APPENDIX - D
Blood Bank Patch LR*5.2* 72 Multidivisional Functionality

> **NOTE:** This appendix includes **only portions** of the Release Notes and Installation Guide. For additional installation details, including pre-installation and post-installation instructions regarding necessary file changes which apply to all facilities using the Blood Bank software, consult the Laboratory Patch LR*5.2*72 Release Notes and Installation Guide.

Preface

The Laboratory Patch LR*5.2*72 Release Notes and Installation Guide Version 5.2 is designed to provide the Department of Veterans Affairs Medical Center (DVAMC), Information Resources Management (IRM), and the Laboratory Information Manager (LIM), and the Blood Bank Supervisor with the necessary technical information required to efficiently and effectively implement, maintain, and manage the installation of Patch LR*5.2*72.

The primary focus of Patch LR*5.2*72 is to provide multidivisional functionality; however, the patch must be installed in **all** facilities. Data dictionary changes and changes in functionality have been included which will affect all sites, even those which are not multidivisional and/or have not been involved in recent consolidations. This patch represents the version of the Blood Bank module software of the DHCP Laboratory package which is being submitted for FDA registration as a medical device. Based on the FDA memorandum dated
November 13, 1995 which was sent to all registered blood establishment regarding "Guidance for Blood Establishments Concerning Conversions to FDA Reviewed Software Product", an extension was requested for all VA facilities using DHCP software. In this request the timetable indicated that release of this patch would be accomplished by the end of June 1996 and that implementation would be completed by December 31, 1996. Based on this extension request, **installation and validation of this patch must be completed prior to December 31, 1996.**

Installation of this patch will require either **validation or revalidation** of the Blood Bank software for all sites. A revised listing of the 'Control Functions in the Version 5.2 Blood Bank Module' and sheets for recording the 'Tracking of Test Case Testing for Version 5.2 Blood Bank Module' are provided on the following pages.

*Prior to installation of this patch, all of the V5.2 patches which involved Blood Bank routines or the files included in this patch must have been installed. These are detailed in the Release Notes. For those patches involving the Blood Bank software, i.e.,

LR*5.2*1	LR*5.2*16	LR*5.2*25	LR*5.2*26	LR*5.2*35
LR*5.2*77	LR*5.2*78	LR*5.2*79	LR*5.2*97	LR*5.2*100

the description of the changes and the testing scenarios to be used for validation are included with the individual patch and this information is NOT duplicated in these release notes.

All Blood Bank patches released after LR*5.2*72 will require installation of this patch; however, support for Version 5.2 without Patch LR*5.2*72 will continue to be provided until December 31, 1996.

Overview of Multidivisional Functionality

In order to accommodate multidivisional functionality, it is necessary to clearly identify the primary site as defined by VA FileMan, the associated divisions for which data is being entered and accessed as defined in the INSTITUTION file (#4) and the associated divisions to which individual users may be assigned as defined by the NEW PERSON file (#200), DIVISION field (#16). Based on the data dictionaries, the primary site is assigned a numeric code (3 digits) and the associated divisions are defined based on suffixes attached to that numeric code. In addition, since units of blood are assigned to specific locations just as patients are, it is necessary to have appropriate entries in the HOSPITAL LOCATION file (#44). When units are relocated, locations are screened to make sure that they are assigned to the appropriate division, based on the division designated in the HOSPITAL LOCATION file (#44) for the specific location. If a patient is transferred and the assigned units need to be relocated to a location in a different division, the unit must first be transferred to that division.

To minimize confusion, the term institution is used in conjunction with the word primary to indicate the parent facility at which the software and the database reside, i.e. the one with the straight numeric in INSTITUTION file (#4). The other facilities are referred to as divisions and will have a suffix appended to the numeric portion for their entry in the INSTITUTION file (#4).

For purposes of reports and other items with medicolegal implications, the name of the primary institution will be utilized; however, reference to the specific division will be included whenever possible and appropriate.

Whenever possible, the accession area or division to which the user is currently assigned is displayed to minimize confusion for those users who may be assigned to more than one division. For Blood Bank, comparisons are based on the DUZ(2) of the user and the division of either the unit in BLOOD INVENTORY file (#65) or the component in BLOOD PRODUCT file (#66).

Blood Bank Data Dictionary and Functionality Changes Related to Multidivisional Functionality

New/Edited Fields

1. The input transform for the BLOOD BANK DIVISION field (#.01) of the BLOOD BANK INSTITUTION field (#8.1) multiple of the LABORATORY SITE file (#69.9) has been edited and a screen has been added. These changes allows the site to indicate that there is more than one Blood Bank accession area and to access the appropriate division based on the DUZ(2) of the user.

2. A **new** field has been added to ACCESSION file (#68). The **new** ASSOCIATED DIVISION field (#.091) is a multiple which allows the site to indicate which divisions are to be associated with that specific accession area.

> **NOTE:** There is a screen on the **new** field to allow entry of only those divisions associated with the site to be selected, i.e. S DIC("S")="I +$G(^DIC(4,+Y,99))=+$$SITE^VASITE".

3. A **new** field has been added to BLOOD PRODUCT file (#66). The **new** ASSOCIATED DIVISION field (#10) is a multiple which allows the site to indicate which divisions are to be associated with that specific blood component.

> **NOTE:** There is a screen on the input transform for the **new** ASSOCIATED DIVISION field (#10) to allow entry of only those divisions associated with the site to be selected, i.e. S DIC("S")="I +$G(^DIC(4,+Y,99))=+$$SITE^VASITE".

4. The input transform for the LAB DATA file (#63), BLOOD COMPONENT REQUEST field (#.084) has been **edited** to allow selection of only those components which have the appropriate entry in the **new** ASSOCIATED DIVISION field (#10) in the BLOOD PRODUCT file (#66).

> **NOTE:** This evaluation is based on the DUZ(2) for the person entering the request.

5. A **new** field has been added to the BLOOD INVENTORY file (#65). The **new** DIVISION field (#.16) indicates the current division where the unit resides.

> **NOTE:** There is a screen on the input transform for the new field to allow entry of only those divisions associated with the site to be selected, i.e.
> S DIC("S")="I +$G(^DIC(4,+Y,99))=+$$SITE^VASITE"

New/Edited Options

6. A **new** option Transfer unit to new division [LRBLJTR] has been added to the Inventory [LRBLI] menu. This option allows units to be transferred from one division to another as appropriate to reflect patient movement and allow subsequent entry of the transfusion data.

7. The ENTRY ACTION for the Specimen log-in [LRBLPLOGIN] option in the Patient [LRBLP] menu has been **edited** to evaluate whether the site has multiple areas for the division in order to determine whether to ask the prompt for the accession area and if so, to display the accession area.

8. The edit template [LRBLILG] used by the Edit unit log-in [LRBLSEL] option in the Supervisor [LRBLS] menu has been **edited** to include the new DIVISION field (#.16).

9. A **new** option Change to new division [LRUCHGDIV] has been added to the Patient [LRBLP] menu. This **new** option allows the site to change from one division to another, as appropriate based on the entry(ies) for DIVISION field (#16) for that user in the NEW PERSON file (#200), without having to log out and sign back in.

Blood Bank Data Dictionary and Functionality Changes Unrelated to Multidivisional Functionality

New/Edited Fields

10. The illegal cross references for BLOOD PRODUCT file (#66), (the B cross references) on the DESCRIPTION field (#1) and the (C cross reference) on the SYNONYM field (#2), are fixed in the pre-install routine LR72PRE. This will allow access to all fields via VA FileMan options. (NOIS ISL-0395-50334)

11. The BLOOD PRODUCT file (#66), ANTICOAGULANT field (#.12) name and set of codes has been **changed**. The ANTICOAGULANT field (#.12) was changed to ANTICOAGULANT/ADDITIVE field (#.12). The additive "Adsol" was added to the set of codes as a fourth choice. The set of codes were **changed** to restore functionality which existed prior to Laboratory V. 5.2. (Mailman Message #16854290)

12. The BLOOD DONOR file (#65.5), DONATION OR DEFERRAL multiple field (#5), ANTICOAGULANT field (#4.11) name and set of codes has been **changed**. The ANTICOAGULANT field (#4.11) name was changed to ANTICOAGULANT/ ADDITIVE field (#4.11). The additive "Adsol" was added to the set of codes as a fourth choice. The set of codes were changed to restore functionality which existed prior to Laboratory V. 5.2.

13. The BLOOD DONOR file (#65.5), DONATION OR DEFERRAL field (#5), ANTIGEN field (#20) set of codes has been **changed**. In the set of codes, "positive" was changed to "reactive" and "not done" was added. The set of codes are now consistent with the other Enzyme Immuno Assay (EIA) methodologies and transfusion transmitted disease marker testing that is performed on blood donors.

14. The OREO ON field (#1) in the LABORATORY SITE file (#69.9), which was inadvertently exported will be removed by the pre-install routine LR72PRE.

Blood Bank Option and Functionality Changes

Donor [LRBLD] menu

1. In the Test review/Component labeling/release [LRBLDRR] option, the division of the user who is labeling/releasing the unit to inventory is captured and attached to the unit when it is moved from the BLOOD DONOR file (#65.5) to the BLOOD INVENTORY file (#65).

2. In the Donor collection/processing [LRBLDC] option, the BLOOD DONOR file (#65.5), DONATION OR DEFERRAL multiple field (#5), ANTICOAGULANT field (#4.11) name and set of codes were **edited**. The ANTICOAGULANT field (#4.11) was changed to ANTICOAGULANT/ADDITIVE field (#4.11). The additive "Adsol" was added to the set of codes as a fourth choice. The set of codes were **edited** to restore functionality which existed prior to Laboratory V. 5.2.

3. In the Donor unit supplemental testing proof list [LRBLDTRS] option, a revision was made in the [LRBL DONOR TESTING SUPPLEMENT] print template for BLOOD DONOR file (#65.5) to accommodate the addition of the HIV ANTIGEN field (#20) as a follow-up to patch LR*5.2*97.

Inventory [LRBLI] menu

4. In the Log-in regular (invoices) [LRBLILR] option, the division of the user is displayed upon entry to minimize confusion. The division which is displayed is then subsequently assigned to any units logged in during that session.

5. In the Disposition - not transfused [LRBLIDN] option, the division of the user is assessed and is displayed to minimize confusion for those users who may have access to more than one division. Only those units currently assigned to the same division can be accessed.

6. In the Disposition - relocation [LRBLIDR] option, the division of the user is assessed and is displayed to minimize confusion for those users who may have access to more than one division. Only those units currently assigned to the same division are displayed and can be accessed. The units may be relocated only to other locations assigned to the same division based on the entry in the HOSPITAL LOCATION file (#44).

> **NOTE:** For units being relocated back to the Blood Bank, the entry in HOSPITAL LOCATION file (#44) **must** contain BLOOD BANK; however, it does not matter whether there is a prefix or suffix attached.

7. In the Disposition - relocation [LRBLIDR] option, units with a previous entry of "unsatisfactory" cannot be released from the Blood Bank. These units are indicated with a (#) sign in front of the unit number.

8. In the Disposition - relocation [LRBLIDR] option, an additional control function was **added** to prevent an entry in the relocation multiple in BLOOD INVENTORY file (#65), DATE/TIME UNIT RELOCATION multiple field (#3), DATE/TIME UNIT RELOCATION field (#.01) which is prior to the entry in the PATIENT XMATCHED/ASSIGNED multiple field (#2), DATE/TIME UNIT ASSIGNED field (#.02). (E3R #6386)

9. In the Enter blood inventory typing charges [LRBLILS] option, the division of the user is assessed. Only those units currently assigned to the same division can be accessed.

10. In the Enter blood inventory typing charges [LRBLILS] option, the routine was **edited** to correct the error in the name of the file requiring the entry. LAB SUPPLY was changed to BLOOD PRODUCT. (NOIS SDC-0696-60834)

11. In the Unit phenotyping [LRBLIUP] option, the division of the user is assessed. Only those units currently assigned to the same division can be accessed.

12. In the Unit ABO/Rh confirmation [LRBLIUC] option, the division of the user is assessed. If the data entry is done by unit ID, only those units currently assigned to the same division can be accessed. In addition, the division and accession area are displayed to minimize confusion for those users who may have access to more than one division.

> **NOTE:** If the entry is done by batch (by specifying the date and the invoice number), access is not restricted.

13. In the Inventory ABO/Rh testing worksheet [LRBLIW] option, the division of the user is assessed. The division is printed on the first line and the accession area is included on the second line of the worksheet. Only those units currently assigned to that division are included.

14. In the Pediatric unit preparation [LRBLPED] option, the division of the user is assessed. Only those units currently assigned to the same division can be accessed.

15. The **new** Transfer unit to new division [LRBLJTR] option has been added to the Inventory [LRBLI] menu. This **new** Transfer unit to new division [LRBLJTR] option allows: **a)** units to be transferred from one division to another as appropriate to reflect patient movement **b)** and subsequent entry of the transfusion data.

When units are transferred, there is **no** change other than the entry in the BLOOD INVENTORY file (#65), DIVISION field (#.16). The unit is still assigned, etc.

