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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Appendix E-4 Laboratory V. 5.2 March 2001 Blood Bank User Manual

# 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.
	1. 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.

* 1. 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.

* 1. 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.
	2. 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.
1. 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.
2. 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.
3. At a minimum, the change control records should include:
	1. a description of the change,
	2. the date of the change,
	3. the person making the change,
	4. equipment or other functions that are affected by the change,
	5. an authorization signature,
	6. the validation risk assessment, and
	7. the documentation of approval and acceptance.

### Procedure

## Planning

#### VistA Patch/Version Update

* 1. Review the information provided with the patch/new version to determine the scope of the changes.
	2. Determine the potential impact of this specific change on your individual division/ facility.
	3. Determine what the training needs are, i.e., who will require training and what type of training is necessary.
	4. Have the patch/new version loaded in a mirrored test account so that the functionality and the impact of the patch can be assessed.
	5. 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.

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

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

#### 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

#### 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

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

* 1. 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.
	2. 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.
	3. 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

#### 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

## 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.

#### 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.

#### 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:

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

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

* 1. No specific computer training is necessary for additions of new suppliers to an existing blood product in File (#66).
	2. 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.

#### 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:

* 1. 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
	2. the entries for the new entry involve software control for which training has not previously been provided.

#### 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.

#### 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.

## Implementation

#### 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 effect on blood bank functionality.

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

* 1. Use the Edit blood products file [LRBLSEB] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.
	2. 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.
	3. 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.

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

* 1. Use the Edit blood bank utility [LRBLSEU] option in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.
	2. 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.
	3. 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.
	4. 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.
	5. 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.

#### 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.

* 1. 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.
	2. 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.

#### 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..

* 1. 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.
	2. 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.
	3. 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.

## 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.

#### 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.

#### Additions/Changes to Files unrelated to patches/version updates

* 1. 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
			1. 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
			2. 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.
			3. 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.
	2. 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

## 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.
		1. 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.
		2. 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:
		1. a description of the change,
		2. the date of the change,
		3. the name of the person making the change,
		4. any equipment or other functions that are affected by the change,
		5. an authorization signature,
		6. a validation risk assessment, and
		7. 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 productChange in blood product entry |
|  | [ | ] | (Specify: ) |
| **REASON FOR REQUEST:** | [[[[ | ]]]] | VistA Software Patch (Patch #: ) Change in standard operating procedure Change in scope of services providedOther (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) | **Valida- tion** |
| .01 NAMEidentifies product |  | (free text, 2-40 characters) | Accept.Unaccept. |
| .02 ABBREVIATIONcharacteristic used to access/identify this specific component |  | (free text, 1-4 characters) | Accept.Unaccept. |
| .03 CAN BE MODIFIEDdetermines whether this product can be modified into other products |  | (set) YESNO | Not needed Accept.Unaccept. |
| .04 IDENTIFIERdetermines whether this file entry can be accessed (only component/derivatives withIDENTIFIER = BB should be accessible at any prompt which references component |  | (set)BB ABT | Not needed Accept.Unaccept. |
| .05 PRODUCT CODEcharacteristic used to by bar code reader or by manual entry to access this specific component. 5 characters for Codabarlabeled components, 8 characters for ISBT 128 labeled components. |  | (free text, 1-8 characters) | Not needed Accept.Unaccept. |
| .055 DOD CODEused 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) | **Valida- tion** |
| .06 MODIFICATION CRITERIAdetermines the edit template used when this product is selected during modification of another product |  | (set) DIVIDED POOLED WASHED/ FROZENLEUKOCYTE POOR REJUVENATED DEGLYCEROLIZED IRRADIATED SEPARATED | Accept. Unaccept. |
| .07 PATIENT/PRODUCT ABOdetermines whether units selected for a patient must be identical or must be red cell compatible |  | (set)MUST MATCHMUST BE COMPATIBLE | Not needed Accept.Unaccept. |
| .08 PATIENT/PRODUCT RHdetermines whether units selected for a patient must be identical or must be red cellcompatible |  | (set)MUST MATCHMUST BE COMPATIBLE | Not needed Accept.Unaccept. |
| .09 PATIENT/PRODUCT REQUIREMENTdetermines whether units must be crossmatched or if the product containslarge volumes of plasma which should be compatible with the patient’s red cells |  | (set) CROSSMATCHPLASMA/ PATIENT COMPATIBILITY | Not needed Accept.Unaccept. |
| .1 VOLUME (ml)characteristic |  | (number, 0 decimals, 1-1000) | Not needed |
| .11 DAYS LEFTcalculates 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/ ADDITIVEprevents mixing of components during modifications (e.g., a product which has CPDA-1 cannot be modified to a productwhich has CPD as the anticoagulant) |  | (set) CPD ACD CPDA-1ADSOL | Not needed Accept.Unaccept. |
| .13 COLLECTION/PREP HOURSin the donor module options only, i.e., indicates the maximum time allowable between the DATE/TIME COLLECTIONSTARTED (65.54,4.2) and the DATE/TIME STORED (65.66,.03) |  | (number, 0 decimals,1-144) | Accept. Unaccept. |

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| **Additions/Change to the BLOOD PRODUCT File (#66) continued** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| .135 MAXIMUM STORAGE DAYSin 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 RELEASEprevents 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 REQUESTEDprevents selection of products which should not be accessed/selected |  | (set)YES NO | Not needed Accept.Unaccept. |
| .16 PATIENT SPECIMEN AGE ALLOWEDprevents selection of units of this product for specimens IF the difference between the current time and the BLOOD SAMPLEDATE/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 PREPARATIONdetermines whether units of this product must be retyped before issue/release. If YES, units which are created using the [LRBLIDN] option will appear on theInventory testing worksheet generated by [LRBLIW]. |  | (set) YES NO | Not needed Accept.Unaccept. |

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| **Additions/Change to the BLOOD PRODUCT File (#66) continued** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| .19 CONTAINS RED BLOOD CELLS1. 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 USEdetermines whether units of this product can be modified into pediatric units |  | (number in days, 0 decimals, 1-1827) | Accept.Unaccept. |
| .22 PEDIATRIC PRODUCTdetermines 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 GRAVITYin 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 COMPONENTdetermines whether additional data is neededto restrict selection of the unit for the intended patient (RESTRICTED FOR field) |  | (set) AUTOLOGOUS DIRECTED NEITHER | Not needed Accept.Unaccept. |
| .26 ADMINISTRATIVE CATEGORYused 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 RBCFROZEN RBC DEGLYC RBCLEUCODEPLETED RBC WASHED RBCFFP | Not needed Accept.Unaccept. |

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| **Additions/Change to the BLOOD PRODUCT File (#66) continued** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| .27 POOLED PRODUCTdetermines whether a unit of that specific product can be accessed through the Edit pooled blood product [LRBLJM] option; used by the integrity check routine in the [LRBLII] option to determine which fieldsmay have missing data |  | (set) YESNO | 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) YESNO | Accept. Unaccept. |
| .29 IS ISBT128Required 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 samelabeling type. |  | (set) YESNO | Accept. Unaccept. |
| 1 DESCRIPTION (Subfile 66.09).01 DESCRIPTIONintended for use for display purposes in future |  | (word processing; 1-50 characters) | Not Applicable |
| 2 SYNONYM (Subfile 66.021).01 SYNONYMused for look-up access purposes only |  | (free text; 2-50 characters) | Accept.Unaccept. |
| 3 MODIFY TO (Subfile 66.03).01 MODIFY TOdetermines 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 entriesin the IS ISBT128 field. |  | (pointer to File 66-enter name. ) | Accept. Unaccept. |
| 3 MODIFY TO (Subfile 66.03).02 NOT ONLY ONE ALLOWEDdetermines whether more than one productmay be created when modifying a unit in inventory using the [LRBLIDN] option |  | (set) YES NO | Accept. Unaccept. |
| 4 SUPPLIER (Subfile 66.01).01 SUPPLIERname of supplier - determines characteristics based on subfields detailed below |  | (free text; 1-30 characters) | Accept. Unaccept. |

