

R 51-08 (DRAFT)

SUSPENSIONS, WITHDRAWALS AND RE-INSTATEMENT OF ACCREDITED OR GLP/GCP COMPLIANT ORGANISATIONS

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1. Purpose and Scope

This document describes the procedure to be followed when sanctions, such as suspension, **reduction or** withdrawal of accreditation or GLP/GCP compliance, are imposed on accredited / compliant organisations, including the procedures for re-instatement of suspended organisations.

This procedure applies to all SANAS accredited conformity assessment bodies and GLP/GCP compliant facilities.

2. Definitions and References

2.1 References

PM	SANAS Policy Manual
A 01	References, Acronyms and Definitions
F 147	SANAS Terms and Conditions of Accreditation
F 199	SANAS Terms and Conditions of GLP/GCP Compliance
P 12	Handling of Complaints and Appeals
P 20	The Responsibilities and Duties of the Approval Committees and Accreditation Managers in the Approval and Decision on Accreditation
R 04	Conditions for the use of Accreditation Symbols, Reference to Accreditation and Combined Marks

2.2 Acronyms and Definitions

Organisation	in the context of this document refers to a conformity assessment body and/or a GLP/GCP compliant facility.
Terms and Conditions	means the SANAS Terms and Conditions of Accreditation and of GLP/GCP Compliance
Compliance	means GCP or GLP compliance

3. General

In order to ensure compliance to the relevant accreditation or GLP/GCP compliance, and where applicable, regulatory requirements, safeguard the integrity of the accreditation / GLP/GCP compliance system and the reliability of results produced by an any accredited / compliant organisation, SANAS applies various sanctions to accredited / compliant organisations found to have **failed to meet the** requirements **of** accreditation or GLP/GCP compliance, as applicable, including those specified in any accreditation standard, guide, regulation and/or any IAF/ILAC/OECD mandatory document which applies to an organisation, the Act and any policies, procedures, **rules** and requirements of SANAS which applies to an organisation.

Sanctions may include suspension of an organisation's accreditation / compliance or part thereof, or where warranted, **reduction or** withdrawal of an organisations' accreditation / compliance status.

A decision to suspend, **reduce** and/or withdraw an organisation's accreditation / compliance can have a major impact on both its employer and employees and therefore SANAS does not take such decisions lightly. Suspensions, **reductions** and withdrawals could either be self-imposing (voluntary) or imposed by SANAS, as described in sections 4 and 7 of this document.

SANAS procedure P 12 "Handling of Complaints and Appeals" sets out the process that must be followed by an organisation should it wish to appeal against a suspension, **reduction** or withdrawal of their accreditation / compliance.

4. Suspension of Accreditation or GLP/GCP Compliance

4.1 Suspension of accreditation / compliance means that accreditation / compliance is temporarily made invalid for the full scope of accreditation / compliance, or part thereof. Suspension of an organisation may result from:

4.1.1 Voluntary suspension, which is normally requested by an organisation for reasons which includes, but is not limited to:

- Loss of all technical signatories or competent staff members;
- Relocation of the organisation, part thereof or movement/change of equipment that may have an impact on the results produced;
- Restructuring or changes that affects the organisation's ability to produce reliable results;
- A breakdown of the organisation's management system;
- Any other reason that might compromise the integrity of the results produced by the organisation or compliance with the accreditation / compliance requirements;
- Where during an assessment / inspection or special investigation, SANAS finds that the organisation no longer complies with accreditation / compliance requirements; or
- Any other circumstances that SANAS may deem appropriate warranting the suspension of an organisation.

The organisation must apply to the **Accreditation Manager (AM)** in writing, with valid reasons and the effective date, to be placed under suspension. Organisation's that are placed in voluntary suspension shall give an undertaking to adequately address the circumstances that caused the request for suspension within three months of the effective date of suspension.

The **Accreditation Manager** may approve an organisation's written request, if received prior to the deadline and containing valid reasons, to extend the period for the clearance of non-conformances. (Refer to 7.5).

