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Full Length Research Paper

Quality Assurance of test results using the techniques of statistical quality control According to ISO/IEC 17025:2005

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The research aims to show the importance of availability of quality control procedures in laboratories for monitoring the validity of executed tests, they are considered the important tools used in evaluation of performance level in order to ensure that all reported data meet the required purpose, however they help the customers or regulatory bodies for the selection of qualified laboratories. This research includes a practical study for evaluation of technical competence of Spinning laboratory in the Industrial Testing and Research Center. This laboratory adopts initially some requirements of the International Standard (ISO 17025:2005) in order to gain the International Accreditation certificate, it uses the most common ways of statistical control tools (testing the hypothesis, control charts) to handle the results in a scientific way enabling the researchers to find out the gaps and weak points in the laboratory performance, consequently provides feedback and technical recommendations that will help finding the measurement problems and give suggestions to apply practical ways for performance control of analysis that fulfill all quality requirement. It also helps to remove the causes may affect the performance quality throughout all steps of analyzing. As these recommendations are adopted, the laboratory will be able to gain The International Accreditation certificate according to ISO 17025:2005.

Keywords: competence – Quality Assurance – Accreditation – Laboratory. Performance.

INTRODUCTION

The disparity in laboratories performance in the Textile industries in public and private sectors create a real problem, especially when finding discrepancies in test

results of specific sample among these laboratories, even though these results are approved by the government authorities e.g. ministries of Commerce, Economy, Industry and others.

The main reason of this discrepancy is the analytical processes inside the laboratory does not associate with applying of quality control criteria, consequently affects negatively on competence of these laboratories.

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Therefore, the Quality control procedures are very basic in the laboratories in order to monitor the validity of the executed tests. The resulting data shall be recorded in such a way that their patterns of distribution and trends are detectable and, where practicable, statistical techniques shall be applied to review the results. Quality control results monitoring shall be planned and reviewed and may include, but not be limited to, the following (ISO/IEC 17025, 2005):

- a) regular use of certified reference materials and/or internal quality control using secondary reference materials.
- b) participation in interlaboratory comparison or proficiency-testing programs.
- c) replicate tests or calibrations using the same or different methods.
- d) retesting or recalibration of retained items.
- e) correlation of results for different characteristics of an item.

Upon knowing the research problem, aiming to rise up the level of laboratory performance, consolidating the trust of these laboratories through monitoring various aspects of quality required in the analytical process regularly by analyzing of their external and/or internal control data enabling us to ensure that all laboratory activities work as requested ,including applied testing methods, used equipment in the test, qualified staff and training programs.

The research put out the following queries:

- 1- Is the test results reported by the Spinning lab are true (no difference between a parameter(mean value) and a reference value at the 95 percent confidence level)
- 2- Does the spinning laboratory have procedures to verify its ability to apply the reference measurement procedure and get matching results.
- 3- The utilized analytical operations in the executed tests in Spinning Lab is statistically controlled via time.

Theoretical Reference

To verify that any product meets the requirements, we depend on testing and inspection. As these results usually lead us to take decisions if they meet or not with the technical specifications, So there should be a kind of ensuring of measurement accuracy According to the International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM) (International Vocabulary of Metrology, 2007), The term of (Measurement accuracy) is known as "closeness of agreement between a measured quantity value and a true quantity value of a measured".

The concept "measurement accuracy" is not a quantity and is not given a numerical quantity value.

The term "measurement accuracy" should not be used for measurement trueness and the term measurement precision should not be used for "measurement"

accuracy", which, however, is related to both these concepts.

for test results in order to make decisions.

However, as mentioned above the problem is located in the discrepancy in the test results, to a degree of conflict or contradiction due to a some variation in analytical process, as this process is a subject to many changes, some of these changes can be controlled (regular errors) and the other cannot be controlled (random errors) which we have to live with , but try to reduce them as low as we can. So, in order to gain right and accurate test results, ISO 17025:2005 must be applied.

Accreditation according to ISO/IEC 17025:2005

The laboratory that aims to gain the International Accreditation Certificate according to ISO 17025:2005 is required to use the statistic techniques of Quality control as well as to fulfill the other requirements related.

