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An American National Standard

Standard Practice for Demonstrating Capability to Comply with a Lotan 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 lot 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 a lot an acceptance procedure, using estimates of the parameters of the distribution of test results from the lot. 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 multiple-stageacceptance 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 E2234Practice for Sampling a Stream of Product by Attributes Indexed by AQL

E2281Practice for Process and Measurement Capability Indices

E2282 Guide for Defining the Test Result of a Test Method

E2586 Practice for Calculating and Using Basic Statistics

E2587Practice for Use of Control Charts in Statistical Process Control Practice for Calculating and Using Basic Statistics

3. Terminology

3.1 *Definitions:*

3.1.1 See Terminology E456 for a more extensive listing of terms in ASTM Committee E11 standards.

3.1.2 *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**

3.1.3 *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**

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

3.1.5 *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**

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

3.2 *Definitions of Terms Specific to This Standard:*

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[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.

3.2.1 *acceptable parameter region*, *n*—the set of values of parameters characterizing the distribution of test results for which the probability of passing the ~~lot~~ 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 ~~a lot~~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

~~4.1Lot acceptance procedures are used in industry for inspecting quality characteristics of raw materials, in-process product, and finished product. These procedures, together with process controls, comprise a quality control program. For additional information on process control see Practice E2281 dealing with process capability evaluation and Practice E2587 dealing with the use of control charts in statistical process control.~~

~~4.1.1Lot inspection procedures classify quality characteristics as either attributes (measured on discrete scales such as percent defective) or variables (measured on continuous scales such as length, weight, or concentration).~~

~~4.1.2Operating characteristic curves, which plot the relationship of the lot acceptance probability versus the true lot percent defective, are used to evaluate the discriminatory power of a given lot inspection procedure, or acceptance sampling plan, and are discussed in Practice E2234.~~

~~4.2This practice considers inspection procedures that may involve multiple-stage sampling, where at each stage one can decide to accept the lot or to continue sampling, and the decision to reject the lot is deferred until the last stage.~~

~~4.2.1At 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).~~

~~4.3The methodology in this practice defines an acceptance region for a set of test results from the lot such that, at a prescribed confidence level, the probability that a sample from the lot will pass the original lot acceptance procedure is greater than or equal to a prespecified lower bound.~~

~~4.3.1Having test results fall in the acceptance region is not equivalent to passing the original lot acceptance procedure, but provides assurance that a sample would pass the lot acceptance procedure with a specified probability.~~

~~4.3.2This information can be used for process demonstration or validation.~~

~~4.3.3This information can be used for lot release (acceptance), but the lower bound may be conservative in some cases.~~

~~4.3.4If the results are to be applied to test results from future lots from the same process, then it is assumed that the process is in a state of statistical control (see 4.1). If this is not the case then there can be no guarantee that the probability estimates would be valid predictions of future process performance.~~

~~4.4This methodology was originally developed by J. S. Bergum~~

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, 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: content uniformity and dissolution, as respectively defined in chapters <905> and <711> of the United States Pharmacopeia **(5)** .~~

~~4.5Mathematical derivations would be required that are specific to the individual criteria of each test.~~ ffor 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.

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

5. Methodology

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

5.1.1An 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.

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

5.2.1 When the characteristic is normally distributed, parameters are the mean (μ) and standard deviation (σ) of the lot.

5.2.2An expression for the exact probability of passing the lot acceptance procedure may be intractable. A lower bound for the probability may be used. For multiple stage tests, the following lower bounds on the probability of passing the procedure as a function of probabilities of passing stages, and on the probability of passing a stage having multiple criteria as a function of the probabilities of passing the criteria, may be useful (**4**).

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:

(1) $P(Si) = P(Ci1 \text{ and } Ci2 \ldots \text{ and } C\,im) \geq 1 - j{=}1m\,(1 - P(Cij))$

(1) $P(Si) = P(Ci1 \text{ and } Ci2 \ldots \text{ and } C\,im) \geq 1 - j{=}1m\,(1 - P(Cij))$

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.

5.3Determine the contour of the region of parameter values for which the expression for the probability of passing the given lot acceptance procedure is at least equal to the required lower bound (LB) on the probability of acceptance (p). This defines the region of acceptable parameters.

5.3.1For a normally distributed population, this will be a 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

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:

(2) $P\text{ (pass } k - \text{stage procedure)} \geq \max\ \{P(S1), P(S2), \ldots, P(Sk)\}$

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*.

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.