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| **Additions/Change to the BLOOD PRODUCT File (#66) continued** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| 4 SUPPLIER (Subfile 66.01)used for look-up and information purposes only1. ADDRESS LINE 1
2. ADDRESS LINE 2
3. ADDRESS LINE 3
4. CITY
5. STATE
6. ZIP CODE
7. PHONE
 |  | 1. ADDRESS LINE 1

(free text; 1-30 charac.)1. ADDRESS LINE 2

(free text; 1-30 charac.)1. ADDRESS LINE 3

(free text; 1-30 charac.)1. CITY

(free text; 1-30 charac.)1. STATE

(pointer to State File(#5))1. ZIP CODE

(free text; 5-9 characters)1. PHONE

(free text; 4-30 charac.) | Accept. Unaccept. |
| 4 SUPPLIER (Subfile 66.01).02 COSTcalculates expenses for reports |  | (number, 0-9999) | Accept.Unaccept. |
| 4 SUPPLIER (Subfile 66.01).1 SUPPLIER PREFIX NUMBERdetermines 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 NUMBERused for reference/information only |  | (free text, 7-9 digits) | Not applicable |

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| **Additions/Change to the BLOOD PRODUCT File (#66) continued** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| 4 SUPPLIER (Subfile 66.01).12 UNIT LABEL NON-STANDARDcontrols the translation of the unit ID scanned by the bar code reader whenentering a unit in inventory using the [LRBLILR] option |  | (set)YES Non-Standard= numericNO Standard=alphanumeric | Accept. Unaccept. |
| 1 LOT # (Subfile 66.02)1. LOT #
2. 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 USEintended 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)1. TESTS TO CHECK
2. SPECIMEN
3. > OR < TEST VALUE
 |  | 1. TESTS TO CHECK

pointer to Laboratory Test File (#60)1. SPECIMEN

pointer to Topography Field File (#61)1. > OR < TEST VALUE

free text | Accept. Unaccept. |
| 7 REQUISITION INSTRUCTIONS (Subfile 66.07).01 REQUISITION INSTRUCTIONSintended for use for display purposes in future |  | (word processing) Not applicable | Not applicable |

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| **Additions/Change to the BLOOD PRODUCT File (#66) continued** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| 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)1. PRE-OP TESTS TO CHECK
2. SPECIMEN
3. > OR < TEST VALUE
 |  | 1. TESTS TO CHECK

pointer to Laboratory Test File (#60)1. SPECIMEN

pointer to Topography Field File (#61)1. > OR < TEST VALUE

free text | Accept. Unaccept. |
| 9 EQUIVALENT PRODUCTThe 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 futuredatabase 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 DIVISIONlimits access to products based the division of the user at a given point in time with the products attempting to be requested; allowsmultiple entries for multidivisional facility |  | (pointer to INSTITUTION File (#4)) | Not needed Accept.Unaccept. |
| 500 WKLD CODE(Subfile 66.06).01 WKLD CODEused for workload capture by the [LRBLIDN] option and the [LRBLDCP] option |  | (pointer to WKLD CODE File (#64))86183 Irradiation86269 Cryo prep (>4)86271 Cryo prep86272 Cryo thaw/pooling 86275 Frozen Bld Prep 86276 Deglyc. Froz. Bld 86277 Rejuvenation86390 Plt prep (>4)86392 Plt prep86393 Platelet pooling86670 Washed RBC86795 RBC prep86796 RBC prep (>4)86800 FFP86801 FFP prep (>4)86805 FFP thawing86810 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: Signature: Signature:

(BB Supervisor)

(BB Medical Director) (LIM/IRM Staff)

Date Implemented in Production:

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

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| **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 NAMEfree text, 2-40 characters | identifies product, i.e., blood/blood component | Not Applicable |
| .02 ABBREVIATIONfree text, 1-4 characters | characteristic/property; used to access thisspecific component and to identify the components on displays and/or reports | Not Applicable |
| .03 CAN BE MODIFIEDset; yes/no | software control function, i.e., determines whether this product can be modified intoother products | Required- use the [LRBLIDN] option |
| .04 IDENTIFIERset; BBAB 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 ABcannot be accessed. |
| .05 PRODUCT CODEfree 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 correctproduct |
| .055 DOD CODEfree text, 2-5 characters | characteristic/property; free text used by the Department of Defense | Not Applicable for VA use |
| .06 MODIFICATION CRITERIA set; DIVIDEDPOOLED WASHED FROZENLEUKOCYTE 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 |

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| **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 MATCHMUST 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 entriesfunction appropriately |
| .08 PATIENT/PRODUCT RH set; MUST MATCHMUST 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 REQUIREMENTset; CROSSMATCH/ PLASMA/ PATIENTCOMPATIBILITY | 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’sred cells | No additional validation necessary once it has been demonstrated that other file entriesfunction appropriately |
| .1 VOLUME (ml)number, 0 decimals, 1-1000 | characteristic/property; | Not Needed |
| .11 DAYS LEFTnumber, 2 decimals, .16-2557 | software control function, i.e., calculates the new expiration date required if this product isprepared from another product present in inventory. | Required- use the [LRBLIDN] option |
| .12 ANTICOAGULANT/ ADDITIVEset; CPDACD 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 |

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| **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 HOURSnumber, 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) andthe DATE/TIME STORED (65.66,.03) | Required- use the [LRBLDC] option |
| .135 MAXIMUM STORAGE DAYSnumber, .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) forpotential data entry errors | Required- use the [LRBLDC] optionRequired- use the [LRBLILR] option |
| .14 MODIFIED BEFORE RELEASEset; YESNO | 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 REQUESTEDset; YESNO | 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 entriesfunction appropriately |
| .16 PATIENT SPECIMEN AGE ALLOWEDnumber, 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 withthe same time entry function appropriately |

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| **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 PREPARATIONset; YESNO | 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 willappear 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 CELLSset; YESNO | 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 USEnumber, 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 PRODUCTpointer 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 theANTICOAGULANT/ ADDITIVE field | Required- use the [LRBLPED] option |
| .23 SPECIFIC GRAVITYset; 1.061.081.03 | 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 functionappropriately |

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| **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 fileentries function appropriately |
| .25 AUTOLOGOUS/ DIRECTED COMPONENTset; 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 functionappropriately |
| .26 ADMINISTRATIVE CATEGORYset; WHOLE BLOOD RBCFROZEN RBC DEGLYCRBC LEUCODEPLETED RBC WASHED RBCFFP CRYORANDOM PLAT APHERESIS PLATGRANULOCYTES | 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 PRODUCTset; YESNO | algorithm function used by the integrity check routine in the [LRBLII] option to determine which fields may have missing datasoftware control function, i.e., determines whether a unit of that specific product can be accessed through the Edit pooled blood product [LRBLJM] option | No additional validation necessary once it has been demonstrated that other comparable file entries function appropriatelyRequired-use the [LRBLJM] option |
| .28 ASK BAG LOT #set; YESNO | software control function, i.e., determines whether the BAG LOT # field (65,1.1) shouldbe included in the edit template used by the [LRBLIDN] option when modifying units | Required-use the [LRBLIDN] option |

