1. Purpose: This document lists and explains the terms used by the BPMM Task Force of AOAC International.

2. Scope: The definitions included in this Appendix are common terms used in the BPMM Task Force for AOAC International report to the contractor.

3. References:

FSIS Lab Quality Manual – Appendix A: Glossary, Rev. 02
Analytical Terminology for Codex Use, 2002.
AOAC INTERNATIONAL Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025, 2004.
AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis, 2002.
Official Methods of Analysis of AOAC INTERNATIONAL, 17th edition.
ISO Guide 2, 30, 9000.
State of Massachusetts Environmental Protection Agency Glossary for Quality Assurance Terminology.
21 CFR Part II.

4. Definitions:

Accuracy of a Measured Value: A measure of the expected "closeness of agreement" between a measured value and the accepted, "true," or reference value. It is the expected value of the absolute value of the difference between the measured value and the true or accepted reference value.

Accuracy of an Attribute Test: The percentage of correct responses.

Accuracy Index: The square root of the sum of the bias squared and the variance for individual results, used as a measure of test accuracy within and among laboratories.

Alpha α-probability: The probability of a Type I error.

Analyte: The microorganism, substance or chemical constituent that is analyzed.

ANOVA: An acronym for a statistical procedure entitled Analysis Of Variance.

Assignable Cause(s): The reason, (root cause(s)) that a Shewhart Chart produces an "Out of Control Signal." Assignable causes may not ever be identified; in fact they may not exist.

Attribute (k-class) test – A test for which the measurement procedure yields k possible answers; applied usually when k is equal to 2 (e.g., pass/fail), or 3(e.g., acceptable, marginal, unacceptable).

Average ($\overline{X}$) **Chart:** A Shewhart Chart that plots the average of results from units considered as one sample versus sample number.

Beta β-probability: The probability of a Type II error.

Bias: The difference between the expected value of test results and an accepted reference value: Note: Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

Binomial Probability Distribution: A probability distribution characterized by situations having two possible outcomes, such as, coin toss or in microbiological situations the presence or absence of a pathogen: e.g. if p is the probability of a head, then on N independent tosses of the coin, the number of heads is distributed as a binomial distribution with parameter vales N and p. The expected value of the number of heads, considered as a random variable, is Np and the variance is Np(1-p).

Blank: A substance that contains none of the analytes of interest subjected to the usual analytical or measurement process to establish a baseline or background value. There are several types of blanks, each with a specific purpose including:

Reagent Blank - A blank containing no matrix elements that are carried through the analytical method to detect any contamination occurring during sample analysis.

Method (Tissue) Blank - A blank prepared to represent the sample matrix as closely as possible and treated like a sample through one or more phases of sample preparation and analysis. It serves to provide an estimate of all contamination occurring during all the processing/analysis steps to which it is subjected, as well as any endogenous matrix interferences.

Calibration: The set of operations which establish, under specified conditions, the relationship between values of quantities by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Calibration Laboratory: A laboratory that performs calibration (as a service).

Calibration Method: A specified technical procedure for performing a calibration.

Certified Reference Material (CRM): A reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence

NOTE 1: The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities

NOTE 2: Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35
NOTE 3: ISO Guide 31 gives guidance on the contents of certificates

Certified Reference Culture (CRC): Microbiological; a reference culture certified by technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body; e.g., cultures used for verifying test systems, validation of methods. Cultures used for QC tests of media must include strains traceable to a type culture collection, where feasible.

Coefficient of Variation (CV%): 100 times the ratio of the standard deviation to the mean, expressed as a percentage, e.g., a CV of 20% means that the standard deviation is 0.2 times the mean. The CV is sometimes referred to as the Relative Standard Deviation.

Common Cause Variation: See inherent variation.

Consensus Distribution: The test sampling distribution used by a laboratory for evaluating laboratory performance within a quality assurance program.

Consensus Standard: A reference standard for a test agreed to by a group of laboratories as representing a value that can be used for proficiency testing.

Confidence Interval: A possible range of values for a parameter of interest (e.g., analyte concentration in a test sample), constructed from the observed result, based on the sampling procedure and method of measurement, so that this range has a specified probability of including the true value of the parameter (over identically repeated sampling, given all things being equal except for specified random variation). The specified probability (e.g., 95%) is called the confidence level, and the end points of the confidence interval are called the confidence limits or bounds.

