System Requirements Specification for BSIS (Blood Safety Information System) DONOR & BLOOD MANAGEMENT Version 1.3

Programme: Blood Safety Systems Strengthening

Document Control

Version	Description of Change	Author	Date
0.6	Revised based on original BSIS requirements document v0.5.3 (developed by Rob Wilkinson, Brian Gibbs, Pete Zacharias, Linda Taylor, Daniel Futerman, Carolyn Smith) and review of other BECS user requirements documentation, and input from the Lesotho Blood Service and AABB team.	Linda Taylor	29th August 2015
0.7	Revised following review workshop with Rob Wilkinson, Daniel Futerman and Linda Taylor 14-16 September 2015	Linda Taylor	30th September 2015
0.7.1	Revised following feedback from QCP	Linda Taylor	30th October 2015
0.7.2	Updated to incorporate changes from testing process. Changed Donor Panel to Venue throughout.	Linda Taylor	1st November 2015
0.7.3	Removed sections not relevant to Donor Management module for use in LBTS OQ and PQ	Linda Taylor	1st December 2015
0.7.4	Added revised sections for the Blood Management module for next phase of development	Linda Taylor	29th April 2016
1.0	Reviewed for V1.0 release. Added Appendix: Component and Inventory Status Rules and additional diagrams.	Linda Taylor	30th August 2016
1.1	Added new requirements for features to be included in V1.1 release:	Linda Taylor	November 2016
1.2	Added new requirements for features to be included in V1.2 release:	Linda Taylor	December 2016
1.3	Added new requirements for features to be included in V1.3 release:	Linda Taylor	March 2017

Authors

The Authors signatures represent the BSIS Project Team Group and signify that this document is complete and that, to the best of their knowledge, it adequately addresses the document's intended purpose and scope and it is accurate.

BSIS Quality Control Panel

The BSIS Quality Control Panel signatures signify that this document has been reviewed and satisfies the project governance, business and system needs.

Document Title: System Requirements Specification for BSIS (Blood Safety Information System) Donor and Blood Management Version 0.7.4
Year: 2015

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Table of Contents

Figures

Tables

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 was made by CDC, in conjunction with Georgia Tech, to allow it to undergo further development and enhancement to result in a production-ready information system ready to be implemented in working blood services.

1.1 Purpose

The aim of this document is to capture, define and document the functional, non-functional and informational requirements for BSIS (Blood Safety Information System). Software requirements specifications are complete and detailed descriptions of all the functional, informational and non-functional requirements the software must fulfil to meet business and user needs. Software requirements are more detailed than user requirements and provide the basis for the technical specifications used by developers to build the software.

This document has been produced by the BSIS Project Work Group, under the authority of the BSIS Quality Control Panel.

1.2 Scope

The intention of this document is to provide a clear, complete and unambiguous statement of the functional, non-functional and informational requirements for **BSIS (Blood Safety Information System*)* Donor Management Module and the Blood Management Module V1.3** It covers the requirements identified for the provision of:-

- Donor Management
- Donation Management
- Testing of Donations
- Component Processing
- Blood Component Inventory Management
- Operational Reports
- Management Reporting

1.3 Assumptions and Dependencies

- These requirements are for a single instance of the system running in a central blood service.
- The need to migrate data from existing electronic systems will vary widely and will also be dealt with as an implementation activity.
- The first versions (1.0 – 1.3) will be available in English only.

1.4 Related Documents

Version	Date	Document Name	Author
V0.2	01022017	BSIS Haemovigilance V0.2 01022017	L. Taylor
v1.3	01032017	Critical Control Points in BSIS V1.3	L. Taylor

1.5 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)
8. Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products (Ver 1.0 April 2013)

2 Scope and Context

2.1 Stakeholders

The following table lists the different groups of stakeholders involved in this project and describes their desired outcomes and needs.

Stakeholder	Interests / need
Jembi Executive Management	• Aligns with Jembi's strategic goals and financial governance framework
Jembi BSSP programmes team	• Successful delivery of the programme, capacity building within Jembi and the national blood services, and monitoring and evaluation.
Jembi Technical team	• Delivery of the BECS software solution and provision of technical and product support
Lesotho National Blood Transfusion Services - Beta test site	• Needs an information system solution to meet organisational goals and assist in AfSBT accreditation process • Reduction in rate of HIV,HBV,HCV and syphilis transmitted by unsafe blood • Better forecasting of blood demand due to improved reporting • Improved rates of donor recruitment and retention due to improved quality and availability of information
Centre for Disease Control (CDC)	• Reduction in rate of HIV transmitted by unsafe blood • More sustainable BECS solution for use in African blood services • Increase in the number of AfSBT accredited blood services in sub-Saharan Africa
American Association of Blood Banking (AABB) Safe Blood for Africa (SBFA)	• Reduction in rate of HIV transmitted by unsafe blood • Better forecasting of blood demand due to improved reporting • Improved rates of donor recruitment and retention due to improved quality and availability of information
African Society of Blood Transfusion (AfSBT)	• Progress towards achieving accreditation status by national blood services using BSIS
World Health Organisation (WHO)	• Requires statistics from blood transfusion services to compile the Global blood safety database that is then analysed and used to inform global strategies and policies for safe blood use.

Table 1: Stakeholders Summary

3 BSIS Overview

3.1 Business Area Scope

The BSIS solution must capture, track and report information across the following business areas of a blood transfusion service organisation:

- donor recruitment activities
- donor counselling services
- donor clinics where donors are registered and donations are collected
- TTI testing laboratory for infectious disease screening
- serology testing laboratory for blood grouping
- blood component production laboratories including pack labelling
- blood component inventory management

The following diagram shows the functional areas of a typical national blood services and highlights which of those functional areas are in and out of scope for BSIS.

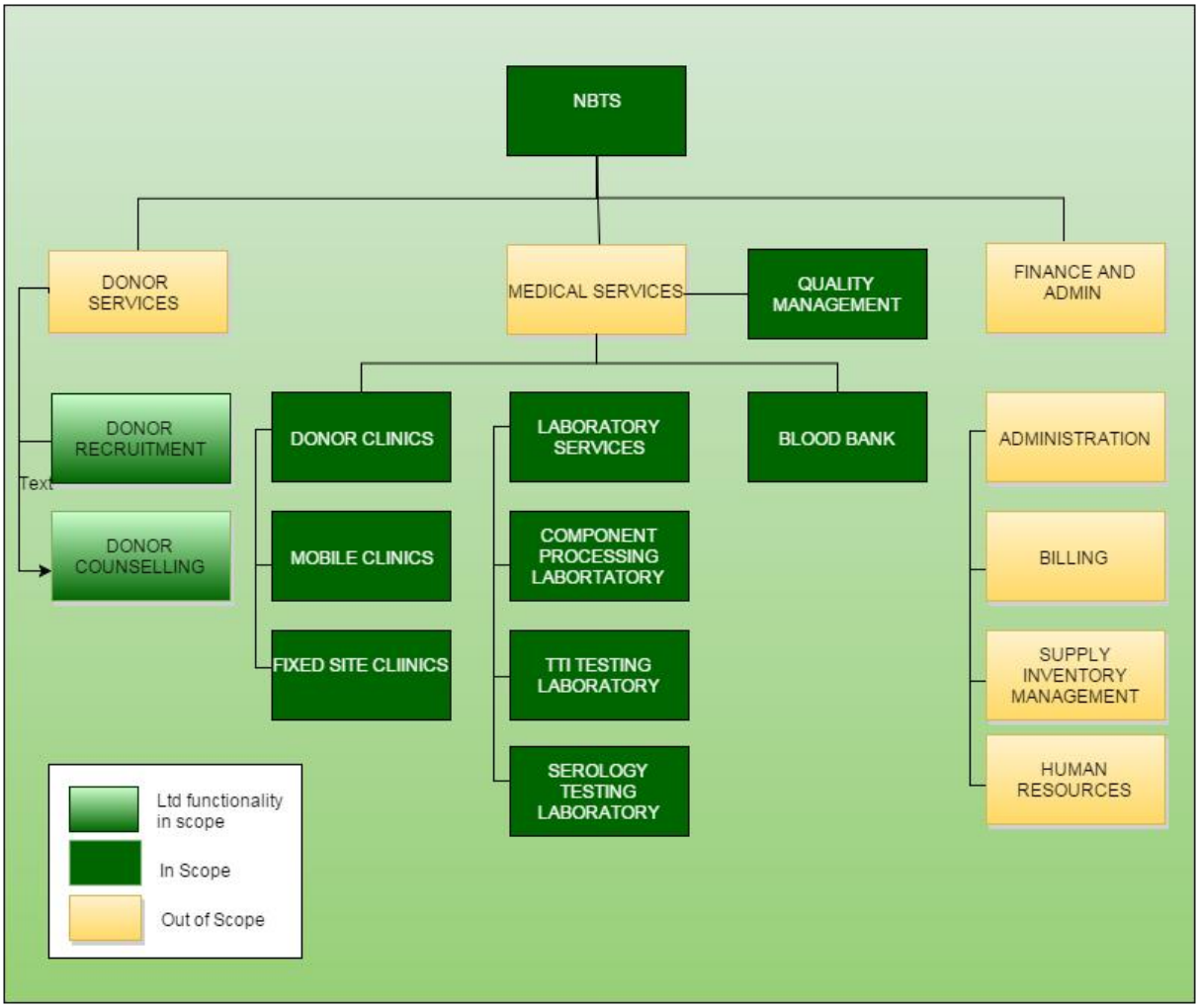


Figure 1: BTS Functional Decomposition

3.2 Solution Architecture

Blood Safety Information System (BSIS) has been designed and built using open source technologies, in line with Jembi strategy. The conceptual solution diagram is shown below.

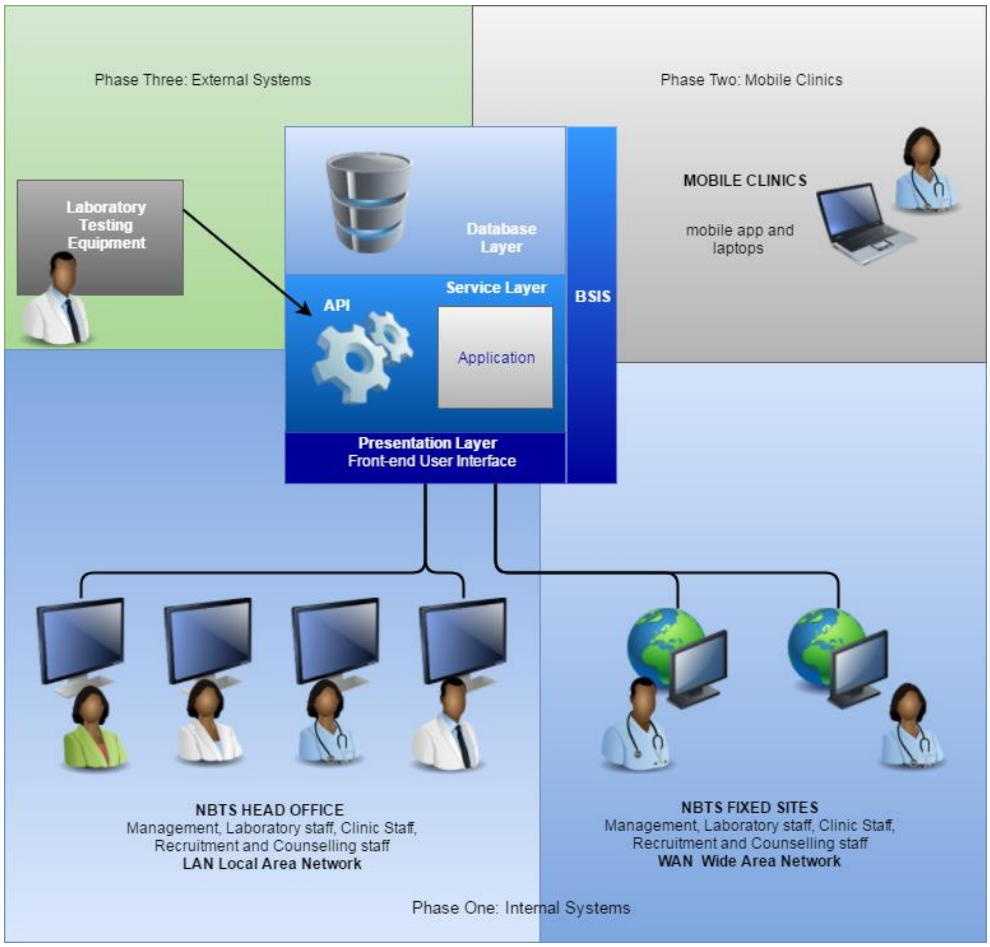


Figure 2: BSIS Solution Architecture

3.3 Technical Architecture

BSIS is a web-based Java J2EE application, and makes use of:

- Spring - the Spring Model-View-Controller (MVC) framework is used.
- Hibernate and JPA
- MySQL database
- JQuery and other JavaScript and AJAX plugins
- AngularJS, Bootstrap, HTML for the front-end.

The following diagram shows the technical architecture of the application.

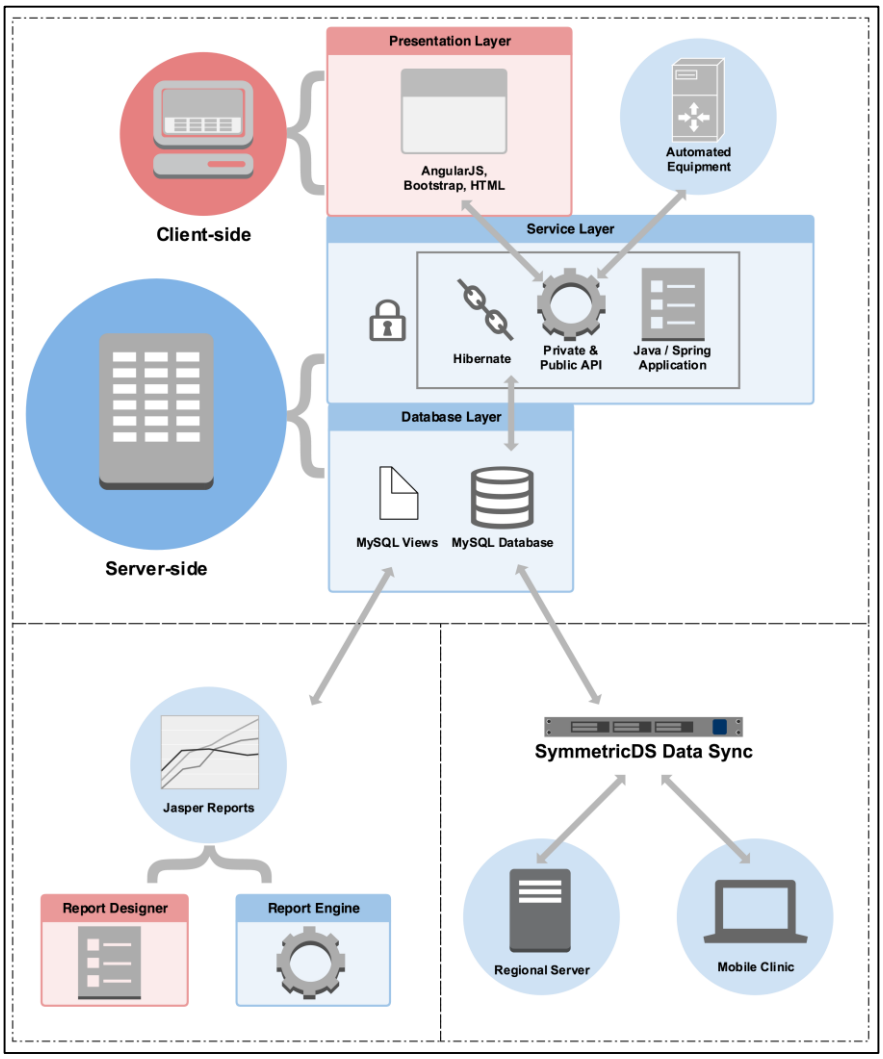


Figure 3: BSIS Technical Architecture

3.4 Operating Environment Requirements

BSIS is designed to operate using a client-server architecture, making use of a dedicated high-spec server to host the BSIS application on a web server hosted in a local or wide area network. The system makes use of a MySQL database and requires MySQL to be installed on the server. The recommended setup is to use an open-source Ubuntu server to host the application. BSIS is designed to be accessed via a Windows 7 machine using the free Google Chrome browser.

For additional reporting Jasper Reports can be used to design and generate reports that interrogate BSIS SQL Views to provide more detailed analysis of the data.

The application is also designed to be used with additional hardware that requires barcode printers and scanners and Zebra pack label printers. Pre-printed Donation Identification Numbers DIN labels are also a pre-requisite as are blank labels for printing Donor Numbers. Materials used must be suitable for use in a blood safety environment and label sizes and number formats must be confirmed with Jembi before ordering from suppliers.

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.

3.5 System Scope

Two of the most important requirements of a BECS are traceability and auditability. Therefore, the key objectives of the system can be described as:

- To provide access to donor, donation and component data on a real-time basis where the infrastructure allows
- To enable offline access to donor, donation and component data where internet connectivity is intermittent
- To provide full traceability of donations throughout the collection, component processing, testing, labelling, inventory and issuing processes
- To allow the flexible extraction of information necessary for the management of a Blood Transfusion Service
- To ensure strict access control to confidential data
- To provide full auditability including the ability to identify the individual(s) responsible for performing key steps throughout the processes.
- To support the process of accreditation by African blood services to AfSBT standards under PEPFAR programme by the provision of key information

3.5.1 In scope

The following areas of functionality are in scope for version 1.3:

1. Donor management including donor recruitment list and post-donation counselling
2. Donation management
3. Capture of donation test outcomes using test batches with double entry
4. Configuration and system administration
5. Operational reporting
6. Component processing
7. Labelling and label verification of components
8. Discard management
9. Inventory (Blood bank stock control)
10. Recording of transfusion information for issued units to support haemovigilance

11. Management reporting

The following context diagram shows the functional areas in scope for the BSIS v1.3

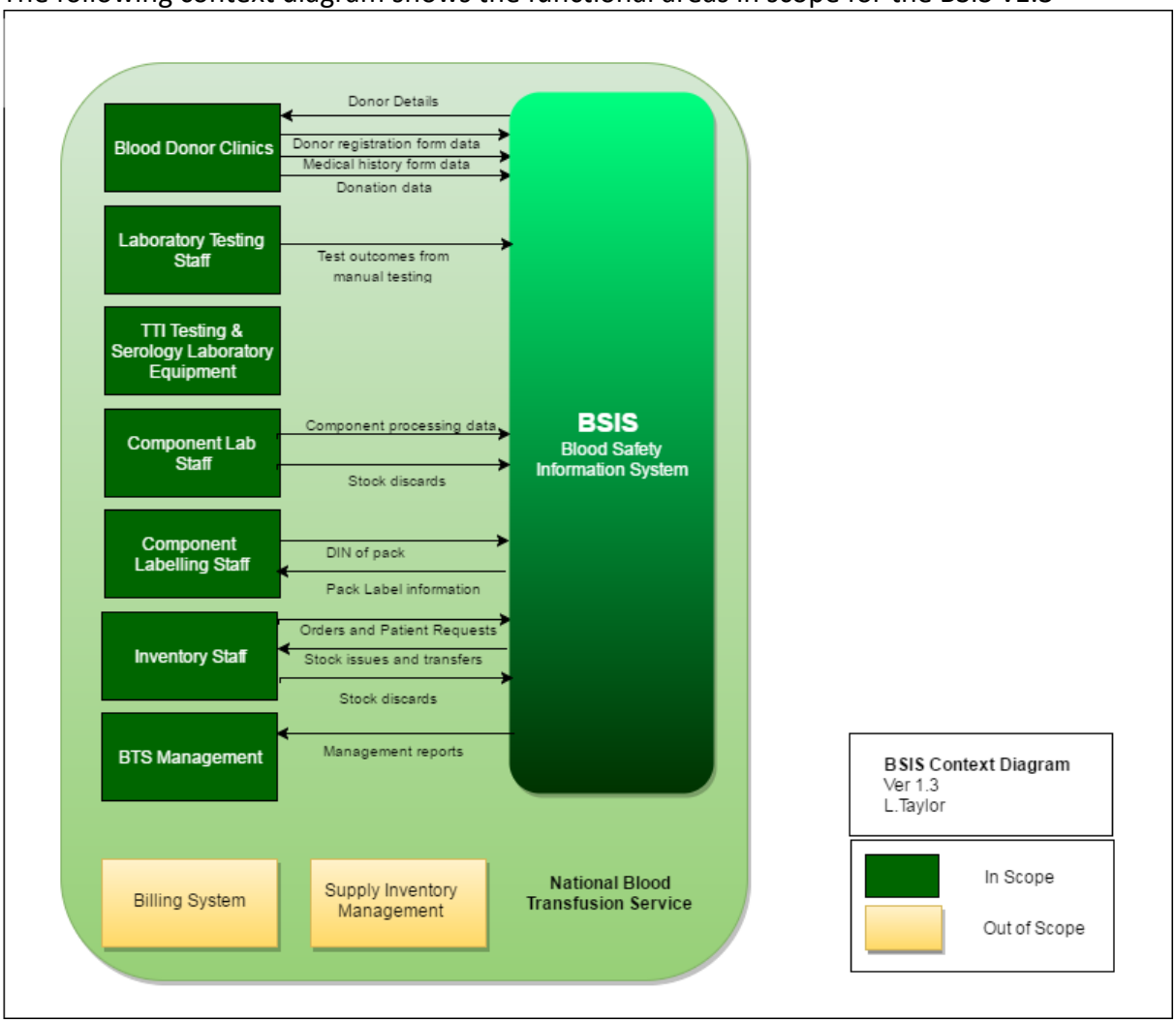


Figure 4: BSIS V1.3 Context Diagram

3.5.2 Out of scope

The following areas of functionality are out of scope for Version 1.3 of the system, but are planned for or will be considered for inclusion in later versions:

1. Synchronisation of data between laptops and the central database for mobile clinic use
2. Internationalisation : ability to support other languages per instance e.g. French
3. Device interfacing with laboratory equipment
4. Comprehensive donor recruitment and planning
5. Automation of Donor Communications
6. ISBT128 support
7. Supply inventory management

3.6 User Classes and Characteristics

Protection of personal information is a critical for blood services and the core principle under which a blood service operates is the separation of roles between donor management and blood donation management to limit access to sensitive information. Staff who need access to information about the donor must not have access to information about the test outcomes of the blood donated and vice versa. Only staff at supervisory level, donor counsellors, some authorised management staff and the Medical Officer should have access to both the donor information and their donation test results. Aggregated, non-identifiable data may be reported to the Ministry of Health. The system must therefore support the following classes of users are summarised in Table 1 below.

	User Class	**Characteristics**
1	Donor Clinic Staff	Access limited to donor information and donor processes only
2	Donor Clinic Supervisor	Access limited to donor information and donor processes only
3	Donor Counselling Staff	Access to donor information and TTI results. Can link TTI results to specific donors.
4	Donor Communications Staff	Access to donor contact information
5	Serology Staff	Access limited to donation information and testing processes
6	Serology Supervisor	Access to printing and checking of laboratory results. Correction of some laboratory data.
7	TTI Testing Staff	Access limited to donation information and testing processes
8	TTI Testing Supervisor	Access to printing and checking of laboratory results. Correction of some laboratory data.
9	Component Laboratory Staff	Access limited to component processing and labelling of components
10	Component Laboratory Supervisor	Access limited to component processing and labelling of components
11	Inventory Staff	Access limited to management of labelled components in and

		distribution management i.e. order, issues, transfers and returns
12	Administrator	Access to all functions within the system including management reporting. This includes access to configuration and set-up. Generally this would include the medical officer, QA manager and system administrator

Table 2. BSIS User Classes

3.7 Documentation Requirements

Accompanying the BSIS software codebase is a set of documentation as follows:

- A set of User Manuals intended for use by the end-users of the system
  - Donor Clinic User Manual
  - Laboratory Staff User Manual
  - Supervisor and Administration Manual
- A set of Implementation Guides to provide guidelines and checklists for the deployment, training, support and change management process
- A document providing an overview of the system functionality
- Requirements documentation including process models, information models and use cases
- Technical specifications

In addition, a set of standard operating procedures (SOPs) describing the user interaction with the system will be required by implementing blood services. These SOPs will differ according to local policies and procedures and will be developed by each blood service and their technical assistance provider, according to their own quality assurance policies and procedures, with support from Jembi.

4 High-Level Business Processes

The following diagram shows the high level business processes for a blood service for those functions within the scope of this project.

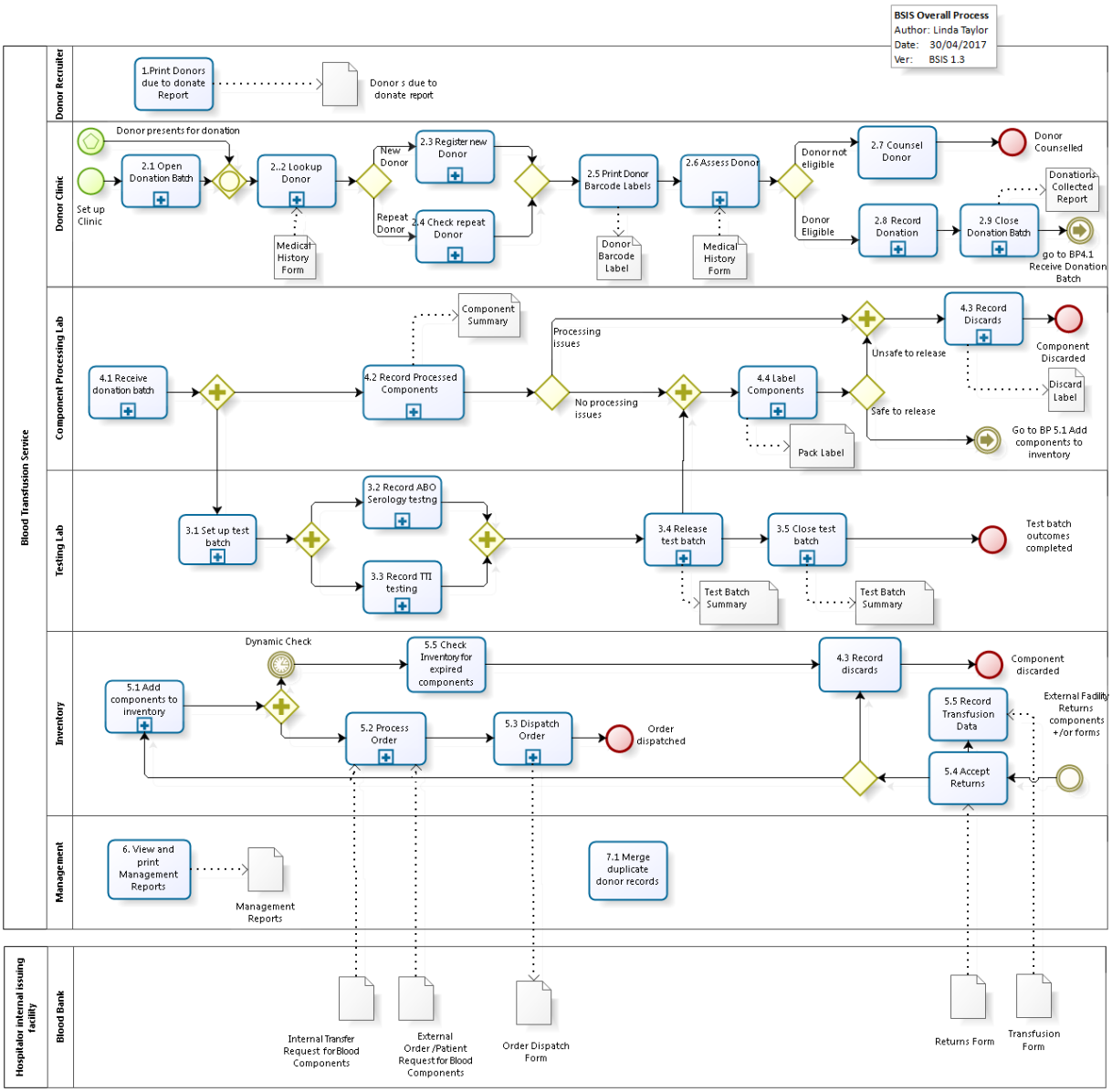
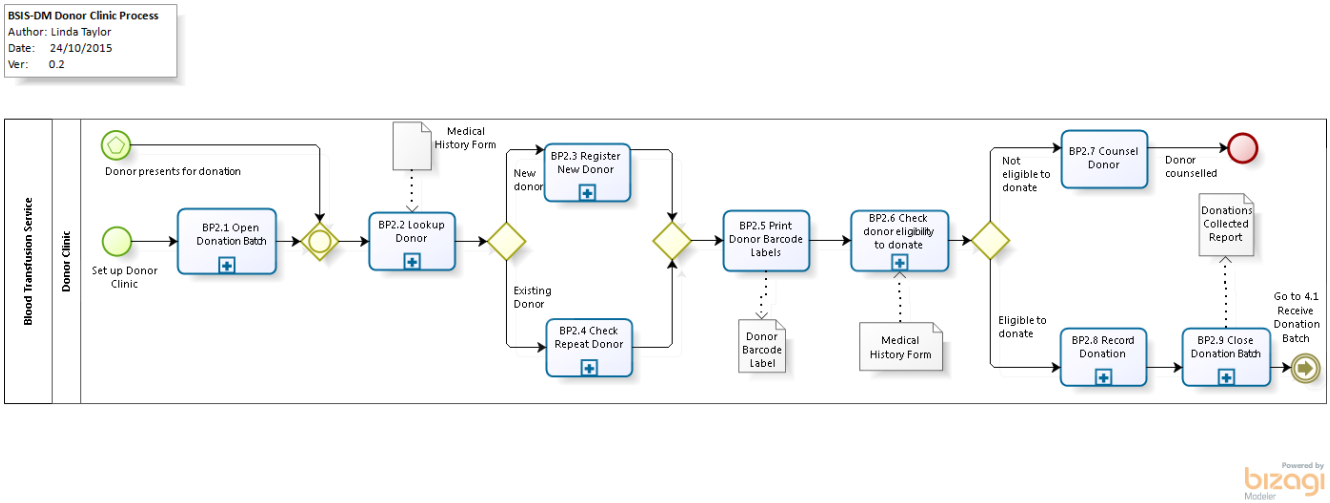


Figure 5 BSIS High-level business process

The following processes show those business processes that are within the scope of the Donor Management section.

4.1 Donor Clinic Process

DONOR CLINIC PROCESS



General Business Process Notes

2.1 Open Donation Batch

1. During a donor clinic session a donation batch is used to group donations into batches according to the venue (Venue) and a date and time for control and traceability purposes. For clinics held at the central service or fixed sites, these sessions would generally be opened and closed at the start and end of each day. For mobile clinics, each session would be grouped into a donation batch.
2. Before any donations can be added, a donation batch must be opened by specifying the Venue (donor panel). (This is a configurable option and may be configured to allow donations to be added without opening a donation batch).

2.2 Lookup Donor

3. The donor completes the Medical History Form and takes it to the registration desk. Donor clinic staff user searches the system to determine whether the donor is a first-time donor or a repeat donor (i.e. whether a record of the donor already exists in the system).

2.3 Register New Donor

4. If the donor is a first-time donor, the donor is registered on the system and assigned a unique system-generated Donor Number.

2.4 Manage Repeat Donor

5. If the donor is a repeat donor, then the user checks the demographic data displayed to make sure it is indeed the correct donor. The user will also be able to see if the repeat donor is currently (or permanently) deferred and can then refer the donor for counselling as he/she cannot donate.

2.5 Print Donor Barcode Labels

6. Two barcode Donor Numbers are printed for the donor and attached to the Medical History form and the Clinic Worksheet. The donor takes the Medical History Form with the donor barcode

attached to the next station: either the Donor Counsellor or the Phlebotomist.

2.6 Check Donor's Eligibility to Donate

7. Donor clinic staff conduct one-on-one counselling with the donor and assess the information on the Medical History Form to determine if the donor is a suitable candidate and qualifies for donating blood.
8. Unsuitable donors are marked as deferred in the system, along with a deferral reason and the period of time for which they are to be deferred for a temporary deferral. The deferral may also be permanent. These donors are advised of their deferral and receive additional counselling if required. Pre-printed barcoded Donation Identification Numbers (DIN) may be assigned to deferred donors or not, according to local procedures.
9. If the donor is qualified as suitable to donate, the type of bag into which the blood is to be collected is selected according to component requirements. A pre-printed DIN is assigned and the DIN labels are affixed to the pack(s), the specimen tubes, the Medical History Form and the Clinic Worksheet.

2.7 Counsel Donor

10. If a donor is referred for counselling due to a positive TTI test outcome, the donor counsellor counsels the donor and records that the donor received counselling and may also add a comment/notes to the donor record for additional information. The donor counsellor may also record whether or not the donor was referred for further testing, care and treatment and the referral site.

2.8 Record Donation

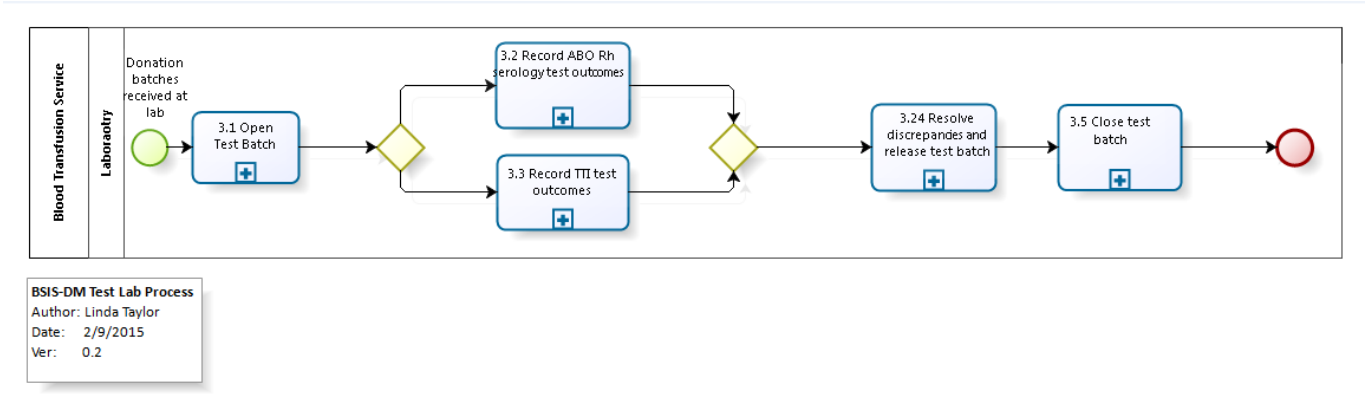
11. Once a donation batch is open, donations can be added directly to the batch by the user, or they can be added from the donor dashboard by specifying which batch to assign the donation to.
12. Accepted donors proceed to the collection bed and the blood is collected according to local procedures. This consists of the donation pack and a number of sample tubes.
13. After the donation, the donor assessment data consisting of the donor's weight, pulse, haemoglobin level (Hb) and blood pressure (BP) may be recorded in the system and must be recorded on the form by the phlebotomist.
14. The DIN is linked with the Donor Number by scanning both the DIN and Donor Number barcode labels on the pack and the Medical History Form.
15. During this process the system automatically updates the donor record by incrementing the number of donations by one and changing the date of the last donation.
16. The status of all donation units is automatically recorded as quarantined.
17. If there are issues during the collection process (e.g. the donor was not able to be bled, the donor fainted) this information is captured in the system as an adverse event.