NOTE: Although the accession area may not seem relevant to units in inventory, it is used for including changes in verified data on the audit trail, with the following exception. Data changes in the BLOOD INVENTORY file (#65), DIVISION field (#.16) are **not** captured on the audit trail of changes in verified data. However, they are reflected in the entries in the DATA CHANGE DATE multiple field (#999), a field not previously utilized. The DATA CHANGE DATE multiple field (#999) includes the date of the change, the person making the change, the data element changed (in this case the division), the old value, and the new value. This field is displayed with the other data if a lookup is done for the unit using the single unit information options.

Inquiries [LRBLQ] menu

16. In the Single donor information [LRBLQSD] option, the BLOOD DONOR file (#65.5) HIV ANTIGEN field (#20) (previously exported with LR*5.2*97 patch) was added to the tests included in the display.

17. In the Single unit status [LRBLQST] option, the division of the unit has been included if the MULTIPLE ACCESSION AREA field (#8.1) of the LABORATORY SITE file (#69.9) is set to YES.

Patient [LRBLP] menu

18. In the Specimen log-in [LRBLPLOGIN] option, the division of the user is assessed and displayed at the beginning of the option. Tests are assigned to a specific accession area based on the setup in LABORATORY TEST file (#60). If two divisions utilize the same accession area, the numbers will be sequential based on accessioning.

> **NOTE:** Regardless of the division, the information regarding clinically significant antibodies, previous transfusion reactions, autologous or directed donor units available for the patient, current units assigned with their current locations, all specimens accessioned within the past 72 hours for which the specimen is BLOOD, etc. are displayed.

*CAUTION: Unfortunately, for those sites which have been consolidated, this data will reflect only data from the primary site until such time as the data merger routines for the LAB DATA file (#63) have been completed.

> **NOTE:** The entry in ACCESSION file (#68) for the accession area need only contain "BLOOD BANK"; it no longer needs to start with those ten characters.

19. In the Enter test data [LRBLPET] option, the division of the user is assessed. Upon entry, the division and accession area are displayed to minimize confusion for those users who may have access to more than one division. Only accession areas assigned to the same Associated Division can be accessed.

20. In the type of Enter test data [LRBLPET] option was changed from "Action" to "run routine".

21. In the Blood component requests [LRBLPCS] option of the Request/select/ xmatch blood components [LRBLPC] menu, the division of the user is assessed. Only components assigned to the same ASSOCIATED DIVISION field (#10) in the BLOOD PRODUCT file (#66) can be accessed at the Select prompt. New components **cannot** be added if not appropriate. However, if the last component request entered was for a different division and is being shown as the default, no screening is done.

> **NOTE:** Regardless of the division, the information regarding clinically significant antibodies, previous transfusion reactions, autologous or directed donor units available for the patient, current units assigned, etc. are displayed.

***CAUTION:**   Unfortunately, for those sites which have been consolidated, this data will reflect only data from the primary site until such time as the data merger routines for LAB DATA file (#63) have been completed.

22. In the Select units for patients [LRBLPIC] option, the division of the user is assessed. Upon entry, the division and accession area are displayed to minimize confusion for those users who may have access to more than one division.

Only components assigned to the same ASSOCIATED DIVISION field (#10) in the BLOOD PRODUCT file (#66) can be accessed. Only specimens within the designated time period for the designated division are displayed. If the user indicates that he wishes to see the available inventory, he will be given a choice of whether the units from the other divisions should be included. If the units are included, for those assigned to the other division, the division will be indicated.
Even though the units may be displayed, only those units from the same division as the user can be accessed. If there is an autologous or directed unit which needs to be accessed, it **must** first be transferred to the appropriate division.

> **NOTE:** Regardless of the division, the information displayed regarding clinically significant antibodies, previous transfusion reactions, autologous or directed donor units available for the patient, etc. are displayed.

***CAUTION:** Unfortunately, for those sites which have been consolidated, this data will reflect only data from the primary site until such time as the data merger routines for LAB DATA file (#63) have been completed.

23. In the Select units for patients [LRBLPIC] option, the control function in which the ABO/Rh of the unit was compared to the patient's historical ABO/Rh was **changed**. In addition to evaluating the patient's historical ABO/Rh, a comparison is now done with the results of the current specimen (if one exists). If the patient's history and current results do not match, a warning message is displayed and the user is prevented from continuing with unit selection. (NOIS ISL-0696-51163)

24. In the Blood transfusion results [LRBLPT] option, the division of the user is assessed and only those units currently assigned to the same division are displayed and can be accessed.

25. A **new** option Change to new division [LRUCHGDIV] has been added to the Patient [LRBLP] menu. This **new** option allows the site to change from one division to another, as appropriate based on the entry(ies) for DIVISION field (#16) for that user in the NEW PERSON file (#200), without having to log out and sign back in.

26. The Unit CAUTION tag labels [LRBLILA] option has been added to the Request/select/xmatch blood components [LRBLPC] submenu in the Patient [LRBLP] menu to minimize the need to switch menus. This option will also remain in the Reports [LRBLR] menu.

Reports [LRBLR] menu

27. The Patient antibody report [LRBLPR] option has been **edited**. The accession number was added to improve the usefulness of the information and minimize confusion.

28. The Patient accession list [LRBLPAL] option has been **edited.** The division of the accession area selected is included in the header of the report.

29. In the Crossmatch/Transfusions by Specialty/Physician [LRBLAA] option, of the [LRBLIUS] submenu has been **edited**. The division of each unit has been included for each unit for informational purposes.

30. The Blood Bank Administrative Data [LRBLA] option of the Blood bank workload reports [LRBLRWK] submenu has been **edited.** Data from the BLOOD INVENTORY file (#65) can be printed for a single division.

31. The HIV Antigen test has been added to the group of donor transfusion transmitted disease marker tests included in the Blood Bank Administrative Data [LRBLA] option of the Blood bank workload reports [LRBLRWK] submenu. The data is based on the new HIV ANTIGEN subfield (#20) of the DONATION OR DEFERRAL DATE field (#5) of the BLOOD DONER file (#65.5) which was added in a previous patch.

Supervisor [LRBLS] menu

32. The illegal cross references for BLOOD PRODUCT file (#66), (the B cross references) on the DESCRIPTION field (#1) and the (C cross reference) on the SYNONYM field (#2), are fixed in the pre-install routine LR72PRE. This will allow access to all fields via VA FileMan options. (NOIS ISL-0395-50334)

33. In the Edit unit log-in [LRBLSEL] option of the Blood bank inventory edit options [LRBLSI] submenu, the division of the user is assessed and only those units currently assigned to the same division can be accessed.

34. In the Edit unit - patient fields [LRBLSEC] option of the Blood bank inventory edit options [LRBLSI] submenu, the division of the user is assessed and only those units currently assigned to the same division can be accessed.

35. In the Edit unit disposition fields [LRBLSED] option of the Blood bank inventory edit options [LRBLSI] submenu, the division of the user is assessed and only those units currently assigned to the same division can be accessed.

36. In the Print data change audits [LRBLAD] option of the Summary and Deletion Reports [LRBLSSR] submenu, data may be included for all Blood bank accession areas or may be restricted to a single accession area, based on the entry at the START WITH NAME prompt.

37. In the Remove data change audits [LRBLAR] option of the Summary and Deletion Reports [LRBLSSR] submenu, data may be removed **only** for the division to which the user is currently assigned.

38. In the Antibodies by patient [LRBLPAB] option of the Summary and Deletion Reports [LRBLSSR] submenu, the lock which was inadvertently distributed with Version 5.2 was removed to allow access to the option.

39. The HIV Antigen test has been **added** to the group of donor transfusion transmitted disease marker tests included in the Print ex-donors [LRBLDEX] option of the Summary and Deletion Reports [LRBLSSR] submenu. The data is based on the new HIV ANTIGEN subfield (#20) of the DONATION OR DEFERRAL DATE field (#5) of the BLOOD DONER file (#65.5) which was added in a previous patch.

40. In the Edit blood bank files [LRBLEF] submenu, the **name** of the Blood component request edit [LRBLSRQ] option was **changed** to Edit blood component request file.

41. Options Edit group user manual [LRUPUME] and Print a user group manual [LRUPUM] in the Summary and Deletion Reports [LRBLSSR] submenu were deleted as they were inappropriately released with Version 5.2 and were not documented in the Blood Bank User Manual.

42. In each of the options in the Blood Bank Inventory edit options [LRBLSI] submenu, the division of the user is displayed at the beginning of the option. In addition, the flexibility was added to allow the accession area to merely contain BLOOD BANK, rather than to equal BLOOD BANK.

Instructions for Blood Bank for Multidivisional Sites

> **NOTE:** The asterisk (*****) indicates changes which **must** be done before the software will run as multidivisional, but not necessarily immediately.

1. Review/edit the necessary field changes in HOSPITAL LOCATION file (#44) in the primary site.

The fields to be reviewed/edited include:

NAME: **must contain "BLOOD BANK"**
ABBREVIATION:
TYPE: OTHER LOCATION//
TYPE EXTENSION: OTHER LOCATION//
INSTITUTION: **must be primary site as defined in the Global ^DD("SITE")**
DIVISION: **must be a division whose numeric portion is the same as that of the primary site. Although this is not screened by FileMan, it is screened by the LRBL routine.**

    a.   If there is **only** one Blood Bank and units are not transfused in other divisions, there should be **only** one entry in the HOSPITAL LOCATION file (#44) for BLOOD BANK. If there is **more** than one division with a Blood Bank, there **must** be one entry for each division; however, the name field has some flexibility as long as it contains "BLOOD BANK". This is the location to which units are assigned once they are relocated and then subsequently returned to Blood Bank.

2. Review/edit the necessary field changes in ACCESSION file (#68) in the primary site.

The fields to be reviewed/edited include:

AREA: **must contain "BLOOD BANK"**
LR SUBSCRIPT: **must be "BLOOD BANK"**
ACCESSION TRANSFORM: DAILY//
BYPASS ROLLOVER: YES//
ABBREVIATION: to be determined by the site
Select ASSOCIATED DIVISION: **must be a division whose numeric portion is the same as that of the primary site.**

    a.   If there is only one Blood Bank and units are not transfused in other divisions and specimens are not drawn by the other divisions, you would only have a single Blood Bank accession area entry in ACCESSION file (#68), with a single associated division.

    b.   If there is only one Blood Bank and units are not transfused in other divisions, but specimens are drawn and some testing is done by the other divisions, you can either:

        1) have a single Blood Bank accession area with multiple associated divisions (giving you a single numbering system much like that obtained if you indicate common accession #s for the CH subscript areas).
        2) have multiple Blood Bank accession areas each with a single associated division (giving you unique numbering).
    c.   If there are multiple Blood Banks and units are transfused in multiple divisions, you would have multiple Blood Bank accession areas, each with a single associated division (giving you unique numbering for each).

3.   Make the necessary changes in BLOOD PRODUCT file (#66) in the primary site.

NOTE: The LRBLFX72 conversion routine has already been run at each site as part of the installation of the patch. This routine entered the primary institution as the first entry in the ASSOCIATED DIVISION field (#10) for each entry in BLOOD PRODUCT file (#66).

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a.   If there is an entry in BLOOD PRODUCT file (#66) which should not be accessible to the primary institution, edit that entry accordingly.

b.   If there is only one Blood Bank and units are not transfused in other divisions, no additional changes are required.

c.   If there are multiple Blood Banks and units are transfused in multiple divisions AND the other parameters defined in BLOOD PRODUCT file (#66) are to be identical for each division,

1) use FileMan to add the appropriate ASSOCIATED DIVISIONs for each component to be accessible at that particular division.

2) make whatever other changes are appropriate to reflect the operations, e.g. additional TESTS TO CHECK or additional SUPPLIERS.

d.   If there are multiple Blood Banks and units are transfused in multiple divisions AND the other parameters defined in BLOOD PRODUCT file (#66) are NOT identical for each division, use FileMan to add new entries in BLOOD PRODUCT file (#66) with the appropriate ASSOCIATED DIVISIONs assigned.

e.   Develop procedures/controls regarding access to BLOOD PRODUCT file (#66), including a methodology for documenting changes made once validation testing has been completed.

DATA MERGER Information for Consolidation Sites

Data merger routines will be available for Blood Bank data in LAB DATA file (#63); however, these will be issued as a separate patch.

BLOOD INVENTORY file (#65)

Data in BLOOD INVENTORY file (#65) should be archived or printed/purged if possible to minimize the volume of data which will need to be merged.

The data for the new division field will have been entered by the post install routine LRBLFX72.

Data will need to be entered manually as merger routines do not exist. This can best be accomplished by printing all of the data in BLOOD INVENTORY file (#65) for each unit. This can be accomplished using the Single unit information-print [LRBLIPSP] option in the Single unit (display/print) information [LRBLQSU] submenu of the Blood inventory status reports [LRBLIS] submenu of the Blood Bank Reports [LRBLR] menu.

BLOOD DONOR file (#65.5)

Data in BLOOD DONOR file (#65.5) will not be merged. Data can either be accessed via the legacy system or can be entered manually via the appropriate donor menu option for those deemed necessary.

LAB DATA file (#63)

Laboratory data on the legacy systems will be available for a long period of time and all Lab data that is normally available through a health summary component IS going to be viewable on the primary system; however, for Blood Bank, this is not adequate. It is far too cumbersome to make the user go look it up and does not allow the software to do the actual comparison of current data with previous data or to check the current units against any historical entries in the antibodies identified field. By not having the data there, a patient whose current results do not demonstrate the antibody might experience an adverse (hemolytic) transfusion reaction.

