TECHNICAL REPORT

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Guide for the selection of statistical methods in standardization and specification

Guide pour la sélection des méthodes statistiques en normalisation et en spécifications

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Contents

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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.

The main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 13425, which is a Technical Report of type 3, was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 3, *Application of statistical methods in standardization*.

Introduction

Statistical methods have numerous practical applications in the manufacturing and service industries, marketing, research, laboratories and other spheres. Their effectiveness depends firstly on the suitability of the chosen method for the intended purpose and secondly on the application, the way it is used. Incorrect choice or poor application can lead to improper deductions and therefore to crucial errors and inappropriate decisions.

This is one of the reasons why ISO has produced a range of International Standards for the application of statistical methods.

This Technical Report should be seen as a descriptive catalogue of the available ISO/TC 69 International Standards and guides, published or in course of preparation, to assist readers in selecting those most suitable for their purposes, according to their needs, whether these be in decision making, problem solving or in achieving a given purpose.

Guide for the selection of statistical methods in standardization and specification

Scope

This Technical Report describes the International Standards and guides prepared by ISO/TC 69.

The documents are listed in tables according to their subject matter. The main table lists the general application categories with their subdivision into specific tables listing the documents by title and number. The types of document are identified as follows:

Published International Standard:	ISO xxxxxx
Draft International Standard:	DIS
Committee Draft:	CD
Working Draft:	WD
New work item proposal:	NP
Draft Technical Report:	DTR
Published Technical Report:	TR

Annex A gives a survey of the content and use of all the referenced standards and DISs developed by ISO/TC 69. DISs are drafts which can be amended. Both categories are documents which are available to the public. The annex contains two sets of abstracts: non-technical abstracts and technical abstracts of all these documents. Each abstract presents a brief survey of the content of the actual standard or DIS. It also gives some indications of the use of the document in different areas.

The non-technical abstracts are usually brief. In these abstracts, the number of technical terms is kept to a minimum. They give brief outlines of the actual documents.

The technical abstracts are somewhat longer. More technical terms are used. The technical abstracts also go into more depth with regard to the content and use of the actual document than the non-technical abstracts. For many documents, the two abstracts supplement each other.

Annex B lists the committee drafts, working drafts and new work item proposals in the ISO/TC 69 work programme.

Main table

AREA	SUB-AREA	SEE TABLE
General Methods	Guides	1
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Reliability		See IEC/TC 56 standards
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Table 1 : Guides

ITEM	DOCUMENT
For the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots	TR 8550
For implementation of statistical process control (SPC)	CD 11462-1
Control charts - General guide and introduction	ISO 7870

Table 2 : Terminology

ITEM		DOCUMENT
Statistics	Probability	ISO 3534-1
	Statistics	ISO 3534-1
	Symbols	ISO 3534-1
Quality control		ISO 3534-2
Design of experiments		ISO 3534-3
Measurements methods	Accuracy	ISO 5725-1
	Capability of detection	DIS 11843-1
Attribute sampling system		ISO 2859-0

Table 3 : Estimation

ITEM	DOCUMENT	
	Variance known	Variance unknown
Mean	ISO 2854	ISO 2602
Difference of two means	ISO 2854	ISO 2854
Difference of two means (paired observations)	ISO 3301	
Variance	ISO 2854	
Ratio of two variances	ISO 2854	
Tolerance interval	ISO 3207	
Confidence interval	ISO 2602	
Median	ISO 8595	
Proportions	ISO 11453	
Power of tests	ISO 3494	

Table 4 : Comparison to a given value

ITEM	DOCUMENT
Mean	ISO 2854
Difference of two means	ISO 2854
Variance	ISO 2854
Ratio of two variances	ISO 2854
Proportions	ISO 11453
Power of tests	ISO 3494

Table 5 : Comparison of two samples

ITEM	DOCUMENT
Means	ISO 2854
Variances	ISO 2854
Paired observations	ISO 3301
Proportions	ISO 11453
Power of tests	ISO 3494

Table 6 : Tests for types of distribution

ITEM	DOCUMENT
Tests for normality	DIS 5479

Table 7 : Statistical process control (SPC)

ITEM		DOCUMENT
Guideline for implementation of SPC		CD 11462-1
Process capability		WD 12783
Control charts	General guide and introduction	ISO 7870
	Shewhart control charts	ISO 8258
	Acceptance control charts	ISO 7966
	For arithmetic average with warning limits	ISO 7873
	Cumulative sum charts	TR 7871

Table 8 : Sampling

ITEM		DOCUMENT	
		attributes	variables
Discrete "items"	Guide for selection of a sampling system, scheme or plan	TR 8550	
	Introduction to ISO 2859 sampling system	ISO 2859-0	
	Sampling plans and procedures :		
	- Indexed by Acceptable Quality Level (AQL)	ISO 2859-1	
	- Indexed by Limiting Quality Level (LQL) (for isolated lots)	ISO 2859-2	
	Skip-lot sampling procedures	ISO 2859-3	
	For percent non conforming		ISO 3951
	Sequential sampling plans	ISO 8422	ISO 8423
Bulk material	Acceptance sampling plans		CD 10725
	Statistical aspects of sampling		WD 11648
Audit	Sampling plans for audit sampling (for product or process)	NP 13447	

Table 9 : Accuracy and uncertainty

ITEM		DOCUMENT
Accuracy of measurement methods and results	General principles and definitions	ISO 5725-1
	Basic method for determination of repeatability and reproducibility	ISO 5725-2
	Intermediate measures of the precision	ISO 5725-3
	Basic methods for estimating the trueness	ISO 5725-4
	Alternative methods for the determination of the precision of a standard measurement method	WI 5725-5
	Practical applications	ISO 5725-6
Proficiency testing		NP 13528

Table 10 : Use of reference materials (RMs)

