AFRICA SOCIETY FOR BLOOD TRANSFUSION

STANDARDS

STEP-WISE ACCREDITATION PROGRAMME
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INTRODUCTION

The Standards for the Africa Society for Blood Transfusion Step-Wise Accreditation Programme were prepared by a sub-group of the Task Team for Accreditation established by the Africa Society for Blood Transfusion (AfSBT) with guidance from AABB. AABB has licensed Section 1 of these standards to AfSBT for the purpose of implementing and administering the AfSBT Step-Wise accreditation programme within Africa. AABB retains all other rights, title and interest to the licensed material.

The goal of the Standards is to provide a benchmark for accreditation of facilities and to maintain and enhance the quality and safety of blood transfusion in Africa. The effective date of this revision of the first edition of the Standards is 1 June 2014.

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A facility or blood service and/or other country governments and officials that make use of these Standards shall:

- Acknowledge the ownership of AfSBT in documents that are developed from perusal of AfSBT standards and/or accreditation documents.
- State the document and version number used in the development of derivative documents.
- Use these documents only for guidance and as a basis for the development of facility/country documents.
- Adopt or reference these documents only if they are acknowledged as AfSBT intellectual property.
- Not publish AfSBT Standards or derivative documents as works of the facility/organization/government without the express written authorization of AfSBT. Requests should be directed to AfSBT. AfSBT acknowledges its supporters in this programme: AABB (Standards documentation), National Bioproducts Institute of South Africa (funding), ICCBBA (funding), and the US Centers for Disease Control and Prevention (funding).

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These Standards apply to blood services or individual facilities that perform any or all of the following functions: mobilization, recruitment, selection and screening of blood donors; collection of blood; processing of blood into blood components; testing of blood for group and transfusion transmissible infectious diseases; pre-transfusion/compatibility testing; and the storage, handling, transportation and distribution of blood and blood components. Once a qualifying blood service or facility decides to become accredited, the accreditation process will include every activity covered under the standards. At present, however, AfSBT’s Accreditation programme is not structured to accommodate accreditation of facilities that only transfuse blood. In cases where activities such as compatibility testing and oversight of transfusion activities are not the responsibility of the blood service or facility and are outside the control of the blood service, the corresponding requirements would not apply. However, there will be differences in organizational structure and in the co-ordination of responsibility for these activities between countries, and even within countries. Accordingly, for some countries, additional interpretation or consultation with AfSBT may be necessary before accreditation can move forward.

The AfSBT sub-group used an evidence-based decision-making process, where possible, to modify existing requirements or create new specific requirements. These Standards are based on input from a variety of sources, including comments from AfSBT and AABB members, and recognized experts in blood banking and transfusion medicine.

Notes on Language

Some terms or phrases are specifically defined for purposes of these Standards. The term “shall” is used to indicate a mandatory statement and describe the single acceptable activity or method; failure to meet the specified requirement would constitute a non-conformance under an accreditation programme. The phrase “the blood facility shall have a procedure” or “shall have a process” indicates
that the institution must have a specific policy or process to achieve the goal required by the standard. The word “should” is used to indicate a recommendation. “Should” is advisory, but is not mandatory for accreditation. It indicates a commonly accepted activity for which there may be effective alternatives. The term “may” is used to reflect an acceptable method or practice that is recognized but not required.

A glossary is included for the purpose of defining terms to reflect their usage in the context of these Standards, not necessarily general usage. Therefore, it is recommended that users of these Standards review the glossary before reviewing the standards.

Notes on Format, Regulatory and Legal Issues

These Standards represent accepted minimum performance requirements that may be exceeded in practice. Many organizations working in special situations can, and should, be more rigorous in their internal requirements. These Standards have been developed on the basis of good medical practice and, when available, scientific data. There may be legal requirements of local governments that apply as well. It should be noted that compliance with these Standards will not always result in compliance with all applicable laws and requirements. These Standards are not intended as a substitute for legal advice and the content should not be relied upon for legal purposes.

Every effort was made to take all existing technologies into account; however, in some areas, the manufacturer’s directions for the use of a material or device or the requirements for its use may be more prescriptive or even in conflict with the requirements contained in this publication. In these cases, the material or device should be used in accordance with the manufacturer’s directions. Users of this publication who encounter such issues are encouraged to submit their feedback to the AfSBT Management Office.

The standards are specific and usually require the existence of procedures that address elements of day-to-day operations. The most specific requirements are reference standards, which are presented in tabulated form. The tables contain information that is most easily summarized and understood when presented by tabulation (as charts). It is important to note, however, that all requirements are of equal importance, whether contained in a chart, a specific technical requirement, or a general standard. In addition, a requirement, once stated, is not repeated because it applies throughout all of the Standards.

When a pen symbol [.] follows a standard, it indicates a written record requirement associated with the fulfilment of the standard. The reader should refer to Table 1 for the specific record to be maintained.

When an information symbol (i) appears in a standard, it indicates that guidance / explanatory notes are provided in the “AfSBT Step-Wise Accreditation Standards – Guidance Document” (OMD-E-002).

When reference is made to a procedure as a requirement, it means that the procedure shall be in a written format and shall be followed accurately by personnel carrying out the procedure.

Variances and Other Considerations

Alternative methods or approaches that deviate from these Standards may, at times, allow equally safe practice. Such situations are infrequent, and for organizations seeking accreditation against these Standards, alternative methods can be used to meet requirements of these Standards provided that justification is documented by the requesting facility or programme. Such methods or approaches shall be approved or disapproved by the Standards Committee and shall apply only to that facility or programme and only for a single certification/accreditation cycle. Information relating to approved variances will be reviewed for possible inclusion in future editions of the Standards. Variances will not be granted for any request that increases the safety risk to donors and/or transfusion recipients.

The guiding principle of this document is to be consistent with available scientific information while advocating patient safety and focusing on optimal care for donors who provide blood and blood components. The requirements are intended to be simple, clear and practical. The use of these Standards should aid materially in developing and maintaining policies, processes, and procedures that will provide safe and effective blood transfusion, as well as a safe working environment for personnel of blood services or facilities.
GLOSSARY – of terms used in these Standards

Adverse Event: A complication in a donor or patient which may occur in relation to a blood donation or a transfusion.

Agreement: A contract, order, or understanding between two or more parties, such as between a facility and one of its customers, suppliers or sub-contractors, or a medical director and the individual contracted to make medical decisions in the absence of the medical director.

Agreement Review: Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented and achievable.

Assessment: A systematic, independent examination that is performed at defined intervals and at sufficient frequency to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments may include comparison of actual results to expected results. Types of assessments include external assessments, internal assessments, quality assessments, peer-review assessments, and self-assessments.

Audit: An audit is an evaluation of an individual, organisation, system, process or product. In the context of these Standards, the term Audit is used interchangeably with Assessment.

Blood Components: Blood components are often also referred to as blood products. Blood components may be prepared from a whole blood collection or may be produced through an automated collection e.g. red blood cells, plasma and platelets.

Blood Service: An organization, generally with multiple facilities, that performs one or more of the following activities: donor mobilization, donor screening, blood collection, processing of blood into components, compatibility testing, storage, selection, and distribution of blood and blood components.

By a Method known to: Use of published data to demonstrate the acceptability of a process or procedure, particularly for blood and blood component preparation.

Change Control: A structured method of revising procedures (defined as a policy, process or procedure), including hardware or software design, transition planning, and revisions to all related documents.

Closed System: A system in which the contents are not exposed to air or outside elements during preparation and separation of blood.

Collection Facility: A facility that collects blood and/or blood components from a donor

Competence: Ability of an individual to perform a specific task according to procedures.

Compliance: See Conformance.

Conformance: Fulfilment of requirements. Requirements may be defined by customers, standards, regulatory agencies, or law.

Corrective Action: An activity performed to correct an existing non-conformance, or other undesirable situation.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the facility's products or services.

Customer: The receiver of a product or service. A customer may be internal (i.e. another department within the same organization) or external (i.e. another organization).

Deviation: A departure from policies, procedures, applicable regulations, standards, or specifications.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, policies, procedures, and forms.

Document (verb): To capture information for use in documents through writing or electronic media.

Equipment: A durable item, instrument, or device used in a process or procedure.

Event: A generic term to encompass the terms “incident,” “error,” and “accident.”
Expiry: The last day or time in which the blood or blood component is considered suitable for transfusion or infusion.

Facility: A location or operational area within an organization. The part of the organization that is assessed by an accrediting or certifying body and receives accreditation/certification for its specific activities.

Guidelines: Documented recommendations.

High Titre: Anti-A and/or anti-B in plasma or serum, which when diluted to 1 in 64 in normal saline, agglutinates red cells containing the corresponding antigens (i.e. A1, B or A1B).

Inspect: To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.

Issue: To release for clinical use (i.e., transfusion).

Label: An inscription affixed to a unit of blood, a blood component or a specimen for identification.

Labelling: Information that is required or selected to accompany a unit of blood, blood component, or specimen, which may include content, identification, storage requirements, expiry date, cautionary statements, or indications for use. Unless specifically required in the standard, labelling requirements need not be affixed to the unit of blood or blood component, provided there is a means of tracing the information to that unit.

Lived with: Resided in the same dwelling (e.g. home, apartment, immediate family or relatives’ residence).

Maintain: To keep in the current state.

Material(s): Goods or items used in the processing or testing of blood or blood components. Materials are a type of input product. Reagents are a type of material.

Neonate: A child less than 4 months of age.

Non-conformance: Failure to meet requirements.

Open System: A system in which the contents are exposed to air and outside elements during preparation and separation of components.

Organization: An institution, or part thereof, which has its own functions and top management.

Paid Donor: A donor, who is compensated by a facility or a family for donating blood.

