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An American National Standard

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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ε^1 NOTE—Section 3 was editorially corrected in August 2013.
ε^2 NOTE—Terms were editorially corrected in April 2016.

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:*[3]

ISO 3534-1 Statistics—Vocabulary and Symbols, Part 1: Probability and General Statistical Terms
ISO 3534-2 Statistics—Vocabulary and Symbols, Part 2: Statistical Quality Control

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*—Unless otherwise noted in this standard, all terms relating to quality and statistics are defined in Terminology E456.

3.1.1 *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.

3.1.2 *confidence bound, n*—see *confidence limit*. **E2586**

3.1.3 *confidence coefficient, n*—see *confidence level*. **E2586**

3.1.4 *confidence interval, n*—an interval estimate [L, U] with the statistics L and U as limits for the parameter θ and with confidence level $1 - \alpha$, where $\Pr(L \leq \theta \leq U) \geq 1 - \alpha$. **E2586**

3.1.4.1 *Discussion*—The confidence level, $1 - \alpha$, reflects the proportion of cases that the confidence interval [L, U] would contain or cover the true parameter value in a series of repeated random samples under identical conditions. Once L and U are given values, the resulting confidence interval either does or does not contain it. In this sense "confidence" applies not to the

[1] This practice is under the jurisdiction of ASTM Committee E11 on Quality and Statistics and is the direct responsibility of Subcommittee E11.30 on Statistical 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 thestandard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

particular interval but only to the long run proportion of cases when repeating the procedure many times.

3.1.5 *confidence level, n*—the value 1-α, of the probability associated with a confidence interval, often expressed as a percentage. **E2586**

3.1.6 *confidence limit, n*—each of the limits, L and U, of a confidence interval, or the limit of a one-sided confidence interval. **E2586**

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

3.1.7.1 *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).

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

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

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

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

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

3.1.11 *probability sample, n*—a sample in which the sampling units are selected by a chance process such that a specified probability of selection can be attached to each possible sample that can be selected. **E1402**

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 *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 λ = 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:

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

5.3.1.1 Table 1 contains the calculated upper confidence

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

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:

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

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:

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

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:

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

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.

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

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.

$$C = 1 - \frac{\binom{N - D_u}{n}(1 - \theta_1)^n + \sum_{x=1}^{\min(D_u, n)} \binom{N - D_u}{n - x}(1 - \theta_1)^{n-x}\binom{D_u}{x}\theta_2^x}{\binom{N}{n}} \quad (6)$$

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 … 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, … 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 $D \le D_0$, 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:

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

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:

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

5.3.3.2 To determine the confidence demonstrated, C_d, in the claim that $\lambda \le \lambda_0$, 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:

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

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 $n \ge 100$ and $np \le 10$. 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:

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

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 θ_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

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

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:

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

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 will provide this protection? Using Eq 3 with misclassification error parameters set to 0, we have:

$$n_R = \frac{ln(1-0.9)}{ln(1-0.004)} \approx 575 \quad (12)$$

6.1.1.2 A sample of 575 without incidence of a non-conforming item is sufficient. Suppose next that a total of 500 items have been inspected without incidence of a non-conforming item. What confidence may we have in the claim that $p \leq p_0 = 0.004$? Using Eq 4 with misclassification error parameters set to 0, we have:

$$C_d \geq 1 - (1 - 0.004)^{500} = 0.8652 \quad (13)$$

6.1.1.3 There is at least 86.5 % confidence that we meet the requirement.

6.1.2 Consider the effect of a misclassification error due to θ_1. Suppose for the example in 6.1.1 that $\theta_1 = 0.1$ and $\theta_2 = 0$. Using Eq 2 we find that $p_u = -0.1047$. This result indicates the strange effect of misclassification errors on such calculations. Since p_u is an upper bound for a probability, it must itself be bounded between 0 and 1. The problem can be understood mathematically by considering the numerator in Eq 2. For a specified confidence, C, in order for this numerator to be greater than 0, we must have that:

$$\theta_1 < 1 - \sqrt[n]{1-C} \quad (14)$$

6.1.2.1 That is, when zero non-conforming items appear in the sample, the error due to θ_1 must always be less than the upper bound that would result when no misclassification error is considered. In this example this means that $\theta_1 \leq 0.00574$. However, for a confidence level of $C = 0.9$, the sample size would have to be no larger than $n = 21$ to consider $\theta_1 = 0.1$.