The figure (1) shows a Model for Quality Management System in the laboratory based on a process approach, includes all requirements of ISO/IEC 17025:2005 (Gille, 2010).

In order to enable the laboratory to give reliable technical results for any test, there should be availability of technical competence requirements, Depending on ISO 17025:2005. There are several factors define reliability and trueness of executed test by this laboratory. These factors, presented in figure (2) include contributions from (Yumkella, 2009):

- human factors
- accommodation and environmental conditions
- test methods and method validation
- Equipment
- measurement traceability
- Sampling
- the handling of test items

In this research, we will adopt the tools of statistical control of quality as a guide for researchers to agree or disagree on accuracy of the analytical results.

Trueness and Precision of test results (ISO 5725-1, 1994)

The figure (3) clarifies the characteristics of analytical result:

According to the International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM) (International Vocabulary of Metrology, 2007), The term of (Measurement trueness) is known as "closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value", however the term (Measurement precision) is known as "closeness of agreement between indications or measured quantity values obtained by

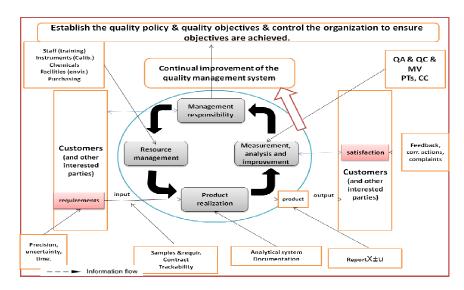


Figure 1. Proposed Model for Quality Management System in the laboratory based on a process approach

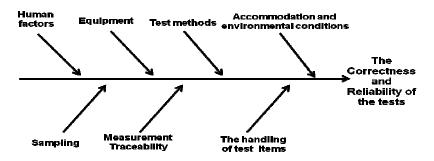


Figure 2. cause and effect diagram

replicate measurements on the same or similar objects under specified conditions".

Laboratory Quality Control Program (ORA Laboratory Procedure, 2010):

Laboratory quality control is an essential aspect of ensuring that data released is fit for the purpose determined by the quality objectives (i.e. accuracy and precision).

When properly executed, quality control samples can monitor the various aspects of data quality on a routine basis. In instances where performance falls outside acceptable limits, the data produced can be questioned and, after investigation, a determination made as to its validity. With professional experience and a common sense approach quality control is the principal recourse available for ensuring that only quality data is released. The dual foundations of the laboratory quality control program is its internal quality control, composed of day-to-day and sample-set to sample-set monitoring of

analytical performance, and its external QC, based on the laboratory's performance in proficiency testing programs or inter-laboratory comparison. The QC data generated is recorded in such a manner to detect trends

METHODS AND MATERIALS OF RESEARCH

The study process uses (ISO 5725-2, 1994), (Joseph, 2009), (ISO 8258, 1991) in order to prove the research hypotheses or deny it, this is achieved by using the Statistical Package in (Excel) program to analyze the results that have been collected in this research, as well as a group of other tools such as statistical control cards. Here are some test results interpreted as follows:

Descriptive statistics

Descriptive statistics describe the data set, but does not allow us to draw any conclusions or make any

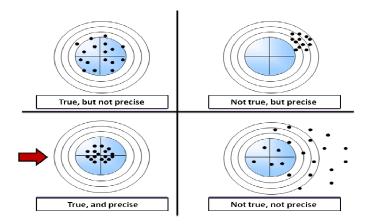


Figure 3. Trueness and Precision of test results

Table 1. Test results determine the melting point

_						
	156.7	156.5	156.5	157.2	157.3	157.2

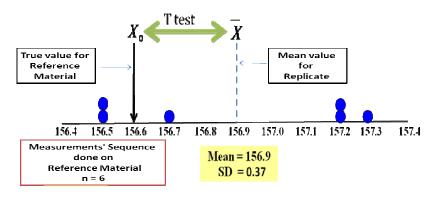


Figure 4. T test

interferences about the data. Hence we need another branch of statistics: Inferential statistics.

a- Central tendency parameters (Mean, Median, Mode) describe the data curve, the one most common used is the arithmetic Mean: Total divided on number, this is considered enough scale for the central tendency if the data belong to distribution is symmetrical, and not having outliers.

b- Dispersion tendency parameters (standard deviation, Range) describe how close the data are from the arithmetic Mean or from each other. It is the most important scale used in defining the variance, it is the standard deviation calculated by using all data. It is the square root of the average of square data deviations from the arithmetic Mean.

