

**STANDARDS
OF PRACTICE FOR
BLOOD TRANSFUSION
IN SOUTH AFRICA**

7th Edition

Issued March 2016

Amendment October 2016

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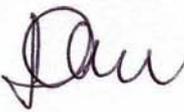
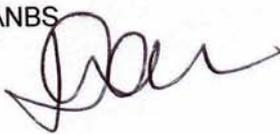
STANDARDS OF PRACTICE FOR BLOOD TRANSFUSION IN SOUTH AFRICA

Approved by the Medical Directors of Western Province Blood
Transfusion Service (WPBTS) and South African National Blood
Service (SANBS), and endorsed for use by the Board of
Directors of WPBTS and the CEO of SANBS

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CEO/ Medical Director, WPBTS: 	Medical Director SANBS: 
For WPBTS Board of Directors: 	CEO SANBS: 

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SECTION 1 : INTRODUCTION

These Standards represent accepted performance requirements that may be exceeded in practice and establishments may be more rigorous in their internal requirements. There may be legal and government requirements that apply as well. While every effort has been made to comply with the relevant Acts and Regulations governing blood transfusion in South Africa, no assurance can be given that compliance with these Standards will guarantee compliance with all relevant legislation. Nevertheless, by conforming to these Standards, policies, processes and procedures will be maintained that will ensure safe and effective blood transfusion practice and a safe working environment.

Definitions

In these Standards any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned and, unless the context otherwise indicates -

“**allogeneic**” (allogenic) means genetically dissimilar within the same species.

“**apheresis**” means removal of one component of blood and the return of the remaining components to the donor.

“**blood**” means blood intended for transfusion purposes including the components thereof, but excluding blood specimens intended for pathology testing.

“**blood component**” and/or “**blood product**” and/or “**component**” means any constituent of blood derived from 12 or fewer blood donations which is separated from blood by physical and/ or chemical means;

“**blood donor**” means any living, voluntary, non-remunerated person from whom blood is withdrawn for the subsequent administering thereof to another living person or to himself or for the processing into blood products.

“**blood donation**” means the act of withdrawing blood or plasma from a blood donor and may also refer to the unit of blood so collected.

“**Blood transfusion service**” means the national blood transfusion services licensed in terms of the regulations to withdraw blood from blood donors, to process blood into blood components and to issue such blood and blood components to health care professionals for administration to patients; the national fractionation establishments and other approved institutions.

“**calibration**” means a procedure that confirms under defined conditions, the relationship between values obtained from an instrument or system with those obtained using an appropriate certified standard. It may also include an adjustment activity.

“**compatibility test**” means a procedure whereby a donor blood component is tested to ensure serological compatibility with the intended recipient.

“**constituent part**” means any regional units, branches, offices or any other units or premises of the national blood transfusion services.

“**Chief Executive Officer**” means the executive director appointed by the board of the blood transfusion service as the director ultimately responsible for the overall effective functioning of the establishment.

“**crossmatch**” means a procedure whereby the donor red blood cells are directly mixed with the recipient serum to confirm ABO and/or other red cell antigen compatibility.

“**cytapheresis**” means the removal of the cellular components of blood and the return of the remaining components to the donor without causing anaemia or hypovolaemia.

“**document**” means all written instructions and records involved in providing a product or service.

“**document control**” means the control of the issue, use and review of authorised documents within the quality management system.

“**donor**” means the same as “blood donor”.

“**establishment**” means the national blood transfusion services including all their constituent parts and delegated responsibilities.

“**fractionation**” means the preparation of blood components or fractions by physical and/ or chemical processes.

“**haemoglobin**” means the constituent of red blood cells responsible for the oxygen carrying capacity.

“**haematocrit**” means the proportion of red blood cells in the blood.

“**he/his/him**” automatically includes the opposite gender as well.

“**Good Laboratory Practice (GLP)**” means ensuring that laboratory functions are carried out in accordance with regulatory requirements and may include planning, performance, monitoring, recording and reporting of laboratory functions.

“**Good Manufacturing Practice (GMP)**” means ensuring that products are consistently produced and controlled in accordance with appropriate standards and regulatory requirements.

“**licensed**” means licensed by the appropriate government body.

“**management**” means senior personnel appointed by the Chief Executive Officer (and other executive directors) to supervise and manage designated departments of the blood transfusion service.

“**medical director**” means the executive director qualified by training and/or experience in blood transfusion and related disciplines, who has the responsibility and authority for all medical and technical policies and procedures and for all support services which relate to the safety of donors and the recipients of blood products.

“**plasmapheresis**” means the removal of the plasma component of blood and the return of the remaining components to the donor without causing anaemia or hypovolaemia.

“**proficiency programme**” means a system where blind samples are tested and results submitted for review and comparison with expected outcomes, to monitor the capability of staff and test procedures to perform correctly. It may include external Quality Assurance (EQA) and/ or Inter-laboratory programmes (ILP).

“**quality assurance**” means the planned and systematic activities implemented by the establishment in a quality management system to ensure that services and blood products meet specifications and quality requirements.

“**quality audit**” means a systematic examination of the quality management system and related activities by an internal or external quality auditor or audit team.

“**quality control (QC)**” means a system of routine activities, to measure the quality of activities involved in the production of blood and blood products.

“**quality management system**” means a system which includes the establishment of a quality policy, quality objectives and the overseeing of all activities needed to maintain the desired level of excellence and implementation of continual improvement.

“**quality record**” means a document stating results achieved or providing evidence of activities performed which have an effect on quality.

“**regulations**” means the Regulations Relating to Blood and Blood Products.

“**sample**” means a small quantity of blood taken from a blood donor, donation or a patient for testing purposes.

“**standard operating procedure (SOP)**” means a document that provides step by step instructions for the performance of a particular procedure which could impact on the safety of donors and recipients of blood and blood products, and such procedures include medical, laboratory and clerical procedures, as well as the computer programmes associated with them.

“**therapeutic phlebotomy**” means the removal of whole blood from patients for therapeutic purposes.

“**validation**” means a planned and systematic exercise to ensure that new equipment, tests or processes are fit for their intended purpose and meet predefined specifications.

“**withdrawal of blood**” means the taking of a blood sample or donation.

“**work instruction (WI)**” means the same as “standard operating procedure” and can be used interchangeably.

SECTION 2 : QUALITY MANAGEMENT SYSTEM

Standard 1 Resources

- 1.1 Financial resources
 - 1.1.1 The establishment shall identify financial resource requirements adequate to perform, verify and manage its activities.
 - 1.2.1 The establishment shall develop a budget to ensure its ongoing operation.
 - 1.3.1 Relevant areas of the establishment shall be furnished with all the necessary equipment required for the correct performance of operations and/or tests.
- 1.2 Human resources
 - 1.2.1 The establishment shall have sufficient, trained managerial and technical personnel to carry out their duties, including the implementation, maintenance and improvement of the quality management system.
 - 1.2.2 Personnel performing specific assigned tasks shall be qualified on the basis of education, training and/or experience.
 - 1.2.3 Personnel shall be registered with the relevant professional body, in the correct category.

Standard 2 Organisation and structure

- 2.1 Responsibility for the activities detailed in these Standards shall be assigned to individuals. These individuals may be responsible for more than one activity.
- 2.2 Organogram
 - 2.2.1 There shall be an authorised organogram that shows clear delineation of reporting structure, and inter-relationships between operations, support services and quality functions. This organizational structure shall be captured in writing or electronically.
 - 2.2.2 The organogram shall be reviewed at establishment defined intervals and updated as required.

2.3 Chief Executive Officer (CEO)

- 2.3.1 The establishment shall be under the direction of a designated person(s) qualified by training and/or experience who shall be responsible and accountable for ensuring that all operations are carried out properly and competently as required by the relevant laws and regulations. This individual may also be the Medical Director.

2.4 Medical Director

- 2.4.1 The establishment shall have a Medical Director qualified by education, training and/or experience in blood transfusion.
- 2.4.2 The Medical Director shall have responsibility and authority for all medical matters and for the consultative and support services relating to the care and safety of donors and/or patients. The Medical Director may delegate these responsibilities to another qualified individual (Medical Officer); however, the Medical Director shall retain ultimate responsibility for the delegated duties.
- 2.4.3 Exceptions to procedures warranted by clinical situations shall require justification and pre-approval by the Medical Director/ Medical Officer on a case-by-case basis. This deviation shall be documented.

2.5 Quality manager

- 2.5.1 A designated individual shall be appointed with overall responsibility for quality within the establishment. This individual shall be responsible for the implementation and maintenance of the quality system.
- 2.5.2 This individual shall report directly to the top management, or to another designated individual who has no direct managerial or supervisory role in collection, processing, testing or distribution of blood.
- 2.5.3 In the event of a lack of consensus between the quality manager and persons responsible for operational areas, the Chief Executive Officer shall make the final decision and the circumstances shall be documented.

2.6 Technical manager(s)

- 2.6.1 The establishment shall have technical manager(s), qualified by education, training and/or experience, responsible for decisions relating to technical aspects of blood collection, processing, testing and issue.

Standard 3 Personnel and Training

3.1 Job descriptions

- 3.1.1 The establishment shall retain job descriptions for all personnel that outline key responsibilities and duties to be performed. Personnel shall have access to their job descriptions.
- 3.1.2 Job descriptions shall be reviewed at defined intervals and updated as required.
- 3.1.3 Job title and reporting structure detailed in the job description shall correlate with the pertinent information in the establishment's organogram(s).

3.2 Training and competence

- 3.2.1 There shall be a training policy and documented programme to ensure all personnel are trained and competent to perform their assigned activities.

- 3.2.2 There shall be a system for identifying the training needs of staff.
- 3.2.3 There shall be a system for competence assessment of individual personnel at establishment defined intervals.
- 3.2.4 Records shall be kept of staff training and competency assessments.

Standard 4 Quality management system

- 4.1 The establishment shall design, implement, maintain and improve a quality management system, including a quality policy, to address the requirements of this section.
- 4.2 The quality system shall be communicated within the establishment so that all personnel understand their role in ensuring quality.
- 4.3 Management shall review and evaluate the quality system at planned intervals and take action to ensure its continuing suitability, adequacy and effectiveness.
- 4.4 The establishment shall maintain a quality manual that explains how the elements of the quality system apply or have been implemented. This shall include the structure of the documentation used in the system.
- 4.5 The establishment shall have Standard Operating Procedures (SOPs) for all processes that may impact on the quality of blood products and services.

Standard 5 Document control

- 5.1 The establishment shall establish and maintain a system for controlling documents that may affect the quality of products or services.
- 5.2 The system shall address document creation, identification, review, approval, revision, and retention and shall define procedures for making changes to documents, obtaining the necessary authorisation and communicating these changes to staff.
- 5.3 Documents that affect the quality of products or services shall be:
 - 5.3.1 Uniquely identified
 - 5.3.2 In a standardized format in any medium, such as hardcopy or electronic media, provided that legal requirements are met. Additional procedures may be referenced, eg. manufacturer's instructions.
 - 5.3.3 Current and dated to prevent the use of invalid or obsolete documents
 - 5.3.4 Reviewed and approved by authorized personnel prior to use
 - 5.3.5 Legible and readily accessible to personnel who rely on them to perform activities. Methods of copying/ archiving shall be appropriate for the system in use.
 - 5.3.6 Reviewed at least every two years and revised, as needed, according to establishment defined change control procedures
 - 5.3.7 Removed from points of issue or use when obsolete or invalid
 - 5.3.8 Archived according to the establishment's defined retention policy
- 5.4 Obsolete/invalid master documents shall be suitably marked and archived for legal and/or reference purposes.
- 5.5 Changes to procedures/ instructions shall be approved by authorised personnel responsible for making the change and the nature of the change should be documented.