NOTE: Confidence intervals reflect only the effects of random errors. They do not take systematic errors (bias) into account.

Confirmation: The unambiguous determination of an analyte's presence.

Controlled Document: A document subjected to controls that will ensure that the same version of the document is held by or is available to all personnel to whom the document is applicable.

Control Chart: See Shewhart Chart.

Control Limit: A line placed on a Shewhart Chart that is three standard deviations above, (Upper Control Limit, UCL), or below, (Lower Control Limit, LCL), the process average or process target value.

Control Measure (CM): An action or activity that is used to assure that a Performance Criterion (PC) or a Performance Standard (PS) is met.

Controlled Variation: Variation that is both expected and predictable over time. It is indicative of points falling randomly between the control limits on a Shewhart Chart (also see Inherent Variation).

Count (C) Chart: A Shewhart Chart that plots obtained counts on samples versus sample number.

Counts per Unit (U) Chart: A Shewhart Chart that is plots obtained the ratio of count versus sample size on samples versus sample number.

Coverage Factor: A numerical factor used as a multiplier of the standard deviation to determine a confidence interval.

Covariance: A measure of strength of association of two variables, x and y, calculated as: the expected value of the product of the deviations of the two variables for the same units from their respective expected values:

Correlation: A standardized measure of association of two variables equal to the ratio of the covariance divided by the product of the two standard deviations.

CUSUM Chart: A cumulative sum chart that cumulates, over successive samples, deviations from some target value. For charting purposes, the lower bound for the CUSUM value (for detecting positive bias) and an upper bound for the CUSUM value (for detecting negative bias) are imposed. This chart is especially useful if one wishes to detect moderate biases (relative to the standard deviation).

Discrete Test – A test for which the measurement procedure yields possible answers that can be mapped into the set of whole numbers.

Empirical Method: A method that determines a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured.

Measurement Error: The difference between an individual test result and the true value of the measurand.

Expected value: The expected value of a quantity is the weighted average of all possible values of that quantity within some defined population of units that are assigned values of the quantity, where the weight for an individual value is equal to the probability of obtaining that value. The designation of the expected value is: E(x), where x is the variable of interest – considered as a random variable - and E is the expected value operator.

False Negative: A test result that wrongly identifies an analyte as absent, when in fact it is present.

False Negative Rate: The probability of a false negative (given that the analyte is present).

False Positive: A test result that wrongly identifies an analyte as present, when in fact it is absent.

False Positive Rate: The probability of a false positive (given that the analyte is absent).

Fitness for Purpose: The degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides an acceptable level of risk for the designated population.

Harmonized Collaborative Validation (HCV): HCV provides the highest measure of ruggedness in analytical methods. Method performance is characterized in a specified number of laboratories. (See also Interlaboratory Study.)

Individual (Xi) Chart: A Shewhart Chart that plots the results versus sample number.

Inherent Variation: Variation that is due to many random, unknown, events that affect the true results associated with individual units of some (homogeneous) population to differ from the expected value,

Interlaboratory Study: A study in which several laboratories measure a specified quantity in one or more "identical" portions of sufficiently homogeneous, stable materials under documented conditions, the results of which are compiled into a single document.

NOTE: The larger the number of participating laboratories, the greater the confidence that can be placed in the resulting estimates of the statistical parameters. The IUPAC-1987 protocol (Pure & Appl. Chem., 66, 1903-1911(1994)) requires a minimum of eight laboratories for method-performance studies.

Interlaboratory Comparisons: The organization, performance and evaluation of tests on the same or similar test items by two or more laboratories in accordance with predetermined conditions.
[ISO 13528:2005]

Known Value (see reference material and recovery): A value of some measurand that has measurement uncertainty which is considered insignificant to the extent that any value within the confidence interval associated with the measured value would not affect the evaluation of the true value.

Laboratory: A body that calibrates and/or tests.

Limit of Detection (LOD): The lowest concentration of analyte or level of measurand that can be reliably (with specified degree of confidence, e.g., 97.5% or 2 standard deviations above the

mean blank value) be observed or found in the sample matrix by the method used, when compared to the reagent blank or method tissue blank.

LOD_{50}: The concentration of analyte or level of measurand at which 50% of replicate samples are positive (e.g., exceed 2 standard deviations above the mean blank value) and 50% of replicate samples are negative.