Inferential statistics (testing hypothesis)

The aim of this statistical test is to test any hypothesis

related to one or more factor values, it includes four elements:

- The null hypothesis
- Test statistics
- Rejection region
- The alternative hypothesis

A Statistical hypothesis is an opinion about a population parameter. The opinion may or may not be true i.e. we can test the hypothesis like this: The null hypothesis states that there is no difference between a parameter (or parameters) and a specific value or two equal averages or, our decision to accept or reject the null hypothesis is built on information we gain from testing a sample in the study. The sample values are used to calculate certain number as decision maker. Called Test statistics (T test- Grubbs test - Cochran Test).

Then, divide all values taken by test statistics into two groups, first called rejection region and second called acceptance region, reject the null hypothesis if the value taken by test calculated from the sample located in the

Table 2. Factors of descriptive statistics for the test results determine melting point

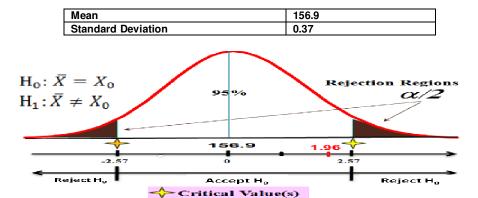


Figure 5. The acceptance and rejection regions for the null Hypothesis

Table 3. Comparing the results of laboratory, Liner density of Yarn

	nsity of Yarn Cotton yarn	(Ne)						
Lab no	Mean	Standard Deviation	Coefficient of Variation	Number of replicates	Cochra	n test	Grubbs test	Z- score
1	30.74	0.15	0.49	10				0.73
2	30.56	0.48	1.57	10				0.46
3	29.57	0.62	2.10	10				-1.02
4	29.99	0.11	0.37	10				-0.39
5	29.97	0.52	1.74	10				-0.42
6	29.89	0.05	0.17	10				-0.54
7	30.6	0.17	0.56	10				0.52
8	29.57	0.41	1.39	10				-1.02
9	31.6	0.39	1.23	10				2.01
10	29.54	0.4	1.35	10				-1.06
11	29.94	0.11	0.37	10				-0.47
12	31.35	0.24	0.77	10				1.64
13	30.5	1.58	5.18	10	0			0.37
14	29.95	0.32	1.07	10				-0.45
Tests for outliers		O - denotes an outlier						
			S - denotes a stra	S - denotes a straggler				
Cochran-Test		Number of outlier						
Grubbs-Test			Number of outlier	s 0				
Statistics			Warning Limits					
Number of labs		13		Mean - 2.0		28.91		
Grand mean 30.25		30.25		Mean + 2.0) SD	31.59		
SD Within 0.31		Action Limits						
Reproducibility SD 0.67			Mean - 2.6	SD	28.51			
	•			Mean + 2.6	3 SD	31.99		

rejection region, while accept the hypothesis if this value located in the acceptance region.

Quality Control Chart

The control charts are used to determine if the measurement system process is in control and whether

the results generated by the measurement system are acceptable. The control chart provides the tool for distinguishing the pattern of indeterminate (random) variation from the determinate (assignable cause) variation. This technique displays the test data from a process or method in a form which graphically compares the variability of all test results with the average or expected variability of small groups of data, in effect, a

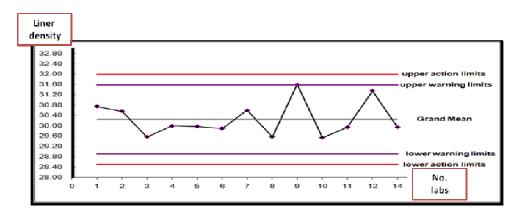


Figure 6. Controlchartof results for participant laboratories in the test of Liner density

