Requirements Definition for Version 1.0 of BSIS

Project: **Blood Safety Information System**

Programme: **Blood Safety Systems Strengthening**

Document Control

Version	Description of Change	Author	Date
0.1	Initial draft based on project team CT meeting	Rob Wilkinson, Brian Gibbs, Pete Zacharias, Linda Taylor, Daniel Futerman, Carolyn Smith	02/07/2013
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0.3	Added additional information based on team discussion	Linda Taylor	17/09/2013
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0.5	Updated based on requirements workshop	Rob Wilkinson, Daniel Futerman, Linda Taylor, Carolyn Smith	24/01/2013
0.5.1	Updated following feedback from project team	Pete Zacharias, Brian Gibbs	14/02/2014
0.5.2.	Added more detail after milestone review and after gap analysis with the LBTS user requirements	Linda Taylor – reviewed by BSIS technical team	22/08/2014

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1. Introduction

In May 2013, a low-cost blood establishment computer software (BECS); hereafter referred to as Blood Safety Information System (BSIS) was spun-off to Jembi Health Systems NPC (Jembi) from the Computing for Good (C4G) course at the Georgia Institute of Technology in Atlanta, GA. Faculty and students from C4G had led the research-and-development phase of V2V, the initial version of BSIS, since 2007. During the R&D phase, Georgia Tech consulted frequently with end-users in a number of African countries, including Zambia, Cameroon and Namibia. Additional technical assistance was provided to Georgia Tech by BECS experts from South Africa. The decision to spin-off V2V (now BSIS) was made by CDC, in conjunction with Georgia Tech, when it became clear that V2V was approaching a level of technical sophistication that could allow it to undergo final development in a simulated field environment, and, eventually, pass an external validation phase and be implemented in working blood services.

1.1 Purpose

The aim of this document is to capture, define and document the functional and non-functional requirements for BSIS (Blood Safety Information System) from various stakeholders.

1.2 Project Scope

The Blood Safety Strengthening Programme (BSSP) is the programme built around the development of the BSIS software to a production level and the implementation of the BSIS software in national blood services in countries in Africa. The programme looks at the implementation of the BSIS software as more than the simple deployment of the system at site, taking a whole system approach that acknowledges the interconnection between policy, practice and technology and looks at: Environment (where will the system be used?); Process (how will the system be used?); Technology (what hardware/software will be used?); Capacity building (who will use the system?), and; Sustainability (how much will it cost and who will pay?). The aim is to implement an effective and sustainable eHealth system that facilitates the achievement of improved blood safety and availability in countries in Africa. As such BSIS is not simply a software intervention but part of a larger programme strategy to improve quality management in low resource blood services in Africa.

1.3 Abbreviations and acronyms

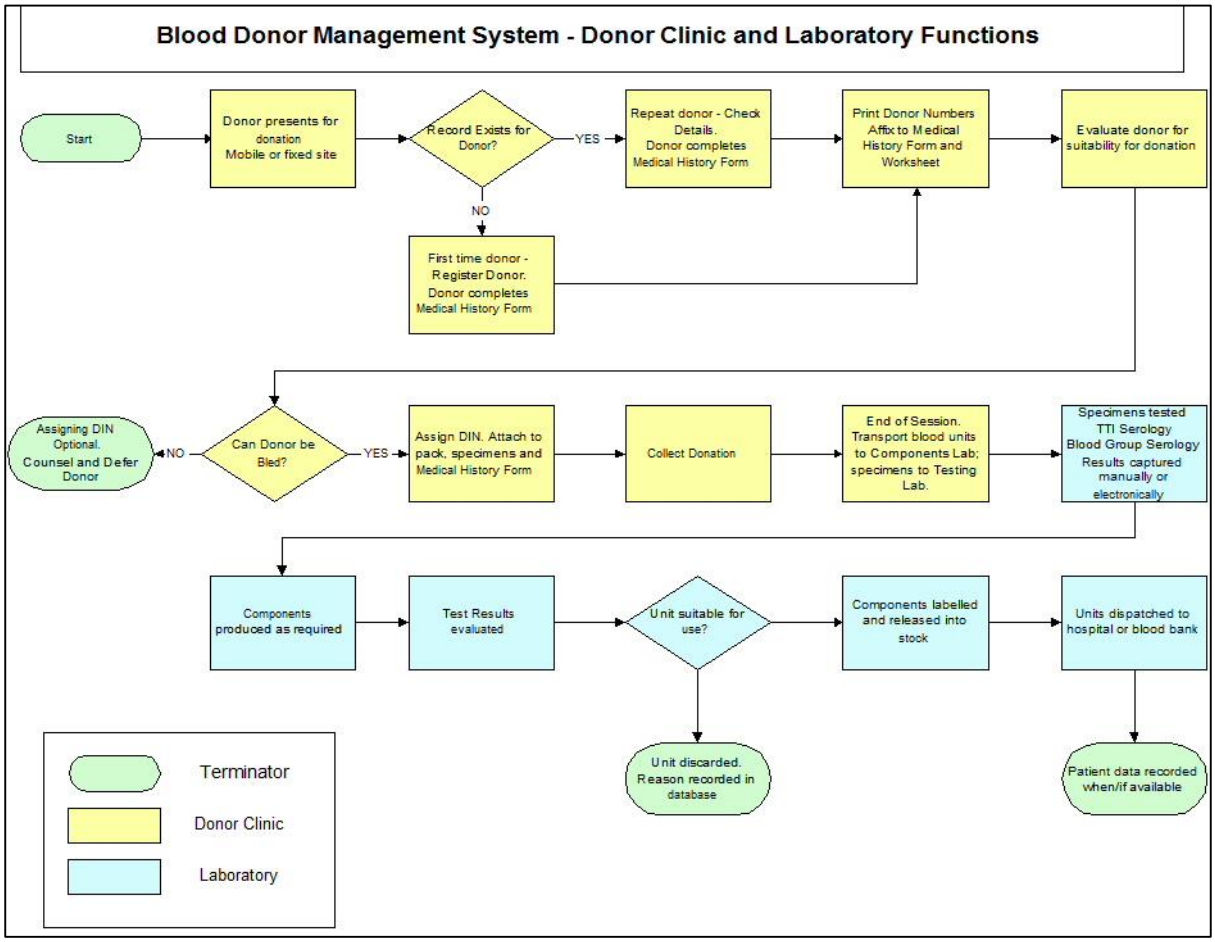
AHG	Anti-human Globulin
BSIS	Blood Safety Information System
BECS	Blood Establishment Computer System
BP	Blood pressure
BP Systolic	Blood Pressure Systolic
BP Diastolic	Blood Pressure Diastolic
BC	Buffy Coat
Cryo	Cryoprecipitate
DIN	Donation Identification Number
ELISA	Enzyme-linked immunosorbent assay
FBC	Full Blood Count
Hb	Haemoglobin
Hct	Haematocrit
NBTS	National Blood Transfusion Service
Plts	Platelets
RBC	Red blood cells
Rh	Rh
SOP	Standard Operating Procedure
TTI	Transfusion Transmissable Infections
VNRD	Voluntary non-remunerated donors
WBC	White blood cells

