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An American National Standard

Standard Practice for Demonstrating Capability to Comply with an Acceptance Procedure[1]

This standard is issued under the fixed designation E2709; 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 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

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:*[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.

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

[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.

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, such as the average, standard deviation, or coefficient of variation (relative standard deviation).

4.2 The methodology in this practice defines an acceptance region for a set of test results from the sampled population such that, at a prescribed confidence level, the probability that a sample from the population will pass the acceptance procedure is greater than or equal to a prespecified lower bound.

4.2.1 Having test results fall in the acceptance region is not equivalent to passing the acceptance procedure, but provides assurance that a sample would pass the acceptance procedure with a specified probability.

4.2.2 This information can be used for process demonstration, validation of test methods, and qualification of instruments, processes, and materials.

4.2.3 This information can be used for lot release (acceptance), but the lower bound may be conservative in some cases.

4.2.4 If the results are to be applied to future test results from the same process, then it is assumed that the process is stable and predictable. If this is not the case then there can be no guarantee that the probability estimates would be valid predictions of future process performance.

4.3 This methodology was originally developed **(1-4)**[3] for use in two specific quality characteristics of drug products in the pharmaceutical industry but will be applicable for acceptance procedures in all industries.

4.4 Mathematical derivations would be required that are specific to the individual criteria of each test.

5. Methodology

5.1 The process for defining the acceptance limits, starting from the definition of the acceptance procedure, is outlined in this section. A computer program is normally required to produce the acceptable parameter region and the acceptance limits.

5.1.1 An expression for the exact probability of passing the acceptance procedure might be intractable when the procedure consists of multiple stages with multiple criteria, hence a lower bound for the probability may be used.

5.2 Express the probability of passing the acceptance procedure as a function of the parameters characterizing the distribution of the quality characteristic for items in the sampled population.

5.2.1 For each stage in the procedure having multiple acceptance criteria, determine the lower bound on the probability of that stage as a function of the probabilities of passing each of the criteria in the stage:

$$P(S_i) = P(C_{i1} \text{ and } C_{i2} \ldots \text{ and } C_{im}) \geq 1 - \sum_{j=1}^{m} \left(1 - P(C_{ij})\right) \quad (1)$$

where:

$P(S_i)$ = is the probability of passing stage i,
$P(C_{ij})$ = is the probability of passing the j-th criterion of m within the i-th stage.

5.2.2 Determine the lower bound on the probability of passing a k-stage procedure as a function of probabilities of passing each of the individual stages:

$$P\left(\text{pass } k - \text{stage procedure}\right) \geq \max\{P(S_1), P(S_2), \ldots, P(S_k)\} \quad (2)$$

5.3 Determine the contour of the region of parameter values for which the expression for the probability of passing the given acceptance procedure is at least equal to the required lower bound (LB) on the probability of acceptance (p). This defines the *acceptable parameter region*. Since the acceptance parameter region is a lower bound, it should be compared to the simulated probability of passing the acceptance procedure.

5.4 For each value of a statistic or set of statistics, derive a joint confidence region for the distribution parameters at confidence level, expressed as a percentage, of 100(1-α). The size of sample to be taken, n, and the statistics to be used, must be predetermined (see 5.6).

5.5 Determine the contour of the *acceptance region*, which consists of values of the statistics for which the confidence region at level 100(1-α) is entirely contained in the acceptable parameter region. The *acceptance limits* lie on the contour of the acceptance region.

5.6 To select the size of sample, n, to be taken, the probability that sample statistics will lie within acceptance limits should be evaluated over a range of values of n, for values of population parameters of practical interest, and for which probabilities of passing the given acceptance procedure are well above the lower bound. The larger the sample size n that is chosen, the larger will be the acceptance region and the tighter the distribution of the statistics. Choose n so that the probability of passing acceptance limits is greater than a predetermined value.