ITEM	DOCUMENT
Linear calibration using reference materials	ISO 11095
Generalities	Guide ISO 35
Use of certified reference materials	Guide ISO 33

Table 11 : Decision limit(s)

ITEM	DOCUMENT
Specifications - Construction of limiting value	CD 10576
Definitions	DIS 11843-1
Methodology	WD 11843-2

Annex A

Content and use of the referenced standards and DIS

A.1 Short non-technical abstracts of ISO/TC 69 Standards and DIS

ISO Guide 33 : Uses of certified reference materials (Developed jointly by REMCO and ISO/TC 69)

A reference material (RM) is a substance or an artefact for which one or more properties are established sufficiently well to validate a measurement system. There exist several kinds of RMs: An internal reference material is a RM developed by a user for its own internal use. An external reference material is a RM provided by someone other than the user. A certified reference material (CRM) is a RM issued and certified by an organization recognized as competent to do so. CRMs are widely used in modern technology and the demand is expected to increase. CRMs must be used consistently in order to ensure reliable measurements. The purpose of this Guide is to introduce basic concepts and practical aspects related to the use of CRMs and examine the conditions under which CRMs are properly used and when they are misused.

ISO Guide 35 : Certification of reference materials - General and statistical principles. (Developed jointly by REMCO and ISO/TC 69).

The purpose of this Guide is to provide a basic introduction to concepts and practical aspects related to the certification of reference materials (RMs). ISO Guide 33 (see above) more fully addresses concepts and practical aspects related to their use. The present Guide is intended to describe the general and statistical principles for the certification of RMs. Another purpose of this Guide is to assist in understanding valid methods for the certification of RMs and also to help potential users to better define their technical requirements. The Guide should be useful in establishing the full potential of certified reference materials as aids to assuring the accuracy and interlaboratory compatibility of measurements on a national or international scale.

ISO 2602: Statistical interpretation of test results - Estimation of the mean - Confidence interval

This international standard is limited to the point and interval estimation of the mean of a normal population on the basis of observations from a series of tests applied to a random sample of individuals drawn from such a population. The intervals may be one- or two- sided. It deals only with the case where the variance is unknown. Formulae are given for both ungrouped and grouped observations. It is not concerned with the calculation of an interval containing, with a fixed probability, at least a given fraction of the population (statistical tolerance limits).

ISO 2854 : Statistical interpretation of data - Techniques of estimation and test relating to means and variances

This international standard specifies the techniques required to estimate the mean and variance and to examine certain hypotheses concerning the values of these parameters for samples of observations from one or two normal populations drawn at random and independently. Methods to check the normality are provided. Conditions for using the methods when the assumptions are not completely satisfied are discussed. Formulae are given for ungrouped observations. The methods are illustrated by many examples.

ISO 2859-0 : Sampling procedures for inspection by attributes - Part 0 : Introduction to the ISO 2859 attribute sampling system

Part 0 of ISO 2859 is a guidance document, not a source of sampling schemes or plans. It consists of two sections. Section 1 General introduction to acceptance sampling is essentially an introduction to the sampling schemes employed in ISO 2859 and ISO 8422 but it treats the subject in a general way. It contains explanations of terms, gives practical advice on sampling inspection and discusses some underlying concepts. Section 2 The ISO 2859-1 system extends Section 1 and amplifies the introductory text and instructions contained in ISO 2859-1, by giving detailed comments and examples to assist in using the procedures and tables that make up the ISO 2859-1 system.

ISO 2859-1 : Sampling procedures for inspection by attributes - Part 1 : Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

Part 1 of ISO 2859 specifies sampling plans and procedures for the case where lots consist of discreet items and where all the product characteristics involved in the assessment of quality are attributes. It contains sampling plans indexed by percent nonconforming and by nonconformities per 100 items. In addition to single sampling plans it contains double sampling (i.e. two-stage) and multiple sampling (seven stage) plans. ISO 2859-1 contains normal, tightened and reduced inspection plans that are intended for coordinated use on a continuing series of lots, with switching between these different levels of sampling severity in response to the recent sampling history. Through the economic and psychological pressure of potential non-acceptance, a supplier is thereby encouraged to maintain a process average quality at least as good as that which has been agreed with the customer.

ISO 2859-2 : Sampling procedures for inspection by attributes - Part 2 : Sampling plans indexed by limiting quality (LQ) for isolated lot inspection

Part 2 of ISO 2859 establishes procedures that can be used when the switching rules of ISO 2859-1 cannot be applied, with sampling plans indexed by limiting quality (LQ). Procedure A is used when both the supplier and the customer wish to regard the lot in isolation. Procedure B is used when the supplier regards the lot as one of a continuing series, but the customer considers the lot received in isolation. The LQ is used to indicate a quality level at which there is usually less than a 10% risk of the customer accepting the lot. The LQ is expressed in terms of the percentage nonconforming in the submitted lots, but can also be used for the case where quality is expressed in terms of nonconformities per 100 items.

ISO 2859-3 : Sampling procedures for inspection by attributes - Part 3 : Skip-lot sampling procedures

Part 3 of ISO 2859 supplements the procedures contained in ISO 2859-1. It provides a procedure for reducing the inspection effort on products submitted by suppliers who have demonstrated their ability to control all facets of product quality effectively and to produce superior quality material consistently. However, the procedure must not be used for the inspection of product characteristics that involve the safety of personnel. Skip-lot sampling applies only to a continuing series of lots. Some lots in a series will be accepted without inspection when the sampling results for a stated number of immediately preceding lots meet stated criteria. The lots to be inspected are chosen randomly with a pre-determined frequency.

