



Designation: E2161 – 15 (Reapproved 2019)

Standard Terminology Relating to Performance Validation in Thermal Analysis and Rheology¹

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

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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, *n*—the agreement between an experimentally determined value and the accepted reference value.

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

analyte, *n*—the specific component measured in an analysis.

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

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

bow, *n*—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, *v*—to check, adjust, or systematically standardize the gradations of a quantitative measuring signal.

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

certification, *n*—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, *n*—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 accompanied by an uncertainty at a stated level of confidence.

coefficient of variation, *n*—the standard deviation divided by the value of the parameter measured.

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

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

drift, *n*—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.

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.