6.1.2.2 On a more practical level, recall that θ_1 is the probability of misclassifying a conforming item as non-conforming. Even for a modest sample size, we should not expect to observe zero non-conforming items in the sample when $\theta_1 = 0.1$. Indeed, if the proportion p were really 0, and if θ_1 were really as high as 0.1, the probability that zero non-conforming items would result in a sample of 400 items can be shown to be approximately 5E-19, or essentially 0. Again, using $C = 0.9$ and $p = 0$ to begin with, even when $n = 50$, the probability of zero non-conforming items when $\theta_1 = 0.1$ is approximately 0.005, a rare event. Because of these problems and the rather drastic effect that θ_1 has on the case of a sample containing all conforming items, it is recommended that θ_1 be known equal to 0 in this standard.

6.1.3 Consider the effect of misclassifying a non-conforming item as a conforming one. Again, suppose for the example in 6.1.1 that $\theta_1 = 0$ and $\theta_2 = 0.1$. Using Eq 2 we find that: $p_u = 0.00638$. Here p_u increases by a modest amount from 0.00574, without misclassification error. Now a sample size of $n = 360$, but with no misclassification error, would also achieve approximately $p_u = 0.00638$. Thus, the elimination of misclassification error, in this example, would effectively reduce the sample size by 40 observations.

6.2 *Case 2 Examples and Illustrations:*

6.2.1 A lot of $N = 5000$ items was just received and a sample of $n = 200$ indicated zero defective items. At 90 % confidence what is the upper bound, D_u, for the number of non-conforming items, D, in the lot? Use Eq 5 in a table such as Table 2.

6.2.1.1 From Table 2 it is seen that confidence (C) will be just slightly more than 0.9 when $D_u = 57$. Thus the upper bound at 90 % confidence is $D_u = 57$. A table such as Table 2 is easily created in a spreadsheet type program by programming Eq 5 and evaluating the formula at a range of values of D_u.

6.2.2 Packaging is often an important component of a product, and damaged product is often revealed by the presence of damaged packaging. In inspecting a shipment of delicate electronic product containing $N = 2000$ units, a firm would like to claim that the lot contains no more than 1 % damaged items, at 95 % confidence. What sample size would satisfy this requirement? For example, is $n = 100$ adequate? Assume no misclassification error, and let $C = 0.95$. Set $D_u = (0.01)2000 = 20$ and use Eq 5 iteratively. Again, a table of values of C versus n will reveal the sample size.

6.2.2.1 From Table 3 it is seen that Confidence (C) will be just slightly more than 0.95 when $n = 277$. The required sample size is 277. If zero non-conforming items should be the result in a sample of 277 items, the upper bound of the number of defective items in the lot ($N = 2000$) is $D_u = 20$.

6.2.3 Consider a misclassification error of 20 % or $\theta_2 = 0.20$, and suppose that under such relaxed measurement conditions we might choose to increase the sample size to $n = 400$ from the 277. Would this preserve a confidence of 95 % that $D \leq D_u = 20$? Using Eq 6 with $N = 2000$, $n = 400$, $D_u = 20$ and $\theta_2 = 0.20$ we can solve for C and find that $C = 0.970$. In fact as few as $n = 347$ would make the confidence just above 0.95. The actual value is $C = 0.9502$.

6.2.4 *Further Considerations, With Finite Lots*—Under illustration 6.2.2, suppose the consumer complained that a quality level of 20 out of 2000 was not good enough and asks what would happen to the sample size if D_u were set at its most stringent level, 1 out of 2000. Application of Eq 5 reduces to $C = n/N$. The confidence is seen to be no larger than the fraction

TABLE 2 Value of C in Eq 5 where $N = 5000$, $n = 200$, and Varying D_u

D_u	C	D_u	C
40	0.805906	51	0.876637
41	0.813733	52	0.881622
42	0.821245	53	0.886407
43	0.828456	54	0.890999
44	0.835377	55	0.895407
45	0.842021	56	0.899637
46	0.848397	57	0.903697
47	0.854518	58	0.907594
48	0.860392	59	0.911333
49	0.866030	60	0.914922
50	0.871442	61	0.918367