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| **BLOOD PRODUCT File (#66) continued** |
| **Field # and Name** | **Purpose of the field (software control function,****characteristic/property, algorithm function)** | **Changes Require Validation?** |
| .29 IS ISBT128set; YESNO | Indicates whether product type belongs to ISBT128 or to CODABAR | No additional validation necessary once it has been demonstrated that other comparable fileentries function appropriately |
| 1 DESCRIPTION (Subfile 66.09).01 DESCRIPTIONword processing; 1-50 characters | characteristic/property; intended for use for display purposes in future | Not applicable |
| 2 SYNONYM (Subfile 66.021).01 SYNONYMfree 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 TOpointer 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 Filethat have matching entries in the IS ISBT128 field. | Required- use the [LRBLIDN] option |
| 3 MODIFY TO (Subfile 66.03).02 NOT ONLY ONE ALLOWEDset;YESNO | 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 SUPPLIERfree 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 |

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| **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)1. ADDRESS LINE 1

free text; 1-30 characters1. ADDRESS LINE 2

free text; 1-30 characters1. ADDRESS LINE 3

free text; 1-30 characters1. CITY

free text; 1-30 characters1. STATE

pointer to State File (#5)1. ZIP CODE

free text; 5-9 characters1. 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 COSTnumber, 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 NUMBERfree 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 NUMBERfree text, 7-9 digits | characteristic/property; used for reference/information only | Not applicable |

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| **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- STANDARDset; YESNO | 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] optionNOTE: 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)1. LOT #

free text, 1-30 characters1. EXPIRATION DATE

date | not currently used by the software | Not applicable |
| 5 CRITERIA FOR USE (Subfile 66.05).01 CRITERIA FOR USEword processing | characteristic/property; intended for use for display purposes in future | Not applicable |
| 6 TESTS TO CHECK (Subfile 66.08)1. TESTS TO CHECK

pointer to Laboratory Test File (#60)1. SPECIMEN

pointer to Topography Field File (#61)1. > 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 INSTRUCTIONSword processing | characteristic/property; intended for use for display purposes in future | Not applicable |

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| **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)1. PRE-OP TESTS TO CHECK

pointer to Laboratory Test File (#60)1. SPECIMEN

pointer to Topography Field File (#61)1. > 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 afuture product. | Not Applicable |
| 10 ASSOCIATED DIVISION (Subfile 66.1).01 ASSOCIATED DIVISIONpointer 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 functionappropriately |
| 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 fileentries function appropriately |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **TYPE OF REQUEST:** | [[ | ]] | Additional blood group antigen/antibodyChange in blood group antigen/antibody entry |
|  | [ | ] | (Specify: ) |
| **REASON FOR REQUEST:** | [[[[ | ]]]] | VistA Software Patch (Patch #: ) Change in standard operating procedure Change in scope of services providedOther (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.

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| **Additions/Change to the FUNCTION FIELD File (#61.3)** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| .01 NAMEidentifies antigen/antibody |  | (free text, 1-30 characters) |  |
| .04 CORRESPONDING ANTIGEN/ANTIBODYcompares entries in the ANTIBODIES IDENTIFIED field (#63,.075) for a specific patient with entries in the RBC ANTIGEN S ABSENT field (#65,70) forthe unit. |  | (pointer to File 61.3) | Accept. Unaccept. |
| .06 COMPATIBILITY FACTORused to calculate the percentage of compatible units for inclusion on the Blood Bank Consultation Report generated for patients with clinicallysignificant antibodies |  | (number, 3 decimals, 0-1) | Accept. Unaccept. |

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| **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 |  | .01 TITLE OF ARTICLEfree text, 1-80 characters | Accept.Unaccept. |
| 1 AUTHOR | 1 AUTHORfree text, 1-80 characters |  |
| 2 MEDICAL JOURNAL |  |  |
| 3 VOLUME | 2 MEDICAL JOURNALpointer to LAB JOURNAL file (#95) |  |
| 4 STARTING PAGE |  |  |
| 5 DATE | 3 VOLUMEfree text, 1-6 characters |  |
| 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 | 4 STARTING PAGEfree text, 1-6 characters |  |
|  | 5 DATEdate |  |
| 1. JOURNAL REFERENCE (Subfile 61.32) continued
2. 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 COMMENTprints on the Blood Bank ConsultationReport 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: Signature: Signature:

(BB Supervisor)

(BB Medical Director) (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 NAMEfree text, 1-30 characters | identifies antigen/antibody |  |
| .04 CORRESPONDING ANTIGEN/ANTIBODYpointer 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. | Required - use the [LRBLPX] and the [LRBLIDR] options |
|  | 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. |  |
| .06 COMPATIBILITY FACTORnumber, 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 clinicallysignificant 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 freetext, 1-80 characters | 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 |
| 1 AUTHOR freetext, 1-80 characters |  |  |
| 2 MEDICAL JOURNALpointer to LAB JOURNAL file (#95) |  |  |
| 3 VOLUME freetext, 1-6 characters |  |  |
| 4 STARTING PAGEfree text, 1-6 characters |  |  |
| 5 DATE date |  |  |
| 5 JOURNAL REFERENCE | software control, i.e., determines which | Required - use the |
| (Subfile 61.32) | journal references to include on the Blood | [LRUCN] option |
| 6 LIST ON PATIENT RECORD | Bank Consultation Report generated for |  |
| set; YES | patients with clinically significant antibodies if |  |
| NO | field 61.32,6 is set to YES |  |
| 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 providedOther (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) | **Valida- tion** |
| .01 NAMEidentifies 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 SCREENdetermines which entries in the file areaccessible during specific data entry options |  | (set)GROUP AFFILIATIONDEFERRAL CODE | Not neededAccept. |
|  |  | Unaccept. |
|  | COLLECTION SITE |  |
|  | GR0UP AFFILIATION& COLLECTION SITE |  |
|  | DONOR REACTION |  |
|  | TRANSFUSION REACTION |  |

|  |
| --- |
| **Additions/Change to the BLOOD BANK UTILITY File (#65.4) continued** |
| **Field # and Name** | **Current Entry\***\*if applicable | **New Entry**(format for entry) | **Valida- tion** |
| .03 FULL NAMEcharacteristic/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: Signature: Signature:

(BB Supervisor)

(BB Medical Director) (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 questionChange in existing donor history question |
|  | [ | ] | (Specify: ) |
| **REASON FOR REQUEST:** | [[[[ | ]]]] | Change in accrediting/regulatory requirement Change in standard operating procedure Change in scope of services providedOther (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) | **Valida- tion** |
|  |  | 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: Signature: Signature:

(BB Supervisor)

(BB Medical Director) (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 providedOther (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) | **Valida- tion** |
|  |  | 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: Signature: Signature:

(BB Supervisor)

