



Standard Practice for Applying Statistical Quality Assurance Techniques to Evaluate Analytical Measurement System Performance¹

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1. Scope

1.1 This practice provides information for the design and operation of a program to monitor and control ongoing stability and precision and bias performance of selected analytical measurement systems using a collection of generally accepted statistical quality control (SQC) procedures and tools.

NOTE 1—A complete list of criteria for selecting measurement systems to which this practice should be applied and for determining the frequency at which it should be applied is beyond the scope of this practice. However, some factors to be considered include (1) frequency of use of the analytical measurement system, (2) criticality of the parameter being measured, (3) system stability and precision performance based on historical data, (4) business economics, and (5) regulatory, contractual, or test method requirements.

1.2 This practice is applicable to stable analytical measurement systems that produce results on a continuous numerical scale.

1.3 This practice is applicable to laboratory test methods.

1.4 This practice is applicable to validated process stream analyzers.

NOTE 2—For validation of univariate process stream analyzers, see also Practice D 3764.

1.5 This practice assumes that the normal (Gaussian) model is adequate for the description and prediction of measurement system behavior when it is in a state of statistical control.

NOTE 3—For non-Gaussian processes, transformations of test results may permit proper application of these tools. Consult a statistician for further guidance and information.

1.6 This practice does not address statistical techniques for comparing two or more analytical measurement systems applying different analytical techniques or equipment components that purport to measure the same property(s).

2. Referenced Documents

2.1 ASTM Standards:

¹ This practice is under the jurisdiction of ASTM Committee D02 on Petroleum Products and Lubricants and is the direct responsibility of Subcommittee D02.94 on Quality Assurance and Statistics.

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D 3764 Practice for Validation of Process Stream Analyzer Systems²

D 5191 Test Method for Vapor Pressure of Petroleum Products (Mini Method)²

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods³

E 178 Practice for Dealing with Outlying Observations³

E 456 Terminology Relating to Quality and Statistics³

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method³

3. Terminology

3.1 Definitions:

3.1.1 *accepted reference value, n*—a value that serves as an agreed-upon reference for comparison and that is derived as (1) a theoretical or established value, based on scientific principles, (2) an assigned value, based on experimental work of some national or international organization, such as the U.S. National Institute of Standards and Technology (NIST), or (3) a consensus value, based on collaborative experimental work under the auspices of a scientific or engineering group.

(E 456/E 177)

3.1.2 *accuracy, n*—the closeness of agreement between an observed value and an accepted reference value.

(E 456/
E 177)

3.1.3 *assignable cause, n*—a factor that contributes to variation and that is feasible to detect and identify.

(E 456)

3.1.4 *bias, n*—a systematic error that contributes to the difference between a population mean of the measurements or test results and an accepted reference or true value.

(E 456/
E 177)

3.1.5 *control limits, n*—limits on a control chart that are used as criteria for signaling the need for action or for judging whether a set of data does or does not indicate a state of statistical control.

(E 456)

3.1.6 *lot, n*—a definite quantity of a product or material accumulated under conditions that are considered uniform for sampling purposes.

(E 456)

² Annual Book of ASTM Standards, Vol 05.02.

³ Annual Book of ASTM Standards, Vol 14.02.