Standard 6 **Records**

- 6.1 Record-keeping
 - 6.1.1 Records are created when forms are completed or data entered onto a computer system. The establishment shall ensure identification, collection, indexing, access, filing, storage, and disposition of records.
 - 6.1.2 Records shall be legible, complete, retrievable in a period of time appropriate to the circumstances, and protected from damage.
 - 6.1.3 A system for storage of records, to prevent unauthorized access, copying, modification or destruction and to ensure confidentiality of information, shall be established and followed.
 - 6.1.4 The record system shall make it possible to trace blood or blood products from source to final disposition; including key processing and testing instrumentation used (eg. plasma separators, laboratory analysers), screening and testing results, the result of any other monitoring performed, and to investigate adverse reactions in patients.
- 6.2 Records of the following, with relevant details, are required for donors:
 - 6.2.1 Surname, first name and other initials
 - 6.2.2 Gender
 - 6.2.3 Date of birth
 - 6.2.4 Verified identity number, where possible
 - 6.2.5 Contact address and telephone numbers
 - 6.2.6 ABO, Rh and any other blood group antigens present, if tested previously
 - 6.2.7 Relevant remarks as to suitability/deferral for future donations.
 - 6.2.8 Unique identifier to allow information to be linked to the donor.
- 6.3 Records of the following are required for donations:
 - 6.3.1 Collection or processing site
 - 6.3.2 Unique serial number of donation (linked to donor record)
 - 6.3.3 Date collected
 - 6.3.4 Staff responsible for the collection/processing of the blood
 - 6.3.5 Processing/separation date and time, where applicable
 - 6.3.6 Expiry date
 - 6.3.7 ABO and Rh grouping
 - 6.3.8 Test results for transfusion transmissible diseases
 - 6.3.9 Person responsible for checking the unit of blood for suitability prior to issue
 - 6.3.10 Unsuitable units, with a reason and discard details, including waste container number
 - 6.3.11 Final disposition of the unit

- 6.3.12 Person, hospital, institution or laboratory blood was issued to
- 6.3.13 Date and time of issue.
- 6.4 The establishment shall keep a record of statistics with the following information:
 - 6.4.1 The number of registered blood donors.
 - 6.4.2 The total number of blood donors from whom blood is withdrawn.
 - 6.4.3 The number of containers of blood.
 - 6.4.4 The total number of containers of blood issued as whole blood or red cell concentrates.
 - 6.4.5 The total number of containers of blood processed into blood products.
 - 6.4.6 The number of containers of blood which were condemned or discarded and the reason for which they were condemned or discarded.
 - 6.4.7 The number of untoward reactions, including transfusion transmissible diseases, or deaths.
- 6.5 The establishment shall keep the following records for all commercial or in-house test kits, cells and antisera:
 - 6.5.1 Name, batch number and expiry date
 - 6.5.2 Procedures followed for preparation
 - 6.5.3 Quality Control performed, daily or with each batch of tests
 - 6.5.4 Pre-acceptance testing/ checking
 - 6.5.5 Storage temperature compliance.
- 6.6 The establishment shall keep a record on which shall be entered every reported incident of an untoward reaction, including transfusion transmissible disease, or death apparently caused by the administering of blood or a blood product supplied by the establishment, and the serial number or designation of the container(s) involved in the incident.
- 6.7 The establishment shall maintain haemovigilance records.
- 6.8 Records shall be created concurrently with performance of each critical activity. The actual result of each test performed shall be recorded immediately and the final interpretation shall be recorded upon completion of testing.
- 6.9 Changes or corrections made shall be dated and signed. Equivalent measures shall be in place for electronic documents.
- 6.10
 - 6.10.1 Strict confidentiality shall be observed by all employees with regard to all information pertaining to blood donors, recipients and staff in whose treatment the blood transfusion service is involved.
 - 6.10.2 Access to sensitive medical information shall be limited to only those individuals in the organisation who are authorised.
- 6.11 The establishment shall retain records pertaining to donor assessment, laboratory tests, patient records and final disposition of each product, as well as SOPs, in accordance with legislation. Retention time for all other records is to be stipulated in relevant SOPs.

- 6.12 Electronic records
- 6.12.1 There shall be procedures to support the management of computer systems.
 - 6.12.2 There shall be a system in place for routine backup of all critical data. Backup data shall be stored in an off-site location.
 - 6.12.3 Procedures shall be in place to ensure that data are retrievable and usable.
 - 6.12.4 Electronic documents shall indicate who the signatory is, although this does not have to be by physical signature.
- 6.13 Where the establishment has identified the need for statistical analysis for monitoring and controlling processes, this analysis shall follow acceptable statistical techniques and be documented.

Standard 7 Computer systems

- 7.1 The establishment should, where feasible, use an electronic information technology (IT) system(s) in donor management, laboratory testing and product issuing systems for the recording, extraction and analysis of data.
- 7.2 The responsibility for final validation, or acceptance of the validation by the supplier of the software, is that of the establishment. The establishment shall give particular attention to the validation of integrated systems involving disparate software from different sources.
- 7.3 The establishment shall ensure that the design, validation, documentation and changes to software, which may affect the quality of products or services, are carried out by qualified persons and controlled in a systematic way.
- 7.4 The establishment shall have procedures to ensure continuous operation of essential processes in the event of any IT system failure.
- 7.5 The establishment may use an IT system to facilitate accurate review of records, and to permit or withhold the issue of an individual blood product or result, however, the issuing of correct products or results, is the responsibility of the designated person issuing them.
- 7.6 Where a computer system is used to capture data directly from test equipment, the establishment shall have a procedure for the verification of this data, be able to demonstrate the accuracy of the system and ensure that it is fully secure against the possibility of non-conforming product or test results being released.
- 7.7 Computer systems (hardware and software) shall be maintained to protect the integrity of data and to ensure retrieval of data when required.
- 7.8 The establishment shall have defined levels of access, and ensure protection against unauthorised access, to computer systems.
- 7.9 An audit trail permitting the identification of operators entering data or editing records shall be available. A record of the original data shall be available.
- 7.10 The establishment shall have procedures for the back-up, disaster recovery and restoration of data.

Standard 8 Management review

- 8.1 The establishment shall have a procedure for management to review the quality system at defined intervals to ensure its continued suitability, to assess opportunities for improvement, and the need for changes to the quality system.
- 8.2 The review shall include:

- 8.2.1 Feedback, including complaints, from donors and customers/clinicians.
- 8.2.2 The number of untoward reactions, including transfusion transmissible diseases, or deaths.
- 8.2.3 Outcomes of internal audits and external assessments, including safety if applicable.
- 8.2.4 Corrective and preventive actions
- 8.2.5 Statistics collected on the number of registered blood donors, total number of blood donors from whom blood is withdrawn, total number of containers of blood issued as whole blood or red cell concentrates, total number of containers of blood processed into blood products.
- 8.2.6 The number of containers of blood which were condemned or discarded and the reason for which they were condemned or discarded.
- 8.2.7 Results of EQA along with any corrective action where necessary
- 8.3 Records of the management review shall be maintained.
- 8.4 Monitoring and evaluation data shall be used to improve establishment operations.

Standard 9 Purchasing and materials

- 9.1 The establishment shall have procedures to ensure that purchased items that have an effect on product quality, conform to specified internal requirements.
- 9.2 The establishment shall receive, inspect and test, as necessary, incoming products and critical materials before acceptance or use.
- 9.3 Acceptance criteria for critical incoming materials ie. blood packs, labels, reagents and test kits shall be available and records of acceptance kept.
- 9.4 Materials, including items listed above, shall be stored in accordance with manufacturer's instructions.
- 9.5 The establishment shall develop, implement and maintain an inventory management system.
- 9.6 Reagents prepared by the establishment shall be appropriately labelled and standardised to meet or exceed specifications. Results of tests performed on reagents shall be documented.
- 9.7 The establishment shall have procedures for the evaluation and selection of suppliers based on the supplier's ability to meet specific technical and quality assurance requirements.
- 9.8 A list of approved suppliers for critical items shall be maintained and reviewed at defined intervals.
- 9.9 Contracts shall be maintained between the establishment and suppliers for critical materials.

Standard 10 Evaluation of sub-contractors

- 10.1 The establishment shall evaluate and select sub-contractors on the basis of their ability to meet specific technical and quality assurance requirements.
- 10.2 Records of approved sub-contractors shall be maintained and reviewed at defined intervals.
- 10.3 Contracts for testing must define the test methods to be used.
- 10.4 Contracts and agreements must be reviewed and updated when required.
- 10.5 The establishment is responsible for ensuring that subcontractors performing services are preferably accredited and comply with these Standards.

Standard 11 Process Control

- 11.1 The establishment shall ensure that activities that affect the quality of blood, blood products, and services are carried out under controlled conditions.
- 11.2 Testing methods
 - 11.2.1 Test methods used must preferably be in accordance with international/national/regional standards, or published scientific text, or as specified by the manufacturer of the test equipment, reagent or kit.
 - 11.2.2 Procedures shall be in place for the transportation, acceptance criteria, receipt, handling, storage and disposal of samples/test items.
 - 11.2.3 Test results must be reported accurately, clearly, unambiguously and objectively.
 - 11.2.4 The establishment shall document which staff are authorised to verify and issue results and records should include the identity of personnel responsible for testing and releasing of results.
- 11.3 Validation activities
 - 11.3.1 The establishment shall develop and implement procedures for the validation of new or changed procedures, test methods, reagents and software prior to implementation.
 - 11.3.2 Validation plans should be approved prior to the work being undertaken.
 - 11.3.3 Results shall be reviewed and acceptance/rejection decisions made by authorised individuals.
 - 11.3.4 Re-validation shall be performed where changes have occurred or results indicate the need.
- 11.4 Internal and External Quality Assessment (IQA/EQA)
 - 11.4.1 The establishment shall develop and implement a system for determining the accuracy and reliability of tests. If the establishment does not participate in a formal EQA programme for some or all tests, there shall be an IQA, proficiency or inter-laboratory programme to ensure the accuracy of tests.
 - 11.4.2 Results of IQA and EQA shall be reviewed and corrective action taken, where appropriate, when expected results are not achieved.
- 11.5 Quality Control
 - 11.5.1 A programme of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods function as expected.
 - 11.5.2 The establishment shall randomly sample and perform quality control testing on blood components.
 - 11.5.3 The establishment shall analyse quality control results. If analysis shows a consistent deviation away from specifications, the cause thereof shall be investigated and corrective measures shall be taken.
- 11.6 Change Control
 - 11.6.1 The establishment shall have procedures for the management of changes to the establishment's operations, and quality system so that the quality of products and services is maintained.

Standard 12 Equipment

- 12.1 Selection of equipment
 - 12.1.1 The establishment shall define, select and evaluate equipment on the basis of its ability to meet specific technical and quality assurance requirements. Equipment shall be capable of achieving the required acceptance criteria.
 - 12.1.2 Service contracts/ Service Level Agreements (SLA) should be maintained between the establishment and suppliers of critical equipment.
- 12.2 Equipment qualification
 - 12.2.1 All critical equipment shall be qualified on-site for its intended use.
- 12.3 Use of equipment
 - 12.3.1 Equipment shall be adequate in number and placed in a location suitable for its optimal operation.
 - 12.3.2 Equipment shall be operated by authorised personnel in accordance with manufacturer's instructions.
 - 12.3.3 Equipment shall be uniquely identified.
 - 12.3.4 There shall be a list of critical equipment, including emergency donor care equipment, and its location.
- 12.4 Calibration
 - 12.4.1 Calibration programmes shall be established for critical instruments where these have a significant effect on results.
 - 12.4.2 Calibrations shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations shall be performed before use, after activities that may affect the calibration and/or at intervals prescribed by the manufacturer.
 - 12.4.3 Calibration measurements must be traceable to the International System of Units (ie. SI units), where possible.
 - 12.4.4 There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting.
 - 12.4.5 Correction factors shall be applied and recorded on calibration records, together with reference equipment used.
- 12.5 Equipment monitoring and maintenance
 - 12.5.1 There shall be scheduled monitoring and preventive maintenance programmes so that equipment remains fit for use.
 - 12.5.2 The programmes shall include/define: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.
 - 12.5.3 Records shall be kept of maintenance carried out.
 - 12.5.4 Equipment shall be decontaminated prior to any maintenance, calibration or investigation, where possible.
- 12.6 Equipment malfunction. Investigation and follow-up of equipment malfunctions, or damage shall include:

- 12.6.1 Removal of the equipment from use and/or isolation, and identification as not suitable for use.
- 12.6.2 Assessment of blood and blood products affected by equipment that is found to be out of calibration.
- 12.6.3 Assessment of the effect on donor eligibility and donor and patient safety.
- 12.6.4 Investigation of the malfunction or damage.
- 12.6.5 Steps for requalification of the equipment.
- 12.6.6 Reporting the nature of the malfunction or damage to the manufacturer, when indicated.

