How to Meet ISO 17025 Requirements for Method Verification

PURPOSE

The purpose of the guide is to define the activities that are required to fulfill method verification based on analytical method performance characteristics.

ISO 17025:2005 section 5.4.2 states:

> "…The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated."

In this guide, to confirm is the same as to verify.

Verification that a laboratory can adequately operate a standard method requires that the laboratory provide objective evidence the performance parameters specified in the test method have been met with the matrices to which the method is being applied. Most often, the critical requirements are the accuracy and the precision (generally accepted as repeatability and reproducibility) which are reflected in the measurement uncertainty. The objective evidence is the accuracy and precision obtained from actual lab data.

SCOPE AND APPROACH

The scope of this guide encompasses AOAC *Official Methods*℠, EPA, FDA and FSIS official methods, and NADA methods and methods used in Microbiological, Food and Pharmaceutical labs.

Different industries may have differing terminology when describing categories of analytical methods and analytical parameters. This guide attempts to use the terminology commonly used by AOAC.

Different industries may have specific requirements. A particular federal agency or client may have very specific criteria for method verification. In this case the client's or agency's requirements would override those in this guide.

The analytical test methods are grouped according to the category of method based on its purpose. The lab can identify the category of test method it is verifying and find the corresponding parameters that need to be verified.

When a method is verified, the laboratory is required to demonstrate that it can achieve certain specific performance characteristics/parameters established during the validation study. The validation study must contain all pertinent performance characteristics. Certain performance characteristics, such as linearity, will not vary from lab to lab and do not need to be verified. Other parameters, such as repeatability, are specific to the lab performing the method and need to be verified. Thus, the performance characteristics that need to be verified are a subset of the performance characteristics included in a method validation.

This guide treats chemical test methods and microbiology methods separately.

CHEMICAL METHODS

Categories of Chemical Methods

Chemical analytical methods fulfill many different purposes, from quantifying an analyte at a low concentration to identifying a material. With such a variety of methods, it is logical that different test methods require varying verification. For ease of discussion, the test methods can be divided into six different categories based on their purpose. The categories are listed below. For each of the categories of test methods only relevant performance characteristics need to be included in a method verification. The approach of this guide is to list all performance characteristics needed for verification, and explain the reason for verifying the performance characteristic.

The six categories of chemical analytical methods are:

1. Confirmation of Identity, a method that ensures a material is what it purports to be or confirms the detection of the target analyte.

2. Quantifying an analyte at a low concentration.

3. Determining if an analyte is present above or below a specified, low concentration (often called a Limit Test). The specified concentration is close to the LOQ.

4. Quantifying an analyte at a high concentration.

5. Determining if an analyte is present above or below a specified, high concentration (often called a Limit Test). The specified concentration is substantially above the LOQ.

6. Qualitative test.

Since the activities needed for method verification are a subset of those needed for validation, the required performance characteristics for validation will be presented first. The performance characteristics needed for the validation of each of six main categories of chemical test methods are identified in Table 1. If a performance characteristic is not needed for validation, it is not needed for verification. In Table 1, "Yes" means the performance characteristic must be included for validation and "No" means the performance characteristic does not need to be included for validation. **Tb1**

Table 1. Categories of Chemical Test Methods: Since the activities needed for method verification are a subset of those needed for validation, the required performance characteristics for validation are presented in this table

	Performance Characteristics Included in a Validation					
Performance Characteristic	Identification 1	Analyte at Low Concentration Quantitative 2	Analyte at Low Concentration Limit Test 3	Analyte at High Concentration Quantitative 4	Analyte at High Concentration Limit Test 5	Qualitative 6
Accuracy	No	Yes	No	Yes	Yes	No
Precision	No	Yes	No	Yes	Yes	No
Specificity	Yes	Yes	Yes	Yes	Yes	Yes
LOD	No	Yes	Yes	Yes/No	No	No
LOQ	No	Yes	No	Yes/No	No	No
Ruggedness	No	Yes	No	Yes	No	No
Linearity/Range	No	Yes	No	Yes	No	No

Requirements of Method Verification for the Six Categories of Chemical Test Methods

In Tables 2–5, "Yes" means the performance characteristic must be included for verification and "No" means the performance characteristic does not need to be included for verification. **Tbs2-5**

Category 6. Qualitative Tests:

Qualitative tests are used to identify a specific element or compound (analyte) based on the response of a material to the test. The most important characteristic of a qualitative test is its ability to reliably identify the analyte in the presence of other substances. This is referred to as the "specificity."

