



SLOVENSKI STANDARD SIST ISO 5725-2:2003

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Accuracy (trueness and precision) of measurement methods and results -- Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method

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Exactitude (justesse et fidélité) des résultats et méthodes de mesure -- Partie 2: Méthode de base pour la détermination de la répétabilité et de la reproductibilité d'une méthode de mesure normalisée

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Ta slovenski standard je istoveten z: **ISO 5725-2:1994**

ICS:

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17.020	Meroslovje in merjenje na splošno	Metrology and measurement in general

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INTERNATIONAL STANDARD

ISO 5725-2

First edition
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Accuracy (trueness and precision) of measurement methods and results —

Part 2:

Basic method for the determination of
repeatability and reproducibility of a standard
measurement method

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Partie 2: Méthode de base pour la détermination de la répétabilité et de la reproductibilité d'une méthode de mesure normalisée



Reference number
ISO 5725-2:1994(E)

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5725-2 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

ISO 5725 consists of the following parts under the general title *Accuracy (trueness and precision) of measurement methods and results*:

- Part 1: *General principles and definitions*
- Part 2: *Basic method for the determination of repeatability and reproducibility of a standard measurement method*
- Part 3: *Intermediate measures of the precision of a standard measurement method*
- Part 4: *Basic methods for the determination of the trueness of a standard measurement method*
- Part 5: *Alternative methods for the determination of the precision of a standard measurement method*
- Part 6: *Use in practice of accuracy values*

Parts 1 to 6 of ISO 5725 together cancel and replace ISO 5725:1986, which has been extended to cover trueness (in addition to precision) and intermediate precision conditions (in addition to repeatability and reproducibility conditions).

Annex A forms an integral part of this part of ISO 5725. Annexes B and C are for information only.

Introduction

0.1 ISO 5725 uses two terms “trueness” and “precision” to describe the accuracy of a measurement method. “Trueness” refers to the closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted reference value. “Precision” refers to the closeness of agreement between test results.

0.2 General consideration of these quantities is given in ISO 5725-1 and so is not repeated in this part of ISO 5725. ISO 5725-1 should be read in conjunction with all other parts of ISO 5725, including this part, because it gives the underlying definitions and general principles.

0.3 This part of ISO 5725 is concerned solely with estimating by means of the repeatability standard deviation and reproducibility standard deviation. Although other types of experiment (such as the split-level experiment) are used in certain circumstances for the estimation of precision, they are not dealt with in this part of ISO 5725 but rather are the subject of ISO 5725-5. Nor does this part of ISO 5725 consider any other measures of precision intermediate between the two principal measures; those are the subject of ISO 5725-3.

0.4 In certain circumstances, the data obtained from an experiment carried out to estimate precision are used also to estimate trueness. The estimation of trueness is not considered in this part of ISO 5725; all aspects of the estimation of trueness are the subject of ISO 5725-4.

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Accuracy (trueness and precision) of measurement methods and results —

Part 2:

Basic method for the determination of repeatability and reproducibility of a standard measurement method

1 Scope

1.1 This part of ISO 5725

- amplifies the general principles to be observed in designing experiments for the numerical estimation of the precision of measurement methods by means of a collaborative interlaboratory experiment;
- provides a detailed practical description of the basic method for routine use in estimating the precision of measurement methods;
- provides guidance to all personnel concerned with designing, performing or analysing the results of the tests for estimating precision.

NOTE 1 Modifications to this basic method for particular purposes are given in other parts of ISO 5725.

Annex B provides practical examples of estimating the precision of measurement methods by experiment.

1.2 This part of ISO 5725 is concerned exclusively with measurement methods which yield measurements on a continuous scale and give a single value as the test result, although this single value may be the outcome of a calculation from a set of observations.

1.3 It assumes that in the design and performance of the precision experiment, all the principles as laid down in ISO 5725-1 have been observed. The basic method uses the same number of test results in each laboratory, with each laboratory analysing the same levels of test sample: i.e. a balanced uniform-level experiment. The basic method applies to procedures that have been standardized and are in regular use in a number of laboratories.

NOTE 2 Worked examples are given to demonstrate balanced uniform sets of test results, although in one example a variable number of replicates per cell were reported (unbalanced design) and in another some data were missing. This is because an experiment designed to be balanced can turn out to be unbalanced. Stragglers and outliers are also considered.