ISO 3207 : Statistical interpretation of data - Determination of a statistical tolerance interval

This International Standard specifies methods enabling a sample to be used as the basis for determining a statistical tolerance interval, i.e. an interval such that there is a fixed probability (confidence level) that the interval will contain at least a proportion *p* of the population from which the sample is taken. The statistical tolerance interval may be two-sided or one-sided. The limits of the interval are called "statistical tolerance limits" or "natural limits of the process". These methods are applicable only where it may be assumed that in the population under consideration the sample units have been selected at random and are independent and the distribution of the characteristic being studied is normal. Several examples are illustrating the methods.

ISO 3301 : Statistical interpretation of data - Comparison of two means in the case of paired observations

This International Standard specifies a method for comparing the mean of a population of differences between paired observations with zero or any other preassigned value. The method, known as the method of paired observations, is a special case of a method described in ISO 2854: Statistical interpretation of data - Techniques of estimation and tests relating to means and variances. The method can only be applied if the following two conditions are satisfied: the series of differences of the observed pairs can be considered as a series of independent random items, and the distribution of these differences is supposed to be normal or approximately normal.

ISO 3494 : Statistical interpretation of data - Power of tests relating to means and variances

This International Standard is a further development of ISO 2854. In connection with statistical tests ISO 2854 considered the type I risk, i.e. the probability of rejecting a null hypothesis (tested hypothesis) if this hypothesis is true. The present Standard puts forward notions of the type II risk, the probability of not rejecting the null hypothesis if it is false. Furthermore, the power of the tests are given. The conditions are the same as in ISO 2854 that the observations can be considered as independent and approximately distributed according to the normal distribution.

ISO 3534-1 : Statistics - Vocabulary and Symbols - Part 1 : Probability and General Statistical Terms

This part of ISO 3534 defines probability and general statistical terms. They may be used in the drafting of other international standards. In addition, symbols are defined for many of the terms.

The terms are classified under four main headings :

1) Terms used in the theory of probability ;

2) General statistical terms ;

3) General terms relating to observations and test results ;

4) General terms relating to methods of sampling.

The entries are arranged analytically and alphabetical indexes are provided. The standard includes a list of symbols and abbreviations used in this part of ISO 3534.

ISO 3534-2 : Statistics - Vocabulary and Symbols - Part 2 : Statistical Quality Control

This part of ISO 3534 defines statistical quality control terms which may be used in the drafting of other international standards.

The terms are classified under three main headings :

1) General statistical quality control terms ;

2) Sampling and acceptance sampling terms ;

3) Terms related to process measures.

The entries are arranged analytically and alphabetical indexes are provided. A list of symbols and abbreviations used in this part of ISO 3534 is provided.

ISO 3534-3 : Statistics - Vocabulary and Symbols - Part 3 : Design of Experiments

This part of ISO 3534 defines the terms used in the field of design of experiments and may be used in the drafting of other international standards.

The terms are classified under three main headings :

1) General terms ;

2) Terms related to arrangements of experiments ;

3) Terms related to methods of analysis.

The entries are arranged analytically and alphabetical indexes are provided. A list of symbols and abbreviations used in this part of ISO 3534 is provided.

ISO 3951 : Sampling procedures and charts for inspection by variables for percent nonconforming

ISO 3951 is a system of single sampling plans that is applicable where quality involves just one product characteristic that is a variable having, at least approximately, a normal distribution. It applies when there is a single upper or lower specification limit of the variable and also where there are both. A lot is judged as unacceptable when sample measurements of the variable give grounds for believing that the proportion of the items in the lot for which the variable lies outside specification is at an unacceptably high level. Assessment of acceptability is made in terms of the sample mean and the sample standard deviation (or process standard deviation, if known) of the variable. A choice is available between equivalent numerical and graphical acceptance criteria.

ISO/DIS 5479 : Tests for departure from the normal distribution

Many statistical methods used in International Standards are based on the assumption that some basic variable(s) are distributed according to the normal distribution. This assumption may be doubtful in many cases. A large number of "tests of normality" have therefore been developed, each of which is more or less sensitive to a particular feature of the distribution. In this draft International Standard graphical methods, moment tests, regressions tests, and characteristic function tests are considered.

ISO 5725-1 : Accuracy (trueness and precision) of measurement methods and results - Part 1 : General principles and definitions

Part 1 of ISO 5725 contains definitions of terms that are used to describe the accuracy of a measurement method: "Trueness", "repeatability", reproducibility" and "intermediate precision". "Trueness" is a measure of the closeness of agreement between the average of large series of measurement results and an accepted reference value, whereas the others are used to describe the closeness of agreement between measurement results. Part 1 also sets out the principles to be followed when planning experiments to estimate the values of these parameters, and gives guidance on how the results of such experiments should be published in standards.

ISO 5725-2 : Accuracy (trueness and precision) of measurement methods and results - Part 2 : The basic method for the determination of repeatability and reproducibility of a standard measurement method

Part 2 of ISO 5725 describes in detail how to organise experiments to determine the repeatability and reproducibility standard deviations for a standardized measurement method, it sets out the tasks to be performed by personnel involved in the experiments, and gives guidance on how to prepare the samples of materials that are required. It also specifies how to analyse the data obtained in such experiments, and how to present and report the results. It contains several examples that illustrate the method of analysis.

ISO 5725-3 : Accuracy (trueness and precision) of measurement methods and results - Part 3 : Intermediate measures of the precision of a standard measurement method

Part 2 of ISO 5725 is concerned with measurements that are obtained under repeatability and reproducibility conditions. However, it is common in process control for measurements to be made under conditions that are intermediate between those to which repeatability and reproducibility can be applied. Part 3 of ISO 5725 supplements Part 2 by introducing measures of precision that are appropriate under these intermediate conditions. It also describes experiments to use to estimate their values.

