



## Standard Terminology Relating to Performance Validation in Thermal Analysis<sup>1</sup>

This standard is issued under the fixed designation E 2161; 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 ( $\epsilon$ ) 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 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 document 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*.

### 2. 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.

*NOTE 1*—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.

*NOTE 2*—Each certified value should be accompanied by an uncertainty at a stated level of confidence.

**coefficient of 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.

**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.

**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.

<sup>1</sup> 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.

Current edition approved May 1, 2008. Published May 2008. Originally approved in 2001. Last previous edition approved in 2007 as E 2161–07a.

**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.

NOTE 3—Each certified value 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.

2.1 Terminology commonly used in the study of precision and bias, in thermal analysis, and thermophysical properties may be found in ASTM terminology standards E 177, E 473, and E 1142. Additional information on method validation may be found in the US Pharmacopeia and National Formulary, United States Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, MD 20852.

*ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.*

*This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.*

*This standard is copyrighted by ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org).*