Policy: A documented general principle that guides present and future decisions.

Preventive Action: An action taken to eliminate the cause of a possible non-conformance and to reduce the potential for non-conformances or other undesirable situations to recur.

Procedure: As used in these standards, a policy, a process and/or a procedure.

Process Control: Activities to standardize and control processes in order to produce predictable output.

Product: A tangible result of a procedure.

Proficiency Testing: The structured evaluation of procedures, equipment, materials and personnel to establish suitability.

Qualification: With respect to individuals, the aspects of an individual’s education, training, and experience that are deemed necessary to successfully meet the requirements of a position. Specifically for equipment, verification that specified attributes required to accomplish the desired task, have been met.

Quality: Characteristics of a unit of blood, blood component or specimen, critical material, or service that bear on its ability to meet requirements.
Quality Control: Testing routinely performed on materials and equipment to check their proper function. When quality control testing does not provide the expected results, the tests done in parallel are to be deemed invalid.

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management.

Quality System: The organization’s structure, responsibilities, policies, procedures and resources established by top management to achieve quality.

Quarantine: To isolate untested or nonconforming blood, blood components, or materials to prevent their distribution or use.

Reagent: A substance used to perform an analytical procedure.

Record (noun): Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record (verb): To capture information for use in records through writing or electronic media.

Regulations: Rules promulgated by government authorities to implement laws enacted by legislative bodies.

Release: Removal of component from quarantine or in-process status for issue and distribution.

Repeat (Regular) Donor: For purposes of these Standards, a donor who has previously donated one or more times.

Replacement Donor (also Family Replacement Donor): A donor, who has been asked by the family of a patient in need of a transfusion to give blood for a specific recipient, or to replace the blood transfused to a specific recipient.

Service: An intangible result of a process or procedure.

Sexual Contact: Any of the following activities (whether or not a condom or other protection was used): vaginal sex (contact between penis and vagina); oral sex (mouth or tongue on someone’s vagina, penis, or anus); anal sex (contact between penis and anus).

Shall: A verb used to indicate a requirement.

Specified Requirements: Any requirements in these Standards including, but not limited to, government requirements; requirements of a facility’s internal policies, processes and procedures; manufacturers’ instructions; customer agreements; and requirements of accrediting organizations.

Supplier: An entity that provides an input material or service.

Top Management: The highest level personnel within an organization, including employees and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization’s quality policy. Top management may be an individual or a group of individuals.

Traceability: The ability to follow the history of a product or service by means of recorded identification.

Transfusion Transmissible Infection: An infection that is capable of giving rise to a disease or condition caused by a virus, bacterium, fungus, parasite, agent of transmissible spongiform encephalopathy or other unidentified micro-organism that may be transmitted by transfusion of blood or blood components.

Unit: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor. Collection may be by apheresis.

Validation: Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.
**Variance:** A variance to standards is an alternative method or approach that deviates from, but meets the intent of, the Standards, and does not increase the safety risks to donors and/or transfusion recipients.

**Verification:** Confirmation by examination and provision of objective evidence that specified requirements have been met. In the context of validation, verification means that a previously validated process has been effectively implemented in a different location.

**Voluntary Non-Remunerated Blood Donor (VNRBD):** A donor who has been motivated to donate blood without expectation of compensation or pursuant to third party pressure.
SECTION 1 – QUALITY SYSTEM

1.1 ORGANIZATION AND STRUCTURE

The blood service or facility shall have a structure that clearly defines the parties responsible for the activities covered by these Standards. This organizational structure shall be captured in writing or electronically.

1.1.1 Organization

Responsibility for the activities detailed in these Standards shall be assigned to individuals and these individuals may be responsible for more than one activity. Some activities may be delegated to another entity provided the terms of delegated authority and responsibility are clearly defined.

1.1.1.1 There shall be an organogram that shows a clear delineation of responsibilities, accountability and inter-relationships.

1.1.1.2 The organogram shall be reviewed at facility defined intervals and updated as required.

1.1.2 Top Management

The facility 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, regulations and standards.

1.1.2.1 Top management shall be responsible for the quality policy and shall provide support to the development, implementation and maintenance of the quality system.

1.1.3 Medical Director

The facility shall have a medical director qualified by education, training and/or experience in a scientific or medical field. The medical director shall have responsibility and authority for all medical matters and for the consultative and support services that relate to the care and safety of donors and/or patients. The medical director may delegate these responsibilities to another qualified individual; however, the medical director shall retain ultimate responsibility for the delegated duties.

1.1.3.1 Exceptions to procedures warranted by clinical situations shall require justification and pre-approval by the medical director on a case-by-case basis.

1.1.4 Quality Manager

A designated individual, with training and experience in quality management, shall be appointed with overall responsibility for quality within the facility. This individual shall be responsible for the implementation and maintenance of the quality system. 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.

1.2 QUALITY SYSTEM

The facility shall develop, implement and maintain a quality system, including a quality policy, to address the requirements of Section 1 of these Standards.

1.2.1 The quality system shall be communicated within the facility so that all personnel understand their role in ensuring quality.

1.2.2 Top management shall review and evaluate the quality system at planned intervals and take action to ensure its continuing suitability, adequacy and effectiveness.

1.2.3 The facility shall maintain a quality manual that explains how the elements of the quality system apply or have been implemented in the facility. The elements that shall be included are:

1.2.3.1 Organization and Structure.
1.2.4 Quality system standards shall apply to all activities performed.

1.3 RESOURCES

There shall be adequate financial and human resources allocated to meet the requirements of these Standards.

1.3.1 Financial Resources

The facility shall identify financial resource requirements that are adequate to perform, verify and manage its activities.

1.3.1.1 The facility shall develop a budget to ensure its ongoing operation.

1.3.2 Human Resources

The facility shall have sufficient, trained personnel, working under supervision, to perform its activities. Personnel performing specific assigned tasks shall be qualified on the basis of education, training and/or experience.

1.3.3 Job Descriptions

The facility shall retain job descriptions, which are required for all personnel, and outline key responsibilities and duties to be performed. Personnel shall have access to their job descriptions.

1.3.3.1 Job descriptions shall be reviewed at facility defined intervals and updated as required.

1.3.3.2 Job title and reporting structure as detailed in each individual’s job description shall correlate with the pertinent information in the facility’s organogram(s).

1.3.4 Training and Competence

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

1.3.4.1 There shall be a system for competence assessment of individual personnel at facility defined intervals.

1.4 DOCUMENTS AND RECORDS

The facility shall develop, implement and maintain a document control system that addresses document creation, identification, review, approval, revision, and retention. The document control system shall define procedures for making changes to documents.

1.4.1 Documents

Documents shall be:

1.4.1.1 Uniquely identified.

1.4.1.2 In a standardized format (additional procedures may be referenced, e.g. manufacturer’s instructions).

1.4.1.3 Current and dated to prevent the use of invalid or obsolete documents.

1.4.1.4 Reviewed and approved by authorized personnel prior to use.

1.4.1.5 Legible and readily accessible to personnel who rely on them to perform activities.
1.4.1.6 Reviewed at least every two years and revised, as needed, according to facility defined change control procedure.

1.4.1.7 Removed from points of issue or use when obsolete or invalid and archived according to the facility defined retention policy.

1.4.2 Records

The facility shall ensure identification, collection, indexing, access, filing, storage, and disposition of records. Records shall be legible; complete; retrievable in a period of time appropriate to the circumstances; and protected from accidental or unauthorized destruction or modification.

1.4.2.1 Copies of records shall be identified as such, and verified to contain the original content and shall be legible, complete and accessible.

1.4.2.2 A system designed to prevent unauthorized access and ensure confidentiality of records shall be established and followed.

1.4.2.3 The record system shall make it possible to trace blood or blood components from source to final disposition; including all screening and testing results, the result of any other monitoring performed, and to investigate adverse reactions in patients.

1.4.2.3.1 The record system shall ensure that donors are uniquely identified.

1.4.2.4 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.

1.4.2.4.1 Changes or corrections made shall be dated and signed.

1.4.2.5 Electronic records:

There shall be procedures to support the management of computer systems.

1.4.2.5.1 There shall be a system in place for routine backup of all critical data. Backup data shall be stored in an off-site location.

1.4.2.5.2 Procedures shall be in place to ensure that data are retrievable and usable.

1.5 SUPPLIERS AND SERVICE PROVIDERS

The facility shall have procedures to evaluate the ability of suppliers of critical materials, equipment, and services to consistently meet specified requirements.

1.5.1 The facility shall participate in the selection of suppliers, when possible, before acceptance of an agreement.

1.5.1.1 If the facility is not the procurement authority, it shall report any supplier’s failure to meet specified requirements to the procurement authority.

1.5.2 The facility shall maintain records of suppliers’ performance. These shall be reviewed and updated at facility defined intervals.

1.5.3 The facility shall develop, implement and maintain an inventory management system.

1.5.4 Agreements:

Agreements, including changes to existing agreements, shall define supplier and customer expectations and shall reflect agreement between the parties.

The responsibilities for activities covered by these Standards, when more than one facility is involved, shall be specified by agreement.

1.5.4.1 Agreement Review:

Agreements shall be reviewed at facility defined intervals and communicated to all parties.

1.5.4.2 When subcontractors perform activities covered by these Standards the responsibilities shall be specified by agreement. The subcontractor shall perform the agreed upon services as defined by these Standards.
1.6 INCOMING RECEIPT, INSPECTION AND TESTING

The facility shall maintain a procedure for the qualification or acceptance of incoming products and critical materials prior to use. Incoming products and critical materials shall be received, inspected and tested, as necessary, before acceptance or use. [✓]

1.6.1 Critical materials shall meet specified requirements and conform to international or national laws, regulations or standards.

