patch (Patch #: _____)
[ ] Change in standard operating procedure
[ ] Change in scope of services provided
[ ] Other (Specify: _____)

NOTE: Only 1 entry exists in this file, i.e. HOSPITAL. Additions to the file cannot be made. Editing of the file entry should be done using the "Edit blood bank site parameters [LRBLSSP]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. This option restricts access to only specific fields applicable to the Blood Bank software.

Consult the table on Validation Requirements for File Changes to the LABORATORY SITE FILE (#69.9) which includes the columns labeled "purpose of the field" and "changes require validation?" for the rationale and details regarding the functionality of the field and whether additions/changes require software validation.

Additions/Change to the LABORATORY SITE FILE (#69.9)

Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
.18 BLOOD DONOR UNIT ID PREFIX characteristic which identifies the number of eye readable (non bar coded) characters which appear as a prefix for the facility's blood donor unit ID number allowing the cross references to be set appropriately		(number, 1-3 characters)	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .01 BLOOD BANK OPTION (multiple)		1 DONOR 2 INVENTORY** 3 PATIENT 4 INQUIRIES** 5 REPORTS** 6 SUPERVISOR** 7 TEST WORKLISTS** 8 WARD**	Not Applicable -see specifics below

**potential future use; not currently in use by the software

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT For DONOR: determines whether ABO/Rh test results should be moved from the Donor File (#65.5) to the Inventory File (#65)		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT For PATIENT: determines whether prompts for direct antiglobulin testing should be included in the LRBLSCREEN edit template used in the [LRBLPET] option to enter test results		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .03 SECOND DEFAULT For DONOR: determines whether the military rank should be asked- used only by the Department of Defense		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .04 THIRD DEFAULT For DONOR: determines whether the bag lot # should be included in the [LRBLDC] option		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .05 FOURTH DEFAULT For DONOR: determines whether the donor's social security number should be included in the [LRBLDR] option		(set) YES NO	Accept. Unaccept.

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Validation**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .06 FIFTH DEFAULT For DONOR: determines whether ALT testing is to be included in the transfusion transmitted disease testing performed on blood donors		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .07 SIXTH DEFAULT For DONOR: determines whether HIV Antigen testing is to be included in the transfusion transmitted disease testing performed on blood donors		(set) YES NO	Accept. Unaccept.
8 BLOOD BANK DEFAULTS (Subfile 69.98) .1 MAJOR SECTION characteristic/property, i.e., accession area to be used for workload recording purposes		(pointer to Accession File (#68)	Not Applicable
8 BLOOD BANK DEFAULTS (Subfile 69.98) .11 SUBSECTION characteristic/property, i.e., accession area to be used for workload recording purposes		(pointer to Accession File (#68)	Not Applicable
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .01 BLOOD BANK INSTITUTION characteristic/property, i.e., institution to be considered primary for this site		(pointer to Institution File (#4)	Not Applicable

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Valida-tion**
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY MAJOR SECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)		(pointer to Accession File (#68)	Not Applicable
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY SUBSECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)		(pointer to Accession File (#68)	Not Applicable
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .04 DONOR MAJOR SECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)		(pointer to Accession File (#68)	Not Applicable
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .05 DONOR SUBSECTION characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)		(pointer to Accession File (#68)	Not Applicable

Additions/Change to the LABORATORY SITE FILE (#69.9) continued			
Field # and Name	**Current Entry*** *if applicable	**New Entry** (format for entry)	**Valida-tion**
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .06 MULTIPLE ACCESSION AREA determines whether the site is multidivisional and/or has more than one accession area for Blood Bank NOTE: This field cannot be accessed through the [LRBLSSP] option. It must be edited by someone with a higher security level for access to FileManager.		(set) YES NO	Accept. Unaccept.

Change Control Summary for Additions/Changes to the LABORATORY SITE file (#69.9)

Training

[ ] None needed [ ] Completed/documented (Date _____ by _____)

Comments: _____

Documentation

[ ] New printout of file obtained

[ ] No procedure change needed

[ ] Procedure change completed (Date _____)

Name of procedure: _____

Validation Risk Assessment and Testing Summary:
*see separate attached documentation for test cases

Date Tested _____ Tested by: _____

[ ] None needed [ ] Acceptable* [ ] Unacceptable*

Comments: _____

Supervisory Review:

Signature: _____ (BB Supervisor)

Signature: _____ (BB Medical Director)

Signature: _____ (LIM/IRM Staff)

Date Implemented in Production: _____

Validation Requirements for File Changes to the LABORATORY SITE file (#69.9)

LABORATORY SITE File (#69.9)		
NOTE: Only one entry exists in this file, i.e. HOSPITAL. Additions to the file cannot be made. Editing of the file entry should be done using the "Edit blood bank site parameters [LRBLSSP]" option in the "Edit blood bank files [LRBLEF]" submenu of the "Supervisor [LRBLS]" menu. This file allows the site to customize some functionality. In the case of Blood Bank, this feature is used primarily for determining the content of specific edit templates for which there is some variability in the data which an individual facility may enter.		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
.18 BLOOD DONOR UNIT ID PREFIX number, 1-3 characters	software control, i.e. identifies the number of eye readable (non bar coded) characters which appear as a prefix for the facility's blood donor unit ID number to allow creation of an appropriate cross reference for the bar coded portion	Required - use the [LRBLDCP] option to scan the unit ID number to access the unit, and then by manual entry of the entire unit ID
8 BLOOD BANK DEFAULTS (Subfile 69.98) .01 BLOOD BANK OPTION (multiple) 1 DONOR 2 INVENTORY** 3 PATIENT 4 INQUIRIES** 5 REPORTS** 6 SUPERVISOR** 7 TEST WORKLISTS** 8 WARD**	software control functions as detailed in the subfields below ** indicates placeholders for future functionality (not currently in use)	Not Applicable- see specific subfields below
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT set:YES NO)	software control, i.e. for DONOR: determines whether ABO/Rh test results should be moved from the Donor File (#65.5) to the Inventory File (#65). This requires the donor rechecks to be done and entered via the [LRBLDUC] option before the unit is released. If the results are not moved, the unit rechecks must be done before the unit can be released on a patient.	Required - use the [LRBLDRR] option to release the unit and the [LRBLISPD] option to see whether the ABO and Rh were transferred

**potential future use; not currently in use by the software

LABORATORY SITE File (#69.9) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .02 FIRST DEFAULT set:YES NO	software control, i.e., for PATIENT: determines whether prompts for direct antiglobulin testing should be included in the LRBLSCREEN edit template used in the [LRBLPET] option to enter test results	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .03 SECOND DEFAULT set:YES NO	software control, i.e., for DONOR: determines whether the military rank should be asked- NOTE: used only by the Department of Defense	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .04 THIRD DEFAULT set:YES NO	software control, i.e., for DONOR: determines whether the bag lot # should be included in the [LRBLDC] option	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .05 FOURTH DEFAULT set:YES NO	software control, i.e., for DONOR: determines whether the donor's social security number should be included in the [LRBLDR] and the [LRBLDD] options	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .06 FIFTH DEFAULT set:YES NO	software control, i.e., for DONOR: determines whether ALT testing is to be included in the transfusion transmitted disease testing performed on blood donors	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .07 SIXTH DEFAULT set:YES NO	software control, i.e., for DONOR: determines whether HIV Antigen testing is to be included in the transfusion transmitted disease testing performed on blood donors	Yes
8 BLOOD BANK DEFAULTS (Subfile 69.98) .1 MAJOR SECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes	Not needed - used for workload recording purposes

LABORATORY SITE File (#69.9) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8 BLOOD BANK DEFAULTS (Subfile 69.98) .11 SUBSECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes	Not needed - used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .01 BLOOD BANK INSTITUTION pointer to Institution File (#4)	characteristic/property, i.e., institution to be considered primary for this site	Not needed - used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY MAJOR SECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)	Not needed - used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .02 INVENTORY SUBSECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Inventory File (#65)	Not needed - used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .04 DONOR MAJOR SECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)	Not needed - used for workload recording purposes
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .05 DONOR SUBSECTION pointer to Accession File (#68)	characteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated with the Blood Donor File (#65.5)	Not needed - used for workload recording purposes

LABORATORY SITE File (#69.9) continued		
Field # and Name	**Purpose of the field (software control function, characteristic/property, algorithm function)**	**Changes Require Validation?**
8.1 BLOOD BANK INSTITUTION (Subfile 69.981) .06 MULTIPLE ACCESSION AREA set; YES NO	software control function, i.e. determines whether the site is multidivisional and/or has more than one accession area for Blood Bank NOTE: This field cannot be accessed through the [LRBLSSP] option. It must be edited by someone with a higher security level for access to FileManager.	Yes - see the listing of control functions and the Test Case Tracking sheets. Editing of this parameter would entail significant validation of multidivisional functionality.

Blood Bank Software Validation—Designing a full package validation test plan

Blood Bank Software validation guidance contained in this section was previously distributed as a section of Lab Multidivisional Patch LR*5.2*72 Blood Bank User Manual Appendix D along with release notes to patch LR*5.2*72 in July 1996. The generic validation guidance contained in that appendix has been updated and is now included as part of this updated Appendix E to the Blood Bank User Manual v 5.2.

This intent of this section of Appendix E is to provide guidance to users of the VistA Blood Bank software in setting up a validation test plan for their particular needs. Each VA Medical Center has different practices within their facility and the validation test plan in use should reflect these individual practices.

The guidance provided in this document is designed to provide the tools necessary for each site to develop a validation test plan that is fully compliant with all regulatory agencies including FDA, AABB, CAP, JCAHO.

Responsibilities

Based on the requirements of the American Association of Blood Banks (AABB), responsibility for various aspects of the computer system in use has been assigned to specific individuals. Details of the assignment follows.

VENDOR RESPONSIBILITIES:
The vendor is responsible for identifying potential control functions, for providing a listing of error and warning messages, and for informing the user of override capabilities. These are published and available as Laboratory V 5.2 Blood Bank User Manual Appendix J.

INSTITUTION RESPONSIBILITIES:
The institution is responsible for providing appropriate operator support, for providing appropriate hardware, and for providing appropriate backup procedures. Depending on the type of system and the institutional organization, this might be delegated to the Department of Clinical Laboratories level, or might be contracted to an outside contractor.

BLOOD BANK MEDICAL DIRECTOR RESPONSIBILITIES:
The blood bank Medical Director is responsible for approval of the overall functionality and for review of validation testing results.

BLOOD BANK SUPERVISOR RESPONSIBILITIES:
The blood bank Supervisor is responsible for ensuring appropriate procedures are in place, including the validation test plan, for maintaining required documentation, for ensuring adequate training of personnel, for identifying control functions for options and routines used at that facility, for understanding the documentation provided by the vendor, and for assessing the spectrum of control for the control functions.

