APPENDIX G
VISTA BLOOD BANK USER MANUAL
SAFETY CRITICAL REQUIREMENTS

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VISTA Laboratory Blood Bank Software Version 5.2 Safety Critical Requirements

Introduction

As defined by the Food and Drug Administration (FDA), a safety critical requirement is one that is implemented to ensure the safety, quality, identity, potency and purity of blood/blood products and/or donor safety. These requirements are based on a variety of regulatory and accreditation requirements of the FDA, the American Association of Blood Banks (AABB) and the College of American Pathologists (CAP). Consistent with the software and the other documentation, the safety critical requirements detailed in this document have been divided into three major categories, (i.e., donor, inventory and patient). These categories relate to the file structures used for data storage as well as to the logical groupings of functional activities in the blood bank.

Information provided in Appendix E of the Blood Bank User's Manual provides details for each of the Blood Bank files. Included are some ancillary files which are not fully detailed in this document, but have some software control and should be used as an additional reference.

In Appendix F of the Blood Bank User Manual, a listing is provided of the fields and subfields for the files used for data storage for each of the major categories. The format selected indicates the hierarchical arrangement of the file structure. In addition to the field number and field name, a designation has been included to indicate whether changes in verified data for that specific field for that specific donor/unit/patient are tracked by being entered on the audit trail. Fields that exist, but are not currently in use have been included and have been so designated. For those fields which are not accessible for editing or which serve as the reference point for the subfields, an 'NA' has been used.

A listing of the safety critical requirements is provided on the following pages. These are also referenced in the software requirement specifications in Appendix H and the hazard analysis in Appendix 1. Appendix H of the Blood Bank User's Manual provides additional details on the software requirements specifications. These will include the design safeguard, e.g. algorithms, truth tables, error checking, record locking, etc. to ensure that the safety critical requirements(s) is met.

BLOOD PRODUCT file (#66) Data Elements and Descriptions of Use

Because the BLOOD PRODUCT file (#66) plays a significant role in the software design and is referenced frequently in the safety critical requirements, the listing of the data elements is provided here as a quick reference.

Field #	Field Name	Description Of Use
.01	NAME	Identifies product.
.02	ABBREVIATION	Characteristic used to access/identify this specific component.
.03	CAN BE MODIFIED	Determines whether this product can be modified into other products.
.04	IDENTIFIER	Determines whether this file entry can be acc component/derivatives with IDENTIFIER = BB) should be accessible at any prompt which references component.
.05	PRODUCT CODE	Characteristic used to by bar code reader or by manual entry to access this specific component.
.055	DOD CODE	Used by the Department of Defense.
.06	MODIFICATION CRITERIA	Determines the edit template used when this product is selected during modification of another product.
.07	PATIENT/PRODUCT ABO	Determines whether units selected for a patient must be identical or must be red cell compatible.
.08	PATIENT/PRODUCT RH	Determines whether units selected for a patient must be identical or must be red cell compatible.
.09	PATIENT/PRODUCT REQUIREMENT	Determines whether units must be crossmatched or if the product contains large volumes of plasma that should be compatible with the patient's red cells.
1	VOLUME (ml)	Characteristic
.11	DAYS LEFT	Calculates the new expiration date required if this product is prepared from another product present in inventory.

Field #	Field Name	Description Of Use
.12	ANTICOAGULANT/ ADDITIVE	Prevents mixing of components during modifications (e.g., a product that has CPDA- I cannot be modified to a product that has CPD as the anticoagulant).
.13	COLLECTION/PREP HOURS	In the donor module options only, (i.e., indicates the maximum time allowable between the Date/Time Collection Started field (#65.54,4.2) and the Date/Time Stored field (#65.66, .03).
.135	MAXIMUM STORAGE DAYS	In the donor module option, calculates the default shown for the Expiration Date field (# .04), in the Inventory Module option, Screens the Entry For the Expiration Date/ Time field (#.06) for potential data entry errors.
.14	MODIFIED BEFORE RELEASE	Prevents issue/relocation of products which must be modified such as Frozen Red Blood Cells which must be deglycerolized before issue.
.15	CAN BE REQUESTED	Prevents selection of products that should not be accessed/selected.
.16	PATIENT SPECIMEN AGE ALLOWED	Prevents selection of units of this product for specimens. IF the difference between the current time and the BLOOD SAMPLE DATE/TIME exceeds the entry in this field for this product.
.18	RETYPE AFTER PREPARATION	Determines whether units of this product must be retyped before issue/release. If YES, units which are created using the Disposition-not transfused [LRBLIDN] option will appear on the Inventory ABO/Rh testing worksheet generated by the [LRBLIW] option.
.19	CONTAINS RED BLOOD CELLS	(1) Determines whether units of this product retyped before issue/release. If YES, units will not be able to be released using the Disposition-relocation [LRBLIDR] option until required recheck results are entered. (2) Used for sorting purposes on some reports.
.21	MAX AGE FOR PEDIATRIC USE	Determines whether units of this product can be modified into pediatric units.
.22	PEDIATRIC PRODUCT	Determines which products can be accessed when modifying a unit in inventory using the Pediatric unit preparation [LRBLPED] option; (both must also have the same entry in the BLOOD PRODUCT file (#66), Anticoagulant/Additive field (#12).