1.7 EQUIPMENT

The facility shall identify the equipment that is critical to the provision of blood, blood components and services. The facility shall have procedures to ensure that calibration, monitoring and maintenance of equipment meet specified requirements.

1.7.1 Selection of Equipment: ◊

The facility shall define the selection criteria and use them for selection of equipment to ensure that equipment meets the needs of the facility’s activities. Equipment shall be capable of achieving the accuracy required. [✓]

1.7.2 Equipment Qualification: [✓] ◊

All critical equipment shall be qualified for its intended use.

1.7.3 Use of Equipment:

Equipment shall be adequate in number, placed in a location suitable for optimal operation and used in accordance with manufacturer’s instructions.

1.7.4 Identification of Equipment:

Equipment shall be uniquely identified. The facility shall maintain a list of critical equipment and its location.

1.7.5 Calibration:

Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. [✓]

1.7.5.1 There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting.

1.7.5.2 At a minimum, calibrations and/or adjustments shall be performed:

1.7.5.2.1 Before use.

1.7.5.2.2 After activities that may affect the calibration.

1.7.5.2.3 At intervals prescribed by the manufacturer.

1.7.6 Equipment Monitoring and Maintenance:

The facility shall have scheduled monitoring and preventive maintenance programmes so that equipment remains fit for use. The programme shall include/define: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results. [✓]

1.7.7 Equipment Malfunction:

Investigation and follow-up of equipment malfunctions, or damage shall include:

1.7.7.1 Removal of the equipment from use and/or isolation, and identification as not suitable for use.

1.7.7.2 Assessment of blood and blood components affected by equipment that is found to be out of calibration.

1.7.7.3 Assessment of the effect on donor eligibility and donor and patient safety.

1.7.7.4 Investigation of the malfunction or damage.

1.7.7.5 Steps for requalification of the equipment.

1.7.7.6 Reporting the nature of the malfunction or damage to the manufacturer, when indicated.[✓]
1.7.8 Computer systems: ☑

The facility shall have procedures to support the implementation and modification of hardware, related software and databases relating to the specified requirements. There shall be procedures to support the management of computer systems.

1.7.8.1 In the event that computerized data and computer-assisted functions are unavailable, an alternative system that ensures continuous operation shall be available. The alternative system shall be tested periodically. Procedures shall address mitigation of the effects of disasters and recovery plans. [✓]

1.7.8.2 A system designed to prevent unauthorized access to computers and electronic records shall be established and followed.

1.8 WORK ENVIRONMENT AND SAFETY

1.8.1 The work environment shall be suitable for the activities performed.

1.8.1.1 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. ☑

1.8.1.2 Premises shall allow for an orderly workflow with adequate separation between different functions.

1.8.1.3 The facility shall take adequate measures to ensure protection of the environment, and disposal of waste, including biohazardous waste.

1.8.2 The facility shall have procedures to ensure the provision of safe working conditions that meet national laws and regulations (where applicable).

1.8.2.1 Accidents and incidents in the workplace shall be reported and investigated in accordance with national regulations. [✓] ☑

1.8.2.2 Necessary personal protective equipment and clothing shall be defined, provided and used.

1.8.2.3 The facility shall maintain procedures to ensure the safety of donors, patients and visitors on the premises.

1.9 INTERNAL AND EXTERNAL AUDITS

The facility shall have procedures to ensure that internal and external audits of operations and quality systems are scheduled and conducted. The facility shall have procedures for reviewing the outcomes of all audits.

1.9.1 Internal Audits:

1.9.1.1 Personnel performing audits shall be independent of the area being audited.

1.9.1.2 The internal audit reports shall be reviewed by personnel having responsibility for the area audited and the quality/auditing manager. [✓] ☑

1.9.1.3 When non-conformances are identified, corrective action shall be taken. [✓]

1.9.2 External Audits: ☑

The facility shall participate in external audit programme(s) performed by a qualified independent body. [✓]

1.10 NON-CONFORMANCES ☑

The facility shall have procedures to detect, capture, assess, investigate and monitor non-conformances, including those found as the result of internal and external audits. The responsibility for review and authority for the disposition of non-conforming blood, blood components, critical materials, and services shall be defined. [✓]

1.10.1 The facility shall have procedures for corrective action of non-conformances, complaints, workplace accidents and incidents, to include the following elements:

1.10.1.1 Description of the event.

1.10.1.2 Immediate remedial action.
1.10.1.3 Investigation of the root cause.
1.10.1.4 Determination of corrective action required.
1.10.1.5 Evaluation to ensure that corrective action is taken in a defined time frame and that it is effective.

1.10.2 Preventive Action:

The facility shall have procedures for preventive action that include the following elements:

1.10.2.1 Review of information including audit results, proficiency testing results, quality control records, and complaints to detect and analyse potential causes of non-conformances.
1.10.2.2 Determination of steps needed to respond to potential problems requiring preventive action.
1.10.2.3 Initiation of preventive action and application of controls to monitor effectiveness.

1.10.3 There shall be scheduled reviews of non-conformances to detect trends and address areas requiring specific actions.

1.10.4 Non-conforming Components:

1.10.4.1 Authorized Use:

In exceptional circumstances, at the discretion of the medical director, blood and blood components may need to be issued when not conforming to all mandatory test requirements. Upon receipt of the request the facility shall notify the recipient’s physician that all requirements cannot be met. []

1.10.4.1.1 The recipient’s physician shall acknowledge in writing that the clinical situation is sufficiently urgent to require the release of the blood component before completion of the compatibility and/or infectious disease testing.
1.10.4.1.2 A label on the container shall indicate that the required tests have not yet been performed or completed. Section 6.3.2 applies.
1.10.4.1.3 The required testing shall continue after the release of the units, and if any of the blood units are found to be unsuitable, it shall be reported immediately to the attending physician who shall be instructed to stop the transfusion immediately. The non-conforming unit(s) shall be recalled, if possible.

1.10.4.2 Discard:

The facility shall have a procedure for the discard of non-conforming blood or blood components. Such units shall be labelled as not suitable for therapeutic use and shall be disposed of as biohazardous waste. []

1.10.4.3 Recall:

The facility shall have procedures for the recall of non-conforming blood or blood components that are determined after release not to meet specified requirements.

1.11 CONTINUAL IMPROVEMENT

1.11.1 The facility shall have procedures for obtaining feedback, including complaints, from donors and customers/clinicians. []

1.11.2 The facility shall have procedures to collect and evaluate quality indicator data on a scheduled basis.

1.11.3 The facility shall use reviews of the quality system to assess opportunities for improvement, and the need for changes to the quality system. []

1.11.4 Monitoring and evaluation data shall be used to improve facility operations.

1.12 PROCESS CONTROL

The facility shall ensure that activities that affect the quality of blood, blood components, and services are carried out under controlled conditions.
1.12.1 Validation Activities:

The facility shall develop and implement procedures for the validation of new or changed procedures, test methods, and software prior to implementation. 

1.12.1.1 Validation plans shall be approved prior to the work being undertaken.

1.12.1.2 Results shall be reviewed and acceptance/rejection decisions made by authorized individuals.

1.12.1.3 Re-validation shall be performed where changes have occurred or results indicate the need.

1.12.2 Change Control:

The facility shall have procedures for the management of changes to the facility’s operations, and quality system so that the quality of the components and services is maintained.

1.12.3 Internal and External Quality Assessment (IQA/EQA):

The facility shall develop and implement a system for determining the accuracy and reliability of tests. If the facility does not participate in a formal EQA programme for some or all tests, there shall be an IQA programme to ensure the accuracy of those tests.

1.12.3.1 Results of IQA and EQA shall be reviewed and corrective action taken, where appropriate, when expected results are not achieved.

1.12.4 Quality Control:

1.12.4.1 A programme of quality control shall be established that is sufficiently comprehensive to ensure that personnel, reagents, equipment and methods function as expected.

1.12.4.1.1 The facility shall randomly sample and perform quality control testing on blood and blood components.

1.12.4.2 The facility shall analyse quality control results. If the analysis shows a consistent deviation away from specifications, the cause thereof shall be investigated and corrective measures shall be taken.

1.12.5 Use of Materials:

All materials (including containers and solutions used for collection, preservation and storage of blood, blood components, and reagents used for required tests on blood specimens) shall be stored and used in accordance with the manufacturer’s written instructions and shall meet specified requirements.

1.12.5.1 Reagents that are prepared by the facility shall be standardized to meet or exceed performance specifications of commercial reagents.

1.12.6 Identification and Traceability:

For each critical step in collection, processing, blood grouping, transfusion transmissible infection screening, compatibility testing and transportation of blood and blood components, there shall be a mechanism to identify the individual who performed the step and when it was performed.

1.12.6.1 Traceability:

The facility shall ensure that blood, blood components and critical materials used in their processing, as well as laboratory specimens and donor and patient records, are identified and traceable from source to final issue or disposition.
SECTION 2 – BLOOD DONOR MANAGEMENT

2.1. MOBILIZATION AND RECRUITMENT OF BLOOD DONORS

Prior to collection the facility shall educate potential donors regarding the donation process and the risk of transmitting infectious diseases through blood transfusions.

2.1.1. Blood shall be collected from healthy, voluntary non-remunerated donors identified by the facility to be at low-risk for transfusion transmissible infections.

   2.1.1.1. Efforts shall be directed towards encouraging and retaining at least 10% repeat (regular) donors.

2.1.2. The facility shall have procedures to monitor emerging infectious diseases that may be transmissible by blood.

2.1.3. The facility shall not offer incentives that discourage candid responses to donor eligibility criteria.

2.2. DONOR SELECTION CRITERIA

2.2.1. The facility shall develop donor selection criteria that are based on these Standards, national laws and regulations, if applicable, and local epidemiological data of infectious diseases, risk behaviour and local customs that may have an effect on the safety of the donor or recipient. [Reference: Table 2]

2.2.2. The facility shall have procedures to ensure that medical consultation is available when necessary. Records of such consultation and outcome shall be kept.

