NACRW Reference Materials Working Group
Draft Glossary of Terms

The Reference Materials (RM) Working Group of the NACRW is interested in the development of a common glossary of terms to benefit RM users. The draft glossary contained in the following pages is a collection of terms deemed relevant to this user group from various resources, including the *RM Guidelines* published by the AOAC Technical Division on Reference Materials, the Eurachem Guides on *The Selection and Use of Reference Materials* and *Terminology in Analytical Measurement*, Guidelines for the Validation of Chemical Methods for the FDA FVM Program, International Vocabulary of Metrology (VIM), ISO 17034:2016(E), and ISO Guide 30. No specific references to ISO Guide 31 are included because the terms included in that Guide are referenced to other sources that have already been included.

This draft glossary contains multiple definitions for some terms, based on slightly different definitions from the various sources. Moving forward, the tasks for the Working Group are:

1. Determine if any important resources are missing from the reference list.
2. Determine if any important terms are missing from the draft glossary.
3. Determine if any terms currently on this list are not necessary.
4. Consolidate definitions for terms with multiple entries.

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Term	Definition	Source
Accuracy	The closeness of agreement between a test result and an accepted reference value. When applied to test results, accuracy includes a combination of random and systematic error. When applied to test method, accuracy refers to a combination of trueness and precision.	FDA [1]
	Closeness of agreement between a measured quantity value and a true quantity value of a measurand	VIM [2]
Action level	Level of concern or target level for an analyte that must be reliably identified or quantified in a sample.	FDA [1]
Analyte	The chemical substance measured and/or identified in a test sample by the method of analysis.	FDA [1]
Analytical batch	An analytical batch consists of samples, standards, and blanks which are analyzed together with the same method sequence and same lots of reagents and with the manipulations common to each sample within the same time period (usually within one day) or in continuous sequential time periods.	FDA [1]
Bias	The difference between the expectation of the test result and the true value or accepted reference value. Bias is the total systematic error, and there may be one or more systematic error components contributing to the bias.	FDA [1]
	Estimate of a systematic measurement error	VIM [2]
Blank	A substance that does not contain the analytes of interest and is subjected to the usual measurement process. Blanks can be further classified as method blanks, matrix blanks, reagent blanks, instrument blanks, and field blanks.	FDA [1]
Calibration	Determination of the relationship between the observed analyte signal generated by the measuring/detection system and the quantity of analyte present in the sample measured. Typically, this is accomplished through the use of calibration standards containing known amounts of analyte.	FDA [1]
	Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication	VIM [2]
Calibration Standard	A known amount or concentration of analyte used to calibrate the measuring/detection system. May be matrix matched for specific sample matrices.	FDA [1]

Term	Definition	Source
Carryover	Residual analyte from a previous sample or standard which is retained in the analytical system and measured in subsequent samples. Also called *memory*.	FDA [1]
Certified Reference Material (CRM)	Reference material accompanied by documentation (certificate) issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures. Note: Standard Reference Material (SRM) is the trademark name of CRMs produced and distributed by the National Institute of Standards and Technology (NIST).	FDA [1]
	Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures	VIM [2]
	Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability	ISO 17034 [3] ISO Guide 30 [4]
Certified Value	Value, assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the reference material certificate	ISO 17034 [3] ISO Guide 30 [4]
Check Analysis	Result from a second independent analysis which is compared with the result from the initial analysis. Typically, check analyses are performed by a different analyst using the same method.	FDA [1]
Commutability	Property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures, and the relation obtained among the measurement results for other specified materials	VIM [2]
	Property of a reference material, demonstrated by the equivalence of the mathematical relationships among the results of different measurement procedures for an reference material and for representative samples of the type intended to be measured	ISO Guide 30 [4]
Confirmation of Identity	Unambiguous identification of an analyte(s) by a highly specific technique such as mass spectrometry or by demonstration of results from two or more independent analyses in agreement.	FDA [1]
Confirmatory Analysis/Method	Independent analysis/method used to confirm the result from an initial or screening analysis. A different method is often used in confirmation of screening results.	FDA [1]
Coverage Probability	Probability that the set of true quantity values of a measurand is contained within a specified coverage interval	VIM [2]

