AFRICA SOCIETY FOR BLOOD TRANSFUSION

GUIDANCE DOCUMENT

STEP-WISE ACCREDITATION PROGRAMME

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PREFACE

The AfSBT Task Team for Accreditation developed the following guidance to assist facilities in understanding the requirements of the proposed AfSBT Step-Wise Accreditation Programme for blood facilities in Africa.

While the original concept of the group was to develop an accreditation programme with progressing levels of achievement, the drafters recognized that an accreditation programme, to be useful, must have a defined set of standards or requirements against which accreditation is measured. This recognition, in turn, led to the development of a set of standards that include both quality and technical requirements which must be satisfied in order to attain accreditation. These standards are set forth as “AfSBT Step-Wise Accreditation Standards” (OMD-E-001).

The working group determined that rather than develop three separate levels of standards, the accreditation programme would differentiate three distinct and increasingly difficult levels or steps of compliance with the Standards: Step 1 towards Accreditation (Basic level certification), Step 2 towards Accreditation (Intermediate level certification) and Full Accreditation (Step 3). Each step is supported by a separate assessment tool that describes the evidence that must be available to support the specific level of compliance sought.

The Standards drafters also came to the conclusion that the accreditation programme must be sufficiently flexible to allow accreditation of either individual facilities or more integrated blood service programmes, whether regional or national. A corollary of this conclusion is that compliance with any standard must be within the control of the facility or service. For this reason, the requirements that the facility have specific delegated authority from the government and government support in the form of both allocated financial resources and a national blood policy are not applicable to individual facilities. Instead, these requirements, as well as others, have been incorporated as requirements for national or regional blood services that choose to seek accreditation of their programme in Section 11 – National Blood Service Accreditation Requirements.

THE AFSBT STEP-WISE ACCREDITATION STANDARDS ARE BASED ON SEVERAL IMPORTANT DRAFTING PRINCIPLES:

The Standards contain requirements only

The Standards are designed to establish universally acceptable technical and quality requirements that must be followed. For that reason, some of the standards are less prescriptive than they might be, allowing national differences that can align with nationally set priorities and allow for different ways of achieving the desired outcome. Use of the word “should” in the Standards signals situations in which a practice may or may not be followed, but, once followed, must be performed in a specific way in order to prevent harm to the patient.

The Standards incorporate the concepts of cascading and hierarchy

The concept of cascading means that a requirement, once stated, is assumed to apply to all of the underlying or secondary requirements. In the context of the Standards this means two things. Firstly, the requirements in Section 1, Quality System, apply to all of the following sections, 2-11. A specific example is Standard 1.4, Documents and Records, which requires that all “procedures,” defined as procedures, processes and policies, be captured in writing or electronically. This requirement applies to all procedures referenced through the Standards. Similarly, Records, or evidence that an activity has occurred, must also be captured in writing or electronically. In order to remind readers of the cascading nature of the documentation requirements, the Pen Symbol [✓] can be found next to each standard which has a requirement for written or electronic records. Secondly, within a specific Section, the general requirements set forth in the standard apply to the underlying sections of that standard. As an example, the general statement in Standard 5.1, Test Procedures, requires that all test methods must be validated prior to implementation. This requirement applies to all test methods under Section 5.
Not every standard applies to every facility

A standard does not apply if the facility is not responsible for the activity. Such standards are specifically identified in the guidance. As an example, if the facility does not perform or is not responsible for compatibility testing, the requirements in that section do not apply. However, a facility cannot abrogate its responsibility for ensuring that critical functions, such as transmissible infection testing, is performed in compliance with these Standards, even if the function is outsourced to a third party provider or subcontractor. In that instance, the facility must ensure that the agreement between the facility and the third party provider or subcontractor requires the third party provider to adhere to the relevant requirements. See Section 1.5.4.2.

The essential requirements for a Quality System are contained in 1.2 - Quality Systems

Although the quality requirements are contained in a separate section, they apply to each of the standards that follow. To the extent possible, the standards in the Quality System section employ terminology developed by the Organization for International Standardization (ISO). For example, the document speaks of “quality system,” rather than “quality management system,” although they are really one and the same. Similarly, the standards reference “top management,” rather than “executive management” or “management.” It is hoped that the use of this terminology will facilitate access to additional outside resources, information and materials, that can assist in implementation of the Standards.

Defined terms are contained in a Standards Glossary included in the standards

A specific example of a defined term is the frequent reference to “specified requirements” in the standards.

Wherever appropriate, technical standards are captured in chart form to facilitate ease of understanding

The technical standards in chart form are requirements.

Guidance is provided when necessary to assist in the application and interpretation of a standard

Guidance is not provided for every standard. Guidance is generally aimed at the level of Full Accreditation (Step 3), but guidance also references best practices that might be preferred but which realistically cannot be universally implemented. Facilities can be assured that they are in compliance with the Standards if they follow these best practices, but they may also develop a different way of meeting the referenced standard. In general, guidance is expressed as a “should,” as facilities may (or may not) adopt the practice. When guidance is provided for a specific standard, an Information Symbol ☀ is used to denote this in the Standards document.
SECTION 1 – QUALITY SYSTEM

This section describes the required elements of a functioning quality system: organization and structure, quality system, resources, documents and records, suppliers and service providers, incoming receipt, inspection and testing, equipment, work environment and safety, internal and external audits, non-conformances, continual improvement and process control. Each element applies to the requirements contained in the standards (Sections 2-11) that follow.

