# APPENDIX H
# VISTA BLOOD BANK USER MANUAL SOFTWARE REQUIREMENTS SPECIFICATIONS

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# VISTA Blood Bank Software Version 5.2 Software Requirements Specifications

## Introduction

The Software Requirement Specifications (SRS) provide detailed information regarding the functionality of the software. These requirements are based on the intended uses detailed in Appendix F and the Safety Critical Requirements detailed in Appendix G. A variety of tools are available for use in meeting these specifications. In general, the data dictionary for specific files provides a great deal of control through the data type, pattern matches, and input transform requirements. However, specific algorithms have been included in the software routines where appropriate and Kernel Security and Menu Management provides additional tools (i.e., menu access and security keys for meeting the specifications).

As with the file structure and the rest of the documentation, the Software Requirement Specifications are divided into one general (G) and three major categories, donor (D), inventory (I) and patient (P). The numbering system used indicates which category is assigned to that particular specification (e.g., SRS#G1) is the first in the general category.

In order to assist in cross-referencing material and minimizing duplication whenever possible, the information in the column labeled "Functionality" roughly corresponds to the Safety Critical Requirements in Appendix G and the options. However, the term "general" has been used for those SRS which apply to more than one functionality. In addition, the Safety Critical Requirements do not include those SRS that relate only to the generation of administrative and management reports.

## Software Requirements Specifications General

| SRS# | Functionality | Description |
|------|---------------|-------------|
| G1 | General | Requires both an access code and a totally encrypted verify code that must be changed every 90 days in order to access computer system. |
| G2 | General | Requires assignment of specific menu options and specific security keys in order to access/enter donor data. |
| G3 | General | Utilizes an automatic time-out algorithm and site specified time-out parameters to prevent potentially inappropriate access, in the event that an authorized user were to breach the usual security measures and leaves the CRT unattended while still signed on. |
| G4 | General | Provides on-line documentation and help prompts based on the data dictionaries for the files used by the donor menu options/routines. |
| G5 | General | Provides detailed data dictionaries for each file which provide all of the specific details, including name and number of the field, the global location, the type of data, etc. Additional details are provided in Appendix F that includes a detailed description of the data elements for the various files as part of the Intended Uses. |
| G6 | General | Requires assignment of specific menu options and specific security keys in order to access/enter inventory/patient data. |
| G7 | General | For sites which are defined as multidivisional in the INSTITUTION file (#4), requires assignment of user access by division in order to access/enter data for a specific division. |
| G8 | General | For sites which are defined as multidivisional in the INSTITUTION file (#4), assigns the division of the user based on data entered during the sign-on process and uses this division for determining access as detailed in other specific SRS. |
| G9 | General | For sites which are defined as multidivisional in the INSTITUTION file (#4), allows user to change divisions during a 'session', providing the user has the appropriate access |
| G10 | General | Utilizes a variety of VA FileMan features and tools to routinely provide a $\leq$ 2-second average response time between prompts. |
| G11 | General | Provides an interface with a bar code reader as a peripheral device, connected in-line between the CRT and CPU via cables, which is able to read Stop Codes and Codabar symbology in accordance with the Uniform Blood Labeling Act. |
| G12 | General | Provides ability for the user facilities to document the software validation performed by the site. |
| G13 | General | Provides audit trail report of the changes in verified data. **Note:** This report requires a higher level of security to access. |
| G14 | General | Restricts data entry based on the data type and the input transforms for the specific field. |

