

# **AfSBT Step-Wise Accreditation Programme**

## **Perspectives: Directing, Managing, Assessing**

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**Africa Society for Blood Transfusion**

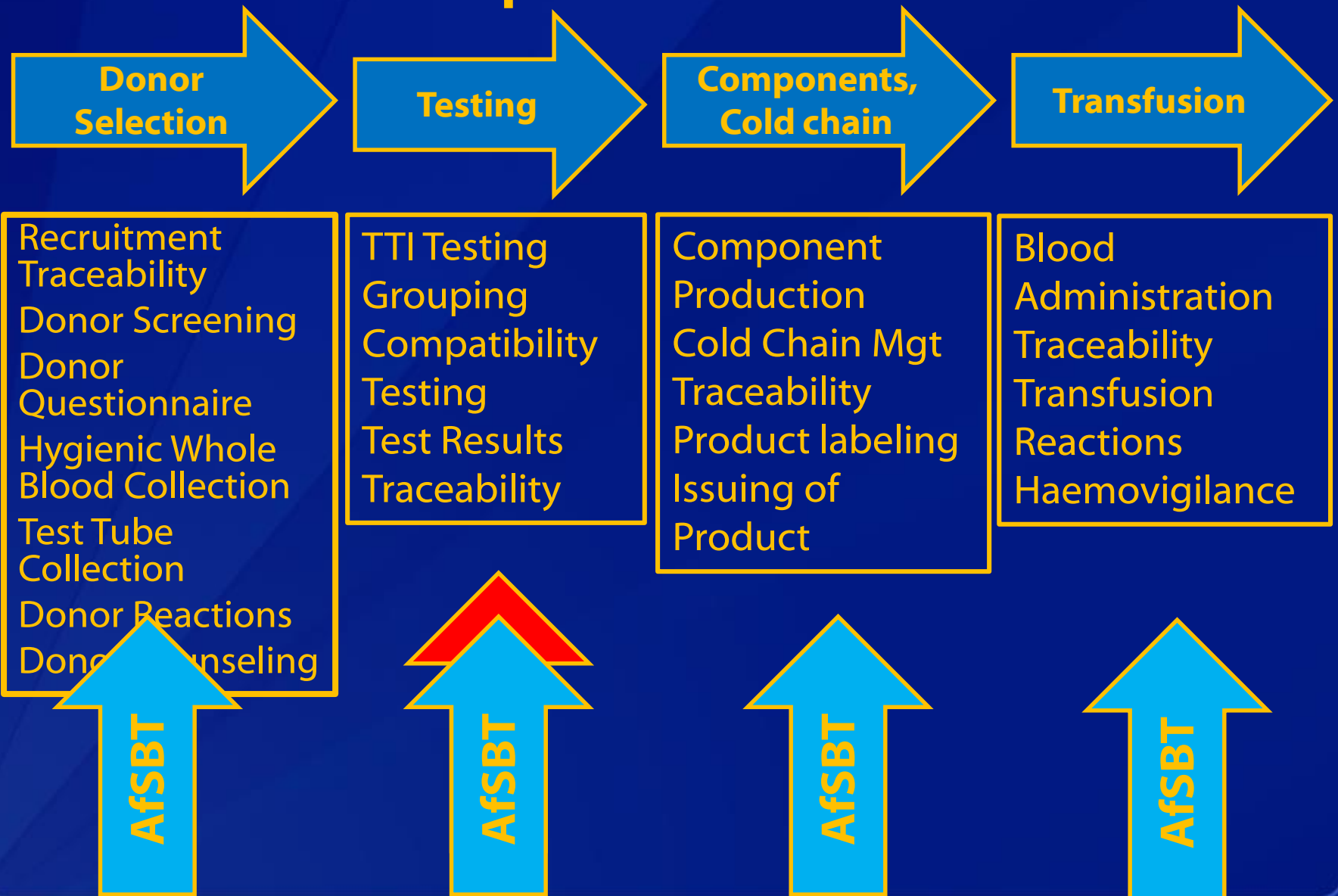


# Requirement - One



- ❑ Available to all countries in Africa
- ❑ Available in three languages
  - English
  - French
  - Portuguese
- ❑ Affordable

# Requirement - Two



## Requirement - Three

- ❑ **Large disparities within blood services in Africa**
  - level of testing and components available
  - adequacy of the blood supply
  - collections from voluntary blood donors
  - level of training available
  - level of funding available

**“One size fits all” solution simply not practical.**

## Conclusion

- ❑ A new accreditation programme was required.
- ❑ A step-wise approach was required.

