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1. APPLICATION

This document describes the corrective and preventive action process (recording, managing, resolving, and improvement) to be followed for all non-conformances, deviations from standard best practices or potential non-conformances. The main objective of having an efficient process for both corrective and preventive action is to demonstrate continual improvement to our processes and services. The outcome of this process should be a permanent and effective solution to problems or issues.

This procedure applies to all affiliates within the SGS RZA region and covers all business lines.
This document shall be read in conjunction with the *Non-Conforming product* PR-(RZA)-[GEN]QU-004 and the *Complaints and compliments* procedures PR-(RZA)-[GEN]QU-006.

2. DEFINITIONS

- **Correction:** Action taken to eliminate a detected nonconformity.
- **Corrective action:** Action taken to eliminate the cause of a detected nonconformance or other undesirable situation in the management system or process so as to prevent recurrence.

  NOTE: Deals with nonconformity that has occurred.
- **IR:** Improvement Request.
- **Non-conformance:** Non-fulfillment of a requirement.

  NOTE: This means that there is a gap between what is and what should be.
- **Preventive action:** Action taken to determine and eliminate the causes of a potential non-conformance or other undesirable potential situation to prevent occurrence.

  NOTE: Addresses the potential for non-conformance to occur.
- **Risk and opportunities:** Is the effect of uncertainty on objectives, that is managed through the identification, evaluation and prioritization of risks followed by coordinated resources and measures to minimize, monitor and control these uncertainties – either to opportunise on the positive impacts or reduce potential negative impacts.
- **Requirement:** A need or expectation that is stated, generally implied or obligatory.
- **Root cause:** A root cause is something that initiates a chain of events that eventually leads to a problem or issue of interest. The root cause is basically the reason why a problem started in the first place.

3. RESPONSIBILITIES AND AUTHORITY

3.1 **Any employee** who experiences or identifies an operational/management system problem or feels there is a need for an improvement has the responsibility and authority to initiate an IR.

3.2 **Managers** or **delegates** have the responsibility and authority to ensure that all *Improvement Request* form PF-(RZA)-[GEN]QU-012 are processed and any resultant improvement is implemented, effective and managed to completion within the predetermined time limit.

3.3 The **Manager** or **designated person** will monitor the improvement process to ensure the effective implementation of the solutions.

3.4 The **Manager** has the responsibility to inform the Operational Integrity Manager and higher-level management of any serious non-conformances that could lead to legal action.

3.5 A **designated person** shall be responsible for keeping the electronic *Improvement list* PF-(RZA)-[GEN]QU-008 up to date at all times

4. GENERAL

Non-conformances are normally a result of the following, but not limited to:

- Failure of resources (equipment, people, etc.) to meet either performance requirements or other specified requirements;
- Failure of organization and staff to comply with documented policies and procedures or work instructions; and
- Failure of test/inspection/verification data to meet required standards; i.e.:
  - Failure to meet all conditions necessary to ensure the integrity and representativeness of the sample (i.e. sample history deficiencies exist);
  - Failure to comply with the test/inspection/verification method and supporting work instructions;
  - Failure in method performance as demonstrated by results provided by QC samples;
  - Inherent property of the sample that compromises testing (e.g. as verified by method of standard additions); and
  - Relevant evidence as provided by data validation.
- Where any non-conformances are identified and cast doubt on the section's compliance with its own policies or procedures or to an ISO standard, special attention shall be given to the appropriate areas of activity during the next internal audit. An additional audit shall be arranged when non-conformances pose a serious issue or risk to the business.

5. CORRECTIVE ACTION

5.1 Need for corrective action

- Non-Conformances can be dealt with by simply correcting an abnormal condition or undertaking the more formal process of corrective action.
- Corrective action requires both careful consideration to determine the root cause of non-conformance and involves a number of individuals. Corrective action includes measures to immediately address problem (correction) and to see that the problems does not arise again.
- Corrective action shall be taken in the event of the following but not limited to:
  - Correction is not enough to prevent re-occurrence of a non-conformance;
  - Non-conformance adversely affect a business unit's ability to demonstrate competence;
  - Non-conformance creates an unacceptable risk to SGS; and
  - Reoccurrence of non-conformances that were dealt with through correction only.