ISO 5725-4 : Accuracy (trueness and precision) of measurement methods and results - Part 4 : Basic methods for the determination of the trueness of a standard measurement method

Part 4 of ISO 5725 describes how to use the inter-laboratory experiment from Part 2 to determine the bias of a standard measurement method. It also describes an experiment that may be carried out in a single laboratory to determine the bias of that laboratory. Both experiments require materials for which an accepted reference value has been established, e.g. reference materials, or by preparation of known samples, or by the use of measurement standards or a reference measurement method.

ISO 5725-6 : Accuracy (trueness and precision) of measurement methods and results - Part 6 : Use in practice of accuracy values

Part 6 of ISO 5725 describes a number of practical applications of the values determined by the methods described in Parts 2 to 5, including the calculation of repeatability and reproducibility limits, the use of these limits to check the acceptability of measurement results, the assessment and control of the quality of laboratory operations, and how to compare alternative measurement methods.

ISO 7870 : Control charts - General guide and introduction

This International Standard presents a discussion of key elements and the philosophy of statistical process control by means of control charts, and identifies a wide variety of control charts, including those related to Shewhart control charts and those with process acceptance or on-line predictive emphasis. An overview is given over the basic principles and concepts and illustrates the relationship among various control charts approaches. Statistical control methods for different charts are specified in ISO 7873, ISO 7966, and ISO 8258.

ISO/TR 7871 : Guide to quality control and data analysis using cusum techniques

This Technical Report gives an introduction to the use of the cumulative sum chart, usually called cusum chart, in statistical process control. This is a highly informative graphical presentation of data which are ordered in a logical sequence. A cusum chart monitor is intended to check a process for departure from a reference value. The construction and applications are illustrated by means of number of examples. Different modifications for special purposes are proposed. The performance of the cusum techniques are compared with the Shewhart control charts and their relative merits are discussed. Generally, the cusum chart is found to be more efficient for detecting small changes in the process level than the corresponding Shewhart chart.

ISO 7873 : Control charts for arithmetic average with warning limits

The statistical control of processes using arithmetic average control charts with warning limits is a modification of Shewhart control charts, see ISO 8258. Arithmetic average control charts with warning limits are able to reveal smaller shifts of the mean value of the controlled quality measure because of additional information obtained from the points being accumulated in the warning zone. In addition, sudden large shifts in process level are detectable if sample average values fall beyond action limits.

ISO 7966 : Acceptance control charts

This International Standard describes uses of acceptance control charts and gives methods of determining action limits and decision criteria. Examples are included to illustrate a variety of circumstances under which this technique has advantages, and to show details of sample-size determination and calculation of limits. A comparison of this type and other types of control charts as well as the basic philosophy and concepts regarding the use of control charts for statistical process control is given in ISO 7870.

ISO 8258 : Shewhart control charts

This international standard is a guide to the use and understanding of the Shewhart control chart approach to statistical process control. It is limited to the treatment of statistical process control methods using only the Shewhart system of charts. Some supplementary material that is consistent with the Shewhart approach, such as the use of warning limits, analysis of trend patterns and process capability is briefly introduced (See also ISO 7873). A general description of several other control chart procedures can be found in ISO 7870.

ISO 8422 : Sequential sampling plans for inspection by attributes

The purpose of this standard is to provide sampling plans for acceptance sampling of lots when lot quality level is specified as a percentage nonconforming, or nonconformities per 100 items, and inspection is by attributes. The sequential sampling procedure allows the inspector to select and inspect the items one by one. After inspection of each individual item, a decision is made whether another item shall be inspected, or whether there is sufficient information to accept or reject the lot. Generally, the use of a sequential sampling plan leads to a smaller average sample size than single sampling plans having the same operating characteristic, but in individual cases the necessary sample size may considerably exceed that of a corresponding plan for single sampling. Sequential sampling may be a relevant alternative to single sampling plans when the inspection of individual items is costly in comparison with inspection overheads.

ISO 8423 : Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)

The purpose of this International Standard is to provide sampling plans for acceptance sampling of lots when lot quality level is specified as a percentage nonconforming, and the inspection method provides the numerical magnitude of the characteristic. The applicability of this standard is restricted to situations where the within lot standard deviation of the characteristic may be considered to be known. The sequential sampling procedure allows the inspector to select and inspect the items one by one. After inspection of each individual item, a decision is made whether another item shall be inspected, or whether there is sufficient information to accept or reject the lot. Generally, the use of a sequential sampling plan leads to a smaller average sample size than single sampling plans having the same operating characteristic, but in individual cases the necessary sample size may considerably exceed that of a corresponding plan for single sampling. Sequential sampling may be a relevant alternative to single sampling plans when the inspection of individual items is costly in comparison with inspection overheads.

ISO/TR 8550 : Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots

The primary purpose of ISO Technical Report 8550 is to give guidance in the selection of an acceptance sampling system, scheme or plan. It does this principally in the context of existing or draft ISO standards. It reviews the available systems and shows ways in which they can be compared in order to assess their suitability for an intended application. The guide also indicates how prior knowledge of the manufacturing or service delivery process and quality performance can influence the choice of sampling system, scheme or plan, and also how the particular needs of the customer affect the selection. Some specific circumstances encountered in practice are described and the method of choosing a plan is explained. Some check lists or pointers and tables are provided to assist users in selecting an appropriate system, scheme or plan for their purpose. Two charts are included to illustrate the procedures followed in the selection process.

ISO 8595 : Interpretation of statistical data - Estimation of a median

This International Standard describes procedures for establishing the point estimate and the confidence intervals of a median of a probability distribution of a population, based on a random sample of size *n* from the population.

