ASTM INTERNATIONAL

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Standard Practice for
Setting an Upper Confidence Bound For a Fraction or Number of Non-Conforming items, or a Rate of Occurrence for Non-conformities, Using Attribute Data, When There is a Zero Response in the Sample[1]

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1. Scope

1.1 This practice presents methodology for the setting of an upper confidence bound regarding a unknown fraction or quantity non-conforming, or a rate of occurrence for nonconformities, in cases where the method of attributes is used and there is a zero response in a sample. Three cases are considered.

1.1.1 The sample is selected from a process or a very large population of discrete items, and the number of non-conforming items in the sample is zero.

1.1.2 A sample of items is selected at random from a finite lot of discrete items, and the number of non-conforming items in the sample is zero.

1.1.3 The sample is a portion of a continuum (time, space, volume, area etc.) and the number of non-conformities in the sample is zero.

1.2 Allowance is made for misclassification error in this standard, but only when misclassification rates are well understood or known and can be approximated numerically.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E141 Practice for Acceptance of Evidence Based on the Results of Probability Sampling

E456 Terminology Relating to Quality and Statistics

E1402 Guide for Sampling Design

E1994 Practice for Use of Process Oriented AOQL and LTPD Sampling Plans

E2586 Practice for Calculating and Using Basic Statistics

2.2 *ISO Standards:*

ISO 3534-1 Statistics—Vocabulary and Symbols, Part 1: Probability and General Statistical Terms[3]

ISO 3534-2 Statistics—Vocabulary and Symbols, Part 2: Statistical Quality Control[3]

NOTE 1—Samples discussed in this standard should meet the requirements (or approximately so) of a probability sample as defined in Terminologies E1402 or E456.

3. Terminology

3.1 *Definitions:*

3.1.1 Terminology E456 provides a more extensive list of terms in E11 standards.

3.1.2 *attributes, method of, n*—measurement of quality by the method of attributes consists of noting the presence (or absence) of some characteristic or attribute in each of the units in the group under consideration, and counting how many of the units do (or do not) possess the quality attribute, or how many such events occur in the unit, group or area.

3.1.3 *confidence bound, n*—see *confidence limit*.

3.1.4 *confidence coefficient, n*—the value, *C*, of the probability associated with a confidence interval or statistical coverage interval. It is often expressed as a percentage. **ISO 3534-1**

3.1.5 *confidence interval, n*—an interval estimate of a population parameter, calculated such that there is a given long-run probability that the parameter is included in the interval.

3.1.5.1 *Discussion*—A one-sided confidence interval is one for which one of the limits is plus infinity, minus infinity, or a natural fixed limit (such as zero).

3.1.6 *confidence level, n*—see *confidence coefficient*.

3.1.7 *confidence limit, n*—the upper or lower limit of a confidence interval.

3.1.8 *item, n*—an object or quantity of material on which a set of observations can be made.

3.1.8.1 *Discussion*—As used in this standard, "set" denotes a single variable (the defined attribute). The term "sampling unit" is also used to denote an "item" (see Practice E141).

3.1.9 *non-conforming item, n*—an item containing at least one non-conformity. **ISO 3534-2**

3.1.9.1 *Discussion*—The term "defective item" is also used in this context.

3.1.10 *non-conformity, n*—the non-fulfillment of a specified requirement. **ISO 3534-2**

3.1.10.1 *Discussion*—The term "defect" is also used in this context.

3.1.11 *population, n*—the totality of items or units of material under consideration. **E2586**

3.1.12 *sample, n*—a group of observations or test results taken from a larger collection of observations or test results , which serves to provide information that may be used as a basis for making a decision concerning the larger collection. **E2586**

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *probability sample, n*—a sample of which the sampling units have been selected by a chance process. At each step of selection, a specified probability of selection can be attached to each sampling unit available for selection. **E1402**

3.2.2 *zero response, n—in the method of attributes*, the phrase used to denote that zero non-conforming items or zero non-conformities were found (observed) in the item(s), unit, group or area sampled.