Standard 13 Identification and Traceability

- 13.1 The status of a blood product shall be identified by appropriate labelling. If the product is not labelled, it shall be stored in a particular physical location that is segregated and labelled indicating the status.
- 13.2 The establishment shall ensure that blood and blood products are identified and traceable from source to final issue or disposition. Critical materials used in processing, laboratory samples, donor and patient records shall be identified and traceable.
- 13.3 For each critical step in collection, processing, blood grouping, transfusion transmissible infection screening, compatibility testing and transportation of blood and blood products, there shall be a mechanism to identify who performed the step and when it was performed.

Standard 14 Non-conforming product

- 14.1 Identification and segregation
 - 14.1.1 The establishment shall have procedures to record, identify and segregate blood products that are found to be unacceptable for further processing or issue at any stage in processing, from collection to issue.
- 14.2 Authorised use
 - 14.2.1 The Medical Director (or designated Medical Officer) shall be responsible for reviewing and giving authority for the acceptance of non-conforming blood products where the non-conformance is not anticipated to have an adverse effect on the recipient, and this shall be documented.
- 14.3 Discard
 - 14.3.1 The establishment shall have a procedure for the discard of non-conforming products.
 - 14.3.2 Such products shall be labelled as not suitable for therapeutic use and shall be disposed of as biohazardous waste.
 - 14.3.3 Disposal methods shall comply with the requirements of the waste disposal authority and/or local environmental regulations.
 - 14.3.4 The establishment shall keep a record, including date, reason and waste container number, of disposal of non-conforming blood products for purposes of completing the audit trail for such products.
- 14.4 Recall
 - 14.4.1 The establishment shall have procedures for the recall of non-conforming products, including those issued in an emergency, that are determined after release not to meet specified requirements.

Standard 15 Non-conformances, corrective and preventive actions

- 15.1 The establishment shall have procedures to detect, capture, assess, investigate and monitor non-conformances, including those found as the result of internal and external audits.
- 15.2 The responsibility for review and authority for the disposition of non-conforming blood, blood products, critical materials, and services shall be defined.
- 15.3 Corrective action. The establishment shall have procedures for addressing non-conformances, complaints, work place accidents and incidents that include the following elements:
 - 15.3.1 Description of the event
 - 15.3.2 Immediate remedial action
 - 15.3.3 Investigation of the root cause
 - 15.3.4 Determination of corrective action required
 - 15.3.5 Verification/checking of corrective action should be performed.
- 15.4 Preventive action. Procedures for preventive action shall include the following elements:
 - 15.4.1 Review of information including audit results, proficiency testing results, quality control records, and complaints to detect and analyse potential causes of non-conformances.
 - 15.4.2 Determination of steps needed to respond to potential problems requiring preventive action.
 - 15.4.3 Initiation of preventive action and application of controls to monitor effectiveness.
 - 15.4.4 There shall be scheduled reviews of non-conformances to detect trends and address areas requiring specific action.

Standard 16 Donor and clinician interface

- 16.1 The establishment shall have a procedure for recording, reviewing and investigating relevant complaints and for giving feedback to the complainant.
- 16.2 There shall be a system for obtaining feedback from donors and clinicians.
- 16.3 The establishment shall provide clinical guidelines for the appropriate use of blood and blood products.
- 16.4 The establishment shall provide continuing education in transfusion practice for clinicians.
- 16.5 The establishment shall have procedures for providing timely clinical consultation to clinicians.
- 16.6 There shall be procedures to communicate with clinicians that promote availability and appropriate use of blood and blood products.
- 16.7 There shall be procedures to communicate with clinical personnel about reporting of adverse events.
- 16.8 The establishment shall perform ongoing evaluations of the need for blood and blood products, and their supply that includes periodic monitoring of blood usage.

Standard 17 Internal and external audits

- 17.1 Internal audits
 - 17.1.1 The establishment shall establish and maintain a documented quality audit programme to monitor compliance with requirements.

- 17.1.2 The establishment shall designate trained personnel, independent of those having direct responsibility for the activity being audited, to carry out internal quality audits.
- 17.1.3 Internal auditors shall prepare reports including the deficiencies found, target date for completion of corrective action, and the person(s) responsible for carrying out the corrective action.
- 17.1.4 Internal audit reports shall be reviewed and signed by the head of the relevant department of an establishment and by quality assurance/auditing department staff.
- 17.1.5 Additional/unscheduled internal quality audits shall be performed where necessary eg. where findings cast doubt over validity of test results.

17.2 External audits

- 17.2.1 The establishment shall participate in external audit programme(s) performed by a recognised institution.

Standard 18 Work environment and safety

- 18.1 The work environment shall be suitable for the activities performed.
- 18.2 Premises shall be adequate in size, well ventilated, adequately lit and shall not invalidate or adversely affect operations. Special conditions for mobile collections shall apply.
- 18.3 Premises shall allow for an orderly workflow with adequate separation between different functions.
- 18.4 Adequate measures shall be taken to ensure protection of the environment, and disposal of waste, including biohazardous waste.
- 18.5 The establishment shall have procedures to ensure the provision of safe working conditions that meet national laws and regulations (where applicable).
- 18.6 Accidents and incidents in the workplace shall be reported and investigated in accordance with national regulations.
- 18.7 Necessary personal protective equipment and clothing shall be defined, provided and used.
- 18.8 The establishment shall maintain procedures to ensure the safety of donors, patients and visitors on the premises.

SECTION 3 : BLOOD DONOR SELECTION

Standard 19 Criteria for the selection of whole blood and apheresis donors

- 19.1 Blood donations shall be given on a voluntary basis and donors shall not be remunerated for their donation. The following criteria serve as guidelines but decisions can be made by the Medical Director taking individual circumstances into account. Justification for non-compliance with the Standards shall be documented.
- 19.2 Informed consent
 - 19.2.1 The first time donor shall be given verbal or written information about the procedure (whole blood donation or apheresis) so that he or she can give written consent for the procedure.
 - 19.2.2 A donor shall give written consent prior to each donation by completing the relevant section in the questionnaire. Apheresis donors shall also sign consent for the administration of necessary fluids and additives and the re-infusion of their own blood components.

- 19.3 Age
 - 19.3.1 Blood donors shall be healthy persons 16 years and older.
 - 19.3.2 Under special circumstances, persons under the age of 16 may donate blood if the parent, or legal guardian, and the Medical Director/Medical Officer give written consent.
 - 19.3.3 First time allogeneic blood donors shall not be older than 65 years.
- 19.4 Donor weight
 - 19.4.1 Whole blood donors shall weigh 50 kg or more. The Medical Director/ Medical Officer may grant consent for acceptance of apheresis donor weighing less than 50 kg, but smaller volumes shall be taken i.e. the extracorporeal volume in one apheresis procedure shall not exceed 15 % of the total blood volume.
 - 19.4.2 Unexplained recent weight loss of more than 10% of body weight shall be a reason for deferral.
- 19.5 Identification
 - 19.5.1 The blood donor shall be identified as the particular person who is registered or is being registered by the establishment at each donation.
 - 19.5.2 The person performing the withdrawal of the blood is responsible for ensuring that the donor in question has been positively identified.
- 19.6 Donation interval
 - 19.6.1 The interval between consecutive whole blood donations shall not be less than 56 days unless authorised by a Medical Officer.
- 19.7 General health
 - 19.7.1 Before each donation, the prospective donor shall be questioned verbally or in writing to confirm that he or she is in good health and has not suffered, or is not suffering from any serious illness. If the information is obtained verbally it shall be suitably documented.
 - 19.7.2 The establishment shall maintain a document detailing the medical conditions and medications (including immunisations and vaccinations) and exposure to potential transfusion transmissible diseases constituting grounds for deferral of donors, whether temporary or permanent.
 - 19.7.3 The document referred to in the paragraph above shall be readily available at all times to staff whose responsibility it is to assess the fitness of donors.
 - 19.7.4 A suitable screening procedure may be developed by the establishment to permit non-medical staff to interview potential donors.
 - 19.7.5 Where medical judgement is required to determine suitability of potential donors to donate (with regard to medical conditions or surgical procedures not covered under the acceptance criteria) the donors shall be assessed by a medical practitioner or registered professional nurse acting on behalf of the medical practitioner. This assessment may be performed via telephonic consultation if a medical practitioner or registered professional nurse is not on site.
 - 19.7.6 Any person who appears to be clearly under the influence of alcohol or any drug having a narcotic or other adverse effect or who appears not to be providing coherent answers to the medical history or other questions shall not be accepted as a blood donor.

19.8 Medication

- 19.8.1 A registered professional nurse or medical practitioner shall evaluate a prospective donor who is taking medication to determine his suitability to donate blood. This procedure may be via telephonic consultation.

19.9 Haemoglobin or haematocrit

- 19.9.1 Each prospective donor shall be screened for haemoglobin levels or haematocrit prior to donation.
- 19.9.2 The recommended haemoglobin should not be less than 12,5 g/dl (125 g/l). Deviation from this is permitted provided there is supporting data from local reference range studies.

19.10 Therapeutic phlebotomy

- 19.10.1 Therapeutic phlebotomy shall be performed only when prescribed by the patient's physician and with the consent of the Medical Director/Medical Officer. Acceptance criteria for therapeutic donors may differ from those of allogeneic donors.
- 19.10.2 Individuals with haemochromatosis/ secondary polycythaemia may become allogeneic blood donors with the consent of the Medical Director/ Medical Officer. However, the first unit of blood drawn may not be used for transfusion.
- 19.10.3 Units classified as therapeutic phlebotomies for primary erythrocytosis (polycythemia vera) and high affinity haemoglobin shall not be used for allogeneic transfusion.
- 19.10.4 The Medical Director, designated Medical Officer or attending physician will determine the bleeding intervals for therapeutic donors.
- 19.10.5 Therapeutic donors shall be monitored by nursing staff during the donation procedure.

19.11 Pulse and blood pressure

- 19.11.1 The pulse rate and blood pressure shall be determined for each prospective donor prior to donation and shall fall within the parameters set by the establishment.
- 19.11.2 The donor's pulse rate shall not exhibit any irregularity and shall be between 50 to 100 beats per minute, except in athletes where a lower pulse rate may be acceptable.
- 19.11.3 The systolic blood pressure shall not be lower than 90 mm Hg or higher than 180 mm Hg and the diastolic no lower than 50 mm Hg or higher than 100 mm Hg.

19.12 Pregnancy

- 19.12.1 Known existing pregnancy shall preclude routine donation until 3 months following conclusion of pregnancy.
- 19.12.2 Autologous donation from a pregnant or post-partum woman is acceptable if approved by the woman's physician and the establishment's Medical Director/Medical Officer.
- 19.12.3 A directed donation from a pregnant or post-partum woman, intended for transfusion to the infant is acceptable if approved by the woman's physician and the Medical Director/Medical Officer of the blood transfusion service.

19.13 Full blood count (for apheresis donors only)

- 19.13.1 Prospective apheresis donors require a full blood count prior to enrolment in the programme and the results shall be within the reference range set by the establishment.

- 19.13.2 At each visit, samples shall be taken for full blood count pre and post donation and the results shall be within acceptable limits for apheresis donation. Donors with blood counts outside the acceptable limits may be accepted at the Medical Director's/Medical Officer's discretion.

Standard 20 Notifying donors of abnormal test results

- 20.1 The establishment shall send a letter or notify donors verbally of any medically significant abnormality detected during the pre-donation evaluation or as a result of subsequent laboratory tests and advise them to seek counselling and/or treatment.
- 20.2 All putative HIV positive donors should be requested to return to the establishment for confirmation and counselling where possible and a record shall be kept.