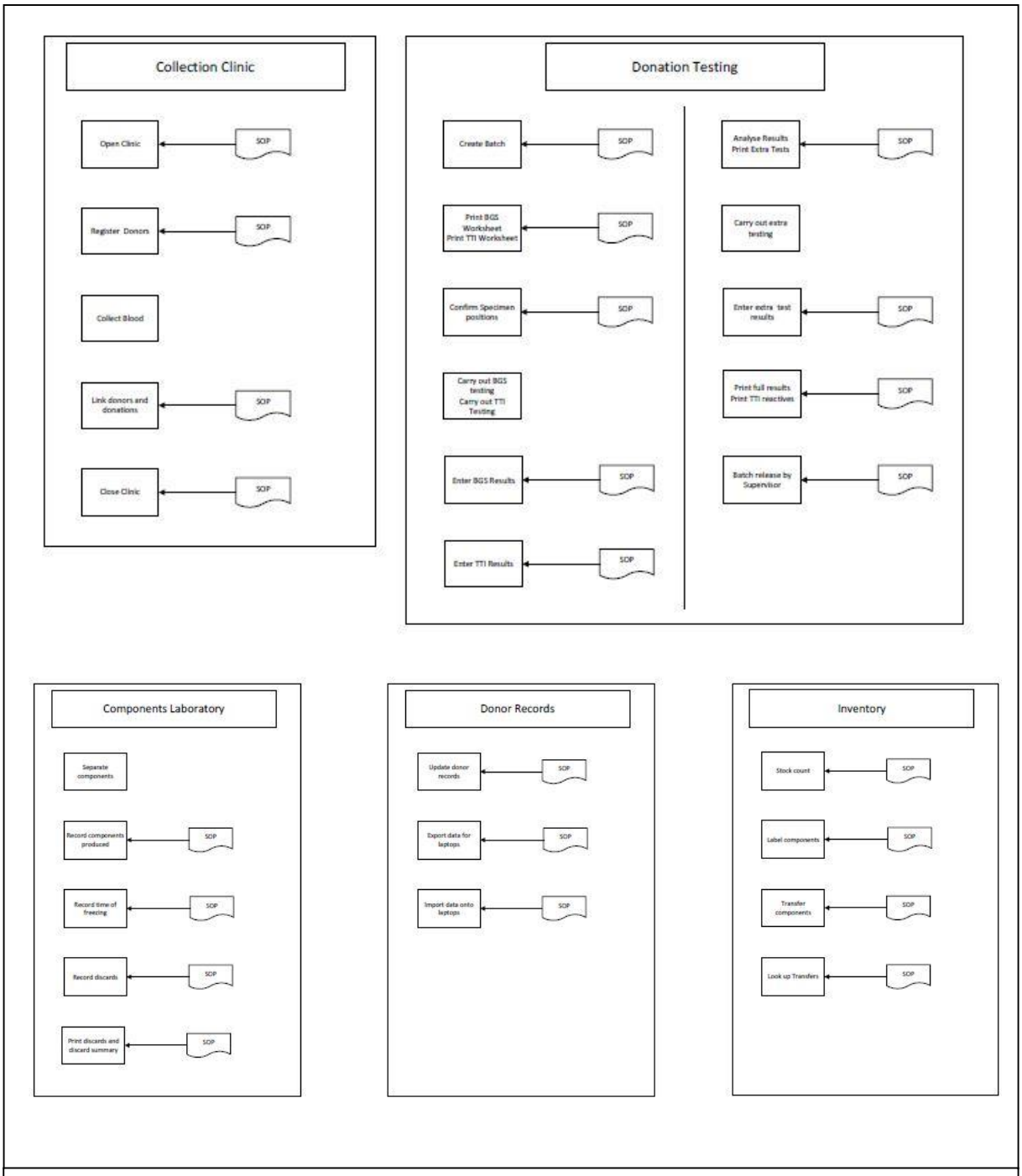
1.4 References

1. Blood donor selection: guidelines on assessing donor suitability for blood donation. (WHO 2012)
2. AfSBT Step-Wise Accreditation Standards (Africa Society for Blood Transfusion, 2013)
3. ISBT 128 For Blood Components An Introduction (ICCBBA 2011)
4. ISBT Guidelines for Validation of Automated Systems in Blood Establishments (ISBT Science Series 2010)
5. United States Industry Consensus Standard for the Uniform Labelling of Blood and Blood Components Using ISBT 128 (ICCBBA Version 2.0.0 2005)
6. WHO guidelines on good manufacturing practices for blood establishments (WHO Technical Report Series, No. 961, 2011)
7. WHO Aide memoire – Safe Blood Components (WHO 2005)

2. Overall Description

2.1 High Level Functional Overview




Collection Clinic
Open Clinic
SOP
Register Donors
SOP
Collect Blood
Link donors and donations
SOP
Close Clinic
SOP
Donation Testing
Create Batch
SOP
Print BGS Worksheet
Print TTI Worksheet
SOP
Confirm Specimen positions
SOP
Carry out BGS testing
Carry out TTI Testing
Enter BGS Results
SOP
Enter TTI Results
SOP
Analyse Results
Print Extra Tests
SOP
Carry out extra testing
Enter extra test results
SOP
Print full results
Print TTI reactives
SOP
Batch release by Supervisor
SOP
Components Laboratory
Separate components
Record components produced
SOP
Record time of freezing
SOP
Record discards
SOP
Print discards and discard summary
SOP
Donor Records
Update donor records
SOP
Export data for laptops
SOP
Import data onto laptops
SOP
Inventory
Stock count
SOP
Label components
SOP
Transfer components
SOP
Look up Transfers
SOP
Component Issues
Record issues to patients
SOP
View components issued
SOP
Close issue batch
SOP
Donor Communications
View / Print donor telephone lists
SOP
View / Print donor SMS lists
SOP

2.2 Guiding Principles

- That the systems will positively impact blood safety through the reduction of errors in the donor clinic and in the laboratory.
- That the system is developed as an open-source system with the aim of developing a community of practice to support the on-going development in the long-term
- That the system will facilitate development of blood services and improvement in operational behaviour of implementing blood services. That the adoption of the software advocates and encourages the use of best laboratory and clinical practices, and that some workflow and system changes in the laboratory and the clinic may well have to precede the introduction of the software.
- That the system accounts for WHO and AfSBT guidelines and standards where appropriate.
- That the system is stable, reliable and easy to use.
- That the use of barcodes improves the speed and accuracy of data collection.
- That the workload, overall, is reduced and not increased.
- That the system provides the tools for improved management of donor and laboratory activities.
- That the system will assist the service in meeting the requirements of accreditation.
- This will allow for a fail-over paper-based system and will enable back entry of certain data.
- A mechanism will be provided to allow import of legacy data where possible and where appropriate.
- That the system will allow for some level of configuration according to the needs of the blood service.
- That the system will eventually allow for internationalisation with an initial focus on providing English, Portuguese and French support. The initial version 1.0 will only support English.
- The system will provide auditing across all major functions.
- The system will provide for role-based access.
- This system is focused specifically on low-resource settings with their inherent challenges.
- The system will be strengthened to ensure it is scalable and production-ready for these low-resource environments.

System Scope

The following areas of functionality are out of scope for Version 1.0 of the system:

1. Stock Costing & Billing
2. Internationalisation
3. Portuguese and French Language versions
4. Waste Management Process
5. Automation of Donor Communications
6. ISBT128 support except for ISBT128-compliant labels
7. Donor retested plasma
8. Plasma for fractionation
9. Cross-matching
10. Additional / enhanced reporting
11. Interfacing with testing equipment
    Supply chains

2.3 User Classes and Characteristics

The required classes of users are:

	User Class	Characteristics
1	Donor clinic staff	Access limited to donor information and donor processes only
2	Donor clinic supervisor	Access to confidential comments. Can drill down to previous donation data. Correction of some specified clinic data.
3	Donor Counsellor	Access to TTI results. Can link TTI results to specific donors
4	Donor Communications	Access to donor information
5	Donation testing staff	Access limited to donation information and testing processes
6	Donation testing supervisor	Access to printing and checking of laboratory results. Release of tested units for labelling. Correction of some laboratory data.
7	Component laboratory staff	Access limited component processing
8	Component laboratory supervisor	Access to reversing component preparation and correction of some laboratory data
9	Blood bank staff	Cross-matching and issuing
10	Inventory Staff	Labelling and transfers
11	Medical Officer	Access to donor information and their associated test results. Access to patient data, hospital blood usage, statistical reports.
12	Data Clerk	Access to enter / edit donor demographic data
13	BSIS Administrator	Access to all functions within the system with limited access to configuration and set-up (limited to two individuals) Administrators can create users except for other Administrators and Super users
14	Super user	Full access to whole system (Limited to two IT Technical Support Staff and Jembi Health Systems IT Technical Support Staff as authorised by the NBTS.) Can create users except for other Administrators and Super users

2.4 Operating Environment

The BSIS system is designed to run as a Java web-based application, ensuring platform independency, and will run across operating systems with a modern web browser (e.g. Chrome, Firefox) and Java installed. The system will be installed using the client-server model, so that clients do not have to install the application, but access this over a closed local-area network, or a more distributed wide-area network, where network and infrastructure resources are appropriate and available.

This design allows for simpler deployment and updates, adaptability to mobile access, and broader access than desktop applications (but with strict access control mechanisms to provide role-based access as required).

With this model, the hardware requirements necessitate high-spec server(s) that are able to manage the client request loads; this will vary according to the needs of each implementation.

