Improvement of testing laboratories competency for economic and social growth

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Abstract
Consumers everywhere expect consistent provision of quality products that they purchase. They need constant assurance that products procured exhibit little or no variation and are safe for use. These expectations can be satisfied when there is conformity, especially in measurements made during the manufacturing processes. To ensure this conformity, the testing laboratories must provide accurate analytical results, manned by well trained staff with well calibrated equipments so as to be able to reduce costs due to reduce wastage and health risks. Laboratory accreditation and profiency testing (PT) yield correct results that enable better technical and socio-economic decisions to be made and thus enhance efficiency of our businesses. We have about 300 testing laboratories in Kenya out of which only less than 10 are accredited. The accredited laboratories are required to periodically participate in PT. In the Second Round EAC PT in 2007, 25 and 33 laboratories in EA region paticipated in chemical composition for drinking water and wheat flour PT respectively. The z-scores were used as a basis for proficiency assessment for analytes for each respective determinands. The result from the participating laboratories in the wheat flour PT was: 53% (13) produced satisfactory results; 28% (7) did not produce reliable results with 9% (2) as questionable results and 19% (5) as unsatisfactory results; 19% (5) did not submit the results of their tests. The results for chemical composition for drinking water PT was: 60% (20) produced satisfactory results; 24% (8) did not produce reliable results; 16% (5) did not submit the results of their tests. These inconsistent results from different laboratories after analysing the same sample demonstrate that the quality of data obtained from some of our laboratory is questionable. This paper therefore proposes that our testing laboratories should aggressively seek to be competent by getting accreditation by recognised accrediting bodies.

Key words: laboratory accreditation, proficiency assessment, testing laboratories, proficiency testing, calibration, z-score, determinands, socio-economic

INTRODUCTION

Research results obtained from laboratory testing may exhibit variability for the same test of a given sample. The reasons may range from the suitability, calibration and maintenance of test equipment; testing environment; validity and appropriateness of test methods; and quality assurance of test and calibration data (ILAC, 2001). The sampling, handling and transportation of test items, traceability of measurements and calibrations to national standards and competence and training of the laboratory staff may also have an impact on the laboratory results (Silva, 2007). Reliable, traceable and comparable measurements provide the rational basis for evaluation of the quality of a result and the starting point for recognized laboratory accreditation in any national area (Buzoianu and Enein, 1998). There are many effective management training programs but many times training alone does not guarantee observable changes in laboratory practice (Yao *et. al.*, 2010). Without accurate, precise and reliable laboratory results, it would be difficult for researchers to come up with any meaningful innovations. This challenge may be overcomed by accreditation of laboratories.

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Accreditation is third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (KENAS, 2009). It provides feedback to laboratories as to whether they are performing their work in accordance with international criteria for technical competence (Kanagasabapathy and Rao, 2005). Essentially, it provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing, measurement and calibration services able to meet their needs (ILAC, 2001). Accreditation eliminates the need for suppliers of products or services to be certified in each country where they sell their products or services (Behrens and Wloka, 2008). The heart of the accreditation process is a scope of accreditation which is well-defined to constitute a credible attestation to the qualifications of a laboratory to avoid ambiguity and it's important in deterrmining technical competence of laboratory (Leclercq, 2002).

Laboratory accreditation is important because laboratory studies, tests, and chemical analyses play an important role in the economy, medicine, foodstuff control, military science, environmental protection and social transformations (Zolotov, 2009). For instance, the Goverment of Kenya (GoK) increased the recurrent expenditure of Kenya Council of Science and Technology from 118.0 million in 2006/2007 financial year to 535.5 million in 2010/2011 financial year (KNBS, 2011). This vast allocation of funds to KCST was as deliberate effort of GoK to promote meaningful research that leads to innovations that promote her Vision 2030. Unfortunately, this goal will not be easily realized if the scientists perform research in unaccredited laboratories that are still contending with both technical and non-technical factors that lead to variability in laboratory results. For instance, in Kenya we have about 300 testing laboratories (excluding universities and research institutions) out of which only less than 10 are accredited.

Africa's motivation and commitment to improvement in quality laboratory service processes is due to the fact that, up to 60% of clinical errors during healthcare delivery have a root course traceable to the diagnostic techniques and processes which under proper quality system can be minimised (Omondi, 2012). Studies have shown that there are high occupational hazards to non-accredited medical laboratory such as laboratory-acquired infections and more general risks of laboratory practice such as fires, explosions, gassings, and physical injury. For instance, epidemiological studies of laboratory populations indicated that there was an increased risk among British medical laboratory workers of acquiring tuberculosis of between two and nine times the national rates (Harrington and Shannon, 1977). Further, consequences of producing inaccurate results is detrimental to general public health, damage to corporate image, loss of economic profits and exposure to legal proceedings (EAC WF PT Report, 2007).