(BB Medical Director) (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 NAMEfree 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 SCREENset; 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 previouslyNo additional validation necessary once it has been demonstrated that other comparable file entries functionappropriately |
| .03 FULL NAMEfree text, 1-80 characters | characteristic/property | Yes - need to make sure that it is accurate and accesses the correct fileentry |
| 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 CITYfree text, 1-30 characters | characteristic/property | Not Applicable |
| 1.5 STATEpointer to State File (#5) | characteristic/property | Not Applicable |
| 1.6 ZIP CODEfree text, 5-9 characters | characteristic/property | Not Applicable |
| 1.7 PHONE 1free text, 3-15 characters | characteristic/property | Not Applicable |
| 1.8 PHONE 2free text, 3-15 characters | characteristic/property | Not Applicable |
| 1.9 GROUP LEADER free text, 3-30 characters | characteristic/property | Not Applicable |
| 2 DONOR HISTORYword processing | software control, i.e. entries on the donor history questionnaire | Yes- use the [LRBLDR] option |
| 3 COMMENTword 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 entryChange in entry |
|  | [ | ] | (Specify: ) |
| **REASON FOR REQUEST:** | [[[[ | ]]]] | VA Software Patch (Patch #: ) Change in standard operating procedure Change in scope of services providedOther (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) | **Valida- tion** |
| .18 BLOOD DONOR UNIT ID PREFIXcharacteristic 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 setappropriately |  | (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) | **Valida- tion** |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).02 FIRST DEFAULTFor 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 DEFAULTFor PATIENT: determines whether prompts for direct antiglobulin testing should be included in the LRBLSCREENedit template used in the [LRBLPET] option to enter test results |  | (set) YES NO | Accept. Unaccept. |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).03 SECOND DEFAULTFor DONOR: determines whether themilitary 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 DEFAULTFor DONOR: determines whether thebag lot # should be included in the [LRBLDC] option |  | (set) YES NO | Accept. Unaccept. |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).05 FOURTH DEFAULTFor DONOR: determines whether thedonor’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) | **Valida- tion** |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).06 FIFTH DEFAULTFor 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 DEFAULTFor 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 SECTIONcharacteristic/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 SUBSECTIONcharacteristic/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 INSTITUTIONcharacteristic/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 SECTIONcharacteristic/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 SUBSECTIONcharacteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recordingpurposes 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 SECTIONcharacteristic/property, i.e., accession area to be used for workload recording purposes; used for workload recording purposes for workload associated withthe Blood Donor File (#65.5) |  | (pointer to Accession File (#68) | Not Applicable |
| 8.1 BLOOD BANK INSTITUTION (Subfile 69.981).05 DONOR SUBSECTIONcharacteristic/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 AREAdetermines whether the site is multidivisional and/or has more than one accession area for Blood BankNOTE: This field cannot be accessed through the [LRBLSSP] option. It must be edited by someone with a highersecurity 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: Signature: Signature:

(BB Supervisor)

(BB Medical Director) (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 PREFIXnumber, 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 codedportion | Required - use the [LRBLDCP] option to scan the unit ID number to access the unit, and then by manual entry ofthe entire unit ID |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).01 BLOOD BANK OPTION(multiple) | software control functions as detailed in the subfields below\*\* indicates placeholders for future functionality (not currently in use) | Not Applicable- see specific subfields below |
| 1. DONOR
2. INVENTORY\*\*
3. PATIENT
4. INQUIRIES\*\*
5. REPORTS\*\*
6. SUPERVISOR\*\*
7. TEST WORKLISTS\*\*
8. WARD\*\*
 |  |  |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).02 FIRST DEFAULTset:YESNO) | 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. | Required - use the [LRBLDRR] option to release the unit and the [LRBLISPD] option to see whether the ABO and Rh were transferred |
|  | If the results are not moved, the unit rechecks must be done before the unit can be released on a patient. |  |

\*\*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 DEFAULTset:YESNO | 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 DEFAULTset:YESNO | 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 | software control, i.e., for DONOR: determines whether the bag lot # should be included in the [LRBLDC] option | Yes |
| set:YESNO |  |  |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).05 FOURTH DEFAULT | 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 |
| set:YESNO |  |  |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).06 FIFTH DEFAULT | software control, i.e., for DONOR: determines whether ALT testing is to be included in the transfusion transmitted disease testingperformed on blood donors | Yes |
| set:YESNO |  |  |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).07 SIXTH DEFAULT | software control, i.e., for DONOR: determines whether HIV Antigen testing is to be includedin the transfusion transmitted disease testing performed on blood donors | Yes |
| set:YESNO |  |  |
| 8 BLOOD BANK DEFAULTS(Subfile 69.98).1 MAJOR SECTION | characteristic/property, i.e., accession area to be used for workload recording purposes | Not needed - used for workload recording purposes |
| pointer to Accession File (#68) |  |  |

|  |
| --- |
| **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 | characteristic/property, i.e., accession area to be used for workload recording purposes | Not needed - used for workload recording purposes |
| pointer to Accession File (#68) |  |  |
| 8.1 BLOOD BANK INSTITUTION (Subfile 69.981).01 BLOOD BANK INSTITUTION | characteristic/property, i.e., institution to be considered primary for this site | Not needed - used for workload recording purposes |
| pointer to Institution File (#4) |  |  |
| 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) | Not needed - used for workload recording purposes |
| pointer to Accession File (#68) |  |  |
| 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 workloadassociated with the Inventory File (#65) | Not needed - used for workload recording purposes |
| pointer to Accession File (#68) |  |  |
| 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 workloadassociated with the Blood Donor File (#65.5) | Not needed - used for workload recording purposes |
| pointer to Accession File (#68) |  |  |
| 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 workloadassociated with the Blood Donor File (#65.5) | Not needed - used for workload recording purposes |
| pointer to Accession File (#68) |  |  |

|  |
| --- |
| **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 AREAset; YESNO | software control function, i.e. determines whether the site is multidivisional and/or has more than one accession area for Blood BankNOTE: 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/.](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.

Determining 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 cross-references 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**

