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Revision No.:  
Issue 11

Page: 1 of 23

Subject: Management System Manual for SABS Commercial SOC Ltd.  
Continual Improvement Process

Compiler: Process Manager: Laboratory Accreditation

Effective date:  
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Compiler: Process Manager: Certification Accreditation

To be reviewed by:  
October 2021

Approving Officer: Group Manager: Accreditation Management

This Management System procedure for:  
Continual Improvement Process

Issue 11 dated 26 February 2019 and consisting of 23 Pages has been reviewed for adequacy by the Process Manager: Laboratory Accreditation and the Process Manager: Certification Accreditation and is issued on the authority of the Group Manager: Accreditation Management.

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The definitive version of this manual is available to all SABS staff and is maintained in pdf format on a secure server of the SABS Management Information System.

Printed copies of this management system policy manual may be issued under controlled conditions (See SC-SP-001) and will be replaced in entirety when any changes or revisions are made.

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## 1. BACKGROUND

In order to continue to identify areas of continuous improvement and respond effectively to non-conformities, deficiencies, or out-of-control situations, SABS Commercial have developed and documented a process to identify, receive, evaluate, monitor and make decisions on non-conformities including customer complaints.

Complaints arising from grievances are received from customers and users of SABS services as well as from organizations and members of the public who may consider that the SABS has not fulfilled its duties and obligations.

## 2. PURPOSE

**The purpose of this document is to:**

- a) Outline the process for receiving, validating and investigating non-conformities, including complaints, appeals & disputes as well as for deciding what actions need to be taken in response to them;
- b) Track and record non-conformities, including actions undertaken in response to them;
- c) Ensuring that any appropriate corrections and corrective actions are taken.

## 3. SCOPE

3.1 This document covers the process for continual improvement within SABS Commercial SOC Ltd. and covers the following elements:

- a) Complaints, appeals and disputes;
- b) non-conforming work; and
- c) Audit findings.

3.2 It also covers the process for registration, classification, investigation, root cause analysis, corrective and preventative actions for IRQs.

3.3 Finally, it covers the procedures for complaints, appeals and disputes, non-conforming work, improvement, corrective action and preventive action have been combined into one procedure to identify the improvement process herein referred to as (IRQ) system within SABS Commercial SOC Ltd.

3.4 This procedure does not replace and shall be read in conjunction with CSP 120: SABS Group customer complaints handling system.

3.5 This document covers the requirements of the clauses of the following Standards/ Guides (To verify clause numbers for each standard):

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### Reference to applicable clause number

Standard	Complaints	Non-conforming work	Improvement	Corrective action	Preventive action	Appeals and disputes	Risks
ISO/IEC 17020	7.5 and 7.6	7.4 and 8.7	N/A	8.7	8.8	7.5 and 7.6	N/A
ISO/IEC 17021	4.7 and 9.8	9.4.9	N/A	9.4.10 & 10.2.7	N/A	9.7	4.8
ISO/IEC 17025	7.9	7.10	8.6	8.7	N/A	N/A	8.5
ISO/IEC 17043	5.8	5.9	5.10	5.11	5.12	5.8	N/A
ISO/IEC 17065	7.13	7.11.1	N/A	8.7	8.8	7.13	N/A

#### 4. REFERENCE DOCUMENTS

- ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection.
- ISO/IEC 17021 General requirements for bodies providing audit and certification of management systems.
- ISO/IEC 17025 General Requirements for the competence of Calibration and Testing Laboratories.
- ISO/IEC 17043 General requirements for proficiency testing.
- ISO/IEC 17065 General requirements for bodies operating product certification systems.
- CSP 120 SABS group customer complaint handling system
- CSP 122 Occupational Health and Safety Management System

#### 5. DEFINITIONS

- Appeal**  
A request by a Certified Company or a Laboratory participating in the SABS Proficiency Testing Scheme, for the reconsideration of a decision, made by SABS Commercial, that is not acceptable to a person or organisation that was affected by the original decision.
- Complaint**  
An expression of dissatisfaction with the service received by a person or organisation from SABS Commercial, which relates to the operational activities or service delivery of SABS Commercial.
- Consumer concern**  
An expression of dissatisfaction with products or services received by a person or organisation from SABS commercial certified organisation.
- Dispute**  
A disagreement that arises out of the contractual agreement, or the interpretation thereof, between SABS Commercial and the organization that entered into an agreement with SABS Commercial.

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- e) **IRQ**  
SABS Improvement Request
- f) **Major non-conformity**  
For **Laboratories Services**, a non-conformity is classified as a major when the technical competence of the laboratory has either been, or is in imminent danger of being, seriously compromised (SANAS A 01).  
For **Certification and Inspection schemes**, a non-conformity that affects the capability of the management system to achieve the intended results (ISO/IEC 17021-1).
- g) **Minor non-conformity**  
For **Laboratories Services**, a non-conformity is classified as a minor when the failure has no immediate or imminent effect on a lab's competence to perform work within the limits of this accreditation schedule. (SANAS A 01).  
For **Certification**, non-conformity that does not affect the capability of the management system to achieve the intended results (ISO/IEC 17021-1).
- h) **Observation**  
A comment made by a member of the assessment team when noting a situation or action which may prejudice the CAB's ability to meet SANAS accreditation requirements during the transition to a new standard / guide process. (SANAS A 01).