METHODS

Thirty-three and twenty-five laboratories in EA region paticipated in EAC PT (second round, 2007) for wheat flour and chemical composition for drinking water repectively. After analysing the samples for each respective determinands, the laboratories submited each of their results to PT provider in a standard results template. The PT provider allocated these laboratories confidential Laboratory Code numbers and used Robust Statistics version (based on Median Absolute Difference - MAD) for statistical evaluation of the proficiency testing results. As a result, the z-scores were used as a basis for proficiency assessment; that is:

$$z - score = \frac{x_i - X}{\sigma}$$; Where:

x_i was laboratory result; X was assigned value for determinand derived from median of results of all the participating laboratories; σ was standard deviation for the proficiency assessment. The standard deviations for proficiency assessment σ were identical with reproducibility standard deviations from the intercomparison standard deviation in those cases where the latter were smaller than the upper limits for the relative standard deviations. In exceptional case, the standard deviations for proficiency assessment σ were obtained as a product of assigned value and the upper limit for the relative standard deviation (RSD). The upper limit of RSD for different parameters was set in the PT scheme to avoid unrealistic large tolerance limits due to a wide scatter of laboratory results.

RESULTS

Table 1 and Table 2 show EAC PT (Round 2 in 2007) for wheat flour and chemical composition for drinking water respectively. The z-scores were used as a basis for the proficiency assessment for the both 25 wheat flour proficiency testing laboratories and 33 compositition of water testing laboratories. The general criterion for z-scores was as follows:

$|z| \leq 2$: Satisfactory results

: Questionable results – This is a warning signal, that something wrong is about to happen and vigilance is needed to prevent things from going astray.

Unsatisfactory results – This is a corrective signal and it is an indication that something has already gone wrong and corrective action needs to be carried out.

The number of laboratories that obtained satisfactory results, questionable results, unsatisfatory results and who did not submit back their results for different analystes were summarized as a percentage in Table 1 and Table 2.

Table 1: Summary of Performance of 25 Laboratories on Wheat Flour Content Determination (Source: EAC Proficiency Testing Round 2 in October, 2007)

Lab Performance	Moisture Content	Total Ash	Crude Fat	Crude Protein	Acidity as Lactic Acid	Acidicty as Sulphuric Acid	Total %
Satisfactory results	84%	80%	48%	56%	32%	20%	53%
Questionable results	12%	8%	4%	4%	12%	12%	9%

Unsatisfactory results	4%	12%	32%	20%	20%	28%	19%
Results not returned	0%	0%	16%	20%	36%	40%	19%
	100%	100%	100%	100%	100%	100%	100%

Table 2: Summary of Performance per Laboratory on Six Tests of Wheat Flour Composition (Source: EAC Proficiency Testing Round 2 in October, 2007)

Lab Code	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
Satisfactory Level in % from All Parameters	50	33	67	50	50	33	33	67	33	67	33	50	67
Lab Code	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	
Satisfactory Level in % from All Parameters	83	83	16	33	50	50	67	50	50	33	100	83	

The wheat flour content PT invoved participants analysing moisture content, total ash, crude fat, crude protein, acidity as lactic acid, acidicty as sulphuric acid of wheat flour sample. From Table 1, it can be demonstrated that the quality of anlytes obtained from laboratory that participated in the wheat flour proficiency testing in 2007, only 53% produced satisfactory results. Twenty-eight per cent of the results obtained from the laboratories did not produce reliable results with 9% as questionable results and 19% as unsatisfactory results. The acidity as lactic acid and acidicty as sulphuric acid analysis had a widest variability with the lowest satisfactory results by 32% and 20% of the laboratories respectively (see Figure 1 and Figure 2). The highest satifactory results were obtained from analysis of moisture content and total ash by 84% and 80% of the laboratories respectively. It should be noted from Table 2 that only 4% (one) laboratory that participated in PT obtained satisfactory results for all the six tests; that is 100% for all tests. If the threshold of performance is set at 83% and 67%, the performance on six tests for laboratories will be 16% (4 laboratories) and 32% (8 laboratories) as indicated in Table 2. Sixty-eight per cent of the laboratories had 50% and below satisfactory level on all the six parameters.