For Blood Bank, this will include the following fields:

field .05 ABO GROUP
field .06 RH TYPE
field .07 RBC ANTIGENS PRESENT (multiple)
field .075 ANTIBODIES IDENTIFIED (multiple)
field .076 BLOOD BANK COMMENTS
field .08 RBC ANTIGENS ABSENT (multiple)
field .085 TRANSFUSION RECORD (at least a portion, if not all of fields)

field .086 TRANSFUSION REACTION DATE (multiple)
    It does **not** include:
    field .084 BLOOD COMPONENT REQUEST (multiple)
    field 1 BLOOD BANK (multiple) this is where most of the data is kept

Prior to adding the data extracted from the associated division (original site) to that of the primary institution, an evaluation will be done. If data already exists for the patient, an assessment will be made to determine whether the data matches, is consistent with or is discrepant. If the data is discrepant, the data will not be merged automatically, but the data will be detailed on an exception report for future resolution.

Blood Bank Software Validation

* Originally distributed as part of the training materials for the DHCP Laboratory package training materials; however, it has been updated to reflect LR*5.2*72.

*FYI: The slides shown are intended to be viewed in conjunction with the discussion preceding the slide.

Unlike some other standards of the various accrediting/regulatory agencies, the user requirements for computer information systems do not conflict with one another. When doing a side-by-side comparison of all current and proposed regulations, the areas of emphasis are slightly different from one agency to another; however, there are no conflicts. For example, excluding the proposed CLIA'88 rules, the Food and Drug Administration (FDA) concentrates inspections of facilities using the computer software on the existence of standard operating procedures, validation testing, software modification, error tracking and training of personnel, with very limited specific requirements for responsibility, security, product suitability and data integrity. The College of American Pathologists (CAP) provides additional requirements for maintenance, security, product suitability and data integrity. The American Association of Blood Bank (AABB) then goes further in detailing the responsibilities of the vendor, the institution, the Blood Bank Medical Director, the Blood Bank Supervisor and the user.

SLIDE 1

Blood Bank Software Requirements

Food and Drug Administration (FDA)
College of American Pathologists (CAP)
American Association of Blood Bank (AABB)

NOTE: A list of specific references are provided at the end before the control functions and the test case tracking worksheets..

The spreadsheet entitled Blood Bank Computer Requirements Summary details specific requirements of the various accrediting and regulatory agencies. This document was provided in Appendix A of the Version 5.2 Blood Bank User Manual. It also provides a listing of quick references for the material included in the sample Blood Bank Policy which precedes that document.

Based on the requirements of the AABB, responsibility for various aspects of the computer system in use has been assigned to specific individuals. 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. 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. The Blood Bank Medical Director is responsible for approval of the overall functionality and for review of validation testing results.

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. 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.

SLIDE 2

Blood Bank Computer Requirements Summary Spreadsheet

Blood Bank Computer Software Requirements Policy

To assist you in fulfilling the requirements of the facility and the Blood Bank Supervisor, a variety of documents have been included with this software release. The next few slides detail the documents provided for Patch LR*5.2*72 and in some cases, previously provided for V.5.2. In some cases, comparable materials were provided for the previous versions and in other cases, the material is new to this release. Each of the documents is designed for a specific target audience; however, it is important that the Blood Bank Supervisor, the Laboratory Information Manager and the IRM staff be aware of the existence of all of the materials in case the document which each routinely uses does not contain the necessary information for a specific issue/problem. The first of the documents to be discussed is the Planning and Implementation Guide. If one were focusing on a single target audience, the target audience for this manual is probably the Laboratory Information Manager; however, for those facilities who have not previously implemented the Blood Bank package, it will be necessary for the Blood Bank Supervisor to access/review that portion related to the Blood Bank package. For those facilities who are already utilizing the Blood Bank package, but have not yet activated workload capture for the Blood Bank, it will be necessary for the Blood Bank Supervisor to access/review that portion on Blood Bank Workload Implementation.

```
SLIDE 3

Documents Provided for Version 5.2

Planning and Implementation Guide
        Blood Bank section
                Implementation Objectives & Topics
                Interaction of Blood Bank with non-BB Files
                Building/Editing Blood Bank Files
                Blood Bank File Print Templates
                Transferring Blood Bank Files from a test account to a live account
                Entering the Database
                Adapting the Blood Bank Module Menu to Fit Your Needs
                Computerizing a Manual System
                Bar code readers
                Training Information
                Blood Bank Workload Implementation
                Accreditation Requirements
```

The next document to be discussed is the Blood Bank User Manual. Again, if one were focusing on a single target audience, the target audience for this manual is probably the Blood Bank Supervisor and the Blood Bank staff who actually utilize the software. The option descriptions 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.

The sample Blood Bank Policy included in Appendix A reflects the requirements detailed in the references and in M-2, Part VI, Chapter 5, "Immunohematology, Blood Transfusion and Transfusion Medicine", paragraph 5.16 "Computer Requirements for Blood/Blood Component Transfusion", dated February 16, 1994. Appendix B provides a sample training checklist which can be used prior to initial implementation **or** in conjunction with training provided to new employees. It is **NOT** intended to provide detailed training for all options, but merely an overview for the most commonly used in the performance of routine duties.

SLIDE 4

Documents Provided for Version 5.2

Blood Bank User Manual
  Introduction *(goals, functional description & general comments)*
  Package Management & Operations *(detailed menu, file interactions)*
  Option by option description of software

  Appendix A   Sample Blood Bank Policy entitled Blood Bank Computer
  Software Requirements

  Appendix B   Training Implementation Checklist

  Appendix C   Accreditation Requirements
     AABB Requirements
      CAP Requirements
      V5.2 Control Functions
      V5.2 Test Case Tracking

Appendix C included five separate documents, as detailed on the slide. The first section entitled 'Accreditation Requirements' with the subheading "Complying with the accreditation requirements of the American Association of Blood Banks" provides some guidance in devising a system to meet specific requirements and to generate the necessary hard copy information on a regular basis or prior to the inspection. For each of the topics, the material includes the specific reference from the Standards and/or the Inspection Report Form (IRF), an explanation from the Accreditation Requirements Manual (ARM) and a section entitled comments where an interpretation is provided as to how this is handled by DHCP and the VA.

For the last topic, i.e. records required for review, a detailed listing is provided which includes an indication as to whether the record is available on the computer and/or on hard copy and which option(s) can be used to generate the record.

SLIDE 5

Documents Provided for Version 5.2

Blood Bank Manual
  Appendix C
  4 Accreditation Requirements
      Facility Records
      Identification of Personnel
      Quality Assurance of Transfusion Practices
      Records Required for Review
    AABB Requirements
    CAP Requirements
    V5.2 Control Functions
    V5.2 Test Case Tracking

To further assist in responding to the specific questions on the AABB Inspection Report Form (IRF) and the computer portion of the CAP General Checklist, proposed responses have been included. The spreadsheet entitled "Proposed DHCP Standardized Responses to AABB Computer Requirements" was developed based on the May 1993 version of the IRF. The spreadsheet entitled "Proposed DHCP Standardized Responses to CAP Computer Requirements" was developed based on the 1992 version of the CAP Checklist. Although the CAP does not generally focus on the Blood Bank module since it is not a stand-alone system, the information might be useful in providing additional perspective on the specific regulations.

SLIDE 6

Documents Provided for Version 5.2

Blood Bank Manual
  Appendix C
    Accreditation Requirements
  4 AABB Requirements "Proposed DHCP Standardized Responses to
      AABB Computer Requirements"
  4 CAP Requirements   "Proposed DHCP Standardized Responses to
      CAP Computer Requirements"
    V5.2 Control Functions
    V5.2 Test Case Tracking

With the release of patches for Laboratory V. 5.2, each patch contains information specific to that patch. In addition to identifying information, as shown this slide,

---

SLIDE 7

Example of Patch Information

Run Date: DEC 19, 1995   Designation: LR*5.2*79
Package: LR-LAB SERVICE   Priority: MANDATORY
Version: 5.2 SEQ #65   Status: Released

Subject: NO CHECK IF UNITS MUST BE MODIFIED

Category: ROUTINE

---

the patch will include the description, the rationale for issuing the patch, the test sites, the description, the rationale for issuing the patch, the test sites, and the test scenarios(s). In the example shown in Slide 8, Patch LR*5.2*79 was released to fix problems reported and documented in 3 separate NOIS calls. The specific NOIS call log numbers are included in the patch as reference points. Depending on access to the FORUM module, the Laboratory Information Manager and/or the IRM staff can access the specific NOIS call to obtain information and view the status of the resolution. In this particular case, 2 problems were identified, the first of which is detailed in the portion of the patch message shown in the slide on the next page.

SLIDE 8

Example of Patch Information- LR*5.2*79

Description:

Reference NOIS: BRK-0995-12370
                                    MAD-0895-41933
                                    HAM-0895-20001

Reporting Site: Brockton, Madison, Hampton

Test Site(s):   Hines, Madison, Long Beach & Hampton

DESCRIPTION: **NOTE:** This is not the entire patch description for this patch.
 ============
 This patch fixes 2 problems as reported in BRK-0995 & MAD-0895-41933
(Prob#1) and HAM-0895-20001 (Prob#2)

 PROBLEM 1:
 Prior to this patch, version 5.2 was not evaluating correctly whether a
 product type needed to be modified prior to release. After this patch,
 the appropriate warning is displayed when trying to relocate units which
 require to be modified prior to release:

Test Scenario Prior to patch:
 1.   Select a component which has the following fields defined in file 66
       CAN BE REQUESTED=YES
       MODIFIED BEFORE RELEASE=YES

 2.   Using standard Blood Bank procedures for the component requested, assign a unit of the above
component to a patient.

 3.   DO NOT MODIFY THIS UNIT!! Using the Disposition -relocation [LRBLIDR]
option, relocate the unit out of the Blood Bank.

 4.   Before the patch, the unit will either be relocated without being modified, or an Undefined error
may occur.

 After the patch is installed:
 1.   Follow the same scenario as described above, steps 1,2,3.

 2.   After the patch, you will not be allowed to release the unit and also the warning flag "This unit
needs to be modified before release" will
 appear by the unit(s).

The patch will also include a summary of the routines and the installation instructions.

SLIDE 10

Example of Patch Information- LR*5.2*79

ROUTINE SUMMARY:
=================

The second line of the routine now looks like:

<tab>   ;;5.2;LAB SERVICE;**[patch list]**;Sep 27, 1994

                    Checksum Values

Routine Name	Before Patch	After Patch	Patch List
LRBLJL	16947383	17014884	16,79
LRBLJL1	7275954	8687646	79

Installation Instructions:
==========================

1.   Patch 72 must NOT be installed (Multidivisional BB/AP in beta test)

2.   Users may remain on the system.

3.   No options need be placed out of order.

4.   Install patch during non-peak hours.

NOTE: Revisions of either the Control Function listing or the Test Case Tracking worksheets are NOT provided with the majority of individual patches. This means that each site will need to detail how this validation testing will be documented, detailing the differences between focused validation testing for the patch and revalidation of the entire package.

With the release of Patch LR*5.2*72, additional documentation was provided because of the scope of the patch.

SLIDE 11

Documents Provided for Patch LR*5.2*72

Release Notes and Installation Guide

Blood Bank User Manual
        Appendix D   Notes for LR*5.2*72
        Appendix E   Suggested Change Control Policy for File 66

The actual process of performing the software validation will be discussed in detail on subsequent slides. At that time, the purpose of the spreadsheet entitled "Control Functions in the Version 5.2 Blood Bank Module, DHCP Laboratory Package Software" for LR*5.2*72 will become evident. In general, this spreadsheet itemizes the control functions by functional area and option name.

SLIDE 12

Documents Provided for LR*5.2*72

Release Notes and Installation Guide

Blood Bank User Manual
        Appendix D   Notes for LR*5.2*72
                4   V5.2/LR*5.2*72 Control Functions
                    V5.2/LR*5.2*72 Test Case Tracking

        Appendix E   Suggested Change Control Policy for File 66

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.

SLIDE 13

Control function definition
      system function that causes an activity to occur
      or
      that influences the behavior of the user of the system

Types of control functions
      Process control
      Decision support

The spreadsheet indicates the type of process control, a brief description of the control function, an indication as to whether a warning message is provided, an indication as to whether the control function can be overridden or not and has space to record the date and/or outcome of the validation testing. Override capabilities designated as 'limited' indicate that additional security access is required, either in the security keys, FileMan access level or through additional edit options which are tracked by the audit trail.

SLIDE 14

Functional area (patient, inventory or donor)
Option name
Menu name
Type of control
Control function description
Warning message (yes/no)
Override capability (yes/no/limited)

NOTE: Security/access is primarily provided by Kernel; however, menu management can also be an effective tool when used in combination with security keys.

With Patch LR*5.2*72 which includes multidivisional functionality for the Blood Bank module, an additional level of security was added to specific options and/or file access. These changes are detailed in both the Release Notes and Installation Guide for the patch and on pages 5-17 of this appendix.

SLIDE 15

Example:

3. A **new** field has been added to BLOOD PRODUCT file (#66). The **new** ASSOCIATED DIVISION field (#10) is a multiple which allows the site to indicate which divisions are to be associated with that specific blood component.