Standard 21 Criteria for the protection of a recipient

- 21.1 Donor assessment
- 21.1.1 No blood shall be released for transfusion purposes if there is any reason to suspect from the donor's medical history, lifestyle, past donation record, physical condition or post-donation notification, that his blood may transmit disease.
- 21.1.2 Should it be established after a donation has been given, that there is any reason to suspect from the donor's medical history, lifestyle, past donation record or physical condition that his blood may transmit disease, that unit of blood shall not be released for transfusion purposes and shall be destroyed (unless utilised for reagent or research purposes).
- 21.1.3 The Medical Director of the establishment shall determine, periodically review and document acceptance criteria for blood donors that meet an acceptable risk profile in terms of transfusion transmissible diseases. These criteria will also be used to determine blood product release strategy.
- 21.2 Venepuncture site
- 21.2.1 The skin at the venepuncture site shall be free of lesions.
- 21.3 Receipt of blood or blood components
- 21.3.1 Prospective blood donors who have received blood or blood components or other human tissues known to be possible sources of blood-borne pathogens shall be deferred for a period of 6 months following such receipt.
- 21.4 Infectious diseases: HIV or AIDS (Acquired Immunodeficiency Syndrome)
- 21.4.1 Prior to enrolment by the establishment, all prospective blood donors shall be given and/or be shown educational materials informing them of the high-risk behaviour activities for HIV or AIDS, and that persons who indulge in these high-risk activities shall refrain from donating blood.
- 21.4.2 Persons unable to understand such information shall not be eligible to donate blood.
- 21.4.3 A prospective blood donor shall give consent in writing for his donation to be tested for HIV-infection.
- 21.4.4 A mechanism shall be established to permit a donor to request, in confidence and/or subsequent to donation, that his donation be discarded.

21.5 Infectious diseases: Hepatitis

21.5.1 Individuals with a history of jaundice or hepatitis shall only be considered as blood donors 6 months after recovery from the illness. At this stage, all approved tests and all tests for re-entry algorithms for Hepatitis B and Hepatitis C shall be negative.

21.5.2 Prospective blood donors who have been in close contact with an individual with hepatitis shall be deferred for a 6 month period.

21.6 Sexually transmitted diseases (eg. Syphilis/ Gonorrhoea)

21.6.1 Prospective donors with a history of sexually transmitted diseases must be deferred for 6 months post successful treatment.

21.7 All forms of Creutzfeldt-Jakob Disease

21.7.1 Individuals who have received pituitary growth hormone, dura mater grafts or corneal transplants, unless of synthetic origin, shall not donate blood and shall be deferred permanently. Individuals who have had neurosurgery may donate at discretion of the Medical Director after consideration of the indication, timing and type of procedure, and post-surgical neurological sequelae.

21.7.2 Individuals who have spent a total of more than 12 months in the United Kingdom between 1980 and 1996 may donate blood but the plasma of these donors may not be used for fractionation.

21.8 Potential exposure to blood or body fluids

21.8.1 Prospective donors shall be deferred from donating blood for 6 months following:

- a tattoo
- scarification
- mucous membrane exposure, including eye splashes, to blood or blood products.
- skin penetration with instruments, weapons, or equipment contaminated with blood or body fluids. However, ear or body piercing, acupuncture or Botox injections using sterile disposable equipment are acceptable.

21.9 Malaria

21.9.1 A prospective donor who has suffered an acute attack of malaria and has not had a relapse for more than 3 years may donate.

21.9.2 Malaria areas within South Africa:

21.9.2.1 Prospective donors who live in or frequently visit these areas may be bled, but the red blood cells shall be labelled with a malaria area label and shall preferably be retained for use in the malaria area.

21.9.2.2 A prospective donor who has occasionally or only once visited these areas, whether on prophylaxis or not, may be bled after a period of 4 weeks following his return. If the donor donates within 3 months of exiting the area, a malaria area label shall be applied to each donation.

21.9.3 Malaria areas outside South Africa:

- 21.9.3.1 Prospective donors who grew up in these areas shall be deferred for a period of 3 years from the date they last left the malaria area. Donors who revisit any malaria endemic area, will be deferred for an additional 3 years after each visit.
- 21.9.3.2 Prospective donors visiting these areas occasionally or only once (whether on prophylaxis or not) may donate 4 weeks after their return. If the donor donates within 3 months of exiting the area, a malaria label shall be applied to each donation.
- 21.9.4 The malaria area label shall clearly draw the attention of the person transfusing the unit to the possibility of transmitting malaria.
- 21.9.5 The plasma of donors in 21.9.2 and 21.9.3 above may be used.
- 21.10 Prophylactic immunisations
 - 21.10.1 Donors who have had vaccines with attenuated bacteria and viruses shall be deferred for four weeks eg. BCG, yellow fever, rubella, measles, poliomyelitis (oral), mumps, live attenuated cholera vaccine.
 - 21.10.2 Donors who have had vaccines with killed bacteria may be accepted if well at time of donation eg. cholera, typhoid, capsular polysaccharide typhoid fever vaccine.
 - 21.10.3 Donors who have had vaccines with inactivated viruses may be accepted if well at time of donation eg. poliomyelitis (injection), influenza vaccine.
 - 21.10.4 Donors who have had vaccines with toxoids may be accepted if well at time of donation eg. diphtheria, tetanus vaccine.
 - 21.10.5 Donors who have had other vaccines such as Hepatitis A vaccine or Hepatitis B vaccine should be deferred for 7 days.
 - 21.10.6 Donors who have had other vaccines such as Rabies, tick-borne encephalitis vaccine may be accepted if well at time of donation. If post exposure, donor may be accepted one year after exposure.
- 21.11 Transfusion Related Acute Lung Injury (TRALI)
 - 21.11.1 Donors implicated in TRALI or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.

SECTION 4 : BLOOD COLLECTION

Standard 22 General blood collection

- 22.1 Responsibility
 - 22.1.1 The Medical Director of the establishment is ultimately responsible for the correct safe procedure for the collection of blood.
 - 22.1.2 The Medical Director may delegate immediate responsibility at the blood collection centre to another medical practitioner, a registered professional nurse, an enrolled nurse or a registered phlebotomist, in attendance at such centre.
 - 22.1.3 Where a blood collection centre is supervised by an enrolled nurse or registered phlebotomist, a medical practitioner or registered professional nurse must be available to provide telephonic consultation on medical matters.
- 22.2 Documentation

- 22.2.1 The establishment shall have written procedures for all activities of the blood collection procedure including:
- Donor identification.
 - Haemoglobin or haematocrit screening.
 - Preparation of the venepuncture site.
 - Preparation of the blood pack.
 - Performance of the venepuncture.
 - Blood donation procedure and donor care
 - Taking of samples.

22.3 Withdrawal of blood/ phlebotomy

- 22.3.1 Withdrawal of blood from a donor may only be done by a qualified medical practitioner or by a registered professional nurse, enrolled nurse or registered phlebotomist working under his delegated authority.
- 22.3.2 The skin of the blood donor at the site of venepuncture shall be prepared by a method that provides reasonable assurance that the blood collected will be sterile.
- 22.3.3 The collection shall be by an aseptic technique using a sterile closed system and a single venepuncture.
- 22.3.4 The establishment shall have procedures and relevant equipment for handling donor adverse reactions.
- 22.3.5 Taking of samples
- 22.3.5.1 Samples taken for laboratory testing (ABO, Rh, TTI) shall be taken at the same time as the donation.
 - 22.3.5.2 Taking of samples shall not breach the sterility of the donation.
 - 22.3.5.3 Samples for any additional testing shall be adequately labelled before or at the time of collection and the identity checked after filling.
- 22.3.6 The donor shall be observed during donation and provided with post donation advice.

22.4 Containers

- 22.4.1 Only sterile, pyrogen-free containers containing anticoagulants/preservative solutions that are licensed for use in South Africa shall be used to collect blood and for subsequent separation into blood components.
- 22.4.2 With the exception of certain modified red cell concentrates, the original container (or closed system of blood containers), with a segment attached as an integral part thereof, shall be the final container for blood or red cell concentrates.
- 22.4.3 Prior to collection of blood, the container to be filled shall be inspected in a manner recommended by the manufacturers to ensure that the hermetic seal is intact, that there has been no leakage of the anticoagulant or preservative solution from the container and that the container is in all other respects suitable for use.
- 22.4.4 If there is reason to suspect that the seal is not intact or that leakage has occurred, the container shall not be used for the collection of blood.

- 22.5 Volume of blood
- 22.5.1 The amount of blood collected shall be in accordance with manufacturers' limits, however, may not exceed a total of 575 ml, including the anticoagulant solution.
- 22.6 Labelling
- 22.6.1 Donor session staff shall ensure that the unique number assigned to the donation appears on the donor session record, the primary pack and all the sample tubes used.
- 22.6.2 If additional numbers are required for secondary packs or for other purposes, they shall be affixed to the primary pack or pack which will be the final red blood cell pack.
- 22.6.3 The procedure shall be such as to avoid the possibility of errors in the labelling of blood containers and blood samples.
- 22.6.4 The donation record, blood container, and corresponding sample tubes shall be labelled or checked at the chair-side.
- 22.6.5 The site in the clinic where each donor is bled shall be arranged to ensure that there is no possibility of crossover of donor samples and labels.
- 22.7 Mixing
- 22.7.1 The container shall be regularly mixed during the donation process to ensure adequate mixing of the blood and anticoagulant.
- 22.8 Inspection
- 22.8.1 Prior to release from the blood collection session, the pack and its associated tubing shall be re-inspected for defects and its integrity shall be checked to detect any leaks.
- 22.8.2 Any defective pack shall be marked for disposal and held separately from intact packs.

Standard 23 Apheresis

- 23.1 Facilities for apheresis
- 23.1.1 In any apheresis unit or donor session where apheresis is performed, a telephone shall be immediately available so that emergency services can be promptly summoned.
- 23.1.2 The Medical Director/Medical Officer of the establishment undertaking apheresis shall ensure that all staff who undertake the supervision of apheresis procedures are trained in cardiopulmonary resuscitation techniques and receive regular updating.
- 23.1.3 A Medical Officer or registered professional nurse shall be immediately available on the premises at all times when donors are undergoing apheresis.
- 23.1.4 A current copy of the Standard Operating Procedure (SOP) and relevant manufacturer's manual for each type of machine in use shall be available on site.
- 23.2 Frequency of apheresis and volume collected
- 23.2.1 Cytapheresis
- 23.2.1.1 The interval between procedures for cytappheresis donors shall be at least 48 hours.
- 23.2.1.2 A cytappheresis donor shall not undergo the procedure more than twice in a 7 day period or 24 times in a rolling 12 month period except in unusual

circumstances as determined by the Medical Director or designated Medical Officer.

23.2.1.3 A cytopheresis donor shall be tested appropriately to detect a developing cytopenia. Abnormal results shall be reviewed by the Medical Director or Medical Officer to consider continued suitability for donation.

23.2.1.4 Donor's platelet count shall not be $< 150\ 000 \times 10^6/l$ before procedure is performed.

23.2.2 Plasmapheresis

23.2.2.1 A donor shall not normally undergo plasmapheresis more than once in 14 days, except in circumstances as determined by the Medical Director or designated Medical Officer.

23.2.2.2 Except at the discretion of a Medical Officer, not more than 300 ml/kg of plasma shall be donated by one donor in a year. A donor may not donate more than 2,4 litre plasma in any 4 week period and more than 1 litre in any one week.

23.2.2.3 Total serum protein levels shall be measured at the commencement of a plasmapheresis programme and shall be greater than 60 g/l. Donors on long-term plasmapheresis programmes shall have their serum protein levels measured annually.

23.2.3 Apheresis donors shall not donate whole blood for 48 hours after an apheresis procedure.

23.2.4 The final collection volume (exclusive of anticoagulant) shall not exceed 15% of total blood volume, unless intravenous replacement fluid is given. Male/female differences in blood volume should be taken into account.

23.2.5 After a red cell donation, or the loss of an equivalent volume of red cells during a failed apheresis procedure, a donor shall not normally donate plasma, platelets or leucocytes for a period of 56 days, except at the discretion of the Medical Director/Medical Officer.

23.2.6 After a double red cell donation, a donor shall not normally donate plasma, platelets or leucocytes for a period of 112 days, except at the discretion of the Medical Director or Medical Officer.

23.3 Apheresis procedure

23.3.1 Blood components shall be collected by apheresis using sterile, single use disposable items from a licensed manufacturer.

23.3.2 A licensed anticoagulant shall be used at a ratio that achieves a final concentration of 15 - 25 mmol/l citrate.

23.3.3 A record shall be kept of all lot numbers and/or batch numbers of all apheresis harness components and injectable materials used, in accordance with the establishment's quality systems.

23.3.4 Machines shall be correctly installed and commissioned according to manufacturer's instructions.

23.3.5 The collection procedure shall be detailed in SOPs and/or the machine manual.

23.3.6 Apheresis platelet components shall be stored at 20 °C - 24 °C with continuous gentle agitation ie. in accordance with platelet agitator manufacturer's recommendations, as stated in internal procedures.

