Designation: E2161 – 15

Standard Terminology Relating to Performance Validation in Thermal Analysis and Rheology[1]

This standard is issued under the fixed designation E2161; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 Validation of methods and apparatus is requested or required for quality initiatives or where results may be used for legal purposes.

1.2 This standard provides terminology relating to validating performance of thermal analysis and rheology methods and instrumentation. Terms that are generally understood or defined adequately in other readily available sources are not included.

1.3 The terminology described in this standard is that of the validation process and may differ from that traditionally encountered in ASTM standards.

1.4 A definition is a single sentence with additional information included in a *Discussion*.

1.5 Terminology commonly used in the study of precision and bias, in thermal analysis, rheology, and thermophysical properties may be found in Terminologies E177, E473, and E1142. Additional information on method validation may be found in the U.S. Pharmacopeia and National Formulary.[2]

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E473 Terminology Relating to Thermal Analysis and Rheology

E1142 Terminology Relating to Thermophysical Properties

3. Terminology

accuracy—the agreement between an experimentally determined value and the accepted reference value.

DISCUSSION—Accuracy is also known as bias in ASTM practice.

analyte—the specific component measured in an analysis.

baseline—the resultant analytical trace when no test specimen is present.

blank—the measured value obtained when a specific component is not present during the measurement.

bow—the maximum deviation between an actual instrument reading and the reading predicted by a straight line drawn between upper and lower calibration points, expressed as a percent of full scale.

calibration—to check, adjust, or systematically standardize the gradations of a quantitative measuring signal.

certificate—a formal document testifying to the truth of a matter (see also certification).

certification—process of issuing a formal document testifying to the truth of a matter.

DISCUSSION—Includes conditions (such as accreditation), materials (such as reference materials), processes (such as calibration), and the like.

certified reference material—a reference material lot, the property(ies) of which, determined by measurement is/are certified by an identified organization and found on an accompanying certificate.

DISCUSSION—Each certified value should be is accompanied by an uncertainty at a stated level of confidence.

coefficient or variation—the standard deviation divided by the value of the parameter measured.

conformance—agreement of a product, process or service with specification requirements.

detection limit—the minimum quantity of analyte that can be reliably detected but not necessarily quantified.

drift—the relatively slow change in baseline output due to instrument performance taken to be the maximum deviation between any two points within a specified time period.

figure-of-merit—a performance characteristic of a method believed to be useful when deciding its applicability for a specific measurement situation.

DISCUSSION—Typical figures-of-merit include accuracy, repeatability, sensitivity, etc.

[1] This terminology is under the jurisdiction of ASTM Committee E37 on Thermal Measurements and is the direct responsibility of Subcommittee E37.03 on Nomenclature and Definitions.

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[2] Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

full-width at half- maximum (FWHM), *n*—the difference between the two extreme values of a peak of the independent variable at which the dependent variable is equal to half of its maximum value.

interlaboratory study, ILS, *n*—a study undertaken to provide between laboratory precision and accuracy information for a test method.

interlaboratory testing, *n*—evaluation of a test method in more than one laboratory by analyzing data obtained from one or more materials that are as homogeneous as practical.

intralaboratory study, *n*—a study undertaken to provide within laboratory precision and accuracy information for a test method.

linearity—the maximum deviation of output points from the "best fit" linear curve to the data excluding proven outliers expressed as a percentage of the full-scale computed output.

noise—the maximum amplitude, peak-to-peak, for all random variations.

noise, short term—is that with a frequency greater than six cycles per min (equivalent to a period of 10 seconds or less).

DISCUSSION—Short Term Noise determines the smallest signal detectable and limits the precision attainable in quantitation of low level measurements.

noise, long term—is that with a frequency between 0.6 and 6 cycles per min (equivalent to periods of 100 and 10 s).

DISCUSSION—Long Term Noise may be mistaken for the response of a test specimen.

precision—the degree of agreement among or between repeated measurements of the same property.

quantitation limit—the minimum amount that can be quantified with acceptable accuracy and precision.

reference material—a material or substance, the property for which is sufficiently homogeneous and well established to be used for the calibration of apparatus, or the assessment of a measurement method.

relative standard deviation—the coefficient of variation expressed as a percentage.

repeatability—a quantitative measure of the precision of the results by a single analyst in a given laboratory using a given apparatus.

reproducibility—a quantitative measure of the precision of the results between two laboratories.

resolution—a quantitative measure of the ability to separate closely spaced transitions at an appropriate analytic level.

DISCUSSION—Resolution is one component of selectivity.

selectivity—the ability to accurately and specifically measure the analyte in the presence of components that may be expected to be present in the test specimen.

sensitivity—the capability of methodology or instrumentation to discriminate between samples having differing concentrations or containing differing amounts of an analyte.

DISCUSSION—Detection Limit and Quantitation Limit are indicators of sensitivity.

slope—the ratio of rise (change in Y-axis) to run (change in X-axis) for a linear curve or tangent to a point on a non-linear curve.

standard deviation—a measure of variation or scatter around the arithmetic average or mean.

standard reference material—a certified reference material, one or more properties of which have been certified by a national metrology institute.

DISCUSSION—Each certified value is should be accompanied by an uncertainty at a stated level of confidence.

time constant—a measure of the rapidity of response of a system.

DISCUSSION—The time constant is a measure of an instrument's ability to respond to a signal and limits resolution. The shorter the time constant, the better the resolution.

validation—the process of providing documented evidence that something does what it is intended to do.

4. Keywords

4.1 performance validation; rheology; terminology; thermal analysis