System Requirements Specification for BSIS (Blood Safety Information System)

DONOR & BLOOD MANAGEMENT Version 1.0

Programme: Blood Safety Systems Strengthening

**Document Control**

|  |  |  |  |
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**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 Panelsignatures 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

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# 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.

## 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.

## 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 V1.0** It covers the requirements identified for the provision of:-

* Donor management
* Donation management
* Testing of donations
* Operational Reports
* Component Processing
* Blood bank/Inventory
* Management Reporting
* Integration with automated laboratory equipment
* Syncing of data for use with laptops at mobile clinics

## Assumptions and Dependencies

* These requirements are for a single instance of the system running in a central blood service.
* The laboratory equipment interfaces for specific equipment have been defined but it must be noted that the ability to directly import from automated blood grouping and TTI testing equipment is highly dependent on the implementation environment and will be dealt with as an implementation activity.
* Similarly the need to migrate data from existing electronic systems will vary widely and will also be dealt with as an implementation activity.
* The first version (1.0) will be available in English only.

## 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) | Industry standard term for a computer system designed to assist in the management of donors, donations and allied aspects of a blood transfusion service. |
| 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. |
| 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 in a country. |
| Buffy Coat | The layer of white cells and platelets that is seen between the red cells and the plasma in a bag of whole blood that has been centrifuged. |
| 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. Products include red blood cells, plasma and platelets.  Also known as a product or blood product. |
| 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. Also known as a product type. |
| Conformance | Fulfilment of requirements. Requirements may be defined by customers, standards, regulatory agencies or law. |
| Cross-match | Procedure whereby donor red cells are mixed directly with the recipient plasma/ serum to detect ABO and/ or other red cell antigen compatibility.  Also known as a compatibility test. |
| 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. |
| Diagnosis | The medical reason for which a blood transfusion is prescribed. |
| Discard | The act of destroying a unit of blood or blood component that is not suitable for transfusion. |
| Discard label | 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 |  |
| 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 site | The place where the blood donations take place. May be either a mobile site or a fixed site. Also known as a collection site or venue. |
| 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 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. |
| Hospital | An institution providing medical and surgical treatment and nursing care for sick or injured people. Blood transfusions are usually carried out in hospitals. |
| 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. |
| Non-reactive | A negative test result. |
| 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. |
| Processed | Used to describe a donation that has been processed by the component laboratory and split or pooled 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. |
| Result | The visible or measurable endpoint of a test. |
| Reactive | A positive test result. |
| 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. |
| 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 reactive | Exhibiting a positive reaction for a TTI test, meaning that the blood being tested 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. |
| 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 1: Glossary of terms

## Related Documents

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version** | **Date** | **Status** | **Document Name** | **Author** |
|  |  |  |  |  |
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|  |  |  |  |  |
|  |  |  |  |  |

## 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)

# Scope and Context

## 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) | * 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 |
| Safe Blood for Africa (SBFA) |
| 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 2: Stakeholders Summary

