XXI IMEKO World Congress "Measurement in Research and Industry"
August 30 – September 4, 2015, Prague, Czech Republic

# HOW TO MONITOR PERFORMANCE IN PROFICIENCY TESTING

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***Abstract*** – Proficiency testing provides objective evidence of laboratories testing competence. Laboratories quality control procedures can monitor the validity of tests and calibrations undertaken by measuring continuing performance in multiple rounds of a proficiency testing program. Such monitoring will allow laboratories to identify problems, check for testing bias and other trends and review the effectiveness of corrective actions where problems were highlighted by a proficiency test.

***Keywords***: Monitoring, Proficiency, Quality, Charts

## 1. INTRODUCTION

The competence of accredited laboratories is assessed by two complimentary techniques. One technique is the on-site evaluation by an assessment team, which examines the technical competence of the laboratories and their compliance with the requirements of ISO/IEC 17025 [1]. The other technique is by proficiency testing which involves the determination of laboratory testing performance by means of interlaboratory comparisons. The two techniques have their own advantages and when combined give a high degree of confidence in the overall competence of an accredited laboratory.

ISO/IEC 17025 recognises that participation in interlaboratory comparisons or proficiency testing programs as one way to assure the quality of test and calibration results. It is noted that the standard requires that if proficiency testing is used by the laboratory then this should be monitored:

ISO/IEC 17025 5.9.1 *"The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include but not limited to: … (b) participation in interlaboratory comparison or proficiency-testing programmes"*

Internal quality control for the laboratory involves a continuous, critical evaluation of the laboratory's own analytical methods and working routines. Internal quality control is conducted by the laboratory as a check that if the process is out of control then there is a need for an investigation and correction. The control encompasses the analytical process which can include the proficiency testing sample entering the laboratory and ending with the analytical report of results submitted to the proficiency testing provider.

Therefore this aspect of monitoring proficiency testing performance is a requirement of accreditation bodies using ISO/IEC 17025. The accreditation bodies assessing the technical competence of laboratories would require general satisfactory performance in proficiency testing over time as significant evidence of a laboratory's ability to produce reliable results.

## 2. MONITORING PEFORMANCE OVER TIME

For a single proficiency test ISO/IEC 17043 [2] clearly defines the criteria for performance evaluation by the statistical determination for z-scores as:

$|Z| \leq 2.0$ indicates "satisfactory" performance and generates no signal;

$2.0 < |Z| < 3.0$ indicates "questionable" performance and generates a warning signal;

$|Z| \geq 3.0$ indicates "unsatisfactory" performance and generates an action signal

However when laboratories monitor proficiency testing performance over time this single review of each performance may not be adequate as it may fail to identify a trend in testing that may lead to a future problem. There may be cases where single proficiency tests for a specific determination is satisfactory however when checked against past performance in a continuous program may indicate an action. Also a possible trend may be developing which could lead to a testing problem which could be confirmed with a review of the z-score for the next scheduled round of the program.

## 3. CONTROL CHARTS TO MONITOR PERFORMANCE

Where a proficiency testing provider uses a standardised score such as a z-score to evaluate laboratory performance for a test over several rounds of a program then this information may be presented in a graph to monitor performance over time. The use of graphs in which the scores for several rounds are combined, may allow for the identification of trends and other inconsistencies and show performance which varies randomly. Such features of combining the results would not be apparent when each

round is examined separately.

A laboratory's quality control procedures can monitor the analytical process for statistical control and alert users when corrective action is required. Control charts can be used as a simple graphical means of interpreting test data. Traditionally "Shewart" control charts are useful for graphical monitoring of combined standardised scores. The use of these control charts is detailed in ISO 13528 [3].

For proficiency testing Shewart control charts are the simplest and most convenient method to monitor results. A control chart can be maintained for any individual test with the z-score plotted sequentially (time ordered). Control charts are based on the distribution of the control values around a true or expected value (assigned value for proficiency testing) and assume that the distribution around the assigned value is normal. The Shewart control charts can easily identify the reporting bias by the laboratory.