5.2 Seriousness and urgency evaluation

- **High**
  - When a non-conformance has a direct impact on current and/or previous outcomes or poses a high business risk, then immediate action shall be taken. See 5.1 for guidance.
  - The investigation shall commence within 48hrs of the non-conformance being picked up.
  - The urgency shall be indicated as high on *the Improvement Request* form PF-(RZA)-[GEN]QU-012.
  - The impact on previously released results should be reassessed to ensure that were not affected or compromised in the process.

    NOTE: Where there is an indication that previously released results may have been affected or compromised, the *Non-Conforming Work* Procedure PR-(RZA)-[GEN]QU-004 shall be followed.

  - Corrective action - in the action plan and its due date should reflect the urgency and seriousness of the problem.
  - Investigation and corrective action should at least be completed within a month. In certain circumstances that are beyond the site/division's control the corrective action might take longer.

    NOTE: The reasons for not completion the corrective actions within the expected date shall be documented.

  - An additional month shall be added on the action plan to monitor and evaluate the effectiveness of the corrective action taken.
  - The seriousness of the non-conformance should be kept in mind at all times when setting due dates for action steps.

- **Medium**
  - When a non-conformance does not have a direct impact on outcomes or only poses a medium business risk, immediate action is not required.
  - The investigation shall commence within a week of the non-conformance being identified.
  - The urgency shall be indicated as medium on the Improvement Request form.
  - Corrections and action plans shall at least be completed within two months.
  - An additional month shall be added on the action plan to monitor and evaluate the effectiveness of the corrective action taken.

- **Low**
  - Non-conformances of an administrative nature or improvements could be considered as low.
  - The urgency shall be indicated as low on the *Improvement Request* form PF-(RZA)-[GEN]QU-012.
  - The investigation shall commence within a month of the non-conformance being identified.
  - Corrections and action plans shall at least be completed within two months.
  - An additional month shall be added on the action plan to monitor and evaluate the effectiveness of the corrective action taken.

5.3 Record keeping

- A non-conformance that requires corrective action shall be recorded on an *Improvement Request form* PF-(RZA)-[GEN]QU-012 (hard copy or electronic) and registered on the electronic *Improvement List* PF-(RZA)-[GEN]QU-008 so that information is properly controlled and measured.
- Corrections shall also be indicated and recorded on the *Improvement Request form* PF-(RZA)-[GEN]QU-012 (hard copy or electronic).
- Records shall be kept of any pre-investigations of a non-conformance.

  NOTE: Evidence should previous outcomes that were assessed for impact should be available.

- Where root cause analysis is required, it shall, preferably, be performed on the hard copy *Improvement Request* form PF-(RZA)-[GEN]QU-012. As an alternative, a separate list of possible root causes can be created but the same principles for investigation will apply as indicated under section 6.
- Action plans can either be documented on the *Improvement Request* form PF-(RZA)-[GEN]QU-012 or electronic *Improvement List* PF-(RZA)-[GEN]QU-008.
- Close out signatures shall be recorded on the hard copy *Improvement Request* form PF-(RZA)-[GEN]QU-012.
- Changes in system documents resulting from corrective actions shall be processed as document changes.

5.4 Identification of non-conformance causes

- Management shall incorporate root-cause analysis (as appropriate) into the corrective action process.
- See Annexure 1 for examples of possible causes of non-conformances.

  NOTE: Whenever a person's involvement relating to behaviour was indicated as the root cause, the human resource *Employee Relations Policy* RZA-HR-PO-ER-009 shall be followed.

6. IMPROVEMENT REQUEST (IR)

6.1 IR Process (Also see Annexure 2)

Initiator ↓

Any staff member who experience or identify an operational/management system problem or feels there is a need for an improvement has the authority to initiate an IR. Details of the problem/non-conformance/preventive action to be entered onto the IR form.

