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2nd Workshop on QA/QC in Analysis
Combined meeting of the Expert Panel on Deposition
and Working Group on Soil Solution
16-20 October 2005, Rovaniemi, Finland

Using a control chart as an internal QA/QC tool in a laboratory

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Guides for control charts

- **ICP Forests Manual, Part VI, Sampling and Analysis of Deposition**, chapter 5:

  Quality assurance programme in the laboratory

- **ISO 8258:1991**

- **Internal Quality Controll, Handbook for Chemical Laboratories**

  NT Technical report, TR 569, 2005

  revised for the demands of ISO/IEC 17025 standard

  Handbook available at www.nordicinnovation.net/nordtest.cfm

  (choose Rapporter/NT tech 569)

Introduction

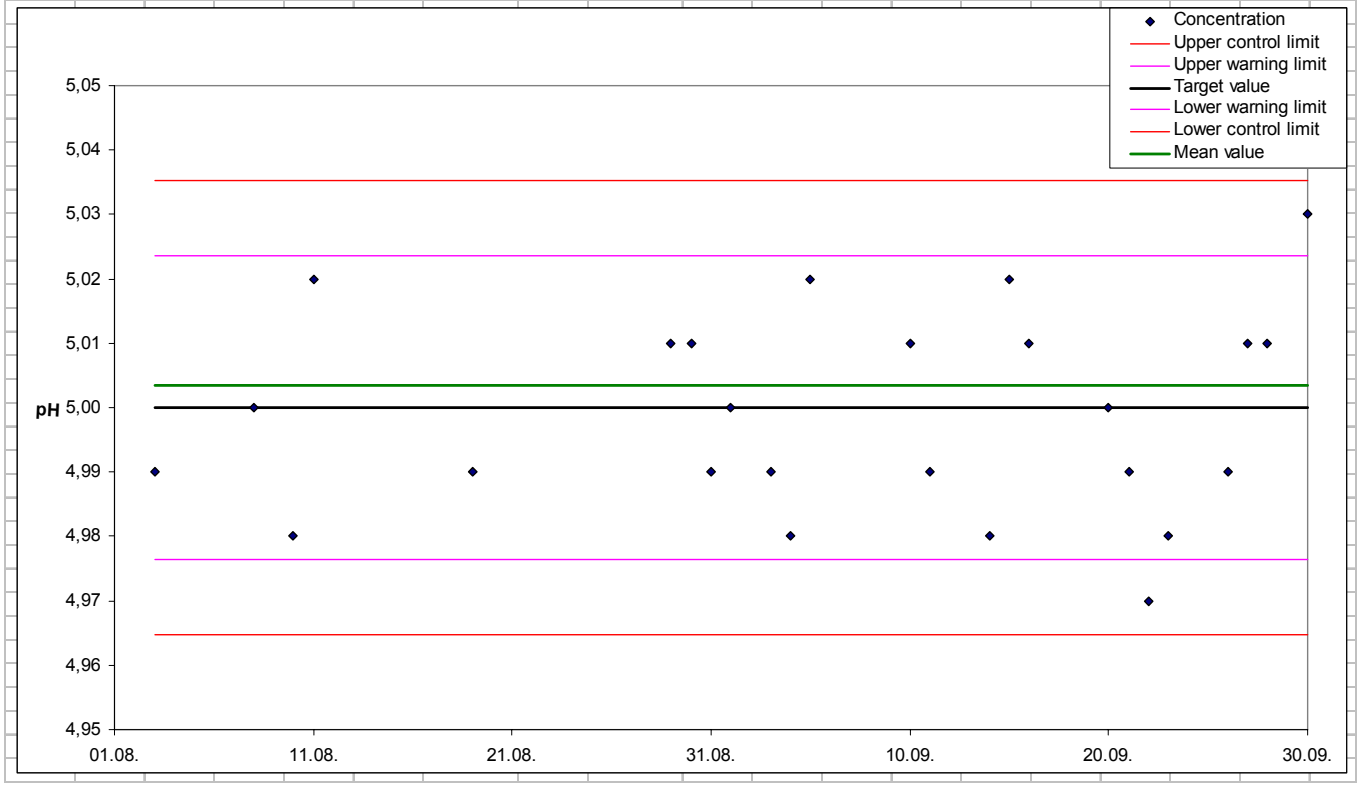
- Internal quality control at the chemical analytical laboratory, involves a continuous, critical evaluation of the laboratory's own analytical methods and working routines.

- 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. The basis is that the laboratory runs control samples together with the routine samples. The control values are plotted in a control chart. In this way it is possible to demonstrate that the measurement procedure performs within given limits. If the control value is outside the limits, no analytical results are reported and remedial actions have to be taken to identify the sources of error, and to remove such errors.