**Note that any reference to a non-conformity, root cause or corrective action throughout this document also refers to non-conformities, root causes and corrective actions. In the same way, references to plural also apply to singular.**

## 6. POLICY

It is the policy of SABS Commercial to:

- a) Investigate all complaints, consumer concerns, appeals and disputes in order to determine the validity and make decisions on each;
- b) SABS assume responsibility for all decisions related to complaints at all levels of the complaints handling process;
- c) Ensure that complaints, concerns, appeals and disputes received do not result in any discriminatory actions against the complainant;
- d) Ensure that the process is subject to the requirements for confidentiality, as it relates to the complainant and to the subject of the complaint; see section 8.3 of CSP 120;
- e) Plan and implement the necessary monitoring, measurement and analysis processes to ensure customer requirements are met and that the conformity and improvement of the management system is maintained;
- f) Implement a corrective action process by determination of the root cause of complaints and non-conformities.
- g) Implement risk analysis by evaluating the impact or lack thereof, on the previous results.

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## 7. IMPROVEMENT REQUEST (IRQ) SYSTEM

7.1 The types, categories and classification of IRQs raised are described in paragraph 7.2.

7.2 The following non-conformities are not registered as an IRQ.

- a) **Safety incidents:** Reported as per the HSE system implemented in SABS, refer to CSP 122 using form SCF-004.
- b) **Corporate Internal Audit findings:** Reported as per the Internal Audit Manual implemented in SABS.

## 8. PROCESS

### 8.1. Central register

The Customer Relation Management (CRM) System is used to administer IRQs. The BI Publisher Enterprise Software System is the central database for IRQ's registered on the CRM. Reports indicating the status of the IRQ's with all relevant information can be obtained from the system.

### 8.2 IRQ Registration

The responsibility for registration of non-conformities shall be as follows:

	Type of IRQ	Category	Classification	Responsible person
a)	Complaints, consumer concerns, appeals and disputes.	External	Major	Customer Service Department.
b)	Non-conformities detected by BU Management and Personnel.	Internal	Major/Minor	Staff member identifying the non-conformity.
c)	Accreditation Internal Audit non-conformities.	Internal	Major/Minor	Accreditation Internal Audit.
d)	Internal complaints within SABS Commercial.	Internal	Major	Customer Service Department
e)	External audit non-conformities arising from accreditation bodies (SANAS, RVA, IEC ect.)	External	Major/Minor	Accreditation Internal Auditors.
f)	Customer audits.	External	Major/Minor	Laboratory Business Unit Manager.
g)	Suspensions.	Suspensions	Major	Business Unit Manager.
h)	Non-conformities arising from management review meetings.	MR CAL/ Internal	Major/Minor	MR Secretariat.
i)	Approval Board matters.	Internal	Major/Minor	Approvals Board & Quality Assurance Members.
j)	Impartiality Committee.	Internal	Major/Minor	Process Manager: Certification
k)	Compliments.	Internal/ External	Major	Personnel identifying the compliment.
l)	Non-conformities arising from PTS/ILC/Intra-lab comparison	Internal	Major	BU Manager/ Designated personnel

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For the registration of an IRQ, refer to the Step-by-step procedure 'SC-SP-004A' on how to register an IRQ on the CRM System.

### 8.3 Types of IRQs

#### 8.3.1 Complaints

##### 8.3.1.1 Handling and management of complaints

- The detailed process for handling customer complaints is defined and outlined in CSP 120.
- For the Laboratory Services Division, the handling of complaints is described in LSD-SP-7.1
- Refer to CSP 120 for timeline for Complaints.
- General Rule:** Should a complaint be received that could have as a root cause a problem with Standards or Corporate Services, in combination with one or more of the other Clusters of SABS Commercial, the General Manager, will, after evaluation of the complaint, allocate the complaint to a specific BU to take the lead in addressing the problem, and to ensure liaison with other relevant BUs or Divisions.

##### 8.3.1.2 IRQ'S arising as a result of complaints shall be investigated to achieve the following objectives:

- To determine the validity of the complaint, consumer concern, appeal or dispute received (this function shall be performed by the Customer Service Department),
- to determine the root cause of the complaint;
- to determine if there are other customers affected by the cause;
- to notify other customers, where relevant, of the potential effect on the service supplied to them; and
- to determine why the subject of complaint was not detected by the Management system prior to the complaint being lodged and to correct the system to allow for improved monitoring, where relevant.

##### 8.3.1.3 Preparation for closure

- Customer Services department is responsible for the management of all complaints and shall issue a formal report, compiled by investigator(s), to the complainant on completion of the investigation.
- A customer satisfaction/ dissatisfaction survey form (SCF 009) shall be attached to the report, to request feedback from the customer. If the customer does not return the satisfaction survey, the responsible person shall submit evidence that a survey was forwarded to the customer before the complaint may be closed.
- Accreditation Management Department will be responsible for verification of complaints prior to closure.
- Records shall be kept of the final conclusion to the complaint by Customer Service Department and on CRM.

#### 8.3.2 Appeals

##### 8.3.2.1 Any person or organization that feels aggrieved by a

- Certification decision;
- Consignment inspection decision;
- Proficiency testing scheme decision made by SABS Commercial, can appeal to the Executive of SABS Commercial.

##### 8.3.2.2 An appeal shall be lodged through the complaint system and an IRQ shall be raised to ensure that remedial action(s) will be identified and implemented that will lead to the satisfactorily resolution of the appeal.

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- 8.3.2.3 The Executive SABS Commercial for Certification or Laboratory Services Division, where applicable, shall ensure that an independent, impartial and competent person is appointed to investigate the appeal, to obtain the factual information and to determine the possible root cause(s) of the appeal.
- 8.3.2.4 The appointed person shall be responsible for the confirmation of the root cause and the implementation of the corrective action(s).
- 8.3.2.5 Appeals shall be finalized within 30 working days of receipt the appeal. A written response will be compiled and provided to the appellant as proof that the appeal has been formally addressed.
- 8.3.2.6 Records shall be kept of all appeals and their supporting evidence and documentation.
- 8.3.2.7 Appeals shall be reported at the scheduled management review meeting for monitoring purposes.