2.2.3. Assistance shall be given by donor registration personnel to donors with special needs, including illiterate donors according to facility defined criteria.

2.3. DONOR SCREENING

A donor health history questionnaire that is designed to elicit information about risk factors to the donor or patient shall be used. The questionnaire shall be evaluated, periodically updated and used in a confidential manner and shall be completed prior to all collections.

2.3.1. A donor medical history section of the questionnaire shall be prepared in a language which is understood by the donor, and shall be completed prior to each donation, in order to determine eligibility for donation.

2.3.2. Donors shall be interviewed to determine their suitability for donation. This interview shall be conducted in a manner that preserves the privacy of the donor.

2.4. DONOR CONSENT

2.4.1. Donors shall be informed about the blood donation procedure, potential adverse reactions and post-donation care, the tests carried out on the donated blood, the process for notification of abnormal results, and information that may be released to a third party.

2.4.2. Written consent for testing the blood at the time of donation or in the future shall be obtained from all donors prior to donation. The donor shall have the opportunity to ask questions and refuse consent. In the event that a potential donor refuses to provide consent, the blood donation shall not be drawn.

2.4.3. A mechanism shall be established to permit a donor to request in confidence and/or subsequent to donation, that their donation be discarded.

2.5. DONOR COUNSELLING

2.5.1. Donors shall be notified in a confidential manner of test results for transfusion transmissible infection (TTI) markers and any medically significant finding(s) identified during the pre-donation evaluation.
2.5.2. Donors found to be reactive during screening for one or more TTI shall be provided with counselling services. When counselling services are not available, the facility shall identify and refer donors to appropriate external medical services. [✓][✓]
SECTION 3 – COLLECTION OF BLOOD FROM DONORS

3.1 STERILITY

The blood collection equipment shall be sterile, pyrogen-free and for single-use, with a closed system of collection.

3.2 PROTECTION AGAINST CONTAMINATION

Prior to collection of blood, the container to be filled shall be inspected in a manner recommended by the manufacturer 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.

3.2.1 The venepuncture site shall be disinfected so as to minimize the risk of microbial contamination by following a validated method and using a qualified material that will not adversely affect the blood collected.

3.2.2 Blood shall be collected by single venepuncture and the flow of blood shall be continuous.

3.2.2.1 Maximum collection time for whole blood intended for production of labile components shall be no longer than 12 minutes for platelets and 15 minutes for cryoprecipitate and FFP.

3.3 SPECIMENS

The blood specimens for laboratory tests shall be collected at the same time as the collection of blood, as part of the collection process. Specimens shall be labelled before the collection begins and shall be re-identified with the blood container immediately after filling.

3.3.1 Each specimen shall be identified by a numeric or alpha-numeric system at the time of collection of blood, so that donations can be traced back to the donor.

3.3.2 The pilot tubing of the plastic blood bag shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent testing.

3.4 RATIO OF BLOOD TO ANTICOAGULANT

The volume of blood collected shall be proportionate to the volume of anticoagulant according to the manufacturer’s instructions.

3.4.1 At intervals during collection, the blood shall be gently agitated using a method that has been shown to mix the blood and anticoagulant in a manner that prevents the formation of microclots and thus the consumption of clotting factors.

3.5 TEMPERATURE DURING TRANSPORTATION

After collection, blood shall be stored under conditions appropriate for the components to be made from it.

3.6 DONOR REACTIONS

Resources shall be available and personnel shall be trained in the management of adverse reactions in donors, both for mobile and fixed sites.

3.7 APHERESIS

This section relates only to apheresis of healthy, voluntary donors and not to any therapeutic procedure.

3.7.1 Donor Selection:

Apheresis donors shall comply with all the donor selection and deferral criteria for allogeneic while blood donations except where specifically indicated.

3.7.2 Donors who have ingested aspirin or similar drugs within 72 hours of donation shall not be suitable for plateletpheresis.
3.7.3 Collection
The apheresis procedure shall be carried out using only equipment that automatically returns blood to the donor.

3.7.4 Apheresis components shall be collected using sterile, single-use disposable kits.

3.7.5 Anticoagulant shall be used at a ratio that meets, while not exceeding, manufacturer’s instructions.

3.7.6 Extracorporeal blood volume, including final collection volume, shall not exceed 15% of the donor’s estimated blood volume.

3.7.7 Apheresis donor records shall include:

3.7.7.1 Results of laboratory tests including platelet count and serum protein levels.
3.7.7.2 Date of last apheresis procedure or other donation.
3.7.7.3 Frequency of donation.
3.7.7.4 Volume of component separated.
3.7.7.5 Drugs administered.
3.7.7.6 Duration of procedure.
3.7.7.7 Lot number of disposables.
3.7.7.8 Replacement fluids.
3.7.7.9 Adverse reactions and their management.

3.7.8 The minimum interval between two apheresis collections shall be 48 hours and, at most, 24 procedures shall be performed on any individual donor within a 12 month period.

3.7.8.1 If plasma is donated more frequently than once every 4 weeks, the donor shall be checked before every procedure to ensure that their haemoglobin and/or haematocrit and total serum protein levels meet the minimum levels required by facility defined criteria.

3.7.8.2 Donors who undergo apheresis for cellular components more than once every 12 weeks, shall be tested in accordance with facility defined criteria for haemoglobin/haematocrit, total serum protein and platelet count.

3.7.9 Donors shall be observed during apheresis for adverse reactions.

3.7.10 If it becomes impossible to return the donor’s red cells during apheresis, at least 8 weeks shall elapse before a subsequent apheresis procedure.
SECTION 4 – HANDLING, TRANSPORTATION AND STORAGE

4.1. The facility shall have procedures to ensure that blood and blood components are handled, stored and transported in a manner that prevents damage, limits deterioration and meets specified requirements.

4.2. Following collection, blood shall be placed in a qualified container for a maximum of 24 hours. The transportation container shall have sufficient refrigeration capacity to cool the blood continuously towards the required temperature range of +2°C to +10°C unless platelet concentrates are to be prepared, in which case blood donations shall be cooled towards +22°C until arrival at the processing laboratory.

4.3. PRE-PROCESSING STORAGE

4.3.1. Blood collected for processing shall be placed in an environment with a temperature range of +4°C ±2°C within 8 hours of collection.

4.3.2. Blood intended for platelet production shall be maintained at a temperature range of +22°C ±2°C.

4.4. STORAGE DEVICES FOR BLOOD AND BLOOD COMPONENTS

4.4.1. Storage devices shall have the capacity and design to ensure that the correct temperature is maintained.

4.4.2. Refrigerators, freezers and platelet incubators shall have their temperature either continuously monitored or shall be monitored at least 3 times at regular time intervals over 24 hours.

4.4.3. If storage utilizes liquid nitrogen, liquid nitrogen levels or temperature shall be either continuously monitored or monitored 3 times at regular time intervals over 24 hours.

4.4.4. The facility shall use designated storage areas to limit deterioration and prevent damage to materials, in-process and final products. The facility shall control access to such areas.

4.4.5. Refrigerators or freezers used for blood storage shall contain only donor blood, blood specimens, reagents or blood components and no other items, such as foodstuffs.

4.4.6. The facility shall have procedures to maintain blood and blood components at the required temperature, in the event of failure of power or equipment.

4.5. ALARM SYSTEMS

Storage devices for blood and blood components shall have alarms that conform to the following standards:

4.5.1. The alarm shall be set to activate under conditions that will allow timely action to be taken before blood or blood components reach an unacceptable temperature.

4.5.2. The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches an unacceptable level.

4.5.3. Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action.

4.6. TRANSPORTATION OF BLOOD AND BLOOD COMPONENTS

Containers used for the transportation of blood and blood components shall be validated to ensure they are suitable for maintaining required temperatures.

4.6.1. The facility shall verify that the establishment receiving the containers of blood and blood components maintains a system for checking that such containers arrive at their destination within the stipulated temperature ranges.
SECTION 5 – TESTING OF DONATED BLOOD

5.1. TEST PROCEDURES

Blood group serology and testing for infectious diseases shall be carried out on a specimen collected at the time of donation, on every unit of whole blood or apheresis unit collected. ①

5.1.1. Quarantine:

The facility shall have procedures for the appropriate segregation and quarantine of untested units or those waiting further testing.

5.1.2. Discrepancies:

Discrepancies shall be resolved before the unit is released from quarantine and made available for transfusion.

5.2. BLOOD GROUP SEROLOGY

Records of testing for blood groups shall be maintained. [↩]

5.2.1. ABO and RhD groups shall be tested at each donation. In new donors, the ABO and RhD groups shall be confirmed by performing two independent determinations prior to transfusion. In repeat donors, the ABO and RhD groups obtained shall be compared with previous records from the same donor and shall concur. ①

5.2.1.1. When ABO and/or RhD groups on record do not concur with current test results an investigation to resolve the anomaly shall be undertaken. Units in which an anomaly remains unresolved shall not be transfused.

5.2.1.2. The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma with A and B cells for the detection of expected antibodies.

5.2.1.3. The RhD type shall be determined with anti-D reagent. If blood is initially typed as RhD negative it shall be further tested to detect weak D unless a monoclonal IgM anti-D reagent has been used. When the test for weak D is positive, the unit shall be labelled as Rh positive. When the tests for RhD and weak D are negative, the unit shall be labelled as RhD negative. ①

5.2.2. Group O donations shall be tested for ABO antibodies of a high titre ① and whole blood units found to contain high titre allo-agglutinins shall be labelled as such and issued only to group O patients.