1.1. ORGANIZATION AND STRUCTURE

1.1.1 Organogram

An organogram can be in writing or captured electronically, provided that it clearly describes the structure and organization of the facility, the key individuals in the organization and their relationship to each other.

1.1.2 Top management

The standards require that each facility be under the direction of “top management.” Top management can be a single individual, or a group of individuals, provided that top management is clearly defined in the organogram. Top management is responsible for supporting the development, implementation and maintenance of the quality system.

1.1.3 Medical Director

Each facility must have a Medical Director responsible for all medical matters.

The Medical Director need not be the head of the organization, but a requirement for full accreditation at Step 3 of these Standards, is to have a Medical Director as part of the top management team.

For Steps 1 and 2, a Medical Director who is responsible for donor and patient safety requirements in the Standards, may be appointed as an external consultant. This concession allows for the seconding of a physician from a hospital or other organization to perform the function of the medical director for the blood service / facility. Delegation of that authority to an external consultant must be documented and captured in an agreement. That individual must also be qualified, by experience or training (which can be delivered by the facility) in donor acceptance and deferral criteria, donor safety and recipient safety issues, including adverse event management.

1.1.4 Quality Manager

The Quality Manager is responsible for all quality matters within the facility.

At Step 1 (Basic certification level) and Step 2 (Intermediate certification level), it is recognized that this individual may have more than one responsibility. At Step 3 (Full accreditation level), it is expected that the facility will have an individual dedicated to quality matters in the facility, who is not part of operations. Specifically, at Step 3, the Quality Manager must report to a member of Top Management who is not responsible for operations, or, at a minimum, there must be a procedure to ensure that the Quality Manager also reports issues relating to specific operations to another member of Top Management who is not responsible for that area of operations. The individual responsible for this function may have any title, provided that the responsibility for the quality activities is clearly assigned and is in compliance with the Level of certification/accreditation sought.

1.2. QUALITY SYSTEM

The facility must develop a quality system that incorporates all of the elements in Section 1, Quality Systems.
1.2.2 Quality Review

Examples of sources of information that can be used to review the quality system include:

a. Outcomes of audits performed
b. Non-conformances/errors and corrective and preventive outcomes recorded
c. Production and component monitoring records
d. Personnel training activities
e. Blood donor and customer feedback
f. Outcomes and actions from previous reviews
g. Changes within the facility

Corrections or improvements resulting from this review should be considered in sub-section 1.11, Continual Improvement.

1.2.3 Quality Manual

A quality manual should explain and document how each of the quality elements described in Section 1 (Quality System) have been implemented in the facility. In order to develop a quality manual, the facility must plan the activities that will make the facility compliant with each of these requirements.

1.2.4 In cases where activities are performed outside the control of the facility, the requirements of Section 1.5 apply. Also see Section 1.5 Guidance.

1.3. RESOURCES

1.3.1 Financial Resources

This standard attempts to address the needs of two distinct types of facilities, those that are autonomous and self-funded through cost-recovery, insurance, and/or donor funding and those whose budgets are funded primarily by the government. In the latter case, the primary responsibility of top management is to develop a proposed budget that supports compliance with the standards and to advocate for that funding at the appropriate ministry, parliament or legislature. In either case, the facility is responsible for adhering to the budget developed.

Facilities are encouraged to develop financial plans for several years to project costs and revenues and ensure the financial sustainability of the facility operations.

1.3.1.1 Budgets

Facilities must develop budgets to support a continuous supply of all capital, consumable and disposable items, including buildings, leases, equipment, maintenance, personnel and other items or services needed in order to ensure that adequate supplies of safe blood and blood components are available.

1.3.2 Human Resources

Supervision can be either direct or indirect. Supervision is generally defined as “direct supervision” if the supervisor is within the same work area as personnel carrying out the particular task and can be consulted quickly and face to face should the need arise. In this case, personnel performing the task exercise limited discretion and ultimate responsibility for the quality of the work resides with the supervisor. Personnel who have not yet been trained or qualified as competent should be under “direct supervision.” The supervisor should be appropriately qualified by training and experience to provide the necessary function.
Supervision is defined as “indirect supervision” if personnel performing a particular task or function can contact the supervisor by telephone or other means that allows discussion between them to take place. The supervisor should be able to reach the workplace within a stipulated time (generally no more than one hour) should the need arise. In this case, the responsibility for the quality of the work rests with personnel performing the work, usually pursuant to procedures. Again, the supervisor should be appropriately qualified by training and experience to provide the necessary assistance. Medical Directors are commonly “indirect” supervisors.

“Working under supervision” may include periodic onsite supervision and/or remote review of work by an individual qualified to supervise the activity.