TABLE 3 Value of C in Eq 5 where N = 2000, D_u = 20, and Varying n

n	C	n	C
100	0.643314	274	0.948285
125	0.726689	275	0.948884
150	0.791327	276	0.949476
175	0.841265	277	0.950063
200	0.879709	278	0.950642
225	0.909197	279	0.951216
250	0.931731	280	0.951782
275	0.948884	281	0.952343
300	0.961889	282	0.952898

of the sample size relative to the finite lot size. For a confidence of 95 % and for N = 1000, the sample size would have to be at least n = 0.95(1000) = 950.

6.2.4.1 Alternatively, if one desires a confidence C that the population contains 0 defects, anticipating X = 0 defects in the sample, then one must sample at least n = CN units. From a practical point of view, any sampling fraction much over two-thirds of the lot size would lead one to inspect every item. T. Wright (1990) (**2**), who concluded that to attain 99 % confidence the sample size should be at least 99 % of the lot size, pointed out this result.

6.3 *Case 3 Examples and Illustrations:*

6.3.1 An extrusion process produces plastic tubing used in various engines to transfer coolant fluid. An inspector will look at 100 ft of the product for the presence of blemishes on the outer surface. The material will be released or accepted whenever X = 0 blemishes are observed. It is convenient to use the size of the sample as the base unit for the rate when the sampled amount is specified. In this illustration, this is the 100-ft length. At 98 % confidence, what is the upper confidence bound for the rate, λ, of blemish generation in 100 ft lengths of this tubing? Assuming no misclassification error, using Eq 7 we have:

$$\lambda \leq \lambda_u = -ln(1 - 0.98) = 3.9 \qquad (15)$$

6.3.1.1 A consumer may decide that a blemish rate of λ_0 = 1 is the largest tolerable rate for 100 foot lengths. What is the confidence demonstrated that $\lambda \leq \lambda_0 = 1$ when zero blemishes are observed in 100 foot lengths of tubing. Using Eq 9, and again assuming no misclassification errors, the answer is:

$$C_d = 1 - e^{-1} = 0.632 \qquad (16)$$

6.3.1.2 This confidence, approximately 63 %, is not acceptable to the consumer; however, when x = 0 blemishes is observed on the 100 foot sample, it is not possible to meet the requirement of λ_0 = 1 defect per 100 ft of product with a confidence of 98 %. To meet the requirement as stated we must specify a larger sample; that is, a longer tubing length. This is accomplished by remembering that the rate constant λ is proportional to the size of the sample. For our requirement, C = 0.98, and so -ln(1– 0.98) = 3.9. If the size of the new sample is denoted by s, then the proportion is:

$$\frac{3.9}{s\text{ ft}} = \frac{1}{100\text{ ft}} \rightarrow s = 390\text{ ft} \qquad (17)$$

6.3.1.3 One should then look at 390 ft of the product and find x = 0 blemishes. This would achieve the required confidence of C = 0.98 that $\lambda \leq \lambda_0$ = 1 blemish per hundred ft of tubing.

6.3.2 Consider a misclassification error rate of θ_2 = 20 % in failing to detect blemishes. Use Eq 8 and the upper bound becomes λ_u = –ln(1 – 0.98)/(1 – 0.2) = 4.89 blemishes per 100 ft of tubing length. To meet a requirement of λ_u = 1, we follow the same proportional argument as before, we solve:

$$\frac{4.89}{s\text{ ft}} = \frac{1}{100\text{ ft}} \rightarrow s = 489\text{ ft} \qquad (18)$$

6.3.2.1 One should look at 489 ft of the product and find x = 0 blemishes to satisfy the requirement. Note the increase in the size of the sample (390 to 490 ft) due to the presence of misclassification error.