5.2.2.1. Donations from which the plasma shall not be transfused, need not be tested for high titre allo-agglutinins.

5.2.2.2. Whole blood donations converted into red cell concentrates by removal of most of the plasma need not be labelled high titre.

5.2.2.3. Group O plasma containing high titre allo-agglutinins shall be labelled as such and transfused only to group O patients.

5.2.3. Serum or plasma from donors shall be tested for unexpected antibodies using a method known to detect clinically significant antibodies. ① When these are detected, plasma from these units shall not be used for transfusion.

5.3. TESTS FOR INFECTIOUS DISEASES ①

5.3.1. The following tests shall be performed on blood specimens taken at the time of collection: [↩]

5.3.1.1. Human Immunodeficiency Virus (HIV). Minimum – antibodies to HIV-1 and HIV-2. ①

5.3.1.2. Hepatitis B virus (HBV). Minimum – Hepatitis B surface antigen i.e. HBsAg.

5.3.1.3. Hepatitis C virus (HCV). Minimum – antibodies to HCV.

5.3.1.4. Syphilis (Treponema pallidum). Minimum – antibodies to T. pallidum or VDRL test or RPR test.

5.3.1.5. Further testing shall be performed on all reactive specimens according to the facility defined algorithm.
5.3.2. Additional infectious disease testing shall be performed according to local epidemiological conditions.

5.3.3. The facility shall maintain algorithms for testing procedures and the rejection or re-entry of repeatedly reactive donors.
SECTION 6 – BLOOD COMPONENT PRODUCTION

6.1. SEPARATION PROCEDURES

Methods that ensure the quality and safety of components, including aliquots and pooled components, shall be employed. [Reference: Table 3]

6.1.1. Blood components shall be separated from whole blood no more than 24 hours after collection. ☑

6.1.2. The expiry date of blood or blood components shall be calculated by considering the day of donation as day zero.

6.1.3. The sterility of components shall be maintained during processing by the use of closed systems, aseptic methods and sterile pyrogen-free disposable bags and solutions. If the closed system is compromised, the expiry of the component shall be 4 hours from the time of opening ☑, unless indicated otherwise in Table 3.

6.2. VISUAL INSPECTION AND RELEASE

6.2.1. The component shall be physically inspected for container integrity and normality of appearance prior to release. Action shall be taken if anomalies or errors are detected. ☑

6.3. LABELLING AND ISSUE

6.3.1. All blood and blood components shall be accurately labelled using clear and legible labels that adhere firmly to pack surfaces at the range of temperatures experienced.

6.3.2. Label(s) shall not interfere with inspection of the contents or normal function of the container. Additional labels affixed shall not obscure/cover information that will subsequently be relied upon to identify the unit and its important characteristics.

6.3.3. The facility shall use a numeric or alphanumeric system that will make it possible to:

6.3.3.1. Uniquely identify every unit and blood component and its status at any stage during process.

6.3.3.2. Trace any unit of blood or blood component from source to final disposition and to recheck records applying to the specific unit.

6.3.3.3. Identify the blood establishment that carried out any part of the preparation.

6.3.4. The numeric or alphanumeric identification on the label shall be applied by the collecting facility to each unit of blood and/or its components. [≠]

6.3.5. After processing the blood, a final label shall contain the following information, as a minimum:

6.3.5.1. Name of the component.

6.3.5.2. The unique numeric or alphanumeric identification.

6.3.5.3. The date of collection of the blood or component from the donor.

6.3.5.4. The name and volume of anticoagulant solution and additive solution and the approximate volume of blood collected.

6.3.5.5. For platelet concentrates, plasma and components obtained through apheresis donation, the approximate volume of the component.

6.3.5.6. Storage and transportation temperature.

6.3.5.7. Expiry date, and time where appropriate.

6.3.5.8. The ABO blood group and RhD type of the donor (except for fresh frozen plasma and cryoprecipitate where RhD type is not required).

6.3.5.9. Name of the blood collection facility.

6.3.6. The blood collection facility shall provide the transfusing facility with information on the handling and administration of blood and blood components including: ☑

6.3.6.1. Content shall not be used if there is any visible evidence of deterioration.

6.3.6.2. Agitate gently before use.

6.3.6.3. Do not add medications to the blood components.
6.3.6.4. Match blood group on label and blood group of the recipient (if known) to check for suitability before administration.

6.3.6.5. Use a sterile and pyrogen-free disposable transfusion set with filter to transfuse blood.

6.3.6.6. Check identity of patient against the blood or blood component.

6.3.6.7. What to do in the event of transfusion reaction.

6.3.6.8. Instructions to be followed if blood is to be warmed.
SECTION 7 – RECEIPT, ORDERING, SELECTION AND ISSUING OF BLOOD AND BLOOD COMPONENTS

7.1. RECEIPT OF BLOOD COMPONENTS

The facility shall have procedures to check all incoming blood and blood components for product integrity, expiry date, group and temperature on receipt. Discrepancies shall be reported to the collecting facility and shall be resolved before use. [\(\bullet\)]

7.2. ORDERS FOR BLOOD COMPONENTS

7.2.1. A request for blood for a specific patient shall be authorized by a medical practitioner or other authorized healthcare professional. [\(\bullet\)]

7.2.2. The request form for blood or blood components, shall accompany the recipient’s blood specimens, be legible and include the following information:

- Recipient’s given name and surname.
- Hospital number (or second identifier, if hospital number is not available).
- Date of birth, sex, hospital and ward.
- Name of the individual ordering the blood.
- Quantity and specific blood or blood components needed.
- Routine or emergency.
- Date and time the blood is required.
- Clinical diagnosis / reason for transfusion.
- Name and signature of the individual completing the request form.
- Date and time the request form was completed.

7.2.3. The individual taking the recipient’s specimen shall label the specimen with at least the following information:

- Recipient’s given name and surname.
- Hospital number.
- Name of hospital and ward.
- Date and time taken.
- Name and signature of individual drawing the blood specimen.

7.2.4. The request form and blood specimens which are received in the compatibility testing laboratory shall be reviewed. In case of discrepancy, incomplete forms, unsuitable specimens, or doubt, the specimen shall not be used; a new specimen and request form shall be requested and used.

7.2.5. If additional transfusions are required and the time period since the last specimen was drawn is more than 72 hours, a new specimen shall be submitted to perform compatibility testing. [\(\bullet\)]

7.3. SELECTION OF BLOOD AND BLOOD COMPONENTS FOR TRANSFUSION

7.3.1. Red Blood Cell-Containing Components:

- Recipients shall receive whole blood and red blood cell-containing components which are ABO compatible.
- RhD negative recipients should receive RhD negative whole blood or red blood cell-containing components.
- The facility shall have a procedure determining the circumstances for the transfusion of RhD positive red blood cell-containing components to RhD negative recipients. [\(\bullet\)]
- If clinically significant unexpected antibodies are detected in the recipient or the recipient has a history of such antibodies, whole blood or red blood cell components which do not have corresponding antigens and are compatible shall be prepared for transfusion. If antigen typing of donor blood is not possible, crossmatch compatible blood shall be issued. [\(\bullet\)]
7.3.2. Plasma and Platelet Components: ❶

7.3.2.1. Plasma and platelet components should be ABO compatible for transfusion.
SECTION 8 – COMPATIBILITY TESTING

8.1. Each blood specimen submitted shall be tested for ABO group, RhD type and for clinically significant unexpected antibodies. [☞] ①

8.2. SEROLOGIC COMPATIBILITY TESTING

8.2.1. A specimen of the recipient’s serum or plasma shall be compatibility tested with a specimen of the donor’s red cells from an originally attached whole blood or red blood cell segment before being issued for transfusion. The compatibility testing procedure shall include methods that demonstrate ABO incompatibility, and detect clinically significant antibodies to red cell antigens in the serum or plasma of the intended recipient.

8.2.1.1. There shall be a process to ensure that the historical record of ABO group, RhD type and clinically significant antibodies have been reviewed and compared to current records and that discrepancies have been investigated and appropriate action taken before a unit is issued for transfusion. [☞]

8.2.1.2. If no clinically significant antibodies are detected in tests performed and there is no record of previous detection of such antibodies in the patient, at a minimum, a test to detect ABO incompatibility shall be performed. ①

8.2.2. If clinically significant red blood cell antibodies are detected in the recipient, red cell-containing components lacking the corresponding antigens shall be compatibility tested by a method that includes an antiglobulin phase.

8.2.3. A transfusion record shall be completed for each recipient and shall include all units of blood or blood components issued, indicating the: [☞] ①

8.2.3.1. Recipient’s name.
8.2.3.2. Hospital identification number.
8.2.3.3. Recipient ABO group and RhD type, if applicable.
8.2.3.4. Donor unit or pool identification number.
8.2.3.5. Donor ABO group and RhD type.
8.2.3.6. Interpretation of compatibility tests if performed.
8.2.3.7. Name/signature of the individual who performed the compatibility testing.
8.2.3.8. Date of issue for transfusion.

8.2.4. A label shall be attached securely to each unit intended for transfusion. The following information shall appear on the label:

8.2.4.1. Recipient’s given name and surname.
8.2.4.2. Hospital name and number.
8.2.4.3. ABO and RhD type of recipient.
8.2.4.4. Date of compatibility test.
8.2.4.5. Name/signature of individual who performed the compatibility testing.

If it is not possible to include the name/signature of the individual who performed the compatibility testing on the label of the unit, there shall be a method to associate that individual with the unit.

