SABS MANUAL			To be revised by:
Subject: **Management System Manual for SABS Commercial SOC Ltd. Continual Improvement Process**			**Page 1 of 26**
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Compiler:	**MANAGER: LABORATORY ACCREDITATION**	**Signature:**	**Date:**
Approving Officer:	**SENIOR MANAGER: ACCREDITATION MANAGEMENT**	**Signature:**	12-03-2013

This Management System Procedure for Continual Improvement Process

Issue 9 dated 12 March 2013 consisting of 25 pages has been reviewed for adequacy by the Manager: Laboratory Accreditation and is issued on the authority of the Senior Manager: Accreditation Management.

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Manager: Laboratory Accreditation Date

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Senior Manager: Accreditation Management Date

The definitive version of this procedure 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 procedure may be issued under controlled conditions (See SC-SP-001) and will be replaced in entirety when any changes or revisions are made.

CONTENTS

1 SCOPE

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

a) SABS Commercial Improvement Request (IRQ) System.
b) Customer complaints, appeals and disputes.
c) Non-conforming work.
d) Improvement.
e) Corrective action.
f) Preventive action.

1.2 The procedures for customer complaints, appeals and disputes, non-conforming work, improvement, corrective action and preventive action have been combined into one procedure to identify the improvement process, including the improvement request (IRQ) system in place within SABS Commercial SOC Ltd.

1.3 This document covers the requirements of the clauses of the following Standards/ Guides:

Reference to applicable clause number						
Standard ISO/IEC	Customer complaints	Non-conforming work	Improvement	Corrective action	Preventive action	Appeals and disputes
ISO/IEC 17020	7.5 7.6	7.4 8.7		8.7	8.8	7.5 7.6
ISO/IEC 17021	4.7 9.8	7.2.10	10.2.4.2	10.2.6	10.2.7	9.7
ISO/IEC 17025	4.8	4.9	4.10	4.11	4.12	-
ILAC-G13	2.8	2.9	2.10	2.11	2.12	-
ISO/IEC 17043	5.8	5.9	5.10	5.11	5.12	5.8
ISO/IEC 17065	4.2(p) 4.5.3(m) 4.8.1(f) 7.1	4.5.3(k)	4.5.2(b)	2.7.1(b) 4.5.3(k)	7.2(b)	4.2(p) 4.5.3(w) 4.8.1(f) 7.1
ISO 9001	7.2.3`	8.2.4 8.3	6.1(a) 8.1 8.2.1 8.4 8.5.1	8.2.2 8.2.3 8.5.2	8.2.2 8.2.3 8.5.3	

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.

ILAC-G13
Guidelines for the requirements for the compliance of providers of Proficiency Testing Scheme.

ISO/IEC 17043
General requirements for proficiency testing.

ISO/IEC 17065
General requirements for bodies operating product certification systems.

ISO 9001 Quality Management Systems – Requirements.

2 POLICY

It is the policy of SABS Commercial to:

a) Investigate all customer complaints, appeals and disputes in order to determine the validity of each. complaint, appeal and dispute to determine the root cause applicable and to take corrective and preventive action to prevent the recurrence of the cause.
b) Identify major non-conforming work or services that does not conform to own procedures or to the agreed requirements of the customer.
c) Plan and implement the necessary monitoring, measurement and analysis processes to ensure. customer requirements are met and that the conformity and improvement of the quality management. system is maintained.
d) Implement a corrective action process by determination of the root cause of complaints and non-conformities.
e) Implement a preventive action process to ensure that the risks of potential non-conformities are identified and that actions are taken to eliminate such risks, or to reduce them to tolerable level.

3 IMPROVEMENT REQUEST (IRQ) SYSTEM

Informative reference: CSP121 SABS Improvement System

IRQ's are raised for any of the following:

NOTE: The categories are indicated in brackets

a) Customer complaints, appeals and disputes (CC).
b) Non-conformities detected by the departmental management and staff (Int).
c) Internal audit non-conformities (Int).
d) Internal complaints within SABS Commercial (Int).
e) External audit non-conformities arising from the accreditation bodies (SANAS, RvA, IEC) and similar institutions (Ext).
f) Customer audits (Ext).
g) Suspensions (Others: SUS).
h) Non-conformities arising from management review meetings (INT) or (MR CAL).
I) Approval Board Issues (CrtF 64 Form).

NOTE: Safety incidents are reported as per the HSE system implemented in SABS.