BLOOD BANK STAFF RESPONSIBILITIES:
The blood bank staff is responsible for referring to and following established procedures in the procedure manual(s) and for maintaining appropriate security at all times.

Listing of Pre-Existing Documentation Relating to the VistA Blood Bank Software V 5.2

The VistA Blood Bank Software v 5.2 is a module of the VistA Laboratory Package, v 5.2. The original release of this version (then known as DHCP, not VistA) was October 1994. This date was prior to the date that the Blood Bank software was submitted and cleared as a medical device by the FDA. Sometime after the original release date and before the submission to FDA the name of the software was changed from DHCP to VistA. For the purposes of this document, it is assumed that if previously existing documentation refers to the software as DHCP, the information contained within that document is still considered valid for VistA. In order to assist in the full understanding of the functionality of this software, a variety of documentation exists. This section will give a brief description of each existing document. All documentation is available for download from the VistA Documentation Library Page, http://vista.med.va.gov/vdl/. Once on that page, click on "Lab: Blood Bank" to obtain the Blood Bank documents and then on "Laboratory" to obtain the Planning and Implementation Guide.

LABORATORY V 5.2 PLANNING AND IMPLEMENTATION GUIDE
This manual contains information for the entire VistA Laboratory package but does have specific sections that pertain to the setup of Blood Bank specific files.

LABORATORY V 5.2 BLOOD BANK USER MANUAL
This manual contains descriptions of Blood Bank options that are included in the manual according to their arrangement in the exported menus. At the beginning of each section, a process flow diagram/chart has been included where appropriate to show the data flow and to indicate which option(s) should be used to accomplish a specific task. For each option, the introductory text provides a detailed description of the functionality, including all control functions, as well as any relevant comments which need to be considered in using the option. Several specific examples are then included which reflect the actual screens. Where appropriate, information on the data sets and explanatory text has also been included. This manual was originally published with appendices A, B, and C included. Appendix D of the Blood Bank User Manual details information as to Multidivisional functionality of the Blood Bank software as a result of patch LR*5.2*72 and information contained within Appendix D replaces any existing information in the original user manual.

LABORATORY V 5.2 BLOOD BANK USER MANUAL APPENDIX F
This document details the Intended Uses of the VistA Blood Bank Software v 5.2. Also listed are software limitations of the current VistA Blood Bank Software v 5.2.

LABORATORY V 5.2 BLOOD BANK USER MANUAL APPENDIX G
This document details the Safety Critical Requirements of the VistA Blood Bank Software v 5.2.

LABORATORY V 5.2 BLOOD BANK USER MANUAL APPENDIX H
This document details the Software Requirement Specifications of the VistA Blood Bank Software v 5.2

LABORATORY V 5.2 BLOOD BANK USER MANUAL APPENDIX I
This document details the results of a hazard analysis that was performed for each Intended Use of the Blood Bank software.

LABORATORY V 5.2 BLOOD BANK USER MANUAL APPENDIX J

This document details all of the alerts and warning messages, the design safeguards, the logic behind the functionality of these alerts and warning messages.

Patches to the Blood Bank Software

When changes must be made to the current Blood Bank software, these changes are provided in the form of a "patch". The patch itself contains both actual software and a description of the software. The description contained within patches to the Blood Bank software direct that the text portion of the patch be forwarded to the blood bank supervisor at the site and that installation of the patch be coordinated with the blood bank supervisor at the site. This is to provide the opportunity for the blood bank supervisor or designee to become familiar with the changes being introduced with the patch and to establish a validation test plan for any appropriate changes introduced in the patch.

Suggested validation testing scenarios are always included with each patch to the Blood Bank software, however, it is the responsibility of the site to determine the final scope of validation testing to be performed. Suggested validation scenarios that accompany a patch always assume that a full validation of the software has been previously performed. The suggested validation scenarios that accompany a patch are designed to re-validate an option based on the changes that have been made in the software.

Developing a Validation Test Plan

A validation test plan for a site must reflect the policies and procedures in place at the particular site. For example, if a site does not process any blood donors, then options within the Donor portion of the software do not need to be validated. It is further recommended that options not in use at a site be disabled so that they are not inadvertently accessed. This can be done by having someone in the Information Resource Management (IRM) department assign a security key to the options not held by blood bank technologists, such as the LRLIASON key.

This section describes the tools provided (the CONTROL FUNCTION SPREADSHEET and TEST CASE TRACKING WORKSHEETS, both found at the end of this appendix) and the process by which a site can develop their validation test plan.

Definitions:
A control function is a system function that causes an activity to occur or that influences the behavior of the user of the system. Control functions may exist even when competent human intervention occurs. There are two types of controls, i.e. process control and decision support.

- PROCESS CONTROL exists when the system makes a decision using available information and algorithms.
- DECISION SUPPORT exists if an individual bases a decision on information obtained from the system.

In order to assist the blood bank supervisor develop a validation test plan, tables identifying control functions by functional area (CONTROL FUNCTION SPREADSHEET) and option name are provided at the end of this document. Also provided are sample worksheets that can be used as is or modeled after for documentation/tracking of validation testing performed (TEST CASE TRACKING WORKSHEETS). These are discussed briefly below and again in detail later in this document.

For each option in the Blood Bank software that contains control function, the CONTROL FUNCTION SPREADSHEET includes the following information:

- Functional area (Patient, Donor or Inventory) of the listed option
- Menu option name (Actual option name, not the menu text—example LRBLPET, Not Enter test data)
- Menu option abbreviation (How you navigate there, i.e. P-ET for LRBLPET)
- Type of Control (Process Control or Decision Support)
- Control function brief description (brief description of what is supposed to happen)
- Warning message? (Yes/No. Indicates whether or not a warning message is displayed)
- Override Capability? (Yes/No/NA/Limited--Indicates whether or not function can still be allowed if user indicates. Limited indicates that an additional security key is required to override)
- Validation—is a blank space and is provided if a site wishes to make copies and use the spreadsheet for record keeping.

The spreadsheet entitled "TEST CASE TRACKING WORKSHEETS" provides a listing of all exported options, by functional area, in order by the menu abbreviation. The pages can be copied from this document and used as is for test case tracking or the spreadsheet can be used as an example for a site to

create their own mechanism for documenting validation at their site. Each page of the TEST CASE TRACKING WORKSHEET includes the following information:

- The functional area (Patient, Donor or Inventory) of the listed option.
- Menu option abbreviation (How you navigate there, i.e. P-ET for LRBLPET)
- Menu option name (Actual option name, not the menu text—example LRBLPET, Not Enter test data)
- Menu option name (The menu text—example Enter test data for the option LRBLPET)
- Generic option description (Indicates whether the function of the option is data entry, data entry/editing, result review/data entry, form generation, report generation or data inquiry only)
- A column is provided for the user to indicate whether access to the option is limited (i.e. restricted by security keys)
- Additional columns are provided for indicating the scope of testing performed (Normal, Exceptional, Boundary, Invalid or Stress). These situations will be discussed later in this document.

Each page of the TEST CASE TRACKING WORKSHEET also contains an area to indicate:

- the review of the validation testing
- the outcome (implementation approved/disapproved)
- an area for comments
- space for signatures of the blood bank Supervisor, the blood bank Medical Director and the Laboratory Information Manager/IRM staff, documenting both internal and external review

Once you have reviewed the materials provided, it is time to develop a strategy for a comprehensive validation of the Blood Bank software as it is used at your site. By having a comprehensive validation test plan in place for the entire package that is tailored to meet your needs, when additional or re-validation of Blood Bank options are required, such as when new patches to the software are exported or your system experienced a crash while executing an option, you can refer to it for guidance in defining the scope of any re-validation required.

You may wonder why validation and/or re-validation is necessary. There are several reasons why validation must be performed in the system that the software is being used in.

- System testing and verification done by the software developers is not adequate if there is a basic flaw in the requirements/design phase. Acceptance testing, or validation, done by the user allows evaluation of the software in a real world environment.
- The behavior of some control functions are determined based on individual facility file setup entries. In particular, how specific fields within the BLOOD PRODUCT File (#66) are defined control the behavior of how a specific blood product behaves.
- Prospective validation testing must be performed before new software is put into use for daily operations. This testing must be completed before any parallel, manual systems are discontinued and the computer is no longer redundant.
- Patches or changes/additions to local files, i.e. change control, must undergo prospective validation testing before revisions or modifications in software are put into use for daily operations. Although suggested validation scenarios are included with all patches, the final decision as to the scope of validation testing rests with the management at the site.
- Any system change that affects the way a Blood Bank user will access the software. Example, use of T1 line used at consolidated/integrated sites.

Validation testing must be performed in an environment that is a duplicate of the operating system file structure, programs, site specific options, etc. of those found in production. Although performance of

this testing in a test account may seem preferable, this may not be possible if a mirrored test account is not available for some unforeseen reason. If the final testing must be done in production, there must be strict controls to ensure that it does not adversely affect daily operations and that testing data is not confused with actual patient, donor or inventory data. In the event that there is no test account, installation of a patch should be scheduled in such a way that validation can occur in a timely manner—affected options should not be used until successful validation is complete.
Test cases must reflect the actual procedures and workflow of the individual VA Medical Center; however, the Blood Bank User Manual for the appropriate version of the software should be consulted for examples which can be used as test cases in addition to those listed on the Control Functions included later in this document. In addition to testing the functionality described in the various documents, the tester/user should be creative in testing other scenarios to ascertain whether it is possible to trick the system or have the system not function as intended/desired. Scenarios and test cases should reflect the answer to the questions, "What is it we do around here?" and "What kinds of things/people do we process?"

Validation testing must include routine operations as well as all control functions. Routine operations to be tested include:

- all data entry methods (scanner vs. manual data entry)
- security procedures (validate using various security keys for options requiring increased security)
- program overrides (including those requiring increased security)
- data storage and retrieval of results/data (review reports)
- traceability of results (check for changes in verified data to appear in audit trail report).

Testing Conditions to be Considered

Five types of test conditions are detailed below and are described in the introduction for the 'Tracking of Test Case Testing' worksheets. Stress testing is not done for each option and must therefore be documented in a slightly different manner.

Although all of these conditions may not be applicable for many of the options, a variety of test conditions must be addressed Following is an overview of testing conditions and a brief definition:

- NORMAL data—this is what happens on a very good day when nothing goes wrong
- EXCEPTIONAL data--this provides an unusual twist for the program to force the program to react to data or a situation that might be unexpected (i.e. enter a date instead of a product name when ordering blood components for a patient)
- BOUNDARY situations to force the evaluation of conditions that are of borderline validity, such as entering attempting to enter crossmatch results on a patient who has not had any ABO/Rh and/or antibody screen results entered within the past 72 hrs.
- INVALID data to force a program to prove that it can detect invalid input and stress conditions to determine whether the system has acceptable performance limits. An example of invalid data would be attempting to enter something like "Z" as an ABO group or an absurd date.
- STRESS conditions—designed to determine whether the system has acceptable performance limits, e.g. large volumes of data to be stored, multiple users on the system and adequate response time would be areas to target when designing stress scenarios.

