ANNEX 10
Gap Analysis Plan

Laboratory	**SAZ (STANDARD ASSOCIATION OF ZIMBABWE) MICROBIOLOGY LABORATORY**
Address	17 Coventry Rd, Workington I P O Box 2259 I Harare, Zimbabwel
Contact	Ms. Eve GADZIKWA, Director General Mr. Cyril M. SIRINGWANI, Director Technical Services Ms. Penia MUBIKA, Chem. & Food Manager
Standards / Guidelines	ISO IEC 17025 ISO 7218 SADCAS (SOUTHERN AFRICAN DEVELOPMENT COMMUNITY ACCREDITATION) requirements for testing laboratories ISO Technical standards related to the scope of accreditation

Expert	Marcel GBAGUIDI
Provisional Scope of accreditation	– *Total Plate Count* – *E Coli* – *Total Coliform bacterial* – *Salmonella* – *Yeast and molds*
Type of intervention	On site diagnosis
Period	07 – 09 APRIL 2014
Site	Microbiology Laboratory (COVENTRY)

Purpose of the Gap Analysis

Verify if the technical and organizational arrangements established and implemented on the microbiology laboratory aims to assure that the quality of services relating to accreditation scope, are technically valid, adapted to the services provided, in accordance with the requirements of ISO IEC 17025 & SADCAS, the guidelines of ISO 7218 & relevant technical standards and are effectively and efficiently implemented.

Gap Analysis methodology:

The Gap Analysis methodology consists:

→ **mainly of reviews of level of application of requirements of relevant standards & guidelines mentioned above to sort out strengths and weaknesses of the laboratory QMS:**

- Technical and organizational provisions and evidence of their implementation ;
- Life of the quality system through reports of internal audits and management reviews, quality actions plans, management of non-conforming work, measurement of customer satisfaction and processing claims;
- The competence of persons performing all or part of the tests of the scope of accreditation;
- The realization of all or part of the tests;
- Participation in interlaboratory comparisons.

→ **Opportunities and threats analysis to study impact of the external environment on the laboratory QMS**

This Gap Analysis plan could be subject to adjustments.

Gap Analysis Plan

07 – 09 April 2014		
07 April 2014		
Hours	**Opening meeting**	
9h30 AM – 04PM Break at 1H00 PM (about 60mn)	- Presentation of participants - Reminder: type of assessment, assessment objectives, standards, - Assessment organization, Assessment Plan	**E***
	Review of technical requirements - Validation of accreditation scope - Review of requirements related to personnel: Enabling, qualifications, competence maintenance, training plan, job descriptions, deputy positions, and test reports signatories - Test methods, validation - Equipment & metrology - Reagents & consumables - Facilities, premises & environment - Sampling and sample management - Quality of results, reference material - Participation to proficiency tests on inter laboratory comparison - Traceability - Test reports.	**E**
08 April 2014		
9H30 AM – 04PM Break at 1H00 PM (about 1H)	- Review of quality management requirements - Quality policy, organization & quality management, - Document control methodology - Contracts & requests reviews - Subcontracting & Structure - Purchasing products and services - Service aux clients - Management of claims - Management of non conformities - Correction, Corrective & preventive actions - Improvement strategy, indicators - Internal audits & management reviews	**E**
09 April 2014		
Hours	**Assessment Report**	**E**
9h00 AM -10h00 AM	- Report finalization - Closing meeting preparation	**E**
10h00 AM – 11h00 AM	**Closing meeting**	**E**
	- Reminder of audit objectives - Conclusions - Non conformances form - Laboratory comments (if any) - Further actions	**E**

(*): E: Expert: Marcel GBAGUIDI

REPUBLIC OF ZIMBABWE

STANDARDS ASSOCIATION OF ZIMBABWE

ANNEX 11
Microbiology Laboratory
GAP ANALYSIS

ISO IEC 17025 REQUIREMENTS
SADCAS REQUIREMENTS

8-10 APRIL 2014

Marcel GBAGUIDI
International Expert in Management Systems
QUALITY _ CONFORMITY ASSESSMENT_ACCREDITATION

We especially present our gratitude to
SAZ Director General, Ms. Eve GADZWIKA
SAZ Director technical Services, Mr. Cyril SIRINGWANI
SAZ Chemical & Food Manager, Ms. Penia MUBIKA
Microbiology and chemistry laboratory SAZ Staff

SYNOPSIS

I / SAZ Microbiology LMS: Strengths & Opportunities

II / Threats & Points of Effort: **NCs**

III/ Recommendations for improvement

I / SAZ Microbiology LMS: Strengths & Opportunities

- ✓Strong involvement of the Top management
- ✓Strong involvement of the personnel
- ✓Quality Management system well documented

