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Statistical interpretation of data - Part 6: Determination of statistical tolerance intervals

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Interprétation statistique des données - Partie 6: Détermination des intervalles statistiques de dispersion

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2014-01-15

**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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Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms, definitions and symbols.....	1
3.1 Terms and definitions.....	1
3.2 Symbols.....	2
4 Procedures.....	3
4.1 Normal population with known mean and known variance.....	3
4.2 Normal population with unknown mean and known variance.....	3
4.3 Normal population with unknown mean and unknown variance.....	4
4.4 Normal populations with unknown means and unknown common variance.....	4
4.5 Any continuous distribution of unknown type.....	4
5 Examples.....	4
5.1 Data for Examples 1 and 2.....	4
5.2 Example 1: One-sided statistical tolerance interval with unknown variance and unknown mean.....	5
5.3 Example 2: Two-sided statistical tolerance interval under unknown mean and unknown variance.....	6
5.4 Data for Examples 3 and 4.....	6
5.5 Example 3: One-sided statistical tolerance intervals for separate populations with unknown common variance.....	7
5.6 Example 4: Two-sided statistical tolerance intervals for separate populations with unknown common variance.....	8
5.7 Example 5: Any distribution of unknown type.....	10
Annex A (informative) Exact k-factors for statistical tolerance intervals for the normal distribution.....	12
Annex B (informative) Forms for statistical tolerance intervals.....	17
Annex C (normative) One-sided statistical tolerance limit factors, $k_C(n; p; 1-\alpha)$, for unknown σ.....	21
Annex D (normative) Two-sided statistical tolerance limit factors, $k_D(n; m; p; 1-\alpha)$, for unknown common σ (m samples).....	26
Annex E (normative) Distribution-free statistical tolerance intervals.....	40
Annex F (informative) Computation of factors for two-sided parametric statistical tolerance intervals.....	42
Annex G (informative) Construction of a distribution-free statistical tolerance interval for any type of distribution.....	44
Bibliography.....	46

ISO 16269-6:2014(E)

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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.

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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 $p_U + p_L = p_t$ 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 $1 - p_t$.

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]

ISO 16269-6:2014(E)

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 .

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Statistical interpretation of data —

Part 6:

Determination of statistical tolerance intervals

1 Scope

This part of ISO 16269 describes procedures for establishing statistical tolerance intervals that include at least a specified proportion of the population with a specified confidence level. Both one-sided and two-sided statistical tolerance intervals are provided, a one-sided interval having either an upper or a lower limit while a two-sided interval has both upper and lower limits. Two methods are provided, a parametric method for the case where the characteristic being studied has a normal distribution and a distribution-free method for the case where nothing is known about the distribution except that it is continuous. There is also a procedure for the establishment of two-sided statistical tolerance intervals for more than one normal sample with common unknown variance.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3534-1:2006, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

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ISO 3534-2:2006, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

3 Terms, definitions and symbols

For the purposes of this document, the terms and definition given in ISO 3534-1, ISO 3534-2 and the following apply.

3.1 Terms and definitions

3.1.1

statistical tolerance interval

interval determined from a random sample in such a way that one may have a specified level of confidence that the interval covers at least a specified proportion of the sampled population

[SOURCE: ISO 3534-1:2006, 1.26]

Note 1 to entry: The confidence level in this context is the long-run proportion of intervals constructed in this manner that will include at least the specified proportion of the sampled population.

3.1.2

statistical tolerance limit

statistic representing an end point of a statistical tolerance interval

[SOURCE: ISO 3534-1:2006, 1.27]

Note 1 to entry: Statistical tolerance intervals may be either

- one-sided (with one of its limits fixed at the natural boundary of the random variable), in which case they have either an upper or a lower statistical tolerance limit, or

ISO 16269-6:2014(E)

— two-sided, in which case they have both.

3.1.3

coverage

proportion of items in a population lying within a statistical tolerance interval

Note 1 to entry: This concept is not to be confused with the concept *coverage factor* used in the *Guide for the expression of uncertainty in measurement (GUM)* [5].

3.1.4

normal population

normally distributed population

3.2 Symbols

For the purposes of this part of ISO 16269, the following symbols apply.