23.3.7 Apheresis platelet components are tested in accordance with Standards 38 - 40.

23.4 The establishment may collect double red cells during apheresis procedures.

23.4.1 Donors shall meet the following criteria:

- weight: minimum of 70 kg
- height: \geq 165 cm
- haemoglobin: \geq 14,0 g/dl
- donation interval: 112 days

Standard 24 Collection of immune plasma

24.1 If the need for certain specific immunoglobulins is such that an adequate supply is unlikely to be obtained from the general population, deliberate immunisation of suitable donors may be undertaken by the blood transfusion service and the donor shall be fully informed of the procedure and the risks involved.

24.2 Immune plasma donors

24.2.1 The establishment may identify suitable donors by random screening of routine donors or selected screening of those with an appropriate history.

24.2.2 Immunity to the specific antigen for which immunoglobulins are being sought may be acquired through natural infection or through active immunisation.

24.2.3 Immunisation may be for the donor's own protection or may be purposely employed for the production of immune plasma in a suitable and willing donor.

24.2.4 Donation of plasma following natural infection should take place within a period of 1 - 12 months following disappearance of symptoms.

24.2.5 Whenever a donor with a suitable level of an immune antibody is identified, further donations shall preferably be by plasmapheresis in order to obtain maximum yields of the antibody.

24.2.6 Plasma obtained by therapeutic plasmapheresis shall not be used for the preparation of blood products, except in the case of anti-D plasma. In the latter situation, the donor shall be screened and tested and shall conform to the requirements for acceptance by the fractionation unit.

24.3 Immunisation of donors

24.3.1 Immunisation of donors shall be carried out only when sufficient supplies of material of suitable quality cannot be obtained by the selection of appropriate donors from donations identified as suitable by screening.

24.3.2 Before any planned immunisation of a willing donor, the suitability of that individual to donate by plasmapheresis and be immunised shall be assessed by the Medical Director, designated Medical Officer or a professional nurse. A donor for immunisation must pass all the criteria stipulated for a regular blood donor.

24.3.3 When immunisation is intended, the donor shall be informed of the procedure and associated risks and encouraged to seek advice from his general practitioner before agreeing to immunisation. Informed consent shall be obtained.

24.3.4 Donors may undergo investigations that may reveal hypersensitivity to a proposed antigen at the discretion of the Medical Director.

24.3.5 Vaccines used for immunisation shall be registered by the South African medicines licensing authority and be administered by the Medical Director, designated Medical Officer or professional nurse.

24.3.6 Ethical approval for a new immunisation programme shall be obtained from an appropriately constituted ethics committee.

24.4 Red cell immunisation of donors

24.4.1 Any procedure involving red cell immunisation of donors shall be in accordance with a protocol approved by an appropriately constituted ethics committee.

Standard 25 Collection of blood for laboratory use

25.1 It may be justified from time to time to collect blood for use in the establishment's own laboratories. The standards for the protection of blood donors shall apply.

25.2 The establishment may collect donations for laboratory use into licensed packs without anticoagulant.

25.3 The establishment shall obtain informed consent, which may be included in the donor questionnaire, from the donor prior to this procedure.

SECTION 5 : PROCESSING OF BLOOD PRODUCTS

Standard 26 Starting materials for processing

26.1 The starting material for component preparation shall be donated whole blood or products of apheresis collected from donors who satisfy selection criteria in Section 3.

26.2 Platelet concentrates may be obtained either from regular blood donations or by platelet-apheresis.
26.3 Donations for platelet processing should be bled in less than 12 minutes.

26.4 Bleeding time of donations used for FFP and Cryo should not exceed 15 minutes.

26.5 The establishment shall only prepare components from individual donations of blood.

26.6 A single donation may be split into components so that no more than 7 patients are exposed to a single donor's donation.

26.7 Certain components may be pooled provided that the size of a pool never exceeds twelve donations.

Standard 27 Containers for Components

27.1 The final container for a red cell concentrate (other than a modified red cell concentrate) shall be the container in which the blood was originally collected, or satellite container attached as an integral part thereof.

27.2 Alternatively, a sterile container that has been attached to the original container using a validated sterile connecting device may be used.

27.3 When a final container is filled, the establishment shall give such container a number or other symbol to enable identification of the donor(s) of the source blood and any secondary containers shall be similarly labelled.

Standard 28 Transport and Storage of blood donations prior to processing

- 28.1 Blood donations shall be placed in a qualified container which has the capacity to allow blood to cool towards the required temperature and transported to a processing centre within 8 hours of collection. At the processing centre:
- 28.1.1 Blood intended for platelet production shall be placed in an 18 - 24 °C environment and processed within the permitted time period.
- 28.1.2 Blood intended for processing into components other than platelets shall be placed in a 1 - 6 °C environment and processed within the permitted time period.
- 28.2 If transport to a processing centre is likely to exceed 8 hours
- 28.2.1 Blood intended for platelet production shall be placed in an 18 - 24 °C environment within 8 hours of collection and transported to a processing centre within 24 hours from time of collection.
- 28.2.1.1 At the processing centre the blood shall be placed in an 18 -24 °C environment and processed within the permitted time period
- 28.2.2 Blood intended for processing into components other than platelets shall be placed in a 1 - 10 °C environment and transported to a processing centre within 24 hours from time of collection.
- 28.2.2.1 At the processing centre blood shall be placed in a 1 - 6 °C environment and processed within the permitted time period.

Standard 29 Component separation procedures

- 29.1 An SOP describing the procedures involved in component preparation shall be available for each product.
- 29.2 The establishment shall evaluate the methods employed for component separation before implementation of such methods.
- 29.3 At regular intervals the quality of the final products shall be monitored.
- 29.4 The timing of separation of components shall conform to the following:
- 29.4.1 Plasma for preparation of Cryoprecipitate shall be separated from whole blood within 8 hours after collection. Plasma for the preparation of Fresh Frozen Plasma or Cryoprecipitate for Fibrinogen shall be separated preferably within 6 hours but not more than 18 hours after collection. The plasma shall be frozen to a core temperature of minus 30 °C or lower within 45 minutes.
- 29.4.2 Platelets shall be separated from whole blood within 24 hours, provided that they are maintained at 18 - 24 °C during this period.
- 29.4.3 Red cell products in additive solution should be prepared preferably within 72 hours but not more than 7 days after collection.
- 29.4.4 Pre-storage filtered or leucocyte reduced red cell products should be filtered within 72 hours, but preferably within 48 hours, of collection.
- 29.4.5 Frozen red cell products should preferably be frozen within 6 days of collection.

- 29.4.6 Recovered plasma, for fractionation may be separated at any time after collection but not more than 5 days after the expiry date of the whole blood and shall be frozen immediately after separation. The method of separation shall minimise the risk of bacterial contamination.
- 29.5 Separation of blood components by means of centrifugation shall be done in such a manner that the temperature will be maintained within the limits specified in the SOP.
- 29.6 The establishment shall maintain the sterility of all components during processing by using aseptic techniques and pyrogen-free containers.
- 29.7 Where processing solutions are used in the preparation of blood products, criteria for their acceptance (which may include receipt of a Certificate of Analysis from the supplier) must be defined and met.
- 29.8 In special clinical circumstances where components are required to be processed or modified for specific recipient needs (eg. autologous eye serum and platelet derived growth factors), this shall be done with the approval of the Medical Director or designate. If this entails using an open system then the requirements in 34.1.3 shall be complied with.

Standard 30 Storage of blood components after processing

- 30.1 After processing, blood components shall be stored at the following temperatures:
- 30.1.1 Whole blood and red cell products at 1 °C to 6 °C.
- 30.1.2 Frozen red cell products at less than minus 65 °C (in presence of cryopreservative agent).
- 30.1.3 Platelet products at 20 °C to 24 °C with continuous gentle agitation ie. in accordance with platelet agitator manufacturer's recommendations, as stated in internal procedures.
- 30.1.4 All frozen plasma products at lower than minus 18 °C for 1 year and at lower than minus 25 °C for 2 years.
- 30.1.5 Plasma, fresh, freeze-dried below 25 °C.
- 30.1.6 Freeze-dried anti-haemophilic factor at 2 °C to 10 °C.
- 30.2 Whole blood and red cell components shall be continuously kept at 1 °C to 6 °C (except when being transported) until immediately prior to infusion and may only be placed at room temperature for any single period not exceeding 60 minutes as may be necessary for testing, labelling, transfer or processing purposes.

Standard 31 Storage facilities

- 31.1 The establishment shall:
- 31.1.1 Have storage areas for blood components that provide adequate space, suitable lighting and which are arranged and equipped to allow dry, clean and orderly storage.
- 31.1.2 Secure known biohazardous material awaiting disposal in exclusively labelled storage areas/ containers.
- 31.1.3 Maintain security and status labelling of component storage areas.
- 31.1.4 Maintain an inventory of components in each storage category.
- 31.1.5 Install, test and maintain alarm system(s) to ensure that appropriate timeous action can be taken in the event of equipment failure to ensure that storage of the components is not compromised.

- 31.1.6 Monitor temperatures of storage areas and keep a record thereof.
- 31.1.7 Have mechanisms in place to ensure that blood is maintained within the appropriate temperature range.
- 31.1.8 Categorise or separate components, in accordance with GMP, according to their status eg. components awaiting testing, non-conforming components, available stock, expired components.

Standard 32 Transport of blood components

- 32.1 If transported, blood or red-cell components shall be placed in a validated storage container having sufficient refrigeration capacity to cool the blood continuously toward a temperature range between 1 °C and 10 °C. Transportation time should preferably not exceed 24 hours.
- 32.2 The establishment responsible for the transport of containers of blood and red cell components shall maintain a system for checking that such containers arrive at their destination within this temperature range.
- 32.3 Platelets shall be transported within a temperature range of 20 °C to 24 °C. Transportation time should preferably not exceed 24 hours.
- 32.4 Frozen plasma products shall be transported at a temperature of lower than -18 °C.
- 32.5 Freeze-dried anti-haemophilic factor and freeze-dried plasma may be transported at below 25 °C.

Standard 33 Component identification

- 33.1 The establishment shall use a unique bar-coded and/or eye-readable donation number to link the donation to its donor.
- 33.2 When component production requires the use of packs that are not an integral part of the pack assembly, a secure system shall be used to ensure that the correct eye-readable and bar-coded donation number is placed on each additional pack or aliquot used.
- 33.3 To ensure that all constituents of a component pool can be traced, a unique batch number shall be assigned to the pool that shall be placed on the pack containing the pool. A record of the individual units which constitute the pool shall be kept. Alternatively, the donation number referred to above, of each constituent component shall appear on the pack containing the component pool.
- 33.4 When a component is divided for neonatal use, a secure system shall be used to ensure that all sub batches can be traced and this also applies to components prepared by apheresis.

Standard 34 Expiry dates and times

- 34.1 Whole blood and red cell products:
 - 34.1.1 The expiry date for whole blood and red cell products, in additive solution, is in accordance with the container manufacturer's specifications.
 - 34.1.2 Frozen red cell products have an expiry date of 10 years from date of freezing.
 - 34.1.3 If an open system which may not maintain sterility is used, (eg. filtered or washed red cells) the expiry time shall be a maximum of 24 hours after filtration or washing is commenced, but the product should be infused as soon as possible.
 - 34.1.4 Freeze dried products shall be used as soon as possible after reconstitution.
- 34.2 Platelet products:

- 34.2.1 The expiry date for platelet products is 5 days.
- 34.2.2 After pooling using an open system, the expiry time shall be a maximum of 6 hours.
- 34.3 Plasma and serum products:
 - 34.3.1 The expiry date for all plasma or serum products (including cryoprecipitate and cryoprecipitate for fibrinogen) is 2 years if kept frozen at below minus 25 °C and 1 year if kept frozen at below minus 18 °C.
 - 34.3.2 The expiry date for freeze-dried plasma or serum is 2 years.
 - 34.3.3 The expiry date for freeze-dried anti-haemophilic factor is 2 years.
 - 34.3.4 Frozen plasma or serum products (including cryoprecipitate and cryoprecipitate for fibrinogen) shall be thawed at 30 °C to 37 °C and after thawing the expiry time shall be a maximum of 6 hours. It is recommended that the product be transported/stored at no higher than 24 °C after thawing. However, if the product is refrigerated at 1 to 6 °C after thawing, an expiry time of 5 days shall be allocated. This product shall be clearly labelled as 'Thawed FFP' and the label shall include a statement that this product is not to be used in the treatment of labile clotting factor deficiencies.
 - 34.3.5 Expired Fresh Frozen Plasma may be used for preparation of recovered plasma for fractionation provided the expiry date of 2 years has not been exceeded and provided it meets the requirements for plasma for fractionation.