1.3.4 Training and Competence
Facilities must have a programme in place to train personnel and assess their competence to perform activities that can affect the quality of a product or service, before personnel perform the assigned activity independently. Proficiency testing (EQA/IQA), which assesses the performance of the laboratory, is not a substitute for individual competence assessment; however, proficiency tests may be used to assess the competence of the individual performing the task.

1.4. DOCUMENTS AND RECORDS
Document control encompasses both the attributes of documents (identifiers, control of changes to documents) as well as physical control of the documents (location, storage and point of use). A functioning document control system must address all of these elements. An effective document control system must include a master list of all documents.

With respect to the document retention guidelines, the standards set a minimum time for retention of records. If national guidelines require a longer retention period, that retention period should be followed.

1.4.1 Documents
The requirements that documents be in a standardized format does not preclude the practice of referencing external documents such as manufacturer’s instructions or package inserts. Incorporation by reference is a practical way of minimizing the need to continually revise documents to reflect manufacturer’s revisions.

1.4.2 Records
1.4.2.3 This section (Records) requires that a facility be able to trace all blood and blood components, and their associated tests (including specimen tests) and evaluations that affect the quality of the component, from collection to distribution. In facilities that are also responsible for transfusion service activities, the facility should be able to trace the component from collection to transfusion. The concept of traceability is also addressed in 1.12.6.1.

1.4.2.3.1 This section requires that each donor be assigned a unique identifier so that a donor cannot be confused with another donor.

1.4.2.5.1 This standard applies only when the facility uses computer or equipment generated records. It does not apply to paper records. These records should be retained in conformance with the facility’s document retention policy. An off-site location means a different location altogether and not another part of the same building.

1.5. SUPPLIERS AND SERVICE PROVIDERS
This standard ensures that the quality of the facility’s products or services is not adversely affected by work or material that is performed or provided by a third party. It specifically recognizes that work may be subcontracted or delegated to third parties, provided that there is an agreement that controls the delegation and provided that the facility retains ultimate responsibility for ensuring that the products or services provided meet the requirements of these standards.
1.5.2 It is recognized that in some locations the facility may not be authorized to maintain an “approved suppliers list.” In that instance the facility should continue to report supplier’s failures to meet specified requirements to the authorized procurement agency.

Although ISO uses the term “supplies,” the term “supplier” was deliberately used, as many problems relate to the performance of suppliers, as well as to the supplies themselves.

1.5.4.2 See Guidance Preface (Drafting Principles).

1.7. EQUIPMENT

1.7.1 Selection of Equipment

This section provides general requirements applicable to equipment. Equipment must first be suitable (qualified) for its intended use. As an example, a centrifuge that is used to produce red cells must spin within a specific range in order to ensure that the red cells are separated from the other components and are not damaged in the process. Section 4, Handling, Transportation and Storage, includes additional requirements specifically applicable to equipment that is used for storage and transportation of reagents, specimens and blood components.

1.7.2 Equipment Qualification

The purpose of equipment qualification is to verify that the equipment (and all of its ancillary equipment) is installed, operates and performs in accordance with the manufacturer's specifications. It ensures that the equipment has been received as it was designed and specified and ensures that it is properly installed in the selected environment and that the environment is suitable for the operation and use of the equipment.

As an example, blood bags should be qualified for their use (as a collection vehicle that preserves the red cell/plasma/platelet characteristics for the period between the time they are collected and transfused). Blood bags can be qualified by obtaining a certificate of analysis from an independent laboratory that certifies that the bag and the anticoagulant perform to expected levels.

Note that the procedures in which the equipment is used must still be validated. See the discussion of “validation” in Section 1.12 of the Guidance Document.

1.7.8 Computer Systems

The term “computer systems” is intended to cover hardware, software and data bases that are part of an electronic information and communication system. Facilities are advised, however, that software is also part of process control, and thus the requirements that apply to process control apply to software as well. Because the IT Manager will function most efficiently when he/she has knowledge of blood banking software, as well as the ability to manage contractors who provide these products, this standard may be expanded in the future.

Note that the standard requires that a record be created in the event of a computer system failure.

1.8. WORK ENVIRONMENT AND SAFETY

1.8.1.1 It is recognized that mobile collections present particularly challenging situations for blood collectors. It is important that mobile collections be controlled to ensure that the donor interview is conducted in a private setting and that there are adequate facilities to treat donors who experience adverse events.

1.8.2.1 Accidents and incidents are to be reported and investigated as required by existing national regulations. Incidents include events that are not mistakes, but which can adversely affect the quality of a product or service, such as power interruptions, workplace hostility and failure to have functional safety equipment or materials on site, such as fire extinguishers.
1.9. INTERNAL AND EXTERNAL AUDITS

1.9.1.2 Internal audit reports are to be reviewed by personnel having responsibility for the area audited and either the quality manager or the head of office, which is the current practice in some facilities.

1.9.2 External Audits

The purpose of the external audit is to verify that the quality standards that apply to the facility are achieved and maintained. An assessment for accreditation/certification may be regarded as an external audit. The external audit should be by an organization qualified to conduct the external audit.