$k_1(n; p; 1 - \alpha)$	factor used to determine the limits of one-sided intervals i.e. x_L or x_U when μ is known and σ is unknown
$k_2(n; p; 1 - \alpha)$	factor used to determine the limits of two-sided intervals i.e. x_L and x_U when μ is known and σ is unknown
$k_3(n; p; 1 - \alpha)$	factor used to determine the limits of one-sided intervals i.e. x_L or x_U when μ is unknown and σ is known
$k_4(n; p; 1 - \alpha)$	factor used to determine the limits of two-sided intervals i.e. x_L and x_U when μ is unknown and σ is unknown
$k_C(n; p; 1 - \alpha)$	factor used to determine x_L or x_U when the values of μ and σ are unknown for one-sided statistical tolerance interval. The suffix C is chosen because this k-factor is tabulated in Annex C .
$k_D(n; m; p; 1 - \alpha)$	factor used to determine x_{Li} and x_{Ui} ($i = 1, 2, \dots, m; m \geq 2$) when the values of the means μ_i and the value of the common σ are unknown for the m two-sided statistical tolerance intervals. The suffix D is chosen because this k-factor is tabulated in Annex D .
n	number of observations in the sample
p	minimum proportion of the population asserted to be lying in the statistical tolerance interval
u_p	p -fractile of the standardized normal distribution
x_j	j th observed value ..
x_{ij}	j th observed value ($j = 1, 2, \dots, n$) of i th sample ($i = 1, 2, \dots, m$)
x_{\max}	maximum value of the observed values: $x_{\max} = \max \{x_1, x_2, \dots, x_n\}$
x_{\min}	minimum value of the observed values: $x_{\min} = \min \{x_1, x_2, \dots, x_n\}$
x_L	lower limit of the statistical tolerance interval
x_U	upper limit of the statistical tolerance interval
\bar{x}	sample mean, $\bar{x} = \frac{1}{n} \sum_{j=1}^n x_j$

\bar{x}_i	sample mean of i th sample, ($i = 1, 2, \dots, m$), $\bar{x}_i = \frac{1}{n} \sum_{j=1}^n x_{ij}$
s	sample standard deviation, $s = \sqrt{\frac{1}{n-1} \sum_{j=1}^n (x_j - \bar{x})^2} = \sqrt{\frac{n \sum_{j=1}^n x_j^2 - \left(\sum_{j=1}^n x_j \right)^2}{n(n-1)}}$
s_i	sample standard deviation of i th sample, ($i = 1, 2, \dots, m$), $s_i = \sqrt{\frac{1}{(n-1)} \sum_{j=1}^n (x_{ij} - \bar{x}_i)^2}$
s_p	pooled sample standard deviation, $s_p = \sqrt{\frac{1}{m(n-1)} \sum_{i=1}^m \sum_{j=1}^n (x_{ij} - \bar{x}_i)^2} = \sqrt{\frac{1}{m} \sum_{i=1}^m s_i^2}$
$1 - \alpha$	confidence level for the assertion that the proportion of the population lying within the tolerance interval is greater than or equal to the specified level p
μ	population mean
μ_i	population mean of the i th population ($i = 1, 2, \dots, m$)
σ	population standard deviation

4 Procedures <https://standards.iteh.ai/catalog/standards/sist/b53262ab-6a1e-452f-bf3a-757a5bcc1ae5/sist-iso-16269-6-2015>

4.1 Normal population with known mean and known variance

When the values of the mean, μ , and the variance, σ^2 , of a normally distributed population are known, the distribution of the characteristic under investigation is fully determined. There is exactly a proportion p of the population:

- to the right of $x_L = \mu - \mu_p \times \sigma$ (one-sided interval);
- to the left of $x_U = \mu + \mu_p \times \sigma$ (one-sided interval);
- between $x_L = \mu - \mu_{(1+p)/2} \times \sigma$ and $x_U = \mu + \mu_{(1+p)/2} \times \sigma$ (two-sided interval).

In the above equations, μ_p is the p -fractile of the standardized normal distribution.

NOTE As such statements are known to be true, they are made with 100 % confidence.

4.2 Normal population with unknown mean and known variance

When one or both parameters of the normal distribution are unknown but estimated from a random sample, intervals with similar properties to the ones in 4.1 can still be constructed. Suppose for example that the mean is unknown but the variance is known. Then a constant k can be found such that the interval between

$$x_L = \bar{x} - k\sigma \text{ and } x_U = \bar{x} + k\sigma$$

contains *at least* a proportion p of the population with a specified confidence of $1 - \alpha$. Note two important distinctions from the situation in 4.1 where the parameters were assumed known. First, when one or more parameters are estimated the interval contains *at least* a proportion p of the population, not exactly

ISO 16269-6:2014(E)

a proportion p of the population. Secondly, when parameters are estimated, the statement is only true with a pre-specified confidence of $1-\alpha$. The factor k in the expression of the limits above depends on the unknown parameters of the normal distribution, on the proportion p , on the confidence coefficient $1-\alpha$, and on the number of observations in the random sample. 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.

