GENERAL INFORMATION ON THE ACCREDITATION PROCESS

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Executive Committee

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1. **Purpose and Scope**

The purpose of this document is to provide the necessary information on the SANAS accreditation and assessment process required to apply for SANAS accreditation. This document should be read in conjunction with the programme specific procedures on the accreditation process, available on the SANAS website, prior to submitting a formal application for accreditation.

This document is applicable to all areas of accreditation covered by SANAS, i.e.:

- Accreditation of Testing, Calibration, Medical, Veterinary, Pharmaceutical, Forensics, Verification and Blood Transfusion Laboratories;
- Accreditation of Certification and Inspection Bodies;
- Accreditation of BBBEE Verification Agencies;
- Accreditation of Proficiency Testing Providers;
- Accreditation of Certified Reference Material Producers;
- Compliance monitoring of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) CABs

2. **Definitions and References**

PM 01 SANAS Policy Manual  
A 01 References, Acronyms and Definitions  
P 04 Accreditation of Laboratories and Proficiency Testing Schemes  
P 05 The Assessment of Certification Bodies  
P 12 Handling of Complaints and Appeals  
P 14 SANAS Fees  
P 15 Accreditation of Inspection Bodies. Regulatory and Voluntary Domain  
P 16 OECD Good Laboratory Practice (GLP) Compliance Monitoring Programme  
P 17 Accreditation of Verification Laboratories  
P 19 Terms of Reference, Registration and Responsibilities of Specialist Technical Committees  
P 20 The Responsibilities and Duties of the Approval Committees and Field Managers in the Approval and Decision on Accreditation  
P 24 Accreditation of BBBEE Verification Agencies  
P 30 Scoping of Accreditation for Testing Laboratories  
P 31 SANAS Scopes of Accreditation in the Medical Field of Testing  
P 32 Transition to New Standards  
P 33 SANAS Scope of Accreditation for Verification Bodies  
P 34 SANAS Scope of Accreditation for Veterinary, Pharmaceutical, Blood Transfusion and GLP  
P 37 Management of Extraordinary Events or Circumstances and Conditions for Terminating Assessments  
P 41 Sampling for Assessment Purposes

3. **Accreditation**

SANAS accreditation is the official recognition that a Conformity Assessment Body (CAB) is competent to perform specific tasks and has a documented Management System in place to ensure consistent implementation of its processes. An accredited CAB will have demonstrated through formal assessment that it is competent to perform the specific tasks for which accreditation is sought. In addition, the CAB needs to demonstrate that it satisfies both national and international criteria in this respect. The requirements that have to be complied with for the various CABs are given in the SANAS documents relevant to the field of accreditation.

3.1 **GLP Compliance Monitoring**

Compliance monitoring is a regular inspection of test CABs and studies by a Monitoring Authority (SANAS) in order to evaluate the degree of conformity with OECD Principles of Good Laboratory Practice (GLP) and to determine the integrity of data to assure that resulting data are of adequate quality for assessment and decision making by Regulatory Authorities. These inspections result in reports which describe the degree of adherence of a test CAB to the GLP Principles. The
requirements that should be complied with are stated in the SANAS P16 document and OECD series on Principles of Good laboratory Practice available on the OECD website.

**Note:** All ISO/IEC and National documents and standards are only available from the South African Bureau of Standards (SABS). All IAF guidance and mandatory documents are freely available from the IAF web site www.iaf.nu and ILAC guidance from the ILAC web site www.ilac.org. SANAS documents are available from the SANAS web site www.sanas.co.za. OECD documents are freely available from the OECD website www.oecd.org.

4. **Schedule of Accreditation**

Every accredited / compliant CAB is issued with a certificate and schedule of accreditation detailing the scope of activities and functions which satisfy all the necessary accreditation / GLP compliance requirements and for which accreditation / compliance is granted.

Applicants are required to complete the relevant application form (F 14) and provide detailed information on the scope for which accreditation is being sought. If any problems are experienced the applicant should contact the SANAS office for further guidance.

The draft schedule of accreditation will be confirmed with the applicant during the initial assessment, and will only be issued once accreditation has been granted.