# Donor Software Requirements Specifications

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D1 | Donor - General | Requires assignment of specific donor menu options and specific security keys in order to access/enter donor data. |
| D2 | Donor - General | Provides data dictionary for the files used by the donor menu options/routines. See Appendix G for a listing of the data elements in the BLOOD DONOR file (#65) and the BLOOD PRODUCT file (#66). |
| D3 | Donor - General | Provides the ability to set up a site parameter. A site parameter would indicate whether the ABO/Rh results should be moved to the BLOOD INVENTORY file (#65) when the unit is labeled/released because the ABO/RH recheck is performed prior to release. (LABORATORY SITE file (#69.9)), FIRST DEFAULT for DONOR). |
| D4 | Donor - General | Provides the ability set up a site parameter to indicate whether the bag lot # should be included in the edit template for entering collection data. (LABORATORY SITE file (#69.9), THIRD DEFAULT for DONOR). |
| D5 | Donor - General | Provides the ability to set up a site parameter to indicate whether the Donor SSN should be included in the edit template for registering a donor. (LABORATORY SITE file (#69.9), FOURTH DEFAULT for DONOR). |
| D6 | Donor - General | Provides the ability to set up a site parameter. A site parameter is to indicate whether ALT testing should be included in the edit template for entering TTD marker results and for evaluation of results during labeling/release. (LABORATORY SITE file (#69.9), FIFTH DEFAULT for DONOR). |
| D7 | Donor - General | Provides the ability to set up a site parameter. A site parameter is to indicate whether the HIV Antigen testing should be included in the edit template for entering TTD marker results and for evaluation of the results during labeling/release. (LABORATORY SITE file (#69.9), SIXTH DEFAULT for DONOR). |
| D8 | Donor - General | Includes set of codes as choices of potential outcomes of each donation attempt (i.e., whole blood plasmapheresis, cytapheresis, and no donation). |
| D9 | Donor- General | Specifies donation type for each donation, (i.e., homologous, autologous, therapeutic, or directed). |
| D10 | Donor - General | Creates a unique cumulative donor record for each individual blood donor/patient that includes a variety of identification and demographic information. |
| D11 | Donor - General | Creates a unique cumulative donation sub-record for each individual donation/deferral date. |
| D12 | Donor - General | Updates record immediately upon data entry. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D13 | Donor - General | Locks donor record during data entry to prevent access by another terminal/user for specified options. |
| D14 | Donor - General | Tracks the person performing various steps in the process (i.e., person entering data into the computer). |
| D15 | Donor - General | Accommodates the use of a bar code reader for entry of the unit ID. |
| D16 | Donor - General | Tracks changes in verified data for specific data elements defined in the BLOOD DONOR file (#65.5). See Section IX for listing by data element. |
| D17 | Donor-Old Records | Accommodates entry of historical donor information if deemed appropriate and identifies the specific donation dates for which data was entered via that option. |
| D18 | Donor-Old Records | During data entry of each unit ID, checks the unit IDs already in existence in the BLOOD INVENTORY file (#65) to identify potential duplicates/inappropriate entries. |
| D19 | Donor-Old Records | Once the donor record has been created, prevents access to donor through the 'Old records' option. |
| D20 | Donor-Registration, Screening and Collection | During the registration of each blood donor, checks existing entries in the BLOOD DONOR file (#65.5) for duplicate donors, based on comparison of the name and/or a combination of the first letter of the last name, sex, and date of birth. |
| D21 | Donor-Registration, Screening and Collection | Prevents assignment of "duplicate" unit IDs based on a search of existing entries in the BLOOD DONOR file (#65.5). |
| D22 | Donor-Registration, Screening and Collection | Calculates age of donor based on his/her date of birth, then checks age of donor to see if outside limits and uses algorithm to display warning message if donor is $\leq 17$ or >65 years of age. |
| D23 | Donor-Registration, Screening and Collection | If the DONATION TYPE = HOMOLOGOUS, checks the previous donation date to determine if at least 8 weeks has elapsed between the last donation date and the current donation date being entered. Requires additional security access and different option to enter data if collection has already been completed and tracks entry of data for inclusion on audit trail. |
| D24 | Donor-Registration, Screening and Collection | Allows editing of donor history questions at the discretion of the facility in order to meet changes in regulatory and accrediting agency requirements. (Requires higher security level). |
| D25 | Donor-Registration, Screening and Collection | Allows editing of the donor consent at the discretion of the facility in order to meet changes in regulatory and accrediting agency requirements. (Requires higher security level). |
| D26 | Donor-Registration, Screening and Collection | Provides a report of permanently deferred donors for use at remote sites where the computer system is not accessible and preprinted donor history forms may not be available for all potential donors. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D27 | Donor-Registration, Screening and Collection | Prevents entry of collection data if allogeneic (homologous) donor is permanently deferred. Requires additional security access and a different option to enter data if collection has already been completed, and tracks entry of data for inclusion on audit trail. |
| D28 | Donor-Registration, Screening and Collection | If an autologous donor or therapeutic phlebotomy patient is permanently deferred is selected for data entry, displays warning message. |
| D29 | Donor-Registration, Screening and Collection | IF donor is permanently deferred, includes an informational warning message at the bottom of the header on the page used to record the results of the physical exam, (i.e., either page 2 or 3 ) depending on the number of questions. |
| D30 | Donor-Registration, Screening and Collection | Allows entry of free text special comments in the Donor Comments field (#9) for future reference |
| D31 | Donor-Registration, Screening and Collection | Prints donor specific Donor History (DH) forms upon command (i.e., DH forms contains the donor demographics, date of last donation, site specific donor, history questions, site specific donor consent, and a page to use for recording data from the modified physical exam). User can opt to print forms for only those donors in the print queue who can add donors to the queue, either individually or based on a specific group affiliation. User can also specify the collection site and donation date so the forms can be used either for the date on which they are printed or can be printed in advance for an upcoming drive. |
| D32 | Donor-Registration, Screening and Collection | Based on the entry in the Donor Comments field (#9), a 'Special Comments' section is included on the Donor History form. The Special Comments section is used to record the results of the physical exam, depending on the number of donor history questions. The DH form 'Special Comments' section is located at the bottom of the header of the page (i.e., page 2 or 3). |
| D33 | Donor-Registration, Screening and Collection | Provides field for indicating whether the donor had a donor reaction, making information available through a variety of report and inquiry options. |
| D34 | Donor-Registration, Screening and Collection | Provides link between autologous donor/patient and limits entry of patient restrictions for autologous units to patients in the PATIENT file (#2). |
| D35 | Donor-Registration, Screening and Collection | For autologous units, compares birthdate of donor to birthdate of the patient being selected for the entry in the BLOOD DONOR file (#65.5), Restricted For field (#5,1.2). |
| D36 | Donor-Registration, Screening and Collection | Provides field for the input of the bag lot # which can then be detailed in future FileMan search requests. |
| D37 | Donor-Registration, Screening and Collection | Prevents access for entry of collection information on donors entered through 'Old records'. |
| D38 | Donor-Registration, Screening and Collection | Prevents entry of future donation date/time. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D39 | Donor-Registration, Screening and Collection | Prevents entry of a collection completion date/time prior to the collection start date/time. |
| D40 | Donor-Registration, Screening and Collection | Calculates collection volume based on the gross weight, the empty bag weight and the specific gravity of whole blood. |
| D41 | Donor-Component Preparation | Limits access to the donor's most recent donation, i.e., user cannot specify a unit ID that is from other than the most recent donation. |
| D42 | Donor-Component Preparation | Tracks the date/time stored for each specific component of a specific unit ID. |
| D43 | Donor-Component Preparation | Evaluates the elapsed time between the collection time and the date/time stored for the specific component and prevents entry of data for a component for which the maximum allowable component preparation time has been exceeded based on the entry in the BLOOD PRODUCT file (#66), Collection/Prep field (#13). |
| D44 | Donor-Component Preparation | Expiration date field accommodates the entry of time. |
| D45 | Donor-Component Preparation | Evaluates the number of components being prepared against the bag type and prevents entry of more than the maximum that could be logically allowed (i.e., three components cannot be prepared from a double bag). |
| D46 | Donor-Component Preparation | Ensures that no more than 1 RBC component is prepared by excluding selection of other components in the BLOOD PRODUCT file (#66) that has a 'YES' in the Contains Red Cells field (#19). |
| D47 | Donor-Component Preparation | Excludes selection of components based on a comparison of the anticoagulant entered for the collection for the specific component based on the entry in the BLOOD PRODUCT file (#66), Anticoagulant/ Additive field (#12). |
| D48 | Donor-Component Preparation | Calculates the date portion of the expiration date based on the donation date and entry in the BLOOD PRODUCT file (#66), Maximum Storage Days field (#.135) for the specific component. If the entry in the Maximum Storage Days field (#.135) is a whole number, the calculation will be in the format of a date only. Whereas, if the entry is a decimal, the calculation will be in the format of a date and time. |
| D49 | Donor-Processing/TTD Marker Testing | Expedites data entry for donor IDs by incrementing the unit IDs and displaying that number as the default IF the next logical unit ID exists. |
| D50 | Donor-Processing/TTD Marker Testing | Checks current ABO/Rh results for the specific donor unit against the donor's historical record. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D51 | Donor-Processing/TTD Marker Testing | If ABO/Rh unit rechecks are performed prior to the release of the unit to inventory, rather than after the unit is released to inventory and data is entered, compares recheck information to original processing result interpretations. However, the original ABO/Rh are NOT displayed at the time of data entry. |
| D52 | Donor-Processing/TTD Marker Testing | Prevents the same tech from entering both original and recheck results for ABO/Rh based on a comparison of the user identification and the entry in the Tech Entering-ABO Interp field (#10.2) for the original results. |
| D53 | Donor-Processing/TTD Marker Testing | For the tests which have been recently implemented/discontinued (i.e., ALT and HIV Ag) checks the entries in the LABORATORY SITE file (#69.9) to determine whether testing is required and specifically which of these fields should be accessible during data entry. |
| D54 | Donor-Processing/TTD Marker Testing | For each unit ID, requires entry of test result interpretations for subsequent evaluation during labeling/release (no batch entry). |
| D56 | Donor-Processing/TTD Marker Testing | Allows generation of worklists for any of the tests. These lists include any incomplete testing, i.e., unit IDs for which there are no test results or which were added back to the worklist pending completion of repeat and/or confirmatory testing. |
| D57 | Donor-Processing/TTD Marker Testing | If results of the transfusion transmitted disease marker testing are entered as anything other than "negative" or "non-reactive" for units which have already been released to inventory on an emergency basis, a bulletin is automatically generated detailing the test result is sent to all holders of a specific security key, regardless of the donation type. |
| D58 | Donor-Processing/TTD Marker Testing | Prevents editing of results after components are released unless the user has a higher level of security access. |
| D59 | Donor-Processing/TTD Marker Testing | Provides reports of donor testing results to allow data review before the actual labeling of the donor units if so desired. Based on the number of transfusion transmitted disease markers evaluated, the report comes in two parts, each including donation/deferral date, donor unit ID, donor internal file number, permanent deferral status, ABO/Rh, test results, collection disposition, component, component expiration date, labeling tech and verifying tech. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D60 | Donor Phenotyping | Utilizes a standardized coding system (i.e., SNOMED) for identifying both RBC and HLA antigens and antibodies. |
| D61 | Donor Phenotyping | Prevents entry of same antigen as 'present' and 'absent'. |
| D62 | Donor-Labeling/Release | Prevents release of "duplicate" unit IDs to inventory based on a search of existing entries in the BLOOD INVENTORY file (#65). |
| D63 | Donor-Labeling/Release | Checks current ABO/Rh results for the specific donor unit and prevents release of units to inventory if no current ABO/Rh results exist. |
| D64 | Donor-Labeling/Release | Based on the entry in the LABORATORY SITE file (#69.9) for the DONOR OPTION FIRST DEFAULT field (#.02) (i.e., yes or no) determines whether ABO/RH recheck data entered prior to release of the unit to inventory is transferred to the BLOOD INVENTORY file (#65) when the unit is released. |
| D65 | Donor-Labeling/Release | Checks current ABO/Rh results for the specific donor unit against the donor's historical record and if ABO/RH recheck data is to be transferred to the BLOOD INVENTORY file (#65) when the unit is released, prevents release if a discrepancy exists. |
| D66 | Donor-Labeling/Release | Checks current ABO/Rh results for the specific donor unit against the donor's historical record, if ABO/RH recheck data is NOT to be transferred to the BLOOD INVENTORY file (#65) when the unit is released, allows release of unit after displaying warning message, requiring a higher level of security access to release the unit and generating a bulletin if unit is subsequently released with ABO/Rh discrepancy. |
| D67 | Donor-Labeling/Release | Provides detailed reports of donor's historical ABO/RH, permanent deferral (if appropriate), test results and component information for review prior to labeling and/or for hard copy documentation. |
| D68 | Donor-Labeling/Release | Prevents release of homologous, directed donor and therapeutic phlebotomy units with positive disease marker testing results. |
| D69 | Donor-Labeling/Release | Displays required transfusion transmitted testing for review based on site defined criteria in the LABORATORY SITE file (#69.9) for recent changes in TTD markers required, (i.e., ALT and HIV Antigen) FIFTH DEFAULT and SIXTH DEFAULT for BLOOD DONOR, respectively. |
| D70 | Donor-Labeling/Release | Evaluates test result interpretations and automatically changes the status of allogeneic, directed donor, and therapeutic phlebotomy units to quarantine if an attempt is made to label/release a unit for which the results indicate that the unit is not suitable for release to inventory, (i.e. positive or reactive). |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D71 | Donor-Labeling/Release | Requires a higher level of security access (LRBL SUPER key) to make changes in status from 'quarantine'. |
| D72 | Donor-Labeling/Release | Verifies accuracy of labeling of ABO/Rh via bar code reader by comparing the scanned ABO/RH label to the ABO/RH results for that unit ID. |
| D73 | Donor-Labeling/Release | Prevents the same tech doing both labeling and verifying if labeling/release is done manually based on a comparison of the identity of the user attempting to release the unit with the entry in the Tech Labeling field (#.06) for that specific unit. |
| D74 | Donor-Labeling/Release | For each component which is labeled/released, assigns a final disposition of RELEASE to each component in the BLOOD DONOR file (#65.5) and automatically creates a new entry in the BLOOD INVENTORY file (#65) with specific associated data elements. |
| D75 | Donor-Labeling/Release | Assigns the division of the user who is labeling/releasing the unit into inventory to the unit when the unit is assigned a final disposition in the BLOOD DONOR file (#65.5) and unit is entered into the BLOOD INVENTORY file (#65). |
| D76 | Donor-Labeling/Release | Puts an entry of 'YES' in the Pos/Incomp. Screening Tests field (#8) for both allogeneic (homologous) and autologous units which are released to inventory with incomplete transfusion transmitted disease marker testing such that those units are identified if subsequent attempts are made to modify the unit into another blood component or to ship the unit to another facility. |
| D77 | Donor-Labeling/Release | Puts an entry of 'YES' in the Pos/Incomp. Screening Tests field (#8) for autologous units released to inventory with positive/incomplete testing such that those units cannot be released for use by other patients and cannot be modified into other non-autologous components. |
| D78 | Donor-Labeling/Release | Based on entry in the LABORATORY SITE PARAMETERS file (#69.9) for the FIRST DEFAULT for the BLOOD DONOR, determines whether ABO/Rh confirmatory testing results are to be transferred to the BLOOD INVENTORY file (#65). If NO, data is not transferred and unit contains red cells (based on the entry in the BLOOD PRODUCT file (#66) for that component), adds the unit to the queue for inclusion on the Inventory ABO/Rh worklist. If YES, data is transferred and the unit in not added to the queue for inclusion on the Inventory ABO/Rh worklist even if the unit contains red cells. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D79 | Donor-Labeling/Release | For autologous and directed components, displays the name of the patient that the unit is 'RESTRICTED FOR' in an attempt to make sure that the unit is segregated appropriately. |
| D80 | Donor-Records | Provides on-line storage of a unique cumulative donor history for look back purposes. |
| D81 | Donor-Records | Provides ability to print a hard copy of the cumulative donor history before removal of the donors from the computer system for those donors who have not donated since a specified date. |
| D82 | Donor-Records | Requires use of the Print ex-donors [LRBLDEX] option to identify and purge ex-donors, (i.e., those who have not donated since the date specified). **Note:** Higher level of security also required. |
| D83 | Donor-Records | Provides mechanism for merging data (i.e., donation sub-records) from two donor records in the event that a duplicate donor record was created in error. |
| D84 | Donor-Recruitment | Provides report of all donors who indicated a specific group affiliation to provide feedback to donor group chairpersons. Users can specify search criteria for the group affiliation and the range of donation/deferral dates to be included. Reports are sorted by group affiliation and include donor name, ABO/Rh, donation/deferral date, donation/deferral code, donor reaction code and deferral reason. |
| D85 | Donor-Recruitment | Allows entry of data regarding donation group and collection site such that activity reports can be generated to provide feedback to donor group chairpersons. Users can specify search criteria based on the specific report selected. Reports include donor group affiliation, donation group and or collection site in addition to donor name, ABO/Rh, donation/deferral date, donation/deferral code, donor reaction code and deferral reason. |
| D86 | Donor-Recruitment | Provides mechanism for entry of standardized letters that can be generated, based on their group affiliation information, and used for specific targeted donor recruitment efforts. |
| D87 | Donor-Recruitment | Provides mechanism for entry of standardized letters that can be generated based on a search of all donors who lack a specific RBC antigen, and used for specific targeted donor recruitment efforts. |
| D88 | Donor-Recruitment | Provides mechanism for entry of standardized letters, which can be generated, based on a search of all donors who have not donated since a specified date to be used for specific targeted donor recruitment efforts. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| D89 | Donor-Recruitment | Generates post visit thank you letters for donors who attempted to donate based on the list of donors created when the donation/deferral data was entered through the Donor registration [LRBLDLG] option. Selecting the appropriate letter text based is on the donation/deferral code. |
| D90 | Donor-Recruitment | Generates letters for various groupings of donors based on specified criteria and type of letter selected, inserting the donor name and address for the addressee for those donors identified in the search criteria. |
| D91 | Donor-Recruitment | Generates labels for various groupings of donors based on specified criteria, printing the donor name and address on the label for those donors identified in the search criteria. |
| D92 | Donor-Recruitment | Generates a list of donors who have not donated since a specified date, including their name, date of last donation, group affiliation, home phone and work phone. |
| D93 | Donor-Recruitment | Provides report of all donors who have indicated their willingness to be called on an emergency basis, including their name, ABO/Rh, home phone, work phone, last donation date and donation/deferral code from the last donation date. **Note:** Users can specify ABO/Rh and date range for donations to be included on report. |
| D94 | Donor-Recruitment | Provides report of all donors who have indicated their willingness to be called on a regular basis for specified months and/or holidays, including their name, ABO/Rh, home phone, work phone, last donation date, and donation/deferral code from the last donation date. |
| D95 | Donor-Recruitment | Provides a report of all donors who have indicated their willingness to be called, to be apheresis donors, or for which no data was entered regarded their apheresis interest, sorted by ABO/Rh, including their name, ABO/Rh, home phone, work phone, last donation date, and donation/deferral code from the last donation date. |
| D96 | Donor-Recruitment | Calculates cumulative donation totals based on user specific formula and previously entered donation data and provides reports to be used for donor awards. |
| D97 | Donor-Recruitment | Provides a mechanism to enter the fact that a donor was given a gallon donor award and provides a report listing all donors who have received gallon donor awards. |