# BSIS Overview

## 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.

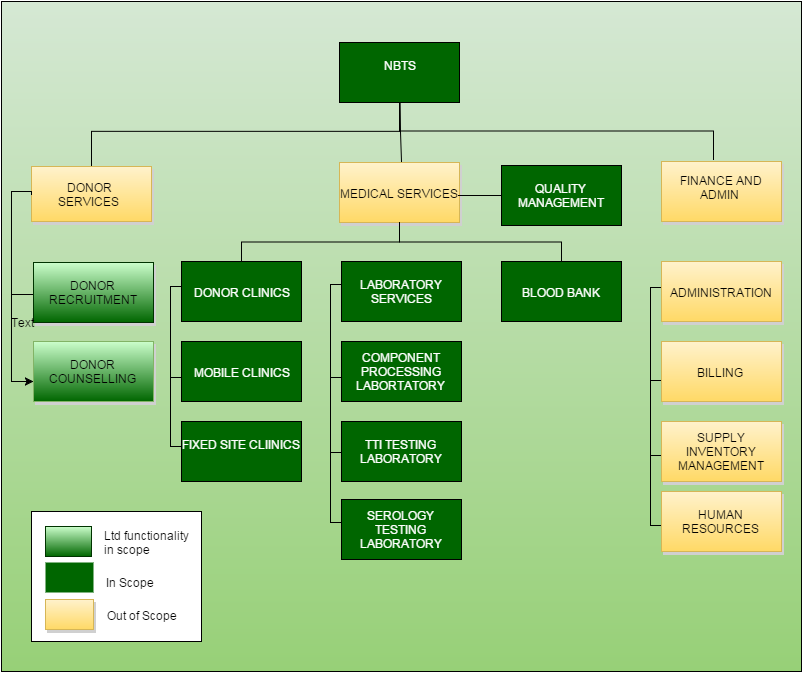


Figure 1: BTS Functional Decomposition

## Solution Architecture

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

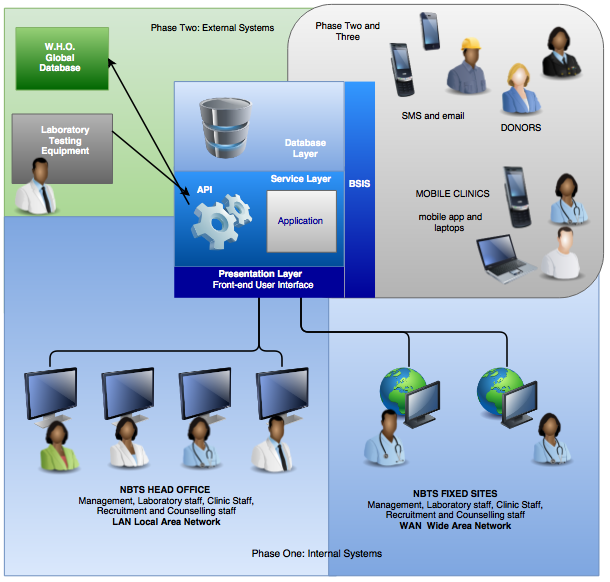


Figure 2: BSIS Solution Architecture

## 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.

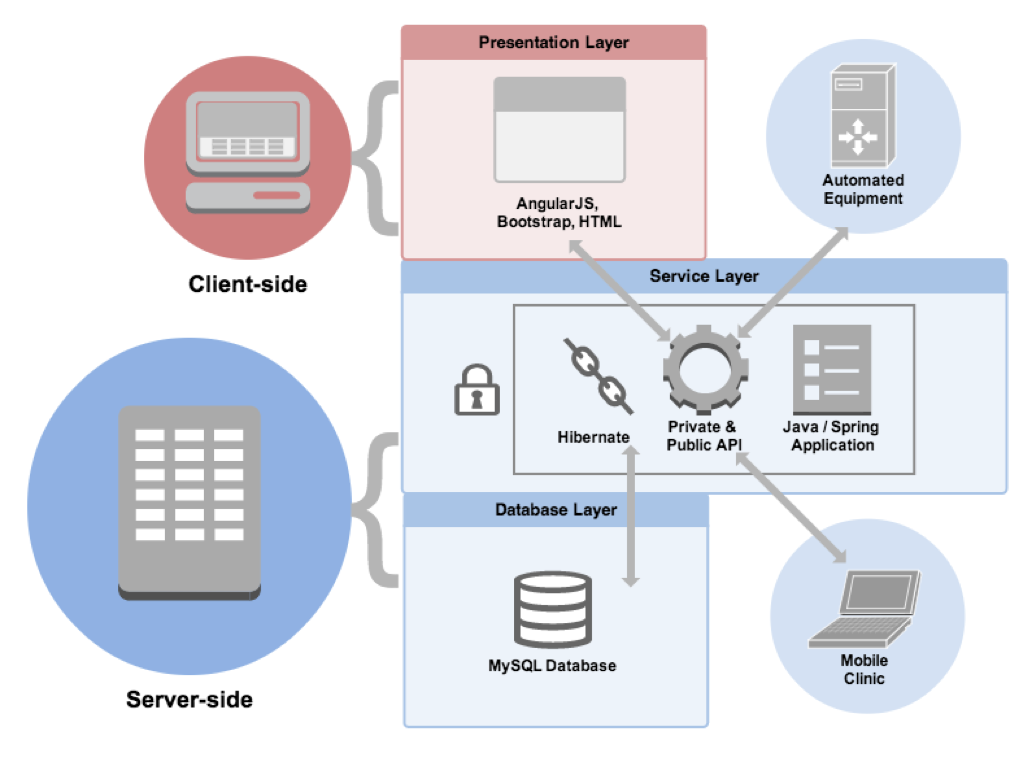


Figure 3: BSIS Technical Architecture

## 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.

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.