Standards 35 Labelling of containers

- 35.1 A container of blood or component shall have a label securely affixed to it and the size of such label shall be such that it will not interfere with inspection of the contents of such container.
- 35.2 The establishment shall ensure that, at the minimum, the following information is printed on a label referred to above in easily legible and indelible letters:
 - 35.2.1 The proper name of the contents of the container.
 - 35.2.2 The type and volume of anticoagulant solution and/or additive solution used in the container, where applicable.
 - 35.2.3 The name and address of the establishment responsible for collecting the blood donation or component.
 - 35.2.4 The unique number of the blood donation or component whereby the donor(s) may be identified.
 - 35.2.5 The date of withdrawal of the blood or component from the donor, where applicable.
 - 35.2.6 The expiry date, and time where appropriate, of the blood or component in the container.
 - 35.2.7 The ABO blood group of the donor (except for Cryoprecipitate, freeze-dried anti-haemophilic factor and Cryofibrinogen).
 - 35.2.8 The allo-agglutinin titre, where high, plus indication to issue to same group patients only.
 - 35.2.9 The Rh D type of the donor (except for Fresh Frozen Plasma, Cryo-poor Plasma, Cryoprecipitate, freeze-dried anti-haemophilic factor and Cryofibrinogen).
 - 35.2.10 The minimum volume or mass of the contents of the container expressed in millilitres or grams, and

35.2.11 Temperature conditions for storage and transport (eg. Store at 1 - 6 °C, and transport at 1-10 °C for whole blood or red cell concentrates).

35.3 There shall be a process to confirm that the ABO/Rh group on the unit is correct.

35.4 If a component is modified and a new product label is applied, there shall be a check in place to ensure the accuracy of the information ie. serial number, ABO group, Rh and expiry date/time.

Standard 36 Labelling of platelet concentrates

36.1 In addition to the data referred to above, a label for platelet concentrates shall bear the following:

36.1.1 The storage temperature of 20 °C to 24 °C.

36.1.2 Instructions that the infusion of the contents shall be completed as soon as possible.

SECTION 6 : TESTING AND DISPOSITION OF BLOOD PRODUCTS

Standard 37 Types of testing

37.1 The establishment shall perform the following tests:

37.1.1 Mandatory red cell serology and screening tests for transfusion transmissible diseases on each donation.

37.1.2 Quality control tests on random units of components.

37.1.3 Visual inspection of a component during processing and immediately prior to issue.

37.1.4 The establishment shall ensure that blood and components cannot be released for transfusion until all the mandatory laboratory tests have been completed, documented and approved, except at the discretion of the Medical Director/ Medical Officer.

Standard 38 Mandatory tests

38.1 The establishment shall perform the following tests on each donation:

38.1.1 Tests for infectious agents for transfusion transmissible diseases.

38.1.2 Red cell serology including ABO grouping and Rh grouping.

38.1.3 Allo-agglutinin titre.

38.1.4 Test for presence of irregular antibodies.

38.2 The establishment shall only perform laboratory tests on a sample taken from a blood donor at the time of collection of blood or component, or, if suitable, such a laboratory test may be done from pre-sealed segments of the pilot tubing that is an integral part of the final container.

38.3 The results of the mandatory tests shall be used to ensure the safety and correct labelling of all units of blood or components intended for transfusion and for compatibility testing purposes where appropriate.

38.4 Recipient notification (Look-Back)

38.4.1 The establishment shall implement procedures to identify recipients of blood components from donors who at subsequent donations are found to have infection with HIV or Hepatitis B or C or other transfusion transmissible infectious agents and, as far as possible, to have the recipients informed of the risk of infection.

- 38.4.2 If such a component has been supplied to the fractionation unit, the fractionation unit shall be informed accordingly.
- 38.4.3 The establishment shall investigate all instances of recipients claiming to have acquired a transfusion transmissible infection from a blood transfusion.

Standard 39 Tests for infectious agents

- 39.1 The establishment shall perform the following tests on each donation:
 - 39.1.1 Serological test for syphilis.
 - 39.1.2 Tests for Hepatitis B surface antigen (HBsAg), antibodies to the Hepatitis C virus (anti-HCV), and antibodies to Human Immunodeficiency Virus Type 1 and 2 (anti-HIV 1 & 2) .
 - 39.1.3 Screens for Hepatitis B virus (HBV), Hepatitis C virus (HCV) and Human Immunodeficiency Virus Type 1 (HIV-1) by a test utilising nucleic acid amplification in individual donation format.
- 39.2 The establishment shall maintain algorithms for the rejection of reactive units and the deferral or re-entry of donors to the panel.
- 39.3 Only test kits approved by an internationally recognised institution (eg. FDA, CE etc) shall be used by the establishment and the test systems in which such a test kit is used shall also be validated by the establishment.
- 39.4 If the establishment uses any modification of commercial assays, such modification shall be validated by that establishment before being put into use for testing blood donations.

Standard 40 Red-cell grouping

- 40.1 ABO grouping
 - 40.1.1 The establishment shall classify the ABO blood group of all donors by testing the red blood cells with standardised antisera and by testing the serum (or plasma) with typed reagent red cells. For first time donors, this ABO classification shall be confirmed by two independent determinations which may be performed using the same sample.
 - 40.1.2 Before issue, the establishment shall also confirm the blood group of red cell containing components from all donors, by doing an additional test on a sample from a segment of the pilot tubing of the blood pack.
 - 40.1.3 For repeat donors, the results of tests referred to in paragraphs 40.1.1 and 40.1.2 shall agree with each other and with those obtained with previous donations from the same donor.
 - 40.1.4 If the results of testing referred to above are inconclusive, the establishment shall not issue the blood or component until the donor's group has been confirmed by retesting.
- 40.2 Rh grouping
 - 40.2.1 The establishment shall classify a donation as blood type Rh D positive or Rh D negative based on results of testing for the presence of the D red cell antigen.
 - 40.2.2 The establishment shall not issue blood or components from first time donors as Rh negative unless the donor's blood has been subjected to two independent D blood group tests and both have tested negative for the D red cell antigen. The reagent for the confirmatory test shall be able to detect weak forms of the D antigen, in particular partial D VI.

- 40.2.3 For repeat donors, Rh D testing need only be done if the donor was previously found to be Rh D negative. For repeat donors previously found to be Rh D positive, the unit can be labelled as Rh D positive without the testing being repeated.
- 40.3 Status labelling for ABO blood grouping
 - 40.3.1 Donations from all first time donors shall be tagged with a cautionary label stating "CAUTION: BLOOD GROUP NOT CONFIRMED" and this label shall only be removed if confirmation of blood group has been completed and there are no discrepancies in the results.
 - 40.3.2 Alternatively, if a computerised stock control system is being utilised, the above requirement may be waived, provided that a validated computer programme is in place to prevent release of units with discrepancies or where the blood groups have not yet been assigned.
- 40.4 Investigation of discrepancies
 - 40.4.1 An investigation by the establishment shall commence as soon as possible to ascertain the cause of any discrepancy in the results of the blood grouping tests.
 - 40.4.2 In the investigation, the blood group of the donation shall be checked by subjecting at least two separate samples (one of which is from a segment of the pilot tubing of the container in question) to independent tests carried out by different investigators; and, if indicated:
 - 40.4.2.1 The blood group of the donor should be similarly checked by testing independently an additional sample of the donor's blood, and
 - 40.4.2.2 The identity of such a blood donor shall be verified to ensure that the blood donation in question was in fact obtained from the correct donor.
 - 40.4.3 If an investigation referred to above indicates that the discrepancy in the results of the blood grouping tests was the result of a mistake in identifying the blood donor, the possibility that similar mistakes were made in identifying other donors who attended the clinic from which the donation in question came shall be fully investigated by the establishment.
 - 40.4.4 If the discrepancy in the results of the blood-grouping tests is resolved by an investigation referred to above and the identity of the blood donor, his blood group and the blood group of the unit are firmly established, the container of blood in question may be deemed safe for issue.
 - 40.4.5 If the criteria referred to in these Standards are not or cannot be met, the donation or red cell component in question may not be used for transfusion.

Standard 41 Quality control tests

- 41.1 The establishment shall have written procedures for the random sampling and quality control testing of blood components.
- 41.2 The target testing quantity is 1% of the annual production, with a recommended minimum of 4 units per month, but the volume of production and the regularity with which components are made influences the quantity and frequency with which quality control tests are required.
- 41.3 If a component is made, on average, less than 4 times per month, each component should be tested.
- 41.4 If a sample is taken from a blood product, or component derived there from, that is intended for transfusion, it shall be done in such a manner that the sterility of the product is not compromised.

- 41.5 The establishment shall analyse the quality control results and if the results of analysis show a consistent deviation away from the specifications detailed in the relevant SOPs, the cause thereof shall be investigated.
- 41.6 The investigation process by the line manager, or designate, should include the following steps:
- 41.6.1 A review of the testing and production procedures.
 - 41.6.2 Checking that SOPs are up to date and followed.
 - 41.6.3 Checking the operation of equipment and storage conditions.

Standard 42 Visual inspection

- 42.1 A donation of blood, or component derived there from, shall be inspected by the establishment during processing and immediately before issue and shall not be issued if there is any evidence of leakage, excessive air, suspicion of microbial contamination (eg. unusual turbidity, haemolysis, frothiness or change of colour), or any other abnormality.
- 42.2 In addition to the above, plasma products shall also be inspected for red cell contamination and absence of visible aggregates or clots.

Standard 43 Release of components not conforming to mandatory testing requirements

- 43.1 In exceptional circumstances, at the discretion of the Medical Director (or designated Medical Officer), blood or components may need to be issued when they do not conform to all mandatory testing requirements.
- 43.2 The establishment shall have an SOP on the procedure that details the circumstances under which blood or components referred to above can be issued and these instructions shall, as a minimum, include the following:
- 43.2.1 Components that have not been subjected to all the mandatory testing requirements shall have a warning attached to the container indicating testing not performed.
 - 43.2.2 The establishment shall notify the registered medical practitioner of the issue of components referred to above and such notification shall be documented.
 - 43.2.3 The reason for the issue of components referred to above shall be fully documented.
 - 43.2.4 The name of the recipient shall be entered on the issue documentation and on the component.
 - 43.2.5 The required testing shall continue after the release of the units, and if any blood units are found to be unsuitable, it shall be reported to the attending physician immediately.

Standard 44 Discard of non-conforming components

- 44.1 The establishment shall have a procedure for the discard of non-conforming components arising at any stage during processing or testing and ensure that an appropriate record of discard is maintained.
- 44.2 Donations that are repeatedly positive for mandatory screening tests; or donations from donors whose records indicate that their components should be destroyed because of previous mandatory test results, shall be classified and discarded as biohazardous.
- 44.3 The establishment shall ensure that all non-conforming components and samples are disposed of and this includes:
- 44.3.1 Labelling of the component to indicate that it is not suitable for therapeutic use.

44.3.2 Using a system to trace all components prepared from any donation; and

44.3.3 Maintaining a record of the person or laboratory discarding each non-conforming component.

44.4 When non-conforming material, eg. plasma, is retained for laboratory use, the establishment shall store such material in a secure and appropriately labelled area, separate from any components or products which might be used for therapeutic purposes and in a manner which will prevent it ever being used for transfusion.

SECTION 7 : BLOOD PRODUCT SPECIFICATIONS

Standard 45 Compliance with specifications

45.1 The establishment shall ensure that the components it produces comply with the specifications in this section. Unless otherwise stated, these specifications are deemed to have been met if more than 80% of the units tested meet the requirements.