8.2.5. The recipient’s specimens shall be kept at +4°C ±2°C for a minimum of 5 days after the transfusion.

8.3. ISSUE OF BLOOD AND BLOOD COMPONENTS FOR TRANSFUSION ①

8.3.1. At the time a unit is issued for transfusion, there shall be a final check of facility records and each unit of blood or blood component. Verification shall include:

8.3.1.1. Comparison with existing records of the patient.
8.3.1.2. The intended recipient’s two independent identifiers, as well as ABO group, and RhD type.
8.3.1.3. The donation identification number, the donor ABO group, and, if required, the RhD type.
8.3.1.4. The interpretation of compatibility testing, if performed.
8.3.1.5. The date and time of issue.
8.3.1.6. Name/signature of individual who releases the blood component.
8.3.1.7. Name/signature of individual taking delivery of the blood component, if applicable.
8.3.1.8. Visual inspection of blood and blood component.

8.3.2. In the case of an anomaly or error detected during the time of issue, the unit shall be withheld for further investigation and appropriate corrective and preventive action taken.

8.4. SPECIAL INSTANCES

8.4.1. Massive Transfusion:

8.4.1.1. The facility shall have a procedure regarding compatibility testing when, within 24 hours, a patient has received an amount of blood or blood components approximating or exceeding the patient’s total blood volume.

8.4.2. Neonatal transfusion (i.e. for infants under the age of 4 months): ①

8.4.2.1. Only anti-A and anti-B reagents are required to determine the neonatal ABO group. The RhD type shall be determined as previously prescribed.
8.4.2.1.1. ABO group compatible red blood cell components shall be issued. ①
8.4.2.1.2. RhD compatible red blood cell components shall be issued. ①
8.4.2.2. The serum or plasma of the mother shall be used to perform the test for clinically significant antibodies and if unavailable, then the neonatal specimen shall be used. If the screening test for red cell antibodies is negative, and the neonate is to be transfused with group O blood, it is unnecessary to perform compatibility testing for the initial or subsequent transfusions.
8.4.2.3. If the initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible by indirect antiglobulin compatibility testing.
8.4.2.4. In the management of haemolytic disease of the newborn, the mother’s specimen shall be used for compatibility testing. In the absence of maternal serum or plasma, neonatal serum or plasma shall be used. Blood units selected for compatibility testing shall be ABO and RhD compatible with both neonate and mother.
8.4.2.5. If a non-group O neonate is to receive group specific red cells that are not compatible with the maternal ABO group, the neonate’s specimen shall be used for compatibility testing. Test methods shall include an antiglobulin phase.

8.4.3. Blood transfused in cases of dire emergency: ①

When a specimens from the patient is submitted for compatibility testing, but the blood is required prior to testing due to the emergency of the situation, then segments from the units provided for transfusion shall be retained and the compatibility testing shall be completed after the blood is issued.
SECTION 9 – HAEMOVIGILANCE AND CLINICAL INTERFACE

9.1. ADVERSE TRANSFUSION EVENTS

A facility that performs compatibility testing or administers blood shall educate its health care workers on the identification, recording, management and reporting of adverse events in transfusion recipients.

9.1.1. When a suspected transfusion reaction is reported and specimens are provided, the facility that performed the compatibility testing or administered the blood shall investigate the adverse event. At a minimum the investigation shall include:

9.1.1.1. A clerical check of all relevant transfusion records.
9.1.1.2. Visual inspection of blood or blood components transfused (if available), and of post-transfusion specimen for haemolysis.
9.1.1.3. Determination of ABO group and RhD type of both pre- and post-transfusion specimens.
9.1.1.4. Compatibility testing using both pre- and post-transfusion specimens.
9.1.1.5. Direct antiglobulin test on both pre- and post-transfusion specimens.

9.1.2. When an adverse event occurs, the results of the evaluation shall be recorded in the transfusion record of the patient and shall be reported to the patient’s physician.

9.2. TRANSFUSION TRANSMITTED INFECTIONS

9.2.1. When transmission of an infectious disease is suspected to be the result of transfusion, the facility that transfused the blood shall report that information to the collecting facility.

9.2.1.1. The collecting facility shall have procedures for investigating and deferring donors when such reports are received.

9.2.2. Look-Back

The collecting facility shall have procedures to notify the physician of recipient(s) of units from a blood donor who is subsequently found to be infected with HIV, HBV or HCV.

9.3. CLINICAL INTERFACE

9.3.1. A facility that transfuses blood shall develop or adopt clinical guidelines on the appropriate use of blood and blood components and promote continuing education in transfusion practice for clinical personnel.

9.3.2. A facility that transfuses blood shall have procedures to communicate with clinical personnel to promote availability and appropriate use of blood and blood components.

9.3.3. A facility that transfuses blood shall have procedures in place to provide timely clinical consultation to clinical personnel.

9.4 MONITORING OF BLOOD USAGE

A facility that collects or issues blood for transfusion shall perform ongoing evaluations of blood need and blood supply with periodic monitoring of blood usage.
SECTION 10 – BLOOD ADMINISTRATION

10.1. There shall be procedures for the administration of blood and blood components including the use of infusion devices and ancillary equipment and the identification, evaluation and reporting of adverse events related to transfusion. ☞

10.1.1. The medical practitioner/transfusionist shall advise the patient, in a language that he/she understands, of the risks and benefits of transfusion and obtain consent ☞ for the transfusion from the patient. At a minimum, elements of consent shall include:

10.1.2. A description of the risks, benefits and treatment alternatives (including non-treatment).

10.1.3. The opportunity to ask questions.

10.1.4. The right to accept or refuse transfusion.

10.1.5. Before transfusion the blood or blood component shall be visually inspected and the expiry date on the label confirmed. T

10.1.6. Immediately before transfusion, two individuals shall verify the identity of the patient at the bedside, the blood component, blood group and compatibility testing report and associated records. The recipient’s vital signs shall be assessed and recorded prior to transfusion. ☞

10.1.7. The transfusion shall be given with a sterile, pyrogen-free and disposable transfusion set with filter.

10.1.8. Medication shall not be added to the blood component being transfused. Similarly no other intravenous fluid shall be administered with blood components, except solutions that do not contain calcium or dextrose.

10.1.9. Transfusion of one unit of blood or a component shall not take longer than 4 hours. For patients requiring long-term transfusion the intravenous (IV) line shall be changed at least every 24 hours.

10.1.10. All identifications attached to the blood or blood component container shall remain attached during and after transfusion. ☞

10.1.11. The individual administering the blood or blood component shall regulate the speed of the transfusion and observe the patient for the first 15 minutes at the start of the transfusion, approximately every hour during the transfusion and periodically for 24 hours after the transfusion to observe any evidence of untoward reaction. ☞

10.1.12. In the event of an adverse reaction ☞ the transfusion shall be stopped immediately and reported promptly to the attending physician and the compatibility testing laboratory.

10.2. Blood Warmers: ☞

10.2.1. Warming of blood to body temperature should be done in cases of rapid transfusion, massive transfusion, for patients with cold agglutinins and for exchange transfusion in infants. Blood shall not be warmed above +37°C.

10.2.2. Where applicable warming of blood should be accomplished using a blood warming device attached to the transfusion set. The warming device shall be equipped with an alarm system. Blood that has been warmed shall be transfused within 4 hours and if not transfused, shall not be used for another patient.

Section 1.7.2, Equipment Qualification and Section 1.12 applies.

10.3. Administration of Platelet Concentrate:

10.3.1. Platelets shall be administered through a standard platelet filter. Micro aggregate filters shall not be used for the administration of platelet components.

10.4. Thawing of Fresh Frozen Plasma: ☞
10.4.1. Plasma that has been thawed shall not be refrozen. The transfusion shall be completed within 4 hours of completion of thawing or 24 hours if the plasma is kept at +4°C ±2°C.
SECTION 11 – NATIONAL BLOOD SERVICE ACCREDITATION REQUIREMENTS

11.1. LEGAL AND REGULATORY REQUIREMENTS

11.1.1. The National Blood Service (NBS) shall have delegated responsibility from the government for the provision of a safe and adequate supply of blood that is accessible to all patients in need.

11.1.2. There shall be full commitment and support for the NBS from the government, with the provision of adequate resources, unless the NBS is adequately self-funded.

11.1.3. There shall be a clearly defined national blood policy and a legal framework.

11.1.3.1. The NBS shall operate in compliance with this legal framework.

11.1.4. The NBS shall have a quality system that meets the requirements of Section 1.

11.1.5. The NBS shall have a system in place to calculate the total cost of the service, including the unit cost of blood.

11.2. BLOOD SUPPLY

11.2.1. There shall be a strategic plan for blood safety, availability and accessibility in the country.

11.2.2. There shall be periodic assessment of the blood needs of the country that includes analysis of population, clinical uses of blood, institutional use of blood and patient access to medical care.

11.2.3. There shall be 100% reliance on voluntary non-remunerated blood donors (VNRBD).

11.2.3.1. There shall be a procedure to increase and maintain at least 10% of donations from repeat VNRBD.

11.2.4. All donations shall be tested for syphilis, and also for HIV, hepatitis B and hepatitis C by using a validated method at least as sensitive as ELISA-based technology.

11.2.5. There shall be national blood donor deferral guidelines that are in compliance with Section 2 of these Standards.

11.2.6. There shall be a national blood donor registry.

11.2.7. The NBS shall have in place a risk management process for assessing the residual risk of transmitted transfusion infection in the blood supply. Residual risk shall be calculated on an annual basis using an appropriate statistical model and, at a minimum, be in place for HIV. The NBS shall have systems in place to calculate the risk of infection from donations of first time and repeat donors and shall take action to mitigate against risks in the future.

11.3. EQUIPMENT AND SUPPLIES

11.3.1. There shall be a procurement system in place that ensures timely access to equipment suitable for its intended use and continuous access to reagents and supplies.