IN SAZ

- ✓Culture of quality (Certification System Service accredited, inspection body accredited)
- ✓SAZ Chemistry Lab accredited
- ✓Qualified internal auditors
- ✓Internal metrology service

AT NATIONAL LEVEL & IN THE REGION

- ✓Microbiology laboratory accredited in Harare & in the region (South Africa) for benchmarking
- ✓National Metrology Institute
- ✓Accredited Calibration Laboratories in the region (South Africa)

II / Threats & Points of Effort: NCs

A/ ISO IEC 17025 Quality requirements

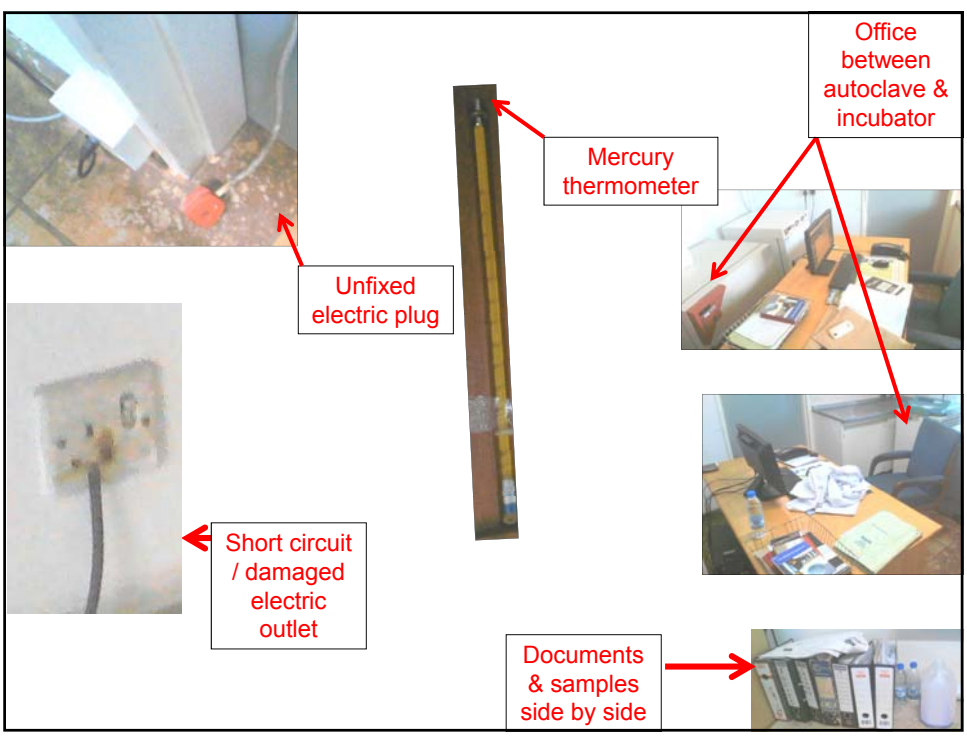
B/ ISO IEC 17025 technical requirements

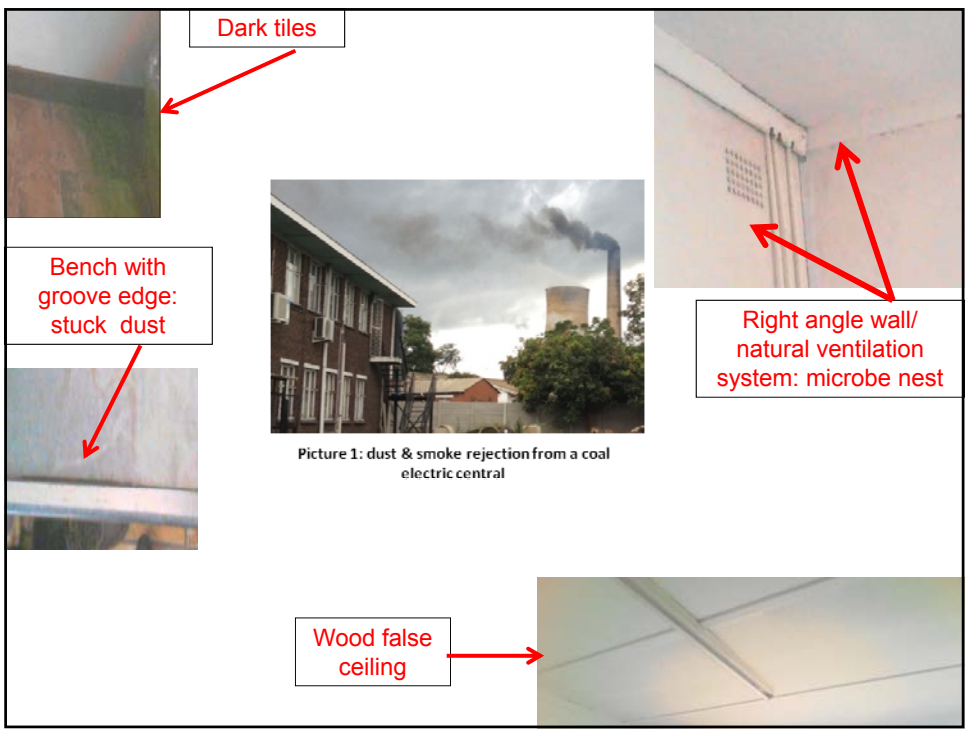
✓The premises do not comply with the applicable guidelines in food microbiology (ISO IEC 7218) as well as safety rules