Standard 46 Whole blood and red cell products

PRODUCT	SPECIFICATIONS	
Whole blood	Volume (500 ml donation) Volume (450 ml donation)	525 ± 50 ml (incl. anticoagulant) 513 ± 45 ml (incl. anticoagulant)
Whole blood, leucocyte depleted	Volume Leucocyte count	475 ± 50 ml (incl. anticoagulant) ≤ 5 × 10 ⁶ /unit
Red cells in additive solution, buffy coat removed	Volume Haematocrit Leucocyte count	300 ml ± 50 ml 0,6 l/l ± 0,1 l/l ≤ 2,4 × 10 ⁹ /unit
Red cells in ACD, buffy coat removed	Volume Haematocrit Leucocyte count	300 ml ± 50 ml 0,6 l/l ± 0,1 l/l ≤ 2,4 × 10 ⁹ /unit
Red cells, leucocyte depleted	Volume Haematocrit Leucocyte count	260 ml ± 50 ml 0,6 l/l ± 0,1 l/l ≤ 5 × 10 ⁶ /unit
Red cells, leucocyte depleted, paediatric	Volume	120 ml ± 30 ml
Red cells, leucocyte depleted, infant/ neonate	Volume	55 ml ± 20 ml
Red cells, washed	Volume Haematocrit Total protein content	> 185 ml 0,6 l/l ± 0,1 l/l < 5 mg/ unit
Red cells, cryopreserved	Volume Haematocrit Sterility	> 185 ml 0,6 l/l ± 0,1 l/l Negative

Standard 47 Platelet products

PRODUCT	SPECIFICATIONS
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Pooled platelets	Volume (x no. units in pool) Platelet count (for pool ≥ 5) Leucocyte count, if leucodepleted pH (not more than 24 hours after expiry)	> 40 ml $\geq 2,4 \times 10^{11}$ $\leq 5 \times 10^6$ /unit > 6,4 at 20 - 24 °C
Apheresis platelets	Volume Platelet count Leucocyte count, if leucodepleted pH (not more than 24 hours after expiry)	≥ 200 ml $\geq 2,4 \times 10^{11}$ $\leq 5 \times 10^6$ /unit > 6,4 at 20 - 24 °C
Apheresis platelets – paediatric	Volume Platelet Count	150 ml \pm 50 ml $1,0 - 2,3 \times 10^{11}$ /l
Apheresis platelets – infant/ neonate	Volume Platelet Count: $0,5 - 0,9 \times 10^{11}$ /l	50 ml \pm 10 ml $0,5 - 0,9 \times 10^{11}$ /l

Standard 48 Plasma products

PRODUCT	SPECIFICATIONS	
Fresh frozen plasma (FFP)	Volume FVIII:C	280 ml \pm 70 ml $\geq 0,7$ IU/ ml
Cryo-poor plasma	Volume	270 ml \pm 70 ml
Fresh frozen plasma, paediatric (Group AB)	Volume FVIII:C	130 ml \pm 30 ml $\geq 0,7$ IU/ ml
Fresh frozen plasma, infant (Group AB)	Volume FVIII:C	75 ml \pm 15 ml $\geq 0,7$ IU/ ml
Plasma, fresh, freeze-dried (on random batch samples)	Moisture Sterility	≤ 2 % Negative
Cryoprecipitate	Volume FVIII:C Fibrinogen	15 ml \pm 10 ml ≥ 80 IU/ unit ≥ 12 mg/ ml
Cryoprecipitate for fibrinogen	Volume Fibrinogen	30 \pm 10 ml ≥ 300 mg/ unit
Heat treated, freeze-dried anti-haemophilic factor (on random batch samples)	FVIII:C Moisture Sterility	≥ 80 % stated activity ≤ 2 % Negative

SECTION 8 : COMPATIBILITY TESTING AND TRANSFUSION OF BLOOD PRODUCTS

Standard 49 Compatibility testing

- 49.1 The establishment shall undertake a compatibility test, as detailed in this section, prior to the commencement of a transfusion of any red cell containing product, and only compatible units shall be administered except in cases of emergency as described below.
- 49.2 In hospitals where there is no access to a staffed blood bank, it is recommended that Group O, low-titre red cell components be kept in a temperature monitored refrigerator at 1 °C to 6 °C, in a quantity appropriate to anticipated requirements for emergency use.
- 49.3 The hospital where the emergency fridge, as stated in (2) above, is kept, may perform an Rh D test on a blood sample from the recipient to determine the appropriate Rh type to be used.
- 49.4 Rh D negative blood shall always be issued to females prior to or during the childbearing years if there is any doubt about the interpretation of the test.

Standard 50 Requests for Blood Components

- 50.1 Request forms for blood or components and the blood sample(s) from the recipient shall contain sufficient information to uniquely identify the recipient and shall include at least 2 independent identifiers (eg. first and last names, identity number, or hospital identification number).
- 50.2 The establishment shall accept only complete and legible requests.
- 50.3 Requests received for emergency patients shall have at least one unique identifier (eg. emergency unit number and gender).
- 50.4 If there is no unique identifier in a life-threatening situation, Group O blood only may be issued until a request form and sample are received.
- 50.5 A request form for a blood component shall include the name and/or signature of the requesting medical practitioner.
- 50.6 The request form shall include the name of the person taking the recipient sample.
- 50.7 The request form for a blood component shall include the date and time that the sample was drawn.
- 50.8 The patient identifiers on the request form and sample label shall correspond.

Standard 51 Testing of donor blood

- 51.1 The establishment performing a compatibility test shall confirm the ABO group of all units of blood and red cell components.
- 51.2 Discrepancies shall be reported to the collecting facility and shall be resolved before issue of the blood for transfusion.

Standard 52 Testing of recipient's blood

- 52.1 Each blood sample submitted to the establishment with a request for transfusion of blood or red cell components shall be tested by such establishment for ABO group and Rh type and shall be tested for clinically significant irregular antibodies. ABO group shall be determined by cell and serum grouping ie. forward and reverse grouping. The Rh test for weak D is not necessary.
- 52.2 If a recipient has been transfused within the preceding 3 months with a red cell component, or has been pregnant within the preceding 3 months, or if the history is uncertain or unavailable, such sample shall be obtained no more than 3 days prior to the scheduled transfusion.
- 52.3 The recipient sample shall not be more than 72 hours old at time of compatibility test.

- 52.4 If additional blood/blood products are requested, the specimen shall be checked and shall only be used if less than 72 hours old and no more than 72 hours would have elapsed since the first issue of blood using the same sample, by the time the requested blood is issued.
- 52.5 There shall be a procedure for handling unsuitable samples and notifying the requesting practitioner.

Standard 53 Compatibility test

- 53.1 A major compatibility test using donor red cells from a segment of the component to be transfused and the recipient's serum or plasma shall be performed before administration of blood and red cell components.
- 53.2 In cases of dire emergency, blood may be administered without a compatibility test.
- 53.3 The compatibility test shall use methods that demonstrate ABO incompatibility and incompatibility due to other clinically significant antibodies.
- 53.4 If no clinically significant antibodies are detected in the recipient, the final crossmatch test between recipient and donor need only be a serological test sufficient to detect ABO incompatibility.
- 53.5 If irregular, clinically significant antibodies are found during screening, or there is a history of clinically significant antibodies, a full crossmatch, including an indirect antiglobulin phase, is required.
- 53.5.1 Where clinically significant antibodies are detected, additional testing shall be performed to attempt to identify these antibodies and if antisera are available, units shall also be confirmed negative for the corresponding antigen.
- 53.5.2 Where a patient has an unidentified, clinically significant antibody, or typing antisera is unavailable, a second compatibility test which includes an antiglobulin phase shall be performed to confirm serologic compatibility.
- 53.6 Anti-human globulin results, interpreted as negative, shall be validated using IgG sensitised cells. Where the test system does not allow for the addition of IgG sensitised cells, the control system indicated by the manufacturer, shall be in place to validate negative results.
- 53.7 If a computer system has been validated to prevent the release of ABO incompatible blood and components, then it may be used prior to transfusion to detect ABO incompatibility instead of a serological crossmatch, provided that:
- 53.7.1 There have been 2 independent determinations of the recipient's ABO group.
- 53.7.2 The system contains the donor unit number, the component name, ABO group and Rh type of the component, the interpretation of the ABO confirmatory test of the product and recipient information of the ABO group and Rh type.
- 53.7.3 There is a method to verify correct entry of data.
- 53.7.4 The system contains logic to alert the user to discrepancies between donor unit labelling and blood group confirmatory test interpretation and to ABO incompatibilities between the recipient and the donor unit.
- 53.7.5 Suitable irregular antibody screening test(s) have been completed on the recipient's blood sample and found to be negative.

Standard 54 Transfusion responsibilities

- 54.1 Transfusions of blood, red cell components and other components shall be prescribed in the medical records of the recipient by the doctor in charge and administered under medical direction.

- 54.2 The transfusionist shall be a medical practitioner or a registered professional nurse who is working under his delegated authority.
- 54.3 The recipient shall be observed during the transfusion and for an appropriate time thereafter for possible adverse reactions.
- 54.4 The patient shall be positively identified and this identity verified against that on the accompanying documents and the units to be transfused.

Standard 55 Selection of blood products for transfusion

- 55.1 The establishment shall ensure that recipients receive ABO group compatible red blood cell components, or components which have been significantly contaminated by red cells.
- 55.2 Rh D negative recipients shall receive Rh D negative blood except that in times of emergency, males and post-menopausal females may be issued with Rh positive blood.
- 55.3 Rh positive recipients may receive either Rh D positive or Rh D negative blood or red cell components.
- 55.4 Plasma and platelet products should preferably be ABO compatible, especially in the case of infants. However, low titre ABO incompatible plasma and platelet products may be transfused provided they are not significantly contaminated with red cells.
- 55.5 Platelets prepared by apheresis shall have a red cell compatibility test performed if there are visible signs of red cell contamination.
- 55.6 Rh D negative blood shall always be issued to females prior to or during the childbearing years if there is any doubt about the interpretation of the recipient's Rh D type.
- 55.7 The following special considerations are applicable to a recipient under the age of 4 months:
 - 55.7.1 An initial pre-transfusion sample shall be tested in order to determine ABO group and Rh type. (For ABO grouping, only anti-A and anti-B reagents are required).
 - 55.7.2 The serum or plasma of either the infant or the mother may be used to perform the test for irregular antibodies.
 - 55.7.3 Repeat ABO grouping and Rh typing may be omitted for the remainder of the neonate's hospital admission.
 - 55.7.4 If the initial screen for red cell antibodies is negative, it is unnecessary to crossmatch donor red cells for initial or subsequent transfusions and repeat testing may be omitted for the remainder of the neonate's hospital admission, provided Group O Rh compatible blood is used.
 - 55.7.5 If the initial antibody screen demonstrates clinically significant irregular red cell antibodies, components shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible by a full antiglobulin compatibility test.
 - 55.7.6 If non-Group O red cells are to be issued that are not compatible with the maternal ABO group, the neonate's serum or plasma shall be tested for anti-A and anti-B. If anti-A or anti-B antibodies are detected, red cells lacking the corresponding antigen shall be transfused.

Standard 56 Issue of blood products for transfusion

- 56.1 Before blood is released for transfusion, interpretations of current tests shall be compared with the recipient's records (if any) to detect possible error or potentially dangerous clinical situations.

- 56.2 A label with the recipient's first and last names and hospital identification number and interpretation of compatibility tests (if performed), shall be attached securely by the blood bank staff to the blood container.
- 56.3 A record shall be completed for each unit of blood or component (or pooled component) issued, indicating the:
- 56.3.1 Intended recipient's name.
 - 56.3.2 Hospital identification number.
 - 56.3.3 Recipient ABO group, Rh D type and antibody status.
 - 56.3.4 Donor unit or pool identification number.
 - 56.3.5 Donor ABO group and Rh D type (except for plasma products), and
 - 56.3.6 Interpretation of compatibility tests if performed
 - 56.3.7 Date and time of issue.
- 56.4 A sample of blood from the recipient that was used for compatibility testing shall be stored at 1 °C to 6 °C for a minimum of 5 days post transfusion.
- 56.5 A pamphlet of information shall be issued by the establishment with the first container of a component issued for transfusion.
- 56.6 The pamphlet referred to above shall contain information relating to the following responsibilities of the transfusionist and conditions of transfusion:
- 56.6.1 The name, address and telephone number of the establishment that issued the unit.
 - 56.6.2 The instruction that the transfusionist shall carefully inspect the container and the blood therein for any abnormalities and check that the expiry date of the component has not passed.
 - 56.6.3 The instruction that the container shall be maintained within a temperature range stipulated for the specific product at all times during storage and until immediately prior to the transfusion. Blood shall be transported within a temperature range stipulated for the specific product.
 - 56.6.4 The requirement that blood and its components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient. A filter with a pore size of 150 to 240 µm is recommended.
 - 56.6.5 The requirement that blood-warming apparatus specifically designed for that purpose shall be used for warming blood and the temperature shall never exceed 37 °C. Warmed units shall be clearly identified as such with date and time of warming.
 - 56.6.6 The instruction that drugs or medication shall not be added to blood or its components.
 - 56.6.7 The danger of prematurely piercing the hermetic closure of the container prior to transfusing the blood.
 - 56.6.8 The responsibility of the transfusionist to ensure that a recipient is satisfactorily identified as the recipient for whom each container of blood is intended, and that a pre-transfusion compatibility test has been carried out.
 - 56.6.9 The responsibility of the transfusionist, or Blood Bank if packs are returned, to ensure that each container used is retained at a temperature of 1 °C to 10 °C for not less than 48 hours after completion of the transfusion.

