ASTM INTERNATIONAL

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

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 acceptance procedure, using estimates of the parameters of the distribution of test results from the lot.

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-stage 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

E2234 Practice for Sampling a Stream of Product by Attributes Indexed by AQL

E2281 Practice 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

E2587 Practice for Use of Control Charts in Statistical Process Control

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 $\overline{X}$*, sum of the observed values in a sample divided by the sample size. **E2586**

3.1.3 *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.

3.1.4 *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 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 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 Lot acceptance procedures are used in industry for inspecting quality characteristics of raw materials, in-process product, and finished product. These procedures, together with

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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.

4.1.1 Lot 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).

4.1.2 Operating 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.

4.2 This 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.

4.2.1 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).

4.3 The 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.

4.3.1 Having 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.

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

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

4.3.4 If 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.

4.4 This methodology was originally developed by J. S. Bergum (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).

4.5 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 original lot acceptance procedure, is outlined. A computer program is normally required to produce the acceptable parameter region and acceptance limits.

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

5.1.1 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.

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.

5.2.2 An 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).

$$P\,(pass\ k - stage\ procedure) \geq max\,\{P(S_1), P(S_2), \dots , P(S_k)\} \quad (1)$$

where:
$P(S_i)$ = is the probability of passing stage i, evaluated regardless of whether previous stages pass or not.

$$P(S_i) = P(C_{i1}\ and\ C_{i2} \dots and\ C_{im}) \geq 1 - \sum_{j=1}^{m}(1 - P(C_{ij})) \quad (2)$$

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

5.3 Determine 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.

5.3.1 For 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 Fig. 1.

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

5.4.1 For a normally distributed lot, the method of Lindgren (6) 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. 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

$$\delta = (1 - \sqrt{1 - \alpha})/2$$

meet this condition. Then

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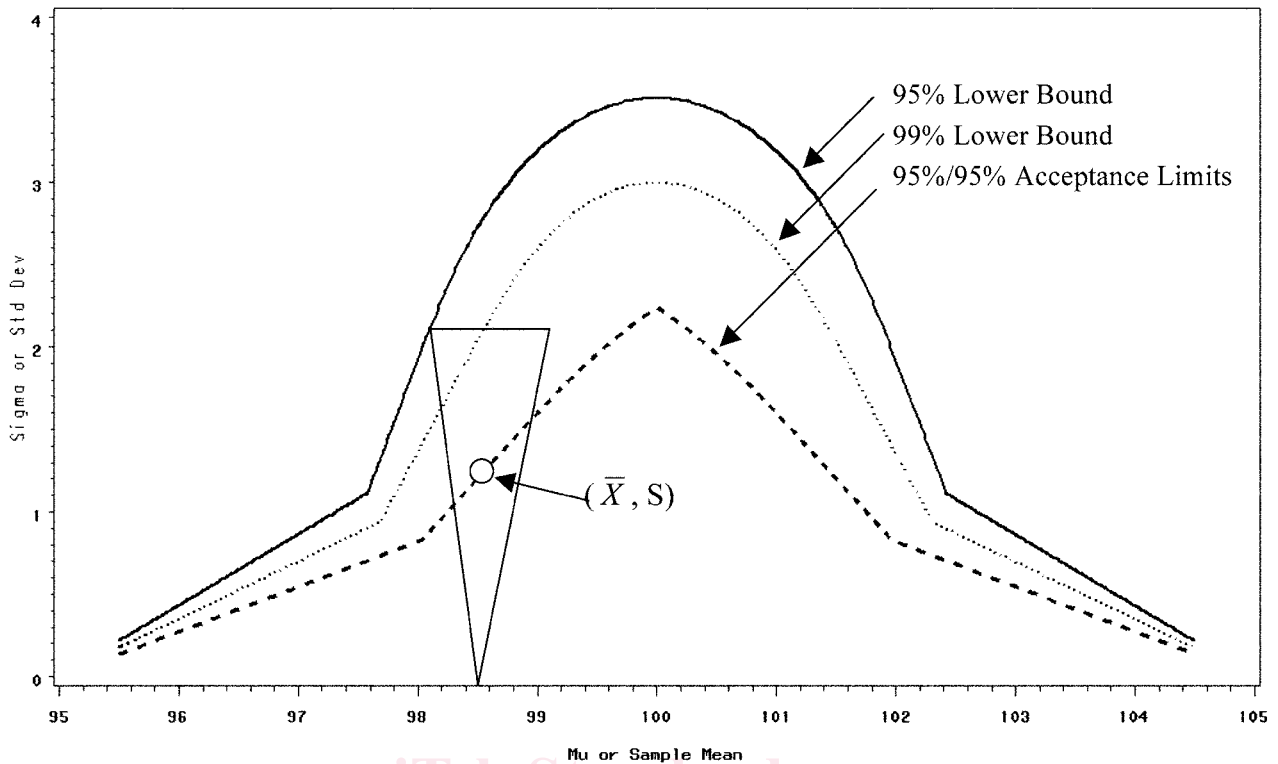
$$= (1 - \alpha) \quad (3)$$