2.9 Close Donation Batch

18. Once all donations and samples have been collected during a session, the donation batch must be closed off. A summary of the donations collected must be verified by the supervisor and printed off. This can be used as a packing list by mobile clinic staff to verify that the physical units collected match what has been recorded.
19. Once a donation batch is closed, the samples from that batch can be added to a test batch for testing: If however the donation batch is still open, the samples from that batch cannot be added to any test batch.

4.2 Laboratory Testing Process

TESTING PROCESS



General Process Notes

In the testing laboratory, two types of testing are done:

- Blood grouping serology which includes ABO and Rh typing, screening for unexpected antibodies and testing for high titre ABO antibodies,
- Transfusion-transmitted infection (TTI) testing, to screen for markers of infections such as HIV, Hepatitis B, Hepatitis C, and Syphilis.

The donation packs are sent to the component processing laboratory and the samples are sent to the testing laboratory.

3.1 Open test batch

1. Testing is done in batches according to date and time tested for control and traceability. A sample may not be tested unless it is allocated to an open test batch but the test batch may have only one sample. Samples from more than one donation batch may be added to one test batch but a sample can only be allocated to one test batch.

3.2 Capture ABO Rh serology test outcomes

2. The testing for ABO Rh serology and TTI may be done in parallel. The outcomes (interpreted results) of the blood group serology tests are captured in the system from the lab worksheet, whether testing is done manually or by automated laboratory testing equipment.

3.3 Capture TTI test outcomes

3. The outcomes (interpreted results) of the TTI tests are captured in the system, from the lab worksheet, whether testing is done manually or by automated laboratory testing equipment.

3.4 Verify and release test batch

4. Once the outcomes have been captured, they are analysed by the system. Results are compared to the results of previous donations, if any, and any discrepancies are highlighted. All samples with test outcomes that are complete may now be released but any samples that have outstanding pending tests or discrepancies will not be released.
5. As pending test outcomes become available and are entered and discrepancies are resolved the samples are released automatically on an individual basis.

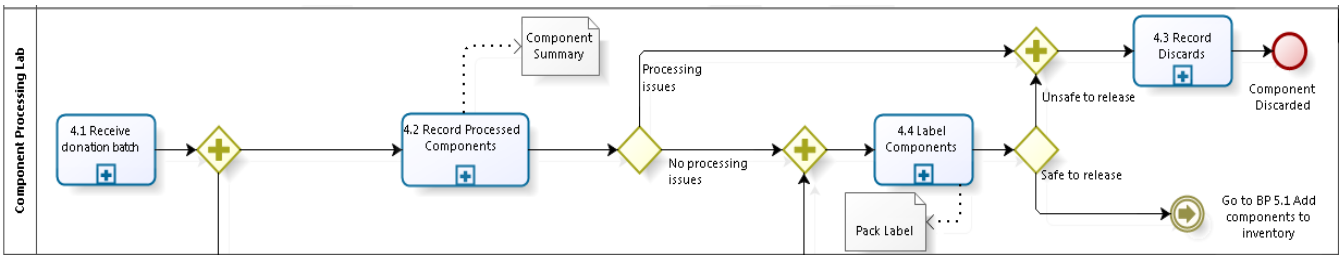
3.5 Close test batch

6. Once all outcomes have been determined, and all discrepancies have been resolved, the test batch

summary is printed off and verified before the batch can be closed off.

The following processes show those business processes that are within the scope of the Blood Management section.

4.3 Component Processing Process



General Business Process Notes

4.1 Record donations received

- The donation packs and sample tubes are delivered to the laboratory from the donor clinic where they were collected. These are verified against the delivery note (also called a packing list or blood transportation form). This form records the number of packs, the number of sample tubes, the number of blood transportation boxes and the names of the person who packed the blood transportation box/es and the name of the person who checked them at the clinic. The lab technician who receives the delivery verifies this information against the actual physical units and then records the temperature in the cool box/es and the date and time of delivery.
- The sample tubes are sent to the testing laboratory to be tested for TTIs and blood group serology whilst the component processing is happening in parallel in the component laboratory.
- The bleed times that are written on the pack by the phlebotomist are checked by the lab technician.
- The packs are then placed in the quarantine fridge until they are ready to be processed.

4.2 Record components processed

- Based on what is in inventory, the lab supervisor decides what components need to be made from the packs and the processing of components begins. The components that are created are recorded in the system.
- In BSIS the user scans in the DIN of the component that is about to be/has been processed.
- The packs are weighed and the weight of each pack is recorded in BSIS. The system checks that the pack weight entered is within the acceptable weight range for that pack type and displays a warning is the pack is over or underweight. If the pack is underweight or overweight then BSIS flags the component as unsafe. The physical packs are set aside to be discarded.
- The user records the components that will be/have been made from the initial starting component. BSIS validates the combination of components to be processed to ensure that only

valid combinations can be entered to minimise data entry errors. The type of pack that the blood was collected in limits the combination of components that can be made from it. The pack weight of the processed component is recorded in BSIS.

- The components are then placed in the quarantine fridge until the TTI and ABO Rh and serology testing is complete and they are ready to be labelled.

4.3 Record component discards

- If there are any issues that occur during the clinic, during transportation or during component processing, such that the component cannot be used (such as a leaking or broken bags or if temperature or time limits are exceeded) these packs must be discarded. Also:
    - Components that are unsafe i.e. where any of the initial screening TTI test outcomes is Positive must also be removed from storage and discarded as soon as the test outcome is known.
    - Components already labelled and in inventory may also be discarded if they are damaged or reach their expiry date.
    - Components that have been returned from another distribution site or from an authorised facility may be discarded.
- In BSIS, the user scans in the DIN for each pack to be discarded and enters the discard reason and a comment. BSIS automatically flags the component as discarded. If the component was in inventory then BSIS automatically removes it from the system inventory.
- The packs are then discarded according to SOPs e.g. the discarded packs are placed in a bin ready to be taken to incineration within the facility or at another facility.

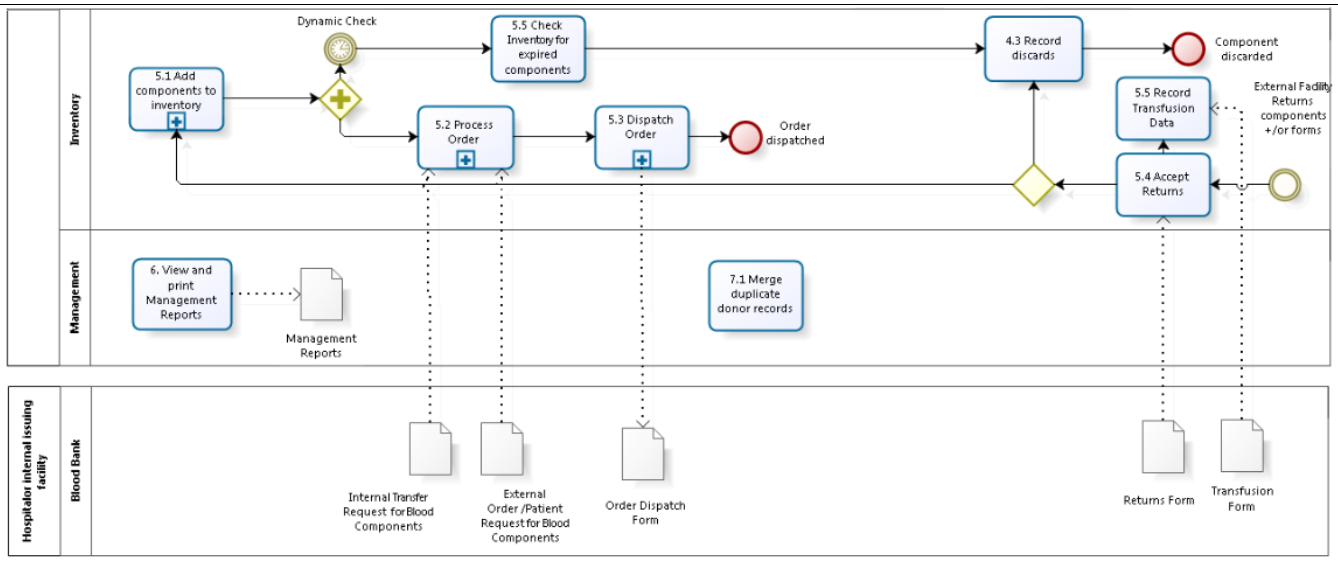
4.4 Label components

- Once the components processed have been recorded they are placed in the quarantine fridge until the TTI and serology testing process for the associated samples are complete (i.e. when the test results have been checked and signed off as correct). Then the component labelling process is performed. The components packs are usually labelled in batches by type (e.g. RCC or FFP).
- The user selects the component type of the component to be labelled and scans in the DIN.
- BSIS checks the component record to verify if the component is able to be labelled according to the following criteria:
    - TTI testing is complete and TTI Status is SAFE
    - ABO Rh testing is complete and ABO Rh blood group is determined
    - The initial pack weight is within the acceptable range
    - The donor should not have been ineligible to donate at the time of donation
    - The component has not already expired or been discarded
- If the component is available for labelling then the user selects the Print Pack Label option which generates a pack label to be placed on the component.
- If the component is unsafe BSIS will not allow a pack label to not be printed and it will be blocked from release to inventory. The user has the option to print a discard label for the unsafe component.
- A lab technician must verify the labelled packs to ensure the correct label has been placed on the

correct pack. BSIS automatically releases the component to the system inventory at this point.

- The labelled components are then placed into the dispatch fridge as they are now ready for issue and use.

4.4 Inventory Management Process



General Business Process Notes

5.1 Add Components to Inventory

- The labelled components are added to inventory and placed in the dispatch fridge as they are now ready for issue and use.

5.2 Manage Orders

- Internal orders (also known as Transfer requests) from other distribution sites within the blood service are sent or phoned into Head Office. Alternatively the Head Office may determine the requirements based on current stock levels and analysis of past trends. A form is filled in. (*See Blood Requisition form)*
- External orders from authorised facilities such as hospitals and clinics are sent in or phoned in. These external orders may be bulk orders or may be a Patient Request for a specific recipient. A form is filled in (See Order Form)
- Both types of order specify the number of units, the component type(s) and blood group(s) required.

5.3 Dispatch Order

- The orders are then filled by allocating the packs in the storage fridges against the orders. Any shortage between what was requested and what can be fulfilled is noted on the Dispatch Note.
- After checking, the Dispatch Note is printed and the packed orders are then dispatched. The dispatched components are automatically removed from the system inventory.

5.4 Manage Returns

- Hospitals and clinics and other distribution sites within the blood service may return un-used components to the blood service. If the storage and transport conditions can be guaranteed to have been within the required limits then the components are returned to inventory (Usually

only internal transfers). If these conditions cannot be guaranteed then these components will be discarded.

5.5 View Stock Levels

- The user must be able to view stock levels to determine what components need to be processed.
- On a daily or weekly basis the inventory is checked to verify stock levels and also to check if any components have expired and need to be discarded.

5.6 Record and View Transfusion Information

- The user must be able to record any transfusion information that the usage site may send back to the blood service as part of national haemovigilance programmes. Information available may be limited must may include the transfusion date, that patient details of the recipient and the transfusion outcome, as well as any related adverse transfusion events.
- The user must be able to view transfusion information that has been recorded.

NOTE:

- *Order – from an external authorised facility i.e. a hospital or clinic or an internal order from another facility within the blood service for units of blood*
- *Patient Request - from an external authorised facility or service provide i.e. a hospital/clinic or doctor ordering units of blood for a specific patient*
- *Transfer – to another facility within the blood service*
- *Issue - to an external authorised facility i.e. a hospital or clinic*
- *Return – from an external authorised facility i.e. a hospital or a clinic*

5 Functional Requirements List

Functional requirements define the software requirements from the user's point of view, describing the tasks that users need to accomplish. The following tables summarise the main functional requirements for the BSIS Donor Management Module.

M	**M**andatory requirement
D	**D**esirable requirement
Risk	Risk of requirement according to impact on donor or recipient safety Categorised as **H**igh, **M**edium, **L**ow

5.1 FR01 Manage Donors

FR01	**Manage Donors**			
Ref	**Description**	**M /D**	**Risk**	**BP Ref**
FR01-01	**Search for donor** The system must provide the ability to search for a donor by first name, last name, Donor Number or Donation Identification Number (DIN)	M	H	2.2
FR01-02	**Register new donor** The system must provide the ability to register a new donor and assign a system-generated unique identifier (Donor Number) to the new donor.	M	H	2.3
FR01-03	**Collect demographic and contact details for donor** The system must provide the ability to collect the donor's demographic details, contact details, preferred method and language of communication.	M	H	2.3
FR01-04	**Assign donor to Venue** The system must provide the ability to assign a donor to a Venue	M	M	2.3
FR01-05	**Manually defer donor** The system must allow for a donor clinic staff member to defer the donor from donating blood for a period of time. The deferral may be temporary or permanent. The system must use configurable deferral code reasons with associated deferral periods that are based on WHO and country-defined standards.	M	H	2.6 2.3
FR01-06	**Print Donor Number barcode labels** The system must be able to print a barcode label with the Donor Number. The number of each label to print must be configurable.	M	H	BP2.5
FR01-07	**Check donor's eligibility to donate** The system must check each category of donor against the following criteria to determine if they are eligible to donate:	M	H	BP2.6
FR01-07-01	Check new donor's eligibility to donate A new donor is defined as a donor who does not have any previous donations recorded in the system. The system must check that the new donor's age is within the allowable range as configured.	M	H	BP2.6
FR01-07-02	Check repeat donor's eligibility to donate A repeat donor is defined as a donor whose previous donation was within the last 12 months. The system must check that the repeat donor's age is still within the allowable range as configured. The system must check that the donor is not currently or permanently deferred and must also check that the interval since the last donation	M	H	BP2.6

	conforms to the configured minimum interval. (*NOTE: The age range and minimum interval between donations vary between blood services according to national blood safety standards and so must be configurable).*			
FR01-08	**Collect clinical assessment data for donor** The system must provide the ability to collect the donor's clinical assessment details of weight, Hemoglobin count (Hb), blood pressure (BP) and pulse. The user must be able to add a manual deferral for the donor if they think this is warranted based on clinical reasons.	M	H	BP2.8
FR01-09	**Automatically defer donors with positive TTI**	M	H	
FR01-09-01	The system must automatically set a permanent deferral for any donor with a donation that has a TTI positive test outcome. Donors who are permanently deferred must not be eligible to donate.	M	H	3.4
FR01-09-02	The system must automatically block for release and flag as unsafe any components processed from the donation with the TTI positive test outcome.	M	H	3.4
FR01-10	**Record post-donation counselling for TTI positive donors**			
FR01-10-01	If a donation tests positive for a TTI, the system must automatically flag the associated donor to receive post-donation counselling. This must happen only after the confirmatory tests are done and when the test batch is closed. *If the configuration setting "testing.deferDonorsWithNegRepeatOutcomes" is set to false then the system must not flag donors for counselling if the initial TTI test is POS and the two repeat tests are NEG.*	M	H	3.4
FR01-10-02	**Record post-donation counselling outcome for TTI positive donors** The system must allow the donor counsellor to record the counselling status of the donor to indicate whether he/she: 1) Received counselling; 2) Refused counselling; 3) Did not receive counselling	M	M	2.7
FR01-10-03	The system must allow the donor counsellor to add a comment/notes to the post-donation counselling field for a donor for additional information.	M	L	2.7
FR01-10-04	The system must allow an authorised user to print a list of donors requiring post-donation counselling (See Information Requirement IFR01-006 for the report specifications)	M	H	2.7
FR01-10-05	The system must allow the donor counsellor to record whether or not the donor was referred for further testing, care and treatment and the referral site that the donor was referred to.	M	M	2.7
FR01-11	**Record adverse events**			
	The system must allow an authorised user to record an adverse event with additional notes for a donation either at the time of the donation or in the event that a donor reports an adverse event that occurred post-donation.	M	M	2.8
FR01-12	**View Adverse Events** The donor clinic staff must be able to view previous adverse events for a donor	M	H	2.2 2.4 2.8
FR01-13	**Merge duplicate donor records** The system must allow an authorised user to be able to view and merge donor records that are duplicates of the same donor to create a new donor record with a new system-generated Donor Number. The system must retain the previous duplicate donor records for traceability but user must no longer be able to access them.	D	H	7.1

Table 3: Functional Requirements for Donor Management

5.2 FR02 Manage Donations

Ref	Description	M/D	Risk	Business Process
FR02-01	**Open donation batches** The system must allow a donor clinic staff user to open a donation batch at the beginning of the donation clinic. All donations entered during the clinic will be assigned by the system to this batch. The system must provide a configuration option so that it is possible to prevent new donors from being added if no donation batch is open.	M	H	2.1
FR02-02	**Assign DIN and link donation to donor**	M	H	2.8
FR02-02-01	The system must be able to allocate the unique pre-printed Donation Identification Number (DIN) to the donation in order to uniquely identify the donation. The system must not allow a duplicate DIN to be entered into the system.	M	H	2.8
FR02-02-02	The system must be able to link the DIN of the donation and the Donor Number of the donor. These will be irreversibly linked to ensure that the donation unit is always traceable back to the donor who provided it.	M	H	2.8
FR02-03	**Record a donation** The system must be able to record data related to the donation as follows:	M	H	2.8
FR02-03-01	The system must be able to assign a Pack Type to the donation. Pack types determine the type of components that can be produced. Pack types must be configurable with a standard default set of types.	M	H	
FR02-03-02	The system must be able to record if a sample only was collected for testing.	M	H	
FR02-03-03	The system must be able to record if a DIN was allocated but a donation was not successfully collected.	M	H	
FR02-03-04	The system must be able to record the Donation Type i.e. Voluntary, Family Replacement, Autologous or Other.	M	H	
FR02-03-05	The system must be able to record the start and end time of the bleed.	M	H	
FR02-04	**Close donation batches** The system must allow the donor clinic staff to close the donation batch when the clinic/session ends and print a summary of the donations collected in the batch for the clinic staff to use as a checklist to verify the donations collected. (See IR05 Donations Collected Report)	M	H	2.9
FR02-05	**Search for and view donations by donation batch** The system must allow a donor clinic staff user to search for a donation batch by: Venue, date period, DIN and must be able to view information about the donations within the donation batch. See user interface specification for detail.	M	M	

Table 4: Functional Requirements for Donation Management

5.3 FR03 Manage TTI and Blood Group Serology Testing

FR03	Manage TTI and Blood Group Serology Testing			
Ref	**Description**	**M/D**	**Risk**	**Business Process**
FR03-01	**Record blood grouping and serological test outcomes** The system must provide for a laboratory staff user to manually enter test outcomes for ABO and Rh serology tests for each blood donation sample tested. The four mandatory serological tests are: ABO grouping, Rhesus grouping, Titre and Antibody screening.	M	H	3.2
FR03-02	**Record TTI test outcomes** The system must provide for a laboratory staff user to manually enter test outcomes for each blood donation sample tested for each of the four mandatory Transfusion Transmissible Infections (TTI) tests: HIV, Hepatitis B (HBV), Hepatitis C (HBC) and Syphilis. Valid outcomes are positive (POS), negative (NEG) or Not Tested (NT).	M	H	3.3
FR03-03	**Capture blood grouping and serological test outcomes from automated laboratory testing equipment.** The system must be able to capture ABO Rh blood group serology test results via an import of a file containing test results from automated laboratory testing equipment. See the Lab Equipment Interface Requirements for more detailed specifications. **OUT OF SCOPE FOR BSIS V 1.2**	M	H	3.2
FR03-04	**Capture TTI test outcomes from automated laboratory testing equipment.** The system must be able to capture TTI test results via an import of a file containing test results from automated laboratory testing equipment. See the Lab Equipment Interface Requirements for more detailed specifications. **OUT OF SCOPE FOR BSIS V 1.2**	M	H	3.3
FR03-05	**Provision for additional tests** The system must make provision for the configuration of additional tests such as screening for malaria parasites, if required by the blood service.	M	H	Config
FR03-06	**Record test batch information** The system must provide traceability of test outcomes by recording for each test sample the date, time, test batch and the user who recorded the testing. A testing batch is defined as: All units tested during a single test run within the testing laboratory.	M	H	3.1
FR03-07	**View test batch information** The system must 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 or sample.	M	H	3.4
FR03-08	**Print test batch information** The system must provide the facility for all test results in a test batch to be printed so that the results can be checked and signed off	M	H	3.4
FR03-09	**Enforce ABO Rh and serology testing rules**	M	H	3.4

	The system must be able to determine the need for additional or repeat tests based on defined criteria as follows:			
FR03-09-01	The system must enforce the entry of repeat ABO Rh blood group serology outcomes for first time donors and must flag any discrepancies. The system must provide the means to record resolution of a mismatch.	M	H	3. 2 3.4
FR03-09-02	The system must automatically do a comparison with ABO Rh blood group serology outcomes from previous donations from the same donor and will flag any discrepancies allowing the user to record the resolution of a mismatch.	M	H	3.2 3.4
FR03-09-03	The system must record a test outcome for the titre test. Valid outcomes are Low, High and Not Tested. The system must check the titre test outcome and if titre is High for the component where the blood group is type O then the system must print High Titre information on the pack label for any associated components.	M	M	3.2
FR03-09-03-1	The system must allow the entry of Not Tested for Titre if this test is not performed. This will have no impact on the components.	M	M	3.2
FR03-09-04	The system must record a test outcome for antibody screening. Valid outcomes are Pos, Neg and Not Tested.	M	H	3.4
FR03-09-04-1	If the antibody screening test outcome for a sample is positive then the system must flag any components processed from that donation that contain plasma as unsafe. Any associated red cell concentrate components are safe and may be labelled for use if all the TTI test outcomes are negative and other labelling criteria are met.	M	H	3.4
FR03-09-04-2	The system must allow the entry of Not Tested for Antibody Screening if this test is not performed**. NOTE: This will have no impact on the components: the system will NOT flag a component as unsafe.**	M	H	3.4
FR03-10	Enforce TTI Testing rules Block donations and defer donors based on TTI test rules The system must automatically flag donations and their associated components as unsafe based on defined test outcomes and must block the components from release to inventory. The system must automatically defer the donor according to the test rules.	M	H	3.2 3.3 3.4

Table 5: Functional Requirements for Testing

5.4 FR-04 Manage Component Processing and Labelling

FR04	**Manage Component Preparation Processing**						
Ref	**Description**	**M/D**	**Risk**	**Business Process**	**UC Ref**	**SI Ref**	**Output Ref**
FR04-001	**Configure components** The system must be able to configure component types. The system must allow the user to configure the name of the component, the component code and the expiry period in days. The system must allow the user to configure the storage, transport and volume information to be printed on the pack label for the component.	M	H	Config			
FR04-002	**Configure component processing rules** The system must be able to configure processing rules that determine what components can be made manufactured based on:	M	H	Config			

002-01	• Different types of components may be made and specified combinations of components may be made from each pack type e.g. single, double, triple, quad • **NOTE: This configuration must be set up and validated as part of the initial deployment and Operational Qualification process.**	M	H				
002-02	• Temperature of the environment during transport and storage • **OUT OF SCOPE FOR BSIS V1.3**	M	H				
002-03	• *Bleed time elapsed since the donation was collected* • *Duplicate requirement – SEE FR04-007*						
002-04	• *Bleed interval when the donation was collected* • *Duplicate requirement ID – SEE FR04-008*						
FR04-003	**Record pack lot number and lot expiry date** The system must be able to record the manufacturer's Lot Number and the expiry date of the lot for each pack type in use. **OUT OF SCOPE FOR BSIS V1.3**	M	H	?			
FR04-004	**Assign component expiry date** The system must assign each component an expiry date, which is calculated from donation date and time and the expiry period set for that component type.	M	H	4.2			
FR04-005	**Record receipt of donations** The system must be able to record the receipt of donations and must be able to record the time of receipt and the temperature of the cooler box that the donation was transported in.	M	H	4.1			
FR04-006	**Record and verify pack weight** The system must check if the pack weight is within the limits for that pack type and if not, then the system must display an alert and ensure that the component is flagged as unsafe. **The system must check if the pack weight is between the minimum weight and low volume weight and if it is then the system must display an alert and any components containing plasma must be flagged as unsafe**. The maximum and minimum **and low volume weight** limits must be configurable according to the pack type.	M	H	4.1	UC 04-006		
FR04-007	**Check bleed times of donation** When recording the processing of a component, the system must be able to check the bleed times of a donation (i.e. the time between the start bleed time and the end bleed time) and provide an alert if bleed times exceed the configured limit for that component type. For example: • Platelets – bleed time interval must be 12 minutes or less • FFP – bleed time interval must be 15 minutes or less • Cryoprecipitate - bleed time interval must be 15 minutes or less Ref: See AfSBT standard 3.2.2.1 on page 19 of 40 " Maximum collection time for whole blood intended for production of labile components shall be no longer than 12 minutes for platelets and 15 minutes for cryoprecipitate and FFP."	M	H	4.2			
FR04-I008	**Check time since collection** When recording the processing of a component, the system must	M	H	4.2			

	check the time that has elapsed since the donation was collected and the system must alert the user if time limits are exceeded according to the component processing rules						
FR04-009	**Record processing of components** The system must be able to record which the processing of a component according to the processing rules (the combination of components possible from a parent component) and must assign a component code to each component to enable the unique identification of components.	M	H	4.2			
009-01	• The system will provide for the splitting of blood components as specified: See component processing rules	M	H	4.2			
009-02	• *The system will allow for the pooling of specified components as specified: See component processing rules* • **OUT OF SCOPE FOR BSIS V1.3**	M	H	4.2			
009-03	• The system must be able to record the weight of the processed components.	M	M	4.2			
009-04	• The weight of the processed component, must be used to calculate the volume of the processed component and this volume must be printed on the pack label. If the weight of the processed component is not entered then the volume is excluded from the printed pack label.	M	M	4.2			
FR04-010	**Assign Component Code** The system must assign a Component Code to the component according to the type of component. The DIN and Component Code together form a unique Identification number that is derived from and linked to the unique DIN of the primary source pack to ensure that it can be traced back to the donation and to the donor who provided it. For paediatric components where the DIN and the Component Code are the same a numeric suffix must be assigned to each component to enable it to be uniquely identified.	M	H	4.2			
FR04-011	**Configure minimum, maximum and low volume weight limits per pack type** The system must allow an authorised user to configure the minimum and maximum pack weight and unit of measurement for each pack type in use. These weight limits are used to verify if a pack is under or overweight. The low volume weight limits is used to verify when packed red cells can be made from an underweight pack.	M	H	4.2			
FR04-012	**Assign component status** The system must be able to automatically assign the status of the component as follows: • Quarantined (This is the default status of each component – this includes whole blood. Quarantined donations cannot be labelled for release) • Processed (The original component such as whole blood has been split into components and therefore does not exist anymore) • Unsafe (The component has been flagged for discard)	M	H	4.1,4.2, 4.3, 4.4			

	• Available (The component has been tested and is safe and ready to be labelled) • Expired (This means that he component's expiry date has been exceeded) • Discarded (The component has been recorded as discarded with an associated discard reason) • Issued (The component has been labelled and issued to a usage site and is therefore no longer in inventory)						
FR04-013	**Print a Pack Label** The final Pack Label will incorporate standardised information about the donation unit based on information required by the ISBT128 labelling standards. The following information must be printed on the pack label and each piece of information should have an eye-readable barcode printed as well if it is a date or an identifier: • DIN • ABO/RH blood group • Collection date • Component Code • Component Name • Expiration Date and Time • Name of the Blood Service • Initial pack volume, processed component volume, storage and transport information • For ABO group type O only: if titre testing is done and the outcome is High then High Titre must be displayed on the pack label **SEE OUTPUT SPECIFICATION FOR PACK LABEL DESIGN**	M	H	4.4			
FR04-014	**Print a Discard Label** Although most components that must be discarded are discarded before the labelling process, the system must also allow for the printing of a discard / biohazard labels that will incorporate standardised information about the donation unit. **SEE OUTPUT SPECIFICATION FOR DISCARD LABEL DESIGN**	D	H	4.4			
FR04-015	**Label a Component** The labelling of a component is a critical control point which determines whether that component meets the criteria to be labelled for use and release into inventory for use or if it is unsafe and must be discarded. Only those components that pass *each and every criteria* in the labelling management control point can be labelled i.e. a pack label can be printed:	M	H	4.4		SI04-15	See Pack Label Spec
015-01	• The **status of the component** must be checked to determine if it is suitable for release. If it is flagged as Quarantined, Unsafe, Expired, Processed, Discarded or Issued, a pack label must not be printed.			4.4			
015-02	The **status of TTI and Blood Group Serology testing** for the component must be checked to determine if it is suitable for release.			4.4			

	• Components that form part of a donation where ANY of the TTI screening test outcomes are POSITIVE must be flagged as UNSAFE and must not allow a pack label to be printed. • Components that form part of a donation where TTI Testing is incomplete must not allow a pack label to be printed • Components that form part of a donation where ANY of the TTI screening test outcomes are NOT TESTED must be flagged as UNSAFE and must not allow a pack label to be printed. • Components that form part of a donation where Blood Group Serology Testing is incomplete must not allow a pack label to be printed. • Components that form part of a donation where the ABO Rh blood group status is MISMATCH must not allow a pack label to be printed. This occurs when the first ABO Rh test outcomes for a first time donor do not match the repeat ABO Rh test outcomes. • Components that form part of a donation where the ABO Rh blood group status is AMBIGUOUS must not allow a pack label to be printed. This occurs when the ABO Rh test outcomes for a repeat donor do not match the ABO Rh group of the donor's previous donation. • Components that form part of a donation where the ABO Rh blood group status has NO TYPE DETERMINED must not allow a pack label to be printed. • Components that form part of a donation where the ABO Rh blood group status is INDETERMINATE because either or both the ABO and Rh test outcome is NOT TESTED must not allow a pack label to be printed. • Components that form part of a donation where the Antibody Screening outcome is POSITIVE must not allow a pack label to be printed.						
015-03	• The **status of the donor record** associated with the component must be checked to see if there are any current temporary AND/OR permanent deferrals. If any exist, the pack label must not be printed.						
FR04-016	**View component information** The system must provide the facility for an overview of all components, filterable by component status. Components should be searchable and viewable by: • DIN • Component Type • Date of collection	M	M	4.1, 4.2, 4.3, 4.4			
FR04-018	**Rollback component processing** The system must provide the ability to rollback a processed component back to its original state in order to correct data entry errors e.g. if the wrong component is selected to be processed or the combination of components selected is incorrect. However, if the parent component or any of the child components have already been labelled, discarded or issued, then the system must not allow the rollback.	D	H	4.2			

FR04-017	**Verify pack label** The system must provide the ability for the user to verify that the printed pack label has been placed on the correct pack. The system must allow the user to scan the original DIN on the pack and compare it to the DIN on the printed pack label and to warn the user if the DINs do not match. The system must also be able to distinguish between the DIN barcode on the pack label and the original DIN barcode on the pack to ensure that the user has not scanned the same barcode twice.	M V1.1	H	4.4			

5.5 FR-05 Discard Components

FR06	**Discard Components**						
Ref	**Description**	**M/D**	**Risk**	**Business Process**	**UC Ref**	**SI Ref**	**Output Ref**
FR05-001	**Record discarded components** The system must be able to record discards of components at any point within the workflow: before processing, during processing, during TTI and serology testing, at the point of labelling and release, when the blood is in stock, when the blood has expired, when blood has been returned. The user must be able to select components to be discarded by DIN and by component type.	M	H	4.3			
FR05-002	**Record discard reason and discard date** The system must be able to record a discard reason and date discarded and a comment.	M	H	4.3			
FR05-003	**View discards** The system must be able to allow a user to view all blood and blood components discarded, by DIN, date of collection and/or component type	M	H	4.3			
FR05-004	**Undo Discards** The system must be able to undo a component discard in order to correct a data entry error. The system must revert to the previous component status to allow the user to re-enter the discard correctly.	M	H	4.3			

5.6 FR-06 Manage component inventory, distribution, issue and returns

FR06	**Manage blood component inventory, distribution, issue and returns**						
Ref	**Description**	**M/D**	**Risk**	**Business Process**	**UC Ref**	**SI Ref**	**Output Ref**
FR06-001	**Record orders for blood units** The system must be able to record a new order from other distribution sites within the blood service (where the order type is a transfer) and orders from authorised facilities such as hospitals or clinics (where the order type is an issue or patient request). Order information must include:	M	M	5.2			

	1. Order date 2. Location order to be dispatched from 3. Location order to be dispatched to The system must allow the user to void the order if the order has not yet been dispatched.						
FR06-002	**Record order information** The system must be able to record multiple line items on the order and each line item must include: 1. Component type 2. Blood group 3. No of units ordered The system must allow the user to edit or remove a line item from an order during order entry.						
FR06-002-01	**Record patient information for patient request orders** The system must display an **additional section** on the order form to record Patient Details as follows: • First Name - mandatory • Last Name - mandatory • Date of Birth - optional • Gender – select Unknown /Male/Female from dropdown • Patient Number – optional (alphanumeric) • Hospital Blood Bank Number – optional (alphanumeric) • Hospital Ward No - optional (alphanumeric) • Blood Group – optional	M	M	5.2			
FR06-002	**Record orders from usage sites** The system must be able to record and process external orders from authorised facilities i.e. Hospitals and clinics. These authorised facilities must have been added as usage sites in the configuration settings.	M	M	5.2			
FR06-003	**Record blood units allocated to orders** The system must be able to record the fulfilment of the order including any discrepancy between what was ordered and what was issued or transferred. The order may be only partially fulfilled. The system must verify that the components allocated to the order: • match what has been ordered (component type and ABO Rh blood group) • are in stock at the location from which the order is being dispatched • have not been allocated to another order • are not unsafe • Have not expired or been discarded	M	M	5.2			
FR06-004	**Record transfers between distribution sites** The system must be able to record a transfer between two facilities within the blood service. The system must automatically remove components from inventory at the dispatched-from location and add components to inventory at the dispatched-to location.	M	H	5.3			
FR06-005	**Record dispatches to usage sites** The system must be able to record when an issue is dispatched to an authorised facility and print a dispatch note. The system must	M	H	5.3			

	automatically remove components from inventory when the order is dispatched to the authorised facility.						
FR06-006	**Record returns** The system must be able to record a return from an authorised facility. The system must automatically add the component into inventory when the return is recorded. Only components that have previously been issued to the facility may be returned from that facility. The system must allow the user to void a return prior to confirming the return to stock.	M	H	5.4			
FR06-007	**Discard returns** The system must be able to discard components that have been returned from an authorised facility as a batch discard. The system must automatically remove the components from inventory when the batch discard is recorded.	M	H	5.4			
FR06-008	**View and print order information** The system must enable the user to view, display and print:	M	H	5.1, 5.2, 5.3, 5.4			
	• components received and still being processed	M					
	• components labelled and released to inventory	M					
	• components assigned to internal orders and transferred to another internal facility	M					
	• components assigned to external orders and issued to authorised external facilities	M					
	• components due to expire soon and components that have already expired	M					
	• components that have been discarded	M					
	• components that have been returned from internal facilities within the blood service	M					
	• **components that have been returned from external facilities**	M					
FR06-009	**Check for expired components** The system must be allow the user to check inventory for components that are about to expire on a selected date or components that have already expired	M	H	5.5			
FR06-010	*The system must be able to record stock-takes and adjust stock levels accordingly.* ***OUT OF SCOPE FOR BSIS V1.3***	M	M	5.5			
FR06-011	**Assign inventory status** The system must be able to automatically assign the status of the component in inventory as follows: • Not in stock (this means that the component is still being processed or has pending test results i.e. the component has been received at the lab but has not yet been labelled) • In stock (this means the component has been labelled and is available for issue or transfer)	M	H				

5.7 FR-07 Configuration

The following parameters are configurable within the system in order to meet the varying requirements and different workflows and policies of national blood services. There are two types of configuration of the system:

- One type is usually done as part of the initial installation of the system by an Administrator when it will be configured according the national blood service needs and will include those settings which should not change over time or are very unlikely to change over time. This forms part of the Operational Qualification process.
- The other type are settings relating to operational use that can be set and changed by an Administrator under specific circumstances.