Figure 1: Z-Scores for Acidity as Lactic Acid in Wheat Flour Test Material

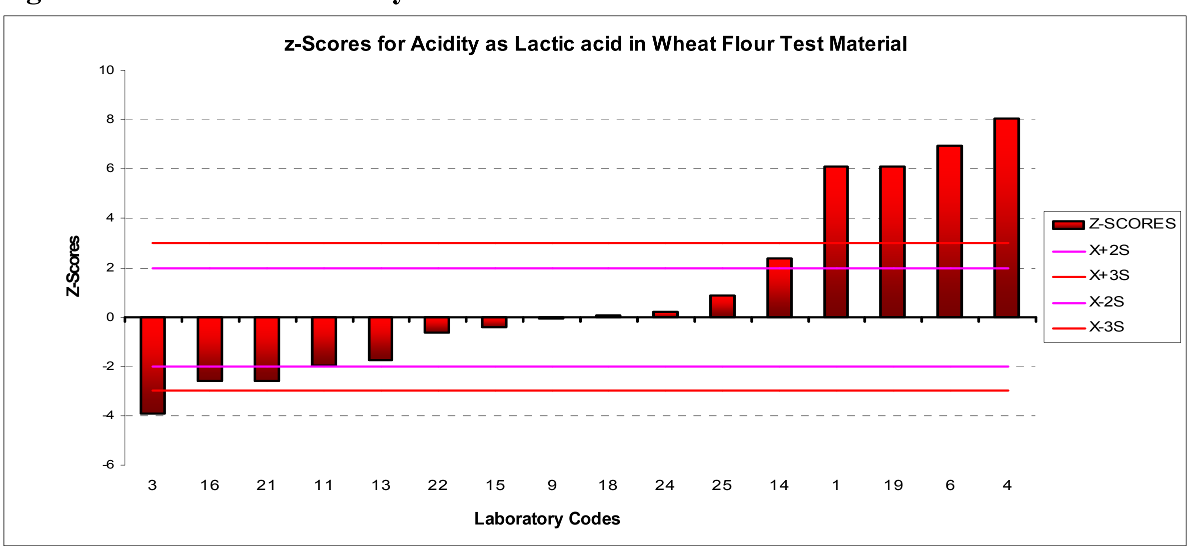

Figure 2: Z-Scores for Acidity as Sulphuric Acid in Wheat Flour Test Material

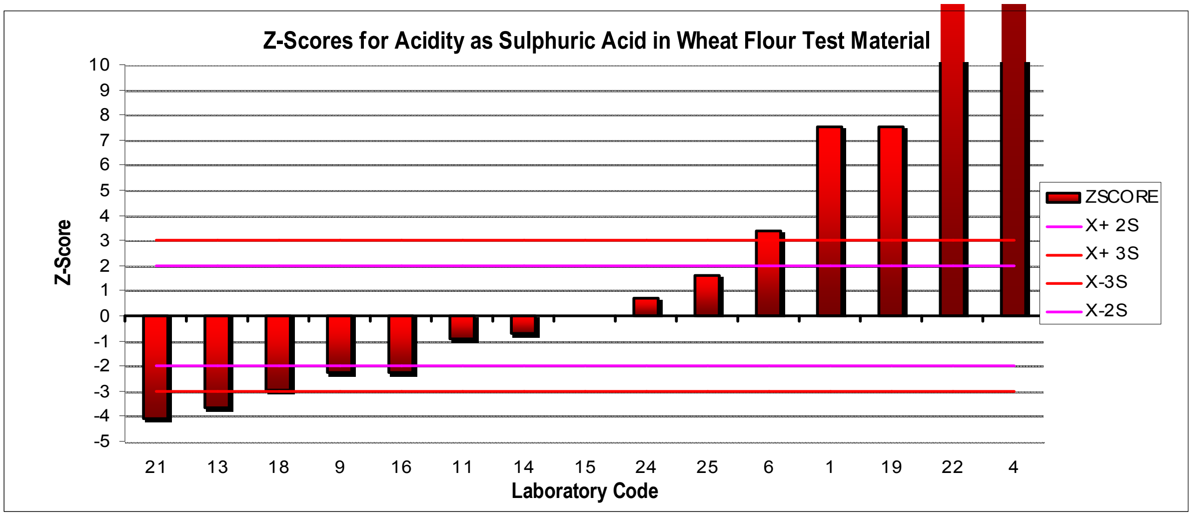

Table 3: Summary of Performance of 33 Laboratories on Chemical Composition of Drinking Water Content Determination (Source: EAC Proficiency Testing Round 2 in October, 2007)