3.3 *Symbols:*

3.3.1 *A*—the assurance index, as a percent or a probability value.

3.3.2 *C*—confidence coefficient as a percent or as a probability value.

3.3.3 C_d—the confidence coefficient calculated that a parameter meets a certain requirement, that is, that $p \leq p_0$, that $D \leq D_0$ or that $\lambda \leq \lambda_0$, when there is a zero response in the sample.

3.3.4 *D*—the number of non-conforming items in a finite population containing *N* items.

3.3.5 D_0—a specified value of *D* for which a researcher will calculate a confidence coefficient for the statement, $D \leq D_0$, when there is a zero response in the sample.

3.3.6 D_u—the upper confidence bound for the parameter *D*.

3.3.7 *N*—the number of items in a finite population.

3.3.8 *n*—the sample size, that is, the number of items in a sample.

3.3.9 n_R—the sample size required.

3.3.10 *p*—a process fraction non-conforming.

3.3.11 p_0—a specified value of *p* for which a researcher will calculate a confidence coefficient, for the statement $p \leq p_0$, when there is a zero response in the sample.

3.3.12 p_u—the upper confidence bound for the parameter *p*.

3.3.13 λ—the mean number of non-conformities (or events) over some area of interest for a Poisson process.

3.3.14 λ_0—a specific value of λ for which a researcher will calculate a confidence coefficient for the statement, $\lambda \leq \lambda_0$, when there is a zero response in the sample.

3.3.15 λ_u—the upper confidence bound for the parameter λ.

3.3.16 θ_1—the probability of classifying a conforming item as non-conforming; or of finding a nonconformity where none exists.

3.3.17 θ_2—the probability of classifying a non-conforming item as conforming; or of failing to find a non-conformity where one should have been found.

4. Significance and Use

4.1 In Case 1, the sample is selected from a process or a very large population of interest. The population is essentially unlimited, and each item either has or has not the defined attribute. The population (process) has an unknown fraction of items *p* (long run average process non-conforming) having the attribute. The sample is a group of *n* discrete items selected at random from the process or population under consideration, and the attribute is not exhibited in the sample. The objective is to determine an upper confidence bound, p_u, for the unknown fraction *p* whereby one can claim that $p \leq p_u$ with some confidence coefficient (probability) *C*. The binomial distribution is the sampling distribution in this case.

4.2 In Case 2, a sample of *n* items is selected at random from a finite lot of *N* items. Like Case 1, each item either has or has not the defined attribute, and the population has an unknown number, *D*, of items having the attribute. The sample does not exhibit the attribute. The objective is to determine an upper confidence bound, D_u, for the unknown number *D*, whereby one can claim that $D \leq D_u$ with some confidence coefficient (probability) *C*. The hypergeometric distribution is the sampling distribution in this case.

4.3 In Case 3, there is a process, but the output is a continuum, such as area (for example, a roll of paper or other material, a field of crop), volume (for example, a volume of liquid or gas), or time (for example, hours, days, quarterly, etc.) The sample size is defined as that portion of the "continuum" sampled, and the defined attribute may occur any number of times over the sampled portion. There is an unknown average rate of occurrence, λ, for the defined attribute over the sampled interval of the continuum that is of interest. The sample does not exhibit the attribute. For a roll of paper this might be blemishes per 100 ft^2; for a volume of liquid, microbes per cubic litre; for a field of crop, spores per acre; for a time interval, calls per hour, customers per day or accidents per quarter. The rate, λ, is proportional to the size of the interval of interest. Thus, if $\lambda = 12$ blemishes per 100 ft^2 of paper, this is equivalent to 1.2 blemishes per 10 ft^2 or 30 blemishes per 250 ft^2. It is important to keep in mind the size of the interval in the analysis and interpretation. The objective is to determine an upper confidence bound, λ_u, for the unknown occurrence rate λ, whereby one can claim that $\lambda \leq \lambda_u$ with some confidence coefficient (probability) *C*. The Poisson distribution is the sampling distribution in this case.

