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Quality Control in Accredited Laboratory

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Abstract

Quality control (QC.) includes all technical activities that measure the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer. It also includes operational techniques and activities that are used to fulfill requirements for quality .This study involved the identification and the effectiveness in accuracy in results of implementation quality control program at central laboratory for technical services and calibration (CLTSC) and checked the laboratories performance. Laboratory indicated some methods of quality control being applied such as duplication of tests, replicate of tests, participate in international quality control program proficiency testing and passed for all accredit tests and (PT) schemes insured the samples results. If the performance indicator control limits were exceeded, management informed and corrective action initiated. Most of the quality control test results obtained for the different parameters have a small standard deviation and it can also be seen that most of the values obtained are within acceptable range.

Keywords: *Quality Control, services, calibration.*

1. Introduction

Nowadays, a wide range of socio-economic activities depend on measurements. Food safety, health and environmental protection are dependent on chemical analyses. As we rely heavily on them, our confidence in chemical measurements can only be boosted by their accuracy. Laboratory accreditation, achieved through the implementation of the ISO/IEC 17025:2005 standard is the process which determines the competence of laboratories in delivering accurate results. On the global scale, with the economic crisis, manufacturers and suppliers need to reduce their operating costs. Using accurate and reliable data, emanating from internationally recognized accredited laboratories, eliminates the need for retesting, thus, reducing costs and minimizing technical barriers to trade.

1.1 Quality Control in Chemical Laboratories

Considering how demand for quality assurance (QA) has grown in analytical laboratories, we show the trends in analytical science, illustrated through international standard ISO/IEC 17025, validation, measurements of uncertainty, and quality-control (QC) measures. A detailed review of the history of analytical chemistry indicates that these concepts are consistently used in laboratories to demonstrate their traceability and competences to provide reliable results.

The laboratories should operate systematic internal quality control (QC) checks and participate wherever possible in proficiency testing schemes (external QC).

1.2 Accreditation Advantages

When it comes to competing in today's globalized environment, testing and calibration laboratories accredited under ISO/IEC 17025:2005 have a clear advantage. All is well as long as the laboratories are staffed adequately with appropriately qualified personnel having relevant experience and training in their respective areas of testing and calibration. The elucidation of some ISO/IEC 17025 Standard prepositions is presented to facilitate implementation of the standard by accreditation bodies and analytical laboratories claiming accreditation. Validations are performed to illustrate method compliance. Technical requirement of the quality system such as equipment selection, calibration and personnel training are detailed. The new laboratory accreditation standard, ISO/IEC 17025, reflects current thinking on good measurement practice by requiring more explicit and more demanding attention to a number of activities. These include client interactions, method validation, traceability, and measurement uncertainty. Since the publication of the standard in 1999 there has been extensive debate about its interpretation. The laboratory shall have documented policy and procedures for the resolution of complaints received from customers or other parties about the laboratory's activities or results. The policy shall include the notice that "Any complaint about the quality of reported results may be referred to the accrediting body if such complaints cannot be resolved directly with the customer. Internal quality control at the chemical analytical laboratory involves a continuous, critical evaluation of the laboratory's own analytical methods and working routines. The control encompasses the analytical process starting with the sample entering the laboratory and ending with the analytical report. The most important tool in this quality control is the use of control charts.

2. Methodology

2.1 Quality Control

The quality control program activities were prepared and reviewed and insured that the human and financial resources were available.

2.2 Sample Blank

The samples blank test were conducted to measure the contamination and interferences that effected on the tests results' within the laboratory and it compared with the method detection limit obtained at the methods validation studies or equipment detection limit to determine whether the source of any contamination present and insured blank sample results is less than detection limit.

$$B_{blank} \leq LOD$$

2.3 Duplicate analysis test samples

The precision of the samples were checked before releasing the results.
The two samples were tested, calculated the relative percent difference (RPD) and compared with the repeatability limit (r) for the staff which obtained at the methods verification studies.

$$\frac{|R_1 - R_2|}{\overline{R}} X\,100 \leq r$$

Ref. CLTSC/Mg.P/4.9.