1.10. NON-COMFORMANCES

The requirements relating to the management of non-conforming components (including quarantine and recalls) are included here as part of the quality system and applicable to all components although more specific requirements may be found in other sections. In that case, the requirements of this section still apply.

Immediate remedial action should be taken to correct the effects of a non-conformance or manage the situation while an investigation is taking place and a long-term solution is sought. Immediate remedial action could include quarantine of blood components that might have been adversely affected by the non-conformance or failure to follow procedures. Corrective action refers to the final action taken to rectify the non-conformance and prevent its recurrence.

1.11. CONTINUAL IMPROVEMENT

The term “continual improvement” is borrowed from ISO and replaces the term “process improvement.” It was adopted to broaden the sources of feedback that are traditionally relied upon by laboratories to “improve process,” such as internal and external audits and monitoring and evaluation data. In addition to these sources of data, the facility should consider:

a. Improvements in the effectiveness of the quality system and its procedures;

b. Improvements in meeting customer product requirements;

c. Feedback from clinicians and donors, and

d. Resource needs.

1.12. PROCESS CONTROL

The Standards drafters determined there was a need to specify the general elements of Process Control, or operating under controlled conditions. These elements include:

1) validating procedures prior to implementation (including procedures managed by software and test methods) defined as ensuring that new procedures and methods are validated
   a) internally or
   b) externally by the manufacturer or other implementing facility or institution;

In the event that procedures or methods are validated “externally,” they must still be verified upon implementation at each specific site.

2) managing change control;

3) implementing a system for determining whether tests are performed accurately and reliably in the facility;

4) implementing a programme of quality control to ensure that reagents, equipment and methods function as expected;
5) ensuring that all materials are stored and used in accordance with the manufacturer’s instructions and meet specified requirements; and ensuring the identification and traceability of blood, blood components and critical materials.

The intent of including traceability in the Quality System section is to emphasize the critical nature of this concept in implementing a quality system with respect to blood transfusion. This specific requirement requires that blood components be traced to the recipient, which, for facilities will only be possible if the facility performs crossmatching. If the facility’s operations do not include crossmatching, the traceability requirement will extend only to the distribution of blood to the transfusing facility.

1.12.3 Internal and External Quality Assessment (IQA/EQA)

It is a requirement of Step 3 that facilities participate in EQA or IQA programmes for tests that are carried out by the facility on donors and patients. These programmes should include the following:

- Screening tests for TTIs
- ABO and RhD typing
- Screening for unexpected antibodies
- Compatibility testing
- Antibody identification
- Haemoglobin estimation / Full blood counts

1.12.4 Quality Control

1.12.4.1 A minimum of 1% of the total number of each component routinely prepared or 4 units per month, whichever is higher, should be tested and at least 80% of components tested should comply with the specifications set. A test for sterility should be done on 1% of the blood units collected or 10 per month whichever is higher. The microbiological test should not be done by a method that entails breaching the final container before the blood is transfused. The blood specimen from the tubing attached to the container should be used for sterility testing using appropriate techniques.
SECTION 2 – BLOOD DONOR MANAGEMENT

2.1. MOBILIZATION AND RECRUITMENT OF BLOOD DONORS

2.1.1. Facilities should also attempt to use donor testing data to identify and mitigate the risk of collecting blood from donors at sites that have higher than expected TTI rates.

2.1.2. Facilities should have a procedure for communicating with public health authorities about emerging diseases that may be transmissible. If an emerging disease is identified and there is an available test for the agent, the facility may want to test donor specimens to estimate the rate of infection in the donor population.

2.1.3. The facility should have a programme that recognizes donors for their donations. However, recognition of donors should not create undue incentives for donors to conceal risk factors. Although there are no specific criteria for "undue incentives," facilities may want to monitor the effect of specific incentives on the TTI rate among donors from that collection site. Some facilities provide incentives for all potential donors who present, rather than only those who successfully donate, to ensure that the incentive does not influence responses to the donor questionnaire. Still others provide incentives only to donors who have successfully donated more than 5 times.

2.2. DONOR SELECTION CRITERIA

Some of the specific requirements relating to allogeneic donor qualification are presented in table -- format. Where these requirements conflict with national policy, national laws or regulations, national policies, laws or regulations should be followed unless they fall below the requirement stipulated in these Standards and negatively affect donor or patient safety. In circumstances where a standard requires conformance with national policy, and no national policy exists, the facility should adopt policy that is internationally recognized and based on the best available evidence.

Malaria: The facility should have procedures for mitigating the risk of transmission of malaria to the recipient. These procedures could entail minimizing or eliminating collections from endemic locations, either temporarily or permanently, or treating transfusion recipients, either prophylactically or if symptoms warrant, for malaria. If the latter option is implemented, the facility should communicate with the transfusing hospital to verify that such a protocol is being followed.

2.2.1. Deferral guidelines should detail medical and surgical conditions, medications (including immunizations and vaccinations) and exposure to potential transfusion transmissible diseases constituting grounds for deferral of donors, whether temporary or permanent.