### **8.3.3 Disputes (Certification only)**

- 8.3.3.1 In the event of a disagreement arising out of a SABS Commercial contract, or the interpretation of the contractual requirements and/or obligations therein, the contracting parties must first try to reach an agreement or a settlement before a formal dispute can be lodged.
- 8.3.3.2 The dispute shall be recorded as an IRQ and shall be referred to the Executive of SABS Commercial who will endeavor to settle the dispute through *bona fide* negotiations.
- 8.3.3.3 In the event that the contracting parties are still unable to reach agreement through the intervention of the Executive of SABS Commercial, the dispute shall then be submitted to and decided by SABS Executive Committee.
- 8.3.3.4 Records shall be kept of all disputes and their supporting evidence and documentation.
- 8.3.3.5 Disputes shall be reported to the annual management review meeting for monitoring purposes.

### **8.3.4 Consumer Concern (Certification only)**

- 8.3.4.1 All Consumer concerns related to the products and/or services provided by organisations certified by SABS Commercial shall be handled through the same process as described for complaints against SABS Commercial Services, with the exception that the proposed closure timeline is defined by the investigating BU Manager in conjunction with Customer Services department. The examination of the complaint shall consider the effectiveness of the certified management system.
- 8.3.4.2 Any valid complaint about a certified client shall also be referred to the certified client in question at an appropriate time.
- 8.3.4.3 SABS Commercial shall determine, together with the certified client and the complainant, whether the subject of the complaint and its resolution shall be made public and, if so, to what extent.
- 8.3.4.4 All complaints relating to products and/or services provided by organisations claiming "SABS Approval" but which are not certified by SABS Commercial shall be forwarded to SABS legal for further action as per SABS Corporate procedure.

## **8.4 Non-conforming work**

- 8.4.1 Each employee has the responsibility and authority to take prompt action and report non-conformities, incidents, deficiencies, or out-of-control situations, at any stage of the process, in order to ensure timely detection and action.
- 8.4.2 BU managers shall document the procedure, which shall be followed in relation to the handling and control of

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non-conforming work. The document shall cover the following directives:

- a) Define the responsibilities and authorities for the management of non-conforming work;
- b) evaluate the significance and acceptability of the non-conforming work; taking into consideration the related risks as identified by the BU;
- c) determine the root cause of the non-conformity;
- d) define the responsibility of halting work and/ or withholding test reports;
- e) determine the type of corrective and preventive action to be taken;
- f) define the responsibility for resumption of work;
- g) where necessary, notify the customer and recall work and
- h) if consistent test failures occur, despite internal quality controls, additional inter- laboratory comparisons and / or proficiency testing shall be arranged to ensure correlation of results before closing the non-conformity;

8.4.3 In case where nonconforming work requires an investigation process to determine the corrective action to be taken, a formal Improvement Request (IRQ) shall be raised against the BU Manager on the CRM system within 2 working days from the date non-conformity was detected. Proper process will be followed to ensure through investigation and timeous closure of the IRQ.

#### 8.4.4 Equipment calibration and verification

Defective equipment shall be rectified and re-calibrated, where necessary. Non-conforming results caused by defective equipment shall be investigated and the appropriate corrective action determined to prevent recurrence of the deficiency. Specified calibration/verification requirements shall be confirmed after the defective equipment has been repaired and has been placed back into operation/usage.

#### 8.5 Actioning of an IRQ

8.5.1 The registered IRQ will be allocated to the relevant Manager, as appropriate.

8.5.2 The relevant Business Unit manager is responsible for the investigation process, including gathering and verifying all necessary information to validate the IRQ, and shall be responsible for the confirmation of the root cause and the implementation of the corrective action(s). The General Manager and/ or Senior Manager together with the BU manager shall ensure that all the IRQs are investigated and dealt with in accordance with this process or any other procedure mentioned herein.

8.5.3 In the case of a complaint being registered against a General Manager or Senior Manager, the complaint shall be forwarded to the Laboratory Services/ Certification Executives for allocation to (an) independent and impartial person(s). The relevant Executive shall be responsible for the confirmation of the root cause and the implementation of the corrective action(s).

#### 8.6 Investigation

All IRQ's shall be investigated to determine the root cause of the deficiency. The proposed corrective action shall be recorded in the relevant part on the CRM system. Documented evidence shall be available of the investigation process (e.g. root cause analysis forms and evidence of implementation). The designated responsible person shall implement the corrective action within the time scale provided in this document and any other normative documents. Records of the corrective actions completed shall be kept on the CRM system.

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## 8.6.1 Cause analysis

8.6.1.1 A root cause analysis shall be done to determine the real cause (not symptoms or explanations) of all non-conformities. A decision about the corrective actions to be taken will be based on the risk levels determined by the BU. This will be done by verifying if the previous results were affected by the non-conforming work. If significant risk is identified it shall be included in the risk register.

8.6.1.2 To determine the root cause of the deficiency, a formal process of identifying all possible causes is conducted. Following this process facilitates the identification of the correct root cause (s) and the most appropriate corrective actions (s) to address it/them. The fishbone diagram (annexure C) or other recognized techniques such as '5 Why's' (form SCF 017 or LSD-F 8.7A) shall be used whenever the root cause(s) of the problem is/are unknown.