Forward ↓

Depending on the level where an IR has been initiated in a division / department / section it shall be:

- Forwarded to a line manager on a level higher than the initiator;
- To a peer for handling; or
- Handled by the manager himself

Initial Evaluation

The line manager/peer shall:

- Ensure that the detail entered onto IR form adequate for understanding and sign;
- Conduct a preliminary investigation to determine the nature and validity of the non-conformance;
- Where possible keep record of what considered during investigation;
- Determine whether correction is necessary or corrective/preventive action. When corrective/preventive action is required, the *Root Cause: Required* block on the form should be marked;
- Determine the seriousness and urgency with which IR needs to be dealt with and mark the relevant block (See 5.2 for guidance); and
- Identify a Designated Champion to make correction or to investigate.

Registration

The line manager/peer shall hand IR to designated person for registration.

- The designated person registers the IR on the electronic *Improvement List* PF-(RZA)-[GEN]QU-008 and fills in the necessary data.
- Hand IR form to Designated Champion to make correction or take corrective action.

Investigation

Correction only

The champion:

- If only correction is required, no root cause analysis needs to be done.
- Shall develop an action plan with responsibilities and time limits and indicate on IR form or electronic *Improvement List* PF-(RZA)-[GEN]QU-008*.*

Corrective action

The champion shall:

- Where corrective action needs to be taken, get together a team to investigate the problem. It is highly recommended that the person who raised the IR is part of this team, as well as a line manager;
- Ensure agreement amongst team on the problem statement;

  NOTE: A PROBLEM STATEMENT is a statement of exactly "what is wrong with what". In other words, what is the object and what is the defect. Team should make sure, problem statement is the real problem and not just a symptom or effect.

- Perform root-cause analysis and record details of all possible causes on the back of the IR form or in a list. See Annexure A to assist with identifying possible causes;
- Provide reasons for any of the possible causes that are eliminated;
- Table the possible causes and prioritize them on the *Improvement Request* form PF-(RZA)-[GEN]QU-012 or on electronic *Improvement List* PF-(RZA)-[GEN]QU-008*;*

Action plans

Develop an action plan with responsibilities and time limits and indicate on *Improvement Request* form PF-(RZA)-[GEN]QU-012 or electronic *Improvement List* PF-(RZA)-[GEN]QU-008*;*

- Allocate a realistic target date for close out;

  NOTE: The final due date is dependent on the duration of action steps but seriousness of non-conformance should always be kept in mind.

- All due dates shall be set in conjunction with the Line Manager who is to make a judgment call on the final due date setting; and
- Communicate target date and plan to management and designated person keeping electronic register.

Monitoring

The line manager is responsible to:

- Review the action plan for adequacy and timeliness;
- Monitor action plan progress; and
- Train employees on changes made.

Implementation

The champion is responsible to:

- Ensure that the necessary correction, corrective and preventive action is taken on time; and
- Gather evidence that the necessary actions have been taken.

Completion

The champion will:

- Complete the IR form once evidence is obtained that all the actions have been completed;
- Forward the form with evidence to the Manager in the department;
- Notify the Initiator of the action taken; and
- Circulate information as to the nature of the action taken to all interested/affected employees.

Evaluation

Should the Initiator consider the problem not to be satisfactorily addressed, and then refer the initial recourse to the Manager concerned. If agreement cannot be reached, the resolution of the matter should be directed to the designated person for further consideration.

The Manager shall:

- Immediately check how effective the investigation and implementation were carried out and do initial sign off if satisfied after a month;
- Sign off of IR if only correction was required (no investigation needed);
- After a month check whether the actions taken are still effective (may delegate); and
- Close out the IR through final sign off.

NOTE: The evaluation of effectiveness must be justified by evidence before final sign off.

Record keeping

Designated person shall:

- Ensure that the *Improvement List* PF-(RZA)-[GEN]QU-008 is kept up to date; and
- Completed IR forms plus information pertinent to the resolution of the feedback kept on file.

Trend analysis

Line management is responsible to investigate possible trends relating to on-the-spot actions.

The Manager is responsible for trend analysis on the improvements register so as to initiate further investigations or improvements.

