Africa Society for Blood Transfusion (AfSBT)

MANAGEMENT OF AfSBT STANDARDS

1. PRINCIPLE

The purpose of the *AfSBT Standards: Step-Wise Accreditation Programme (ACR-R01),* hereafter referred to as the Standards, is to provide a benchmark for accreditation of blood facilities and to maintain and enhance the quality and safety of blood transfusion in Africa.

The AfSBT accreditation programme differentiates between three distinct and increasingly difficult levels or steps of compliance within a single set of Standards. Step 1 makes provision for basic-level certification, Step 2 for intermediate-level certification and Step 3 for full accreditation.

Initially, AfSBT performs baseline assessments to determine the preparedness of a blood facility for accreditation. This may be followed by a progress assessment, to confirm the progress made since the baseline assessment, before a formal assessment is performed for the granting of accreditation/certification. Baseline and progress assessments are performed by trained AfSBT educators while formal assessments are performed by trained AfSBT assessors.

Evolving improvements in blood transfusion technology and practice dictate that the Standards shall be regularly reviewed and revised as necessary. Standards are subject to change and will be adapted to new technology, international regulations or blood transfusion-associated risks.

2. PURPOSE

This SOP explains the structure and use of the AfSBT Standards and provides guidance to the AfSBT Management Office regarding the maintenance and revision of the Standards.

3. HISTORY OF DEVELOPMENT

The first edition of the AfSBT Standards was prepared by a sub-group of the Task Team for Accreditation established by the AfSBT with guidance from the American Association of Blood Banks (AABB). These Standards are based on input from a variety of sources, including comments from AfSBT, WHO and AABB members, and recognized experts in blood banking and transfusion medicine.

Basis for the Standards

The guiding principle of the Standards 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.

The following documents were used as references during the initial drafting of the Standards: AABB Quality Standards; European Guide to the Preparation, Use and Quality Assurance of Blood Components; South African Standards for the Practice of Blood Transfusion; WHO Basic Requirements for Blood Transfusion; Zimbabwe National Standards for Blood Transfusion; WHO GMP Guide.

The AfSBT sub-group used an evidence-based decision-making process, where possible, to modify existing requirements or create new specific requirements. During a workshop between AfSBT and AABB staff, each individual standard was developed and reviewed to ensure it was understandable, relevant, achievable and measurable. Careful attention was paid to the wording to ensure it was clear and unambiguous and input from a legal professional on the team ensured that standards were not open to misinterpretation.

3. HISTORY OF DEVELOPMENT (cont'd)

The sub-group and experts also ensured that standards were adapted to local epidemiology and practices such as malaria endemicity or family replacement donation.
Subsequent to their introduction, the Standards have been reviewed and revised regularly to ensure they remain current and relevant.

4. OWNERSHIP

5. STANDARDS FRAMEWOK

General
The Standards have been designed with a clear framework. The technical content is divided into Sections A, B and C which are preceded by an introduction, a glossary and instructions on how to use the Standards.

Main Sections
The three main sections of the Standards are divided as follows, each with relevant sub-headings as shown on the Contents page of the document:

- Section A - Quality System Requirements
- Section B - Technical Requirements
- Section C - Requirements if Plasma is Provided for Fractionation.

Introduction
Information contained in the introduction to the Standards is divided under the following sub-headings:

- Purpose
- Standards Development
- User Obligations
- Scope of Standards
- Notes on Language
- Notes on Format
- Notes on Regulatory and Legal Issues
- Variances and other considerations.

Glossary
A glossary of terms used in the Standards is provided with terms listed in alphabetical order. Terms are defined to reflect their usage in the context of the Standards, not necessarily in general use.

Instructions for Use
The instructions provided on how to use the Standards explain their usage in terms of the Step-Wise Accreditation Programme. Furthermore, the Standards are based on several important drafting principles and these are outlined to facilitate a more comprehensive understanding of the document.

6. USE OF STANDARDS

1. The Standards are used by AfSBT Management Office staff, together with AfSBT educators and assessors, when conducting training or accreditation assessments of blood facilities.
2. The Standards may be used by blood facilities for the performance of a self-assessment prior to AfSBT conducting an assessment.
3. The Standards may also be used by blood facilities and/or country governments and officials as a reference document in developing policies, processes and procedures.
4. Obligations for users are laid out in the introduction to the Standards.
5. AfSBT has no agreements with other independent parties regarding specific use of the Standards.