CSP 122 "Organizational Health and Safety Management System'
Form SCF-004: Incident: HSE

3.1 Central register

The Accreditation Management Department shall hold on record a central register with associated Improvement Request (IRQ) forms.
Open IRQ registers are available on H:\SABS Commercial\Administration and Support\ IRQ's & Cluster Registers & CA Plans\Registers; Open IRQ registers are updated weekly and the updated open IRQ registers are placed in the archive folder within each cluster, for reference purposes. A complete IRQ register is available on request from the Quality Officer: Accreditation Management.
An excel spreadsheet is updated at least once a month containing all information of open and closed IRQ's which can be filtered to extract relevant information. "All IRQ's 2007-2010 to filter" is available on H:\SABS Commercial\Administration and Support\IRQ's & Cluster Registers & CA Plans\Registers.

3.2 Opening of an IRQ

Non-conformities arising from audits done by Accreditation Management shall be recorded on form:
SCF 006: 'Internal Audit Non-Conformity Report',

An Improvement Request (IRQ) form SCF 004 shall be completed for all complaints, appeals and disputes, non-conformities and self-audit non-conformities and forwarded to the Accreditation Management Department. Alternatively an electronic form can be completed and forwarded electronically to the Accreditation Management Department for registering. H:\SABS Commercial\SABSCOM General\Forms;
The following fields are completed on the form:

Initiator: The person initiating the IRQ.

General Manager: Relevant General Manager of the cluster against which the IRQ is raised.

Type of deficiency/incident: Select by highlighting the correct box: External Non-conformity; Customer Complaint; Internal Non-conformity; HSE incident or other.

Department and Cost Centre: Indicate the department and cost centre no. against which the IRQ is raised. The lab accreditation number is also added.

Person responsible for investigation: Relevant Departmental Manager.

Category: Select by highlighting the correct box: Cert, Lab,HSE or Other.

Classification: Select by highlighting the correct box: Major, Minor, Observation, Improvement. (Refer to paragraph 3.2.1).

Standard: The relevant standard to which the department did not comply with e.g. ISO/ IEC 17025.

Clause: The relevant clause number of the relevant standard to which the department did not comply with e.g. Clause 4.6.

IRQ No and status: An IRQ reference number is allocated on 'SABSCOM IRQ REPORT' form, once it is registered by Accreditation e.g. Int 123/2010, Ext 456/2010 or CC 001/2010 The status is indicated as 'Open', 'Closed' or 'Under Investigation'.

Description of deficiency/incident: A clear description of the deficiency/incident is entered, including the date of the deficiency/incident identified.

3.2.1 Classification of IRQ

Major:

For laboratories, the 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, failure to fulfil one or more requirements of the management system standard, or a situation that raises significant doubt about the ability of the client's management system to achieve its intended outputs. (SANS 17021 par 9.1.15b).

Minor:

For laboratories, a non-conformity is classified as a minor when the failure has no immediate or imminent effect on its competence to perform work within the limits of its approved accreditation schedule.
(SANAS A 01)
For Certification and Inspection schemes, or any other non-conformities not classified as a major.
(SANS 17021:2006 par 9.1.15c)

Observation:

When noting a situation or action which may prejudice the department's ability to meet an accreditation bodies' or own management system requirements, which may result in a non-conformity if no action is taken. (SANAS A 01).

Standard and Clause:

The relevant standard and clause number, to which the department did not comply to, is entered for the purpose of trend analysis.

Description of deficiency:

A clear description of the deficiency is entered, including the date of the deficiency identified.

3.3 Actioning of an IRQ

3.3.1 The registered complaint, non-conformity, or audit non-conformity will be forwarded to the relevant Manager, Quality Officer (where applicable), General Manager/Regional Manager/Senior Manager and Accreditation Manager/Auditor as appropriate.

3.3.2 The relevant departmental manager is responsible for the investigation process, and shall be responsible for the confirmation of the root cause and the implementation of the corrective action(s).

NOTE: An IRQ raised for an appeal will be handled as stated in clause 4.2 below.

3.3.3 In the case of a complaint being registered against a Cluster General Manager, Accreditation Manager or the Senior Manager Shared Services, the complaint shall be forwarded to the Executive SABS Commercial for allocation to an independent and impartial person(s). The Executive of SABS Commercial shall be responsible for the confirmation of the root cause and the implementation of the corrective action(s).

3.3.4 In the case of a complaint being registered against a department, the complaint shall be forwarded to the Cluster General Manager, the Accreditation Manager or the Senior Manager Shared Services, for allocation to an independent and impartial person(s). The relevant GM shall be responsible for the confirmation of the root cause and the implementation of the corrective action(s).