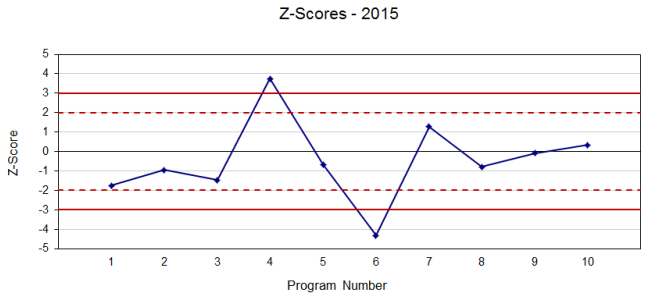


Fig. 1. Shewart Control Chart

The control limits can be based on the interpretation of z-scores. The z-scores may be plotted for each round where the warning limit may be based on the questionable performance $2.0 < |Z| < 3.0$ which equates to roughly $2\sigma$. This warning limit is set at a 95% confidence limit (1/20) and is expressed as:

$$\pm 2.0$$

The action limit based on unsatisfactory performance $|Z| \geq 3.0$ and equates to roughly $3\sigma$. This action limit is set at 99.7% confidence limit (1/1000) and is expressed as:

$$\pm 3.0$$

The acceptance range may be interpreted as per the satisfactory performance range for z-scores evaluation as $|Z| \leq 2.0$ being satisfactory.

The probability of any sample point (z-score plot) falling above the centre line is equal to 0.5, provided that the laboratory quality control procedure is in statistical control. The probability that two consecutive sample points will fall above the centre line is equal to 0.5 times 0.5 = 0.25.

Accordingly, the probability that 9 consecutive points on one side of the centre line is $0.5^9 = 0.00195$, which is approximately the probability that a sample point can be expected to fall outside the $3\sigma$ limit. It is expected that approximately 5% of proficiency testing z-scores will fall between the warning limit and the action limit. When a sample point falls outside the control limits, the laboratory may no longer be in statistical control.

Additionally, laboratories should use the control charts to examine systematic trends, that is a series of sample points in the same direction or points in the same side of the centre line, even though they are all within the control limit. To use control charts for trend analysis they must be maintained and used on a real time basis. If laboratories prepare control charts after a considerable time delay they only provide a history of analytical performance with little opportunity for the laboratory to control the measurement process.

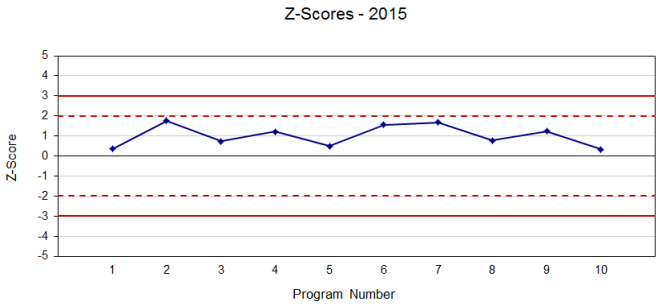


Fig. 2. Control chart with points above the centre line

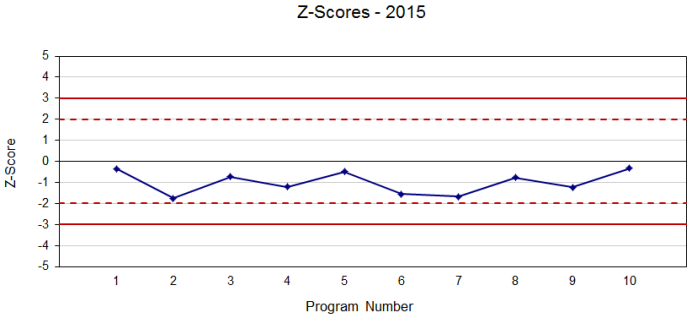


Fig. 3. Control chart with points below the centre line

The simplest interpretation of the control chart for z-scores is to identify any point greater than |3|. The probability of a point falling outside these warning limits is 0.3%. The probability of a point falling between the warning limit |2| and the control limit |3| is about 5%. Another simple check is to identify two consecutive points between the control and warning limits may need action.

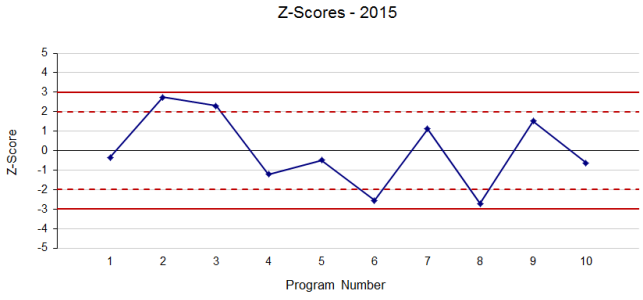


Fig. 4. Control chart indicating questionable performance

Other simplified rules for action may be identification of seven consecutive points on the same side of the centre line. It can be considered that seven consecutive points increasing may be considered for action. Similarly seven consecutive points decreasing may be considered for action.