Entry of normal data should reflect the facility's standard operating procedure manual. Whether the procedure has detailed instructions on what data is to be entered at each prompt or merely indicates "Enter data using the 'such and such' option as per the Blood Bank User Manual, Version 5.2" is up to

the individual facility. In either case, the procedure manual will need to be updated to reflect any changes introduced into the software.

The creativity of the person doing the validation testing plays a major role in developing test cases for the 'exceptional' and the 'invalid' conditions since the object is to come up with scenarios which the developers and verifiers did not already test. In some options, the user is required to answer all prompts, so it will not be possible to test a scenario where data is not complete.

Although there are a few examples which might involve a 'boundary' situation as described above, this test condition relates primarily to entry of numerical data in which the software is then interpreting the data. One example from private industry of such a scenario would be transfusion-transmitted disease testing in which actual optical density readings are transmitted and then interpreted by the software. Such functionality is not included in this software package.

For initial implementation of the Blood Bank module, it would be appropriate to define the expectations for growth of the various files and to ascertain whether the storage capacity of the hardware being utilized at the facility can accept that capacity. This is not so much an issue as it was when the software was first released in as prior versions. Blood Bank data is stored in different globals depending on the specific file. For the most part, the growth of these specific globals is minimal based on the manner in which the data is stored. Unlike the global which stores orders for laboratory tests and has a rapid growth rate, the space required for the BLOOD INVENTORY File (#65) is not significant and, based on experience to date, the capacity in most facilities can easily accommodate permanent storage of data. This makes the performance of look-backs extremely easy.

Evaluation of the acceptability of response time is somewhat subjective. While there are a few donor recruitment reports which utilize straight FileMan search and print templates, the majority of the reports utilize routines which significantly decrease the time required to compile the data for the report. For those few which do not, the Blood Bank User Manual includes a note to that effect and suggests that the report be tasked for a time other than during peak hours. In general, the response time is more reflective of the operating system and hardware configuration at the facility than of the application software.

One specific issue to be addressed under 'stress' condition is the ability to simultaneously access the same record from more than one CRT. While commercial software can be purchased to populate files in order to challenge the system and evaluate the effect of such a massive burden, this would not seem to be applicable to a hospital-wide system which has sufficient history to address the impact of storage limitations. However, this is not to say that evaluation of any problems or storage errors is not required.

Testing must be done with each of the various levels of security key access. Testing of menu options and LRLAB and LRVERIFY keys, with no LRBLOODBANK key, must be included to ensure that individuals with the full lab menu cannot access Blood Bank data inappropriately, particularly in the area of blood donors. Testing of menu options and the LRLAB and LRVERIFY and LRBLOODBANK keys, but with no LRBLSUPER key , must be included to ensure that individuals with specific menu options cannot perform restricted data entry/editing functions.

For facilities which are defined as multidivisional in the Institution File (#4), testing must also be done to ensure that individuals assigned to specific divisions cannot perform restricted data entry/editing functions. Those areas which limit access by division are detailed in the control function listing.

Validation of the software must also include validation of the hardware, specifically the peripheral devices. If the majority of the testing is being done on one specific device in order to take advantage of a

pass through printer or the ability to print screens, it will be necessary to make some accommodations to include the other peripheral devices, particularly any bar code readers.

Determing the optimal number of validation test cases is difficult. If you plan too many cases, you will not have enough time to complete them. If you plan too few, you may miss validating parts of the system. When attempting to design your validation test plan it is recommended that you:

- Base validation cases on real world examples.
- Test all control functions.
- Test all options in use (functional testing).
- Do more testing on areas of high risk.
- Don't rely solely on the Blood Bank User Manual.
- Make sure you can answer "Was the right system designed?" as well as "Was the system designed right?"
- Consider assigning the validation test cases a case number to make crossreferences easy.

Suggested Formats for Developing a Validation Test Plan
A site may choose to develop scripts, outlines, flow charts or any other method to represent their validation test plan.

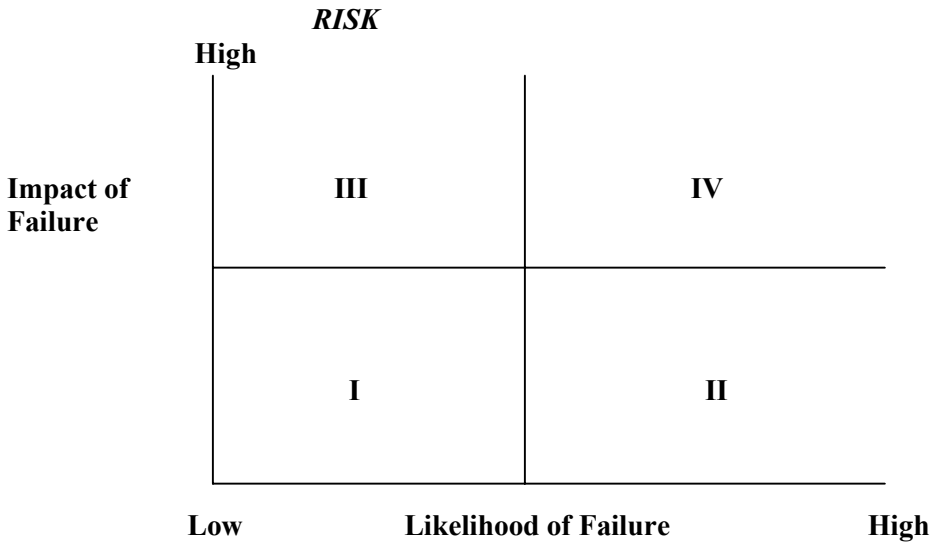
- Scripts can be created and used to convey a sequence of actions performed when conducting a test. It should contain the software options to be accessed, the actions to be performed and the expected results.
- An outline can be developed. The outline format is quick and simple might be referenced to the procedure in the Blood Bank Procedure Manual. In an outline format, the scenario for adding a new donor might look like:
    - Search for donor
    - Enter donor information on new donor.
    - Search for donor just added.
    - Create and print donor letter
- By using a graphical format, such as a flowchart, normal workflow processes can be broken down into manageable units. The structure of the flowchart will help ensure that all potential outcomes of a process which might involve several decision points are adequately addressed. If flowcharts have already been prepared as part of the AABB Quality Program, these could also be used for this purpose.

Determining Risk

NOTE: While it is possible to develop and utilize prioritization matrices which are very sophisticated and accommodate evaluation of multiple characteristics, this model of risk analysis shown on the next page is easy to use and is applicable to a variety of situations, including establishment of validation priorities or the need for stringent change control procedures. A simple way of viewing the relationship of risk to validation is to associate the likelihood of an event to the impact of the event. In this case, the event is system failure. Scores can be assigned on a scale of 0- 10 with midpoints. The systems defined by the AABB Quality Program and the FDA could be used, with the control functions of the software serving as system checks. In addition, Laboratory v 5.2 Blood Bank User Manual Appendix I titled VISTA

LABORATORY BLOOD BANK USER MANUAL HAZARD ANALYSIS can be used as a reference to determine the hazard associated with a specific option.

Risk Analysis Decision Matrix



In this model, it would be logical to focus validation activities on those systems/processes that fall in quadrant IV, followed by III, etc. For example, processes which fall in quadrant IV may be done first, may have more test cases defined, may be defined as critical functions, etc. All test cases must perform as detailed in the documentation provided, i.e. the appropriate version of the Blood Bank User Manual, the appropriate version of the Release Notes or the documentation provided with the patch. The acceptance criteria must be defined in the Validation Test Plan. Some examples of acceptance criteria could be:

- All validation test cases have been executed.
- All validation test cases have shown the correct results.
- There are no known defects/bugs.
- There are no outstanding defects/bugs to be fixed.
- Sign-offs by all responsible individuals as designated in the plan.

Once the testing is performed, the blood bank Supervisor must determine whether the testing is acceptable. This determination must be documented. The 'TEST CASE TRACKING WORKSHEETS' provided later in this document can be used to provide the mechanism for detailing this information on an option by option basis. If the option is not used, a notation should be made to that effect on the form. If a specific test condition is not appropriate for that specific option, e.g. boundary or stress, an NA notation should be made on the form. If additional access is required beyond the LRLAB, LRVERIFY and LRBLOODBANK keys, this should be recorded on the form.

In the event that the software does not perform as expected or does not meet the requirements of the blood bank, an evaluation must be done to determine whether the failure is critical or non-critical. If an error ("bug") occurs, this must be recorded in a log designated for this purpose. If the software does not function as described in the appropriate documentation or results in an error, the blood bank Supervisor

must evaluate the ramifications of the failure, i.e. is it critical to the function of the software or does it merely represent an opportunity for improvement?

For example, one of the most common issues raised the first time that a facility performs validation, i.e., following initial installation, is whether the appropriate control functions exist when issuing/relocating units on patients with clinically significant antibody problems. Under the Inventory option in the Disposition Relocation (DR) section of the Blood Bank User Manual, an explanation is included which indicates that for patients with an entry in the ANTIBODIES IDENTIFIED field, the relocation of the unit for transfusion is contingent on a corresponding entry in the RBC ANTIGENS ABSENT field for the unit. The explanation also indicates which option can be used to enter the phenotyping results. In addition, the Select Units for Patients (RS-US) section under the Inventory option of the Blood Bank User Manual includes information detailing the difference between the SERUM ANTIBODY and ANTIBODIES IDENTIFIED fields, indicating that evaluation of the appropriateness of units for transfusion is based on entries in the ANTIBODIES IDENTIFIED field for the patient and the RBC ANTIGENS ABSENT field for the unit. The file setup that provides this control function can be found in the Supervisor option, under the Edit Corresponding Antigen/Antibody (EF-AA) section of the Blood Bank User Manual. By using the "Edit Corresponding Antigen/Antibody [LRBLSNO]" option in the Supervisor menu [LRBLS], the facility can indicate which entries in the FUNCTION FIELD File (# 61.3) should be linked to which other entries by editing the CORRESPONDING ANTIGEN/ANTIBODY field (#.04). For example, since anti-K is a clinically significant antibody, if you selected "51810 ANTI K", you would expect to find an entry of "50500 K" in the CORRESPONDING ANTIGEN/ANTIBODY field.