4.3 Normal population with unknown mean and unknown variance

Forms A and B, given in [Annex B](#), are applicable to the case where both the mean and the variance of the normal population are unknown. Form A applies to the one-sided case, while Form B applies to the two-sided case. Form A is used with the tables of k -factors in [Annex C](#), or alternatively using the exact formula for the k -factor given in [clause A.5](#) in [Annex A](#). Form B is used with the k -factors given in the first column of the tables of [Annex D](#). Details about the derivation of the k -factors of [Annex D](#) are given in [Annex E](#).

4.4 Normal populations with unknown means and unknown common variance

Form C, given in [Annex B](#), is applicable to the case where both the means and the variances of the normal populations are unknown. Furthermore, the variances are assumed to be identical for all populations under consideration, in which case we talk of the common variance.

4.5 Any continuous distribution of unknown type

If the characteristic under investigation is a variable from a population of unknown form, then a statistical tolerance interval can be determined from the sample order statistics $x_{(i)}$ of a sample of n independent random observations. The procedure given in Form D used in conjunction with Tables E.1 and E.2 provides the steps for the determination of the required sample size based on the order statistics to be used, the desired confidence level, and the desired content.

NOTE 1 Statistical tolerance intervals where the choice of end points (based on order statistics) does not depend on the sampled population are called *distribution-free* statistical tolerance intervals.

NOTE 2 This International Standard does not provide procedures for distributions of known type other than the normal distribution. However, if the distribution is continuous, the distribution-free method may be used. Selected references to scientific literature that may assist in determining tolerance intervals for other distributions are also provided at the end of this document.

5 Examples

5.1 Data for Examples 1 and 2

Forms A to B, given in [Annex B](#), are illustrated by Examples 1 and 2 using the numerical values of ISO 2854:1976 [2], [Clause 2](#), paragraph 1 of the introductory remarks, Table X, yarn 2: 12 measures of the breaking load of cotton yarn. It should be noted that the number of observations, $n = 12$, given here for these examples is considerably lower than the one recommended in ISO 2602 [4]. The numerical data and calculations in the different examples are expressed in centinewtons (see [Table 1](#)).

Table 1 — Data for Examples 1 and 2

Values in centinewtons

x	228,6	232,7	238,8	317,2	315,8	275,1	222,2	236,7	224,7	251,2	210,4	270,7
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These measurements were obtained from a batch of 12000 bobbins, from one production job, packed in 120 boxes each containing 100 bobbins. Twelve boxes have been drawn at random from the batch and a bobbin has been drawn at random from each of these boxes. Test pieces of 50 cm length have been

cut from the yarn on these bobbins, at about 5 m distance from the free end. The tests themselves have been carried out on the central parts of these test pieces. Previous information makes it reasonable to assume that the breaking loads measured in these conditions have virtually a normal distribution. It is demonstrated in ISO 2854; 1976 that the data do not contradict the assumption of a normal distribution.

By using the box plot graphical test of outliers given in ISO 16269-4, one can also conclude that none of the data values can be declared as outlier with significance level $\alpha = 0,05$.

The data in [Table 1](#) give the following results:

Sample size: $n = 12$

Sample mean: $\bar{x} = \frac{1}{n} \sum_{j=1}^n x_j = 3\,024,1/12 = 252,01$

Sample standard deviation: $s = \sqrt{\frac{n \sum_{j=1}^n x_j^2 - \left(\sum_{j=1}^n x_j \right)^2}{n(n-1)}} = \sqrt{\frac{166\,772,27}{12 \times 11}} = \sqrt{1\,263,4263} = 35,545$

The formal presentation of the calculations will be given in Example 1 using Form A in [Annex B](#) (one-sided interval, unknown variance and unknown mean).

5.2 Example 1: One-sided statistical tolerance interval with unknown variance and unknown mean

A limit x_L is required such that it is possible to assert with confidence level $1 - \alpha = 0,95$ (95 %) that at least 0,95 (95 %) of the breaking loads of the items in the batch, when measured under the same conditions, are above x_L . The presentation of the results is given in detail below.