1.4 The statistical model of clause 5 of ISO 5725-1:1994 is accepted as a suitable basis for the interpretation and analysis of the test results, the distribution of which is approximately normal.

1.5 The basic method, as described in this part of ISO 5725, will (usually) estimate the precision of a measurement method:

- a) when it is required to determine the repeatability and reproducibility standard deviations as defined in ISO 5725-1;
- b) when the materials to be used are homogeneous, or when the effects of heterogeneity can be included in the precision values; and

- c) when the use of a balanced uniform-level layout is acceptable.

1.6 The same approach can be used to make a preliminary estimate of precision for measurement methods which have not reached standardization or are not in routine use.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5725. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5725 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*.

ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*.

3 Definitions

For the purposes of this part of ISO 5725, the definitions given in ISO 3534-1 and in ISO 5725-1 apply.

The symbols used in ISO 5725 are given in annex A.

4 Estimates of the parameters in the basic model

4.1 The procedures given in this part of ISO 5725 are based on the statistical model given in clause 5 of ISO 5725-1:1994 and elaborated upon in subclause 1.2 of ISO 5725-1:1994. In particular, these procedures are based on equations (2) to (6) of clause 5 of ISO 5725-1:1994.

The model is

$$y = m + B + e$$

where, for the particular material tested,

m is the general mean (expectation);

B is the laboratory component of bias under repeatability conditions;

e is the random error occurring in every measurement under repeatability conditions.

4.2 Equations (2) to (6) of ISO 5725-1:1994, clause 5 are expressed in terms of the true standard deviations of the populations considered. In practice, the exact values of these standard deviations are not known, and estimates of precision values must be made from a relatively small sample of all the possible laboratories, and within those laboratories from a small sample of all the possible test results.

4.3 In statistical practice, where the true value of a standard deviation, σ , is not known and is replaced by an estimate based upon a sample, then the symbol σ is replaced by s to denote that it is an estimate. This has to be done in each of the equations (2) to (6) of ISO 5725-1:1994, giving:

s_L^2 is the estimate of the between-laboratory variance;

s_W^2 is the estimate of the within-laboratory variance;

s_r^2 is the arithmetic mean of s_W^2 and is the estimate of the repeatability variance; this arithmetic mean is taken over all those laboratories taking part in the accuracy experiment which remain after outliers have been excluded;

s_R^2 is the estimate of the reproducibility variance:

$$s_R^2 = s_L^2 + s_r^2 \quad \dots (1)$$

5 Requirements for a precision experiment

5.1 Layout of the experiment

5.1.1 In the layout used in the basic method, samples from q batches of materials, representing q different levels of the test, are sent to p laboratories which each obtain exactly n replicate test results under repeatability conditions at each of the q levels. This type of experiment is called a balanced uniform-level experiment.

5.1.2 The performance of these measurements shall be organized and instructions issued as follows.

- a) Any preliminary checking of equipment shall be as specified in the standard method.
- b) Each group of n measurements belonging to one level shall be carried out under repeatability conditions, i.e. within a short interval of time and by the same operator, and without any intermediate recalibration of the apparatus unless this is an integral part of performing a measurement.
- c) It is essential that a group of n tests under repeatability conditions be performed independently as if they were n tests on different materials. As a rule, however, the operator will know that he/she is testing identical material, but the point should be stressed in the instructions that the whole purpose of the experiment is to determine what differences in results can occur in actual testing. If it is feared that, despite this warning, previous results may influence subsequent test results and thus the repeatability variance, it should be considered whether to use n separate samples at each of the q levels, coded in such a way that the operator will not know which are the replicates for a given level. However, such a procedure could cause problems in ensuring that repeatability conditions will apply between replicates. This would only be possible if the measurements were of such a nature that all the qn measurements could be performed within a short interval of time.
- d) It is not essential that all the q groups of n measurements each be performed strictly within a short interval; different groups of measurements may be carried out on different days.
- e) Measurements of all q levels shall be performed by one and the same operator and, in addition, the n measurements at a given level shall be performed using the same equipment throughout.
- f) If in the course of the measurements an operator should become unavailable, another operator may complete the measurements, provided that the change does not occur within a group of n measurements at one level but only occurs between two of the q groups. Any such change shall be reported with the results.
- g) A time limit shall be given within which all measurements shall be completed. This may be necessary to limit the time allowed to elapse be-

tween the day the samples are received and the day the measurements are performed.