The system is designed to allow for the use of barcode scanners, and pack label and barcode printers, and should work with any modern barcode scanner and label printers supporting the Zebra Programming Language (ZPL). Materials used must be suitable of use in a Blood Safety environment.

2.5 Documentation

- A set of User Manuals intended for use by the end-users of the system
  - Donations User Manual
  - Laboratory User Manual
  - Administration Manual
- A Technical Manual intended for system administrators to manage the system on an on-going basis
- An Implementation Manual to provide guidelines and checklists for the deployment, training, support and change management process
- A set of standard operating procedures (SOPs) describing the user interaction with the system. These SOPs will differ according to local procedures and will be developed in conjunction with each facility.
- A document providing an overview of the system functionality
- Requirements documentation
- Technical specifications

2.6 Assumptions and Dependencies

- That there is an existing quality management system
- That the national programme and their technical assistance provider will update the SOPs to reflect the use of BSIS
- These requirements are for a single instance of the system running in a central blood service.
- The ability to directly import from automated blood grouping and TTI testing equipment is highly dependent on the implementation environment so is excluded from system scope and will be dealt with as an implementation activity
- A minimum infrastructure
  - Stable power supply with UPS
- That the administrator of the BSIS system is available and has the requisite IT and blood safety skills to administer the system
- That English will be the first language available but that there will be a need for internationalisation in later versions
- That all staff will undergo go training and change management interventions as part of the installation

3. Functional Requirements of the System

3.1 FR-01 Management of Donors

Use Case References:

- BSIS User Story–Donor and Donation Management
- BSIS-UC01-001-Register a New Donor
- BSIS-UC01-002-Search and Update Donor Record
- BSIS-UC01-003-Manage Donor Codes
- BSIS-UC01-004-Manage Deferrals
- BSIS-UC01-007-Produce Donor Communications List
- BSIS-UC01-008-Check Donor Eligibility

FR01	Management of Donors
FR01-001	The system must be able to register a new donor and each donor shall be identified using a unique identifier (Donor Number) generated by the system. This Donor Number will not be editable; remains linked to the same individual throughout, and must never be deleted.

FR01-002	The following mandatory data fields WILL be captured for each donor at the time of the first donation:
	• First Name
	• Last name
	• Gender
	  ○ Options= Male/Female
	• Date of birth - with estimated checkbox
	The following additional non-mandatory demographic and other data fields MAY be captured for each donor: such as:
	• Title (Mr, Mrs, Miss Etc.)
	• Calling Name
	• Date of First donation (this can only be captured when the new record is created but cannot be edited later. The system will update this automatically whenever a new donation is linked to this donor)
	• Identifier Type
	  ○ (options = National ID/Passport/(Driver's) Licence No)
	• Identifier Number
	• Preferred Language
	• Mobile telephone number
	• Home telephone number
	• Work telephone
	• Email address
	• Preferred Contact Method
	  ○ (options= None, Telephone, SMS, Email, Mail, Do not contact)
	• Donor Panel
	  ○ (A Donor can only belong to one panel at a time but may change from one panel to another.)
	• Home address
	  ○ Address 1
	  ○ Address 2
	  ○ City
	  ○ District
	  ○ Province
	  ○ Country
	  ○ Zip or Postal Code
	• Postal address
	  ○ Address 1
	  ○ Address 2

<table>
<tr><td></td><td>

City
District
Province
Country
Zip or Postal Code

Work address

Address 1
Address 2
City
District
Province
Country
Zip or Postal Code

Preferred Address Type
Notes (a general text field)

</td></tr>
<tr><td>FR01-003</td><td>
The donor clinic staff user will be able to assign donor codes which could be updated according to results captured during the donation or during the testing process. Donor codes determine whether a donor can donate in the future or not.
<table>
<tr><td>-001</td><td>Donor codes will be grouped by Donor Code Group and only the Donor Code Group will be displayed to donor clinic staff. The detail related to the donor code may contain confidential information and so will only be available to authorised users.</td></tr>
<tr><td>-002</td><td>Valid Donor Code Groups with associated Donor Codes:</td></tr>
<tr><td colspan="2">

Do Not Bleed
<ol type="a">
Biological False Positive
For counselling HCV
For counselling HIV
For counselling HBsAg
For counselling Syphilis
Not counselled HCV
Not counselled HIV
Not counselled HBsAg
Not counselled Syphilis
Counselled HCV
Counselled HIV
Counselled HBsAg
Counselled Syphilis
High Risk (e.g. intravenous drug user)

</td></tr>
</table>
</td></tr>
<tr><td></td><td>

Test Only
<ol type="a">
TTI confirmation HCV
TTI confirmation HIV
TTI confirmation HBsAg
TTI confirmation Syphilis
Antibody Identification
Blood group confirmation
Possible donor misidentification
Test specimen broken / Insufficient specimen
Positive DAT

</td></tr>
</table>

	-002	These Donor Codes and Donor Code Groups must be editable by the Super user.
FR01-004	The system will allow for the management of donor deferrals through the use of configurable deferral codes with associated deferral periods based on WHO and country-defined standards. This process is a manual process determined by the users.	
	-001	Deferral reasons will include the following based on WHO guidelines: • Low weight • Low haemoglobin • Other medical conditions • High risk behaviour • Travel history • Other reasons
	-002	Other deferral reasons may be added by an Super user
	-003	The supervisor may be authorised to override some deferrals under certain circumstances and under the authority of the medical officer and if so, this is logged. Deferral history will be retained.
FR01-005	The system shall provide the ability to synchronise donor and donation data between the laptop computers used in mobile clinics and the main central database	
	-001	The system shall provide the ability to synchronise donor and donation data to laptop computers for use in mobile clinics
	-002	The system shall provide the ability to synchronise the updated donor and donation data from laptop computers used in mobile clinics back into the main central database
FR01-006	The system must provide the ability to search for a donor	
	-001	By donor number, first name, last name
	-002	By DIN (Donation Identification Number)
FR01-007	The system will provide a printable list of donors for donor communications purposes filterable by • Donation site / Donor panel • Donors due to be bled on Date of Clinic • Donors who last donated between two dates • Blood group	
FR01-008	The system will check each donor against the following criteria to determine if they are eligible to donate:	
	-001	New donor • Check donor age is within allowable range as configured by the Administrator.
	-002	Repeat donor • Check interval since last donation and that this conforms with Administrator-configured interval • Check that donor has not been coded “Do Not Bleed” • Check that the donor is not currently deferred • Check donor age is within allowable range as set by the Administrator.

3.2 FR-02 Management of Donations

Use Case References:

- BSIS User Story-Donor and Donation Management
- BSIS-UC02-003-Open & Close Donor Clinic
- BSIS-UC02-004-View Donation Batch
- BSIS-UC02-005-Link Donor and Donation

FR02	**Management of Donations**
FR02-001	A unique pre-printed Donation Identification Number (DIN) will be allocated to the donation.
FR02-005	This DIN and the Donor Number will be irreversibly linked to ensure that the donation unit is always traceable back to the donor who provided it.
FR02-002	The system will be able to capture and store the following data fields for each donation: • Donation Identification Number • Donor Number • Date Bled • Venue • Pack Type • Pack Weight • Donation Batch Number • Donor's ABO Group • Donor's Rh Group • Donor's Haemoglobin • Donor's Systolic Blood Pressure • Donor's Blood Pressure • Donor's Pulse • Donor's weight • Donation comment
FR02-003	The system will be able to group donations into Donation Batches and should generate a unique identifier for each Donation Batch
FR02-004	Donation Batches should be searchable by: 1. Donor Panel 2. Date Period 3. DIN