6.2 If corrective action involves making recommendations to customers, the Business Unit Manager shall review the suitability and form of these recommendations and their implications.

6.3 If corrective action has not been fully completed by the due date and there are valid reasons why due date could not be met, the following shall be reported in writing (either as part of minutes or memo) to the line manager or designated person:

- What actions/steps have already been taken to clear the finding;
- Further actions required; and
- New due date.

NOTE: Due dates on forms or register shall never be changed. Notes can be made to indicate reasons for not meeting deadlines and new due dates. Improvement request could then be considered as still open and not overdue.

6.4 Trend analysis data shall form part of the documentation used for management review input.

6.5 The laboratory manager or designate will update the risks and opportunities identified during planning and implementation of corrective actions. Updating of Risk and Opportunities shall be done on the *Risk and Opportunities Register* PF-(RZA)-[GEN]MA-002.

7. PREVENTIVE ACTION

- **General**
  - Preventive action is a proactive process to identify opportunities for improvement (new and potential non-conformances) rather than a reaction to the identification of problems, non-conformances or complaints.
  - Every employee shall attempt to identify improvements and potential sources of non-conformances, either operational or concerning the management system.
  - The preventative actions taken shall be appropriate to the effects of potential risks or improvement.

- **Sources for preventive action**
  Sources of information for identifying opportunities for prevention or improvement could include, but not limited to:
  - Management reviews
  - Process planning
  - Corrective action
  - Audit results
  - Training
  - Customer feedback
  - Growth objectives
  - Maintenance
  - Employee feedback
  - Market surveys
  - Analysis of data
  - Meetings

- **Preventive Action Process**
  - If preventive action is identified, it shall be reported to the Managers and/or designated person responsible for quality for initiating a working group to investigate. Preventive actions are viewed as strategic issues and the work groups shall investigate and determine appropriate action plans.
  - The work group shall be responsible for implementing and monitoring the action plan to ensure that the appropriate actions are taken within a reasonable time frame and that resulting changes work.
  - Records of the whole process shall be maintained and controlled by a designated person. The format in which the actions should be documented could vary from a formal IR, minutes, management program, reports, project plans, etc.
  - The Manager shall ensure that the effectiveness of preventive action is controlled as he would for corrective actions.

8. REVIEW

The summary of the corrective and preventive actions (IRs, complaints, and compliments) shall be reviewed with laboratory manager (however named) at specified intervals. The annual summary will be reviewed during management review.

9. DOCUMENTS REQUIRED

- *Improvement Request* form PF-(RZA)-[GEN]QU-012
- *Improvement List* PF-(RZA)-[GEN]QU-008
- Evidence of actions taken
- Meeting Minutes
- *Risk and Opportunities Register* PF-(RZA)-[GEN]MA-002

10. REFERENCES

- *Management System Policy Manual* PR-(RZA)-[GEN]MA-001
- *Non-Conforming Work* procedure PR-(RZA)-[GEN]QU-004
- *Complaints and Compliments* procedure PR-(RZA)-[GEN]QU-006
- *Document Control* procedure PR-(RZA)-[GEN]QU-002
- *First, Second and Third-Party Audit* procedure PR-(RZA)-[GEN]QU-007
- *Employee Relations Policy* RZA-HR-PO-ER-009

11. REPLACEMENT AND REVISION HISTORY

This document replaces *Corrective and Preventive Action* PR-(RZA)-[GEN]MA-005 procedure, Rev. 06 dated April 2016.

Type of Change	Section	Date
Revised to align with ISO17025:2017	All Sections	June/July 2018

12. APPROVAL

Authorization	Name	Job Title	Signature	Date
Compiled/reviewed by:	Nyiko Bopape	Quality Manager		August 2018
Approved by:	Mageshan Ramiah	Sub-Saharan Africa Operational Integrity Manager		August 2018

ANNEXURE 1: POSSIBLE ROOT CAUSES

Cause analysis is the key and sometimes the most difficult part in the corrective action process. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required.