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

The 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.

5.5 Determine the contour of the acceptance region, which consists of values of the statistics ($\bar{X}$, s) for which the confidence region (confidence level 1-α) is entirely contained in the acceptable parameter region. This is the acceptance limit.

5.5.1 For 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.

5.5.2 Using a computer program that calculates confidence limits for μ and σ given sample mean $\bar{X}$ 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 = 0) until the confidence limits hit the boundary of the acceptable parameter region, for each potential value of the sample mean.

5.5.3 To select the size of sample to be taken, 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.

5.6 To 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.

6. Examples

6.1 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.

6.2 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. Keywords

7.1 acceptance limits; acceptance sampling inspection; multiple-stage lot acceptance procedures; simultaneous confidence regions; specifications

APPENDIXES

X1. EXAMPLE 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 $95 \leq X_i \leq 105$ for i = 1, …, 5. Therefore:

$$P(passing\ test) = [P((95 - \mu)/\sigma < Z < (105 - \mu)/\sigma\ )]^5 \quad (X1.1)$$

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)**. See 5.4.1.

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.

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

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*** Create Acceptance Limit Table for Single Stage Example***;

%Let D = 1;            /* Increments for Mean */
%Let CILEVEL = 95;     /* Confidence Level */
%Let LBOUND = 95;      /* Coverage Level */
%Let NUMBER = 30;      /* Sample Size */

DATA TABLE;
   n1 = 5;
   D=&D;
   Z = PROBIT((1 + SQRT(&CILEVEL / 100)) / 2);
   N = &NUMBER;
   CHI = CINV(1 - SQRT(&CILEVEL / 100),N - 1);
   SDOLD = 0;
   STARTSD = 0.01;
   DO MEAN = 96.0 TO 104.0 BY D;
      BEGIN = STARTSD;
    DO SAMPSD = BEGIN TO 20 by 0.001;
    SIG = SQRT((N - 1) * SAMPSD * SAMPSD / CHI);
      LLU = MEAN - Z *SIG / SQRT(N);
       p1L = ((probnorm((105-llu)/sig))-probnorm((95-llu)/sig))**n1;
        ULU = MEAN + Z * SIG / SQRT(N);
       p1U = ((probnorm((105-ulu)/sig))-probnorm((95-ulu)/sig))**n1;
        OVERBD = MIN(p1L, p1U);
     IF OVERBD < &LBOUND/100 THEN DO;
      SAMPSD = SAMPSD - 0.001;
       CV = 100*SAMPSD/MEAN;
        OUTPUT;
       SAMPSD = 20.0;
       END;
     end;
      end;
proc sort data=table; by Mean;
Proc print data= Table split = '*';
   format CV 5.2;
   label MEAN = "Mean"
           SAMPSD = 'Standard'*'Deviation'
         CV = "CV(%)";
Title 'Acceptance Limit Table for Simple Example';
    ID Mean;
     var SAMPSD CV;
run;
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FIG. X1.1 SAS Program

X2. EXAMPLE OF A MULTIPLE-STAGE ACCEPTANCE PROCEDURE

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

Stage 1: 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 go to Stage 2.