FR-03 Blood Testing Process

FR03	Management of the Blood Testing Process	
FR03-001	The system will provide for ABO, Rh and other serology tests with results as follows: • A Negative; • A Positive; • AB Negative; • AB Positive; • B Negative; • B Positive; • O Negative; • O Positive; • No Sample (NS); • Not Tested (NT).	
FR03-002	The system will provide for TTI tests as follows: • HIV • Hepatitis B • Hepatitis C • Syphilis The system will provide the following result types: • Negative; • Positive; • No Sample (NS); • Not Tested (NT).	
FR03-003	The system will make provision for the addition of additional tests such as the screening for unexpected antibodies, screening for malaria parasites, etc.	
FR03-004	The system will be able to capture all test results by manual entry using the following methods:	
	-001	Blood group serology carried out in micro titre plates or test tubes. Agglutination results will be captured according to the strength of the reaction (0, 1,2,3,4, H)
	-002	TTI test outcomes will be entered
	-003	Worksheets can be printed to show the position of test specimens if the testing is done manually.
FR03-005	The system will be able to capture TTI test results via an import of a file containing test results from an automated instrument	
	-001	The system will be able to import an Excel spread sheet file containing TTI test result information in a specified format matching the BSIS data model
FR03-006	The system will be able to interpret blood group serology and TTI test results according to a defined algorithm and record the final test outcome	
FR03-007	The system will provide traceability of test outcomes by testing batch. A testing batch is defined as - All units tested during a single test run within the testing laboratory.	
FR03-008	The system will be able to determine the need for additional or repeat tests based on defined criteria	
FR03-009	The system will automatically flag and block donation units based on defined test outcomes	

FR03-010	The system will automatically do a comparison with ABO-Rh test outcomes from previous donations from the same donor and will flag any discrepancies allowing confirmatory testing to resolve a mismatch
FR03-011	The system will allow for entry of confirmatory blood group serology outcomes for first time donors
FR03-012	The system will provide the facility for an overview of all test batch results (including repeat tests) and/or test outcomes to be viewable on screen, as well as being able to view the test result detail of an individual donation unit.
FR03-013	The system will provide the facility for all test results in a test batch to be printed so that the results can be checked and signed off

3.4 FR-04 Component Preparation Process

FR04	**Management of the component preparation process**	
FR04-001	The system will be able to capture component preparation data with full traceability retained throughout	
FR04-002	The system will provide for the splitting of blood components as specified:	
	-001	The system will provide for the splitting of whole blood into between 2 and 5 paediatric units. The number of units prepared must be user-selectable.
	-002	The system will provide for the splitting of whole blood units into red cell concentrate (RCC), buffy coat, plasma or a subset of components.
	-003	The system will provide for further splitting of fresh frozen plasma (FFP) and red cell concentrate (RCC) into between 2 and 5 paediatric units. The number of units prepared must be user-selectable.
	-004	The system will provide for splitting of apheresis platelet units into a combination of adult and paediatric units. The number of units and the combination must be user selectable.
FR04-003	The system will allow for the pooling of specified components as specified:	
	-001	The system will provide for pooling of between 2 and 5 platelet concentrate units. The number of units pooled must be user-selectable.
	-002	The system will provide for pooling of between 2 and 5 cryoprecipitate units. The number of units pooled must be user-selectable.
FR04-004	Components should be searchable by: 1. DIN 2. Component Type	
FR04-005	Each components will have a Component Status that is automatically assigned and which flags the status of each individual component as follows: • Quarantined (This is the default status of each component – this includes whole blood. Quarantined donations cannot be labelled for release) • Processed (This means the original component such as whole blood has been split into components and therefore does not exist anymore) • Unsafe • Issued • Transferred • Expired • Labelled (In stock and can be issued)	

	NOTE: The status of the donation is different to the status of the components e.g. when one component unit has been discarded due to breakage but all other components have not
Fr04-006	Components should be filterable by Component Status when viewing on screen

3.5 FR-05 Management of Component Labelling

FR05	**Management of Component Labelling**
FR05-001	The labelling of a component is a control point which determines whether that component is able to be released for use or must be discarded. (**See** 3.5.1. for a description of the algorithm at this control point)
FR05-002	Components that have been fully tested with all discrepancies resolved are automatically flagged as Safe and a Final Pack Label can be printed.
FR05-003	Components flagged as Quarantined (due to outstanding test results or discrepancies), Expired, Processed or Issued will not allow a final Pack Label to be printed.
FR05-004	Components that form part of a donation where TTI Testing is flagged as Unsafe or Incomplete will not allow a final Pack Label to be printed.
FR05-005	Components that form part of a donation where Blood Serology Testing is flagged as Incomplete, Ambiguous, Mismatch or No Type Determined, will not allow a final Pack Label to be printed.
FR05-006	Components that form part of a donation where the Donor is flagged as deferred at the time of the donation, will not allow a final Pack Label to be printed.
FR05-007	Components that form part of a donation where the Donor has a 'Do Not Bleed' Code Group associated with them, will not allow a final Pack Label to be printed.
FR05-008	Components that form part of a donation where the Donation has a 'Blood Group Issues' Code Group or a 'Bleed Issues' Code Group associated with them, will not allow a final Pack Label to be printed.
FR05-009	Components that have been manually flagged as Discarded will have a Discard/Biohazard label printed
FR05-010	Only components where ALL the following is TRUE, will allow for a final Pack Label to be printed: • Component is flagged as Available (i.e. ready for labelling) • Component forms part of a donation where TTI Testing is flagged as TTI Safe • Component forms part of a donation where Blood Group Serology Testing is flagged as Complete • Component forms part of a donation where the Donor is NOT flagged as deferred at the time of the donation. • Component forms part of a donation where the Donor does NOT have a 'Do Not Bleed' Code Group associated with it. • Component forms part of a donation where the Donation does NOT have a 'Blood Group Issues' Code Group or a 'Bleed Issues' Code Group associated with it. • Component has not been flagged as Discarded
FR05-011	The Final Pack Label will incorporate standardised information about the donation unit. The following information must be printed on the pack label and each piece of

	information should have an eye-readable barcode printed as well where it is a date or an identifier 1. DIN 2. ABO/RH blood group 3. Collection date (Optional) 4. Component Code 5. Expiration Date (and time where relevant) 6. Special Testing (Optional)
FR05-012	The Discard / Biohazard labels will incorporate standardised information about the donation unit.

3.5.1. The Component Labelling Process

(Validation of all conditions including test results and outcomes to ensure the pack is safe for release)

The system will check the following –

- The ABO and Rh on the Donation and the ABO and Rh on the Donor record
  - These will be compared. If not identical, this pack cannot be labelled
- The ABO and Rh on the previous donation if a repeat donor; or the Repeat ABO and Rh if a first time donor
  - These will be compared with the ABO and Rh on the present donation and if not identical, this pack cannot be labelled
- The donor record must be checked to see if the donor was deferred at the time of the donation, or if there is any reason why the component may be used even if the donor was deferred at the time of donation.
- If the Component Status is
  - Quarantined
  - Processed
  - Unsafe
  - Issued
  - Transferred
  - Expired

  Then the pack must not be able to be labelled
- Non-Reactive outcomes will be recorded for the following TTI markers on both the present donation and the previous donation (if a repeat donor) –
  - Anti-HIV
  - Anti- HCV (if stipulated by the Administrator)
  - HBsAg
  - Syphilis test
  - Any other TTI stipulated by the Administrator
  - Any confirmatory screening tests
  - Any other pending tests
    - If and only if ALL of these outcomes are Non-Reactive can the pack then be labelled
    - If any of these outcomes are Reactive, Inconclusive or missing, then the pack cannot be labelled
- Non-Reactive outcomes will be recorded for the following ABO-Rh tests on both the present donation and the previous donation (if a repeat donor) –
  - If and only if ALL of these outcomes are Non-Reactive can the pack then be labelled

- If any of these outcomes are Reactive, Inconclusive or missing, then the pack cannot be labelled

- The Antibody screening test – if this is Reactive then this pack should not be able to be labelled but can be over-ridden by the supervisor because:

    - Antibody screen – if this is Reactive for a clinically important antibody
    - Then this unit must be sent for further testing is to determine the antibodies
    - And then the results are interpreted by the supervisor to see if the unit can be used
    - This requires a manual decision by the supervisor

3.5.1.3. Discard Label

If the donation fails to meet the requirements of the Component Labelling Process and is rejected as being unsafe for use then the system will generate a label that indicates that this is a bio-hazard and is unfit for use. This will include standardised information.

