

APPENDIX I  
VISTA LABORATORY BLOOD BANK  
USER MANUAL  
HAZARD ANALYSIS



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# Introduction

## **Section XI: Hazard Analysis**

### Procedure

A Hazard analysis was performed on the Intended Uses of the **VISTA** Blood Bank Software Version 5.2. The method used to perform this analysis was modeled after the Software Failure Mode, Effects, and Criticality Analysis (SFMECA) mode as described in the NIST Special Publication 500-234 entitled Reference Information for the Software Verification and Validation Process. The report is divided into three sections Donor, Inventory, and Patient. Each Intended Use (as described in Section V) was reviewed for potential software hazard. Related Intended Uses have been combined when the Hazard was similar or related.

### **Definitions of Terms:**

The Intended Use Hazard Analysis is listed using table format.

The First column is the HA#.

The Second column is the actual HAZARD. This is the potential risk involved if the Intended Use does not function as advertised.

The Third column is CAUSES. This is an assessment of possible causes for the Intended Use to not function as advertised or could also be unavoidable consequences of human intervention.

The Fourth column is LEVEL OF CONCERN. This is a qualitative assessment and will use the following terms:

**HIGH:** High probability that patient harm could occur.

**MOD:** Moderate probability that patient harm could occur.

**LOW:** Low probability that patient harm could occur.

**NONE:** No harm to patient possible.

## Introduction

The Fifth column is LIKELIHOOD. This is a qualitative assessment and will use the following terms:

**HIGH:** Very likely that a situation could occur allowing this hazard.

**MOD:** Somewhat likely that a situation could occur allowing this hazard.

**LOW:** Unlikely that a situation could occur allowing this hazard.

**NONE:** This hazard would never occur in a user's environment.

The Sixth column is METHOD(s) OF CONTROL. This is a description of the controls built into the software to prevent the Intended Use Hazard from occurring.

The Seventh column is TRACE. This is a trace to the Software Requirement Specifications (SRS#--see Appendix H) and Safety Critical Requirements (SCR#-see Appendix G) of the Intended Use Hazard.

## Donor Intended Uses Hazards Analysis

| HA# | Hazard   | Causes   | Level of Concern | Likelihood | Method (s) of Control   | Trace   |
|-----|--|--|------------------|------------|---|---|
| HD1 | Chance of duplicate Donor records existing in the BLOOD DONOR file (#65.5). Previous donor deferral history may not be accurately displayed. | 1) Female patient marrying and changing last name.<br>2) Typographical error on donor last name during data entry. | LOW              | LOW        | Software checks donor last name and Date of Birth for possible matches during data entry. Option exists to merge data (donation subrecords) from two donor records in the event that a duplicate donor record is created. | SRS# D10<br>SRS# D20<br>SRS# D83<br><br>SCR# D1 |
| HD2 | Chance of duplicate or incomplete subrecords for a particular donation date.   | Data entry for a donation episode not completed and donor has repeat donation.                                     | LOW              | LOW        | During data entry, only most recent donation/deferral date can be edited.   | SRS# D11<br><br>SCR# D3                         |
| HD3 | Unable to determine correct donation type. Unit testing acceptance criteria are based on donation type.                                      | Data entry error.  | LOW              | LOW        | Autologous requires exact match entry from the PATIENT file (#2) in the Restricted For field (#1.2).  | SRS# D9<br>SRS# D34<br><br>SCR# D4              |
| HD4 | Record incomplete after data entry.  | Computer crash during data entry.  | NONE             | LOW        | Data can be re-entered once computer problem resolved.  | SRS# D11<br>SRS# D12<br><br>SCR# D7             |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method (s) of Control   | Trace                               |
|------|--|---|------------------|------------|---|-------------------------------------|
| HD5  | Unable to determine person performing a particular step in data entry process. | NONE  | NONE             | NONE       | Assignment of responsibility automatic based on identity of individual determined upon log-in to system.            | SRS# D12<br>SRS# D14<br><br>SCR# D7 |
| HD6  | Unable to use bar-code identification of donor units.                          | 1) Site not barcode labeling products processed in-house.<br>2) Barcode Scanner malfunctions. | NONE             | LOW        | If bar-code scanner not used, two separate individuals are required to complete the Labeling/release of donor units | SRS# D15<br><br>SCR# D4             |
| HD7  | Changes in verified data not tracked.  | VA FileMan used to edit fields directly rather than specified menu options.                   | LOW              | LOW        | Direct access to Blood Bank data files through VA FileMan should be restricted by site policy.                      | SRS# D16<br><br>SCR# D5             |
| HD8  | Sensitive Donor data security is compromised                                   | Menu options displaying sensitive data not restricted appropriately                           | LOW              | LOW        | Menu options containing sensitive data should be restricted by security keys.                                       | SRS# D1<br><br>SCR# D2              |
| HD11 | Erroneous Unit ID's assigned to Donor upon data entry of historical data.      | Data entry error.   | LOW              | LOW        | Software searches BLOOD INVENTORY file (#65) for possible duplicate entries.  | SRS# D18<br><br>SCR# N/A            |



Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace  |
|------|---|--|------------------|------------|--|--|
| HD12 | Donation interval for allogenic donor not long enough.                                  | 1) Duplicate record created due to HA# HD1.<br>2) Previous donation at a different site, such as a Red Cross Center. | LOW              | LOW        | A cumulative donation record kept for each donor in system is used to calculate the donation interval and reject donor if criteria for allogenic donation not met. | SRS# D9<br>SRS# D10<br>SRS# D23<br><br>SCR# D10  |
| HD13 | Donor outside of established age limits allowed to donate without proper authorization. | Data entry error.  | LOW              | LOW        | Software calculates the age of the donor based on the DOB entry and displays a warning message if limits exceeded.   | SRS# D10<br>SRS# D22<br><br>SCR# D11<br>SCR# D12 |
| HD14 | Donor history questions do not reflect current guidelines.                              | Responsible individual at site not current on changes in donor history question requirements.                        | LOW              | LOW        | Site responsible for maintaining the list of donor history questions via the option Edit donor history questions [LRBLSEH]   | SRS# D24<br>SRS# D31<br><br>SCR# D13             |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|---|---|------------------|------------|---|--|
| HD15 | Donor consent form does not reflect current guidelines.   | Responsible individual at site not current on donor consent form requirements.  | LOW              | LOW        | Site responsible for maintaining the donor consent form via the option Edit donor consent [LRBLDCX]   | SRS# D25<br>SRS# D31<br><br>SCR# N/A   |
| HD16 | Donor demographic information, donor history questions and consent not available.   | Site not utilizing functionality  | LOW              | LOW        | Donor history physical and consent form [LRBLDR] option when printed contains all necessary info.   | SRS# D10<br>SRS# D29<br>SRS# D31<br><br>SCR# N/A                                     |
| HD18 | A permanently deferred donor could donate at a remote site when the computer system is not accessible and/or preprinted donor history forms available for all potential donors. | 1) Donor not flagged as permanently deferred.<br>2) Preprinted donor history forms not used.<br>3) Copy of the Permanent donor deferral report [LRBLDPD] not brought to site. | LOW              | LOW        | If donor is appropriate -ly marked as "permanent -ly deferred" further processing of donation when return to main donor site is not possible. | SRS# D10<br>SRS# D26<br>SRS# D27<br>SRS# D28<br>SRS# D29<br><br>SCR# D14<br>SCR# D15 |
| HD19 | Allogenic donor marked as "permanently deferred" has donation completely processed.   | NONE  | NONE             | NONE       | Processing of allogenic donation for "permanent -ly deferred" donor not allowed.  | SRS# D9<br>SRS# D10<br>SRS# D26<br>SRS# D27<br><br>SCR# D14<br>SCR# D15              |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace   |
|------|---|--|------------------|------------|---|---|
| HD20 | “Permanently deferred” donor incorrectly processed as Homologous when Autologous is intended. | NONE   | NONE             | NONE       | Only Autologous or Therapeutic donation types are allowed for donors who are flagged as “permanently deferred”. | SRS# D9<br>SRS# D10<br>SRS# D27<br>SRS# D28<br><br>SCR# D14<br>SCR# D15 |
| HD21 | Donors with special handling needs not identified at donor sites.                             | 1) Permanent deferral/special comments [LRBLDEF] option not used to enter appropriate data.<br>2) Donor history, physical and consent form [LRBLDR] not printed prior to collection. | LOW              | LOW        | Information available using option to print Donor history, physical and consent form [LRBLDR].                  | SRS# D10<br>SRS# D30<br>SRS# D31<br>SRS# D32<br><br>SCR# D16            |
| HD22 | Autologous donations not specifically linked to intended donor/patient.                       | Data entry error, not using AUTOLOGOUS as the TYPE of donation during data entry.  | LOW              | LOW        | Autologous type donation cannot be processed without an exact match link to a patient in the PATIENT file (#2). | SRS# D9<br>SRS# D34<br>SRS# D35<br><br>SCR# D9                          |
| HD23 | Cannot determine which units have been collected using a specific lot # collection bag.       | 1) Data entry error.<br>2) BB site parameter not set up to prompt for the bag lot #'s.   | LOW              | LOW        | VA FileMan can be used to search the database for all donations processed using a specific lot #.               | SRS# D4<br>SRS# D36<br><br>SCR# D17<br>SCR# D7                          |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace  |
|------|---|--|------------------|------------|--|--|
| HD24 | Cannot determine the correct volume of a specific donation. | Data entry error   | LOW              | LOW        | User is prompted for Gross weight, empty bag weight during collection data entry. Software calculates volume based on specific gravity of whole blood. | SRS# D11<br>SRS# D40<br><br>SCR# D4                                      |
| HD25 | Assignment of a non-unique Unit ID for a specific donation. | NONE   | NONE             | NONE       | Software searches existing entries in the BLOOD DONOR file (#65.5) for possible duplicate Unit ID. Cannot assign a Unit ID which already exists.       | SRS# D11<br>SRS# D21<br><br>SCR# D7                                      |
| HD26 | Special comments not available to donor room personnel.     | 1) The Permanent deferral/special comments [LRBLDEF] option not used to enter data.<br>2) Donor history, physical, and consent form [LRBLDR] option not printed prior to collection. | LOW              | LOW        | Information available using the print Donor history, physical and consent form [LRBLDR] option.  | SRS# D10<br>SRS# D30<br>SRS# D31<br>SRS# D32<br><br>SCR# D14<br>SCR# D16 |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace                |
|------|---|---|------------------|------------|--|----------------------|
| HD27 | Previous donor reaction information not available during subsequent donation episode. | 1) The Permanent deferral/special comments [LRBLDEF] option is not used to enter donor reaction information.<br>2) Donor history, physical and consent form [LRBLDR] option is not printed prior to donation. | MOD              | MOD        | A separate option Permanent deferral/special comments [LRBLDEF] requiring a higher security access is required to enter donor reaction information which is then printed on the Donor history, physical and consent form [LRBLDR] for the donor. | SRS# D33<br>SCR# D16 |
| HD28 | Future donation episode data entered.   | NONE  | NONE             | NONE       | Software screens date entered. No future dates allowed.  | SRS# D38<br>SCR# D4  |
| HD29 | Inconsistent date/times of collection start and stops                                 | NONE  | NONE             | NONE       | Cannot input a completion date/time prior to the collection start date/time.   | SRS# D39<br>SCR# D4  |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|---|---|------------------|------------|---|--|
| HD30 | Incomplete or inaccurate records of collection dispositions and unit storage. | Data entry errors   | LOW              | LOW        | Software checks parameters defined in the BLOOD PRODUCT file (#66) during unit processing.  | SRS# D11<br>SRS# D14<br>SRS# D42<br><br>SCR# D4<br>SCR# D7<br>SCR# D18 |
| HD31 | No record of person entering component preparation info in computer.          | NONE  | NONE             | NONE       | Software automatically assigns this based on identity of user upon log in to computer.  | SRS# D11<br>SRS# D12<br>SRS# D14<br><br>SCR# D7<br>SCR# D18            |
| HD32 | Previous donation collection information can be edited.                       | NONE  | NONE             | NONE       | User cannot specify a unit ID which is from other than the most recent donation.  | SRS# D11<br>SRS# D41<br><br>SCR# D3                                    |
| HD33 | Component preparation policies/procedures not followed.                       | 1) Data entry errors.<br>2) Specific component entries in the BLOOD PRODUCT file (#66) not fully defined. | LOW              | LOW        | Collection disposition/component preparation [LRBLDCP] option checks parameters defined in the BLOOD PRODUCT file (#66) for validity. | SRS# D47<br><br>SCR# D19   |