Where applicable, applicants who opt to undergo a pre-assessment visit should discuss the schedule of accreditation with the assessor / inspector and try to finalise it as far as possible prior to the initial assessment / inspection.

No CAB is permitted to use the SANAS accreditation / GLP compliance symbol until such time that they have received written confirmation from SANAS that they have been accredited or are GLP compliant.

An accredited / GLP compliant organisation should consult SANAS document R 04 “Conditions for use of the Accreditation Symbols, reference to accreditation and combined marks”, prior to preparing any organisational material, which makes any reference to accreditation / GLP compliance or incorporates the SANAS accreditation symbol.

5. **General Application Information**

The accreditation / GLP compliance process and approximate time-lines are described in Appendix A.

For accreditation or very general enquiries the program-specific SANAS brochures published on the SANAS website may be sufficient to enable the client to gain the information required. For more detailed enquiries, especially with regard to the application process, an information pack may be requested from SANAS.

The Information Pack contains the following documentation:

- The SANAS programme-specific brochure
- The applicable F14 application form – available for electronic completion on the SANAS website
- A 03 “Information on the application Process”
- F 147 “Terms and Conditions of Accreditation”, or F 199 “Terms and Conditions of GLP or GCP Compliance”
- P 14 “SANAS Fees”
- R 03 “Nominated Representative and Signatories: Responsibilities, Qualifications and Approval”
- R 05 “The Requirements, Obligations and Duties of an Accredited/GLP Compliant Facility”
- PM 01 “SANAS Policy manual”
- P 12 “Handling of Complaints and Appeals”
- P 26 “Cross Frontier Accreditation”
- The applicable programme specific document:
The information listed below does not form part of the information pack but can be obtained from the SANAS Website:

- Information on SANAS Training Courses and Dates
- Latest SANAS monthly and quarterly news
- Latest SANAS Annual Report

Alternatively, all the documents listed above are available on the SANAS website at [www.sanas.co.za](http://www.sanas.co.za).

### 6. Scopes of Accreditation Offered by SANAS

The Table below lists the programs and the applicable standards to which SANAS offers accreditation. Accreditation can be voluntary or regulatory.

<table>
<thead>
<tr>
<th>Scopes of Accreditation &amp; (SANAS Document)</th>
<th>Accreditation Standard/Scheme</th>
<th>Voluntary or Regulatory Domain</th>
<th>Covered by:</th>
<th>Validity period of Certificate of Accreditation</th>
<th>Accreditation is granted for:</th>
</tr>
</thead>
</table>
| **Testing Laboratories (P04)**           | ISO/IEC 17025                  | Voluntary                       | ILAC MRA    | 5 years                                       | • Tests performed on specified materials or products to specified test methods;  
                                          |                                |                                  |             |                                               | • Techniques - for specified instrument(s) using specific chemical and / or physical methods, to identify and / or determine a physical property of a material or species contained within. |
| **Medical Laboratories (P04)**           | ISO 15189                      | Voluntary                       | ILAC MRA    | 4 years                                       | • Tests performed on human biological materials to specified test methods. |
| **Calibration Laboratories (P04)**       | ISO/IEC 17025                  | Voluntary                       | ILAC MRA    | 5 years                                       | • Specified types of measurements performed, measurement range and calibration and measurement capability (CMC).  
                                          |                                |                                  |             |                                               | • The transfer of traceability from national standards. |
| **Certification Bodies (P05)**            | ISO/IEC 17021 and IAF mandatory documents, as applicable | Voluntary | IAF MLA | 3 years | • QMS Certifiers for certifying organisations to ISO 9001.  
                                          |                                |                                  |             |                                               | • EMS Certifiers for organisations to ISO 14001.  
                                          |                                |                                  |             |                                               | • Hazards Critical Control Points (HACCP) certified to SANS10330.  
                                          |                                |                                  |             |                                               | • Food Safety Management System (FSMS) certified to ISO/IEC 22000  
                                          |                                |                                  |             |                                               | • Occupational Health and Safety System (OHSAS) certified to ISO/OHSAS 18001  
                                          |                                |                                  |             |                                               | • Responsible Tourism certified to SANS 1162  
                                          |                                |                                  |             |                                               | • Risk Based Inspection (RBI) certified to specific standards in SANS 347  
                                          |                                |                                  |             |                                               | • Energy Management Systems (EnMS) certified to ISO/IEC 50001 |
### Scopes of Accreditation & (SANAS Document)