3.4 Closing of an IRQ

When complaints, appeals, disputes, non-conformities and audit non-conformities are resolved, the Improvement Request 'SABSCOM IRQ REPORT' form (as created by the system once captured) shall be signed off by the Departmental Manager an/or Quality Officer, where applicable, and verified by the Accreditation Management Department before closed out. All records relating to the investigation of an IRQ including corrective and preventive action taken shall be attached to the IRQ.

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

a) Was the root cause of the particular non-conformity identified as per Annexure B of this document?
b) Were the necessary actions put in place to correct the detected non-conformity? (Correction).
c) Were the necessary actions put in place to prevent the non-conformity recurring? (Corrective action taken).
d) Were the necessary preventive action taken to prevent occurrence ?
e) Sufficient documented evidence available for audit and analysis purposes?

NOTE: **All Internal and External IRQ's shall be cleared at least two weeks prior to a SANAS assessment.**
Refer to par 4.1.6 for Corrective action timeline for Customer Complaints.
Refer to par 7.6.1 for SANAS Corrective action timeline.
Refer to par 7.6.2 for Internal Corrective action timeline.
Accreditation Management shall report the status of open IRQ's to Commercial Management two weeks prior to the assessment, to take the necessary action.

3.5 Maintenance of the IRQ register

The IRQ Register shall be maintained by the Accreditation Management Department.

3.6 Verification of closed IRQ's

When corrective action requires verification of implementation, the relevant IRQ's will be noted by the Accreditation auditor and verified at the scheduled 'on-site clearance of findings' visit, or next internal audit to ensure effectiveness of implementation.

3.6.1 Laboratories are required to submit an action plan, form T&CF004 available from the H:\SABS Commercial\SABSCOM General\Forms to request extension for corrective action. The relevant General Manager, Regional Manager or Senior Manager shall authorize the action plan.

3.6.2 Certification shall record the extended date on the relevant IRQ page.

3.6.3 The timeline for close-out non-conformities are defined in par. 7.6.

4 COMPLAINTS, APPEALS AND DISPUTES

4.1 Complaints

4.1.1 Purpose

Complaints arising from grievances are received from clients 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.

4.1.2 Scope

This section covers all complaints and concerns from persons or organizations from outside the SABS with regards to matters arising from the SABS activities, as well as complaints raised by one BU to another (internal complaints).

4.1.3 Informative reference

CSP120: SABS Customer Complaint handling system.

4.1.4 Definitions

A ***complaint*** is defined as an expression of dissatisfaction with the service received by a person or organization from SABS Commercial, which relates to the operational activities or service delivery of SABS Commercial;

An ***appeal*** is defined as a request by a Certified Company or a Laboratory participating in the SABS Proficiency Testing Scheme, for the reconsideration of a decision, that was made by SABS Commercial, that are not acceptable to a person or organization that was affected by the original decision;

A ***dispute*** is defined as 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;

A **Consumer complaint/concern** is defined as an expression of dissatisfaction with products or service Received by a person or organisation from SABS commercial certified organisation.

4.1.5 General Rules

a) The General Manager/ Regional Manager/ Senior Manager is responsible for drawing the attention of the Executive: SABS Commercial to *complaints* of such a serious nature as to have wider implications and which in consequence could require action by the Executive: SABS Commercial.
b) Refer to par.3.3.3 and 3.3.4 for the responsibilities of actioning complaints.

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, Regional Manager or Senior 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 BU's or Divisions.

c) IRQ'S arising as a result of customer complaints shall be investigated to obtain the following objectives:

i) To determine the validity of the complaint;
ii) To determine the root cause of the complaint;
iii) To determine if there are other customers affected by the cause;
iv) To notify other customers, where relevant, of the potential effect on the service supplied to them; and
v) To determine why the subject of complaint was not detected by the Management system prior to the complaint being lodged and correcting the system to allow for improved monitoring, where relevant

d) A *complaint* received by another *BU* shall first be acknowledged within the two day period giving the complainant information as to who will further be handling the *complaint*, before passing it to the relevant General Manager, Regional Manager or Senior Manager, who will arrange for it to be registered and for an IRQ to be raised. A copy of the acknowledgement shall accompany the *complaint*.

e) Complaints which have possible legal implications must be referred to the Manager: Legal Services for Advice before any statement is made or correspondence is sent to the complainant. Such advice shall be given within 2 (two) days of receipt of the request by the Manager: Legal Services.