| SRS# | Functionality | Description |
|------|--------------|-------------|
| D98 | Donor-Recruitment | Provides report of all first time donors for a specified period based on the entry in the date registered/edited field, including collection site, donation group, donor name, work phone, donation/deferral date, donation/deferral type and the deferral reason. |
| D99 | Donor-Recruitment | Provides report of patient credits in order to provide feedback as the effectiveness of any recruitment efforts directed at the friends/relatives of patients, including the patient name, the donor name and the donation/deferral date. |
| D100 | Donor-Management | Provides a report of short draw collections, (i.e., for collection volume that is less than 405 ml), for a specified date range for supervisory review. The report is sorted by donation date, including unit ID, collection volume, donor reaction code, phlebotomist, donation/deferral date, and collection site. |
| D101 | Donor-Management | Provides report on donor temporary deferrals for a designated period, sorted by collection site and donation date. This report may be used for supervisory review in order to identify trends or problems with donor deferrals, including the collection site, deferral date, donation group, donor name, and deferral reason. |
| D102 | Donor-Management | Provides report of units that are quarantined/ discarded before component preparation for supervisory review including specified data fields (i.e., donation date, unit ID, collection site, collection time started and completed, collection volume, donor reaction code, phlebotomist, collection disposition and, collection disposition comment). |
| D103 | Donor-Management | Provides report of the collection and component preparation information, sorted by donation date, for supervisory review, including specified data fields (i.e., unit ID, type of donation, type of bag, anticoagulant, duration of collection in minutes, processing time in minutes, collection disposition, processing tech, blood components prepared, volume of components in ml and storage time). |
| D104 | Donor-Management | Provides blood product rejection report for those units which are collected, have components prepared, and have component dispositions of 'discard' or 'quarantine', sorted by donation/deferral date, including unit ID, collection time, collection volume, component preparation time, component preparation tech, component, date/time component stored, component net weight, component disposition, and component disposition comment. |

| SRS# | Functionality | Description |
|---|---|---|
| D105 | Donor-Management | Provides report of abnormal test results for a specified range of donor unit ID numbers to be used for supervisory review, including donation date, unit ID, donor internal file number and test(s) for which results were abnormal, (i.e., did not meet the criteria for subsequent release for transfusion, and excluding the donor names for confidentiality purposes). |
| D106 | Donor -Statistics | Provides report of all donors who attempted to donate for a specified date range, sorted by donation group, including donor name, work phone number, last attempt date, donation type, and cumulative donations. |
| D107 | Donor -Statistics | Provides report of scheduling information for specified date range for use in evaluating staffing needs, including donation/deferral date, arrival/appointment time, unit ID, donation/deferral code, donation type, and patient credit. |
| D108 | Donor -Statistics | Captures workload information and feeds data to non-Blood Bank laboratory files which is subsequently used for a variety of local and national reports, including the CAP Laboratory Management Index Program and DSS. |