Field #	Field Name	Description Of Use
.23	SPECIFIC GRAVITY	In the Pediatric unit preparation [LRBLPED] option, (i.e., used to convert the volume of the unit in mls. into an equivalent wt. in gms).
.24	MAXIMUM INFUSION TIME(MIN) 	Used to determine which units should be included in the Prolonged transfusion times report. The report is generated by the Prolonged transfusion times [LRBLPIT] option.
.25	AUTOLOGOUS/DIRECTED COMPONENT	Determines whether additional data is needed to restrict selection of the unit for the intended patient Restricted For field (#8) of the BLOOD INVENTORY file (#65).
.26	ADMINISTRATIVE CATEGORY	Used to determine which units should be incl several different reports, (e.g., Phenotyped Units Available [LRBLIPH] and Blood Bank Administrative Data [LRBLA] options).
.27	POOLED PRODUCT	Determines whether a unit specific product can be accessed through the Edit Pooled Blood Product [LRBLJM] option; by the Blood bank inventory integrity report [LLRBLII] option to determine which fields may have missing data.
.28	ASK BAG LOT #	Determines whether the BLOOD INVENTORY file (#65), Bag Lot # field (#1) should be included in the edit template used Disposition-not transfused [LRBLIDN] option when modifying units.
1	DESCRIPTION Subfile (#66.09) Description field (#.01)	Intended for use for display purposes in future.
2	SYNONYM Subfile (#66.021) Synonym field (#.01)	Used for look-up access purposes only.
3	MODIFY TO Subfile (#66.03) Number field (#.001)	Internal file number.
.01	MODIFY TO	Determines which products can be accessed when modifying a unit in inventory using the Disposition-not transfused [LRBLIDN] option.
.02	NOT ONLY ONE ALLOWED	Determines whether more than one product may be created when modifying a unit in inventory using the Disposition-not transfused [LRBLIDN] option.
4	SUPPLIER Subfile (#66.01) Preference number field (#.01)	Controls the display order.
.01	SUPPLIER Name of supplier	Determines characteristics based on subfields detailed below.
.02	COST	Calculates expenses for reports.
.03	ADDRESS LINE 1	Used for look-up and information purposes only.

Field #	Field Name	Description Of Use
.04	ADDRESS LINE 2	Used for look-up and information purposes only.
.08	ZIP CODE	Used for look-up and information purposes only.
.09	PHONE	Used for look-up and information purposes only.
.01	LOT #	Not currently used by the software.
.02	Expiration Date	Not currently used by the software.
5	CRITERIA FOR USE Subfile (#66.05), Criteria For Use field (#.01)	Intended for use for display purposes in the future
6	TESTS TO CHECK Subfile (#66.04), Tests To Check field (#.01)	Used to identify/flag non pre-op requests that exceed the audit criteria (may enter more than one).
.02	SPECIMEN	Type of specimen used for test.
.03	> OR < TEST VALUE	Value to be used to identify/flag non pre-op component requests that exceed the audit criteria.
7	REQUISITION INSTRUCTIONS Subfile (#66.07), Requisition Instructions field (#.01)	Intended for use for display purposes in the future.
8	PRE-OP TESTS TO CHECK Subfile (#66.08), Pre-Op Tests To Check field (# .01)	Used to identify/flag pre-op component requests that exceed the audit criteria (may enter more than one).
.02	SPECIMEN Type of specimen used for test .03 > OR < TEST VALUE	Value to be used to identify/flag pre-op component requests that exceed the audit criteria.
.01	WKLD CODE	Used for workload captures by the Disposition -not transfused [LRBLIDN] option and the Collection disposition/ component preparation [LRBLDCP] option.

Donor Safety Critical Requirements

As with the file structure and the documentation, the safety critical requirements are divided three major categories, donor (D), inventory (I) and patient (P). Within each of the major categories, the term 'general' has been used for those SCR which involve more than one functionality.