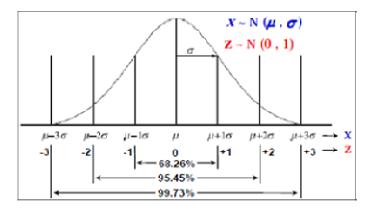


Figure 7. normal distribution (Gaus curve)

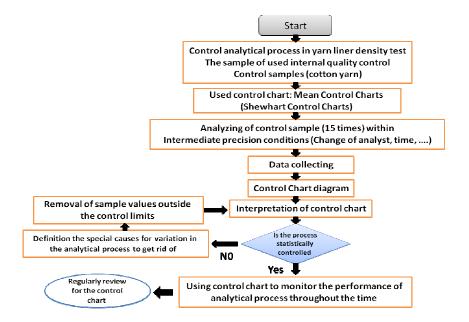


Figure 8. Flow Chart of process Statistical Control

Table 4. Results of analyzing of control sample(liner density Nm)

30.74	30.56	29.57	29.99	29.97	29.89	30.6	29.57
30.83	30.5	29.54	29.94	30.35	29.95	29.87	

Table 5. factors of descriptive statistics of reference sample

Mean	30.12
Standard Error	0.11
Median	29.97
Mode	29.57
Standard Deviation	0.44
Sample Variance	0.19
Kurtosis	-1.30
Skewness	0.25
Range	1.29
Minimum	29.54
Maximum	30.38
Sum	451.87
Count	15.00

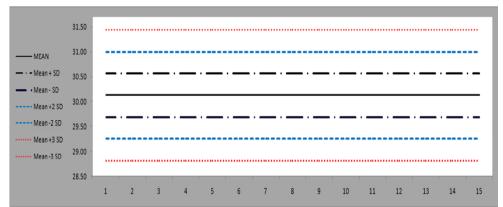


Figure 9. statistic control chart for analytical process

graphical analysis of variance. The average or mean value is calculated and the spread (dispersion or range) is established. Common practice sets the warning limits at ±2 standard deviations while control limits are set at ±3 standard deviations on each side of the mean. Since the distribution of averages exhibits a normal form, the probability of results exceeding the control limits is readily calculated. The control chart is actually a graphical presentation of QC efficiency.

If the procedure is *in-control*, the results will almost always be within established control limits. Further, the chart will disclose trends and cycles from assignable causes which can be corrected. It is emphasized that there is absolutely no substitute for sound judgment based on an appreciation of the analytical system, the technique, the quality control materials utilized, and the analytical interpretation of the data generated by the procedure (ORA Laboratory Procedure, 2010) (ISO 8258, 1991).

DISCUSSION AND RESULTS

Are the test results reported by the Spinning laboratorytrue (no difference between a parameter (mean value) and a reference valueat the 95 percent confidence level)?

To proof and confirm this hypothesis, we will depend on confirming the results trueness of one of the executed test in spinning laboratory (fiber analysis: Qualitative) discrimination of textile materials by melting point (AATCC Test Method 2-, 2007).

To proof this hypothesis, the researcher depends on T test (Gille, 2010) (Joseph, 2009) (comparison of the Mean with real value). T test is to compare the mean of many repetitions of reference sample test with the real value of the reference sample.

The used reference sample (the real value of melting point 156.6 \pm 0.5 $^{\circ}$ C)

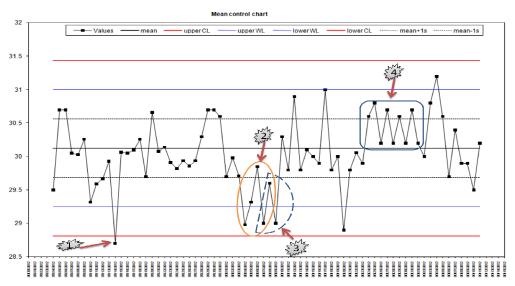


Figure 10. Points distribution on the controlchart

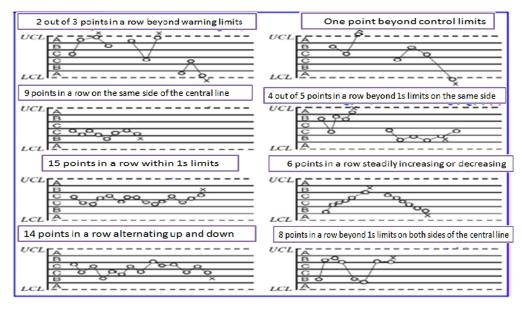


Figure 11. Eight rules to interpret control chart .