***RISK***

#### High

**Impact of Failure**

|  |  |
| --- | --- |
| **III** | **IV** |
| **I** | **II** |

#### Low Likelihood of Failure High

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 situations 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 performing 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 | MenuOption Abbrev | Type ofProcess Control | Brief Description of Control Function | Warning Message | Override Capability | Validation |
| Patient | [LRDELOG] | P-DA | ProcessControl | Prevents deletion ofaccession | Yes | No |  |
| Patient | [LRBLPT] | P-DT | Process Control | Limits access to units currently assigned to the samedivision as the user | No | No |  |
| Patient | [LRBLPT] | P-DT | Process Control | Prevents entry of future transfusiondate/time | No | No |  |
| Patient | [LRBLPT] | P-DT | Processcontrol | Updates patienttransfusion 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 ofunit 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 assignedto the appropriate division | No | Limited |  |
| Patient | [LRBLPCS] | P-RS-CR | Decision Support | Evaluates age of patient specimen (for the accession area for the appropriatedivision) | Yes | NA |  |
| Patient | [LRBLPCS] | P-RS-CR | Decision Support | Evaluates request against audit criteria and current labresults, 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 OptionAbbrev | Type of ProcessControl | 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 patienthistory | Yes | No |  |
| Patient | [LRBLPIC] | P-RS-US | Process Control | Prevents selection of units notABO/Rh compatible | No | Limited |  |
| Patient | [LRBLPIC] | P-RS-US | Process Control | Prevents selection of units not associated with the appropriate division (evenAutologous) | No | No—must transfer unit |  |
| Patient | [LRBLPIC] | P-RS-US | Process Control | Evaluates unit phenotyping againstclinically significant patient antibodies | No | Limited if pos |  |
| Patient | [LRBLPIC] | P-RS-US | Process Control | Prohibits selectionof Autologous unit for different patient | No | Limited |  |
| Patient | [LRBLPIC] | P-RS-US | Process Control | Prohibits use ofpatient specimen which is too old. | Yes | Limited |  |
| Patient | [LRBLPIC] | P-RS-US | Process Control | If requested, limitsselection to unassigned units | No | Limited |  |
| Patient | [LRBLPIC] | P-RS-US | ProcessControl | Prevents selectionof expired units | No | Limited |  |
| Patient | [LRBLPIC] | P-RS-US | DecisionSupport | Checks for lowvolume 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/Rhon 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 |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | Menu OptionAbbrev | Type of ProcessControl | Brief Description of Control Function | Warning Message | Override Capability | Validation |
| Patient | [LRBLPX] | P-RS-XM | Decision Support | Evaluates whether Antibody Screen results are enteredon current specimen | Yes | Yes |  |
| Patient | [LRBLPX] | P-RS-XM | Decision Support | Evaluates unit phenotyping against clinically significant patient antibody, regardless ofdivision | 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 appropriatedivision | 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, regardlessof division | Yes | Na |  |
| Patient | [LRBLPLOGIN] | P-SL | Decision Support | Displays recent lab values for auditing a request, regardlessof division | Yes | Yes |  |
| Patient | [LRBLPLOGIN] | P-SL | Decision Support | Displays Autologous units in inventory, regardless ofdivision | Yes | Yes |  |
| Patient | [LRBLPLOGIN] | P-SL | Decision Support | Evaluates age of patient specimen (for the accession area for the appropriatedivision) | Yes | NA |  |
| Patient | [LRBLPLOGIN] | P-SL | Decision Support | Evaluates request against audit criteria and current lab results, regardless ofdivision | Yes | Yes |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | Menu OptionAbbrev | Type of ProcessControl | 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 Surgeryin Surgery package | Yes | Yes |  |

#### Inventory Functional Area Control Functions

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | Menu OptionAbbrev | Type of ProcessControl | Brief Description of Control Function | Warning Message | Override Capability | Validation |
| Inventory | [LRBLIDN] | I-DN | Process Control | Prevents entry of future dispositiondates | Yes | No |  |
| Inventory | [LRBLIDN] | I-DN | Process Control | Restricts modification of components to specifiedcomponents | Yes | No |  |
| Inventory | [LRBLIDN] | I-DN | Process Control | Prevents modification of Autologous components to non- autologous components if testing isincomplete 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 modificationif 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 multiplemodifications to the same unit | No | No |  |
| Inventory | [LRBLIDN] | I-DN | Process Control | Restricts access to units to those which are assigned to thesame division | No | No |  |
| Inventory | [LRBLIDN] | I-DN | Decision Support | Calculates and suggests new expiration date formodified components | Yes | Yes |  |
| Inventory | [LRBLIDN] | I-DN | Decision Support | Identifies units which were released with incomplete testingresults | Yes | Yes |  |
| Inventory | [LRBLIDR] | I-DR | Process Control | Restricts access to units to those units which are assignedto the same division | Yes | No |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | Menu OptionAbbrev | Type of ProcessControl | Brief Description of Control Function | Warning Message | Override Capability | Validation |
| Inventory | [LRBLIDR] | I-DR | Process Control | Prevents issue if no entry for requiredrecheck results | Yes | Limited |  |
| Inventory | [LRBLIDR] | I-DR | Process Control | Evaluates unit phenotyping against clinicallysignificant patient antibodies | Yes | Limited |  |
| Inventory | [LRBLIDR] | I-DR | Process Control | Prevents issue if inspection isunsatisfactory | Yes | Limited |  |
| Inventory | [LRBLIDR] | I-DR | Process Control | Prevents issue if inspection from previous relocationwas unsatisfactory | Yes | Limited |  |
| Inventory | [LRBLIDR] | I-DR | Process Control | Prevents issue if unit is one which must be modifiedbefore 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 unitwas assigned to the patient | Yes | Limited |  |
| Inventory | [LRBLIDR] | I-DR | Decision Support | Evaluatesexpiration date of unit | Yes | Yes |  |
| Inventory | [LRBLILR] | I-LR | Process Control | Prevents duplicate entry of a unit id ofthe same component | Yes | Limited |  |
| Inventory | [LRBLILR] | I-LR | Process Control | Checks validity of expiration datebased on maximum days | Yes | Limited |  |
| Inventory | [LRBLILR] | I-LR | Process Control | Restricts entry of components to those in File 66with 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 |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | Menu OptionAbbrev | Type of ProcessControl | 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 divisionas the user | No | No |  |
| Inventory | [LRBLPED] | I-PD | Process Control | Restricts component selection to thoseappropriately defined | Yes | No |  |
| Inventory | [LRBLPED] | I-PD | Process Control | Limits access to those units assignedto the same division as the user | No | No |  |
| Inventory | [LRBLPED] | I-PD | Process Control | Restricts unitselection 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 | DecisionSupport | Identifies lowvolume units | Yes | Yes |  |
| Inventory | [LRBLPED] | I-PD | Process Control | Assigns final dispositions to unitswhen volume = 0 after last split | No | No |  |
| Inventory | [LRBLISH] | I-SH | Decision Support | Identifies units which were released withincomplete 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-ininformation | 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 ifappropriate | Yes | Yes |  |
| Inventory | [LRBLIUP] | I-UP | Process Control | Limits access to those units assigned to the same divisionas the user | No | No |  |
| Inventory | [LRBLIUR] | I-UR | Process Control | Prevents release of units from locationother than BB | Yes | No |  |

