

Characterization and Assignment of property Values and Uncertainties

ISO 17034 Clauses 7.12 & 7.13
ISO GUIDE 35 Clause 9

Characterization (as per Clause 9 of ISO Guide 35)

- 9.1 Preamble
- 9.2 Establishing metrological traceability
- 9.3 Characterization using a single reference measurement procedure (as defined in ISO/IEC Guide 99) in a single laboratory
- 9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories
- 9.5 Characterization of an operationally defined measurand using a network of competent laboratories.

Characterization (as per Clause 9 of ISO Guide 35)

- 9.6 Purity
- 9.7 Identity
- 9.8 Presence/Absence
- 9.9 Ordinal Scales
- 9.10 Qualitative properties
- 9.11 Characterization of non-certified values

9.3 Characterization using a single reference measurement procedure in a single laboratory

9.3.1 By reference measurement procedure without direct comparison with a CRM of the same kind

9.3.2 By value transfer from a reference material to a closely matched candidate reference material using a single measurement procedure performed by one laboratory

9.3.3 Selection of RM units for single-laboratory characterization

9.3.4 Formulation methods

9.3.1 Characterization by a reference measurement procedure without direct comparison with a CRM of the same kind

✓ In this approach, a value is assigned by **one laboratory** using **only one measurement procedure without direct comparison of a closely matched CRM**.

✓ This **limitation on the number of procedures and laboratories** greatly limits the possibility to detect unexpected effects. Therefore, this approach **requires the availability of a measurement procedure that is sufficiently well understood that unknown effects can be ruled out**.

9.3.1 Characterization by a reference measurement procedure without direct comparison with a CRM of the same kind

Measurement procedure requirements:

- 1) **completely understood**, meaning that all steps have a sound theoretical foundation so that **systematic error is negligible** relative to the intended use;
- 2) **completely described** by a measurement equation containing **all relevant influence factors** linking the measurand to the properties actually measured, **all of which can be expressed in SI units**;
- 3) measurement equation **does not contain empirically determined factors** that have a major influence on the measurement result (e.g. "recovery rates");
- 4) **no relevant influence of the measured quantity** on any of the influence factors contained in the equation;

9.3.1 Characterization by a reference measurement procedure *without direct comparison with a CRM of the same kind*

Measurement procedure requirements:

- 5) constants contained in the equation** are known with a low uncertainty, which **can be expressed in SI units**;
- 6) realistic uncertainty budget** can be written down in terms of SI units based on the individual quantification of the influence factors contained in the equation;
- 7) measurement uncertainty of the results** obtained by the measurement procedure is **sufficiently small** for the intended use of the RM.

9.3.1 Characterization by a reference measurement procedure *without direct comparison with a CRM of the same kind*

Measurement procedure requirements:

Establishment of the above requirements should be demonstrated by

- ✓ **third party assessment**;
- ✓ **appropriate validation studies**;
- ✓ **measurement uncertainty evaluation in accordance with ISO/IEC 17025**;
- ✓ **verification of performance by comparison with other laboratories, proficiency tests, and so on.**

9.3.2 Characterization by *value transfer from a RM to a closely matched candidate RM using a single measurement procedure performed by one laboratory*

Values are assigned to a "secondary CRM" by directly comparing results on the candidate CRM with those on an already characterized and closely matched CRM (the "primary CRM").

Examples for such materials include

- ✓ **trace element solutions** measured against certified solutions,
- ✓ materials measured against **Pharmacopoeia standards**
- ✓ **absorbance standards** measured against certified absorbance standards.

9.3.2 Characterization by value transfer from a RM to a closely matched candidate RM using a single measurement procedure performed by one laboratory

Primary CRM is the calibrator

The primary CRM and the Candidate RM should be closely matched to enable direct comparison in one laboratory using one method.

The following three aspects should be considered:

- a) primary and secondary CRMs consist of the same matrix** – Characterization of Cd in nitric acid solution against CRM solution of Cd in nitric acid is OK. What about characterization of Cd in granite against CRM solution of Cd in nitric acid?