# Inventory Software Requirements Specifications

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I1 | Inventory - General | Provides the ability to set up the entries in the BLOOD PRODUCT file (#66) for component specific requirements and algorithms to reflect facility-operating procedures. See Appendix G for a listing of the data elements and the descriptions of their use. |
| I2 | Inventory - General | Provides data dictionary for the files used by the inventory related menu options/routines. See Appendix F for a listing of the data elements in the BLOOD INVENTORY file (#65) and Appendix G for a listing of the data elements in the BLOOD PRODUCT file (#66). |
| I3 | Inventory - General | Provides the ability to specify whether the user should be asked for a bag lot number during data entry of unit modification information (Ask Bag Lot # field (#.28) in the BLOOD PRODUCT file (#66)). |
| I4 | Inventory - General | Allows editing of the text which appears on the shipping invoice, (SHIPPING INVOICE entry in the LAB LETTER file (#65.9)). |
| I5 | Inventory - General | Allows editing of the text which appears on the Inventory ABO/Rh testing worksheet generated by the option [LRBLIW], (INVENTORY WORKSHEET entry in the LAB LETTER file (#65.9)). |
| I6 | Inventory - General | Provides the ability for the site to define the RBC antigen that should be absent in units selected for patient(s) with a specific clinically significant antibody. (CORRESPONDING ANTIGEN entry in the FUNCTION FIELD file (#61.3)). |
| I7 | Inventory - General | Provides the ability for the site to define standardized canned comments that are accessible during the release of crossmatched/ assigned units back to available inventory (i.e., entries in the LABORATORY DESCRIPTIONS file (#62.5) for which the SCREEN = BB RELEASE). |
| I8 | Inventory - General | Provides the ability for the site to define standardized canned comments which are accessible during the data entry of disposition information for units with a 'DISPOSITION', 'TRANSFUSE', or 'MODIFY' (entries in the LABORATORY DESCRIPTIONS file (#62.5) for which the SCREEN = BB DISP). |
| I9 | Inventory - General | Provides the ability for the site to define standardized canned comments which are accessible during the data entry of confirmatory testing (rechecks) on units entries in the LABORATORY DESCRIPTIONS file (#62.5) for which the SCREEN = BB TESTING. |
| I10 | Inventory - General | Updates record immediately upon data entry. |