<table>
<thead>
<tr>
<th>Accreditation Standard/ Scheme</th>
<th>Voluntary or Regulatory Domain</th>
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<th>Accreditation is granted for:</th>
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</thead>
<tbody>
<tr>
<td>ISO/IEC 17024 and IAF Mandatory documents</td>
<td>Voluntary</td>
<td>Not signatory to IAF</td>
<td>3 years</td>
</tr>
<tr>
<td>ISO/IEC 17065, and any relevant IAF mandatory documents</td>
<td>Voluntary</td>
<td>IAF MLA</td>
<td>3 years</td>
</tr>
<tr>
<td>ISO/IEC 14065 and IAF mandatory documents, where applicable</td>
<td>Voluntary</td>
<td>Not signatory to IAF</td>
<td>3 years</td>
</tr>
<tr>
<td>GLP / GCP Facilities (P16)</td>
<td>OECD Principles of GLP / VICH Principles of GCP</td>
<td>Voluntary</td>
<td>OECD</td>
</tr>
<tr>
<td>Blood Transfusion Laboratories (P04)</td>
<td>ISO/IEC 17025</td>
<td>Voluntary</td>
<td>ILAC MRA &amp; National Programme</td>
</tr>
<tr>
<td>Proficiency Testing (PT) Providers (P04)</td>
<td>• ISO/IEC 17043</td>
<td>Voluntary</td>
<td>No</td>
</tr>
<tr>
<td>Producers of Certified Reference Materials (CRM) (P07)</td>
<td>• ISO Guide 34 (ISO/IEC 17025 a prerequisite)</td>
<td>Voluntary</td>
<td>No</td>
</tr>
<tr>
<td>Inspection Bodies (P15)</td>
<td>• ISO/IEC17020 and/or the National Standards specific to the field of inspection</td>
<td>Voluntary / Regulatory</td>
<td>ILAC MRA or National Programme</td>
</tr>
<tr>
<td>Verification Laboratories (P17)</td>
<td>SANS 10378 NRCS requirements</td>
<td>Regulated</td>
<td>National Programme</td>
</tr>
</tbody>
</table>
### Scopes of Accreditation & (SANAS Document)

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</tr>
</thead>
<tbody>
<tr>
<td>Broad Based Black Economic Empowerment (BBBEE) Verification (P24)</td>
<td>SANAS R47 and competence to the BBBEE Codes of Good Practice.</td>
<td>Regulatory</td>
<td>National programme</td>
<td>3 years</td>
<td>Accreditation is granted for Verification Agencies verifying an organisation's compliance to the BBBEE codes and the sector codes.</td>
</tr>
</tbody>
</table>

### 7. Application Information

#### 7.1 Following, a brief outline of the accreditation process and documents needed:

- **7.1.1** The applicant writes and implements a management system based on the applicable standard (The standards are obtainable from your local standards body). Programme specific SANAS documentation and the Policy Manual are available on the SANAS website [www.sanas.co.za](http://www.sanas.co.za).

- **7.1.2** The applicant completes all sections of the relevant application form (F14). The application form requires very comprehensive information on the applicant's organisation. This information is necessary to allow SANAS to judge the extent that the organisation's documented Management System satisfies the SANAS accreditation requirements.

- **7.1.3** The application form is submitted to SANAS on-line, together with the Management System (Quality) Manual and required information and documentation as prescribed in each application form.

**Note 1:** If there are any challenges in this regard, information can be submitted to the relevant SANAS Field Manager and posted, couriered or delivered to:

- **Postal Address**: SANAS Private Bag X23 Sunnyside Pretoria 0132
- **SANAS**: Sanas Building G, Ground Floor
- **dti Campus**: 77 Meintjes Street
- **Sunnyside**: 0132

**SANAS Telephone:** +27 12 394 3760
**Facsimile:** +27 12 394 4960

**Note 2:** An organisation may submit a completed application form for the sole purpose of obtaining a detailed quotation. However, the application will not be processed further than the quotation stage without the submission of the organisations quality manual and application fee.