LOD_{90}: The concentration of analyte at which 90% of replicate samples are positive and 10% of replicate samples are negative.

Limit of Quantitation (LOQ): The smallest measured amount of analyte in a sample that can be reliably quantified with a specified degree of precision.

Linear Range: The range of analyte concentrations over which instrumental or method responses are directly proportional to concentration.

Lower Control Limit (LCL): The value that is three standard deviations below a process average or target, or at some specified (low) percentile of a presumed distribution. On a Shewhart chart, the value is depicted as a line, for which an out of control signal occurs when a plotted point is below the line.

NOTE: An out of control signal in the case when monitoring microbiology or chemical characteristics would be interpreted here as a process improvement.

Matrix: The material or compound in which an analyte is retained.

Mean or Sample Mean: The sum of the individual sample values in a set divided by the number of values.

Measurand: The particular quantity subject to measurement.

NOTE 1: For example, vapor pressure of a given sample of water at 20 °C.

NOTE 2: The specification of a measurand may require statements about quantities such as time, temperature and pressure.

Measurement Uncertainty: A parameter, associated with the result of a measurement, which characterizes the dispersion of values that could reasonably be attributed to the measurand. (VIM)

NOTE: A measure of the reliability of an analytical result arising from random variation of measuring a measurand by some (specified) procedure. For a single quantity, for purposes of the AOAC, the measure is typically expressed as a confidence interval with finite confidence limits, symmetrical about a “central” estimate of the measurand. An exception would be in the situation where all sample results are non-detect (negative), or below a certain threshold, for which a confidence interval for the percentage positive or above the threshold would range from 0% to some upper confidence bound. Unless specified otherwise, the confidence level of the measurement of uncertainty is 95%.

Method Detection Limit: See **Limit of Detection.**

Method: A series of steps for performing an activity (e.g. sampling, analysis, quantification), systematically presented in the order they are to be executed.

Moving Range (MR) Chart: A Shewhart Chart plots the range of consecutive sample results versus the higher of the two sample numbers.

Multi-Laboratory Validation (MLV): MLV is a collaborative study of an analytical method for which repeatability and reproducibility are measured in at least two laboratories.

Non-conformity: The non-fulfillment of a requirement to a standard or guideline.

Normal Distribution: The probability distribution commonly referred to as the bell-shaped curve/ distribution. Sixty-eight (68) percent of results are expected to fall within one standard deviation (SD) of the mean and 95% within 2 SD of the mean. It is the distribution most often observed when measurement values are from a population for which the deviations from the expected value are due to inherent variation (see above). Under controlled situations, (processes or laboratory methods) the distribution of measured values can be estimated by assuming a normal distribution. The average of sufficiently many results can be often assumed to be normal distributed.

Number (NP) Chart: A Shewhart Chart that plots the obtained number of units, considered as one sample, which have the characteristic of interest versus the sample number.

Outliers: Specific value(s) from a set of values obtained from samples, considered not to belong to the same distribution of the other sample values, based on a statistical test, typically with specified α-probability (e.g., 5% or less).

Out of Control (of a process): The situation in which factors, not expected within normal operating conditions, are affecting the process output results.

Out of Control Signal (for a process): Results from a quality control sampling plan for which there is a low probability of occurrence, when the process is assumed to not to be out of control (See Statistical Process Control).

Performance Characteristics: Measurable outcomes of a method's behaviour derived from sample analysis, e.g. Accuracy, precision, recovery, specificity (selectivity), sensitivity (limits of detection), inclusivity, exclusivity linearity, range, scope of application,

Performance Criterion (PC): An output quantity and criterion that the output quantity must satisfy in order to provide or contribute to meeting a Performance or Food Safety Objective.

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a Food Safety Objective or Appropriate Level of Protection, as applicable.

Performance Standard (PS): "Objectively measurable" quantities and a set of criteria associated with a process that is used to control some hazard, and is (often) imposed by government regulations. The PS statement envelopes the PC, PO or FSO and control measures (CM) and often is indistinguishable from one of these. The requirement of "objectively measurable" implies that the measures that are used must be easy to obtain, transparent, and reproducible. A consequence of this requirement is that the risk-effects of actions that are needed to comply with a performance standard may not be directly measurable or determinable.

Performance Verification: See Verification.