4.1.6 Procedure

a) Complaints shall be acknowledged in writing within 2 working days by the recipient from date of receipt.
b) Complaints shall be finalized within 2 weeks (14 days) of receiving the complaint.
c) When the *complaint* takes longer than 2 weeks to resolve/clear an interim report with a corrective action plan indicating when the final report is expected to be completed. This report shall be sent by the Manager to the complainant.
d) In these cases where the customer complaint has not been resolved and no feedback has been received by Accreditation Management, by the two week deadline date, a reminder will be forwarded from Accreditation Management to the Manager.

The following information shall be included in the reminder:

a) The IRQ no. and date on which the complaint was registered;
b) Two weeks deadline date - this date is fourteen days after date of receipt;
c) Request for a copy of the corrective action plan/interim report; and
d) Reason why the complaint could not be closed out within the required two week period.

4.1.7 Preparation for closure

a) The Manager shall issue a formal report to the complainant on completion of the investigation.
b) A customer satisfaction/ dissatisfaction survey form (Annexure A) 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 customer complaint may be closed.
c) On completion of this process, the Manager will forward the particular *complaint* with the relevant records to the General Manager, Regional Manager or Senior Manager for approval of corrective action taken.
The General Manager, Regional Manager or Senior Manager shall sign the SABS IRQ investigation form prior to submitting to Accreditation Management for close-out.
d) Records shall be kept of the final conclusion to the *complaint*

4.2 Appeals

Any person or organization that feels him aggrieved by a

a) certification decision;
b) consignment inspection decision;
c) proficiency testing scheme decision;

by SABS Commercial can appeal to the Executive of SABS Commercial and/or where appropriate to the Certification Schemes Advisory Committee.
An appeal shall be lodged through the customer 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.
The Accreditation Manager shall ensure that an independent, impartial and competent person is appointed to investigate the appeal**,** on behalf of the Executive SABS Commercial, to obtain the factual information and to determine the possible root cause(s) of the appeal. The appointed person shall be responsible for the confirmation of the root cause and the implementation of the corrective action(s).

Appeals shall be finalized within 30 working days of receiving the appeal. A written response will be compiled and provided to the appellant as proof that the appeal has been formally addressed.
Records shall be kept of all appeals and their supporting evidence and documentation.
Appeals shall be reported to the quarterly company level management review meeting for monitoring purposes.

4.3 Disputes (not relevant to laboratories)

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.
The dispute shall be recorded as an IRQ and be referred to the Executive of SABS Commercial who will endeavour to settle the dispute through *bona fide* negotiations.

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 arbitration in accordance with the rules of the Arbitration Foundation of Southern Africa (AFSA), by an arbitrator agreed upon between the contracting parties or, failing agreement, appointed by AFSA.
Records shall be kept of all disputes and their supporting evidence and documentation.
Disputes shall be reported to the annual management review meeting for monitoring purposes.

4.4 Consumer Complaints

a) All Consumer complaints related to the products and/or services provide by organisations certified by SABS Commercial shall be handled following the same process as described for complaints against SABS commercial services, with the exception that the proposed closure timeline defined by the investigating BU Manager.

b) All Consumer complaints relating to product and/or services provided by organisations claiming “SABS Approval” but not certified by SABS Commercial shall be forwarded to SABS legal for further action as per SABS Corporate procedure.

5 NON-CONFORMING WORK

5.1 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.

5.2 The departmental manager shall document the procedure, which shall be followed in relation to the handling and control of 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;
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, the customer is notified and work recalled;
h) if consistent failure results appears despite internal quality control, additional external inter-laboratory

comparisons and / or proficiency testing should be arranged to ensure compliance before closing the non-conformity;

In the case where the nonconforming work requires an investigation process to determine the corrective action to be taken, a formal Improvement Request (IRQ) shall be raised.

6 IMPROVEMENT

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 is maintained.

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

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

QUESH reports are prepared for the following:

a) status of open IRQ's.
b) status of open customer complaints.
c) status of registrations, peer reviews and competency of auditors.
d) Internal audits scheduled for laboratories.
e) SANAS assessments scheduled for laboratories.
f) New Applications: Laboratories.
g) Suspensions and Re-instatements of laboratories.
h) Technical Signatory status including resignations and the effect on the accreditation status of the laboratory.

The Accreditation Manager shall also ensure that awareness of broadband customer requirements are promoted throughout SABS Commercial SOC Ltd.

6.1 Identification of improvement opportunities

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

Customer satisfaction:
SABS Commercial SOC Ltd. shall gather and use information supplied by its staff and by its customers through customer satisfaction surveys conducted by external consultants/agencies and/ or internally, to establish views of the extent to which the customer requirements have been met.