## 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

### In scope for Donor Management Module

The following areas of functionality are in scope for Donor Management Module version 1.0:

1. Donor management including donor recruitment list and post-donation counselling
2. Donation management
3. Capture of donation test outcomes using test batches
4. Configuration and system administration
5. Operational reporting related to donor and donation management

### In scope for the Blood Management Module

1. Component processing
2. Labelling of components
3. Discard management
4. Inventory (Blood bank stock control)
5. Management reporting

The following context diagram shows the functional areas in scope for the BSIS Donor Management Module.

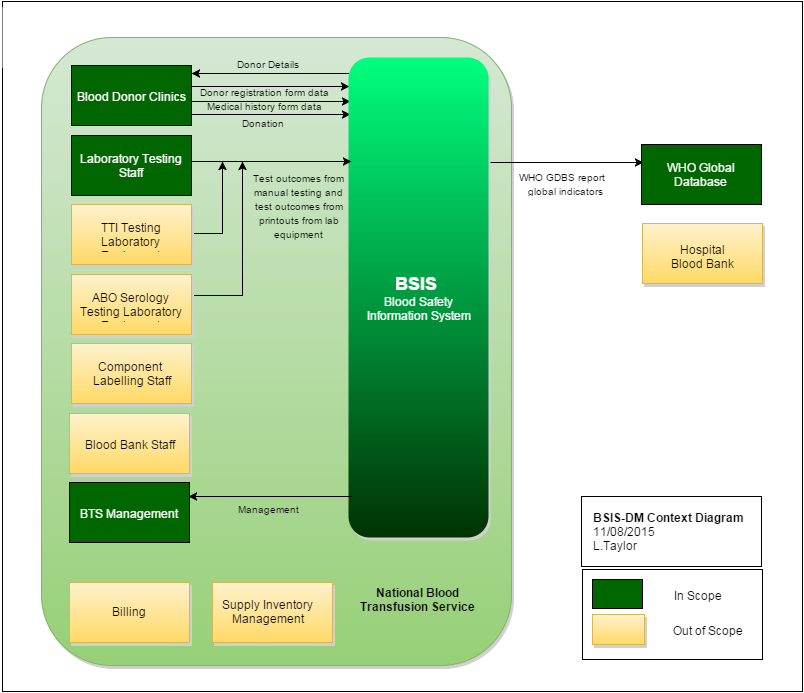


Figure 4: BSIS-DM V1.0 Context Diagram

The following areas of functionality are in scope for the full BSIS (Blood Safety incorporating Donor Management and Blood Management) version 1.0:

The following context diagram shows the areas in scope for BSIS (Blood Safety).

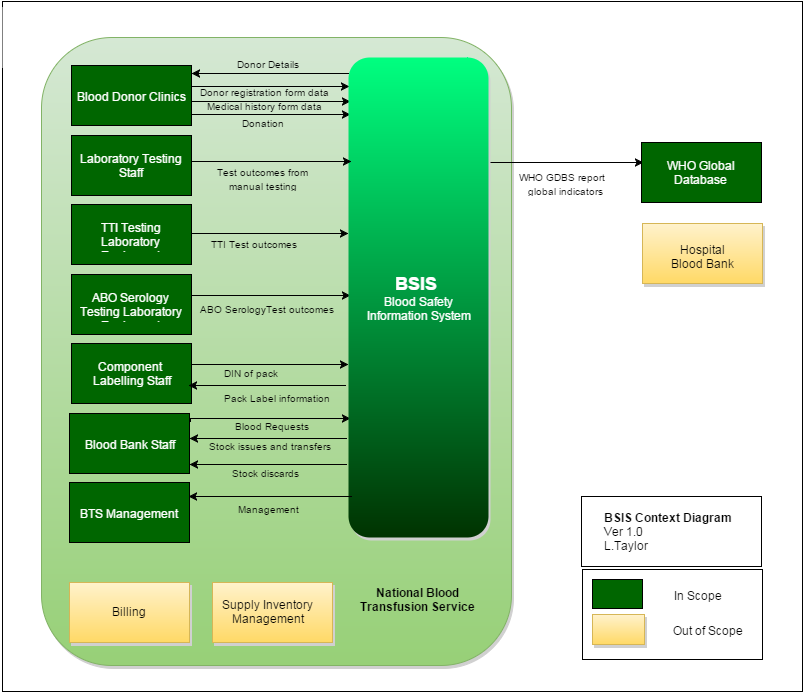


Figure 5: BSIS Blood Safety V1.0 Context Diagram

### Out of scope

The following areas of functionality are out of scope for Version 1.0 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 : Portuguese and French Language versions
3. Device interfacing with laboratory equipment
4. Patient Transfusion information to support haemovigilance
5. Comprehensive donor recruitment and planning
6. Automation of Donor Communications
7. ISBT128 support except for ISBT128-compliant labels
8. Supply inventory management

## 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 | Data Entry Clerk | Access to enter donor and donation data |
| 13 | 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 3. BSIS User Classes

## 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 Technical Manual intended for system administrators to manage the system on an on-going basis
* An Implementation Manual to provide guidelines and checklists for the deployment, training, support and change management process
* A 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.