4.4 A variation on Case 3 is the situation where the sampled "interval" is really a group of discrete items, and the defined

attribute may occur any number of times within an item. This might be the case where the continuum is a process producing discrete items such as metal parts, and the attribute is defined as a scratch. Any number of scratches could occur on any single item. In such a case the occurrence rate, λ, might be defined as scratches per 1000 parts or some similar metric.

4.5 In each case a sample of items or a portion of a continuum is examined for the presence of a defined attribute, and the attribute is not observed (that is, a zero response). The objective is to determine an upper confidence bound for either an unknown proportion, p (Case 1), an unknown quantity, D (Case 2), or an unknown rate of occurrence, λ (Case 3). In this standard, confidence means the probability that the unknown parameter is not more than the upper bound. More generally, these methods determine a relationship among sample size, confidence and the upper confidence bound. They can be used to determine the sample size required to demonstrate a specific p, D or λ with some degree of confidence. They can also be used to determine the degree of confidence achieved in demonstrating a specified p, D or λ.

4.6 In this standard allowance is made for misclassification error but only when misclassification rates are well understood or known, and can be approximated numerically.

4.7 It is possible to impose the language of classical acceptance sampling theory on this method. Terms such as Lot Tolerance Percent Defective, Acceptable Quality Level, Consumer Quality Level are not used in this standard. For more information on these terms, see Practice E1994.

5. Procedure

5.1 When a sample is inspected and a zero response is exhibited with respect to a defined attribute, we refer to this event as "all_zeros." Formulas for calculating the probability of "all_zeros" in a sample are based on the binomial, the hypergeometric and the Poisson probability distributions. When there is the possibility of misclassification error, adjustments to these distributions are used. This practice will clarify when each distribution is appropriate and how misclassification error is incorporated. Three basic cases are considered as described in Section 4. Formulas and examples for each case are given below. Mathematical notes are given in Appendix X1.

5.2 In some applications, the measurement method is known to be fallible to some extent resulting in a significant misclassification error. If experiments with repeated measurements have established the rates of misclassification, and they are known to be constant, they should be included in the calculating formulas. Two misclassification error probabilities are defined for this practice:

5.2.1 Let θ_1 be the probability of reporting a non-conforming item when the item is really conforming.

5.2.2 Let θ_2 be the probability of reporting a conforming item when the item is really non-conforming.

5.2.3 Almost all applications of this standard require that θ_1 be known to be 0 (see 6.1.2).

5.3 Formulas for upper confidence bounds in three cases:

5.3.1 *Case 1*—The item is a completely discrete object and the attribute is either present or not within the item. Only one response is recorded per item (either go or no-go). The sample items originate from a process and hence the future population of interest is potentially unlimited in extent so long as the process remains in statistical control. The item having the attribute is often referred to as a defective item or a non-conforming item or unit. The sample consists of n randomly selected items from the population of interest. The n items are inspected for the defined attribute. The sampling distribution is the binomial with parameters p equal to the process (population) fraction non-conforming and n the sample size. When zero non-conforming items are observed in the sample (the event "all_zeros"), and there are no misclassification errors, the upper confidence bound, p_u, at confidence level C ($0 < C < 1$), for the population proportion non-conforming is:

$$p_u = 1 - \sqrt[n]{1 - C} \qquad (1)$$

5.3.1.1 Table 1 contains the calculated upper confidence bound for the process fraction non-conforming when $x=0$ non-conforming items appear in a sample of size n. Confidence is 100C%. For example, if $n=250$ objects are sampled and there are $x=0$ non-conforming objects in the sample, then the upper 95% confidence bound for the process fraction non-conforming is approximately 0.01191 or 1.191% non-conforming. Eq 1 was applied.