✓The external environment is not favourable for trace analysis, with the presence in the neighbourhood of a coal electric central and an industrial manufacturing unit for production of agricultural fertilizers (rejection of smoke & dust containing various micro pollutants)

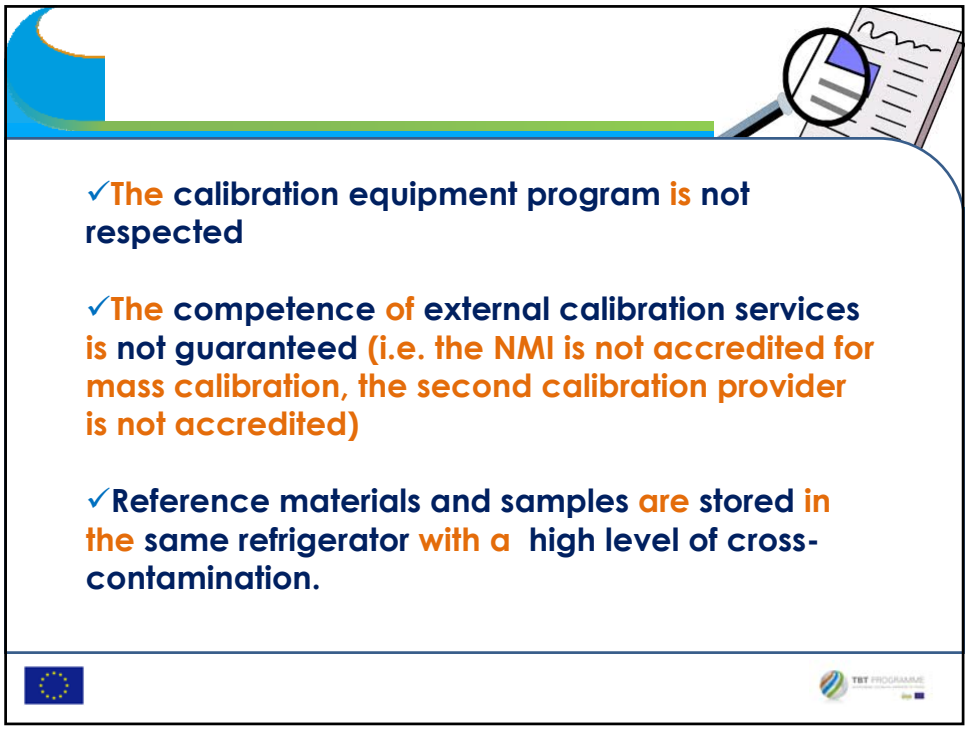
✓Office of technical officer installed between the autoclave (high pressurized equipment for destroying contaminated products) and incubators (heating equipment containing contaminated products)

