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 **V*IST*A** 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.

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	Likeli hood	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. 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 SRS# D20 SRS# D83 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 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 SRS# D34 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 SRS# D12 SCR# D7

HA#	Hazard	Causes	Level of Concern	Likeli hood	Method (s) of Control	Trace
HD5	Unable to determine person performing a particular step in data entry process.	NONE	NONE	NONE	Assignment of respon-sibility automatic based on identity of individual determined upon log-in to system.	SRS# D12 SRS# D14 SCR# D7
HD6	Unable to use bar-code identification of donor units.	1) Site not barcode labeling products processed in-house. 2) Barcode Scanner malfunctions.	NONE	LOW	If bar-code scanner not used, two separate individuals are required to complete the Labeling/rel ease of donor units	SRS# D15 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 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 SCR# D2
HD11	Erroneous Unit ID's assigned to Donor upon data entry of historical data.	Data entry error.	LOW	LOW	Software searches BLOOD IN-VENTORY file (#65) for possible duplicate entries.	SRS# D18 SCR# N/A

HA#	Hazard	Causes	Level of Concern	Likeli hood	Method(s) of Control	Trace
HD12	Donation interval for allogenic donor not long enough.	1) Duplicate record created due to HA# HD1. 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 SRS# D10 SRS# D23 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 SRS# D22 SCR# D11 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 SRS# D31 SCR# D13

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SRS# D31 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 SRS# D29 SRS# D31 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. 2) Preprinted donor history forms not used. 3) Copy of the Permanent donor deferral report [LRBLDPD] not brought to site.	LOW	LOW	If donor is appropriatly marked as “permanentl y deferred” further processing of donation when return to main donor site is not possible.	SRS# D10 SRS# D26 SRS# D27 SRS# D28 SRS# D29 SCR# D14 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 SRS# D10 SRS# D26 SRS# D27 SCR# D14 SCR# D15

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 "permanent ly deferred".	SRS# D9 SRS# D10 SRS# D27 SRS# D28 SCR# D14 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. 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 SRS# D30 SRS# D31 SRS# D32 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 SRS# D34 SRS# D35 SCR# D9
HD23	Cannot determine which units have been collected using a specific lot # collection bag.	1) Data entry error. 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 SRS# D36 SCR# D17 SCR# D7

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SRS# D40 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 SRS# D21 SCR# D7
HD26	Special comments not available to donor room personnel.	1) The Permanent deferral/special comments [LRBLDEF] option not used to enter data. 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 SRS# D30 SRS# D31 SRS# D32 SCR# D14 SCR# D16

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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 SCR# D16
HD28	Future donation episode data entered.	NONE	NONE	NONE	Software screens date entered. No future dates allowed.	SRS# D38 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 SCR# D4

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SRS# D14 SRS# D42 SCR# D4 SCR# D7 SCR# D18
HD31	No record of person entering component preparation info in computer.	NONE	NONE	NONE	Software automatical -ly assigns this based on identity of user upon log in to computer.	SRS# D11 SRS# D12 SRS# D14 SCR# D7 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 SRS# D41 SCR# D3
HD33	Component preparation policies/procedu res not followed.	1) Data entry errors. 2) Specific component entries in the BLOOD PRODUCT file (#66) not fully defined.	LOW	LOW	Collection disposition/c omponent preparation [LRBLDCP] option checks parameters defined in the BLOOD PRODUCT file (#66) for validity.	SRS# D47 SCR# D19

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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 SRS# D46 SRS# D47 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 SRS# D48 SCR# D20
HD36	Cannot determine date/time stored for a particular component.	NONE	NONE	NONE	This is a required field.	SRS# D11 SRS# D42 SCR# D4 SCR# D18 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 SCR# D18 SCR# D19

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 SRS# D50 SRS# D51 SRS# D52 SRS# D65 SRS# D66 SRS# D67 SRS# D72 SCR# D21 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 SRS# D7 SRS# D53 SRS# D69 SCR# D22

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SRS# D59 SRS# D69 SCR# D4
HD42	TDD inadvertently not performed for a particular Donor ID.	1) Worklists provided by software not used. 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 SRS# D59 SRS# D69 SRS# D76 SCR# D23 D26
HD43	Appropriate personnel not notified if positive TDD marker testing entered on a unit previously released to inventory.	Users with LRBLSUPER 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 LRBLSUPER key if such a unit is tested.	SRS# D57 D105 SCR# D24