2.4 Replicate Analysis of the Test Sample

The precision between the laboratory staff was insured. The staff were retested thesame sample portions and the two results were compared with the reproducibility limit (R) between the laboratory staff obtained at the methods verification studies.

$$\frac{|R_1 - R_2|}{\overline{R}} X\,100 \leq R$$

Ref. CLTSC/Mg.P/4.9.

2.5 Laboratory Control Sample (LCS)

The accuracy of the staff was checked and the LCS results were compared with the method bias.

$$LCS \leq Bias$$

2.6 Constructing the Quality Control Charts

The CLTSC used two types of the quality control charts, Shewart chart for monitoring and control the trend of laboratory accuracy and RPD chart for monitoring and control the trend of laboratory precision by using the duplicate analysis results.

2.7 External Quality Control Program

The proficiently test scheme PT scheme is conducted and the PT provider submit the laboratory by the PT report, the reports were analyzed, for the PT results not comply with designed criteria the corrective action was initiated.

3. Results

3.1 Duplicate sample (Determination of Conductivity in Water)

Table 3.1: Analyst Repeatability limit

Analyst	Analyst (A)	Analyst (B)	Analyst (C)	Analyst (D)	Analyst (E)	Analyst (F)
Repeatability Limit (r) %	0.15171	0.1610	0.688	0.799	1.46	1.219

Sample / **Date**	**Analyst**	**Result (1)**	**Result (2)**	**Average**	**RPD**	**Acceptance (Y/N)**
C042/16/W630 / 24/9/2016	B	189.2	189.2	189.2	0.00	**Y**
C063/16/W635 / 2/10/2016	B	170.90	17.80	170.85	0.058	**Y**
C570/16/W637 / 4/10/2016	F	1396	1396	1396	0.00	**Y**
C042/16/W644 / 11/10/2016	B	177.9	177.9	177.9	0.00	**Y**

C272/16/W654 18/10/2016	E	1420	1420	1420	0.00	**Y**
C204/16/W655 18/10/2016	B	278	278	278	0.00	**Y**
C545/16/W675	B	4.06	4.07	4.065	0.15	**Y**

Table 3.2: Result of Duplicate Sample Limits

Reproducibility limit (R) %	0.15

Sample **Analyst 1** **Analyst 2** **Date**	**Result** **(1)**	**Result** **(2)**	**RPD**	**Acceptance (Y/N)**
Water Analyst 1 Analyst 2 4/7/2016	0.5	0.5	0	**Y**
Water Analyst 3 Analyst 4 4/7/2016	0.5	0.5	0	**Y**
Water Analyst 5 Analyst 6	0.5	0.5	0	**Y**

4/7/2016				
Water	7.01	7.00	0.14	**Y**
Analyst 7				
Analyst 8				
4/7/2016				

Table 3.3: LCS Result

Test	Measured	UCL	UWL	CL	LWL	LCL
Batch 1	1.194	1.311	1.275	1.203	1.131	1.095
Batch 2	1.120	1.311	1.275	1.203	1.131	1.095
Batch 3	1.208	1.311	1.275	1.203	1.131	1.095
Batch 4	1.204	1.311	1.275	1.203	1.131	1.095
Batch 5	1.226	1.311	1.275	1.203	1.131	1.095
Batch 6	1.233	1.311	1.275	1.203	1.131	1.095
Batch 7	1.229	1.311	1.275	1.203	1.131	1.095
Batch 8	1.228	1.311	1.275	1.203	1.131	1.095
Batch 9	1.226	1.311	1.275	1.203	1.131	1.095
Batch 10	1.225	1.311	1.275	1.203	1.131	1.095