5.7 To use the acceptance limit, sample randomly from the population. Compute statistics for the sample. If statistics fall within the acceptance limits, then there is 1-α confidence that the probability of acceptance is at least p.

6. Procedures for Sampling from a Normal Distribution

6.1 An important class of procedures is for the case where the quality characteristic is normally distributed. Particular instructions for that case are given in this section, for two sampling methods, simple random and two-stage. In this standard, these sampling methods are denoted Sampling Plan 1 and Sampling Plan 2, respectively.

6.2 When the characteristic is normally distributed, parameters are the mean (μ) and standard deviation (σ) of the population. The acceptable parameter region will be the region under a curve in the half-plane where μ is on the horizontal axis, σ on the vertical axis, such as that depicted in Fig. 1.

6.3 For simple random sampling from a normal population, the method of Lindgren (**5**) constructs a simultaneous confidence region of (μ, σ) values from the sample average $\bar{X}$ and the sample standard deviation s of n test results.

[3] The boldface numbers in parentheses refer to a list of references at the end of this standard.

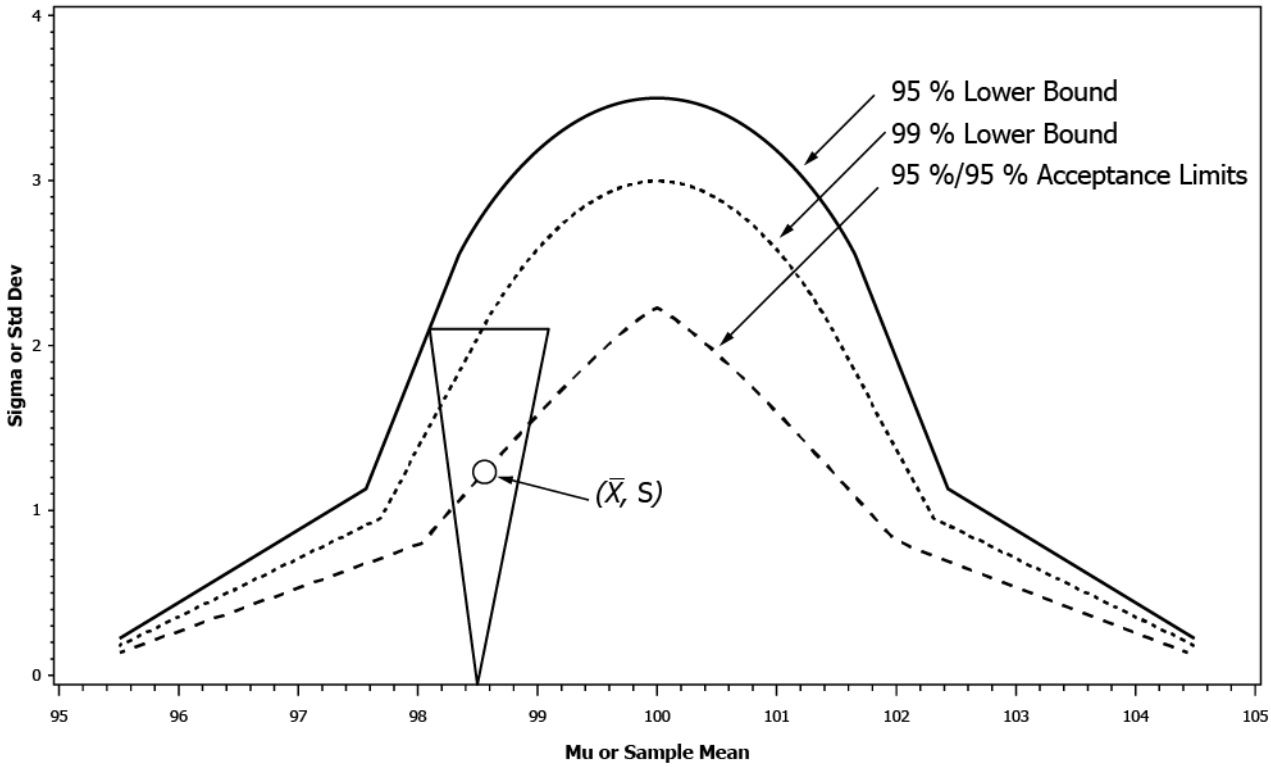

FIG. 1 Example of Acceptance Limit Contour Showing a Simultaneous Confidence Interval With 95 % and 99 % Lower Bound Contours