- **7.1.4** The signing / acceptance of the application form binds the applicant to the SANAS Terms and Conditions of Accreditation. F 147 “Terms and Conditions of Accreditation”, or F 199 “Terms and Conditions of GLP or GCP Compliance” are available on the SANAS website.

**Note:** CABs are advised to read the relevant SANAS documents for their scope of application as well as the SANAS Terms and Conditions for accreditation prior to completing and submitting the SANAS application form.
7.1.5 SANAS will review the application and all information submitted and clarify all outstanding issues with the applicant before proceeding to the next step.

**Note:** Failure to complete and submit all the required supporting documentation may result in a delay in processing the application.

7.1.6 SANAS quotes and invoices the CAB for the application fee as per SANAS Fees documents (P 14).

7.1.7 A SANAS lead assessor / inspector is appointed, and on acceptance of the Lead Assessor by the CAB, is given one month (from the date of receipt of the completed application) to evaluate the Management System Manual / documentation.

7.1.8 The applicant is provided with a document review report, and is given a maximum of 6 months to correct any deficiencies noted in the report.

7.1.9 Once the Management System Manual satisfactorily addresses all the requirements of the applicable accreditation standard, the relevant Field Manager prepares a quote and the CAB is invoiced for a pre-assessment or initial assessment / GLP inspection, as applicable. On receipt of payment, a pre-assessment / initial assessment / inspection date is arranged.

7.1.10 **The Pre-assessment**

i) A Pre-assessment visit may be requested by an applicant in the voluntary domain or may be required after review of the applicants’ documents.

ii) The pre-assessment is a site visit normally only carried out by a Lead Assessor over a period of 1 day. At the end of the assessment, the Lead Assessor will only supply the CAB with a list of findings to be addressed.

iii) A pre-assessment is compulsory for CABs operating in the regulatory domain. On positive recommendation from the Field Manager, based on the outcome of the pre-assessment, SANAS will notify the applicant and award a letter of acknowledgement in order for the applicant to apply to the relevant regulator for temporary approval to operate.

iv) A pre-assessment in the regulatory domain is conducted to give the regulator confidence that the applicant has a management system in place, thus allowing the regulator to grant the applicant a temporary approval to entrench the system and build sufficient technical evidence to allow for a full technical evaluation of the applicants’ facility.

v) CAB’s in the regulatory domain are required to provide SANAS with evidence of corrective action taken for any non-conformances identified. Such corrective actions should be cleared and the initial assessment must have been successfully completed within the maximum period as allowed by the specific regulator, calculated from the date of the pre-assessment.

vi) The CAB may need to make changes to its policies, procedures and practices prior to SANAS undertaking the initial assessment. The CAB is responsible to inform SANAS when they have addressed all the findings and are ready for the initial assessment.

7.1.11 **The Initial Assessment**

i) The CAB must ensure that there are sufficient records to confirm that the system is implemented prior to the initial assessment / inspection visit. SANAS requires that a complete internal audit and management review be conducted by the applicant prior to the assessment / inspection visit.
ii) An initial assessment is a comprehensive site visit carried out by the lead assessor and technical assessors with the required expertise for the scope of accreditation applied for, normally within 2 days.

iii) The CAB will be required to submit to SANAS evidence of corrective action for any non-conformances identified during the initial assessment within a maximum period of 6 months from the date of the initial assessment.

iv) Once all non-conformances recorded at the assessment / inspection have been satisfactorily cleared, the assessment documentation is submitted to the SANAS Approval Committee, who decides on whether accreditation can be granted.

v) Once a CAB is accredited, SANAS will provide the CAB with a Certificate and Schedule of Accreditation, valid for a specified period. The Certificate and Schedule of Accreditation will be published on the SANAS website.

7.1.12 After accreditation has been obtained, SANAS will check that the CAB continues to comply with accreditation requirements by carrying out regular on-site surveillance visits at specified intervals.