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace   |
|------|---|--|------------------|------------|---|---|
| HD34 | Inappropriate number and type of components prepared from a donation. | 1) For donor units containing red cells, site does not have field in the BLOOD PRODUCT file (#66) CONTAINS RED BLOOD CELLS=YES.<br>2) User enters incorrect PRIMARY BAG during data entry. | LOW              | LOW        | Collection disposition/component preparation [LRBLDCP] option checks the number of components prepared against the type of bag used in original collection. Only allows one red cell component type per donation. | SRS# D45<br>SRS# D46<br>SRS# D47<br><br>SCR# D18            |
| HD35 | Inappropriate expiration date assigned to a prepared unit.            | Maximum Storage Days field (#135) in the BLOOD PRODUCT file (#66) not defined correctly.   | LOW              | LOW        | Prior to utilization of the package, the BLOOD PRODUCT file (#66) should be reviewed and customized.  | SRS# D44<br>SRS# D48<br><br>SCR# D20                        |
| HD36 | Cannot determine date/time stored for a particular component.         | NONE   | NONE             | NONE       | This is a required field.   | SRS# D11<br>SRS# D42<br><br>SCR# D4<br>SCR# D18<br>SCR# D19 |
| HD37 | Component can be prepared from an inappropriately stored collection.  | Collection/Prep Hours field (#13) in the BLOOD PRODUCT file (#66) not defined correctly.   | LOW              | LOW        | Prior to utilization of the package, the BLOOD PRODUCT file (#66) should be reviewed and customized.  | SRS# D43<br><br>SCR# D18<br>SCR# D19                        |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace   |
|------|--|---|------------------|------------|--|---|
| HD38 | TDD Marker testing information can be entered for incorrect unit ID. | Data entry error.   | LOW              | LOW        | Lab tests (not ABO/Rh) on donor units [LRBLDT] option automatically increments Unit ID but also checks for its existence before display.   | SRS# D49<br>SCR# D4   |
| HD39 | Blood Component labeled with incorrect ABO/Rh.                       | Data entry error  | LOW              | LOW        | Test review/ Component labeling/ release [LRBLDRR] option checks ABO/Rh of donor historical record if present for a match. Software requires two separate individuals to do ABO/Rh recheck before unit is released to inventory. | SRS# D3<br>SRS# D50<br>SRS# D51<br>SRS# D52<br>SRS# D65<br>SRS# D66<br>SRS# D67<br>SRS# D72<br><br>SCR# D21<br>SCR# D27 |
| HD40 | Donor Unit TDD testing not performed according to current standards. | Site did not correctly set the site parameters to turn on HIV Ag testing and turn off ALT testing when standards changed. | LOW              | LOW        | Specific instructions distributed to sites when TDD testing standards changed. (LR*5.2*97)   | SRS# D6<br>SRS# D7<br>SRS# D53<br>SRS# D69<br><br>SCR# D22  |



Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace   |
|------|---|---|------------------|------------|---|---|
| HD41 | Donor unit TDD results falsely entered as NEGATIVE when in fact POSITIVE.   | Data entry error  | LOW              | LOW        | No batch entry of TDD results allowed. Results displayed for review prior to release to inventory.  | SRS# D54<br>SRS# D59<br>SRS# D69<br><br>SCR# D4                     |
| HD42 | TDD inadvertently not performed for a particular Donor ID.  | 1) Worklists provided by software not used.<br><br>2) User ignores warning message that testing is incomplete when releasing units to inventory. User then answers "YES" to override to complete the release. | LOW              | LOW        | Worklist provided which includes all TDD testing. Specimens easily added back into a worklist when indicated. Test review/ Component labeling/ release [LRBLDRR] option alerts user if TDD testing is incomplete for Unit ID. | SRS# D56<br>SRS# D59<br>SRS# D69<br>SRS# D76<br><br>SCR# D23<br>D26 |
| HD43 | Appropriate personnel not notified if positive TDD marker testing entered on a unit previously released to inventory. | Users with LRBSUPER key do not read electronic mail for extended period of time.  | LOW              | LOW        | Bulletin is automatically generated and delivers a Mailman message to all users of LRBSUPER key if such a unit is tested.   | SRS# D57<br>D105<br><br>SCR# D24                                    |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace   |
|------|---|---|------------------|------------|---|---|
| HD44 | Results of TDD testing on a unit can be edited after a unit is released to inventory. | Users with LRBSUPER key can edit TDD result testing after a unit is released. | LOW              | LOW        | Distribution of the LRBSUPER key should be restricted to the BB supervisor and/or designee.   | SRS# D57<br>SRS# D58<br><br>SCR# D6<br>SCR# D24 |
| HD45 | Donor unit with positive TDD testing is labeled.                                      | TDD testing report not reviewed prior to labeling of product.                 | NONE             | NONE       | Unit automatically quarantined if attempt is made to release a non-autologous unit with a positive TDD result.                          | SRS# D68<br>SRS# D69<br><br>SCR# D27            |
| HD46 | Ambiguous antigen testing results entered for donor phenotyping.                      | Data input error.   | LOW              | LOW        | Software does not allow the same antigen both 'present and absent'. Entries limited to valid antigens part of the SNOMED coding system. | SRS# D60<br>SRS# D61<br><br>SCR# D4             |
| HD47 | Units released to Inventory that are the same Unit ID as a unit already in inventory. | NONE  | NONE             | NONE       | Software searches the BLOOD INVENTORY file (#65) for possible duplicate Unit ID. Does not allow.  | SRS# D62<br><br>SCR# D7<br>SCR# D29             |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                |
|------|---|--|------------------|------------|--|----------------------|
| HD48 |   | Units released to Inventory prior to completion of ABO/Rh testing. | NONE             | NONE       | Release of units to inventory prohibited if no current ABO/Rh results exist.   | SRS# D63<br>SCR# D25 |
| HD49 | Results of Donor Unit testing done prior to release to Inventory not available. | System crash during Donor labeling/release process.                | LOW              | LOW        | Selected data is transferred from the entry in the BLOOD DONOR file (#65.5) to the specific unit in the BLOOD INVENTORY file (#65) upon Labeling/release. If data not in BLOOD INVENTORY file (#65) unit is not available for patient use. | SRS# D64<br>SCR# D7  |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace   |
|------|---|---|------------------|------------|---|---|
| HD50 | Donor unit incorrectly labeled for ABO/Rh can be released to Inventory. | Data entry error by two separate individuals. | LOW              | LOW        | 1) Release of units to inventory prohibited if check of the current ABO/Rh results for the specific donor unit against the donor's historical record indicate a discrepancy<br>2) Software requires a second individual to perform ABO/Rh recheck before unit can be relocated.<br>3) Warning message given when entering crossmatch results on units with no ABO/Rh recheck results. | SRS# D3<br>SRS# D50<br>SRS# D51<br>SRS# D52<br>SRS# D65<br>SRS# D66<br>SRS# D72<br>SRS# D73<br><br>SCR# D21<br>SCR# D27<br>SCR# D28 |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|--|--|------------------|------------|---|--|
| HD51 | Donor unit incorrectly labeled for ABO/Rh appears to be released to Inventory. | Current ABO/Rh testing results entered do not match historical ABO/Rh results for a specific donor AND the site does not require ABO/Rh recheck prior to Labeling/Release of component to the BLOOD INVENTORY file (#65) per site parameter in the LABORATORY SITE file (#69.9). | LOW              | LOW        | Automatic generation of a bulletin detailing the test result sent to all holders of the LRBLSUPE R key if the current ABO/Rh results for a specific donor unit against the donor's historical record indicate a discrepancy . the software always requires a second tech to perform an ABO/Rh recheck before the unit can be relocated. | SRS# D64<br>SRS# D66<br><br>SCR# D21<br>SCR# D27 |

Donor Intended Uses Hazard Analysis

| <b>HA#</b> | <b>Hazard</b>  | <b>Causes</b> | <b>Level of Concern</b> | <b>Likelihood</b> | <b>Method(s) of Control</b>   | <b>Trace</b>   |
|------------|--|---------------|-------------------------|-------------------|---|--|
| HD52       | Homologous, directed or therapeutic phlebotomy unit with positive disease marker testing can be released to inventory. | NONE          | NONE                    | NONE              | TDD results evaluated at time of labeling/ release. If an attempt is made to release a donor unit with a positive/ reactive TDD result, the unit is automatically quarantined. Requires a higher level of security access to make changes in status of a component previously placed in quarantine. | SRS# D9<br>SRS# D68<br>SRS# D69<br>SRS# D70<br>SRS# D71<br><br>SCR# D6 |
| HD53       | Unit ID created in the BLOOD INVENTORY file (#65) with incorrect data from BLOOD DONOR file (#65.5).                   | NONE          | NONE                    | NONE              | Software transfers specific data fields from the BLOOD DONOR file (#65.5) to the BLOOD INVENTORY file (#65) upon labeling/ release of component.  | SRS# D74<br><br>SCR# D7<br>SCR# D29                                    |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace                           |
|------|--|--|------------------|------------|---|---------------------------------|
| HD54 | Donor unit assigned to the incorrect division when released to inventory if site is multidivisional. | User division is defined during user log on.<br>1) Invalid choices assigned by system administrator.<br>2) User with multiple choices chooses incorrectly when logging in. | LOW              | LOW        | Unit is automatically assigned to the division of the user who releases it to inventory. Transfer unit to new division [LRBLJTR] option is available to transfer a unit to a new division if necessary. | SRS# D75<br>SCR# D7             |
| HD55 | Donor units with incomplete TDD marker testing are modified or transferred to another facility.      | Shipping invoice not utilized when transferring units to a different facility.   | LOW              | LOW        | 1) Cannot modify a non-autologous unit with incomplete TDD results.<br>2) When processing a unit to Send Elsewhere, software prompts user that testing is incomplete. Override required.                | SRS# D76<br>SRS# D77<br>SCR# D7 |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|--|--|------------------|------------|---|--|
| HD56 | Autologous unit with positive TDD testing results assigned to a different patient than originally assigned.  | NONE   | NONE             | NONE       | Software prevents release of autologous unit with positive TDD testing from original patient assigned. Also prevents modification of unit into non-autologous components                | SRS# D9<br>SRS# D34<br>SRS# D77<br><br>SCR# D9 |
| HD57 | ABO/Rh confirmatory testing results not transferred to the BLOOD INVENTORY file (#65) upon release of unit.  | 1) Site parameter not set up for functionality.<br>2) System crash during labeling/release of donor unit.  | NONE             | LOW        | Warning message given when ABO/Rh confirmatory testing not done when entering crossmatch results.   | SRS# D64<br>SRS# D78<br><br>SCR# D7            |
| HD58 | Donor unit is omitted from the Inventory ABO/Rh worklist if unit contains red cells and ABO/Rh confirmatory testing not transferred to Inventory based on the site parameters. | 1) BLOOD PRODUCT file (#66) setup for component doesn't have the Contains Red Cells field (#19) set to "YES".<br>2) User doesn't utilize the Inventory ABO/Rh worklist.<br>3) Printer malfunctions during print of worklist. | LOW              | LOW        | User is alerted when crossmatch results are entered on a unit with no ABO/Rh confirmatory results available. Unit CANNOT be relocated if ABO/Rh confirmatory results are not available. | SRS# D64<br>SRS# D78<br><br>SCR# N/A           |



Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|---|---|------------------|------------|---|--|
| HD59 | Autologous and/or directed components not segregated appropriately.                           | User ignores display of RESTRICTED FOR patient name during various screens of the software package. | LOW              | LOW        | Software displays the name of the patient which the unit is 'restricted for' whenever the unit is displayed on the screen and on the Inventory reports.                     | SRS# D9<br>SRS# D34<br>SRS# D79<br><br>SCR# D9                         |
| HD60 | No online storage of cumulative donor history for look-back purposes.                         | Total system crash/failure  | NONE             | LOW        | Individual sites perform regular backups of data. If a total system crash/failure, a previous day's backup can be restored and lost data can be rebuilt from paper records. | SRS# D10<br>SRS# D80<br><br>SCR# D7<br>SCR# D8                         |
| HD61 | No historical cumulative donor history for donors who have not donated since a specific date. | Output of report Print ex-donors is printed but then discarded.                                     | LOW              | LOW        | Option is available to print Ex donor data prior to removal from the system. Donor data cannot be removed unless previously printed.  | SRS# D10<br>SRS# D80<br>SRS# D81<br>SRS# D82<br><br>SCR# D7<br>SCR# D8 |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|---|--|------------------|------------|---|--|
| HD62 | Cannot provide recruitment information to donor group chairpersons.                               | 1) Group affiliation information not entered at time of donation.<br>2) Demographic data entry incomplete.   | NONE             | LOW        | User is prompted for information during data entry. Various reports are available to assist the donor group chairpersons.                 | SRS# D8<br>SRS# D10<br>SRS# D84<br>SRS# D85<br><br>SCR# N/A                          |
| HD63 | Cannot target certain groups for donor recruitment.   | 1) Group affiliation information not entered when processing donors.<br>2) Antigen typing on specific donors not entered.<br>3) Demographic data incomplete. | NONE             | LOW        | Standardized letters can be generated based on:<br>1) Group affiliation or 2) Lack of a specific antigen to be used for donor recruiting. | SRS# D84<br>SRS# D85<br>SRS# D86<br>SRS# D87<br>SRS# D90<br>SRS# D91<br><br>SCR# N/A |
| HD64 | Cannot target donors who have not donated since a specific date for special recruitment efforts.  | 1) Donor records removed from database using the Remove Ex donor option.<br>2) Demographic data incomplete.  | NONE             | LOW        | Consideration should be given to this prior to removing ex-donors from the database.  | SRS# D88<br>SRS# D90<br>SRS# D91<br>SRS# D92<br><br>SCR# N/A                         |
| HD65 | Cannot send post visit thank you letters for donors who attempted to donate.                      | 1) Donor room personnel do not enter rejected donors into database.<br>2) Demographic data incomplete.   | NONE             | LOW        | All donation attempts should be entered into the computer.  | SRS# D89<br>SRS# D90<br>SRS# D91<br><br>SCR# N/A                                     |
| HD66 | Cannot determine donors willing to be called on emergency or regular basis, or cannot reach them. | Incomplete data retrieval and/or data entry during donor processing.   | NONE             | LOW        | Various reports are available for tailoring recruitment efforts.  | SRS# D93<br>SRS# D94<br>SRS# D95<br><br>SCR# N/A                                     |