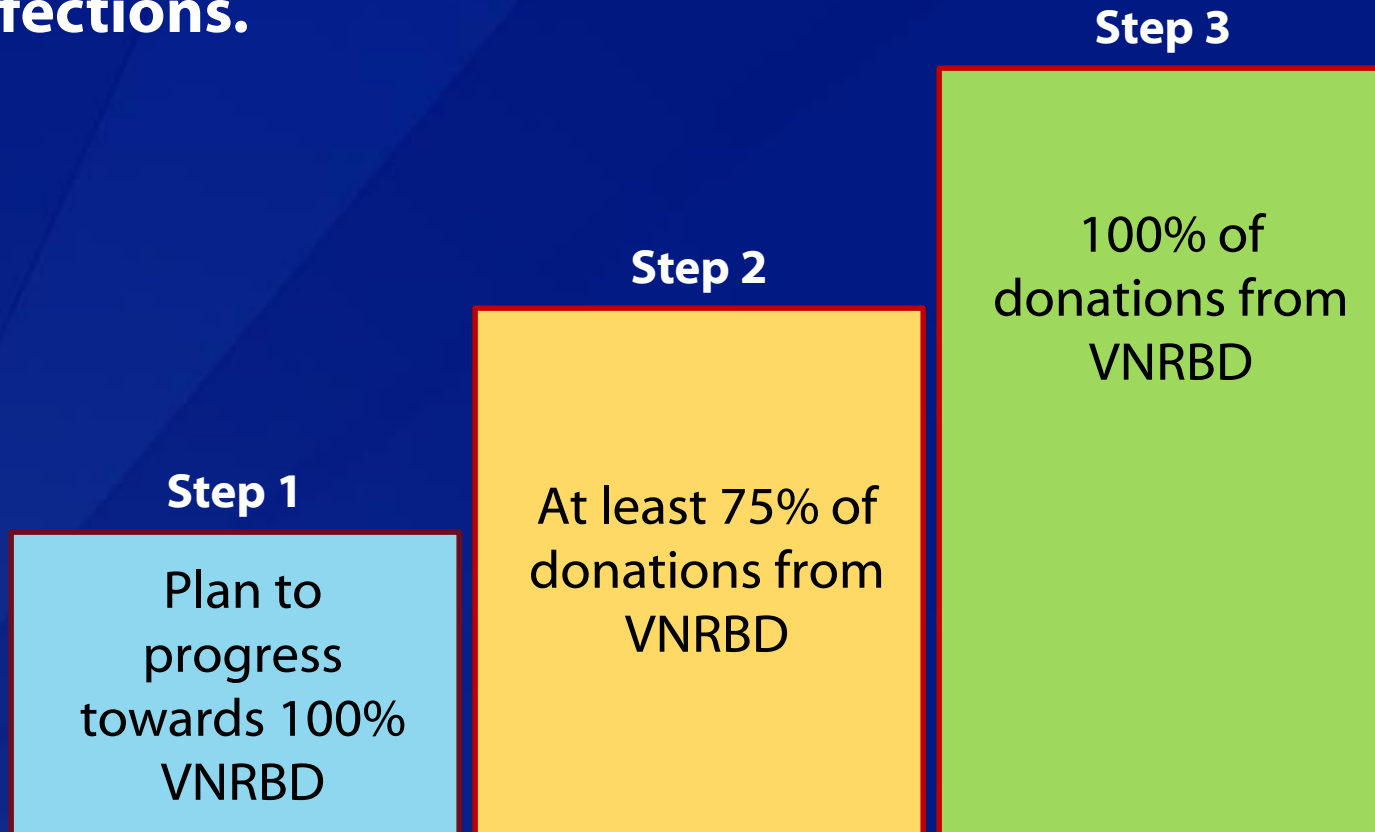


## Development of the Standards

- ❑ Small group of AfSBT and AABB experts developed *Standards* to finalization: Oct 2010 - Jan 2012
- ❑ *Standards* are written to express international requirements
- ❑ Requirements to meet each *Standard* assigned to progressively reach the highest level.