Term	Definition	Source
Coverage Factor	Number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty	VIM [2]
Cut-off Concentration	In qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods). See also *Threshold Value*.	FDA [1]
Error	Measured quantity value minus a reference quantity value	VIM [2]
False Negative Rate	In qualitative analysis, a measure of how often a test result indicates that an analyte is not present, when, in fact, it is present or, is present in an amount greater than a threshold or designated cut-off concentration.	FDA [1]
False Positive Rate	In qualitative analysis, a measure of how often a test result indicates that an analyte is present, when, in fact, it is not present or, is present in an amount less than a threshold or designated cut-off concentration.	FDA [1]
Fitness for Purpose	Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.	FDA [1]
Guidance Level	Level of concern or action level issued under good guidance practices that must be reliably identified or quantified in a sample.	FDA [1]
Homogeneity	Uniformity of a specified property value throughout a defined portion of a reference material	ISO Guide 30 [4]
Incurred Samples	Samples that contain the analyte(s) of interest, which were not derived from laboratory fortification but from sources such as exogenous exposure or endogenous origin. Exogenous exposure includes, for example, pesticide use, consumption by an animal, or environmental exposure.	FDA [1]
Indicative Value	Value of a quantity or property, of a reference material, which is provided for information only. An indicative value cannot be used as a reference in a metrological traceability chain	ISO Guide 30 [4]
Interference	A positive or negative response or effect on response produced by a substance other than the analyte. Includes spectral, physical, and chemical interferences which result in a less certain or accurate measurement of the analyte.	FDA [1]
Intermediate Precision	Within-laboratory precision obtained under variable conditions, e.g., different days, different analysts, and/or different instrumentation.	FDA [1]
	Measurement precision under a set of conditions that includes the same measurement procedure, same location, and replicate measurements on the same or similar objects over an extended period of time, but may include other conditions involving changes	VIM [2]

Term	Definition	Source
Internal Standard	A chemical added to the sample, in known quantity, at a specified stage in the analysis to facilitate quantitation of the analyte. Internal standards are used to correct for matrix effects, incomplete spike recoveries, etc. Analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard should have similar physico-chemical properties to those of the analyte.	FDA [1]
Level of Concern	Level of concern is the concentration of an analyte in a sample that has to be exceeded before the sample can be considered violative. This concentration can be a regulatory tolerance, safe level, action level, guidance level or a laboratory performance level.	FDA [1]
Limit of Detection (LOD)	The minimum amount or concentration of analyte that can be reliably distinguished from zero. The term is usually restricted to the response of the detection system and is often referred to as the *Detection Limit*. When applied to the complete analytical method it is often referred to as the *Method Detection Limit* (MDL).	FDA [1]
	measured quantity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a component in a material is β, given a probability α of falsely claiming its presence	VIM [2]
Limit of Quantitation (LOQ)	The minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision. Limit of quantitation (or quantification) is variously defined but must be a value greater than the MDL and should apply to the complete analytical method.	FDA [1]
Limit Test	A type of semi-quantitative screening method in which analyte(s) has a defined level of concern. Also referred to as binary or pass/fail tests.	FDA [1]
Linearity	The ability of a method, within a certain range, to provide an instrumental response or test results proportional to the quantity of analyte to be determined in the test sample.	FDA [1]
Matrix	All the constituents of the test sample with the exception of the analyte.	FDA [1]
Matrix Blank	A substance that closely matches the samples being analyzed with regard to matrix components. Ideally, the matrix blank does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples. The matrix blank is used to determine the absence of significant interference due to matrix, reagents and equipment used in the analysis.	FDA [1]
Matrix Effect	An influence of one or more components from the sample matrix on the measurement of the analyte concentration or mass. Matrix effects may be observed as increased or decreased detector responses, compared with those produced by simple solvent solutions of the analyte.	FDA [1]
Matrix Reference Material	Reference material that is characteristic of a real sample	ISO Guide 30 [4]

Term	Definition	Source
Matrix Source	The origin of a test matrix used in method validation. A sample matrix may have variability due to its source. Different food matrix sources can be defined as different commercial brands, matrices from different suppliers, or in some cases different matrices altogether. For example, if a variety of food matrices with differing physical and chemical properties are selected, the number of sources for each food sample matrix may be one or more.	FDA [1]
Matrix spike	An aliquot of a sample prepared by adding a known amount of analyte(s) to a specified amount of matrix. A matrix spike is subjected to the entire analytical procedure to establish if the method is appropriate for the analysis of a specific analyte(s) in a particular matrix. Also referred to as a *Laboratory Fortified Matrix*.	FDA [1]
Measurand	Quantity intended to be measured	VIM [2]
Measurement	Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity	VIM [2]
Measurement Procedure	Detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result	VIM [2]
Measurement Traceability	Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty	VIM [2]
Method blank	A substance that does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples. An aliquot of reagent water is often used as a method blank in the absence of a suitable analyte-free matrix blank.	FDA [1]
Method Detection Limit (MDL)	The minimum amount or concentration of analyte in the test sample that can be reliably distinguished from zero. MDL is dependent on sensitivity, instrumental noise, blank variability, sample matrix variability, and dilution factor.	FDA [1]
Method Development	The process of design, optimization and preliminary assessment of the performance characteristics of a method.	FDA [1]
Method Validation	The process of demonstrating or confirming that a method is suitable for its intended purpose. Validation includes demonstrating performance characteristics such as accuracy, precision, specificity, limit of detection, limit of quantitation, linearity, range, ruggedness and robustness.	FDA [1]
Method Verification	The process of demonstrating that a laboratory is capable of replicating a validated method with an acceptable level of performance.	FDA [1]
Metrology	Science of measurement and its application	VIM [2]