9.3.2 Characterization by value transfer from a RM to a closely matched candidate RM using a single measurement procedure performed by one laboratory

- b) If the measurand is not operationally defined, the matrix is of a kind that, for the measurement in question, the measurement procedure can be regarded as completely understood** - chromatographic determination of a solution of benzo[a]pyrene vs chromatographic determination of benzo[a]pyrene in soil or soil extract

- c) The difference in the quantity level of the measured property** does not result in a significant bias between the measurement results of the primary and secondary CRM.

Measurement procedure used for characterization in this approach should fulfil all criteria for traceability

9.3.2 Characterization by value transfer from a RM to a closely matched candidate RM using a single measurement procedure performed by one laboratory

Assigned Value and u_{char}

- ✓ Assigned value is calculated by **direct comparison** between the results obtained on the primary and secondary CRMs.

✓ **Valid methods include**

- (a) bracketing,
(b) multi-point calibration curves with the primary CRM,
(c) one point calibration with a primary CRM of closely matched certified value and adding the measured difference to the certified value.

9.3.2 Characterization by **value transfer from a RM to a closely matched candidate RM** using a single measurement procedure performed by one laboratory

U_{char} consists of a combination of

- a) **uncertainty of certified value of the primary CRM,**
- b) **uncertainty of calibration** according to the chosen calibration model (which includes contribution due to the selectivity of the technique), and
- c) **effect of repeatability on the results of the secondary CRM.**

9.3.2 Characterization by **value transfer from a RM to a closely matched candidate RM** using a single measurement procedure performed by one laboratory

Traceability:

The certified values of the secondary CRM are traceable, via the primary CRM, to the same reference as the values of the primary CRM.

EXAMPLE: A solution of Cd in HNO₃ (secondary CRM) is characterized by measurement against a certified solution of Cd in HNO₃ (primary CRM).

9.3.3 **Selection of RM units** for single laboratory characterization

RMP should select a measurement scheme (No. of RM units and No. of replicates) that is capable of achieving the intended uncertainty for each certified value

9.3.4 Formulation methods

This approach is usually applied for the production of calibration solutions from pure substances and also for gas mixtures, the production of which is described in a separate standard.

The approach is sometimes also used in the production of matrix materials.

9.3.4 Formulation methods

The value of the **measurand** and its **uncertainties**, in **all materials to be mixed**, has to be known in order to calculate a certified value and uncertainty.

This is equivalent to **determining the purity** of the material of interest (see 9.6) and confirmation of the absence of the material of interest in the material to which it is added (for example, a solvent or 'blank' matrix material).

9.3.4 Formulation methods

Points to be considered:

Important to guard against change in content between acquisition and mixing; for example, water loss or uptake should be excluded, where appropriate.

If gravimetric mixtures of several materials, all of which contain the measurand in question, are to be prepared, **each of the materials should be characterized** using one of the approaches described in this clause.

Volumetric production follows similar principles in the calculation of the assigned value and uncertainty but entails an additional need to pay close attention to **non-additive volumes in mixing liquids** (for example, ethanol/water mixture) and other factors affecting measured volume, particularly temperature.

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

Inter Laboratory Multiple method characterization

For many measurands, no reference measurement procedures are available that provide accurate results. The approach described in this clause uses a number of data sets, obtained using different measurement procedures and/or in different laboratories to

- a) demonstrate absence of significant bias in measurement procedures by showing that independent procedures yield same results;
- b) demonstrate the absence of significant laboratory bias for each laboratory by agreement among results;
- c) improve the reliability of the assigned value by averaging results, thus reducing the effect of repeatability and randomizing and reducing the effect of between-laboratory or between-method variation.

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

Inter Laboratory Multiple method characterization

The concept of the determination of the method-independent property values of an RM based on agreement among different measurement procedures, potentially performed in different laboratories, is based on at least **two assumptions**:

- a) There exists a **population of procedures and/or laboratories** that is capable of determining the characteristics of the RM and providing results with acceptable accuracy.
- b) For most data evaluation approaches, it is assumed that the **differences between individual results**, both within and between measurement procedures/laboratories, **are random in nature**.

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

Inter Laboratory Multiple method characterization

For this approach to be valid, all results of all measurement procedures and/or laboratories involved should determine the same measurand and the **results should be traceable to the same system of units**. This requires careful selection of **calibration standards** and careful investigation of the **measurement procedures** used.