Method validation includes determining any cross reactivity with other known entities. The lack of cross reactivity demonstrates the specificity of the method. If samples are identical to those for which the method is intended, no verification of specificity is required. If any matrix components are unique to the lab's samples, the lab will need to demonstrate there is no impact on specificity.

The method precision of qualitative tests is generally expressed as false-positive/false-negative rates and is determined at several concentration levels. Verification of a lab's ability to properly operate a qualitative method can be demonstrated by analyzing populations of negative and positive fortified samples. For example, for each different sample matrix, duplicate samples are analyzed at three levels. Suggested levels are blanks (no analyte), low level (near the

Table 2. Category 1: Confirmation of Identity—A method that ensures a material is what it purports to be or confirms the detection of the target analyte

Performance Characteristic	Verification	Verification Activities	Reason for Verification
Specificity	No—if the lab's samples are identical to those in the standard method and if any differences in instrumentation do not impact specificity.	NA	If the samples have the same matrix, the specificity which is based on basic principles, will not be impacted. Basic principles are chemical reactions, e.g. reaction of Ag with Cl to create a precipitate.
	Yes—if the lab's samples differ from those in the standard method.	Same as those required for validation.	
	Yes–if differences between instruments could affect specificity.	The activity need only deal with the unique aspect's of the lab's samples or instrumentation.	Specificity can be impacted by differences in instrumentation.

Table 3. Category 2: Analyte at Low Concentration, Quantitative

Performance Characteristic	Verification	Verification Activity	Reason for Verification
Accuracy	Yes	If the concentration range for which the method is validated is narrow (<1 order of magnitude), analyze one reference material/standard/spike at one concentration. Otherwise, demonstrate accuracy at each concentration level (low, middle and high) by analyzing one reference material/standard/spike at each level.	Over a narrow concentration range, the accuracy and precision should not vary, therefore, the demonstration at one concentration is sufficient. Over a wide concentration range, the accuracy and precision can vary, thus they need to be verified at the different concentration levels.
Precision	Yes	Perform the repeatability test once. If the method covers a concentration range >1 order of magnitude, then the repeatability test must include low, middle and high concentrations.	Over a narrow concentration range, the accuracy and precision should not vary, therefore, the demonstration at one concentration is sufficient. Over a wide concentration range, the accuracy and precision can vary, thus they need to be verified at the different concentration levels. Intermediate precision, between analysts, is handled by making sure the analysts are trained and can adequately perform the method.
Specificity	No/Yes	*See* Specificity in General Requirements	*See* Specificity in General Requirements
LOD	Yes	Run a sample close to LOD	LOD is very likely to be matrix and instrument specific
LOQ	Yes	Run a sample close to LOQ	LOQ is very likely to be matrix and instrument specific

lower range of the method) and high level (near the high end of the range). Standard additions can be used to obtain the correct concentration levels. Rates comparable to those stated in the validated method demonstrate the labs ability to operate the method.

USING MEASUREMENT UNCERTAINTY IN METHOD VERIFICATION OF CHEMICAL TESTS

The estimate of measurement uncertainty (MU) for a measurand is the indicator of precision, and the MU is one of the components that can be used to verify a lab can perform the method satisfactorily.

When there is no validation data available, the MU may be the only parameter that can be compared to the specification to ensure the method works.

The comparison of a lab's performance (bias and precision) can be compared to those from the collaborative study using the approach as described in ISO Technical Specification ISO/TS 21748, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation.*

Additional guidance, including examples of using the approach suggested in ISO/TS 21748 will be posted on the AOAC Website.