1. Donor Functions

SCR#	Functionality	Description
D1	Donor - General	A unique cumulative donor record must exist for each individual blood donor/patient.
D2	Donor - General	A system to ensure confidentiality of donor Records must be established and followed.
D3	Donor - General	A unique cumulative donation sub-record must exist for each individual blood donation.
D4	Donor - General	Data should be accurate and the potential for data entry errors should be minimized when ever possible.
D5	Donor - General	A system must exist to track changes made to verified data for specified data elements.
D6	Donor - General	A system must exist to require a higher level of security access in order to perform specified functions, (e.g., removal of units from quarantine).
D7	Donor - General	Each facility must have a record-keeping system which makes it possible to trace any unit of blood/blood component from source to final disposition, to recheck the records applying to a specific unit and to investigate adverse reactions manifested by the recipient.
D8	Donor - General	Facility records be complete, retrievable in a reasonable period of time, preserved and protected from accidental or unauthorized destruction of modification and maintained for the required retention period.
D9	Donor - General	Autologous units and directed donor units should be made available for a patient before homologous blood is selected.
D10	Donor-Registration, Screening, and Collection	Allogeneic (homologous and directed) blood donors may and Collection not donate whole blood more often than every 8 weeks.
D11	Donor-Registration, Screening, and Collection	If blood donors are not at least 17 years of age, they and Collection must have permission to donate. Prospective donors who are considered minors may be accepted if written consent to donate has been obtained in accord with applicable law.

SCR#	Functionality	Description
D12	Donor-Registration, Screening, and Collection	Elderly prospective donors may be accepted at the and Collection discretion of the blood bank physician.
D13	Donor-Registration, Screening, and Collection	Donor history questions must meet the requirements of and Collection the FDA and the AABB.
D14	Donor-Registration, Screening, and Collection	All permanently deferred donors must be appropriately and Collection identified in order to prevent the donation or the inappropriate release of units to inventory.
D15	Donor-Registration, Screening, and Collection	All permanent deferral information must be traceable, and Collection including changes in status..
D16	Donor-Registration, Screening, and Collection	Donors who require special handling should be and Collection identified so that appropriate procedures can be implemented.
D17	Donor-Registration, Screening, and Collection	All units collected in bags of a specific lot must be able and Collection to be identified in case of potential recalls.
D18	Donor-Component Preparation	A mechanism must exist to track all collection dispositions and to track the storage of each/all components prepared.
D19	Donor-Component Preparation	Components must be prepared within the maximum time allowable for that specific component.
D20	Donor-Component Preparation	If the dating period for the product is < 72 hours, the expiration date must include the hour of expiration.
D21	Donor-Processing/ Transfusion transmitted disease (TDD) marker testing	Current ABO/Rh test results must be in agreement transmitted disease (TDD) with the donor's historical record, and if a discrepancy marker testing exists, release of units of blood/ blood components to inventory requires a higher level of security access.
D22	Donor-Processing/ Transfusion transmitted disease (TDD) marker testing	Implementation of the required transfusion transmitted disease (TTD) transmitted disease marker testing must be done as marker testing required by the FDA.
D23	Donor-Processing/ Transfusion transmitted disease (TDD) marker testing	A system should exist for detecting missing specimens transmitted disease (TTD) in order to minimize the possibility of errors in marker testing transfusion transmitted disease marker testing.

SCR#	Functionality	Description
D24	Donor-Processing/ Transfusion transmitted disease (TDD) marker testing	If results are entered after the unit of blood/ blood transmitted disease (TDD) component has been released on an emergency basis, marker testing the results must be immediately evaluated to determine whether the quality or the safety of the product is adversely affected.
D25	Donor-Labeling/Release	Units cannot be released to inventory, even under emergency circumstances, until current ABO/Rh testing has been entered.
D26	Donor-Labeling/Release	Under routine circumstances, allogeneic should only be released to inventory after all of the required testing has been completed and meets current FDA requirements.
D27	Donor-Labeling/Release	Sufficient safeguards should be in place in the labeling/release procedure to prevent labeling errors.
D28	Donor-Labeling/Release	Whenever possible, technology should be utilized to verify the accuracy of labeling instead of relying on a second person.
D29	Donor-Labeling/Release	A unique cumulative unit record must be created in the Inventory File when units are released from the Donor File in order to prevent data entry errors.
D30	Donor-Labeling/Release	A mechanism must exist to track the final disposition of each and all components prepared.