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 LRBLSUPER key can edit TDD result testing after a unit is released.	LOW	LOW	Distribution of the LRBLSUPE R key should be restricted to the BB supervisor and/or designee.	SRS# D57 SRS# D58 SCR# D6 SCR# D24
HD45	Donor unit with positive TDD testing is labeled.	TDD testing report not reviewed prior to labeling of product.	NONE	NONE	Unit automatical -ly quarantined if attempt is made to release a non-autologous unit with a positive TDD result.	SRS# D68 SRS# D69 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 SRS# D61 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 IN-VENTORY file (#65) for possible duplicate Unit ID. Does not allow.	SRS# D62 SCR# D7 SCR# D29

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 IN-VENTORY file (#65) upon Labeling/release. If data not in BLOOD IN-VENTORY file (#65) unit is not available for patient use.	SRS# D64 SCR# D7

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 2) Software requires a second individual to perform ABO/Rh recheck before unit can be relocated. 3) Warning message given when entering crossmatch results on units with no ABO/Rh recheck results.	SRS# D3 SRS# D50 SRS# D51 SRS# D52 SRS# D65 SRS# D66 SRS# D72 SRS# D73 SCR# D21 SCR# D27 SCR# D28

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SRS# D66 SCR# D21 SCR# D27

HA#	Hazard	Causes	Level of Concern	Likeli hood	Method(s) of Control	Trace
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 automatical -ly quarantined Requires a higher level of security access to make changes in status of a component previously placed in quarantine.	SRS# D9 SRS# D68 SRS# D69 SRS# D70 SRS# D71 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 INVENTOR Y file (#65) upon labeling/rel ease of component.	SRS# D74 SCR# D7 SCR# D29

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 1) Invalid choices assigned by system administrator. 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 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. 2) When processing a unit to Send Elsewhere, software prompts user that testing is incomplete. Override required.	SRS# D76 SRS# D77 SCR# D7

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SRS# D34 SRS# D77 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. 2) System crash during labeling/release of donor unit.	NONE	LOW	Warning message given when ABO/Rh confirm-atory testing not done when entering crossmatch results.	SRS# D64 SRS# D78 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". 2) User doesn't utilize the Inventory ABO/Rh worklist. 3) Printer malfunctions during print of worklist.	LOW	LOW	User is alerted when crossmatch results are entered on a unit with no ABO/Rh confirmator y results available. Unit CANNOT be relocated if ABO/Rh confirmator y results are not available.	SRS# D64 SRS# D78 SCR# N/A

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SRS# D34 SRS# D79 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 SRS# D80 SCR# D7 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 SRS# D80 SRS# D81 SRS# D82 SCR# D7 SCR# D8

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. 2) Demographic data entry incomplete.	NONE	LOW	User is prompted for information during data entry. Various reports are available to assist the donor group chair-persons.	SRS# D8 SRS# D10 SRS# D84 SRS# D85 SCR# N/A
HD63	Cannot target certain groups for donor recruitment.	1) Group affiliation information not entered when processing donors. 2) Antigen typing on specific donors not entered. 3) Demographic data incomplete.	NONE	LOW	Standardiz-ed letters can be generated based on: 1) Group affiliation or 2) Lack of a specific antigen to be used for donor recruiting.	SRS# D84 SRS# D85 SRS# D86 SRS# D87 SRS# D90 SRS# D91 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. 2) Demographic data incomplete.	NONE	LOW	Considerati on should be given to this prior to removing ex-donors from the database.	SRS# D88 SRS# D90 SRS# D91 SRS# D92 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. 2) Demographic data incomplete.	NONE	LOW	All donation attempts should be entered into the computer.	SRS# D89 SRS# D90 SRS# D91 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 SRS# D94 SRS# D95 SCR# N/A

HA#	Hazard	Causes	Level of Concern	Likeli hood	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	Acknow-ledge donor award by deletion [LRBLDAWARD] option available to acknow-ledge donor awards for various donation types.	SRS# D96 SRS# D97 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 acknowledg ement can be made.	SRS# D98 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 effectivenes s of recruiting efforts.	SRS# D10 SRS# D84 SRS# D85 SRS# D99 D106 D107 D108 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 D100 SCR# N/A

HA#	Hazard	Causes	Level of Concern	Likeli hood	Method(s) of Control	Trace
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 D104 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 manufact-ure.	SRS# D14 D102 D103 SCR# N/A