Table 4. Category 3: Analyte is present above or below a specified, low concentration (Limit Test)

Performance Characteristic	Verification	Verification Activity	Reason for Verification
LOD	Yes	Run a sample close to LOD	LOD is very likely to be matrix and instrument specific
LOQ	Yes	Run a sample close to LOQ	LOQ is very likely to be matrix and instrument specific
Specificity	No/Yes	*See* Specificity in General Requirements	*See* Specificity in General Requirements

Table 5. Category 4: Quantifying an analyte at high concentration and Category 5: Analyte above or below a specified, high concentration (often called a Limit Test)

Performance Characteristic	Verification	Verification Activity	Reason for Verification
Accuracy	Yes	If the method is a limit test or if the concentration range for which the method is validated is narrow (<1 order of magnitude), analyze one reference material/standard/spike at one concentration. Otherwise, demonstrate accuracy at each concentration level, low middle and high by analyzing one reference material/standard/spike at each level.	Over a narrow concentration range, the accuracy and precision should not vary, therefore, the demonstration at one concentration is sufficient. Over a wide concentration range, the accuracy and precision can vary, thus they need to be verified at the different concentration levels.
Precision	Yes	Perform the repeatability test once. If the method covers a concentration range >1 order of magnitude, then the repeatability test must include low, middle and high concentrations.	Over a narrow concentration range, the accuracy and precision should not vary, therefore, the demonstration at one concentration is sufficient. Over a wide concentration range, the accuracy and precision can , thus they need to be verified at the different concentration levels. Intermediate precision, between analyst, is handled by making sure the analysts are trained and can adequately perform the method.
Specificity	No/Yes	*See* Specificity in General Requirements	*See* Specificity in General Requirements

Table 6. Categories of Microbiological Test Methods: Performance Characteristics Included in a Validation Study

Performance Characteristic	Identification	Quantitative	Qualitative (P/A)	Verification (where applicable)
Relative Accuracy	Yes	Yes	No	No
Matrix Effects	No	Yes	Yes	Yes
Precision	No	Yes	No	Yes
Selectivity	No	Yes	Yes	No
Specificity	Yes	Yes	Yes	No
Inclusivity	Yes	Yes	Yes	No
Exclusivity	Yes	Yes	Yes	No
False-Positive Rate	No	Yes	Yes	No
False-Negative Rate	No	Yes	Yes	No
LOD	No	Yes	Yes	No
LOQ	No	Yes	No	No
Ruggedness	Yes	Yes	Yes	No
Linearity/Range	No	Yes	No	No

MICROBIOLOGICAL METHODS

The performance characteristics needed for the validation and verification of each of three main categories of microbiological test methods are identified in Table 6. **Tb6**

Verification Guidelines

Verification of microbiological methods also requires that the following parameters are addressed:

1. Laboratory competency of achieving method performance characteristics on an on-going basis.

2. Analyst performance: Can your analysts perform the method with the equivalent degree of precision and accuracy?

Measurement Uncertainty for Microbiology

Measurement uncertainty is a parameter associated with the result of a measurement that characterizes the *dispersion of the values* that could reasonably be attributed to the measurand, in other words, the variance or standard deviation of the result or the degree of confidence in an analytical result. Calculation of MU is more reliable with a minimum of 30 observations in order to obtain the 95% confidence limits of the overall precision of the method. Therefore it is not unreasonable to expect that each of the required performance characteristics would also be based on 30 observations. MU usually requires the inclusion of repeatability and reproducibility of all factors that contribute to >10% of the variability and uses the root sum of squares in the calculation, e.g. where there are 2 key factors (Uc) = $RSD_1^2 + RSD_2^2$. In its simplest determination, however relativeMU or RelativeUe = 2 RSD_R (Relative Standard Deviation of Reproducibility) when all factors that could impact on the reliability of a result are taken into consideration.

In this regard, Validation data can be used comparatively for method verification since the validation study provides reference values for RSD_R and RSD_r (Relative Standard Deviation of Reproducibility and Relative Standard Deviation of Repeatability).

For example a validation study of Pour Plate counting obtained the following data:

RSD_r 7.7% (0.077) (within analysts)

RSD_R 18.2% (0.182) (between analysts)

Calculation of combined uncertainty for counting:

Sum of squares: $(0.077)^2 + (0.182)^2 = 0.0371$

Combined relative uncertainty = (0.0371) = 0.193 = 19.3%

Expanded relative uncertainty for counting: (Use coverage factor k = 2 for 95% confidence) = 2 19.3% = 38.6%

The MU for this technique is 38.6% and becomes the reference value for the MU determined by in-house method verification.

