INTERNATIONAL LINKS

SANAS, in association with the Blood Transfusion Service Laboratory Specialist Technical Committees (STC), aligns its requirements and procedures relating to accreditation of laboratories with those of international counterparts. SANAS is signatory to the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation (ILAC).

ENQUIRIES

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ACCREDITATION OF BLOOD TRANSFUSION SERVICES

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THE NEED FOR GLOBAL RECOGNITION

Accreditation provides formal recognition that a facility meets certain standards. These are standards of quality, performance, technical expertise and competence.

The need for South African Blood Transfusion Services to achieve national recognition as well as conformity against international standard led to the establishment of an accreditation programme for Blood Transfusion Services under the auspices of the South African National Accreditation System (SANAS).

SANAS is a government-endorsed body that provides formal recognition of competence for Blood Transfusion Services, Laboratories, Certification bodies and Inspection bodies in South Africa. Blood Transfusion Services accredited by SANAS are allowed to display the SANAS symbol on their communication, certificates and reports. A directory of these accredited services is maintained on the SANAS website - www.sanas.co.za

REQUIREMENTS FOR ACCREDITATION

- Quality management, scientific and technical aspects of Blood Transfusion Service as determined by ISO/IEC 17025 and the Standard for the Practice of Blood Transfusion in South Africa;
- Technical requirements documents which may have been developed by the SANAS Specialist Technical Committee (STC);
- Participation in proficiency testing or inter-laboratory comparisons;
- Compliance with Occupational Health and Safety requirements;
- Requirements of other professional bodies related to the practice of pathology.

PROFILE OF ASSESSORS

The assessors are representatives of the public, private and academic sectors. They undergo comprehensive training and are identified for training in new fields as required.

Participants are trained in:
- laboratory systems and technical requirements as defined in ISO/IEC 17025;
- the SANAS criteria for Blood Transfusion Services;
- Assessment techniques.

A standard part of the course is simulated laboratory assessments based on real case studies.

THE ASSESSMENT TEAM

The assessment team is made up of a lead assessor and at least one technical assessor with experience relevant to the area being assessed.

Role of the lead assessor

The lead assessor is responsible for managing the assessment team and assessment process, and assessing the management requirements. The assessment plan is communicated to the applicant organisation prior to the initial assessment.

Role of the technical assessors

The technical assessors are responsible for advising the lead assessor on specialist matters relating to the capabilities of the organisation being assessed. The assessors' functions are to:
- observe the performance of tests;
- evaluate the suitability of technical procedures;
- evaluate laboratory personnel with respect to experience, qualifications, performance and training;
- interview staff members.

APPLICATION FOR ACCREDITATION

An organisation wishing to obtain accreditation:
- Submits a completed application form (F14 TC) to SANAS together with the laboratory’s quality manual;
- SANAS provides prospective applicants with a detailed quotation based on the scope of the application;
- SANAS arranges for a document review of the organisation’s quality manual;
- If the quality manual addresses all the requirements of ISO/IEC 17025 and/or the Standard for the Practice of Blood Transfusion in South Africa, the arrangements for the initial assessment may proceed;
- If not, the organisation is required to make the necessary amendments and submit these to SANAS.

RESULTS OF ASSESSMENT

The assessment team records the details of areas assessed and makes a recommendation to the Approval Committee (AC).

Where deficiencies are identified, these are recorded as non-conformances requiring action by the laboratory prior to granting accreditation. Non-conformances are generally means for ensuring continual improvement.

GRANTING ACCREDITATION

After SANAS has received evidence that all non-conformances have been addressed, the SANAS AC reviews all documentation associated with the assessment and advises the CEO on the decision for accreditation.

After accreditation is granted, a six-month follow-up assessment is scheduled to ensure that the system has remained fully operational. Surveillance visits are scheduled thereafter.

Accreditation is valid for four (4) years, subject to all accreditation requirements being maintained.