Table 3.4: Shewart Chart: Engine Oil Viscosity @ 100° C Test

Date	**Responsible**	**LCS Assign Value**	**Results**	**Criteria**	**Decision**	
					Accept.	**Reject**
11/ 6 /2016	Analyst (1)	7.00	7.00	± 0.02	√	
19/6 /2016	Analyst (2)	7.00	7.01	± 0.02	√	
25/ 6 /2016	Analyst (3)	7.00	7.00	± 0.02	√	

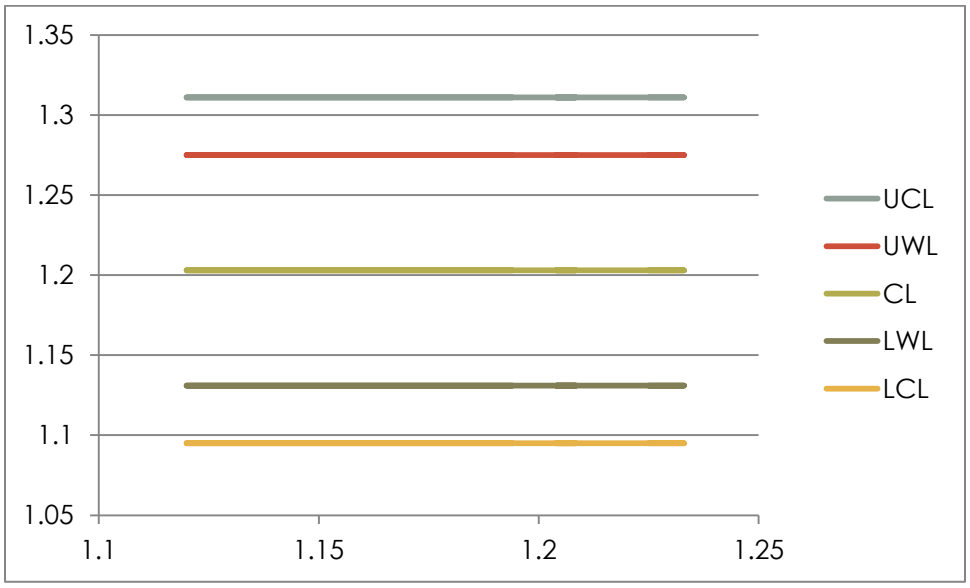

Figure 3.1: Shewart Chart

Mean = 1.203

STD = 0.036

UCL = 1.311

UWL = 1.275

CL = 1.203

LWL = 1.131

LCL = 1.095

Table 3.5: RBD Chart: Engine Oil Viscosity @ 100° C Test

Date	R1	R2	RPD %	CL	WL	UL
Batch 01	7.320	7.270	0.69	0.00	0.38	0.49
Batch 02	15.627	15.623	0.03	0.00	0.38	0.49
Batch 03	30.137	30.134	0.01	0.00	0.38	0.49
Batch 04	14.704	14.712	0.05	0.00	0.38	0.49
Batch 05	17.268	17.272	0.02	0.00	0.38	0.49
Batch 06	18.861	18.865	0.02	0.00	0.38	0.49
Batch 07	19.626	19.622	0.02	0.00	0.38	0.49
Batch 08	14.352	14.352	0.00	0.00	0.38	0.49
Batch 09	21.750	21.780	0.14	0.00	0.38	0.49
Batch 10	15.650	15.620	0.19	0.00	0.38	0.49