Figure 1 illustrates the most common type of control chart, the X-chart.

Institute		X-CONTROL CHART				METHOD:	ROLVAxx			CONTROL SAMPLE:	
Laboratory		**PERIOD:**	**03.08.04**	**-**	**30.09.04**	INSTRUMENT:	MagicChem			**Reagecon 5.00**	
Analyte	Target value (Tv)	Warning limits (Tv± 2STD)				Control limits (Tv± 3STD)				Mean value (M̄)	Standard deviation (STD)
pH	5,000	Upper	5,024	Lower	4,976	Upper	5,035	Lower	4,965	5,003	0,012



- From the requirement on the analytical results the analyst sets up the control program:
  - Type of QC sample
  - Type of QC charts
  - Control limits – warning and action limits (or warning and control limits)
  - Control frequency
- When the control program encompasses the whole analytical process from the sample entering the laboratory to the analytical report the control results will demonstrate the within-laboratory reproducibility. The within-laboratory reproducibility will indicate the variation in the analytical results if the same sample is given to the laboratory at different times.

- The results of the control program may be used in several ways - the analyst will have an important quality tool in his/her daily work, the customer can get an impression of the laboratory's quality and the laboratory can use the results in the estimation of the measurement uncertainty.

- The QC has to be part of a quality system and should be formally reviewed on a regular basis. Other important elements of the quality system are the participation in interlaboratory comparisons (proficiency test), the use of certified reference materials and method validation.

- In practical work it is necessary that the quality control is limited to fulfilling the requirements on the analytical results – a good balance between control work and analyses of samples is essential.

Principles of quality control charting

- Control charting is a powerful and simple tool for the daily quality control of routine analytical work. The basis is that the laboratory runs control samples together with the routine samples in an analytical run. Material of control samples can be standard solutions, real routine samples, blank samples, in-house control materials and certified reference materials.

- Immediately after the analytical run is completed the *control values* are plotted on a control chart.

- The central line (CL) in the control chart is representing the mean value of the control values or the nominal value of a certified reference material. In addition to the central line, the control chart normally has four lines. Two of these, the so-called *warning limits*, are located at a distance of ± two times the standard deviation from the central line (CL ± 2s). Provided that the results are normally distributed, about 95 % of the results should be within these limits. In the control chart two other lines are also drawn at a distance of ± three times the standard deviation from the central line (CL ± 3s). These lines are called the action limits and 99,7 % of the data normally distributed should be within these limits. Statistically only three out of 1000 measurements are thus located outside the action limits. If the control value is outside the action limits, there is a high probability that the analysis is in error.

Setting the control limits and the central line

- The control limits can be set based on method performance – statistical control limits or according to the requirement on *within-laboratory reproducibility* – target control limits.
- The central line in the control chart can be the calculated mean value of the control values or a reference value for the control sample. In most cases a mean central line is used.

Statistical control limits

The control limits are set based on the analytical performance of the control sample. From a longer time period, e.g. a year, the standard deviation *s* is calculated from the control values. Warning limits will be +2 *s* and – 2 s. Action limits will be +3 *s* and – 3 *s*.

Target control limits

The control limits are set based on the requirement on the analytical quality. The standard deviation for the control chart, *s*, is estimated from the requirement on s_{Rw} Warning limits will be +2 *s* and – 2 s. Action limits will be +3 *s* and – 3 *s*.

Mean central line

The mean value is estimated from control values obtained during a longer time, e.g. a year. The central line is set to this mean value.

Reference central line

The control sample is a reference material or a well-characterised material. The central line is set to the nominal value.

Setting up a quality control programme

- Control samples types
- Concentration ranges
- Frequency of control analyses
- Position of control samples in an analytical run

- A good balance between QC and test samples is important

- Daily interpretation of quality control

- Long term evaluation of quality control data

How often should control limits be evaluated?

- For successful use of control charts it is important that the control limits and the central line remain stable over a long period of time. The central line and control limits should not be changed frequently since this will make it difficult to detect gradual changes in analytical quality. The laboratory should have a policy for how often control limits are evaluated and how it is decided if a change is needed.
- Control limits and central line should be evaluated every year or after collection of 20 (or 30) data sets as indicated above. But the evaluation does not necessarily mean that the control limits should be changed. A change should only be considered if a significant change in spread or the bias has taken place.

Other uses of quality control data and control charts

- Measurement uncertainty
- Method validation
- Method comparison
- Estimation of limit of detection (LOD)
- Person comparison or qualification
- Evaluation of proficiency tests
- Environmental parameters and similar checks

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