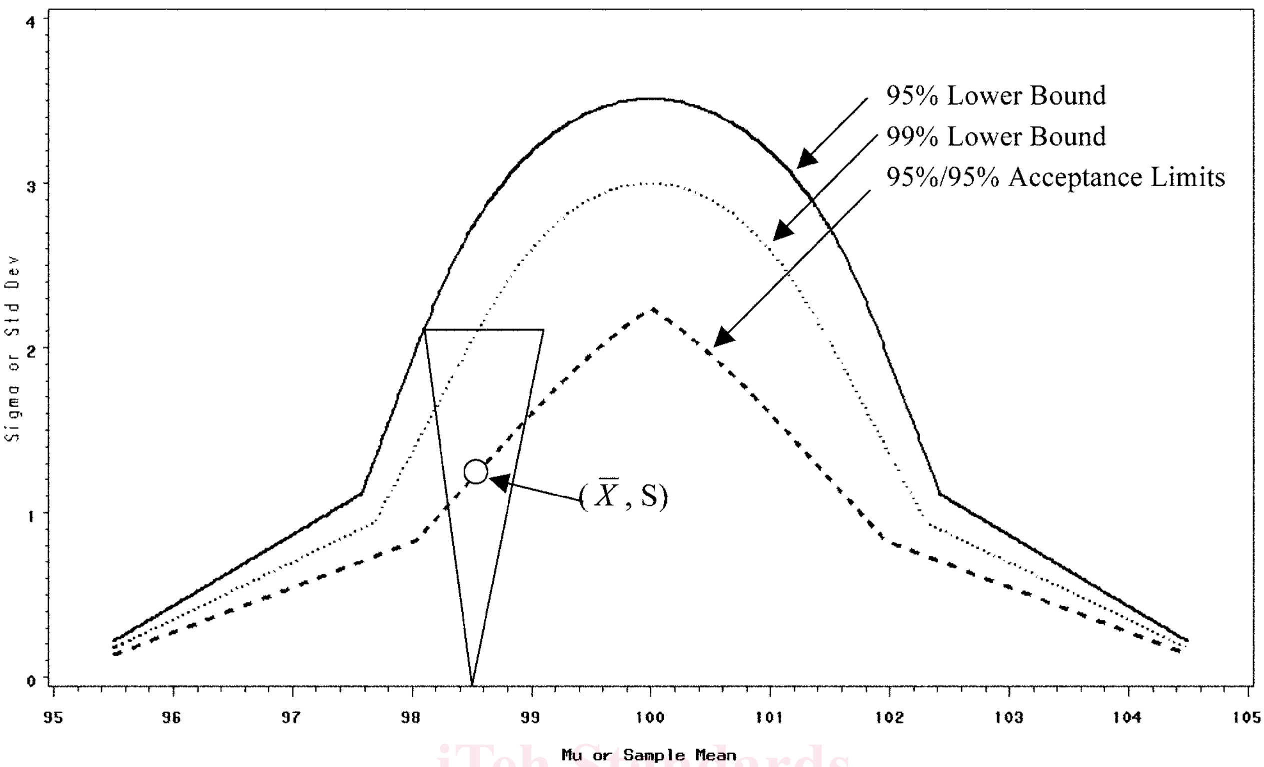

FIG. 1 Example of Acceptance Limit Contour Showing a Simultaneous Confidence Interval With 95 % and 99 % Lower Bound Contours

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 $\overline{X}$ and the sample standard deviation *s* from a set of *n* test results.

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 100(1-α), choose δ and ε such that (1-α) = (1-2δ)(1-ε). The values:

$$\epsilon = 1 - \sqrt{1-\alpha}$$

and

-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 tha

and δ = (1 –1 – α)/2

meet this condition. Then

)/2

which equally splits the overall alpha between estimating μ and σ. Then:

$$P\left\{\left(\frac{\overline{X}-\mu}{\sigma/\sqrt{n}}\right)^2 \le Z^2_{1-\delta}\right\} P\left\{\frac{(n-1)s^2}{\sigma^2} \le \chi^2_{1-\epsilon}\right\} = (1-2\delta)(1-\epsilon) \quad (3)$$

$$P\left\{\left(\frac{\overline{X}-\mu}{\sigma/\sqrt{n}}\right)^2 \le Z^2_{1-\delta}\right\} P\left\{\frac{(n-1)s^2}{\sigma^2} \le \chi^2_{1-\varepsilon}\right\} = (1-2\delta)(1-\varepsilon) = \alpha \quad (3)$$

(3) =(1–α)

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 ($\overline{X}$, 0), as depicted in Fig. 1.