4.1.2 Suspension enforced by SANAS for the full scope of accreditation / compliance or part thereof.

- SANAS shall, in its sole and absolute discretion, immediately suspend an organisation's accreditation / compliance or part thereof, by means of written notification, for conditions as specified in the SANAS Terms and Conditions.
- **Where a CAB fails to comply with the requirements for transition to a standard by the end of the transition period, the Accreditation Manager will suspend the CAB upon the end of the transition period. The P20 Approval Committee process will not apply in this case where an assessment did not take place.**

5. **Withdrawal and Reduction of Accreditation or GLP/GCP Compliance**

5.1 **Withdrawal of accreditation / compliance means the cancellation of the statement of conformity for the full scope of accreditation / compliance. Reduction of accreditation / compliance means the cancellation of part of the scope of accreditation.**

Withdrawal **or reduction of accreditation** may be either:

- 5.1.1 Voluntary (self-imposed), as requested by an organisation; or
- 5.1.2 Imposed by SANAS.

- 5.2 SANAS shall, in its sole and absolute discretion, immediately **reduce or** withdraw an organisation's accreditation / compliance, by means of written notification, for conditions as specified in the SANAS Terms and Conditions.
- 5.3 **Where there is evidence of fraudulent behaviour, or the CAB intentionally provides false information or conceals information, SANAS shall initiate the process for withdrawal of accreditation.**

6. Process of Implementing a Suspension or Withdrawal

6.1 Decisions to suspend, reduce or withdraw accreditation are made by either:

i) **The SANAS Approval Committee (following an assessment) – refer to SANAS P20 “The Responsibilities and Duties of the Approval Committees and Accreditation Managers in the Approval and Decision on Accreditation”;**

ii) **The relevant Executive, in consultation with the relevant AM in the case of voluntary or enforced suspensions for failure to comply with the conditions as stipulated in the Terms and Conditions of Accreditation / GLP Compliance (F147 or F199 as applicable) and not following the outcome of an assessment.**

The Executive's decision will be based on written recommendation and with valid reasons by the relevant AM / Finance Manager, as required.

iii) **The CEO in consultation with the relevant Executive and/or AM in the case of voluntary or enforced withdrawals or reductions of accreditation for failure to comply with the conditions as stipulated in the Terms and Conditions of Accreditation / GLP Compliance (F147 or F199 as applicable) and not following the outcome of an assessment.**

The CEO's decision will be based on written recommendation and with valid reasons by the relevant Executive / Legal Council, as required.

6.2 SANAS will issue a letter of suspension, **reduction** or withdrawal, as is relevant, detailing amongst others:

- The effective date of the suspension / **reduction** / withdrawal;
- The reasons for suspension / **reduction** / withdrawal;
- The extent of the suspension / **reduction** / withdrawal;
- The implications and conditions during the suspension period / **reduction** / withdrawal;
- The conditions for re-instatement in the case of suspensions.

6.3 The CEO may delegate the authority to issue the letter to suspend accreditation / compliance to the relevant **Executive.**

6.4 **Letters of withdrawal / reduction of accreditation will be issued by the CEO on written recommendation and with valid reasons by the relevant Executive / Legal Council / Approval Committee, as the case may be.**

6.5 During the period of suspension the SANAS Terms and Conditions will remain valid subject to the conditions contained in this document as well as in SANAS document R04 “Conditions for the use of Accreditation Symbols, Reference to Accreditation and Combined Marks”.

- 6.6 A record of the reasons for suspension, reduction or withdrawal, the duration of suspension and a record that all suspension, reduction and withdrawal procedures have been adhered to will be maintained by the relevant Accreditation Manager.
- 6.7 SANAS will update the accreditation status of the CAB on the SANAS website, including the applicable dates of the suspension or withdrawal and the affected scopes.

Note: In exceptional cases, access to certain information can be limited upon the CAB's request (e.g. for security reasons), however the request shall be submitted in writing to the CEO with valid justification.