56.6.10 The responsibility of the medical practitioner who transfuses, or who has prescribed the transfusion of blood or a component, to report promptly to the establishment any untoward reaction or death of the recipient as an apparent result of the transfusion.

56.7 A container of blood intended for transfusion shall not be opened or entered by piercing the hermetic closure unless for the purpose of preparing for a transfusion.

56.8 Once the need for special transfusion requirements has been identified, there shall be a mechanism in place to ensure that all future requests for that patient meet these requirements.

Standard 57 Irradiation of blood products

57.1 Cellular components shall be irradiated in order to reduce the risk of graft-versus-host disease in the following recipient categories:

57.1.1 Foetuses receiving intrauterine transfusions.

57.1.2 Immuno-compromised recipients.

57.1.3 Recipients of donations from a blood relative, and

57.1.4 Recipients who have undergone bone marrow or peripheral blood progenitor cell transplantation.

57.1.5 Transfusion of HLA matched components.

57.2 The dose delivered shall be between 25 and 50 Gy and targeted to the central portion of the container. Once irradiated, the component shall be appropriately labelled by the establishment performing the irradiation.

57.3 For persons over 12 years of age, irradiated units expire 28 days after irradiation or on originally assigned expiry date (whichever occurs first).

57.4 For children under 12 years of age, the establishment shall define criteria for the irradiation of blood.

Standard 58 Re-issue of whole blood and red cell concentrates

58.1 Whole blood and red cell components issued by the establishment shall not be re-issued, unless:

58.1.1 The component container closure has not been disturbed.

58.1.2 Segments, containing an adequate amount of blood for pre-transfusion testing purposes are still attached to the container, unless re-issued to the same recipient within 72 hours.

58.1.3 There is satisfactory evidence that the unit of blood has been maintained at a temperature of 1 °C to 10 °C and is returned within 24 hours of issue.

58.1.4 It is recorded that the component is being re-issued.

58.1.5 The label of compatibility attached to the component is cancelled and replaced with a new one, unless re-issued to the same recipient within 72 hours.

58.2 If a returned donation is deemed as not safe for re-issue, it shall immediately have a label conspicuously and securely affixed to it indicating that the unit shall not be used for transfusion.

58.3 The plasma from a component deemed unsafe for issue following its return, may, nevertheless, be sent to a blood fractionation establishment for fractionation, provided that it conforms to the minimum specifications of that establishment.

Standard 59 Urgent requirement for blood

- 59.1 When a delay in transfusion may be detrimental to the recipient, blood may be issued as follows:
- 59.1.1 Recipients whose ABO group is not known shall receive group O red cells.
 - 59.1.2 Recipients, whose ABO group has been determined without reliance on previous records, may receive ABO group-compatible blood or red cell components before other tests for compatibility have been completed.
 - 59.1.3 Where the Rh type is unknown, urgent blood issued should be Rh (D) negative if issued to a female prior to or during childbearing years.
 - 59.1.4 There shall be a record signed by the requesting medical practitioner indicating that the urgency of the clinical situation was sufficient to require release of red cells before completion of compatibility testing.
 - 59.1.5 The container-label shall clearly indicate that compatibility testing has not been completed at the time of issue.
 - 59.1.6 Standard compatibility tests shall be completed promptly.
 - 59.1.7 If any blood units are found to be unsuitable, it shall be reported to the attending physician immediately who shall be instructed to stop the transfusion. The unsuitable units shall be recalled if possible.

Standard 60 Transfusion complications

- 60.1 Handling of transfusion reactions by hospital staff
- 60.1.1 Any adverse reaction experienced by a recipient in association with a transfusion is to be regarded as a suspected transfusion reaction.
 - 60.1.2 In the event of a suspected transfusion reaction, the person attending the recipient shall notify a responsible medical practitioner immediately.
 - 60.1.3 The medical practitioner referred to above shall report the incident as soon as possible in writing to such establishment. In event of mortality or major morbidity, the report may be verbal initially and then subsequently in writing.
 - 60.1.4 If there are symptoms or findings suggestive of a haemolytic, or other, transfusion reaction the following shall be done immediately:
 - 60.1.4.1 The transfusion stopped forthwith.
 - 60.1.4.2 The label on the blood containers and all other records examined to determine if an error has occurred in identifying the recipient or the blood.
 - 60.1.5 Obtain a labelled blood sample from the recipient and send it, with all blood-containers and any attached transfusion set and intravenous solutions, promptly to the establishment.
 - 60.1.6 Circulatory overload or mild allergic reactions need not be evaluated as possible haemolytic transfusion reactions.
 - 60.1.7 Where there has been a severe reaction or death following the transfusion of blood or a component, the medical practitioner responsible for the transfusion shall report it to the Inspectorate of the Department of Health as well as to the establishment.
- 60.2 Evaluation by the establishment
- 60.2.1 The establishment shall maintain records of all reported transfusion reactions and these shall be promptly evaluated in accordance with written procedures.
 - 60.2.2 Immediately on receipt of the blood sample and container(s) referred to above, the establishment shall do at least the following:
 - 60.2.2.1 Inspect the recipient's post-transfusion serum or plasma for evidence of haemolysis.
 - 60.2.2.2 Perform an ABO group on the recipient's pre- and post- transfusion samples as well as on the donor pack(s).
 - 60.2.2.3 Perform a direct-antiglobulin test on the post-transfusion sample.
 - 60.2.2.4 Inspect the returned container(s) for any abnormalities.
 - 60.2.2.5 Ascertain that no clerical error has occurred.
 - 60.2.3 The establishment shall evaluate the results of the investigation and any clinically significant findings shall be immediately reported to the treating physician.
 - 60.2.4 If the patient requires further transfusion, the crossmatch shall be performed using a post-reaction sample. Any unused units from the initial crossmatch shall be re-crossmatched against the post-reaction sample before re-issue.

- 60.2.5 A written report of all investigations shall also be forwarded to the treating physician for recording in the recipient's file.
- 60.2.6 If a delayed haemolytic transfusion reaction is detected or suspected, tests shall be done by the establishment to determine and confirm the cause of the reaction.
- 60.2.7 The establishment shall conform to the requirements of the national haemovigilance programme.
- 60.2.8 There shall be a procedure implemented by the establishment to encourage reporting of suspected cases of transfusion transmissible diseases and each report shall be investigated by the establishment.

SECTION 9 : AUTOLOGOUS AND DESIGNATED DONATIONS

Standard 61 Autologous donation service

- 61.1 The establishment may establish an autologous donation collection service for purposes of re-infusion of blood or components back to the donor or recipient.
- 61.2 An autologous donation collection service referred to above shall comply with these Standards in so far as they apply to Good Manufacturing Practice and quality requirements.

Standard 62 Pre-operative autologous donation

- 62.1 Pre-operative autologous blood donation requires the written consent of the autologous donor's physician and the establishment's Medical Director, or designated Medical Officer, or registered professional nurse provided specified criteria are being met.
- 62.2 Informed written consent for the autologous donation shall be obtained from the donor.
- 62.3 Blood collected is to be used solely for the purpose of autologous donation except at the discretion of the Medical Director/Medical Officer.

Standard 63 Criteria for donation of autologous blood

- 63.1 Because of the special circumstances attending autologous blood transfusion, rigid criteria for donor selection are not required.
- 63.2 Suitable guidelines for the autologous donation of blood shall be documented by the establishment.
- 63.3 The following minimum standards regarding the donation of blood shall be met by the establishment:
 - 63.3.1 The volume of blood collected at any one procedure shall comply with Standard 22.5.
 - 63.3.2 The haemoglobin concentration of the autologous donor's blood shall be no less than 11 g/dl (110 g/l), or a haematocrit of 0,33 l/l unless specifically authorised by the Medical Director or designated Medical Officer of the establishment.
 - 63.3.3 Blood shall not be drawn from the donor/recipient within 72 hours of the time of anticipated surgery or transfusion.
 - 63.3.4 Pre-operative donation shall not be undertaken when the autologous donor has, or is being treated for bacteraemia, viraemia or has a significant bacterial or viral infection.

Standard 64 Testing of autologous donations

- 64.1 Autologous donations undergo the same mandatory testing as for blood donors as in Section 6.

- 64.2 Compatibility testing as laid out in Standard 53 shall be carried out on autologous donations.
- 64.3 The autologous donor's physician shall be informed of any abnormal test results with informed consent from the donor.

Standard 65 Labelling requirements

- 65.1 In addition to the labelling requirements outlined in Section 5 for allogeneic blood, the following information shall appear on a label attached, by the establishment, to the blood container: AUTOLOGOUS DONOR.
- 65.2 In addition to the labelling requirements outlined in Section 4 for allogeneic blood, if it is unsuitable for allogeneic use, the following information shall appear on a label attached, by the establishment, to the blood container: FOR AUTOLOGOUS USE ONLY.
- 65.3 A biohazard label shall be applied to each unit by the establishment if any of the tests are positive for HIV, Hepatitis B or Hepatitis C.

Standard 66 Pre-transfusion testing

- 66.1 Pre-transfusion testing shall include obtaining a blood sample from the autologous donor and confirming that the ABO group and Rh D type match the donated units before issue in accordance with Section 8.

Standard 67 Peri-operative collection

- 67.1 Blood may be collected from the autologous donor immediately pre-operatively, or collected intra-operatively from the operative site or from an extra-corporeal circuit. The following standards shall be adhered to:
- 67.1.1 Blood collected peri-operatively shall not be transfused to another recipient.
 - 67.1.2 Methods for peri-operative blood collection and re-infusion shall be safe, aseptic and ensure accurate identification of all blood and blood components collected.
 - 67.1.3 Equipment used for peri-operative blood collection and re-infusion shall be pyrogen-free, shall include a filter capable of retaining particles potentially harmful to the recipient and shall preclude air-embolism.
 - 67.1.4 A comprehensive SOP of all peri-operative collection procedures shall be maintained.
 - 67.1.5 Units collected as above shall be stored under one of the following conditions prior to transfusion:
 - 67.1.5.1 At room temperature for up to 6 hours; or
 - 67.1.5.2 At 1 °C to 6 °C for up to 24 hours;
 - 67.1.6 The storage criteria referred to above also apply to units collected and processed under sterile conditions with a device for intra-operative blood collection that washes with 0,9% saline solution for injection.
 - 67.1.7 Transfusion of blood collected intra-operatively by other means shall begin within 6 hours of initiating the collection.

Standard 68 Designated donations

- 68.1 The provisions determined in Section 3 shall apply to designated donors.

- 68.2 Irradiation of designated units in accordance with Standard 57.4 is recommended for all cases in which cellular blood components are transfused to first or second-degree relatives.
- 68.3 In view of undue pressure which may have been applied to friends or relatives to donate, it is recommended that only blood donations procured from previously enrolled donors be used for other recipients in the event of the donation not being used for the recipient for whom it was procured.

SECTION 10: TESTING FOR EXTERNAL PARTIES

Standard 69 Requirements for testing of blood and blood products from external parties

- 69.1 The establishment shall define criteria for acceptance of samples with regard to age and condition of sample. Sample age shall be less than 72 hours or as prescribed by the package insert.
- 69.2 There shall be a procedure, including tests to be performed, for each type of test request.
- 69.3 Issuing of results shall comply with requirements and confidentiality shall be maintained.

SECTION 11: PLASMA FOR FRACTIONATION

Standard 70 Plasma for Fractionation

- 70.1 Plasma for Fractionation may be collected, transported and stored in accordance with the requirements of these Standards.
- 70.2 Plasma for Fractionation shall be separated from whole blood within 9 days after expiry of the whole blood.