# ANALYTICAL QUALITY CONTROL
# THE COMPLEMENTARITY OF THE TOOLS

*Summary of the talk by Mr. TROSSAT (CECALAIT) at CECALAIT's AGM 2006*

**Analysis laboratories adopt quality assurance systems in order to respond at best to requirements concerning the reliability of their results. The participation in proficiency tests and the use of standard reference materials are key elements among the various tools permitting to demonstrate and/or to control the accuracy and the traceability of the analysis methods applied by the laboratories. However, the use of only one tool is insufficient to ensure a satisfactory follow-up of the results accuracy. It is therefore necessary to establish a typical control program.**

## THE QUALITY ASSURANCE TOOLS

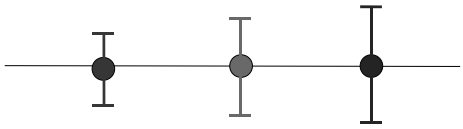
Laboratories have three principal quality assurance tools at their disposal:

- **Proficiency tests (PT)**: The frequency of these tests must be monthly to quarterly according to the matrix. Many samples, covering the measurement range of the method, are sent "in blind" to the participating laboratory. For each sample, a consensual assigned value is calculated from the results of all the participating laboratories (after selection according to the method applied and elimination of outliers). This tool permits to detect systematic or random deviations, level effects…
  Control of the homogeneity and stability permits to ensure the quality of the results for participating laboratories.

- **External standard reference materials (ESRM or SRM)**: Generally, the frequency of use of these samples is weekly to monthly. The samples are commonly mono-level (method control) or pluri-level (calibration). They are sent to user laboratories with a reference value obtained from results of an interlaboratory test realised with expert laboratories.
  A control of homogeneity and stability is performed on each batch of samples.

- **Internal standard reference materials (ISRM, pilot, temoin…)**: These samples must be used daily to weekly. The reference value (or target) is attributed by the user (by test, by comparison with external reference materials, by standard addition…). As with the external reference materials, the samples are generally mono-level (method control) or pluri-level (calibration).
  A control of homogeneity and stability must be performed on each batch of samples.

These tools differ at many levels:
- Their aim (objectives) is different,
- The uncertainties on the assigned values are different, so, the maximal tolerated errors vary according the tool.



PT ESRM ISRM

The use of proficiency tests or standard reference materials only is insufficient to ensure the test quality. Indeed, these tools used individually are photographs of the laboratory's accuracy at an instant T. Therefore, they do not permit to ensure a satisfactory traceability of the determinations' accuracy over the period.
The solution would be to equal the complete analytical traceability film over a given period. It is then necessary to build a program of the analytical quality control operations (with control of traceability).

## A TYPICAL QUALITY CONTROL PROGRAM

A typical control program corresponds to a combination of the various tools available to ensure the traceability of accuracy over time. In practice, this program must define the use of ESRM and ISRM tools between two proficiency tests.
To imagine this program, it is necessary to:
- clearly define the quality objectives by method. These objectives must be based on the laboratory's needs, the client's expectations, the method's robustness and the economical aspect of the measurand ;
- list the available internal and external tools.

This program will then be built associating different tools and considering the uncertainty (linked with the maximum tolerated error), the desired reactivity, the feed back in case of anomaly and the impact on the laboratory work.

## INTERPRETATION OF THE RESULTS

When the program is applied, it is indispensable to analyse and interpret the results obtained with the various tools, in order to set up adapted curative and corrective actions.

➢ **Proficiency tests:** The laboratory may evaluate its results in relation to the assigned values and compare the statistical parameters (mean and deviation of standard deviation) calculated from results of all the samples, to the fixed limits.
In the case of limit overshooting, the causes of the deviations must be found in order to set up corrective action.

➢ **External and internal reference materials:** Firstly, the maximal tolerated errors (or tolerance) must be defined by analytical methods. They could be calculated, either according to ISO 5725-6 standard (critical deviation), or fixed a priori by the laboratory.
The laboratory could also fix operating and data interpretation modes (setting up of a control chart of individual results with the use of the cumulated or "floating" mean).

The follow-up of the quality control program then permits the rapid implementation of technical corrective actions and an immediate feed-back on the previous results. According to the case, this program will be modified by an intensification of the controls or by a validation of new arrangements with external reference materials.

## CONCLUSION

The setting up of a structured analytical quality control program by method is indispensable, to respond at best to the laboratories' needs and clients' expectations.
Thanks to its necessary potential for evolution, according to the performances obtained, it will be an effective tool to ensure the quality of a laboratory's analytical results.