### 8.6.1.3 The following steps are followed during the analysis process:

- a) Identify the problem. This step is to ensure that the problem is clearly and accurately defined.
- b) Analyse the problem. This step assists in identifying the root cause of the problem. Causes are analysed to establish how they lead to problems.
- c) Identify potential corrective actions. Once the root cause or causes have been identified, matching corrective actions also need to be identified. In identifying corrective actions to the problem, it should not be limited to one corrective action only.
- d) Select and plan corrective action. The selection of the corrective action shall be based on its effectiveness, efficiency and mitigation of the identified risk.
- e) Implementation of the corrective action shall be properly planned and executed.
- f) Evaluate the effectiveness of the corrective action. This provides an opportunity to review and verify whether the corrective action works.
- c) Maintain and improve. To prevent recurrence, the effectiveness of the corrective action needs to be maintained.

### 8.6.1.4 Categories of possible root causes (refer to Annexure A)

Major categories of possible root causes have been identified as:

- a) Man (representing management and personnel);
- b) Method;
- c) Equipment;
- d) Materials;
- f) Environment; and
- g) Measurement.

Contributing causes are further divided into sub-causes (categories) and they are then targeted for corrective action and/or improvement.

8.6.1.5 Documented evidence shall be available of the investigation process.

## 8.6.2 Corrective Action

8.6.2.1 The proposed corrective action shall be recorded in the relevant part of the CRM system. The corrective action shall have the objective of eliminating the root cause of the non-conformity, taking the necessary action to prevent its recurrence and, where necessary, of notifying the relevant customers of possible

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effects on any data which may have been issued prior to the detection of the non-conformity. An evaluation on the significance of the non-conforming work shall be done, including any impact that could have occurred on previous results.

The implementation and efficacy of corrective actions for IRQs requires monitoring and control on a continuous basis. Monitoring and controlling in this regard is performed by the activities of auditing, approvals board outcomes and management reviews.

#### 8.6.2.2 Identification of corrective action sources

Corrective actions may be identified through the following activities:

- process quality control outputs;
- auditing/ assessments;
- management reviews;
- complaints;
- departures from the documented management system; and
- equipment calibration and verification status.

#### 8.6.2.3 Monitoring Corrective actions

Managers shall verify the implementation of the corrective action and the effectiveness of this action. The outcome of the verification of whether the corrective actions are effective or not shall be recorded (LSD-F-8.7C). Simple output verification for effectiveness is required unless the corrective action covers a process with several variable outputs and as such involves system correction. Under such circumstances, BU managers shall monitor the implementation of the corrective action, and schedule an additional independent and impartial audit to verify effectiveness of the corrective action implemented.

#### 8.6.2.4 Reviewing the effectiveness of corrective actions

Accreditation Management auditors shall monitor effectiveness of implemented corrective actions (internal audit IRQs and SANAS NCs) by scheduled onsite clearance of findings visits.

After reviewing the effectiveness of corrective actions implemented for all RQs, a formal report of on-site clearance of findings shall be provided to BU manager.

BU manager shall establish ways of monitoring effectiveness of implemented corrective actions prior to the schedule onsite clearance of findings visit.

### 8.7 Closing of an IRQ

8.7.1 When IRQs are resolved the root cause analysis proposed correction, and corrective action to prevent reoccurrence shall be completed on the CRM system by BU manager and/or designated person and verified as per delegation of authority prior to the submission to Accreditation Management for clearance. All records (POE) relating to the investigation of an IRQ including corrective and preventive action taken shall be uploaded/attached to the IRQ on the CRM system.

8.7.2 The following criteria shall be applied to ensure the effective close out of corrective and preventive actions:

- Was the root cause of the particular non-conformity identified?
- Were the necessary actions put in place to correct the detected non-conformity?

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- c) Were the necessary preventive actions taken to prevent occurrence?
- d) Is there sufficient documented evidence available for audit and analysis purposes?
- e) Was the evaluation of risk related to activities performed in the BU adequately done and put in place to assure that other customers' results were not affected?

## 9. CLEARANCE OF INTERNAL AND EXTERNAL AUDIT FINDINGS

9.1 The corrective action response for both internal and external findings shall be submitted to SABS Accreditation Management within 15 days of the audit closing meeting for processing and closure. The following timeline (15 days) and process shall be followed.

### 9.2 Assessment Day, Accreditation Body responsible:

The Accreditation Body Assessment team will provide copies of the recommendation report and non-conformity report(s) to the facility representative (Laboratory/ Certification/ Inspection and Training) during the closing meeting of the assessment.

### 9.3 Day 1 of 15, Accreditation Management responsible:

- 9.3.1 All copies external/ internal non-conformances recorded and recommendation report where applicable shall be scanned and saved on H-Drive for access by Laboratory Services Division personnel or Sharepoint by Certification personnel.
- 9.3.2 The relevant Accreditation Management Internal auditor shall notify the responsible personnel (e.g. Quality Manager for Laboratory Services Division or Quality Assurance manager for Certification). The Group Manager of Accreditation Management shall provide copies of the assessment recommendation report and audit findings (if any) to the relevant Executive.
- 9.3.3 The Executive may invite the General Managers/ Senior Managers to the same meeting to discuss the findings or plan a separate follow up meeting once he/she has analysed the report.

### 9.4 Day 2 of 15, Accreditation Management responsible:

All internal/external non-conformances shall be registered on CRM by Accreditation Management Department internal auditors.

### 9.5 Day 10 of 15, General Managers responsible:

The General Managers shall submit management response to the Executive including root cause analysis, corrective and preventative action plan, implementation plan and ensure the response addresses the findings. Note it is the responsibility of the General Managers in operations to ensure that sufficient and reliable portfolio of evidence supporting the corrective and preventative action taken to address the audit finding is submitted together with corrective action plans.

### 9.6 Day 12 of 15, Testing/ Certification Executive

The Executive shall review and reengage GMs on gaps and approve the management responses for submission to the Accreditation Management.