3.6 FR-06 Management of the distribution and issue of blood

FR06	**Management of the distribution and issue of blood**	
FR06-001	The system shall provide the ability to have full traceability of all components from donor to patient, **where the patient information is available.**	
FR06-002	The system shall provide full traceability of units discarded or not issued or not transferred	
FR06-003	The system will provide the facility to manage requests for blood units at an individual patient level.	
	-001	The system will provide the ability to add, view and edit (only prior to issue) an Individual Request
	-002	Mandatory information required when adding a new Individual Request is: • Patient Identifier • Site (Authorised facility such as a hospital or clinic) • Cross match type (e.g. emergency) • Date of request • Requested components
	-003	Additional information that can be captured when adding or editing a new Individual Request is: • Patient demographic data and blood type and diagnosis and cross match information • Site/Facility information • Other information such as Requested By
	-004	The system will provide the facility to search for and track the Request using date period, type, site, as well as a filter to include fulfilled requests if needed.
FR06-004	The system shall allow for the ability to track the movement of blood units transferred to authorised facilities and subsequent transferrals between facilities	
FR06-005	The system will provide the facility to manage Transfers of blood units to an authorised facility i.e. hospital	

	-001	The system will provide the ability to add, view and edit (pending issue only) a Request
	-002	Mandatory information required when adding a new Request is: • Site (Authorised facility such as a hospital or clinic) • Date of request • Requested by • Requested Components
FR06-006	The system will provide the ability to print the Transfer or Issue Summary (Packing List) which includes information from the request form and the issued components	
FR06-007	When components are transferred or issued the pack status is updated	

3.7 FR-07 Configuration by Administrator and Super user

The following parameters are configurable within the system in order to meet local requirements.

FR07	**Configuration**	
	There are two levels of configuration of the system. 1. One is at the level where only a Super user is able to set or change parameters. This will be part of the initial installation of the system when it will be configured according the national blood service needs and will include those settings which will be very unlikely to change over time. 2. At the second level parameters can be set and changed by a BSIS Administrator.	
	Configuration and initial set-up by Super user	
FR07-001	The system shall provide the ability for the Super user to configure the following parameters in order to meet local requirements:	
FR07-002	Role-based user access (see 2.3 User Classes and Characteristics for a list of standard roles)	
	-001	The Super user should be able to add a new role and assign permissions to that role
	-002	The Super user should be able to edit an existing role
FR07-003	Global Properties should only be configurable by a Super user. These are: • Donor Code Groups and Donor Codes Donation Code formats • Donor minimum age • Donor maximum age • Number of days between consecutive donations – Whole blood • Number of days between consecutive donations – Apheresis	
FR07-004	Valid combinations of components that can be separated from other components should be defined by the super user. Standard combinations are: Separated from Whole Blood: • Red cells 1-1 • Fresh Frozen Plasma 1-1 • Platelet Rich Buffy Coat 1-1 • Paediatric Whole Blood (2 – 5 units) Separated from Red Cells • Paediatric red cells (2 – 5 units) Separated from Fresh Frozen Plasma • Paediatric Fresh Frozen Plasma (2 – 5 units)	

	It should be possible to pool units of the following components (pools of 2 – 5 units) • Platelets • Cryoprecipitate	
FR07-005	Blood Tests – Standard blood tests provided in the system (which may be set to "inactive" if not required). The super user may add additional tests. 1. Blood Group Serology ▪ Anti-A ▪ Anti-B ▪ Anti-A, B ▪ A1 cells ▪ A2 cells ▪ B cells ▪ Cells ▪ Anti-D – saline ▪ Anti-D – enzyme ▪ Anti-D – AHG ▪ Antibody screen – enzyme ▪ Antibody screen – AHG ▪ DAT ▪ Haemolysin 2. TTI-Tests ▪ Anti-HIV ▪ Anti-HCV ▪ HBsAg ▪ TPHA ▪ VDRL ▪ Malaria screen	
FR07-006	Blood typing rules – Super user only	
FR07-007	Lab set-up – Super user only	
	-001	The Super user should be able to select the method for Blood Group Serology from a pre-defined list: • Testing in ELISA plates with manual entry of test results • Testing in test tubes with manual entry of test results using worksheets
	-002	The Super user should be able to select the method for TTI testing from a pre-defined list which includes: • ELISA testing with manual entry of test outcomes • ELISA testing with electronic transfer of test outcomes
FR07-008	Internationalisation This functionality will not be available in Version 1.0 but will be available in later versions	
	Configuration by BSIS Administrator	
	The system shall provide the ability for the BSIS Administrator to configure the following parameters in order to meet local requirements:	
FR07-009	Role-based user access (see 2.3 User Classes and Characteristics)	
	-001	The BSIS Administrator should be able to add a new User and assign a Role to that User which will inherit permissions associated with that Role
	-002	The BSIS Administrator should be able to edit an existing User

	-003	The BSIS Administrator should be able to remove an existing User who will no longer then be able to access the system. The record will be retained as a voided record for audit purposes.
	-004	The BSIS Administrator should be able to assign and manage/re-set passwords associated with the User.
	-005	The BSIS Administrator should not be able to create a super user or additional administrators
FR07-010	The BSIS Administrator should be able to create Code Groups and Codes and associate Codes to Code Groups	
	-001	Code Groups • Do Not Bleed • Test Only • Blood Group Issues
	-002	Codes • TTI Positive • For Counselling • Blood Group Mismatch • Pending 2nd blood group test results
FR07-011	The Administrator should be able to create and edit Deferral information as follows:	
	-001	• Deferral Reasons for which a donor may be deferred ○ Low weight ○ Low haemoglobin ○ Other medical conditions ○ High risk behaviour (permanent) ○ Travel history ○ Other reasons
	-002	• Deferral Periods – the time period for which donors may be deferred
FR07-012	The Administrator should be able to create the following sites:	
	-001	Centre Types of centres based on the WHO definition are: ○ Collection ○ Testing ○ Processing ○ Distribution
	-002	Donation Site (same as a Donor Panel) The following will be provided as standard: ○ Fixed site ○ School ○ Community Centre ○ Church ○ Factory / business ○ Service Club (e.g. Rotary Club) ○ Other mobile ○ Shopping Centres

	-003	Request / Usage Site The following will be provided as standard: o Hospital o Blood Bank o Centre
FR07-013	Pack Types - The Administrator should be able to define the Pack Types. The following are provided : • Single • Triple • Quad • Apheresis • Apheresis twin-pack • Dry Pack • No Pack Used	
FR07-014	The Administrator should be able to manage component types and component combinations which may be made by splitting a unit of whole blood.	
	-001	Component Types will include: NB: Names from "United **States Industry Consensus Standard for the Uniform Labelling of Blood and Blood Components Using *ISBT 128* - Version 2.0.0 – November 2005".** Note that very few of these products will be prepared in most BTSs and if not in use will be flagged "Inactive". Each type will be associated with an expiry period. Whole blood Red blood cells Washed red blood cells Frozen red blood cells Frozen rejuvenated red blood cells Deglycerolized red blood cells Deglycerolized rejuvenated red blood cells Rejuvenated red blood cells Apheresis red blood cells Fresh frozen plasma Thawed fresh frozen plasma Recovered plasma Apheresis fresh frozen plasma Thawed apheresis fresh frozen plasma Apheresis plasma Source plasma Thawed apheresis plasma Liquid apheresis plasma Plasma Thawed plasma Liquid plasma Platelet-rich plasma Platelets Washed platelets Pooled platelets Washed pooled platelets Apheresis platelets

		Frozen apheresis platelets Thawed apheresis platelets Washed apheresis platelets Cryoprecipitate Thawed cryoprecipitate ahf Pooled cryoprecipitate ahf Thawed pooled cryoprecipitate ahf Apheresis cryoprecipitate ahf Thawed apheresis cryoprecipitate ahf Granulocytes Apheresis granulocytes Pooled granulocytes Apheresis granulocytes/platelets Leukocytes Apheresis leukocytes Pooled plasma Liquid apheresis plasma Washed apheresis red blood cells Frozen apheresis red blood cells Deglycerolized apheresis red blood cells Rejuvenated apheresis red blood cells Frozen rejuvenated apheresis red blood cells Deglycerolized rejuvenated apheresis red blood cells Platelet-rich buffy coat
FR07-015	Purchased components **This forms part of the Distribution and Issue Process and will only be available in Version** 2 This refers to components not produced by the BTS, e.g., 'fractionation components'. These can be listed by the Administrator if they are managed by the blood service.	
FR07-016	The Administrator should be able to set the Cross-Match Type that may be requested. The following are provided: • Group and Screen • None • Emergency • Standard Can we remove this for version 1 and say only available in version 2 ?	
FR07-017	The Administrator should be able to set the type of Cross-Match Tests Can we remove this for version 1 and say only available in version 2 ?	
FR07-018	The Administrator should be able to set the Diagnoses codes for which blood may be requested • Use of standard IPC codes (50+) • ICD9 or ICD10 codes • Other Can we remove this for version 1 and say only available in version 2 ?	
FR07-019	The Administrator should be able to define Reasons for Discards. These should include the following based on WHO categories: • Incomplete Donation • Reactive for TTIs ○ HIV ○ HCV ○ HBV	

	○ Syphilis ○ Other • Passed Expiry Dates • Storage Problems • Transport Problems • Processing Problems
FR07-020	The Administrator should be able to define the Donor Types of a particular donation based on the status of the donor at the time the donation was given. The following are provided - • Voluntary, non-remunerated donors (VNRD) • Family replacement donors • Paid donors • Autologous • Other
FR07-021	The Administrator should be able to define the Donation Category based on the status of the donor at the time the donation was given. The following are provided – • First time donor • Repeat Donor • Lapsed Donor

3.8 FR-08 Management Reporting Requirements

Management reporting produces information to enable better planning and to meet organizational and national reporting needs.