Deferrals due to contact or potential exposure to HBV, HCV and/or HIV is 12 months, If, however, the facility or programme has implemented individual donation nucleic acid amplification testing (ID-NAT) for HBV, HCV and/or HIV, the facility may request a variance for the relevant deferrals.

2.2.2 Medical consultation may be required for the evaluation of potential donors or the interpretation of medical findings in order to determine the suitability or otherwise of a potential donor for blood donation. A record of the findings and the decision arising therefrom should be recorded in the donor’s record.

2.5. DONOR COUNSELLING

2.5.1. The definition of “medically significant findings” can vary from facility to facility. The Medical Director should be responsible for determining which findings are medically significant.

2.5.2. Donors are to be provided counselling concerning their test results. The facility may provide these services or, alternatively, the facility may identify and refer donors to available external medical services, including client initiated testing and counselling clinics, where available. In the event that
If a facility relies on the services of an external clinic, the facility should discuss this plan with the clinic(s) to ensure the capacity of the clinic(s) to handle these referrals and should document the plan in an agreement.
SECTION 3 – COLLECTION OF BLOOD FROM DONORS

3.3. SPECIMENS

The purpose of this section is to ensure the traceability of testing to the blood or blood component.

3.6. DONOR REACTIONS

Implicit in this standard is the concept that personnel shall be trained in the recognition and management of adverse reactions in donors; that procedures controlling the recognition and management of donor reactions shall be on site; and that every mobile and fixed collection site shall have equipment, consumables and drugs that are necessary to treat donors who experience adverse events.

3.7. APHERESIS

This section is intended to apply only to facilities that collect units from healthy volunteer donors by apheresis.

Currently, the Standards do not address apheresis for therapeutic purposes, although facilities that do perform this service should review the procedures for non-therapeutic collections to establish appropriate parameters for therapeutic procedures.
SECTION 4 – HANDLING, TRANSPORTATION AND STORAGE

4.2. BLOOD TRANSPORTATION CONTAINER

Blood collected on mobiles present special challenges. Ideally, blood donations should be placed in an insulated container within 30 minutes of collection. When platelet concentrates are to be made from the blood, butane-1,4-diol coolant packs or plates may be used to cool the blood and maintain its temperature at +22°C ±2°C, for a maximum period of 24 hours. When coolant packs are used, they should be individually attached to each unit of blood collected. When coolant plates are used, they should be placed over each layer of blood bags in the insulated container. When the facility does not intend to make platelets from the donations, blood should be cooled to +4°C ±2°C in the insulated container, using ice packs of wet ice frozen to approximately minus 18°C. In all cases, the system must be validated to ensure that the temperature is maintained within these specified limits for the maximum duration of the holding/storage and transportation time under the expected environmental conditions.

4.4. STORAGE DEVICES FOR BLOOD AND BLOOD COMPONENTS

4.4.2. Whenever possible, temperatures of refrigerators and freezers in which blood and/or blood components are stored should be fitted with a device that continually measures and records the temperature inside the cabinet. Where continuous monitoring and recording is not possible, a maximum and minimum thermometer should be placed in the refrigerator or freezer and the following temperatures should be recorded a minimum of three times a day, either every 8 hours or, if this is not feasible, then, for example, at 8:00, 12:30 and 17:00:
   a. Maximum temperature reached since the last reading was made.
   b. Minimum temperature reached since the last reading was made.
   c. Current temperature at the time the reading was made.

These temperatures should be recorded and the maximum and minimum thermometer should be re-set following each reading.

4.5. ALARM SYSTEMS

The purpose of this section is to allow action to be taken to ensure that the blood components are maintained at a temperature that does not degrade the components.
SECTION 5 – TESTING OF DONATED BLOOD

5.1. TEST PROCEDURES

Although not explicitly stated in this standard, all test methods must be validated prior to implementation. The requirement to use validated methods is set forth in the sub-section Process Control, in Section 1: Quality Systems, of these Standards. See also Section 1.12 Process Control guidance for clarification of validation and verification requirements.

5.2. BLOOD GROUP SEROLOGY

5.2.1. The blood collecting facility may satisfy the requirement that there be two independent determinations of ABO and RhD group prior to transfusion by testing the unit twice in the collecting facility, or by comparing the current result against the previous result from the same donor to ensure that the correct donor has been bled.

5.2.1.3. This standard requires that each donation will be tested for RhD using a reagent capable of detecting weak D antigen.

Two different systems are currently in use to detect weak D.

a. Monoclonal IgM anti-D which is directly added in equal proportions to the test cells and centrifuged at room temperature. Results are read immediately and interpreted. No further manipulation of the tubes is required should they continue to be RhD negative.

b. In the absence of the availability of monoclonal IgM (or in addition to the procedure described above) indirect antiglobulin testing (IAT) can be used. In this method, tubes that show RhD negative results using polyclonal IgM/IgG blend are incubated at +37°C for 15 minutes, followed by IAT. This approach is cheaper and uses reagents that are more routinely found in compatibility testing laboratories; it is however, slower and more error-prone because of the manual steps required to wash the cells and add reagents.