The researchers performed 6 tests on the reference sample in accordance with approved standard work method in the Spinning laboratory. The results were as per following:

In this test, we define the follows as presented in the figure (4): (Gille, 2010) (Joseph, 2009)

- 1. The null Hypothesis (H0): No real difference between the average of repetitions and the true value of the reference sample $\bar{x}=156.6$, while thealternate hypothesis (H1): There is real difference between the average of repetitions and the real value of the reference sample $\bar{x}\neq156.6$.
- 2. The test critical value, taken from reference tables related to the T test (Gille, 2010) (Joseph,

2009),degrees of freedomv = n - 1 = 5 and confidence level 95%: $T_{cril} = 2.57$.

3. The calculated value of T test (T_{cal}) from the following rule Formula (Gille, 2010):

$$T_{cal} = \frac{\bar{x} - x_0}{\frac{s}{\sqrt{n}}} \tag{1}$$

 \bar{x} :is a Mean to chain of data generated by the test.

 x_0 : the real value to reference sample = 156.6

s: is standard deviation for chain of data generated by the test.

n: number of test repetitions.

Calculate the Mean and Standard deviation for the results:

Consequently:
$$T_{cal} = \frac{156.9 - 156.6}{\frac{0.37}{\sqrt{6}}} = 1.96$$
Rejection Region: this case is for

Rejection Region: this case is for a two tailed 4. test:

$$H_1: \bar{X} \neq X_0$$

 $\begin{array}{c} {\rm H_1\colon} \overline{X} \neq X_0 \\ {\rm As} \quad X_0 = 156.6 \text{ is previously proposed which is the true} \\ {\rm value\:for\:the\:reference\:sample.} \\ {\rm Therefore} \quad {\rm the\:\:Acceptance\:\:Region\:\:is:\:\:} \left[-t_{\frac{\alpha}{2}}\,, +t_{\frac{\alpha}{2}}\right] = 0. \end{array}$

[-2.57, +2.57]The Rejection Region is:

[
$$t < -t\frac{\alpha}{2} = -2.57$$
 $t > t\frac{\alpha}{2} = 2.57$]

The figure (5) clarifies the acceptance and rejection regions for the null Hypothesis.

The test result in accordance with T Test is $T_{cal} = 1.96$, as long as it is in the acceptance region we accept the null hypothesis H_0 , and reject alternate Hypothesis H_1 . Consequently, there is no real difference between the average of repetitions and the real value of reference sample $\bar{x} = 156.6$, we conclude that the used method in the test of defining the type of textile materials by melting point gives true results.

Does the spinning laboratory have procedures to verify its ability to apply the standard operation procedures (test methods) and get matching results?

The Spinning laboratory in the Industrial Testing and Research center prepares a standard operation procedures (SOPs) as a strict application for reference specifications, hence the spinning laboratory is required to obtain procedures in order to proof its capability of proceeding the test and having identical results.

The inter-comparison tests among labs besides the quality control by using referential materials, are tools allow us to trust these results.

The researchers depended on the inter-comparison tests to prove a testing procedures standard used in the density linear test prepared as a strict application in line with (EN ISO 2060, 1995), however the inter-comparison tests gains their importance through their role in monitoring the performance of laboratory and presenting it statistically, thus it helps the spinning laboratories to detect errors which cannot be detected via internal procedures of quality control, consequently to proceed with right corrective action.

The inter-laboratory comparison Programs randomly selected subsamples from a source of material are distributed simultaneously to participating laboratories for testing (ISO/IEC 17043, 2010).