6.3.3 Consider a shipment, of U.S. burley tobacco. A test portion of 200 g was assayed and no disease was found. To reflect the seriousness of the transmission event it is appropriate to set C = 0.99 and, using Eq 7, assuming no misclassification error, the upper bound for λ is λ_u = 4.6. The inference is that, although no disease was found in 200 g, the underlying rate may be as much as 4.6 viable spores per 200 g.

6.3.4 To further illustrate the proportionality between the size of the unit sampled and the average number of defects, λ, per unit, suppose a 300 ft length were inspected with x = 0 blemishes found. Assume no misclassification error. At a 90 % confidence level what is the upper confidence bound on the mean number of blemishes? For a unit defined as a 300 ft length λ_u = –ln(1 – 0.9) = 2.3 blemishes per 300 ft. We can use this result to find the mean number of blemishes for any arbitrary unit length. For a 1000 ft unit, λ_u = 2.3(1000/300) = 7.7 blemishes per 1000 ft of tubing. For a 250 ft unit λ_u = 2.3(250/300) = 1.9 blemishes per 250 ft of tubing.

6.3.5 We consider a process where the output is a discrete item but where a defined attribute may occur any number of times on any item. A sample of n items is selected and zero occurrences of the defined attribute is observed. We want to compute λ_u for this case. Suppose a paper company produces sheets of paper and is interested in the rate of blemishes that occurs in batches of 1000 sheets from the process. A sample of 500 sheets is inspected for the presence of blemishes and a zero response is reported. What is λ_u for batches of size 1000 sheets?

6.3.5.1 Assuming no misclassification error, and using a confidence level of 90 %, first compute the upper bound for the initial sample of 500 sheets using Eq 7. This is $\lambda \leq \lambda_u$ = –ln(1 – 0.9) = 2.3 blemishes per 500 sheets. For 1000 sheets, using the proportionality idea, we double this figure. Thus, for 1000 sheets of the paper, $\lambda \leq \lambda_u$ = 4.6 at 90 % confidence.

6.4 These illustrations clearly show the role of misclassification error. Two conclusions may be drawn. First, any procedure that rests on getting zero non-conforming items (or nonconformities) in a sequence of observations, such as those considered in this standard, cannot tolerate the error of calling a conforming item non-conforming (or mistakenly finding non-conformances where none exist). This error probability is θ_1. Any time a defect is recorded it should be checked and validated as genuine. Second, there should be some way to insure that the error of calling a non-conforming item conforming (or of missing non-conformances), θ_2, does not get out of hand, although a moderate error of this type, say $\theta_2 < 20$ %, is not too serious.

6.4.1 Inspectors should be properly trained, and, whenever possible, one should introduce genuine non-conformances at random places among the observations and verify that they are recorded as non-conforming. The inspectors would be advised of this "salting" and be on heightened alert. This would tend to keep θ_2 minimized. Under these two operating conditions it is reasonable to assume that if there is any misclassification error it will be of the kind where $\theta_1 = 0$ and $\theta_2 < 0.2$.

7. Comments Concerning Confidence and Upper Confidence Bounds

7.1 Whenever $x = 0$ events is observed, whether this be a process, a finite lot or a continuum, there are really a whole set of confidence coefficients and associated upper bounds that one could choose. To illustrate, suppose we find $x = 0$ events in a sample of $n = 50$ from a process whose unknown event probability is p. We might claim that $p \le 0.0273$ with 75 % confidence or $p \le 0.0450$ with 90 % confidence or $p \le 0.0582$ with 95 % confidence. This is graphically depicted in Fig. 1 where confidence, C, is plotted against the upper confidence bound, p_u, for the process case. Eq 1 was used for Fig. 1. This is:

$$p_u = 1 - (1 - C)^{\frac{1}{50}} \quad (19)$$

7.1.1 To see how the sample size affects the relationship between confidence and the upper bound consider Table 4. This shows the upper confidence bound as a function of selected sample sizes and confidence coefficients.