11.4. CLINICAL USE

11.4.1. There shall be nationally adopted clinical guidelines on the use of blood and blood components that are consistent with internationally recognized guidelines.

11.4.2. There shall be a system for the collection of blood utilization data in the country.

11.4.3. There shall be a national non-punitive system of haemovigilance for monitoring, investigating and reporting adverse events in donors and recipients of transfusions.

11.4.3.1. Records relating to this system shall be centrally managed and the information used to establish and maintain systems to minimize the serious hazards of transfusion.

11.4.3.2. Medical personnel involved in the transfusion process shall be given information on identifying and reporting adverse reactions in recipients.
### TABLE 1: RECORD RETENTION

<table>
<thead>
<tr>
<th>Item</th>
<th>Standard</th>
<th>Record to be Maintained</th>
<th>Minimum Retention Time (yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>1.1.1.1</td>
<td>The facility’s organogram</td>
<td>5</td>
</tr>
<tr>
<td>2.</td>
<td>1.1.3.1</td>
<td>Approved exceptions</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>1.2.2</td>
<td>Top management review of the quality system</td>
<td>5</td>
</tr>
<tr>
<td>4.</td>
<td>1.2.3</td>
<td>Quality manual</td>
<td>5</td>
</tr>
<tr>
<td>5.</td>
<td>1.3.4</td>
<td>Training policy</td>
<td>5</td>
</tr>
<tr>
<td>6.</td>
<td>1.3.4.1</td>
<td>Evaluation of competence</td>
<td>1 year after termination of service</td>
</tr>
<tr>
<td>7.</td>
<td>1.5.2</td>
<td>Approved suppliers</td>
<td>5</td>
</tr>
<tr>
<td>8.</td>
<td>1.5.4.1</td>
<td>Agreement review</td>
<td>5</td>
</tr>
<tr>
<td>9.</td>
<td>1.5.4.2</td>
<td>Agreement concerning subcontractors</td>
<td>5</td>
</tr>
<tr>
<td>10.</td>
<td>1.5.5</td>
<td>Inspection of incoming materials and products</td>
<td>5</td>
</tr>
<tr>
<td>11.</td>
<td>1.6.6</td>
<td>Monitoring and maintenance of equipment</td>
<td>5 years past life of equipment</td>
</tr>
<tr>
<td>12.</td>
<td>1.7.1</td>
<td>Selection criteria for equipment</td>
<td>5</td>
</tr>
<tr>
<td>13.</td>
<td>1.7.2.1</td>
<td>Accident and incident reporting</td>
<td>10</td>
</tr>
<tr>
<td>14.</td>
<td>1.9.1.2</td>
<td>Internal audit review</td>
<td>5</td>
</tr>
<tr>
<td>15.</td>
<td>1.9.1.3</td>
<td>Corrective action</td>
<td>5</td>
</tr>
<tr>
<td>16.</td>
<td>1.9.2</td>
<td>Review of external audit performance results</td>
<td>5</td>
</tr>
<tr>
<td>17.</td>
<td>1.10</td>
<td>Detection, capture, assessment, investigation and monitoring of non-conformances</td>
<td>5</td>
</tr>
<tr>
<td>18.</td>
<td>1.10.4.1</td>
<td>Medical director approval of the issue of blood and blood components that may not conform to all mandatory test requirements</td>
<td>10</td>
</tr>
<tr>
<td>19.</td>
<td>1.10.4.2</td>
<td>Discard of non-conforming units</td>
<td>10</td>
</tr>
<tr>
<td>20.</td>
<td>1.11.1</td>
<td>Review of feedback from donors and customers/ clinicians</td>
<td>10</td>
</tr>
<tr>
<td>21.</td>
<td>1.12.1</td>
<td>Validation of new or changed procedures, test methods or software implementation</td>
<td>10</td>
</tr>
<tr>
<td>22.</td>
<td>1.12.4.1</td>
<td>Quality control programme</td>
<td>10</td>
</tr>
<tr>
<td>23.</td>
<td>1.12.6.1</td>
<td>Traceability of blood, blood components and critical materials</td>
<td>10</td>
</tr>
<tr>
<td>24.</td>
<td>2.2.1</td>
<td>Donor selection criteria</td>
<td>10</td>
</tr>
<tr>
<td>25.</td>
<td>2.2.2</td>
<td>Donor deferral criteria</td>
<td>10</td>
</tr>
<tr>
<td>26.</td>
<td>2.3.1</td>
<td>Donor history questionnaire</td>
<td>10</td>
</tr>
<tr>
<td>27.</td>
<td>2.4.1 and 2.4.2</td>
<td>Donor consent</td>
<td>10</td>
</tr>
<tr>
<td>28.</td>
<td>3.7.7</td>
<td>Apheresis donor records including:</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.1 Results of laboratory tests including platelet count and serum protein levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.2 Date of last apheresis procedure or other donation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.3 Frequency of donation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.4 Volume of component separated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.5 Drugs administered</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.6 Duration of procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.7 Lot number of disposables</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.8 Replacement fluids</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7.7.9 Adverse reactions and their treatment</td>
<td></td>
</tr>
<tr>
<td>29.</td>
<td>4.4.2</td>
<td>Temperature monitoring of refrigerators, freezers and platelet incubators</td>
<td>10</td>
</tr>
<tr>
<td>30.</td>
<td>4.4.3</td>
<td>Monitoring of liquid nitrogen level or temperatures</td>
<td>10</td>
</tr>
<tr>
<td>31.</td>
<td>5.2</td>
<td>Blood group serology</td>
<td>10</td>
</tr>
<tr>
<td>32.</td>
<td>5.3.1</td>
<td>Infectious disease testing of blood specimens</td>
<td>10</td>
</tr>
<tr>
<td>33.</td>
<td>6.3.4</td>
<td>Unique identification of blood or blood components</td>
<td>10</td>
</tr>
<tr>
<td>34.</td>
<td>7.1.1</td>
<td>Receipt of blood or blood components</td>
<td>10</td>
</tr>
</tbody>
</table>
### 7.2.1 Requests for blood or blood components

Test results of ABO group and RhD type

### 8.1 Test results of ABO group and RhD type

<table>
<thead>
<tr>
<th>37.</th>
<th>8.2.3</th>
<th>Blood transfusion record that includes:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.2.3.1</td>
<td>Recipient’s name</td>
</tr>
<tr>
<td></td>
<td>8.2.3.2</td>
<td>Hospital identification number</td>
</tr>
<tr>
<td></td>
<td>8.2.3.3</td>
<td>Recipient ABO group and RhD type, if applicable</td>
</tr>
<tr>
<td></td>
<td>8.2.3.4</td>
<td>Donor unit or pool identification number</td>
</tr>
<tr>
<td></td>
<td>8.2.3.5</td>
<td>Donor ABO group and RhD type</td>
</tr>
<tr>
<td></td>
<td>8.2.3.6</td>
<td>Interpretation of compatibility tests if performed</td>
</tr>
<tr>
<td></td>
<td>8.2.3.7</td>
<td>Name/signature of the individual who performed the compatibility test</td>
</tr>
<tr>
<td></td>
<td>8.2.3.8</td>
<td>Date of issue for transfusion</td>
</tr>
</tbody>
</table>

### 8.2.3.1 Requests for blood or blood components

#### 8.2.1 Test results of ABO group and RhD type

| 36. | 8.1 | Test results of ABO group and RhD type |

### 8.2.3 Blood transfusion record that includes:

- Recipient’s name
- Hospital identification number
- Recipient ABO group and RhD type, if applicable
- Donor unit or pool identification number
- Donor ABO group and RhD type
- Interpretation of compatibility tests if performed
- Name/signature of the individual who performed the compatibility test
- Date of issue for transfusion

### 9.1 Management of adverse reactions in recipients

#### 9.1.3 Investigation of the transmission of transfusion transmitted infections

### 9.1.4 Look back to identify recipient(s) of units from a blood donor who is subsequently found to have been infected with HIV, HBV or HCV