The results are reported at the management review meetings.

a) Analysis of data to evaluate where continual improvement to the management system can be made
b) Process quality control outputs
c) Inter laboratory comparison and proficiency test results
d) Audit results

e) Management review
f) Departures from the documented management system and review of concessions.

6.2 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, 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 QUESH meetings and management review meetings.

Where improvements have an effect on our customers, the impact shall be communicated to our customers.

7 CORRECTIVE ACTION

The implementation and the efficacy of a corrective action system require monitoring and control on a continuous basis. Monitoring and controlling in this regard is performed by the activities of auditing, corrective action and management review. When corrective action is required the responsible person as defined in par 7.5.1 shall initiate a formal Improvement Request (IRQ) as described in par 3. The corrective action shall have the objective of determining 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 effects on any data which may have been issued prior to the detection of the non-conformity.

7.1 Identification of corrective action sources

The need for corrective action may be identified through the following activities:

a) Process quality control outputs.
b) Auditing.
c) Management review.
d) Customer complaints.
e) Departures from the documented management system.
f) Equipment calibration and verification status.

7.2 Departures from the documented management system

Corrective action shall have the objective of determining any modifications, amendments, revisions or additions to the documented management system to improve an identified deficiency in the system raised during the document review process or management review process.
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;

7.3 Equipment calibration and verification

Defective equipment needs to be rectified and re-calibrated, where necessary. Non-conforming results caused by defective equipment needs to 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 have been placed back into operation/ usage.

7.4 Cause analysis

A root cause analysis shall be done to determine the real cause (not symptoms or explanations) of non-conformities raised by complaints, internal or external audit non-conformances or through external inter-laboratory comparisons / proficiency testing to determine the corrective action to be taken.

The following steps are followed during the analysis process:

7.4.1 Identify the problem. This step is to ensure that the problem is clearly and accurately defined.

7.4.2 Analyse the problem. This step assists in identifying the real cause of the problem. Causes are analysed to establish how they lead to problems.

7.4.3 Identify potential solutions. Once the root cause or causes have been identified, matching solutions also need to be identified. In identifying solutions to the problem, it should not be limited to one solution only. A number of possible solutions need to be identified.

7.4.4 Select and plan solution. The selection of the solution should be based on its effectiveness and efficiency.

7.4.5 Implement the solution. Implementation of the corrective action is properly planned and executed.

7.4.6 Evaluate the effectiveness of the solution. This provides an opportunity to review and verify whether the solution works.

7.4.7 Maintain and improve. To prevent problems resurfacing, the effectiveness of the solution needs to be maintained.

Major categories of possible root causes have been identified as:

a) Management.
b) People.
c) Systems.
d) Equipment.
e) Materials.
f) Environment.
g) Measurement.

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

The list of ‘Possible root causes’ adopted by SABS Commercial is given in **Annexure B**.

7.5 Selection and implementation of corrective action

7.5.1 Initiation

Since all personnel are responsible for quality they have the authority to initiate an IRQ where a deficiency in a procedure or system is identified. The identified deficiency is raised as an IRQ as per par 3.2 of this document.

7.5.2 Investigation

All IRQ's shall be investigated to determine the root cause of the deficiency. This is done through a formal process of identifying all possible solutions to correct the deficiency and the most appropriate solution(s) selected. The fishbone diagram or other technique such as '5 Why's' technique will be used where the root cause of the problem is unknown. The proposed corrective action shall be recorded in the relevant part of the Improvement Request Form. Documented evidence shall be available of the investigation process. The designated responsible person shall implement the corrective action within the time scale given in par 7.6. Records shall be kept of corrective action completed.

7.5.3 Monitoring Corrective actions

The Manager shall verify the implementation of the corrective action and the effectiveness of this action. 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, the departmental manager shall monitor the implementation of the corrective action, and schedule an additional independent and impartial audit to verify effectiveness of the corrective action implemented. If verification is acceptable he/she will authorise the closure of the IRQ. If it is not acceptable the IRQ shall not be closed out, and further action taken as required.

7.6 Corrective action timeline for SANAS Non-conformances

7.6.1 The timeline for corrective and preventive action for non-conformities raised by SANAS, are given below. SABS Commercial has adopted this corrective action timeline for clearance of all IRQ's raised by SANAS.

NOTE: If the timeline can not be met for any justified reason, it must be communicated to the accreditation department to request extension from sanas. An action plan is required, indicating the intended time of completion. The request for extension shall be approved by a level higher than the requestor.