- h) All samples shall be clearly labelled with the name of the experiment and a sample identification.

5.1.3 In 5.1.2 and elsewhere in this part of ISO 5725, reference is made to the operator. For some measurements, there may in fact be a team of operators, each of whom performs some specific part of the procedure. In such a case, the team shall be regarded as "the operator" and any change in the team shall be regarded as providing a different "operator".

5.1.4 In commercial practice, the test results may be rounded rather crudely, but in a precision experiment test results shall be reported to at least one more digit than specified in the standard method. If the method does not specify the number of digits, the rounding shall not be coarser than half the repeatability standard deviation estimate. When precision may depend on the level m , different degrees of rounding may be needed for different levels.

5.2 Recruitment of the laboratories

5.2.1 The general principles regarding recruitment of the laboratories to participate in an interlaboratory experiment are given in 6.3 of ISO 5725-1:1994. In enlisting the cooperation of the requisite number of laboratories, their responsibilities shall be clearly stated. An example of a suitable enlistment questionnaire is given in figure 1.

5.2.2 For the purposes of this part of ISO 5725, a "laboratory" is considered to be a combination of the operator, the equipment and the test site. One test site (or laboratory in the conventional sense) may thus produce several "laboratories" if it can provide several operators each with independent sets of equipment and situations in which to perform the work.

5.3 Preparation of the materials

5.3.1 A discussion of the points that need to be considered when selecting materials for use in a precision experiment is given in 6.4 of ISO 5725-1:1994.

5.3.2 When deciding on the quantities of material to be provided, allowance shall be made for accidental spillage or errors in obtaining some test results which may necessitate using extra material. The amount of material prepared shall be sufficient to cover the experiment and allow an adequate stock in reserve.

Questionnaire for interlaboratory study

Title of measurement method (copy attached)

1. Our laboratory is willing to participate in the precision experiment for this standard measurement method.

YES NO (tick appropriate box)

2. As a participant, we understand that:

- a) all essential apparatus, chemicals and other requirements specified in the method must be available in our laboratory when the programme begins;
- b) specified "timing" requirements such as starting date, order of testing specimens and finishing date of the programme must be rigidly met;
- c) the method must be strictly adhered to;
- d) samples must be handled in accordance with instructions;
- e) a qualified operator must perform the measurements.

Having studied the method and having made a fair appraisal of our capabilities and facilities, we feel that we will be adequately prepared for cooperative testing of this method.

3. Comments

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(Company or laboratory)

Figure 1 — Enlistment questionnaire for interlaboratory study

5.3.3 It should be considered whether it is desirable for some laboratories to obtain some preliminary test results for familiarization with the measurement method before obtaining the official test result and, if so, whether additional material (not precision experiment samples) should be provided for this purpose.

5.3.4 When a material has to be homogenized, this shall be done in the manner most appropriate for that material. When the material to be tested is not homogeneous, it is important to prepare the samples in the manner specified in the method, preferably starting with one batch of commercial material for each level. In the case of unstable materials, special instructions on storage and treatment shall be specified.

5.3.5 For the samples at each level, *n* separate containers shall be used for each laboratory if there is any danger of the materials deteriorating once the container has been opened (e.g. by oxidation, by losing volatile components, or with hygroscopic material). In the case of unstable materials, special instructions on storage and treatment shall be specified. Precautions may be needed to ensure that samples remain identical up to the time the measurements are made. If the material to be measured consists of a mixture of powders of different relative density or of different grain size, some care is needed because segregation may result from shaking, for example during transport. When reaction with the atmosphere may be expected, the specimens may be sealed into ampoules, either evacuated or filled with an inert gas. For perishable materials such as food or blood samples, it

may be necessary to send them in a deep-frozen state to the participating laboratories with detailed instructions for the procedure for thawing.

6 Personnel involved in a precision experiment

NOTE 3 The methods of operation within different laboratories are not expected to be identical. Therefore the contents of this clause are only intended as a guide to be modified as appropriate to cater for a particular situation.