# High-Level Business Processes

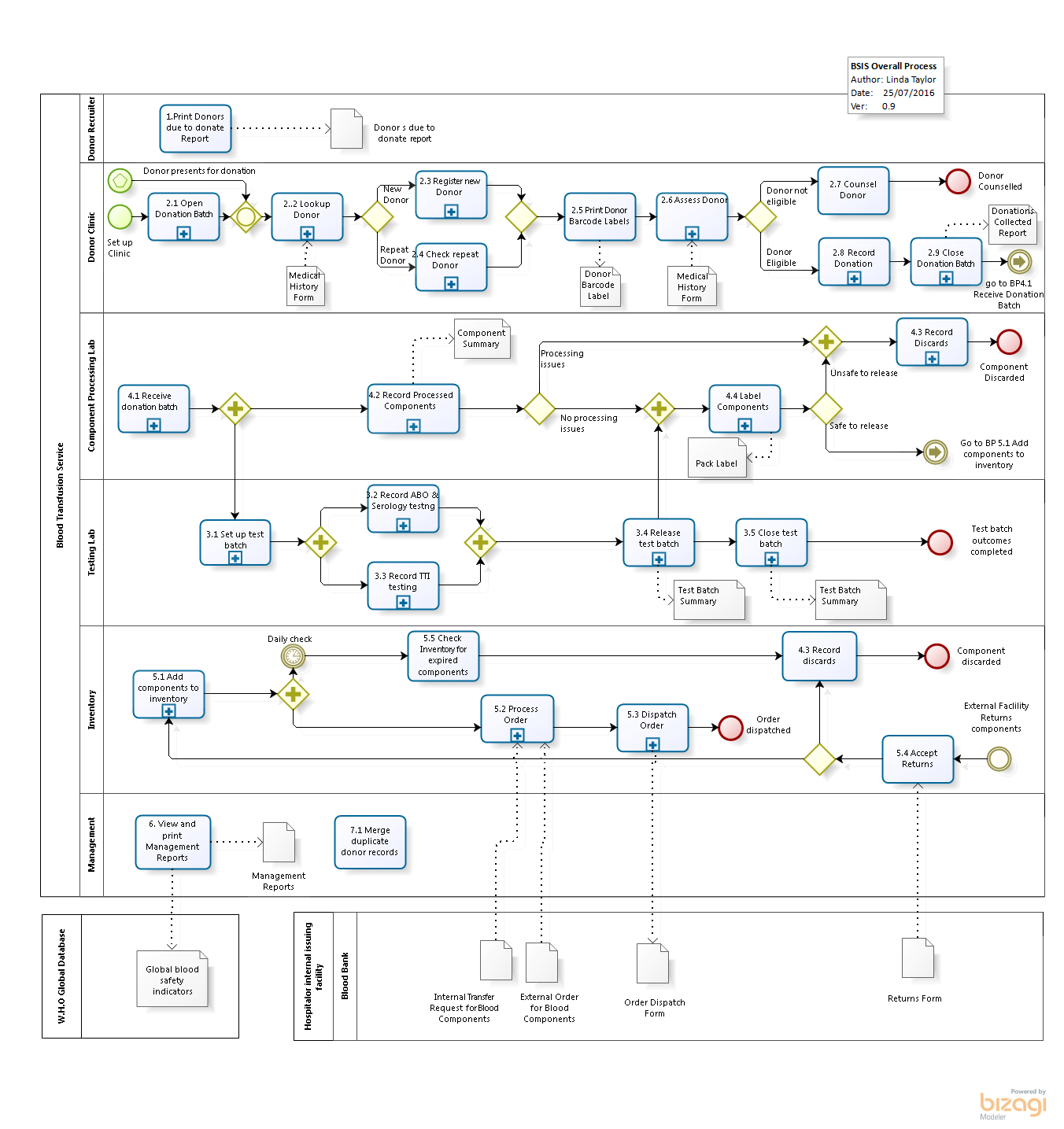
The following diagram shows the high level business processes for a blood service for those functions within the scope of this project.   