Donor Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|--|---|------------------|------------|---|--|
| HD67 | Cannot determine donors who have qualified and been given gallon donor awards. | Acknowledge donor award by deletion [LRBLDAWARD] option not used to enter donor award data. | NONE             | MOD        | Acknowledge donor award by deletion [LRBLDAWARD] option available to acknowledge donor awards for various donation types. | SRS# D96<br>SRS# D97<br><br>SCR# N/A   |
| HD68 | Cannot acknowledge first time donors appropriately                             | Donor room personnel do not completely gather and enter donor demographic data.             | NONE             | LOW        | First time blood donors [LRBLDFD] option is available to list all first time donors so acknowledgment can be made.        | SRS# D98<br><br>SCR# N/A   |
| HD69 | Cannot effectively evaluate recruitment efforts of donor program.              | Donor room personnel do not completely gather and enter all donor demographic data.         | NONE             | LOW        | Various reports available to determine effectiveness of recruiting efforts.   | SRS# D10<br>SRS# D84<br>SRS# D85<br>SRS# D99<br>D106<br>D107<br>D108<br><br>SCR# N/A |
| HD70 | Cannot systematically review short draw collections for QA purposes.           | All pertinent information not entered into computer when processing donors.                 | NONE             | LOW        | Report available for supervisory review to see if any patterns in low volume unit collections.                            | SRS# D14<br>D100<br><br>SCR# N/A   |

Donor Intended Uses Hazard Analysis

| <b>HA#</b> | <b>Hazard</b>   | <b>Causes</b>  | <b>Level of Concern</b> | <b>Likelihood</b> | <b>Method(s) of Control</b>   | <b>Trace</b>                             |
|------------|---|--|-------------------------|-------------------|---|--|
| HD71       | Cannot review history of temporary deferrals and/or component quarantines and discards. | Deferred donor information not entered into computer.                | NONE                    | LOW               | Report available for supervisory review of temporary deferrals to identify problem areas. | SRS# D101<br>D104<br><br>SCR# N/A        |
| HD72       | Cannot review Quality Assurance data from Donor room.                                   | Donor room supervisor does not print out and review various reports. | NONE                    | LOW               | Various reports available to monitor quality of blood product manufacture.                | SRS# D14<br>D102<br>D103<br><br>SCR# N/A |

# Inventory Intended Uses Hazard Analysis

| HA# | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                         |
|-----|---|--|------------------|------------|--|-------------------------------|
| HI1 | No unique cumulative unit history available.  | Package not fully utilized   | LOW              | LOW        | If all functions related to Inventory are utilized, there will be a unique cumulative unit history for each blood component.   | SRS# I18<br>I57<br>SCR# I1    |
| HI2 | Patient record confidentiality compromised.   | Menu options displaying sensitive data not restricted appropriately                                      | LOW              | LOW        | Menu options containing sensitive data should be restricted by security keys.  | SRS# N/A<br>SCR# I2           |
| HI3 | Software requirements for individual components does not reflect facility operating procedures. | Site did not edit entries in the BLOOD PRODUCT file (#66) to reflect the site's individual requirements. | LOW              | LOW        | Prior to implementation, sites are instructed to review entries in the BLOOD PRODUCT file (#66) and customize this file to reflect the site's individual requirements.       | SRS# I1<br>SRS# I2<br>SCR# I3 |
| HI4 | Inventory records not current.  | Total system failure/crash during data entry.  | NONE             | LOW        | 1) Edit options available to edit any records affected by system crash.<br>2) Integrity report available to check for incomplete records so site can remedy.                 | SRS# I10<br>SCR# I7           |
| HI5 | Inventory data inappropriately accessed, causing corrupted records.                             | Two separate individuals entering unit confirmation data at the same time.                               | NONE             | LOW        | Unit confirmation option compares ABO/Rh data entry with log in information. Warning message is displayed if a discrepancy. Records are updated immediately upon data entry. | SRS# I11<br>SCR# I3           |

Inventory Intended Uses Hazard Analysis

| HA# | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace               |
|-----|--|--|------------------|------------|---|---------------------|
| HI6 | Barcode reader/ scanner not used to scan Unit ID.  | 1) Site not utilizing scanner technology.<br>2) Tech choose to not use scanner.<br>3) Scanner is not working.  | NONE             | MOD        | Use of the barcode scanner is optional. It is recommended but the software functions with or without the scanner. | SRS# I12<br>SCR# I3 |
| HI7 | Barcode reader/ scanner not used to scan the blood product code.   | 1) Site not utilizing scanner.<br>2) Tech chooses to not use scanner.<br>3) Scanner is not working for some reason.<br>4) Code field in the BLOOD PRODUCT file (#66) not filled in.                                  | NONE             | MOD        | Use of the barcode scanner is optional. It is recommended but the software functions with or without the scanner. | SRS# I29<br>SCR# I3 |
| HI8 | Barcode reader/ scanner not used to scan the expiration date.  | 1) Site not utilizing scanner.<br>2) Tech choose to not use scanner.<br>3) Scanner is not working.<br>4) Blood Component not labeled with a barcode expiration date label or label is bar-coded with a 4-digit year. | NONE             | MOD        | Use of barcode scanner is optional. It is recommended but the software functions with or without the scanner.     | SRS# I25<br>SCR# I3 |
| HI9 | Units can be accessed which do not reside in the current division site is multi divisional and is an operating Blood Bank in more than one division. | User division is defined during user log on.<br>1) Invalid choices assigned by system administrator.<br>2) User with multiple choices chooses incorrectly when logging in.   | LOW              | LOW        | Unit choice is automatically restricted to those units in the division assigned to the user during log on.        | SRS# I14<br>SCR #I3 |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method (s) of Control   | Trace                       |
|------|---|---|------------------|------------|---|-----------------------------|
| HI10 | Cannot determine the identity of person entering test results into computer.              | NONE  | NONE             | NONE       | Assignment of responsibility automatic based on identity of individual determined upon log-in to system.  | SRS# I14<br>SCR# I7         |
| HI11 | Changes in verified data not tracked.   | VA FileMan used to edit various fields directly rather than specified menu options.                   | LOW              | LOW        | Direct access to Blood Bank data files through VA FileMan should be restricted by site policy.  | SRS# I15<br>I16<br>SCR# I4  |
| HI12 | Cannot determine the exact date and time inventory units are received.                    | Data input error.   | LOW              | LOW        | The Date/Time Received field is required<br>Future date/times are not allowed.  | SRS# I17<br>SCR# I7         |
| HI13 | Identical components with identical Unit ID's exist.                                      | NONE  | NONE             | NONE       | Software searches BLOOD INVENTORY file (#65) for possible duplicates during unit log in process.  | SRS# I18<br>SCR# I1         |
| HI15 | Autologous or Directed units with pos/incomplete screening tests not properly identified. | During the unit log in process, an incorrect entry is made at the prompt POS/INCOMP. SCREENING TESTS. | LOW              | LOW        | User is prompted during unit log in process to enter if a positive (autologous only) or incomplete screening test is present.   | SRS# I21<br>SCR# I16<br>I26 |
| HI16 | Units previously discarded can be re-entered into Inventory.                              | NONE  | NONE             | NONE       | 1) Software prevents the existence of identical components with identical Unit ID's.<br>2) In the event that a unit is shipped to another facility, the unit can be re-accepted into Inventory, reactivating the previous record. | SRS# I22<br>SCR# I1         |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method (s) of Control   | Trace                               |
|------|--|---|------------------|------------|---|-------------------------------------|
| HI17 | Units re-entered into Inventory do not have a cumulative Unit history.   | NONE  | NONE             | NONE       | For units which are re-entered, there is transfer of the original log-in and disposition data which creates a cumulative record.  | SRS# I23<br>SCR# I6<br>I7           |
| HI18 | Short dated units do not have an appropriate date and time of expiration assigned.   | During unit log in, the appropriate time is not entered along with the date for specific blood products.  | LOW              | MOD        | The expiration date field accommodates the entry of time. If no time is entered, then midnight is assumed.  | SRS #I24<br>SCR #I10                |
| HI19 | Donor units with positive or incomplete tests are not identified as a potential biohazard when shipped to an outside facility. | The shipping invoice provided with the software may not be acceptable to some blood suppliers and may not be used.  | LOW              | MOD        | 1) The shipping invoice provided with the software clearly identifies units which may be a potential biohazard.<br>2) The text appearing on the shipping invoice can be modified to satisfy most blood suppliers. | SRS# I21<br>I26<br>SCR #I11<br>#I16 |
| HI20 | Inappropriate or incomplete information appears on the system generated shipping invoice.                                      | Site did not review and edit the information that appears on the shipping invoice as defined in the LAB LETTER file (#65.9).  | LOW              | LOW        | A menu option exists which allows users to edit the information which appears on the shipping invoice.  | SRS# I4<br>SCR# I11                 |
| HI21 | Recording of temperature information not recorded on the system generated shipping invoice.                                    | 1) Site edited the exported LAB LETTER file (#65.9) entry for SHIPPING INVOICE removing the prompts for this information.<br>2) User ignores prompts and does not record information. | LOW              | LOW        | The exported SHIPPING INVOICE entry contains these prompts. Access to the option used to edit the LAB LETTER file (#65.9) should be restricted.   | SRS# I4<br>I27<br>SCR# I12          |



Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method (s) of Control  | Trace                  |
|------|---|---|------------------|------------|--|------------------------|
| HI22 | Units assigned an inappropriate product type during log in.   | Site did not edit the BLOOD PRODUCT file (#66) to reflect product types and suppliers.                                    | LOW              | LOW        | The software prevents logging in of component types which do not have at least one supplier identified.  | SRS# I1 I28<br>SCR# I3 |
| HI23 | Inappropriate expiration dates can be assigned to blood product types during inventory log in.  | The Maximum Storage Days field (#135) for a particular component entered in the BLOOD PRODUCT file (#66) is inappropriate | LOW              | LOW        | 1) Sites are responsible for reviewing the contents of the BLOOD PRODUCT file (#66) for accuracy and edit according to site policy.<br>2) During log in, the user is always prompted to review log in data for accuracy and can edit if necessary. | SRS# I30<br>SCR# I22   |
| HI24 | 1) Inappropriate units can be edited using the option Edit pooled blood product.<br>2) Pooled blood products cannot be edited using the option Edit pooled blood product. | The BLOOD PRODUCT file (#66) entry for a product has the Pooled Product field (#27) inappropriately set.                  | LW               | LOW        | Units which can be edited using the Edit pooled blood product [LRBLJM] option must have the Pooled Product field (#27) in their BLOOD PRODUCT file (#66) entry set to "YES".   | SRS# I31<br>SCR# I3    |
| HI25 | Volume of a unit of blood cannot be determined.   | Site did not define the VOLUME (ml) field (#.1) correctly for the blood product involved.                                 | NONE             | LOW        | Software assumes the average volume for a unit, based on the entry in the VOLUME (ml) field (#.1) in the BLOOD PRODUCT file (#66) for that specific blood component.   | SRS# I32<br>SCR# I7    |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method (s) of Control  | Trace                       |
|------|---|---|------------------|------------|--|-----------------------------|
| HI26 | 1) Cannot determine the cost of blood products between various suppliers.<br>2) Inaccurate cost accounting when units are RETURNED TO SUPPLIER. | Site does not maintain the COST field (#.02) for specific SUPPLIERS for components in the BLOOD PRODUCT file (#66).   | NONE             | MOD        | This is a required field but must be maintained for accuracy at each site whenever supplier costs change.  | SRS# I33<br>I34<br>SCR# N/A |
| HI27 | Incomplete records when a unit is transferred to a different DIVISION of a multidivisional facility.  | 1) Site parameters for Multidivisional site not defined according to VA Standards.<br>2) Transfer unit to new division [LRBLJTR] option is not used to transfer unit to a different division. | LOW              | LOW        | Transfer unit to new division [LRBLJTR] option available to transfer a unit to a valid division of a multidivisional institution as defined by the site's INSTITUTION file (#4) entry in the DIVISION field (#.16)<br>All historical data stays with the unit. | SRS# I35<br>SCR# I6         |
| HI28 | Inventory units have future disposition dates.  | NONE  | NONE             | NONE       | Software prohibits entry of a future disposition date.   | SRS #I36<br>SCR #I3         |
| HI29 | Cannot record site-specific special comments during unit disposition.   | Site does not utilize option Edit blood bank descriptions file [LRBLSEF] to create "canned comments" to be used during disposition other than Modify or Transfuse.                            | NONE             | LOW        | Edit blood bank descriptions file [LRBLSEF] option allows creation of "canned comments" to be used during data entry of unit disposition.  | SRS# I8<br>SCR# I6          |
| HI30 | Data entered and verified in error during log in of inventory cannot be corrected.  | Misuse of barcode scanner, other data entry errors.   | LOW              | LOW        | Edit unit log-in [LRBLSEL] option available to edit log in data which requires a higher security.  | SRS# I16<br>I37<br>SCR# I5  |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method (s) of Control  | Trace                       |
|------|--|--|------------------|------------|--|-----------------------------|
| HI31 | Data entered and verified in error during unit disposition cannot be corrected.                            | Data entry error   | NONE             | LOW        | Edit unit disposition fields [LRBLSED] option is available to edit unit disposition data which requires a higher security.   | SRS# I16 I38<br>SCR# I5     |
| HI32 | Data entered in error during the pooling of units cannot be corrected                                      | Data entry error   | NONE             | LOW        | Edit pooled blood product [LRBLJM] option is available to edit Pooled Units which requires a higher security.  | SRS# I16 I39<br>SCR# I5     |
| HI33 | Units which require confirmatory ABO/Rh testing prior to use do not get tested.                            | 1) BLOOD PRODUCT file (#66) setup for specific product does not have the Contains Red Cells field (#.19) and/or Retype After Preparation field (#.18) set to "YES".<br>2) User does not print out the Inventory ABO/Rh testing worksheet [LRBLIW]. | LOW              | LOW        | Units received from an outside facility or created through a modification of other units should appear on the Inventory ABO/Rh testing worksheet [LRBLIW] option report if the blood component has a "YES" in the Contains Red Cells field (#.19) in the BLOOD PRODUCT file (#66). | SCR# I40 I47<br>SCR# I9 I13 |
| HI34 | Confirmatory ABO/Rh testing on Inventory does not agree with log in information.                           | User input error   | NONE             | LOW        | Software compares confirmatory test results to the unit log in information and displays a warning message if results disagree.   | SRS# I41<br>SCR# I13        |
| HI35 | ABO/Rh recheck testing results entered on units from a different division if the site is multi-divisional. | NONE   | NONE             | NONE       | Software restricts access to units in inventory to those in the same division as the user, as determined by the user log in.   | SRS# I42<br>SCR# I9         |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method (s) of Control  | Trace                                       |
|------|--|---|------------------|------------|--|---|
| HI36 | Data transcription errors on ABO/Rh unit confirmation worksheets.          | Barcode scanner not used during unit log in and user creates a transcription error during log in.   | LOW              | LOW        | 1) Report available which lists units which require ABO/Rh retesting based on initial login.<br>2) Barcode scanners greatly reduce the incidence of transcription errors.<br>3) Option available to edit unit log in if necessary and report can be reprinted. | SRS#<br>I40<br>I43<br><br>SCR#<br>I3        |
| HI37 | Interpretations of actual test results not readily available.              | Site did not enter appropriate data into the LAB LETTER file (#65.9) which controls the text which appears on the Inventory ABO/Rh testing worksheet. | NONE             | LOW        | Edit lab letter file [LRBLSLL] option exists to edit the Inventory ABO/Rh testing worksheet to reflect site's policy of test result interpretations.   | SRS#<br>I5<br><br>SCR#<br>I7<br>I9          |
| HI38 | Individual comments relating to ABO/Rh confirmatory testing not available. | Site did not create special "canned comments" to be used during entry of ABO/Rh confirmatory testing interpretations.                                 | NONE             | LOW        | Software allows for "canned comments" to be available for entry during ABO/Rh confirmation data entry. These comments stay associated with the unit at all times.  | SRS#<br>I9<br><br>SCR#<br>I7<br>I9          |
| HI39 | Cannot track lifecycle of units modified while in the Blood Bank.          | Disposition –not transfused [LRBLIDN] option not used when modifying inventory units.   | LOW              | LOW        | Software creates a new entry in the BLOOD INVENTORY file (#65) for new components created and assigns a final disposition of MODIFIED to the original unit being modified.   | SRS#<br>I44<br>I50<br>I91<br><br>SCR#<br>I6 |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method (s) of Control   | Trace                |
|------|--|--|------------------|------------|---|----------------------|
| HI40 | Units created as a result of modification of units in inventory are missing critical data.   | Disposition –not transfused [LRBLIDN] option not used when modifying inventory units.  | LOW              | LOW        | When a new unit is created as a result of modification of an existing unit, critical data is transferred to the new file entry in the BLOOD INVENTORY file (# 65).                                | SRS# I45<br>SCR# I14 |
| HI41 | ABO/Rh recheck results on units created by modification of existing units is not transferred to the newly created unit when appropriate. | Site did not set the BLOOD PRODUCT file (#66), Retype After Preparation field (#.18) = NO for the newly created component to reflect the site's policy.              | LOW              | LOW        | ABO/Rh confirmatory testing results automatically transferred to new units created unless the Retype After Preparation field (#.18) =YES in the BLOOD PRODUCT file (#66) for the product created. | SRS# I46<br>SCR# I14 |
| HI42 | An ABO type is assigned to a pool product when the individual components of the pool are not all of the same ABO types.                  | If a pool is created using individual products of mixed ABO types, an ABO group for the pool is assigned using the ABO group of the first unit assigned to the pool. | LOW              | HIGH       | If site policy allows pooling of units from different ABO groups, the software assigns the ABO group of the first unit added to the pool.   | SRS# I48<br>SCR# N/A |
| HI43 | A pool containing an individual unit which is Rh Positive is assigned a Pool Rh type of Negative.  | NONE   | NONE             | NONE       | Assignment of the Rh of a pool will be deemed positive if any of the units in the pool are Rh positive, regardless of the order in which the units were pooled.                                   | SRS# I49<br>SCR# I15 |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method (s) of Control   | Trace                                     |
|------|--|---|------------------|------------|---|---|
| HI44 | Cannot determine the number of aliquots created when dividing a unit.  | Disposition-not transfused [LRBLIDN] options or Pediatric Unit Preparations [LRBLPED] option is used to create aliquoted units. | LOW              | LOW        | When a product is divided using these options, the number of aliquots is calculated by the software and the number is stuffed into the Pooled/Divided Units field (#4.4) for the original unit in the BLOOD INVENTORY file (#65). | SRS# I50<br>SCR# I6                       |
| HI45 | An Autologous unit with a YES entry in the Pos/Incomp. Screening Tests field (#8.1) can be modified into a non-autologous component. | NONE  | NONE             | NONE       | Software does not allow the modification of an autologous unit with a "YES" entry in the Pos/Incomp. Screening Tests field (#8.1).  | SRS# I21<br>I51<br>I52<br>SCR# I16<br>I26 |
| HI46 | Units in inventory can be modified into inappropriate component types.   | Site did not edit the BLOOD PRODUCT file (#66), Modify To field (#.03) for the specific components being modified.              | NONE             | LOW        | When modifying units in inventory, choices of components being created is limited to those defined in the Modify To field (#.03) in the BLOOD PRODUCT file (#66) for the specific component being modified.                       | SRS# I1<br>I54<br>SCR# I3                 |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method (s) of Control  | Trace                                |
|------|--|---|------------------|------------|--|--------------------------------------|
| HI47 | Units in inventory can be modified into inappropriate numbers of components.                             | Site did not edit the BLOOD PRODUCT file (#66), Not Only One Allowed field (#.02) for the specific components being modified. | NONE             | LOW        | When modifying units in inventory the BLOOD PRODUCT file (#66), Not Only One Allowed field (#.02) for the specific component being modified controls whether more than one unit can be created from the original unit. | SRS# I1<br>I55<br><br>SCR#<br>I3     |
| HI48 | A unit in inventory can be modified more than once.  | NONE  | NONE             | NONE       | When a unit is modified, a disposition is automatically assigned. The software prevents selection of a unit with a disposition assigned for modification.  | SRS#<br>I56<br><br>SCR#<br>I3        |
| HI49 | Units created as a result of modification of an existing unit are not uniquely identified.               | NONE  | NONE             | NONE       | Software requires the assignment of a unique Unit ID for units created through modification of existing units in inventory.  | SRS#<br>I57<br>I58<br><br>SCR#<br>I1 |
| HI50 | A unit can be divided/split into other components whose total volumes exceed the original unit's volume. | NONE  | NONE             | NONE       | 1) Software keeps track of unit volume as pediatric units are prepared.<br>2) Software calculates unit volume of divided units based on original volume and the number of aliquots prepared.                           | SRS#<br>I59<br><br>SCR#<br>I3        |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method (s) of Control  | Trace   |
|------|--|---|------------------|------------|--|---|
| HI51 | Units created by modifying units already in inventory have incorrect/invalid expiration dates.   | 1) Site did not edit the BLOOD PRODUCT file (#66), Days Left field (#.11) for the product being created.<br>2) Unit modification data entry not done in real time. The suggested expiration date of the new units is calculated based on a modification date/time of NOW. | MOD              | MOD        | Software generates a suggested expiration date for units created via modification based on the Days Left field (#.11). However, this expiration date/time is not assigned unless accepted by the user. The user is prompted for review and can enter new expiration date/time during data entry.                         | SRS#<br>I24<br>I53<br>I60<br><br>SCR#<br>I10<br>I22 |
| HI52 | A unit created as a result of modifying a unit already in inventory is inappropriately assigned an expiration date which exceeds the expiration date of the original unit. | Alert message generated by software when this occurs is inappropriately ignored by the user.  | LOW              | LOW        | Software evaluates the calculated expiration date of the new unit against the expiration date of the original unit and displays an alert message if the new unit expiration date exceeds the original expiration date, or in the case of a pooled product, the original expiration date of any of the units in the pool. | SRS#<br>I61<br><br>SCR#<br>I10<br>I22               |
| HI53 | A future disposition date is entered.  | NONE  | NONE             | NONE       | Software prohibits entry of a future disposition date.   | SRS#<br>I62<br><br>SCR#<br>I3                       |



Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method (s) of Control  | Trace                      |
|------|---|--|------------------|------------|--|----------------------------|
| HI54 | A pediatric component can be created from a unit which is too old.                  | 1) Disposition – not transfused [LRBLIDN] option, not Pediatric unit preparation [LRBLPED] option is used to prepare Pediatric component.<br>2) Site did not edit the BLOOD PRODUCT file (#66), Max Age For Pediatric Use field (#.21) appropriately for the component of the unit being modified. | LOW              | LOW        | Pediatric unit preparation [LRBLPED] option evaluates the age of the unit selected for Pediatric component preparation against the entry in the BLOOD PRODUCT file (#66), Max Age For Pediatric Use field (#.21) for the component being modified.                   | SRS# I63<br>SCR# I3        |
| HI55 | Pediatric units are inadvertently created from low volume units.                    | Disposition – not transfused [LRBLIDN] option is used to create pediatric units instead of Pediatric unit preparation.   | LOW              | LOW        | Pediatric unit preparation [LRBLPED] option evaluates the volume of the original unit and displays those with a volume <150ml.   | SRS# I64<br>SCR# I3        |
| HI56 | The combined volume of pediatric units prepared exceeds the original unit's volume. | NONE   | NONE             | NONE       | The Pediatric Unit preparation [LRBLPED] option updates the volume of the original volume based on the number and volume of Pediatric units prepared. When the original unit has a volume of zero, a final disposition of MODIFIED is assigned to the original unit. | SRS# I65<br>I66<br>SCR# I3 |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method (s) of Control  | Trace                   |
|------|---|---|------------------|------------|--|-------------------------|
| HI57 | Units created by modifying units already in inventory cannot be traced by the bag lot #.  | 1) Data entry error.<br>2) BB site parameter not set up to prompt for the bag lot #'s during data entry.  | LOW              | LOW        | VA FileMan can be used to search the database for all donations/units processed using a specific lot #.  | SRS# I3 I67<br>SCR# I17 |
| HI58 | Patient and unit information on system generated caution tag does not match current information in computer.                            | Disposition – relocation [LRBLIDR] option not used to verify information at the time a unit is signed out to ward personnel and the units were “released” from the patient in the computer but units were not untagged. | LOW              | LOW        | The system generated caution tag cannot be printed until all necessary pretransfusion testing is complete and entered into computer. If a unit is no longer appropriate to transfuse to a patient for any reason, it must be manually untagged as well as “released” from the patient in the computer. | SRS# I68<br>SCR# I24    |
| HI59 | Patients with autologous and/or directed units available are transfused with homologous units instead of the autologous/directed units. | 1) Units not logged into system as autologous or directed.<br>2) User ignores the alert message displayed on the screen that autologous or directed units are available on the patient.                                 | LOW              | LOW        | When autologous or directed units are logged into the computer, the user is required to enter a valid PATIENT NAME in the Restricted For field (#8). This causes the autologous or directed units to be flagged on the screen whenever the Patient is selected for options in the Blood Bank software. | SRS# I69<br>SCR# I8     |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method (s) of Control   | Trace                |
|------|--|--|------------------|------------|---|----------------------|
| HI60 | A “double crossmatched” unit is inappropriately transfused.  | 1) Warning message that the unit selected is double crossmatched is not evaluated thoroughly prior to proceeding with relocation.<br>2) Disposition – relocation [LRBLIDR] option not used at the time a unit is relocated.  | LOW              | LOW        | Disposition relocation [LRBLIDR] option displays a warning message if the unit selected has been double crossmatched and is still assigned to another patient at the time the unit is being issued for transfusion.   | SRS# I70<br>SCR# I24 |
| HI61 | Presence of patient antibody or other special BLOOD BANK COMMENTS not available when units being issued. | 1) Special instructions [LRBLPSI] option not used to enter important data.<br>2) Antibody ID not entered in the Antibodies Identified field (#.075) during Enter Test Data [LRBLPET] option.<br>3) Disposition – relocation [LRBLIDR] option not used at the time a unit is relocated. | LOW              | LOW        | 1) Special instructions [LRBLPSI] option can be used to enter specific data to be displayed for a patient when using Blood Bank options.<br>2) Antibodies entered using the Antibodies Identified field (#.075) will always be displayed with the patient, even if the current specimen does not have a detectable titer. | SRS# I71<br>SCR# I19 |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace                       |
|------|---|---|------------------|------------|--|-----------------------------|
| HI62 | Can issue units which are not assigned to the patient.  | Disposition – relocation [LRBLIDR] option not used at time of issue.  | LOW              | LOW        | Disposition – relocation [LRBLIDR] option limits the selection of units for issue, which have a current status of ‘assigned’ to the patient specified.   | SRS# I72<br>SCR# I19 I24    |
| HI63 | Patients with clinically significant antibodies can be issued units not typed and found to be negative for the corresponding antigen. | 1) Site did not use the Edit Corresponding Antigen/ Antibody [LRBLSNO] option to define clinically significant Antibodies.<br>2) Antibody ID not entered in the Antibodies Identified field (#.075) when entering patient test data.<br>3. Disposition–relocation [LRBLIDR] option not used at time of issue. | LOW              | LOW        | For patients with an entry in the Antibodies Identified field (#.075) the Disposition – relocation [LRBLIDR] option evaluates unit phenotyping of allogenic units against clinically significant antibodies and prevents issue if unit phenotyping is not appropriate, i.e., for each entry in the Antibodies Identified field (#.075), there must be a corresponding entry in the RBC Antigen Absent field (#.05) for the unit. | SRS# I6 I73<br>SCR# I19 I25 |
| HI64 | Units which require crossmatch can be issued prior to completion of crossmatch.   | Site did not edit the Patient/Product Requirement field (#.09) for the specific product in the BLOOD PRODUCT file (#66).  | LOW              | LOW        | Products with an entry of CROSSMATCH in the PATIENT/PRODUCT REQUIREMENT field (#.09) cannot be given the status of “assigned” until there is an entry in the Crossmatch Result field (#.04) for the unit.  | SRS# I74<br>SCR# I19        |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                       |
|------|--|--|------------------|------------|--|-----------------------------|
| HI65 | Unit requiring ABO/Rh recheck to be done can be issued without ABO/Rh recheck results entered. | 1) Site did not define the BLOOD PRODUCT file (#66), Contains Red Cells =YES field (#.19) for the specific component.<br>2) Disposition – relocation [LRBLIDR] option not used at time of issue. | LOW              | LOW        | Disposition – relocation [LRBLIDR] option prevents issue if no recheck results are entered for a component defined in the BLOOD PRODUCT file (#66), Contains Red Blood Cells = YES field (#.19). | SRS# I75<br>SCR# I19<br>I20 |
| HI66 | Units with a previous inspection of “Unsatisfactory” can be issued.                            | Disposition – relocation [LRBLIDR] option not used at time of issue.   | LOW              | LOW        | Disposition – relocation [LRBLIDR] option prevents issue if the unit has had a previous inspection of “Unsatisfactory”.  | SRS# I76<br>I77<br>SCR# I21 |
| HI67 | Expired units can be issued.   | 1) Disposition – relocation [LRBLIDR] option not used at time of issue.<br>2) User ignores warning message that unit is expired.   | LOW              | LOW        | Disposition – relocation [LRBLIDR] option evaluates the unit’s expiration date and displays a warning message if unit is expired when compared to the current time.                              | SRS# I78<br>SCR# I22        |
| HI68 | Units which should be modified before release can be issued.                                   | Site did not edit the BLOOD PRODUCT file (#66) and set the Modified Before Release field (#.14) to “YES” for specific components.  | LOW              | LOW        | When the Modified Before Release field (#.14) is set to “YES”, the Disposition – relocation [LRBLIDR] option prevents issue, thereby forcing the user to ‘modify’ the unit.                      | SRS# I79<br>SCR# I23        |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                      |
|------|---|--|------------------|------------|--|----------------------------|
| HI69 | Inappropriate date/time of relocation/issue can be entered.       | Supervisory edit option, Edit unit patient fields [LRBLSEC] option is used rather than Disposition–relocation [LRBLIDR] option to issue units. | LOW              | LOW        | 1) Disposition – relocation [LRBLIDR] option evaluates the date/time relocation and prevents entry of a date time prior to the date/time the unit was assigned to the patient or a future date/time.<br>2) Supervisory edit option [LRBLSI] should have restricted access. | SRS# I80 I81<br>SCR# I3 I6 |
| HI70 | Inappropriate locations can be used to relocate units.            | Disposition–relocation [LRBLIDR] option user enters an inappropriate hospital location and overrides the warning message.                      | LOW              | LOW        | Standard locations are restricted to those entries in the HOSPITAL LOCATION file (#44) with the same division as the user. Non-standard locations can be entered, however, the user is given a warning message and chance to override.                                     | SRS# I82<br>SCR# I3        |
| HI71 | Issue/relocation data entered in error cannot be corrected.       | NONE   | NONE             | NONE       | Edit unit - patient fields [LRBLSEC] option available to edit verified information relating to the issue/relocation of a specific unit ID. (Requires a higher level of security).  | SRS# I83<br>SCR# I5        |
| HI72 | Unable to standardize the identification of RBC and HLA antigens. | NONE   | NONE             | NONE       | Software uses the SNOMED nomenclature to standardize RBC and HLA typing.   | SRS# I6 I84<br>SCR# I25    |

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace                    |
|------|---|---|------------------|------------|---|--------------------------|
| HI73 | Unable to define which RBC antigens are valid choices.                | Site did not review and edit the FUNCTION FIELD file (#61.3) entries prior to use of software.  | LOW              | LOW        | The FUNCTION FIELD file (#61.3) is exported populated with standardized Identifier field (#4) entries for RBC antigens.   | SRS# I6 I85<br>SCR# I25  |
| HI74 | Clinically significant alloantibodies cannot be defined for the site. | Site did not use the Edit Corresponding Antigen/Antibody option prior to use of software to fill in the Corresponding Antigen/Antibody field (#04) in the FUNCTION FIELD file (#61.3).            | LOW              | MOD        | The Edit Corresponding Antigen/Antibody [LRBLSNO] option is available for sites to use to define which all antibodies are to be considered clinically significant. Requires a higher security.  | SRS# I6<br>SCR# I19 I25  |
| HI75 | Cannot determine units in inventory which have been phenotyped.       | 1) Site does not enter phenotyping results in system.<br>2) Site does not print out report provided by software.  | LOW              | LOW        | Report Phenotyped units available [LRBLIPH] option provides a listing of all units in inventory which have been phenotyped, including all entries for RBC antigens present and absent, for a specified component of a specified ABO/Rh. | SRS# I86<br>SCR# I18 I25 |
| HI76 | User can enter same antigen as both present and absent on a unit.     | Site did not use the Edit Corresponding Antigen/Antibody [LRBLSNO] option prior to use of software to fill in the Corresponding Antigen/Antibody field (#.04) in the FUNCTION FIELD file (#61.3). | LOW              | MOD        | Software checks the Corresponding Antigen/Antibody field (#.04) in the FUNCTION FIELD file (#61.3) entry to determine if the response entered by the user is valid.   | SRS# I6 I87<br>SCR# I25  |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace                      |
|------|--|---|------------------|------------|--|----------------------------|
| HI77 | Donor records not updated when a donor unit is phenotyped after the unit has been released to Inventory.                       | Unit phenotyping results not entered into computer.   | NONE             | LOW        | Software checks donor records when the supplier for the unit is SELF and updates the donor record with the phenotyping results for future reference.                 | SRS# I88<br>SCR# I18       |
| HI78 | Autologous/directed donor unit with a 'yes' in the Pos/Incomp. Screening Tests field (#8.1) can be released for allogenic use. | NONE  | NONE             | NONE       | Software prevents release of autologous/directed donor units with a 'yes' in the Pos/Incomp. Screening Tests field (#8.1) for allogenic use.                         | SRS# I89<br>SCR# I26       |
| HI79 | Units located out of the Blood Bank are made available in Inventory.   | NONE  | NONE             | NONE       | Units release to stock (cancel) by patient [LRBLIUR] option evaluates the location of unit and only allows release if the location is the Blood Bank.                | SRS# I90<br>SCR# I3<br>I6  |
| HI80 | Cannot create meaningful QA reports for Blood Utilization Review.  | Site did not create canned comments which can be used when releasing crossmatched/assigned units back to inventory. | NONE             | LOW        | Edit blood bank descriptions file [LRBLSEF] option available to create canned comments for use when releasing assigned units to inventory.                           | SRS# I7<br>SCR# I6         |
| HI81 | Cannot trace unit history when a new unit is created through modification.   | User does not use option Disposition –not transfused [LRBLIDN] option to modify unit from one component to another. | LOW              | LOW        | Software tracks the unit modification information for both the unit being modified and the unit(s) created to include data on unit's Modified To/From field (#.091). | SRS# I91<br>SCR# I6<br>I14 |



Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                                   |
|------|---|--|------------------|------------|--|---|
| HI82 | The BLOOD INVENTORY file (#65) may have missing data nodes. | User does not use the Blood bank inventory integrity report [LRBLII] option to check for missing data after system crash.        | NONE             | LOW        | It is recommended that the Blood bank inventory integrity report [LRBLII] option be used on a regular bases and after unexpected system down time to check the BLOOD INVENTORY file (#65) for missing data.                  | SRS# I92<br>SCR# I7                     |
| HI83 | Cannot examine unit history for look-back purpose.          | Print units with final disposition [LRBLRUF] option used prior to Remove units with final disposition, then report is discarded. | LOW              | LOW        | Inventory data can be kept on line indefinitely. However, if a site needs to purge the BLOOD INVENTORY file (#65), an option exists which can purge units with a final disposition, but requires that they be printed first. | SRS# I93<br>I96<br>I97<br>SCR# I6<br>I7 |
| HI84 | Cannot view cumulative unit history.                        | BLOOD INVENTORY file (#65) purged.   | LOW              | LOW        | Option exists which can print hard copy or display on screen the complete unit history.  | SRS# I93<br>I94<br>SCR# I1<br>I6<br>I7  |
| HI85 | Cannot view current status of a unit in inventory.          | Computer system downtime.  | LOW              | LOW        | Single unit (display/print) information [LRBLQSU] option exists which can print hard copy or display on screen the complete unit history and current status.   | SRS# I95<br>SCR# I7                     |
| HI86 | Cannot search inventory for CMV negative units.             | Users do not enter CMV testing results into computer.  | NONE             | LOW        | CMV Antibody Status Report [LRBLICV] option searches the database for CMV negative units.  | SRS# I98<br>SCR# I18                    |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace                                      |
|------|--|---|------------------|------------|---|--|
| HI87 | Cannot perform utilization review for inventory units that have a final disposition but were not transfused. | Incomplete data entry by site.  | NONE             | LOW        | Report for a specified range of disposition dates for a specified disposition is available for supervisory review.  | SRS# I99<br>SCR# I7                        |
| HI88 | Cannot determine units in inventory and their status.  | System downtime   | NONE             | LOW        | Report available which lists all in-date units. Sorted by component, ABO/Rh and expiration date.  | SRS# I100<br>SCR# I7                       |
| HI89 | Cannot determine if Inventory records are complete.  | Units with no disposition [LRBLRUN] option not reviewed regularly.  | NONE             | LOW        | Units with no disposition [LRBLRUN] option is available which lists all units that have no disposition data entered (both in date and outdated). This should be reviewed regularly to check for incomplete data entry.          | SRS# I101<br>SCR# I7                       |
| HI90 | Cannot properly manage inventory by appropriately releasing units from patients.                             | NONE  | NONE             | NONE       | Units on Xmatch by date/time Xmatched [LRBLIX] option available to assist in managing inventory by listing units in "assigned" status in chronological order by date/time assigned.   | SRS# I102<br>SCR# I6                       |
| HI91 | Cannot accurately determine supplier charges for blood products.   | Responsible person does not maintain the COST field (#.02) in the BLOOD PRODUCT file (#66) and/or edit the charges for an individual unit when appropriate. | NONE             | LOW        | 1) Edit unit log-in [LRBLSEL] option allows editing of supplier cost for an individual unit.<br>2) Special typing charges (inventory) [LRBLRIS] option exists to allow recording of any special typing charges by the supplier. | SRS# I33<br>I34<br>I103<br>I104<br>SCR# I6 |

