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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—Eq 4 was corrected editorially in May 2007.

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]

E 141 Practice for Acceptance of Evidence Based on the Results of Probability Sampling

E 456 Terminology Relating to Quality and Statistics

E 1402 Terminology Relating to Sampling

E 1994 Practice for Use of Process Oriented AOQL and LTPD Sampling Plans

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 E 1402 or E 456.

3. Terminology

3.1 *Definitions:*

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. **E 456**

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

3.1.3 *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**

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

3.1.5 *confidence limit*, *n*—each of the limits, T_1 and T_2, of the two sided confidence interval, or the limit *T* of the one sided confidence interval. **ISO 3534-1**

3.1.6 *one sided confidence interval*, *n*—when *T* is a function of the observed values such that, θ being a population parameter to be estimated, the probability $P\ (T \geq \theta)$ or the probability $P\ (T \leq \theta)$ is at least equal to *C* where *C* is a fixed positive number less than 1. The interval from the smallest value of θ up to *T* or the interval from *T* to the largest possible value of θ is a one sided, *C*, confidence interval for θ. **ISO 3534-1**

[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 Data Analysis.
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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 teh standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute, 11 W. 42nd Street, 13th Floor, New York, NY 10036.

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

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

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 *population*, *n*—the totality of items or units of material under consideration. **E 456**

3.1.10 *sample*, *n*—a group of items, observations or test results, or portion of material taken from a large collection of items or quantity of material, which serves to provide information that may be used as a basis for making a decision concerning the larger collection or quantity. **E 456**

3.1.11 *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. **E 1402**

3.1.12 *item*, *n*—an object or quantity of material on which a set of observations can be made. **E 456**

3.1.12.1 *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 E 141).

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.

Symbols:

A = the assurance index
C = confidence coefficient as a percent or as a probability value
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
D = the number of non-conforming items in a finite population containing N items
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
D_u = the upper confidence bound for the parameter D
N = the number of items in a finite population
n = the sample size, that is, the number of items in a sample
n_R = the sample size required
p = a process fraction non-conforming
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
p_u = the upper confidence bound for the parameter p
λ = the mean number of non-conformities (or events) over some area of interest for a Poisson process
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
λ_u = the upper confidence bound for the parameter λ
θ_1 = the probability of classifying a conforming item as non-conforming; or of finding a nonconformity where none exists
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 E 1994.

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:

$$p_u = 1 - \sqrt[n]{1 - C} \tag{1}$$

5.3.1.1 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:

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

5.3.1.2 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:

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

5.3.1.3 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:

$$C_d = 1 - ((1 - p_0)(1 - \theta_1) + p_0\theta_2)^n \tag{4}$$

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.

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

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.

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

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 $D \leq D_0$, 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:

$$\lambda_u = -ln(1 - C) \tag{7}$$

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:

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

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:

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

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:

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

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 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:

$$p_u = 1 - \sqrt[4]{1 - 0.9} = 0.00574 \tag{11}$$

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:

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

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:

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

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 θ_1 = 0.1 and θ_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:

$$\theta_1 < 1 - \sqrt[n]{1 - C} \tag{14}$$

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 θ_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 θ_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 θ_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

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