## Example – Step-Wise Progression

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





## The Role of AfSBT in Accreditation

- ❑ To be the accrediting body
- ❑ To be the custodian of the *Standards*
- ❑ To maintain a cadre of qualified and experienced assessors in Africa
- ❑ To seek funding from international agencies to assist in keeping the programme affordable
- ❑ To provide training and assistance to facilities seeking accreditation



# The Control of the Programme

## □ Standards Committee

- Review *Standards* every two years
- Consider suggestions for changes to *Standards*
- Consider emergent *Standards*
- Consider variances to meeting *Standards*

## □ Accreditation Committee

- Assign requirements for each Step for each Standard
- Review procedure and outcome of each assessment

## Four main documents

1. **AfSBT Step-Wise Accreditation Standards**

The detailed Standards that must be met in order to be accredited by the Society.

2. **AfSBT Standards Guidance Document**

Provides additional information on the interpretation of the standards.

## Four main documents

### 3. Chart of Evidence of Compliance for the Standards

Provides details of the evidence of compliance that will be looked for by assessors.

### 4. Tool: Assessment of Preparedness for Accreditation

- Initial assessment of a facility to establish the level of preparedness for accreditation.
- To develop a work-plan, timeline and budget to correct any deficiencies.
- To decide when and at what *Step* the assessment should be carried out.

## End Section 1 – Director perspective



# Six Steps in the Accreditation Process

- 1 Preliminary assessment
- 2 Decide at what step and when  
Develop remedial work-plan
- 3 Develop a programme and budget for the  
formal assessment
- 4 Appoint Lead Assessor and team
- 5 Desk review
- 6 Assessment & post-assessment activities

**1**

## **Preliminary Assessment**

**1**

**Self-assessment using the AfSBT assessment tool**

**OR**

**2**

**Third party assessment e.g. by TA provider using the AfSBT assessment tool**



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## ASSESSMENT OF PREPAREDNESS FOR ACCREDITATION

### STEP-WISE ACCREDITATION PROGRAMME

[Name of Blood Transfusion Service]

[Name and email address of contact person]



**2**

## **Decide at what Step and When**

**1**

**Facility examine preliminary assessment results**

**2**

**Estimate time required for corrective actions**

**3**

**Decide the step**

**4**

**Develop a remedial work-plan**

**5**

**Decide the date for the assessment**

**3**

## **Develop a programme and budget for the assessment**

**1**

**Scope of the assessment**

**2**

**Number of facilities**

**3**

**Geographical location of facilities**

**4**

**Agree on shared costs**

**4**

## **Appoint Lead Assessor and team**

**1**

**Lead assessor from AABB**

**2**

**Two (?) assessors from AfSBT**

**3**

**Accreditation Manager from AfSBT**

**5**

## **Desk Review**

**1**

**Six weeks before assessment AfSBT requests named documents from facility -**

- **Organogram**
- **Quality Policy**
- **Quality Manual**
- **Index of SOPs**
- **SOP for blood collection**
- **Job Description for e.g. Laboratory Technician**
- **List of external proficiency programmes**

**6**

## **Assessment**

**1**

**Opening Meeting**

**2**

**Assessment**

**3**

**Summary report**

**4**

**Closing Meeting**

**6**

## **Post-Assessment Activities**

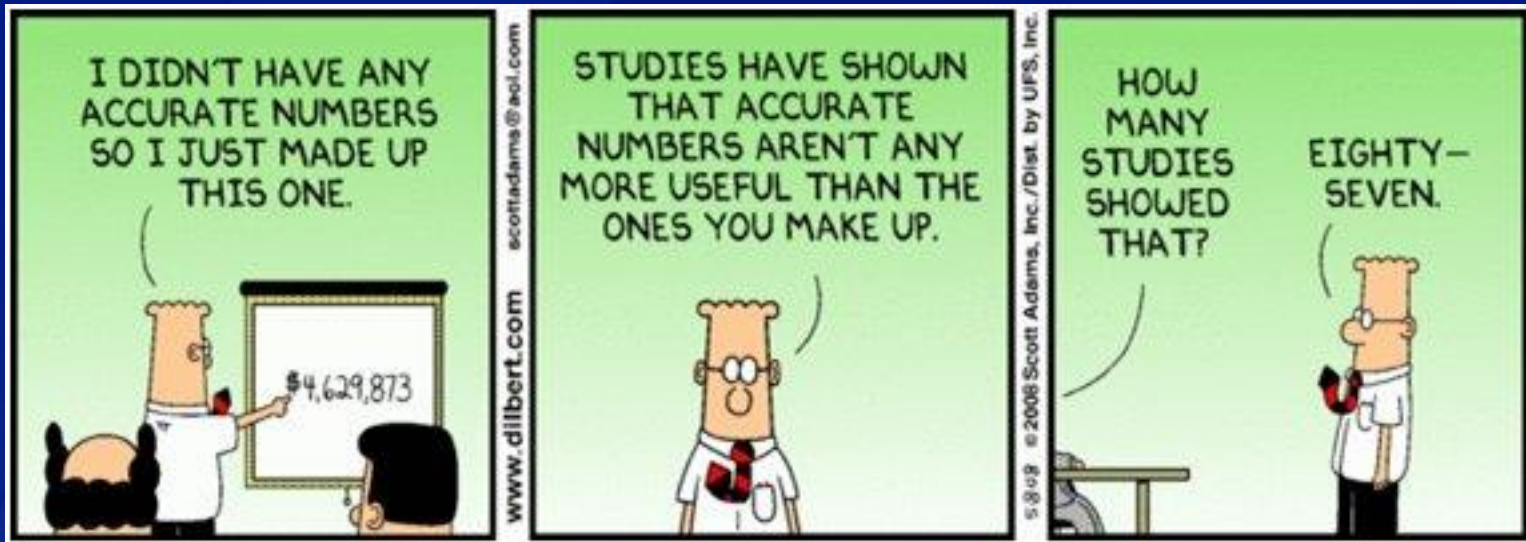
- 1 Lead Assessor – Assessment report and recommendation**
- 2 Facility - Correct any non-conformances and provide evidence to lead assessor**
- 3 Final decision on certification / accreditation**