FR07	**Configuration**		
Ref	**Description**	**M/D**	**Risk**
Configuration and initial set-up by Jembi Implementer			
The system shall provide the ability for the Jembi Implementer to configure the following parameters in order to meet local requirements:			
FR07-01	**Blood Tests and Blood Testing Rules.** The configuration of blood tests requires both the set-up of the tests and the rules that determine how these tests are applied and what the outcomes are.	M	VERY HIGH
FR07-01-01	**Blood Tests** The configuration of blood tests used within the blood service. The system must allow for a set of mandatory blood tests and also allow for new blood tests to be added. A blood test must be able to be set to "inactive" if the test are no longer in operational use but are still used for reporting purposes. The mandatory blood tests are pre-configured and consist of: Transfusion Transmissible Infections: • Human Immunodeficiency Virus - HIV • Hepatitis B Virus - HBV • Hepatitis C Virus - HCV • Syphilis ABO Rh blood grouping and serology: • ABO • Rhesus (Rh) • Titre • Antibody screening Additional Blood Tests must be able to be configured as needed.	M	VERY HIGH
FR07-01-02	**Blood Testing Rules**. These rules determine how these blood tests are implemented and applied in the system in terms of valid test outcomes, negative and positive test outcomes and whether or not a component should be flagged as unsafe.	M	VERY HIGH
FR07-02	**Component Processing Rules** The component processing rules that determine valid combinations of components that can be processed from whole blood and/or other components. A default set of component type combinations must be supplied but these must be able to be verified and amended at installation.	M	HIGH
Configuration by System Administrator			
The system shall provide the ability for the System Administrator to configure the following parameters in order to meet local requirements:			
FR07-04	**Manage Role-based User Access** (see 2.3 User Classes and Characteristics for a default set of roles)	M	H
FR07-04-01	The System Administrator must be able to add a new Role with a name and description and associate that role with a set of permissions and must also	M	H

	be able to edit/amend a Role		
FR07-04-02	The System Administrator must be able to add a new User with an email address and assign a role to that user who will inherit the permissions associated with that role	M	H
FR07-04-03	The System Administrator must be able to edit/amend an existing User	M	H
FR07-04-04	The System Administrator must be able to remove an existing User who must then no longer then be able to access the system. The record will be retained as a voided record for audit purposes.	M	H
FR07-04-05	The System Administrator must be able to assign and manage or re-set passwords associated with the User.	M	H
FR07-04-06	The user must have the ability to re-set their own password	M	H
FR07-04-07	The System Administrator must not be able to create a Super User or additional Administrators	M	H
FR07-05	**Configure Adverse Events**	M	M
FR07-05	The system must be pre-configured with a default list of standard Adverse Event Types. The Administrator must be able to create and edit additional Adverse Event Types as needed. The Adverse Event Types that are no longer used must be disabled but not deleted.	M	M
FR07-06	**Configure Deferral Reasons**	M	H
FR07-06-01	The system must be pre-configured with a default list of standard Deferral Reasons with associated deferral periods according to AfSBT guidelines. The Administrator must be able to create and edit additional Deferral Reasons. Deferral Reasons that are no longer used must be disabled but not deleted.	M	H
FR07-06-02	A Deferral Reason must be defined as either Permanent or Temporary.	M	H
FR07-06-03	A Deferral Reason must have a default deferral duration in days associated with it.	M	H
FR07-07	**Configure Locations and Divisions**	M	M
FR07-07-01	The Administrator must be able to add, edit/amend and disable Locations	M	M
FR07-07-02	The Location must have a name and must be defined as one or more location type: • Venue: a collection site/donor panel- these may be Fixed or Mobile • Processing site : the location where the blood component processing is done • Testing site: the location where the TTI and blood serology testing is done • Distribution site: the location where blood and blood components inventory is managed • Usage Site: the authorised facilities that blood and blood components are issued to and returned from – usually hospitals or clinics • Referral Site: the site to which a counsellor may refer a TTI positive donor for further care and treatment	M	M
FR07-07-02	The Location must be able to be categorised as either Urban or Rural for reporting purposes. **OUT OF SCOPE FOR BSIS V1.3**	D	L
FR07-07-03	**Assign a division to a location** The administrator must be able to configure a location as one of three divisional levels so that aggregate and operational reporting can be better managed. • If the division is a second or third level division then the parent division must be defined. • If the division is a first level division then no parent division is required.	D	H

FR07-08	**Configure Pack Types** The system must be pre-configured with a default list of Pack Types. The Administrator must be able to add or edit additional Pack Types. The Pack Type used will determine the type of components that may be produced and whether or not a test sample will be produced. The pack type used for a donation will also determine if the donation can be counted as a donation and therefore will also determine the time period in days before the donor is eligible to donate again. See the default list of standard Pack Types and the business rules listed below.	M	H
FR07-09	**Configure Components** The Administrator must be able to manage component types and component combinations which may be made by splitting a unit of whole blood.	M	H
FR07-010	**Configure Discard Reasons** The system must be pre-configured with a default list of Discard Reasons according to WHO guidelines. The System Administrator must be able to add or edit additional Discard Reasons. Discard Reasons that are no longer used must be disabled but not deleted.	M	H
FR07-011	**Configure Donation Types** The system must be pre-configured with a default list of Donation Types based on WHO and PEPFAR reporting guidelines. The System Administrator must be able to create and edit additional Donation Types. The Donation Types that are no longer used must be disabled but not deleted. (NOTE: The donation type describes a particular donation based on the status of the donor at the time the donation was given. The status of the donor may change over time but the type of the donation will not)	M	H
FR07-012	**View Audit Log**		
FR07-012-01	Authorised users must be able to view the audit log for a specified period/ date range	M	M
FR07-012-02	The viewable audit log must display the date and time that an entity within the system was added, modified, or deleted and the user who performed that action	M	M
FR07-013	**Configure Transfusion Reaction Types** As an Administrator I need to be able to configure transfusion reaction types so that the system can record and report on adverse transfusion reaction events.	M	M

Table 6: Functional Requirements for Configuration

FR07-03	**General Configurations** These are Global Properties that apply throughout the system and must only be configurable by a Super User. These configurations must have a Data Type and a Value defined. The following global properties are can be defined:		
Name	**Description**	**DataType**	**Default Value**
FR07-03-01	**The system must have the ability to set the date and time format throughout the system**		
dateFormat	Global Date Format (the date format used throughout BSIS)	text	dd/MM/yyyy
dateTimeFormat	Global Date Time Format (the date and time format used throughout BSIS)	text	dd/MM/yyyy hh:mm:ss a
timeFormat	Global Time Format (the time format used throughout BSIS)	text	hh:mm:ss a
FR07-03-02	**The system must have the ability to set units and range values for donor assessment data**		
donation.hbNumericValue	Allows the capturing of a numeric haemoglobin value	boolean	true
donation.hbQualitativeValue	Allows the capturing of a qualitative haemoglobin value	boolean	false
donation.donor.bpSystolicMin	Donation Donor's Blood Pressure Systolic Minimum	integer	70
donation.donor.bpSystolicMax	Donation Donor's Blood Pressure Systolic Maximum	integer	190
donation.donor.bpDiastolicMin	Donation Donor Blood Pressure Diastolic Minimum	integer	40
donation.donor.bpDiastolicMax	Donation Donor Blood Pressure Diastolic Maximum	integer	100
donation.donor.hbMin	Donation Donor Hemoglobin Minimum	integer	1
donation.donor.hbMax	Donation Donor Hemoglobin Maximum	integer	25
donation.donor.weightMin	Donation Donor weight Minimum	integer	30
donation.donor.weightMax	Donation Donor weight Maximum	integer	300
donation.donor.pulseMin	Donation Donor pulse Minimum	integer	30
donation.donor.pulseMax	Donation Donor pulse Maximum	integer	200
donation.bpUnit	Donation Blood Pressure Unit	text	mmHg
donation.hbUnit	Donation Hemoglobin HB unit	text	g/dL
donation.weightUnit	Donation Weight Unit	text	kg
donation.pulseUnit	Donation Pulse Unit	text	bpm
FR07-03-03	**The system must have the ability to limit access to functional areas within the system**		
ui.donorsTabEnabled	Donors Tab Enabled	boolean	true
ui.componentsTabEnabled	Components Tab Enabled	boolean	true

ui.testingTabEnabled	Testing Tab Enabled	boolean	true
ui.labellingTabEnabled	Labelling Tab Enabled	boolean	true
ui.inventoryTabEnabled	Inventory Tab Enabled	boolean	true
ui.reportsTabEnabled	Reports Tab Enabled	boolean	true
ui.mobileClinicTabEnabled	Mobile Clinic Tab Enabled	boolean	true
FR07-03-04	**The system must have the ability to set the donor number format and set donor registration and counselling rules according to local needs**		
donor.donorNumberFormat	Donor Number Format	text	%06d
locale.default	Default Locale	text	en
log.level	Log Level	text	info
donor.searchMode	Donor Search Mode	text	start_and_end
donors.registration.openBatchRequired	Block donor registration when no donation batches are open	boolean	true
testing.deferDonorsWithNegConfirmatoryOutcomes	Defer donors with a POS TTI test outcome, where all confirmatory outcomes are NEG	boolean	false
donors.minimumAge	The minimum age of a new donor	integer	16
donors.maximumAge	The maximum age of a new donor	integer	16
FR07-03-05	**The system must have the ability to define how address information is displayed according to local formats**		
ui.address.addressLine1.enabled	Determines whether address line 1 is visible	boolean	true
ui.address.addressLine1.displayName	Address line 1 display name	text	Address
ui.address.addressLine2.enabled	Determines whether address line 2 is visible	boolean	true
ui.address.addressLine2.displayName	Address line 2 display name	text	
ui.address.cityTownVillage.enabled	Determines whether city / town / village is visible	boolean	true
ui.address.cityTownVillage.displayName	City / town / village display name	text	City
ui.address.districtRegion.enabled	Determines whether district / region is visible	boolean	false
ui.address.districtRegion.displayName	District / region display name	text	District
ui.address.province.enabled	Determines whether province is visible	Boolean	true
ui.address.province.displayName	Province display name	text	Province
ui.address.state.enabled	Determines whether state is visible	boolean	false
ui.address.state.displayName	State display name	text	State
ui.address.country.enabled	Determines whether country is visible	boolean	true
ui.address.country.displayName	Country display name	text	Country
ui.address.postalCode.enabled	Determines whether postal/zip code is visible	Boolean	true
ui.address.postalCode.displayName	Postal / zip code display name	text	Postal Code

ui.division.level1.displayName	Name to be used for division level 1	text	First-level
ui.division.level2.displayName	Name to be used for division level 2	text	Second-level
ui.division.level3.displayName	Name to be used for division level 3	text	Third-level
FR07-03-06	**The system must have the ability to disable component processing when the component processing functionality is not in use**		
components.createInitialComponents	Enables the creation of initial components when a donation is recorded. Can be disabled in the case where components are not managed by the system I.E. for the Donor Management module.	boolean	true
FR07-03-07	**The system must have the ability to allow for double-entry of test outcomes for TTI and serology tests**		
testing.reEntryRequired	Enable or Disable Re Entry of test outcomes	boolean	true
FR07-03-08	**The system must have the ability to set the donor number format and donation identification number format**		
donation.dinLength	Determines the length of the Donation Identification Number used to identify donations	integer	7
FR07-03-09	**The system must have the ability to display the name and address of the blood service on the pack label**		
packLabel.serviceInfoLine1	Blood Service information to be printed on Pack Labels (line 1)	text	Not intended for actual use
packLabel.serviceInfoLine2	Blood Service information to be printed on Pack Labels (line 2)	text	
FR07-03-10	**The system must have the ability to display the description of the BSIS instance on the login screen and application header**		
ui.header.warningMessage	Text to be displayed on BSIS header and login screen to identify the BSIS instance in use i.e. production (live), testing or training.		New installation - configure message in Settings
FR07-03-11	**The system must have the ability to set up the email server details if used for re-setting user passwords**		
smtp.port	smtp port	integer	25
smtp.auth.username	Username	text	
smtp.auth.password	Password	password	not visible
FR07-03-12	**The system must have the ability to add the blood service logos to the report headers**		
ui.report.base64headerLogo1	Logo used for top left side of report header	text	base64 value for

			BSIS logo
ui.report.base64headerLogo2	Logo used for top right side of report header	text	base64 value for BSIS logo

Table 7: Functional Requirements for Global Properties

5.7.1 Default Configuration Values

5.7.1.1 Default Deferral Reasons and Deferral Periods

Reason	Description	Period
TTI Unsafe	Present or past clinical or laboratory evidence of infection with HIV, HBV, HCV or Syphilis	Permanent
High Risk Behaviour	Sexual contact with an individual with HIV infection or at high risk of HIV infection.	365 days / 12 months
Low Haemoglobin	Below the clinically recommended guidelines for the country	3 months
Low Weight	Below the clinically recommended guidelines for the country	3 months
Travel History	Visit to Malaria area within the last 3 months	3 months
Other Medical Conditions	Other conditions such as recent infections, changes in blood pressure, etc.	180 days / 9 months
Other Reasons	Other reasons such as dental treatment within last week, tattoos and piercings within last 6 months, etc.	3 months

Table 8: Default Deferral Reasons and Deferral Periods

5.7.1.2 Default Discard Reasons

Reason	Description
Incomplete donation	
Processing problems	
Passed Expiry Date	
Reactive for TTIs	
Storage problems	
Transport problems	

Table 9: Default discard reasons

5.7.1.3 Default Adverse Event Types

Adverse Events	Description
Accident	Donor has an accident as a result of donating blood
Allergy	Donor has an allergic reaction as a result of donating blood
Arterial puncture	Needle inserted into artery rather than a vein
Convulsions	Involuntary convulsions as a result of donating blood
Haematoma	Swelling of clotted blood with the tissues (bruising)
Hyperventilation	Donor hyperventilates as a result of donating blood
Nausea	Donor has nausea as a result of donating blood
Nerve injury	An injury to nerve tissue as a result of donating blood
Thrombophlebitis	Inflammation of the vein relating to a blood clot
Vasovagal	Fainting as result of donating blood
Other	Any other reaction as a result of donating blood

Table 10: Default Adverse Events

5.7.1.4 Default Transfusion Reaction Types

Transfusion Reaction Types	Description
Reference:	[1]A Guide to Establishing a National Haemovigilance System 2016 - WHO http://apps.who.int/iris/bitstream/10665/250233/1/9789241549844-eng.pdf?ua=1
ABO incompatibility	Immunological haemolysis due to ABO incompatibility
Allo-antibody	Haemolysis Immunological haemolysis due to other allo-antibody
Anaphylaxis	Anaphylaxis/hypersensitivity
NI Haemolysis	Non-immunological haemolysis
Other	Other reactions
PTP	Post-transfusion purpura
TA-GVHD	Transfusion-associated – graft versus host disease
TACO	Transfusion-associated circulatory overload
TRALI	Transfusion-related acute lung injury
TT-HBV	Transfusion-transmitted viral infection HBV
TT-HCV	Transfusion-transmitted viral infection HCV

TT-HIV	Transfusion-transmitted viral infection HIV
TT-Malaria	Transfusion-transmitted parasitical infection (malaria)
TT-Other	Transfusion-transmitted viral infection other
TT-Parasitical	Transfusion-transmitted parasitical infection (other)
TTBI	Transfusion-transmitted bacterial infection

Table 11: Transfusion Reaction Types

FR08	Manage blood transfusion information						
Ref	**Description**	**M/D**	**Risk**	**Business Process**	**UC Ref**	**SI Ref**	**Output Ref**
FR08-01	**Record transfusion information for units that were issued** The system must be able to record transfusion information related to any whole blood or blood components that were issued to a usage site. This should include usage site, date of transfusion, transfusion outcome, where available, patient (recipient) information and any adverse transfusion event details.	D	H				
FR08-02	**View transfusion information for units that were issued** The system must provide the ability to view transfusion information related to issued units, including whether or not the unit was transfused, and any adverse transfusion events.	D	H				

6 Business Rules

BR01	Business Rules governing Donors
BR01-01	A donor can only be registered and allowed to donate only if he/she meets the minimum and maximum age criteria according to the national blood service policy.
BR01-02	A donor must be assigned to a venue (also known as a donor panel). This is the location where the donor usually donates and is used for planning and communication purposes. The donor may however donate at any venue e.g. if the donor is assigned to the venue that is their workplace he/she may choose to donate at a venue at a shopping centre instead.
BR01-03	If the donor is permanently deferred he/she must be blocked from making a donation.
BR01-04	If the donor is temporarily deferred at the time of donation, he/she must be blocked from making a donation until the end of the deferral period.
BR01-05	If the donor has made a blood donation then they must not be allowed to make another donation before the minimum interval between donations has passed. The standard interval is 56 days but this may vary between blood services.
BR01-06	A donor record can be voided only if there are no recorded donations, deferral reasons and donor comments for the donor.
BR01-07	A donor who has been permanently deferred due to a positive TTI donation must be contacted for counselling and the results of this counselling must be recorded (i.e. was the donor referred for appropriate care, did the donor refuse counselling)
BR01-08	The time period for which a donor is temporarily deferred may be edited : the deferral period may be shortened, it may be extended or it may be ended as at the current date
BR01-09	The time period for an automated permanent deferral may not be edited or ended. The time period for a manual permanent deferral may be ended at the current date but a reason must be entered and the deferral record is retained
BR01-10	If there are discrepancies between the ABO Rh blood groups of any donor records selected for merging, then the correct blood group cannot be assumed. The merged donor record must not be assigned a blood group and must be treated as a first time donor the next time he/she donates blood as far as ABO Rh testing is concerned.
BR01-12	A donor record may not be voided if a barcode label with the Donor Number has been printed **NOT IMPLEMENTED**
BR01-13	A donor record may be edited: • Before a recorded donation or deferral: • After a recorded donation or deferral: Only the donor's name/date of birth and/or gender may be edited in order to correct errors.

BR02	Business Rules governing Donations
BR02-01	A donation must be part of a donation batch for traceability purposes. If there are no open donation batches, then a donor may not be registered and a donation may not be recorded.
BR02-02	A venue (donor panel) can only have one donation batch open at any one time
BR02-03	A donation record can be deleted only if there are no recorded test results, processed components, donation comments or adverse events for the concerned donation
BR02-04	On a donation record, bleed times and pack type can be modified only if there the donation batch that it is associated with has not been closed and assigned to a test batch.
BR02-05	Every Donation Identification Number (DIN) issued must be recorded for traceability even if there is no donation associated with it.
BR02-06	If a donation is collected, the system must update: • the number of donations that the donor has made by incrementing it by one • the donor's date due to donate by adding the minimum interval in days for the pack type used to the current date
BR02-07	Donations can only be voided if the donation batch has not been closed.
BR02-08	A donation batch can only be opened for one venue (donor panel) at a time.
BR02-09	A donation batch must have one or more donations
BR02-10	A donation batch may be voided only if there are no donations in the batch. A donation batch with 0 donations cannot be closed: it must be voided.
BR02-11	A donation batch may be re-opened and edited before it has been assigned to a test batch but cannot be edited after it has been assigned to a test batch.

BR03	Business Rules governing Pack Types				
	The type of pack used to collect the blood donation has an impact as to whether a test outcome is expected for the pack, whether or not components may be produced, whether the pack should be discarded, whether the number of donations the donor has made should be updated and whether the minimum period between donations should be invoked. This information must be recorded for traceability purposes.				
	Pack Type Rules	Pack exists	Produces Test Outcome	Produces Component/s	Update donor's number of donations and interval between donations
BR03-01	Where the collection of blood counts as a donation.				

	Single pack	Yes	Yes	Yes	Yes
	Double pack	Yes	Yes	Yes	Yes
	Triple Pack	Yes	Yes	Yes	Yes
	Quad Pack	Yes	Yes	Yes	Yes
BR03-02	Where the collection of blood does NOT count as a donation.				
	Test Only	No	Yes	No	No
	Did not bleed	No	No	No	No
BR03-04	The pack type should be editable • If the sample has test results that have been entered/released/closed AND the pack type is changed from one with a test sample to another pack type with a test sample The pack type should not be editable when: • The initial component has been processed or discarded or labelled (and therefore is in stock in inventory) • The test batch containing the associated sample has been released or closed AND the pack type is changed from one where a test sample was not produced to one where a test sample is produced				
BR04	**Business Rules governing Laboratory Testing**				
BR04-01	Once a donation batch is closed, the samples from that batch can be added to a test batch for testing: If however the donation batch is still open, the samples from that batch cannot be added to any test batch.				
BR04-02	A sample may not be tested unless it is allocated to an open test batch.				
BR04-03	A test batch may contain samples from one or more donation batches but a donation batch can only be assigned to one test batch.				
BR04-04	A test batch may have only one sample.				
BR04-05	Each donation sample must be tested for each of the four mandatory test types (HIV, HCV, HBV, Syphilis)				
BR04-06	If ANY of the four mandatory TTI test types return a POSITIVE TTI test outcome then the donation must be flagged as unsafe and discarded as soon as possible				
BR04-07	If any donation sample has a confirmed POSITIVE TTI test outcome the donor must be deferred from donating blood permanently and must be contacted for counselling as soon as possible				
BR04-08	Each donation sample must be tested for the ABO and Rh to determine the blood group.				
BR04-09	If ANY donation sample has an ABO Rh blood group that is a mismatch to the ABO Rh blood group of the previous donation for that donor then then the donation must be flagged as unsafe and discarded as soon as possible and the donor must be flagged for investigation				
BR04-10	If ANY donation sample has an ambiguous ABO Rh blood group where the Rh status cannot be determined that then the donation must be flagged as unsafe and discarded as soon as possible and the donor must be flagged for investigation				
BR04-11	A test batch can only be released if there are no outstanding test outcomes for the initial set of required tests (i.e. the mandatory set of TTI				

	screening and blood group serology tests).
BR04-12	When a test batch is released, all samples that don't have any discrepancies are released. The samples that still have discrepancies are not released yet. The initial batch release is a bulk release; following that each sample is released as the discrepancy is resolved. Once all discrepancies have been resolved, the batch can be closed.
BR04-13	A test batch can only be closed once all discrepancies have been resolved and there are no outstanding test outcomes required.
BR04-14	Editing a test batch: TTI outcomes If the screening test is NEG, it can be edited until the test batch is released If the screening test is POS, it can be edited until ONE OR BOTH repeat tests have been recorded If repeat tests require a third additional confirmatory test, they can be edited until the confirmatory test outcome has been recorded
BR04-15	For a sample, if ANY of the four test TTI tests have a NOT TESTED test outcome then the donation must be flagged as unsafe and discarded as soon as possible
BR04-16	For a sample, if an ABO or Rh test have a NOT TESTED test outcome then the donation must be flagged as unsafe and discarded as soon as possible
BR04-17	If the antibody screening test is done and the outcome is positive then any associated components **that contain plasma** must be flagged as unsafe and should be discarded.
BR04-18	A test batch may be voided only if no test outcomes have been entered. If one or more test outcomes for any of the samples (DINs) in the batch have been entered, then the test batch cannot be voided.
BR04-019	The date and location of the test batch may be edited if the test batch is open. Once the test batch is closed then the date and location may not be edited. The date of the individual test outcomes is the date of the test batch when the sample (DIN) is released.
BR05	**Business Rules governing Component Processing and Labelling**
BR05-01	A component must automatically be Quarantined at the time it is created and must not be able to be labelled for release until all TTI and serology testing is complete and component processing has been done.
BR05-02	A component can have the following status: • Quarantined - the testing for the samples related to this component are still in progress • Processed - This means the original component i.e. whole blood - has been split into new components and therefore does not exist anymore • Available – Is available for labelling / has been released to inventory where it can be issued • Unsafe – Unsafe for use and must be discarded • Issued – Has been dispatched from inventory and issued to an authorised facility • Transferred - Has been dispatched from inventory and transferred to another facility within the blood service • Returned - Has been returned from the authorised facility that it was issued to

	• Expired – Has passed the expiry date and must be discarded • Discarded – Has been discarded
BR05-03	Components that have been fully tested with all discrepancies resolved are automatically flagged as Available (Safe) and a Final Pack Label can be printed.
BR05-04	Components flagged as Quarantined (due to outstanding test results or discrepancies), Expired or Processed will not allow a final Pack Label to be printed.
BR05-05	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.
BR05-06	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.
BR05-07	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.
BR05-08	Components that form part of a donation where the Donor is flagged as permanently deferred will not allow a final Pack Label to be printed.
BR05-09	Components that have already been Issued, Transferred or Discarded will not allow a final Pack Label to be printed
BR05-10	Components may only be processed according to the defined component processing rules which are determined by the starting Pack Type. These are configured at installation time.
BR05-11	A component record can only be deleted or modified if it has not been released, discarded or processed again
BR05-12	If the component record needs to be edited or deleted, then the change must be reverted rather than deleted i.e. the component must be rolled back / restored to its previous state
BR05-13	When a component has successfully been labelled i.e. a pack label has been printed, then the component must be automatically added to inventory
BR06	**Business Rules governing Component Discards**
BR06-01	A component must be flagged as unsafe and must be discarded if the associated sample has a positive TTI outcome i.e. the component is infected with one or more of the Transfusion Transmissible Infective agents
BR06-02	A component must be flagged as unsafe and must be discarded if the associated sample has an ambiguous blood grouping i.e. If the RH Negative status cannot be conclusively determined or if the donor's previous donation shows a different blood group type.
BR06-03	A component must be discarded if the pack is physically damaged at any point in the process
BR06-04	A component must be discarded if the cold chain is not maintained i.e. if there are storage or transport problems that result in the pack not being kept at the required temperature.
BR06-05	A component must be discarded if it has reached its expiry date. Different components have different expiry periods.

BR06-06	A discard label may be printed when the component status = UNSAFE, DISCARDED, EXPIRED and the donation sample in test batch has been released.
BR06-07	A component must be flagged as unsafe and must be discarded if the associated sample has one or more TTI outcome with a value of Not Tested i.e. the sample was not tested for one or more of the Transfusion Transmissible Infective agents
BR06-08	If the discard record needs to be edited or deleted, then the change must be reverted rather than deleted i.e. the discard must be rolled back / restored to its previous state
BR07	**Business Rules governing Blood Component Inventory**
BR07-01	The component may only be issued only if the component has not been discarded, processed again, expired or previously issued
BR07-02	A delivery note can be deleted ONLY if any of the components listed on the delivery note has not been returned **NOT YET IMPLEMENTED**
BR07-03	A component may only be returned if it was initially recorded in BSIS i.e. components from an unknown source cannot be returned
BR07-05	An order can only be cancelled prior to dispatch
BR07-06	A component return may only be voided prior to returning to stock
BR07-07	The date, order type and dispatched to fields on a delivery note can be edited prior to confirming the dispatch: the dispatched from field can only be edited if no units have been supplied.
BR08	**Business Rules governing Blood Transfusion Information**
Business Rule BR08-07	The system can only record transfusion information related to a unit dispatched from same blood service.

Table 12: Business Rules for BSIS

7 Detailed Functional Requirements Specifications

7.1 FR01-05 Record a Manual Deferral

Requirement ID & Name	**FR01-05**	**Record a Manual Deferral**
Requirement Description	The system must allow for a donor clinic staff member to defer the donor from donating blood for a period of time. The deferral may be temporary or permanent. The deferral may be entered at various points within the donor clinic workflow. The system must use configurable deferral code reasons with associated deferral periods that are based on WHO and country-defined standards.	
Purpose	There are a number of reasons why a donor may be deferred from donating blood for a period of time, either to protect the safety of the donor or the safety of the recipient. The system must be able to record the reason for a deferring a donor and the time interval until the donor can donate again and must ensure that a donation cannot be recorded for a donor who is deferred.	
Business Process	BP2.4	Check Repeat Donor (check age and allow user to enter a deferral if over age)
	BP2.6	Check Donor Eligibility to Donate (check deferrals, valid donation and minimum interval between donations)
Related Requirements	FR07-06	Configure Deferral Reasons
	FR07-06-01	The system must be pre-configured with a default list of standard Deferral Reasons with associated deferral periods according to AfSBT guidelines. The Administrator must be able to create and edit additional Deferral Reasons. Deferral Reasons that are no longer used must be disabled but not deleted.
	FR07-06-02	A Deferral Reason must be defined as either Permanent or Temporary.
	FR07-06-03	A Deferral Reason must have a default deferral duration in days associated with it.
Use Case	UC	
Inputs	Donor Number or Name or DIN	
Outputs	Deferral information on donor dashboard	
USE CASE NARRATIVE		
Use Case No	UC	
Use Case Name	Add a manual deferral to a donor	

Goal	To be able to add a manual deferral, either permanent or temporary, to a donor that will prevent the donor from making a donation for the period that he/she is deferred for
Preconditions	User has logged in User has searched for and found the donor, using either the Donor Number, Donor's name or the DIN that is associated with the donor
Success End Condition	User adds a deferral to a donor
Failed End Condition	
User Roles	Donor clinic staff, donor clinic supervisor
Trigger	User selects Add Deferral
Main success scenario	1. The user selects the Add Deferral option 2. The user selects a reason for the deferral from a drop-down list 3. The system displays the end date for the deferral period based on the default time periods as configured 4. The user may change the deferral end date to another date, earlier or later than the default date 5. The user may enter additional information as a comment/ note. 6. The user saves the deferral 7. The system must update the donor's deferred status to currently deferred and must display the deferral end date on the donor dashboard 8. The system must block the addition of a donation during the period that the deferral is active for.
Variation 9.	1. The user may decide that the deferral must be extended to a later date than the current end date 2. The user searches for and finds the donor 3. The user selects the existing deferral reason from the donor dashboard 4. The system displays the start and end date of the deferral period, the reason for the deferral, any additional comments and the name of the user who added the original deferral. 5. The user selects the option to edit the deferral and can change the end date of the deferral to different end date 6. The user saves the change 7. The system must update the end deferral date to the newly entered date 8. The system must block the addition of a donation during the extended period that the deferral is active for.
Variation 10.	1. The user may decide that the deferral may be ended earlier than the current end date 2. The user searches for and finds the donor 3. The user selects the existing deferral reason from the donor dashboard 4. The system displays the start and end date of the deferral period, the reason for the deferral, any additional

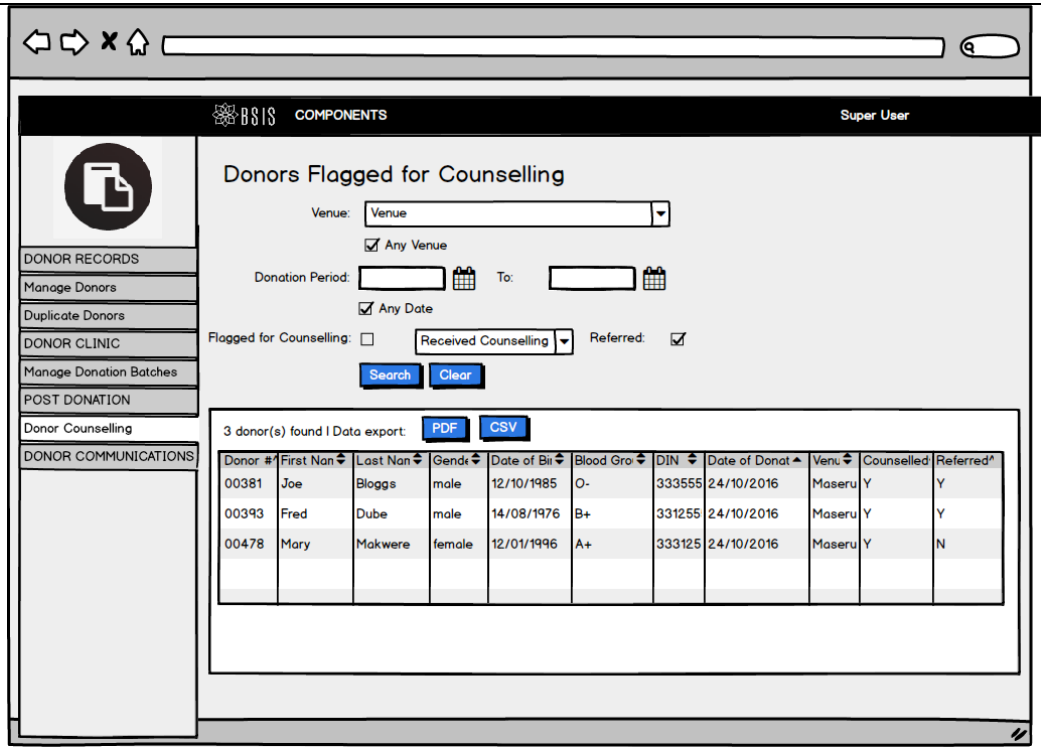
	comments and the name of the user who added the original deferral. 5. The user selects the option to end the deferral 6. The system must ensure that the user adds a comment or note and as to why the deferral is being ended 7. The user saves the change 8. The system must update the end deferral date to the current date, meaning that the donor is no longer deferred and can donate blood 9. The system must retain both the original reason for deferral and the reason as to why the deferral was ended

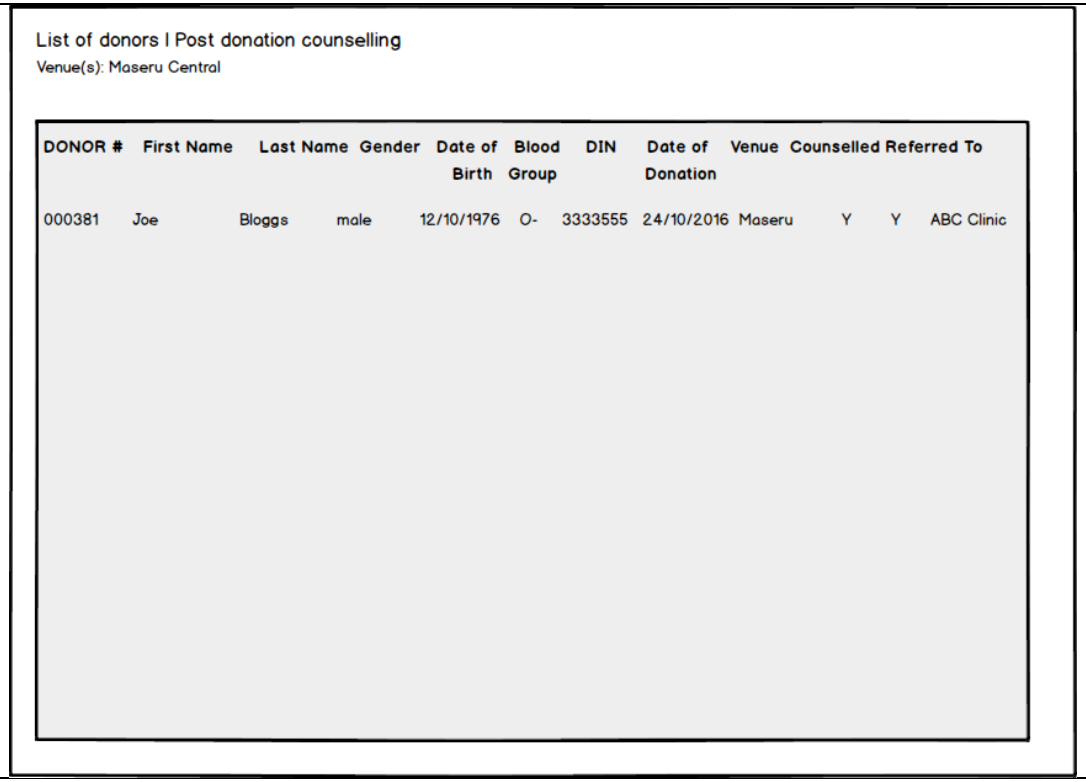
7.2 FR01-10 Record post donation counselling

Requirement ID & Name	FR01-10	Record post donation counselling
	FR01-10-01	If a donation tests positive for a TTI, the system must automatically flag the associated donor to receive post-donation counselling. This must happen only after the confirmatory tests are done and when the test batch is closed. *If the configuration setting "testing.deferDonorsWithNegRepeatOutcomes" is set to false then the system must not flag donors for counselling if the initial TTI test is POS and the two repeat tests are NEG.*
	FR01-10-04	The system must allow an authorised user to print a list of donors requiring post-donation counselling (See Information Requirement IFR01-006 for the report specifications)
	FR01-10-02	The system must allow the donor counsellor to change the counselling status of the donor to indicate whether he/she: Received counselling/Refused counselling / Did not receive counselling
	FR01-10-03	The system must allow the donor counsellor to add a comment/notes to the post-donation counselling field for additional information.
	FR01-10-05	The system must allow the donor counsellor to record whether or not a donor was referred to another service for further testing, care and treatment.
	FR01-10-06	The system must allow the donor counsellor to record the referral site that the donor was referred to for further testing, care and treatment.