#### Donor Functional Area Control Functions

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | MenuOption Abbrev | Type ofProcess Control | Brief Description of Control Function | Warning Message | Override Capability | Validation |
| Donor | [LRBLDCP] | D-CP | Process Control | Checks number of components preparedagainst bag type | Yes | No |  |
| Donor | [LRBLDCP] | D-CP | Process Control | Ensures that no more than one RBCcomponent is prepared | Yes | No |  |
| Donor | [LRBLDCP] | D-CP | Process Control | Checks time between collection andcomponent preparation | Yes | No |  |
| Donor | [LRBLDCP] | D-CP | Process Control | Compares anticoagulant of collection with thatfor components | Yes | No |  |
| Donor | [LRBLDCP] | D-CP | Process Control | Prevents access todonors 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 topatients 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 ofduplicate donor IDs within 5 years | Yes | No |  |
| Donor | [LRBLDC] | D-DC | Process Control | Prevents entry of completion date/timeprior to start date/time | Yes | No |  |
| Donor | [LRBLDC] | D-DC | Process Control | Eliminates some gender specific questions onDonor History form | No | NA |  |
| Donor | [LRBLDC] | D-DC | Process Control | Prevents access to donors entered through‘Old Records’ | Yes | No |  |
| Donor | [LRBLDC] | D-DC | DecisionSupport | Checks for duplicatedonors | 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 ispermanently deferred | Yes | No |  |
| Donor | [LRBLDR] | D-DH | Decision Support | Includes special comments on DonorHistory form if appropriate | NA | Yes |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | Menu OptionAbbrev | Type of ProcessControl | Brief Description of Control Function | Warning Message | Override Capability | Validation |
| Donor | [LRBLDO] | D-DO | Process Control | Prevents entry of duplicate donor IDswithin 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 permanentlydeferred | 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 topatients 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 | DecisionSupport | Checks for duplicatedonors | Yes | Yes |  |
| Donor | [LRBLDUC] | D-DU-DC | Process Control | Compares recheck infoto original processing results | Yes | Yes |  |
| Donor | [LRBLDUC] | D-DU-DC | Process Control | Prevents same tech from entering both original and recheckresults | Yes | Limited |  |
| Donor | [LRBLDAT] | D-DU-DT | Decision Support | Checks current results against donor’shistorical record | Yes | Yes |  |
| Donor | [LRBLDT] | D-DU-LA | Process Control | Generates bulletin if positive results entered after componentreleased | Yes | No |  |
| Donor | [LRBLDT] | D-DU-LA | Process Control | Prevents editing of results after componentsare released | Yes | Limited |  |
| Donor | [LRBLDT] | D-DU-LA | Decision Support | Adds units needing repeat testing to worklist | 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 SITEFILE) | No | No |  |
| Donor | [LRBLDRR] | D-DU-LR | Process Control | Checks currentABO/Rh results against historical record | Yes | Limited |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Functional Area | Menu Option Name | Menu OptionAbbrev | Type of ProcessControl | Brief Description of Control Function | Warning Message | Override Capability | Validation |
| Donor | [LRBLDRR] | D-DU-LR | Process Control | Generates bulletin if unit released with ABOdiscrepancy | 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 HIVAntigen | No | No |  |
| Donor | [LRBLDRR] | D-DU-LR | Process Control | Prevents release of homologous units withpositive disease marker testing | Yes | No |  |
| Donor | [LRBLDRR] | D-DU-LR | ProcessControl | Enters units intoinventory if ‘released’ | No | No |  |
| Donor | [LRBLDRR] | D-DU-LR | Process Control | Verifies accuracy oflabeling via barcode reader | Yes | No |  |
| Donor | [LRBLDRR] | D-DU-LR | Process Control | Prevents same tech doing both labeling and release if barcode readernot used | Yes | No |  |
| Donor | [LRBLDRR] | D-DU-LR | Process Control | Assigns the division of the user who is labeling/releasing the unit into inventory when it is moved fromthe 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 inventorywith Positive/Incomplete testing | No | NA |  |
| Donor | [LRBLDRR] | D-DU-LR | Process Control | Flags homologous units released to inventorywith incomplete testing | No | NA |  |

#### Supervisor Functional Area Control Functions

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

# 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 | MenuAbbv. | Option Name | Menu Name | OptionDesc. | LimitedAccess | Norm | Except | Bound | Inval |
| Donor | D-CP | [LRBLDCP] | Collection disposition/component preparation | DataEntry |  |  |  |  |  |
| Donor | D-DC | [LRBLDC] | Donorcollection/processing | Data entry |  |  |  |  |  |
| Donor | D-DD | [LRBLDD] | Donor demographics | Data entry |  |  |  |  |  |
| Donor | D-DH | [LRBLDR] | Donor history, physical and consentform | Form generation |  |  |  |  |  |
| Donor | D-DO | [LRBLDO] | Old blood donor records | Data entry |  |  |  |  |  |
| Donor | D-DP | [LRBLDPH] | Donor phenotyping | Dataentry/edit |  |  |  |  |  |
| Donor | D-DR | [LRBLDLG] | Donor registration | Dataentry/edit |  |  |  |  |  |
| Donor | D-DU-CR | [LRBLDCR] | Component preparation report | Report generation |  |  |  |  |  |
| Donor | D-DU-DA | [LRBLDTA] | Abnormal donor tests | Reportgeneration |  |  |  |  |  |
| Donor | D-DU-DC | [LRBLDUC] | Donor unit ABO/Rhrecheck | Dataentry/ edit |  |  |  |  |  |
| Donor | D-DU-DL | [LRBLDDAW] | Donor unit testing work list | Report generation |  |  |  |  |  |
| Donor | D-DU-DR | [LRBLDTR] | Donor unit testingproof list | Reportgeneration |  |  |  |  |  |
| Donor | D-DU-DS | [LRBLDTRS] | Donor unit testingsupplemental proof list | Reportgeneration |  |  |  |  |  |
| 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 donorunits | Data entry/edit |  |  |  |  |  |
| Donor | D-DU-LR | [LRBLDRR] | Test review/componentlabeling/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:

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 –nottransfused | 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 inventorytyping charges | Data entry |  |  |  |  |  |
| Inventory | I-PD | [LRBLPED] | Pediatric unit preparation | Data entry |  |  |  |  |  |
| Inventory | I-SH | [LRBLISH] | Shipping invoices forblood components | Formgeneration |  |  |  |  |  |
| Inventory | I-TR | [LRBLJTR] | Transfer unit to newdivision | Data entry |  |  |  |  |  |
| Inventory | I-UC | [LRBLIUC] | Unit ABO/Rh confirmation | Data entry |  |  |  |  |  |
| Inventory | I-UP | [LRBLIUP] | Unit phenotyping | Dataentry/edit |  |  |  |  |  |
| Inventory | I-UR | [LRBLIUR] | Units release to stock(cancel) by patient | Unit statuschange |  |  |  |  |  |
| Inventory | I-UW | [LRBLIW] | Inventory ABO/Rhtesting worksheet | Formgeneration |  |  |  |  |  |

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

## 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 newdivision | Data entry |  |  |  |  |  |
| Patient | P-DA | [LRBLDELOG] | Remove anaccession | 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 forpatients | Data entry |  |  |  |  |  |
| Patient | P-RS-XM | [LRBLPX] | Enter crossmatchresults | 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 anaccession | Data edit |  |  |  |  |  |
| Patient | P-TW | [LRBLTTW] | Test work list | Formgeneration |  |  |  |  |  |
| Patient | P-WL | [LRUW] | Accession area worklist | Form generation |  |  |  |  |  |

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 I approve implementation of the software effective

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

## 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 donordemographic information | Data inquiry |  |  |  |  |  |
| Inquiries | Q-OR | [LROS] | Order/test status | Datainquiry |  |  |  |  |  |
| Inquiries | Q-PA | [LRUPT] | Show list of accessionsfor a patient | Datainquiry |  |  |  |  |  |
| Inquiries | Q-PH | [LRBLPH] | Patient medication list | Data inquiry |  |  |  |  |  |
| Inquiries | Q-PR | [LRBLQDR] | Patient blood bankrecord | Datainquiry |  |  |  |  |  |
| Inquiries | Q-SD | [LRBLQSD] | Single donorinformation | Datainquiry |  |  |  |  |  |
| Inquiries | Q-ST | [LRBLQST] | Single unit status | Data inquiry |  |  |  |  |  |
| Inquiries | Q-SU | [LRBLIPSD] | Single unit information-display | Datainquiry |  |  |  |  |  |
| Inquiries | Q-UA | [LRBLQPR] | Units assigned/components requested | Datainquiry |  |  |  |  |  |
| Inquiries | Q-VD | [LRBLVALI] | ValidationDocumentation | Datainquiry |  |  |  |  |  |
| Inquiries | Q-VT | [LREV] | Test descriptioninformation | Datainquiry |  |  |  |  |  |
| Ward | W-PO | [LRUPT] | Show list of accessionsfor a patient | Datainquiry |  |  |  |  |  |
| Ward | W-PR | [LRBLQDR] | Patient blood bankrecord | Datainquiry |  |  |  |  |  |