| SRS# | Functionality | Description |
|---|---|---|
| I11 | Inventory - General | Locks unit record during data entry to prevent simultaneous access via a different terminal/user for specified options. |
| I12 | Inventory - General | Accommodates the use of a bar code reader for entry of the unit ID using CODABAR symbology. |
| I14 | Inventory - General | Limits access to those units assigned to the same division as the user based on a comparison of the division assigned to the unit and the division currently assigned to the user. |
| I14 | Inventory - General | Tracks the person entering test results and/or performing various steps in the process (i.e., person entering the data into the computer). |
| I15 | Inventory - General | Tracks changes in verified data for specific data elements defined for the BLOOD INVENTORY file (#65). See Section IX for listing by data element. |
| I16 | Inventory - General | Tracks verified data entered for specific data elements defined for the BLOOD INVENTORY file (#65) and the LAB DATA file (#63) when data is entered/edited via the supervisory edit options requiring a higher level of security. |
| I17 | Inventory-Receipt, Shipment and Discard of Units | Requires entry of an exact date and time for the date/time received. |
| I18 | Inventory-Receipt, Shipment and Discard of Units | During data entry of each unit ID, checks the unit IDs already in existence in the BLOOD INVENTORY file (#65) to prevent entry of a duplicate unit ID of the same component. |
| I19 | Inventory-Receipt, Shipment and Discard of Units | For autologous and directed donor units being entered, records the appropriate Donation Type for the unit (i.e., component selected has an "A" or "D" in the Autologous/Directed field (#.25) in the BLOOD PRODUCT file (#66)). |
| I20 | Inventory-Receipt, Shipment and Discard of Units | For autologous and directed donor units being entered requires the entry of a patient name in the Restricted For field (#8) (i.e., component selected has an 'A' or 'D' in the Autologous/ Directed field (#.25) in the BLOOD PRODUCT file (#66)). |
| I21 | Inventory-Receipt, Shipment and Discard of Units | For autologous and directed donor units being entered to accommodates the entry of data in the Pos/Incomp. Screening Tests field (#8) if appropriate based on the results of the required TTD marker testing (i.e., component selected has an 'A' or 'D' in the Autologous/ Directed field (#.25) in the BLOOD PRODUCT file (#66)). |
| I22 | Inventory-Receipt, Shipment and Discard of Units | Limits re-entry of units to those with dispositions of 'S' (sent elsewhere) or 'R' (returned to supplier). |
| I23 | Inventory-Receipt, Shipment and Discard of Units | For units that are re-entered, transfers the original log-in and disposition data to appropriately designated fields to allow tracking of the original data Subfile (#65.15). See Appendix F for listing by data element. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I24 | Inventory-Receipt, Shipment and Discard of Units | The expiration date field accommodates entry of the time. |
| I25 | Inventory-Receipt, Shipment and Discard of Units | Accommodates the use of a bar code reader for entry of the expiration date using CODABAR symbology for dates that are in the mo-da-yr format. |
| I26 | Inventory-Receipt, Shipment and Discard of Units | In an effort to ensure appropriate handling, identifies potentially biohazardous units, by including a notation on the shipping invoice for units which were released from the donor module with incomplete results, (i.e., unit has a 'YES' in the Pos/Incomp. Screening Tests field (#8)). |
| I27 | Inventory-Receipt, Shipment and Discard of Units | Includes information on the shipping invoice to allow recording of information on shipping temperatures based on the wording entered in for in the LAB LETTER file (#65.9) for SHIPPING INVOICE. |
| I28 | Inventory-Receipt, Shipment and Discard of Units | Restricts selection of blood components to those in the BLOOD PRODUCT file (#66) with suppliers, etc. |
| I29 | Inventory-Receipt, Shipment and Discard of Units | Accommodates the use of a bar code reader for entry of the blood component (based on the product code) using CODABAR symbology. |
| I30 | Inventory-Receipt, Shipment and Discard of Units | Evaluates the validity of the expiration date based on the entry in the Maximum Storage Days field (#.135) for that blood component in the BLOOD PRODUCT file (#66). |
| I31 | Inventory-Receipt, Shipment and Discard of Units | When editing data on a pooled product, limits access to those units for which the component is defined as a pooled product based on the entry in the Pooled Product field (#.27) in the BLOOD PRODUCT file (#66). Requires a higher level of security access. |
| I32 | Inventory-Receipt, Shipment and Discard of Units | Utilizes an average volume for the component for the unit volume, based on the entry in the Volume field (#1) in the BLOOD PRODUCT file (#66) for that specific blood component. |
| I33 | Inventory-Receipt, Shipment and Discard of Units | Records the cost of the unit based on the entry in the Cost field (#.02) for the specific SUPPLIER for that specific component in the BLOOD PRODUCT file (#66). |
| I34 | Inventory-Receipt, Shipment and Discard of Units | For units which are 'RETURNED TO SUPPLIER', records the cost of the unit in the Return Credit field (#.14) of the BLOOD INVENTORY file (#65). |
| I35 | Inventory-Receipt, Shipment and Discard of Units | Accommodates the transfer of a unit to a different DIVISION within a multidivisional facility, providing the numeric portion of the parent institution in the INSTITUTION file (#4) for the new DIVISION matches that of the existing entry in the BLOOD INVENTORY file (#65), Division field (#.16). |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I36 | Inventory-Receipt, Shipment and Discard of Units | Prevents entry of future disposition dates. |
| I37 | Inventory-Receipt, Shipment and Discard of Units | Provides ability to edit verified information relating to the receipt (log-in) for a specific unit ID. (Requires a higher level of security access). |
| I38 | Inventory-Receipt, Shipment and Discard of Units | Provides ability to edit verified information relating to the disposition of a specific unit ID. (Requires a higher level of security access). |
| I39 | Inventory-Receipt, Shipment and Discard of Units | Provides ability to edit verified information relating to the contents of a pooled product for a specific unit ID. (Requires a higher level of security access). |
| I40 | Inventory - Confirmation testing of units | For units received from an outside facility or created through modification of other units, places unit in the queue for inclusion on the Inventory ABO/Rh testing worklist report if the blood component has a "YES" in the BLOOD PRODUCT file (#66), Contains Red Cells field (#.19). |
| I41 | Inventory - Confirmation testing of units | Compares confirmatory (recheck) test results to unit log-in information and displays warning message if results do not agree. |
| I42 | Inventory - Confirmation testing of units | Limits access to those units assigned to the same division as the user if data entry is done by unit (not if done by batch). |
| I43 | Inventory - Confirmation testing of units | Provides testing worksheet that includes unit #s of units to be tested for use in manually recording actual test results. |
| I44 | Inventory - Modification of Units | Creates a new entry in the BLOOD INVENTORY file (#65) for each new blood component created and assigns a final disposition to the original unit being modified. |
| I45 | Inventory - Modification of Units | Attaches appropriate pieces of data to the new unit created when a unit is modified. See Appendix F for a listing by data element. |
| I46 | Inventory - Modification of Units | Determines whether the ABO/Rh confirmatory testing information should be attached to the new unit created based on the entry in the BLOOD PRODUCT file (#66), Retype After Preparation field (#.18) for the component. |
| I47 | Inventory - Modification of Units | Places unit in queue for inclusion on the Inventory ABO/Rh testing worklist if the component created has a "YES" in the BLOOD PRODUCT file (#66), Retype After Preparation field (#.18). |
| I48 | Inventory - Modification of Units | Assigns ABO of pool based on the ABO of the first unit in the pool. |
| I49 | Inventory - Modification of Units | Assigns Rh of pool such that regardless of the order in which the units are pooled, the pool will be deemed Rh positive if any of the units in the pool were Rh positive. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I50 | Inventory - Modification of Units | If a product is divided calculates the number of aliquots into which the unit was divided and enters the data in the Pooled/Divided Units field (#4.4) for the original unit. |
| I51 | Inventory - Modification of Units | Prevents modification of an autologous component to a non-autologous component if an entry exists in the Pos/Incomp. Screening Tests field (#8) indicating that testing for transfusion transmitted disease markers is incomplete or positive. |
| I52 | Inventory - Modification of Units | Identifies units for further evaluation as to the suitability of the unit for modification if the unit has an entry in the Pos/Incomp. Screening Tests field (#8) indicating that the unit was released from the donor module with incomplete results. |
| I53 | Inventory - Modification of Units | The Expiration Date field (#.06) accommodates entry of the time of the BLOOD INVENTORY file (#65). |
| I54 | Inventory - Modification of Units | Restricts selection of component choices to those defined in the Modified To/From field (#.01) in the BLOOD PRODUCT file (#66) for the specific component of the unit being modified. |
| I55 | Inventory - Modification of Units | Determines whether more than one new unit can be created from a unit being modified based on the entry in the Not Only One Allowed field (#.01) in the BLOOD PRODUCT file (#66) for the specific component of the unit being modified. |
| I56 | Inventory - Modification of Units | Prevents multiple modifications to the same unit by excluding selection of units which already have a disposition entered. |
| I57 | Inventory - Modification of Units | Requires entry of a new unit ID for units being created, deleting the entire new entry in the BLOOD INVENTORY file (#65) if no new unit ID is entered. |
| I58 | Inventory - Modification of Units | Requires entry of a new unit ID for units being created, deleting dispositions in the BLOOD INVENTORY file (#65) for all units being modified into a pooled product if no new unit ID is entered for the pooled product. |
| I59 | Inventory - Modification of Units | If a unit is being divided/split into other components, evaluates the sum of the new unit volumes to make sure the sum does not exceed the volume of the original unit. |
| I60 | Inventory - Modification of Units | Calculates the expiration date of the unit being created based on the time of the data entry and the entry in the Days Left field (#.11) of the BLOOD PRODUCT file (#66). If the entry in the field is a whole number, the calculation will be a date only; whereas, if the entry is a decimal, the calculation will be in the format of a date and time. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I61 | Inventory - Modification of Units | Evaluates the calculated expiration date of the new unit against the expiration date of the unit being modified and displays alert message if the calculated expiration date of the new unit 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. |
| I62 | Inventory - Modification of Units | Prevents entry of future disposition dates. |
| I63 | Inventory - Modification of Units | If a pediatric component is being created, restricts unit selection to those of appropriate age based on the entry in the Max Age For Pediatric Use field (#21) in the BLOOD PRODUCT file (#66) for the component of the unit being modified. |
| I64 | Inventory - Modification of Units | If a pediatric component is being created, identifies low volume units, (i.e., those with a volume < 150ml. and displays the volume). |
| I65 | Inventory - Modification of Units | For pediatric units, calculates the volume of the unit being created using an algorithm based on the weight entered and the specific gravity of the component as defined in the BLOOD PRODUCT file (#66). |
| I66 | Inventory - Modification of Units | If a pediatric unit is being created, assigns a final disposition of 'MODIFIED' to units with 0ml remaining volume after the unit has been modified, (i.e., divided into aliquots). |
| I67 | Inventory - Modification of Units | Provides field for the input of the bag lot # which can then be detailed in future FileMan search requests IF the entry in the Ask Bag Lot # field (#.28) in the BLOOD PRODUCT file (#66) for the specific component being created is "YES". |
| I68 | Inventory - Issue/relocation of units for transfusion | Displays patient and unit information on the CRT for comparison with the label generated by the Unit CAUTION tag labels [LRBLILA] option after the necessary pretransfusion testing has been completed. |
| I69 | Inventory - Issue/relocation of units for transfusion | Displays alert message for any patients selected who have autologous and/or directed components in inventory, based on a match with the name entered in the BLOOD INVENTORY file (#65), Restricted For field (#8) of for the unit(s). |
| I70 | Inventory - Issue/relocation of units for transfusion | Displays 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. |
| I71 | Inventory - Issue/relocation of units for transfusion | Displays alert message for any patients selected who have an entry in either the Antibodies Identified field (#.075) or the Blood Bank Comments field (#.076) in the LAB DATA file (#63). |
| I72 | Inventory - Issue/relocation of units for transfusion | Limits selection of units for issue to those units that have a current status of 'assigned' and are assigned to the patient specified. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I73 | Inventory - Issue/relocation of units for transfusion | For patients with an entry in the LAB DATA file (#63), Antibodies Identified field (#.075) uses algorithm to evaluate unit phenotyping of allogeneic (homologous) units against each clinically significant patient antibody and prevents issue if unit phenotyping s not appropriate, (i.e., for each entry in the LAB DATA file (#63), Antibodies Identified field (#.075,.01) there must be a corresponding entry in the BLOOD INVENTORY file (#65), RBC Antigen Absent field (#.05) of the unit). |
| I74 | Inventory - Issue/relocation of units for transfusion | Prior to its issue for subsequent transfusion, evaluates the crossmatch requirements in the BLOOD PRODUCT file (#66) for the specific component of the unit selected to determine whether crossmatch results must be entered and prevents issue if a crossmatch is required and no results have been entered for the unit. |
| I75 | Inventory - Issue/relocation of units for transfusion | Uses an algorithm to prevent issue if no recheck results are entered based on component specific parameters defined in the BLOOD PRODUCT file (#66), (i.e., if CONTAINS RED CELLS = YES, an ABO recheck is required, and if unit is Rh negative, the Rh recheck is also required). |
| I76 | Inventory - Issue/relocation of units for transfusion | Prevents issue of unit if the inspection is entered as unsatisfactory for that specific relocation. |
| I77 | Inventory - Issue/relocation of units for transfusion | Prevents issue of unit if the inspection from any previous relocation of that unit is 'unsatisfactory'. |
| I78 | Inventory - Issue/relocation of units for transfusion | Evaluates the expiration date of the unit and displays a warning message if the unit is expired when compared to the current time. |
| I79 | Inventory - Issue/relocation of units for transfusion | Prevents issue of the unit if the component is one for which there is an entry of "YES" in the Modified Before Release field (#.14) in the BLOOD PRODUCT file (#66). |
| I80 | Inventory - Issue/relocation of units for transfusion | Prevents relocations with a date/time that is prior to the date/time the unit was assigned to the patient. |
| I81 | Inventory - Issue/relocation of units for transfusion | Prevents entry of a future relocation date/time. |
| I82 | Inventory - Issue/relocation of units for transfusion | Restricts relocation of units to standard locations within the same associated division based on the entries in the HOSPITAL LOCATION file (# 44) *unless* user enters a non-standard location and overrides the check. |
| I83 | Inventory - Issue/relocation of units for transfusion | Provides ability to edit verified information relating to the issue/relocation of a specific unit ID. (Requires a higher level of security access). |
| I84 | Inventory - Phenotyping of units | Utilizes a standardized coding system, (i.e., SNOMED, for identifying both RBC and HLA antigen typings on units). |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I85 | Inventory - Phenotyping of units | Provides the ability for the site to define which entries in the FUNCTION FIELD file (#61.3) are accessible during the data entry of unit RBC phenotyping results (entries in the FUNCTION FIELD file (#61.3) for which the SCREEN = AN). |
| I86 | Inventory - Phenotyping of units | Provides report 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. |
| I87 | Inventory - Phenotyping of units | Prevents entry of the same antigen in the BLOOD INVENTORY file (#65), RBC Antigen Present field (#.04) and RBC Antigen Absent field (#.05) for a given unit ID. |
| I88 | Inventory - Phenotyping of units | Updates donor record in the BLOOD DONOR file (#65.5) to reflect any unit phenotyping performed and entered for the donor unit after the unit has been released to the BLOOD INVENTORY file (#65). |
| I89 | Inventory-Release of units to stock/available inventory | Prevents release of the autologous/directed donor units for allogeneic (homologous) use, i.e., deletion of RESTRICTED FOR information, for units with a 'YES' in the Pos/Incomp. Screening Tests field (#8). |
| I90 | Inventory-Release of units to stock/available inventory | Prevents release of units from locations other than BLOOD BANK. |
| I91 | Inventory- Records | Tracks unit modification information for both the unit being modified and the unit(s) being created to include data on units MODIFIED TO or MODIFIED FROM as appropriate. |
| I92 | Inventory- Records | Uses algorithm to search the BLOOD INVENTORY file (#65) to look for missing data. See the listing on the next page for the specific data elements being evaluated. |

## BLOOD INVENTORY file (#65) Data Integrity Check

If data exists in fields in Column A, data should also exist in fields detailed in Column B.