NOTE: There is a screen on the input transform for the **new** ASSOCIATED DIVISION field (#10) to allow entry of only those divisions associated with the site to be selected, i.e. S DIC("S")="I +$G(^DIC(4,+Y,99))=+$$SITE^VASITE".

The last spreadsheet in Appendix D is entitled "Tracking of Test Case Testing for Version 5.2, Blood Bank Module, DHCP Laboratory Package Software". This spreadsheet is an updated version of the one included in Appendix C and represents the changes included as part of LR*5.2*72 as well as in all patches which have been released prior to LR*5.2*72 which are documented in the Laboratory Patch LR*5.2*72 Release Notes and Installation Guide on page 26. This spreadsheet provides a listing of all exported options, by functional area, in order by the menu abbreviation.

SLIDE 16

Documents Provided for LR*5.2*72

Release Notes and Installation Guide

Blood Bank User Manual
        Appendix D   Notes for LR*5.2*72
                            V5.2/LR*5.2*72 Control Functions
                  4   V5.2/LR*5.2*72 Test Case Tracking

        Appendix E   Suggested Change Control Policy for File 66

Each page of the V5.2/LR*5.2*72 Test Case Tracking spreadsheet includes the identifying information for each exported option, including the menu abbreviation and the menu name and the option name. The option description is generic and 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. Columns are then provided for the user to indicate whether access to the option is limited. The final group of five 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.

```
SLIDE 17

Functional area
Menu abbreviation
Option name
Menu name
Option description
Limited access?
Acceptability of Test Cases
```

Each page also contains an area to indicate the review of the validation testing, the outcome (implementation approved/disapproved), an area for comments and space for signatures of the Blood Bank Supervisor, the Blood Bank Medical Director and the Laboratory Information Manager/IRM staff. Although the Blood Bank Supervisor may be involved in the validation process, the review by the Blood Bank Medical Director and either the Laboratory Information Manager or the IRM staff is intended to function as evidence of external QA review.

For Laboratory V. 5.2, each facility received the Planning and Implementation Guide and the Blood Bank User Manual and the Laboratory V. 5.2 Release Notes. Recently, the National Center for Documentation distributed some revisions for both the Planning and Implementation Guide and the Blood Bank User Manual.

For Patch LR*5.2*72, each facility received the Laboratory Patch LR*5.2*72 Release Notes and Installation Guide, Appendix A for the Anatomic Pathology Manual, as well as Appendices D and E for the Blood Bank User Manual. The portions of the Release Notes relevant to the function and validation of the Blood Bank software have been included in the beginning of this appendix (Appendix D). This information is divided into major sections, i.e., Data Dictionary/Functionality Changes and Option/Functionality Changes. The content of the Data Dictionary Changes portion focuses on the technical details; however, some explanation is provided to describe the purpose or ramifications of the change whenever the change was not self-explanatory. For Patch LR*5.2*72, the Data Dictionary changes for Blood Bank include 6 files.
The implications of the changes for those facilities already utilizing the Blood Bank package are significant and should be reviewed in great detail prior to validation testing and implementation.

The portion of the Release Notes and Installation Guide which is included in Appendix D, pages 5-15, requires a methodical review to assess the implications at the individual facility. Specific test cases will need to be added to the software validation to reflect these functionality changes.

SLIDE 18

Documents Provided for Patch LR*5.2*72

Release Notes and Installation Guide

Blood Bank User Manual
      Appendix D   4   Notes for LR*5.2*72
                              Overview of Multidivisional Functionality
                  4   Data Dictionary and Functionality Changes Related to Multidivisional Functionality
                  4   Data Dictionary and Functionality Changes Unrelated to Multidivisional Functionality
                  4   Blood Bank Option and Functionality Changes Instructions for Blood Bank for Multidivisional Sites Data Merger for Consolidation Sites Blood Bank Software Validation Information V5.2/LR*5.2*72 Control Functions V5.2/LR*5.2*72 Test Case Tracking

      Appendix E   Suggested Change Control Policy for File 66

Once you have reviewed the materials provided, it is time to develop a strategy for validation of a new version. Although validation is also required for patches and local modifications, the scope of the new version validation is significantly larger.
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.

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 local modifications, i.e. change control, must undergo prospective validation testing before revisions or modifications in software are put into use for daily operations. This validation testing may encompass a more limited scope depending on the nature of the change and the interaction of that specific routine on other functions. An example of a patch was shown on slide 8. Validation is also required and is crucial for any local modifications made since these modifications do not go through the usual regimented verification process.

SLIDE 19

Required Validation Testing
     Retrospective
     New version
     Patch
     Local Modification

Validation testing must be performed in an environment which 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 the test account is not complete or well maintained. 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.

SLIDE 20

Validation - Where?

As detailed in the sample policy previously described in Appendix A, validation testing must include routine operations as well as ALL control functions. Routine operations to be tested include all data entry methods, security procedures, program overrides, data storage and retrieval of results/data, and traceability of results.

SLIDE 21

Routine operations to be tested
4 data entry methods,
4 security procedures, i.e. access beyond the LRLAB, LRVERIFY and
        LRBLOODBANK security keys
4 program overrides, including those requiring additional security access
4 data storage and retrieval of results/data
4 traceability of results, including changes in significant data elements and test   results.

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 in Appendix D. 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.

SLIDE 22

Sources of Test Cases

Listing of control functions in the Blood Bank Module for Version 5.2 inclusive of patches through LR*5.2*72 (Appendix D)
Option description examples in the Blood Bank User Manual
Facility's Blood Bank Standard Operating Procedures Manual
Tester's creativity

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?"

Scripts can be created and used for the validation testing. The purpose of a test script is 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. While a test script can help to ensure that all of the necessary functions have been tested, this is not the only method for accomplishing this objective.
By using the worksheets provided in Appendix D and the software as detailed in subsequent slides, the user can assure that the necessary testing has been completed.

Five types of test conditions are detailed in the sample policy and are described in the introduction for the 'Tracking of Test Case Testing' worksheets. Four of these are included on the 'Tracking of Test Case Testing for LR*5.2*72' 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, including normal data, exceptional data which provides an unusual twist for the program to force the program to react to data or a situation that might be unexpected, boundary situations to force the evaluation of conditions that are of borderline validity, 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.

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 changes in the new version of the software.

SLIDE 23

Test conditions to be tested

4 normal data

    exceptional data which provides an unusual twist for the program to force the program to react to data or a situation that might be unexpected, e.g. data entered out-of-order from the usual workflow, or not completely entered

    boundary situations to force the evaluation of conditions that are of borderline validity, e.g. crossmatches which are 'IG' or donors in which testing is not completed

    invalid data to force a program to prove that it can detect invalid input , e.g. absurd dates, or invalid ABO types

    stress conditions to determine whether the system has acceptable performance limits, e.g. large volumes of data to determine whether the storage capacity and response time are appropriate or multiple users trying to access the same information

---

NOTE: Scenarios can be developed in outline format or in graphical format. 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:

1. Search for donor
2. Enter donor information on new donor.
3. Search for donor just added.
4. 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.

```
                              ┌──────────────┐
                             ╱                ╲            Yes        ╭──────────╮
┌────────────────┐         ╱    Donor Exists?   ╲──────────────────▶│   End    │
│ Search for donor│───────▶▷                     ╲                   ╰──────────╯
└────────────────┘          ╲                   ╱
                             ╲                ╱
                              └──────┬───────┘
                                     │  No
                                     ▼
                            ┌─────────────────┐
                            │ Enter donor name,│
                            │  address, etc.   │
                            └────────┬────────┘
                                     ▼
                              ╱            ╲          No       ┌──────────────┐
                             ╱   Add Donor ? ╲───────────────▶│ Cancel add of │
                             ╲               ╱                 │ donor record  │
                              ╲            ╱                   └──────┬───────┘
                              └─────┬─────┘   Yes                     │
                                    ▼                                 │
                            ┌─────────────────┐                       │
                            │ Search for donor │◀─────────────────────┘
                            │   just added     │
                            └────────┬────────┘
                                     ▼
                              ╱            ╲        Yes      ┌──────────────────┐
                             ╱ Donor record ╲─────────────▶│ Print donor letter │
                             ╲   found ?    ╱               └──────────────────┘
                              ╲            ╱
                              └─────┬─────┘
                                    │  No
                                    ▼
                               ╭─────────╮
                               │   End   │
                               ╰─────────╯
```

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.

SLIDE 24

Test conditions to be tested

   normal data

4 exceptional data which provides an unusual twist for the program to force the program to react to data or a situation that might be unexpected, e.g. data entered out-of-order from the usual workflow, or not completely entered

   boundary situations to force the evaluation of conditions that are of borderline validity, e.g. crossmatches which are 'IG' or donors in which testing is not completed
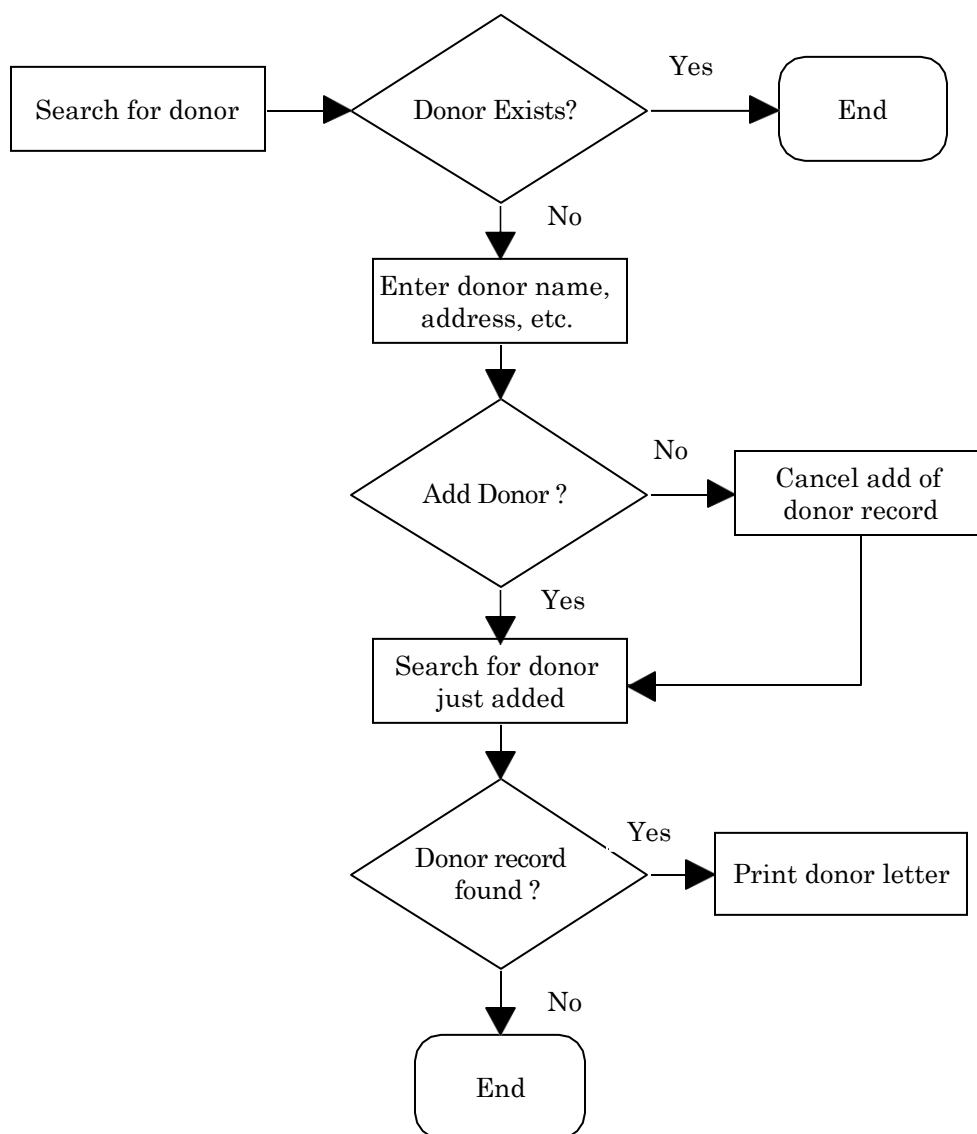
4 invalid data to force a program to prove that it can detect invalid input , e.g. absurd dates, or invalid ABO types

   stress conditions to determine whether the system has acceptable performance limits, e.g. large volumes of data to determine whether the storage capacity and response time are appropriate or multiple users trying to access the same information

---

Although there are a few examples which might involve a 'boundary' situation as shown on the slide, this test condition relates primarily to entry of numerical data in which the software is then interpreting the data. One example 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.

SLIDE 25

Test conditions to be tested

normal data

exceptional data which provides an unusual twist for the program to force the program to react to data or a situation that might be unexpected, e.g. data entered out-of-order from the usual workflow, or not completely entered

4 boundary situations to force the evaluation of conditions that are of borderline validity, e.g. crossmatches which are 'IG' or donors in which testing is not completed

invalid data to force a program to prove that it can detect invalid input , e.g. absurd dates, or invalid ABO types

stress conditions to determine whether the system has acceptable performance limits, e.g. large volumes of data to determine whether the storage capacity and response time are appropriate or multiple users trying to access the same information.

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. 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 Inventory File (#65) is not significant and, based on experience to date, the capacity in most facilities can easily accommodate several years 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.

