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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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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 practice, but only when misclassification rates are well understood or known and can be approximated numerically.

1.3 The values stated in inch-pound units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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 practice should meet the requirements (or approximately so) of a probability sample as defined in Guide E1402 or Terminology 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

[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 the standard'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.

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 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 practice, "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 practice, 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 practice, 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, and consumer quality level are not used in this practice. 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 practice 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 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 100*C* %. 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:

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

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:

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

5.3.1.4 To find the confidence demonstrated (C_d) in the claim that an unknown fraction non-conforming *p* is no more