NOTE: 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

MANAGEMENT

- **Belief system**
  - Placing budgetary considerations ahead of quality;
  - Placing schedule considerations ahead of quality;
  - Placing political considerations ahead of quality;
  - Being arrogant;
  - Lacking fundamental knowledge, research or education;
  - Pervasively believing in entitlement; and
    Practicing autocratic behaviors, resulting in "endullment".
- **Communication**
  - Communication tools lacking;
  - Communication systems lacking;
  - Ineffective communication system;
  - Inefficient communication system; and
  - Lack/Inadequate of Handover.
- **Structure**
  - Wrong management structure;
  - Inadequate supervision; and
  - Inadequate support.
- **Responsibilities and authorities**
  - Inadequate definition of tasks;
  - Accountability; and
  - Deputies for key positions.
- **Resource provision**
  - Inadequate planning for future;
  - Inadequate human resources;
  - Inadequate equipment/ materials/suppliers; and
  - Lack of contingency plans.
- **Job review**
  - Job review not performed;
  - Inadequate job review;
  - Customer requirements not understood;
  - Not capability to perform job/service; and
  - Over promise.

PEOPLE

- **Human error (not intentional)**
  - Misreading;
  - Typing;
  - Oversight; and
  - Mislabeling.
- **Mentoring/Coaching**
  - Mentors not assigned;
  - Mentors not skilled; and
  - Coaching neglected.
- **Competence**
  - Training needs not identified;
  - Training plans not formalized;
  - Training plans not complete;
  - Lack of training; and
  - Inefficient training.
- **Behaviour**
  - Negligence;
  - Poor work practices;
  - Non-adherence to procedures;
  - De-motivated; and
  - Unsafe acts.
- **Skills**
  - Lack of appropriate skills;
  - Staff recruited with wrong attributes;
  - Lack of understanding of significance of job;
  - Lack of understanding of significance of business; and
  - Career path missing.

SYSTEMS (methods)

- **Processes**
  - Processes not defined;
  - Ineffective processes/systems;
  - Inefficient processes/systems; and
  - Ineffective support services.
- **Documentation**
  - System documentation not available;
  - Incomplete system documentation;
  - Ineffective system documentation; and
  - Inefficient system documentation.

EQUIPMENT

- **Machinery**
  - Equipment not fit for purpose;
  - Inadequate validated equipment;
  - Equipment contamination;
  - Equipment out of calibration;
  - Ineffective calibration;
  - Lack of maintenance;
  - Inefficient maintenance; and
  - Defective equipment.
- **Technology**
  - Old technology used;
  - System errors;
  - Design problem; and
  - Design investigation not done properly.

MATERIALS

- **Consumables**
  - Unsatisfactory service from Suppliers;
  - Unsatisfactory product from supplies;
  - Stock level control lacking; and
  - Reference materials/consumables/services not fit for purpose.
- **Sample handling**
  - Non-representative sampling/sample preparation;
  - Non-homogeneous sample; and
  - Contamination/deterioration due to incorrect storage or handling.
- **Sample analysis**
  - Dilution errors;
  - Reagent/reference material error;
  - Sample identification;
  - Sample matrix problems; and
  - Sample concentration out of analysis range/recovery.