SLIDE 26

Test conditions to be tested

   normal data

   exceptional data which provides an unusual twist for the program to force the program to react to data or a situation that might be unexpected, e.g. data entered out-of-order from the usual workflow, or not completely entered

   boundary situations to force the evaluation of conditions that are of borderline validity, e.g. crossmatches which are 'IG' or donors in which testing is not completed

   invalid data to force a program to prove that it can detect invalid input , e.g. absurd dates, or invalid ABO types

4 stress conditions to determine whether the system has acceptable performance limits, e.g. large volumes of data to determine whether the storage capacity and response time are appropriate or multiple users trying to access the same information

---

Testing must be done with each of the various levels of 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.

SLIDE 27

Security to be tested

4 LRLAB and LRVERIFY keys, with no LRBLOODBANK key

4 LRLAB, LRVERIFY and LRBLOODBANK keys, but with no LRBLSUPER   key

     Access to specific divisions if appropriate

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.

SLIDE 28

Security to be tested

     LRLAB and LRVERIFY keys, with no LRBLOODBANK key

     LRLAB, LRVERIFY and LRBLOODBANK keys, but with no LRBLSUPER   key

4 Access to specific divisions if appropriate

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.

SLIDE 29

Peripheral devices to be tested

4   Printers

4   Bar code readers

Each facility needs to prepare their own Validation Test Plan which lists the specific test cases in addition to the other relevant information. With the exception of the actual test cases, the majority of the information which needs to be included in the Validation Test Plan is detailed in the policy entitled Blood Bank Software Requirements found in Appendix A of the Blood Bank User Manual.

SLIDE 30

Validation Test Plan
    Validation Team Members & Responsibilities
    Environment & Time Requirements
    Hardware & Peripheral Devices
    Scope/Methodology/Test Cases
    Acceptance Criteria
    Evaluation of Testing
    Documentation

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.

SLIDE 31

Tips and Techniques for Defining Validation Cases

· 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 # to make cross-references   easy.

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.

RISK ANALYSIS

High   **RISK**

| | III | IV |

Impact of
Failure

| | I | II |

Low   Likelihood of Failure   **High**
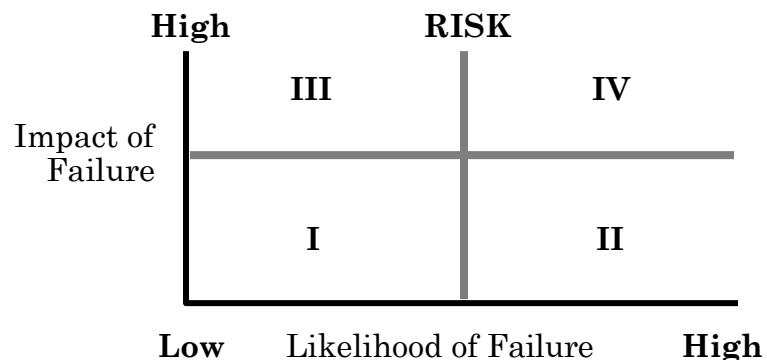
In this model, it would be logical to focus validation activities on those systems/processes which fall in quadrant IV, followed by III, etc. For example, processes which fall in quadrant IV may be done first, may have more test cases defined, may be defined as critical functions, etc.

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 are detailed in Slide 32.

SLIDE 32

Acceptance Criteria

Examples:
    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 'Tracking of Test Case Testing for Version 5.2, Patch LR*5.2*72' in Appendix D of the Blood Bank User Manual provides 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.

Specific areas on the bottom of the worksheet have been provided for documentation of the evaluation, comments, signatures of the reviewing/approving officials and the implementation date. Although the Blood Bank Supervisor may have participated in the testing, the inclusion of review by the Blood Bank Medical Director and the Laboratory Information Manager/IRM staff provides the required external QA review of the findings.

SLIDE 33

Evaluation of testing

New version release   Use the Tracking of Test Case Testing for LR*5.2*72

Patch release   Use the Patch Documentation (mail message)

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? The sample policy included in Appendix A of the Blood Bank User Manual details the procedure for resolving problems in paragraph 1.06.

In some instances, the software may not function as described in the documentation because the file setups are not as intended or because a different edit or print template is being referenced. These problems can generally be resolved quickly by the CLIN2 support team.

SLIDE 34

Evaluation of testing which does not perform as expected

Choices:
• Consult the Blood Bank User Manual to determine what file or template controls the software.
• Contact a member of the CLIN2 software support team.
• Send a mail message in FORUM to G.LAB SUPPORT NATIONAL

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.

SLIDE 35

Evaluation of testing which does not perform as expected

Choices:
4 Consult the Blood Bank User Manual to determine what file or template controls the software.
•   Contact a member of the CLIN2 software support team.
•   Send a mail message in FORUM to G.LAB SUPPORT NATIONAL

On page 134 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, pages 169 and 184 include information detailing the difference between the SERUM ANTIBODY and ANTIBODIES IDENTIFIED fields, clearly 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 which provides this control function is then detailed on page 375. 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 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.

SLIDE 36

Evaluation of testing which does not perform as expected

Is it critical to the function of the software or does it merely represent an opportunity for improvement?

Choices:
- Continue with implementation because it is acceptable, but less than optimal

- Continue with implementation, but alter workflow processes until the situation is corrected.

- Delay implementation until situation is corrected.

NOTE: As previously indicated, when situations are encountered where the software does not perform as expected, they should be reported according to established procedures. This procedure is detailed in Appendix A of the Blood Bank User Manual. 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 support team. Reporting to the CLIN2 team can be done either by telephone or by initiating a NOIS call.

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 any correction action, the signature and date of approval by the Blood Bank medical director and the implementation date.

This should be done by a combination of notes on the actual testing printouts and the use of the forms previously discussed.

SLIDE 37

Documentation of validation testing

•   observations from testing, e.g. screen prints, logging files, printed reports,   written
transcriptions, data tapes, data disks, etc.
•   review of the test cases, i.e. acceptability of the output based on the data entered
•   a record/log of unusual occurrences, bugs, deviations from the BB User Manual   & their
resolutions,
•   conclusion of the testing, i.e. acceptability
•   any corrective actions
•   final approval by other responsible individuals, including the BB Medical   Director
and the LIM
•   implementation date/time

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.

SLIDE 38

Documentation of validation testing

   must be retrievable by function!

File 66.2 (Blood Bank Validation) 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.

SLIDE 39

File 66.2   Blood Bank Validation

Data entry in this file is **NOT** intended to replace the mandated documentation of the validation testing for those items included on the slide;

SLIDE 40

Data entry in this file is **NOT** intended to replace:
• 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 BB User Manual & their resolutions, or
• final approval by other responsible individuals, including the BB Medical Director and the LIM.

---

however, data entry in this file is may be used to replace some items.

SLIDE 41

Data entry in this file **MAY** be used to replace:
4 the documentation of the review,
4 the acceptability/outcome of the review,
4 the date/signature of approval, and
4 the date of implementation.

This file offers longitudinal tracking of software validation. The content and formatting of the file is consistent with the worksheets provided in Appendices C and D of the Blood Bank User Manual and complies with the requirements of the American Association of Blood Banks.

SLIDE 42

Tracks software validation required for:
New version releases
Patch installation
Local modifications

With Version 5.2, the Blood Bank Validation File (#66.2) was exported 'with data', i.e. the option description information already exists. The fields which already contained data, as shown on Slide 41, are not included in the input templates for the data entry option Blood Bank Validation Documentation [LRBLVAL] in the Edit blood bank files [LRBLEF] submenu of the Supervisor [LRBLS] menu.

SLIDE 43

NAME: LRBLPET   MENU NAME: Enter test data
  MENU ABBREVIATION: ET   FUNCTIONAL AREA:PATIENT
  OPTION DESCRIPTION: DATA ENTRY

One new option was exported with Patch LR*5.2*26 and two new options are included in Patch LR*5.2*72. For those new options, information for the fields shown in slide 44 will need to be added via FileMan before those specific options can be accessed via the data entry option Blood Bank Validation Documentation [LRBLVAL].

```
SLIDE 44

NAME: LRBLJTR                                  MENU NAME: Transfer unit to new division
 MENU ABBREVIATION: TR                         FUNCTIONAL AREA: INVENTORY
 OPTION DESCRIPTION: DATA ENTRY
```

Data can be entered into the file in any order once the validation testing has been done. The nature of the VA FileMan software is such that the display order for the data for each entry is determined by preset algorithms. It may be desirable to enter the information about the current validation, then to go back and enter the data for the patch installations and/or previous versions if that has not already been entered.

For the most part, the order of the prompts and the information entered reflects that on the Test Case Tracking Sheets included in Appendix D of the Blood Bank User Manual.

```
SLIDE 45

Select Blood Bank supervisor menu Option: S Supervisor

Select Supervisor Option: VD Blood Bank Validation Documentation

Select BLOOD BANK VALIDATION NAME: LRBLPET          Enter test data

OPTION IN USE: YES
```

NOTE: If the option is not in use, no additional information is required. However, in such a case, the option should not be included in any menu in use **OR** consideration should be given to disabling the option if local menus are not in use at the facility. his would prevent inadvertent use of an option which had not been validated.

The Date/Time Validated is a multiple field. For each date/time validated for a specific option, additional information must be recorded. The version number should be entered regardless of the reason for the validation. If the validation is for a patch, the patch number should be entered; otherwise this should be left empty.

SLIDE 46

Select DATE/TIME VALIDATED: 6/7/90 JUN 7, 1990
  ARE YOU ADDING 'JUN 7, 1990' AS A NEW DATE/TIME VALIDATED (THE 1ST FOR THIS BLOOD BANK VALIDATION)? Y(YES)

  REASON FOR VALIDATION: ?
    In accordance with M-2, Part VI, Chapter 5, validation testing must be
    performed at these specific times.
    CHOOSE FROM:
      1   NEW VERSION
      2   PATCH
      3   RETROSPECTIVE
      4   LOCAL MODIFICATION
  REASON FOR VALIDATION: 3 RETROSPECTIVE

  VERSION NUMBER: V5.0

  PATCH NUMBER:

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 BB User Manual and approved implementation should be entered as 'approved by'.

Appendix D

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.

```
SLIDE 47

Select PERSON PERFORMING VALIDATION: BBUSER,TEN
   ARE YOU ADDING 'BBUSER,TEN' AS A NEW PERSON PERFORMING VALIDATION (THE
1ST FOR THIS DATE/TIME VALIDATED)? Y(YES)

Select PERSON PERFORMING VALIDATION:

 OUTCOME: ?
   CHOOSE FROM:
     1      ACCEPTABLE
     2      ACCEPTABLE WITH CORRECTIVE ACTION
     3      NOT ACCEPTABLE
 OUTCOME: 1 ACCEPTABLE
 APPROVED BY: BBUSER,ELEVEN
 DATE APPROVED: 6/30/90 (JUN 30, 1990)
 DATE IMPLEMENTED: 5/19/90 (MAY 19, 1990)
 COMMENT:
 1>

Select DATE/TIME VALIDATED:
```

Comments might include:
        the type and rationale for any change and an indication to "see release notes"
        any pending corrective action required
        the rationale if the outcome was unacceptable.

Appendix D-54   Laboratory Patch LR*5.2*72   July 1996
                                 Blood Bank User Manual

In order to review information about that specific option for historic or tracking purposes, it is possible to either view the information on the screen for a single option or to print the information. n the next 3 slides, all of the data is included for 1990-1993 for this specific option.

SLIDE 48

Select Inquiries Option: VD Blood Bank Validation Documentation

Select BLOOD BANK VALIDATION NAME: LRBLPET   Enter test data
NAME: LRBLPET   MENU NAME: Enter test data
 MENU ABBREVIATION: ET   FUNCTIONAL AREA: PATIENT
 OPTION DESCRIPTION: DATA ENTRY   OPTION IN USE: YES

DATE/TIME VALIDATED: SEP 30, 1993   REASON FOR VALIDATION: NEW VERSION
 VERSION NUMBER: V5.14T7   OUTCOME: ACCEPTABLE
 APPROVED BY: BBUSER,TWELVE   DATE APPROVED: OCT 25, 1993
 DATE IMPLEMENTED: SEP 28, 1993
PERSON PERFORMING VALIDATION:BBUSER,TEN
 COMMENT: Changes to automatically capture workload.

NOTE: The data entry for September 6, 1991 where the reason for the validation was the installation of a patch which was required to meet AABB accreditation requirements for redisplay of results entered prior to verification. As is also indicated in the Comments, this change also involved a change in the LRBLSCREEN and the LRBLPCMBS edit templates.

SLIDE 49 (continuation from previous slide)

DATE/TIME VALIDATED: FEB 18, 1993   REASON FOR VALIDATION: NEW VERSION
 VERSION NUMBER: V5.14   OUTCOME: ACCEPTABLE
 APPROVED BY:BBUSER,TEN   DATE APPROVED: MAR 1, 1993
 DATE IMPLEMENTED: FEB 17, 1993
PERSON PERFORMING VALIDATION:BBUSER,TEN

DATE/TIME VALIDATED: SEP 6, 1991   REASON FOR VALIDATION:PATCH
 VERSION NUMBER: V5.1   PATCH NUMBER: LR*5.1*9
 OUTCOME:ACCEPTABLE   APPROVED BY: BBUSER,TWELVE
 DATE APPROVED: SEP 6, 1991   DATE IMPLEMENTED: SEP 6, 1991
 PERSON PERFORMING VALIDATION: BBUSER,TEN
 COMMENT: Change required to meet AABB accreditation requirements for redisplay of results entered prior to verification. Change in LRBLSCREEN & LRBLPCMBS edit templates.