	IFR-01-006-1	The system must generate a report that lists all donors according to their counselling status, and whether they were referred and if so, where.
Requirement Description	The system must automatically flag any donor for counselling if the donation has one or more positive test outcomes. The system must generate a list of all donors flagged for counselling according to date and venue of donation. Once the results of counselling have been recorded, then the donor will no longer appear on the list. If a counselling status is recorded in error, then the user must be able to remove the status and the system must re-flag the donor for counselling.	
Purpose	The list of donors is intended to be used by an authorised user i.e. a donor counsellor to be able to see those donors who have recently tested positive for one or more TTIs, so that they can identify and contact those donors and provide counselling services with referral to further testing, care and treatment.	
Business Process	2.7	Counsel Donor
Related Requirements	FR07-07-02	The system must allow the user to add and edit referral sites
USE CASE NARRATIVE		
Use Case No	UC01-10-05	
Use Case Name	Print Post Donation Counselling List	
Preconditions	User is a Donor Counsellor, Administrator or Superuser User has logged in Donations from the venue and date range selected have completed testing and samples have been released Configuration setting *"testing.deferDonorsWithNegRepeatOutcomes"* is set to true	
Trigger	Initiated by user / ad-hoc	
Main success scenario	1. User selects a Venue or checks the Any checkbox 2. User enters a date range for Donation Period or checks the Any Date checkbox 3. User can select a checkbox to select all donors that were flagged for Counselling or 4. User can select the counselling status (Received Counselling, Refused Counselling or Did Not Receive Counselling) and/or 5. User can select a checkbox to select all donors that were referred to another service (Referred= True) 6. The system generates a report and displays on screen with the option to print to PDF or CSV. ● *If the Flagged checkbox is selected then the system must include any donors who donated at the selected venue and within the selected date range and where flaggedForCounselling= TRUE*	

	● If the Counselled checkbox is selected then the system must also include any donors who donated at the selected venue and within the selected date range and where their Counselling Status= Counselling Status selected. (one of Received Counselling, Refused Counselling, Did Not Receive Counselling) ● If the Referred checkbox is selected then the system must include any donors who donated at the selected venue and within the selected date range and who were referred (isReferred= True) 7. The system must display the following information for each donor: ● Donor Number ● First Name ● Last Name ● Gender ● Date of Birth ● Blood Group ● DIN ● Date of donation ● Venue of donation ● Counselled = Y/R/N ● Date Counselled (PDF/CSV only) ● Referred = Y/N ● (Referral Site)Referred To (PDF/CSV only)

Screen Design	

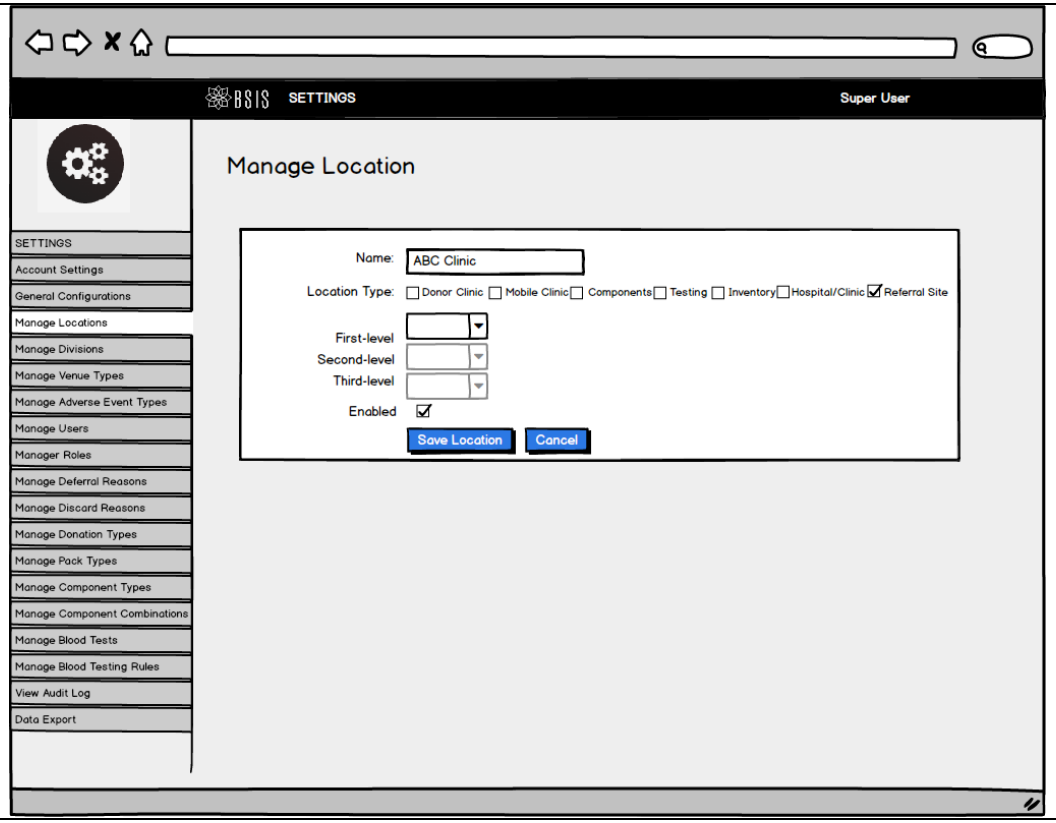
Report Design	

USE CASE NARRATIVE	
Use Case No	UC01-10-04
Use Case Name	Record Post Donation Counselling for POS TTI Donors
Preconditions	User is a Donor Counsellor, Administrator or Superuser User has logged in Configuration setting *"testing.deferDonorsWithNegRepeatOutcomes"* is set to true
Trigger	Initiated by user / ad-hoc
Main success scenario	1. User selects the donor counselling dashboard view (User either generates the Donor Counselling List for donors flagged for counselling and then clicks on the row to select the donor or the user uses Find Donor and clicks on View Flagged for Counselling on the donor's overview

	tab) 2. The system must display the selected donor's counselling dashboard showing the last donation information and all the related test outcomes 3. The system must provide the option for the user to: ○ record the date of counselling (date defaults to current date) ○ select a counselling status (Received Counselling, Refused Counselling, Did Not Receive Counselling) ○ Enter additional information in a comment text field. ○ Check a checkbox to indicate that the donor has been referred to another service ○ If the Referred checkbox is selected then the system must ensure that the user selects a referral site from the drop-down list 4. If the user records any counselling status then the system must remove the flag for counselling on the donor's record.
Alternate scenario	1. If a user has previously recorded a counselling status for a donor who was flagged for counselling the system must allow the user to view the donation from the donor dashboard and to remove the counselling status and/or referral status. 2. The system must then re-flag the donor for counselling so that the donor will be included on the Donor Counselling report again.
Alternate scenario	If a user has previously recorded a Referred status for a donor who was flagged for counselling the system must: 1. Allow the user to edit and update the referral site or 2. Allow the user to remove the Referred status and automatically remove the referral site.

Screen Design	

USE CASE NARRATIVE	
Use Case No	UC01-10-06
Use Case Name	Add Referral Sites
Preconditions	User is an Administrator or Superuser User has logged in
Trigger	Initiated by user / ad-hoc
Main success scenario	As an administrator I need to be able to add and edit referral sites i.e. add or edit a location that has a Location Type = Referral Site. Given that the user is logged in as administrator or superuser When the user selects Manage Locations

	Then the user must be able to add a new location or update an existing location and select a Location Type = Referral Site and save the location. NOTE: This will be used when recording the referral site that the TTI positive donors are referred to during post-donation counselling.
	On the Manage Locations page, 'Referral Site' must be added as an option to Location Type dropdown list to allow users to search for all Referral sites.
Screen Design	

7.3 FR02-03 Record a Donation

Requirement ID & Name	**FR02-03**	**Record a Donation**
Requirement Description	**Record a donation** The system must be able to record data related to the donation as follows: • The system must be able to assign a pack type to the donation. • The system must be able to record if a sample only was collected for testing. • The system must be able to record if a donation was not successfully collected. • The system must be able to record the donation type. • The system must be able to record the start and end time of the bleed.	
Purpose	The goal of this function is to record and store all essential information about the blood donation taken from a donor on a particular date and time, to enable traceability throughout the blood processing chain. This includes the status of the donor **at the time he/she made the donation** (i.e. voluntary non-remunerated donor, replacement, autologous, other) because this is an indicator of the risk of the donor. Blood services can only reach the third level of accreditation if the % of donors that are VNRD is 80% or more. Blood services try to convert autologous or replacement donors to voluntary non-remunerated donors.	
Business Process	BP 2.8	Record donation
Related Requirements	FR06	Check Donor's eligibility to donate

Use Case	UC02-04	Record a donation - live data entry during the donor clinic
	UC02-05	Back entry of data from medical history forms post-clinic
Inputs	Medical History Form	
Outputs	Screen – see prototypes below: • View Donation Batch Summary • View Donation • View Donor Dashboard	
USE CASE NARRATIVE		
Use Case No	UC02-04	
Use Case Name	Record a donation - live data entry during the donor clinic	
Goal	To record the mandatory information about a donation that has been collected from a donor during donor clinic	
Preconditions	The user has logged into the system There is an existing open donation batch for the donor panel/venue The phlebotomist bleeds the donor and collects a blood donation The user selects Manage Donor to record the donation while the bleed is still in progress or as soon as the donation has been collected	
Success End Condition	A donation is recorded	
Failed End Condition	An unsuccessful donation is recorded	
Actor	Donor Clinic Staff (phlebotomist)	
Trigger	The user selects Find Donor	
Main success scenario	1. The user selects the Find Donor option from the Manage Donors menu option 2. The user scans in the Donor Number from the barcode label on the Medical History Form and selects Search 3. The system displays the Donor Number, First and Last Name, Gender Age and Date of Birth so that the user can verify that this is the correct donor 4. The user selects the donor and the overview tab is displayed 5. The user selects the Donations tab and selects Add Donation 6. The user selects the open donation batch according to venue from the drop down list 7. The user scans the DIN from the barcode label on the pack into which the blood has been collected 8. The user selects the pack type from a dropdown list 9. The user selects the donation type from a dropdown list 10. The system displays the bleed start time and bleed end time as the current time but the user can change this as	

	needed to record the actual bleed time. 11. The user clicks "Save" to save the donation record. 12. The user can view the Donor Overview and must be able to see that the number of donations has been updated by 1, the due to donate field has been updated to today's date + interval period and the summary data about the donation.	
Variation 5.1	There may sometimes be a donation event where a DIN (donation identification number) is issued and a pack is used but there is no "actual" donation associated with it i.e. a donation may be initiated but it is not completed successfully (e.g. donor faints during the bleed, the pack is under or over the weight limits i.e. not enough blood was collected / too much blood was collected). This has an impact as to whether a test outcome is expected for the pack, whether or not components may be produced, whether the pack should be discarded, whether the number of donations the donor has made should be updated and whether the minimum period between donations should be invoked. Therefore this information must be recorded for traceability purposes. • The user must be able to select a "Did Not Bleed" pack type from the dropdown list to record the unsuccessful donation. The user may need to amend the pack type and change it to a "Did Not Bleed" pack type if another pack type has already been entered. This pack type will have specific rules associated with it.	
Exclusions	The bleed time is required because if the bleed time is too long then the blood cannot be used. Currently the authorised user will determine whether or not the blood should be discarded: it is not a system intervention as it requires clinical judgement based on many factors.	
Business Rules	BR02-06	If a donation is collected, the system must update: • the number of donations that the donor has made by incrementing it by one • the donor's date due to donate by adding the minimum interval in days for the pack type used to the current date
USE CASE NARRATIVE		
Use Case No	UC02-05	
Use Case Name	Historical Data Entry of data using Donation Batch	
Goal	In cases where real time data capture is not possible e.g. power outage during a clinic, a lack of resources whereby there are not enough staff or equipment to capture data during the clinic, the donor clinic staff record all information on the donor's medical history form and this is sent back to head office along with the barcoded samples and donations at the end of the clinic. At Head Office this data is entered into the system in batches by a data entry clerk BEFORE the testing and component processing can begin.	
Preconditions	The user has logged into the system The first time donors have been registered on the system	

Success End Condition	All donations from the donation batch are recorded in the system
Failed End Condition	None
Actor	Data Entry Clerk
Trigger	The user selects the Manage Clinics
Main success scenario	1. The system must display the batches that are already open on the Open Batches tab 2. The user selects the venue from the drop-down list, selects the checkbox for Historical Data Entry and selects Add Donation Batch 3. The user selects the newly created donation batch 4. The user selects the Add Donation option from the donation batch screen 5. The user scans in the Donor Number from the barcode label on the Medical History Form 6. The system displays the Donor First and Last Name, Gender and Date of Birth so that the user can verify that this is the correct donor 7. The user scans the DIN from the barcode label on the Medical History Form 8. The user selects the pack type from a dropdown list 9. The user selects the donation type from a dropdown list 10. The system displays the bleed start time and bleed end time as the current time but the user must enter the actual start and end time from the Medical History Form. 11. The user clicks Save to save the donation record. 12. The system must display the Manage Donation Batch screen so that the user can see the donation that has just been added and can then add the next donation.
Exception 5.1	In very rare cases, there may be a need to record a donation that was collected in error when the donor was or should have been deferred. For purposes of traceability, the system must account for each DIN issued and for each donation collected and must alert supervisors and the medical director of a serious non-conformance issue. This will only occur when the system is not in real-time use i.e. where the data is back entered post-clinic. 5. The user scans in the Donor Number from the barcode label on the Medical History Form 6. The system displays the Donor First and Last Name, Gender and Date of Birth so that the user can verify that this is the correct donor and the system must show **Do Not Bleed** if the donor is currently deferred or is not due to donate 7. The user scans the DIN from the barcode label on the Medical History Form 8. The user selects the pack type from a dropdown list 9. The user selects the donation type from a dropdown list 10. The system displays the bleed start time and bleed end time as the current time but the user must enter the actual

	start and end time from the Medical History Form. 11. The system must display a warning that this is an ineligible donor and that the donation will be flagged as unsafe. It must provide the option to cancel or continue. 12. If the user selects continue the donation will be recorded but the donation and all associated test samples (with the same DIN label) will be automatically flagged for discard immediately. This is to ensure that all donations actually collected, even in error, are captured and tracked.	
Assumptions	None	
Exclusions	None	
Business Rules	BR02-05	Every Donation Identification Number issued must be recorded for traceability even if there is no donation associated with it.
	BR02-06	If a donation is collected, the system must update: • the number of donations that the donor has made by incrementing it by one • the donor's date due to donate by adding the minimum interval in days for the pack type used to the current date

7.4 FR01-07 Check Donor's Eligibility to Donate

Requirement ID & Name	**FR01-07**	**Check Donor's Eligibility to Donate**
Requirement Description	The system must check each category of donor against the following criteria to determine if they are eligible to donate blood: *FR01-07-01 Check a new donor's eligibility to donate* A new donor is defined as a donor who does not have any previous donations recorded in the system. The system must check that the new donor's age is within the allowable range as configured. *FR01-07-02 Check a repeat donor's eligibility to donate* A repeat donor is defined as a donor whose has one or more previous donations recorded in the system. The system must check that the repeat donor's age is still within the allowable range as configured. The system must check that the interval since the last donation conforms to the configured minimum interval. The system must check that the donor is not currently or permanently deferred	
Purpose	The aim of this requirement is to ensure both the health and safety of the donor and the health and safety of the	

	donated blood (and therefore the blood recipient) by checking against criteria determined according to national clinical standards and alerting the user of any donor that does not meet the criteria and blocking the entry of a donation for that donor. This minimises the possibility of unsafe blood being collected by excluding high-risk donors. It also minimises the possibility of the donor having an adverse reaction and/or a negative health outcome following the donation.	
Related Requirements	FR01-03-1	The system must provide for a global property to set the minimum and maximum ages allowable for a donor, according to blood service policy and national clinical guidelines. Default configuration must be 16 years for minimum age and 65 years for the maximum age.
Business Processes	BP2.3	Register New Donor (check age and automatically block registration if under age)
	BP2.4	Check Repeat Donor (check age and allow user to enter a deferral if over age)
	BP2.6	Check Donor Eligibility to Donate (check deferrals, valid donation and minimum interval between donations)
Use Case	UC02-01	Check new donor eligibility - live data entry during the donor clinic
	UC02-02	Check repeat donor eligibility - live data entry during the donor clinic
	UC02-03	Back entry of data from medical history forms post-clinic
Inputs	Medical History Form	
Outputs	Alert on Donor Dashboard	
USE CASE NARRATIVE		
Use Case No	UC02-01	
Use Case Name	Check new donor eligibility - live data entry during the donor clinic	
Goal	To check whether or not a new donor is eligible to donate blood at the time of registration	
Preconditions	User is logged into the system. The donor presents at the clinic and has completed the Medical History Form.	
Success End Condition	New donor is registered	
Failed End Condition	New donor is not registered	
Actor	Donor Clinic Staff User (donor registration staff, phlebotomist)	
Trigger	User searches for donor	
Main success scenario	1. User searches for the donor by name and surname to ensure that the donor has not registered already to minimise duplicate donor entries 2. There is no donor with that name and the system confirms this and allows the user to Add Donor	

	3. The user selects Add New Donor 4. The system retains the Name and Surname from the search 5. The user enters the donor's Title and Calling Name 6. The user enters the Date of Birth 7. The system calculates the donor's current age and if the donor's age conforms to the age limits specified within the system, the user can then enter the Venue and the donor's preferred language of communication. 8. The system creates a unique Donor Number for the donor.
Variation 7.1	• The system calculates the donor's current age using the date of birth and if the age is less than the minimum age as configured (e.g. if the donors current age is 15 and the configured minimum age is 16) then the system must block the registration and must display a message on the screen explaining to the user that the donor is under the age limit.
USE CASE NARRATIVE	
Use Case No	UC02-02
Use Case Name	Check repeat donor eligibility - live data entry during the donor clinic
Goal	To check whether or not a repeat donor is eligible to donate blood
Preconditions	User is logged into the system. The donor presents at the clinic and has completed the Medical History Form.
Success End Condition	Repeat donor is able to proceed to the clinical assessment
Failed End Condition	Repeat donor is not able to proceed to the clinical assessment
Actor	Donor Clinic Staff User (donor registration staff, phlebotomist)
Trigger	User searches for donor
Main success scenario	1. User searches for the donor by name and surname, or by Donor Number 2. The system finds the donor and displays the summary information on the donor dashboard 3. If the donor is not currently or permanently deferred, the system will display "No current deferrals" and the user can continue 4. The system calculates the donor's current age and if the donor's age is still within the maximum age limit specified within the system, the user can continue 5. The system checks the donor's date due to donate against the current date and if the interval between donations exceeds the minimum interval specified then the user can continue. 6. The user can then proceed to the clinical assessment where the user can then add a Donation.
Variation 3.1	• If the donor is permanently or currently deferred then the system displays a message and does not allow the user to proceed to Add a Donation

Variation 4.1	• The system calculates the donor's current age using the date of birth and if it is greater than the maximum age as configured (e.g. if the donors current age is 66 and the configured maximum age is 65) then the system must block the registration and must display a message on the screen explaining to the user that the donor is over the age limit.	
Variation 5.1	• The system checks the donor's date due to donate (as displayed on the Donor Dashboard Overview) against the current date and if the interval between donations is less than or equal to the minimum interval specified then the system must not allow the user to Add a Donation. • If the user attempts to add a Donation then the system displays a message "Do Not Bleed".	
Exception 6.2	If the interval between donations is less than the minimum period stipulated then the blood service may allow the donor clinic supervisor to have the discretion to over-ride the deferral if it is only a few days short of the minimum period based on their clinical judgment. • The system must allow a Donor Clinic Supervisor user to over-ride the age deferral and record the reason for doing so. • The Donor Clinic Staff User will then be able to proceed and add a Donation as normal.	
Assumptions	The system will not differentiate between current donors (who have made a donation within the last 12 months) and lapsed donors (who have made a donation previously but more than 12 months ago). Any donor who has a previous donation is treated as a repeat donor.	
Exclusions	Initially the system will not have the capability to define different minimum intervals between donations according to age and gender criteria. This feature may be included in future version.	
Business Rules	BR01	A donor must be the minimum age or older AND younger than the maximum age allowed in order to be able to donate blood.
	BR02	If the donor is a repeat donor then the donor clinic staff also checks whether time between the previous donation and the current date meets the minimum time period required according to national guidelines. If it does not meet the minimum time then the donor will be deferred until the date when the minimum time period is met.
	BR03	A donor who is permanently deferred must never be allowed to donate blood.
	BR04	A donor who has been temporarily deferred must not be able to donate blood until the deferral period has passed.
	BR05	A donor who is permanently or currently deferred can be bled to produce a sample for testing purposes only. This is known as a Test Only Donation.
Processing Rules for BP 2.6 CHECK DONOR ELIGIBILITY TO DONATE		

See decision tree diagram below

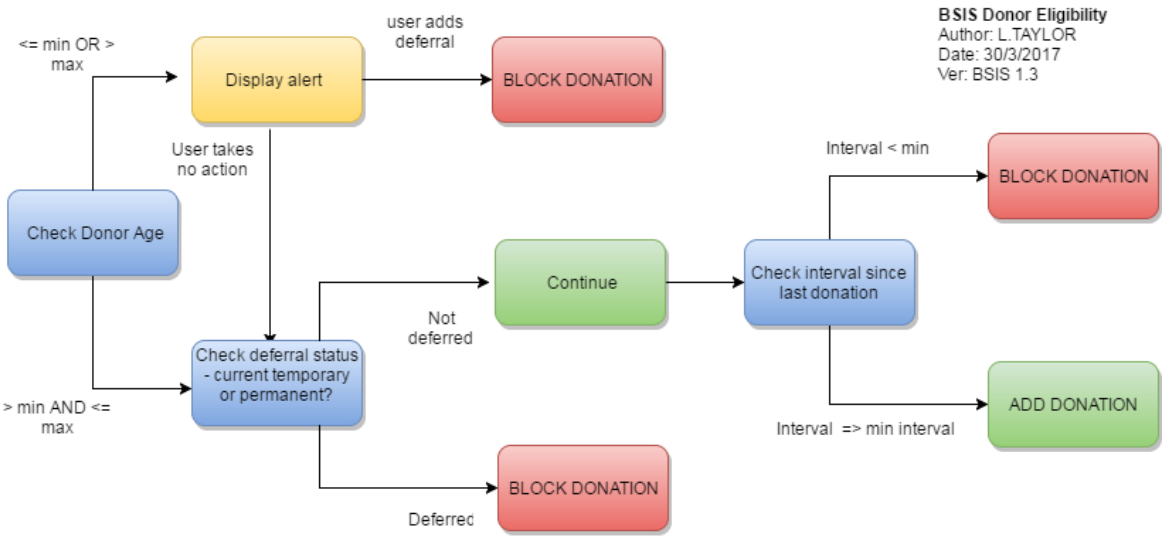


Figure 6: Donor Eligibility Decision Tree

Condition:	**CHECK DONOR'S ELIGIBILITY TO DONATE BLOOD**							
Is the donor's current age => minimum age AND < maximum age?	Y	Y	Y	Y	N	N	N	N
Is the donor deferred?	Y	Y	N	N	Y	Y	N	N
Does it meet the minimum interval since last donation?	Y	N	Y	N	Y	N	Y	N
Action:								
Allow a donation	**BLOCK**	**BLOCK**	**ALLOW**	**BLOCK**	**AGE ALERT BLOCK**	**AGE ALERT BLOCK**	**AGE ALERT ALLOW**	**AGE ALERT BLOCK**
Allow if donations does not Count as Donation? i.e. is a sample for Test Only	**ALLOW**	**ALLOW**	**ALLOW**	**ALLOW**	**AGE ALERT ALLOW**	**AGE ALERT ALLOW**	**AGE ALERT ALLOW**	**AGE ALERT ALLOW**

Figure 7: Eligibility Rules Decision Table

7.5 FR03-06 Record Test Batch Information

Requirement ID & Name	**FR03-06**	**Record Test Batch Information**
Requirement Description	The system must provide traceability of test outcomes by recording for each test sample the date, time, test batch and laboratory technician who performed the testing. A testing batch is defined as: All units tested during a single test run within the testing laboratory.	
Purpose	To ensure traceability of test outcomes	
Business Process	BP 3.1	Set up Test Batch
	BP 3.2	Record ABO Rh and serology testing
	BP 3.3	Record TTI testing
	BP 3.4	Release test batch
	BP 3.5	Close test batch
Related Requirements	FR03-01	Record blood grouping and serological test outcomes
	FR03-02	Record TTI test outcomes
	FR03-07	View test batch summary
	FR03-08	Print test batch summary
	FR03-09	Enforce testing rules for additional and confirmatory serological tests
Use Case	UC03-03	Manage a test batch
Inputs	Lab testing worksheet	
Outputs	Test Batch Summary Report	
USE CASE NARRATIVE		
Use Case No	UC03-03	
Use Case Name	Manage a test batch	
Goal	To open a test batch, add donation batch(es) to the test batch, record TTI and serological test outcomes, and to release and close the test batch	
Preconditions	User has logged in There are one or more closed donation batches waiting to be tested	

Success End Condition	To open a test batch, add donation batch(es) to the test batch, record TTI and serological test outcomes, and to release and close the test batch
Failed End Condition	
Actor	TTI testing staff, TTI testing supervisor, Serology staff, Serology Supervisor
Trigger	Add new test batch
Main success scenario	1. The user creates a new test batch by selecting one or more donation batches from the list of closed donation batches 2. The system creates a test batch with the current date and time that includes all the samples from the donation batches selected 3. The samples must have a default TTI Status of Not Done and a Blood Group Serology Status of Not Done 4. The user must be able to enter the test outcomes for the four mandatory TTI tests for each sample in the test batch. (See FR03-10 below for more detail) 5. The user must be able to enter the test outcomes for the mandatory serological tests: blood group (ABO and Rh) Titre and Antibody screening (See FR09-09 below for more detail) 6. The user must be able to release a test batch when the majority of samples in the test batch have completed TTI and serology testing according to the testing rules defined. Any samples that have outstanding test outcomes or discrepancies will not be released and the test batch must remain open so that these can be entered as soon as they are available. 7. The user must be able to close the test batch when all samples have completed testing and any discrepancies have been resolved.

7.6 FR03-09 Enforce ABO Rh and serology testing rules

Requirement ID & Name	**FR03-09**	**Enforce ABO Rh and serology testing rules**
Requirement Description	The system must be able to determine the need for additional or repeat tests based on defined criteria as follows: -01 The system must enforce the entry of confirmatory ABO Rh blood group serology outcomes for first time donors and must flag any discrepancies allowing confirmatory testing to resolve a mismatch -02 The system must automatically do a comparison with ABO Rh blood group serology outcomes from previous donations from the same donor and will flag any discrepancies allowing confirmatory testing to resolve a mismatch -03 The system must check the titre test outcome and if titre is high then the system must print High Titre information	

	on the pack label for any associated components. -04 The system must check the antibody screening outcome and if is positive then the system must flag any associated components containing plasma for discard. Any associated red cell concentrate components may be labelled for use.	
Purpose	To ensure that the ABO Rh grouping and serology testing rules related to the need for first screening test and confirmatory tests are adhered to and that any discrepancies are flagged for investigation. Any donations that are potentially unsafe must be blocked from release to inventory and immediately flagged for discard. This is a critical control point to determine the safety of both the donor and the blood donation. *Note: This is the algorithm that determines the blood group, titre level and antibody screening status of the donation. The decision to release blood to inventory happens at the labelling process when the TTI status of the donation is also taken into account.*	
Business Process	BP 3.2	Record ABO Rh and serology testing
	BP 3.4	Release test batch
	BP 3.5	Close test batch
Related Requirements	FR03-01	**Record blood grouping and serological test outcomes** The system must provide for a laboratory staff user to manually enter test outcomes for ABO and Rh serology tests for each blood donation sample tested. The four mandatory serological tests are: ABO grouping, Rhesus grouping, Titre and Antibody screening.
	FR03-02	**Record TTI test outcomes** The system must provide for a laboratory staff user to manually enter test outcomes for each blood donation sample tested for the for each of the four mandatory Transfusion Transmissible Infections (TTI) tests: HIV, Hepatitis B (HBV), Hepatitis C (HBC) and Syphilis;
USE CASE NARRATIVE		
Use Case No	UC03-09	
Use Case Name	Record ABO and Rh test outcomes	
Goal	To record the test outcomes for a sample to determine the ABO Rh blood group and to flag any discrepancies for investigation To record the titre for a sample and to note any samples that have high titre levels To record the antibody screening test outcomes and to flag any components with a positive outcome and block those containing plasma from release to inventory.	
Preconditions	User has logged in	
Success End Condition	User is able to record ABO Rh test, titre and antibody screening results for a donor	
Failed End Condition		

Actor	Serology Staff, Serology Supervisor	
Trigger	Open a test batch	
Main success scenario	1. User records ABO and Rh test outcomes for a first time donor 2. User records ABO and Rh repeat test outcomes for the first time donor 3. System checks if test and repeat test outcomes match 4. If tests match then blood group is determined for that sample and donor is updated	
	1. User records ABO and Rh test outcomes for a repeat donor 2. System checks if test outcomes match the blood group on the donor's previous donation record 3. If blood groups match then blood group is determined for that sample	
Variation 5.1 A	5. User records ABO Rh test outcomes with an AMBIGUOUS outcome i.e. the initial and repeat blood groups do not match 6. User can resolve this discrepancy and record the confirmed ABO Rh test outcome	
Variation 5.1 B	7. User records ABO Rh test outcomes with an AMBIGUOUS outcome i.e. the initial and repeat blood groups do not match 8. User cannot resolve this discrepancy and record a NO TYPE DETERMINED outcome.	
Assumptions	NONE	
Exclusions	NONE	
Business Rules	BR04-08	Each donation sample must be tested for the ABO and Rh to determine the blood group
	BR04-09	If ANY donation sample has an ABO Rh blood group that is a mismatch to the ABO Rh blood group of the previous donation for that donor then then the donation must be flagged as unsafe and the donor must be flagged for investigation
	BR04-10	If ANY donation sample has an ambiguous ABO Rh blood group where the Rh status cannot be determined that then the donation must be flagged as unsafe and the donor must be flagged for investigation
Processing Rules for determining the ABO Rh blood group	**NOTE:** The ABO and Rh are entered as separate test outcomes but both outcomes are needed to determine the blood group. Valid blood groups are A+, A-, B+, B-, AB+, AB-, O+,O-	

For each donation sample in a test batch, perform the following checks:

Enter the ABO and Rh test outcome

Check the DONOR'S ABO Rh blood type

If donor does not have a blood type (i.e. is a new donor NO_MATCH)
Then repeat the test and compare with the first test
If first test and repeat test match
then DONOR's ABO Rh TYPE is confirmed and complete
and DONATION's ABO Rh TYPE is confirmed and complete
Else if first test and repeat test do not match
then DONATION's ABO Rh TYPE is AMBIGUOUS
and must be investigated
Else if the donor does have an existing blood type (i.e. is a repeat donor)
Then compare the test with the existing blood group
If test and donor's blood type match
then DONOR's ABO Rh TYPE is confirmed and complete
and DONATION's ABO Rh TYPE is confirmed and complete Else if test and donor's blood type do not match
then DONATION'S ABO Rh TYPE is AMBIGUOUS
and must be investigated.