# Maintaining Accreditation

- 1 Accreditation valid for three years**
- 2 Extent of re-assessment will be influenced by first assessment, but may be shorter**
- 3 Facility must notify AfSBT of changes to key staff, or major changes to accredited procedures**



## End of Section 2 – Management perspective



## **Purpose of the assessment**

**To evaluate compliance to AfSBT Standards**



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**To evaluate compliance to AfSBT Standards**



## **Aim of the assessor team**

**Does the facility comply with AfSBT Standards?**

**If Yes, at which level?**

## **Assessment team**

- ❑ **Lead assessor**
- ❑ **Technical Assessors ( 1-2)**
- ❑ **Technical adviser ( Occasional)**
- ❑ **Accreditation Manager**

## Selection of Assessors

- ❑ Appropriate **expertise** for activity to be accredited
- ❑ Objectivity, Integrity, based on experience
- ❑ Technical knowledge, based on experience and education
- ❑ Assessment knowledge, based on experience and training

# Conflict of Interest

## Impartiality

- ❑ To know some of the quality staff
- ❑ To work in the country or in the setting
- ❑ To have a relative who works there
  
- ❑ AfSBT selects assessors
- ❑ Assessors have option to accept or decline assignment
- ❑ Facility has option to accept or decline members of the assessment team

# ROLE OF ASSESSMENT TEAM

- 1 Preliminary Assessment
- 2 Decide at What Step and When
- 3 **Desk Review**
- 4 **Assessment**
- 5 **Post-assessment Activities**
- 6 Maintaining Accreditation



## ROLE OF ASSESSMENT TEAM

- ❑ **Conduct on-site assessment** of facility
- ❑ **Obtain evidence** on compliance with AfSBT standards, applicable laws, regulations and guidelines.
- ❑ **Provide the report** to AfSBT
- ❑ **Maintain confidentiality** on all matters relating to the assessment

# ROLE OF ASSESSMENT TEAM

## Activities include:

- ❑ **Verify the effectiveness of Quality System**
- ❑ **Review related documents using audit techniques**
- ❑ **Raise non-conformances**
- ❑ **Examine the technical competence of the blood bank in terms of manpower, qualification, experience, up to date knowledge, equipment and other related elements.**
- ❑ **Record detailed non-conformances as they are identified**

# ROLE OF ASSESSMENT TEAM

## Team Leader

- ❑ Plans, organizes and directs assessment
- ❑ Leads team in evaluating evidence
- ❑ Prevents and resolves conflicts
- ❑ Get an endorsement from the blood bank
- ❑ Monitor the performance of Assessor(s)
- ❑ Writes assessment report
  - Areas
  - Deficiencies/ Non conformances
  - Recommendations/required actions

# ROLE OF ASSESSMENT TEAM

## Assessors

- ❑ Assist the Lead assessor in preparing and organizing assessment
- ❑ Gather objective evidence during assessment
  - Observations
  - Interviews
- ❑ Contribute to assessment report

# CONCLUSION

## Assessors

**Do not grant accreditation but make a recommendation on whether accreditation (or certification) should be awarded.**

**End of Section 3 – Assessor's perspective**

**Thank you for your attention !**

**Africa Society for Blood Transfusion**