This is very good technique to keep and maintain the laboratory competence. Assistance in the identification of measurement problems and have minimum mistakes. we use this program to discover errors that couldn't be found with internal quality control.

Success of inter-laboratory comparison tests depends good organization, selecting the participant laboratories, select the pre tested materials, test plan, distribution of samples, collection and analyzing the test

The researchers, in coordination with the General Organization of Textile Industries prepared an application for participation in the comparative program for Spinning, distributed it to the related companies, all samples were prepared in the Spinning laboratory in the faculty of mechanical and electrical engineering in Damascus University, then, filled in special boxes and sent to all participants laboratories via freight forwarders.

The participated laboratories were in: Al Shahba for Spinning, United Arabia, Al Walid for Spinning, Al Sahel for Spinning, Latakia textures, Al Ahlia Company, Hama for Cotton Yarns, Yarn General Company in Idleb, Spinning and Texturing in Damascus, Al hassaka for Spinning, Al Khumasia Company, Idleb for Spinning, The productive control in the General Organization of Textile Industries and The Industrial testing and research Center.

The incoming results were collected from laboratories and handled as per (Gille, 2010) (ISO 5725-1, 1994) (ISO 5725-2, 1994), for statistic calculation. The study used two patterns for exclusion the results of laboratories that might have problems in their analytical processes. These two patterns are Grubbs test and Cochran test. i.e. any result pointed with (Outlier) in Cochran test, means that there is a problem in standard deviation of this laboratory results, consequently the arithmetic Mean will be excluded from calculation. While any result pointed with (outlier) in Grubbs test, means that there is a problem in the arithmetic Mean. consequently it will be exclude from calculation.

On the other hand, if the result is pointed with (Straggler) in either Cochran or Grubbs tests, it will be included in the calculation, gut the laboratory has to detect the reason of this result.

Attention should be given results that may be out of limits of interference, even if they passed the both Cochran and Grubbs tests, So all laboratories should be verified.

The table (3) and control chart (figure 6)show test results location in relation to medium value:

After statistical analysis, the results of Spinning laboratory in Research Center number (14) in the test of liner density presented in figure (6) and table (3), were the most in line with mean values of sent samples. Consequently, we have got a reliable or confident proof that the spinning laboratory is capable of applying the set tests and having identical results.

Are the utilized analytical operations in the executed tests in Spinning Laboratory statistically controlled via time?

The researchers verified that one of the analytical process used in the executed tests in the spinning laboratory is statistically disciplined via time, that analytical process used in the test of (yarn twisting [13]) is controlled statistically using the 'statistic control' of analytical process. i.e. what meant by 'control' is to inspect any variables in order to adjust, and meant by 'statistic' is collect, organize, analyze and interpret the numerical data. Knowing that this statistic control for analytical process cannot be fulfill the required quality in the test result if there was any problem in executed analytical method.

We are going to use the of statistic control tool which is called control charts, these charts are statistical designs depend on Gaus curve characteristics (normal distribution) shown in the figure (7): (Gille, 2010) (Joseph, 2009)

The researchers will invest Gaus curve to evaluate the performance of analytical processes throughout the time, by checking results, inspecting changes, marking out the causes then to take right procedures to get rid of.

This tool depend on the resulted data of using internal quality control sample by points set on a chart having central line (CL), two horizontal lines having the distance of CL, these are the upper and low limits (UCL & LCL), any changes can be predicted will be via the points on the these two lines with progress along with time.

If points between the two lines are random this indicate that analytical process in controlled, if not random as per figure 11, this indicates the process in not controlled statistically.

When any abnormality occurs, the test will be repeated, If points distribution changes, the test will be completed. If not the test will stopped and check out the reason (Gille, 2010).

The feasible implementation will pass through steps clarified in the following Flow chart (figure 8):

Mechanism of Statistical Processing:

A sample of internal quality control (Cotton Yarn sample) has been analyzed (one of the tools directed as per standard test method for yarn number (EN ISO 2060, 1995) in medium accuracy conditions. The results were as follows:

Ingredients of Control chart (ISO 8258, 1991):

Central line

It is in the middle of the chart, its value represents average results.

$$\bar{X} = 30.12$$

Control lines:

As a result, the shape of control chart will be as follows (figure 9):

After formation the statistic control chart as per above figure, it is ready to be used for every test of quality control, that could be analyzed and measured as specified in the way of adopted quality control in the test method (analyzing control sample before testing the customer sample).