| Column A | | Column B |
|---|---|---|
| Field #  Field Name | Data Entry | Field #  Field Name |
| | | |
| .04 COMPONENT | **(any entry)** | |
| *AND* | | |
| BLOOD PRODUCT file (#66), Pooled Product field (#.27) | **=YES** | |
| *AND* | | |
| BLOOD INVENTORY file (#65,), Source field (#.02) | **=SELF** | 9 MODIFIED TO/FROM (Subfile 65.091)<br>.001 NUMBER<br>.01 MODIFIED TO/FROM<br>.02 UNIT ID<br>.03 FROM/TO |
| | | |
| 4.1 DISPOSITION | **(any entry)** | 4.2 DISPOSITION DATE<br>4.3 DISPOSITION ENTERING PERSON |
| | | |
| 4.1    DISPOSITION | **MO** | 9 MODIFIED TO/FROM (Subfile 65.091)<br>.001 NUMBER<br>.01 MODIFIED TO/FROM<br>.02 UNIT ID<br>.03 FROM/TO |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I93 | Inventory- Records | Provides on-line storage of unit cumulative history for look- back purposes. |
| I94 | Inventory- Records | Provides ability to display/print a hard copy of the cumulative unit history. |
| I95 | Inventory- Records | Provides display of selected current information on the status of a unit, (i.e., unit ID, component, expiration date, ABO/Rh, patient assigned is currently assigned, date assigned if currently assigned, current location, and the date last relocated if unit has ever been relocated). |
| I96 | Inventory- Records | Provides the ability to print a hard copy of the cumulative unit history for units entered into the BLOOD INVENTORY file (#65) within a specified date range for which have a final disposition has been entered for use as a permanent record prior to the removal of the unit from the computer system. |
| I97 | Inventory- Records | Requires use of the Print units with final disposition [LRBLRUF] option to print a hard copy of the cumulative unit history in the BLOOD INVENTORY file (#65) in order to purge units for which a final disposition has been assigned. **Note:** Higher level of security access also required. |
| I98 | Inventory- Management | Provides report of units which have been tested for CMV antibody and for which results have been entered, allowing user to specify ABO/Rh and whether the report should include CMV Antibody positive or CMV Antibody negative units. |
| I99 | Inventory- Management | Provides report for a specified range of disposition dates for a specified disposition of units (as long as the disposition selected "TRANSFUSE") and can be used for supervisory or utilization review. The report is sorted by component and includes specified data fields; for most dispositions (i.e., unit ID, disposition date, supplier (source), ABO/Rh, date received, and disposition comment). IF 'MODIFY' is selected for the disposition, the report will include the unit ID, disposition date, the component into which the unit was modified and the new unit ID instead. |
| I100 | Inventory- Management | Provides report for a specified component (or all components), for a specified ABO/Rh (or all groups) of units which are available, (i.e., are in date and have no final disposition, sorted by component, by ABO/Rh and by expiration date within the ABO/Rh) which can be used for checking available inventory or for supervisory or utilization review. The Report includes ABO/Rh, unit ID, expiration date, current location, patient assigned is currently assigned, specimen date is appropriate, and totals for each ABO/Rh for each component. In addition, if the units autologous or directed, the patient's name is included even if the unit is not currently in the assigned status. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I101 | Inventory- Management | Provides a report for a specified component (or all components), for a specified ABO/Rh (or all groups), of units which have no final disposition (both indate and outdated), sorted by component, by ABO/Rh and by expiration date within the ABO/Rh which can be used for checking inventory and data entry records. The Report includes ABO/Rh, unit ID, expiration date, current location, patient assigned is currently assigned, specimen date is appropriate, and totals for each ABO/Rh for each component. In addition, if the unit is autologous or directed, the patient's name is included even if the unit is not currently in the assigned status. |
| I102 | Inventory- Management | Provides report of units in the "assigned" status in chronological order by date/time assigned for use evaluating which units should be canceled/released or for other types of supervisory/utilization review. Report includes the date/time crossmatched (or assigned if component does not require crossmatching), specimen date/time if appropriate, unit ID, ABO/Rh, current location, unit expiration date/time, component abbreviation and patient (name and SSN). |
| I103 | Inventory- Management | Provides ability to edit supplier charges for individual units before generating costing reports by invoice number or by transaction. |
| I104 | Inventory- Management | Provides ability to enter and/or edit supplier charges for special typing charges on individual units before generating costing reports for special typing charges. |
| I105 | Inventory- Management | Provides report of units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by supplier and by invoice # within the supplier for use in verifying billing invoices received. Report includes the component, Invoice #, date/time received, unit ID, expiration date, ABO/Rh, cost, disposition if already entered, counts, cost subtotals, and cost totals. |
| I106 | Inventory- Management | Provides report of units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by component, then by date received, then by ABO/Rh for use in verifying billing invoices received or for a review of transactions. Report includes the supplier, component, date/time received, invoice #, unit ID, ABO/Rh, expiration date, cost, disposition if already entered, counts, cost subtotals and cost totals. **Note:** Report differs from the report by invoice number in both format and count as the report by transaction includes unit modifications done on-site. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| I107 | Inventory- Management | Provides report of all special charges for units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by date/time received, for use in verifying billing invoices received. Report includes the unit ID, component, supplier (source), invoice #, date/time received, cost, log-in tech, ABO/Rh, volume and special typing charge. |
| I108 | Inventory- Management | Provides report detailing the disposition of autologous units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by date received, which have a disposition = TRANSFUSE, for supervisory and/or utilization review. Report includes the patient information, unit ID, # days present in inventory (calculated from date received to disposition date), component treating specialty of the patient when transfused and totals by type of component. |
| I109 | Inventory- Management | Provides report detailing the disposition of autologous units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by patient, which have a disposition TRANSFUSE, for supervisory and/or utilization review. Report includes the patient information, component, disposition, unit ID, # days present in inventory (calculated from date received to disposition date) and totals by type of component. |
| I110 | Inventory- Management | Provides report of all issues/relocations for a specified date range, sorted by date/time relocation, for use as a semi-permanent record/utilization review or as a quick reference in other clinical lab sections. Report includes the date/time relocation, unit ID, component abbreviation, inspection results, tech performing inspection, person issued to, patient name, location issued to, patient SSN, counts by location and by component, and totals by component. |
| I111 | Inventory- Statistics | Provides report of tallies for ABO recheck and Rh rechecks entered for units entered into the BLOOD INVENTORY file (#65) for a specified date range. |
| I112 | Inventory- Statistics | Captures workload information and feeds data to non-BB laboratory files which is subsequently used for a variety of local and national reports, including the CAP Laboratory Management Index Program and DSS. |

# Patient Software Requirements Specifications

| SRS# | Functionality | Description |
|------|--------------|-------------|
| P1 | Patient - General | Provides data dictionary for the file used by the patient related menu options/routines. See Appendix F for a listing of the data elements and the descriptions of their intended use. |
| P2 | Patient - General | Provides the ability to set up the entries in the BLOOD PRODUCT file (#66) for component specific requirements and algorithms to reflect the facility-operating procedures. See Appendix G for a listing of the data elements and the descriptions of their use. |
| P3 | Patient - General | Provides the ability set up a site parameter to indicate whether the fields for direct antiglobulin testing should be included in the edit template for entering ABO/Rh and antibody screening results. (LABORATORY SITE file #69.9, FIRST DEFAULT for PATIENT). |
| P4 | Patient - General | Provides the ability for the site to define standardized canned comments in the LABORATORY DESCRIPTIONS file (#62.5) which are accessible during data entry based on the entry in the Screen field (#5). See Appendix F for a listing of the data elements and the specific screen. |
| P5 | Patient - General | Provides the ability for the site to define consultation reports in the LAB LETTER file (#65.9) for both serum antibodies and positive direct antiglobulin tests, specifying standardized text to be included. |
| P6 | Patient - General | Provides the ability for the site to define (i.e., in the FUNCTION FIELD file (#61.3)) which antibodies are clinically significant and to designate what corresponding antigen should be lacking in units of red blood cells selected for a patient possessing that antibody. |
| P7 | Patient - General | Provides the ability for the site to define which test results should be displayed when accessioning blood bank specimens/entering blood component requests. |
| P8 | Patient - General | Provides the ability for the site to define types of transfusion reactions (i.e., in the BLOOD BANK UTILITY file (#65.4)) for use in data entry. |
| P9 | Patient - General | Creates a unique cumulative record for each individual patient. |
| P10 | Patient - General | Locks the patient record during data entry to prevent simultaneous access via a different terminal/user for specified options. |
| P11 | Patient - General | Updates cumulative patient data/transfusion record, including data on clinically significant antibodies, transfusion reactions and units transfused, immediately upon data entry. |