The ambiguous result/ discrepancy must be resolved by investigation outside of BSIS.

If the discrepancy can be resolved then the system must be able to record the confirmed test outcome, must update the donor's blood group and the donation's blood group to the confirmed blood group. The first test outcome must be however be recorded for traceability purposes.

If it cannot be resolved then the system must be able to record a NO_TYPE_DETERMINED result. This will flag the donation and associated components as unsafe and they must be blocked from release to inventory.

Immune-hematology: Antibody Screening Processing Rules

For each donation sample in a test batch, perform the Antibody Screening Test (AbScr):
If the Antibody screening test is NEGATIVE or NOT-TESTED
Then DONOR_STATUS=SAFE and COMPONENT_STATUS=SAFE
Else if the Antibody screening test is POSITVE

Then DONOR_STATUS=SAFE and COMPONENT_STATUS= UNSAFE

NOTE: Although AfSBT standards require antibody screening to be done, if the test is not performed then a NT (Not_Tested) outcome can be recorded in BSIS.

Immune-hematology - Titre

For each donation sample in a test batch, perform the TITRE Test:

If the TITRE = HIGH

Print a label noting HIGH TITRE RESULT on component labels for Whole Blood, FFP and platelets.

NOTE: Although only applicable to Type O blood group BSIS allows entry of a TITRE outcome for any blood group If the test is not performed then a NT (Not_Tested) outcome can be recorded.

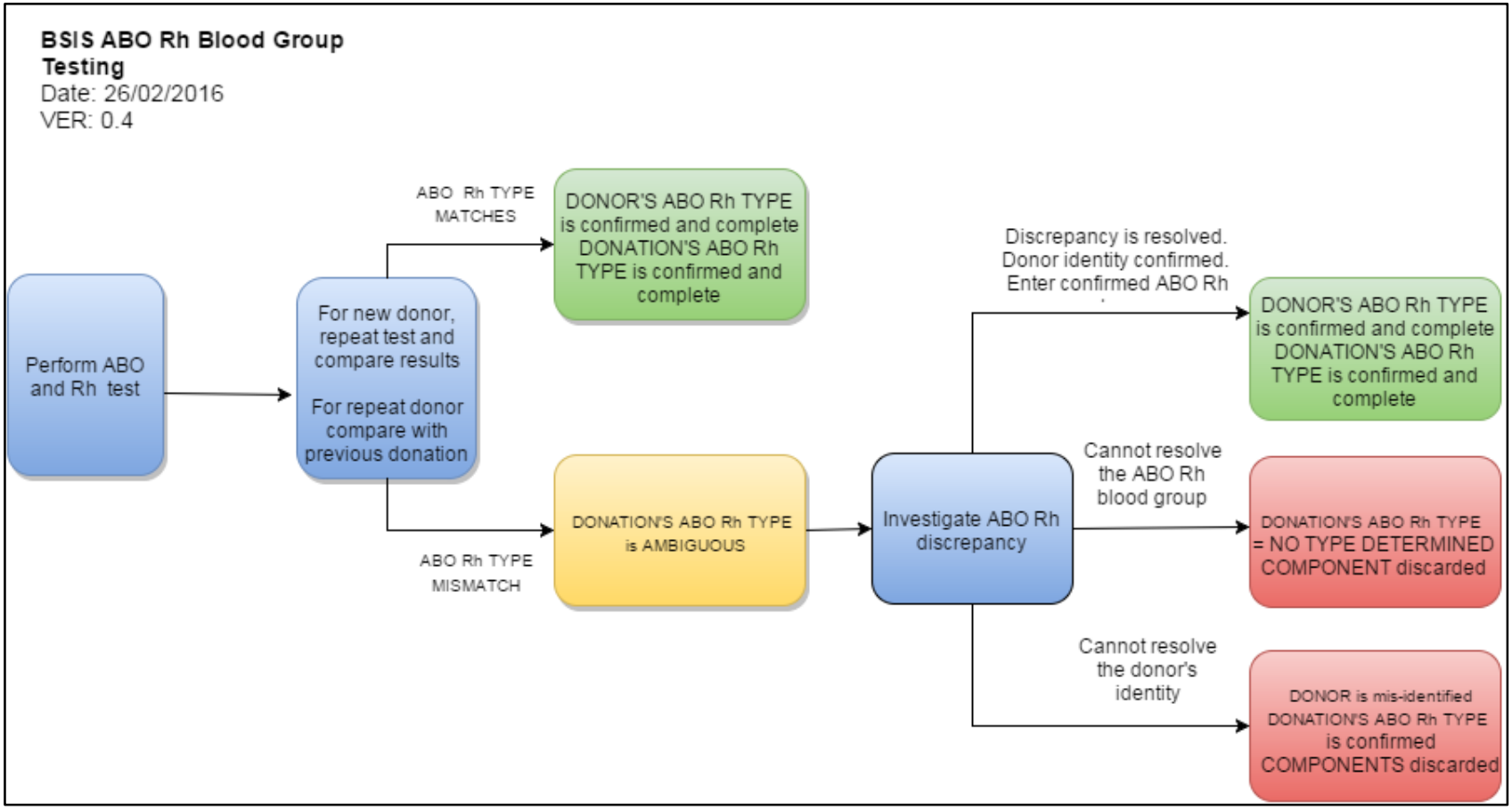


Figure 8: ABO Rh Testing

Requirement ID & Name	**FR03-09-04-1**	If the antibody screening test outcome for a sample is positive then the system must flag any components processed from that donation as unsafe.
Requirement Description	The system must be able to determine the safety of the components processed from the donation according to the AbScr test as follows: The system must check the antibody screening outcome and if is positive then the system must flag any associated components for discard.	
Purpose	To ensure that the antibody screening rules related are adhered to and that any donations that are potentially unsafe must be flagged as unsafe and blocked from labelling. This is a critical control point to determine the safety of the blood donation. *Note: This is the algorithm that determines the antibody screening status of the donation. The decision to release blood to inventory happens at the labelling process when the TTI status and blood grouping status of the donation is also taken into account.*	
Business Process	BP 3.2	Record ABO Rh and serology testing
	BP 3.4	Release test batch
	BP 3.5	Close test batch
Related Requirements	FR03-01	**Record blood grouping and serological test outcomes** The system must provide for a laboratory staff user to manually enter test outcomes for ABO and Rh serology tests for each blood donation sample tested. The four mandatory serological tests are: ABO grouping, Rhesus grouping, Titre and Antibody screening.
Business Rule	BR04-17	If the antibody screening test is done and the outcome is positive then any associated components **that contain plasma** must be flagged as unsafe and should be discarded.
USE CASE NARRATIVE		
Use Case No	**UC03-09-04-1**	
Use Case Name	Check antibody screening test outcomes	
Goal	To record the antibody screening test outcomes at the point of releasing the sample (DIN) and for those samples that have a positive AbScr test outcome, to flag any components as unsafe.	
Preconditions	User has logged in User has recorded an antibody screening (AbScr) test outcome for a sample	
Success End Condition	System flags components as Unsafe if a POS AbScr test outcome is recorded	
Failed End Condition		
Actor	System	

Trigger	Release test batch
Main success scenario	1. System checks the AbScr test outcome 2. If the AbScr test outcome is POSITIVE then the system checks all the components that have the same DIN and flags these as UNSAFE 3. If the AbScr test outcome is NEGATIVE or NOT TESTED then leave the component status unchanged
Assumptions	NONE
Exclusions	NONE

Immune-hematology: Antibody Screening Processing Rules

For each donation sample in a test batch, perform the Antibody Screening Test (AbScr):

If the Antibody screening test is NEGATIVE or NOT_TESTED
Then COMPONENT_STATUS=SAFE
Else if the Antibody screening test is POSITVE and component contains plasma
Then COMPONENT_STATUS= UNSAFE
Else if the Antibody screening test is POSITVE and component does NOT contain plasma
Then COMPONENT_STATUS= SAFE

Note:

- At the point of labelling: Any donation with a positive antibody screening test outcome AND contains plasma will be flagged as UNSAFE in BSIS and cannot therefore be labelled for use.
- If the antibody screening is positive there is no impact on the donor so no deferral is required.
- Although AfSBT standards require antibody screening to be done, if the test is not performed then a NT (Not_Tested) outcome can be recorded in BSIS. There is no impact on the component status if a Not Tested (NT) outcome is recorded.

7.7 FR03-10 Enforce TTI testing rules

Requirement ID & Name	FR03-10	**Enforce TTI testing rules** *Block donations and automatically defer donors according to TTI test rules*
Requirement Description	The system must automatically flag donations and their associated components based on TTI defined test outcomes in order to block the components from release to inventory. The system must automatically defer the donor according to the test rules.	
Purpose	To ensure that the TTI testing rules related to the need for first screening test, repeat tests and confirmatory tests are adhered to and that any donations that are unsafe are blocked from release to inventory and immediately flagged for discard. The associated donor must be permanently deferred from donating if the donation is confirmed as positive for TTIs, but is not permanently deferred if the repeat and confirmatory tests are negative. This is a critical control point to determine the safety of both the donor and the blood donation. *Note: The confirmatory tests are usually carried out by a third party lab and is a different type of test so the test outcomes may only be available several days later.* *Note: This is the algorithm that determines the safety of the donation according to whether or not it is infected with a TTI. The decision to release blood to inventory happens at the labelling process when the other factor, the determination of the correct ABO Rh blood group, is also taken into account.*	
Business Process	BP 3.3	Record TTI testing
	BP 3.4	Release test batch
	BP 3.5	Close test batch
Related Requirements	FR03-03	**Record TTI test outcomes** The system must provide for a laboratory staff user to manually enter test outcomes for each blood donation sample tested for each of the four mandatory Transfusion Transmissible Infections (TTI) tests: HIV, Hepatitis B (HBV), Hepatitis C (HBC) and Syphilis.
	FR03-09	**Enforce testing rules for additional and confirmatory tests** The system must be able to determine the need for additional or repeat tests based on defined criteria as follows:
	FR03-10-01	If a donation tests positive for a TTI, the system must automatically flag the associated donor to receive post-donation counselling. This must happen only after the confirmatory tests are done and when the test batch is closed.
Use Case	UC03-01	Check recorded TTI test outcomes according to the TTI processing rules
Inputs	TTI Testing Worksheet produced by the TTI testing staff during the manual testing process	

Outputs	Test Batch Outcomes Summary Report
USE CASE NARRATIVE	
Use Case No	UC03-01
Use Case Name	Check recorded TTI test outcomes according to the TTI processing rules
Goal	To verify the TTI test outcomes entered by a lab technician and ensure that repeat tests outcomes and confirmatory test outcomes are entered according to the processing rules defined and flag the donation and donor as safe or unsafe accordingly.
Preconditions	The user has logged into the system There is an existing open test batch The user has the laboratory testing worksheet with the test outcomes from manual testing recorded against each donation sample by DIN
Success End Condition	All test outcomes (except for confirmatory tests if required) for the samples in the donation batch are recorded in the system and the test batch can be released
Failed End Condition	The test batch cannot be released
Actor	TTI Testing Staff TTI Testing Supervisor
Trigger	User records a screening test outcome for each of the four mandatory TTIs for a donation sample
Main success scenario	8. User selects the open test batch from the Manage Test Batch screen 9. The test batch containing all the donation samples is displayed showing a TTI Status of NOT DONE for all samples 10. User selects Record TTI Test Results 11. The screen displays a list of all donation samples sorted by DIN 12. User enters a NEG value for the HIV, HBV, HCV and Syphilis for each donation sample in the test batch 13. User saves the results 14. The screen display a list of all donation samples sorted by DIN with a TTI Status of SAFE 15. User can proceed to Release Test Batch
Variation 5.1 A Screening test is POSITIVE and repeat tests (Conf1 and Conf2) are both NEGATIVE	9. User enters a POS value for any of the HIV, HBV, HCV and Syphilis for one or more donation samples in the test batch 10. User saves the results 11. The screen display a list of all donation samples sorted by DIN with a TTI Status of SAFE for all those samples with all NEG outcomes and a TTI Status of UNSAFE for any samples with one or more POS outcomes 12. The screen displays *Record Confirmatory Test Results* 13. User selects *Record Confirmatory Test Results*

	14. The screen headed *Record Pending Test Results* displays a list of any donation samples sorted by DIN that have a TTI Status of UNSAFE with the repeat test 1 (Conf1) and repeat test 2(Conf2) for the POS TTI that must be entered 15. User enters a NEGATIVE outcome for repeat test 1 AND repeat test 2 for all samples with a TTI Status of UNSAFE and saves the results 16. According to the processing rules below the screen displays the relevant TTI Status for each donation sample and no confirmatory test is required 17. All donations samples that have all necessary tests completed will be displayed as TTI Status of SAFE or UNSAFE 18. The user can proceed to Release Test Batch. *(NOTE: The ABO serology testing that happens in parallel with TT testing must also be complete before the batch can be released – see UC03-02 for details)*
Variation 5.1 B Screening test is POSITIVE and one or both repeat tests are POSITIVE	19. User enters a POS value for any of the HIV, HBV, HCV and Syphilis for one or more donation samples in the test batch 20. User saves the results 21. The screen display a list of all donation samples sorted by DIN with a TTI Status of SAFE for all those samples with all NEG outcomes and a TTI Status of UNSAFE for any samples with one or more POS outcomes 22. The screen displays *Record Confirmatory Test Results* 23. User selects *Enter Confirmatory Test Results* 24. The screen headed *Record Pending Test Results* displays a list of any donation samples sorted by DIN that have a TTI Status of UNSAFE with the repeat test 1 and repeat test 2 for the POS TTI that must be entered 25. User enters a. a POSITIVE outcome for repeat test 1 (Conf1) AND repeat test 2 (Conf2) b. OR a POSITIVE outcome for one test and a NEGATIVE outcome for the other repeat test for all samples with a TTI Status of UNSAFE and saves the results 26. According to the processing rules below the screen displays the relevant TTI Status for each donation sample and displays *Record Confirmatory Test Results* as a third confirmatory test (Conf 3) is now required 27. The screen headed *Record Pending Test Results* displays a list of any donation samples sorted by DIN that have a TTI Status of UNSAFE with the confirmatory test 3 for the POS TTI that must be entered 28. If the confirmatory outcomes are available the user can enter these for the samples requiring confirmatory results and save the results 29. All donations samples that have all necessary tests completed will be displayed as TTI Status of SAFE or UNSAFE. The user can now proceed to Release Test Batch and these tests will now be released. *(NOTE: The ABO serology testing that happens in parallel with TT testing must also be complete before the batch can be released – see UC03-02 for details)*

	30. Any donation samples that still have outstanding confirmatory tests will be displayed as NOT DONE 31. If the confirmatory outcomes are not yet available the user can still proceed to Release Test Batch. Those donation samples with a NOT DONE TTI status will NOT be released and will be retained in the open test batch until the confirmatory test outcomes can be entered.	
Exception 17.1	If the confirmatory test outcomes are never received the TTI testing supervisor must have the ability to select the open batch and record a TTI Status of NOT CONFIRMED for any donation samples that have outstanding confirmatory test results. The TTI testing supervisor may then proceed to Close Test Batch. All donations will remain flagged as UNSAFE and all associated donors will also be flagged according to the processing rules.	
Business Rules	BR04-05	Each donation sample must be tested for each of the four mandatory test types (HIV, HCV, HBV, Syphilis)
	BR04-06	If ANY of the four test types return a POSITIVE TTI test outcome then the donation must be flagged as unsafe and discarded as soon as possible
	BR04-07	If any donation has a confirmed POSITIVE TTI test outcome the donor must be deferred from donating blood permanently and must be contacted for counselling as soon as possible

TTI Testing processing rules for HIV, HCV, HBV and Syphilis

For EACH test type
For EACH sample in the test batch perform Initial the following check:
If the TTI screening test outcome is NEGATIVE
Then DONOR_STATUS=SAFE and DONATION_TTI_STATUS = SAFE
If the TTI screening test outcome is POSITIVE
Then perform two repeat tests to check for false positives
If repeat test 1 AND repeat test 2 are NEGATIVE
Then DONATION_TTI_STATUS = SAFE and DONOR_STATUS=SAFE
If repeat screening test 1 AND repeat screening test 2 are POSITIVE
Then DONATION_TTI_STATUS = UNSAFE and DONOR_STATUS=DO NOT BLEED and add PERMANENT DEFERRAL to DONOR
go to Perform Confirmatory Test
IF repeat test 1 is POSITIVE and repeat test 2 is NEGATIVE
Then DONATION_TTI_STATUS = UNSAFE and DONOR_STATUS=DO NOT BLEED and add INDEFINITE DEFERRAL TO DONOR
Then Perform Confirmatory Test
IF confirmatory test is POSITIVE
Then DONATION_TTI_STATUS = UNSAFE and DONOR_STATUS=DO NOT BLEED
and add PERMANENT DEFERRAL TO DONOR
IF confirmatory test is NEGATIVE
Then DONOR_STATUS=SAFE and DONATION_TTI_STATUS = UNSAFE and remove DEFERRAL

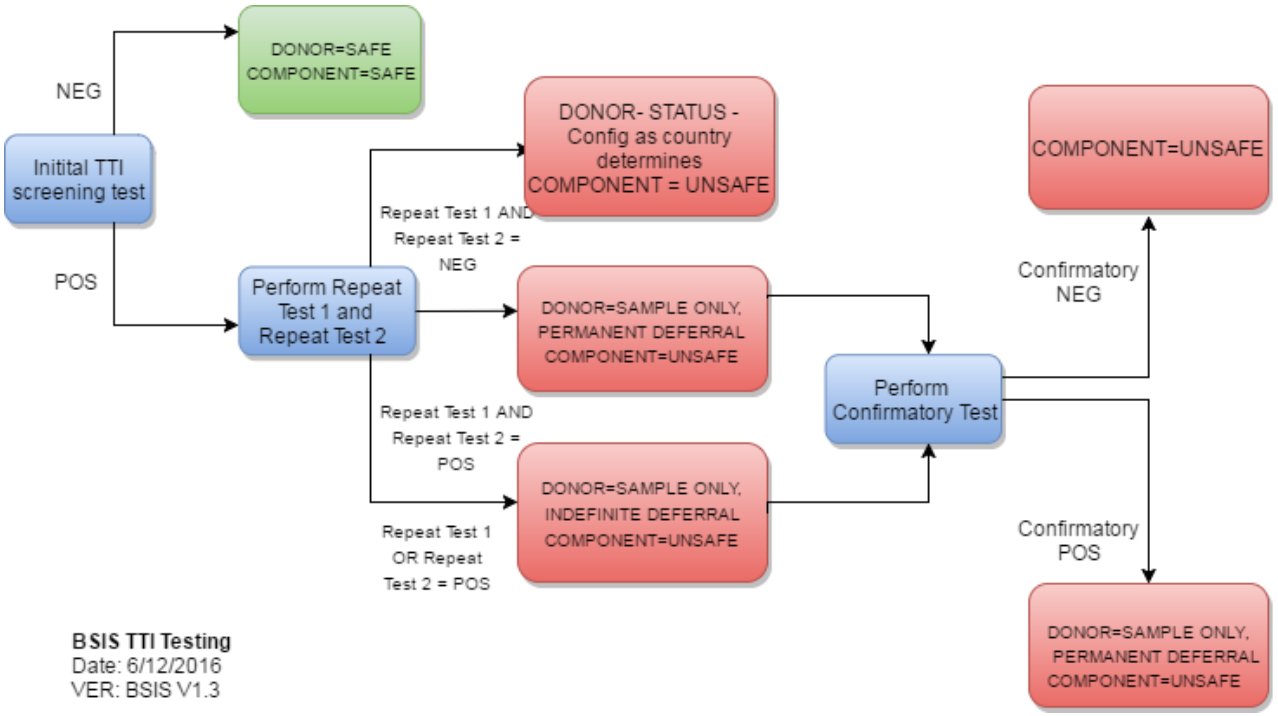


Figure 9: BSIS TTI Testing Algorithm

Requirement ID & Name	**FR01-13**	**Merge Duplicate Donor Records**
Requirement Description	For an authorised user to be able to view and merge donor records that are duplicates of the same donor to create a new donor record with a new system-generated Donor Number. The system must retain the previous duplicate donor records for traceability but user must no longer be able to access them.	
Purpose	To maintain the integrity of the data by ensuring that duplicate records that have been correctly identified as duplicates can be merged into one donor record.	
Business Process	BP 7.1	Merge Duplicate Donor Records
Related Requirements	NONE	
Use Case	UC01-13	
USE CASE NARRATIVE		
Use Case No	UC01-13	
Use Case Name	Merge duplicate donor records	
Preconditions	User has logged in	
Success End Condition	Duplicate records are identified and merged successfully	
Failed End Condition	Duplicate records are not merged because the information about each record is not sufficient to ensure they are duplicates	
Actor	Donor Clinic Supervisor	
Trigger	User selects Merge Duplicate Donors	
Main success scenario	System identifies duplicate donors based on an exact match with first name, last name and date of birth User selects which records should be merged User select which fields of each record should be retained in the merged record User reviews choices prior to finalising merge User selects merge System merged the two existing records and creates a new record and assigns a new donor number to the new record System retains existing records but does not display the records when the previous Donor Number/s are searched for	
Assumptions	NONE	
Exclusions	NONE	
Business Rules	BR01-08	If there are discrepancies between the ABO Rh blood group of the two (or more) donor records

		selected for merging, then the correct blood group cannot be assumed. The merged donor record must not be assigned a blood group and must be treated as a first time donor the next time he/she donates blood as far as ABO Rh testing is concerned.

7.8 FR04-006 Record and verify pack weight AMENDED

Requirement ID & Name	**FR04-006**	**Record and verify pack weight** The system must check if the pack weight is within the limits for that pack type and if not, then the system must display an alert and ensure that the component is flagged for discard
Requirement Description	As a component laboratory staff user, I need to record information about the weight of a pack prior to processing, so that I can effectively manage underweight and overweight packs. The allowed range is 10% above and below the pack type's volume: the volume of the pack is converted to a weight and this weight is then used to check if a pack is within the allowed weight range to be processed. • If the pack is an underfill (if the pack's weight is less than the **low volume weight** for that pack type) then the components must be flagged for discard. • If the pack is an overfill (i.e. if the pack's weight is greater than the **maximum weight** for that pack type) then the components must be flagged for discard. • If the **weight is > low volume and < minimum** then system must display a warning that only packed red cells (red cell concentrate) can be made and the system must flag the any components that contain plasmas as unsafe. **Packed red cells are not flagged as unsafe.**	
Purpose	For safety purposes a pack that is under or overweight (i.e. the volume is less or greater than the allowed volume) must not be processed as the ratio of anti-coagulant to blood will not be correct and the safety of the blood is compromised.	
Business Process	4.1	Receive donation batch/Receive components
Related Requirements	FR04-011	**Configure minimum, maximum and low volume weight limits per pack type** The system must allow an authorised user to configure the minimum and maximum pack weight and unit of measurement for each pack type in use. These weight limits are used to verify if a pack is

		under or overweight.
Use Case	UC04-006	Record and verify pack weight
USE CASE NARRATIVE		
Use Case No	UC04-006	
Use Case Name	Record and verify pack weight	
Preconditions	User has logged in The donation (pack) has been recorded in BSIS as part of a donation batch The associated component has been recorded as received in BSIS	
Success End Condition	The pack's weight is recorded and used to determine if the pack can be processed or not	
Failed End Condition	The pack's weight is not recorded	
Actor	Component Laboratory Staff / Component Laboratory Supervisor	
Trigger	User selects Record Component	
Main success scenario	1. The user selects Record Component 2. The user scans in the DIN from the pack or types in the DIN if a scanner is not available 3. BSIS finds and displays the component record 4. The user weighs the pack and enters the weight(mass) in grams 5. BSIS checks the weight of the pack against the pack weight limits for that pack type according to the processing rules defined below 6. If the weight is within the limits BSIS records the weight of the pack 7. If the weight is outside the limits BSIS must display a message warning that the pack is an over or under the weight limits fill and ask the user to confirm that the pack is to be discarded 8. If the user confirms, then BSIS must flag the component for discard 9. If the user cancels then BSIS must allow the user to re-enter the weight	
Alternate scenario	7a. If the weight is > low volume and < minimum then system must display a warning that only packed red cells (red cell concentrate) can be made and ask user to confirm. If user confirms then system must flag the any components that contain plasmas as unsafe.	
Assumptions	1. The acceptable volumes and therefore calculated weight for each pack type must be determined and set by the user as different countries use slightly different means of calculating the weight ranges. See background information for more detail. 2. The mass of the packs differs from manufacturer to manufacturer. The SOPS should require staff to tare the scale with an identical empty bag so that when the filled pack is weighed the mass measured is for the contents	

	only. The SOPs always require the user to tare the scale prior to entering the pack weight so the weight entered is always the weight of the contents only.	
Exclusions	NONE	
Business Rules	BR0-04-006	The acceptable volumes for component processing depend on the type of bags used. The volume must be within 10% of the target volume (bag volume). The commonly used bags are 500ml and 450 ml bags. To determine the acceptable range of weight for a pack, the equivalent weight is calculated by multiplying the volume of the pack by the nominal specific gravity of the component contained in the pack. This calculation is done outside the system and the maximum and minimum weight limits are set by the user. See background information for examples.
Processing Rules	The system must check the weight of the pack against the acceptable weight range for that pack type: 1. If the weight of the pack is > the maximum weight then flag the component for discard 2. If the weight of the pack is =< maximum weight and => minimum weight then continue to process component **3.** If the weight of the pack is > low volume weight and < minimum weight low volume weight then the component may only be used to make packed red cells **i.e. any component that contains plasma must be flagged as unsafe** (*Ref AABB Technical manual 18th edition pp 141: Low volume between 300 and 404ml may be used to prepare packed cells only*) 4. If the weight of the pack is < the low volume weight then flag the component for discard	
	Example: For a 450ml pack If the pack weight > 520g then discard If the pack weight =< 520g and => 427g then process **If the pack weight > 316g and < 427g then any components that contain plasma must be flagged as unsafe** If the pack weight < 316g then discard	
Background information	To calculate the acceptable range for the pack type: 1. Calculate the maximum weight of pack type = The maximum target volume of the pack (pack type volume * 1.1) * nominal specific gravity of the component 2. Calculate the minimum weight = The minimum target volume of the pack (pack type volume – (pack type volume * 0.1)) * nominal specific gravity of the component Check the weight of the pack against the range for that pack type:	

Component Type	Volume of pack			Weight(mass) as calculated	
Whole Blood & packed red cells	Pack Volume	Pack Volume + 10%	Pack Volume - 10%	Lower limit (min vol * gravity)	Upper limit (max vol * gravity)
AABB (SG 1.053)	450 ml	495 ml	405 ml	426.5	519.1
UK guidelines (SG 1.06)				429.3	524.7
AABB (SG 1.053)	500 ml	550 ml	450 ml	473.85	579.15
UK guidelines (SG 1.06)				477	583
Exception: Can be used for packed red cells only	Range between 300ml and 404ml			+300*1.053= 315.9	+404*1.053= 425.412
Plasma & platelets (1.03)					
	450 ml	495 ml	405 ml	417.15	509.85
	500 ml	550 ml	450 ml	463.50	566.50

References:

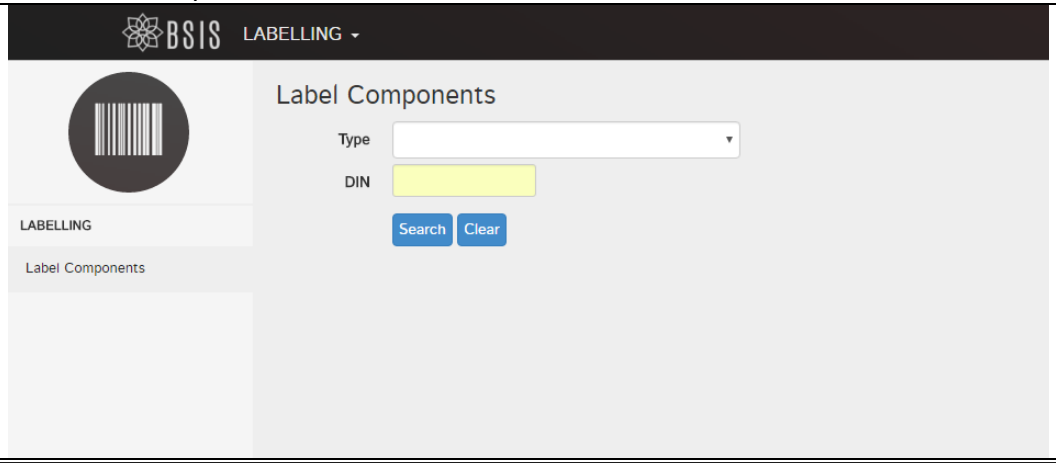
- *Volumes higher than 495 for 450ml bags must be discarded. (ref AABB Technical manual 18th edition pp 141)*
- *Volumes less than 300 and above 495ml for 450ml bag must be discarded*
- *Low volume between 300 and 404ml may be used to prepare packed cells only (ref AABB Technical manual 18th edition pp 141)*
- *The nominal specific gravity for whole blood and packed cells is 1.06 according to the UK guidelines for blood transfusion and 1.053 according to the AABB technical manual 18th edition. Nominal specific gravity for platelets and plasma products is 1.03*

Definitions	Tare weight is the weight of an empty container. By subtracting it from the gross weight, the weight of the contents (the net weight) may be determined.

7.9 FR04-13 Print Pack Label

Requirement ID & Name	**FR04-15**	**Label a Component**
Requirement Description	The labelling of a component is a critical control point which determines whether that component meets the criteria to be labelled and released into inventory for use or if it is unsafe and must be discarded. Only those components that pass *each and every criteria* in the labelling management control point can be labelled i.e. a pack label can be printed: • The **status of the component** must be checked to determine if it is suitable for release. If it is flagged as Quarantined, Unsafe, Expired, Processed, Discarded or Issued, a pack label must not be printed. • The **status of TTI and Blood Group Serology testing** for the component must be checked to determine if it is suitable for release. o Components that form part of a donation where ANY of the TTI screening test outcomes are POSITIVE must be flagged as UNSAFE and must not allow a pack label to be printed. o Components that form part of a donation where TTI Testing is incomplete must not allow a pack label to be printed o Components that form part of a donation where ANY of the TTI screening test outcomes are NOT TESTED must be flagged as UNSAFE and must not allow a pack label to be printed. o Components that form part of a donation where Blood Group Serology Testing is incomplete must not allow a pack label to be printed. o Components that form part of a donation where the ABO Rh blood group status is MISMATCH must not allow a pack label to be printed. This occurs when the first ABO Rh test outcomes for a first time donor do not match the repeat ABO Rh test outcomes. o Components that form part of a donation where the ABO Rh blood group status is AMBIGUOUS must not allow a pack label to be printed. This occurs when the ABO Rh test outcomes for a repeat donor do not match the ABO Rh group of the donor's previous donation. o Components that form part of a donation where the ABO Rh blood group status has NO TYPE DETERMINED must not allow a pack label to be printed.	