Poisson Probability Distribution: A distribution of the set of non-negative integers (e.g., counts) typically used when sampling from a medium for which the concentration, density or level (per gram or ml) is uniformly distributed throughout the medium. The distribution is characterized by one parameter, which is the expected value of the counts.

Precision: A measure of the expected closeness of agreement between independent test results under stipulated conditions; the square root of the expected value of the square of the difference of two "independent" results, given the stipulated conditions.

NOTE: Precision may also refer to the defined quantity divided by the square root of 2, which would provide an estimate of the standard deviation of individual results.

Probability (of a value): A number between zero and 1, inclusive, which is coupled with the value that is assigned to units of some population (of units). The quantity is equal to the proportion of times that the value is obtained when, either all the units with their corresponding values are listed, or when the units are randomly selected, an arbitrary large number of times (or infinite number of times), such that each unit has the same "chance" of being selected.

NOTE: The latter part of this definition is somewhat circular since the definition includes the notions of randomness and equal chance which are probabilistic notions. The definition is based on a frequentist view point – the implication is that probabilities and thus statistical characterizations of method and process performance cannot be made unless data are collected and the probabilities are estimated using statistical procedures. For a further discussion of probability, see von Mises (1951, "Probability, Statistics, and Truth, 2nd revised English ed, prepared by H. Geiringer, The MacMillan Co, NY, 1957).

Procedure: A series of detailed processes that impact on an analytical outcome.

Process: A step or steps that transform inputs (materials, labor, energy, methods and machines) into measurable outputs.

Process Control Testing - Sampling product of a process, and making measurements on the samples to determine whether the process is in control or not.

Proportion (P) Chart: A Shewhart Chart that plots the proportion of individual units (results from the units recorded together) having the characteristic of interest.

Proficiency Testing: Determination of laboratory calibration or testing performance by means of interlaboratory comparisons or comparison to assigned value of analyte.

Proficiency Test Sample: Test material with microorganisms or chemical analytes that is tested periodically by a number of locations to determine the proficiency of recovery, using statistical analysis where appropriate.

Qualitative Method: A method that identifies analytes based on chemical, biological, or physical properties and that gives a result in the form of presence or absence in a certain size of test portion.

Quality Assurance (QA): Those systematic activities, defined by management, that are done outside of the actual analysis to provide confidence that the analysis will satisfy given requirements for quality.
Note: Examples of these activities include training, audit and review.

Quality Control (QC):

1) Those activities that are performed during the analysis to fulfill the requirements for assuring quality. Examples include control charting, blank determinations, spiked samples, repeat determinations and blind samples.
2) Activities performed by an establishment to assure that process controls are not "out of control." Sampling of product and plotting results on a Shewhart control chart is an example of a QC activity.

Quality Control Sample (QCS): A test portion sample with known contents of analytes to carry through the entire method to verify and monitor laboratory performance.

Quantitative Method: A method that identifies analytes and provides an estimate of the amount present in the test sample, expressed as a numerical value in appropriate units, with trueness and precision fit for the purpose.

Range:

1. The range of an analytical procedure is the interval between the upper and lower concentration (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of uncertainty.
2. When used to measure and control variation as with the Range (R) Shewhart Chart the range is the largest value in a subgroup of data minus the smallest value in the same subgroup.

Range (R) Chart: A Shewhart Chart that plots the range of results from units considered as one sample, versus sample number.

Recovery: The fraction of analyte quantified by the analytical method, expressed as a percentage of the amount "known" to be present in the sample.

Reference Culture (RC): A traceable culture with characteristics sufficiently well established to be used to calibrate/verify test systems, test media and validate methods.

Reference Distribution: The test sampling distribution used by a laboratory for evaluating its performance (within a quality assurance program).

Reference Material: Material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

NOTE 1: The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.

NOTE 2: Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.

NOTE 3: ISO Guide 31 gives guidance on the contents of certificates

Relative Percent Difference: Difference between two values divided by the average of the two, expressed as a percentage.

Reference Standard: A standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are derived.

NOTE: Generally, this refers to recognized national or international traceable standards such as National Institute of Standards and Technology (NIST) thermometers and weights. Other standards may not be traceable to a national standard such as filters for setting wavelengths.

Relative Standard Deviation (RSD%): See coefficient of variation.

Repeatability: (of results of measurements): The standard deviation of results of measurements of the same measurand carried out under the same conditions of measurement.