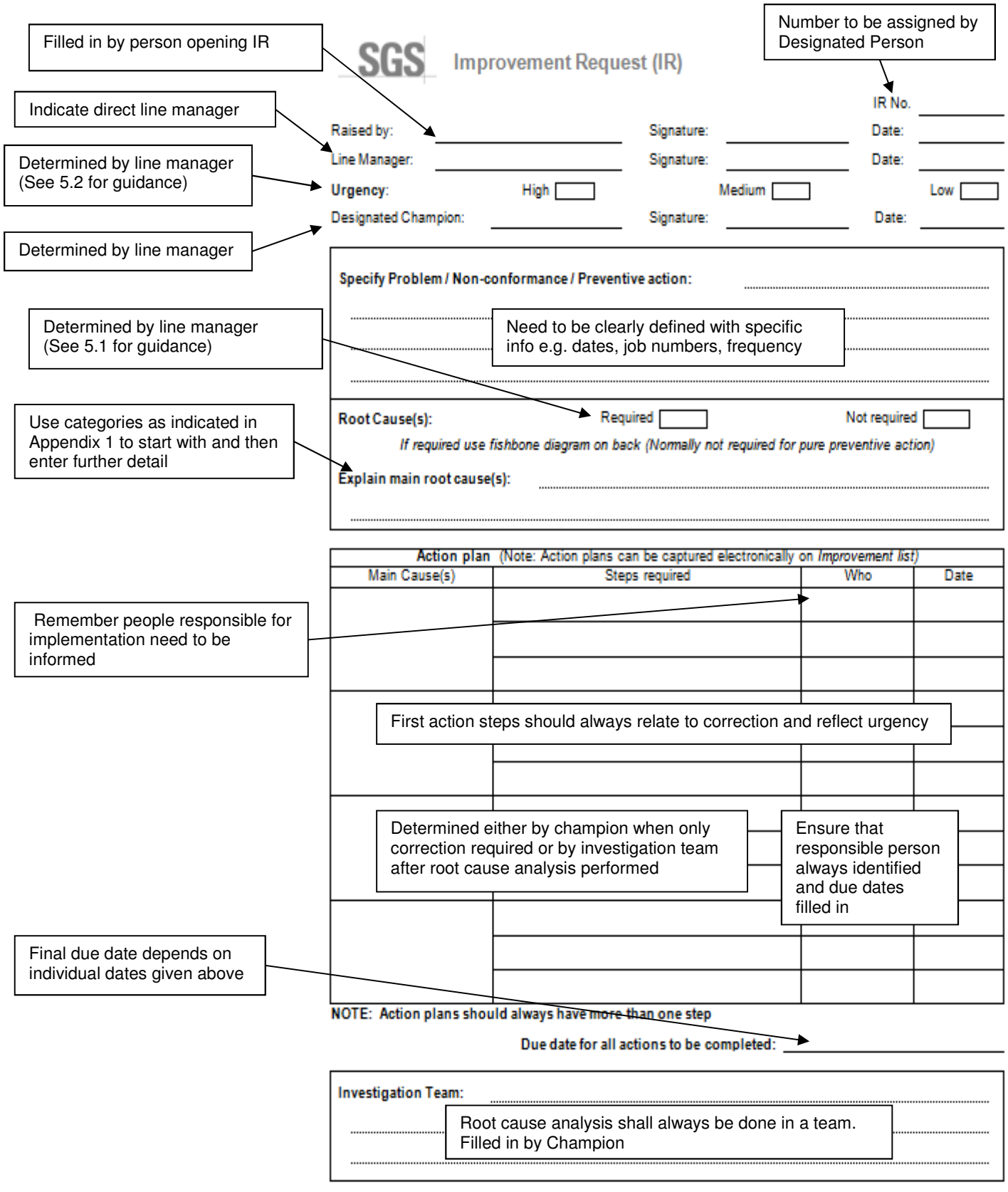
ENVIRONMENT

- **Physical**
  - Unsafe environment;
  - Unhealthy environment;
  - Uncontrolled testing/calibration conditions;
  - Inadequate facilities; and
  - Inadequate security.
- **Emotional**
  - Blaming culture;
  - Victimization;
  - Undue pressure; and
  - Unethical practices.