Inventory Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace  |
|------|---|--|------------------|------------|--|--|
| HI92 | Cannot verify billing from outside suppliers.                                   | Responsible person does not maintain the Cost field (#.02) in the BLOOD PRODUCT file (#66) and/or edit the charges for an individual unit when appropriate.                                  | NONE             | LOW        | Reports available for units entered into the BLOOD INVENTORY file (#65) for a specified date range to review supplier charges, both standard and special typing.                         | SRS#<br>I33<br>I34<br>I103<br>I104<br>I105<br>I106<br>I107<br><br>SCR#<br>I5 |
| HI93 | Cannot review Autologous program for QA purposes.                               | Autologous units not identified as Autologous during data entry.   | NONE             | LOW        | Autologous disposition report [LRBLJB] option exists for monitoring Autologous units with a disposition of TRANSFUSE for QA review.  | SRS#<br>I19<br>I108<br>I109<br><br>SCR#<br>I8                                |
| HI94 | Cannot track unit relocations.  | Disposition - relocation [LRBLIDR] option not used to enter all unit relocations.  | NONE             | LOW        | Unit issue book entries [LRBLIRB] option exists to detail all relocation activity within the Blood Bank for a specified date range.  | SRS#<br>I110<br><br>SCR#<br>I6   |
| HI95 | Cannot determine the numbers of ABO/Rh rechecks done on inventory units.        | ABO/Rh confirmation testing results not entered into computer.   | NONE             | LOW        | Inventory ABO/Rh recheck counts [LRBLC] option exists which tallies the ABO/Rh rechecks results entered in computer.   | SRS#<br>I111<br><br>SCR#<br>I9   |
| HI96 | Cannot accurately determine workload statistics for local and national reports. | Responsible person does not enter workload codes in specific Blood Bank and the EXECUTE CODE files (#62.07) according to guidelines included in the Planning and Implementation Guide v 5.2. | NONE             | LOW        | When workload codes are defined for particular tests, products, and procedures, workload is automatically collected as a background activity whenever data is entered into the computer. | SRS#<br>I112<br><br>SCR#<br>N/A  |

## Inventory Intended Uses Hazard Analysis

## Patient Intended Uses Hazard Analysis

| HA# | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                   |
|-----|---|--|------------------|------------|--|-------------------------|
| HP1 | Site routinely does Direct AHG pretransfusion testing but can't easily enter patient results.                       | Site parameter which controls whether these fields are prompted for during data entry not set properly.                                    | LOW              | LOW        | Site parameter is available to indicate whether fields for Direct AHG test results are to be included in the edit template for entering ABO/Rh results.  | SRS# P3<br>SCR# P11 P20 |
| HP2 | Site specific canned comments not used for Patient testing result data entry.                                       | Site does not use the Edit blood bank descriptions file [LRBLSEF] option to build meaningful canned comments to be used during data entry. | NONE             | LOW        | Both previously defined canned comments and free text are acceptable for input for comment fields during data entry. Canned comments are easily defined and can be screened to be choices at specific areas of data entry. | SRS# P4<br>SCR# N/A     |
| HP3 | No consultative reports for patients with antibodies or positive direct AHG tests available for placement on chart. | 1) Site did not customize the LAB LETTER file (#65.9) entry for specific reports.<br>2) Blood bank consultation reports not used.          | LOW              | LOW        | Blood bank consultation reports available which can be placed on a patient's chart for future reference.   | SRS# P5 P54<br>SCR# P11 |
| HP4 | Cannot determine which antibodies are clinically significant so antigen checking can be done on RBC units.          | Site did not use the Edit Corresponding Antigen/Antibody [LRBLSNO] option to define clinically significant antibodies.                     | LOW              | LOW        | Edit Corresponding Antigen/Antibody [LRBLSNO] option must be used by the site to define which antibodies need to have units phenotyped and found negative for the corresponding antigens.                                  | SRS# P6<br>SCR# P7      |

Patient Intended Uses Hazard Analysis

| HA# | Hazard   | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|-----|--|---|------------------|------------|---|--|
| HP5 | Cannot do prospective review of blood utilization when requesting components on a patient, both pre-op and not pre-op. | Site did not use option Tests for display on patient look-up to define tests which will display upon patient component request.               | LOW              | LOW        | Tests for display on patient look-up [LRBLST] option exists to define Tests for display on patient look-up. When defined, the most recent lab value of the defined tests are displayed during component request functions. This allows Blood Bank personnel a chance to do prospective utilization review and take action if necessary. | SRS#<br>P7<br>P37<br><br>SCR#<br>P17                     |
| HP6 | Cannot define standard transfusion reaction types to facilitate reporting.   | Site did not use the Edit blood bank utility file [LRBLSEU] option to define acceptable transfusion reaction types for use during data entry. | LOW              | LOW        | During transfusion result data entry user is prompted if a transfusion reaction associated with the unit. There is also a separate option to report transfusion reactions which cannot be associated with a specific unit. Free text entry is not allowed.  | SRS#<br>P8<br><br>SCR#<br>P12                            |
| HP7 | Cannot provide a unique cumulative record for each individual patient.   | NONE  | NONE             | NONE       | Records update immediately upon data entry. Print single BB patient report [LRBLP PRINT SINGLE] option provides a cumulative record for Blood Bank testing data on each patient.  | SRS#<br>P9<br>P11<br>P52<br>P86<br><br>SCR#<br>P1<br>P12 |
| HP8 | Patient record confidentiality is compromised  | Menu options displaying sensitive data not restricted appropriately.  | LOW              | LOW        | Menu options containing sensitive data should be restricted by security keys.   | SRS#<br>N/A<br><br>SCR#<br>P2                            |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|---|---|------------------|------------|---|--|
| HP9  | Cannot determine pre transfusion requirements for specific blood components.  | Responsible person did not edit the BLOOD PRODUCT file (#66) to reflect site policies prior to implementation.  | LOW              | LOW        | Edit blood product file [LRBLSEB] option should be used to customize the requirements for blood products currently in use at specific sites.  | SRS#<br>P2<br><br>SCR#<br>P16<br>P19<br>P25<br>P26 |
| HP10 | Corrupted patient records due to duplicate data entry.  | NONE  | NONE             | NONE       | Record locking is employed which prevents Patient blood bank test data entry by more than one individual at a time.   | SRS#<br>P10<br><br>SCR#<br>P1                      |
| HP11 | Cannot review transfusion history on a patient.   | Computer down-time  | LOW              | LOW        | Patient report available which displays the patient's transfusion record in reverse chronological order for a specified date range. Report includes history of transfusion reactions, antibodies identified, and BLOOD BANK COMMENTS. | SRS#<br>P12<br><br>SCR#<br>P1                      |
| HP12 | Patient can be assigned units from a different division if site is multidivisional and a Blood Bank exists at more than one site. | User division is defined during user log on.<br>1) Invalid choices assigned by system administrator.<br><br>2) User with multiple choices choose incorrectly when logging in. | NONE             | LOW        | Access is limited to units from the division of the user that is determined during log on to system. Even if computer allowed units to be assigned, units would not physically be available.  | SRS#<br>P13<br>P79<br><br>SCR#<br>P3               |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace                            |
|------|--|--|------------------|------------|---|----------------------------------|
| HP13 | Barcode scanner not used to read Unit ID.  | 1) Site does not use scanner.<br>2) Scanner not working.<br>3) User chooses to not use scanner | NONE             | LOW        | Software accommodates both scanner and manual input of Unit ID interchangeably.   | SRS# P14<br>SCR# P3              |
| HP14 | Cannot track changes to verified data in the Blood Bank Patient records.                 | VA Fileman used to edit fields directly rather than specified menu options.                    | LOW              | LOW        | Direct access to Blood Bank data files through VA Fileman should be restricted by site policy.  | SRS# P15<br>P16<br>SCR# P4       |
| HP15 | Cannot determine who entered data in computer.   | NONE   | NONE             | NONE       | Assignment of responsibility automatic based on identity of individual determined upon log-in to system.  | SRS# P17<br>SCR# P8              |
| HP16 | Unit Inventory record not updated when appropriate data entered through Patient options. | Total system crash/failure.  | NONE             | LOW        | Edit unit - patient fields [LRBLSEC] option can be used if necessary to update entries in the BLOOD INVENTORY file (#65) to reflect current Patient data. (Requires a higher security). | SRS# P11<br>P18<br>SCR# P3<br>P9 |
| HP17 | Cannot review patient demographic data during data entry.                                | NONE   | NONE             | NONE       | All patient options display demographic data, including first and last names, social security number, date of birth, ABO/Rh of record (if one exists) and admitting diagnosis.          | SRS# P19<br>SCR# P13<br>P15      |



Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|---|--|------------------|------------|---|--|
| HP18 | Cannot determine a patient's previous antibody history.                       | User did not enter presence of antibody in the Antibodies Identified field (#.075) during data entry.    | LOW              | LOW        | Antibodies entered in the Antibodies Identified field (#.075) during the Enter test data option will always display with the patient name, regardless of division or whether the antibody is still detectable on the current specimen.  | SRS#<br>P20<br><br>SCR#<br>P12<br>P14        |
| HP19 | Cannot determine previous transfusion reactions on a patient.                 | Previous transfusion reaction data not entered into computer.  | LOW              | LOW        | 1) Blood transfusion results [LRBLPT] option prompts for entry of Transfusion Reaction associated with a specific unit.<br>2) Unknown unit transfusion reaction [LRBLPTXR] option allows entry of transfusion reaction not associated with a specific unit.<br>Transfusion reaction data always displayed along with demographic data when present. | SRS#<br>P21<br>P83<br>P87<br><br>SCR#<br>P12 |
| HP20 | Cannot determine if autologous or directed units are available for a patient. | Autologous or directed units not properly identified and restricted to patient when logged in to system. | LOW              | LOW        | When units defined as either autologous or directed are logged in to the BLOOD INVENTORY file (#65), the user is required to enter a valid patient name at the RESTRICTED FOR: prompt. These units are always displayed along with the patient name when blood bank patient options are executed.   | SRS#<br>P22<br><br>SCR#<br>P18               |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace  |
|------|--|--|------------------|------------|--|--|
| HP21 | Can request inappropriate components for a patient.                                    | Site did not edit the Can Be Requested field (#.15) in the BLOOD PRODUCT file (#66).   | LOW              | LOW        | Component requests are limited to those components with the Can Be Requested field (#.15) = YES in the BLOOD PRODUCT file (#66).   | SRS#<br>P2<br>P23<br><br>SCR#<br>P19<br>P25  |
| HP22 | Blood Bank Supervisor cannot review work as required by accreditation agencies.        | Reports not regularly printed.   | LOW              | LOW        | A variety of reports exist to facilitate supervisory review of all work done in the Blood Bank as required by accreditation agencies.  | SRS#<br>P24<br><br>SCR#<br>P8                |
| HP23 | Cannot determine if patient has any special component requirements.                    | Special instructions [LRBLPSI] option not used to enter patient specific special instructions.   | LOW              | LOW        | Data entered via the Special instructions [LRBLPSI] option are displayed along with demographic data whenever Blood Bank patient options are executed.   | SRS#<br>P25<br>P27<br>P62<br><br>SCR#<br>N/A |
| HP24 | Patient transfusion history prior to implementation of software not available on line. | Site chooses to not use the Previous records [LRBLPER] option enter patient transfusion history available prior to automation of the Blood Bank. | LOW              | LOW        | Use of functionality is voluntary. Sites may choose to update patient records completely or rely on a combination of automated and manual records. Since actual testing results still need to be maintained, sites usually have transfusion history records available. | SRS#<br>P26<br><br>SCR#<br>P1                |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace                                |
|------|--|---|------------------|------------|--|--------------------------------------|
| HP25 | Units currently in inventory can be entered as having been historically transfused to a patient using the option Previous records [LRBLPER]. | NONE  | NONE             | NONE       | Software searches the BLOOD INVENTORY file (#65). If a unit is present, then it cannot be entered via the Previous Records [LRBLPER] option.                       | SRS#<br>P26<br>P28<br><br>SCR#<br>P1 |
| HP26 | Cannot edit information entered from old records prior to computerization.   | NONE  | NONE             | NONE       | Previous records [LRBLPER] option allows editing of patient testing information but restricts editing of previous transfusion episodes entered via this option.    | SRS#<br>P29<br><br>SCR#<br>N/A       |
| HP27 | Cannot use computer to place orders for pretransfusion or other Blood Bank related tests.  | 1) Computer system is down.<br>2) Appropriate tests not defined in the LABORATORY TEST file (#60).  | NONE             | LOW        | Sites are required to have a contingency plan in the event that the computer system is not working. Data entry can be then done at a later time to update records. | SRS#<br>P30<br><br>SCR#<br>P20       |
| HP28 | Ward personnel cannot view test description information.   | 1) Menu Test description information [LREV] option not assigned to appropriate personnel.<br>2) Key information not defined for Blood Bank tests in the LABORATORY TEST file (#60). | NONE             | LOW        | Test description information [LREV] option lists key entries for Laboratory tests as defined in the LABORATORY TEST file (#60).                                    | SRS#<br>P31<br><br>SCR#<br>N/A       |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace   |
|------|--|---|------------------|------------|--|---|
| HP29 | Orders for Blood Bank tests placed by ward personnel cannot be accepted into the Blood Bank, updating the status of the order. | Computer system is down.  | NONE             | LOW        | Sites are required to have a contingency plan in the event that the computer system is not working. Data entry can be then done at a later time to update records.   | SRS#<br>P32<br><br>SCR#<br>N/A  |
| HP30 | Cannot review previous Blood Bank accessions for a specific patient.   | Computer system is down.  | LOW              | LOW        | Sites are required to have a contingency plan in the event that the computer system is not working. Patients with antibodies identified and/or other special instructions should be readily identifiable in the event of computer downtime.  | SRS#<br>P33<br><br>SCR#<br>P12  |
| HP31 | Blood Bank personnel cannot enter specific component requests for a patient.   | Site did not edit the Can Be Requested field (#.15) in the BLOOD PRODUCT file (#66).  | LOW              | LOW        | Component requests are limited to those components with the Can Be Requested field (#.15) = "YES" in the BLOOD PRODUCT file (#66).   | SRS#<br>P2<br>P34<br><br>SCR#<br>P3<br>P25                              |
| HP32 | Cannot determine if a valid pretransfusion specimen is already present in the Blood Bank.                                      | 1) Site did not define test Transfusion Request in the LABORATORY TEST file (#60), Required Comment field (#320) = TRANSFUSION.<br>2) Site did not define the specimen used for pretransfusion testing to have a site/ specimen of BLOOD. | LOW              | LOW        | When the Required Comment field (#320) = TRANSFUSION the software evaluates previous specimens for Blood Bank accessions to see if any meets the requirements based on the entry in the Maximum Specimen Age field of the BLOOD PRODUCT file (#66) for the specific component requested. | SRS#<br>P2<br>P35<br>P36<br>P57<br><br>SCR#<br>P16<br>P20<br>P25<br>P26 |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace   |
|------|---|--|------------------|------------|--|---|
| HP33 | Cannot do prospective utilization review of blood component requests based on current patient lab values. | BLOOD PRODUCT file (#66) entries for specific products do not have the Tests To Check field (#.04) and/or Pre-Op Tests To Check field (#.08) defined for high/low values of lab tests to check.                      | LOW              | LOW        | When components are requested, the software evaluates the most recent lab values for the patient based on the entries in the BLOOD PRODUCT file (#66), Tests To Check field (#.04) and Pre-Op Tests To Check field (#.08). If results are outside the set limits, the user is prompted to enter additional justification and the request is included in the Inappropriate transfusion requests report. | SRS#<br>P2<br>P7<br>P37<br>P95<br><br>SCR#<br>P17 |
| HP34 | Cannot review preoperative component requests to compare against MSBOS.                                   | 1) Site did not define the MSBOS parameters for specific surgery using the Maximum surgical blood order edit [LRBLSMS] option.<br>2) Surgical staff does not enter specific CPT codes when scheduling their surgery. | LOW              | HIGH       | The review of MSBOS using the Blood component requests option is triggered by the CPT code of the surgery the patient is scheduled for. This is not a required field and surgery departments often do not enter a CPT code until after surgery is complete. The specific MSBOS files are built by defining surgery by each possible CPT code.  | SRS# P3<br>P39<br><br>SCR#<br>P17                 |
| HP35 | Cannot review ordering practices by treating specialty.   | Report assigns requests based on treating specialty on admission. Transfusion may be ordered by other physician.   | NONE             | MOD        | Report should be checked against the manually prepared SF 518 forms used by the VA for actual blood order and transfusion recording.   | SRS#<br>P40<br><br>SCR#<br>P8<br>P17              |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace                                       |
|------|---|---|------------------|------------|---|---|
| HP36 | Accession with verified data is deleted from system.  | NONE  | NONE             | NONE       | Cannot delete an accession if any data has been entered.  | SRS#<br>P43<br><br>SCR#<br>P1               |
| HP37 | No record of ABO/Rh interpretation maintained on patients for future comparison.                | NONE  | NONE             | NONE       | The first time ABO/Rh interpretation results are entered for a patient, a historical record is created which is used in all future testing for comparison.                              | SRS#<br>P44<br><br>SCR#<br>P14              |
| HP38 | Historical ABO/Rh record inappropriately edited.  | Patient ABO/Rh edit [LRBLPEDIT] option inappropriately used to edit a patient historical record.            | LOW              | LOW        | Patient ABO/Rh edit [LRBLPEDIT] option should be restricted by security keys to the Blood Bank supervisor or designee.  | SRS#<br>P45<br><br>SCR#<br>P14              |
| HP39 | No warning if comparison of current ABO/Rh interpretations with historical record do not agree. | NONE  | NONE             | NONE       | Software compares current ABO/Rh type of specimen to the patient history and displays a warning message if a discrepancy exists.  | SRS#<br>P46<br><br>SCR#<br>P3<br>P14        |
| HP40 | No warning if no historical ABO/Rh record exists for comparison.                                | NONE  | NONE             | NONE       | Software displays warning message if no historical ABO/Rh record exists.  | SRS#<br>P47<br>P69<br><br>SCR#<br>P3<br>P14 |
| HP41 | Cannot evaluate positive direct antiglobulin tests to see if drug induced.                      | 1) Site not fully utilizing Pharmacy package.<br>2) Patient taking drugs prescribed from non-VA physicians. | LOW              | LOW        | Upon entry of a positive direct AHG result, the software automatically reviews pharmacy profiles for the patient and provides report of all current medications prescribed for patient. | SRS#<br>P48<br>P49<br><br>SCR#<br>P11       |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace  |
|------|--|--|------------------|------------|--|--|
| HP42 | Cannot track patient data entry errors for ABO/Rh interpretations.                     | Print data change audits [LRBLAD] option not reviewed regularly by Supervisor or designee. | LOW              | LOW        | Data entry errors for ABO/Rh are automatically captured by the software and are included in the Print data change audits report [LRBLAD] option, which should be reviewed regularly and saved according to record retention requirements.  | SRS#<br>P50<br><br>SCR#<br>P4<br>P8                |
| HP43 | Changes in verified data for patient testing is not clearly marked on patient reports. | NONE   | NONE             | NONE       | Changes in verified data for ABO/Rh, antibody screening or direct AHG testing are clearly marked and included in the Blood Bank Test Report for the patient.   | SRS#<br>P51<br><br>SCR#<br>P4<br>P5                |
| HP44 | Cumulative patient Blood Bank test report not available.                               | NONE   | NONE             | NONE       | The Blood Bank Test report includes patient demographics, historical and current ABO/Rh interpretations, antibodies identified, and if requested, current component requests. This can be printed by individual patient or batch printed. As a patient data is entered, the report goes onto a print queue for batch printing. | SRS#<br>P11<br>P52<br>P53<br>P86<br><br>SCR#<br>P1 |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control  | Trace  |
|------|---|--|------------------|------------|---|--|
| HP45 | Expired units can be routinely selected for transfusion.                                | NONE   | NONE             | NONE       | Select units for patients [LRBLPIC] option only allows indate units to be selected. In case of computer downtime, the supervisory Edit unit - patient fields [LRBLSEC] option is available (i.e., which requires a higher level of security) to enter compatibility information and assign an expired unit to a patient.  | SRS#<br>P16<br>P55<br>P56<br><br>SCR#<br>P21                             |
| HP46 | Units can be inappropriately assigned to a patient if no valid patient specimen exists. | 1) Site did not edit the Patient/Product Requirement field (#09) to be CROSSMATCH for specific product types.<br>2) The Edit unit - patient fields [LRBLSEC] option is used inappropriately to assign units to patients. | LOW              | LOW        | Select units for patients [LRBLPIC] option evaluates the Patient/Product Requirement: field (#.09) in the BLOOD PRODUCT file (#66) for the product selected. If set to CROSSMATCH, then the software searches for a valid specimen. If no valid specimen exists, user is alerted to obtain a valid specimen and cannot proceed. Edit unit - patient fields [LRBLSEC] option is available (requires a higher level of security) which can be used in the event of prolonged computer down time to enter required data. This option should be restricted. | SRS#<br>P16<br>P35<br>P36<br>P57<br>P58<br><br>SCR#<br>P20<br>P25<br>P26 |



Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace  |
|------|--|--|------------------|------------|--|--|
| HP47 | ABO/Rh incompatible units can be selected for a patient.                                 | BLOOD PRODUCT file (#66), Patient/Product ABO field (#.07) and Patient/Product Rh field (#.08) not defined properly for specific blood components.                 | LOW              | LOW        | Software evaluates specific requirements for components based on the Patient/Product ABO field (#.07) and Patient/Product Rh field (#.08) and determines compatibility based on entries here.          | SRS#<br>P59<br><br>SCR#<br>P23<br>P24<br>P25<br>P26        |
| HP48 | Under special circumstances an ABO/Rh incompatible unit cannot be assigned to a patient. | NONE   | NONE             | NONE       | Edit unit - patient fields [LRBLSEC] option can be used to assign ABO/Rh incompatible units when indicated. This option requires a higher level of security and should be restricted.                  | SRS#<br>P16<br>P60<br><br>SCR#<br>P23<br>P24<br>P25<br>P27 |
| HP49 | Cannot "double crossmatch" units.  | During the Select units for patients [LRBLPIC] option, user does not answer "NO" to the prompt Select only unassigned/uncrossmatched units ? YES//                 | NONE             | LOW        | During unit selection, there is a user controlled choice as to whether selection of units should be limited to those not currently assigned to another patient.  | SRS#<br>P61<br><br>SCR#<br>N/A                             |
| HP50 | Blood Bank personnel not made aware of a patient's special needs.                        | Special Instructions [LRBLPSI] option not used to enter patient specific comments which are displayed whenever a Blood Bank option is used for patient data entry. | LOW              | LOW        | Special Instructions [LRBLPSI] option should be used to enter patient specific information. This information is then displayed with demographic data whenever patient Blood Bank options are executed. | SRS#<br>P27<br>P62<br><br>SCR#<br>N/A                      |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace                       |
|------|---|---|------------------|------------|--|-----------------------------|
| HP51 | Cannot determine if a unit is a low volume unit.  | 1) BLOOD PRODUCT file (#66) entry for specific component has an incorrect value entered in the Volume (ml) field (#.1).<br>2) Unit not properly labeled as a low volume unit by site. | LOW              | LOW        | Units with a volume less than the average volume for the component as defined in the BLOOD PRODUCT file (#66), Volume (ml) field (#.1) have the volume displayed in parenthesis by the Unit ID when such a unit is selected for a patient.                               | SRS# P63<br>SCR# N/A        |
| HP52 | Cannot determine the number of days before expiration of unit.  | Data entry error during unit log in.  | LOW              | LOW        | During unit selection for a patient, the software calculates and displays the number of days left before expiration of unit.   | SRS# P64<br>SCR# P21        |
| HP53 | Crossmatch results interpretations can be routinely entered on units not specifically selected for a patient. | Edit unit -patient fields [LRBLSEC] option used routinely to assign units and enter crossmatch results.   | LOW              | LOW        | Enter crossmatch results [LRBLPT] option restricts access to those units selected for the patient. For special circumstances, like after extended downtime, the Edit unit -patient fields [LRBLSEC] option can be used for data entry. This option should be restricted. | SRS# P16<br>P65<br>SCR# P3  |
| HP54 | Units requiring ABO/Rh confirmatory testing are crossmatched on a patient.                                    | User ignores warning message displayed during Enter crossmatch results [LRBLPT] option if required confirmatory data not present for specific unit ID.                                | LOW              | LOW        | Enter crossmatch results [LRBLPT] option checks if confirmatory testing is required for a unit. If no confirmatory results are available on the unit, a warning is displayed to the user.  | SRS# P66<br>SCR# P22<br>P25 |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace                                       |
|------|---|---|------------------|------------|--|---|
| HP55 | Units whose ABO/Rh recheck results do not match the log-in information are available for crossmatch.                    | NONE  | NONE             | NONE       | Enter crossmatch results [LRBLPT] option prohibits entry of crossmatch results for any units with a discrepancy between the ABO/Rh during log in and confirmatory testing.   | SRS#<br>P67<br><br>SCR#<br>P3<br>P22        |
| HP56 | Historical ABO/Rh record on a patient can be deleted.   | NONE  | NONE             | NONE       | Software prohibits actual deletion of historical ABO/Rh.   | SRS#<br>P68<br><br>SCR#<br>P14              |
| HP57 | Patient whose current ABO/Rh results do not match historical record or have no ABO/Rh results entered are crossmatched. | NONE  | NONE             | NONE       | 1) During patient test data entry, the current ABO/Rh results are checked against the historical record and a warning message is displayed requiring override to accept discrepant results.<br>2) Select units for patients [LRBLPIC] option compares current specimen ABO/Rh results to historical record. If discrepancy exists or no ABO/Rh testing results available user is given an alert message and is exited from the option. | SRS#<br>P69<br>P70<br><br>SCR#<br>P3<br>P14 |
| HP58 | Transcription error occurs on creation of required label to be attached to crossmatched unit.                           | User does not generate software provided label and attach to crossmatched unit. | LOW              | LOW        | Software provides for generation of a label containing patient and unit information to be used to attach to the tie tag as required by accreditation agencies.   | SRS#<br>P72<br><br>SCR#<br>P3               |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                                 |
|------|---|--|------------------|------------|--|---------------------------------------|
| HP59 | Units phenotyped as positive for an antigen which corresponds to a clinically significant antibody in a patient can be selected for crossmatch to that patient.             | 1) Site did not use the Edit Corresponding Antigen/Antibody [LRBLSNO] option to define clinically significant antibodies.<br>2) User does not enter unit phenotyping results into computer.  | LOW              | LOW        | Select units for patients [LRBLPIC] option evaluates unit phenotyping if the patient crossmatched has an entry in the Antibodies Identified field (#.075) and if that antibody has a corresponding antigen defined. Select units for patients [LRBLPIC] option prevents selection of a unit typed positive for that antigen.                               | SRS#<br>P6<br>P73<br><br>SCR#<br>P7   |
| HP60 | User not warned when a patient has a clinically significant antibody and units selected for crossmatch are not phenotyped and found negative for the corresponding antigen. | 1) Site did not use the Edit Corresponding Antigen/Antibody [LRBLSNO] option to define clinically significant antibodies.<br>2.) User does not enter unit phenotyping results into computer. | LOW              | LOW        | Enter crossmatch results [LRBLPX] option evaluates unit phenotyping if the patient crossmatched has an entry in the Antibodies Identified field (#.075) and if that antibody has a corresponding antigen defined. If the corresponding antigen is not entered in the RBC Antigen Absent field for the unit being crossmatched, a warning message is given. | SRS#<br>P6<br>P74<br><br>SCR#<br>P7   |
| HP61 | Units can be issued if crossmatch is required and crossmatch is not completed.  | Site did not set the BLOOD PRODUCT file (#66), Patient/Product Requirement field (#.09) = CROSSMATCH when appropriate.   | LOW              | LOW        | Units are not given the status of 'assigned' until acceptable crossmatch results are entered for the unit if the product PATIENT/PRODUCT REQUIREMENT = CROSSMATCH. Only units 'assigned' can be signed out using the Disposition - relocation [LRBLIDR] option.  | SRS#<br>P75<br><br>SCR#<br>P16<br>P26 |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                      |
|------|--|--|------------------|------------|--|----------------------------|
| HP62 | Units with incompatible crossmatch results can be issued.  | NONE   | NONE             | NONE       | Software prevents units with crossmatch results other than 'C' or 'IG' from being given a status of 'assigned'.  | SRS# P76<br>SCR# P28       |
| HP63 | Units with previous incompatible crossmatch results can be inappropriately issued.   | NONE   | NONE             | NONE       | Status of a unit which was not compatible for a patient can only be changed by a user with a higher level of security access.  | SRS# P77<br>SCR# P6<br>P28 |
| HP64 | Units which are incompatible for a particular patient are not available for other patients.  | NONE   | NONE             | NONE       | Units with crossmatch results entered that are not 'C' or 'IG' are automatically released back to inventory.   | SRS# P78<br>SCR# P28       |
| HP65 | An autologous unit can be selected for a patient other than the one designated.  | 1) Site did not set the Autologous/ Directed Component field (#25) appropriately for autologous component in the BLOOD PRODUCT file (#66).<br>2) Autologous unit not logged into system as autologous. | LOW              | LOW        | When autologous units are logged in to the system, the user is prompted to enter a valid patient name at the RESTRICTED FOR: prompt. This is a required field. That unit can then only be selected for that patient when using the Select units for patients [LRBLPIC] option. | SRS# P80<br>SCR# P3        |
| HP66 | Current patient component request and units assigned/ available information not available when requesting and selecting units for a patient. | NONE   | NONE             | NONE       | Software automatically displays current patient information on component requests and units assigned/available for issue when requesting and selecting components for a patient.   | SRS# P81<br>SCR# N/A       |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace  |
|------|---|---|------------------|------------|--|--|
| HP67 | Cannot determine the number of individual units contained within a pool that is transfused. | 1) Disposition - not transfused [LRBLIDN] option not used to process a pooled product from products already in inventory.<br>2) Blood transfusion results [LRBLPT] option not used for data entry.  | LOW              | LOW        | When a pooled unit is created from units in inventory using the Disposition -not transfused [LRBLIDN] option and transfusion results are entered for the pool the number of units within the pool is calculated and this number is stuffed into the Pooled/ Divided Units field (#.4) for the pooled product.  | SRS# P82<br>SCR# P9                              |
| HP68 | Transfusion data for a future date/time is entered.   | NONE  | NONE             | NONE       | Future transfusion date/time data is prohibited.   | SRS# P84<br>SCR# P3                              |
| HP69 | Cannot evaluate transfusion practices by treating specialty.                                | 1) Patient is discharged prior to transfusion results entered into computer. Blood Bank tech may not know the treating specialty of the patient at the time of transfusion.<br>2) Transfusion ordered from a different treating specialty than admission. | NONE             | MOD        | Treating Specialty field (#.02) is a required field when entering transfusion results. Reports automatically assign treating specialty on admission to transfusion episodes for inpatients. Treating specialty must be entered by the Blood Bank Technologist at time of Blood transfusion result entry when patients have been discharged or were transfused as outpatient. | SRS# P40<br>P41<br>P42<br>P85<br>P91<br>SCR# P17 |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                              |
|------|--|--|------------------|------------|--|------------------------------------|
| HP70 | Cannot determine if patient has had previous transfusion reaction not associated with a specific unit. | Unknown unit transfusion reaction [LRBLPTXR] option not used to enter delayed transfusion results not associated with a specific unit.   | LOW              | LOW        | Unknown unit transfusion reaction [LRBLPTXR] option can be used to enter transfusion reaction data of this type. These are then displayed with demographic data whenever blood bank patient options are executed.  | SRS# P87<br>SCR# P12               |
| HP71 | Cannot investigate transfusion reaction patterns at a facility.  | Appropriate options not used to enter transfusion reaction data on patients.   | LOW              | LOW        | Report available for all transfusion reaction data, sorted by patient. Includes both reactions associated with specific units and those not associated with specific units.  | SRS# P83<br>P87<br>P88<br>SCR# P17 |
| HP72 | Cannot identify potential cases of transfusion transmitted disease.                                    | 1) Tests for transfusion follow-up [LRBLTX] option not used to define tests and limits which could be indicative of transfusion transmitted disease.<br>2) Report Transfusion follow-up tests [LRBLTXA] option not reviewed.<br>3) Some test results may not be entered in computer. | LOW              | LOW        | Report Transfusion follow-up tests uses parameters defined in the Tests for transfusion follow-up [LRBLTX] option and searches patients who have been transfused within a specified time period for test values which may be indicative of possible transfusion transmitted disease. | SRS# P89<br>SCR# P17               |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control  | Trace   |
|------|---|---|------------------|------------|---|---|
| HP73 | Cannot review crossmatch:transfusion ratios by treating specialty.                                  | Treating specialties assigned to patient treating specialty upon admission. Transfusion may have been ordered by someone else.          | NONE             | MOD        | Crossmatch/Transfusions by Specialty/Physician [LRBLAA] option is available for review but report should be checked against paper records for accuracy.     | SRS#<br>P42<br>P85<br>P90<br><br>SCR#<br>P17        |
| HP74 | Cannot review data on patients crossmatched for a specified date range to review ordering patterns. | NONE  | NONE             | NONE       | Crossmatch: Transfusion report [LRBLRCT] option provides data on patients crossmatched by date/time crossmatched which is used to review ordering patterns. | SRS#<br>P40<br>P41<br>P42<br>P91<br><br>SCR#<br>P17 |
| HP75 | Cannot evaluate utilization patterns of autologous units  | 1) Autologous products not defined in the BLOOD PRODUCT file (#66) as such.<br>2) Autologous units not logged in to inventory properly. | LOW              | LOW        | Autologous disposition report [LRBLJB] option can be used to review autologous program utilization patterns.  | SRS#<br>P92<br><br>SCR#<br>P17                      |



Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                              |
|------|---|--|------------------|------------|--|------------------------------------|
| HP76 | Cannot identify units with prolonged infusion time, based on local parameters, for use in Transfusion committee review. | 1) Maximum Infusion Time(Min) field (#.24) in the BLOOD PRODUCT file (#66) not defined for specific products.<br>2) Accurate sign-out date/time not entered using Disposition – relocation option.<br>3) Accurate date/time not entered when entering Blood transfusion results for a specific unit. | LOW              | LOW        | Report Prolonged transfusion times is available which lists instances of prolonged transfusion times based on the entry in the Maximum Infusion Time (Min) field (#.24) for specific blood products in the BLOOD PRODUCT file (#66). | SRS# P93<br>SCR# P17               |
| HP77 | Cannot readily obtain administrative data requested on the annual AABB questionnaire.                                   | Not all administrative data entered into computer.   | NONE             | LOW        | Report Blood Bank Administrative Data [LRBLA] is designed to capture data requested on the annual AABB questionnaire. It is requested by date range.   | SRS# P94<br>SCR# P17               |
| HP78 | Cannot monitor inappropriate transfusion requests for QA purposes.  | The Tests To Check field (#.04) and Pre-Op Tests To Check field (#.08) are not defined with high/low values of lab tests for specific blood products to be monitored.  | LOW              | LOW        | Inappropriate transfusion requests report can be printed to review ordering patterns. Requests which are outside tolerances defined for the specific blood product are included in the report.                                       | SRS# P40<br>P41<br>P95<br>SCR# P17 |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard  | Causes  | Level of Concern | Likelihood | Method(s) of Control   | Trace                              |
|------|---|---|------------------|------------|--|------------------------------------|
| HP79 | Cannot perform outcome analysis on blood component therapy based on post-transfusion lab results. | Tests for inclusion in transfusion report [LRBLSET] option not used to define tests to be used to monitor outcome analysis.   | LOW              | LOW        | Patient transfusions and hematology results [LRBLPCH] option report can be requested by patient for a selected date range. Report lists components transfused by date along with laboratory test results based on tests defined through option Tests for inclusion in transfusion report [LRBLSET] option. | SRS# P96<br>SCR# P17               |
| HP80 | Cannot review all transfusions within a specific date range.                                      | NONE  | NONE             | NONE       | Transfusion data report provides a hard copy of all units transfused within a specified date range and includes a variety of information useful to the Blood Bank supervisor for QA reviews.   | SRS# P97<br>P98<br>P99<br>SCR# P17 |
| HP81 | Patient blood bank data is archived and is no longer available for lookup.                        | NONE  | NONE             | NONE       | Patient Blood Bank data is not included in the algorithm which is used for archiving other Laboratory results.   | SRS# P100<br>SCR# P10              |
| HP82 | Cannot provide a hard copy listing of patients who have clinically significant antibodies.        | 1) Users do not enter patient antibody data in the Antibodies Identified field (#.075) when entering test data.<br>2) Site did not use option Edit Corresponding Antigen/ Antibody to define clinically significant antibodies. | LOW              | LOW        | Antibodies by patient [LRBLPAB] option provides a listing of patients who have clinically significant antibodies.  | SRS# P101<br>SCR# P10              |

Patient Intended Uses Hazard Analysis

| HA#  | Hazard   | Causes   | Level of Concern | Likelihood | Method(s) of Control   | Trace                 |
|------|--|--|------------------|------------|--|-----------------------|
| HP83 | Cannot provide a hard copy listing of patients who have Blood Bank data for reference during computer downtimes. | 1) Users do not enter patient antibody data in the Antibodies Identified field (#.075) when entering test data.<br>2) Site did not use option Edit Corresponding Antigen/Antibody [LRBLSNO] to define clinically significant antibodies. | LOW              | LOW        | Patient antibody report (long-list) [LRBLPRA] option is available to provides a hard copy listing of patients with Blood Bank data that can be used during computer downtimes.           | SRS# P102<br>SCR# P10 |
| HP84 | Cannot accurately determine workload statistics for local and national reports.                                  | Site did not accurately enter workload codes in specific Blood Bank files according to the guidelines included in the Laboratory Planning and Implementation Guide V 5.2.  | NONE             | LOW        | When workload codes are defined for particular tests, products, and procedures, workload is automatically collected as a background activity whenever data is entered into the computer. | SRS# P103<br>SCR# N/A |