Lab Performance	Calcium	Magnesium	Sodium	Potassium	Total Hardness	Chloride	pH	Elec trical Conductivity	Sulphate	Total %
Satisfactory results	70%	70%	36%	24%	67%	52%	94%	64%	64%	60%
Questionable results	3%	3%	9%	3%	6%	6%	3%	0%	3%	4%
Unsatisfactory results	21%	24%	13%	33%	15%	27%	0%	18%	24%	20%
Results not returned	6%	3%	42%	40%	12%	15%	3%	18%	9%	16%
	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Table 3 indicates the results of analysis of two water samples: one sample (EAC PT 2007/1) containing the cations calcium, magnesium, sodium, potassium; while the second one (EAC PT 2007/1) contained the anions chloride and sulphate where also pH and electrical conductivity was determined. The overall laboratories performance on the nine tests (calcium, magnesium, sodium, potassium, total hardness, chloride, pH, electrical conductivity and sulphate) is captured as Total % in the last column of Table 3. As a result, 60% (20) of the laboratories that participated in the tests produced satisfactory results; 21% (7) produced unsatisfactory results; 4% (1) produced questionable results; and 16% (5) did not return the results although they received the samples for testing. The most accurate results were obtained during pH testing with 94% (31) of laboaratories producing satisfactory results; 3% (1) producing questionable results; 3% (1) of the laboratories did not return the results;

and no laboratotory produced unsatisfactory results. The worst tests was for potassium where results for laboratories was 24% (8) for satisfactory results; 3% (1) for questionable results; 33% (11) for unsatisfactory results; while 40% (13) of the laboratories did not submit back results to PT provider after the analysis.

DISCUSSION

The ISO/IEC 17025 accreditation requires that laboratories within a given country or region take part in proficiency testing (PT) – if a suitable one exists. For example, laboratories in Kenya, Uganda and Tanzania can participate in PT through East Africa Community (EAC) PT Scheme which is mandated to provide a quality assurance tool to laboratories in the region. This paper focused on the results obtained during the EAC PT (2007) for wheat flour and chemical composition of drinking water content determination to demonstrate that accreditation and PT is important aspect in any given economy. Figure 1 and Figure 2 shows a wide variability of results obtained from analysis of acidicty as lactic acid (ALA) and acidicty as sulphuric acid (ASA) of wheat flour sample by 25 different laboratories. This variability is due to inaccurate results obtained by 32% (8) and 40% (10) of the participating laboratories for analytes ALA and ASA respectively (Table 1). Evident also from Table 1 is that 36% (9) and 40% (10) of the participating laboratories for analytes ALA and ASA respectively shied away from submiting back their results to PT provider. One of the possible explanations is that there was possibility the results were erroneous and as result they were not confident enough to release them. Assuming that these inaccurate results are from a food chemistry laboratory of a given food industry, then this can cause misinformation to production unit and pose health risk to consumers. Moreover, the wrong data might find its way into journals and mislead the academia. For instance, our universities and our research institutions annually produce many scientific papers with data generated from laboratories that neither has calibrated equipment nor are they attempting to get international accreditation. It therefore becomes difficult to ascertain the accuracy/credibility of the research findings for product development and these papers are therefore only suitable for the shelves on which they are stored.

Due to increase of water borne diseases like typhoid, the populace are struggling to have access to safe drinking water. This has led to mushrooming of “cottage” water industries which barely have any laboratories for testing purity of water in the first place before selling them as bottled water. This lack of laboratories proper infrastructure, few existing accredited laboratories and inadequate well trained laboratory personnel hinders Kenya’s competitiveness in the international market. It is frightening from Table 3 that only 60% (20) of the participating laboratories had satisfactory results on chemical composition of drinking water content determination. In fact the analysis of potassium had only 24% (8) satisfactory results, 36% (12) inaccurate results and 40% (13) of the participating laboratories did not submit back their results.

CONCLUSION

This paper examined the benefits of laboratory accreditation and their social and economic role within a society. The results from EAC PT (2007) illustrated that laboratory accreditation and their participation in proficiency testing was critical in determining their technical competence to undertake scientific tests or measurements and provides them with a benchmark for maintaining that competence. The ISO15189:2007 and ISO/IEC17025 recertification and reliable PT results acts as an effective marketing tool by increasing the confidence for the user of accredited services like the buyers, regulators, and the general consumers. This facilitates regional and international trade. Consequently the economic and social growth is stimulated.

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