Inter-laboratory and multiple-method characterization rely on averaging across different sources of bias, to achieve a reduction in uncertainty. **Effective averaging relies on representative sampling for different effects.**

- Where possible, measurement procedures should be selected to give a **good representation of different principles of measurement**.
- The choice of participants should be representative of competent laboratories.

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

9.4.2 Study Design

At least **two substantially different measurement principles** should be included in a multiple-method study;

- ✓ Consideration should be given to the **choice of the calibration standard. The purity of the calibrants used should be given due consideration.**
- ✓ **Laboratories should be selected based on demonstrated competence.** Participating laboratories should provide evidence of competence for the measurand in question independent of the measurements on the candidate CRM, ideally before commencement of the study. It is thus impossible to use data on the candidate CRM from the same study as demonstration of competence and for value assignment of a CRM

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

9.4.2 Study Design

- ✓ The RM producer should set a documented **minimum number of technically valid results** for which value assignment will be considered. **The number of data sets should be large enough** to provide a fit-for-purpose uncertainty in the estimated value after allowing for the possibility of
 - a) failure to report,
 - b) exclusion of results for technical reasons and
 - c) the intended statistical evaluation.

The number of participating laboratories is less important than the **number of independent data sets**. A single laboratory might be able to provide several data sets, all obtained by independent procedures, calibrants and/or instruments.

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

9.4.2 Study Design

The RMP should specify the **form of reporting** while conducting ILC. The specification should include

- **instructions on reporting** of individual observations, averages, or both;
- the **measurement units** required for quantitative results;
- the **number of significant digits** required for quantitative results;
- where appropriate, the **form of measurement uncertainty**;
- the nature and form of additional information required such as **measurement procedures** and **measurement standards** used, **dates and times of measurement**, or **run order**

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

9.4.3 Evaluation

- ✓ Data sets should be inspected visually and graphically. Check for completeness and any observed anomaly for possible trivial or non trivial reasons. **If errors or failures are confirmed, the corresponding results should be corrected or rejected.**
- ✓ All results should be checked for **evidence of technical errors**. This term does not refer to measurement data that is shown to be outlying from the data set based solely on statistical considerations.
- ✓ Inclusion of **quality control materials**, with known values, in such studies has been found useful to **identify technical problems**.

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

9.4.3 Evaluation

The pool of **technically accepted data sets** should be evaluated statistically, giving due consideration to evidence of between group differences **(particularly between-method and between-laboratory differences)**

Examine

- ✓ **distribution of values;**
- ✓ **presence of clusters of results;** and
- ✓ **potential outliers.**

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

Assigned value and uncertainty

Value assignment should use appropriate statistical procedures

Instruction on the use of **two commonly used procedures**, the **mean** and **weighted mean**, **(A.2.4)**

The **uncertainty of characterization** can be estimated either by using

- a) **uncertainty statements** submitted by the laboratory
- b) from the **submitted data**, ignoring the uncertainty statements made by the laboratory, or
- c) from a **combination of both**. **(A.2.5)**

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

9.4.4 Single Laboratory Multi method studies

In some cases, organisations have invested an exceptional amount of effort in **method development**, such that the **metrological control of the measurement procedures approaches that of reference measurement procedures**.

RMP should ensure that **these measurement procedures are sufficiently different**. RMP should also ensure that

- a) have access to the **complete quality assurance and validation data**, which should be taken into consideration for the **technical evaluation**;
- b) the **number of data sets is small**. Therefore, more emphasis should be put on the **assessment and proper treatment of measurement uncertainties**.

9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories

9.4.4 Single Laboratory Multi method studies

Where results **agree within the claimed uncertainties**, the **weighted mean (A.2.4) and corresponding uncertainty may be used**.

Where apparently valid results **do not agree well within the claimed uncertainty**, one should carefully **reconsider whether the metrological control of the measurement procedures is sufficient for this approach**. On confirmation, the effect of the excess dispersion of results should be allowed for in the certified value uncertainty.

9.5 Characterization of an operationally defined measurand using a network of competent laboratories

This approach is applicable to the production of RMs certified for **operationally defined measurands** – i.e by a particular **measurement procedure only**.

Hence, **several laboratories** are required.

This approach is largely similar to that described in **9.4**, with the **exception that all laboratories apply the same procedure**.