Figure 6 BSIS High-level business process

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

## 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**   1. 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**   1. 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**   1. 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**   1. 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**   1. 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. 2. 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. 3. 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**   1. 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.   **2.8 Record Donation**   1. 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. 2. 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. 3. 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. 4. 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. 5. 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. 6. The status of all donation units is automatically recorded as quarantined. 7. 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**   1. 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. 2. 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. |

## 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**   1. 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**   1. 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**   1. 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. 2. 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**   1. 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 Module.

## 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 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 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. BSIS automatically releases the component to the system inventory at this point. * 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 second lab technician must verify the labelled packs to ensure the correct label has been placed on the correct pack. * The labelled components are then placed into the dispatch fridge as they are now ready for issue and use. |

## 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. 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. |
| **NOTE:**   * *Order – from an external authorised facility i.e. a hospital or clinic or an internal order from another facility within the blood service* * *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* |

# 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 |

## 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. The barcodes must be in Codabar format. | 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 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).* | M | H | BP2.6 |
| **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 need for 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. | M | H | 3.4 |
| FR01-10-02 | The system must allow the donor counsellor to change the counselling status of the donor to indicate whether he/she: | M | M | 2.7 |
| 1) Received counselling; or 2) Refused counselling; or 3) 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 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 |
| **FR01-11** | **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 4: Functional Requirements for Donor Management

## FR01 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 5: Functional Requirements for Donation Management

## 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 1.0** | 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 1.0** | M | H | 3.3 |
| FR03-05 | **Provision for additional tests**  The system must make provision for the addition of additional tests such as screening for malaria parasites, as required by the blood service.  **OUT OF SCOPE FOR BSIS V 1.0** | 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**  The system must be able to determine the need for additional or repeat tests based on defined criteria as follows: | M | H | 3.4 |
| 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 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*.  **OUT OF SCOPE FOR BSIS V1.0** | 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. | M | M | 3.2 |
| FR03-09-04 | The system must check the antibody screening outcome and if is positive then the system must flag any associated components as unsafe. | 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 may be labelled for use if all the TTI test outcomes are negative****.***  ***OUT OF SCOPE FOR BSIS V1.0*** | 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. | 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 6: Functional Requirements for Testing

## 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 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 V1.0** | M | H |  |  |  |  |
| 002-03 | * Time elapsed since the donation was collected * **OUT OF SCOPE FOR BSIS V1.0** | M | H |  |  |  |  |
| 002-04 | * Bleed interval when the donation was collected * **OUT OF SCOPE FOR BSIS V1.0** | M | H |  |  |  |  |
| 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 V1.0** | 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 maximum and minimum weight limits must be configurable according to the pack type. | M | H | 4.1 |  |  |  |
| 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 and alert if bleed times > the configured limit for that component type as follows:*   * *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.”*  ***OUT OF SCOPE FOR BSIS V1.0*** | M | H | 4.2 |  |  |  |
| FR04-I008 | ***Check time and temperature since collection***  *When recording the processing of a component, the system must check time since donation collected and the temperature and the system must alert the user that only certain components can be made according to the component processing rules.*  ***OUT OF SCOPE FOR BSIS V1.0*** | M | H | 4.2 |  |  |  |
| 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 V1.0** | M | H | 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. | 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)   * 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) | M | H | 4.1,4.2, 4.3, 4.4 |  |  |  |
| 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 * Volume, storage and transport information   **SEE OUTPUT SPECIFICATION FOR PACK LABEL DESIGN**  The pack label barcodes are Code 128 format. | 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.   * 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. |  |  | 4.4 |  |  |  |
| 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 |  |  |  |
| FR04-016 | **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 |  |  |  |

## 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 |  |  |  |

## 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 | 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). Order information must include:   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. | M | M | 5.2 |  |  |  |
| FR06-002 | 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 | 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 | 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 | 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 | The system must be able to record when an issue is dispatched to an authorised facility and print a dispatch note. The system must automatically remove components from inventory when the order is dispatched to the authorised facility. | M | H | 5.3 |  |  |  |
| FR06-006 | 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 | 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 | 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 | 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 V1.0*** | 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) |  |  |  |  |  |  |