Although the validation of this option on July 8, 1991 was acceptable, a comment was still included to indicate that a change had been made in this option for this version.

```
SLIDE 50 (continuation from previous slide)

DATE/TIME VALIDATED: JUL 8, 1991          REASON FOR VALIDATION: NEW VERSION
  VERSION NUMBER: V5.1                     OUTCOME: ACCEPTABLE
  APPROVED BY: BBUSER,TWELVE                DATE APPROVED: JUL 31, 1991
  DATE IMPLEMENTED: JUN 20, 1991
PERSON PERFORMING VALIDATION: BBUSER,TEN
 COMMENT: Changes in format of data entry...see release notes.

DATE/TIME VALIDATED: JUN 7, 1990          REASON FOR VALIDATION: RETROSPECTIVE
  VERSION NUMBER: V5.0                     OUTCOME: ACCEPTABLE
  APPROVED BY: BBUSER,TWELVE                DATE APPROVED: JUN 30, 1990
  DATE IMPLEMENTED: MAY 19, 1990
PERSON PERFORMING VALIDATION: BBUSER,TEN
```

In the event that, for whatever reason, it is desirable to print information to hard copy, this can be done using the option in the Reports menu. The output is identical to that of the option in the Inquiries menu.

```
SLIDE 51

Select Blood Bank supervisor menu Option: R Reports

Select Reports Option: VD Print Blood Bank Validation

START WITH NAME: FIRST// LRBLPET
GO TO NAME: LAST// LRBLPET
DEVICE: PRINTER
```

BLOOD BANK SOFTWARE REFERENCES

(in chronological order by topic)

Journal Articles

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3. Brannigan VM. Regulation of Clinical Information Systems after the 1990 Amendments to the Food and Drug Act. Clin Lab Mgmt Review. 1992; 6(1)49-57.
4. Goossen M. Complete Blood Center Computer Validation. Advance/Laboratory. 1994; (Oct):58.

VA Regulations

5. Department of Veterans Affairs, Veterans Health Administration, M-2, Part VI, Chapter 5, "Immunohematology, Blood Transfusion and Transfusion Medicine", February 16, 1994.

CAP Documents

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

AABB Documents

7. Software Manufacturing Process Guidelines (DRAFT), American Association of Blood Banks. Letter to all institutional members, November 25, 1991.
8. Control Function Guidelines (DRAFT), American Association of Blood Banks. Letter to all institutional members, November 25, 1991.
9. User Validation Guidelines (DRAFT), American Association of Blood Banks. Letter to all institutional members, November 25, 1991.
10. Accreditation Requirements Manual, American Association of Blood Banks. 6th edition, 1995.
11. Standards for Blood Banks and Transfusion Services, American Association of Blood Banks. 17th edition, 1996.

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12. Food and Drug Administration, Requirements for computerization of blood establishments. Letter to all registered blood establishments, September 8, 1989.

13. 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.)

14. "Blood Bank Inspection Checklist and Report Form 2609, part K" Food and Drug Administration, US Department of Health and Human Services, Public Health Service, May 1991.

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16. Food and Drug Administration, CBER Draft Guidelines for Validation of Blood Establishment Computer Systems, Sept. 28, 1993, Docket #93N-0394.

17. Food and Drug Administration, CBER Draft Guidelines for Quality Assurance in Blood Establishments, June 17, 1993, Docket #91N-0450.

18. Food and Drug Administration, Center for Biologicals Evaluation and Research. Letter to Blood Establishment Computer Software Manufacturers, March 31, 1994.

19. "FDA Compliance Program Guidance Manual-Inspection of Licensed and Unlicensed Blood banks", Food and Drug Administration, US Department of Health and Human Services, Public Health Service, January 1995, Document #7342.001.

20. Food and Drug Administration, Guidance for Blood Establishments Concerning Conversions to FDA-Reviewed Software Products. Letter to all registered blood establishments, November 13, 1995.

21. Code of Federal Regulations, 21 CFR, parts 211.68, 606.20, 606.60, 606.100 and 606.160, US Department of Health and Human Services, Public Health Service, 1995.

22. Code of Federal Regulations, Good Manufacturing Practice for Medical Devices, 21 CFR, Part 820, US Department of Health and Human Services, Public Health Service, 1995.

23. Code of Federal Regulations, Medical Device Tracking Requirements, 21 CFR, Part 821, US Department of Health and Human Services, Public Health Service, 1995.

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

Control Function

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.

NOTES: (1) The descriptions of the control functions are abbreviated and the Blood Bank User Manual (V.5.2), documentation of the other BB patches and the listings of data dictionary, functionality and option changes for Patch LR*5.2*72 should be consulted for additional details. (2) Override capabilities designated as 'Limited' indicate that additional supervisory is required, either in the security level or additional specific supervisory level edit options which are tracked by the audit trail.

NOTE: The portion of the information provided which references 'division' is applicable only to those facilities which 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.

Functional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function Brief Description (see User Manual for details)	Warning Mess?	Override Capab?	validation
Patient	[LRDELOG]	P-DA	Process control	Prevents deletion of accession if there is verified data	Yes	No	
Patient	[LRBLPT]	P-DT	Process control	Limits access to those units currently assigned to the same division as the user	No	No	
Patient	[LRBLPT]	P-DT	Process control	Prevents entry of future transfusion dates	No	No	
Patient	[LRBLPT]	P-DT	Process control	Updates patient transfusion record	No	No	
Patient	[LRBLPET]	P-ET	Decision support	Compares current ABO/Rh to patient history	Yes	Yes	
Patient	[LRBLPET]	P-ET	Decision support	Displays previous antibody history, regardless of the division	Yes	NA	
Patient	[LRBLPER]	P-PR	Process control	Prevents entry of unit info if unit is in current Inventory (File 65)	Yes	No	
Patient	[LRBLPCS]	P-RS-CR	Process control	Limits component selection to those which "can be requested" and which are assigned to the appropriate division	No	Limited	

Func-tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function BriefDescription (see User Manual for details)	Warn-ing Mess?	Over-ride Capab?	Valid-ation
Patient	[LRBLPCS]	P-RS-CR	Decision support	Evaluates age of patient specimen (for the acc. area for the appropriate division)	Yes	NA	
Patient	[LRBLPCS]	P-RS-CR	Decision support	Evaluates request against audit criteria & current lab results, regardless of the division	Yes	Yes	
Patient	[LRBLPCS]	P-RS-CR	Decision support	Displays previous antibody history, regardless of the division	Yes	NA	
Patient	[LRBLPCS]	P-RS-CR	Decision support	Displays autologous units in inventory, regardless of the division	Yes	Yes	
Patient	[LRBLPIC]	P-RS-US	Process control	Compares unit & current specimen ABO/Rh to pt. hx	Yes	No	
Patient	[LRBLPIC]	P-RS-US	Process control	Prevents selection of units not ABO/Rh compatible	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Process control	Prevents selection of units not associated with the appropriate division (even autologous)	No	No-must transfer unit	
Patient	[LRBLPIC]	P-RS-US	Process control	Evaluates unit phenotyping against clin. significant pt. antibody	No	Limited if +	
Patient	[LRBLPIC]	P-RS-US	Process control	Prohibits selection of autologous unit for different patient	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Process control	Prohibits use of pt. specimen which is too old	Yes	Limited	
Patient	[LRBLPIC]	P-RS-US	Process control	If requested, limits selection to unassigned units	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Process control	Prevents selection of expired units	No	Limited	
Patient	[LRBLPIC]	P-RS-US	Decision support	Checks for low volume units	Yes	Yes	
Patient	[LRBLPIC]	P-RS-US	Decision support	Displays days left before expiration of unit	Yes	NA	
Patient	[LRBLPIC]	P-RS-US	Decision support	Displays autologous units in inventory, regardless of division	Yes	Yes	
Patient	[LRBLPX]	P-RS-XM	Process control	Prevents entry of XM if no ABO/Rh on current specimen	Yes	Limited	
Patient	[LRBLPX]	P-RS-XM	Process control	Evaluates unit recheck results against unit history	Yes	No	
Patient	[LRBLPX]	P-RS-XM	Process control	Prevents status change to 'assigned' unless XM is 'C' or 'IG'	No	Limited	

Func-tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function BriefDescription (see User Manual for details)	Warn-ing Mess?	Over-ride Capab?	Valid-ation
Patient	[LRBLPX]	P-RS-XM	Process control	Prevents status change based on 'IG' unless appropriate access	No	Limited	
Patient	[LRBLPX]	P-RS-XM	Decision support	Evaluates whether AbScreen results are entered on current specimen	Yes	Yes	
Patient	[LRBLPX]	P-RS-XM	Decision support	Evaluates unit phenotyping against clin. significant pt. antibody, regardless of division	Yes	Limited if+	
Patient	[LRBLP-LOGIN]	P-SL	Process control	Limits component selection to those which "can be re-quested" and which assigned to the appropriate division	No	Limited	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Checks for previous specimen within 72 hours, regardless of division	Yes	NA	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Displays previous antibody history, regardless of division	Yes	NA	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Displays previous transfusion reactions, regardless of division	Yes	NA	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Displays recent lab values for auditing request, regardless of division	Yes	Yes	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Displays autologous units in inventory, regardless of division	Yes	Yes	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Evaluates age of patient specimen (for the acc. area for the appropriate division)	Yes	NA	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Evaluates request against audit criteria & current lab results, regardless of division	Yes	Yes	
Patient	[LRBLP-LOGIN]	P-SL	Decision support	Evaluates request against MSBOS audit criteria, regardless of division	Yes	Yes	

Func- tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function BriefDescription (see User Manual for details)	Warn- ing Mess?	Over- ride Capab?	Valid- ation
Inven-tory	[LRBLIDN]	I-DN	Process control	Prevents entry of future disposition dates	Yes	No	
Inven-tory	[LRBLIDN]	I-DN	Process control	Restricts modification of components to specified components	Yes	No	
Inven-tory	[LRBLIDN]	I-DN	Process control	Prevents modification of autologous components to non-autologous comp. if testing incomplete or positive	Yes	No	
Inven-tory	[LRBLIDN]	I-DN	Process control	Checks volumes of modified(split/divided)units against maximum	Yes	No	
Inven-tory	[LRBLIDN]	I-DN	Process control	Deletes modification if no new unit ID entered	Yes	No	
Inven-tory	[LRBLIDN]	I-DN	Process control	Assigns ABO/ Rh of pool	NA	No	
Inven-tory	[LRBLIDN]	I-DN	Process control	Prevents multiple modifications to the same unit	No	No	
Inven-tory	[LRBLIDN]	I-DN	Process control	Restricts access to units to those units which are assigned to the same division	No	No	
Inven-tory	[LRBLIDN]	I-DN	Decision support	Calculates new expiration date for modified components	Yes	Yes	
Inven-tory	[LRBLIDN]	I-DN	Decision support	Identifies units which were released w/ incomplete results	Yes	Yes	
Inven-tory	[LRBLIDR]	I-DR	Process control	Restricts access to units to those units which are assigned to the same division	Yes	No	
Inven-tory	[LRBLIDR]	I-DR	Process control	Prevents issue if no entry for required recheck results	Yes	Limited	
Inven-tory	[LRBLIDR]	I-DR	Process control	Evaluates unit phenotyping against clin. significant pt. antibody	Yes	Limited	
Inven-tory	[LRBLIDR]	I-DR	Process control	Prevents issue if inspection is unsatisfactory	Yes	Limited	
Inven-tory	[LRBLIDR]	I-DR	Process control	Prevents issue if inspection from previous relocation was unsatisfactory	Yes	Limited	
Inven-tory	[LRBLIDR]	I-DR	Process control	Prevents issue if unit is one which must be modified before being released	Yes	No	
Inven-tory	[LRBLIDR]	I-DR	Process control	Restricts relocation of units to locations within the same associated division	Yes	Limited	