Stage 2: Randomly sample five additional units from the lot and measure a numerical quality characteristic (X_i) of each unit. Criteria: Pass if the average of the 10 test results is between 97 and 103 and all 10 individual results are between 90 and 110; otherwise fail.

X2.2 To obtain the lower bound on the probability of acceptance, 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. Let S_i denote the event that the test results meet the acceptance criteria for Stage i, and let C_{ij} denote the event that the j-th criterion for the i-th stage is met.

X2.2.1 For Stage 1, the criterion C_{11} is $95 \leq X_i \leq 105$ for i = 1, …, 5. Therefore:

$$P(S_1) = P(C_{11}) = [P((95 - \mu)/\sigma < Z < (105 - \mu)/\sigma)]^5 \quad \text{(X2.1)}$$

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

X2.2.2 For Stage 2, the criterion C_{21} is:

$$97 \leq \bar{X} \leq 103$$

Where $\bar{X}$ is the average of the 10 test results, and the criterion C_{22} is $90 \leq X_i \leq 110$ for i = 1, …, 10. Therefore:

$$P(C_{21}) = [P(\sqrt{10}(97 - \mu)/\sigma < Z < \sqrt{10}(103 - \mu)/\sigma) \quad \text{(X2.2)}$$

$$P(C_{22}) = [P((90 - \mu)/\sigma < Z < (110 - \mu)/\sigma)]^{10} \quad \text{(X2.3)}$$

$$P(S_2) \geq P(C_{21}) + P(C_{22}) - 1 \quad \text{(X2.4)}$$

For any given values of μ and σ, the probability of passing Stage 2 can be determined.

X2.3 The lower bound (LB) = Max [P(S1), P(S2)] can be determined for any values of μ and σ, and a LB value for σ can be generated for each selected value of μ by increasing σ from 0 in increments until the prescribed LB is attained.

X2.3.1 A computer program was used to generate the lower bounds for this example, using values of μ ranging from 97.0

TABLE X2.1 Calculation for 95 % Lower Bound Contour

Population		Probability of Passing				
Mean	Std Dev	P(S$_1$)	P(C$_{21}$)	P(C$_{22}$)	P(S$_2$)	LB
97.0	0.86	0.950	0.500	1.000	0.500	0.950
98.0	1.92	0.737	0.950	1.000	0.950	0.950
99.0	3.19	0.485	0.976	0.974	0.950	0.950
100.0	3.51	0.432	0.993	0.957	0.950	0.950
101.0	3.19	0.485	0.976	0.974	0.950	0.950
102.0	1.92	0.737	0.950	1.000	0.950	0.950
103.0	0.86	0.950	0.500	1.000	0.500	0.950

TABLE X2.2 Acceptance Limit Table (95 % Confidence Interval/ 95 % Coverage)

Mean	Standard Deviation
97.0	0.546
98.0	0.819
99.0	1.599
100.0	2.240
101.0	1.599
102.0	0.819
103.0	0.546

to 103.0 in increments of 1.0. Table X2.1 lists the output for selected mean and standard deviation pairs on the lower bound contour. The probabilities of passing the three criteria and the two stages are also listed in the output.

X2.3.2 Since the bound is a lower bound on the probability of passing the procedure, the actual probability is always equal to or greater than the lower bound. A comparison of the lower bound to the actual probability of passing the procedure can be performed using a computer simulation.

X2.4 The acceptance table corresponds to a sample size of 30 using a 95 % confidence interval and a 95 % lower bound. Table X2.2 lists the output showing the upper bound on the sample standard deviation for sample means between 97 and 103.

X2.5 95 % and 99 % contours (μ, σ) for the acceptance region for this example as well as the acceptance table contour (mean and standard deviation) are depicted in Fig. X2.1. Note that the curve changes shape at the two points where the maximum stage probability for the lower bound changes over from Stage 1 to Stage 2.

X2.6 A SAS program listing for the generation of the contours and acceptance table follows. See Fig. X2.2.