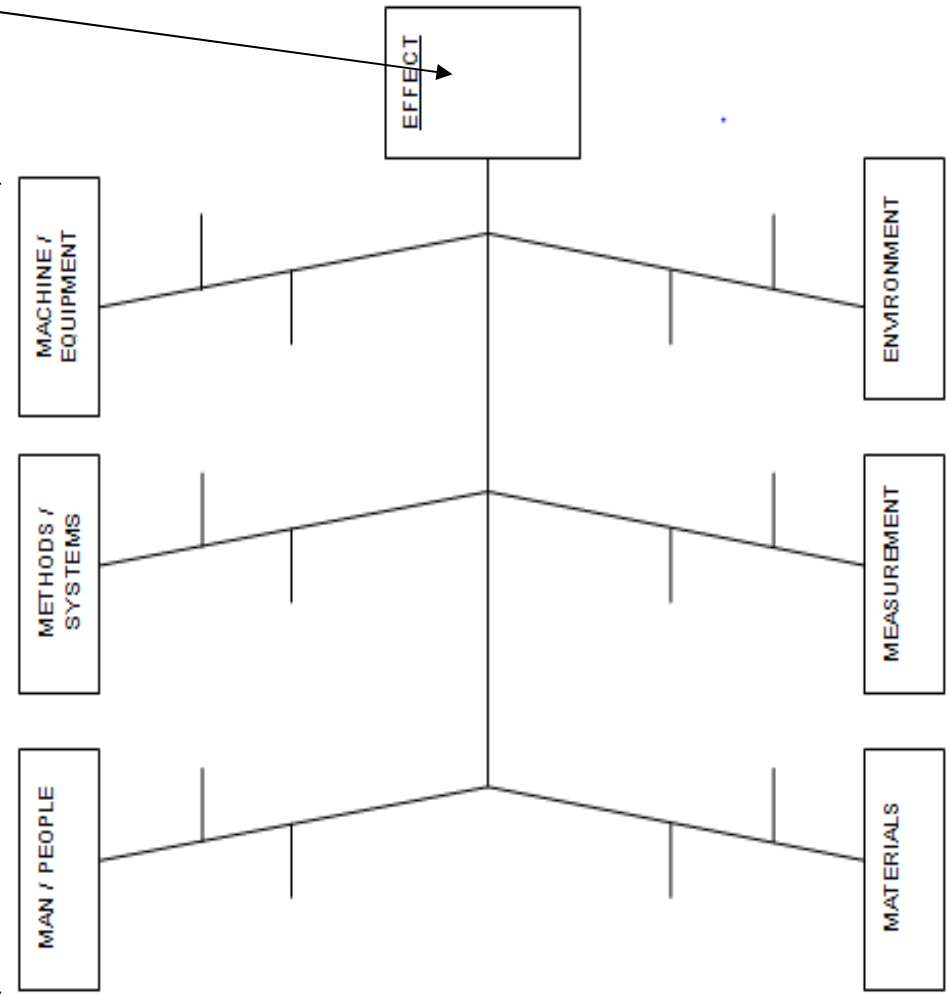
MEASUREMENT

- **Lack of control systems**
  - Insufficient control systems;
  - Inefficient action taken on non-conformities; and
  - No action taken on non-conformities.

ANNEXURE 2 - Guidance on how to complete an *Improvement Request* form PF-(RZA)-[GEN]QU-012



Enter problem statement in the head



1. Determine major categories that could have caused problem and circle
2. **Brainstorm** potential root causes to problem and group them under the "bones" of fish. Examples ask… "**What** under "people" causing the problem?"
3. By asking "**Why** does it happen?" several times, drill down into causes by adding sub-causes.
4. **Team** decides what most likely root causes of problem are. Elements eliminated should be crossed through and reasons for elimination recorded. Most likely causes put into action plan.

NOTE: Refer to Appendix A on *Corrective and Preventive Action* Procedure for possible root causes

See definitions for guidance to classify

Action taken: Correction ☐ Corrective ☐ Preventive ☐

Action Completed by: Signature: _____ (Designated Champion) Completion Date: _____

Designated champion to ensure this section completed when all action taken and evidence available

Effectiveness of Change / Action (a month after implementation):

Was the immediate problem fixed?	Y	N	Was corrective action taken to prevent re-occurrence?	Y	N
Was root cause analysis performed?	Y	N	Is there evidence to support actions taken?	Y	N
Was the action plan implemented based on root cause analysis?	Y	N	Was corrective action followed up within a reasonable time period?	Y	N

Close out:

Initial: Signature: _____ (Line manager) Date: _____

Final: Signature: _____ (Line manager / designated person) Date: _____
(a month after implementation)

Sign off done by manager / designated person immediately if only correction taken. Final sign off by manager / designated person only after at least a month when corrective action taken.