The measured value of the quality control sample should be recorded on the chart, by putting a sign X on the opposite coordinate on the vertical scale (Y-axis), putting the date of register on the horizontal scale (X-axis). Then the points resulted out of the regular tests for the control sample during two months on the control chart as follows (figure 10):

From the relation of points with control lines and frequency with the time, and via the next eight rules, we can judge that there is an abnormal case.

From the Control chart presented in figure (10), we can figure out the follows:

During the period 4-13/7/2012, points order was random, this is an indicator that the analytical process was controlled statistically.

On 14/7/2012, the case showed was: one point beyond control limits, this an indicator that the analytical process was not controlled statistically. In this case, the test was repeated, so the points were re distributed randomly between 14/7/2012 and 7/8/2012, therefore the analytical process controlled statistically.

On 8/8/2012, the case showed was: 4 out of 5 points in a row beyond 1S limits on the same side, this was indicator that it is not controlled statistically. The test was repeated on 9/8/2012, but the result did not change the distribution, and the case showed was: 2 out of 3 points in a row beyond warning limits, so the test was stopped, an inspection for reasons showed that the balance used in the test needed calibration in addition to a change in the performance of technician.

After calibration, points were distributed randomly between 10/8/2012 and 1/9/2012, Hence, it was controlled. on 2/9/2012, the case showed was:9 points in a row on the same side of the central line, this indicated not controlled, the test was repeated, the result did not change, therefore, the test was stopped and inspection started. The reason was because of change in

environmental conditions, as the spinning tests should be achieved in temperature 21 $^{\circ}C \mp 2 ^{\circ}C$, and humidity

 65 ± 4 % (ISO 139, 2005), This was concluded statistic control charts related to temperature and humidity which were measured daily in laboratory of spinning industries.

After fixing the environmental conditions in the laboratory, points were distributed randomly between 2/9/2012 and 12/9/2012, so the analytical process used in the test controlled statistically till that date. Thus, the researchers proved that the analytical operation was statistically controlled along with the time.

CONCLUSIONS

Upon finalizing the above study and handling all incoming data from practical section, after analyzing and checking, the searcher gained the following conclusions:

- 1- In Spinning lab. Partial implementation for quality management system as per ISO 17025, does not lead to legal integrity, or enough ensuring of stabilization of test results, therefore, In order to gain reliable results and good control, there should be fulfillment of all requirements of ISO 17025 in the lab of Industrial textures as soon as possible.
- 2- All spinning labs must understand the importance of using statistical techniques for quality control as well as fulfilling all other requirements related to ISO 17025:2005, to be sure that all test results are accurate and true, in addition to their big role in detecting the weak pints and gaps in the performance. The lab should use the results of statistical treatment as a an extra tool to define all problems might appear. The rejected results may appear during the statistical analysis must be checked to know the root cause analysis of unaccepted performance, that may be a mistake by the analyzer, equipment calibration, sample handling, test process, lab condition or others..... hence, do the corrective action.
- 3- There should be frequent participation in the Inter laboratory comparison programs, and deal with the program samples as if coming from the customer, The results of the Inter laboratory comparison tests should be used as an additional tool to confirm the reference test methods, and to identify the hidden problems in the lab. In Respect to the importance of these programs, we emphasize on the necessity of organizing this program by the central lab of the General Establishment of texture industries in order to help other labs to evaluate performance continuously, furthermore increasing the number of participants will raise the level of analytical performance in the labs to gain results may be comparable in practice.
- 4- The analytical process performance must be evaluated over timethrough the control charts which detect changes in the process, determine the causes

leading to it and then take appropriate and necessary corrective actions to get rid of them. One of these causes is not set required surrounding conditions to perform the tests.

5- The spinning laboratory instruments must be calibrated according to an annual plan, then taking into account their results is very important to ensure the accuracy during work.

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