Func-tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function BriefDescription (see User Manual for details)	Warn-ing Mess?	Over-ride Capab?	Valid-ation
Inven-tory	[LRBLIDR]	I-DR	Process control	Prevents relocations with a date/time prior to the date/time the unit was assigned to the patient	Yes	Limited	
Inven-tory	[LRBLIDR]	I-DR	Decision support	Evaluates expiration date of unit	Yes	Yes	
Inven-tory	[LRBLILR]	I-LR	Process control	Prevents duplicate entry of unit ID of the same component	Yes	Limited	
Inven-tory	[LRBLILR]	I-LR	Process control	Checks validity of expiration date based on maximum days	Yes	Limited	
Inven-tory	[LRBLILR]	I-LR	Process control	Restricts entry of components to those in File 66 w/suppliers, etc.	No	No	
Inven-tory	[LRBLILR]	I-LR	Process control	Limits re-entry of units to those with dispositions of 'S' or "R'	Yes	No	
Inven-tory	[LRBLILS]	I-LT	Process control	Limits access to those units assigned to the same division as the user	No	No	
Inven-tory	[LRBLPED]	I-PD	Process control	Restricts component selection to those appropriately defined	Yes	No	
Inven-tory	[LRBLPED]	I-PD	Process control	Limits access to those units assigned to the same division as the user	No	No	
Inven-tory	[LRBLPED]	I-PD	Process control	Restricts unit selection to those of appropriate age	Yes	Limited	
Inven-tory	[LRBLPED]	I-PD	Process control	Prevents entry of expiration date without time	Yes	No	
Inven-tory	[LRBLPED]	I-PD	Decision support	Identifies low volume units	Yes	Yes	
Inven-tory	[LRBLPED]	I-PD	Process Control	Assigns final disp. to units w/0ml remaining volume after split	No	No	
Inven-tory	[LRBLISH]	I-SH	Decision support	Identifies units which were released w/ incomplete results	Yes	Yes	
Inven-tory	[LRBLIUC]	I-UC	Process control	Limits access to those units assigned to the same division as the user if done by unit (not if done by batch)	No	No	
Inven-tory	[LRBLIUC]	I-UC	Decision support	Compares current results to unit log-in information	Yes	Yes	
Inven-tory	[LRBLIUP]	I-UP	Process control	Prevents entry of same antigen as 'present' and 'absent'	Yes	No	
Inven-tory	[LRBLIUP]	I-UP	Process control	Updates donor record if appropriate	Yes	Yes	
Inven-tory	[LRBLIUP]	I-UP	Process control	Limits access to those units assigned to the same division as the user	No	No	
Inven-tory	[LRBLIUR]	I-UR	Process control	Prevents release of units from location other than BB	Yes	No	

Func- tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function Brief Description (see User Manual for details)	Warn- ing Mess?	Over- ride Capab?	Valid- ation
Donor	[LRBLDCP]	D-CP	Process control	Checks # components prepared against bag type	Yes	No	
Donor	[LRBLDCP]	D-CP	Process control	Ensures that no more than 1 RBC component is prepared	Yes	No	
Donor	[LRBLDCP]	D-CP	Process control	Checks time between collection & comp. prepar.	Yes	No	
Donor	[LRBLDCP]	D-CP	Process control	Compares anticoagulant of collection w/that for components	Yes	No	
Donor	[LRBLDCP]	D-CP	Process control	Prevents access to donors entered through 'Old records'	Yes	No	
Donor	[LRBLDCP]	D-CP	Decision support	Calculates the expiration date	NA	Yes	
Donor	[LRBLDC]	D-DC	Process control	Limits entry of pt. restrictions for auto units to pts in Patient File	Yes	No	
Donor	[LRBLDC]	D-DC	Process control	Prevents entry of future donation date/time	Yes	No	
Donor	[LRBLDC]	D-DC	Process control	Prevents entry of duplicate donor IDs within 5 years	Yes	No	
Donor	[LRBLDC]	D-DC	Process control	Prevents entry of completion date/time prior to start date/time	Yes	No	
Donor	[LRBLDC]	D-DC	Process control	Eliminates some gender specific questions on DH form	No	NA	
Donor	[LRBLDC]	D-DC	Process control	Prevents access to donors entered through 'Old records'	Yes	No	
Donor	[LRBLDC]	D-DC	Decision support	Checks for duplicate donors	Yes	Yes	
Donor	[LRBLDC]	D-DC	Decision support	Calculates collection volume	NA	Yes	
Donor	[LRBLDR]	D-DH	Process control	Prevents printing of regular DH form if donor is perm. deferred	Yes	No	
Donor	[LRBLDR]	D-DH	Decision Support	Includes special comments on DH form if appropriate	NA	Yes	
Donor	[LRBLDO]	D-DO	Process control	Prevents entry of duplicate donor IDs within 5 years	Yes	No	
Donor	[LRBLDPH]	D-DP	Process control	Prevents entry of same antigen as 'present' and 'absent'	Yes	No	
Donor	[LRBLDLG]	D-DR	Process control	Prevents entry of data if donor is permanently deferred	Yes	Limited	
Donor	[LRBLDLG]	D-DR	Process control	Enters donor in donor letter print queue	No	No	

Func-tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function Brief Description (see User Manual for details)	Warn-ing Mess?	Over-ride Capab?	Valid-ation
Donor	[LRBLDLG]	D-DR	Process control	Limits entry of pt. restrictions for auto units to pts in Patient File	Yes	No	
Donor	[LRBLDLG]	D-DR	Decision support	Checks age of donor to see if outside limits	Yes	Yes	
Donor	[LRBLDLG]	D-DR	Decision support	Checks for duplicate donors	Yes	Yes	
Donor	[LRBLDUC]	D-DU-DC	Process control	Compares recheck info to original processing results	Yes	Yes	
Donor	[LRBLDUC]	D-DU-DC	Process control	Prevents same tech from entering both original & recheck results	Yes	Limited	
Donor	[LRBLDAT]	D-DU-DT	Decision support	Checks current results against donor's historical record	Yes	Yes	
Donor	[LRBLDT]	D-DU-LA	Process control	Controls the specific tests included, i.e. ALT and HIV Ag, based on entries in File 69.9 (LABORATORY SITE)	No	No	
Donor	[LRBLDT]	D-DU-LA	Process control	Generates bulletin if positive results entered after component released	Yes	No	
Donor	[LRBLDT]	D-DU-LA	Process control	Prevents editing of results after components are released	Yes	Limited	
Donor	[LRBLDT]	D-DU-LA	Decision support	Adds units needing repeat testing to worklist	Yes	Yes	
Donor	[LRBLDRR]	D-DU-LR	Process control	Checks current ABO/Rh results against historical record	Yes	Limited	
Donor	[LRBLDRR]	D-DU-LR	Process control	Generates bulletin if unit released with ABO discrep.	Yes	No	
Donor	[LRBLDRR]	D-DU-LR	Process control	Displays required transfusion transmitted testing for review based on entries in File 69.9, i.e. for ALT and HIV Antigen	No	No	
Donor	[LRBLDRR]	D-DU-LR	Process control	Prevents release of homologous units with positive disease marker testing	Yes	Limited	
Donor	[LRBLDRR]	D-DU-LR	Process control	Enters units into inventory if 'released'	No	No	
Donor	[LRBLDRR]	D-DU-LR	Process control	Verifies accuracy of labeling via bar code reader	Yes	No	
Donor	[LRBLDRR]	D-DU-LR	Process control	Prevents same tech doing both labeling & verifying if manual	Yes	No	

Func-tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function BriefDescription (see User Manual for details)	Warn-ing Mess?	Over-ride Capab?	Valid-ation
Donor	[LRBLDRR]	D-DU-LR	Process control	Assigns the division of the user who is labeling/releasing the unit into inventory to the unit when it is moved from File 65.5. to 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 auto units released to inventory with positive/ incomplete testing	No	NA	
Donor	[LRBLDRR]	D-DU-LR	Process control	Flags homologous units released to inventory with incomplete testing	No	NA	

Func-tional Area	Menu Option Name	Menu Option Abbrev	Type of Control	Control Function Brief Description (see User Manual for details)	Warn-ing Mess?	Over-ride Capab?	Valid-ation
Super-visor	[LRBLSEL]	S-EI-LI	Process control	Limits access to those units assigned to the same division as the user	No	No	
Super-visor	[LRBLSEC]	S-EI-PI	Process control	Limits access to those units assigned to the same division as the user	No	No	
Super-visor	[LRBLSED]	S-EI-DI	Process control	Limits access to those units assigned to the same division as the user	No	No	
Super-visor	[LRBLAR]	S-SR-RA	Process control	Limits removal of data for the same division as the user	No	No	

Note: The Inquiry and Reports menu options do not have any type of data entry, and therefore, have not been included. Conversely, the Supervisory menu options have significant control in determining how the package works. The specific details are included in the Blood Bank User Manual. In addition, the checks provided in the routine data entry options are NOT generally included in these options, except as detailed above. These menu options are locked with the additional LRBLSUPER key. These options allow override capability for many of the control functions available in the routine data entry options. These options do, however, provide more control than straight FileMan access, as well as updating the appropriate cross references and other related data.

Test Case Tracking

Validation testing must include ALL control functions (see separate listing) as well as routine operations. Routine operations to be tested include: (1) all data entry methods, (2) security procedures, i.e. access beyond the LRLAB, LRVERIFY and LRBLOODBANK security keys must be noted, (3) software program overrides, (4) data storage and retrieval of results/data, and (5) traceability of results, including change in significant data elements and test results.

Test conditions must include: (1) normal, i.e. valid data sets used to produce normal outputs, (2) exceptional, i.e. valid data which provides an unusual twist for the program to force the program to react to something that might be unexpected, (3) boundary, i.e. to force the evaluation of conditions that are of borderline validity (applicable only to numeric fields), (4) stress, i.e. significant volume of data to determine whether the system has acceptable performance limits, and (5) invalid data, i.e. invalid data designed to force a program to prove that it can detect invalid data input.

Stress testing must be conducted; however, this is not specific to any option, but rather the overall functionality. Issues to be addressed include: (1) response time, (2) adequacy of file storage for the estimated volume of data needed for a specified period of time, and (3) response of the system to multiple users attempting to access/edit the same record.

For those options in which access is an issue, 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 which are multidivisional, access is also restricted by assigned division.

Although the Blood Bank User Manual and Release Notes 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: (1) definition of successful completion of test case, (2) a determination of whether the user requirements were met, and (3) an evaluation of any unexpected occurrences, i.e. are they critical or not?

The Test Case Tracking sheets 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 BB 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: (1) observations from testing, e.g. screen, prints, logging files, printed reports, written transcriptions, data tapes, data disks, etc., (2) the review of the test cases, i.e. acceptability of output based on data entered (3) a record/log of unusual, occurrences, bugs deviations from the User Manual, Release Notes and/or patch documentation & resolution, (4) the conclusion of the testing i.e. acceptable or not, (5) any corrective action, (6) a date/signature of approval and (7) 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. This file was new in Laboratory Version 5.2. Data entry in this file is NOT intended to replace the mandated documentation; however, data entry in this file may be used to replace some items. Consult the training document entitled Blood Bank Software Validation for specific details. Option descriptions are also included in the Blood Bank User Manual on pages 457-459.

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	Invalid
Donor	D-CP	[LRBLDCP]	Collection disposition/ component preparation	Data entry					
Donor	D-DC	[LRBLDC]	Donor collection/processing	Data entry					
Donor	D-DD	[LRBLDD]	Donor demographics	Data entry (mainly editing)					
Donor	D-DH	[LRBLDR]	Donor history, physical & consent form	Form generation (donor history)					
Donor	D-DO	[LRBLDO]	Old blood donor records	Data entry (history ONLY!)					
Donor	D-DP	[LRBLDPH]	Donor phenotyping	Data entry/editing					
Donor	D-DR	[LRBLDLG]	Donor registration	Data entry/editing					
Donor	D-DU-CR	[LRBLDCR]	Component preparation report	Report generation					
Donor	D-DU-DA	[LRBLDTA]	Abnormal donor tests	Report generation					
Donor	D-DU-DC	[LRBLDUC]	Donor unit ABO/Rh recheck	Data entry/ editing (opt.)					
Donor	D-DU-DL	[LRBLDDAW]	Donor unit testing worklist	Report generation					
Donor	D-DU-DR	[LRBLDTR]	Donor unit testing proof list	Report generation					
Donor	D-DU-DS	[LRBLDTRS]	Donor unit testing supplemental proof list	Report generation					
Donor	D-DU-DT	[LRBLDDAT]	ABO/Rh testing of donor units	Data entry/editing					
Donor	D-DU-LA	[LRBLDT]	Lab tests (not ABO/Rh) on donor units	Data entry/editing					
Donor	D-DU-LR	[LRBLDRR]	Test review/component labeling/release	Result review/ data entry					

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

_____ I approve implementation of the software effective _____.

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

Comments: _____

Signature: _____ (BB Supervisor)   Date: _____

Signature: _____ (BB Medical Director)   Date: _____

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

Date/time Implemented in Production: _____

						ACCEPTABILITY of TEST CASES			
FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	Normal	Except	Bound	Invalid
Inventory	I-DN	[LRBLIDN]	Disposition-not transfused	Data entry					
Inventory	I-DR	[LRBLIDR]	Disposition-relocation	Data entry					
Inventory	I-LR	[LRBLILR]	Log-in regular (invoices)	Data entry					
Inventory	I-LS	[LRBLILS]	Enter blood inventory typing charges	Data entry					
Inventory	I-PD	[LRBLPED]	Pediatric unit preparation	Data entry					
Inventory	I-SH	[LRBLISH]	Shipping invoices for blood components	Form generation					
Inventory	I-TR	[LRBLJTR]	Transfer unit to new division	Data entry					
Inventory	I-UC	[LRBLIUC]	Unit ABO/Rh confirmation	Data entry					
Inventory	I-UP	[LRBLIUP]	Unit phenotyping	Data entry/editing					
Inventory	I-UR	[LRBLIUR]	Units release to stock (cancel) by patient	Data entry (i.e. unit status change)					
Inventory	I-UW	[LRBLIW]	Inventory ABO/Rh testing worksheet	Form generation					

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

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Signature: _____ (BB Supervisor)   Date: _____
Signature: _____ (BB Medical Director)   Date: _____
Signature: _____ (IRM staff/LIM)   Date: _____
Date/time Implemented in Production_____