TABLE 4 Upper Confidence Bounds for the Process Event Probability *p*, at Selected Sample Sizes, *n*, and Confidence Coefficients, when *X* = 0 Events are Observed in the Sample; Case 1

	Confidence				
n	0.5	0.75	0.9	0.95	0.99
50	0.0138	0.0273	0.0450	0.0582	0.0880
100	0.0069	0.0138	0.0228	0.0295	0.0450
150	0.0046	0.0092	0.0152	0.0198	0.0302
200	0.0035	0.0069	0.0114	0.0149	0.0228
250	0.0028	0.0055	0.0092	0.0119	0.0183
300	0.0023	0.0046	0.0076	0.0099	0.0152
350	0.0020	0.0040	0.0066	0.0085	0.0131
400	0.0017	0.0035	0.0057	0.0075	0.0114
450	0.0015	0.0031	0.0051	0.0066	0.0102
500	0.0014	0.0028	0.0046	0.0060	0.0092

7.2 For a process continuum case, consider observing $x = 0$ events in a sample of 100 ft of plastic tubing. For the average number of events per 100 ft of tubing the conclusion could be, "Not more than 3 defects with a confidence of 95 %." It could also be, "Not more than 4.6 defects with 99 % confidence" or "Not more than 6.9 defects with confidence 99.9 %." Going the other way, "Not more than 0.7 defects with 50 % confidence" or "Not more than 2.3 defects with 90 % confidence." This is graphically depicted in Fig. 2 where confidence, C, is plotted against the upper confidence bound for the average event rate, λ_u, for the process continuum case. Relationship Eq 7 was used. This is:

$$\lambda_u = -ln(1 - C) \quad (20)$$

7.2.1 There is thus a natural trade-off between the confidence coefficient and the upper confidence bound. For a fixed sample size (or fixed portion of a continuum), if more confidence is desired one has to settle for a larger upper confidence bound; if it is desired to shrink the upper confidence bound, one shall have to settle for less confidence. In any case, all of the possible confidence/upper bound pair statements are part of the conclusion, so that a more complete inference would assert all of them. It has been suggested that a collection of C values such as {50 %, 90 %, 95 % and 99 %} be used as a standard. The four associated bounding values could be called "the standard boundary" or "confidence set" for a given sample size. Applying this to the examples in this section leads to the following "standard boundary."

Case 1 example: $n = 50$, process, $p \le p_u$

Confidence	50 %	90 %	95 %	99 %
Bound, p_u	0.0138	0.0450	0.0582	0.0880

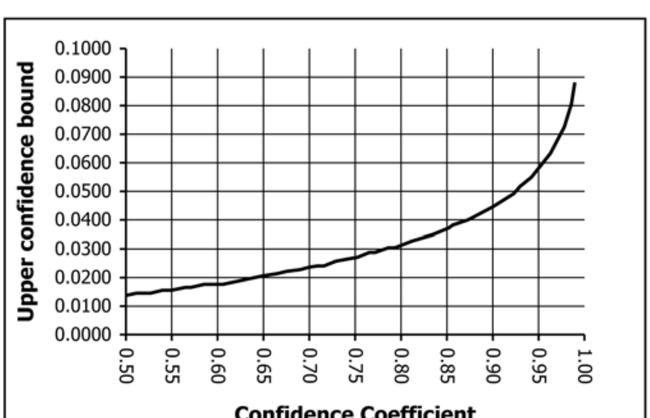

FIG. 1 Confidence Coefficient versus Upper Confidence Bound for a Process Event probability, *p*; Sample Size, *n* = 50; Case 1

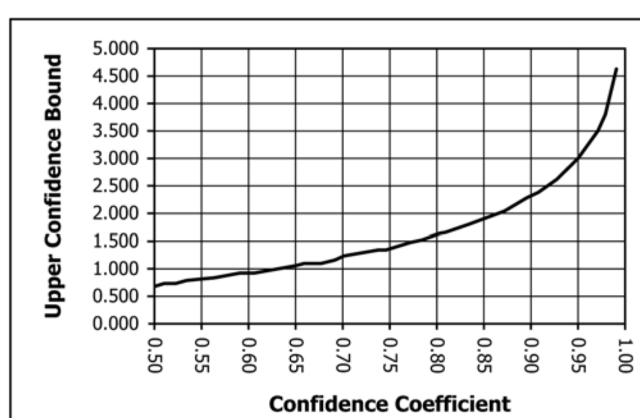

FIG. 2 Confidence Coefficient versus Upper Confidence Bound for the Average Number of Events, λ; Case 3 (Process Continuum)