9.5 Characterization of an operationally defined measurand using a network of competent laboratories

- ✓ **A well-described measurement procedure should be chosen.** This should be a published standard method, ideally an internationally agreed procedure (e.g. ISO, ASTM, AOAC or IFCC).
- ✓ **Participants should be instructed to follow the procedure exactly,** allowing only those variations that are permitted within the procedure.
- ✓ **Any modification of such a procedure agreed by all participants**
- ✓ **Quality control samples can also be used in this case to demonstrate that a particular instrument fulfils all specifications.**

9.5 Characterization of an operationally defined measurand using a network of competent laboratories

EVALUATION

In the case of operationally defined measurands, the defining procedure is (by definition) unbiased and it is then necessary only to consider **possible laboratory bias** and **within-laboratory effects** in an uncertainty evaluation.

Design & evaluation of studies for characterization of a **non-operationally defined measurand** using **two or more methods** of demonstrable accuracy in **one or more competent laboratories**

INTERLAB MULTIPLE METHOD STUDIES
or
SINGLE LAB MULTIPLE METHOD STUDIES

**INTERLAB MULTIPLE METHOD STUDIES or
SINGLE LAB MULTIPLE METHOD STUDIES**

(A) STUDY DESIGN

- 1) Selection of measurement procedures
- 2) Choice of calibration standards
- 3) Selection of laboratories
- 4) Number of independent data sets
- 5) Number of units and replicate determinations
- 6) Quality control materials
- 7) Instructions for participants
- 8) Reporting

(A) STUDY DESIGN

1) Selection of measurement procedures

At least **two substantially different measurement principles** should be included in a multiple-method study. When selecting measurement procedures, variation of among others the following aspects should be considered:

- **sample preparation**, (e.g) grinding/milling, extraction or clean-up;
- **sample introduction and/or separation**, (e.g) using LC/GC;
- **quantification principles**, (e.g) molecular or atomic absorption, mass spectrometry, flame ionization or fluorescence; and
- **calibration procedures**.

(A) STUDY DESIGN

1) Selection of measurement procedures- continued

Maximum possible variation should be sought. For example, if **Gas Chromatography** is the only available separation technique, then the study should at least aim to include:

- ✓ **different injection techniques**,
- ✓ **different columns**
- ✓ **temperature programs** and
- ✓ **quantification by different detectors**.

- (a) **Validated measurement methods** only to be used +
(b) **MU** should have been estimated for each procedure and the same **is reasonable**.

(A) STUDY DESIGN**2) Choice of calibration standards**

An important decision is **whether all laboratories should use the same calibrator** or whether laboratories should be given **free choice of the calibrator**.

- ✓ Using a single calibrator reduces variation caused by different calibrators from different suppliers.
- ✓ Any bias in this single calibrator will translate into the same bias in the certified values.
- ✓ A single calibrator requires very careful characterization of this calibrator

As a general guideline: (a) where experience shows that the quality of available calibration standards is sufficient, **giving laboratories the free choice of standards is usually preferable**; and (b) where there is significant doubt about the quality of standards on the market, the efforts needed to characterize **a common standard are often justified**.

(A) STUDY DESIGN**3) Selection of laboratories**

Labs should be selected based on **demonstrated competence**.

Evidence for the demonstration of competence may include:

- results **from proficiency tests**;
 - results on **independent CRMs** (possibly distributed as quality control materials together with the candidate CRM);
 - **method validation data**;
 - **a full and credible uncertainty budget**;
 - **previous participation in other RM certification campaigns** for the same measurand; and
 - **third party assessment** of conformance with ISO/IEC 17025
- It is important to obtain **information on performance** in addition to evidence of third party assessment as per ISO/IEC 17025

(A) STUDY DESIGN**4) Number of independent data sets**

The **number of participating laboratories is less important** than the **number of independent data sets**. A single laboratory might be able to provide several data sets, all obtained by independent measurement procedures.

Complete independence of results is difficult to achieve if measurements are performed in a single laboratory. The RM producer should **critically review the variation of all critical steps as outlined in (1)** to check whether sufficient method variability is present

The RM producer should **set a documented minimum number of technically valid results** for which value assignment will be considered.

(A) STUDY DESIGN**4) Number of independent data sets**

For interlaboratory studies using a network of testing laboratories, the characterization should include **five or more participants** providing technically valid data.