Experimental data for calculating MU can be obtained from:

- Proficiency testing (PT) programs
- Reference samples
- Spike recovery
- Method verification replicates
- Sample duplicates

More information on estimating Measurement Uncertainty for microbiological methods can be found in the American Association for Laboratory Accreditation in the Guideline "G108—Guidelines for Estimating Uncertainty for Microbiological Counting Methods."

Analyst Performance in Microbiology

Only analysts who have been adequately trained to perform a method should participate in method verification. Training and qualification of analysts require a written protocol of activities with documented results of achievement. Trained analysts need to be assessed on an on-going basis.

Assessment tools may include:

- Blind samples (known positive and known negative samples)
- Observation of performance
- Written test; e.g. on Quality Control Practices, calculations, interpretation of results, knowledge of quality policies and procedures
- Daily checks on precision of duplicate counts*
- Proficiency testing**

*Precision of Duplicate Counts:

1. All analysts perform duplicate counts on 15–30 samples for each type of matrix, record as D1 and D2

2. Convert data to Log_{10}

3. Determine the absolute value of the range and its log (R_{log}) for each pair (D1 – D2)

4. Calculate the mean $\check{R}$ for each set of data

$$\check{R} = \frac{R_{log}}{n}$$

5. Analysts can now run daily duplicates

6. 99% Precision criteria: R 3.27 $\check{R}$

7. Plot results on a control chart to monitor variability

Ref. SMEWW. 1998. 20th ed. (9-11)
**Proficiency Testing

1. Intralaboratory Proficiency Testing:

Internally controlled "check sample" or spiked samples" used as:

- An ongoing assessment of analytical performance and competency by individual analysts within a laboratory
- A means to demonstrate competence for tests not covered by external proficiency programs
- To detect training needs

2. Interlaboratory Proficiency Testing

Proficiency panels from outside source; e.g. AOAC, FDA

(a) Provides a measure of precision and relative accuracy of analytical methods performed by different laboratories

(b) Provides an estimate of the relative accuracy and precision of results between laboratories

(c) Can be used for intralaboratory proficiency testing, but by itself is not designed for assessment of the competency of individual analysts

GENERAL REQUIREMENTS

The lab must have a management system consistent with that described in ISO/IEC 17025:2005.

The analysts must be adequately trained:

- The analyst must have the appropriate knowledge, experience, and training to perform the procedure.
- The analyst must be competent in performing the given functions of the lab:
  - operating the instrumentation
  - performing the analysis as specified
  - understanding the analytical technique
- The training must be documented.

The verification exercise must be planned, approved, and documented and a final report kept on file to demonstrate the lab can perform the method adequately.

Verification documentation should be created that:

- Describes the procedure to be verified
- Details the analytical performance characteristics to be evaluated
- Establishes acceptance criteria used to determine that the procedure performs suitably
- Justifies deviations from Reference Method

General Requirements—Specificity

For specificity in all categories of methods, if samples are identical to those for which the method is intended and validated, and the method is based on basic principles then no verification is needed. If the samples have the same matrix, the specificity which is based on basic principles, will not be impacted. Basic principles are chemical reactions, e.g. reaction of Ag with Cl to create a precipitate. For some methods, the specificity can be affected by the instrument used. In these cases the lab should assess if the instrument differences could affect the specificity, and if so, include specificity in the verification, e.g. the different resolution and/or detection systems in inductively coupled plasma optical emission spectrophotometers may result in different interferences.

METHOD SELECTION "FIT FOR USE"

Analytical methods are evaluated based on attributes such as accuracy, precision, specificity, sensitivity, detectability and practicality. Compromise between attributes is inherent in the selection of methods. However, any method selected for use must be appropriate to the requirements of the regulatory function and must be within the capabilities of the laboratory

staff. Depending on the documentation available on a method, varying degrees of method verification or validation are recommended before it is adopted for routine use.

The lab must first ensure the chosen method is applicable to the samples the lab will be analyzing with the method. If there is any difference between the lab's samples and those for which the method is validated, the extent of the difference and its impact must be assessed. The impact of the difference could require a partial validation to include the performance characteristics that are impacted or the method may require complete validation.

CIRCUMSTANTIAL CHANGES/DEVIATIONS FROM THE METHOD AS VALIDATED

For a number of reasons, a lab may not be able to perform the method exactly as validated. In these circumstances, the method verification may have to deal with these differences. A number of unforeseen scenarios are shown in Table 7. If a scenario does occur the listed equivalency study shall be performed. There may be other scenarios; this list is not all inclusive. **Tb7**

Table 7.