Case 3 example: process continuum, $\lambda \leq \lambda_u$

Confidence	50 %	90 %	95 %	99 %
Bound, λ_u	0.693	2.30	3.00	4.61

7.2.2 Table 4 illustrates/compares how the "standard boundary" changes as a function of sample size for the process, Case 1 model. Of course in the continuum case, one has to bear in mind that the upper bound is proportional to the size of the sampled portion. Some users may prefer the simplicity of a single bound but they should be aware that the complete inference is, in fact, the whole boundary set with differing confidence levels along its extent. Often a customer will specify the confidence level requirement in advance. C = 90 % is common in the mechanical component industry; C = 95 % is common in many other quarters. Still, other industries/applications will require greater confidence.

7.3 It makes some sense that a higher confidence and a larger sample size should be expected for situations where there are grave consequences if even a very small chance exists of a non-zero response. Conversely, when a small sample size is being used then one should expect lower levels of confidence and a higher bound. In the majority of applications the user will have to assess the possible losses involved if some chance exists of a non-zero response and set the sample size in accordance with his/her tolerance for the probability of a non-zero response.

7.3.1 There may be, however, cases where a certain sample size is conventional and/or the user wishes to avoid the complexities of the "standard boundary." In such cases, the user may use the so-called "assurance" inference. See Ref (3). An assurance of A means that there is a confidence A that the upper confidence bound is no more than $1 - A$. For example, for a process quality scenario, with a sample of n = 250, an assurance of 98.37 % may be reached. This means that the confidence coefficient is C = 98.37 % and the upper bound is p_u = 0.0163. For a sample of n = 1000, an assurance of 99.48 % may be reached. In this case the achieved confidence coefficient is C = 99.48 % and the upper bound is p_u = 0.00524. For a given sample size, the assurance achieved is fixed. Table 5 shows the sample size required to achieve a specified assurance where x = 0 events is expected.

7.3.2 In working with the assurance concept, the following equations may be used. Eq 21 is an algebraic variant of the definition of assurance as the point at which $p_u = 1 - C$. Eq 22 is Eq 21 solved for n.

$$A^n + A - 1 = 0 \qquad (21)$$

$$n = \frac{ln(1 - A)}{ln(A)} \qquad (22)$$

7.3.3 For a given sample size, n, the solution to Eq 21 is the achieved assurance. For a sample size requirement to achieve a desired assurance use Eq 22 to solve for the required n. For example, what assurance can be claimed for a sample of n = 640? Eq 21 is solved iteratively for A. The answer: A = 99.24 %. If the desire is to state an assurance of A = 99.73 %, the sample size required, using Eq 22, is n = 2188.

8. Keywords

8.1 attribute; confidence coefficient; defect; defective; non-conforming item; non-conformity; zero response

TABLE 5 Sample Size (*n*) for Achieving an Assurance (*A*%)

A	p_u	n
99.99	0.0001	92099
99.9	0.0010	6904
99.5	0.0050	1057
99	0.0100	458
97	0.0300	115
95	0.0500	58
93	0.0700	37
90	0.1000	22

APPENDIX

(Nonmandatory Information)

X1. MATHEMATICAL MATERIAL

X1.1 The Binomial Distribution

$$f(x) = \binom{n}{x} p^x (1 - p)^{n-x},\ x = 0,1,2,3,\ \ldots n \qquad (X1.1)$$

X1.1.1 For the binomial, n is the sample size, p is a fixed "success" probability and x is the number of observed successes among a sample of n trials. The probability function $f(x)$ is the probability of observing exactly x successes in a sample of n. In the context of this standard p may be taken as the unknown fraction nonconforming that a process is generating and a "success" is defined as a non-conforming item. $f(x)$ is the probability that a sample of n items contains exactly x non-conforming items. When $x = 0$ is observed, we say that the sample exhibited a "zero-response" or "all_zeros." The probability P(all_zeros) is the same thing as $f(0)$. For the binomial this is:

$$P(all\_zeros) = f(0) = (1 - p)^n \qquad (X1.2)$$

X1.1.2 When p is known we can calculate $f(0)$ directly from Eq X1.2. When p is unknown, we may ask for the largest p that would make $f(0)$ small, yet still reasonably probable. To find such a p, set $f(0)$ equal to some probability, say $1 - C$, and solve the equation $f(0) = 1 - C$ for p. Let p_u be the value of p so obtained. Then p_u is called the upper confidence bound at confidence level C. This result is Eq 1.