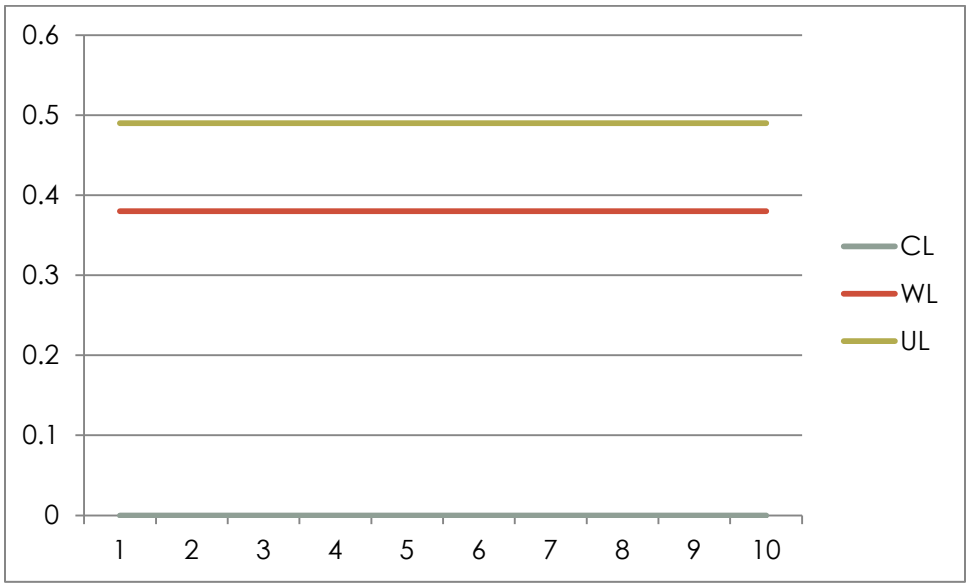

Figure 3.2: Engine Oil Viscosity @ 100° C Test

Mean = 0.15

CL = 0.49

WL = 0.38

Table 3.6: CLTSC Proficiently test results (PT)

Date	Field	Test	Satisfactory results (Yes/NO)	Comment
July 2015	Water	- Conductivity of aqueous solution - pH of aqueous solution - Determination of magnesium, potassium, aluminum, sulfate, & nitrate using Photometer. - Determination of sulfate & manganese using spectrophotometer	Y	No comment
September 2015	Petroleum product (Fresh Engine Oil)	- Flash point PMcc - Flash point COC -Density @ 15c - Viscosity @40 c - Viscosity @100 c	Y	Viscosity results for both 40 &100c are out layer
July 2015	Soil lab	-Sodium , Calcium and Potassium by (flame photometer) - Gold & cupper By (AAS)	Y	No comment
July 2015	Geotechnical services	- Sieve analysis - Aterbage Limit	Y	No comment
November 2015	Petroleum product (Fresh transformer Oil)	- Bake down Voltage - Determination of density @20 C - Interfacial surface tension - Kinematic viscosity @ 40C - Water content	Y N	viscosity@40C and water content needs corrective action

4. Discussions

Quality control results obtained from the tests carried out on the samples of CLTSC laboratories were shown From Table (3.1) and (3.2) it can be deduced, from the acceptable range, that most of the test results were acceptable or permissible limits of the test methods. Better results would have been obtained with at least 10 replicates using the method indicated in Table (3.5). Laboratory indicated some methods of quality control being applied such as duplication of tests, replicate of tests, participate in Proficiency Testing (PT) schemes. Table (3.6) and all tests were passed with two cements and the corrective action was done. The laboratory can also use its records to generate control charts such as Shewart Chart and RBD chart and identified the upper, lower limits.

5. Conclusion

To improve the quality of services it will be important to insure the quality control program was done either internal or external. Improved laboratory quality was increased confidence and increased personnel awareness and performance. For accreditation to be implemented and maintained in the laboratory there is difficulty in establishing an laboratory staff culture oriented toward quality and in reducing staff turnover. It was necessary to do corrective action to the failed quality control results to avoid repetition in system of routine, planned technical External quality control reports should indicate clearly whether performance is satisfactory or not. If it is not satisfactory, two general actions must be taken. Most of the quality control test results obtained for the different parameters have a small standard deviation and it can also be seen that most of the values obtained are within acceptable range.

6. Summary

Implementation of ISO 17025 provides a system for continuous improvement of daily laboratory practices and the main benefits is faster identification and resolution of issues, improved customer satisfaction, meeting of quality requirements and an overall increasing in laboratory business. Using quality control program can be an invaluable tool in your decision-making and reduce risk management and confidentiality of tests results.

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