Parameter in Validated Method	Difference from Validated Method	Required Equivalence Study
a. Apparatus and equipment used	a. Either some of the apparatus and equipment are outdated or the lab does not have them, and the lab wants to use available apparatus and equipment	An instrument equivalence bridging study is needed to ensure that the "numbers" generated by alternate apparatus and equipment relate in some reproducible way to the concentrations determined in the validated method.
b. Specific detector	b. The lab may not have the specific detector and the lab would like to use one that is available.	b. An equivalence study is needed comparing the "numbers" obtained between the two detectors to ensure that the "numbers" generated relate in some reproducible way to the concentrations determined in the validated method.
c. Sample preparation: Occasionally samples are prepared in liquid nitrogen to prevent loss of analyte(s)	c. If the lab has production type environment, it can process sample quickly at room temperature.	c. A bridging study comparing the two sample preparations is needed to ensure that the "numbers" generated relate in some reproducible way to the concentrations determined in the validated method.
d. Other possible scenarios:		d. Any of the scenarios mentioned in column 2 require bridging to ensure that the "numbers" generated relate in some reproducible way to the concentrations in the validated method.
i. Columns and cartridges	i. The lab wishes to use available columns and cartridges of different vendors.	
ii. Mobile phase	ii. Occasionally mobile phase used in the validated method is found to be corrosive and detrimental to pump and seals. In this case a compatible substitute can be used.	
iii. Mobile phase gradient	iii. The lab may not have the required 3-pump gradient system; solvents are pre-mixed for two-pump gradient.	
iv. Throughput	iv. Subtle modifications in extraction and purification steps may be needed such as exchange of extraction solvent of less health hazard solvent, shaking vs. vortexing, use of compatible solvent, use of SPE cartridges of different vendor(s), etc.	

PHARMACEUTICAL

To prevent confusion, the use of the term Identity in the pharmaceutical industry is explained here.

In the pharmaceutical industry, identity tests are intended to ensure the identity of an analyte in a sample. Identity—is the material what it is supposed to be?

In other analytical fields Identity has a different meaning, e.g. in the Eurachem definition. "It is necessary to establish that the signal produced at the measurement stage, or other measured property, which has been attributed to the analyte, is only due to the analyte and not from the presence of something chemically or physically similar or arising as a coincidence. This is confirmation of identity." *Analytical Methods A Laboratory Guide to Method Validation and Related Topics,* p. 14

Thus in the pharmaceutical industry the term Identity describes a "category of analytical test" while in the Eurachem guide Identity describes an analytical parameter.

FOOD

Chemical Testing Category 3: Method determining if an analyte is present above or below a specified, low concentration (often called a Limit Test).

This category is pretty delicate as it is located at the interface of quantitative–qualitative determinations. However, for food safety it represents a very important category, i.e. residues of banned vet drug, which must not be present in food of animal origin. In the EU this is covered by Decision 657/2002/EC. In the EU much more emphasis is placed on the validation of such methods in comparison to those included in this guide.

DEFINITIONS

Accuracy: For the purposes of this document, the term accuracy is defined as:

> The closeness of agreement between the measured value and the accepted, "true," or reference value. Accuracy is indicative of the bias of the measurement process. Accuracy is often evaluated by repetitively spiking the matrix or placebo with known levels of analyte standards at or near target values. The fraction or percentage of added analyte recovered from a blank matrix is often used as the index of accuracy. Added analyte, however, may not always reflect the condition of the natural analyte in the materials submitted for analysis. (*Official Methods of Analysis of AOAC INTERNATIONAL*, 18th Ed., Appendix E).

This guide acknowledges that the *Official Methods of Analysis* (OMA) definition of "accuracy" is not fully in line with the current version of the VIM-3rd edition which defines in clause

2.13 (3.5)

measurement accuracy
accuracy of measurement
accuracy

closeness of agreement between a **measured quantity value** and a **true quantity value** of a **measurand**

NOTES

1. The concept 'measurement accuracy' is not a **quantity** and is not given a **numerical quantity value**. A **measurement** is said to be more accurate when it offers a smaller **measurement error**.