7. STANDARDS MEASUREMENT

1. During assessments of blood facilities, AfSBT assessors and educators evaluate performance against each individual standard dependent on the defined Step in the accreditation programme.
2. Compliance with each standard is indicated by stating either 'Yes' or 'No' on the *AfSBT Assessment Record (ACR-F08).* Where partial compliance is achieved, explanatory comments are provided.
3. For formal accreditation/certification assessments, overall achievement is measured by compliance with all applicable standards. Where compliance is not achieved, non-conformances are raised and these must be satisfactorily addressed before accreditation/certification can be granted.
4. For baseline and progress assessments, non-conformances are not raised but a gap analysis is prepared from which a work plan is developed to assist facilities in preparing for a formal accreditation/ certification assessment.
5. The methodology for measuring and recording compliance on the assessment record is explained and demonstrated to assessors and educators during their theoretical and practical training.
6. Guidelines are provided to blood facilities on how to use the Standards for self-assessment purposes at the beginning of the assessment record.
7. There is an opportunity for facilities to request a review of the interpretation of a standard if they feel something is not clear. The form *Record of Differences in Standards Interpretation (ACR-F13)* is used.
8. Facilities may also request a variance from a standard if they follow an alternative method or approach from the Standards that allows for equally safe practice. The form used for this purpose is *Request for Variance to AfSBT Standards (ACR-F14).*
9. Facilities and AfSBT assessors have the opportunity to provide feedback on the Standards after an assessment, uisng the form *Post-Assessment Feedback on AfSBT Standards (ACR-F26).*
10. Information relating to differences in interpretation and approved variances is reviewed for possible inclusion in future editions of the Standards, as is the post-assessment feedback.

8. AfSBT STANDARDS COMMITTEE

1. The AfSBT Standards Committee has been appointed to review and, if necessary, propose revisions to the Standards when required.
2. The current chairperson of the committee is the AfSBT Accreditation Manager. Other members of the committee include assessors, blood facility representatives and experts in blood transfusion from various countries in Africa.
3. The panel of non-voting members includes experts with experience at international organisations such as World Health Organisation (WHO), International Society of Blood Transfusion (ISBT) and AABB.
4. The committee also responds to requests for interpretation of specific standards and to variance requests by blood facilities when a specific standard is not met.
5. The role of the committee is defined in the document titled *AfSBT Standards Committee - Terms of Reference (EXE-R09)*.

9. REVISION PROCESS SUMMARY

Initiation of revision process by AfSBT Standards Committee chairperson

- *Collation of feedback received since last update and drawing-up of table of changes*
- *Marking-up of proposed changes on Standards*
- *Circulation of documents for review and feedback*

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AfSBT Management Office review and feedback

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AfSBT Standards Committee review, evaluation and feedback

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Additional evaluation by assessors, blood facilities

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Posting of Standards on AfSBT website for public comment

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Finalisation of Standards based on feedback and evaluation

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Approval of Standards

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Issuing of Standards

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Final implementation of Standards (6 months after date of issuing)

10. REVISION PROCESS

Coordination

1. The review and revision process is coordinated by the chairperson of the AfSBT Standards Committee.
2. The Standards are reviewed every two years, or sooner if circumstances require, and revised as needed.
3. At any stage during the two year cycle, feedback regarding changes to the Standards may be submitted to the chairperson by blood facilities, government bodies, AfSBT staff, AfSBT assessors and educators or other interested individuals.

Initiation of Review Process

1. The chairperson, together with the Quality Manager, draws up a plan for the revision process and allocates target dates for activities, using form AfSBT *Standards Revision Plan (ACR-F27)*. The plan is updated during the process, as required.
2. The chairperson collates all feedback obtained since the last update, taking into account the post-assessment feedback obtained from assessors, blood facilities or other stakeholders as well as any variance requests submitted by blood facilities. He/she tabulates proposed changes on the form titled *Changes to AfSBT Standards (ACR-F23).* This is referred to as the table of changes.
3. The chairperson marks-up the proposed changes on the Standards and the AfSBT Guidance Document, creating new draft versions. The chairperson may work with the Quality Manager on this task.
4. A RUMBA analysis is performed by the chairperson and the Quality Manager to determine whether each new or revised standard is relevant, understandable, measurable, beneficial and achievable.