7. Conditions of Suspension, Reduction or Withdrawal of Accreditation or GLP/GCP Compliance

- 7.1 An organisation shall, upon suspension or withdrawal of SANAS accreditation / compliance, immediately cease to issue certificates and any other materials displaying the SANAS accreditation / compliance symbol, the combined mark or containing references to SANAS accreditation / compliance.
- 7.2 In the case of partial suspension or reduction of accreditation / compliance, reports shall clearly identify the scopes for which accreditation / compliance cannot be claimed. Failure to comply with this requirement is a criminal offence and can result in prosecution. Refer to R04 "Conditions for the use of Accreditation Symbols, Reference to Accreditation and Combined Marks".
- 7.3 The CAB shall inform their affected clients of the suspension, reduction or withdrawal of its accreditation and the associated consequences without delay.
- 7.4 A CAB is required to immediately return their certificate and schedule of accreditation / compliance to SANAS as soon as withdrawal of their accreditation / compliance is effective.
- 7.5 A CAB may not be under suspension for longer than 3 months without the written authorisation of the AM. It is the CAB's responsibility to apply to the relevant AM, in writing, with valid reasons, and no later than two (2) weeks prior to the expiry of the suspension period, to extend their suspension for each additional one-month period, but for no longer than 9 additional months, after which accreditation / compliance will be withdrawn.
- 7.6 Where an application for extension of the suspension period has not been received, SANAS has the right to elect by means of written notification, to withdraw or reduce the CAB's scope of accreditation / compliance. Withdrawal of accreditation / compliance will result in the CAB having to re-apply for accreditation / compliance as a new applicant with the associated costs and penalties. (Refer to P 14 "SANAS Fees").
- 7.7 The organisation shall be responsible for all costs associated with a suspension or withdrawal, such as any additional on-site visits or re-instatement visits as required by SANAS, and any costs associated the handling of an appeal against such adverse decisions (refer to P 12 "Handling of Complaints and Appeals"). An organisation shall remain liable for all fees whilst in suspension. If withdrawal of accreditation / compliance has occurred then a pro-rata percentage of their annual fees are still due to SANAS for the financial year. If the organisation was assessed / inspected in the same financial year as their withdrawal, they will also be liable for the travel and subsistence costs of the assessment / inspection.

8. Re-instatement of Accreditation or GLP/GCP Compliance

8.1 Re-instatement of suspended organisations

- 8.1.1 An organisation under suspension is required to submit to SANAS evidence of appropriate corrective action taken, prior to the end of the suspension period.

- 8.1.2 SANAS shall evaluate the non-conformances/reasons that led to the suspension, during the re-instatement assessment / inspection and subsequent assessments / inspections if necessary.
- 8.1.3 In the case of loss of all technical signatories, the organisation shall remain under suspension until such time that SANAS has verified the competence of any new proposed technical signatory for the relevant accredited scope(s).
- 8.1.4 Where an organisation has been suspended for non-payment of fees, SANAS shall re-instate the accreditation / compliance of an organisation immediately upon receipt of payment made within the suspension period of any outstanding amounts due to SANAS, **subject to their being no other outstanding issues.**

Note: The Finance Manager shall always first confirm with the relevant Accreditation Manager that the facility has not also been suspended for any other issues.

- 8.1.5 Where an organisation has received **AM** approval for a suspension period of longer than 6 months, the re-instatement visit will be treated as a full re-assessment / re-inspection.
- 8.1.6 Once an organisation has satisfactorily addressed the issues which resulted in suspension, accreditation / compliance may be re-instated on approval by the relevant **AM** and, where a re-instatement visit is required, on approval by the AAC.
- 8.1.7 An organisation that is under suspension may be required to have an on-site assessment / inspection, at the discretion of the relevant **AM**, where the reasons for the suspension indicated that the competency of the organisation was affected. A positive recommendation by the assessment / inspection team is required prior to re-instatement of accreditation / compliance. The extent of such an assessment / inspection will be determined by the relevant **AM** based on the reasons for suspension, and the associated risk. All costs will be for the account of the organisation.
- 8.1.8 Notification of re-instatement of accreditation / compliance will be sent to the organisation, detailing the scope that the re-instatement applies to.
- 8.1.9 The organisation's accreditation / compliance certificate will be restored on the SANAS website once accreditation / compliance has been re-instated.
- 8.1.10 SANAS reserves the right not to reinstate accreditation / compliance of an organisation should the organisation be successfully prosecuted in terms of the Accreditation Act, or obtain any other judgement and/or order and/or restraint including an interdict against such an organisation that operates, amongst others, in a manner that brings accreditation / compliance or SANAS into disrepute.

8.2 Re-instatement of Accreditation or GLP/GCP compliance that has been withdrawn

- 8.2.1 Should an organisation wish to re-instate accreditation / compliance after it has been withdrawn, the organisation will be required to re-apply for accreditation / compliance as a new applicant with the associated costs.
- 8.2.2 Where the full scope of accreditation / compliance has been withdrawn, the previous accreditation / compliance number will be made obsolete, and the organisation will be issued a new SANAS accreditation / compliance number once re-accredited or once GLP/GCP compliance has been granted again.

ADDENDUM 1: AMENDMENT RECORD

Proposed By:	Section	Change