FR08	**Management Reporting Requirements**
FR08-001	All reports should be printable, with the option to export to other software such as PDF or Excel.
FR08-002	Donors due to be bled report Used for the Donor Communication Process - operational printout (Daily) (Text based PDF) Header to contain – Report name, panel name and location, date printed, filters in place. Details required - full name, blood group, home and business telephone numbers, email address, comments. Exclude deferred and coded donors as DO NOT BLEED. Pages to be numbered. Sorted into alphabetical order (Last name, First name) or by telephone number. Filtered by selection as follows: ○ Site ○ Blood group ○ Date of last donation (i.e. last donation between two selected dates) Print the barcode DONOR NO
FR08-003	Count of components discarded report (Monthly) Include graphs Printable PDF Header to contain – Report name, date printed, Start date and End date. Details required:

	○ Component type, number of units discarded for each reason in the "Discard Reasons" table. ○ Drill down possible to actual unit details. ○ Filtered by selection as follows: ▪ Start and end dates for time period ▪ Processing facility/ Centre
FR08-004	Units of blood collected report Used in the Donations Process – operational printout (Daily) export to Excel or print graphs, Printed PDF Header to contain – Report name, date printed, Start date and End date. Details required – counts for each donor type (voluntary, family replacement etc.), type of pack, blood group. Filtered by selection as follows: ○ Start and end dates for time period ○ Collection Site (Type of Venue (School, Factory, Fixed site etc.))
FR08-005	TTI Prevalence report (Monthly) Printed PDF , export to Excel or print graphs Header to contain – Report name, date printed, Start date and End date. Details required – counts for each donor type (voluntary, family replacement, etc.), sub-divided into First time, lapsed, repeat donations, and for each TTI. Screen reactive and confirmed positives to be shown as separate counts. Filtered by selection as follows – ○ Start and end dates for time period ○ Collection Site (Type of Venue (School, Factory, Fixed site etc.))
FR08-006	Components Issued report. (Monthly) Printed PDF , export to Excel or print graphs Header to contain – Report name, date printed, Start date and End date. Details required – counts for each component issued by diagnosis, component type, and blood group. Filtered by selection as follows: ○ Start and end dates for time period ○ Component ○ Request/Usage site
FR08-007	Components Transferred report. (Monthly) Printed PDF , export to Excel or print graphs Header to contain – Report name, date printed, Start date and End date. Details required – counts for each component transferred by component type, and blood group. Filtered by selection as follows: ○ Start and end dates for time period ○ Component ○ Request/Usage site
FR08-008	Pack Audit report. (Monthly) Printed PDF , export to Excel or print graphs Header to contain – Report name, date printed, Start date and End date. Details required – list of all blood components (WB, RCC, FFP, etc.) that have not been issued or discarded, but have reached or passed the expiry date. Filtered by selection as follows: ○ Start and end dates for time period ○ Component

	○ Date Bled and Expiry date ○ Location of component (Status)
FR08-009	Report listing the Family Replacement Donors and their contact details (phone numbers, email addresses) Part of Donor Communication Process- To be used for conversion of Family Replacement Donors to Non remunerated donors Based on the most recent donation from this donor (Monthly) Printed PDF Filtered by selection as follows: Start and end date
FR08-010	WHO GDBS reporting protocol as a Printed PDF to be used to enter data on the excel spread sheet and an excel export (Every 6 months) The data required for this report, and available from BSIS, are listed here: (NB selectable for any time period by entering Start Date and End Date) Numbers shown are the reference numbers in the WHO GDBS2011 Report and the report generated by BSIS should reflect these numbers. • 1.4 Start date and End date for the report • 3.5.1 Total number of VNRD who donated during the time period • 3.5.2 Total number of Family Replacement Donors who donated during the time period • 3.5.3 Total number of Paid Donors who donated during the time period (based on most recent donation within the period reported) • 3.5.4 Total number of Donors who donated Whole Blood during the period (3.5.1.-3.5.4. excludes autologous) • 3.6.1 Number of WB units collected from VNRD during the time period • 3.6.1.1 Number of WB units collected from First-time VNRD during the time period • 3.6.1.2 Number of WB units collected from Repeat VNRD during the time period (includes lapsed donors) • 3.6.2 Number of WB units collected from Family replacement donors during the time period • 3.6.3 Number of WB units collected from Paid donors during the time period • 3.6.4 Number of WB units collected from Other donors during the time period (specify type of donors) • 3.6.5 Total number of donations collected during the time period • 3.7 Are any donations collected through Apheresis (Yes or No) • 3.7.1 Number of Apheresis procedures involving VNRD during the time period • 3.7.1.1 Number of Apheresis procedures involving First-time VNRD during the time period • 3.7.1.2 Number of Apheresis procedures involving Repeat VNRD during the time period • 3.7.2 Number of Apheresis procedures involving Family replacement donors during the time period • 3.7.3 Number of Apheresis procedures involving Paid donors during the time period • 3.7.4 Number of Apheresis procedures involving Other donors during the time period (specify type of donors)

	• 3.7.5 Total number of Apheresis procedures during the time period
	• 3.8.1 Number of donors permanently deferred during the time period
	• 3.8.2 Number of donors temporarily deferred during the time period
	• Number of donors deferred because of –
	  ○ 3.9.1 Low weight
	  ○ 3.9.2 Low haemoglobin
	  ○ 3.9.3 Other medical condition
	  ○ 3.9.4 High risk behaviour
	  ○ 3.9.5 Travel history
	  ○ 3.9.6 Other reasons (Specify)
	  ○ 3.9.7 Total number of deferrals
	• 3.10.1 Number of WB Donations from Male donors
	• 3.10.2 Number of WB Donations from Female donors
	• 3.11.1 Number of WB Donations from donors aged under 18
	• 3.11.2 Number of WB donations from donors aged 18 – 24
	• 3.11.3 Number of WB donations from donors aged 25 - 44
	• 3,11,4 Number of WB donations from donors aged 45 - 64
	• 3.11.5 Number of WB donations from donors aged over 65
	• 3.12 Number of autologous blood donations
	• 4.5.1 Number and % of WB and Apheresis donations tested for HIV
	• 4.5.2 Number and % of WB and Apheresis donations tested for HBV (HBsAg)
	• 4.5.3 Number and % of WB and Apheresis donations tested for HCV
	• 4.5.4 Number and % of WB and Apheresis donations tested for Syphilis
	• 4.5.5 Number and % of WB and Apheresis donations tested for Chagas Disease
	• 4.5.6 Number and % of WB and Apheresis donations tested for Malaria
	• 4.5.7 Number and % of WB and Apheresis donations tested for HTLV I/II
	• 4.5.8 Number and % of WB and Apheresis donations tested for Other TTIs (Specify)
	• 4.7.1 Number and % of donations screened reactive for HIV
	• 4.7.2 Number and % of donations screened reactive for HBV (HBsAg)
	• 4.7.3 Number and % of donations screened reactive for HCV
	• 4.7.4 Number and % of donations screened reactive for Syphilis
	• 4.7.5 Number and % of donations screened reactive for Chagas disease
	• 4.7.6 Number and % of donations screened reactive for Malaria
	• 4.7.7 Number and % of donations screened reactive for HTLV I/II
	• 4.7.8 Number and % of donations screened reactive for Other TTIs (Specify)
	• 4.8.1 Number and % of WB donations from VNRD screened reactive for HIV
	• Number and % of Apheresis donations from VNRD screened reactive for HIV
	• Total number and % of WB and Apheresis donations from VNRD screened reactive for HIV
	• 4.8.1.1 Total number and % of WB and Apheresis donations from First Time VNRD screened reactive for HIV
	• 4.8.1.2 Total number and % of WB and Apheresis donations from Repeat VNRD screened reactive for HIV
	• 4.8.2 Total number and % of WB and Apheresis donations from Family replacement donors screened reactive for HIV