10. REVISION PROCESS (cont'd)

Management Office Review

1. The chairperson circulates the documents below to relevant Management Office staff for their feedback. (The Education and Accreditation Managers use the Standards regularly during assessments and are therefore in the best position to propose changes and improvements.)
   - Marked-up version of the *Standards*
   - Marked-up version of the *Guidance Document*
   - Form titled *Changes to AfSBT Standards (ACR-F23).*
   - Completed *RUMBA analysis (ACR-F25)*
   - Blank form titled *Evaluation of Standards (ACR-F24).*
2. The chairperson reviews the evaluation forms and feedback received and updates the above-listed documents accordingly.
3. Note: This Management Office review may be done concurrently with, or after, the committee review below, at the discretion of the chairperson depending on the extent and nature of the changes.

Standards Committee Review and Evaluation

1. The chairperson circulates the revised Standards and Guidance documents, the table of changes, the RUMBA analysis and an evaluation form to members of the AfSBT Standards Committee for review and feedback on further suggested changes. Additional knowledgeable experts may also be asked for input.
2. in addition to evaluating each new or revised standard, members are required to check that the wording used is clear and unambiguous and that the overall framework of the Standards is acceptable.
3. Committee members are required to review the RUMBA analysis to check that each standard is relevant, understandable, measurable, beneficial and achievable.
4. Each committee member is required to review the amendments to the Standards against any Standards or reference documents that they work with or are familiar with e.g. Standards from AABB, European or African countries, WHO documents, ISBT documents, relevant government regulations.
5. Committee members make their changes, comments or suggestions to the chairperson via the table of changes, the evaluation form or a separate document or email.
6. The chairperson collates all responses, finalises the table of changes and the RUMBA analysis, and makes the changes to the Standards and Guidance Document, in collaboration with the Quality Manager.

Additional Evaluation by Assessors, Blood Facilities

1. The chairperson may circulate the revised documents, the table of changes, the RUMBA analysis and an evaluation form, to a group of selected assessors/educators and blood facility representatives for review and evaluation. This will depend on the nature and extent of the changes to the Standards.
2. Group members are selected on the basis of previous working experience with the Standards.
3. Members of the group are required to evaluate each new or revised standard and to check that the wording used is clear and unambiguous and that the overall framework of the Standards is acceptable.
4. Each member is required to review the RUMBA analysis and to list any reference documents consulted.
5. Members return the evaluation form, with any additional feedback, to the chairperson who collates the responses and makes the changes to the Standards and Guidance Document. (Queries may be referred to the committee if deemed necessary.)
6. The chairperson and Quality Manager finalise the proposed new editions of the documents.

Public Comment and Finalisation

1. The chairperson arranges for the proposed new edition of the Standards to be posted on the AfSBT website for public comment, for a period of 7 to 14 days, depending on the extent of the changes.

10. REVISION PROCESS (cont'd)

2. All AfSBT members are advised that the revised Standards have been posted on the website for comment. Blood facilities and AfSBT assessors/educators may submit comments during this time.
3. All feedback received is given due consideration by the chairperson for incorporation into the Standards. Where deemed necessary, the chairperson may refer issues to the committee for further discussion.
4. The chairperson finalises the Standards and the Guidance Document and forwards them to the AfSBT Quality Manager. The table of changes, Rumba analysis and evaluation forms are also sent to the Quality Manager for archiving.

11. APPROVAL

1. The AfSBT Quality Manager inserts an effective date into the Standards and Guidance documents.
2. The AfSBT Quality Manager arranges for the revised Standards and Guidance documents to be approved by the AfSBT Committee Chairperson and finally authorised by the AfSBT Managing Director. Prior to signing, the AfSBT Managing Director forwards a copy of the Standards to the AfSBT Board for information. Should the Board raise any issues, these are to be addressed before authorisation.
3. The AfSBT Quality Manager forwards the signed Standards and Guidance documents to the committee chairperson who submits the documents to Copyright House Limited, registered in the UK, for the issue of copyright certificates.
4. The chairperson forwards the copyright certificates to the Quality Manager for archiving.
5. In due course, the chairperson arranges for the Standards and Guidance documents to be translated into French and Portuguese. These documents will be approved and copyrighted as above.