Inventory Safety Critical Requirements

2. Inventory Functions

SCR#	Functionality	Description
11	Inventory General	A unique cumulative unit history record must exist for each individual blood component.
12	Inventory General	A system to ensure confidentiality of patient records/transfusion histories must be established and followed.
13	Inventory General	Data should be accurate and the potential for data entry errors should be minimized whenever possible.
14	Inventory General	A system must exist to track changes made to verified data for specified data elements.
15	Inventory General	A system must exist to require a higher level of security access in order to perform specified functions.
16	Inventory General	Each facility must have a record-keeping system that makes it possible to trace any unit of blood/blood component from source to final disposition, to recheck the records applying to a specific unit and to investigate adverse reactions manifested by the recipient.
17	Inventory General	Facility records be complete, retrievable in a reasonable period of time, preserved and protected from accidental or unauthorized destruction of modification and maintained for the required retention period.
18	Inventory General	Autologous units and directed donor units should be made available for a patient before homologous blood is selected.
19	Inventory General	Required A.BO/Rh confirmatory testing must be done after the unit has been labeled to permit detection of labeling errors.
110	Inventory Receipt, Shipment, and Discard of Units	If the dating period for the product is 72 hours, the and Discard of Units expiration date must include the hour of expiration.
111	Inventory Receipt, Shipment, and Discard of Units	If units are shipped outside of the collecting facility, all and Discard of Units required transfusion transmitted disease marker testing must have been performed and units must be handled in accordance with FDA regulations.

SCR#	Functionality	Description
112	Inventory Receipt, Shipment, and Discard of Units	Facilities need to maintain shipping records indicating and Discard of Units that appropriate temperatures have been maintained.
113	Inventory - Confirmation Testing of units	Test results for confirmatory ABO/Rh must be in of units agreement with the unit's historical record and the unit may not be released for transfusion if a discrepancy exists.
114	Inventory – Modification of Units	Critical information regarding patient assignments (if Units any), special phenotypings, CMV antibody status, etc. is maintained when a unit is modified.
115	Inventory – Modification of Units	If any unit within a pooled product is Rh positive, the Units pooled product should be labeled as Rh positive.
116	Inventory – Modification of units	Appropriate procedures must be in place to minimize Units risks to employees who may handle biohazardous materials., i.e. units with incomplete or positive test results for transfusion transmitted disease markers.
117	Inventory - Modification of units	Records must be maintained of the lot numbers of all Units bags used in the manufacturing process and a specific lot must be able to be identified in case of potential recalls.
118	Inventory - Issue\relocation of units for transfusion	Delays in providing appropriately tested units for units for transfusion should be minimized.
119	Inventory - Issue/relocation of units for transfusion	Before a unit is released for transfusion, current test units for transfusion results should be complete and compared with the patient history to detect possible ors in ABO/Rh or a previous history of a clinically significant antibody.
120	Inventory - Issue\relocation of units for transfusion	Required ABO/Rh confirmatory testing must be units for transfusion completed before the unit is released for transfusion.
121	Inventory - Issue\relocation of units for transfusion	Units shall not be issued for transfusion if the visual units for transfusion inspection indicates the presence of an abnormal color or physical appearance.
122	Inventory - Issue\relocation of units for transfusion	Units should not be transfused after the expiration units for transfusion date & time indicated on the unit.

SCR#	Functionality	Description
123	Inventory - Issue\relocation of units for transfusion	Units which require further modification, such as units for transfusion frozen red blood cells, must not be issued until further modification has been completed.
124	Inventory - Issue\relocation of units for transfusion	A label or tie tag with the required information must units for transfusion be attached to the unit before it is issued for transfusion.
125	Inventory - Phenotyping of units	A standardized coding system should be utilized for units identifying both RBC and HLA antigens and antibodies in order to minimize problems associated with free text.
126	Inventory - Release of units to stock/available inventory	Autologous units which are collected preoperatively stock/available inventory must be segregated and used solely for this purpose unless the donor-patient and the donated unit meet all of the allogeneic donor requirements.

Patient Safety Critical Requirements

3. Patient Functions

SCR#	Functionality	Description
P1	Patient - General	A unique cumulative patient history record must exist for each patient that includes the ABO/Rh, clinically significant antibodies, transfusion reactions and units transfused.
P2	Patient - General	A system to ensure confidentiality of patient records/transfusion histories must be established and followed.
P3	Patient - General	Data should be accurate and the potential for data entry errors should be minimized whenever possible.
P4	Patient - General	A system must exist to track changes made to verified data for specified data elements.
P5	Patient - General	When changes are made in data which has been previously transmitted outside of the laboratory, there must be a means to clearly identify the original and the corrected data.
P6	Patient - General	A system must exist to require a higher level of security access in order to perform specified functions, (e.g., approval of the status change to 'assigned' for units with incompatible crossmatches which may be transfused with the Blood Bank Medical Director's approval.
P7	Patient - General	A standardized coding system should be utilized for identifying RBC antigens and antibodies in order to minimize problems associated with free text.
P8	Patient - General	Supervisors should review test results and exception reports.
P9	Patient - General	Each facility must have a record-keeping system which makes it possible to trace any transfusion from receipt of the unit to final disposition, including, but not limited to, confirmatory testing, pretransfusion testing (if applicable) and issue/relocation.
P10	Patient - General	Facility records, including patient ABO/Rh results for the past 12 months and any previous history of clinically significant antibodies must be retrievable in a reasonable period of time, preserved and protected from accidental or unauthorized destruction or modification and maintained for the required retention period.

