Africa Society for Blood transfusion

The Step-Wise Accreditation Programme

BACKGROUND

The certification or accreditation of a Blood Transfusion Facility by the Africa Society for Blood Transfusion (AfSBT) provides formal recognition that the facility meets all the requirements of the stipulated step of the "Standards: Step-Wise Accreditation Programme". The competence of the facility to perform the functions to be certified or accredited will be assessed through a formal process designed to show that the functions routinely satisfy the stipulated criteria and that the documented Quality System is fully implemented to support these functions.

Key to the system is the ‘step-wise’ concept that recognizes that African services operate on widely different levels of sophistication and that all cannot be inspected and certified for accreditation purposes at the same level. An individual facility – or blood service – can estimate its position in the system through a formal self-assessment process and after reviewing the results can request to be assessed at the appropriate step of the programme.

The system entails three steps progressing towards full accreditation:

Step 1: Certification: minimum (basic) quality and operational requirements

Step 2: Certification: intermediate quality and operational requirements

Step 3: Full accreditation at international standard

The stages shown below provide an outline of the accreditation process. This is provided as a guide only, and points may be omitted or changed as dictated by circumstances. The timescale for carrying out listed tasks will be decided jointly between AfSBT and the applicant. The time taken for accreditation to be achieved will depend on several factors, including the state of preparedness of the facility when the application is made; the extent to which training and technical assistance are required; the availability of AfSBT assessors and the availability of funding.

The AfSBT Step-Wise Accreditation Programme provides for three steps of compliance, with certification being given by AfSBT for compliance with the requirements of Step 1 and Step 2, and accreditation being given for compliance with the requirements of Step 3. For the sake of simplicity this difference is ignored in the following stage guide and only the term “accreditation” is used.

Stage 1 – Preliminary Steps

1. The applicant submits an email enquiry about accreditation to AfSBT
2. AfSBT sends an information pack to the applicant electronically, including -
   a. Application form
   b. Accreditation Standards
   c. Compliance Charts and Guidance Document
   d. Self-Assessment document
3. The applicant submits the completed application to AfSBT
4. AfSBT acknowledges receipt of the application by email

Stage 2 – Self-Assessment

1. The applicant completes the self-assessment form. This is a lengthy process and is in fact a full assessment conducted by the facility’s own quality staff, with responses required to each of the questions to be addressed in the formal assessment
2. The applicant submits the completed self-assessment form to AfSBT
3. The AfSBT Accreditation Programme Manager reviews the self-assessment document and makes recommendations on how deficiencies, if any, can be addressed.
4. As appropriate, the facility is requested to submit sample documents in support of the self-assessment results.
5. Senior staff at the facility decide on the step at which the facility is to be accredited, and the approximate date for the assessment, and notify AfSBT of this decision.

Stage 3 – Development of Budget

1. AfSBT will develop a budget for the assessment.
2. AfSBT may be able to assist with funding to partially subsidise the assessment, but this will depend on the circumstances prevailing at the time, AfSBT may also be able to advise on where the facility may seek funding if required.
3. The facility and AfSBT formally agree to the budget responsibility.

Stage 4 – Desk Review

1. AfSBT appoints a Lead Assessor, and Second Assessor for the project
2. Four weeks prior to the assessment, the facility submits documents requested by AfSBT for a full desk review. These documents will include the facility’s quality manual, index of standard operating procedures, the facility organogram and any other example documents that may be required by the Lead Assessor.
3. The Lead Assessor reviews the application, carries out a desk review of submitted documents and requests additional information if required.
4. Provided that the desk review is satisfactory, AfSBT and Applicant agree on dates and a plan for the accreditation assessment.

Stage 5 - Accreditation Assessment

1. The Lead Assessor conducts the accreditation assessment and raises non-conformances as required
2. The Applicant corrects all non-conformances by the agreed deadline and submits proof of this to the Lead Assessor
3. When all non-conformances have been cleared the Lead Assessor decides whether to award accreditation in full, in part, or whether further action is required
4. The Lead Assessor refers the accreditation report and recommendation to the AfSBT Accreditation Committee for confirmation.
5. The applicant is notified of the decision.

Roles and responsibilities of the facility and AfSBT
In order for the accreditation process, as described above, to proceed smoothly and in accordance with the expectations of all parties, it is necessary for the organisation to be assessed and AfSBT to work closely together and to fully understand their roles and responsibilities. Communication lines via email must be reliable.

The obligations of the facility may be summarised as follows:

1. The Ministry of Health must be made aware of, and support, the accreditation initiative. This support should be confirmed in writing.

2. The facility should apply for corporate membership of AfSBT.

3. All key staff should apply for individual membership of AfSBT. Key staff include the following:
   a. CEO
   b. Medical Director
   c. Quality Manager
   d. Heads of Technical and Collection departments

4. All key staff must be briefed before the visit from the AfSBT assessors, and should make themselves available for the opening and closing meetings, and for the time during which their work area is visited by the assessors.

5. All key staff should be familiar with the AfSBT Step-Wise Accreditation Standards (OMD-E-001) as applicable within their work area prior to the assessment.

6. When arranging dates for the visit, the organisation must inform AfSBT of public holidays or religious holidays so that visits can be planned accordingly.

7. There must be a commitment from key staff to correct deficiencies that are identified during the assessment, in terms of the workplan that will be developed during the assessment, and to provide regular progress reports to AfSBT.

8. One individual, preferably the Quality Manager, should be identified as the focal point for all communication with AfSBT, and this individual will be responsible for ensuring that reporting deadlines are adhered to. This individual must have the authority and accountability for communicating with AfSBT as the facility spokesperson, and must also have the authority and responsibility to drive the programme locally. All correspondence should be attended to promptly.

9. The facility shall cover its portion of the costs in terms of the budget agreed with AfSBT.

10. Monies utilised during the assessment process are not refundable by AfSBT.

The obligations of AfSBT may be summarised as follows:

1. AfSBT will appoint assessors who have been thoroughly trained and are conversant with the requirements of the AfSBT Step-Wise Accreditation Standards as well as the operations of a blood transfusion facility. AfSBT may be assisted by AABB, in the provision of experienced assessors who also understand and are thoroughly conversant of the concept of the AfSBT Step-Wise Accreditation programme.

2. AfSBT shall cover its portion of the costs in terms of the budget agreed with the facility.
3. The Lead Assessor appointed by AfSBT will be responsible for communication with the facility regarding all reports in respect of the assessment.

4. Assessors will be bound to a confidentiality agreement to protect the rights of the facility and its customers.

5. As appropriate, AfSBT may include observer auditors, and cover their costs.

6. Reports arising from the assessment will not be shared with any other facility or individuals without the written permission of the CEO of the facility assessed.

7. Training and assistance in meeting the requirement of the AfSBT Step-Wise Accreditation Standards will be provided by AfSBT in accordance with an agreed programme. Financial restrictions may influence the extent of in-country training that can be provided.

If your blood service is interested in being assessed in terms of the programme described above, please email us an expression of interest and we will send you the necessary application forms.

All correspondence should be addressed to the AfSBT Accreditation Programme Manager, Mr Rob Wilkinson at robwilkinson795@gmail.com.

Mrs Beryl Armstrong
Programmes Director
June 2014.