ISO 11095 : Linear calibration using reference materials

Calibration is an essential part of most measurement procedures. It is a set of operations which establish, under specified conditions, the relationship between values indicated by a measurement system and the corresponding accepted values of some "standards". In this International Standard, the standards are reference materials (RMs). This International Standard applies to measurement systems for which reference materials are available. No distinction is made among the various types of RMs and it assumes that the accepted values of the RMs selected to calibrate the measurement system are without error. This International Standard applies to measurement systems with an assumed linear calibration function. It offers a method to examine the assumption of linearity. If it is known that the calibration function is non-linear, then this International Standard does not apply unless one uses the "bracketing technique" described at the end of this International Standard.

ISO 11453 : Statistical interpretation of data - Tests and confidence intervals relating to proportions

This International Standard describes specific statistical methods for addressing the following questions : a) Given a population of items from which a sample of *n* items has been drawn, *x* of the sample items are found to show a specific characteristic. What proportion of the population has that characteristic ? b) Does the sample provide sufficient evidence to claim that the proportion differs from a nominal (specified) value ? c) Given samples from two distinct populations, do the samples provide sufficient evidence to claim that the proportions with the characteristic in the two populations differ from each other ? d) In b) and c) how many items must be sampled from the population(s) to be sufficiently sure that a given difference will be detected ?

ISO/DIS 11843-1 : Decision limit - Detection limit - Capability of detection - Part 1 : Terms and definitions

The purpose of this Draft International Standard is the standardization of terms and definitions relating to the characterization of a measurement series, a measurement system, a laboratory, or a measurement method. The standard addresses concepts related to the detection of a difference of an actual state of a system and its basic state. The general concepts laid down, critical value of the response variable, critical value of the net state variable and minimum detectable value of the net state variable, apply to various situations such as checking the existence of a certain substance in a matrix, the emission energy from samples or plants, or the geometric change in static system under distortion. The standard applies to all quantities measured on a continuous scale. It applies to measurement processes and measurement equipments where the functional relationship between the expected value of the response value and the state variable is described by a calibration function.

A.2 Technical abstracts of ISO/TC 69 standards

ISO Guide 33 : Uses of certified reference materials. (Developed jointly by REMCO and ISO/TC 69).

Certified Reference Materials (CRMs) must be used consistently to ensure reliable measurements. However, in doing so, the magnitude of the supply of that CRM, its relative cost, its availability (accessibility) and the measurement technique, be it destructive or non-destructive, must be considered.

Guide 33 has three sections :

- Section 1 presents definitions (with indication of their sources) of terms used, and sets out the statistical considerations on which the Guide is based ;

- Section 2 presents recommendations for developing criteria for the assessment of the precision and trueness of a measurement process by the use of CRMs. It pertains only to CRMs characterized to be homogeneous as described in ISO Guide 35. The use of the CRMs is essential for assessment of trueness and optional for assessment of precision ;

- Section 3 discusses the use of CRMs for the definition and realisation of conventional measurement.

ISO Guide 35 : Certification of reference materials. General and statistical principles. (Developed jointly by REMCO and ISO/TC 69)

The purpose of this Guide is to assist in understanding valid methods for the certification of Reference Materials (RMs) and also to help potential users to better define their technical requirements. The Guide should be useful in establishing the full potential of certified RMs as aids to assuring the accuracy and interlaboratory compatibility of measurements on a national or international scale. The Guide discusses the various measurement roles played by RMs. It deals with two of the most important technical considerations in the certification of RMs: measurement uncertainties and material homogeneity. This is followed by general principles for RM certification. Two commonly used general approaches to assuring technically valid RM certification are then discussed: a "definitive" or "absolute" method and an interlaboratory testing approach. Finally, a metrological approach is discussed that has for objective the production of certified values the accuracy and uncertainty of which are demonstrated by experimental evidence.

ISO 2602 : Statistical interpretation of test results - Estimation of the mean - Confidence interval

This International Standard is limited to the point and interval estimation of the mean of a normal population on the basis of observations from a series of tests applied to a random sample of individuals drawn from such a population. The intervals may be one- or two- sided. It deals only with the case where the variance is unknown. Formulae are given for both ungrouped and grouped observations. It is not concerned with the calculation of an interval containing, with a fixed probability, at least a given fraction of the population (statistical tolerance limits).

ISO 2854 : Statistical interpretation of data - Techniques of estimation and test relating to means and variances

This International Standard specifies the techniques required to estimate the mean and variance and to examine certain hypotheses concerning the values of these parameters for samples of observations from one or two normal populations drawn at random and independently. Methods to check the normality are provided. Conditions for using the methods when the assumptions are not completely satisfied, are discussed. Formulae are given for ungrouped observations. The methods are illustrated by many examples.

ISO 2859-0 : Sampling procedures for inspection by attributes - Part 0 : Introduction to the ISO 2859 attribute sampling system

Part 0 of ISO 2859 is a guidance document, not a source of sampling schemes or plans. It consists of two sections. Section 1 General introduction to acceptance sampling is essentially an introduction to the sampling schemes employed in ISO 2859 and ISO 8422 but it treats the subject in a general way. It contains explanations of terms, gives practical advice on sampling inspection and discusses some underlying concepts. Section 2 The ISO 2859-1 system extends Section 1 and amplifies the introductory text and instructions contained in ISO 2859-1, by giving detailed comments and examples to assist in using the procedures and tables that make up the ISO 2859-1 system.

ISO 2859-1 : Sampling procedures for inspection by attributes - Part 1 : Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

This part 1 of ISO 2859 is a sampling system indexed by lot-size ranges, inspection levels and AQLs and specifies sampling plans and procedures for inspection by attributes of discrete items. It contains sampling plans for single, double and multiple sampling indexed by percent nonconforming and nonconformities per 100 items. ISO 2859-1 is intended to be used as a system employing tightened, normal and reduced inspection on a continuing series of lots to achieve customer protection while assuring the producer that, if quality is better than the AQL, acceptance will occur most of the time. The objective in ISO 2859-1 is to induce a supplier, through the economic and psychological pressure of potential non-acceptance, to maintain a process average quality at least as good as the specified AQL, while at the same time providing an upper limit for the risk to the consumer of accepting the occasional lot of poor quality. The continuing series of lots should be of sufficient duration to allow the switching rules to be applied.