## 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 levels of configuration of the system:

* One is at the level where only a Super User is able to set or change parameters. This will be part of the initial installation of the system when it will be configured according the national blood service needs and will include those settings which MUST not change over time or are very unlikely to change over time.
* At the second level parameters 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 the back-end system in order to meet local requirements: | |  |  |
| FR07-01 | Blood Tests – Standard mandatory blood tests provided in the system (which may be set to “inactive” if not required). |  |  |
|  | 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 |  |  |
| FR07-02 | The component processing rules that determine valid combinations of components that can be processed from whole blood and/or other components must be defined at installation.  ***See detailed requirement of Blood Management Module for rules*** |  |  |
| **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) |  |  |
| 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 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 |  |  |
| FR07-04-03 | The System Administrator must be able to edit/amend an existing User |  |  |
| 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. |  |  |
| FR07-04-05 | The System Administrator must be able to assign and manage or re-set passwords associated with the User. |  |  |
| FR07-04-06 | The user must have the ability to re-set their own password |  |  |
| FR07-04-07 | The System Administrator must not be able to create a Super User or additional Administrators |  |  |
| **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** | 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 and 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 | 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 V1.0** | D | L |
| **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.  Se*e detailed requirement and related business rules for Blood Management module* |  |  |
| **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 |  |  |
| 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 |  |  |

Table 7: 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 |
| **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 |
| **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 |

Table 8: Functional Requirements for Global Properties

### Default Configuration Values

#### 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 9: Default Deferral Reasons and Deferral Periods

#### Default Discard Reasons

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

Table 10: Default discard reasons

#### 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 11: Default Adverse Events

# 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 deleted 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 a permanent deferral may not be edited or ended. | | | | |
| BR01-10 | If there are discrepancies between the ABO Rh blood group 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. | | | | |
| BR01-11 | A donor record can be deleted only if there are no recorded donations and/or deferral reasons and/or donor comments associated with the donor. | | | | |
| BR01-12 | A donor record may not be deleted if a barcode label with the Donor Number has been printed | | | | |
| 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 (or donor panel) can only have one donation batch open at any one time i.e. all donations collected at the venue during that session must be recorded as one batch. | | | | |
| 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 deleted if there are no donations in the batch.  A donation batch with 0 donations cannot be closed: it must be deleted. | | | | |
| 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 |
|  |  | | | | |
| **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 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 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 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 | | | | |
|  |  | | | | |
|  |  | | | | |
| **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 | | | | |
| 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 | | | | |
| BR07-04 | A component may only be returned from the usage site that it was issued to | | | | |
| BR07-05 | An order can only be cancelled prior to dispatch. | | | | |
|  |  | | | | |

Table 12: Business Rules for BSIS

# Detailed Functional Requirements Specifications

## 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 | |

## 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 | Back entry of data using Donation Batch Entry | | |
| 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.   1. The user scans in the Donor Number from the barcode label on the Medical History Form 2. 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 3. The user scans the DIN from the barcode label on the Medical History Form 4. The user selects the pack type from a dropdown list 5. The user selects the donation type from a dropdown list 6. 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. 7. 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. 8. 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 | |

## 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 | | | |

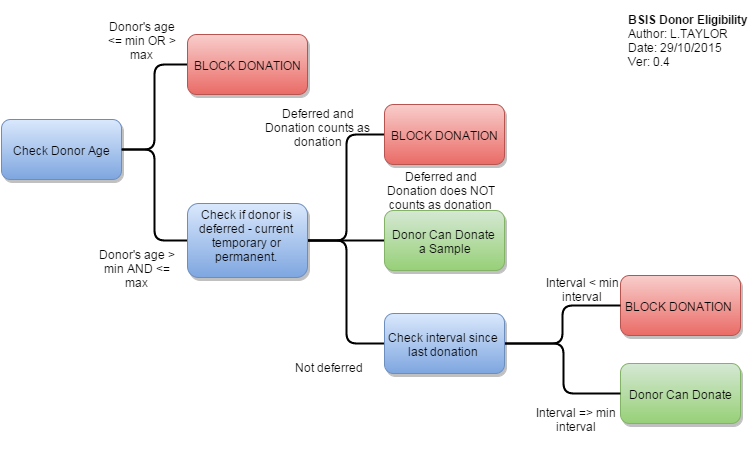


Figure 7: Donor Eligibility Decision Tree

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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** | **BLOCK** | **BLOCK** | **BLOCK** | **BLOCK** |
| Allow if donations does not Count as Donation? i.e. is a sample for Test Only | **ALLOW** | **ALLOW** | **ALLOW** | **ALLOW** | **BLOCK** | **BLOCK** | **BLOCK** | **BLOCK** |