8. Application for Extension of Accreditation / Approval of Personnel

8.1. Applications for Extension of the Accreditation scope applies to CABs which:

- Have already been accredited, where the CAB wishes to extend the accredited scope of tests / inspections / certifications within the existing accredited field.
- Where an already accredited CAB wishes to apply for accreditation in a new field altogether, but under the same management system.

The following procedure shall apply for extension of accreditation scope:

The CAB is required to complete the relevant sections of the application form (F14) and submit it to the relevant Field Manager at least 6 weeks before the next scheduled assessment.

8.2. CABs wishing to add a new technical signatory or nominated representative to the Certificate and Schedule of Accreditation, must complete the relevant sections of the F14 application form on-line at least 6 weeks before the next scheduled assessment. (This does not apply to Medical Laboratories).

8.3 Where possible, assessment or witnessing of extensions for accreditation or approval of personnel will be carried out at the next surveillance or reassessment visit, however, when requested by the CAB, or required by SANAS based on the evaluation of the application, additional visits will be arranged. Pro-rata fees will be invoiced for additional visits and annual fees will be adjusted to accommodate the cost associated with the changes.

8.4 Applications for extension of scope or approval of personnel may not require a full review of the quality manual.

8.5 On receipt of payment, an assessment date is arranged. The CAB must ensure that there are sufficient records for the scope of extension to confirm that the system is implemented prior to the assessment visit.

8.6 The assessment is conducted on site by the lead and/or technical assessor/s. The names of the assessment team member(s) are made known to the CAB prior to the planned visit, to allow the CAB to object to members of the team, with good reason.

8.7 Once all non-conformances recorded at the assessment are cleared, the Approval Committee may grant or decline the extension and/or approval of the signatory/ Nominated Representative, based on the outcome of the assessment.
9. Application for Renewal of Accreditation

9.1 Accredited CABs are required to re-apply for accreditation 6 months prior to, and in the case of Inspection Bodies, 9 months prior to the expiry date of the Certificate of Accreditation. All sections of the relevant application form (F14) must be completed.

9.2 The application form must be accompanied by the CAB’s Management System Manual and the information / documentation as prescribed on the relevant application form.

9.3 As with an initial assessment, SANAS will appoint a Lead Assessor to review the Management System documentation and provide the CAB with a document review report. The CAB will not be required to submit evidence of corrective action for any deficiencies noted in the report, as implementation of the corrective action will be verified on site during the re-assessment.

Note: SANAS will not invoice the CAB for the application.

9.4 The CAB will be quoted and invoiced for the re-assessment. On receipt of payment, SANAS will arrange a re-assessment approximately 3 months prior, and in the case of Inspection Bodies, 6 months prior to the expiry date of the Certificate of Accreditation.

9.5 The re-assessment will be similar to an initial assessment, except that previous history of the CAB will be taken into consideration. A comprehensive assessment of the management system will be conducted by the Lead Assessor, and the technical assessors(s) will conduct an assessment of the technical aspects of the scope of application, including any personnel or extensions applied for, in accordance with SANAS document P41 “Sampling for Assessment Purposes”.

9.6 The CAB will be required to submit evidence of corrective actions to SANAS for any non-conformances identified within 25 working days of the re-assessment.

9.7 Once all, if any, non-conformances have been satisfactorily cleared by the assessors, SANAS will arrange for the Approval Committee to review the assessment pack and make a decision on the renewal of accreditation.

9.8 On successful renewal of accreditation, SANAS will provide the CAB with a new Certificate and Schedule of Accreditation valid for a specified period.

10. Confidentiality

All information submitted to SANAS in support of the application form shall be treated in confidence. All assessors used by SANAS are required to sign the SANAS Assessor Contract, as well as confidentiality agreements at each assessment performed. Any breach of confidentiality will be treated extremely seriously. SANAS will request written permission from all accredited CABs or applicants prior to releasing any information to a third party. SANAS may be required to release confidential information in compliance with the law, when required.