Term	Definition	Source
Metrological Traceability Chain	Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference	VIM [2]
Minimum Detectable Concentration (MDC)	In qualitative analysis, an estimate of the minimum concentration of analyte that must be present in a sample to ensure at a specified high probability (typically 95% or greater) that the measured response will exceed the detection threshold, leading one to correctly conclude that an analyte is present in the sample.	FDA [1]
Minimum Sample Size	Lower limit of the amount of an RM, usually expressed as a mass quantity, that can be used in a measurement process such that the values or attributes expressed in the corresponding RM documentation are valid	ISO Guide 30 [4]
Operationally Defined Measurand	measurand that is defined by reference to a documented and widely accepted measurement procedure to which only results obtained by the same procedure can be compared	ISO 17034 [3]
Precision	The closeness of agreement between independent test results obtained under specified conditions. The precision is described by statistical methods such as a standard deviation or confidence limit of test results. See also *Random Error*. Precision can be further classified as *Repeatability, Intermediate Precision*, and *Reproducibility*.	FDA [1]
	Closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions	VIM [2]
Primary Standard	Measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention	VIM [2]
	Measurement standard that is designated or widely acknowledged as having the highest metrological qualities and whose property value is accepted without reference to other standards of the same property or quantity, within a specified context	ISO Guide 30 [4]
Production Batch or Lot	Definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality	ISO Guide 30 [4]
Qualitative Analysis/Method	Analysis/method in which substances are identified or classified on the basis of their chemical, biological or physical properties. The test result is either the presence or absence of the analyte(s) in question.	FDA [1]
Quantitative Analysis/Method	Analysis/method in which the amount or concentration of an analyte may be determined (or estimated) and expressed as a numerical value in appropriate units with acceptable accuracy and precision.	FDA [1]
Quantity Value	Number and reference together expressing magnitude of a quantity	VIM [2]

Term	Definition	Source
Random error	Component of measurement error that in replicate measurements varies in an unpredictable manner. See also *Precision*.	FDA [1]
	Component of measurement error that in replicate measurements varies in an unpredictable manner	VIM [2]
Range	The interval of concentration over which the method provides suitable accuracy and precision.	FDA [1]
Reagent Blank	Reagents used in the procedure taken through the entire method. Reagent Blanks are used to determine the absence of significant interference due to reagents or equipment used in the analysis.	FDA [1]
Recovery	The proportion of analyte (incurred or added) remaining at the point of the final determination from the analytical portion of the sample measured. Usually recovery is expressed as a percentage.	FDA [1]
Reference material	A material, sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.	FDA [1]
	Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties	VIM [2]
	Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. Properties can be quantitative or qualitative.	ISO 17034 [3] ISO Guide 30 [4]
Reference Material Certificate	Document containing the essential information for the use of a CRM, confirming that the necessary procedures have been carried out to ensure the validity and metrological traceability of the stated property values	ISO Guide 30 [4]
Reference Material Certification Report	Document giving detailed information, in addition to that contained in a reference material certificate, e.g. the preparation of the material, methods of measurement, factors affecting accuracy, statistical treatment of results, and the way in which metrological traceability was established	ISO Guide 30 [4]
Reference Material Document	Document containing all the information that is essential for using any reference material, covering both the product information sheet and reference material certificate	ISO 17034 [3]
Reference Material Producer	Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces	ISO 17034 [3] ISO Guide 30 [4]

Term	Definition	Source
Reference standard	A standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived. Note: Generally, this refers to recognized national or international traceable standards provided by a standards producing body such as the National Institute of Standards and Technology (NIST).	FDA [1]
	Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location	VIM [2]
Repeatability	Precision obtained under observation conditions where independent test results are obtained with the same method on identical test items in the same test facility by the same operator using the same equipment within short intervals of time.	FDA [1]
	Measurement precision under a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time	VIM [2]
Representative Analyte	An analyte used to assess probable analytical performance with respect to other analytes having similar physical and/or chemical characteristics. Acceptable data for a representative analyte are assumed to show that performance is satisfactory for the represented analytes. Representative analytes should include those for which the worst performance is expected. Representative analytes are used mostly for non-targeted analysis and unknown screening procedures.	FDA [1]
Representative Matrix	Matrix used to assess probable analytical performance with respect to other matrices, or for matrix-matched calibration, in the analysis of broadly similar commodities. For food matrices, similarity is usually based on the amount of water, fats, protein, and carbohydrates. Sample pH and salt content can also have a significant effect on some analytes.	FDA [1]
Reproducibility	Precision obtained under observation conditions where independent test results are obtained with the same method on identical test items in different test facilities with different operators using different equipment.	FDA [1]
	Measurement precision under a set of conditions that includes different locations, operators, measuring systems, and replicate measurements on the same or similar objects	VIM [2]
Resolution	Smallest change in a quantity being measured that causes a perceptible change in the corresponding quantity value provided by a measuring instrument or a measuring system	VIM [2]
Ruggedness/Robustness	A measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.	FDA [1]
Sample	Portion (amount) of material taken from a batch	ISO Guide 30 [4]