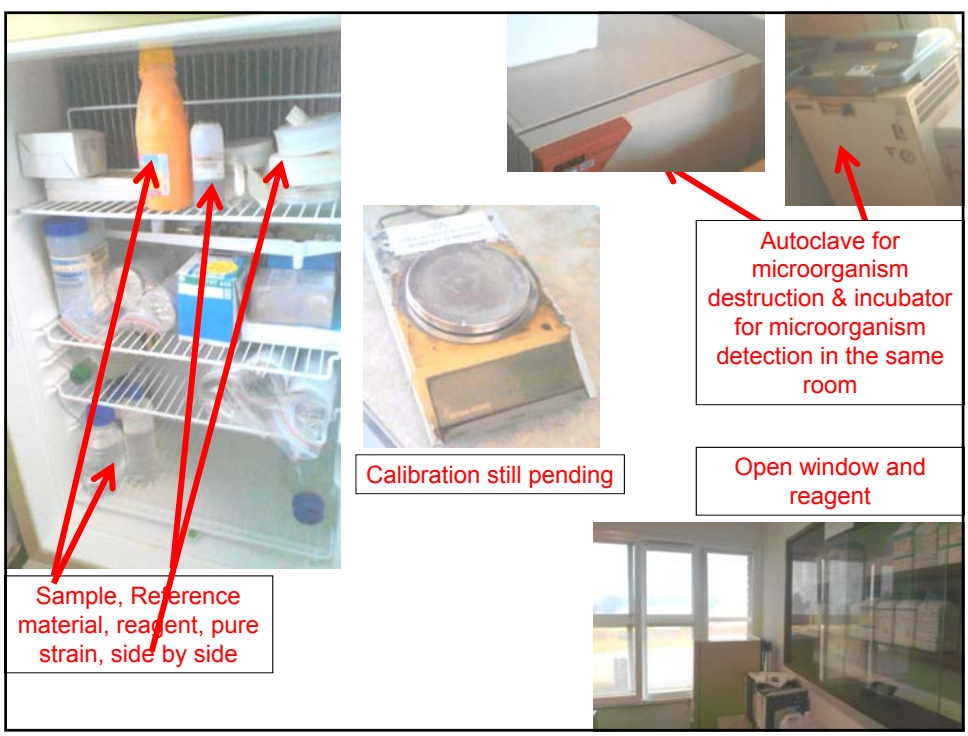
✓The premises do not allow early detection of potential sources of contamination and are not conducive to the cleaning activities for prevention of contamination (dark tile, paint water on walls, false ceiling, wall angle law, bench with groove edges, lava hand hard to reach)

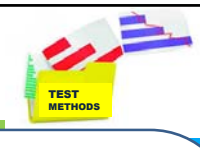




- ✓The sources of external contamination are not controlled (window pane giving free access to dust)
- ✓The design of the premises not avoid the risk of cross contamination.
- ✓ Thermometer, in the room dedicated to culture medium preparation, does not allowed to properly collect the current temperature
- ✓The current temperature of the room can easily reach 28^0C - 30^0C during the hot season while the incubation temperature for the determination of yeast and molds is 25^0C


✓The calibration equipment program is not respected
✓The competence of external calibration services is not guaranteed (i.e. the NMI is not accredited for mass calibration, the second calibration provider is not accredited)
✓Reference materials and samples are stored in the same refrigerator with a high level of cross-contamination.

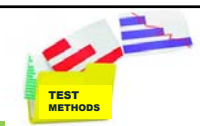

Sample, Reference material, reagent, pure strain, side by side
Calibration still pending
Autoclave for microorganism destruction & incubator for microorganism detection in the same room
Open window and reagent



✓The analytical methods used by the laboratory are neither validated (technical requirement) nor approved (document control requirement). Their requirements are not applied correctly (incubation realized at 37C while 36C is required in the method)

✓The required intermediate monitoring of temperature during incubation is not realized
The internal thermometers of incubators & autoclave are not enough to ensure that these equipments are heating correctly

✓The inter-comparison results are not generally satisfactory.



✓The measurement of uncertainty is not determined

✓The designation of persons authorized to sign the test reports and issue opinions & interpretations is not documented.

✓The analysis report provides no section for filling information on programme and sampling procedures

✓Traceability is not ensured: the realization of the different activities related to testing is not recorded in due time.

✓The evidences of the competence of The 2 microbiologists for the tests selected for accreditation are not available (no witness report).
✓The laboratory officer spent a year without performing analysis: The competence of personnel performing microbiology test are not guaranteed.

✓Records related to training, job description experience, etc. of the two microbiologist are not complete.

✓Quality of consumables after delivery is not checked.

✓ The place of storage of reagents (near open windows) is conducive to cross-contamination.

✓The temperature conditions specified by the supplier for the storage of reagents are not always respected

III/ Recommendations for improvement

Recommendation 1
Build as soon as possible suitable premises for sensitive testing activities presenting a high level of risk of cross contamination such as microbiology and analysis of contaminants, especially pesticide residues.

Recommendation 2
Continue Strengthening capacity building of laboratories technicians in MQS tools

Recommendation 3
Implement the priority actions identified in the correction actions plan to ensure the minimum compliance with safety & quality requirements in microbiology.

Thank you for your attention

Time to……..

Questions, Comments?