These rules provide for the following :

1) an automatic protection to the customer (by means of a switch to tightened inspection or to discontinuation of inspection) in the event that an apparent deterioration in quality is detected ;

2) an incentive to reduce inspection costs (by means of a switch to reduced inspection - at the discretion of a Responsible Authority) if consistently good quality is being achieved. The plans in ISO 2859-1 may also be used for the inspection of lots in isolation, but in this case the user is strongly advised to consult the operating characteristic curves to find a plan which will yield the desired protection. A much simpler procedure to follow in this type of situation is presented in ISO 2859-2.

ISO 2859-2 : Sampling procedures for inspection by attributes - Part 2 : Sampling plans indexed by limiting quality (LQ) for isolated lot inspection

This Part 2 of ISO 2859 established sampling plans indexed by limiting quality and procedures that can be used when the switching rules of ISO 2859-1 cannot be applied. The LQ is used to indicate the customer protection. The plans are primarily intended for use with single lots (procedure A), or lots isolated from a series (procedure B) where the use of the switching rules is precluded. Both procedures treat the limiting quality as an indicator of the actual percentage nonconforming in the lots submitted. They can also be used to cover cases where quality is expressed in terms of nonconformities per 100 items. The two procedures provide for situations often met in practice. Procedure A is used when both the supplier and the customer wish to regard the lot in isolation and it is also used as the default procedure (i.e. it is used unless there is a specific instruction to use procedure B). Procedure B is used when the supplier regards the lot as one of a continuing series, but the customer considers the lot received in isolation. The plans employed permit a producer to maintain consistent procedures for his customers, irrespective of whether the customers receive individual lots or a continuing series of lots. The manufacturer is concerned with all of the production but the individual customer only with the particular lot received. For procedure A, plans are identified by their lot size and LQ ; for procedure B they are identified by lot size, LQ and inspection level. Procedure A includes plans with an acceptance number of zero, whereas procedure B does not. Double and multiple sampling plans can be used as alternatives to single sampling plans in procedure B and for the non-zero acceptance number plans in procedure A.

ISO 2859-3 : Sampling procedures for inspection by attributes - Part 3 : Skip-lot sampling procedures

This Part 3 of ISO 2859 is a sampling system that extends the procedures contained in ISO 2859-1. It provides a procedure for reducing the inspection effort on products submitted by suppliers who have demonstrated their ability to control, in an effective manner, all facets of product quality and to produce superior quality material consistently. However, this procedure must not be used for the inspection of product characteristic that involve the safety of personnel. The skip-lot programme uses the acceptance sampling plans described in ISO 2859-1 and is intended only for a continuing series of lots. It is totally inappropriate for isolated lots. All lots in the series are expected to be of a similar quality and the customer should have no reason to believe that lots not inspected are of a poorer quality that the ones inspected. In a skip-lot sampling procedure some lots in a series are accepted without inspection when the sampling results for a stated number of immediately preceding lots meet stated criteria. The lots to be inspected are chosen randomly with a stated frequency, called the "skip-lot frequency".

ISO 3207 : Statistical interpretation of data - Determination of a statistical tolerance interval

This international standard specifies methods enabling a sample to be used as the basis for determining a statistical tolerance interval, i.e. an interval such that there is a fixed probability (confidence level) that the interval will contain at least a proportion *p* of the population from which the sample is taken. The statistical tolerance interval may be two-sided or one-sided. The limits of the interval are called "statistical tolerance limits" or "natural limits of the process". These methods are applicable only where it may be assumed that in the population under consideration the sample units have been selected at random and are independent and the distribution of the characteristic being studied is normal. Several examples are illustrating the methods.

ISO 3301 : Statistical interpretation of data - Comparison of two means in the case of paired observations

This international standard specifies a method for comparing the mean of a population of differences between paired observations with zero or any other preassigned value. The method, known as the method of paired observations, is a special case of a method described in ISO 2854 : Statistical interpretation of data - Techniques of estimation and tests relating to means and variances. The method can only be applied if the following two conditions are satisfied: the series of differences of the observed pairs can be considered as a series of independent random items, and the distribution of these differences is supposed to be normal or approximately normal.

ISO 3494 : Statistical interpretation of data - Power of tests relating to means and variances

This international standard follows on from ISO 2854: Statistical interpretation of data - Techniques of estimation and tests relating to means and variances. The conditions for applying this standard are the same as those stated for ISO 2854, i.e. that the data are observations from one or two normal distributions drawn at random and independently. ISO 2854 is concerned only with the type I risk (also called "significance level" or "producer's risk") of rejecting the null hypothesis (tested hypothesis) if this hypothesis is true. This international standard deals with notions of the type II risk, β, (also called "consumer's risk"), the probability of not rejecting type the null hypothesis, when it is false. The complement of the type II error, $(1 - \beta)$, is the "power" of the test. The operating characteristic curve of a test is the curve which shows the value of β of the type II risk as a function of the parameter defining the alternative. The standard provides operating characteristic curves for the tests considered in ISO 2854 for different values chosen for the type I risk and different sizes of the samples.

ISO 3534-1 Statistics - Vocabulary and symbols - Part 1 : Probability and general statistical terms

This international standard gives definitions, in English and French, of statistical terms which may be used in the drafting of other international standards. In addition, it defines symbols for a limited number of these terms. The terms are classified in four sections: The first contains terms used in the theory of probability, the second one general statistical terms, the third section contains general terms relating to observational and test results, and the fourth general terms relating to methods of sampling. Many terms are given in both sections 1 and 2 as the terms in their probabilistic sense apply to principles, independent of any practical application, and are defined in terms of properties of populations, while the terms in their statistical sense apply to sets of observations to which they relate: these definitions are of specifically operational character. Many of the terms in section 3 are considered in more detail in ISO 5725 : Accuracy (trueness and precision) of measurement methods and results in particular in Part 1.