Term	Definition	Source
Screening Analysis/Method	An analysis/method intended to detect the presence of analyte in a sample at or above some specified concentration (action or target level). Screening methods typically attempt to use simplified methodology for decreased analysis time and increased sample throughput.	FDA [1]
Secondary Standard	Measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind	VIM [2]
	Measurement standard whose property value is assigned by comparison with a primary measurement standard of the same property or quantity	ISO Guide 30 [4]
Selectivity	The extent to which a method can determine particular analyte(s) in a mixture(s) or matrix(ces) without interferences from other components of similar behavior. Selectivity is generally preferred in analytical chemistry over the term *Specificity*.	FDA [1]
	Property of a measuring system, used with a specified measurement procedure, whereby it provides measured quantity values for one or more measurands such that the values of each measurand are independent of other measurands or other quantities in the phenomenon, body, or substance being investigated	VIM [2]
Sensitivity	The change in instrument response which corresponds to a change in the measured quantity (*e.g.*, analyte concentration). Sensitivity is commonly defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ.	FDA [1]
	Quotient of the change in an indication of a measuring system and the corresponding change in a value of a quantity being measured	VIM [2]
Specificity	In quantitative analysis, specificity is the ability of a method to measure analyte in the presence of components which may be expected to be present. The term *Selectivity* is generally preferred over Specificity.	FDA [1]
Spike Recovery	The fraction of analyte remaining at the point of final determination after it is added to a specified amount of matrix and subjected to the entire analytical procedure. Spike Recovery is typically expressed as a percentage. Spike recovery should be calculated for the method as written. For example, if the method prescribes using deuterated internal standards or matrix-matched calibration standards, then the reported analyte recoveries should be calculated according to those procedures.	FDA [1]
Standard	A substance of known identity and purity and/or concentration.	FDA [1]
	Realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference	VIM [2]
Stability	Characteristic of a reference material, when stored under specified conditions, to maintain a specified property value within specified limits for a specified period of time	ISO Guide 30 [4]

Term	Definition	Source
Standard Reference Material (SRM)	A certified reference material issued by the National Institutes of Standards and Technology (NIST) in the United States. (www.nist.gov/SRM).	FDA [1]
Systematic error	Component of measurement error that in replicate measurements remains constant or varies in a predictable manner. This may also be referred to as *Bias*.	FDA [1]
	component of measurement error that in replicate measurements remains constant or varies in a predictable manner	VIM [2]
Threshold Value	In qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods). See also *Cut-off Concentration*.	FDA [1]
Transportation Stability	Stability of a reference material property for the time period and conditions encountered in transportation to the user of the reference material.	ISO Guide 30 [4]
Trueness	The degree of agreement of the mean value from a series of measurements with the true value or accepted reference value. This is related to systematic error (bias).	FDA [1]
	Closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value	VIM [2]
Uncertainty	Non-negative parameter characterizing the dispersion of the values being attributed to the measured value.	FDA [1]
	Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used	VIM [2]
Working Standard	Measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems	VIM [2]

Other Resources

AOAC TDRM RM Guidelines, AOAC INTERNATIONAL, Gaithersburg, Maryland, USA (2015)

Eurachem Guide: The Selection and Use of Reference Materials (2002) https://www.eurachem.org/index.php/publications/guides/usingrm

VJ Barwick and E Prichard (Eds.), *Eurachem Guide: Terminology in Analytical Measurement – Introduction to VIM 3* (2011) https://www.eurachem.org/index.php/publications/guides/terminology-in-analytical-measurement

References

[1] *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Ed., US Food & Drug Administration Office of Foods and Veterinary Medicine (2015)

[2] International Vocabulary of Metrology (VIM) *Basic and general concepts and associated terms*, 3rd Ed., 2008 version with minor corrections. Bureau International des Poids et Mesures (BIPM) (2012) https://www.bipm.org/en/publications/guides/vim.html

[3] ISO 17034:2016(E) *General requirements for the competence of reference material producers*, ISO, Geneva, Switzerland (2016)

[4] ISO Guide 30, Terms and definitions used in connection with reference materials, ISO, Geneva, Switzerland (2015)