### 9.7 Day 15 of 15, Accreditation Management responsible

The Group Manager shall review and sign off the corrective action, make necessary system changes and submit to Accreditation Bodies e.g. SANAS, RvA for external audit findings. Acceptance of the approved corrective action plan shall be communicated to the Executive and monitoring of the implementation of corrective actions will be managed through monthly reports.

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**9.8** If the timeline cannot be met for any justifiable reason, it must be communicated to the Executive to request extension from Accreditation Management department and the Accreditation Bodies. An action plan is required, indicating the intended time of completion. The request for extension shall be approved by the Executive for Certification Division and the General Manager/ Senior Manager for Laboratory Services/GM Accreditation Management or assigned personnel.

The request for an extension shall not be made on the 15<sup>th</sup> day, and substantial evidence must be provided to show what has been done until the day of extension request. Root cause and proposed corrective action must be completed on the CRM system.

**9.9 Clearance of Initial Assessment Non-conformances-** The SANAS due date for submission of corrective actions for clearance of non-conformances is 3 months after the initial assessment, therefore the SABS due date for submission of corrective actions shall be a month prior to the SANAS due date. The same process for submission and verification of non-conformances prior to SANAS submission shall be followed as stipulated above.

## 10. IMPROVEMENT

10.1 SABS Commercial SOC Ltd. shall plan and implement the necessary monitoring, measurement and analysis processes to ensure customer requirements are met, customer satisfaction enhanced and conformity and improvement of the management system and test and calibration activities are maintained.

By analysing and evaluating reports and data, management shall ensure that quality policies and objectives are maintained and improved.

10.2 The Accreditation Department shall prepare monthly reports to SABS Commercial Executive management on the performance of the management system and include any recommendations for improvement in these reports.

10.3 The Customer Service Department shall prepare a monthly report to SABS Commercial Executive management on any open complaints and include any recommendations for improvement in these reports.

### 10.4 The reports shall include the following:

- a) status of all other IRQs;
- b) status of open complaints;
- c) status of registrations, peer reviews and competency of auditors;
- d) internal audits scheduled;
- e) SANAS assessments scheduled;
- f) new Applications;
- g) suspensions and re-instatements; and
- h) Technical Signatory status including resignations and the effect on the accreditation status of the laboratory.

### 10.5 Identification of improvement opportunities

The need for improvement may be identified through the following activities:

#### 10.5.1 Customer satisfaction:

SABS Commercial SOC Ltd. shall gather and use information supplied by its staff and by its customers

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through customer satisfaction surveys conducted by external consultants/agencies and/or internally, to establish views of the extent to which customer requirements have been met.

Customer satisfaction results are reported at management review meetings.

- 10.5.2 Analysis of data to evaluate where continual improvement to the management system can be made;
- 10.5.3 Process quality control outputs;
- 10.5.4 Inter laboratory comparison and proficiency test results where applicable;
- 10.5.5 Audit results;
- 10.5.6 Management review;
- 10.5.7 Departures from the documented management system and review of concessions,
- 10.5.8 identified improvements or recommendations for improvement shall be recorded. Monitoring of recommendations improvement shall be done to ensure successful implementation or fulfillment.

## 10.6 Continual improvement

SABS Commercial SOC Ltd. shall maintain a recurring process for identifying opportunities to improve the effectiveness of the management system through the use of audit results, approvals board results, analysis of data and management reviews. In addition, management and staff are encouraged to offer suggestions for improvement in the operational processes and service to customers to support the quality principle "continual improvement".

Improvement requests are co-ordinated, registered, managed and reported at the monthly operational meetings. Where improvements have an effect on our customers, the impact shall be communicated to our customers.

## 11. RISK BASED APPROACH

- 11.1 A risk based approach shall be implemented to ensure that the risks of potential nonconformities are identified and that specific actions are taken to eliminate such risks, or to reduce them to a tolerable level.
- 11.2 SABS Commercial SOC Ltd. will implement a risk based approach process through the SABS Commercial Management Review meetings chaired by cluster managers, and Commercial Executive Management meetings to ensure that:
  - a) The necessary action is taken to prevent the reoccurrence of such deficiency
  - b) The risks of potential nonconformities are identified and that actions are taken to eliminate such risks, or to reduce them to a tolerable level.
- 11.3 Opportunities for identifying potential sources of non-conformities, either technical or system based, shall be identified through:
  - a) management reviews;
  - b) trend and risk analyses;
  - c) document review;
  - d) inter laboratory comparison and proficiency testing results;
  - e) incidents (near misses);
  - f) analysis of data to evaluate where continual improvement to the management system can be made;
  - g) process quality control outputs;
  - h) audit results;
  - i) preventive actions are reviewed during Management reviews, and processed through the Corrective Action Log' (CAL) system;
  - j) if long-term preventive action is required, Managers shall develop action plans, implement them and monitor their effectiveness. Action shall be taken in accordance with the current CAL system in SABS

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- Commercial; and
- k) customer feedback.

## **12. DEPARTURES FROM THE DOCUMENTED MANAGEMENT SYSTEM**

- 12.1 Corrective action shall have the objective of determining any modifications, amendments, revisions or additions to the documented management system to rectify an identified deficiency in the system, raised during the document review process or management review process.
- 12.2 A formal Improvement Request (IRQ) shall be raised where departure from the documented management system is identified. The corrective action shall have the following objectives:
  - a) To determine whether technical or procedural changes are required;
  - b) To determine whether the scope of accreditation in test and calibration laboratories requires review.

## **13. MAINTENANCE OF THE IRQ REGISTER**

The IRQ Register is maintained by the automated system BI Publisher available on the SABS intranet.