6.1 Panel

6.1.1 The panel should consist of experts familiar with the measurement method and its application.

6.1.2 The tasks of the panel are:

- a) to plan and coordinate the experiment;
- b) to decide on the number of laboratories, levels and measurements to be made, and the number of significant figures to be required;
- c) to appoint someone for the statistical functions (see 6.2);
- d) to appoint someone for the executive functions (see 6.3);
- e) to consider the instructions to be issued to the laboratory supervisors in addition to the standard measurement method;
- f) to decide whether some operators may be allowed to carry out a few unofficial measurements in order to regain experience of the method after a long interval (such measurements shall never be carried out on the official collaborative samples);
- g) to discuss the report of the statistical analysis on completion of the analysis of the test results;
- h) to establish final values for the repeatability standard deviation and the reproducibility standard deviation;
- i) to decide if further actions are required to improve the standard for the measurement method or with regard to laboratories whose test results have been rejected as outliers.

6.2 Statistical functions

At least one member of the panel should have experience in statistical design and analysis of experiments. His/her tasks are:

- a) to contribute his/her specialized knowledge in designing the experiment;
- b) to analyse the data;
- c) to write a report for submission to the panel following the instructions contained in 7.7.

6.3 Executive functions

6.3.1 The actual organization of the experiment should be entrusted to a single laboratory. A member of the staff of that laboratory should take full responsibility; he/she is called the executive officer and is appointed by the panel.

6.3.2 The tasks of the executive officer are:

- a) to enlist the cooperation of the requisite number of laboratories and to ensure that supervisors are appointed;
- b) to organize and supervise the preparation of the materials and samples and the dispatch of the samples; for each level, an adequate quantity of material should be set aside as a reserve stock;
- c) to draft instructions covering all the points in 5.1.2 a) to h), and circulate them to the supervisors early enough in advance for them to raise any comments or queries and to ensure that operators selected are those who would normally carry out such measurements in routine operations;
- d) to design suitable forms for the operator to use as a working record and for the supervisor to report the test results to the requisite number of significant figures (such forms may include the name of the operator, the dates on which samples were received and measured, the equipment used and any other relevant information);
- e) to deal with any queries from laboratories regarding the performance of the measurements;
- f) to see that an overall time schedule is maintained;
- g) to collect the data forms and present them to the statistical expert.

6.4 Supervisors

6.4.1 A staff member in each of the participating laboratories should be made responsible for organizing the actual performance of the measurements, in keeping with instructions received from the executive officer, and for reporting the test results.

6.4.2 The tasks of the supervisor are:

- a) ensure that the operators selected are those who would normally carry out such measurements in routine operations;
- b) to hand out the samples to the operator(s) in keeping with the instructions of the executive officer (and to provide material for familiarization experiments, if necessary);
- c) to supervise the execution of the measurements (the supervisor shall not take part in performing the measurements);
- d) to ensure that the operators carry out the required number of measurements;
- e) to ensure adherence to the set timetable for performing the measurements;
- f) to collect the test results recorded to the agreed number of decimal places, including any anomalies and difficulties experienced, and comments made by the operators.

6.4.3 The supervisor of each laboratory should write a full report which should contain the following information:

- a) the test results, entered legibly by their originator on the forms provided, not transcribed or typed (computer or testing machine printout may be acceptable as an alternative);
- b) the original observed values or readings (if any) from which the test results were derived, entered legibly by the operator on the forms provided, not transcribed or typed;
- c) comments by the operators on the standard for the measurement method;
- d) information about irregularities or disturbances that may have occurred during the measurements, including any change of operator that may have occurred, together with a statement as to which measurements were performed by which operator, and the reasons for any missing results;
- e) the date(s) on which the samples were received;
- f) the date(s) on which each sample was measured;
- g) information about the equipment used, if relevant;
- h) any other relevant information.

6.5 Operators

6.5.1 In each laboratory the measurements shall be carried out by one operator selected as being representative of those likely to perform the measurements in normal operations.

6.5.2 Because the object of the experiment is to determine the precision obtainable by the general population of operators working from the standard measurement method, in general the operators should not be given amplifications to the standard for the measurement method. However, it should be pointed out to the operators that the purpose of the exercise is to discover the extent to which results can vary in practice, so that there will be less temptation for them to discard or rework results that they feel are inconsistent.

6.5.3 Although normally the operators should receive no supplementary amplifications to the standard measurement method, they should be encouraged to comment on the standard and, in particular, to state whether the instructions contained in it are sufficiently unambiguous and clear.