SCR#	Functionality	Description
P11	Patient - General	In order to provide appropriate clinical information to the patient's MD, the patient's physician should be notified of abnormal test results.
P12	Patient - Old records	Patients with a previous history of a clinically significant antibody or a transfusion reaction should be identified so that appropriate blood components can be selected.
P13	Patient - Specimen receipt and order entry	Requests for blood components must contain sufficient order entry on for positive identification of the recipient, i.e. at least the first and last names and an identification number.
P14	Patient - Specimen receipt and order entry	Before a unit is released for transfusion, current test order entry results must be compared with the patient history to detect possible errors in ABO/Rh or a previous history of a clinically significant antibody.
P15	Patient - Specimen receipt and order entry	Before a specimen is used for pretransfusion testing, a order entry qualified person in the transfusion service must be confirm the identification information on the request form and the specimen label which includes at least the recipient's first and last names, identification number and the date of the sample collection.
P16	Patient - Specimen receipt and order entry	If the patient has been transfused in the preceding three order entry months with a blood component containing red blood cells or if the history is uncertain or unavailable, the specimen used for pretransfusion testing must be obtained from the patient within three days of the scheduled transfusion.
P17	Patient - Specimen receipt and order entry	Because of the risks inherent to blood transfusion, order entry there needs to be an active blood usage review process.
P18	Patient - Specimen receipt and order entry	Autologous and directed units should be made order entry available for patient before allogeneic (homologous) blood is selected.
P19	Patient - Specimen receipt and order entry	Access to components which require further processing order entry should be limited.
P20	Patient - Test result entry (other than crossmatching)	Each blood sample must be tested for ABO/Rh and for (other than crossmatching) unexpected antibodies as part of the pre-transfusion testing.
P21	Patient - Unit selection and pretransfusion testing	Access to units which are expired should be limited pretransfusion testing.
P22	Patient - Unit selection and pretransfusion testing	Required ABO/Rh confirmatory testing must be done to pretransfusion testing permit detection of labeling errors.

SCR#	Functionality	Description
P23	Patient - Unit selection and pretransfusion testing	Recipients shall receive ABO specific whole blood or pretransfusion testing ABO compatible red blood cell components.
P24	Patient - Unit selection and pretransfusion testing	Rh negative recipients should receive Rh negative red pretransfusion testing blood cells.
P25	Patient - Unit selection and pretransfusion testing	Criteria for selection of units for transfusion must be pretransfusion testing defined and should be component specific and deviations must be approved and documented per the facility's SOP.
P26	Patient - Unit selection and pretransfusion testing	Criteria for required testing must be defined and pretransfusion testing should be component specific.
P27	Patient - Unit selection and pretransfusion testing	The rationale for the release of units which are not pretransfusion testing ABO/Rh compatible must be provided by the requesting physician and must be documented.
P28	Patient - Unit selection and pretransfusion testing	Required compatibility testing must be performed and pretransfusion testing results acceptable before the unit is made available for issue for subsequent transfusion.
P29	Patient - Unit selection and pretransfusion testing	Before a unit is released for transfusion, current test pretransfusion testing results should be compared with the patient history to detect possible errors in ABO/Rh or a previous history of a clinically significant antibody.
P30	Patient - Unit selection and pretransfusion testing	A label or tie tag with the recipients first and last pretransfusion testing names and identification number, the donor unit number and the interpretation of the compatibility tests, if performed, must be attached to the unit before it is issued for transfusion.
P31	Patient - Unit selection and pretransfusion testing	If clinically significant antibodies are demonstrated or pretransfusion testing if there is a history of such, units should lack the corresponding red cell antigen.
P32	Patient - Investigation of adverse effects	A mechanism must exist to record and evaluate all diverse effects cases of suspected t transmitted disease.
P33	Patient - Investigation of adverse effects	Each facility shall have a system for documenting adverse effects transfusion complications in the patient's record.