### 10.2 Consent from patient, for transfusion

### 10.3 Inspection of blood and blood components prior to release for transfusion

### 10.4 Verification of patient identity at the bedside, prior to transfusion

### 10.8 Transfusion record in hospital file

### 10.9 Observation record during transfusion episode

**Note:** Where national guidelines differ from the retention times prescribed in this standard, the national guidelines shall be followed.
### TABLE 2: REQUIREMENTS FOR ALLOGENEIC DONOR QUALIFICATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Criteria/Description/Examples</th>
<th>Deferral Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Conform to national guidelines – if not defined, then donors shall be 16 years of age or more.</td>
<td></td>
</tr>
<tr>
<td>Whole blood volume collected</td>
<td>Volume collected shall not exceed 10.5 mL/kg of donor weight, including specimens. Proportional to the volume of anticoagulant, with a maximum of ±10% variation.</td>
<td></td>
</tr>
<tr>
<td>Donor body mass (weight)</td>
<td>The lower limit of body weight shall be 50 kg. No more than 10.5 mL/kg body weight shall be drawn. Unexplained recent weight loss of more than 10% of body weight shall be a reason for deferral.</td>
<td>6 months</td>
</tr>
<tr>
<td>Donation interval</td>
<td>A minimum of 56 days after whole blood donation. The minimum interval between two apheresis collections shall be 48 hours and at most, 24 procedures shall be performed on any individual donor within a 12 month period.</td>
<td></td>
</tr>
</tbody>
</table>
| Blood pressure and pulse         | Conform to national guidelines – if not defined, then the following shall apply:  
• BP not >180/100 mmHg; not <100/60 mmHg  
• Pulse rate: regular and not <60 or >100 beats/minute                                                                                                                                 |                 |
| Haemoglobin / Haematocrit        | Conform to national guidelines – if not defined, then lower limit shall be 125 g/L. Colour scale shall be allowed for Step 1 and Step 2 and shall be confirmed using another method (e.g. Haemocue or similar). For Step 3 more sensitive methods shall be used to determine haemoglobin. |                 |
| Drug Therapy                     | Aspirin                                                                                                                                                                                                                           | 3 days (>72 hours) before platelet production |
| Medical history and general health | The prospective donor shall appear to be in good health, and not under the influence of alcohol or drugs. The prospective donor shall be free of major organ disease (e.g. heart, liver, lungs) cancer, or abnormal bleeding tendency, unless determined eligible by the medical director.  
The venepuncture site shall be evaluated for lesions on the skin. The venepuncture site shall be free from infectious skin disease and any disease that might create a risk of contaminating the blood.  
Defer for dental extraction or surgery in accordance with national guidelines.                                                                                                                                                               | National guidelines or if absent, facility defined guidelines |
| Pregnancy                        | Defer for pregnancy and during lactation, or in accordance with national guidelines.                                                                                                                                               |                 |
| Receipt of blood, or blood component(s) | Defer for 12 months or according to national guidelines for receipt of blood, blood components, or plasma-derived clotting factor concentrates.                                                                                     | 12 months       |
| Immunizations and vaccinations    | Receipt of live attenuated viral and bacterial vaccines. [Measles (rubella), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever].                                                                                                   | 2 weeks or according to national guidelines |
### Infectious diseases

<table>
<thead>
<tr>
<th>Condition</th>
<th>Duration/Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt of live attenuated viral and bacterial vaccines. [e.g., German measles (rubella), Chicken pox (varicella zoster), BCG].</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Receipt of other vaccines, including unlicensed vaccines.</td>
<td>12 months unless otherwise indicated by medical director</td>
</tr>
<tr>
<td>Present or past clinical or laboratory evidence of infection with HIV, HBV, and HCV.</td>
<td>Permanent</td>
</tr>
<tr>
<td>A history of trypanosomiasis, or Chagas’ disease.</td>
<td>Permanent</td>
</tr>
<tr>
<td>Mucous membrane exposure to blood.</td>
<td>12 Months or conform to national guidelines</td>
</tr>
<tr>
<td>Non-sterile skin penetration with instruments, equipment, or weapons contaminated with blood or body fluids other than the donor’s own. Includes tattoos, body piercing, and scarification.</td>
<td>12 Months or conform to national guidelines</td>
</tr>
<tr>
<td>Sexual contact or lived with an individual who:</td>
<td></td>
</tr>
<tr>
<td>a) Has acute or chronic hepatitis B (positive HBsAg test, HBV NAT)</td>
<td>12 months after last contact †</td>
</tr>
<tr>
<td>b) Has symptomatic hepatitis C</td>
<td></td>
</tr>
<tr>
<td>c) Is symptomatic for any other viral hepatitis</td>
<td></td>
</tr>
<tr>
<td>Sexual contact with an individual with HIV infection or at high risk of HIV infection.</td>
<td>Permanent</td>
</tr>
<tr>
<td>Following the diagnosis of a sexually transmitted infection such as syphilis or gonorrhea (shall have completed treatment.)</td>
<td>12 months</td>
</tr>
<tr>
<td>The prospective donor shall be evaluated for potential risks of transmitting malaria † in section 2.2</td>
<td></td>
</tr>
</tbody>
</table>

In the absence of National Guidelines, facility defined guidelines shall be used unless they fall below the standard stipulated in these Standards.
TABLE 3: REQUIREMENTS FOR SEPARATION, PREPARATION, STORAGE AND EXPIRY (of blood and blood components)

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
<th>Preparation</th>
<th>Storage</th>
<th>Expiry Date</th>
<th>Additional Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Whole Blood</td>
<td>N/A</td>
<td>+2°C to +6°C.</td>
<td>35 days after collection if CPDA-1 (citrate phosphate dextrose with adenine)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>21 days if ACD-A (acid citrate dextrose) or CPD (citrate phosphate dextrose) or CPG (citrate-phosphate-glucose) is used as anticoagulant solution.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If an open system is used with aseptic technique, the expiry time shall be 4 hours after separation.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Red Blood Cell Components</td>
<td>• Separate red cells and plasma within 6 to 18 hours after collection (if platelets are not being produced).</td>
<td>+2°C to +6°C.</td>
<td>If a closed system is used for separation, the expiry date shall be the same as whole blood. If additive solution is used, the expiry date may be extended in accordance with the blood container manufacturer’s recommendations.</td>
<td>Haematocrit shall be 0.6 L/L ±0.1.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Prepare components within 72 hours preferably but not more than 7 days after collection.</td>
<td></td>
<td>If an open system is used with aseptic technique, the expiry date shall be 24 hours after separation.</td>
<td>Leukocyte count shall be ≤2.4 x 10⁹/unit for red cells in additive solution, buffy-coat removed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Prepare plasma-reduced red cells from whole blood collected in plastic bags, preferably in double or multiple bag systems.</td>
<td></td>
<td>If aseptic technique is not used, the expiry time shall be 4 hours after separation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Suspend red cells in additive solution, or other suitable solution.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Leukocyte-reduced Red Cell</td>
<td>Prepare within 5 days of collection. Prepare by a method known to reduce leukocytes in the final components to specified levels. For achieving a level less than 5 x 10⁶, use a leukocyte filter.</td>
<td>+2°C to +6°C.</td>
<td>If a closed system is used, each component shall have the same expiry date as the original donation from which it was prepared.</td>
<td>Haematocrit shall be 0.6 L/L ±0.1.</td>
</tr>
<tr>
<td></td>
<td>Concentrates</td>
<td></td>
<td></td>
<td>If an open system is used, the expiry time shall be 24 hours.</td>
<td>Leukocyte count shall be ≤5 x 10⁹/unit when intended to prevent febrile reactions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Leukocyte count shall be ≤5 x 10⁹/unit when required to prevent allo-immunisation or minimize the risk of CMV infection.</td>
</tr>
<tr>
<td>Step</td>
<td>Description</td>
<td>Temperature</td>
<td>Expiry</td>
<td>Haematocrit</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
<td>-------------</td>
<td>--------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Washed red cells</td>
<td>+2°C to +6°C.</td>
<td>The expiry time is reduced to 24 hours from the time that the unit was opened.</td>
<td>Haematocrit shall be 0.6 L/L ±0.1.</td>
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<td>2.</td>
<td>Frozen red cells</td>
<td>Minus 65°C to minus 196°C.</td>
<td>10 years from date of freezing. Once thawed and washed, the components shall be used within 24 hours.</td>
<td>Haematocrit shall 0.6 L/L ±0.1.</td>
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<td>3.</td>
<td>Random Donor Platelets</td>
<td>+20°C to +24°C with continuous gentle agitation using horizontal agitator or rotor.</td>
<td>3-5 days after blood collection, depending on the nature of the plastic bag used, except if an open system has been used then the unit shall be used within 6 hours.</td>
<td>Platelet count shall be ≥2.4 x 10¹¹. Leukocyte count, if leukocyte-reduced, shall be ≤5 x 10⁹/unit. pH at +20°C to +24°C, at not more than 24 hours after expiry, shall be ≥6.0.</td>
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<td>4.</td>
<td>Apheresis Platelets</td>
<td>+20°C to +24°C with continuous gentle agitation using horizontal agitator or rotor.</td>
<td>5 days after blood collection - except if an open system has been used, then the unit shall be infused within 6 hours.</td>
<td>Platelet count shall be ≥3 x 10¹¹. Leukocyte count, if leukocyte-reduced, shall be ≤5 x 10⁹/unit. pH at +20°C to +24°C, at not more than 24 hours after expiry, shall be ≥6.0.</td>
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<td>5.</td>
<td>Fresh Frozen Plasma (FFP)</td>
<td>Separate fresh plasma from whole blood within 6 to 18 hours of collection and freeze solid at minus 18°C or, preferably, at minus 25°C or lower as early as possible.</td>
<td>Minus 18°C or below, or minus 25°C or below.</td>
<td>12 months if stored at minus 18°C or below. 24 months if stored at minus 25°C or below. After thawing, the component shall be transfused as soon as possible but within 4 hours.</td>
<td>FVIII:C should be ≥0.7 IU/ml. Test to be done where possible.</td>
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<td>6.</td>
<td>Frozen Plasma (other than FFP)</td>
<td>Separate plasma from whole blood following either centrifugation or undisturbed sedimentation at any time up to 5 days after the expiry of the whole blood. Freeze immediately after separation. This includes plasma recovered for fractionation.</td>
<td>Minus 18°C or below, or minus 25°C or below.</td>
<td>12 months if stored at minus 18°C or below OR 24 months if stored at minus 25°C or below. After thawing, suitable component shall be transfused as soon as possible but within 6 hours.</td>
<td>N/A</td>
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<td>7.</td>
<td>Cryoprecipitate</td>
<td>Freeze fresh plasma for preparation of cryoprecipitate at minus 60°C to minus 70°C and thaw in a +4°C circulating water bath or in a +4°C cold room/blood bank refrigerator. Drain supernatant and freeze the remaining cryoprecipitate within 1 hour.</td>
<td>Minus 18°C or below, or minus 25°C or below.</td>
<td>3 months if stored between minus 18°C and minus 25°C OR 24 months if stored at minus 25°C or below. After thawing, the component shall be transfused as soon as possible but within 6 hours.</td>
<td>FVIII:C should be ≥80 IU/unit. Fibrinogen should be &gt;12 mg/ml or &gt;300 mg/unit if cryoprecipitate for fibrinogen. Tests for above to be done where possible.</td>
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