## **14. DOCUMENTS REQUIRED**

- 14.1 Procedure as required in this procedure.

## **15. RECORDS REQUIRED**

- 15.1 Evidence of preventative action/ action plan.
- 15.2 Records of IRQs raised.
- 15.3 Records of root cause analysis conducted.
- 15.4 Records of corrective action taken.

## **16. REPLACEMENT**

This document replaces SC-SP-004 Issue 10 dated 2016-09-01

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**Annexure A**

**POSSIBLE ROOT CAUSES**

<b>1</b>	<b>MAN (MANAGEMENT and PEOPLE)</b>	<b>2.2</b>	<b>DOCUMENTATION</b>
<b>1.1</b>	<b>BELIEF SYSTEM</b>	2.2.1	System documentation not available
1.1.1	Placing budgetary considerations ahead of quality	2.2.2	Incomplete system documentation
1.1.2	Placing schedule considerations ahead of quality	2.2.3	Ineffective system documentation
1.1.3	Lacking fundamental knowledge, research or education	2.2.4	Inefficient system documentation
1.1.4	Practicing autocratic behaviours, resulting in "annulment"	<b>2.3</b>	<b>ANALYTICAL METHODS</b>
<b>1.2</b>	<b>COMMUNICATION</b>	2.3.1	Method not fit for purpose
1.2.1	Communication tools lacking	2.3.2	Inadequate validated methods
1.2.2	Communication systems lacking		
1.2.3	Ineffective communication system	<b>3</b>	<b>EQUIPMENT</b>
1.2.4	Inefficient communication system	<b>3.1</b>	<b>TECHNOLOGY</b>
1.2.5	Lack/Inadequate of Handover	3.1.1	Old technology used
<b>1.3</b>	<b>STRUCTURE</b>	3.1.2	System errors
1.3.1	Wrong management structure	3.1.3	Design problem
1.3.2	Inadequate supervision	3.1.4	Design investigation not done properly
1.3.3	Inadequate support	<b>3.2</b>	<b>MACHINERY</b>
<b>1.4</b>	<b>RESPONSIBILITIES AND AUTHORITIES</b>	3.2.1	Equipment not fit for purpose
1.4.1	Inadequate definition of tasks	3.2.2	Inadequate validated equipment
1.4.2	Accountability	3.2.3	Equipment contamination
1.4.3	Deputies for key positions	3.2.4	Equipment out of calibration
<b>1.5</b>	<b>RESOURCE PROVISION</b>	3.2.5	Lack of maintenance
1.5.1	Inadequate planning for future	3.2.6	Inefficient maintenance
1.5.2	Inadequate human resources	3.2.7	Defective equipment
1.5.3	Inadequate equipment/ materials/suppliers		
1.5.4	Lack of contingency plans	<b>4</b>	<b>MATERIALS</b>
<b>1.6</b>	<b>JOB REVIEW</b>	<b>4.1</b>	<b>CONSUMABLES AND SUPPLIERS</b>
1.6.1	Job review not performed	4.1.1	Poor service from suppliers
1.6.2	Inadequate job review	4.1.2	Poor product from suppliers
1.6.3	Customer requirements not understood	4.1.3	Stock level control lacking
1.6.4	No capability to perform job/service	4.1.4	Reference materials not fit for purpose
1.6.5	Over promise	4.1.5	Consumables not fit for purpose
<b>1.7</b>	<b>HUMAN ERROR (NOT INTENTIONAL)</b>	4.1.6	Services not fit for purpose
1.7.1	Misreading	<b>4.2</b>	<b>SAMPLE HANDLING</b>
1.7.2	Typing	4.2.1	Non-representative sampling/ sampling preparation
1.7.3	Oversight	4.2.2	Non-homogeneous sample
1.7.4	Mislabelling	4.2.3	Contamination/ deterioration due to incorrect storage or handling
<b>1.8</b>	<b>MENTORING/COACHING</b>	4.2.4	Deterioration due to incorrect storage or handling
1.8.1	Mentors not assigned	<b>4.3</b>	<b>SAMPLE ANALYSIS</b>
1.8.2	Mentors not skilled	4.3.1	Dilution errors
1.8.3	Coaching neglected	4.3.2	Reagent/reference material error
<b>1.9</b>	<b>COMPETENCE</b>	4.3.3	Sample identification
1.9.1	Training needs not identified	4.3.4	Sample matrix problems
1.9.2	Training plans not formalized	4.3.5	Sample concentration out of analysis range/recovery
1.9.3	Training plans not complete		
1.9.4	Lack of training	<b>5</b>	<b>ENVIRONMENT</b>
1.9.5	Inefficient training	<b>5.1</b>	<b>PHYSICAL</b>

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<b>1.10</b>	<b>BEHAVIOUR</b>		5.1.1	Unsafe environment	
1.10.1	Negligence		5.1.2	Unhealthy environment	
1.10.2	Poor work practices		5.1.3	Uncontrolled testing/calibration conditions	
1.10.3	Non-adherence to procedures		5.1.4	Inadequate facilities	
1.10.4	De-motivated		5.1.5	Inadequate security	
1.10.5	Unsafe acts		<b>5.2</b>	<b>EMOTIONAL</b>	
<b>1.11</b>	<b>SKILLS</b>		5.2.1	Blaming culture	
1.11.1	Lack of appropriate skills		5.2.2	Victimization	
1.11.2	Lack of understanding of significance of job		5.2.3	Undue pressure	
			5.2.4	Unethical practices	
<b>2</b>	<b>SYSTEMS (METHODS)</b>				
<b>2.1</b>	<b>PROCESSES</b>		<b>6</b>	<b>MEASUREMENT</b>	
2.1.1	Processes not defined		6.1	Lack of control systems	
2.1.2	Ineffective processes/systems		6.2	Insufficient control systems	
2.1.3	Inefficient processes/systems		6.3	Inefficient action taken on non-conformities	
2.1.4	Ineffective support services		6.4	No action taken on non-conformities	