	• 4.8.3 Total number and % of WB and Apheresis donations from Paid donors screened reactive for HIV • 5.2 Number and % of WB donations separated into components • 5.3.1 Number of WB units separated into Red Cell Concentrate (Do not include any secondary separations e.g. paediatric RCC) • 5.3.2 Number of WB units separated into Platelet Concentrate • 5.3.3 Number of WB units separated into FFP • 5.3.4 Number of WB units separated into plasma • 5.3.5 Number of WB units separated into Cryoprecipitate • 5.4.1 Number of units of Apheresis red cells collected • 5.4.2 Number of units of Apheresis platelets collected • 5.4.3 Number of units of Apheresis plasma collected • 5.5. Number of WB/RCC discarded ○ 5.5.1 Incomplete blood donation ○ 5.5.2 Reactive for TTIs ○ 5.5.3 Expired ○ 5.5.4 Storage problems ○ 5.5.5 Transportation problems ○ 5.5.6 Processing problems ○ 5.5.7 Total number WB/RCC discarded • 6.4.1 Number of WB units issued (actually units transferred) • 6.4.2 Number of Red Cell Concentrate units issued • 6.4.3 Number of WB derived Platelet units issued • 6.4.4 Number of Apheresis derived platelet units issued • 6.4.5 Number of FFP units issued • 6.4.6 Number of Plasma units issued • 6.4.7 Number of Cryoprecipitate units issued • 6.5 Number of patients transfused • 6.6 Number of patients transfused , by age ○ 6.6.1 Under 5 years ○ 6.6.2 5 to 14 years ○ 6.6.3 15 to 44 years ○ 6.6.4 45 to 59 years ○ 6.6.5 60 years and older

4. Non-functional Requirements

4.1 Performance Requirements

NFR01	Performance Requirements
NFR01-01	The system should be designed to store a minimum of 1,000,000 donor records
NFR01-02	The system should be designed to store a minimum of 4,000,000 donation (collection) records. Each of the donations may be processed into three separate components which will retain the same identification number as the original unit, meaning a total of 16,000,000 possible component records.
NFR01-03	**Need to define** system availability

NFR01-04	**Need to define** actual performance i.e. response times, updates, retrieval and report generation

4.2 Security – Authorisation, Auditing and Logging Requirements

NFR02	Security Requirements
NFR02-001	The system will provide role-based access restrictions based on User Classes defined in section 2.3. A maximum of two Administrator users is allowed. Only Administrator can create users and assign domains.
NFR02-002	All system transactions will be logged in an audit log with the date stamp, a time stamp, and the user-ID of the user. The audit log will never be deleted
NFR02-003	The system will provide for the secure storage and retrieval of passwords
NFR02-004	Additional security for laptop used for donor mobile clinics
NFR02-005	Database backups and disaster recovery
NFR02-006	Use of cloud-based technologies

4.3 Other Requirements

NFR04	Other Requirements
NFR04-01	Requirement to provide a standard import mechanism for legacy data. Existing donor and donation records, and test data from existing legacy systems will be imported into BSIS if possible and where appropriate. This will need to be determined on a case by case basis.

4.5 Minimum Hardware Requirements

Server	• Processor - Intel Core 2 Duo or later • At least 4 GB RAM • 200 GB hard disk drive
LAN	• Wired Ethernet – 100 Mbps Bandwidth • Wireless Router – 802.11g Supported
Workstation	• Processor - Intel Core 2 Duo or later • At least 1 GB RAM • 100 GB Hard Disk Drive • Operating System - Windows 7 or later • Browser – Firefox or Google Chrome
Laptop	• Processor - Intel Core 2 Duo or later • At least 1 GB RAM • 100 GB Hard Disk Drive • Operating System - ? • Browser – Firefox or Google Chrome
Printer	• Any printer supported by the Operating System
Label Printer	• Thermo genic label printer using materials suitable for a blood safety Environment

Barcode printer	• A barcode printer that can be taken to a collection site for printing donor labels • Barcode printer should be able to print barcodes encoded Code 128 barcode format
Barcode reader	• A barcode reader with a USB connector which can scan Code 128 format barcodes
Data back-up system	• An external storage device, e.g., External Hard Disk, with a USB connector which can be stored offsite. • BSIS Software will provide backup and restore functionality – to be elaborated
UPS protection	• UPS should be available for servers, workstations and LAN devices to provide at least 15 minutes of power.

Sign Off

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Appendix A: A detailed description of the workflow supported by BSIS

Appendix B: Terminology used within BSIS

	TERM	ABR	Synonyms	EXPLANATION FOR TERM AS USED IN BSIS
A	Apheresis	-		The process whereby whole blood is taken from the donor and then immediately processed to harvest a particular component. The donor is re-infused with those constituents of their blood that are not needed by the blood bank. An apheresis machine is used to carry out this process. (See plateletpheresis/ plasmapheresis)
	Autologous transfusion	-		Withdrawal and subsequent return of blood to the same person.
	Anti-human Globulin	AHG		Reagent used to detect the presence of antibodies or complement binding to red blood cells.
	Anti-coagulant	-		Substance used to prevent clotting of blood.
	ABO blood groups	-		One of the major blood group systems. The four main groups in the ABO system are A, B, AB and O
B	Blood safety information system	BSIS		The name of the BECS software system based on V2V and developed under the BSSP programme
	Blood Establishment Computer System	BECS		A computer system designed to assist in the management of donors, donations and allied aspects of a blood transfusion service.
	Blood Group Serology		blood grouping/ blood typing/ ABO Rh testing	Identifying the blood group of a donation by serologic testing of a sample of blood. Also refers to the screening and identifying of unexpected antibodies.
	Blood typing rule			The algorithm used to determine a blood group based on test results. Part of the initial system configuration.
	Barcode			An optical machine-readable representation of data relating to the object to which it is attached. Used in BSIS to make data entry faster and more accurate.
	Barcode label			Stick-on labels that may be pre-printed or generated by BSIS and are used throughout the blood chain to identify donations, components and donors.
	Blood Pack			Plastic container into which a donation is collected. May consist of multiple parts into which components may be separated. Can also refer to the completed donation/ product.
	Blood pressure	BP		Measurement of the pressure exerted on the vessel walls by the blood during the active and resting phase of the heartbeat. Measured in mm of mercury and made up of Systolic and Diastolic measurements.

	TERM	ABR	Synonyms	EXPLANATION FOR TERM AS USED IN BSIS
	Blood Pressure Systolic	BP Systolic		Refers to the measurement taken when the heart is contracting in order to pump the blood around the body. This is the time when the arteries are under maximum pressure
	Blood Pressure Diastolic	BP Diastolic		Refers to the measurement taken when the heart is relaxed between contractions.
	Buffy Coat			The layer of white cells and platelets that is seen between the red cells and the plasma in a bag of whole blood that has been centrifuged.
C	Controls			Samples with known results that are tested in parallel with, before or immediately after routine tests using the same environment, reagents and conditions as those of the test sample If these results do not fall into an acceptable range the test results are deemed invalid and the tests must be repeated.
	Component		Product	The therapeutic constituents of whole blood that are prepared by centrifugation and separation.
	Components Laboratory			The laboratory within the blood service which processes whole blood into components
	Component type		Product type	The various components and sub-components which may be processed from a blood donation
	Component code		Product code	Code used to describe the various component types. Includes: • WB = whole blood • RCC =red cell concentrate • FFP= fresh frozen plasma
	Cross match		Compatibility test	Procedure whereby the donor red cells are mixed directly with the recipient plasma/ serum to detect ABO and/ or other red cell antigen compatibility.
	Cryoprecipitate	Cryo		A plasma component prepared from frozen fresh plasma by slow thawing which is rich in Factor VIII.
	Centre			A blood service site which offers two or more of the following services: • Donations(collections) • Testing • processing, • distribution
	Code Group			
	Code			
D	Donor		Blood donor	The person who donates blood