| SRS# | Functionality | Description |
|------|--------------|-------------|
| P12 | Patient - General | Displays patient transfusion record in reverse chronological order for a specified date range (in either detailed or summary format), including any history of previous transfusion reactions and entries in the LAB DATA file (#63), Antibodies Identified field (#075.01) or Blood Bank Comments field (#.076). User can also specify the component if so desired. |
| P13 | Patient - General | Limits access to those units currently assigned to the same division as the user. |
| P14 | Patient - General | Accommodates the use of a bar code reader for entry of the unit ID. |
| P15 | Patient - General | Tracks changes in verified data for specific data elements defined for the LAB DATA file (#63). |
| P16 | Patient - General | Tracks verified data entered for critical data elements as detailed for the LAB DATA file (#63) when entered via the supervisory edit options requiring a higher level of security. |
| P17 | Patient - General | Tracks the person entering the data into the computer. |
| P18 | Patient - General | Eliminates the need for duplicate data entry by also updating the unit record immediately upon data entry. |
| P19 | Patient - General | Displays patient demographics, including first and last names, social security number, date of birth, ABO/Rh of record (if one exists), and admitting diagnosis. |
| P20 | Patient - General | Displays alert message for any patients with a previous antibody history, regardless of division, based on entries in the LAB DATA file (#63), Antibodies Identified field (#.075.01). |
| P21 | Patient - General | Displays previous transfusion reactions, regardless of division, for both unit specific and non-unit specific reactions. |
| P22 | Patient - General | Displays alert message for any patients who have autologous and/or directed units in inventory, regardless of the division, based on a match in the BLOOD INVENTORY file (#65), Restricted For field (#8) of the unit. |
| P23 | Patient - General | Limits component selection to those components for which the Can Be Requested field (#15) in the BLOOD PRODUCT file (#66) = YES and are assigned to the appropriate division. |
| P24 | Patient - General | Provides variety of reports which can be used for supervisory review, including one which details the patient's ABO/Rh, AB Screen results, DAT results and serum/eluate antibodies, for the current specimen and a specified number of previous specimens, as well as entries in the LAB DATA file (#63), Antibodies Identified field (#.075) and Blood Bank Comments field (#.076). |
| P25 | Patient - General | Allows entry of special instructions in the LAB DATA file (#63), Blood Bank Comments field (#.076) regarding specific component requirements. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| P26 | Patient - Old Records | Allows entry of previous transfusion history, ABO/Rh, clinically significant antibodies, red cell phenotyping and transfusion reactions. |
| P27 | Patient - Old Records | Provides access to fields for entry of comments/special instructions that might be relevant for future reference. |
| P28 | Patient - Old Records | Prevents entry of historical unit information if unit is in current the BLOOD INVENTORY file (#65). |
| P29 | Patient - Old Records | Provides the ability to edit information entered from old records before computerization, (i.e., cannot access units in the BLOOD INVENTORY file (#65)). (Requires a higher level of security access). |
| P30 | Patient - Specimen Receipt and Order Entry | Provides the ability for the site to define Blood Bank tests in the LABORATORY TEST file (#60) which can be ordered by both Blood Bank personnel and other hospital personnel, (e.g., transfusion request, type and screen, etc.). |
| P31 | Patient - Specimen Receipt and Order Entry | Displays test description information based on entries for the specific test in the LABORATORY TEST file (#60). |
| P32 | Patient - Specimen Receipt and Order Entry | Provides the ability to accept orders for Blood Bank tests which are entered through other software packages and to update the status of the order as appropriate. |
| P33 | Patient - Specimen Receipt and Order Entry | Displays a listing of accessions for the patient for a specified accession area, including previous transfusion reaction information and data from the LAB DATA file (#63), Antibodies Identified field (#.075.01) and Blood Bank Comments field (#.076), if data exists. |
| P34 | Patient - Specimen Receipt and Order Entry | Provides the ability for the Blood Bank personnel to enter component requests, for those which can be requested, for a specific patient (entries in the BLOOD PRODUCT file (#66) for which CAN BE REQUESTED = YES). (Requires specific security key). |
| P35 | Patient - Specimen Receipt and Order Entry | Checks for previous specimens within 72 hours, regardless of division based on a search of the Date/Time Specimen Taken field (#.01) in the LAB DATA file (#63) for specimens = BLOOD. |
| P36 | Patient - Specimen Receipt and Order Entry | Evaluates age of patient specimens available for the specific accession area and appropriate division to determine whether any meet the requirements based on the entry in the Patient Specimen Age Allowed field (#16) of the BLOOD PRODUCT file (#66) for the specific component, preventing selection of a specimen which is too old. |
| P37 | Patient - Specimen Receipt and Order Entry | Displays most recent lab values for specified tests to allow auditing of the request based on locally defined parameters. |

| SRS# | Functionality | Description |
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| P38 | Patient - Specimen Receipt and Order Entry | Provides the ability for the site to define, by specific surgical procedure in the OPERATIONS (MSBOS) file (#66.5), by specific blood component, the maximum number of units which may be requested without additional justification. |
| P39 | Patient - Specimen Receipt and Order Entry | Evaluates pre-operative component requests against audit criteria as defined by the facility in the OPERATIONS (MSBOS) file (#66.5). |
| P40 | Patient - Specimen Receipt and Order Entry | Provides the ability for the site to define specific audit criteria for pre-op and non pre-op requests, by blood component in the BLOOD PRODUCT file (#66). |
| P41 | Patient - Specimen Receipt and Order Entry | Evaluates request against facility defined audit criteria, as defined in the BLOOD PRODUCT file (#66) for the specific component, and current lab results, flags requests which may be potentially inappropriate and allows for input of additional justification for those requests. |
| P42 | Patient - Specimen Receipt and Order Entry | Captures appropriate data for evaluation of ordering practices by treating specialty through a variety of different reports. |
| P43 | Patient - Specimen Receipt and Order Entry | Prevents deletion of accession if there is verified data entered for that accession. |
| P44 | Patient - Test Result Entry (other than crossmatching) | Creates the patient's historical ABO/Rh record based on the first entry of ABO/Rh results for the patient. |
| P45 | Patient - Test Result Entry (other than crossmatching) | Requires the use of a separate option to edit the patient's historical ABO/Rh record. (Requires a higher level of security access). |
| P46 | Patient - Test Result Entry (other than crossmatching) | Compares current ABO/Rh interpretations to patient history and displays a warning message if a discrepancy exists. |
| P47 | Patient - Test Result Entry (other than crossmatching) | Displays warning message on those patients who have no previous history to be used for comparison with current results. |
| P48 | Patient - Test Result Entry (other than crossmatching) | Automatically displays current listing of patient medications based on entries in the INPATIENT PHARMACY and the OUTPATIENT PHARMACY files if data entry in the DIRECT AHG INTERPRETATION field = POSITIVE. |
| P49 | Patient - Test Result Entry (other than crossmatching) | Upon request, displays/prints current listing of patient medications based on entries in the INPATIENT PHARMACY and the OUTPATIENT PHARMACY files. |
| P50 | Patient - Test Result Entry (other than crossmatching) | Tracks data entry errors for ABO/Rh when comparisons with previous history fail to match even if data is corrected since such errors might adversely affect the patient if not caught. |

| SRS# | Functionality | Description |
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| P51 | Patient - Test Result Entry (other than crossmatching) | If changes are made in verified data for ABO/Rh testing, antibody screening or direct antiglobulin testing, automatically generates a comment "reported incorrectly as" to indicate the original data. This comment is then included on the Blood Bank Test Report. |
| P52 | Patient - Test Result Entry (other than crossmatching) | Provides a cumulative Blood Bank Test Report which includes patient demographics (e.g., name, SSN, DOB, historical ABO/Rh), antibodies identified, test results of individual specimens (i.e., ABO, Rh, Direct AHG, Antibody Screen, Serum Antibody, Eluate Antibody), and if requested the current component requests. |
| P53 | Patient - Test Result Entry (other than crossmatching) | Creates a print queue upon entry of test results and provides the ability to either print the Blood Bank Test Report in batches for all patients in the queue or to delete the queue. |
| P54 | Patient - Test Result Entry (other than crossmatching) | Provides custom consultation reports for patients with irregular antibodies and/or positive direct antiglobulin tests based on data entered for specific specimen and file set-ups for the SNOMED FUNCTION FIELD file (#61.3) and the LAB LETTER file (#65.9). |
| P55 | Patient- Unit Selection & Pretransfusion Testing | Prevents selection of units that are expired through the usual option. |
| P56 | Patient- Unit Selection & Pretransfusion Testing | Provides the ability to enter compatibility information and assign an expired unit to a patient. (Requires a different option and a level of security access). |
| P57 | Patient- Unit Selection & Pretransfusion Testing | Evaluates age of patient specimens available for the pretransfusion testing to determine whether any meet the requirements, based on the entry in the Patient Specimen Age Allowed field (#16) of the BLOOD PRODUCT file (#66) for the specific component and a search of the LAB DATA file (#63) entries for in the Date/Time Specimen Taken field (#.01) for the patient, preventing selection of a specimen which is too old or accessioned to a different division of a multidivisional facility. |
| P58 | Patient- Unit Selection & Pretransfusion Testing | Provides ability to assign units or enter crossmatch results if the age of the specimen exceeds the entry in the Patient Specimen Age Allowed field (#16) of the BLOOD PRODUCT file (#66) for the specific component. (Requires a higher level of security access and a different option than that used routinely). |
| P59 | Patient- Unit Selection & Pretransfusion Testing | Uses predefined algorithm and parameters, defined for the specific component, to prevent selection of units which are not ABO/Rh compatible (based on entries in the BLOOD PRODUCT file (#66) for the Patient/Product ABO field (#.07) and the Patient/Product RH field (#.08). |