If the nature of the problem indicates that there is a system deficiency which can be handled by an alteration in the workflow processes until the situation is corrected, the blood bank Supervisor may decide to continue with the implementation, provided the alternative procedures are implemented. If the nature of the problem indicates that there is a system deficiency which cannot be handled by an alteration in the workflow processes, the blood bank Supervisor should not continue with the implementation until the problem is corrected.

NOTE: When situtations are encountered where the software does not perform as expected, they should be reported according to established procedures. After additional investigation to determine that the problem is not because of an incorrect or absent field in a site-definable file, the problem/error should first be reported to the Laboratory Information Manager, followed by the IRM staff at the facility, then to a member of the CLIN2 National VistA Support team. Reporting to the CLIN2 team can be done either by telephone to the National Help Desk or by initiating a NOIS call on FORUM.

Validation testing must be documented in a comprehensive manner. Testing documentation must include observations from testing. This should be in the form of printouts generated by the pass through printer, or by screen captures, utilized during testing. The signature of the person performing the testing must be included on the actual printouts of the testing. The FDA guidelines are very clear on the point that “Pass/Fail” indications are not enough documentation for validation results. Testing documentation must also include proof of review of the test cases, whether testing met the acceptance criteria or required corrective action, the signature and date of approval by the blood bank medical director, and the implementation date. This can be done by a combination of notes on the actual testing printouts and the use of the forms previously discussed.

While it is generally fairly easy to locate specific information following a single validation, this task becomes increasingly difficult with each subsequent version. Retrieval of information for specific functions or options is also further complicated by the unscheduled installation of patches in between major releases.

Managing the Information Gathered During Validation Using the Blood Bank Validation File (#66.2)

The BLOOD BANK VALIDATION File (#66.2) provides a mechanism for documenting the mandated validation of the Blood Bank software options. This file was new to the Blood Bank module of the Laboratory package with the release of Version 5.2. For the most part, the order of the prompts and the information entered reflects that on the Test Case Tracking Sheets included later in this document. Data is entered through use of the option Blood bank validation documentation [LRBLVAL]. This option requires the user to have the LRBLSUPER security key.

Data entry in this file is not intended to replace the following mandated documentation of the validation testing;

- Observations from testing, e.g. screen prints, logging files, printed reports, written transcriptions, data tapes, data disks, etc.
- A record/log of unusual occurrences, bugs, deviations from the Blood Bank User Manual and their resolutions
- Final approval by other responsible individuals, including the blood bank Medical Director and the LIM.

Data entry in this file may be used to replace:

- the documentation of the review,
- the acceptability/outcome of the review,
- the date/signature of approval, and
- the date of implementation.

This use of the BLOOD BANK VALIDATION File (#66.2) offers longitudinal tracking of software validation. With Version 5.2, the Blood Bank Validation File (#66.2) was exported 'with data', i.e. the option description information already exists. When populating this file with validation data, partial entries can be made, allowing for data to be entered as it is performed. In other words, not all fields need to have data entered during a single session.

The Date/Time Validated is a multiple field. For each date/time validated for a specific option, additional information must be recorded, including the version number and patch designation, if appropriate.

Since several individuals may be involved in the validation testing, the names of all of those individuals can be entered, providing that those individuals exist as entries in the NEW PERSON File (#200). In the event that the outcome is anything other than ‘acceptable’, an assessment of the implications must be done to determine whether the software can be utilized or if the implementation must be delayed until the problem is resolved. The name of person who reviewed the actual test results and the record of errors/deviations from the Blood Bank User Manual and approved implementation should be entered as ‘approved by’. Both the date of the approval and the implementation date should be included. Regardless of the outcome, a specific comment can be entered for future reference.

The option Validation documentation [LRBLVALI] can be used to display to the screen validation information on a specifically requested option. The option Print blood bank validation [LRBLVALP] can be used to generate a hard copy report of the validation history of one or more options.

Control Function Spreadsheets

As stated earlier in this document, a control function is a system function that causes an activity to occur or that influences the behavior of the user of the system. Control functions may exist even when competent human intervention occurs. There are two types of controls, i.e. process control and decision support.

- Process control exists when the system actually makes a decision using available information and algorithms.
- Decision support exists if an individual bases a decision on information obtained from the system.

The following pages contain tables that are designed to assist sites in designing their validation test plan by listing all menu options available as part of the VistA Blood Bank Software v 5.2 that contain control functions and also lists the type control function.

NOTES:

- Override capabilities designated as 'Limited' indicate that additional supervisory access is required, either in the security level or additional specific supervisory level edit options which are tracked by the audit trail.
- The portion of the information provided which references ‘division’ is applicable only to those facilities that are set-up as multidivisional. In some cases, the facility may be multidivisional, but may only be perfoming Blood Bank functions in one division. In those instances, issues of access will need to be validated.

Patient Functional Area Control Functions

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Patient	[LRDELOG]	P-DA	Process Control	Prevents deletion of accession	Yes	No	
Patient	[LRBLPT]	P-DT	Process Control	Limits access to units currently assigned to the same division as the user	No	No	
Patient	[LRBLPT]	P-DT	Process Control	Prevents entry of future transfusion date/time	No	No	
Patient	[LRBLPT]	P-DT	Process control	Updates patient transfusion record	No	No	
Patient	[LRBLPET]	P-ET	Decision Support	Compares current ABO/Rh to patient history	Yes	Yes	
Patient	[LRBLPET]	P-ET	Decision support	Displays previous antibody history, regardless of the division	Yes	NA	
Patient	[LRBLPER]	P-PR	Process Control	Prevents entry of unit info if unit is in current inventory	Yes	No	
Patient	[LRBLPCS]	P-RS-CR	Process Control	Limits component selection to those which 'can be requested' and which are assigned to the appropriate division	No	Limited	
Patient	[LRBLPCS]	P-RS-CR	Decision Support	Evaluates age of patient specimen (for the accession area for the appropriate division)	Yes	NA	
Patient	[LRBLPCS]	P-RS-CR	Decision Support	Evaluates request against audit criteria and current lab results, regardless of the division	Yes	Yes	
Patient	[LRBLPCS]	P-RS-CR	Decision Support	Displays previous antibody history, regardless of the division	Yes	NA	
Patient	[LRBLPCS]	P-RS-CR	Decision Support	Displays Autologous units in inventory, regardless of division	Yes	Yes	

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Patient	[LRBLPIC]	P-RS-US	Process Control	Compares unit and current specimen ABO/Rh to patient history	Yes	No	
Patient	[LRBLPIC]	P-RS-US	Process Control	Prevents selection of units not ABO/Rh compatible	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Process Control	Prevents selecion of units not associated with the appropriate division (even Autologous)	No	No—must transfer unit	
Patient	[LRBLPIC]	P-RS-US	Process Control	Evaluates unit phenotyping against clinically significant patient antibodies	No	Limited if pos	
Patient	[LRBLPIC]	P-RS-US	Process Control	Prohibits selection of Autologous unit for different patient	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Process Control	Prohibits use of patient specimen which is too old.	Yes	Limited	
Patient	[LRBLPIC]	P-RS-US	Process Control	If requested, limits selection to unassigned units	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Process Control	Prevents selection of expired units	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Decision Support	Checks for low volume units	Yes	Yes	
Patient	[LRBLPIC]	P-RS-US	Decision Support	Displays days left before expiration of unit	Yes	NA	
Patient	[LRBLPIC]	P-RS-US	Decision Support	Displays Autologous units in inventory, regardless of division	Yes	Yes	
Patient	[LRBLPX]	P-RS-XM	Process Control	Prevents entry of XM if no ABO/Rh on current specimen	Yes	Limited	
Patient	[LRBLPX]	P-RS-XM	Process Control	Evaluates unit recheck results against unit history	Yes	No	
Patient	[LRBLPX]	P-RS-XM	Process Control	Prevents status change to ‘assigned’ unless XM is “C” or “IG”	No	Limited	
Patient	[LRBLPX]	P-RS-XM	Process Control	Prevents status change based on “IG” unless user has appropriate access	No	Limited	

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Patient	[LRBLPX]	P-RS-XM	Decision Support	Evaluates whether Antibody Screen results are entered on current specimen	Yes	Yes	
Patient	[LRBLPX]	P-RS-XM	Decision Support	Evaluates unit phenotyping against clinically significant patient antibody, regardless of division	Yes	Limited if pos	
Patient	[LRBLPLOGIN]	P-SL	Process Control	Limits component selection to those which 'can be requested' and which are assigned to the appropriate division	No	Limited	
Patient	[LRBLPLOGIN]	P-SL	Decision support	Checks for previous specimen within 72 hrs, regardless of division.	Yes	NA	
Patient	[LRBLPLOGIN]	P-SL	Decision Support	Displays previous antibody history, regardless of division	Yes	NA	
Patient	[LRBLPLOGIN]	P-SL	Decision Support	Displays previous transfusion reactions, regardless of division	Yes	Na	
Patient	[LRBLPLOGIN]	P-SL	Decision Support	Displays recent lab values for auditing a request, regardless of division	Yes	Yes	
Patient	[LRBLPLOGIN]	P-SL	Decision Support	Displays Autologous units in inventory, regardless of division	Yes	Yes	
Patient	[LRBLPLOGIN]	P-SL	Decision Support	Evaluates age of patient specimen (for the accession area for the appropriate division)	Yes	NA	
Patient	[LRBLPLOGIN]	P-SL	Decision Support	Evaluates request against audit criteria and current lab results, regardless of division	Yes	Yes	

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Patient	[LRBLPLOGIN]	P-SL	Decision Support	Evaluates request against MSBOS audit criteria regardless of division, if CPT code of surgery is entered during Request for Surgery in Surgery package	Yes	Yes	

Inventory Functional Area Control Functions

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Inventory	[LRBLIDN]	I-DN	Process Control	Prevents entry of future disposition dates	Yes	No	
Inventory	[LRBLIDN]	I-DN	Process Control	Restricts modification of components to specified components	Yes	No	
Inventory	[LRBLIDN]	I-DN	Process Control	Prevents modification of Autologous components to non-autologous components if testing is incomplete or positive	Yes	No	
Inventory	[LRBLIDN]	I-DN	Process Control	Checks volumes of modified (split/divided) units against maximum	Yes	No	
Inventory	[LRBLIDN]	I-DN	Process Control	Deletes modificatin if no new unit ID entered	Yes	No	
Inventory	[LRBLIDN]	I-DN	Process Control	Assigns ABO/Rh of pool	NA	No	
Inventory	[LRBLIDN]	I-DN	Process Control	Prevents multiple modifications to the same unit	No	No	
Inventory	[LRBLIDN]	I-DN	Process Control	Restricts access to units to those which are assigned to the same division	No	No	
Inventory	[LRBLIDN]	I-DN	Decision Support	Calculates and suggests new expiration date for modified components	Yes	Yes	
Inventory	[LRBLIDN]	I-DN	Decision Support	Identifies units which were released with incomplete testing results	Yes	Yes	
Inventory	[LRBLIDR]	I-DR	Process Control	Restricts access to units to those units which are assigned to the same division	Yes	No	