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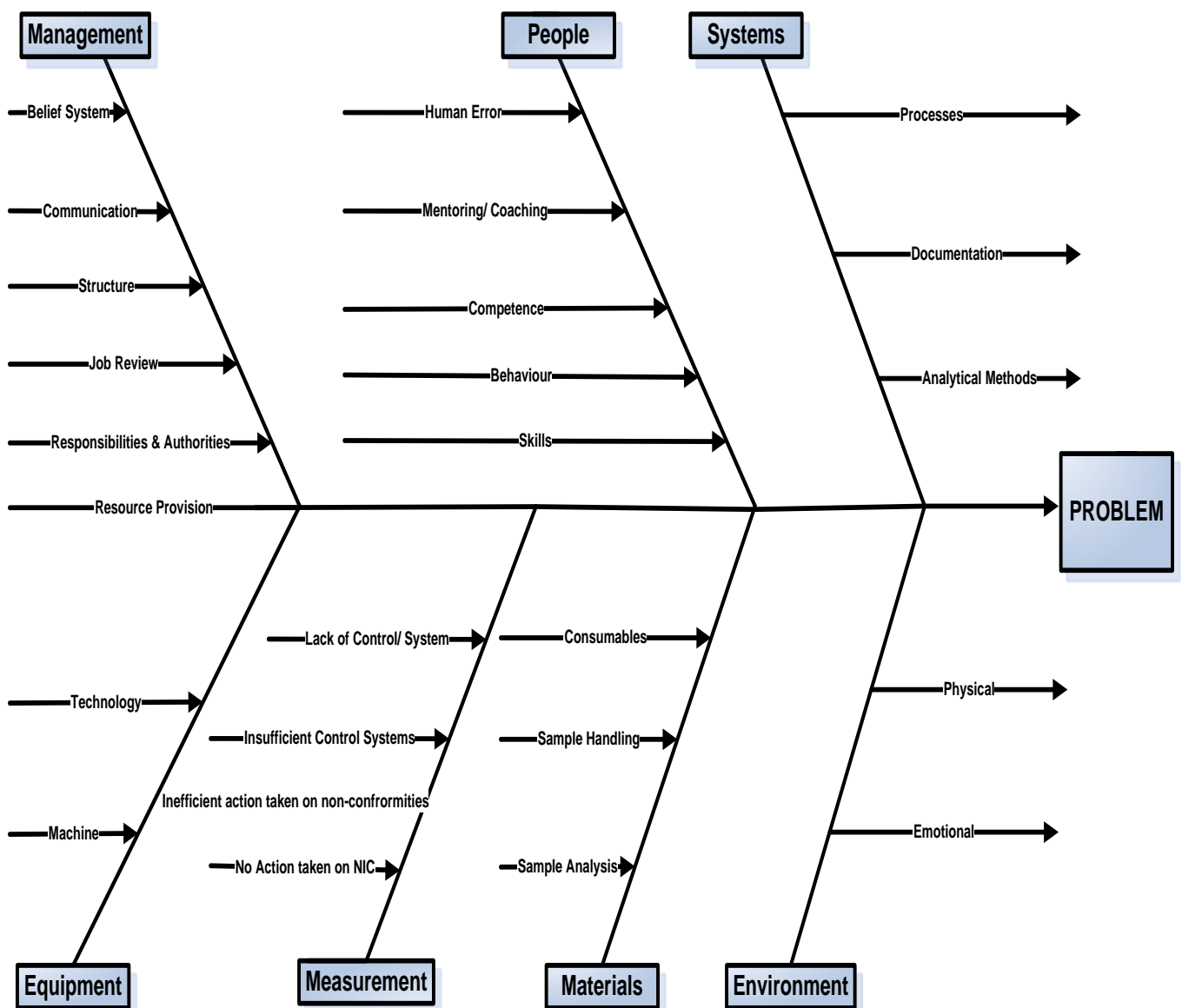
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## Annexure B IMPROVEMENT REQUEST – Root Cause Analysis