5.2.2. High Titre ABO antibodies are defined as 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).

5.2.3. Screening tests for unexpected antibodies are to be done using serum or plasma tested with O RhD positive cells (two individual cell donations, or pools from 2 or 3 donors is acceptable) using a validated method known to be capable of detecting anti-D at a concentration of 0.5 IU/mL or lower. As a minimum the following antigens should be expressed on the screening cells: D, C, c, E, e. Such screening may be carried out selectively, for example, testing for irregular antibodies only in first time donors, donors who have been pregnant, and donors who have been transfused.

5.3. TESTS FOR INFECTIOUS DISEASES

A country is not permitted to opt out of any infectious disease testing requirement in these Standards on the basis of national guidelines or country data that demonstrate that the particular pathogen is not endemic in the country. Any request for variance on this basis will be denied as it would increase the safety risks to the transfusion recipient.

Minimum testing is stipulated in these Standards, and test kits used must be qualified for their purpose and validated.

5.3.1.1 A validated method at least as sensitive as ELISA-based technology is required for full accreditation at Step 3. Facilities should note, however, that to qualify excess plasma for fractionation, nucleic acid amplification testing (NAT) may be required. For Steps 1 and 2 of these Standards, alternative validated methods of testing may be used.
SECTION 6 – BLOOD COMPONENT PRODUCTION

Although not specifically required in the Standards, facilities should have plans to provide blood components instead of whole blood for transfusion.

6.1. SEPARATION PROCEDURES

6.1.1 If a facility plans to use the red cells only and discard the plasma, the separation step can be performed at any point up to the expiry date unless an additive solution is being used, in which case the separation must occur within a maximum of 3-7 days of collection in conformance with the manufacturer’s instructions.

6.1.3 If a blood component must be used beyond the 4-hour period of breaching the seal, the Medical Director must approve the use in writing.

6.2. VISUAL INSPECTION AND RELEASE

6.2.1 Donations should be visually inspected during processing and immediately before issue for evidence of leakage, unusual amounts of air, evidence of possible microbial contamination (e.g., unusual turbidity, haemolysis, frothiness or change of colour) or any other abnormality. “During processing” means any time that the blood or blood component is moved from one place to another, for example, in and out of quarantine.

a. Plasma components:

   Plasma components should be inspected for red cell contamination and, if visible, should be issued only to ABO/RhD compatible recipients.

b. Platelet components:

   Platelets should be checked for swirling phenomenon and the absence of visible platelet aggregates during storage and at issue. Platelet concentrates that are contaminated with red cells should be issued only to ABO/RhD compatible recipients.

6.3. LABELLING AND ISSUE

6.3.6 Information pertaining to the handling and administration of blood components can be provided to the transfusing facility in many different ways, provided that the information is readily available in the wards in which blood is transfused. As an example, handling and administration information can be provided in a transfusion manual.
SECTION 7 – RECEIPT, ORDERING, SELECTION AND ISSUING OF BLOOD AND BLOOD COMPONENTS

This section applies only if the facility is responsible for any of the activities described in the standard, specifically receipt of incoming components? (as a transfusing facility), ordering (including receiving blood orders), selecting blood components for transfusion and issuing blood and blood components for transfusion. As an example, if the facility is not managing the transfusion service, the standards relating to receipt and inspection of incoming blood components will not apply. If, however, the facility is responsible for selecting a specific blood component for a patient, the standards relating to the blood order form and the selection of the specific blood component apply.

7.1.1 Note that blood collection facilities that receive incoming components for further processing or testing have comparable receipt requirements under Section 1.6 Incoming Receipt, Inspection and Testing.

7.2.1. The purpose of this standard is to ensure informed clinical decision making with respect to the selection of blood components. With respect to blood orders, an authorized medical practitioner or healthcare professional can fill out an order form, or may request an order telephonically provided authorized facility personnel simultaneously capture the information, either electronically or in writing.

7.2.2. The specific requirements for a blood order include only the information most relevant to a safe and effective transfusion. Other information was considered but not included. Specifically, it was determined that a history of transfusion, adverse outcomes and obstetrics might be helpful, but may not always be reliably known or available. Similarly, the blood order form does not include patient blood group, as this information is not routinely known and erroneously reported hearsay results in additional and unnecessary testing. In capturing the clinical diagnosis / reason for transfusion facilities should consider embedding or including clinical guideline “check offs” in the blood order form to obtain better information about the patient diagnosis.

7.2.5. The specific reference to 72 hours recognizes the time it takes to develop new antibodies, as well as specimen deterioration.

7.3. SELECTION OF BLOOD AND BLOOD COMPONENTS FOR TRANSFUSION

7.3.1. Red Blood Cell-Containing Components

7.3.1.1. A “red blood cell-containing component” includes any component that has visible red cells or red cell contamination.

7.3.1.3. A suggested procedure for the transfusion of RhD positive red blood cell-containing components to RhD negative recipients, is to seek agreement from the patient’s clinician to administer RhD positive units only when RhD negative units are in short supply or unavailable, and then only to male patients or to female patients without childbearing potential.