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Inventory	[LRBLIDR]	I-DR	Process Control	Prevents issue if no entry for required recheck results	Yes	Limited	
Inventory	[LRBLIDR]	I-DR	Process Control	Evaluates unit phenotyping against clinically significant patient antibodies	Yes	Limited	
Inventory	[LRBLIDR]	I-DR	Process Control	Prevents issue if inspection is unsatisfactory	Yes	Limited	
Inventory	[LRBLIDR]	I-DR	Process Control	Prevents issue if inspection from previous relocation was unsatisfactory	Yes	Limited	
Inventory	[LRBLIDR]	I-DR	Process Control	Prevents issue if unit is one which must be modified before being released	Yes	No	
Inventory	[LRBLIDR]	I-DR	Process Control	Restricts relocation of units to locations within the same division as the user	Yes	Limited	
Inventory	[LRBLIDR]	I-DR	Process Control	Prevents relocations with a date/time prior to the date/time the unit was assigned to the patient	Yes	Limited	
Inventory	[LRBLIDR]	I-DR	Decision Support	Evaluates expiration date of unit	Yes	Yes	
Inventory	[LRBLILR]	I-LR	Process Control	Prevents duplicate entry of a unit id of the same component	Yes	Limited	
Inventory	[LRBLILR]	I-LR	Process Control	Checks validity of expiration date based on maximum days	Yes	Limited	
Inventory	[LRBLILR]	I-LR	Process Control	Restricts entry of components to those in File 66 with suppliers, etc.	No	No	
Inventory	[LRBLILR]	I-LR	Process Control	Limits re-entry of units to those with disposition of “S” or “R”	Yes	No	

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Inventory	[LRBLILS]	I-LT	Process Control	Limits access to those units assigned to the same division as the user	No	No	
Inventory	[LRBLPED]	I-PD	Process Control	Restricts component selection to those appropriately defined	Yes	No	
Inventory	[LRBLPED]	I-PD	Process Control	Limits access to those units assigned to the same division as the user	No	No	
Inventory	[LRBLPED]	I-PD	Process Control	Restricts unit selection to those of appropriate age	Yes	Limited	
Inventory	[LRBLPED]	I-PD	Process Control	Prevents entry of expiration date without time	Yes	No	
Inventory	[LRBLPED]	I-PD	Decision Support	Identifies low volume units	Yes	Yes	
Inventory	[LRBLPED]	I-PD	Process Control	Assigns final dispositions to units when volume = 0 after last split	No	No	
Inventory	[LRBLISH]	I-SH	Decision Support	Identifies units which were released with incomplete results	Yes	Yes	
Inventory	[LRBLIUC]	I-UC	Process Control	Limits access to those units assigned to the same division as the user if done by individual unit (not by batch)	No	No	
Inventory	[LRBLIUC]	I-UC	Decision Support	Compares current results to unit log-in information	Yes	Yes	
Inventory	[LRBLIUP]	I-UP	Process Control	Prevents entry of same antigen as ‘present’ and ‘absent’	Yes	No	
Inventory	[LRBLIUP]	I-UP	Process Control	Updates donor record if appropriate	Yes	Yes	
Inventory	[LRBLIUP]	I-UP	Process Control	Limits access to those units assigned to the same division as the user	No	No	
Inventory	[LRBLIUR]	I-UR	Process Control	Prevents release of units from location other than BB	Yes	No	

Donor Functional Area Control Functions

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Donor	[LRBLDCP]	D-CP	Process Control	Checks number of components prepared against bag type	Yes	No	
Donor	[LRBLDCP]	D-CP	Process Control	Ensures that no more than one RBC component is prepared	Yes	No	
Donor	[LRBLDCP]	D-CP	Process Control	Checks time between collection and component preparation	Yes	No	
Donor	[LRBLDCP]	D-CP	Process Control	Compares anticoagulant of collection with that for components	Yes	No	
Donor	[LRBLDCP]	D-CP	Process Control	Prevents access to donors entered through "Old Records"	Yes	No	
Donor	[LRBLDCP]	D-CP	Decision Support	Calculates and suggests the expiration date	NA	Yes	
Donor	[LRBLDC]	D-DC	Process Control	Limits entry of patient restrictions for Autologous units to patients in VA Patient File	Yes	No	
Donor	[LRBLDC]	D-DC	Process Control	Prevents entry of future donation date/time	Yes	No	
Donor	[LRBLDC]	D-DC	Process Control	Prevents entry of duplicate donor IDs within 5 years	Yes	No	
Donor	[LRBLDC]	D-DC	Process Control	Prevents entry of completion date/time prior to start date/time	Yes	No	
Donor	[LRBLDC]	D-DC	Process Control	Eliminates some gender specific questions on Donor History form	No	NA	
Donor	[LRBLDC]	D-DC	Process Control	Prevents access to donors entered through 'Old Records'	Yes	No	
Donor	[LRBLDC]	D-DC	Decision Support	Checks for duplicate donors	Yes	Yes	
Donor	[LRBLDC]	D-DC	Decision Support	Calculates collection volume	NA	Yes	
Donor	[LRBLDR]	D-DH	Process Control	Prevents printing of regular Donor History form if donor is permanently deferred	Yes	No	
Donor	[LRBLDR]	D-DH	Decision Support	Includes special comments on Donor History form if appropriate	NA	Yes	

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Donor	[LRBLDO]	D-DO	Process Control	Prevents entry of duplicate donor IDs within 5 years	Yes	No	
Donor	[LRBLDPH]	D-DP	Process Control	Prevents entry of same antigen as 'present' and 'absent'	Yes	No	
Donor	[LRBLDLG]	D-DR	Process Control	Prevents entry of data if donor is permanently deferred	Yes	Limited	
Donor	[LRBLDLG]	D-DR	Process Control	Enters donor in donor letter print queue	No	No	
Donor	[LRBLDLG]	D-DR	Process Control	Limits entry of patient restrictions for Autologous units to patients in the Patient File	Yes	No	
Donor	[LRBLDLG]	D-DR	Decision Support	Checks age of donor to see if outside limits	Yes	Yes	
Donor	[LRBLDLG]	D-DR	Decision Support	Checks for duplicate donors	Yes	Yes	
Donor	[LRBLDUC]	D-DU-DC	Process Control	Compares recheck info to original processing results	Yes	Yes	
Donor	[LRBLDUC]	D-DU-DC	Process Control	Prevents same tech from entering both original and recheck results	Yes	Limited	
Donor	[LRBLDAT]	D-DU-DT	Decision Support	Checks current results against donor's historical record	Yes	Yes	
Donor	[LRBLDT]	D-DU-LA	Process Control	Generates bulletin if positive results entered after component released	Yes	No	
Donor	[LRBLDT]	D-DU-LA	Process Control	Prevents editing of results after components are released	Yes	Limited	
Donor	[LRBLDT]	D-DU-LA	Decision Support	Adds units needing repeat testing to work list	Yes	Yes	
Donor	[LRBLDT]	D-DU-LA	Process Control	Controls the specific tests included, i.e. ALT and HIV Ag, based on entries in File 69.9 (LABORATORY SITE FILE)	No	No	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Checks current ABO/Rh results against historical record	Yes	Limited	

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Donor	[LRBLDRR]	D-DU-LR	Process Control	Generates bulletin if unit released with ABO discrepancy	Yes	No	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Displays required transfusion transmitted testing for review based on entries in file 69.9 for ALT and HIV Antigen	No	No	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Prevents release of homologous units with positive disease marker testing	Yes	No	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Enters units into inventory if 'released'	No	No	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Verifies accuracy of labeling via barcode reader	Yes	No	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Prevents same tech doing both labeling and release if barcode reader not used	Yes	No	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Assigns the division of the user who is labeling/releaseing the unit into inventory when it is moved from the Donor File into the Inventory File (#65)	No	NA	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Restricts access to changes in status from 'quarantine'	Yes	Limited	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Flags Autologous units released to inventory with Postive/Incomplete testing	No	NA	
Donor	[LRBLDRR]	D-DU-LR	Process Control	Flags homologous units released to inventory with incomplete testing	No	NA	

Supervisor Functional Area Control Functions

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Process Control	Brief Description of Control Function	Warning Message	Override Capability	Validation
Supervisor	[LRBLSEL]	S-EI-LI	Process Control	Limits access to those units assigned to the same division as the user	No	No	
Supervisor	[LRBLSEC]	S-EI-PI	Process Control	Limits access to those units assigned to the same division as the user	No	No	
Supervisor	[LRBLSED]	S-EI-DI	Process Control	Limits access to those units assigned to the same division as the user	No	No	

Test Case Tracking

The spreadsheet entitled "TEST CASE TRACKING WORKSHEETS" provides a listing of all exported options, by functional area, in order by the menu abbreviation. The pages can be copied from this document and used as is for test case tracking or the spreadsheet can be used as an example for a site to create their own mechanism for documenting validation at their site. Each page of the TEST CASE TRACKING WORKSHEET includes the following information:

- The functional area (Patient, Donor or Inventory) of the listed option.
- Menu option abbreviation (How you navigate there, i.e. P-ET for LRBLPET)
- Menu option name (Actual option name, not the menu text—example LRBLPET, not Enter test data)
- Menu option name (The menu text—example Enter test data for the option LRBLPET)
- Generic option description (Indicates whether the function of the option is data entry, data entry/editing, result review/data entry, form generation, report generation or data inquiry only)
- A column is provided for the user to indicate whether access to the option is limited (i.e. restricted by security keys)
- Additional columns are provided for indicating the scope of testing performed (Normal, Exceptional, Boundary, Invalid or Stress. These situations will be discussed later in this document.

Each page of the TEST CASE TRACKING WORKSHEET also contains an area to indicate:

- the review of the validation testing
- the outcome (implementation approved/disapproved)
- an area for comments
- space for signatures of the blood bank Supervisor, the blood bank Medical Director and the Laboratory Information Manager/IRM staff.

Although all of these conditions may not be applicable for many of the options, a variety of test conditions must be addressed. Following is an overview of testing conditions and a brief definition:

- NORMAL data—this is what happens on a very good day when nothing goes wrong
- EXCEPTIONAL data—this provides an unusual twist for the program to force the program to react to data or a situation that might be unexpected (i.e. enter a date instead of a product name when ordering blood components for a patient)
- BOUNDARY situations to force the evaluation of conditions that are of borderline validity, such as entering attempting to enter crossmatch results on a patient who has not had any ABO/Rh and/or antibody screen results entered within the past 72 hrs.
- INVALID data to force a program to prove that it can detect invalid input and stress conditions to determine whether the system has acceptable performance limits. An example of invalid data would be attempting to enter something like "Z" as an ABO group or an absurd date.
- STRESS conditions—designed to determine whether the system has acceptable performance limits, e.g. large volumes of data to be stored, multiple users on the system and adequate response time would be areas to target when designing stress scenarios.