NOTE: If the timeline cannot be met for any justified reason, it must be communicated to the accreditation Department to Request extension from SANAS. Refer to par.3.6.

Day 1 SANAS responsible
The SANAS Assessment team will provide copies of the recommendation report (SANAS F04) and non-conformity report(s) (SANAS F03) to the facility (laboratory) during the closing meeting of the assessment.

Day 25 Facility (relevant department) responsible
The facility (department) will submit their root cause analysis and corrective action to the Accreditation Department by completed SANAS F03 form and relevant 'SABS pta ISOSYS' form. The Accreditation department will update the IRQ, and forward the SANAS F03 form as well as the SABS pta ISOSYS form containing the root cause analysis with documented evidence of corrective action taken, to SANAS.

Day 50 SANAS responsible
SANAS and the Assessment team will process the completed corrective actions. The Approval Committee meeting will be arranged. SANAS will provide feedback to the facility on the corrective actions status.

Day 51 SANAS responsible
SANAS will determine the necessity for suspension if the facility failed to adhere to the timeline.

NOTE: Refer to par 3.4 for the requirement of clearance of all IRQ's prior to SANAS and other External Assessments.

7.6.2 The timeline for corrective and preventive action for internal findings:

Day 1 Accreditation Management Internal Auditors responsible
The Accreditation Management department will provide copies of the registered findings from Internal Audits to the relevant department

Day 25 Relevant department responsible
The department will submit the root cause analysis on the relevant 'SABS pta ISOSYS' forms, proposed corrective actions in an action plan format, completed corrective actions with sufficient supportive evidence as proposed in the action plan to Accreditation Management and where applicable, request for extension for findings requiring additional time to clear.

Day 35 Accreditation Management Internal Auditors Responsibility
The Accreditation Internal Auditor will verify and recommend acceptance of the root cause analysis, proposed corrective actions and action plans where relevant. The pack is then forwarded to the Quality officer: Accreditation Management to update the IRQ form and forward feedback to the departmental management.

Day 45 Relevant department responsible
The department will submit additional evidence where required by Accreditation Management.

Day 50 Relevant department responsible

All IRQs closed.

8 PREVENTIVE ACTION

A preventive action process is 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.

SABS Commercial SOC Ltd. has implemented a preventive action process through the SABS Commercial monthly Accreditation Review reporting system, regular QUESH management meetings and Management review system to ensure that:

a) The necessary action is taken to prevent the occurrence 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.

Opportunities for identifying potential sources of non-conformities, either technical or system based, shall be identified through:

a) Management review.
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.

Preventive actions are reviewed during Management review, and processed through the 'Corrective Action Log' (CAL) system.
If long-term preventive action is required the Manager shall develop action plans, implement them and monitor their effectiveness. Action shall be taken in accordance with the current CAL system in SABS Commercial.

9 DOCUMENTS REQUIRED

9.1 Procedure as required in par. 5.2.

10 RECORDS REQUIRED

10.1 Evidence of preventative action/ action plan.
10.2 Records of IRQ's raised.
10.3 Records of root cause analysis conducted.
10.4 Records of corrective action taken.

11 REPLACEMENT

This document replaces SC-SP-004 Issue 8 – dated 2012-06-27.

ANNEXURE A

SURVEY

CONFIRMATION OF EFFECTIVE CLOSE-OUT OF CUSTOMER COMPLAINT

DATE:……..

		YES	NO
1	I confirm receipt of an acknowledgement from……..on……	☐	☐
2	I confirm receipt of regular interim reports/ action plans from ……until……..	☐	☐
	Final close-out. (*This might not be applicable if close-out occurred within 2 weeks of acknowledgement, state **"NOT APPLICABLE"** on dotted line)* **…….**		
3	I confirm receipt of a close-out fax/ letter from	☐	☐
4	I confirm my satisfaction with the close-out action; **(If NO, state below what is still unacceptable)**	☐	☐

DISSATISFACTION STATEMENT:

MY PROPOSAL TO ENSURE CLOSE-OUT IS AS FOLLOWS:

SIGNATURE OF COMPLAINANT

DATE

SCF 009 – 2009-07-09

Annexure B

POSSIBLE ROOT CAUSES

1 Management

1.1 Belief system
1.1.1 Placing budgetary considerations ahead of quality
1.1.2 Placing schedule considerations ahead of quality
1.1.3 Placing political considerations ahead of quality
1.1.4 Being arrogant
1.1.5 Lacking fundamental knowledge, research or education
1.1.6 Pervasively believing in entitlement
1.1.7 Practicing autocratic behaviours, resulting in "endullment"

