Eurachem workshop 2012: Key Challenges in Internal Quality Control (2012).
Summary of workshop discussions

QC for qualitative testing

[8 participants]

Performance of QC in qualitative tests is not mandatory but participants recommend doing it. The main problem is how to do it. The use of measurement against control sample is strongly recommended. There are different levels of qualitative analysis. In microbiology the personal judgment is used, in many identification of analytes +both personal judgment and comparison with database are used. Evaluation of false positive and false negative samples is one of QC strategies. Internal QC gives positive feedback for the clients and for accreditation bodies. [Miloslav Suchanek]

Annual or longterm review of the QC programme

(9 participants)

The outcome of the discussion pointed out that a long term review should be mandatory and performed by personnel responsible for the analytical method but including independent people e.g. quality manager. The appropriate time interval has to be set by the laboratory. The control limits and central line in an on-going control may only be changed if there is a clear justification. Additional benefits of the long term review are that long term trends and unusual patterns can be detected and data can be used to update the validation report. [Bertil Magnusson]

Follow-up QC failures

(8 participants)

Criteria of what a QC failure is need to be defined. Main causes for QC failures identified include (in the order of their occurrence) human mistakes, calibration errors, equipment failure, wrong control samples, aged chemicals. A procedure on how to deal with QC failures was recommended as well as clear decision criteria about the effectiveness of a corrective action. A special group are QC failures with no obvious cause, the inducement of these might be found by chance, much later or even never (e.g. shortcut between outlet and inlet of lab air, Cd contamination by smoking, temporary vibrational or electrical influences …). [Martina Hedrich]

QC for multi-methods e.g. screening for pesticides

(# participants not recorded)

The analysis of metals or organic contaminants in food or environmental matrices are some examples of multi-parameter measurements.

If Quality Control (QC) is supported on statistical parameters defined for a confidence level of 95%, one in 20 controls will fail criteria even if measurement performance is equivalent to that observed in the past. Therefore, for multi-parameter measurements of more than 20 analytes, there is a large chance that the QC result for at least one parameter fails criteria. Since individual measurements of multi-parameter procedures are often correlated, an analytical run should be rejected only if significantly more than 5% of tests fail criteria at the 95% confidence level. The assessment of the

correlation between observed deviations in the analysis of various parameters, of a reference material, can be performed using symbolic charts. These charts are tables summarising the outcome of the QC where for each analyte are represented, with symbols, deviations above or below the defined control limits. The correlated deviations of the QC of measurements of different analytes in the same reference material prove measurements are not under control at that stage.

The QC of multi-parameters measurements can be simplified by checking performance for just some analyte/matrix combinations known to have performance parameters equivalent to the measurements of other combinations. The good or bad performance observed in measurements of the representative analyte/matrix combinations is then extrapolated to a wider scope. The selection of representative analytes or matrices can be based on the equivalence of properties or characteristics of various analytes or matrices respectively.

Unfortunately, there are not many available reference materials useful for QC of multi-parameter measurements, particularly for the analysis of organic compounds.

The acceptance of the QC can also depend on the analyte content of characterised samples. For instance, if analyte recovery, in spiked samples analysis, is slightly above maximum acceptable value but samples present estimated content below LD, sample results can be reported as “<LD”.

Since measurement performance varies with the analyte level, quantitative performance should be controlled next to decision limits. [Ricardo Bettencourt da Silva]

Challenges in obtaining fit for purpose control samples

Laboratories use a range of materials as QC sample including certified reference materials, surplus PT materials, laboratory samples and materials specially prepared by customers. Spiked samples prepared in house emerged as a common solution to obtain suitable materials, particularly where there were challenges relating to stability of materials or the range of analytes/concentrations being analysed. [Vicki Barwick]

Setting control limits – statistical and target limits

Although most laboratories use statistical control limits based on intermediate precision, it was agreed that target control limits are beneficial in many cases. For statistical control limits the number of results used in the pre-period should be as high as possible (20 as a minimum). Target control limits can be used for the time of the pre-period until statistical limits are available. Target limits can be based on customers’ requirements or on estimates of intermediate or within-laboratory reproducibility standard deviation. In any case it is advisable to statistically check the feasibility of the target limits. [Michael Koch]