NOTES:

These conditions are called repeatability conditions which include:

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

Repeatability Limit: The value of which the absolute difference between two test results obtained under repeatability conditions may be expected to be less than or equal to, with a probability of 95%, (also called the critical difference for groups of test results).

Replicate Test: An analysis performed more than once. The result of each individual analysis is a replicate test result.

Reproducibility (of results of measurements): The standard deviation of results of measurements of the same measurand carried out under changed conditions of measurement, in the broadest sense. Basically it is assumed that the results arise from a population designated by all possible laboratories, analysts, environmental conditions, measuring instrument, reference standard and other pertinent factors that could affect the results. A valid statement of reproducibility requires specification of the conditions changed.

Reproducibility Limit: The value of which the absolute difference between two test results obtained under reproducibility conditions may be expected to be less than or equal to, with a probability of 95%.

Robustness: A measure of an analytical method capacity to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Ruggedness: The ability of an analytical procedure to resist changes in results when subjected to minor changes in environmental and procedural variables, laboratories, personnel, etc.

Sample: Any material brought into the laboratory for analysis.

Sample Handling: The manipulation to which samples are exposed during the sampling process, from the selection from the original material through to the disposal of all samples and test portions.

Sample Preparation: The process of obtaining a representative test portion from the sample which includes selecting a subsample(s) and in-laboratory processing (i.e. mixing, reducing, coring, quartering, blending, and grinding).

Sampling: A procedure whereby a part of a substance, material or product is taken from a well-defined collection of substances, materials, or product, to be used for characterizing, testing or calibrating features of the population.
Two major types of sampling can be identified:

1. Probability or statistical sampling, where the collected material is considered as a "representative" of the whole – that is, the selected units are collected with known probability of selection, which enables deductively statistical based inferences to be made regarding the whole population.
2. Convenience, such as forensic analysis, where the sample is not "representative" of the population, but is determined by availability or convenience, quota (judgment), and for which inferences to a population must be made with the aid of judgment.

NOTE 1: Sampling procedures should describe the sampling plan, selection, withdrawal, and preparation of a sample. The resulting sample "represents" a larger quantity such as a lot or batch.

NOTE 2: The laboratory staff is often not involved in the sampling process, but analysts may be consulted concerning proper sample size (the amount of the sample, such as 25 grams, 5 one pound packages, etc) or the use of appropriate preservatives, and they may be asked to provide suitably prepared containers. ISO 17025 requires that,

where relevant, a statement to the effect that the results relate only to the items tested shall be made.

NOTE 3: Often the probabilities of selection are not known but can be approximated and assumed to be equal to some values without any significant introduction of bias.

Scope of Application: The range of matrices to which a method may be applied; usually based on method validation studies.

Screening Method: A method designed to detect the presence of an analyte in a sample at or above some specified concentration (target level). .

Segregate: Set apart; can represent setting apart by space and time. An example would be the separation (segregation) of samples and standards to avoid cross-contamination.

Selectivity (Specificity): The extent to which the analytical method can detect/determine particular analyte(s) in a complex mixture without interference from the other components in the mixture.

Exclusivity: The probability that the method will classify a test sample as negative, given that a test sample is a known negative.

Sensitivity: The difference in analyte concentration corresponding to the smallest difference in the response of the method that can be detected. It is represented by the slope of the calibration curve.

Inclusivity: The probability that the method will classify a test sample as positive given that a test sample is a known positive.

Shewhart Chart: A series of charts developed by Dr. Walter Shewhart in the 1920s to provide labors and management with a system for identifying when processes are operating in a steady state or when processes are not stable. They consist of plotting specified sampled results versus sample number, and could include horizontal lines depicting target values and out of control limits.

Single Laboratory Validation (SLV): SLV is a single laboratory study of an analytical method which determines performance characteristics other than reproducibility

Special Cause Variation: Variation that is unexpected and unpredictable over time. It is a type of variation that is responsible for causing “Out of Control Signals.”

Standard Deviation: The square root of the variance.

Standard Deviation (s) Chart: A Shewhart Chart that plots the standard deviation (described above) of the results of units considered as one sample versus sample number.