A characterization uncertainty less than one third of the interlaboratory reproducibility standard deviation requires at least **nine participants** unless laboratories are selected for exceptional performance.

(A) STUDY DESIGN**5) Number of units and replicate determinations**

- ✓ Determined by **practical** as well as evaluation considerations.
- ✓ If the **variation between individual units of the RM is large**, single measurements on **several different units are preferable** to several replicate measurements on a single unit.
- ✓ If contamination, breakage or **heterogeneity are not an issue**, sending **a single unit is sufficient**.

(A) STUDY DESIGN**6) Quality control materials**

- ✓ Inclusion of **additional samples for quality control** has been found to be highly beneficial. Results on these samples **can identify technical problems** and aid the **technical evaluation**.
- ✓ RMs, in particular natural matrix RMs and quality control (QC) materials, may be used to demonstrate the validity of the measurement result when measured alongside the **unknown material to be characterized**.
- ✓ CRMs used for quality control in an interlaboratory study should be supplied **without the original label to avoid identification**

(A) STUDY DESIGN**7) Instructions for participants**

- a) a clear outline of the objective of the study;
- b) instructions to refrain from comparing results with other participants, including the reasons for discouraging collusion (that is, cooperative exchange of information);
- c) the number of units to be tested;
- d) the number of replicate determinations to be performed;
- e) any restrictions or specific details of measurement procedures to be used; (e.g., any need for prior drying and moisture correction);
- f) the minimum test portion size;
- g) requirements with respect to quality and traceability of the measurement results;
- h) the time schedule (distribution of samples, delivery of results);

(A) STUDY DESIGN**7) Instructions for participants**

- i) the mode of dispatch;
- j) instructions for intermediate storage of samples;
- k) specific instructions for sample treatment, if applicable;
- l) instructions on quality control measures to identify potential bias; and
- m) information on the RMP's policy on identification of laboratories and use of data; (e.g. whether laboratories will be identified, whether results will be identified with a particular laboratory etc.,

A meeting with the laboratories/groups involved (prior to distributing the samples and performing the measurements) can help all parties involved to align all actions to be carried out during the collaborative study, and to discuss possible problems and/or pitfalls.

(A) STUDY DESIGN**8) Reporting of results by participants**

- ✓ Use of preformatted reporting forms can be useful as it allows copying of the results, which can reduce transcription errors in the RM producer's collation of results
- ✓ Where there is an option for correction of a known procedural bias, such as extraction recovery, the RM producer should state clearly whether results should be corrected or not
- ✓ Results reported as "less than" make statistical evaluations difficult
- ✓ Where results near detection limits are likely, RM producers should either require laboratories to report the observed results
- ✓ It is recommended that an outline of the measurement procedure used is reported in sufficient detail to permit an understanding of all stages in the measurement process (e.g. digestion/extraction of the sample and separation of the analytes of interest, clean-up, and quantification).

(B) EVALUATION**1) General considerations**

- ✓ Anomalies can arise that require communication with the participant concerned.
- ✓ The producer may contact participants **to assist in the investigation of anomalies** at any stage of the evaluation process.
- ✓ It is recommended that **initial contact should not specify the nature of the anomaly** (for example, the direction of deviation of the results); rather, the participant should initially be **invited to investigate and report any errors discovered**.

(B) EVALUATION**2) Initial screening**

Initial examination of individual participant results should check for evidence of basic reporting or procedural errors such as

- (i) **missing data,**
- (ii) **incorrect numbers of replicates;**
- (iii) **inappropriate conditions of measurement, (iv)**
- incorrect identification of test items**

Unexpectedly **high or low results** or **uncertainties** can also be apparent on receipt and may be referred to the participant for checking at this stage.

(B) EVALUATION**2) Initial screening**

Technical evaluation to identify potential problems may include **grouping results** by techniques

- (i) measurement procedure and principle,
- (ii) sample pre-treatment methods, or
- (iii) calibration technique used.

Technically invalid results should be **removed** from the data set or **corrected**, by repeating the measurement

CAUTION: An apparent outlier may be the only technically valid result in a data set

(B) EVALUATION**3) Statistical Evaluation**

Different procedures can be systematically biased as well as showing laboratory specific bias per data set

The possibility of between-method differences should be considered in evaluating measurement uncertainty.