7.3.1.4. A suggested procedure for transfusion of antigen positive red blood cell-containing components to a recipient with clinically significant antibodies for which compatible blood cannot be found is to seek agreement from the patient’s clinician to administer the least incompatible unit and transfuse the patient under continuous observation. The reasons for the decision should be recorded in the patient record.

7.3.2. Plasma and Platelet Components

The facility should have procedures concerning transfusion of plasma and platelet components containing high titre ABO antibodies.
When components that are non-ABO specific are to be used for transfusion, units with a “low titre” of allo-agglutinins should be selected. (If the facility is preparing concentrated red blood cells [a reduced plasma component], this guidance does not apply and the facility need not label the red blood cell concentrates.)

Units labelled as having “high titre” allo-agglutinins should be selected and issued to the same ABO group patients only.

Thawing of frozen plasma should take place in a water bath filled with clean water, and using a method that prevents the plasma bag from coming into direct contact with the water.

**Platelet Components – additional guidance:**

Platelet components are usually red cell free and can therefore be transfused to any ABO, RhD compatible group.

The plasma in the donor unit should be reduced when ABO incompatible apheresis platelets must be transfused.

When whole blood-derived random donor platelets are pooled, the pools must be composed of units of the same ABO group.

If a pool contains an RhD positive unit, the pool must be labelled as RhD positive.
SECTION 8 – COMPATIBILITY TESTING

This section applies only if the facility seeking accreditation is responsible for compatibility testing.

8.2 SEROLOGIC COMPATIBILITY TESTING

8.2.1.2 The test for ABO incompatibility should include a direct test between the serum or plasma of the patient and the red cells from the donor, and should be carried out regardless of the groups of the patient and donor or the results of any other tests performed.

8.2.3. In addition to the information required in standard 8.2.3, facilities may find it helpful to record difficulties experienced during typing, identification of clinically significant unexpected antibodies, significant adverse reactions to transfusion and special requirements for transfusion and make these available to compatibility testing personnel.

A blood specimen shall be collected from a positively identified intended recipient of the transfusion and be labelled according to the requirements of these standards and this label must be attached to the tube containing the blood specimen.

The blood bank must undertake a compatibility test, as detailed in this section, prior to the commencement of a transfusion of any red blood cell-containing component, and only compatible units must be administered except in cases of emergency as described below.

Methods of testing should be those that demonstrate clinically significant antibodies. They should include incubation at 37°C preceding antiglobulin test using reagent red cells that are not pooled. If on screening, antibodies are detected, they should be identified by red cell panel for specificity and clinical significance. (Blood lacking corresponding antigens on cells should be crossmatched by a method including an antiglobulin phase, and the blood that is compatible should be issued. If antisera are available, units must also be confirmed negative for the corresponding antigen.) If no clinically significant antibodies are detected in tests performed and there is no record of previous detection of such antibodies in the patient, the antiglobulin phase is not necessary.

A control system using red blood cells sensitized by IgG anti-D must be used at the conclusion of all antiglobulin tests to detect false negative results.

ABO group must be confirmed on donor units prior to/during the crossmatch.

8.3. ISSUE OF BLOOD COMPONENTS FOR TRANSFUSION

Facilities are required to perform a final check of records relating to the component at the time of issue. One of the records to be checked is existing records of the recipient. These records provide the previous ABO and RhD type of the recipient, which should match the blood group of the unit to be issued, as well as unusual finds such as the specificity of clinically significant irregular antibodies detected either during compatibility testing or in the process of investigating an adverse event relating to a previous transfusion.

8.4. SPECIAL INSTANCES

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

To perform neonatal exchange transfusions, the freshest (less than 7 days old), usually group O RhD negative, blood is used.

8.4.2.1.1 ABO group compatible red blood cell-containing components shall be issued, which should also be ABO compatible with the mother.

8.4.2.1.2 RhD compatible red blood cell components shall be issued, which should also be compatible with the mother.
8.4.3 Blood transfused in cases of dire emergency:

The facility shall have procedures for the issuing of blood and blood components on an emergency basis when full compatibility testing is not possible.

In this instance, the patient’s physician must weigh the risk of transfusing blood or blood components that have not undergone compatibility testing, or those for which compatibility testing has not been completed, against the risk of delaying transfusion until compatibility testing is complete.

When a delay in transfusion may be detrimental to the recipient, blood and blood components that do not meet requirements should only be released when the following conditions are met:

- The recipient of a transfusion whose blood group is not known should receive blood which is Group O and RhD negative (particularly if the recipient is a female with child bearing potential).
- The recipient of a transfusion whose blood group is known should receive ABO and RhD-compatible, if there has been time to test a current specimen.

In geographic regions where haemoglobin S is prevalent, for exchange transfusion or in hypoxic patients it may be necessary to:

- Screen donors for haemoglobin S.
- Refer the patient to a specialist immunohaematologist, if one is available.
SECTION 9 – HAEMOVIGILANCE AND CLINICAL INTERFACE

9.1. ADVERSE TRANSFUSION EVENTS

The facility may want to develop forms to encourage the recognition and assist in the reporting and management of adverse events related to transfusion, such as transfusion-transmitted infections. The facility should encourage the reporting of these events.