Whilst an investigation and corrective action should be

implemented and monitored it is important that analysts then do not search for special causes that do not exist in order to adjust the process. The adjustments may distort a stable process as well as wasting time and energy.

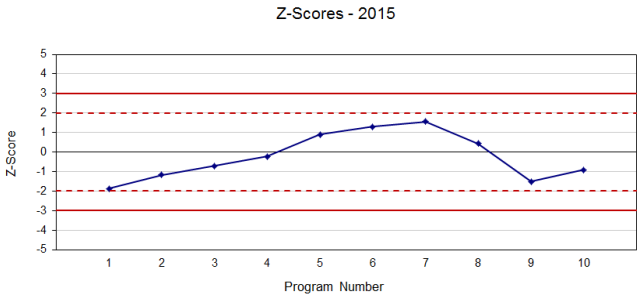


Fig. 5. Control chart indicating increasing trend

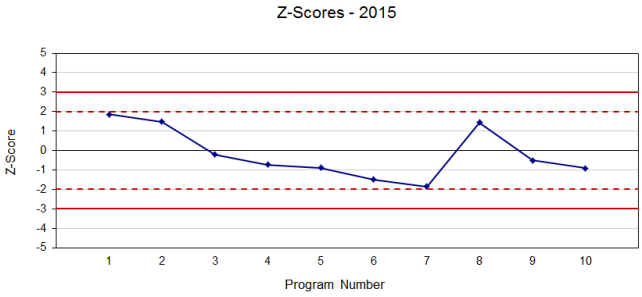


Fig. 6. Control Chart indicating decreasing trend

The best outcome for continuous monitoring in a proficiency testing program is where all points remain well within the warning limits and there is little evidence of a trend in the data. This would be where no results are identified as questionable, no results are outliers, there is no trend for increasing data or no trend for decreasing data and finally that there is data both above and below the centre line.

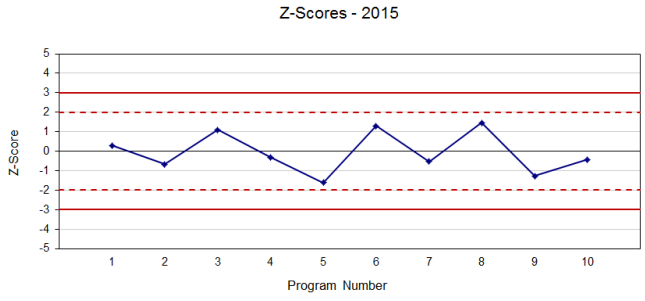


Fig. 7. Control chart indicating performance in control

## 4. BENEFITS OF CONTROL CHARTS

Proficiency testing and other types of interlaboratory comparisons are highlighted in ISO/IEC 17025 as being an important means of monitoring quality. Regular participation in proficiency testing programs is one of the best ways for an analytical laboratory to monitor over a period of time its performance against both its own requirements and peer laboratories.

For the participating laboratory in a proficiency testing program the important part of the evaluation is that the use of control charts will easily identify systematic error or bias and other trends.

The control of the measurement process by proficiency testing is an important means to ensure valid results and should be considered as a continual monitoring process.

The control charts can be easily designed from proficiency test data as many programs reports generate z-score analysis. The z-scores are suitable to plot on a chart and can then identify the warning and action limits for the participating laboratory.

The control charts can be set up for to compare different analytical methods using separate control charts for each method or plotting different method results on the same chart. This may provide valuable method comparison information in particular when a laboratory is in the process of changing a method.

The control charts can be set up for an individual operator in the laboratory or for separate tests in a program as a means to monitor performance. This would be considered as a useful tool when training and qualifying new staff in the laboratory.

## 5. CONCLUSION

Important decisions are made based on the analytical data generated by laboratories. Therefore a laboratory's quality control procedures should be used considering fitness for purpose of the testing results.

The quality control procedures used should be well defined to assure the reporting of high quality data of a known accuracy and precision. Proficiency testing monitoring through the use of control charts is considered as an effective tool to include within a laboratory's documented procedures for quality control.

## REFERENCES

[1] ISO/IEC 17025: 2005 General requirements for the competence of testing and calibration laboratories

[2] ISO/IEC 17043: 2010 Conformity assessment – General requirements for proficiency testing

[3] ISO 13528: 2005 Statistical methods for use in proficiency testing by interlaboratory comparisons