	○ Components that form part of a donation where the ABO Rh blood group status is INDETERMINATE because either or both the ABO and Rh test outcome is NOT TESTED must not allow a pack label to be printed. ○ Components that form part of a donation where the Antibody Screening outcome is POSITIVE must not allow a pack label to be printed. • The **status of the donor record** associated with the component must be checked to see if there are any current temporary AND/OR permanent deferrals. If any exist, the pack label must not be printed.
	The label is required to provide both eye-readable and barcoded information so that the contents of the pack are easily uniquely identifiable, the Blood Group is highlighted and all information related to source, type of component, expiry date and usage and storage and volume is provided.
USE CASE NARRATIVE	
Use Case No	**UC04-015**
Use Case Name	Print pack labels for a batch of components
Preconditions	Authorised user has logged into BSIS Components have been recorded in BSIS Test batch outcomes have been released Label printer has been configured and tested
Success End Condition	Final Pack Label or a Discard Label is printed (to a .zpl file)
Actor	Component Staff User
Main success scenario	• Step 1 - User selects component type Step 2 - User scans in DIN of component. If this matches the component type and the component is available (the component is safe and has been processed) and is therefore ready to be labelled, a pack label can be printed. • User repeats Step 2 until they are finished labelling all components of that type. • If the printer jams or a label is not successfully printed then the user must be able to select Print Pack Label again and re-print the same label. • Step 3 - User selects a DONE/“Select new Component Type” option that takes them back to Step 1, to label all components of another type.
Alternative scenario	Step 2 b- User scans in DIN of component. If this matches the component type and the component is unsafe, then the system must display a warning “Component can be discarded” and provide the option to print a discard label only.
Alternative scenario	Step 2c - User scans in DIN of component. If this matches the component type and the component is still quarantined or the component has not yet been processed, then the system must display a warning “Cannot print pack or discard

	labels for component".
Screen Design	

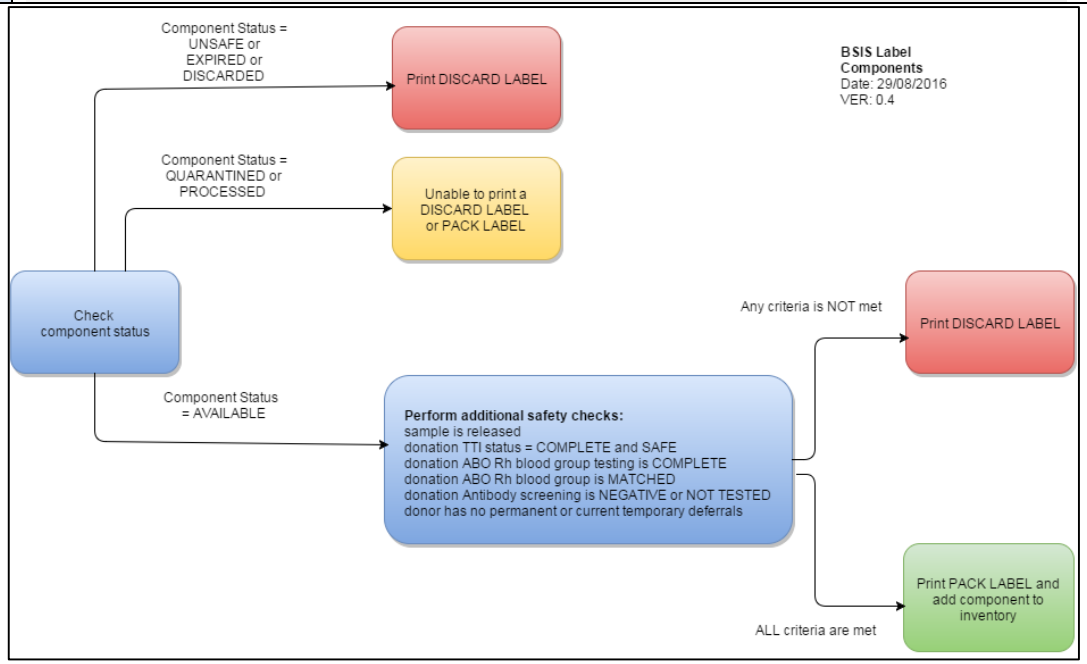


Figure 10: Label Component Rules

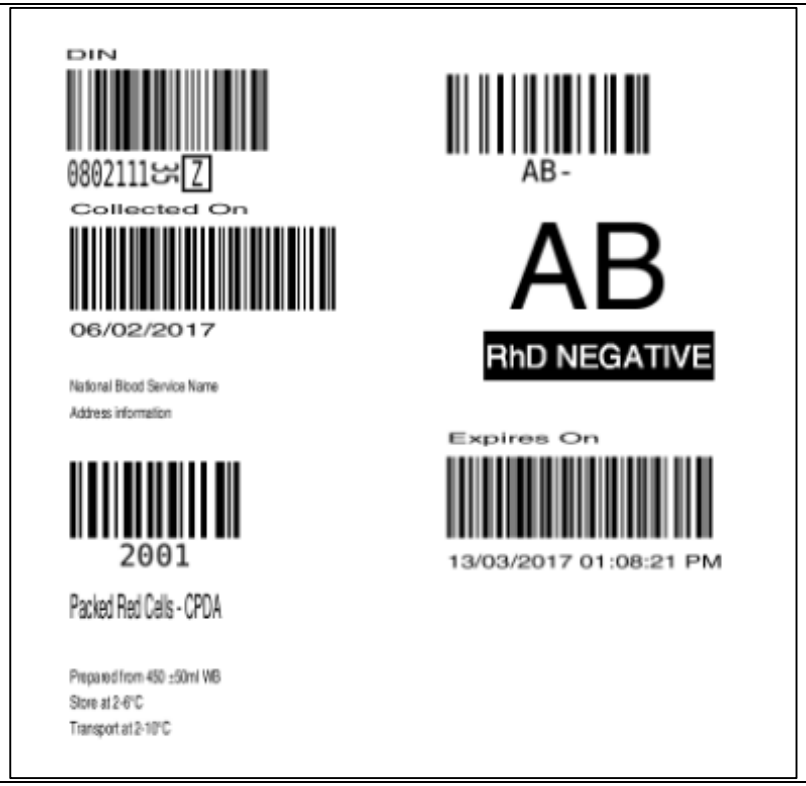
<table>
<tr>
<td>Output Specification

100mm x 100mm pack label according to output specification printable by a Zebra printer</td>
<td>
The Pack Label is based on the ISBT128 four quadrant style ref: ISBT128 Standard Technical Specification Version 4.5.0. The size of the final label is 100mm (+/-2mm) x 100mm(+/-2mm) divided into four equal 50mm (+/- 1mm) by 50mm (+/-1mm) quadrants.

The following information must be displayed:
DIN Donation Identification Number(text and barcode including check digit and flag character)
ABO Rh blood group (text and barcode)
Collection date (text and barcode)
Component Code (text and barcode)
Expiration date (text and barcode)
Volume of pack, storage and transport conditions of the component (Text configurable in Settings)
Source of the donation (Name and address of the Blood Service – Text configurable in Settings)

<table>
<tr><td>DIN Donation Identification Number
Collection Date
Source of the donation</td><td>ABO Rh blood group</td></tr>
<tr><td>Component Code
Component Name
Storage and Transport information</td><td>Expiration Date and Time</td></tr>
</table>

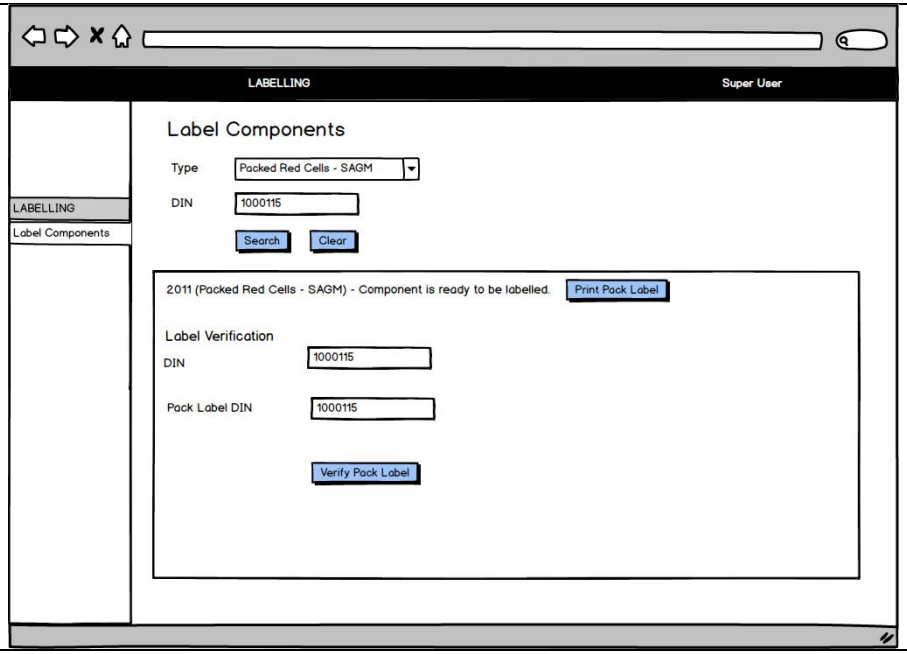
Required Bar Codes:
Donation Identification Number DIN
ABO/Rh Blood Group
Collection Date
Component Code
Expiration Date and Time
</td>
</tr>
</table>

Pack Label Sample		

Discard Label Sample		

7.10 FR04-017 Verify Pack Label

Requirement ID & Name	FR04-017	**Verify pack label**
Requirement Description	The system must provide the ability for the user to verify that the printed pack label has been placed on the correct pack. The system must allow the user to scan the original DIN on the pack and compare it to the DIN on the printed pack label and to warn the user if the DINs do not match. The system must also be able to distinguish between the DIN barcode on the pack label and the original DIN barcode on the pack to ensure that the user has not scanned the same barcode twice.	
Use Case No	**UC04-017**	
Use Case Name	Verify Pack Label	
Preconditions	User has logged in as component staff, component supervisor, administrator or superuser The component is safe and available for labelling (testing has been completed and processing has been done)	
Success End Condition	The label is verified	
Main success scenario	1. The user scans the original DIN on the pack into the system 2. The system prints the pack label 3. The user sticks the printed label on the pack 4. The user scans the original DIN on the pack 5. The user scans the DIN on the printed pack label 6. The system checks whether: a. the DINs on both barcodes are the same b. two different barcodes have been scanned in (by using a check digit on the printed pack label to distinguish this barcode from the original barcode) 7. If the DINs match AND the correct barcodes have been scanned then the system automatically adds the component to inventory (status=in-stock) 8. The user can proceed to label the next unit	
Alternative scenario	7a. If the DINs do NOT match then the system displays a warning “DINs do not match” and allows the user to re-scan the DINs Go to step 4. *The component is not added to inventory*	
Alternative scenario	7b. If the DINS match but the two barcodes are the same (i.e. either the original DIN has been scanned twice OR the printed pack	

	label DIN has been scanned twice) then the system displays a warning message “The same barcode has been scanned twice: please re-scan) Go to step 4. *The component is not added to inventory*
Alternative scenario	The label must be verified EVERY time it is printed or re-printed therefore The system must ensure that the component status = NOT_IN_STOCK after a label has been printed but before it has been verified 2a. The system must be able to re-print a label before the verification step (in case of printer issues)
Alternative scenario	2b. The system must be able to re-print a label after the verification step (in case the pack label is damaged after the component has been placed in inventory).
Alternative scenario (Manual entry)	If the barcode scanner is not working there must be a manual workaround to allow the user to enter the DINs on the labels using a keyboard so that the labelling process is not held up 1. The system must use an eye-readable check digit on the printed pack label to allow the user to type in this check digit to enable verification
Screen Design	
Processing Rules	Print Pack Label

If COMPONENT_STATUS= IN_STOCK
then change COMPONENT_STATUS = NOT_IN_STOCK
Scan DIN1 and DIN2
If DINs do not match
Then display “DINs do not match”
go back to Scan DIN1 and DIN2
else if DINs do match
Then verify check digits
If check digits do match
Then display
“The same barcode has been scanned twice: please re-scan”
go back to Scan DIN1 and DIN2
else if check digits do not match
Then change COMPONENT_STATUS = IN_STOCK

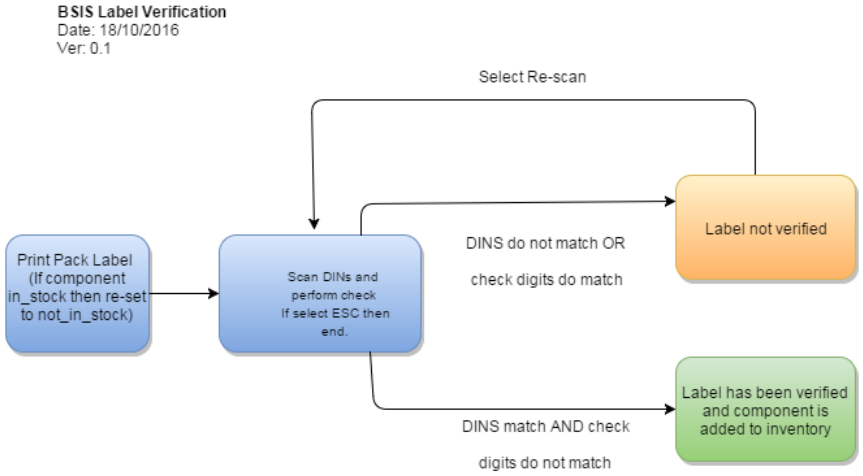


Figure 11: Pack Label Verification

References	Calculation of checksums and the corresponding check characters for the ISBT 128 numbers is described in the ICCBBA Technical Specification. https://www.iccbba.org/uploads/1c/c9/1cc944f45ca4108fd46bf144f528e009/ST-001-ISBT-128-Standard-Technical-Specification-v5.5.0.pdf http://www.transfusionguidelines.org/red-book/chapter-23-specification-for-the-uniform-labelling-of-blood-blood-components-and-blood-donor-samples/23-3-barcode-reading-and-interpretation *Where keyboard entry of donation number is used, the full number and check character should be entered, and application software should verify the string format and check character value. Use of pre-programmed 'hot keys' is not an acceptable alternative*. http://www.transfusionguidelines.org/red-book/chapter-23-specification-for-the-uniform-labelling-of-blood-blood-components-and-blood-donor-samples/23-4-donation-identification-numbers-din

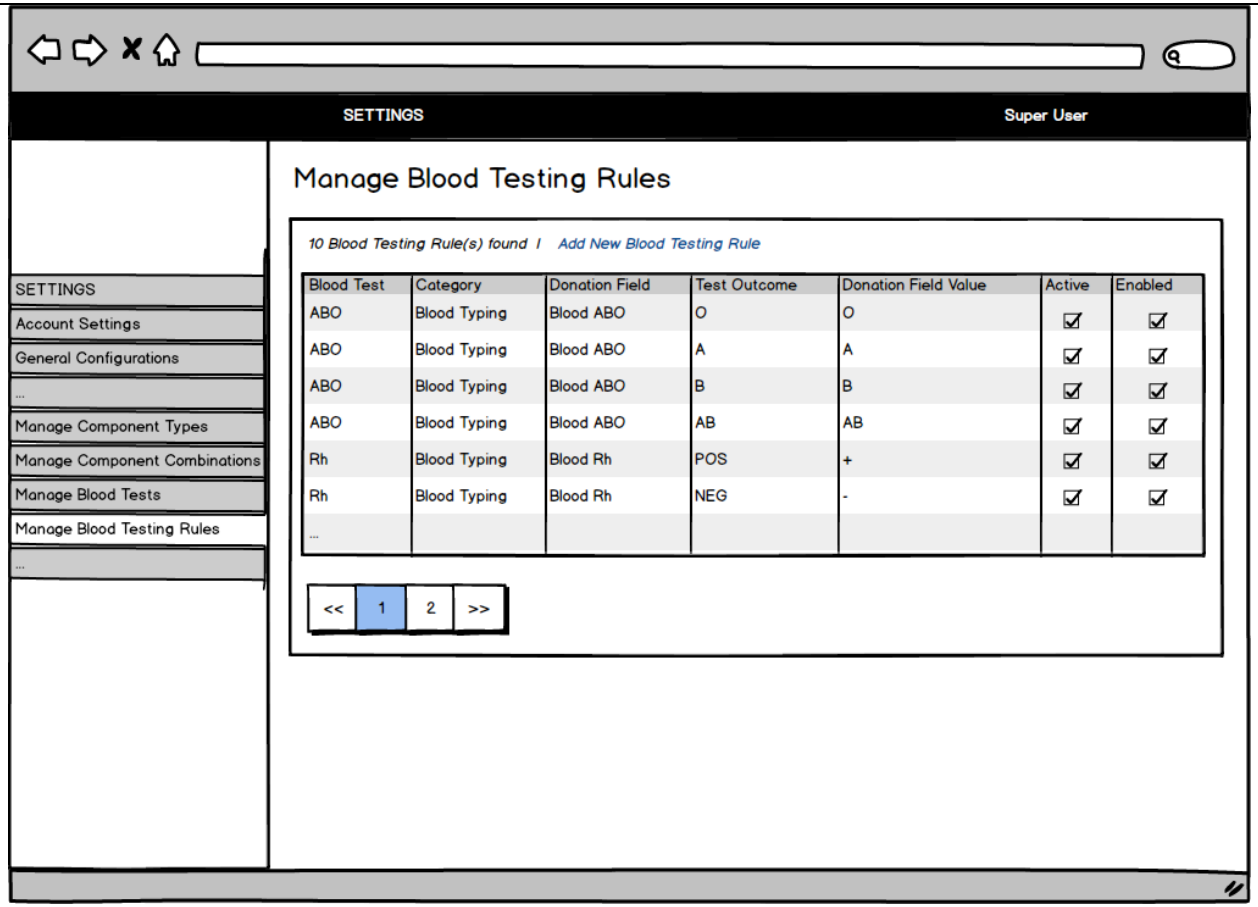
7.11 FR07-01 Configuration of blood test and blood testing rules

Requirement ID & Name	**FR07-01**	**Configuration of Blood Tests and Blood Testing Rules**
Requirement Description		

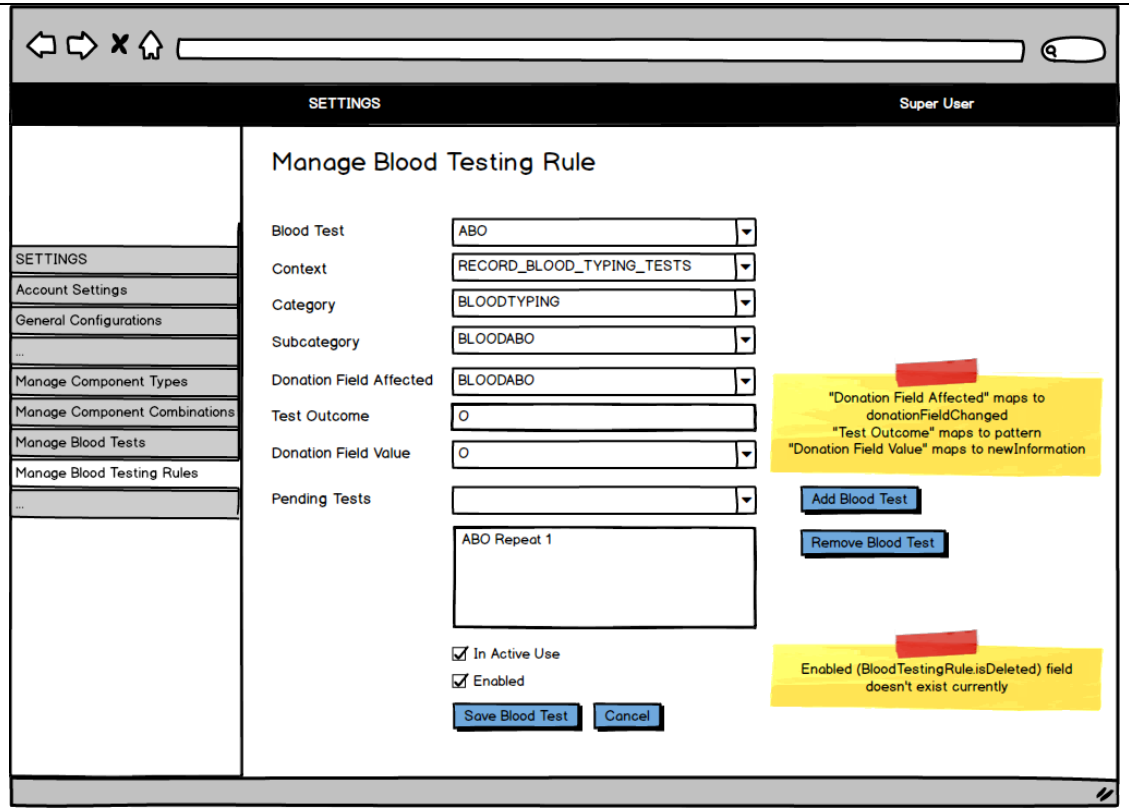
Purpose	**Configure Blood Tests**
	The Blood Tests must be configured in BSIS in order for test outcomes to be entered into the system.
	The Blood Test configuration allows for the following fields to be set up:
	• Name: The name of the Blood Tests used for display purposes on the User Interface and in reports. This must be unique.
	• Short Name: The shortened name of the blood tests.
	• Category: A Blood Test must be assigned to a **Blood Test Category**. These are :
	  ○ BLOODTYPING – used to determine the ABO Rh blood group
	  ○ TTI – used for testing for Transfusion Transmissible Infections
	• Blood Test Type: A Blood Test must also be assigned a Type. These are:
	  ○ BASIC_BLOODTYPING
	  ○ BASIC_TTI
	  ○ CONFIRMATORY_TTI
	  ○ REPEAT_BLOODTYPING
	• Enabled:
	  ○ If the blood test is marked as Enabled, it should appear as an option when recording test outcomes and viewing reports.
	  ○ If the blood test is marked as not Enabled, it should no longer appear as an option when recording test outcomes and viewing reports.
	• In Active Use:
	  ○ If the blood test is marked as In Active Use, it should appear as an option when recording test outcomes and viewing reports.
	  ○ If the blood test is not marked as in Active Use, it should no longer appear as an option when recording test outcomes, but should appear when viewing Management reports.
	
	The default Blood Tests in BSIS are mandatory for AfSBT level 3 accreditation:
	• TTI Testing	

	○ HIV ○ HBV ○ HCV ○ Syphilis • Blood Typing ○ ABO ○ Rh • Additional serology testing ○ Titre ○ Antibody Screening • Valid Outcomes A Blood Test defines the valid test outcomes that are possible for the test e.g. 'A, B, AB, O, NTD' for the ABO Blood Test and "POS, NEG, NT (Not Tested) for TTI Blood Tests. • Positive Outcomes The **positive outcomes** are defined for a Blood Test. These are used by the blood testing rule engine determine when a donation is released for labelling, whether the Components should be flagged as Unsafe and whether the Donor should be deferred according to the blood testing rules engine. • Negative Outcomes The **negative outcomes** are defined for a Blood Test. These are used by the blood testing rule engine determine when a donation is released for labelling, whether the Components should be flagged as Unsafe and whether the Donor should be deferred according to the blood testing rules engine. • Mark Component as Unsafe for POS outcomes. If this is checked then any component where the test is POS will automatically be flagged as Unsafe.
Purpose	**Configure Blood Testing Rules** In order for **Blood Test** outcomes to be processed by the **Blood Testing Rule Engine**, a **Blood Testing Rule** must be defined • Blood Test • Context • Category • Sub-Category

	• Donation Field Affected
	• Test Outcome
	• Donation Field Value
	• Pending Tests
	• In Active Use
	  ○ If the blood testing rule is marked as Active, it should take effect when recording test outcomes, where relevant.
	  ○ If the blood test is not marked as Active, it should no longer take effect when recording test outcomes, where relevant
	• Enabled
	  ○ If the blood testing rule is marked as Enabled, it should take effect when recording test outcomes, where relevant.
	If the blood testing rule is marked as Disabled (i.e. not Enabled), it should no longer take effect when recording test outcomes, where relevant.

Screen Design	

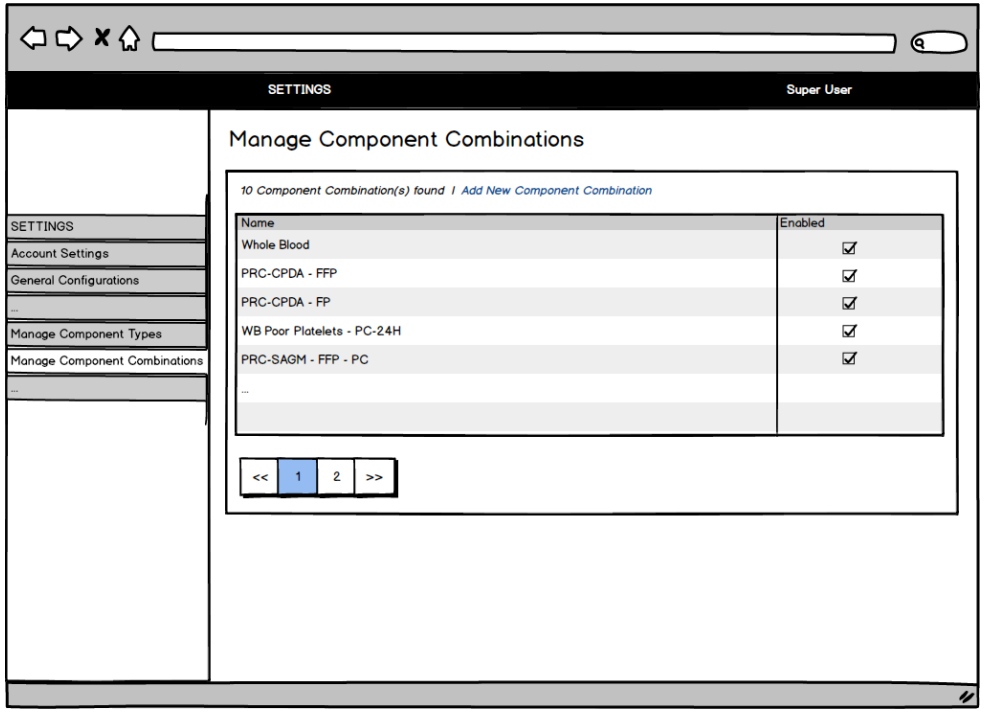
Blood Test	Category	Donation Field	Test Outcome	Donation Field Value	Active	Enabled
ABO	Blood Typing	Blood ABO	O	O	☑	☑
ABO	Blood Typing	Blood ABO	A	A	☑	☑
ABO	Blood Typing	Blood ABO	B	B	☑	☑
ABO	Blood Typing	Blood ABO	AB	AB	☑	☑
Rh	Blood Typing	Blood Rh	POS	+	☑	☑
Rh	Blood Typing	Blood Rh	NEG	-	☑	☑
...						

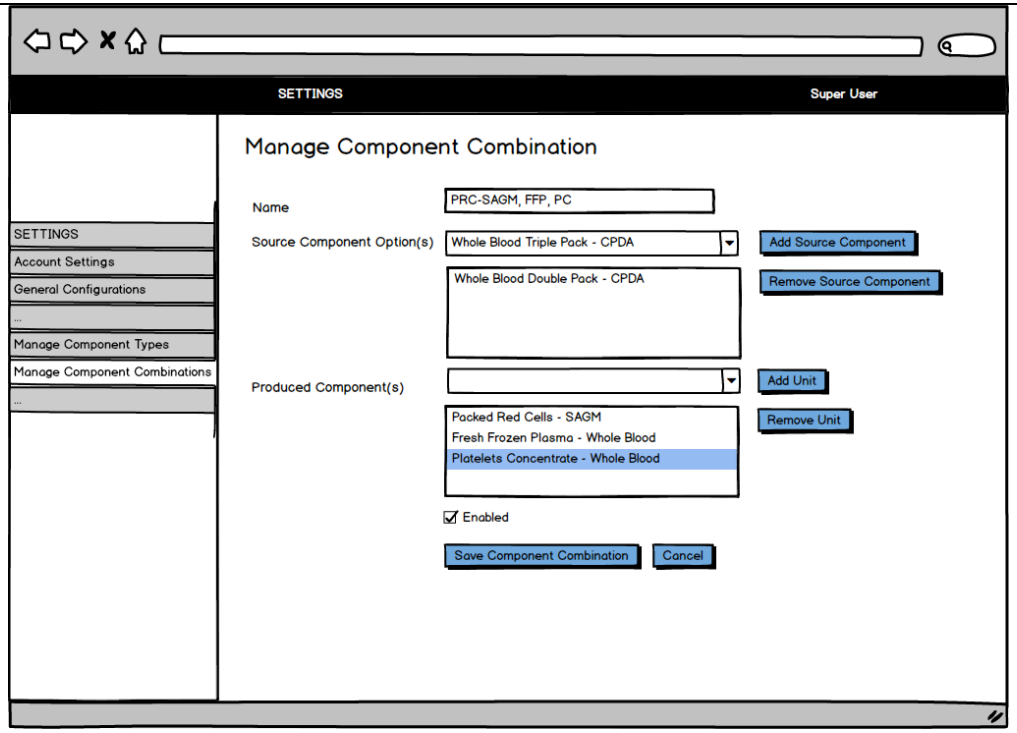

SETTINGS
Super User
SETTINGS
Account Settings
General Configurations
...
Manage Component Types
Manage Component Combinations
Manage Blood Tests
Manage Blood Testing Rules
...
Manage Blood Testing Rule
Blood Test
ABO
Context
RECORD_BLOOD_TYPING_TESTS
Category
BLOODTYPING
Subcategory
BLOODABO
Donation Field Affected
BLOODABO
Test Outcome
O
Donation Field Value
O
Pending Tests
ABO Repeat 1
In Active Use
Enabled
Save Blood Test
Cancel
"Donation Field Affected" maps to donationFieldChanged
"Test Outcome" maps to pattern
"Donation Field Value" maps to newInformation
Add Blood Test
Remove Blood Test
Enabled (BloodTestingRule.isDeleted) field doesn't exist currently

7.12 FR07-02 Configuration of Component Types &Component Processing Rules

Requirement ID & Name	**FRX07-02**	**Configure Components**
Requirement Description		
Purpose	**Configure Component Types** Component types must be configured within the system to enable the processing of different combinations according to processing rules. • Name: The name of the component as displayed in the user interface and reports. • Component Code: Unique code for the component type • Can Be Issued: Whether or not the component can be issued • Contains Plasma: Whether or not the component contains plasma • Expires After: Number of days that the component will expire after calculated based on date of donation • Storage Info: Text about conditions related to storage that is printed on the pack label • Transport Info: Text about conditions related to transport that is printed on the pack label • Preparation Info: Text about conditions related to preparation that is printed on the pack label • Enabled: A default set of component types and component codes is provided.	

Purpose	**Configure Component Combinations**
	
	• Name: Component Combination names are used to identify specific combinations and must be unique
	• Source Component:
	• Processed Component:
	  ○ At least one Source Component and one Produced Component must be selected - i.e. those fields are mandatory in the form, cannot be empty.
	  ○ Some combinations produce multiple units of the same component type - each unit is added individually, but it should be possible to add the same component type multiple times.
	• Enabled
	  ○ If the component combination is marked as Enabled, it should appear as an option when processing components, where relevant.	

	○ If the component combination is marked as Disabled (i.e. not Enabled), it should no longer appear as an option when processing components. • The system can provide for a second round of processing where a component that has been split is then processed into further components. A working example of this is production of Cryoprecipitate, for example: 1. Add a new Component Type "Cryoprecipitate". 2. Add a new Component Type Combination "Cryoprecipitate", source component "Fresh Frozen Plasma - Whole Blood", produced component "Cryoprecipitate".
Screen Design	

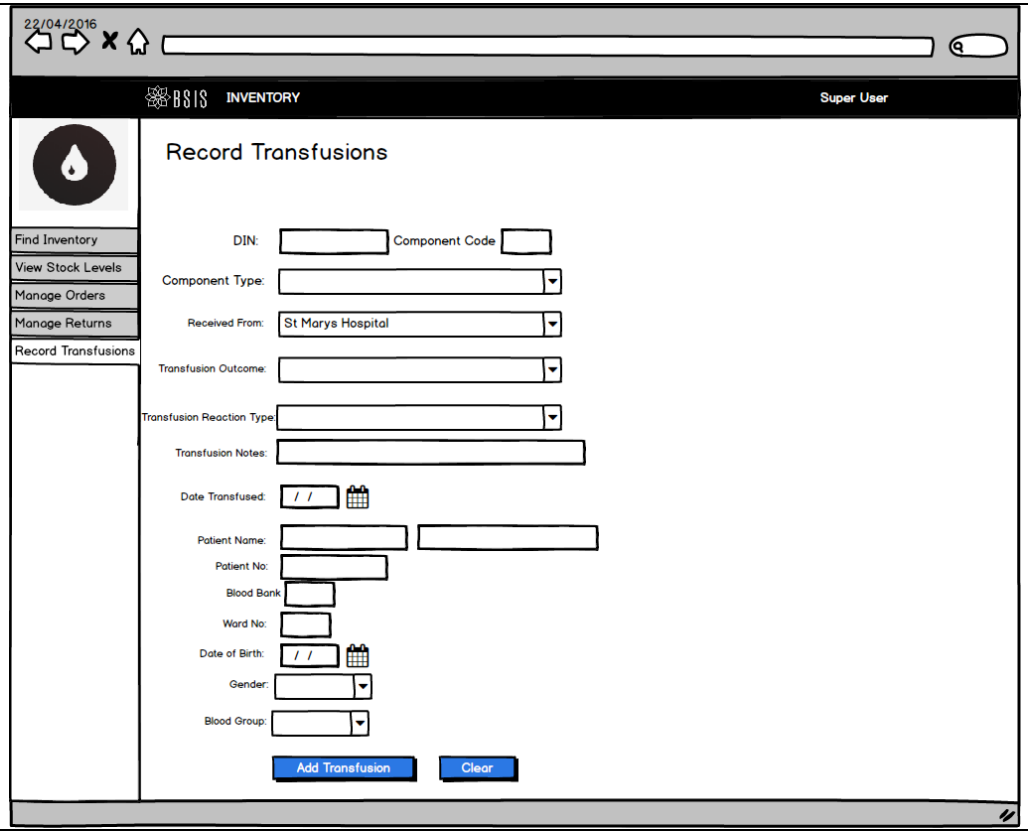

SETTINGS
Super User
SETTINGS
Account Settings
General Configurations
...
Manage Component Types
Manage Component Combinations
...
Manage Component Combination
Name
PRC-SAGM, FFP, PC
Source Component Option(s)
Whole Blood Triple Pack - CPDA
Add Source Component
Whole Blood Double Pack - CPDA
Remove Source Component
Produced Component(s)
Add Unit
Packed Red Cells - SAGM
Fresh Frozen Plasma - Whole Blood
Platelets Concentrate - Whole Blood
Remove Unit
Enabled
Save Component Combination
Cancel

7.13 FR08-01 Record transfusion information

Requirement ID & Name	**FR08-01** Record transfusion information for units that were issued
USER STORY	**BSIS-2582** As an administrator I need to be able to record transfusion data for an issued blood unit so that I can track and report transfusion information.
BDD USE CASE	Given that the user is logged in as an Inventory Staff User or Administrator or a Superuser When the user selects Record Transfusions Then the system must display the Record Transfusions screen and the user must be able to enter the following information: DIN (enter manually or scan DIN from empty pack) - mandatory and either Component Code (scan from empty pack) or Component Type (select from dropdown) Received From: (select Usage site from dropdown) - mandatory Transfusion Outcome: (select one of the following from dropdown) Transfused Uneventfully Transfusion Reaction Occurred Not Transfused Unknown Alternate flow 1: If the user selects **Transfused Uneventfully** Then the user must be able to enter the following Patient Details: Date Transfused: (mandatory) Patient Name1: (mandatory) Patient Name 2: (mandatory)

	Patient No: (optional) Hospital Blood Bank Number – optional (alphanumeric) Ward No: (optional) Date of Birth: (optional) or Age: (optional) Gender: select Male/Female from dropdown (optional) Blood Group – optional (select one of A+,A-,B+,B-,AB+,AB-,O+,O- from dropdown) Alternate flow 2: If the user selects **Transfusion Reaction Occurred** Then the user must select a Transfusion Reaction Type from the dropdown list (mandatory) And then the user may enter Transfusion Notes (text – optional). And then the user must be able to enter the following Patient Details: Date Transfused: (mandatory) Patient Name1: (mandatory) Patient Name 2: (mandatory) Patient No: (optional) Hospital Blood Bank Number – optional (alphanumeric) Ward No: (optional) Date of Birth: (optional) or Age: (optional) Gender: select Male/Female from dropdown (optional) Blood Group – optional (select one of A+,A-,B+,B-,AB+,AB-,O+,O- from dropdown) The fields in this form that are also used in the Patient Request form should be named consistently with how they appear on the Patient Request form. The user must be able to click on Clear and then the system must clear the fields and allow the user to re-enter OR The user must be able to click on Add Transfusion Info and then the system must save the transfusion record. NOTE: For the specific case where the user selects a component type from the dropdown that produces multiple units of the same type (e.g. for

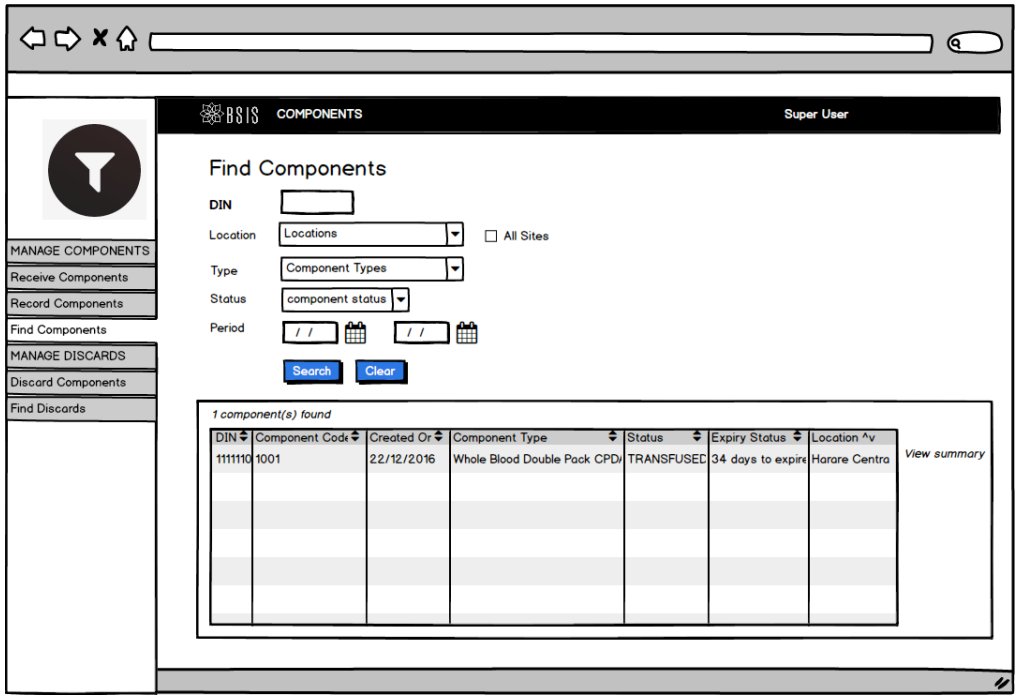
	paediatric components), the component code (which includes the unit number) must be recorded to successfully submit the form. If the component code is not recorded in this case, the following error message should be displayed to the user after form submission: "Selected Component Type produces multiple units: please record component code for transfused unit". If the user records the component code, the form may be submitted successfully (assuming there are no other form validation issues), but if this is not completed, the error message should persist, and the form cannot be processed. *To clarify this issue - without the unit number that's included in the component code, there is no absolute certainty which unit was transfused when the user selects a component type from the dropdown that produces multiple units of the same type, so the requirement is that in this case the component code becomes compulsory. NOTE: One transfusion event (Date + Patient) may be related to many blood units/components.