Inventory Intended Uses Hazard Analysis

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 I57 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 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 SRS# I2 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. 2) Integrity report available to check for incomplete records so site can remedy.	SRS# I10 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 SCR# I3

HA#	Hazard	Causes	Level of Concern	Likeli hood	Method(s) of Control	Trace
HI6	Barcode reader/ scanner not used to scan Unit ID.	1) Site not utilizing scanner technology. 2) Tech choose to not use scanner. 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 SCR# I3
HI7	Barcode reader/ scanner not used to scan the blood product code.	1) Site not utilizing scanner. 2) Tech chooses to not use scanner. 3) Scanner is not working for some reason. 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 SCR# I3
HI8	Barcode reader/ scanner not used to scan the expiration date.	1) Site not utilizing scanner. 2) Tech choose to not use scanner. 3) Scanner is not working. 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 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. 1) Invalid choices assigned by system administrator. 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 SCR #I3

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 I16 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 Future date/times are not allowed.	SRS #I17 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 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 SCR# I16 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. 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 SCR# I1

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 SCR# I6 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 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. 2) The text appearing on the shipping invoice can be modified to satisfy most blood suppliers.	SRS# I21 I26 SCR #I11 #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 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. 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 I27 SCR# I12

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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. 2) During log in, the user is always prompted to review log in data for accuracy and can edit if necessary.	SRS# I30 SCR# I22
HI24	1) Inappropriate units can be edited using the option Edit pooled blood product. 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 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 SCR# I7

HA#	Hazard	Causes	Level of Concern	Likelihood	Method (s) of Control	Trace
HI26	1) Cannot determine the cost of blood products between various suppliers. 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 I34 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. 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) All historical data stays with the unit.	SRS# I35 SCR# I6
HI28	Inventory units have future disposition dates.	NONE	NONE	NONE	Software prohibits entry of a future disposition date.	SRS #I36 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 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 I37 SCR# I5

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 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". 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 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 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 SCR# I9

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. 2) Barcode scanners greatly reduce the incidence of transcription errors. 3) Option available to edit unit log in if necessary and report can be reprinted.	SRS# I40 I43 SCR# 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# I5 SCR# I7 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# I9 SCR# I7 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# I44 I50 I91 SCR# I6

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 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 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 SCR# I15

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 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 I51 I52 SCR# I16 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 I54 SCR# I3

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 I55 SCR# 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# I56 SCR# 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# I57 I58 SCR# 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. 2) Software calculates unit volume of divided units based on original volume and the number of aliquots prepared.	SRS# I59 SCR# I3

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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# I24 I53 I60 SCR# I10 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# I61 SCR# I10 I22
HI53	A future disposition date is entered.	NONE	NONE	NONE	Software prohibits entry of a future disposition date.	SRS# I62 SCR# I3

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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 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 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 I66 SCR# I3

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. 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 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 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. 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 SCR# I8

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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 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. 2) Antibody ID not entered in the Antibodies Identified field (#.075) during Enter Test Data [LRBLPET] option. 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. 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 SCR# I19

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 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. 2) Antibody ID not entered in the Antibodies Identified field (#.075) when entering patient test data. 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 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 SCR# I19

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. 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 SCR# I19 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 I77 SCR# I21
HI67	Expired units can be issued.	1) Disposition – relocation [LRBLIDR] option not used at time of issue. 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 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 SCR# I23

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. 2) Supervisory edit option [LRBLSI] should have restricted access.	SRS# I80 I81 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 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 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 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 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 SCR# I19 I25
HI75	Cannot determine units in inventory which have been phenotyped.	1) Site does not enter phenotyping results in system. 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 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 SCR# I25

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 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 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 SCR# I3 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 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 SCR# I6 I14

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 basis and after unexpected system down time to check the BLOOD INVENTORY file (#65) for missing data.	SRS# I92 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 I96 I97 SCR# I6 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 I94 SCR# I1 I6 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 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 SCR# I18

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 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 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 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 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. 2) Special typing charges (inventory) [LRBLRIS] option exists to allow recording of any special typing charges by the supplier.	SRS# I33 I34 I103 I104 SCR# I6

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# I33 I34 I103 I104 I105 I106 I107 SCR# 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# I19 I108 I109 SCR# 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# I110 SCR# 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 re-check counts [LRBLC] option exists which tallies the ABO/Rh rechecks results entered in computer.	SRS# I111 SCR# 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# I112 SCR# N/A