Figure 8: Eligibility Rules Decision Table

## FR03-06 Record Test Batch Information

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| 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 |  | |
| **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)   1. 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. 2. The user must be able to close the test batch when all samples have completed testing and any discrepancies have been resolved. | |

## FR03-09 Enforce ABO Rh and serology testing rules

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| --- | --- | --- |
| 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** | 1. User records ABO Rh test outcomes with an AMBIGUOUS outcome i.e. the initial and repeat blood groups do not match 2. User can resolve this discrepancy and record the confirmed ABO Rh test outcome | |
| **Variation 5.1 B** | 1. User records ABO Rh test outcomes with an AMBIGUOUS outcome i.e. the initial and repeat blood groups do not match 2. 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.  **OUT OF SCOPE FOR BSIS V1.0** | | |



Figure 9: ABO Rh Testing

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| --- | --- | --- |
| 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. |
| **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  Then COMPONENT\_STATUS= UNSAFE  **Note:**   * At the point of labelling: Any donation with a positive antibody screening test outcome will be flagged as UNSAFE in BSIS and cannot therefore be labelled for use. Although the standards allow for the use of components that do NOT contain plasma if the antibody screening test is POSITIVE, BSIS does not differentiate between components containing plasma and those that do not. This refinement will be included in a future version. * 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. | | |

## FR03-10 Enforce TTI testing rules

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| --- | --- | --- |
| 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 | 1. User selects the open test batch from the Manage Test Batch screen 2. The test batch containing all the donation samples is displayed showing a TTI Status of NOT DONE for all samples 3. User selects Record TTI Test Results 4. The screen displays a list of all donation samples sorted by DIN 5. User enters a NEG value for the HIV, HBV, HCV and Syphilis for each donation sample in the test batch 6. User saves the results 7. The screen display a list of all donation samples sorted by DIN with a TTI Status of SAFE 8. User can proceed to Release Test Batch | |
| **Variation 5.1 A** Screening test is POSITIVE and repeat tests (Conf1 and Conf2) are both NEGATIVE | 1. User enters a POS value for any of the HIV, HBV, HCV and Syphilis for one or more donation samples in the test batch 2. User saves the results 3. 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 4. The screen displays *Record Confirmatory Test Results* 5. User selects *Record Confirmatory Test Results* 6. 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 7. 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 8. According to the processing rules below the screen displays the relevant TTI Status for each donation sample and no confirmatory test is required 9. All donations samples that have all necessary tests completed will be displayed as TTI Status of SAFE or UNSAFE 10. 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 | 1. User enters a POS value for any of the HIV, HBV, HCV and Syphilis for one or more donation samples in the test batch 2. User saves the results 3. 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 4. The screen displays *Record Confirmatory Test Results* 5. User selects *Enter Confirmatory Test Results* 6. 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 7. User enters    1. a POSITIVE outcome for repeat test 1 (Conf1) AND repeat test 2 (Conf2)    2. 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   1. 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 2. 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 3. If the confirmatory outcomes are available the user can enter these for the samples requiring confirmatory results and save the results 4. 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)*   1. Any donation samples that still have outstanding confirmatory tests will be displayed as NOT DONE 2. 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. | |
| Assumptions | NONE | |
| Exclusions | NONE | |
| 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 |

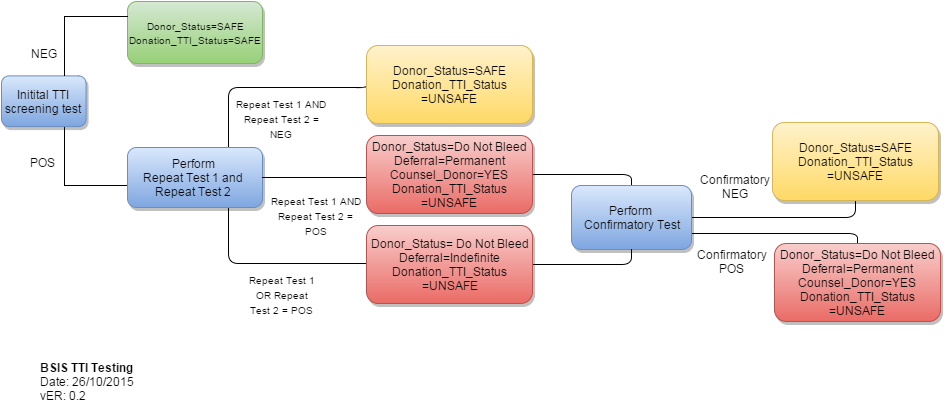


Figure 11: BSIS TTI Testing Algorithm

## FR01-013 Merge Duplicate Donor Records

|  |  |  |
| --- | --- | --- |
| 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 |  |
| Inputs |  | |
| Outputs |  | |
| **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. |