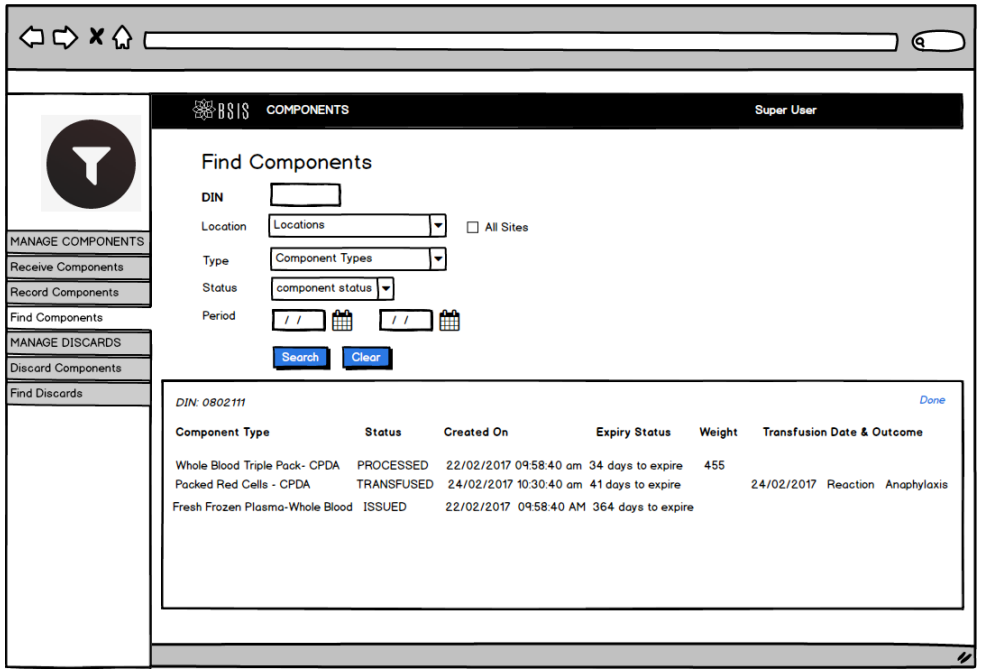


7.14 FR08-02 View Transfusion Information

Requirement ID & Name	**FR08-02** View transfusion information for units that were issued : The user must be able to view • the transfusion status of a unit of whole blood or blood component AND any adverse transfusion reactions
BDD USE CASE	Given that the user is logged in as Component Staff or Component Supervisor Administrator or Superuser When the user uses Find Component to search for a component Then the system must display the transfusion status as follows:

	• If the component was transfused uneventfully or was transfused with a reaction, then the system must display the status as "TRANSFUSED" When the user uses Find Component to search for a component Then the system must allow the user to select Status as "TRANSFUSED" from the status dropdown menu And the system must select and display all components that were transfused uneventfully or was transfused with a reaction and where the status is shown as "TRANSFUSED". When the user clicks on View Summary for a component Then the system must display an additional column "Transfusion Outcome" and must display the following: • If the component's transfusion outcome is not recorded (null?) then the system must display the status as "Not recorded" (blank?) • If the component was not transfused then the system must display the outcome as "Not Transfused" • If the component was recorded as Unknown then the system must display the outcome as "Unknown" • If the component was transfused uneventfully then the system must display the outcome as "Transfused Uneventfully" • If the component was transfused was transfused with a reaction, then the system must display the status as "Transfusion Reaction" AND the system must display the associated Transfusion Reaction Type.

UI Mock-up	 BSIS COMPONENTS Super User Find Components DIN Location Locations All Sites Type Component Types Status component status Period Search Clear 1 component(s) found DIN Component Code Created On Component Type Status Expiry Status Location 1111110 1001 22/12/2016 Whole Blood Double Pack CPD/ TRANSFUSED 34 days to expire Harare Centra View summary MANAGE COMPONENTS Receive Components Record Components Find Components MANAGE DISCARDS Discard Components Find Discards


BSIS
COMPONENTS
Super User
Find Components
DIN
Location
Locations
All Sites
Type
Component Types
Status
component status
Period
Search
Clear
MANAGE COMPONENTS
Receive Components
Record Components
Find Components
MANAGE DISCARDS
Discard Components
Find Discards
DIN: 0802111
Done
Component Type
Status
Created On
Expiry Status
Weight
Transfusion Date & Outcome
Whole Blood Triple Pack- CPDA
PROCESSED
22/02/2017 09:58:40 am
34 days to expire
455
Packed Red Cells - CPDA
TRANSFUSED
24/02/2017 10:30:40 am
41 days to expire
24/02/2017 Reaction Anaphylaxis
Fresh Frozen Plasma-Whole Blood
ISSUED
22/02/2017 09:58:40 AM
364 days to expire

8 Informational Requirements List

Informational Requirements describe what information the users need to get out of the system i.e. reports. They should describe who needs what information, why and when.

This table lists the reporting requirements for authorised users of BSIS. For a detailed specification of each report please see Detailed Informational Requirements. The informational requirements may be classified and prioritised as follows:

Category of report		**Priority of report**	
O	Operational: Supports the day-to-day running of the business	**M**	Mandatory
M	Management: Supports the management decision-making process	**D**	Desirable
G	Global: Supports aggregate reporting of blood safety indicators		
S	System Monitoring: Supports system monitoring i.e. exceptions, etc.		

Info Req ID	Name of Report	Description / content	Purpose	M/D	Category
IR01 Reporting and Data Queries for Donor and Donation Management					
IR01-001	View/Export Donor List	Report listing all existing **eligible** donors who have donated within a selected time period or who are due to donate at the selected date, filtered by venue and blood group. The report must exclude donors who are deferred for any reason within the selected date range and are therefore ineligible to donate as well as those donors who have ineligible due to a positive TTI.	Used by donor recruitment staff when planning clinics to contact the donors, notify them of the planned clinic and encourage them to donate. Also used by donor staff to see list of **eligible** donors who made a donation within a specified date range and venue.	M	O
IR01-002	Donors for Post-Donation Counselling Report	Report listing all donors whose donations tested positive for a TTI within a specified time period and/or a specified venue who have been flagged for counselling. Also used to list those donors who	Used by the donor counselling staff to contact all donors requiring post-donation counselling due to a positive TTI test outcome. Once a counselling outcome has	M	O

		have been counselled and/or referred for additional testing, care and treatment. Must list Donor Number, first and last name, gender, date of birth, blood group, DIN that tested positive and the date of donation and venue where it was collected. Must indicate whether the donor has been counselled or referred.	been recorded for that donor the donor will no longer appear on the list.		
IR01-003	Donor Clinic Lookup	Report listing all existing donors who belong to the selected venue and their eligibility status as at the date selected. Must show Donor Number, First name, Last name, gender, Date of birth, Blood Type and eligibility (Eligible/Not Eligible)	Used by donor clinic staff and used at remote mobile clinic sites to check if a donor is registered in the system and if so, to check their eligibility as at the clinic date. The reason as to why a donor is Not Eligible is not shown to protect the donor's confidential information.	M	O
IR01-004	Donation Batch Report	Operational Report that lists all donations for the selected donation batch. Lists the Donor Number, DIN, pack type and donation type. Available to view on screen and also in printed format so that it can be signed by the dispatcher and the receiver.	Used for control and verification. Used by donor clinic staff at the end of a clinic to verify that the donation packs and samples collected match what has been recorded in the system for that clinic and also used as a packing list that goes with the donations and samples in the refrigerated box that is transported from the mobile site to the centre where the component processing and testing is carried out. The same report is then used by the receiving staff to verify that what they receive matches what was sent.	M	O
IR01-005	Donations Collected by Type	Report listing all donations collected within a selected date range by venue where it was collected, categorised by donation type and donor gender	For planning purposes to be able to see % of donors by type in order to convert family replacement to voluntary donors. Statistics for % of VNRD as a % of total donations is a	M	M

			requirement for AfSBT accreditation.		
IR01-012	Donors Deferred Summary Report	Report listing total donors deferred within a selected date range, by venue, categorised by deferral reasons	M	M	
IR01-014	Donors Adverse Events Summary Report	Report listing total donor adverse events by type over a time period and sorted according to venue.	Used by the Medical Director and management staff to view summary information about adverse events so that they can analyse the data to try and see the cause with a view to minimising these adverse events.	M	M
IR02	Laboratory TTI and Serology Testing				
IR02-001	Test Batch Summary	Report summary of test outcomes of all donations within a test batch showing ABO Rh blood group , TTIs, Titre and Antibody screening (where used) as well as test that are NOT-DONE: DIN, date bled, venue, pack type, TTI status, Blood Grouping status, previous ABO Rh blood group for that donor and test outcomes for all TTI screening, repeat and confirmatory tests and all ABO Rh, repeat, titre and antibody screening tests.	Used by laboratory staff and management staff to view the progress of testing and any pending tests still outstanding. Can also view all DINs that have tested positive for a TTI or have an ambiguous or No Type Determined ABO Rh blood group. May also be used by the component staff for labelling if only the Donor Management module is implemented.	M High	O
IR01-011	TTI Prevalence Report	Aggregate management report summarising all donations collected by venue within a specified period, showing TTI prevalence for HIV,HBV,HCV and Syphilis, categorised by donor gender.	Used by blood service management for planning purposes based on an analysis of donation testing.	M High Priority	M
IR02-003	ABO Rh Blood Grouping Report	Aggregate management report listing the count of all donations collected per venue within a specified period showing test outcomes by ABO Rh blood grouping and categorised by donor gender.	Used by management staff and clinic planning staff to plan clinics and donor recruitment drives according the the venues and donor categories where the blood types that are most in demand are most likely to	M High Priority	M

			be found.		
IR03	Component Proccessing				
IR03-001	Receive Components Delivery List	Report listing all donation batches received by the component laboratory. Shows collection date, processing site, number of components received, delivery date, donation batch status (open/closed) and number of blood transport boxes.	Used by laboratory staff and management staff to see a summary of units collected and delivered to processing site.	M	O
IR03-002	Delivery Note	Report listing all DINs and pack type received at the processing site. Shows date and time of delivery, venue of collection, site delivered to, number and temperature of blood transport boxes	Used by laboratory staff and management staff to see a the detail of units collected and delivered to processing site by donation batch. (*also known as a Blood Transportation Form / Shipping List)*	M	O
IR03-002	Components Produced	Components produced by component type - total components by component type where canBeIssued=true		M	M
IR03-003	Discard report	Total discards by discard reason over a time period, by processing site		M	M
IR04	Inventory				
IR04-001	Stock Level Summary: In Stock	Summary of all components in stock for a selected or all distribution sites grouped by component type and blood group.	Used by laboratory staff, donor clinic planning and management staff to see current stock levels and to to assist with planning of clinics according to blood needs.	M	O
IR04-002	Stock Level Summary: Not Labelled	Summary of all components still undergoing processing prior to labelling for a selected or all distribution sites by component type and blood group. Components that have been flagged for discard are excluded from this report.	Used by laboratory staff, donor clinic planning and management staff to forecast stock levels based on components being processed.	M	O
IR04-003	Dispatch Note	Lists all components ordered and components allocated to a particular order and dispatched to the usage site. Also shows the gap between order		M	O

		and fulfilment.			
IR04-004	Blood Units Issued	Aggregate report summarising while blood and blood components issued within selected time period by usage site and categorised by component type and blood group. Report must also show the gap between components ordered and components supplied and any components returned.	Used by inventory and management staff to determine how well the blood service is meeting the demand for components from usage sites and assist with forecasting and planning.	M	M
IR05	Analysis / Monitoring and Evaluation				
IR05-002	Data Export	Data export of all data in BSIS as defined in CSV format. Date exported must be defined in the export file name.	To be used by management staff and research staff to be used for import into Excel or other data analysis tools in order to perform further data analysis.		
IR08	Transfusion Reports				
IR08-001	Transfusion Summary Report	Aggregate report of Number of units transfused and Number of reported transfusion reactions according to type and total reported transfusion reactions	To be used by management staff in order to be able to analyse the data to support haemovigilance.		

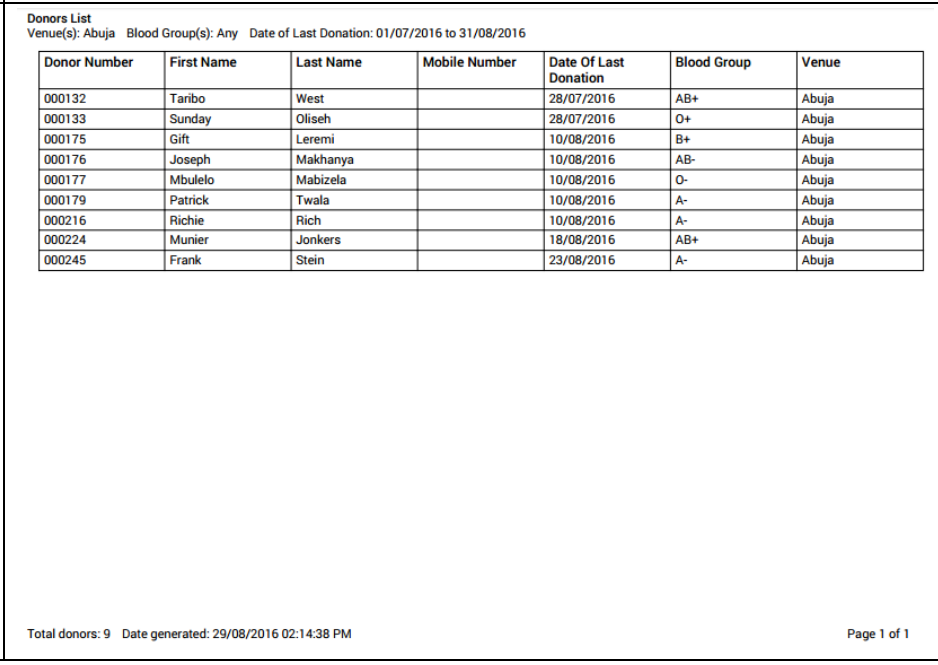
Table 13: Summary of Informational Requirements

9 Detailed Informational Requirements

9.1 Operational Reports

9.1.1 IR01-001 Donor Communications Report

IR01-001	Detailed Requirements
Report Name	View/ Export Donor List Report
Report Description	Report listing all existing eligible donors who have donated within a selected time period or listing all donors who are due to donate at a specified date, selected according to venue and blood group. The report must exclude donors who are ineligible/deferred for any reason within the selected date range / due date.
Purpose	Used by donor recruitment staff when planning clinics to contact the donors, notify them of the planned clinic and encourage them to donate.
Audience	Donor clinic planning staff, donor recruitment/communications staff
Triggers	Authorised user will select this on an ad-hoc basis
Input parameters	The user will select / capture the following report parameters:
	Venue - Select or more from drop-down list
	Blood Group - Select one or more from drop-down list OR Any Blood Group AND/OR No Blood Group
	EITHER: Previous donation - Period between two selected dates-Day, Month, Year
	AND/OR: Date due to donate -Day, Month, Year
Sort Criteria	User can select to sort by Donor Number, First Name, Last Name, Mobile Number, Date of Last Donation, Blood Group or Venue
Sort Sequence	User can select ascending or descending for one of the sort criteria
Layout	Screen Layout: Responsive design – see the UI design below Printed report: A4 Landscape
Headers	Report Name: "Donors List"
Sub-headers	Venue(s): [as selected] Blood Group(s): [as selected] Date of Last Donation: [as selected] OR Date Due to Donate: [as selected]
Content	Donor Number, Donor First Name, Donor Last Name, Mobile Number, Date of Last Donation, Blood Group, Venue (Venue)
Footers	Total donors: Count of all donors , Date and Time Generated, Page number of total number of pages
Media	View on screen / Print to PDF or CSV
Frequency	Ad-hoc

Constraints	Accessible only by authorised users i.e. donor clinic staff and supervisors
Report steps	The user must select View/Export Donors List from the Donor Communications option on main menu
	The user must select report criteria
	The user can view on screen or can select the Print to PDF option or Print to CSV option
Output Design	

Donors List
Venue(s): Abuja Blood Group(s): Any Date of Last Donation: 01/07/2016 to 31/08/2016

Donor Number	First Name	Last Name	Mobile Number	Date Of Last Donation	Blood Group	Venue
000132	Taribo	West		28/07/2016	AB+	Abuja
000133	Sunday	Oliseh		28/07/2016	O+	Abuja
000175	Gift	Leremi		10/08/2016	B+	Abuja
000176	Joseph	Makhanya		10/08/2016	AB-	Abuja
000177	Mbulelo	Mabizela		10/08/2016	O-	Abuja
000179	Patrick	Twala		10/08/2016	A-	Abuja
000216	Richie	Rich		10/08/2016	A-	Abuja
000224	Munier	Jonkers		18/08/2016	AB+	Abuja
000245	Frank	Stein		23/08/2016	A-	Abuja

Total donors: 9 Date generated: 29/08/2016 02:14:38 PM Page 1 of 1

9.1.2 IR01-002 List of Donors for Post-Donation Counselling

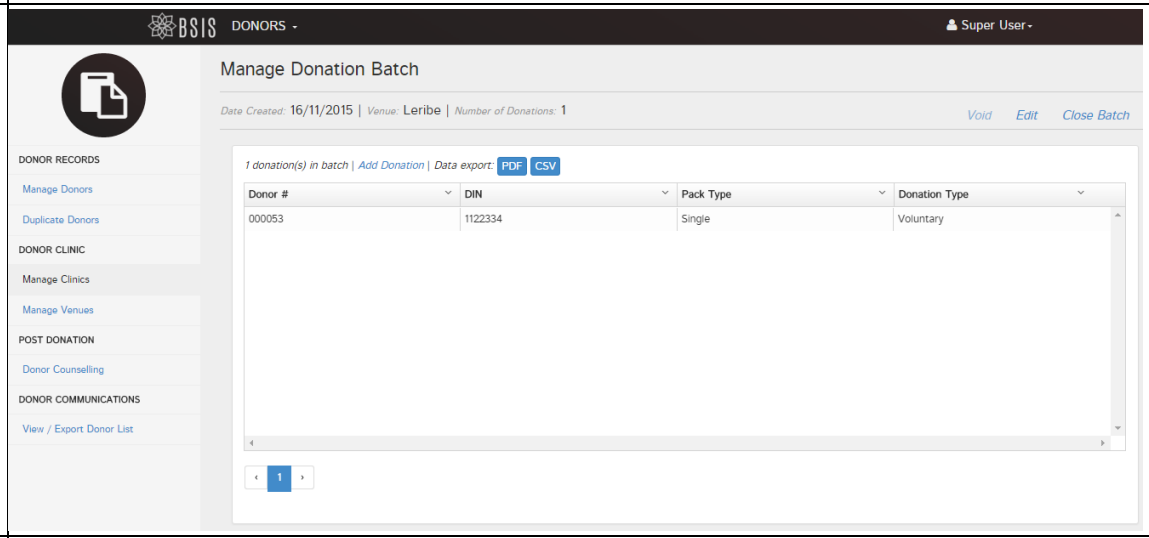
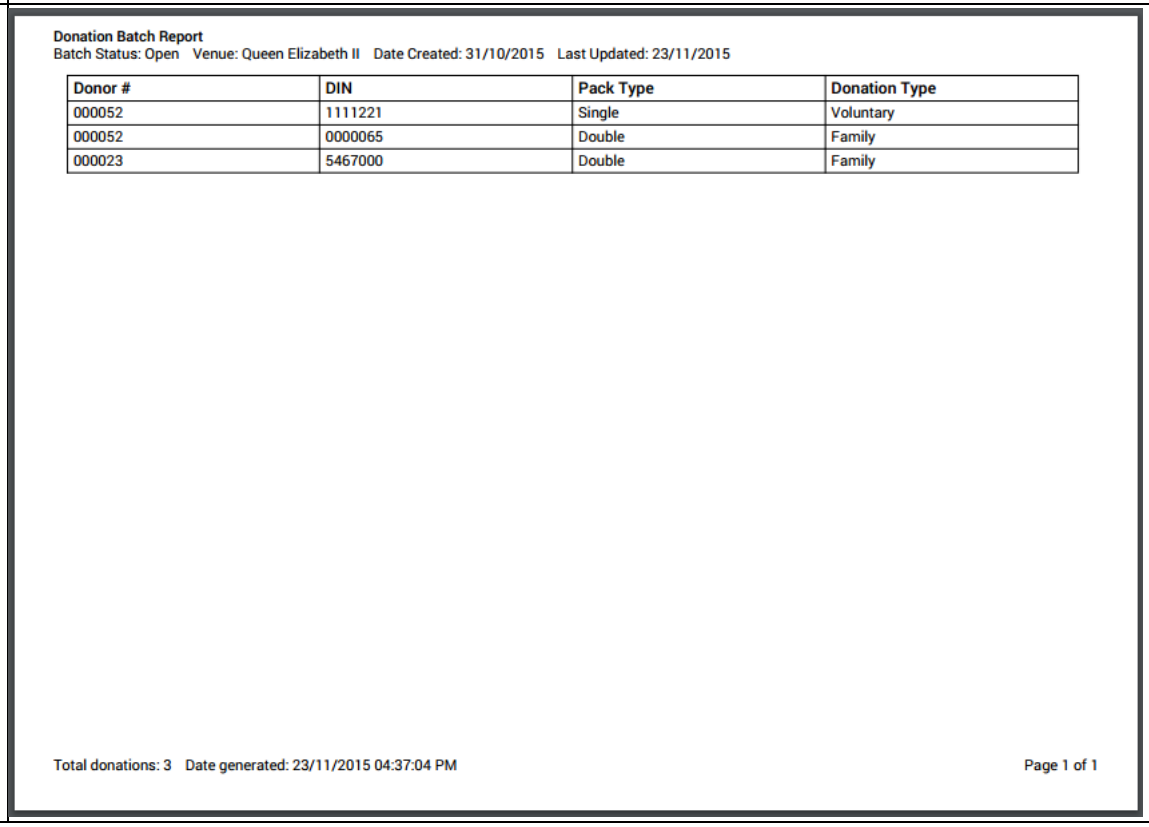
IR01-002	Detailed Requirements
Report Name	List of Donors for Post-Donation Counselling
Report Description	Report listing all donors whose donations tested positive for a TTI within a specified time period and/or a specified venue and who have therefore been flagged for counselling. Must list Donor Number, first and last name, gender, date of birth, blood group, DIN of the donation that tested positive and the date of donation and venue where it was collected. If a counselling status has been recorded then the donor's information will no longer be shown on this report.
Purpose	Used by the donor counselling staff to contact all donors requiring post-donation counselling due to a positive TTI test outcome. Also used to list those donors that have been counselled and referred to further testing, care and treatment.
Audience	Donor counselling staff
Triggers	Authorised user will select this on an ad-hoc basis
Input parameters	The user will select / capture the following report parameters:
	Venue - Select one or more from drop-down list OR select Any Venue
	Donation Period: - Period between two selected dates-Day, Month, Year OR select Any Date
	Counselling Status: - User will either select donors flagged for counselling due to a positive TTI result using a checkbox

	OR user will select one of Received Counselling, Refused Counselling or Did Not Receive Counselling from a drop-down list.
Sort Criteria	User can select to sort by Donor Number, First Name, Last Name, Gender, Date of Birth, Blood Group, Date of Last Donation or Venue, Referred, Counselled, Date of Counselling
Sort Sequence	User can select ascending or descending
Layout	Screen Layout: Responsive design – see the UI design below Printed report: A4 Landscape
Headers	Report Name: "Donor Counselling"
Sub-headers	Venue(s): [as selected] Donation Period : [date from and to as selected] Total Donors: Count of all donors
Content	Donor Number, First Name, Last Name, Gender, Date of Birth, Blood Group, DIN, Date of Donation, Venue, Referred, Counselled, Date Counselled
Footers	Date and Time Generated, Page number of total number of pages
Media	View on screen / Print to PDF or CSV
Frequency	Ad-hoc
Constraints	Accessible only by authorised users
Report steps	The user must select Donor Counselling from the Post Donation option on main menu
	The user must select report criteria
	The user can view on screen or can select the Print to PDF option
Output Design	**List of donors for post donation counselling** Venue(s): Central Blood Service

Donor #	First Name	Last Name	Gender	Date Of Birth	Blood Group	DIN	Date Of Donation	Venue	Referred	Counselled	Date
000251	Doreen	Kamela	female	14/07/1999	B+	8881113	16/03/2016	Central Blood Service			
000252	Jemima	Hewitt	female	14/04/1997	O+	8882222	25/08/2016	Central Blood Service			
000244	Catherine	Culver	female	15/12/1989	B+	1000899	29/08/2016	Central Blood Service			
000283	Sally	Red	female	14/05/1989	O-	1000822	29/08/2016	Central Blood Service			

9.1.3 IR01-004 Donation Batch Report

IR01-004	Detailed Requirements
Report Name	**Donation Batch Report**
Report Description	Operational Report that lists all donations for the selected donation batch. Lists the Donor Number, DIN, pack type and donation type. Available to view on screen and also in printed format so that it can be signed by the donor clinic dispatcher and the components laboratory receiver.
Purpose	Used for control and verification. Used by donor clinic staff at the end of a clinic to verify that the donation packs and samples collected match what has been recorded in the system for that clinic and also used as a packing list that goes with the donations and samples in the refrigerated box that is transported from the mobile site to the centre where the component processing and testing is carried out. The same report is then used by the receiving staff to verify that what they receive matches what was sent.
Audience	Donor clinic staff, Donor clinic supervisor
Triggers	Authorised user will select this on an ad-hoc basis, generally at the end of a clinic
Input parameters	The user will select the donation batch from the listing displayed on the Manage Donation Batches screen
Sort Criteria	User can choose to sort by Donor Number, DIN, Pack Type or Donation Type Default is by Donor Number
Sort Sequence	Default is numerically by Donor Number
Layout	Responsive screen design A4 Landscape
Headers	Report Name: " Donation Batch Report "
Sub-headers	Batch Status: [Open/Closed] Venue: [selected donation batch venue] Date Created: [date of selected donation batch] Last Updated: [date the batch was updated] Total Donations: count of all donations
Content	Column Headers: Donor Number, DIN, Pack Type, Donation Type
	Row: by Donor
Calculation	Total count of all donations in the test batch: sub-header “Total Donations”
Footers	Date and Time Generated, Page number of total number of pages
Media	View on screen with option to print to PDF or print to CSV
Report steps	The user must select Manage Donation Batches from the Donor Clinic option on the main sub-menu
	To view or print an open test batch, the user will see the Open Batches tab as the default view and must select a donation batch from the list displayed
	To view or print a closed test batch, the user must select the Recent Batches tab and can either select a donation batch from the list displayed or must search for a donation batch according to venue and/or date

	The user must select report filter criteria. To print, the user must select either the PDF or CSV option.
Screen Design SI01-004	
Output Design OR01-004	

9.1.4 IR02-002 Test Batch Outcomes Summary Report

IR02-002	Detailed Requirements
Report Name	**Test Batch Outcomes Summary Report**
Report Description	Report summary of test outcomes of all donations within a test batch showing the TTI and ABO Rh status, ABO Rh blood group, Titre and Antibody screening, the four mandatory TTIs including any repeat and confirmatory tests required. Must indicate if the test are complete or still being processed.
Purpose	Used by laboratory staff to check all the status and test outcomes of a test batch, including those where testing has not been completed. May also be used by the labelling staff to see the current status of a sample.
Audience	TTI Testing Staff, Serology Staff
	TTI Testing Supervisor, Serology Supervisor
	Medical Director
Triggers	Authorised user will select this on an ad-hoc basis by selecting the test batch from the Manage Test Batches screen
Input parameters	The user will select / capture the following report parameters:
	Test Batch (select from the list if test batches displayed) Filter by: All Samples OR TTI Unsafe or Incomplete OR Default is All Samples Blood Typing Issues or Incomplete
Sort Criteria	User can choose to sort by DIN, Date Bled, Pack Type, Venue, TTI Status or Blood Group Serology Status Default is by DIN
Sort Sequence	Default is numerically by DIN ascending
Layout	A4 Landscape
Headers	Report Name: " Test Batch Outcomes Summary Report "
Sub-headers	Venue: *venue of selected test batch* Date Created: *date of selected test batch* Number of Samples: *Count of all donation samples in the test batch*
Content	Column Headers: DIN, Date Bled, Pack Type, Venue, TTI Status, Blood Group Serology, Previous ABO/Rh, HIV, HBV, HCV, Syphilis, HIV Repeat1, HIV Repeat 2, HBV Repeat 1, HBV Repeat 2, HCV Repeat f1, HCV Repeat 2, Syphilis Repeat f1, Syphilis Repeat, HIV Conf, HBV Conf, HCV Conf, Syphilis Conf, ABO, Rh, Titre, AbScr, ABO Repeat 1,Rh Repeat 1
	Row: test outcomes per donation by DIN
	If the filter=" TTI Unsafe or Incomplete" is selected, only those donation samples where the TTI Status = Unsafe OR TTI Status = Not Done must be displayed
	If the filter=" Blood Typing Issues or Incomplete" is selected, only those donation samples where the Blood Group Serology = Mismatch OR Blood Group Serology = Ambiguous OR Blood Group Serology = Not Done must be displayed
Calculation	Total count of all donations in the test batch: sub-header "Number of Donations"

Footers	Date and Time Generated, Page number of total number of pages
Media	View on screen with option to print to PDF or print to CSV
Frequency	Ad-hoc
Constraints	None
Report steps	The user must select Manage Test Batches
	To view or print an open test batch, the user will see the Open Batches tab as the default view and must select a test batch from the list displayed
	To view or print a closed test batch, the user must select the Recent Batches tab and can either select a test batch from the list displayed or must search for a test batch according to date
	The user must select report filter criteria. To print, the user must select either the PDF or CSV option.
Output Design	

Test Batch Outcomes Summary Report Created On: 11/08/2016

Venue: Army HQ (Transfer), Date Created: 11/08/2016, Number of Donations: 6

DIN	Date Bled	Pack Type	Venue	TTI Status	Blood Group Serology	Previous ABO/Rh	HIV	HBV	HCV	Syphilis	HIV Repeat 1	HIV Repeat 2	HBV Repeat 1	HBV Repeat 2	HCV Repeat 1	HCV Repeat 2	Syphilis Repeat 1	Syphilis Repeat 2	HIV Conf	HBV Conf	HCV Conf	Syphilis Conf	ABO	Rh	Titre	AbScr	ABO Repeat 1	Rh Repeat 1
1000601	11/08/2016	Single	Army HQ (Transfer)	Safe	Complete - Match (O+)		NEG	NEG	NEG	NEG													O	POS	LOW	NT	O	POS
1000602	11/08/2016	Double	Army HQ (Transfer)	Safe	Complete - Match (O+)		NEG	NEG	NEG	NEG													O	POS	LOW	NT	O	POS
1000603	11/08/2016	Triple	Army HQ (Transfer)	Safe	Complete - Match (O+)		NEG	NEG	NEG	NEG													O	POS	LOW	NT	O	POS
1000604	11/08/2016	Quad	Army HQ (Transfer)	Safe	Complete - Match (O-)		NEG	NEG	NEG	NEG													O	NEG	LOW	NT	O	NEG
1000605	11/08/2016	Apheresis	Army HQ (Transfer)	Safe	Complete - Match (O-)		NEG	NEG	NEG	NEG													O	NEG	NT	NT	O	NEG
1000606	11/08/2016	Double	Army HQ (Transfer)	Safe	Complete - Resolved (O+)		NEG	NEG	NEG	NEG													O	NEG	LOW	NT	O	POS

