Internal quality control in chemical analysis—the big picture

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Internal quality control (IQC) became possible, and simulatnaeously essential, when routine analysis on a large scale became commonplace in the 1960s. Parallel development of methods of IQC took place in the fields of applied geochemistry and clinical biochemistry and have now spilled over into all sectors. Initially IQC methods were concerned with repeatability precision, but between-run precision is of overriding importance in routine analysis.

The three pillars of analytical quality are (i) fitness for purpose; (ii) validation; and (iii) quality control. A **fit-for-purpose** uncertainty is determined simply by the requirements of the application, not from the behaviour of actual analytical methods. **Validation** is the initial process of determining whether a particular analytical method can fulfil the uncertainty requirements of fitness for purpose. **Internal quality control** is the business of ensuring that the uncertainty found under validation is maintained throughout every run of the method.

A distinction has to be made between one-off analysis and routine, multi-run analysis. Only in the latter instance is the concept of statistical control meaningful. Then the control chart becomes the main tool, and it addresses run-to-run precision. But properly setting up and using a control chart is more complex than ususally acknowledged, and its function is widely misunderstood. The choice of the control materials and determination of the control limits are critically important. Duplication within-run addresses only repeatability precision so cannot suffice. In one-off analysis, validation and measurement are aspects of the same one activity.