6.3.1 Let Z_p and χ_p^2 denote percentiles of the standard normal distribution and of the chi-square distribution with n-1 degrees of freedom, respectively. Given a confidence level (1-α), choose δ and ε such that (1-α) = (1-2δ)(1-ε). Although there are many choices for δ and ε that would satisfy this equation, a reasonable choice is: $\varepsilon = 1-\sqrt{1-\alpha}$ and $\delta = \left(1-\sqrt{1-\alpha}\right)/2$ which equally splits the overall alpha between estimating μ and σ. Then:

$$\begin{aligned} & P\left\{\left(\frac{\bar{X}-\mu}{\sigma/\sqrt{n}}\right)^2 \le Z_{1-\delta}^2\right\} P\left\{\frac{(n-1)s^2}{\sigma^2} \ge \chi_\varepsilon^2\right\} \\ &= (1-2\delta)(1-\varepsilon) \\ &= 1-\alpha \end{aligned} \tag{3}$$

6.3.2 The confidence region for (μ, σ), two-sided for μ, one-sided for σ, is an inverted triangle with a minimum vertex at $(\bar{X}, 0)$, as depicted in Fig. 1.

6.3.3 The acceptance limit takes the form of a table giving, for each value of the sample mean, the maximum value of the standard deviation (or coefficient of variation) that would meet these requirements. Using a computer program that calculates confidence limits for μ and σ given sample mean $\bar{X}$ and standard deviation s, the acceptance limit can be derived using an iterative loop over increasing values of the sample standard deviation s (starting with $s = 0$) until the confidence limits hit the boundary of the acceptable parameter region, for each potential value of the sample mean.

6.4 For two-stage sampling, the population is divided into primary sampling units (locations). L locations are selected and from each of them a subsample of n items is taken. The variance of a single observation, σ^2, is the sum of between-location and within-location variances.

6.4.1 A confidence limit for σ^2 is given by Graybill and Wang **(6)** using the between and within location mean squares from analysis of variance. When there are L locations with subsamples of n items, the mean squares between locations and within locations, MS_L and MS_E, have L-1 and L(n-1) degrees of freedom respectively. Express the overall confidence level as a product of confidence levels for the population mean and standard deviation as in 6.3, so that (1-α) = (1-2δ)(1-ε). An upper (1-ε) confidence limit for σ^2 is:

$$\begin{aligned} & [(1/n)\,MS_L + (1-1/n)\,MS_E] + \{[(1/n) \\ & \left((L-1)/\chi^2_{L-1,\,1-\epsilon} - 1\right)MS_L]^2 + [(1-1/n) \\ & \left(L(n-1)/\chi^2_{L(n-1),\,1-\epsilon} - 1\right)MS_E]^2\}^{1/2} \end{aligned} \tag{4}$$

The upper (1-ε) confidence limit for σ is the square root of Eq 4. Two sided (1-2δ) confidence limits for μ are:

$$\bar{X} \pm Z_{1-\delta}\frac{\sigma}{\sqrt{(nL)}} \tag{5}$$

6.4.2 To verify, at confidence level 1-α, that a sample will pass the original acceptance procedure with probability at least equal to the prespecified lower bound, values of (μ, σ) defined by the limits given in Eq 4 and Eq 5 should fall within the acceptable parameter region defined in 5.3.

6.4.3 An acceptance limit table is constructed by fixing the sample within location standard deviation and the standard deviation of location means and then finding the range of