18.7.1 Type of study

Interlaboratory study

A study in which several laboratories measure a quantity in one or more identical portions of homogeneous, stable materials under documented conditions, the results of which are compiled into a single report.

Note: The larger the number of participating laboratories, the greater the confidence that can be placed in the resulting estimated statistical parameter. The IUPAC-1995 protocol requires a minimum of eight laboratories for *method-performance studies*. (See Related paper by Howitz (1995) for Section 18.9).

Method-performance study

An *interlaboratory study* in which all laboratories follow the same written protocol and use the same test method to measure a quantity in sets of identical test samples. The reported results are used to estimate the performance characteristics of the method. Usually these characteristics are within-laboratory and among-laboratories precision, and when necessary and possible, other pertinent characteristics such as systematic error, recovery, internal quality control parameters, sensitivity, limit of determination, and applicability.

Notes:

(1) The materials used in such a study of analytical quantities are usually representative of materials to be analyzed in actual practice with respect to matrices, amount of test component (concentration), and interfering components and effects. Usually the analyst is not aware of the actual composition of the test samples but is aware of the matrix.

(2) The number of laboratories, number of test samples, number of determinations, and other details of the study are specified in the study protocol. Part of the study protocol is the procedure which provides the written directions for performing the analysis.

(3) The main distinguishing feature of this type of study is the necessity to follow the same written protocol and test method exactly.

(4) Several methods may be compared using the same test materials. If all laboratories use the same set of directions for each method and if the statistical analysis is conducted separately for each method, the study is a set of method-performance studies. Such a study may also be designated as a method-comparison study.

Laboratory-performance study

An interlaboratory study that consists of one or more analyses or measurements by a group of laboratories on one or more homogeneous, stable test samples by the method selected or used by each laboratory. The reported results are compared with those from other laboratories or with the known or assigned reference value, usually with the objective of evaluating or improving laboratory performance.

Notes:

(1) Laboratory-performance studies may be used to accredit laboratories or to audit performance. If a study is conducted by an organization with some type of management control over the participating laboratories - organizational, accreditation, regulatory, or contractual - the method may be specified or the selection may be limited to a list of approved or equivalent methods. In such situations, a single test sample is insufficient to judge performance. It is expected that the results from 1 of 20 tests will be outside the limits of the specified performance mean $\pm$ 2 standard deviations due just to chance fluctuations alone.

(2) Sometimes a laboratory-performance study may be used to select a method of analysis that will be used in a method-performance study. If all laboratories, or a sufficiently large subgroup of laboratories, use the same method, the study may also be interpreted as a method-performance study.

(3) Separate laboratories of a single organization with independent facilities, and with different local management, instruments, and calibration materials, are treated as different laboratories.

Material-certification study

An interlaboratory study that assigns a reference value ("true value") to a quantity (concentration or property) in the test material, usually with a stated uncertainty.

Note: A material-certification study often utilizes selected reference laboratories to analyze a candidate reference material by a method(s) judged most likely to provide the least-biased estimates of concentration (or of a characteristic property) and the smallest associated uncertainty.