1.2 Communication
1.2.1 Communication tools lacking
1.2.2 Communication systems lacking
1.2.3 Ineffective communication system
1.2.4 Inefficient communication system
1.2.5 Lack/Inadequate of Handover

1.3 Structure
1.3.1 Wrong management structure
1.3.2 Inadequate supervision
1.3.3 Inadequate support

1.4 Responsibilities and authorities
1.4.1 Inadequate definition of tasks
1.4.2 Accountability
1.4.3 Deputies for key positions

1.5 Resource provision
1.5.1 Inadequate planning for future
1.5.2 Inadequate human resources
1.5.3 Inadequate equipment/ materials/suppliers
1.5.4 Lack of contingency plans

1.6 Job review
1.6.1 Job review not performed
1.6.2 Inadequate job, review
1.6.3 Customer requirements not understood
1.6.4 Not capability to perform job/service
1.6.5 Over promise

Efficient - converting the resources in the right way - achieving the desired Quality by optimizing the resources at the lowest cost. Effective - doing the right things to satisfy internal and external customer needs.

2 People

2.1 Human error (not intentional)
2.1.1 Misreading
2.1.2 Typing
2.1.3 Oversight
2.1.4 Mislabelling
2.2 Mentoring/Coaching
2.2.1 Mentors not assigned

2.2.2 Mentors not skilled
2.2.3 Coaching neglected

2.3 Competence
2.3.1 Training needs not identified
2.3.2 Training plans not formalized
2.3.3 Training plans not complete
2.3.4 Lack of training
2.3.5 Inefficient training

2.4 Behaviour
2.4.1 Negligence
2.4.2 Poor work practices
2.4.3 Non-adherence to procedures
2.4.4 De-motivated
2.4.5 Unsafe acts

2.5 Skills
2.5.1 Lack of appropriate skills
2.5.2 Staff recruited with wrong attributes
2.5.3 Lack of understanding of significance of job
2.5.4 Lack of understanding of significance of business
2.5.5 Career path missing

3 Systems (methods)

3.1 Processes
3.1.1 Processes not defined
3.1.2 Ineffective processes/systems
3.1.3 Inefficient processes/systems
3.1.4 Ineffective support services

3.2 Documentation
3.2.1 System documentation not available
3.2.2 Incomplete system documentation
3.2.3 Ineffective system documentation
3.2.4 Inefficient system documentation
3.3 Analytical methods
3.3.1 Analytical method not fit for purpose
3.3.2 Inadequate validated methods

4 Equipment

4.1 Technology
4.1.1 Old technology used
4.1.2 System errors
4.1.3 Design problem
4.1.4 Design investigation not done properly

4.2 Machinery
4.2.1 Equipment not fit for purpose
4.2.2 Inadequate validated equipment
4.2.3 Equipment contamination
4.2.4 Equipment out of calibration
4.2.5 Ineffective calibration

4.2.6 Lack of maintenance
4.2.7 Inefficient maintenance
4.2.8 Defective equipment

4 Materials

5.1.1 Unsatisfactory service from Suppliers
5.1.2 Unsatisfactory product from supplies
5.1.3 Stock level control lacking
5.1.4 Reference materials/consumables/services not fit for purpose

5.2 Sample handling
5.1.1 Non-representative sampling/sample preparation
5.2.2 Non-homogeneous sample
5.2.3 Contamination/deterioration due to incorrect storage or handling

5.3 Sample analysis
5.3.1 Dilution errors
5.3.2 Reagent/reference material error
5.3.3 Sample identification
5.3.4 Sample matrix problems
5.3.5 Sample concentration out of analysis range/recovery

5 Environment

6.1 Physical
6.1.1 Unsafe environment
6.1.2 Unhealthy environment
6.1.3 Uncontrolled testing/calibration conditions
6.1.4 Inadequate facilities
6.1.5 Inadequate security