11. Time-scale for the Accreditation Process

11.1 SANAS makes every effort to ensure that all applications are processed as efficiently as possible. The time taken to process an application depends on a number of factors, some of which are outside the control of SANAS. The timing is dependent on:

i) The quality of the applicant’s documentation and the extent to which it complies with SANAS and accreditation requirements. A delay can occur due to insufficient documented procedures and submission of inadequate Management System Manuals;

ii) The availability of suitable assessors;

iii) How efficiently the applicant organisation clears the non-conformances after the initial assessment;

iv) The availability of the resources within SANAS.
11.2 Generally, accreditation takes between 3 - 6 months from receipt of the completed application form and all the prerequisite information, to the initial assessment. Refer to Appendix A for an indication of the specific time expectations for each stage of the application process.

11.3 An application that has not proceeded to the initial assessment stage within 1 year from the date of application will lapse. Unless otherwise agreed with SANAS, this may result in the applicant having to re-apply for accreditation. All application fees will be applied for the re-application.
APPENDIX A: Approximate Timeframe for the Accreditation / GLP Compliance Monitoring Process

The Applicant enquires about accreditation / GLP compliance

Within 2 DAYS of enquiry
SANAS sends electronic information pack to applicant.

The applicant submits the completed application, all documentation & information as specified in the relevant application to SANAS.

Within 1 DAY of receipt of application
SANAS sends a letter of acknowledgement of receipt of application and proposes a Lead Assessor / Inspector who will conduct the Document Review.

Within 1 WEEK of receipt of application
1) Field manager reviews application for completeness and requests any additional information required from applicant
2) The Field Manager prepares a quote for the application fee and document review, and finance sends to the applicant.

Applicant accepts the quotation & Lead Assessor / Inspector

Within 1 DAY
SANAS sends the Quality Manual to the Lead Assessor / Inspector to review

Within 1 WEEK
Finance issues invoice for the application fee and document review.

Within 4 WEEKS
The Lead Assessor / Inspector conducts Document Review and submits report with recommendation to the SANAS Field Manager

Within 1 WEEK of receipt of Document Review report from LA
The SANAS Field Manager checks the Document Review report for completeness and the recommendation, and submits to the Applicant

Within a maximum of 6 MONTHS
Where required, the Applicant submits Document Review corrective actions to SANAS

Within 1 WEEK
SANAS sends the Document Review corrective actions to the Lead Assessor / Inspector who reviews to clear the non-conformance if satisfied.
Within 3 MONTHS from date of assessment
The applicant submits corrective actions to SANAS. The Lead / Technical Assessor / Inspector reviews the corrective actions.

Within 2 WEEKS
Once all non-conformances have been cleared, SANAS refers the application with all the supporting assessment / inspection documentation to the Approval Committee (AC) for a decision.

Within 15 DAYS from the AC approval date:
SANAS sends the Certificate and Schedule of Accreditation to the client. For regulatory pre-assessment process – refer to Annexure B below.

Within 6 – 12 MONTHS after initial accreditation
SANAS arranges and conducts a follow-up assessment / inspection.

NOTE: The timescale for the accreditation / GLP compliance monitoring process is approximate and depends on the completeness of the application documentation, the Document Review report, correction of non-conformances (where relevant, the payment of fees, the submission of the signed Accreditation agreement and the availability of the relevant staff.)
## Appendix B: The Accreditation Process

The following table will be the format of the Accreditation Process; procedures are in place to describe the specific requirements for the various accreditation programs with the necessary responsibilities included.

<table>
<thead>
<tr>
<th>The Application Process</th>
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<tbody>
<tr>
<td>Application for Accreditation</td>
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</table>
| - The application criteria and process is described in the programme specific documents (P04, P05, P15, P16, P17 and P24). Applicants will be required to make a formal application on the relevant F14 Application form, which will list the information required by SANAS on application.  
- SANAS will review each application in order to ensure that it has the necessary resources and competence in order to conduct the assessment. |