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	nvalid
Patient	P-CD	[LRUCHGDIV]	Change to new division	Data entry					
Patient	P-DA	[LRDELOG]	Remove an accession	Data editing					
Patient	P-DT	[LRBLPT]	Blood transfusion results	Data entry					
Patient	P-ET	[LRBLPET]	Enter test data	Data entry					
Patient	P-PR	[LRBLPER]	Previous records	Data entry (history ONLY!)					
Patient	P-RS-CR	[LRBLPCS]	Blood component requests	Data entry					
Patient	P-RS-US	[LRBLPIC]	Select units for patients	Data entry					
Patient	P-RS-XM	[LRBLPX]	Enter crossmatch results	Data entry					
Patient	P-SI	[LRBLPSI]	Special instructions	Data entry/editing					
Patient	P-SL	[LRBLPLOGIN]	Specimen log-in	Data entry					
Patient	P-T A	[LRADDTO ACC]	Add tests to a given accession	Data editing					
Patient	P-T D	[LRTSTOUT]	Delete test from an accession	Data editing					
Patient	P-T W	[LRBLTTW]	Test worklist	Form generation					
Patient	P-WL	[LRUW]	Accession area worklist	Form generation					

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

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Signature: _____(BB Supervisor)   Date: _____
Signature: _____ (BB Medical Director)   Date: _____
Signature: _____ (IRM staff/LIM)   Date: _____
Date/time Implemented in Production_____

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	Normal	Except	Bound	Invalid
						ACCEPTABILITY of TEST CASES			
Inquiries	Q-DI	[LRBLSQDD]	Single donor demographic information	Data inquiry only					
Inquiries	Q-OR	[LROS]	Order/test status	Data inquiry only					
Inquiries	Q-PA	[LRUPT]	Show list of accessions for a patient	Data inquiry only					
Inquiries	Q-PH	[LRBLPH]	Patient medication list	Data inquiry only					
Inquiries	Q-PR	[LRBLQDR]	Patient blood bank record	Data inquiry only					
Inquiries	Q-SD	[LRBLQSD]	Single donor information	Data inquiry only					
Inquiries	Q-ST	[LRBLQST]	Single unit status	Data inquiry only					
Inquiries	Q-SU	[LRBLIPSD]	Single unit information - display	Data inquiry only					
Inquiries	Q-UA	[LRBLQPR]	Units assigned/components requested	Data inquiry only					
Inquiries	Q-VD	[LRBLVALI]	Validation Documentation	Data inquiry only					
Inquiries	Q-VT	[LREV]	Test description information	Data inquiry only					

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

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Comments:

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Signature: _____ (BB Supervisor)   Date: _____
Signature: _____ (BB Medical Director)   Date: _____
Signature: _____ (IRM staff/LIM)   Date: _____
Date/time Implemented in Production_____

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	Invalid
Ward	W-PO	[LRUPT]	Show list of accessions for a patient	Data inquiry only					
Ward	W-PR	[LRBLQDR]	Patient blood bank record	Data inquiry only					
Ward	W-T I	[LREV]	Test description information	Data inquiry only					
Ward	W-UA	[LRBLQPR]	Units assigned/components requested	Data inquiry only					

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

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Signature: _____ (BB Supervisor)   Date: _____

Signature: _____ (BB Medical Director)   Date: _____

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

Date/time Implemented in Production_____

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	Invalid
Reports	R-AR	[LRBLPR]	Patient antibody report (short list)	Report generation					
Reports	R-BR-1	[LRBLP ADD]	Add BB patient(s) to report queue	Data entry					
Reports	R-BR-2	[LRBLP DELETE]	Delete BB report print queue	Data/editing					
Reports	R-BR-3	[LRBLP PRINT...	Print single BB patient report	Report generation					
Reports	R-BR-4	[LRBLP PRINT...	Print all BB patient reports on print queue	Report generation					
Reports	R-BR-5	[LRBLCN]	Blood bank consultation reports	Report generation					
Reports	R-CT	[LRBLILA]	Unit CAUTION tag labels	Caution tag label generation					
Reports	R-CV	[LRBLICV]	CMV antibody status report	Report generation					
Reports	R-DR-CD	[LRBLDCD]	Collection disposition report	Report generation					
Reports	R-DR-DR-DA	[LRBLDDA]	Gallon donor report	Report generation					
Reports	R-DR-DR-DD	[LRBLDDR]	Donor deferral report	Report generation					
Reports	R-DR-DR-DL	[LRBLDPL]	List of donors by last attempt date	Report generation					
Reports	R-DR-DR-DS	[LRBLDSC]	Donor scheduling report	Report generation					
Reports	R-DR-DR-ED	[LRBLDEDR]	Emergency donor report	Report generation					
Reports	R-DR-DR-FD	[LRBLDFD]	First time blood donors	Report generation					
Reports	R-DR-DR-GA	[LRBLDGA]	Group affiliation report	Report generation					
Reports	R-DR-DR-GD	[LRBLDGDR]	Group donation report	Report generation					
Reports	R-DR-DR-MC	[LRBLDMC]	Mobile (collection site) report	Report generation					
Reports	R-DR-DR-ML	[LRBLDMR]	Donor monthly/holiday recall list	Report generation					
Reports	R-DR-DR-PC	[LRBLDPCR]	Patient credits from blood donations	Report generation					

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	Invalid
Reports	R-DR-DR-SD	[LRBLDSD]	Donor short draw report	Report generation					
Reports	R-DR-DR-XD	[LRBLDL]	Donor lists/label/letters	Report generation					
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 donor deferral report	Report generation					
Reports	R-DR-PR	[LRBLDPRR]	Blood product rejection report	Report generation					
Reports	R-IS-DU	[LRBLIDU]	Disposition-not transfused	Report generation					
Reports	R-IS-SU-SD	[LRBLIPSD]	Single unit information-display	Report generation					
Reports	R-IS-UA	[LRBLRUA]	Units available (in date/no disposition)	Report generation					
Reports	R-IS-UN	[LRBLRUN]	Units with no disposition	Report generation					
Reports	R-IS-UX	[LRBLIX]	Units on Xmatch by date/time xmatched	Report generation					
Reports	R-IT-IN	[LRBLRIN]	Supplier invoices (inventory)	Report generation					
Reports	R-IT-IS	[LRBLRIS]	Special typing charges (inventory)	Report generation					
Reports	R-IT-IT	[LRBLRIT]	Supplier transactions (inventory)	Report generation					
Reports	R-P L	[LRBLPAL]	Patient accession list	Report generation					
Reports	R-T C	[LRBLTA]	Transfusion reaction count	Report generation					
Reports	R-T R	[LRBLIPTR]	Transfusion reactions report	Report generation					
Reports	R-UP	[LRBLIPH]	Phenotyped units available	Report generation					
Reports	R-UR-AA	[LRBLAA]	Crossmatch/Transfusions by Specialty/Physician	Report generation					
Reports	R-UR-AR	[LRBLJB]	Autologous disposition report	Report generation					

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	Invalid
Reports	R-UR-CT	[LRBLRCT]	Crossmatch/transfusion report	Report generation					
Reports	R-UR-IS	[LRBLIRB]	Unit relocation record book entries	Report generation					
Reports	R-UR-IT	[LRBLPRIT]	Inappropriate transfusion requests	Report generation					
Reports	R-UR-RS	[LRBLJUT]	Transfused RBC for treating specialty	Report generation					
Reports	R-UR-TH	[LRBLPCH]	Patient transfusions & hematology results	Report generation					
Reports	R-UR-TR	[LRBLITR]	Transfusion data report	Report generation					
Reports	R-UR-TS	[LRBLITS]	Transfusion statistics by treating specialty	Report generation					
Reports	R-UR-TX	[LRBLTXA]	Transfusion follow-up tests	Report generation					
Reports	R-VD	[LRBLVALP]	Print blood bank validation	Report generation					
Reports	R-WK-AD	[LRBLA]	Blood bank Administrative Data	Report generation					
Reports	R-WK-CR	[LRBLDCR]	Component preparation report	Report generation					
Reports	R-WK-CT	[LRUPACT]	Test counts by treating specialty	Report generation					
Reports	R-WK-IR	[LRBLC]	Inventory recheck tallies	Report generation					
Reports	R-WK-TC	[LRBLRTC]	Test counts by location	Report generation					

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

_____ I approve implementation of the software effective _____

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

Comments:

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Signature: _____ (BB Supervisor)   Date: _____
Signature: _____ (BB Medical Director)   Date: _____
Signature: _____ (IRM staff/LIM)   Date: _____

Appendix D

Date/time Implemented in Production_____

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	Invalid
Super-visor	S-DO	[LRCENDEL]	Delete entire order or individual tests	Data editing					
Super-visor	S-ED-DC	[LRBLDA]	Donor collection/deferral edit	Data entry/editing					
Super-visor	S-ED-DD	[LRBLDEF]	Permanent deferral/special comments	Data entry/editing					
Super-visor	S-ED-DE	[LRBLDEDIT]	Blood donor group/type edit	Data entry/editing					
Super-visor	S-ED-DH	[LRBLSEH]	Edit donor history questions	Form content definition					
Super-visor	S-ED-DL	[LRBLDLT]	Enter/edit donor letters	Letter content definition					
Super-visor	S-ED-DM	[LRBLDMV]	Move a blood donation	Data transfer					
Super-visor	S-ED-DP	[LRBLDCX]	Edit donor consent	Form content definition					
Super-visor	S-EF-AA	[LRBLSNO]	Edit corresponding antigen/antibody	File setup & software control					
Super-visor	S-EF-BD	[LRBLSEF]	Edit blood bank descriptions file	File setup & software control					
Super-visor	S-EF-BP	[LRBLSEB]	Edit blood product file	File setup & software control					
Super-visor	S-EF-BU	[LRBLSEU]	Edit blood bank utility file	File setup & software control					
Super-visor	S-EF-CR	[LRBLSRQ]	Edit blood component request file	File setup & software control					
Super-visor	S-EF-LL	[LRBLSLL]	Edit lab letter file	Consultation letter content definition					
Super-visor	S-EF-MS	[LRBLSMS]	Maximum surgical blood order edit	File setup & software control					
Super-visor	S-EF-SP	[LRBLSSP]	Edit blood bank site parameters	Edit template setup & software control					
Super-visor	S-EF-VD	[LRBLVAL]	Blood Bank validation documentation	Data entry/editing					
Super-visor	S-EI-DI	[LRBLSED]	Edit unit disposition fields	Data entry/editing					

Super-visor	S-EI-FR	[LRBLSEE]	Free unit from autologous donor	Data entry (i.e. change in unit status					

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound.	Invalid
Super-visor	S-EI-LI	[LRBLSEL]	Edit unit log-in	Data editing					
Super-visor	S-EI-PI	[LRBLSEC]	Edit unit-patient fields	Data entry/editing					
Super-visor	S-EI-PP	[LRBLJM]	Edit pooled blood product	Data entry/editing					
Super-visor	S-EP-LD	[LRBLST]	Tests for display on patient look-up	Software control					
Super-visor	S-EP-PE	[LRBLPEDIT]	Patient ABO/Rh edit	Data entry/editing					
Super-visor	S-EP-PP	[LRBLSPP]	Patient previous transfusion record	Data entry/editing					
Super-visor	S-EP-TH	[LRBLSET]	Tests for inclusion in transfusion report	Software control					
Super-visor	S-EP-TR	[LRBLPTXR]	Unknown unit transfusion reaction	Data entry/editing					
Super-visor	S-EP-TX	[LRBLTX]	Tests for transfusion follow-up	Software control					
Super-visor	S-FD	[LRUFILE]	Outline for one or more files	Report generation					
Super-visor	S-II	[LRBLII]	Blood bank inventory integrity report	Integrity check/Report generation					
Super-visor	S-LL	[LRBLSF]	Edit number of lines in a label	Form/label format control					
Super-visor	S-SR-AD	[LRBLAD]	Print data change audits	Report generation					
Super-visor	S-SR-AP	[LRBLPAB]	Antibodies by patient	Report generation					
Super-visor	S-SR-AR	[LRBLPRA]	Patient antibody report (long list)	Report generation					
Super-visor	S-SR-CD	[LRBLDCU]	Cumulative donations and awards	Calculations & Report generation					
Super-visor	S-SR-DA	[LRBLDAWARD]	Acknowledge donor award by deletion	Data editing					
Super-visor	S-SR-PL	[LRBLSDPL]	Delete a user's patient list	Data editing					
Super-visor	S-SR-PU	[LRBLRUF]	Print units with final disposition	Report generation					
Super-visor	S-SR-PX	[LRBLDEX]	Print ex-donors	Report generation					

FUNC AREA	MENU ABBREV	OPTION NAME	MENU NAME	OPTION DESCRIPTION	Limited Access?	ACCEPTABILITY of TEST CASES			
						Normal	Except	Bound	Invalid
Super-visor	S-SR-RA	[LRBLAR]	Remove audit data changes	Data deletion					
Super-visor	S-SR-RI	[LRBLSRI]	Remove inappropriate transfusion requests	Data deletion					
Super-visor	S-SR-RU	[LRBLSER]	Remove units with final disposition	File entry deletion					
Super-visor	S-SR-RX	[LRBLDK]	Remove ex-donors	File entry deletion					
Super-visor	S-SW	[LRUWL]	Display workload for an accession	Report generation					

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

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Signature: _____ (BB Medical Director)   Date: _____
Signature: _____ (IRM staff/LIM)   Date: _____
Date/time Implemented in Production_____