6.5.4 The tasks of the operators are:

- a) to perform the measurements according to the standard measurement method;
- b) to report any anomalies or difficulties experienced; it is better to report a mistake than to adjust the test results because one or two missing test results will not spoil the experiment and many indicate a deficiency in the standard;
- c) to comment on the adequacy of the instructions in the standard; operators should report any occasions when they are unable to follow their instructions as this may also indicate a deficiency in the standard.

7 Statistical analysis of a precision experiment**7.1 Preliminary considerations**

7.1.1 The analysis of the data, which should be considered as a statistical problem to be solved by a statistical expert, involves three successive stages:

- a) critical examination of the data in order to identify and treat outliers or other irregularities and to test the suitability of the model;
- b) computation of preliminary values of precision and means for each level separately;
- c) establishment of final values of precision and means, including the establishment of a relationship between precision and the level m when the analysis indicates that such a relationship may exist.

7.1.2 The analysis first computes, for each level separately, estimates of

- the repeatability variance s_r^2
- the between-laboratory variance s_L^2
- the reproducibility variance $s_R^2 = s_r^2 + s_L^2$
- the mean m .

7.1.3 The analysis includes a systematic application of statistical tests for outliers, a great variety of which are available from the literature and which could be used for the purposes of this part of ISO 5725. For practical reasons, only a limited number of these tests, as explained in 7.3, have been incorporated.

7.2 Tabulation of the results and notation used

7.2.1 Cells

Each combination of a laboratory and a level is called a cell of the precision experiment. In the ideal case, the results of an experiment with p laboratories and q levels consist of a table with pq cells, each containing n replicate test results that can all be used for computing the repeatability standard deviation and the reproducibility standard deviation. This ideal situation is not, however, always attained in practice. Departures occur owing to redundant data, missing data and outliers.

7.2.2 Redundant data

Sometimes a laboratory may carry out and report more than the n test results officially specified. In that case, the supervisor shall report why this was done and which are the correct test results. If the answer is that they are all equally valid, then a random selection should be made from those available test results to choose the planned number of test results for analysis.

7.2.3 Missing data

In other cases, some of the test results may be missing, for example because of loss of a sample or a mistake in performing the measurement. The analysis recommended in 7.1 is such that completely empty cells can simply be ignored, while partly empty cells can be taken into account by the standard computational procedure.

7.2.4 Outliers

These are entries among the original test results, or in the tables derived from them, that deviate so much

from the comparable entries in the same table that they are considered irreconcilable with the other data. Experience has taught that outliers cannot always be avoided and they have to be taken into consideration in a similar way to the treatment of missing data.

7.2.5 Outlying laboratories

When several unexplained abnormal test results occur at different levels within the same laboratory, then that laboratory may be considered to be an outlier, having too high a within-laboratory variance and/or too large a systematic error in the level of its test results. It may then be reasonable to discard some or all of the data from such an outlying laboratory.

This part of ISO 5725 does not provide a statistical test by which suspected laboratories may be judged. The primary decision should be the responsibility of the statistical expert, but all rejected laboratories shall be reported to the panel for further action.

7.2.6 Erroneous data

Obviously erroneous data should be investigated and corrected or discarded.

7.2.7 Balanced uniform-level test results

The ideal case is p laboratories called i ($i = 1, 2, \dots, p$), each testing q levels called j ($j = 1, 2, \dots, q$) with n replicates at each level (each ij combination), giving a total of pqn test results. Because of missing (7.2.3) or deviating (7.2.4) test results, or outlying laboratories (7.2.5) or erroneous data (7.2.6), this ideal situation is not always attained. Under these conditions the notations given in 7.2.8 to 7.2.10 and the procedures of 7.4 allow for differing numbers of test results. Specimens of recommended forms for the statistical analysis are given in figure 2. For convenience, they will be referred to simply as forms A, B and C (of figure 2).

7.2.8 Original test results

See form A of figure 2, where

- n_{ij} is the number of test results in the cell for laboratory i at level j ;
- y_{ijk} is any one of these test results ($k = 1, 2, \dots, n_{ij}$);
- p_j is the number of laboratories reporting at least one test result for level j (after eliminating any test results designated as outliers or as erroneous).