5.3.1.2 For the case with misclassification errors, when zero non-conforming items are observed in the sample (all_zeros), the upper confidence bound, p_u, at confidence level C is:

TABLE 1 Upper 100C% Confidence Bound, p_u, for the Process Fraction Non-Conforming, p, When Zero non-conforming Units appear in a sample of Size, n

n	C = 0.90	C = 0.95	C = 0.99
5	0.369043	0.450720	0.601893
10	0.205672	0.258866	0.369043
15	0.142304	0.181036	0.264358
20	0.108749	0.139108	0.205672
30	0.073881	0.095034	0.142304
40	0.055939	0.072158	0.108749
50	0.045007	0.058155	0.087989
60	0.037649	0.048703	0.073881
70	0.032359	0.041893	0.063671
80	0.028372	0.036754	0.055939
90	0.025260	0.032738	0.049881
100	0.022763	0.029513	0.045007
150	0.015233	0.019773	0.030235
175	0.013071	0.016973	0.025972
200	0.011447	0.014867	0.022763
225	0.010182	0.013226	0.020259
250	0.09168	0.011911	0.018252
275	0.008338	0.010834	0.016607
300	0.007646	0.009936	0.015233
350	0.006557	0.008523	0.013071
400	0.005740	0.007461	0.011447
450	0.005104	0.006635	0.010182
500	0.004595	0.005974	0.009168
750	0.003065	0.003986	0.006121
1000	0.002300	0.002991	0.004595
1500	0.001534	0.001995	0.003065
2000	0.001151	0.001497	0.002300
5000	0.000460	0.000599	0.000921
10 000	0.000230	0.000300	0.000460
25 000	0.000092	0.000120	0.000184
50 000	0.000046	0.000060	0.000092
80 000	0.000029	0.000037	0.000058
100 000	0.000023	0.000030	0.000046

3

$$p_u = \frac{1 - \theta_1 - \sqrt[n]{1 - C}}{(1 - \theta_1 - \theta_2)} \qquad (2)$$

5.3.1.3 Eq 2 reduces to Eq 1 when $\theta_1 = \theta_2 = 0$. To find the minimum sample size required (n_R) to state a confidence bound of p_u at confidence C if zero non-conforming items are to be observed in the sample, solve Eq 2 for n. This is:

$$n_R = \frac{ln(1 - C)}{ln((1 - p_u)(1 - \theta_1) + p_u \theta_2)} \qquad (3)$$

5.3.1.4 To find the confidence demonstrated (C_d) in the claim that an unknown fraction non-conforming p is no more than a specified value, say p_0, when zero non-conformances are observed in a sample of n items solve Eq 2 for C. This is:

$$C_d = 1 - ((1 - p_0)(1 - \theta_1) + p_0 \theta_2)^n \qquad (4)$$

5.3.2 *Case 2*—The item is a completely discrete object and the attribute is either present or not within the item. Only one response is recorded per item (either go or no-go). The sample items originate from a finite lot or population of N items. The sample consists of n randomly selected items from among the N, without replacement. The population proportion defective is $p = D/N$ where the unknown D is the integer number of non-conforming (defective) items among the N. The sampling distribution is the hypergeometric with parameters N, D and n. When zero non-conforming items are observed in the sample (all_zeros), and there are no misclassification errors, the upper confidence bound, at confidence level C, for the unknown number of non-conforming items, D, in the population is found by solving Eq 5 iteratively for D_u.

$$C = 1 - \prod_{i=1}^{n} \left(1 - \frac{D_u}{N - i + 1}\right) \qquad (5)$$

5.3.2.1 For the case with misclassification errors, when zero non-conforming items are observed in the sample (all_zeros), the upper confidence bound, D_u, at confidence level C is found by solving Eq 6 iteratively for D_u.