	TERM	ABR	Synonyms	EXPLANATION FOR TERM AS USED IN BSIS
	Donor Code			A code assigned to the donor to indicate the current status of that donor according to results captured during the donation or during the testing process.
	Donor Number			A unique system-generated number used to identify the donor
	Donor Type			Donors are categorised into the following types for reporting purposes: • Voluntary, non-remunerated donors (VNRD) • Replacement donors • Paid donors • Autologous • Other
	Donation		Collection	The unit of blood, or blood component, drawn from the donor. May also refer to the act of withdrawing the blood or blood component from a donor
	Donation Identification Number	DIN		A unique pre-generated number applied to the donation which links the donation to the donor and is also applied to any components resulting from this donation
	Donation site		Collection site	The place where the blood donations take place. May be either: • Mobile site • Fixed site
	Donation testing laboratory			The laboratory within the blood service where all blood group serology and TTI testing on blood donations is performed
	Donation batch		Collection batch	A batch consisting of one or more donations that were collected at the same donation site during the same session.
	Donation category			Donations are categorized as being drawn from the following type of donor based on their status at the time of the donation: • First time donor • Repeat Donor • Lapsed Donor
	Date Bled			The day that the blood collection was made.
	Deferral			Refers to delaying the donation from a donor. This may be temporary or permanent.
	Deferral reason			The reason that the donor has been deferred.
	Deferral period			The period for which the donor has been deferred, after which the donor may donate.
	Department			A department within a health facility

	TERM	ABR	Synonyms	EXPLANATION FOR TERM AS USED IN BSIS
	Donor Panel			A collection of blood donors who usually donate at the same donation site.
	Diagnosis			The medical reason for which a blood transfusion is prescribed.
	Discard			The act of destroying a unit of blood or blood component that is not suitable for transfusion.
	Discard Label		Biohazard label	The system-generated printed label affixed to a unit of blood or blood component that is not suitable for transfusion
	Domain			The areas of functionality within BSIS used to determine user access, based on user roles
E	Enzyme-linked immunosorbent assay	ELISA		The enzyme-linked immunosorbent assay is a test method that may be used primarily in TTI screening
	Expiry Date			The date on which a component is deemed to become ineffective and may no longer be transfused. The shelf life differs according to the type of component.
	Expired			Refers to a component which has passed the expiry date and may no longer be transfused
F	Fractionation			Separation of plasma into blood fractions by chemical means. Also refers to the department responsible for this activity.
	Full Blood Count	FBC		Automated test for haematology indicators eg. Hb, Hct, MCV etc.
H	Haemoglobin	Hb		Constituent of red blood cells responsible for the O_2 carrying capacity of red cells.
	Haematocrit	Hct		The term used to describe the proportion of red blood cells in whole blood. The normal haematocrit range for adults is approximately 0·4 to 0·5 l/l.
	Hospital			An institution providing medical and surgical treatment and nursing care for sick or injured people. Blood transfusions are usually carried out in hospitals.
I	Issue			Refers to the issuing of a component for distribution to an individual patient, usually matched against a request
	Inventory			Stock levels of components. Also the name of the department that is responsible for distribution of blood and blood components.
	Inconclusive			A test result or series of test results for which it is not able to determine an outcome.
L	Labelling			Process during which all test results are checked by BSIS and, if the component is suitable for use, a label is printed and affixed to the pack. Biohazard labels are printed and affixed to components that are not suitable for use.
	Low hemoglobin			Hemoglobin level below the value acceptable for blood donation, which is usually 12.5 g/dl

	TERM	ABR	Synonyms	EXPLANATION FOR TERM AS USED IN BSIS
M	Medical History Form		Medical questionnaire	A form that collects personal details and general health information of the donor
N	National Blood Transfusion Service	NBTS		The generic name for the blood transfusion service serving an entire country.
	Non-reactive		Negative	A negative test result. (Negative) (0) (-)
P	Phlebotomy			The process of inserting a needle into the vein of the blood donor in order to collect a unit of blood.
	Plateletpheresis			This process of obtaining only platelet concentrate from a donor and returning all other components (red cells, plasma, white cells) to the donor.
	Pulse			The number of times the heart beats per minute. One of the parameters measured on prospective blood donors.
	Pack label			The system-generated printed label that is applied to the donation pack during the labelling process
	Pack weight			The weight or mass of the blood pack after donation.
	Paid donor			A donor who is paid, either directly by the blood service or by a third party, for donating blood or a component of blood.
	Patient			The person for whom a request for blood is made.
	Patient Number		Hospital Number	Number used to identify a patient on a request form. The patient number is issued by the hospital.
	Plasma			The straw-coloured liquid part of anticoagulated blood remaining after separation from the cellular components. As its major role plasma transports cellular and non-cellular components to the parts of the body where they are required.
	Platelets	Plts		Platelets are small particles found in the blood that play a major role in clotting. They help to stop bleeding from small blood vessels and wounds. They are derived from cells in the bone marrow called megakaryocytes.
	Permissions			Used to define the areas of functionality within the system that a user has access to, dependant on their role
	Processed			A donation which has been processed by the component laboratory and split into components.
	Pending test		Test in progress	A test awaiting a final result or outcome
O	Outcome			The interpretation of a test result, or series of test results, for example Positive or Negative.

	TERM	ABR	Synonyms	EXPLANATION FOR TERM AS USED IN BSIS
Q	Quarantine			All unscreened donations are automatically assigned a Quarantine status which means that until testing process has been completed and the suitability of donations for therapeutic use has been determined they cannot be labelled for release
R	Result			The visible or measurable endpoint of a test.
	Reactive		Positive	A positive test result
	Recipient			A patient who is given a blood transfusion
	Repeat reactive			A reproducible positive result.
	Replacement donor			A blood donor who donates blood or a component of blood in order to replace a unit transfused into a friend or relative.
	Request			A request for one or more blood components made from another facility such as a hospital, another blood bank or a clinic, or from a provider/doctor for a specific patient
	Request number			A number used to identify a request
	Red blood cells	RBC		of the non-nucleated blood cells that contain haemoglobin. Also used to describe a component containing a concentrate of red cells.
	Rh			Refers to the presence (Rh Positive) or absence (Rh Negative) of the D antigen, the major antigen of the **Rh blood group system.**
	Role			The various types of users within the system. Access to functionality within the system is determined by the role a user is assigned.
S	Specimen		Sample	A small quantity of donor/ patient blood used for testing purposes.
	Standard Operating Procedure	SOP	Work Instructions	A document that provides step by step instructions for the performance of a particular procedure which could impact on the safety of donors and recipients of blood and blood products, and such procedures include medical, laboratory and clerical procedures, as well as the computer programmes associated with them
T	Transfusion Transmissable Infections	TTI		Any infection that can be transmitted to a recipient through a blood transfusion. The tests for the following TTIs are performed routinely on donated blood – HIV, HBC, HCV and Syphilis
	TTI Testing			All testing for Transfusion Transmissable Infections
	TTI testing method			The methodology used for TTI testing. Part of the initial system set-up and configuration.
	TTI reactive		TTI Positive	Exhibiting a reaction for a TTI test
	Time Bled			The time that the donor is bled and the donation is collected at the donor clinic. Refers to the time the collection is commenced.

	TERM	ABR	Synonyms	EXPLANATION FOR TERM AS USED IN BSIS
	Test Batch			The batch of donation samples which are tested at the same time. A test batch may include more than one collection batch.
	Test batch release			The manual process during which the supervisor checks all test protocols and signs off that a batch of tests can be released
	Test plate			The microtitre plate on which more than one specimen is tested, and on which more than one test may be carried out on each sample.
	Transfer			A transfer refers to a batch of one or more components that are distributed directly to another facility such as a blood bank, hospital or clinic
	Transfer number			The unique number given to a transfer event by BSIS for tracking purposes
V	Voluntary non-remunerated donors	VNRD		Donors who are not paid for a donation, and are not coerced into donating. Generally considered as lower-risk donors than other donor categories
W	White blood cells	WBC		The nucleated blood cells primarily concerned with immunity. Includes granulocytes and lymphocytes.
	Weight		Body Mass	Body weight recorded for the donor
	Ward			A division within the hospital