5.5Determine the contour of the acceptance region, which consists of values of the statistics (

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 $\overline{X}$, s) for which the confidence region (confidence level 1-α) is entirely contained in the acceptable parameter region. This is the acceptance limit.

5.5.1For a normally distributed characteristic, 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.

5.5.2Using a computer program that calculates confidence limits for μ and σ given sample mean $\overline{X}$ and standard deviation *s*, the acceptance limit for a normally distributed characteristic can be derived using an iterative loop over increasing values of the sample standard deviation s (starting with $s$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.

5.5.3To select the size of sample to be taken,

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, the probability that sample statistics ($\bar{X}$, s) will lie within acceptance limits should be evaluated over a range of values of n, for values of population parameters (μ, σ) of practical interest, and for which probabilities of passing the given lot 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 desired value.

5.6To use the acceptance limit, sample randomly from the batch or lot. Evaluate statistics for the sample. If statistics fall within the acceptance limit, then there is 1-α confidence that the probability of acceptance is at least p-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:

$$[(1/n)\,MS_L + (1 - 1/n)\,MS_E] + \{[(1/n)((L-1)/\chi^2_{L-1,\,1-\epsilon} - 1)MS_L]^2 + [(1 - 1/n)(L(1/n)/\chi^2_{L(n-1),\,1-\epsilon} - 1)\,MS_E]^2\}^{1/2} \quad (4)$$

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

(5) $X \pm Z1{-}\sigma(nL)$

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 overall sample means such that the confidence interval completely falls below the pre-specified lower bound.

7. Examples

7.1 An example of an evaluation of a single-stage lot acceptance procedure is given in Appendix X1. An acceptance limit table is shown for a sample size of 30, but other sample sizes may be considered.

7.2 An example of an evaluation of a two-stage lot acceptance procedure with one or more acceptance criterion at each stage is given in Appendix X2. An acceptance limit table is shown for a sample size of 30.

7.3 An example of an evaluation of a two-stage lot acceptance procedure with one or more acceptance criteria at each stage using Sampling Plan 2 is given in Appendix X3. An acceptance limit table is shown for a sample size of 4 taken at each of 15 locations for a total of 60 units tested.

8. Keywords

8.1 acceptance limits; multiple-stage acceptance procedures; simultaneous confidence regions; specifications

APPENDIXES

(Nonmandatory Information)

X1. EXAMPLE: EVALUATION OF A SINGLE STAGE ACCEPTANCE PROCEDURE

X1.1 A single-stage lot acceptance procedure is stated as follows: Sample five units at random from the lot and measure a numerical quality characteristic (X_i) of each unit. Criterion: Pass if all 5 individual units are between 95 and 105; otherwise, fail.

X1.2 Assume that the test results follow a normal distribution with mean μ and standard deviation σ. Let Z denote the standard normal variate, that is, Z is normally distributed with μ = 0 and σ = 1.

X1.3 The criterion is $95 \le X_i \le 105$ for i = 1, …, 5. Therefore:

(X1.1) $P(\text{passing test}) = [P((95 - \mu)/\sigma < Z < (105 - \mu)/\sigma\,)]5$

For any given values of μ and σ, the probability of passing Stage 1 can be determined.

X1.4 A simultaneous confidence region for μ and σ is generated using the methods of Lindgren **(~~6~~5)**~~. See 5.4.1~~. See 6.3.1.

X1.5 The acceptance limit table for this example was generated by a computer program and is listed in Table X1.1. The table corresponds to a sample size of 30 using a 95 % confidence interval and a 95 % lower bound, and it lists the output showing the upper bound on the sample standard deviation for sample means between 97 and 103.

X1.6 A SAS program for the generation of the acceptance table follows. See Fig. X1.1.

~~X2.EXAMPLE OF A MULTIPLE-STAGE ACCEPTANCE PROCEDURE~~ X2. EXAMPLE: EVALUATION OF A MULTIPLE-STAGE ACCEPTANCE PROCEDURE USING SAMPLING PLAN 1

X2.1 A multiple-stage lot acceptance procedure is stated as follows:

TABLE X1.1 Acceptance Limit Table (95 % Confidence Interval/ 95 % Coverage)

Mean	Standard Deviation
96.0	0.273
97.0	0.546
98.0	0.819
99.0	1.092
100.0	1.350
101.0	1.092
102.0	0.819
103.0	0.546
104.0	0.273