9.2. TRANSFUSION TRANSMITTED INFECTIONS

9.2.2 Look-Back:

In the event that a donor is found to be infected with HIV, HBC and/or HCV, and if blood or blood components from that donor have been transfused in the past, procedures must be in place for notifying the physician, of the recipient(s) of those previous components, of the current status of the donor. These procedures should include details of the method by which the notification is made and details of follow-up provided by the collection facility.

9.3.3 Facilities responsible for transfusing blood and blood components shall have appropriately trained and experienced personnel available to provide advice on the use of blood and blood components, particularly in the case of transfusion events in which the treating physician may have limited experience, such as massive transfusions, exchange transfusions, platelet transfusions and the treatment of haemophilia.

9.4 MONITORING OF BLOOD USAGE

The requirement to evaluate blood need and blood supply with periodic monitoring of usage applies solely to facilities at Step 3.
SECTION 10 – BLOOD ADMINISTRATION

This section applies only if the facility seeking certification/accreditation is responsible for this activity. Facilities which are not responsible for this activity may want to provide the following guidance to transfusing facilities.

10.1 Facilities that are responsible for the administration of blood and blood components shall provide procedures for the use of all transfusion equipment such as blood warmers and the various filters that are available. Information should be made available regarding the obtaining of informed consent and the patient monitoring that is required during transfusion as well as the signs and symptoms indicative of an adverse transfusion event. Procedures should be available for the recognition, evaluation, treatment and reporting of adverse events.

10.10 Management of Adverse Transfusion Events in the hospital:

- Since clerical errors are the most common cause of serious adverse effects of transfusion there should be a system in place to ensure positive identification of specimens, requisition forms, blood and blood components, and patients.
- In the event of an immediate adverse reaction to transfusion, the transfusion should immediately be discontinued. The personnel attending the patient should immediately notify the responsible clinician, the transfusion service and the blood collecting facility’s Medical Director so that the Medical Director can assume responsibility for communication surrounding the event.
- The facility responsible for transfusing the unit should have a system for investigating suspected adverse events to transfusion. This should include a clerical check of patient details, visual inspection for haemolysis, determination of ABO group and compatibility and direct antiglobulin test.
- All suspected transfusion reactions should be promptly evaluated. The evaluation should not delay any proper clinical management of the patient.
- The details of all cases along with the interpretation of evaluation should be recorded and reported to the clinician and, if one exists, the hospital transfusion committee.

10.11 Blood Warmers:

Procedures should be available for the use of blood warmers, and should include details of the medical conditions requiring the warming of blood prior to transfusion; the safety precautions to be observed and the dangers of using equipment not specifically designed for the warming of blood.

10.13 Thawing of FFP should be accomplished using a validated thawing device, specifically designed to thaw frozen plasma. The thawing device should have a temperature monitoring device.
SECTION 11 – NATIONAL BLOOD SERVICE ACCREDITATION REQUIREMENTS

ACCREDITATION STEPS

The following process relates to national or regional blood programmes applying for accreditation as a system, rather than as a single facility.

Step 1: Certification

All existing facilities within the service or programme shall be in compliance with Step 1 compliance requirements as verified by the accrediting entity.

In addition, the following accreditation requirements applicable to a programme, service or system shall be achieved with the stated evidence of compliance.

a. There shall be an organizational structure that controls the entire system or programme, as reflected in an organizational chart that shows the derivation of authority and control
   - Delegated authority from the government to function as a national or regional blood service.
   - Draft National Blood Policy including 100% commitment to voluntary non-remunerated blood donors/donation (VNRBD)
   - Proposed National Legislation delegating authority to a NBS to meet the safety, adequacy and accessibility needs of the country to a blood supply based on 100% VNRBD;

b. There shall be an integrated quality system that meets compliance with Step One requirements for all facilities;

c. NBS Mission, Vision and Values statements;

d. A Strategic Plan for the NBS that describes the growth towards 100% satisfaction of the country’s needs for blood;

e. A system to track TTI rates of donors and the percentage of VNRBD and repeat donors.

Step 2: Certification

a. Compliance of all units within the programme with all elements of Steps 1 & 2 accreditation.

b. Progress towards adoption of National Legislation delegating authority to function as a NBS as evidenced by legislation under consideration outside the ministry of health.

c. A quality system that complies with the requirements for Steps 1 & 2 accreditation.

d. At least 75% of all donations from VNRBD and 10% from regular donors.

e. Plans to conduct a blood needs assessment in the country.

f. Progress towards achieving autonomy / control to ensure the safety, adequacy, accessibility and sustainability of the blood program.

g. Coverage extending to 80% of the population (geographically) as determined by national figures.

Step 3: Accreditation

a. Compliance of all units within the NBS with all elements of Steps 1, 2 & 3 accreditation.

b. Legislation with National Blood Policy (including VNRBD) and country coverage adopted.

c. A quality system that complies with the requirements for Steps 1, 2 and 3 accreditation.
TABLE 1: DOCUMENT RETENTION
The document retention requirements are minimum requirements, which may be exceeded, depending upon facility or government requirements.