



Designation: E2161 – 23c

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 This terminology only includes those terms that are included in an ASTM standard or for which some action is under consideration. It is not intended as an all-inclusive listing of terms relating to performance validation.

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

1.7 *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.*

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>.

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

absolute measurement, *n*—an analytical measurement or result in which the measured variable(s) are evaluated using theoretical principles and fundamental physical constants, without using a reference material for calibration.

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.

bias, *n*—a constant or systematic difference between the test results and an accepted reference value.

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, *n*—the act or process of determining the relationship between a set of standard units of measurement and the output of an instrument or test method.

DISCUSSION—Calibration is intended to improve the reproducibility and bias (accuracy) of a measurement so that results are consistent with other measurements.

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.