

Standard Practice for Demonstrating Capability to Comply with an Acceptance Procedure¹

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^{ε1} NOTE—Editorial corrections made throughout in March 2015.

1. Scope

1.1 This practice provides a general methodology for evaluating single-stage or multiple-stage acceptance procedures which involve a quality characteristic measured on a numerical scale. This methodology computes, at a prescribed confidence level, a lower bound on the probability of passing an acceptance procedure, using estimates of the parameters of the distribution of test results from a sampled population.

1.2 For a prescribed lower probability bound, the methodology can also generate an acceptance limit table, which defines a set of test method outcomes (for example, sample averages and standard deviations) that would pass the acceptance procedure at a prescribed confidence level.

1.3 This approach may be used for demonstrating compliance with in-process, validation, or lot-release specifications.

1.4 The system of units for this practice is not specified.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*²

E456 Terminology Relating to Quality and Statistics

E2282 Guide for Defining the Test Result of a Test Method

E2586 Practice for Calculating and Using Basic Statistics

3. Terminology

3.1 *Definitions*—See Terminology E456 for a more extensive listing of terms in ASTM Committee E11 standards.

¹ This practice is under the jurisdiction of ASTM Committee E11 on Quality and Statistics and is the direct responsibility of Subcommittee E11.20 on Test Method Evaluation and Quality Control.

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² 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.

3.1.1 *characteristic, n*—a property of items in a sample or population which, when measured, counted or otherwise observed, helps to distinguish between the items. **E2282**

3.1.2 *mean, n*—of a population, μ , average or expected value of a characteristic in a population, of a sample $\bar{X}$, sum of the observed values in a sample divided by the sample size. **E2586**

3.1.3 *multiple-stage acceptance procedure, n*—a procedure that involves more than one stage of sampling and testing a given quality characteristic and one or more acceptance criteria per stage.

3.1.4 *standard deviation, n*—of a population, σ , the square root of the average or expected value of the squared deviation of a variable from its mean – of a sample, s , the square root of the sum of the squared deviations of the observed values in the sample divided by the sample size minus 1. **E2586**

3.1.5 *test method, n*—a definitive procedure that produces a test result. **E2282**

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *acceptable parameter region, n*—the set of values of parameters characterizing the distribution of test results for which the probability of passing the acceptance procedure is greater than a prescribed lower bound.

3.2.2 *acceptance region, n*—the set of values of parameter estimates that will attain a prescribed lower bound on the probability of passing an acceptance procedure at a prescribed level of confidence.

3.2.3 *acceptance limit, n*—the boundary of the acceptance region, for example, the maximum sample standard deviation test results for a given sample mean.

4. Significance and Use

4.1 This practice considers inspection procedures that may involve multiple-stage sampling, where at each stage one can decide to accept or to continue sampling, and the decision to reject is deferred until the last stage.

4.1.1 At each stage there are one or more acceptance criteria on the test results; for example, limits on each individual test result, or limits on statistics based on the sample of test results,