For those options in which access is an issue (controlled by security keys such as LRBLSUPER), test cases must be included to evaluate the various levels of access. In some cases, as noted on the listing of control functions, a higher level of access is required to override warning messages or process controls. For those facilities that are multidivisional, access is also restricted by assigned division.

Although the Blood Bank User Manual and/or suggested validation scenarios exported with patches can and should be consulted for examples, the test cases must reflect the actual procedures and workflow of the VA Medical Center and should be detailed in the Validation Test Plan. The Validation Test Plan should list the options to be tested and the types of tests to be done to the extent that they are understandable by the person conducting the testing.

Acceptance criteria must detail:

- definition of successful completion of test case
- a determination of whether the user requirements were met
- an evaluation of any unexpected occurrences, i.e. are they critical or not?

The Test Case Tracking sheets included in this section can be used in a variety of ways. Each page includes the identifying information for each exported options, including the abbreviation, the menu name and the option name. The option description is generic and indicates whether the option is data entry, date, entry/editing result review/data entry, form generation, report generation or data inquiry only. Columns are provided for the user to indicate whether access to the option is limited. The last 4 columns can be used in a variety of ways. Specific dates of testing could be included or some indication, such as a check, might be entered for those done and an NA entered for those not applicable. Each page also contains an area to indicate the review of the validation testing, the outcome (implementation approved/disapproved), an area for comments and spaces for signatures. Although the blood bank Supervisor might actually be involved in the validation testing, the review by the blood bank Medical Director and either the Laboratory Information Manager or the IRM staff provides external oversight for quality assurance purposes.

Documentation of the validation testing must include:

- observations from testing, e.g. screen, prints, logging files, printed reports, written transcriptions, data tapes, data disks, etc.,
- the review of the test cases, i.e. acceptability of output based on data entered
- a record/log of unusual, occurrences, bugs, deviations from the User Manual, Release Notes and/or patch documentation and resolution
- the conclusion of the testing,i.e. acceptable or not
- any corrective action
- a date/signature of approval
- the implementation date/time. This documentation must be also be retrievable by function.

The Blood Bank Validation File (#66.2) provides a mechanism for documenting the mandated validation. Additional information on the use of this file as a tool is contained earlier in this appendix.

Donor Functional Area Test Tracking Worksheet

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Donor	D-CP	[LRBLDCP]	Collection disposition/ component preparation	Data Entry					
Donor	D-DC	[LRBLDC]	Donor collection/processing	Data entry					
Donor	D-DD	[LRBLDD]	Donor demographics	Data entry					
Donor	D-DH	[LRBLDR]	Donor history, physical and consent form	Form generation					
Donor	D-DO	[LRBLDO]	Old blood donor records	Data entry					
Donor	D-DP	[LRBLDPH]	Donor phenotyping	Data entry/edit					
Donor	D-DR	[LRBLDLG]	Donor registration	Data entry/edit					
Donor	D-DU-CR	[LRBLDCR]	Component preparation report	Report generation					
Donor	D-DU-DA	[LRBLDTA]	Abnormal donor tests	Report generation					
Donor	D-DU-DC	[LRBLDUC]	Donor unit ABO/Rh recheck	Data entry/ edit					
Donor	D-DU-DL	[LRBLDDAW]	Donor unit testing work list	Report generation					
Donor	D-DU-DR	[LRBLDTR]	Donor unit testing prooflist	Report generation					
Donor	D-DU-DS	[LRBLDTRS]	Donor unit testing supplemental prooflist	Report generation					
Donor	D-DU-DT	[LRBLDDAT]	ABO/Rh testing of donor units	Data entry/edit					
Donor	D-DU-LA	[LRBLDT]	Lab tests (not ABO/Rh) on donor units	Data entry/edit					
Donor	D-DU-LR	[LRBLDRR]	Test review/component labeling/release	Result review/ data entry					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

___ I approve implementation of the software effective _____

___ I do NOT approve implementation until necessary corrective action is taken.

Comments:

_____

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_____

Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

Inventory Functional Area Test Tracking Worksheet

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Inventory	I-DN	[LRBLIDN]	Disposition –not transfused	Data entry					
Inventory	I-DR	[LRBLIDR]	Disposition –relocation	Data entry					
Inventory	I-LR	[LRBLILR]	Log-in regular (invoices)	Data entry					
Inventory	I-LS	[LRBLILS]	Enter blood inventory typing charges	Data entry					
Inventory	I-PD	[LRBLPED]	Pediatric unit preparation	Data entry					
Inventory	I-SH	[LRBLISH]	Shipping invoices for blood components	Form generation					
Inventory	I-TR	[LRBLJTR]	Transfer unit to new division	Data entry					
Inventory	I-UC	[LRBLIUC]	Unit ABO/Rh confirmation	Data entry					
Inventory	I-UP	[LRBLIUP]	Unit phenotyping	Data entry/edit					
Inventory	I-UR	[LRBLIUR]	Units release to stock (cancel) by patient	Unit status change					
Inventory	I-UW	[LRBLIW]	Inventory ABO/Rh testing worksheet	Form generation					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

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Comments:

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

Patient Functional Area Test Tracking Worksheet

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Patient	P-CD	[LRUCHGDIV]	Change to new division	Data entry					
Patient	P-DA	[LRBLDELOG]	Remove an accession	Data edit					
Patient	P-DT	[LRBLPT]	Blood transfusion results	Data entry					
Patient	P-ET	[LRBLPET]	Enter test data	Data entry					
Patient	P-PR	[LRBLPER]	Previous records	Data entry (history only)					
Patient	P-RS-CR	[LRBLPCS]	Blood component requests	Data entry					
Patient	P-RS-US	[LRBLPIC]	Select units for patients	Data entry					
Patient	P-RS-XM	[LRBLPX]	Enter crossmatch results	Data entry					
Patient	P-SI	[LRBLPSI]	Special instructions	Data entry/edit					
Patient	P-SL	[LRBLPLOGIN]	Specimen log-in	Data entry					
Patient	P-TA	[LRADDTOACC]	Add tests to a given accession	Data edit					
Patient	P-TD	[LRTSTOUT]	Delete test from an accession	Data edit					
Patient	P-TW	[LRBLTTW]	Test work list	Form generation					
Patient	P-WL	[LRUW]	Accession area worklist	Form generation					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

___ I approve implementation of the software effective _____

___ I do NOT approve implementation until necessary corrective action is taken.

Comments:

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

Inquiry and Ward Functional Area Test Tracking Worksheet

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Inquiries	Q-DI	[LRBLSQDD]	Single donor demographic information	Data inquiry					
Inquiries	Q-OR	[LROS]	Order/test status	Data inquiry					
Inquiries	Q-PA	[LRUPT]	Show list of accessions for a patient	Data inquiry					
Inquiries	Q-PH	[LRBLPH]	Patient medication list	Data inquiry					
Inquiries	Q-PR	[LRBLQDR]	Patient blood bank record	Data inquiry					
Inquiries	Q-SD	[LRBLQSD]	Single donor information	Data inquiry					
Inquiries	Q-ST	[LRBLQST]	Single unit status	Data inquiry					
Inquiries	Q-SU	[LRBLIPSD]	Single unit information-display	Data inquiry					
Inquiries	Q-UA	[LRBLQPR]	Units assigned/ components requested	Data inquiry					
Inquiries	Q-VD	[LRBLVALI]	Validation Documentation	Data inquiry					
Inquiries	Q-VT	[LREV]	Test description information	Data inquiry					
Ward	W-PO	[LRUPT]	Show list of accessions for a patient	Data inquiry					
Ward	W-PR	[LRBLQDR]	Patient blood bank record	Data inquiry					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

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___ I do NOT approve implementation until necessary corrective action is taken.

Comments:

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

Reports Functional Area Test Case Tracking Worksheet

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Reports	R-AR	[LRBLPR]	Patient antibody report (short list)	Report generation					
Reports	R-BR-1	[LRBLP ADD]	Add BB patient(s) to report queue	Data entry					
Reports	R-BR-2	[LRBLP DELETE]	Delte BB report print queue	Data edit					
Reports	R-BR-3	[LRBLP PRINT…]	Print single BB patient report	Report generation					
Reports	R-BR-4	[LRBLP PRINT…]	Print all BB patient reports on …	Report generation					
Reports	R-BR-5	[LRBLCN]	Blood bank consultation …	Report generation					
Reports	R-CT	[LRBLILA]	Unit CAUTION tag labels	Caution tag label generation					
Reports	R-CV	[LRBLICV]	CMV antibody status report	Report generation					
Reports	R-DR-CD	[LRBLDCD]	Collection disposition report	Report generation					
Reports	R-DR-DR-DA	[LRBLDDA]	Gallon donor report	Report generation					
Reports	R-DR-DR-DD	[LRBLDDR]	Donor deferral report	Report generation					
Reports	R-DR-DR-DL	[LRBLDPL]	List of donors by last attempt date	Report generation					
Reports	R-DR-DR-DS	[LRBLDSC]	Donor scheduling report	Report generation					
Reports	R-DR-DR-ED	[LRBLDEDR]	Emergency donor report	Report generation					
Reports	R-DR-DR-FD	[LRBLDFD]	First time blood donors	Report generation					
Reports	R-DR-DR-GA	[LRBLDGA]	Group affiliation report	Report generation					
Reports	R-DR-DR-GD	[LRBLDGDR]	Group donation report	Report generation					
Reports	R-DR-DR-MC	[LRBLDMC]	Mobile (collection site) report	Report generation					

Based on a review of the actual observations from the testing of both the control functions and the routine operations AND the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

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Comments:

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

REPORTS FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Reports	R-DR-DR-ML	[LRBLDMR]	Donor monthly/holiday recall list	Report generation					
Reports	R-DR-DR-PC	[LRBLDPCR]	Patient credits from blood donations	Report generation					
Reports	R-DR-DR-PL	[LRBLDAP]	Apheresis donor list	Report generation					
Reports	R-DR-DR-SD	[LRBLDSD]	Donor short draw report	Report generation					
Reports	R-DR-DR-XD	[LRBLDL]	Donor list/label/letters	Report generation					
Reports	R-DR-DS	[LRBLDTRS]	Donor unit supplemental testing prooflist	Report generation					
Reports	R-DR-DT	[LRBLDTR]	Donor unit testing prooflist	Report generation					
Reports	R-DR-PD	[LRBLDPD]	Permanent donor deferral report	Report generation					
Reports	R-DR-PR	[LRBLDPRR]	Blood product rejection report	Report generation					
Reports	R-IS-DU	[LRBLIDU]	Disposition-not transfused	Report generation					
Reports	R-IS-SU-SD	[LRBLIPSD]	Single unit information-display	Report generation					
Reports	R-IS-SU-SP	[LRBLIPSP]	Single unit information-print	Report generation					
Reports	R-IS-UA	[LRBLRUA]	Units available (indate/no disposition)	Report generation					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