ISO 3534-2 : Statistics - Vocabulary and symbols - Part 2 : Statistical quality control

This part of ISO 3534 defines quality control terms which may be used in the drafting of other international standards. The terms are classified in three sections. The first section contains general statistical and quality control terms and covers terms relating to the following topics: process and quality, inspection operations, sample and population terms, specification terms, and test and observation results. The second section contains sampling and acceptance terms relating to the following topics : sampling methods, sampling inspection, acceptance sampling, types of sampling inspection, variations in sampling inspection within an acceptance scheme or system, operating characteristic parameters, quality measures and related terms, and limiting process conditions. The third section contains terms relating to general process measures, process capability measures, control charts, and chart components.

ISO 3534-3 : Statistics - Vocabulary and symbols - Part 3 : Design of experiments

This part of ISO 3534 defines statistical terms relating to the design of experiments. It is divided into three sections. In the first part a number of general statistical terms relating to statistical models, variables, and experiments are defined. The second section is devoted to terms about the arrangements of experiments, in particular different types of experimental designs for different purposes. The third section regards methods of analysis in which different sets of formulae and types of analysis tables are given. The terminology is illustrated by a number of examples.

ISO 3951 : Sampling procedures and charts for inspection by variables for percent nonconforming

ISO 3951 is a sampling system indexed by lot size ranges, inspection levels and AQLs and is complementary to ISO 2859-1. The two Standards share a common philosophy and purpose. ISO 3951 is only applicable where a single product characteristic, measurable on a continuous scale, is considered. The product characteristic should be distributed according to a normal distribution or to a distribution closely approximating normality. (Often a simple mathematical transformation, such as taking the logarithm or square root, will convert a set of measurements from a non-normal to a normal, or near normal, distribution). A lot is judged as unacceptable when the distribution of the product characteristic fails to indicate an average and variability which meets the acceptance criteria for the single or double specification limits prescribed. A choice is available between numerical and graphical acceptance criteria. Procedures are given for the case where the process standard deviation is known and also for the case where it is unknown. Guidance is given on how these procedures can be used in combination with sampling for inspection by attributes, the most important suitable product characteristic being sampled by variables. ISO 3951 is intended primarily for the inspection of a continuing series of lots from one source of sufficient duration to allow the switching rules to operate, but, like ISO 2859-1, it can also be used for lots of an isolated nature. However, inspection carried out on an isolated lot will provide no evidence about the normality of the distribution of the (Epps-Pulley-test)product characteristic and about the standard deviation of the process. Therefore, in practice, ISO 3951 does not apply to the inspection of isolated lots. There are no double or multiple sampling plans in the current edition (1989) of this ISO Standard.

ISO/DIS 5479 : Normality tests

Many of the statistical methods recommended in standards drawn up by the International Standards Organization such as those described in ISO 2854 are based on the assumption that the variable(s) to which these methods apply are independently distributed according to the normal distribution. The following question therefore arises: Is the distribution that is represented by the sample sufficiently close to the normal distribution that the methods provided by these Standards can be used reliably ? There is no simple yes or no to this question which is valid in all cases. For this reason a large number of "tests of normality" has been developed each of which is more or less sensitive to a particular feature of the distribution under consideration, e.g. asymmetry or kurtosis. In this International Standard graphical methods (normal probability graph paper), moment tests (using the skewness or/and the kurtosis), regressions tests (Shapiro-Wilk-rest), and characteristic function tests (Epps-Pulley-test) are considered.

ISO 5725-1 : Accuracy (trueness and precision) of measurement methods and results - Part 1 : General principles and definitions

Part 1 of ISO 5725 contains definitions of terms that are used to describe the accuracy of a standardized measurement method : "Trueness", "repeatability", "reproducibility" and "intermediate precision".

- "Trueness" is a measure of the closeness of agreement between the average of a large series of measurement results and an accepted reference value, and may be expressed in terms of the bias of the measurement method.

The other terms are used to describe the closeness of agreement between measurement results.

- "Repeatability" is used when factors (such as the operator, the equipment and reagents, equipment calibration, the environment, and time) are kept as constant as possible, giving the conditions that minimize the variation between the measurement results ;

- "Reproducibility" is used when measurements are repeated in different laboratories, so that all these factors can cause variation between the results ;

- "Intermediate precision" is used when some, but not all, of these factors contribute to the variability (as is common in process control applications).

Part 1 also sets out the principles to be followed when planning experiments to estimate the values of these parameters, gives tables and charts to help decide how many laboratories and replicate results are required, describes the statistical model that is used as the basis of the analysis of the results, and gives guidance on how the results of such experiments should be published in standards.

ISO 5725-2: Accuracy (trueness and precision) of measurement methods and results - Part 2 : The basic method for the determination of repeatability and reproducibility of a standard measurement method

Part 2 of ISO 5725 describes in detail how to organize experiments to determine the repeatability and reproducibility standard deviations for a standardized measurement method: in particular, it describes the layout of the uniform-level design that is used in Part 2 to give data from which the repeatability standard deviations may be calculated. It sets out the tasks to be performed by the organizing panel, the statistical expert, the executive officer, and the participating laboratory supervisors and operators. It gives guidance on how to prepare the samples of materials that are required. It specifies how to analyse the data obtained in such experiments. Outliers are a common feature of precision experiments : Part 2 describes graphical techniques to use to check the consistency of the data, how to use Grubbs' test and Cochran's test to identify outliers. It gives recommendations on the actions to take when outliers are found. It gives methods for fitting a relationship between the precision values and the mean level, when the experiment contains several levels. It states how the statistical expert should report the results of the experiment to the organizing panel. It contains several examples that illustrate all the above.