<table>
<thead>
<tr>
<th>Initial Assessment Process</th>
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<tbody>
<tr>
<td>Preparation for Assessment</td>
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</tbody>
</table>
| - The applicant's documents will be reviewed by an appointed Lead Assessor, if deficiencies are identified, the CAB will be required to correct these deficiencies prior to the initial assessment.  
- Pre-assessment visits may be requested in the voluntary arena, where deficiencies in the system may be identified.  
- Pre-assessments will be carried out in the regulatory domain. |
| Allocation of the Assessment Team |
| - An assessment team will be appointed, which will include a Lead Assessor and the required number of technical assessors with the appropriate expertise for each specific scope. |
| Initial Assessment |
| - The assessment team will conduct an assessment in accordance with SANAS procedures at the applicants' Head Office and all other premises of the CAB from which key activities are performed, and which are covered by the scope of accreditation.  
- The applicant CAB must satisfy the SANAS assessors that it complies with all relevant ISO/IEC Standard/Guide and any International interpretation thereof, and SANAS accreditation requirements to enable the assessment team to make a positive recommendation to the Approval Committee (AC).  
- CABs that wish to be accredited for on-site activities shall, where relevant, comply with the additional requirements that may be applicable for that specific field. Additional criteria for on-site accreditation are given in SANAS Requirement or Technical Requirement documents where such additional requirements exist. |

<table>
<thead>
<tr>
<th>The Decision-making process</th>
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<tbody>
<tr>
<td>The AC evaluates the adequacy of information provided by the assessment team, and determines whether requirements for accreditation have been fulfilled, and whether accreditation can be granted. The final decision on whether accreditation can be granted or not, is made by the Approval Committee Chairperson, based on the information gathered, submitted and recommendation of the relevant assessment team. (Refer to P20 for procedures of the Approval Committee)</td>
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</tbody>
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<thead>
<tr>
<th>Issue of Certificate and Schedule of Accreditation</th>
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</table>
| - If accreditation is granted by SANAS, an accreditation certificate signed by the CEO, with a schedule detailing the scope of accreditation signed by the relevant Field Manager will be issued to the CAB.  
- Accreditation will remain valid as long as the organisation continues to comply with SANAS requirements. All certificates will be issued with a validity date, subject to changes which can impact the CAB’s status. (E.g. change to scope of accreditation, range of measurements / tests or changes in location, phone number, senior staff, etc.)  
- Refer to P10 “Accreditation / GLP Compliance Certificate”, which describes the format and procedures for the issue and maintenance of Certificates and schedules. |
### Compliance with accreditation and SANAS requirements

- It will be responsibility of the accredited CAB to ensure that it complies with all accreditation criteria at all times. The accredited CAB will be required to report any possible non-compliance with criteria to SANAS immediately. Should an accredited CAB fail to continue to comply with accreditation criteria at any time before the expiry of the certificate the accreditation shall be withdrawn by SANAS. Once withdrawn the accredited CAB shall comply with all requirements in terms of the conditions of the withdrawal.

> Note: The GLP compliance monitoring process is fully described in the document P16 “Good Laboratory Practice (GLP) Compliance Monitoring Program”.

### Maintenance of Accreditation

| 6-month follow-up Assessment | SANAS will verify continued compliance/competence by conducting follow-up visits to all newly accredited CABs approximately 6 - 12 months after the date of initial accreditation. This will normally be undertaken by the Lead assessor unless otherwise delegated by the Field Manager.
| Surveillance Assessments | Surveillance assessments will be scheduled from 12 to no longer than 24 month intervals. (Refer to the program-specific P-documents)
- Surveillance visits will follow the initial assessment format but on a sampling basis (Refer to SANAS P 41 “Sampling for Assessment Purposes”). Each surveillance visit will involve a technical assessment of the CAB together with an assessment of the Quality Management System.
- The program specific P-documents (P04, P05, P15, P16; P17 and P24) detail the surveillance assessment process and intervals of the assessments.
- All Technical Signatories must be available at each assessment. SANAS will assess each technical signatory at least once in an accreditation cycle the selection of who will be assessed will be made by SANAS.
| Re-assessments | On successful re-application by the CAB, re-assessments will be arranged for approximately 3 months prior to the expiry date of the Certificate of Accreditation, and in the case of Inspection Bodies, 6 months prior to the expiry date of the Certificate of Accreditation (Refer to Table 2 for the Validity period of certificates)
- The next cycle will begin with assessments carried out at 12-month to no longer than 24-month intervals, depending on the length of the cycle. SANAS can unilaterally make changes to the assessment interval at any stage of the process, but intervals will not be longer than 24 months;
- Re-assessment visits involve a comprehensive on-site re-examination of the CAB’s management system and assessment activities and will be similar in format and content to the initial assessment, except that previous history will be taken into account (Refer to SANAS P 41 “Sampling for Assessment Purposes”).
- The decision-making process and re-issue of the Certificate and Schedule of Accreditation will follow the Re-assessment, as for the initial assessment.
| Extension of Accreditation | Extensions of accreditation will follow the same process as for initial accreditation.
- Applications for extension shall be made at least six (6) weeks prior to the on-site visit.
- P05 “The Assessment of Certification Bodies” will include procedures for extension(s) in the product certification field for specification addition in an existing accredited EAC code.
| Personnel Evaluations | SANAS Requirement document R03 will define the requirements for the responsibilities, qualifications and approval of Nominated Representatives and Signatories. As part of the assessment, the SANAS team will assess the competence of personnel in the performance of their functions and in their understanding and implementation of SANAS’ requirements. Approval of personnel as signatories or Nominated Representatives will follow the decision-making process as defined above.
A. APPLICATION PROCESS