X1.1.3 Two types of measurement or inspection errors can be introduced into Eq X1.2. Let θ_1 be the probability of reporting a non-conforming item, when the item is really conforming; Let θ_2 be the probability of reporting a conforming item when the item is really non-conforming. An expression for P(all_zeros) that incorporates these misclassification errors may be derived. This is:

$$P(all\_zeros) = f(0) = ((1 - \theta_1)(1 - p) + \theta_2 p)^n \quad (X1.3)$$

X1.1.4 In Eq X1.3 the quantity $(1 - \theta_1)(1 - p)$ is the probability of the event: "the item is actually conforming and it is classified as conforming." The quantity $p\theta_2$ is the probability of the event: "the item is actually non-conforming and it is classified as conforming." These two events are mutually exclusive; the sum of their probability is the probability of classifying an item as conforming, whether actually conforming or not. Eq X1.3 is used in the same manner as Eq X1.2. To find the upper confidence bound, p_u, set Eq X1.3 equal to 1 − *C* and solve for *p*. This is Eq 2.

X1.2 The Hypergeometric Distribution

$$f(x) = \frac{\binom{D}{x}\binom{N-D}{n-x}}{\binom{N}{n}}, x = 0,1, \ldots \min(n,D) \quad (X1.4)$$

X1.2.1 For the hypergeometric, there is a lot of *N* items containing an unknown number, *D*, of non-conforming items. A sample of *n* items is selected from the lot without replacement and *x*, the number of non-conforming items is observed. The probability function *f*(*x*) is the probability of exactly *x* non-conforming items in the sample of *n*. Note that *x* can never be more than n nor larger than *D*. When *x* = 0 is observed, we say that the sample exhibited a "zero-response" or "all_zeros." Here again, *P*(all_zeros) = *f*(0). Substituting *x* = 0 in Eq X1.4 and simplifying algebraically gives the following for *f*(0).

$$P(all\_zeros) = f(0) = \prod_{i=0}^{n-1}\left(1 - \frac{D}{N-i}\right) \quad (X1.5)$$

X1.2.2 For known *D* Eq X1.5 gives the probability of the zero response result. When *D* is unknown, set *f*(0) = 1 − *C*, for confidence level *C*, and solve iteratively for *D*. This is Eq 5. This is essentially a search for the largest *D* just satisfying *f*(0) = 1 − *C*. Such a value, D_u, is called the upper confidence bound for *D* the number of non-conforming items in the lot.

X1.2.3 Where misclassification errors are concerned the reader is directed to Ref (**4**).

X1.3 The Poisson Distribution

$$f(x) = \frac{e^{-\lambda}\lambda^x}{x!}, x = 0,1,2,3, \ldots \quad (X1.6)$$

X1.3.1 For the Poisson distribution, the only parameter is λ, the mean number of non-conformities over an interval (time, space, volume, area etc.). The parameter λ is proportional to the size of the interval so long as there is good physical reason to justify the Poisson model over larger (or smaller) intervals. The incorporation of the misclassification error parameter θ_2, the probability of missing a nonconformity, may be accomplished in the usual way by taking the limit of a binomial distribution with parameters *n* and *p*, as *n* increases and *p* decreases while λ = *np* remains constant.

X1.3.2 For the misclassification error case, the value of *p* is changed to $p(1 - \theta_2)$. We can use Eq X1.6 and set $\lambda = np(1 - \theta_2)$. As *n* increases and *p* decreases and λ = *np* remains constant. When *x* = 0 non-conformities is observed the result is:

$$P(all\_zeros) = f(0) = e^{-\lambda(1-\theta_2)} \quad (X1.7)$$

X1.3.3 When *f*(0) = 1 − *C*, for confidence *C*, upon solving for λ, we obtain the upper confidence bound λ_u of Eq 8.

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