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**Annexure B Continued**

**ROOT CAUSE ANALYSIS ASSESMENT**

**State the apparent problem:**

**State the desired outcome**

**Brainstorm**

See Fishbone Diagram

**State the real/ root cause**

**Evaluation of solutions:**

DRIVING FORCES FOR +	RESTRAINING FORCES AGAINST -

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<b>Amendment No.</b>	<b>Date approved</b>	<b>Nature of amendment</b>
<b>Issue 1 – Amdt 1</b> <b>Issue 1 – Amdt 3</b>	<b>2006-08-01</b> <b>2006-11-01</b>	Amendments were made to: Clause 3; 3.1; 3.2; 3.3; 3.4; 3.5; 3.6; Clause 6.3.2 Par 1.1 Appeals and Disputes added, Par 1.2 Appeals and Disputes added Par 1.3 & 1.4 replaced by table covering all relevant standards and guides. Par 2 Policy: Appeals and disputes added Par 3 IRQ system separated from complaints Par 3.1 – 3.6 re-aligned with headings, covering the central register and verification Par 3.4 Criteria for effective close-out was added Par 4 Definitions added Par 7.3 Equipment & Calibration and Verification updated Par 7.3.2 Investigation: Fishbone Technique added
<b>Issue 2</b>	<b>2006-11-01</b>	Par 8 Replacement: CrtSP 020; CrtSP 024 and CrtSP 037 withdrawn Par 3.1 Paths to IRQ was changed Par 3.2 Path to IRQ was changed
<b>Issue 3</b>	<b>2007-07-01</b>	Clauses 3.3 and 4.2 were amended to address SANAS Non-conformity number Ext 087/2007;
<b>Issue 4</b>	<b>2008-02-14</b>	Procedure revised to include the classification of IRQ's and to re-align the structure of the procedure.
<b>Issue 5</b>	<b>2009-02-03</b>	Par. 3, 4 and 7.6 were updated to address the current processes followed in SABS Commercial.
<b>Issue 6</b>	<b>2009-08-21</b>	All references to 'findings' were replaced with 'non-conformities'. Par 3.4 amended to include the requirement for closure of IRQ,s Par 4.1 'Complaints' was changed in its entirety, to include the requirements of SABS CSP120 'SABS Customer Complaint handling system'. Par 4.4 Consumer complaints added. Par 7.4 'Cause Analysis' was changed to include the requirements of root cause analyses and 'possible sources of root cause analysis'. Annexure A, B, C added. Par. 4.1.6 – 4.1.7 have been revised as per comments received Par 4.1.8 removed Par 6.2: reference to the reward system was removed.
<b>Issue 7</b>	<b>2011-02-23</b>	Changes made to the following paragraphs: Table par 1.3 to include ISO/IEC 17043 Par 3 to include HSE, Various editorial changes. Par 1.3 reference added, par 4.1.7 updated.
<b>Issue 8</b>	<b>2012-06-27</b>	Amendment on Name Change: (Pty) Ltd., replaced by SOC Ltd

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<b>Issue 9</b>	<b>2013-03-06</b>	Amendments were made to: Clause 7.6.1 paragraph 3 were deleted Clause 7.6.2 have been revised as per comments received Clause 1.3 was amended as per comments received Added SANAS corrective action timeline for SANAS Non-conformances on paragraph 7.6
<b>Issue 10</b>	<b>2016-08-02</b>	Added Background, Purpose and scope in the document. Updated Reference to applicable clause number Updated clause 5 (Policy) Added consumer concerns under clause 6a. Added Accreditation under clause 6c. Added Impartially committee under clause 6j. Added Compliments (Int) under 6k. Added Other non-compliance situation under 6i. Added NOTE: Corporate Internal Audits findings are reported as per the SABS Internal Audit Manual under clause 3. Deleted "which includes IRQ's from audits, customer complaints, compliments and any other non-compliance situation as indicated under section 3" under clause 7.1. Added Note: A detailed process for handling complaints is defined on CSP 120 under clause 7.1. Added IRQ registration clause 7.2. Added b, c, and d under clause 8.4. CSP 122 "Organizational Health and Safety Management System" Form SCF-004: Incident: HSE Added" for the Laboratories and CrtF101 C: 'Internal Audit Report Part C' for Certification and Consignment Inspection" on clause 3.2. Added "NOTE: The request for an extension shall not be made on the 25th day, and substantial evidence must be provided to show what has been done until the day of extension request. Root cause and proposed must be completed on the IRQ form" on clause 7.6.1 Added "Day 25 from day of capturing" on clause 7.6.2
<b>Issue 11</b>	<b>2019-02-26</b>	Clause 2 word removed" customer" and word added" appeals & disputes as well as". Clause 3, (a)" word removed" SABS Commercial Improvement Request (IRQ) system which includes, customer". Clause 3.2 word added" it also covers". Clause 3" the whole table is amended". Clause 3.3 the whole sentence is amended. Clause 3.4 word removed" Normative reference". Table amended" table of reference to applicable clause number". Clause 4 to clause 16 numbering sequence changed. Clause 4 reference documents added" (f) and (g)". Clause 5 under definition "the whole section is amended and also numbering sequence changed". Note added at the bottom of clause 5. Clause 6 under policy "the whole section is amended". Clause 7 under improvement request (IRQ) system" the whole section is removed and added clause (7.1 7 & 7.2)". Clause 8.2 amended" table of IRQ table".

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Clause 7.3 changed to clause 8.3, 8.3.1 to 8.3.4" (the whole section is amended)".  
Clause 9 changed to clause 8.4" Non-conforming work" and the whole section is amended".  
Clause 7.4 changed to clause 8.5" actioning of an IRQ" and also numbering sequence changed".  
Clause 7.5 changed to clause 8.6" Investigation".  
Clause 7.5.1 changed to 8.6.1" cause analysis".  
Clause 7.5.1.1 changed to 8.6.2" corrective action" and the whole section is amended".  
Clause 7.5.1.2 changed to 8.6.2.2" Identification of corrective action sources".  
Clause 7.5.1.3 changed to 8.6.2.3" Monitoring corrective actions".  
Clause 8.6.2.4 added" Reviewing the effectiveness of corrective actions".  
Clause 7.5.2 changed to clause 8.7" closing of an IRQ".  
Clause 10 changed to clause 9" Clearance of internal and external audit findings" and the whole section is amended".  
Clause 11 changed to clause 10" Improvement".  
Clause 11.1 changed to clause 10.5" Identification of improvement opportunities".  
Clause 11.2 changed to 10.6" Continual improvement".  
Clause 11 added" Risk based approach".  
Clause 13 changed to clause 12" Departures from the documented management system".  
Clause 14 changed clause 13" Maintenance of the IRQ register".  
Clause 15 changed to clause 14" Documents required".  
Clause 16 changed to clause 15" Records required".  
Clause 17 changed to clause 16" Replacement".  
Annexure A "Confirmation of effective close-out of customer complaint" changed to "Possible root causes".  
Annexure C changed to Annexure

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