12. IMPLEMENTATION & DISTRIBUTION

1. The chairperson, in conjunction with the Quality Manager, draws up a plan for implementing the revised Standards, using form *AfSBT Standards Implementation Plan (ACR-F28)*.
2. The AfSBT Quality Manager saves the revised Standards in Dropbox in PDF for read-access by Management Office staff. The previous version is archived.
3. The AfSBT Quality Manager emails the revised Standards to the AfSBT Communications Manager for posting on the members' section of the AfSBT website. The document is posted in read-only format and the previous version is removed from the website. Blood facilities may access the Standards on the website.
4. The AfSBT Accreditation and Education Managers provide the revised Standards to AfSBT assessors and educators for use during assessments, as required. Education on new or revised standards is provided to the assessors/educators online by circulating a PowerPoint presentation or other document explaining the changes to the Standards. Classroom or on-site training will be provided where this is possible.
5. Blood facilities will be sent the latest version of the Standards when they submit an application for an assessment. If the facility has used the Standards before, changes to the new version will be explained.
6. If the blood facility has not used the Standards before, on-site training is provided prior to any baseline assessment. Training can also be requested prior to any other assessments.
7. Blood facilities will be assessed against the latest revision of the Standards six months after the effective date. Blood facilities with assessment dates that fall during the six month period may elect to be assessed against either the latest or previous revision. If the previous revision is selected, the blood facility will be required to submit evidence of compliance with the new version by the six-month date.
8. The revised Standards may be forwarded by the AfSBT Managing Director to blood facilities, government authorities or other interested parties on request.
9. This SOP is posted on the AfSBT website so that the Standards revision process is available to the public.

13. COMPLEMENTARY DOCUMENTS

1. The following key AfSBT documents are to be revised in conjunction with the Standards:
   - AfSBT Compliance Chart (ACR-R03) - English, French and Portuguese versions
   - AfSBT Assessment Record (ACR-F08) - English and French versions
   - AfSBT presentations (STN-T01 to T18) for Standards training - English, French & Portuguese
   - SOP on Management of AfSBT Standards (QSM-S03) - if necessary.

14. REFERENCES

Reference Docs:	ACR-R01	AfSBT Standards: Step-Wise Accreditation Programme
	ACR-R02	AfSBT Guidance Document
	ACR-R03	AfSBT Compliance Chart
	EXE-R09	AfSBT Standards Committee - Terms of Reference
Forms:	ACR-F08	AfSBT Assessment Record (Basline, Progress, Formal or Self-Assessment)
	ACR-F13	Differences in Standards Interpretation
	ACR-F14	Request for Variance to AfSBT Standards
	ACR-F23	Changes to AfSBT Standards
	ACR-F24	Evaluation of Standards
	ACR-F25	Rumba Analysis
	ACR-F26	Post-Assessment Feedback on AfSBT Standards
	ACR-F27	AfSBT Standards Revision Plan
	ACR-F28	AfSBT Standards Implementation Plan
Presentations:	STN-T01 to T18 AfSBT presentations for Standards training	

15. REVISION SUMMARY

REVISION NO.	DATE	DETAILS OF REVISION	REASON OF REVISION
0	27/03/2019	N/A - new document. *Author: Quality Manager (L Bust)*	N/A
1	06/08/2020	Section 7: Post-assessment feedback included. Section 9: Flowchart summary added. Section 10: More detail included on revision process. Time posted on website amended. Section 11: Guidance Document included. Section 12: Point 1 added to include implementation plan. Point 4 amended to include training. Point 8 amended re MD making documents available.	More detail required to reflect how procedures are carried out

15. SIGNATURES

Accreditation Manager - Francophone	AfSBT Managing Director	AfSBT Quality Manager
Tayou Tagny Claude Tayou Tagny Claude (Aug 6, 2020 19:54 GMT+1)	Mohammed Farouk Mohammed Farouk (Aug 5, 2020 20:22 GMT+3)	pp Lesley Bust Lesley Bust (Aug 6, 2020 09:16 GMT+2) Quality Consultant