9.2 Management Reports

9.2.1 IR01-005 Donations Collected By Type Report

IR01-005	Detailed Requirements
Report Name	Donations Collected By Type Report
Report Description	Report listing all donations collected within a selected date range by venue where it was collected, categorised by donation type and donor gender (Based on LBTS DRDB)
Purpose	For planning purposes to be able to see % of donors by type in order to convert family replacement to voluntary donors. Statistics for % of VNRD as a % of total donations is a requirement for AfSBT accreditation.
Audience	BTS Management
Triggers	Authorised user will select this on an ad-hoc basis
Input parameters	The user will select / capture the following report parameters:
	Date Range: enter date range from / date range to (DD/MM/YYYY)
Sort Criteria	Grouped by Venue
Sort Sequence	Sorted alphabetically by Venue (A-Z)
Layout	A4 Landscape
Headers	Report Name: "Donations Collected By Type"
Sub-headers	Date period: [as selected - from/to]
Content	Column Headers: Venue, For each Donation Type specified in Settings-Male/Female/Total, Total Donations Collected
Calculations	Each row lists data per venue: sum of all donations collected per donor type with sub-totals for male and female donors and total of all donations collected at that site
	Summary row at the end must show totals for all venues per donor type with sub-totals for male and female donors and a total of all donations collected at all venues in the selected period
Footers	Date and Time Generated, Page number of total number of pages
Media	Electronic report
Frequency	Ad-hoc
Constraints	This report must only be available to users with permission to view management reports
Report steps	The user must select Reports option on main menu
	The user must select Donations Collected By Type Report option from sub-menu
	The user must select report criteria and select Print button
Comments	Aggregate report

9.2.2 IR02-003 ABO Rh Blood Grouping Report

IR01-008	Detailed Requirements
Report Name	***ABO Rh Blood Grouping Report***
Report Description	Report listing the count of all donations collected per venue within a specified period showing test outcomes by ABO Rh blood grouping and sub-categorised into male and female donors (Based on LBTS DRDB user requirements)
Purpose	Used for planning purposes to identify venues where the most needed ABO Rh blood group donors reside
Audience	Medical director
	Management
Triggers	Authorised user will select this on an ad-hoc basis
Input parameters	The user will select / capture the following report parameters:
	Date period selected - from/to DD/MM/YYYY DD/MM/YYYY
	Venue : select one from the drop-down list or select All
Sort Criteria	Grouped by Venue (exclude venue from report if no donations were collected within selected period)
Sort Sequence	Sorted alphabetically by Venue (A-Z)
Layout	A4 Landscape / PDF and CSV/Excel format required
Headers	Report Name: **ABO Rh Blood Grouping Report**
Sub-headers	Date period: [as selected - from/to] Venue : [as selected]
Content Summary	Column Headers: Gender, A+,A-,AB+,AB-,B+,B-,O+,O-, NTD, Total Rows: by Venue 1 row for male donors 1 row for female donors 1 row for all donors (note: NTD= No Type Determined)
Calculation	Count of all blood grouping test outcomes per category listed above , with column totals at the last row Percentage of blood groupings per category listed above as % of total donations collected within time period selected
Footers	Date and Time Generated, Page number of total number of pages
Frequency	Ad-hoc
Report steps	The user must select Reports option on main menu
	The user must select **ABO Rh Groups by Venue Report** option from sub-menu
	The user must select report criteria, select option to print to PDF or CSV and then select Print button

9.2.3 IR01-012 Donors Deferred Summary Report

IR01-012	Detailed Requirements
Report Name	Donors Deferred Summary Report
Report Description	Report listing total donors deferred within a selected date range, by venue, categorised by deferral reasons.
Purpose	Used by Medical Director and management staff to view summary information about deferrals within a selected period in order to analyse donor recruitment approaches with the aim of reducing deferrals.
Audience	Medical Director and Management
Triggers	Authorised user will select this on an ad-hoc basis
Input parameters	The user will select / capture the following report parameters:
	Date Range: enter date range from / date range to (Select from calendar DD/MM/YYYY)
Sort Criteria	Grouped by venue Grouped by gender
Sort Sequence	Sorted alphabetically by venue (A-Z)
Layout	A4 Landscape
Headers	Report Name: "Donors Deferred Summary" Column Headers: Deferral Reasons <as configured in Settings>, Total Deferrals
Content	For each venue:
	Count of all donors for each deferral reason that has a start deferral date within the selected date range; one row for female and one row for male
Calculations	Total by column: Sum of all donors deferred for all deferral reasons Summary row: Totals for all venues
Footers	Date and Time Generated, Page number of total number of pages
Frequency	Ad-hoc
Constraints	None
Report steps	The user must select Reports option on main menu
	The user must select Donors Deferred Summary Report option from sub-menu

9.2.4 IR01-014 Donors Adverse Events Summary Report

IR01-014	Detailed Requirements
Report Name	Donor Adverse Events Summary Report
Report Description	Report listing total donors with adverse events within a selected date range, by venue, categorised by adverse event reasons.
Purpose	Used by Medical Director, donor clinic and management staff to view summary information about adverse events within a selected period with the aim of reducing adverse events.
Audience	Medical Director and management (Admin), donor clinic staff
Triggers	Authorised user will select this on an ad-hoc basis, generally on a monthly, quarterly or annual basis
Input parameters	The user will select / capture the following report parameters:
	Date Range: enter date range from / date range to (Select from calendar DD/MM/YYYY) Venue: Select one from dropdown list or select checkbox for All Venues
Sort Criteria	Grouped by venue
Sort Sequence	Sorted alphabetically by venue (A-Z)
Layout	A4 Landscape
Headers	Report Name: "Donor Adverse Events Summary" Column Headers: Adverse Event Reasons <as configured in Settings>, Total Adverse Events
Content	For each venue:
	Count of all donors for each adverse event reason that has a date within the selected date range
Calculations	Total Column: Sum of all donors with an adverse event for all adverse event reasons Summary row: Totals for all venues
Footers	Date and Time Generated, Page number of total number of pages
Frequency	Ad-hoc
Report steps	The user must select Reports option on main menu
	The user must select Donor Adverse Event Summary Report option from sub-menu

9.2.5 IR01-011 TTI Prevalence Report

Report Name	TTI Prevalence Report
Report Description	Aggregate management report summarising all donations collected by venue within a specified period, showing TTI prevalence for HIV,HBV,HCV and Syphilis, categorised by donor gender.
Purpose	Used by blood service management for planning purposes based on an analysis of donation testing
Audience	Management staff, Medical Officer
Triggers	Authorised user will select this on an ad-hoc basis
Input parameters	The user will select / capture the following report parameters:
	Date period selected - from/to DD/MM/YYYY DD/MM/YYYY
Sort Criteria	Grouped by Venue (exclude venue from report if no donations were collected within selected period)
Sort Sequence	Sorted alphabetically by Venue (A-Z)
Layout	A4 Landscape / PDF and CSV format required
Headers	Report Name: **TTI Prevalence Report**
Sub-headers	Date period: [as selected - from/to] Venue : [as selected] Number of venues: [count]
Content Summary and Calculations	Column Headers: Gender, HIV+,HBV+,HCV+, Syphilis+, Total Units TTI+, Total Units Tested, TTI Rate, HIV Rate, HBV Rate, HCV Rate, Syphilis Rate Grouped: by Venue Rows: Female / Male • Total Units TTI+ - The count of all donations that test POS for one or more TTIs • Total Units Tested for TTIs – The count of all donations screened for TTIs • TTI Rate – Rate as a % of count of all donations that test POS for one or more TTs / Total units tested • HIV Prevalence – Count of all donations that tested POS for HIV; rate as % of all units tested • HBV Prevalence - Count of all donations that tested POS for HBV; rate as % of all units tested • HCV Prevalence - Count of all donations that tested POS for HCV; rate as % of all units tested • Syphilis Prevalence - Count of all donations that tested POS for Syphilis; rate as % of all units tested
Footers	Date and Time Generated, Page number of total number of pages
Frequency	Ad-hoc but usually monthly or quarterly

9.2.6 IR02-003 Components Produced Summary Report

Report Name	Components Produced Report
Report Description	An aggregate report showing the components produced per processing site during the selected time period (one month/one quarter/ one year) categorised by component type and blood group.
Purpose	Used by management for analysis and planning.
Audience	Management(Admin), Component Laboratory Staff
Triggers	Run on demand, usually on a monthly, quarterly or annual basis
Input parameters	The user will select / capture the following report parameters:
	Date period selected - from/to DD/MM/YYYY DD/MM/YYYY
	Processing Site – select one from drop-down list or select checkbox for All
Sort Criteria	Grouped by Processing Site
Sort Sequence	Sorted alphabetically by Processing Site (A-Z)
Layout	A4 Landscape / PDF and CSV format required
Headers	Report Name: **Components Produced Report**
Sub-headers	Date period: [as selected - from/to] Processing Site : [as selected] Number of processing sites: [count]
Content Summary and Calculations	Grouped by Processing Site: Column Headers: Blood Groups A+,A-,B+,B-,AB+,AB-, O+,O-, Total Rows: 1 row for each Component Type where the component can be issued e.g. Whole Blood-CPDA, Packed Red Cells, Fresh Frozen Plasma, 1 total row per processing site showing sum for all components per blood group 1 summary row showing sum for all processing sites
Footers	Date and Time Generated, Page number of total number of pages
Frequency	Ad-hoc but usually monthly or quarterly or annual
Comments	Aggregate report This report excludes initial components that cannot be issued. The date selection criteria uses the date that the component is processed. If there are no components processed for a particular component type then the row SHOULD display zeros

9.2.7 IR03-003 Discards Summary Report

IR03-003	Detailed Requirements
Report Name	**Discards Summary Report**
Report Description	Report listing total whole blood and blood components discarded within a selected date range, by processing site and categorised by discard reasons.
Purpose	Used by management and laboratory staff to view summary information about the number and type of whole blood and components discarded within a selected period with the aim of reducing the number of discarded units and thereby reducing cost.
Audience	Medical Director and management (Admin)
	Component Lab staff / Component Lab supervisor
Triggers	Authorised user will select this on an ad-hoc basis, generally on a monthly, quarterly or annual basis
Input parameters	The user will select / capture the following report parameters:
	Date Range: enter date range from / date range to (Select from calendar DD/MM/YYYY) Processing Site: Select one from dropdown list or select checkbox for All Venues Report format: Select PDF or CSV
Sort Criteria	Grouped by processing site
Sort Sequence	Sorted alphabetically by processing site (A-Z)
Layout	A4 Landscape
Headers	Report Name: "Discards Summary Report" Column Headers: Discard Reasons <as configured in Settings>, Total Discards
Sub-headers	Date period: <date from> - <date to> Number of processing sites:
Content	For each processing site:
	A row for each component type
	Columns: Count of all components discarded for each discard reason that has **a date collected** within the selected date range
Calculations	Total Column: Sum of all discards per component type Total row: Totals discards per processing site Summary row: Total discards for all processing sites
Footers	Date and Time Generated, Page number of total number of pages
Frequency	Ad-hoc
Report steps	The user must select Reports option on main menu
	The user must select Discards Summary Report option from sub-menu
Comments	NOTE: ALL component types discarded must be included i.e. CanBeIssued = true and false The date selection criteria uses the date that the component was originally collected. If there are 0 discards for a component type then the row should NOT be displayed

9.2.8 IR04-004 Blood Units Issued Report

IR04-004	Detailed Requirements
Report Name	**Blood Units Issued Summary Report**
Report Description	Summary of all whole blood and blood component issues according to usage site with gap analysis against units ordered
Purpose	To provide information to assist with forecasting blood needs per usage site and improve planning of clinics and collection rates.
Audience	Management staff, Inventory Staff
Triggers	Authorised user will select this on an ad-hoc basis
Input parameters	The user will select / capture the following report parameters:
	Date period selected - from/to DD/MM/YYYY DD/MM/YYYY
Sort Criteria	Grouped by Usage Site (exclude usage site from report if no components were ordered within selected period)
Sort Sequence	Sorted alphabetically by Venue (A-Z)
Layout	A4 Landscape PDF and CSV format required
Headers	Report Name: **Blood Units Issued Summary Report**
Sub-headers	Date period: [as selected - from/to] Usage Site : [as selected] Number of usage sites: [count]
Content Summary and Calculations	Grouped by Usage Site: Column Headers: Ordered, Issued, Gap, % Issued vs Ordered Rows: 1 row for each Component Type e.g. Whole Blood, Packed Red Cells, etc… 1 row totals for all Component Types per venue 1 summary row totals for all venues
Footers	Date and Time Generated, Page number of total number of pages
Frequency	Ad-hoc but usually monthly or quarterly
Report steps	The user must select **Blood Units Issued Summary Report** option from sub-menu
	The user must select report criteria, select option to print to PDF or CSV and then select Print button

9.2.9 IR08-001 Transfusion Summary Report

IR08-001	Detailed Requirements
Report Name	Transfusion Summary Report
Report Description	Report listing the total number of units transfused within a selected date range, by usage site, and total numbers of adverse transfusion reactions reported categorised according to reaction type.
Purpose	Used by management staff to view summary information about transfusion and related transfusion adverse events to support haemovigilance programmes with the aim of reducing adverse transfusion events.
Audience	Medical Director and management (Administrator role)
Triggers	Authorised user will select this on an ad-hoc basis, generally on a monthly, quarterly or annual basis
Input parameters	The user will select / capture the following report parameters:
	Date Range: enter date range from / date range to (Select from calendar DD/MM/YYYY) Usage Site: Select one from dropdown list or select checkbox for All
Sort Criteria	Grouped by usage site
Sort Sequence	Sorted alphabetically by usage site (A-Z)
Layout	A4 Landscape
Headers	Report Name: "Transfusion Summary" Column Headers: Total Units Transfused , Transfusion Reaction Types <as configured in Settings>, Total Reactions,
Content	For each usage site:
	Total Transfused : Sum of all units recorded as transfused with a transfusion date within the selected date range Total Not Transfused : Sum of all units recorded as not transfused with a transfusion date within the selected date range Transfusion Reaction Types: Count of all units recorded as having a related transfusion reaction with a transfusion date within the selected date range per transfusion reaction type Total Reactions: Sum of all units recorded as having a related transfusion reaction with a transfusion date within the selected date range Total Unknown: Sum of all units recorded as having Transfusion Unknown with a date within the selected date range
Calculations	Summary row: Totals for all usage sites
Footers	Date and Time Generated, Page number of total number of pages

10 Non-Functional Requirements List

This section lists the non-functional requirements. In general, functional requirements define what a system is supposed to do whereas non-functional requirements define how a system is supposed to be. Non-functional requirements are also often called "constraints", "quality attributes", "quality goals" and "quality of service requirements," and "non-behavioral requirements." They tend to apply across all functional areas of the system. They can be divided into two main categories:

- Execution qualities, such as security and usability, which are observable at run time.
- Evolution qualities, such as testability, maintainability, extensibility and scalability.

(Key=**M**andatory, **D**esirable)

Requirement ID	Description	M/D
NFR01	**Capacity Requirements**	
NFR01-01	The system should be designed to be scalable in terms of donor records	M
NFR01-02	The system should be designed to be scalable in terms of donation records	M
	The system is expected to be scalable in that there will be growth in both the number of donations and the number of donors during the lifetime of the system.	M
NFR02	**Security Requirements – Identification and Authentication**	
NFR02-001	A User identity and associated password must be used to access the system.	M
NFR02-002	The system must enforce users to change their passwords on first login.	M
NFR02-003	Passwords must never be shown on the computer screen, on printed reports or in back-up media.	M
NFR02-004	The system must provide the ability for users to re-set their own password.	M
NFR03	**Security Requirements –Access Control and Authorisation**	
NFR03-001	The system must not initiate any activities before the user has been authenticated.	M
NFR03-002	Only the Administrator must be able to set and manage user roles and permissions.	M
NFR03-003	The system must be able to control user access to specific functions and procedures by user role and function, managed by permissions.	M
NFR03-004	Where a menu access structure is used, the menu structure should only display those options to which the authenticated user has access.	M
NFR04	**Accountability – Auditing and Logging**	
NFR04-001	The system must be able to display for authorised users a list of users and their current privileges.	M
NFR04-002	The system must be able to record for each log-on and log-off event - the date & time, the user identifier	M
NFR04-003	The system should be able to record for auditing processes each system event – add/update/void record – and the user who performed it	M
NFR04-004	After a defined period, following which there has been no interaction between the user and the system, the system must log the user out of system activity.	M
NFR04-005	When the system automatically logs the user out, the system must exit to a secure prompt.	M
NFR04-006	The system must have a facility for the review of the audit trail by authorised	M

	individuals.	
NFR05	**Data Integrity Requirements**	
NFR05-001	The system must, where appropriate, validate input using range and limit checks, data format and compatibility checks.	M
NFR06	**User Interface**	
NFR08- 001	The system must be developed within a graphical user interface (GUI) windows/web environment.	M
NFR08- 002	The system must have a consistent look and feel and logical navigation.	M
NFR08- 003	The system must provide information, error and warning messages that are useful and informative.	M
NFR08- 004	The system must adhere to good design principles for usability: these include sensible use of common GUI features such as drop down lists, checkboxes and date/time pickers	M

Table 14: Non-Functional Requirements

NFR07	**Equipment Interface Requirements**		
	The system must interface with the following equipment:		
Ref ID	**Equipment**	**Purpose**	**Direction**
NFR07-001	Zebra Label Printer	Labelling blood components and samples.	Unidirectional
NFR07-002	Printer	Generating listings	Unidirectional
NFR07-003	Barcode Scanner	Scanning in barcodes	Unidirectional

Table 15: Equipment Interface Requirements

NFR09	**Donor Data Migration**	
Requirement ID	**Description**	**M/D**
NFR09	At the time of initial deployment, the system must be able to import donor information as specified below from an existing electronic system under the condition that the blood service has quality checked the accuracy and integrity of this donor data and has signed a data verification document accordingly. In addition the system must be able to import donation, deferral and test outcomes data under certain conditions. **NOTE:** Data migration of data is that is not complete and accurate can lead to traceability and data integrity issues and is a high risk activity. The data migration activity will be dealt with on a case by case basis as part of the implementation plan and activities.	M

Table 16: Donor Data Migration Requirements

11 Glossary of terms and abbreviations

The table below lists the terms and abbreviations most commonly-used in this document.

Term (Acronym)	Explanation of term as used in BSIS
ABO blood groups	One of the major blood group systems. The four main groups in the ABO system are A, B, AB and O.
Accreditation	A means of monitoring and measuring blood transfusion services against a defined set of standards.
Adverse event	A complication in a donor or patient which may occur in relation to a blood donation or a transfusion.
African Society for Blood Transfusion (AfSBT)	An organisation that advocates for the highest ethical and professional skills and standards in blood transfusion across Africa through education, training and knowledge-sharing. Has developed and supports the implementation of the Step-wise Accreditation Programme: Step 1 Certification: meeting minimum quality and operational requirements. Step 2 Certification: meeting intermediate quality and operational requirements. Step 3 Full accreditation: meeting quality and operational requirements at international standards.
American Association of Blood Banks (AABB)	The United States-based professional body and standards organisation for blood transfusion services. Provides technical assistance for countries under CDC-PEPFAR Blood systems strengthening programme.
Anti-coagulant	Substance used to prevent clotting of blood.
Autologous	Withdrawal and subsequent return of blood to the same person.
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 bank	A facility that performs, or is responsible for the performance of, the processing, storage, testing and distribution of human blood and/or blood products intended for transfusion.
Blood Establishment Computer System (BECS)	BECS is software designed to be used in a blood establishment and is intended for use in the diagnosis of disease or other conditions in donors, or in the prevention of disease in humans by preventing the release of unsuitable blood and blood components. (FDA definition)
Blood group serology	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. Also known as blood grouping/ blood typing/ABO Rh testing.
Blood pack	Plastic bag into which a donation is collected. May consist of multiple parts into which components may be separated. Also known as Pack.
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.
Blood pressure 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	Refers to the measurement taken when the heart is relaxed between contractions.
Blood Safety Information System (BSIS)	The name of the BECS software system developed under the BSSP programme by Jembi Health Systems in collaboration with CDC, technical assistance providers and blood services.

Term (Acronym)	Explanation of term as used in BSIS
Blood service	A facility that performs one or more of the following activities: donor mobilization, donor screening, blood collection, processing of blood into products, compatibility testing, storage, selection, and issuing of blood and blood products for intended recipients.
Blood Safety Strengthening Programme (BSSP)	CDC and Jembi Health Systems programme focused on the improvement of quality of blood component management in low resource settings.
Blood typing rule	The algorithm used to determine a blood group based on test results. Part of BSIS initial configuration.
Centers for Disease Control and Prevention (CDC)	The CDC is the leading public health institute in the United States of America and the source of all US government global funding for health.
Component	The therapeutic constituents of whole blood prepared by centrifugation and separation. Includes red blood cells, plasma and platelets. **In BSIS the term component also includes whole blood that has been weighed and checked by the component laboratory staff.**
Components laboratory	The laboratory within the blood service that processes whole blood into components.
Component type	The various components and sub-components which may be processed from a blood donation. .
Cryoprecipitate (Cryo)	A plasma component rich in Factor VIII and used in the treatment of Haemophilia. Prepared from frozen fresh plasma by slow thawing.
Date bled	The day that the blood was collected / drawn from the donor.
Deferral	Refers to delaying the collection of blood from a donor. This may be temporary or permanent.
Deferral period	The time for which the donor is not allowed to donate. After this period, the donor may donate.
Deferral reason	The reason that the donor has not been allowed to donate blood.
Discard	The act of destroying a unit of blood or blood component that is not suitable for transfusion.
Discard label	The system-generated printed label affixed to a unit of blood or blood component that is not suitable for transfusion. Also known as biohazard label.
Distribution Site	The location within the blood service where inventory (labelled blood) is managed, dispatched from and returned to.
Domain	The areas of functionality within BSIS used to determine user access based on user role.
Donation	The unit of blood, or blood component, drawn from the donor. Also known as a collection.
Donation batch	A batch consisting of one or more donations that were collected at the same donation site during the same session. Also collection batch.
Donation type	Drawn from the following type of donation based on the status of the donor at the time of the donation: Voluntary Non-Remunerated Donor (VNRD), Family Replacement, Autologous, Other
Donation identification number (DIN)	A unique, pre-generated number applied to the donation which links the donation to the donor. It is also applied to any components resulting from this donation.
Donation testing laboratory	The laboratory within the blood service where all blood group serology and TTI testing on blood donations is performed.
Donor	A person who donates blood. A new donor (first time donor) is defined as a donor who does not have any previous donations recorded in the system. A repeat donor is defined as a donor whose has one or more previous donations recorded in the system.
Donor number	A unique system-generated number used to identify the donor within the system.
Expired	Refers to a component which has passed the expiry date and may no longer be

Term (Acronym)	Explanation of term as used in BSIS
	transfused.
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.
Haemoglobin (Hb)	Constituent of red blood cells responsible for the oxygen-carrying capacity of red cells.
Inventory	Stock levels of components. Also the name of the department that is responsible for distribution of blood and blood components.
Indeterminate	A test result or series of test results for which no outcome can be determined.
Issue	Refers to the issuing of a component for distribution to an authorised facility. Always matched against an order.
ISBT128	A global standard for the identification, labelling and information transfer of medical products of human origin (including blood products) across international borders and disparate health care systems.
Label	An inscription affixed to a unit of blood, blood product or sample for identification. Information that is required may include content, identification, storage requirements, expiry date, cautionary statements, or indications for use.
Labelling	Process during which all safety criteria including test outcomes are checked by BSIS. If the component is suitable for use, a label is printed and affixed to the pack. Biohazard labels may be printed and affixed to components that are not suitable for use.
Low haemoglobin	Haemoglobin level below the value acceptable for blood donation, which is usually 12.5 g/dl
Medical history form	A form that collects personal details and general health information of the donor. Also known as a medical questionnaire.
National Blood Transfusion Service (NBTS)	The generic name for the blood transfusion service serving an entire country.
Outcome	The final interpretation of a test result or series of test results, for example positive or negative.
Pack	The bag into which the blood is collected at the time of donation.
Pack label	The system-generated printed label that is applied to the pack during the labelling process.
Pack type	Pack or bag type determines which components may be processed from the blood donation.
Pack weight	The weight or mass of the pack after donation.
Pending test	A test awaiting a final result or outcome.
Permissions	Used in BSIS to define the areas of functionality that a user has access to dependent on their role.
Phlebotomist	A healthcare professional trained to draw blood from a patient in a safe and sanitary manner.
Phlebotomy	The process of inserting a needle into the vein of the blood donor in order to collect a unit of blood.
Plasma	The straw-coloured liquid part of anti-coagulated blood remaining after separation from the cellular components. Plasma transports cellular and non-cellular components to the parts of the body where they are required.
Platelets	Small particles found in the blood that play a major role in clotting. They help to stop bleeding from small blood vessels and wounds. Derived from cells in the bone marrow called megakaryocytes.
President's Emergency Plan for AIDS Relief (PEPFAR)	The organisation provides all US government funding for HIV and AIDS relief. The CDC and Jembi Health Systems Blood Strengthening Programme is governed by this plan.

Term (Acronym)	Explanation of term as used in BSIS
Processed	Used to describe a donation that has been processed by the component laboratory and split into components.
Pulse	The number of times the heart beats per minute. One of the health parameters measured on prospective blood donors.
Quarantine	To isolate untested or nonconforming blood, blood products or materials to prevent their distribution or use. All unscreened donations are automatically assigned a quarantine status: until testing has been completed and the suitability of donations for therapeutic use has been determined, these donations cannot be labelled for release to inventory and issued for use.
Record (noun)	Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved. These include test records or audit results. Records do not exist until the activity has been performed and documented.
Record (verb)	To capture information for use in records through writing or electronic media.
Recipient	A patient who is given a blood transfusion.
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. Also known as Family Replacement donor.
Rhesus (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 BSIS is determined by the role a user is assigned.
Safe Blood for Africa (SBFA)	Non-profit organisation that provides expertise and technical assistance to guide and assist the national blood services of countries to develop the knowledge, skills and competencies to build a sustainable service supplying safe blood and blood components to all its citizens.
South African National Blood Transfusion Service (SANBS)	A non-profit organisation providing blood and blood products across all of South Africa, with the exclusion of the Western Cape. SANBS also provides blood safety support and training to countries in the SADC region.
Specimen	A small quantity of donor/ patient blood used for testing purposes. Also called a sample.
Standard operating procedure (SOP)	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. Such procedures include medical, laboratory and clerical procedures and the computer programmes associated with them. Also known as work instructions.
Tare weight	Tare weight is the weight of an empty container. By subtracting it from the gross weight, the weight of the contents (the net weight) may be determined.
Technical assistance providers	Organisations that provide expert, specialist advice and assistance to blood services for improving blood safety under the CDC PEPFAR blood systems strengthening programme.
Test batch	A 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 process during which a supervisor checks all test protocols and signs off that a batch of tests can be released.
Traceability	The ability to follow the history of a product or service by means of recorded identification.
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.
Transfusion transmissible infections (TTI)	An 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, HBV, HCV and Syphilis.
TTI positive	Exhibiting a positive reaction for a TTI test, meaning that the blood being tested

Term (Acronym)	Explanation of term as used in BSIS
	contains infective agents and is therefore not safe to transfuse.
TTI testing	Standard protocol for testing of blood donations for transfusion transmissible infections.
TTI testing method	The methodology used for TTI testing by a blood service.
Validation	Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.
Venue	Site of a donor clinic: may be fixed or mobile.
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been met.
Voluntary non-remunerated donors (VNRD)	Donors who are not paid for a donation and are not coerced into donating. Generally considered lower-risk donors than other donor categories. Percentage of VNRD is used as an indicator for accreditation of the blood service.
Weight	Body weight recorded for the donor. Also known as body mass.
Western Province Blood Transfusion Service (WPBTS)	A non-profit, independent organisation operating throughout the Western Cape to supply safe blood and blood products to all communities in the region.
WHO	World Health Organisation.
WHO Global Database on Blood Safety (WHO GDBS)	An online data collection tool used to collect and analyse data from all countries on blood and blood product safety as the basis for effective action to improve blood transfusion services globally. The focus of the analysis is to provide information on the current status of blood transfusion services, assess country needs in improving blood safety, formulate strategic recommendations to countries, plan and implement activities and evaluate progress.

Table 17: Glossary of terms

12 APPENDIX: Component and Inventory Status Rules

This section describes the different statuses applicable to the component records at different stages on the component processing workflow and according to certain criteria.

12.1 Component Status Changes

Component Status	Changes to	When
QUARANTINED		Default status of all donations at the point of collection and prior to TTI, blood grouping and serology testing.
QUARANTINED	UNSAFE	The donor is flagged as Ineligible i.e. during historical data entry only a donation may be recorded in BSIS even if the donor was ineligible to donate and was actually bled in error. The associated donation (component) is automatically flagged as UNSAFE.
QUARANTINED	UNSAFE	• The initial (parent) component's pack weight is out of range i.e. the pack weight is above or below the configured maximum or minimum pack weight limits. • The initial (parent) component's pack weight is below the minimum and above the low volume weight and the component contains plasma.
QUARANTINED	UNSAFE	One or more of the initial screening TTI test outcomes are POSITIVE for this sample (TTIStatus.TTI_UNSAFE)
QUARANTINED	UNSAFE	One or more of the initial screening TTI test outcomes are Not Tested (NT) for this sample (TTIStatus.INDETERMINATE)
QUARANTINED	UNSAFE	The ABO Rh test outcome is ambiguous and cannot be resolved. The ABO Rh test outcome is ambiguous when the ABO Rh blood group of a first time donor's first test outcome does not match the repeat test outcome OR a repeat donor's blood group test outcome does not match the blood group of the previous donation for this donor. (BloodTypingMatchStatus.NO_TYPE_DETERMINED)
QUARANTINED	UNSAFE	The ABO Rh test outcome is indeterminate when either or both the ABO and Rh test outcome is Not Tested (NT) (BloodTypingMatchStatus.INDETERMINATE)
QUARANTINED	UNSAFE	The antibody screening test outcome is POSITIVE and the component contains plasma.
QUARANTINED	PROCESSED	The initial (parent) component has been processed into further components before TTI and serology tests have been released.
QUARANTINED	AVAILABLE	• The sample has been released from TTI • AND serology testing and the sample has NO unsafe test outcomes for TTI • AND NO unsafe test outcomes for ABO Rh

		• AND the Antibody Screening test is Not Tested or Negative OR the Antibody Screening test is Positive and the component does not contain plasma.
QUARANTINED	DISCARDED	The component has been discarded before TTI and serology tests have been released.
QUARANTINED	EXPIRED	The component has expired i.e. the expiry date for the component type has been exceeded before TTI and serology tests have been released.
UNSAFE	DISCARDED	The unsafe component has been discarded.
EXPIRED	DISCARDED	The expired component has been discarded.
EXPIRED	UNSAFE	The component that has already expired has been flagged as unsafe due to test outcomes, pack weight limits or ineligible donor.
AVAILABLE	DISCARDED	The component has been discarded.
AVAILABLE	ISSUED	The component has been issued to an external usage site (hospital/clinic) and has been taken out of inventory.
AVAILABLE	EXPIRED	The component has expired i.e. the expiry date for the component type has been exceeded.
AVAILABLE	UNSAFE	The initial (parent) pack weight is out of range i.e. the pack weight is above or below the configured maximum or minimum pack weight limits. This occurs when the pack is weighed after the test outcomes have been released and before the component has been labelled.
AVAILABLE	UNSAFE	A subsequent donation from the same donor has tested positive for a TTI. Although the component has no positive TTI outcomes it will automatically be flagged as UNSAFE because a subsequent donation has tested positive for a TTI.
AVAILABLE	PROCESSED	The initial (parent) component has been processed into further components after TTI and serology tests have been released. The resulting component's status will be AVAILABLE.
ISSUED	AVAILABLE	A component that was issued has been returned and placed back into stock and is part of inventory. This component may be re-issued.
ISSUED	EXPIRED	A component that was issued has been returned and has expired since it was issued. This component may be NOT be re-issued.
NOTE: *The following status changes will only occur when a user is correcting a data entry error and is updating/correcting a pack weight or rolling back processing or discard of a component.*		
UNSAFE	QUARANTINED	The initial (parent) component's pack weight that was previously out of range has been updated to within range. The component is rolled back to its previous state.
UNSAFE	AVAILABLE	The initial (parent) component's pack weight that was previously out of range has been updated to within range. The component is rolled back to its previous state.
UNSAFE	EXPIRED	The initial (parent) component's pack weight that was previously out of range has been updated to within range.

		The component is rolled back to its previous state.
PROCESSED	QUARANTINED	Only when a component has been rolled back to an Unprocessed state i.e. the component reverts to the original state
PROCESSED	AVAILABLE	Only when a component has been rolled back to an Unprocessed state i.e. the component reverts to the original state
PROCESSED	EXPIRED	Only when a component has been rolled back to an Unprocessed state i.e. the component reverts to the original state
PROCESSED	UNSAFE	Only when a component has been rolled back to an Unprocessed state i.e. the component reverts to the original state
DISCARDED	EXPIRED	The component has been rolled back (Undiscarded) to the previous state
DISCARDED	AVAILABLE	The component has been rolled back (Undiscarded) to the previous state
DISCARDED	QUARANTINED	The component has been rolled back (Undiscarded) to the previous state
DISCARDED	UNSAFE	The component has been rolled back (Undiscarded) to the previous state

12.2 Component's Inventory Status Changes

The component's inventory status	Changes to	When
NOT IN STOCK	IN STOCK	The safe component has been labelled and verified and added to inventory.
IN STOCK	REMOVED	The component has been issued to an external usage site (hospital/clinic).
IN STOCK	REMOVED	The component has been discarded.
REMOVED	IN STOCK	The component has been returned from the external usage site (hospital/clinic) that it was issued to.
IN STOCK	IN STOCK	The component has been transferred from the inventory of one distribution site to another distribution site within the blood service.
IN STOCK	REMOVED	The component has been removed from inventory in order to be re-processed and/or re-labelled.

12.3 Valid Component and Inventory Status Combinations

Inventory Status	Component Status	
The following shows the component status whilst the component is still undergoing processing in the components laboratory prior to labelling:		
NOT IN STOCK	AVAILABLE	The component is ready for labelling as test outcomes have been released
NOT IN STOCK	DISCARDED	The component has been discarded
NOT IN STOCK	EXPIRED	The component has expired
NOT IN STOCK	PROCESSED	The initial (parent) component has been processed into further components.
NOT IN STOCK	QUARANTINED	The test outcomes for this component have not yet been released
NOT IN STOCK	UNSAFE	The component is unsafe due to test outcomes, pack weight limits (under or over bleed) or an ineligible donor
The following shows the component status after the component has been labelled. The printing of a pack label (NOT a discard label) and the verification of that label automatically adds the component to the inventory:		
IN STOCK	AVAILABLE	The component is labelled, verified and is ready for issue or transfer.
IN STOCK	EXPIRED	The component has expired whilst in inventory.
IN STOCK	UNSAFE	A subsequent donation from the same donor has tested positive for a TTI whilst the component is still in inventory.
REMOVED	ISSUED	The component has been issued to an external usage site (hospital/clinic) and is therefore no longer in inventory
REMOVED	DISCARDED	The component has been discarded and is therefore no longer in inventory
REMOVED	PROCESSED	The component has been taken out of stock and processed further into child components. The parent component status will be PROCESSED.
REMOVED	AVAILABLE	The component has been selected for re-processing and needs to be re-labelled.