## FR04-006 Record and verify pack weight

|  |  |  |
| --- | --- | --- |
| 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 minimum weight for that pack type) then the component 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 component must be flagged for discard. | |
| 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 |
| Inputs |  | |
| Outputs |  | |
| **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 pack/component to ensure that only packed red cells (red cell concentrate) can be made from this pack. | |
| 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-xx | 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. |
| Screen Design |  | |
| 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   (*Ref AABB Technical manual 18th edition pp 141: Low volume between 300 and 404ml may be used to prepare packed cells only*)   1. 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 can only make packed red cells or choose to discard  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. | |

## 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.   + 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. * 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 | |  | |
| Processing Rules | |  | |
| Figure 12: Label Component Rules | | | |
| Output Specification  100mm x 100mm pack label according to output specification printable by a Zebra printer | 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)  ABO Rh blood group (text and barcode)  Collection date (text and barcode)  Component Code (text and barcode)  Expiration date (text and barcode)  Volume of initial 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)   |  |  | | --- | --- | | DIN Donation Identification Number  Collection Date  Source of the donation | ABO Rh blood group | | Component Code  Component Name  Storage and Transport information | Expiration Date and Time |   Required Bar Codes:  Donation Identification Number DIN  ABO/Rh Blood Group  Collection Date  Component Code  Expiration Date and Time | | |
| Pack Label Sample |  | | |
| Discard Label Sample |  | | |

# 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.  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. | 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 been recorded for that donor the donor will no longer appear on the list. | M | O |
| 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 requirement for AfSBT accreditation. | 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 be found. | M  High Priority | M |
| IR03 | Component Proccessing and Inventory | | | | |
| 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 |
| 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 and fulfilment. |  | M | O |

Table 13: Summary of Informational Requirements

# Detailed Informational Requirements

## 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 |  |

## 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. |
| 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 or more from drop-down list OR select Any Venue |
| Donation Period: - Period between two selected dates-Day, Month, Year OR select Any Date |
| 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 |
| 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: "List of Donors for Post-Donation Counselling t" |
| 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 |
| 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 |  |

## 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 |  |

## 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 | |
|  | |

## IR01-005 Donations Collected By Type Report

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| --- | --- |
| **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 |

## IR01-011 TTI Prevalence Report

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| --- | --- |
| **IR01-011** | **Detailed Requirements** |
| **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 |
| Media | Electronic report |
| Frequency | Ad-hoc but usually monthly or quarterly |
| Constraints | The user must select Reports option on main menu |
| Report steps | The user must select **TTI Prevalence Report**option from sub-menu |
|  | The user must select report criteria, select option to print to PDF or CSV and then select Print button |
| Comments | Aggregate report |

## IR02-003 ABO Rh Blood Grouping Report

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| --- | --- |
| **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 |
| Media | Electronic report |
| 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 |
| Comments | Aggregate report |

# 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** | **Performance and Capacity Requirements** |  |
| NFR01-01 | The system should be designed to store a minimum of 1,000,000 donor records | M |
| NFR01-02 | The system should be designed to store a minimum of 4,000,000 donation (collection) records. Each of the donations may be processed into three separate components which will retain the same identification number as the original unit, meaning a total of 16,000,000 possible component records. | 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 individuals. | M |
| **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** | **Laboratory Equipment Interface Requirements** | | |
|  | **NB: The system will interface with standard laboratory equipment defined in the table below but laboratory equipment will vary on an implementation-basis and the approach and process followed for a request to interface with other laboratory equipment is defined in the Implementation Guide.** | | |
|  | The system must interface with the following laboratory 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: Laboratory Equipment Interface Requirements

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| --- | --- | --- |
| **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

# 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.

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| --- | --- | --- |
| 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. |
| QUARANTINED | UNSAFE | One or more of the initial screening TTI test outcomes are POSITIVE for this sample  (TTIStatus.TTI\_UNSAFE) |
| QUARANTINED | UNSAFE | One of 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. |
| 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. |
| 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. |
| 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 |

|  |  |  |
| --- | --- | --- |
| 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 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. |

|  |  |  |
| --- | --- | --- |
| 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 whilst after the component has been labelled. The printing of a pack label (NOT a discard label) for a component automatically adds the component to the inventory: | | |
| IN STOCK | AVAILABLE | The component is labelled 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 |