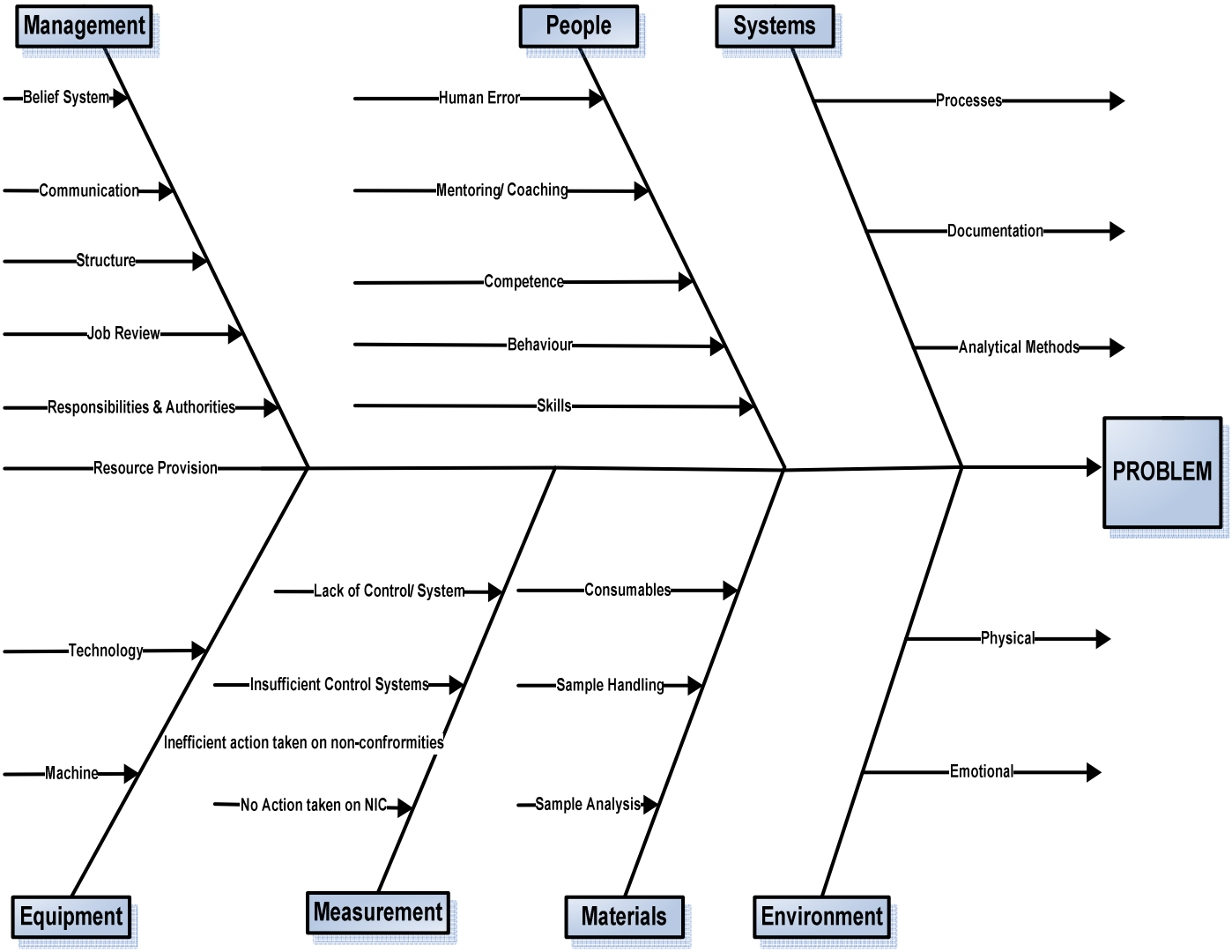
6.2 Emotional
6.2.1 Blaming culture
6.2.2 Victimization
6.2.3 Undue pressure
6.2.4 Unethical practices

6 Measurement

7.1 Lack of control systems
7.2 Insufficient control systems
7.3 Inefficient action taken on non-conformities
7.4 No action taken on non-conformities

Annexure C

IMPROVEMENT REQUEST – Root Cause Analysis



Annexure C 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 -

Amendment No.	Date approved	Nature of amendment
Issue 1 – Amdt 1 **Issue 1 – Amdt 3**	**2006-08-01** **2006-11-01**	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
Issue 2	**2006-11-01**	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
Issue 3	**2007-07-01**	Clauses 3.3 and 4.2 were amended to address SANAS Non-conformity number Ext 087/2007;
Issue 4	**2008-02-14**	Procedure revised to include the classification of IRQ's and to re-align the structure of the procedure.
Issue 5	**2009-02-03**	Par. 3, 4 and 7.6 were updated to address the current processes followed in SABS Commercial.
Issue 6	**2009-08-21**	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.

Issue 7	**2011-02-23**	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.
Issue 8	**2012-06-27**	Amendment on Name Change: (Pty) Ltd, replaced by SOC Ltd.
Issue 9	**2013-03-12**	Amendments were made to: Clause 4.4 new information has been added Clause 7.6.1. paragraph 2 and 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.