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## Reports Functional Area Test Case Tracking Worksheet

|  |  |
| --- | --- |
|  | **Acceptability of Test Cases** |
| Func.Area | MenuAbbv. | Option Name | Menu Name | OptionDesc. | LimitedAccess | 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 | [LRBLPDELETE] | Delte BB reportprint queue | Data edit |  |  |  |  |  |
| Reports | R-BR-3 | [LRBLP PRINT…] | Print single BB patient report | Report generation |  |  |  |  |  |
| Reports | R-BR-4 | [LRBLPPRINT…] | Print all BB patientreports on … | Reportgeneration |  |  |  |  |  |
| Reports | R-BR-5 | [LRBLCN] | Blood bankconsultation … | Reportgeneration |  |  |  |  |  |
| Reports | R-CT | [LRBLILA] | Unit CAUTION tag labels | Caution tag label generation |  |  |  |  |  |
| Reports | R-CV | [LRBLICV] | CMV antibodystatus report | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-CD | [LRBLDCD] | Collectiondisposition report | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-DA | [LRBLDDA] | Gallon donor report | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-DD | [LRBLDDR] | Donor deferralreport | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-DL | [LRBLDPL] | List of donors bylast attempt date | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-DS | [LRBLDSC] | Donor schedulingreport | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-ED | [LRBLDEDR] | Emergency donorreport | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-FD | [LRBLDFD] | First time blooddonors | Reportgeneration |  |  |  |  |  |
| Reports | R-DR- DR-GA | [LRBLDGA] | Group affiliation report | Report generation |  |  |  |  |  |
| Reports | R-DR-DR-GD | [LRBLDGDR] | Group donationreport | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-MC | [LRBLDMC] | Mobile (collectionsite) report | Reportgeneration |  |  |  |  |  |

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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/holidayrecall list | Report generation |  |  |  |  |  |
| Reports | R-DR-DR-PC | [LRBLDPCR] | Patient credits fromblood donations | Reportgeneration |  |  |  |  |  |
| Reports | R-DR- DR-PL | [LRBLDAP] | Apheresis donor list | Report generation |  |  |  |  |  |
| Reports | R-DR-DR-SD | [LRBLDSD] | Donor short drawreport | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-DR-XD | [LRBLDL] | Donorlist/label/letters | Reportgeneration |  |  |  |  |  |
| Reports | R-DR- DS | [LRBLDTRS] | Donor unit supplemental testing proof list | Report generation |  |  |  |  |  |
| Reports | R-DR- DT | [LRBLDTR] | Donor unit testing proof list | Report generation |  |  |  |  |  |
| Reports | R-DR-PD | [LRBLDPD] | Permanent donordeferral report | Reportgeneration |  |  |  |  |  |
| Reports | R-DR-PR | [LRBLDPRR] | Blood productrejection report | Reportgeneration |  |  |  |  |  |
| Reports | R-IS-DU | [LRBLIDU] | Disposition-not transfused | Report generation |  |  |  |  |  |
| Reports | R-IS-SU-SD | [LRBLIPSD] | Single unitinformation-display | Reportgeneration |  |  |  |  |  |
| Reports | R-IS-SU-SP | [LRBLIPSP] | Single unitinformation-print | Reportgeneration |  |  |  |  |  |
| Reports | R-IS-UA | [LRBLRUA] | Units available(in date/no disposition) | Report generation |  |  |  |  |  |

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**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 nodisposition | Reportgeneration |  |  |  |  |  |
| Reports | R-IS-UX | [LRBLIX] | Units on Xmatch bydate/time xmatched | Reportgeneration |  |  |  |  |  |
| Reports | R-IT-IN | [LRBLRIN] | Supplier invoices (inventory) | Report generation |  |  |  |  |  |
| Reports | R-IT-IS | [LRBLRIS] | Special typing charges(inventory) | Reportgeneration |  |  |  |  |  |
| Reports | R-IT-IT | [LRBLRIT] | Supplier transactions(inventory) | Reportgeneration |  |  |  |  |  |
| Reports | R-PL | [LRBLPAL] | Patient accession list | Report generation |  |  |  |  |  |
| Reports | R-TC | [LRBLTA] | Transfusion reactioncount | Reportgeneration |  |  |  |  |  |
| Reports | R-TR | [LRBLIPTR] | Transfusion reactionsreport | Reportgeneration |  |  |  |  |  |
| Reports | R-UP | [LRBLIPH] | Phenotyped units available | Report generation |  |  |  |  |  |
| Reports | R-UR-AA | [LRBLAA] | Crossmatch/Transfusionby Specialty/Physician | Reportgeneration |  |  |  |  |  |
| Reports | R-UR-AR | [LRBLJB] | Autologous dispositionreport | Reportgeneration |  |  |  |  |  |
| Reports | R-UR- CT | [LRBLRCT] | Crossmatch/transfusion report | Report generation |  |  |  |  |  |
| Reports | R-UR-IS | [LRBLIRB] | Unit relocation recordbook entries | Reportgeneration |  |  |  |  |  |
| Reports | R-UR-IT | [LRBLPRIT] | Inappropriatetransfusion requests | Reportgeneration |  |  |  |  |  |
| Reports | R-UR-PT | [LRBLPIT] | Prolonged infusion timereport | Reportgeneration |  |  |  |  |  |
| Reports | R-UR-RS | [LRBLJUT] | Transfused RBC fortreating specialty | Reportgeneration |  |  |  |  |  |

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**REPORTS FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued**

|  |  |
| --- | --- |
|  | **Acceptability of Test Cases** |
| Func.Area | MenuAbbv. | Option Name | Menu Name | OptionDesc. | LimitedAccess | Norm | Except | Bound | Inval |
| Reports | R-UR- TH | [LRBLPCH] | Patient transfusions and hematology results | Report generation |  |  |  |  |  |
| Reports | R-UR-TR | [LRBLITR] | Transfusion datareport | Reportgeneration |  |  |  |  |  |
| Reports | R-UR-TS | [LRBLITS] | Transfusion statisticsby treating specialty | Reportgeneration |  |  |  |  |  |
| Reports | R-UR-TX | [LRBLTXA] | Transfusion follow-uptests | Reportgeneration |  |  |  |  |  |
| Reports | R-VD | [LRBLVALP] | Print blood bankvalidation | Reportgeneration |  |  |  |  |  |
| Reports | R-WK-AD | [LRBLA] | Blood bankAdministrative data | Reportgeneration |  |  |  |  |  |
| Reports | R-WK-CR | [LRBLDCR] | Componentpreparation report | Reportgeneration |  |  |  |  |  |
| Reports | R-WK-CT | [LRUPACT] | Test counts by treatingspecialty | Reportgeneration |  |  |  |  |  |
| Reports | R-WK-IR | [LRBLC] | Inventory rechecktallies | Reportgeneration |  |  |  |  |  |
| Reports | R-WK-TC | [LRBLRTC] | Test counts bylocation | Reportgeneration |  |  |  |  |  |