Anomalies related to reported measurement uncertainties should be resolved by referral to participants for checking and possible correction.

(B) EVALUATION**3) Statistical Evaluation**

Distributions: Check whether there is evidence of deviation from the assumed distribution using visual methods

An approximately normal distribution of data sets is often observed for results well above the limit of quantification; Other distributions include Poisson distributions (e.g. microbe counts) or a Weibull distribution (e.g. mechanical failure of ceramics).

The selected distribution should be in agreement with the reported data as well as with the theoretical and historical knowledge of the measurement in question. If these differ significantly, no value should be assigned unless technical reasons for the unexpected distribution can be given.

In some cases, the results can be transformed so that they become approximately normally distributed. Some commonly used transformations include logarithmic (Microbiology MPN), square root and exponential forms. There should be a technical basis for such a transformation.

(B) EVALUATION**3) Statistical Evaluation**

Outliers: Outliers can be identified by, for example by Grubb's test.

Outlying observations /mean values should not be removed solely on statistical evidence, but may be removed if there is a technical reason .

Technical reasons for outliers can be due to

- (a) inadequate calibration,
- (b) inadequate measurement procedures,
- (c) use of inadequate reagents,
- (d) failure to account for interferences and
- (e) deviation from the certified value of an independent quality control material.

Data points, with unusually large uncertainty, can be removed on technical grounds – i.e lack of intermediate precision or method repeatability

(B) EVALUATION**3) Statistical Evaluation****Robust statistics - Robust estimators and their properties:**

- (a) Median – Mean
- (b) Algorithm A – Mean and SD
- (c) Hampel – Mean
- (d) nIQR – SD
- (e) Scaled median absolute deviation – [MADe] – SD
- (f) Qn- SD

The above robust estimators are suitable subject to the following:

- (i) Results from the labs should be scrutinised for evidence of technical errors and technically invalid results should be removed;
- (ii) There are **at least 10 data points** after any results have been removed for technical reasons;
- (iii) Majority of values in the data set (**usually the central portion**) are **approximately normally distributed** or at least **symmetrically distributed**;

(B) EVALUATION**3) Statistical Evaluation****Grouping ("Clustering"):**

Statistical evaluation should check for occurrence of grouping of results, along (a) measurement procedures, (b) calibrants, or (c) reagents

Three possibilities:

- (i) If the **difference between means for different groups is statistically significant** and is **too large** to permit a sufficiently small uncertainty, then no single property value can be assigned. Where the grouping is along measurement procedure, RMP may provide **an assigned value for each measurement procedure**.

(B) EVALUATION**3) Statistical Evaluation****Grouping ("Clustering"):**

- (ii) If there are **significant differences and the difference between the means of these groups is relatively small**, one single value may be assigned. **An additional uncertainty term accounting for the between-group variation should then be added to the uncertainty of characterization.**

- (iii) If the **difference between these clusters is large and there is no correlation** of these clusters with measurement procedures or other technical explanation for the differences, **no value can be assigned.**

(B) EVALUATION**4) ASSIGNED VALUE**

Where the data set means follow an approximately normal distribution and **no weighting is applied**, the unweighted arithmetic mean of the **p** data is set as assigned value:

Assigned value $y_{\text{char}} = \sum x_i / p$
 where x_i is the mean of each of the **p** data sets

A “**weighted**” mean is usually calculated using the formula:

Assigned value $y_{\text{char}} = \sum w_i x_i / \sum w_i$
 where w_i is the “**weight**” applied to each data set mean.

The simplest choice of weights w_i is given by the formula:

$$w_i = 1/u_i^2$$

where u_i is the reported standard uncertainty for the value x_i

(C) Use of collaborative studies for multiple purposes**5) ASSIGNED UNCERTAINTY**

(i) use of analysis of variance (ANOVA) for uncertainty evaluation – Details in B2 of ISO Guide 35

(ii) where the data set means follow an approximately normal distribution and **no weighting is applied**, standard uncertainty due to characterization, u_{char} can be calculated using the following formula:

$$u_{\text{char}} = s(y)/p$$

where $s(y)$ indicates SD of “**p**” data set mean values