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Determination of the statistical tolerance interval of proportion p :

a) one-sided interval "to the right"

Determined values:

b) proportion of the population selected for the statistical tolerance interval: $p = 0,95$

c) chosen confidence level: $1 - \alpha = 0,95$

d) sample size: $n = 12$

Value of tolerance factor from [Table C.2](#): $k_C(n; p; 1 - \alpha) = 2,736\,4$

ISO 16269-6:2014(E)

Calculations:

$$\bar{x} = \frac{1}{n} \sum_{j=1}^n x_j = 252,01$$

$$s = \sqrt{\frac{n \sum_{j=1}^n x_j^2 - \left(\sum_{j=1}^n x_j \right)^2}{n(n-1)}} = 35,545$$

$$k_C(n; p; 1 - \alpha) \times s = 97,2653$$

Results: one-sided interval “to the right”

The tolerance interval which will contain at least a proportion p of the population with confidence level $1 - \alpha$ has a lower limit:

$$x_L = \bar{x} - k_C(n; p; 1 - \alpha) \times s = 154,7$$

5.3 Example 2: Two-sided statistical tolerance interval under unknown mean and unknown variance

Suppose it is required to calculate the limits x_L and x_U such that it is possible to assert with a confidence level $1 - \alpha = 0,95$ that in a proportion of the batch at least equal to $p = 0,90$ (90 %) the breaking load falls between x_L and x_U .

The column with $m = 1$ and the row with $n = 12$ in [Table D.4](#) gives

$$k_D(n; 1; p; 1 - \alpha) = 2,6703$$

whence

$$x_L = \bar{x} - k_D(n; 1; p; 1 - \alpha) \times s = 252,01 - 2,6703 \times 35,545 = 157,0$$

$$x_U = \bar{x} + k_D(n; 1; p; 1 - \alpha) \times s = 252,01 + 2,6703 \times 35,545 = 347,0$$

5.4 Data for Examples 3 and 4

Suppose the percentage of solids in each of four batches of wet brewer's yeast, each from a different supplier, is to be determined. The percentages of the four batches are normally distributed with unknown means μ_i $i = 1, 2, 3, 4$. From previous experience of these suppliers, it may be assumed that the variances are the same. A test for the following data gives no reason to suppose otherwise. The data are therefore assumed to have a common variance σ^2 . The researcher wants to determine two-sided statistical tolerance intervals for the percentages of solids in each batch.

The values of random samples of size $n = 10$ from four batches [14] are given in [Table 2](#):

Table 2 — Data for Examples 3 and 4

Values in percent

<i>i</i>	<i>j</i>									
	1	2	3	4	5	6	7	8	9	10
1	20	18	16	21	19	17	20	16	19	18
2	19	14	17	13	10	16	14	12	15	11
3	11	12	14	10	8	10	13	9	12	8
4	10	7	11	9	6	11	8	12	13	14

Notice that the *j*th value of the *i*th sample is denoted: x_{ij} .

These results yield the following:

Sample size: $n = 10$

Number of samples: $m = 4$

Sample means of each of the four batches:

$$\bar{x}_1 = 184/10 = 18,4; \quad \bar{x}_2 = 141/10 = 14,1; \quad \bar{x}_3 = 107/10 = 10,7; \quad \bar{x}_4 = 101/10 = 10,1$$

Sample variances of each of the four batches:

$$s_1^2 = \frac{n \sum_{j=1}^n x_{1j}^2 - \left(\sum_{j=1}^n x_{1j} \right)^2}{n(n-1)} = \frac{264}{10 \times 9} = 2,9333; \quad s_2^2 = \frac{n \sum_{j=1}^n x_{2j}^2 - \left(\sum_{j=1}^n x_{2j} \right)^2}{n(n-1)} = \frac{689}{10 \times 9} = 7,6556$$

$$s_3^2 = \frac{n \sum_{j=1}^n x_{3j}^2 - \left(\sum_{j=1}^n x_{3j} \right)^2}{n(n-1)} = \frac{381}{10 \times 9} = 4,2333; \quad s_4^2 = \frac{n \sum_{j=1}^n x_{4j}^2 - \left(\sum_{j=1}^n x_{4j} \right)^2}{n(n-1)} = \frac{609}{10 \times 9} = 6,7667$$

Pooled sample standard deviation:

$$s_p = \sqrt{\frac{1}{m} \sum_{i=1}^m s_i^2} = \sqrt{\frac{1}{4} (2,9333 + 7,6556 + 4,2333 + 6,7667)} = 2,3232$$

Degrees of freedom of the pooled standard deviation:

$$f = m(n - 1) = nm - m = 36$$

5.5 Example 3: One-sided statistical tolerance intervals for separate populations with unknown common variance

Suppose it is desired to calculate lower statistical tolerance intervals for the four suppliers, i.e. it is desired to calculate intervals that contain at least a proportion p for all suppliers. Table C cannot provide