$$C = 1 - \qquad (6)$$

$$\frac{\binom{N - D_u}{n}(1 - \theta_1)^n + \sum_{x=1}^{\min(D_u, n)} \binom{N - D_u}{n - x}(1 - \theta_1)^{n - x}\binom{D_u}{x}\theta_2^x}{\binom{N}{n}}$$

5.3.2.2 Eq 5 and 6 must be solved numerically for D_u. For fixed values of C, N, n, θ_1 and θ_2, we evaluate the right hand side for $D_u = 0,1,2 \ldots$ until we reach a point where the right side is just greater than or equal to the left side. The smallest D_u for which this is true is the upper bound at confidence level C. To find a sample size required (for fixed values of D_u, C, N, θ_1 and θ_2) to make Eq 6 true when zero non-conformances are to be exhibited in the sample, we evaluate the equation iteratively for $n = 1,2,3, \ldots$ until the right side is just greater than or equal to the left side. To determine the confidence demonstrated (for fixed values of D_0, N, n, θ_1 and θ_2) in the claim that $D \leq D_0$, for a specified D_0, solve Eq 6 for C and evaluate the resulting expression, designating C as C_d.

5.3.3 *Case 3*—There is a process but the output is a continuum. The sample is that portion of the continuum observed, and the defined attribute can occur any number of times over the sample. When the attribute is found we often refer to it as a "defect" or non-conformity. As such, there is no integer sample size similar to Cases 1 and 2. It is usual to define λ to be the rate of generation of non-conformities (defects) per unit area, volume or time within the continuum. The sampling distribution is the Poisson with parameter λ. When zero non-conformities are observed in the sample (all_zeros), and there are no misclassification errors, the upper confidence bound, λ_u, at confidence level C, for the process rate λ is:

$$\lambda_u = -ln(1 - C) \qquad (7)$$

5.3.3.1 For the case with misclassification errors, when zero non-conformities are observed in the sample, the upper confidence bound, λ_u, at confidence level C is:

$$\lambda_u = \frac{-ln(1 - C)}{1 - \theta_1 - \theta_2} \qquad (8)$$

5.3.3.2 To determine the confidence demonstrated, C_d, in the claim that $\lambda \leq \lambda_0$, for some specified λ_0, substitute λ_0 for λ_u in Eq 8 and solve for C, designated it as C_d. This gives:

$$C_d = 1 - e^{-\lambda_0(1 - \theta_1 - \theta_2)} \qquad (9)$$

5.3.3.3 A related use for the Poisson distribution, in this context, is as an approximation to the binomial whenever the sample size, n, is large and the fraction non-conforming, p, is small. This approximation is very good when $n \geq 100$ and $np \leq 10$. See Ref (**1**).[4] To use this theory, set $np_u = \lambda_u$ in Eq 8. When $x = 0$, therefore, one has an upper bound, p_u, of:

$$p_u = \frac{-ln(1 - C)}{n(1 - \theta_1 - \theta_2)} \qquad (10)$$

5.3.3.4 In each of the equations of Section 5, we may set θ_1 and/or θ_2 equal to zero if that misclassification error parameter is negligible. We shall see in Section 7 that we often set $\theta_1 = 0$, particularly for large sample sizes.

6. Illustrations and Examples

6.1 *Case 1 Examples and Illustrations:*

6.1.1 An injection-molding machine produces plastic components for the automotive industry. The machine may sometimes produce an incomplete part referred to in the trade as a "short shot." On a daily basis an inspector will look at a sample of $n = 400$ parts from this process for the presence of the "short shot." When zero non-conformances are exhibited in the sample, the day's production is accepted. Determine the 90 % upper confidence bound for the process fraction non-conforming for this sampling scheme. Assume misclassification errors are negligible. Using Eq 1 we have:

$$p_u = 1 - \sqrt[400]{1 - 0.9} = 0.00574 \qquad (11)$$

6.1.1.1 A sample design question is whether $n = 400$ is adequate. Suppose the consumer desires that there be 90 % confidence in the claim that $p = p_0 = 0.004$. What sample size

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