Statistical Process Control (SPC): A system and philosophy about maintaining control in a manufacturing environment that requires one to measure characteristics of process output when the process is presumably in control, using statistical methods, developing criteria based on these results using probability theory, and plotting results using, for example, a Shewhart Chart or CUSUSM chart, and then reacting to situations when the criteria are not being met, which could indicate the process is out of control.

Statistical Process Control Chart: See Shewhart Chart.

Standard Uncertainty: Uncertainty of the result of a measurement expressed as a standard deviation [GUM].

System Suitability: The fitness of instruments for the purpose at hand based on manufacturer specifications, instrumental Standard Operating Procedures, or specific requirements of the method.

Test: A technical operation that consists of the determination of one or more characteristics or the performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

NOTE: The result of a test is normally recorded in a document sometimes called a test report or a test certificate.

Testing Laboratory: A laboratory that performs tests.

Test Method: A specified technical procedure for performing a test.

Test Portion: The actual material weighed or measured for the analysis.

Test Sample: Material prepared from the laboratory sample and from which test portions will be taken.

Traceability: The property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Trueness: See bias.

Type I Error: The error of classifying test results as not belonging to an assumed distribution (often called the "null' hypothesis) when it actually does belong. (See alpha α – probability).

Type II Error: The error of classifying test results as belonging to an assumed distribution when it actually does not belong. (See beta β – probability).

Uncertainty: See Measurement Uncertainty.

Uncontrolled Variation: Variation presumed to exists when a process experiences an "Out of Control Signal."

Upper Control Limit (UCL): The value that is three standard deviations above a process average or target, or at some specified (high) percentile of a presumed distribution. On a Shewhart Chart, the UCL is depicted as a line, for which an out of control signal occurs when a plotted values is above the line.

Validation: Establishment, by systematic laboratory studies, of the performance characteristics of an analytical method when applied to specific matrices and/or analytes. Validation may be performed in a single laboratory (SLV), Multi-laboratory (MLV) or by collaborative study (HCV).

Variables Test – A test that measures a quantitative value for which possible answers can be approximated by an interval of real numbers (possibly of infinite length), e.g., CFU/g of a microorganism in a food.

Variance: The expected value of the squared difference of individual values and the population mean; $E(x-\mu)^2$, where x is a value of the random variable from some distribution over which expected values are taken and μ is the expected value of x.

Verification: Confirmation, through the provision of objective evidence, that the performance characteristics of the method meet the specifications related to the intended use of the analytical results.

Vulnerability: A flaw or weakness in a business process (system procedures, design, implementation, or internal controls) that could be exercised and result in a disruption to the process.

List of symbols used

FP False Positive Test that corresponds to a "positive" result on a sample that is truly negative.

FN False Negative Test that corresponds to a "negative" result on a sample that is truly positive.

NPV Negative Predictive Value defined as the ratio or percentage of TN/(TN+FN)

PPV Positive Predictive Value defined as the ratio or percentage of TP/(TP+FP)

Prev Prevalence defined as the ratio or percentage of (TP+FN)/N where N equals TP+FP+TN+FN

RSD relative standard deviation equal to the ratio of the sample standard deviation divided by the sample mean which is usually converted to percent

RSDr relative standard deviation for a test within a laboratory (intra-laboratory)

RSD_R relative standard deviation for a test between laboratories (inter-laboratory)

SDr repeatability standard deviation for a test.

SD_R reproducibility standard deviation for a test between.

Sn Sensitivity is the probability of correctly detecting the presence of some analyte. This can be expressed as a function of the actual analyte level in the sample; e.g., the test has a sensitivity of 95% at the 0.1 ppb level.

Sp Specificity is the probability of correctly not-detecting the presence of some analyte.

S_{is} standard deviation of initial suspension for an intra-laboratory test equal to the sum of squared differences of identical samples and test protocols differing only in initial suspension conditions

S_R standard deviation of reproducibility

Sr standard deviation of replication and random error for an intra-laboratory test otherwise equal to the sum of squared differences of identical samples and test protocols

S_{cond} standard deviation of laboratory conditions for an intra-laboratory test equal to the sum of squared differences of identical samples and test protocols but including at least technician and time variability

TN Total Negative Tests (excluding FN tests)

TP Total Positive Tests (excluding FP tests)

$\overline{X}$ Arithmetic average

Xi Individual measure

z-score is the standard normal deviate for an observation from a normal sampling distribution which is the difference between the observed value and the expected value divided by the standard deviation.