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Signature: (Blood Bank Medical Director) Date: Signature: (IRM staff/LIM) Date: Date/time Implemented in Production

### Supervisor Functional Area Test Case Tracking Worksheets

|  |  |
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|  | **Acceptability of Test Cases** |
| Func.Area | MenuAbbv. | Option Name | Menu Name | OptionDesc. | LimitedAccess | Norm | Except | Bound | Inval |
| Superv | S-DO | [LRCENDEL] | Delete entire order orindividual tests | Data edit |  |  |  |  |  |
| Superv | S-ED- DC | [LRBLDA] | Donor collection/deferral edit | Data entry/edit |  |  |  |  |  |
| Superv | S-ED- DD | [LRBLDEF] | Permanentdeferral/special comments | Data entry/edit |  |  |  |  |  |
| Superv | S-ED-DE | [LRBLDEDIT] | Blood donor grouptype edit | Dataentry/edit |  |  |  |  |  |
| Superv | S-ED- DH | [LRBLSEH] | Edit donor history questions | Form contentdefinition |  |  |  |  |  |
| Superv | S-ED- DL | [LRBLDLT] | Enter/edit donor letters | Lettercontent definition |  |  |  |  |  |
| Superv | S-ED-DM | [LRBLDMV] | Move a blooddonation | Datatransfer |  |  |  |  |  |
| Superv | S-ED- DP | [LRBLDCX] | Edit donor consent | Formcontent 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 & softwarecontrol |  |  |  |  |  |
| Superv | S-EF-BP | [LRBLSEB] | Edit blood product file | File setup & softwarecontrol |  |  |  |  |  |
| Superv | S-EF-BU | [LRBLSEU] | Edit blood bank utility file | File setup & softwarecontrol |  |  |  |  |  |

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#### SUPERVISOR FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

|  |  |
| --- | --- |
|  | **Acceptability of Test Cases** |
| Func.Area | MenuAbbv. | Option Name | Menu Name | OptionDesc. | LimitedAccess | 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 & softwarecontrol |  |  |  |  |  |
| Superv | S-EF- VD | [LRBLVAL] | Blood Bankvalidation documentation | Data entry/edit |  |  |  |  |  |
| Superv | S-EI-DI | [LRBLSED] | Edit unit dispositionfields | Dataentry/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-patientfields | Dataentry/edit |  |  |  |  |  |
| Superv | S-EI-PP | [LRBLJM] | Edit pooled bloodproduct | Dataentry/edit |  |  |  |  |  |
| Superv | S-EP-LD | [LRBLST] | Tests for display onpatient lookup | Softwarecontrol |  |  |  |  |  |
| Superv | S-EP-PE | [LRBLPEDIT] | Patient ABO/Rh edit | Dataentry/edit |  |  |  |  |  |

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#### SUPERVISOR FUNCTIONAL AREA TEST CASE TRACKING WORKSHEET-Continued

|  |  |
| --- | --- |
|  | Acceptability of Test Cases |
| Func.Area | MenuAbbv. | Option Name | Menu Name | OptionDesc. | LimitedAccess | Norm | Except | Bound | Inval |
| Superv | S-EP-PP | [LRBLSPP] | Patient previous transfusion record | Data entry/edit |  |  |  |  |  |
| Superv | S-EP-TH | [LRBLSET] | Tests for inclusion intransfusion report | Softwarecontrol |  |  |  |  |  |
| Superv | S-EP-TR | [LRBLPTXR] | Unknown unittransfusion reaction | Dataentry/edit |  |  |  |  |  |
| Superv | S-EP-TX | [LRBLTX] | Tests for transfusion follow-up | Software control |  |  |  |  |  |
| Superv | S-FD | [LRUFILE] | Outline for one ormore files | Reportgeneration |  |  |  |  |  |
| Superv | S-II | [LRBLII] | Blood bank inventory integrity report | Integrity check/ Reportgeneration |  |  |  |  |  |
| Superv | S-LL | [LRBLSF] | Edit number of lines in a label | Form/label formatcontrol |  |  |  |  |  |
| Superv | S-SR-AD | [LRBLAD] | Print data changeaudits | Reportgeneration |  |  |  |  |  |
| Superv | S-SR-AP | [LRBLPAB] | Antibodies by patient | Report generation |  |  |  |  |  |
| Superv | S-SR-AR | [LRBLPRA] | Patient antibodyreport (long list) | Reportgeneration |  |  |  |  |  |
| 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 donoraward by deletion | Data edit |  |  |  |  |  |
| Superv | S-SR-PL | [LRBLSDPL] | Delete a user’spatient list | Data edit |  |  |  |  |  |
| Superv | S-SR-PU | [LRBLRUF] | Print units with final disposition | Report generation |  |  |  |  |  |
| Superv | S-SR-PX | [LRBLDEX] | Print ex-donors | Reportgeneration |  |  |  |  |  |
| Superv | S-SR-RA | [LRBLAR] | Remove audit datachanges | Datadeletion |  |  |  |  |  |
| Superv | S-SR-RI | [LRBLSRI] | Remove inappropriate transfusion requests | Data deletion |  |  |  |  |  |
| Superv | S-SR- RU | [LRBLSER] | Remove units with final disposition | Should bedisabled at site |  |  |  |  |  |
| Superv | S-SR-RX | [LRBLDK] | Remove ex-donors | Datadeletion |  |  |  |  |  |
| Superv | S-SW | [LRUWL] | Display workload foran accession | Reportgeneration |  |  |  |  |  |

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# Blood Bank Software References

(in chronological order by topic)

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## CAP Documents

1. CAP Inspection Report Form, Section 1 General,1995.

## AABB Documents

1. Software Manufacturing Process Guidelines (DRAFT), American Association of Blood Banks. Letter to all institutional members, November 25, 1991.
2. Control Function Guidelines (DRAFT), American Association of Blood Banks. Letter to all institutional members, November 25, 1991.
3. User Validation Guidelines (DRAFT), American Association of Blood Banks. Letter to all institutional members, November 25, 1991.
4. Accreditation Requirements Manual, American Association of Blood Banks. 6th edition, 1995.
5. Standards for Blood Banks and Transfusion Services, American Association of Blood Banks. 20th edition, 2001.

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2. Proposed Rule for 42 Code of Federal regulations, Part 405, Subpart P "Computer Systems for Level I and II Testing, US Department of Health and Human Services, Federal Register 55(98), May 21, 1990. (NOTE: Final Rule still pending - not included in Federal Register 57(40), dated February 28, 1992.)
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4. "Instruction Booklet for Blood Bank Inspection Checklist and Report Form 2609", Food and Drug Administration, US Department of Health and Human Services, Public Health Service, May 1991.
5. Food and Drug Administration, CBER Draft Guidelines for Validation of Blood Establishment Computer Systems, Sept. 28, 1993, Docket #93N-0394.
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9. Food and Drug Administration, Guidance for Blood Establishments Concerning Conversions to FDA- Reviewed Software Products. Letter to all registered blood establishments, November 13, 1995.

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3. Code of Federal Regulations, Medical Device Reporting, 21 CFR, Part 803, US Department of Health and Human Services, Public Health Service, 1995.

# 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

Bbp a ti e n t , On e 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: BBPAT I ENT , 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)

* 1. 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: **Bbpa t i en t , One** 5-20-23 000000001 NO NSC VETERAN

Bbp a ti e n t , On e. 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.

1. 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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