REPORTS FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Reports	R-IS-UN	[LRBLRUN]	Units with no disposition	Report generation					
Reports	R-IS-UX	[LRBLIX]	Units on Xmatch by date/time xmatched	Report generation					
Reports	R-IT-IN	[LRBLRIN]	Supplier invoices (inventory)	Report generation					
Reports	R-IT-IS	[LRBLRIS]	Special typing charges (inventory)	Report generation					
Reports	R-IT-IT	[LRBLRIT]	Supplier transactions (inventory)	Report generation					
Reports	R-PL	[LRBLPAL]	Patient accession list	Report generation					
Reports	R-TC	[LRBLTA]	Transfusion reaction count	Report generation					
Reports	R-TR	[LRBLIPTR]	Transfusion reactions report	Report generation					
Reports	R-UP	[LRBLIPH]	Phenotyped units available	Report generation					
Reports	R-UR-AA	[LRBLAA]	Crossmatch/Transfusion by Specialty/Physician	Report generation					
Reports	R-UR-AR	[LRBLJB]	Autologous disposition report	Report generation					
Reports	R-UR-CT	[LRBLRCT]	Crossmatch/transfusion report	Report generation					
Reports	R-UR-IS	[LRBLIRB]	Unit relocation record book entries	Report generation					
Reports	R-UR-IT	[LRBLPRIT]	Inappropriate transfusion requests	Report generation					
Reports	R-UR-PT	[LRBLPIT]	Prolonged infusion time report	Report generation					
Reports	R-UR-RS	[LRBLJUT]	Transfused RBC for treating specialty	Report generation					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

___ I approve implementation of the software effective _____

___ I do NOT approve implementation until necessary corrective action is taken.

Comments:

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

REPORTS FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Reports	R-UR-TH	[LRBLPCH]	Patient transfusions and hematology results	Report generation					
Reports	R-UR-TR	[LRBLITR]	Transfusion data report	Report generation					
Reports	R-UR-TS	[LRBLITS]	Transfusion statistics by treating specialty	Report generation					
Reports	R-UR-TX	[LRBLTXA]	Transfusion follow-up tests	Report generation					
Reports	R-VD	[LRBLVALP]	Print blood bank validation	Report generation					
Reports	R-WK-AD	[LRBLA]	Blood bank Administrative data	Report generation					
Reports	R-WK-CR	[LRBLDCR]	Component preparation report	Report generation					
Reports	R-WK-CT	[LRUPACT]	Test counts by treating specialty	Report generation					
Reports	R-WK-IR	[LRBLC]	Inventory recheck tallies	Report generation					
Reports	R-WK-TC	[LRBLRTC]	Test counts by location	Report generation					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

___ I approve implementation of the software effective _____

___ I do NOT approve implementation until necessary corrective action is taken.

Comments:

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

Supervisor Functional Area Test Case Tracking Worksheets

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Superv	S-DO	[LRCENDEL]	Delete entire order or individual tests	Data edit					
Superv	S-ED-DC	[LRBLDA]	Donor collection/deferral edit	Data entry/edit					
Superv	S-ED-DD	[LRBLDEF]	Permanent deferral/special comments	Data entry/edit					
Superv	S-ED-DE	[LRBLDEDIT]	Blood donor group type edit	Data entry/edit					
Superv	S-ED-DH	[LRBLSEH]	Edit donor history questions	Form content definition					
Superv	S-ED-DL	[LRBLDLT]	Enter/edit donor letters	Letter content definition					
Superv	S-ED-DM	[LRBLDMV]	Move a blood donation	Data transfer					
Superv	S-ED-DP	[LRBLDCX]	Edit donor consent	Form content definition					
Superv	S-EF-AA	[LRBLSNO]	Edit corresponding antigen/antibody	File setup & software control					
Superv	S-EF-BD	[LRBLSEF]	Edit blood bank descriptions file	File setup & software control					
Superv	S-EF-BP	[LRBLSEB]	Edit blood product file	File setup & software control					
Superv	S-EF-BU	[LRBLSEU]	Edit blood bank utility file	File setup & software control					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

___ I approve implementation of the software effective _____

___ I do NOT approve implementation until necessary corrective action is taken.

Comments:

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Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

SUPERVISOR FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Superv	S-EF-CR	[LRBLSRQ]	Edit blood component request file	File setup & software control					
Superv	S-EF-LL	[LRBLSLL]	Edit lab letter	Consultation letter content definition					
Superv	S-EF-MS	[LRBLSMS]	Maximum surgical blood order edit	File setup & software control					
Superv	S-EF-SP	[LRBLSSP]	Edit blood bank site parameters	Edit template setup & software control					
Superv	S-EF-VD	[LRBLVAL]	Blood Bank validation documentation	Data entry/edit					
Superv	S-EI-DI	[LRBLSED]	Edit unit disposition fields	Data entry/edit					
Superv	S-EI-FR	[LRBLSEE]	Free unit from Autologous donor	Data entry (i.e. change in unit status)					
Superv	S-EI-LI	[LRBLSEL]	Edit unit log-in	Data edit					
Superv	S-EI-PI	[LRBLSEC]	Edit unit-patient fields	Data entry/edit					
Superv	S-EI-PP	[LRBLJM]	Edit pooled blood product	Data entry/edit					
Superv	S-EP-LD	[LRBLST]	Tests for display on patient lookup	Software control					
Superv	S-EP-PE	[LRBLPEDIT]	Patient ABO/Rh edit	Data entry/edit					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.

___ I approve implementation of the software effective _____

___ I do NOT approve implementation until necessary corrective action is taken.

Comments:

_____

_____

_____

Signature: _____ (Blood Bank Supervisor) Date: _____

Signature: _____ (Blood Bank Medical Director) Date: _____

Signature: _____ (IRM staff/LIM) Date: _____

Date/time Implemented in Production_____

SUPERVISOR FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Superv	S-EP-PP	[LRBLSPP]	Patient previous transfusion record	Data entry/edit					
Superv	S-EP-TH	[LRBLSET]	Tests for inclusion in transfusion report	Software control					
Superv	S-EP-TR	[LRBLPTXR]	Unknown unit transfusion reaction	Data entry/edit					
Superv	S-EP-TX	[LRBLTX]	Tests for transfusion follow-up	Software control					
Superv	S-FD	[LRUFILE]	Outline for one or more files	Report generation					
Superv	S-II	[LRBLII]	Blood bank inventory integrity report	Integrity check/ Report generation					
Superv	S-LL	[LRBLSF]	Edit number of lines in a label	Form/label format control					
Superv	S-SR-AD	[LRBLAD]	Print data change audits	Report generation					
Superv	S-SR-AP	[LRBLPAB]	Antibodies by patient	Report generation					
Superv	S-SR-AR	[LRBLPRA]	Patient antibody report (long list)	Report generation					
Superv	S-SR-CD	[LRBLDCU]	Cumulative donations and awards	Calculation & report generation					

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SUPERVISOR FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

						Acceptability of Test Cases			
Func. Area	Menu Abbv.	Option Name	Menu Name	Option Desc.	Limited Access	Norm	Except	Bound	Inval
Superv	S-SR-DA	[LRBLDAWARD]	Acknowledge donor award by deletion	Data edit					
Superv	S-SR-PL	[LRBLSDPL]	Delete a user's patient list	Data edit					
Superv	S-SR-PU	[LRBLRUF]	Print units with final disposition	Report generation					
Superv	S-SR-PX	[LRBLDEX]	Print ex-donors	Report generation					
Superv	S-SR-RA	[LRBLAR]	Remove audit data changes	Data deletion					
Superv	S-SR-RI	[LRBLSRI]	Remove inappropriate transfusion requests	Data deletion					
Superv	S-SR-RU	[LRBLSER]	Remove units with final disposition	Should be disabled at site					
Superv	S-SR-RX	[LRBLDK]	Remove ex-donors	Data deletion					
Superv	S-SW	[LRUWL]	Display workload for an accession	Report generation					

Based on a review of the actual observations from the testing of both the control functions and the routine operations and the record of any unusual occurrences, bugs and deviations from the Blood Bank User Manual (all documented separately), I concur with the acceptability of the test cases as noted above.
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Signature: _____ (Blood Bank Supervisor) Date: _____
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Date/time Implemented in Production_____

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Blood Bank Frequently Asked Questions

Question:
A Blood Bank accession was incorrectly processed on the wrong patient and ABO/Rh results were entered and verified. We have determined that the patient was not seen on the day of the accession and that the patient had no previous ABO/Rh performed at this site. We have also determined that no report was sent to the ordering location. How can we delete the results from this patient's record?

Answer:
When ABO and Rh results are entered on an accession for the first time, results are stored, associated with the accession, and a historical record is created for future test comparisons.

Step 1 – Delete the results. Results can be deleted from an incorrectly processed accession by a blood bank technologist using the option ET Enter test data [LRBLPET] and entering @ by the results to be deleted. Details of the deletion will be automatically added to an audit trail, which should be printed, reviewed and stored at your site (option Print data change audits [LRBLAD]).

Step 2 – Delete the historical record by direct global edit. Provide your IRM support person with the full name and social security number of the patient's record to be edited. IRM support must first determine the Internal Entry Number (IEN) of the patient. Using this information, IRM support can determine the patient's Laboratory Reference Number (LRDFN) by looking at the following global reference: ^DPT(IEN,"LR") = LRDFN. Once the LRDFN is known, the global location to be edited is ^LR(LRDFN,0). An example using an LRDFN of 100 looks like: ^LR(100,0) = 100^2^2504^^O^POS. Fields are delimited by the ^. The ABO and Rh are in the 5th and 6th piece of the node. IRM support should edit this node making the 5th and 6th pieces null. Because this transaction will not be captured in an audit trail, a screen capture of this process should be printed, documented, and stored in the blood bank with the audit trail generated in Step 1, above.

Question:
We are unable to enter crossmatch results on units selected for a patient. We have a valid specimen and test results were entered. We get a message saying that there are no ABO &/or Rh results and no Antibody Screen results.

Answer:

The options Delete entire order or individual tests [LRCENDEL], and Remove an accession [LRDELOG] formerly removed all traces of cancelled orders and accessions. After installation of Laboratory patch LR*5.2*221 these activities remain on the system with a status of "Not Performed". This has caused confusion when using the option Select units for patients [LRBLPIC] when assigning units for crossmatch.