1. Within 2 working days
   - Applicant submits application form with Quality Manual & required info, or Document Review corrective actions as applicable

2. 1 day
   - Documents submitted complete
   - Re-submit QM to SANAS, Lead Assessor to review QM, Finance issues invoice
   - SFM appoints Lead Assessor to review QM, Finance issues invoice

3. Within 1 week of receipt of documents
   - Applicant accepts quotation
   - Address shortcomings and recommendations (Max 6 months)
   - FM reviews corrective actions

4. Within 1 week
   - FM approves quotation for application & Document Review

Optional: Voluntary Accreditation

Enquiry Information pack sent via e-mail or post mail

Applicant controlled processes

Voluntary: Approval Committee (AC)
Regulatory: SANAS Field Manager (FM)

SANAS controlled processes

B. ASSESSMENT PROCESS

1. SANAS notified organisation and issues Accreditation Certificate after AC approval on initial assessment outcome

2. Organisation applies to the relevant regulator for temporary approval (where applicable)

3. 6 - 12 month follow-up assessment

4. Surveillance assessment cycle

C. RE-ASSESSMENT PROCESS

1. CAB re-applies for accreditation 6 mths before expiry of certificate (9 mths for Inspection)

2. FM appoints Lead Assessor to review QM, Finance issues invoice for re-assessment

3. FM arranges re-assessment 3 mths prior to expiry of Certificate

AAC process & surveillance assessment cycle

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**Appendix C: Amendment Record**

<table>
<thead>
<tr>
<th>Proposed By:</th>
<th>Section</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>QM</td>
<td>6</td>
<td>Updated accreditation requirements for Medical laboratories – Medical laboratory accreditation is only granted to ISO 15189</td>
</tr>
<tr>
<td>QM</td>
<td>7.1.3</td>
<td>Added &quot;on-line&quot;</td>
</tr>
<tr>
<td>QM</td>
<td>7.1.5</td>
<td>Clause replaced “The application and accompanying documentation must be submitted to the relevant SANAS Field Manager by email, post or courier until such time that the system caters for electronic submissions via the SANAS website. The application and accompanying documentation must be marked for the <strong>ATTENTION: FIELD MANAGER</strong> (of the relevant field) and posted, couriered or delivered to:”</td>
</tr>
<tr>
<td>QM</td>
<td>8.2</td>
<td>“on-line” replaced “and submit it to the relevant Field Manager”</td>
</tr>
<tr>
<td>QM</td>
<td>9.1</td>
<td>Deleted “and submitted to SANAS”</td>
</tr>
<tr>
<td>QM Appendix B</td>
<td>Appendix B</td>
<td>Amended the decision making process.</td>
</tr>
<tr>
<td>QM Appendix B</td>
<td>Appendix B</td>
<td>Changed reference from Approval Advisory Committee (AAC) to Approval Committee (AC)</td>
</tr>
<tr>
<td>QM Appendix B</td>
<td>Appendix B</td>
<td>Deleted the requirements for BEE facilities to have a pre-assessment</td>
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