Patient Intended Uses Hazard Analysis

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 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. 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 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 SCR# P7

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# P7 P37 SCR# 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# P8 SCR# 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# P9 P11 P52 P86 SCR# P1 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# N/A SCR# P2

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# P2 SCR# P16 P19 P25 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# P10 SCR# 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# P12 SCR# 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. 1) Invalid choices assigned by system administrator. 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# P13 P79 SCR# P3

HA#	Hazard	Causes	Level of Concern	Likeli hood	Method(s) of Control	Trace
HP13	Barcode scanner not used to read Unit ID.	1) Site does not use scanner. 2) Scanner not working. 3) User chooses to not use scanner	NONE	LOW	Software accommodates both scanner and manual input of Unit ID interchangeably.	SRS# P14 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 P16 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 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 P18 SCR# P3 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 SCR# P13 P15

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# P20 SCR# P12 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. 2) Unknown unit transfusion reaction [LRBLPTXR] option allows entry of transfusion reaction not associated with a specific unit. Transfusion reaction data always displayed along with demographic data when present.	SRS# P21 P83 P87 SCR# 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# P22 SCR# P18

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# P2 P23 SCR# P19 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# P24 SCR# 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# P25 P27 P62 SCR# 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# P26 SCR# P1

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P26 P28 SCR# 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# P29 SCR# N/A
HP27	Cannot use computer to place orders for pretransfusion or other Blood Bank related tests.	1) Computer system is down. 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# P30 SCR# P20
HP28	Ward personnel cannot view test description information.	1) Menu Test description information [LREV] option not assigned to appropriate personnel. 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# P31 SCR# N/A

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P32 SCR# 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# P33 SCR# 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# P2 P34 SCR# P3 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. 2) Site did not define the specimen used for pretrans-fusion 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# P2 P35 P36 P57 SCR# P16 P20 P25 P26

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P2 P7 P37 P95 SCR# 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 surgica blood order edit [LRBLSMS] option. 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 P39 SCR# 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# P40 SCR# P8 P17

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P43 SCR# 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# P44 SCR# 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# P45 SCR# 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# P46 SCR# P3 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# P47 P69 SCR# P3 P14
HP41	Cannot evaluate positive direct antiglobulin tests to see if drug induced.	1) Site not fully utilizing Pharmacy package. 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# P48 P49 SCR# P11

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P50 SCR# P4 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# P51 SCR# P4 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# P11 P52 P53 P86 SCR# P1

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 in date 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# P16 P55 P56 SCR# 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. 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# P16 P35 P36 P57 P58 SCR# P20 P25 P26

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P59 SCR# P23 P24 P25 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# P16 P60 SCR# P23 P24 P25 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# P61 SCR# 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# P27 P62 SCR# N/A

HA#	Hazard	Causes	Level of Concern	Likeli hood	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). 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 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 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 P65 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 SCR# P22 P25

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P67 SCR# P3 P22
HP56	Historical ABO/Rh record on a patient can be deleted.	NONE	NONE	NONE	Software prohibits actual deletion of historical ABO/Rh.	SRS# P68 SCR# 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. 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# P69 P70 SCR# P3 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# P72 SCR# P3

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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# P6 P73 SCR# 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. 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# P6 P74 SCR# 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# P75 SCR# P16 P26

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 SCR# P6 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 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). 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 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 SCR# N/A

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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 SCR# P9
HP68	Transfusion data for a future date/time is entered.	NONE	NONE	NONE	Future transfusion date/time data is prohibited.	SRS# P84 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. 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 P41 P42 P85 P91 SCR# P17

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 P87 P88 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. 2) Report Transfusion follow-up tests [LRBLTXA] option not reviewed. 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 SCR# P17

HA#	Hazard	Causes	Level of Concern	Likeli hood	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# P42 P85 P90 SCR# 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# P40 P41 P42 P91 SCR# P17
HP75	Cannot evaluate utilization patterns of autologous units	1) Autologous products not defined in the BLOOD PRODUCT file (#66) as such. 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# P92 SCR# P17

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 2) Accurate sign-out date/time not entered using Disposition – relocation option. 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 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 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 P41 P95 SCR# P17

HA#	Hazard	Causes	Level of Concern	Likeli hood	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 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 P98 P99 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 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. 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 SCR# P10

HA#	Hazard	Causes	Level of Concern	Likeli hood	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. 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 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 SCR# N/A