The following example may help explain the issue.

Patient Bbpatient, One had two specimens collected for Type & Crossmatch, one of which was rejected. Test results were entered on the correct accession, but when selecting units for the patient, the wrong accession was chosen. See sample screen below.

```
US  Select units for patients

Select Patient Name: BBPATIENT,ONE        5-20-23    000000001     NO
 NSC VETERAN
Bbpatient,One ID: 000-00-0001 Physician: BBPROVIDER,ONE

Component(s) requested  Units Request date/time Wanted date/time Requestor   By
AS-1 RED BLOOD CELLS      2   02/08/2001 08:28  02/08/2001 08:28 TB          OB

Blood component for unit selection: AS-1  AS-1 RED BLOOD CELLS    04210     AS-1

1) 02/08/2001 08:20 Acc # BB 0208 2
2) 02/08/2001 08:18 Acc # BB 0208 1
Select patient blood sample (1-2): 2
```

(NOTE: Accession BB 0208 2 has results entered, but in the pick list, accession # 2 is choice # 1)

When this happens, the error message/screen looks similar to the example below (capture edited for brevity, user input is underlined).

```
XM  Enter crossmatch results

Select Patient Name: BBPATIENT,ONE        5-20-23    000000001     NO
 NSC VETERAN
Bbpatient, one  0001               O POS
      Unit for XMATCHING                          Exp date        Loc

 1)   045412345     AS-1 RED BLOOD CELLS      O POS 02/26/01        Blood Bank
      No patient ABO &/or Rh results
      No antibody screen results (spec date:02/08/01 08:18 acc#:1)

 2)   047699003     AS-1 RED BLOOD CELLS      O POS 02/26/01        Blood Bank
      No patient ABO &/or Rh results
      No antibody screen results (spec date:02/08/01 08:18 acc#:1)

Select units (1-2) to enter XMATCH results: 1

 1)   045412345     AS-1 RED BLOOD CELLS      O POS 02/26/01        Blood Bank
      No patient ABO &/or Rh results
      No antibody screen results (spec date:02/08/01 08:18 acc#:1)

Sorry, must have ABO/Rh results to enter XMATCH results
```

To correct the situation, it is necessary to unselect the units associated with the incorrect specimen and the component order must be deleted and re-entered using option Blood component requests [LRBLPCS]. See sample screen capture below (edited for brevity):

```
CR  Blood component requests

Select Patient Name: Bbpatient,One        5-20-23    000000001     NO
 NSC VETERAN
Bbpatient,One. ID: 000-00-0001 Physician: BBPROVIDER,ONE

Component(s) requested  Units Request date/time Wanted date/time Requestor   By
AS-1 RED BLOOD CELLS      2   02/08/2001 08:28  02/08/2001 08:28 TB          OB

Select BLOOD COMPONENT REQUEST: AS-1 RED BLOOD CELLS  // @    (Typing in the @
removes this request.)
   SURE YOU WANT TO DELETE THE ENTIRE BLOOD COMPONENT REQUEST? Y  (Yes)
Select BLOOD COMPONENT REQUEST: AS-1 RED BLOOD CELLS      04210     AS-1   1
```

(**NOTE:** You must now re-add the request. Continue with original order information.)

Once this has been completed, the option Select units for patients [LRBLPIC] must be re-executed to select appropriate units, being careful to associate them with the correct accession.

Question:
My blood supplier has begun to ship a new type of blood product. They have not converted to ISBT 128 labeling. The unit ID is totally numeric, but when I use the scanner to read the Unit ID label during Log-in regular (invoices) [LRBLILR], the first two characters are converted to letters.

Answer:
Recheck the SUPPLIER multiple setup in the BLOOD PRODUCT File (#66) for this product as this determines how the Unit ID label is interpreted for Codabar labeled products. Although the Unit ID barcode always scans 7 numeric characters, but the eye-readable Unit ID can be interpreted in 4 different ways. For this reason it is recommended that separate SUPPLIER multiple entries be created for every possible labeling configuration of Codabar blood product that your site may receive. (This will no longer be an issue once the transition to ISBT 128 labels is complete.)

There are three key fields which control the scanner output:

SUPPLIER: Create a unique entry for each variation in Unit ID that is received from your source, i.e. a separate entry for each eye-readable prefix and/or totally numeric Unit ID versus a Unit ID with letters.

SUPPLIER PREFIX NUMBER: For Codabar labels, a blood collection facility, such as the American Red Cross, may append a 2-digit number to the beginning of the Unit ID. This eye-readable prefix identifies the blood collection facility (SUPPLIER) and is not scanned. It must be added to the Unit ID by the Blood Bank software, if there is not an entry in this field for the particular supplier. This activity occurs during the review process of Log-in regular (invoices) [LRBLILR].

UNIT LABEL NON-STANDARD: If you answer NO here, when you scan in a Unit ID for a Codabar-labeled product defined for this supplier, the first two numbers will convert to alpha characters based on an algorithm that is software driven. If you answer YES or NULL, the interpretation of the scanned input remains literal.

Question:
We just got a new scanner and when it reads a blood bag label, it displays letters like a, b, c etc. on either side of the scanned display.

Answer:
These are start and stop codes used in Codabar. You can refer to the manual that came with the scanner or contact the manufacturer to determine how to disable them.

Question:
We just got a new scanner and when our IRM scans a UNIT ID labels at the programmer prompt to test the setup, only numbers are displayed, although the Unit ID has a couple of numbers, then a couple of letters, and five numbers.

Answer:
The UNIT ID label on a Codabar-labeled blood bag always scans 7 numbers. The Blood Bank software interprets this information into what appears on the bag, based upon the information in the BLOOD PRODUCT File (#66) for that product and supplier.

Question:
My site has standardized on Intermec and Zebra printers. Why can't I print Caution Tag labels on these devices?

Answer:
The current Blood Bank software was written, verified and tested to use dot-matrix printers using Kernel device handling utilities, which provides device flexibility. The newer Intermec and Zebra-type printers require specific drivers that work only on certain model printers for specific functions, which the current Blood Bank software does not support. Because the Blood Bank software is scheduled for replacement, there is no initiative to provide this support in the current system.

NOTE: The FDA regards a Caution Tag as part of the Medical Device. The FDA considers any site that writes software to produce Caution Tag labels as the manufacturer of a medical device and subject to the applicable FDA regulations.

Question:
When entering patient transfusion results using the option Blood transfusion results [LRBLPT], sometimes there is a default entry for TREATING SPECIALTY, and sometimes there is not. Why is this?

Answer:
The Blood Bank software displays the TREATING SPECIALTY for patients with an in-patient status. If the patient is transfused as an outpatient or is discharged prior to entry of the transfusion results, the

TREATING SPECIALTY must be entered manually. The transfusion episode cannot be recorded unless this field is populated.

Question:
When printing the report Unit issue book entries [LRBLIRB] sometimes there seems to be information missing on some transactions. What could be causing this?

Answer:
Typically this results from using the Supervisory edit option Edit unit - patient fields [LRBLSEC] to enter data. This option has minimal control functions, allowing the user to enter erroneous or incomplete data. For this reason, the user is required to have the LRBLSUPER key, its access should be restricted, and its use should be limited to modifying previously entered data or to enter data after prolonged computer downtime.

Question:
It is sometimes necessary to transfuse an Rh Negative patient with Rh Positive red cell units. How can we process this in the computer?

Answer:
There are two methods of accomplishing this task, both of which include some risk and require an individual with the LRBLSUPER key:

1. Temporarily modify the BLOOD PRODUCT File (#66) entry for the product to be assigned so that no check is performed for Rh compatibility. To accomplish this, delete the entry for the field PATIENT/PRODUCT RH. When this field is null, there is no system check for Rh compatibility and Rh incompatible units can be assigned. Once the units are assigned, immediately restore the previous entry of MUST BE COMPATIBLE to that field. Crossmatch results can then be entered, the unit relocated, and transfusion results entered, using the standard Blood Bank options.

   Benefit: Standard Blood Bank options can be used for continued processing of the patient. The patient record will be complete and all associated reports will be populated.

   Risk: While the field is null, no checking is done for any patients processed. There is also a risk that the field will not be restored in a timely manner.

2. Process the transfusion 'off-line' and use the option Edit unit – patient fields [LRBLSEC] to enter unit selection, testing and relocation data. Once completed, the standard Blood Bank option Blood transfusion results [LRBLPT] can be used to enter the transfusion results.

   Benefit: Checking for Rh Compatibility functionality is never disabled.

   Risk: Option Edit unit –patient fields [LRBLSEC] is cumbersome for entering new data. In addition, there are no control functions when entering data using this option and no checks are performed to ensure all data is entered correctly.

Question:
Our blood supplier recycles Unit ID numbers every 5 years. Occasionally we receive a blood component with the same Unit ID that already exists in the BLOOD INVENTORY File (#65). What is the best way to deal with these?

Answer:
The Blood Bank software is designed to determine uniqueness based on the combination of the Unit ID and the Component type. When this combination already exists in the BLOOD INVENTORY File (#65), the only option is to return the duplicate unit to the supplier. It is not safe to attempt to process it into the Inventory.

Question:
We had a patient with an antibody and the software didn't check to see that antigen typing had been performed on selected units.

Answer:
This problem typically occurs for one of the following reasons:

1. The site has not used the option Edit Corresponding Antigen/Antibody [LRBLSNO] to indicate antigen/antibody checking to be performed at the site. VistA uses the SNOMED tables for antibody identification, and not all entries classified as antibodies in SNOMED are considered clinically significant It is the responsibility of each site to use this option to associate each antibody considered clinically significant with its associated antigen, also derived from the SNOMED tables.

2. When entering test results, the blood bank tech failed to enter the antibody identification in both the Select SERUM ANTIBODY and Select ANTIBODIES IDENTIFIED prompts. Select SERUM ANTIBODY records the antibody as detected, and only associates it with the specific accession being processed. Clinically significant and not clinically significant antibodies should be entered here. To create a patient's permanent historical record of clinically significant antibodies, an additional entry must be created in the Select ANTIBODIES IDENTIFIED prompt to trigger a check for the absence of a corresponding antigen in assigned red cell units. Should the antibody titer become undetectable, entries made in the Select ANTIBODIES IDENTIFIED prompt ensure future crossmatches will also check for absence of the corresponding antigens.

Question:
Why am I sometimes asked to scan an ABO/Rh label at the beginning of an option? What purpose does this serve?

Answer:
It requires software manipulation to interpret what a barcode scanner reads into what is seen by the user. When you are asked to scan an ABO/Rh label at the beginning of an option, you are telling the computer to expect data from a barcode scanner during the session. The ABO/Rh label was chosen since it has a small subset of possible results and is easy to code.

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