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Statistical interpretation of data —

Part 6:
Determination of statistical tolerance intervals

Interprétation statistique des données —

Partie 6: Détermination des intervalles statistiques de dispersion

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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The committee responsible for this document is ISO/TC 69, *Applications of statistical methods*.

This second edition cancels and replaces the first edition (ISO 16269:2005), which has been technically revised.

ISO 16269 consists of the following parts, under the general title *Statistical interpretation of data*:

— *Part 4: Detection and treatment of outliers*

— *Part 6: Determination of statistical tolerance intervals*

— *Part 7: Median — Estimation and confidence intervals*

— *Part 8: Determination of prediction intervals*

Introduction

A statistical tolerance interval is an estimated interval, based on a sample, which can be asserted with confidence level $1 - \alpha$, for example 0,95, to contain at least a specified proportion p of the items in the population. The limits of a statistical tolerance interval are called statistical tolerance limits. The confidence level $1 - \alpha$ is the probability that a statistical tolerance interval constructed in the prescribed manner will contain at least a proportion p of the population. Conversely, the probability that this interval will contain less than the proportion p of the population is α. This part of ISO 16269 describes both one-sided and two-sided statistical tolerance intervals; a one-sided interval is constructed with an upper or a lower limit while a two-sided interval is constructed with both an upper and a lower limit.

A statistical tolerance interval depends on a confidence level $1 - \alpha$ and a stated proportion p of the population. The confidence level of a statistical tolerance interval is well understood from a confidence interval for a parameter. The confidence statement of a confidence interval is that the confidence interval contains the true value of the parameter a proportion $1 - \alpha$ of the cases in a long series of repeated random samples under identical conditions. Similarly the confidence statement of a statistical tolerance interval states that at least a proportion p of the population is contained in the interval in a proportion $1 - \alpha$ of the cases of a long series of repeated random samples under identical conditions. So if we think of the stated proportion of p of the population as a parameter, the idea behind statistical tolerance intervals is similar to the idea behind confidence intervals.

Statistical tolerance intervals are functions of the observations of the sample, i.e. statistics, and they will generally take different values for different samples. It is necessary that the observations be independent for the procedures provided in this part of ISO 16269 to be valid.

Two types of statistical tolerance interval are provided in this part of ISO 16269, parametric and distribution-free. The parametric approach is based on the assumption that the characteristic being studied in the population has a normal distribution; hence the confidence that the calculated statistical tolerance interval contains at least a proportion p of the population can only be taken to be $1 - \alpha$ if the normality assumption is true. For normally distributed characteristics, the statistical tolerance interval is determined using one of the Forms A, B, or C given in Annex B.

Parametric methods for distributions other than the normal are not considered in this part of ISO 16269. If departure from normality is suspected in the population, distribution-free statistical tolerance intervals may be constructed. The procedure for the determination of a statistical tolerance interval for any continuous distribution is provided in Form D of Annex B.

The statistical tolerance limits discussed in this part of ISO 16269 can be used to compare the natural capability of a process with one or two given specification limits, either an upper one U or a lower one L or both in statistical process management.

Above the upper specification limit U there is the upper fraction nonconforming p_U (ISO 3534-2:2006, 2.5.4) and below the lower specification limit L there is the lower fraction nonconforming p_L (ISO 3534-2:2006, 2.5.5). The sum $p_U + p_L = p_\text{t}$ is called the total fraction nonconforming. (ISO 3534-2:2006, 2.5.6). Between the specification limits U and L there is the fraction conforming $1 - p_\text{t}$.

The ideas behind statistical tolerance intervals are more widespread than is usually appreciated, for example in acceptance sampling by variables and in statistical process management, as will be pointed out in the next two paragraphs.

In acceptance sampling by variables, the limits U and/or L will be known, p_U , p_L or p_t will be specified as an acceptable quality limit (AQL), α will be implied and the lot is accepted if there is at least an implicit $100(1-\alpha)\%$ confidence that the AQL is not exceeded.

In statistical process management the limits U and L are fixed in advance and the fractions p_U, p_L and p_t are either calculated, if the distribution is assumed to be known, or otherwise estimated. This is an example of a quality control application, but there are many other applications of statistical tolerance intervals given in textbooks such as Hahn and Meeker.[13]

In contrast, for the statistical tolerance intervals considered in this part of ISO 16269, the confidence level for the interval estimator and the proportion of the distribution within the interval (corresponding to the fraction conforming mentioned above) are fixed in advance, and the limits are estimated. These limits may be compared with *U* and *L*. Hence the appropriateness of the given specification limits *U* and *L* can be compared with the actual properties of the process. The one-sided statistical tolerance intervals are used when only either the upper specification limit *U* or the lower specification limit *L* is relevant, while the two-sided intervals are used when both the upper and the lower specification limits are considered simultaneously.

The terminology with regard to these different limits and intervals has been confusing, as the “specification limits” were earlier also called “tolerance limits” (see the terminology standard ISO 3534-2:1993, 1.4.3, where both these terms as well as the term “limiting values” were all used as synonyms for this concept). In the latest revision of ISO 3534-2:2006, 3.1.3, only the term specification limits have been kept for this concept. Furthermore, the *Guide for the expression of uncertainty in measurement* [5] uses the term “coverage factor” defined as a “numerical factor used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty”. This use of “coverage” differs from the use of the term in this part of ISO 16269.

The first edition of this standard gave extensive tables of the factor *k* for one-sided and two-sided tolerance intervals when the mean is unknown but the standard deviation is known. In this second edition of the standard those tables are omitted. Instead, exact k-factors are given in Annex A when one of the parameters of the normal distribution is unknown and the other parameter is known.

The first edition of this standard considered statistical tolerance intervals based only on a single sample of size *n*. This edition considers statistical tolerance intervals for *m* populations with the same standard deviation, based on samples from each of the *m* populations, each sample being of the same size *n*.