2. The term "measurement accuracy" should not be used for **measurement trueness** and the term **measurement precision** should not be used for 'measurement accuracy,' which, however, is related to both these concepts.

3. 'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

Intermediate Precision

Intermediate precision: The precision of an analytical procedure expresses the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Intermediate precision expresses within-laboratories variations: different days, different analysts, different equipment, etc. (ICH Validation of Analytical Procedures: Text and Methodology, Q2R).

Intermediate precision: Measurement precision under a set of conditions of measurement. (ISO/DGuide 99999.2, International vocabulary of basic and general terms in metrology (VIM). Third edition, 2.24 without notes.)

Repeatability

Repeatability (of results of measurements): Closeness of the agreement between the results of successive measurements of the same measurand carried out subject to all of the following conditions:

- same measurement procedure
- same observer

- same measuring instrument, used under the same conditions
- same location
- repetition over a short period of time

(ISO Guide 30: 1992 A7)

Repeatability: Measurement precision under the set of repeatability conditions of measurement. (ISO/DGuide 99999.2, International vocabulary of basic and general terms in metrology (VIM). Third edition, 2.22)

Reproducibility

Reproducibility (of results of measurements): Closeness of the agreement between the results of measurements of the same measurand, where the measurements are carried out under changed conditions such as:

- principle or method measurement
- observer
- measuring instrument
- location
- conditions of use
- time

(ISO Guide 30:1992 A.8)

Note: For the purposes of this ALACC guide a change to the principle of measurement would create a new method that would have to be validated.

Reproducibility: Measurement precision under reproducibility conditions of measurement. (ISO/DGuide 99999.2, International vocabulary of basic and general terms in metrology (VIM). Third edition, 2.26 without notes.)

Standard method: A method that has been validated by an authoritative body. Most food and pharmaceutical methods are found in AOAC, USDA, FDA, EPA, AOCS, AACC, ISO, IUPAC, USP, and FCC method manuals. Many trade associations publish their own methods and provide useful resources. A few examples include the Corn Refiners Association, National Food Processors Association, Association for Dressings and Sauces, and the American Spice Trade Association.

Validated method: The planned and documented procedure to establish the method's performance characteristics. The performance characteristics or the validation parameters of the method determine the suitability for its intended use. They define what the method can do under optimized conditions of matrix solution, analyte isolation, instrumental settings, and other experimental features. The inclusion of particular validation parameters in a validation protocol depends on the application, the test samples, the goal of the method, and domestic or international guidelines or regulations, as applicable. *(Official Methods of Analysis of AOAC INTERNATIONAL*, 18th Ed., Appendix E)

Comments:

- Validation of a method establishes, by systematic laboratory studies that the method is fit-for-purpose, i.e., its performance characteristics are capable of producing results in line with the needs of the analytical problem. The important performance characteristics include: selectivity and specificity (description of the measurand), measurement range, calibration and traceability, bias linearity, limit of detection/limit of quantitation, ruggedness, and precision. The above characteristics are interrelated. Many of these contribute to the overall measurement uncertainty and the data generated may be used to evaluate the measurement uncertainty. The extent of validation must be clearly stated in the documented method so that users can assess the suitability of the method for their particular needs.
- Examples of validated methods can be obtained from specific organizations such as AOAC INTERNATIONAL.

Verification

Provision of objective evidence that a given item fulfils specified requirements.

EXAMPLES

(a) Confirmation that a given **reference material** as claimed is homogeneous for the **quantity value** and **measurement procedure** concerned, down to a measurement portion having a mass of 10 mg.

(b) Confirmation that performance properties or legal requirements of a **measuring system** are achieved.

(c) Confirmation that a **target measurement uncertainty** can be met.

NOTES

1. When applicable, **measurement uncertainty** should be taken into consideration.

2. The item may be, e.g., a process, measurement procedure, material, compound, or measuring system.

3. The specified requirements may be, e.g., that a manufacturer's specifications are met.

4. Verification in legal metrology, as defined in VIML [10], and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

5. Verification should not be confused with **calibration.** Not any verification is a **validation**.

6. In chemistry, verification of identity of entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

VIM 3, 2.44

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 9000:2000 3.8.4 without notes).

Comment:

- In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation, or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision either to restore in service, perform adjustments, or repair, or to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.