ISO 5725-3: Accuracy (trueness and precision) of measurement methods and results - Part 3 : Intermediate measures of the precision of a standard measurement method

Part 2 of ISO 5725 is concerned with measurements that are obtained under repeatability and reproducibility conditions. However, it is common in process control for measurements to be made under conditions where some, but not all, of the factors (such as the operator, the equipment and reagents, equipment calibration, the environment, and time), that contribute to the reproducibility standard deviation of a measurement method, are allowed to vary. This creates conditions that are intermediate between those to which repeatability and reproducibility can be applied. Part 3 of ISO 5725 supplements Part 2 by introducing measures of precision that are appropriate under these intermediate conditions. It extends the mathematical model introduced in Part 1 to show how the component of variance between laboratories can be divided up into components relating to the factors listed above. It describes experiments to use within a single laboratory to obtain an estimate of an intermediate precision measure, and a number of fully-nested and staggered-nested experiments to use when estimates of the repeatability or reproducibility standard deviations are also required, or when estimates of the components of variance attributable to several factors are required.

ISO 5725-4 : Accuracy (trueness and precision) of measurement methods and results - Part 4 : Basic methods for the determination of the trueness of a standard measurement method

"Trueness" is a measure of the closeness of agreement between the average of a large series of measurement results and an accepted reference value, and may be expressed in terms of the bias of the measurement method. Part 4 of ISO 5725 shows how to extend the basic statistical model set out in Part 1 of ISO 5725 to include terms for the bias of a standard measurement method or for the bias of a laboratory. It describes how to use the inter-laboratory experiment from Part 2 to determine the bias of that laboratory. (Part 1 contains tables that are used to choose a sufficiently large number of laboratories or replicates so that the uncertainties of these estimates are acceptably small). Both experiments require materials for which an accepted reference value has been established, e.g. reference materials, or by preparation of known samples, or by the use of measurement standards or a reference measurement method. Formulae for the calculation of the estimates and approximate 95% confidence limits are given. An example that illustrates the calculations is included.

ISO 5725-6 : Accuracy (trueness and precision) of measurement methods and results - Part 6 : The use in practice of accuracy values

Part 6 of ISO 5725 describes a number of practical applications of the values determined by the methods described in Parts 2 to 5. It gives a standard way of calculating, from the repeatability and reproducibility standard deviations, the repeatability and reproducibility limits, and other limits that are applicable when replicate results are obtained. It provides rules for using these limits to check the acceptability of measurement results, and gives advice on the action to take when the results are shown to be unacceptable. It describes the use of control charts to monitor continuously the repeatability and stability of the results obtained in a laboratory, and describes how to use these control charts and experiments to determine the laboratory bias to obtain quantitative measures of the quality of the laboratory's operations. Where estimates of the precision of alternative measurement methods are available from the results of experiments, it describes how to use the results to compare the measurement methods. Examples are included of all these applications.

ISO 7870 : Control charts - General guide and introduction

The purpose of this standard is to discuss key elements and the philosophy of statistical process control by means of control charts. It is a general introduction to the following set of standards: ISO 7873, ISO 7966, and ISO 8258, each of which is devoted to special types of control charts. Control charts provide a general, graphical method for evaluating whether or not the process has attained, or continues in, a "state of statistical control". Control charts may be used for either "variables" data, with reference to a continuous measurement scale of some kind, or "attributes" data, which represent observations obtained by counting the presence or absence of some characteristic or attribute in each of the units in the group under consideration. The following general topics are considered: Control limits, rational subgroups, types of control charts, risks associated with control charts decisions and effectiveness criteria. The following chart types are discussed in some detail and compared: Shewhart and related control charts, for which some of the most important types are discussed more fully in ISO 8258 and ISO 7873, acceptance control charts, which are discussed more fully in ISO 7966, and adaptive control charts.

ISO/TR 7871 : Guide to quality control and data analysis using the cusum techniques

The cumulative sum chart, usually called cusum chart, is a highly informative graphical presentation of data which are ordered in a logical sequence, frequently the order of observation of a time scale. A usually constant reference value, *T*, is subtracted from each observation. The cumulative sums of the deviations from *T* are formed, and these cusums are plotted against the serial numbers of the observations. The cusum plotting results in the representation of process level average by the local slope of the chart. Thus by cusum charts changes of the average process level are clearly indicated by changes in the slope of the chart. The guide discusses the requirements for, preparations and decision rules for monitoring and control by means of cusum charts as well as their use for retrospective analyses. The methods are illustrated by means of a number of examples. Different modifications for special purposes are discussed. Comparisons are made with Shewhart control charts. Generally, the cusum chart is found to be more efficient for detecting small changes in the process level than the corresponding Shewhart chart.

ISO 7873 : Control charts for arithmetic average with warning limits

This standard specifies procedures for statistical control of processes by using control charts based upon the arithmetic average of the sample and using warning limits and action limits. This type of statistical control of processes is a modification of the use of Shewhart control charts described in ISO 8256. Control charts for the arithmetic average using both warning and action limits are characterized by a higher sensitivity to a process level shift. Only variables data with reference to a continuous scale of some kind are considered. The conditions for applying this type of charts, including several preparatory steps are discussed. The method of constructing both one-sided and two-sided control charts are explained in detail and is illustrated by an example. The rules of operation for a chart with warning and action limits are such that if a single point is falling beyond the upper or the lower action line or a specified number of successive points are falling between the warning and the action lines on either side this will be considered as an out-of-control signal, and corrective actions should be instituted. In an informative appendix the theoretical principles underlying this standard are outlined.