| SRS# | Functionality | Description |
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| P60 | Patient- Unit Selection and Pretransfusion Testing | Provides ability to assign a unit that is not ABO/Rh compatible according to the component specific parameters defined in the BLOOD PRODUCT file (#66) for the Patient/Product ABO field (#.07) and Patient/Product RH field (#.08). (Requires a higher level of security access and a different option than that used routinely). |
| P61 | Patient- Unit Selection and Pretransfusion Testing | If requested, limits selection to units not currently assigned to another patient. |
| P62 | Patient- Unit Selection and Pretransfusion Testing | Displays any entries in the LAB DATA file (#63), Blood Bank Comments field (#.076) including those which might detail specific component needs. |
| P63 | Patient- Unit Selection and Pretransfusion Testing | Displays warning message if the current volume is less than the average volume for the component as defined in the Volume field (#.1) in the BLOOD PRODUCT file (#66). |
| P64 | Patient- Unit Selection and Pretransfusion Testing | Displays message indicating the number of days left before expiration of unit. |
| P65 | Patient- Unit Selection and Pretransfusion Testing | Prevents access to units that have not been appropriately selected unless data is entered via a different option with a higher level of security and an automatic audit trail. |
| P66 | Patient- Unit Selection and Pretransfusion Testing | Uses algorithm to evaluate confirmatory testing and displays a warning message if required testing has not been completed, (i.e., if the component entry in the BLOOD PRODUCT file (#66) CONTAINS RED CELLS = YES, an entry must exist for the ABO RECHECK, and if the unit is Rh negative, an entry must exist for the RH RECHECK. |
| P67 | Patient- Unit Selection and Pretransfusion Testing | Prevents a change in the status to make the unit available for subsequent issue if the unit recheck results do not match the unit log-in information. |
| P68 | Patient- Unit Selection and Pretransfusion Testing | Prevents deletion of patient's historical record of ABO/Rh unless user has a higher level of security access and no lab data exists. |
| P69 | Patient- Unit Selection and Pretransfusion Testing | Compares unit ABO/Rh to patient history and prevents unit selection if there is no entry. |
| P70 | Patient- Unit Selection and Pretransfusion Testing | Prevents entry of crossmatch interpretation if no ABO/Rh results have been entered on the current specimen. |
| P71 | Patient- Unit Selection and Pretransfusion Testing | Displays warning message if no results are entered for the antibody screening on the current specimen |
| P72 | Patient- Unit Selection and Pretransfusion Testing | Allows generation of a label containing patient identification and unit information to be attached to the tie tag for the unit in order to minimize opportunities for transcription errors. |

| SRS# | Functionality | Description |
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| P73 | Patient- Unit Selection and Pretransfusion Testing | For allogeneic (homologous and directed) units, uses algorithm to evaluate unit phenotyping against clinically significant patient antibody, present in the LAB DATA file (#63), Antibodies Identified field (#.075), and prevents selection if the corresponding antigen is present in the unit, based on the entries in the FUNCTION FIELD file (#61.3) for that specific antibody. |
| P74 | Patient- Unit Selection and Pretransfusion Testing | For allogeneic (homologous) units, uses algorithm to evaluate unit phenotyping against clinically significant patient antibody and displays warning message if the corresponding Ag is not entered in the BLOOD INVENTORY file (#65), RBC Antigen Absent field (#.05). |
| P75 | Patient- Unit Selection and Pretransfusion Testing | Determines whether crossmatch result is required based on the entry in the BLOOD PRODUCT file (#66), Patient/Product Requirement field (#.09) for the specific component. |
| P76 | Patient- Unit Selection and Pretransfusion Testing | If the crossmatch result is anything other than C or IG, prevents status change to assigned for subsequent issue. |
| P77 | Patient- Unit Selection and Pretransfusion Testing | If the crossmatch result is IG, prevents status change to allow issue of the unit unless the initials entered match those of the user <u>and</u> the user also holds the appropriate security key. |
| P78 | Patient- Unit Selection and Pretransfusion Testing | Releases units back to available inventory if the result entered for the crossmatch is not C or IG. |
| P79 | Patient- Unit Selection and Pretransfusion Testing | Prevents selection of units not associated with the appropriate division (even autologous). |
| P80 | Patient- Unit Selection and Pretransfusion Testing | Prohibits selection of autologous unit for a different patient than the patient designated in the Restricted For field (#8). |
| P81 | Patient- Unit Selection and Pretransfusion Testing | Displays current information on component requests and units assigned/available for issue. |
| P82 | Patient - Transfusion Data Entry | If a pooled product is transfused, calculates the number of units in a pool and enters the data in the Pooled/Divided Units field (#4.4) for the pooled product which was created. |
| P83 | Patient - Transfusion Data Entry | Allows entry of unit specific transfusion reaction data, (i.e. type of reaction and appropriate comments). |
| P84 | Patient - Transfusion Data Entry | Prevents entry of future transfusion dates. |
| P85 | Patient - Transfusion Data Entry | Captures appropriate data for evaluation of transfusion practices by treating specialty through a variety of different reports. |

| SRS# | Functionality | Description |
|------|---------------|-------------|
| P86 | Patient - Investigation of Adverse Effects | Updates cumulative patient transfusion record, including data on clinically significant antibodies, transfusion reactions and units transfused, immediately upon data entry. |
| P87 | Patient - Investigation of Adverse Effects | Allows entry of transfusion reaction data that is unrelated to a specific unit. (Requires a higher level of access). |
| P88 | Patient - Investigation of Adverse Effects | Provides report of transfusion data, sorted by patient, including both reactions associated with a specific unit and those not associated with specific units. |
| P89 | Patient - Investigation of Adverse Effects | Provides report for use in identifying potential cases of transfusion transmitted disease, based on search of those patients transfused within the previous 6 month period for specific patient test results using facility specified tests and facility defined values. |
| P90 | Patient - Management/Quality Improvement | Provides a report of crossmatch transfusion ratios, sorted by treating specialty, in either summary or detailed format to allow a review of ordering patterns. |
| P91 | Patient - Management/Quality Improvement | Provides a report of patients crossmatched for a specified date range, sorted by date/time crossmatched, to allow a review of ordering patterns. The report includes specimen info, unit ID, XM result, outcome of XM (released or transfused) and statistics on the # of patients crossmatched, # of specimens crossmatched, # of units transfused, the C T ratio and the # of crossmatches for each result (C, IG, etc.). |
| P92 | Patient - Management/Quality Improvement | Provides a report of autologous unit dispositions, sorted by whether the unit was transfused or not, including the patient information, treating specialty if unit was transfused, component, unit ID and the number of days in inventory, to allow evaluation of utilization patterns. |
| P93 | Patient - Management/Quality Improvement | Provides a mechanism to identify units with a prolonged infusion time, based on component specific local parameters for maximum infusion time, i.e. entries in the BLOOD PRODUCT file (#66). |
| P94 | Patient - Management/Quality Improvement | Provides an administrative data report which details data requested on the annual AABB questionnaire, sorted into inventory and donor groupings. |
| P95 | Patient - Management/Quality Improvement | Provides a report of potentially inappropriate transfusions based on the auditing done during specimen log-in /order entry, sorted by location to which the unit was issued for transfusion. |
| P96 | Patient - Management/Quality Improvement | Provides a patient report, which can be used for outcome assessments, integrating transfusion episodes and clinical lab results for site selected tests. User can request the report for specific patients and date ranges or specify that reports should be printed for all patients transfused within a specified date range. |

| SRS# | Functionality | Description |
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| P97 | Patient - Management/Quality Improvement | Provides hard copy listing of patients who have been transfused for a specified treating specialty, for a specified date range. |
| P98 | Patient - Management/Quality Improvement | Provides a report of all units transfused within a specified date range, sorted in alphabetical order by patient, and in chronological order for the specified disposition dates. Report includes patient name and SSN, unit ID, component, # in pool if appropriate, volume, inspection information, issue location, transfusion date/time and transfusion reaction information. |
| P99 | Patient - Management/Quality Improvement | Provides a report of all units transfused within a specified treating specialty, a specified component and a specified date range, sorted by treating specialty, then by component, then alphabetically by patient. Report includes patient transfused, transfusion date/time, primary care physician, cost, unit ID and statistics for each treating specialty on # patients given RBC components, # patients given non-RBC components and cost. |
| P100 | Patient - Records | Provides permanent on-line storage of Blood Bank data, i.e. data is not included in algorithm used for archiving patient test results. |
| P101 | Patient - Records | Provides hard copy listing of patients who have clinically significant antibodies. (Requires higher level of access because report involves a system intensive search of the database.) |
| P102 | Patient - Records | Provides a hard copy listing of patients who have Blood Bank data in the LAB DATA file (#63) for reference during computer downtimes, including the patients historical ABO/Rh, any entries in the Antibodies Identified field (#.075) or Blood Bank Comments field (#.076), and if requested, results of the most recent ABO/Rh and Antibody Screen. User can specify the range of patients and whether all patients with Blood Bank data should be included or if listing should be limited to those with antibodies or comments. (Requires higher level of access because report involves a system intensive search of the database.) |
| P103 | Patient - Statistics | Captures workload information and feeds data to non-Blood Bank laboratory files which is subsequently used for a variety of local and national reports, including the CAP Laboratory Management Index Program and DSS. |