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Guidelines for the selection of statistical methods in standardization and specification

Lignes directrices pour la sélection des méthodes statistiques dans la normalisation et la spécification

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

In exceptional circumstances, 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), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 13425 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*.

This third edition cancels and replaces the second edition (ISO/TR 13425:2003), which has been technically revised.

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 TC 69 International Standards and Guides, published or in course of preparation, to assist the reader in selecting those most suitable for his purpose, according to his needs, whether these be in decision making, problem solving or in achieving a given purpose.

Guidelines for the selection of statistical methods in standardization and specification

1 Scope

This Technical Report gives guidance on the selection and an overview of all the referenced standards, guides, technical reports and DIS developed by ISO/TC 69 from a user prospective. DIS are drafts which can be amended. Both categories are documents, which are available to the public. This Technical Report also gives two descriptions of the content of the standards by 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.

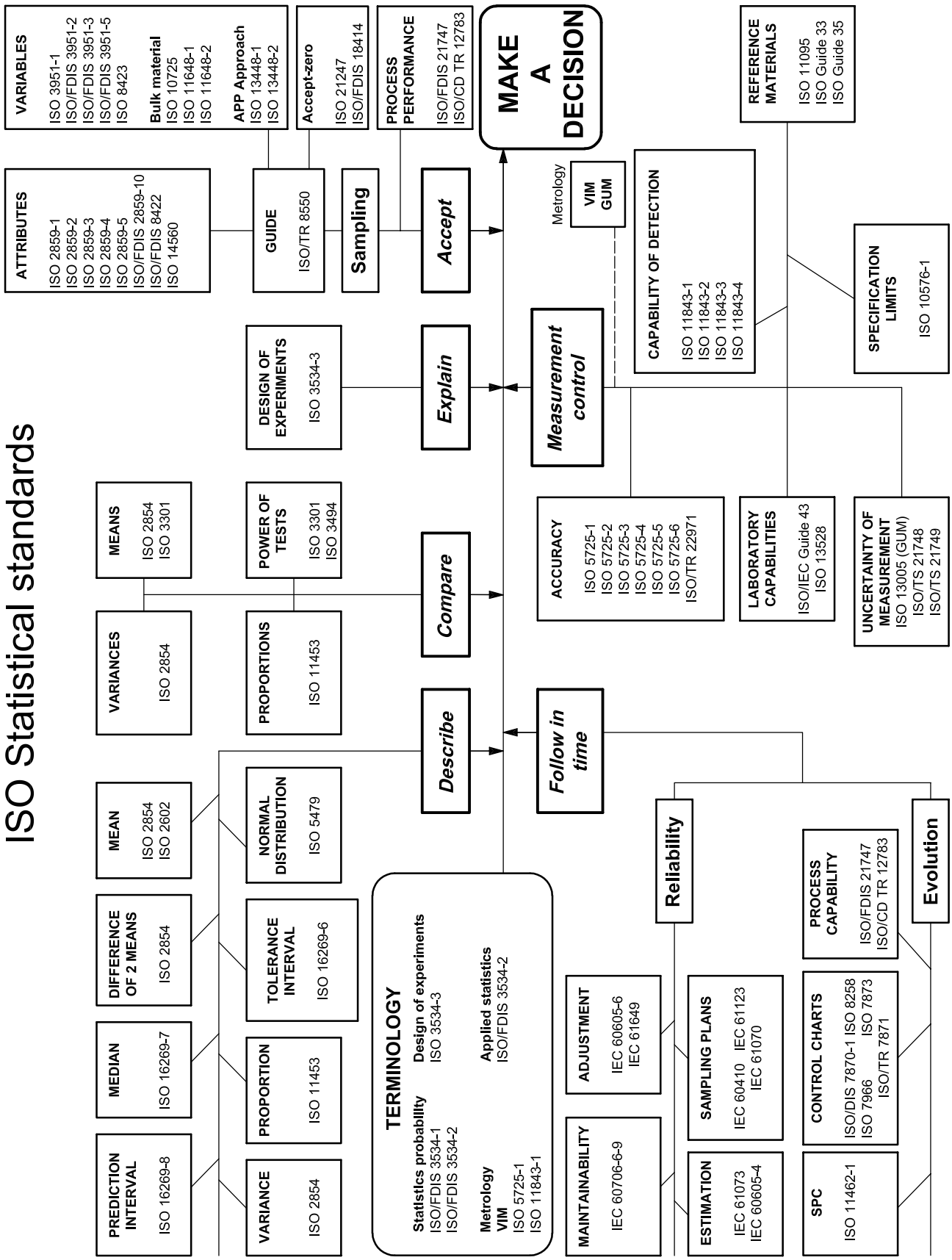
Annex A gives the non-technical and technical abstracts. The non-technical abstracts are usually brief. In these abstracts, the number of technical terms are kept to a minimum. They give brief outlines of the actual documents. The technical abstracts are somewhat longer. More technical terms are used. The technical abstracts also go more into depth with regard to the content and the 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 program.

The types of document are identified as follows:

Published International Standard:	ISO xxxxxxx
Final Draft International Standard:	FDIS
Draft International Standard:	DIS
Committee Draft:	CD
Working Draft:	WD
New work item proposal:	NP
Draft Technical Report:	DTR
Published Technical Report:	TR
Technical Specification	TS

2 Cartography



Annex A
(informative)

Content and use of the referenced standards and DIS

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

ISO Guide 33:2000 ***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 RM:

— 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. CRM are widely used in modern technology and the demand is expected to increase. CRM 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 CRM and examine the conditions under which CRM are properly used and when they are misused.

ISO Guide 35:—[1)] ***Reference materials — General and statistical principles for certification*** **(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 (RM). 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 RM. Another purpose of this Guide is to assist in understanding valid methods for the certification of RM 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 2602:1980 [2)] ***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).

1) To be published. (Revision of ISO Guide 35:1989, *Certification of reference materials — General and statistical principles*)

2) Under revision.

ISO 2854:1976 [3] ***Statistical interpretation of data — Techniques of estimation and tests 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 2859-0:1995 [4] ***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 2859-1:1999 ***Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance 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 discrete 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 2859-2:1985 [5] ***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 2859-3:2005 ***Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures***

ISO 2859-3:2005 is a revision of ISO 2859-3:1991. The purpose of this revision was to make the skip-lot rules more concise and easier to use. This part of ISO 2859 specifies generic skip-lot sampling procedures for reducing the inspection effort on products submitted by those suppliers who have demonstrated their ability to control in an effective manner all facets of quality and who consistently produce lots that meet requirements. The reduction in effort is achieved by determining at random, with a specified probability, whether a lot submitted for inspection will be passed without inspection. This procedure extends to the inspection of lots the principle of random selection applied within ISO 2859-1:1999 to the individuals comprising a lot. ISO 2859-3 is

3) Under revision.

4) Under revision as ISO 2859-10.

5) Under revision.

to be used only for characteristics inspected by attributes as designated in ISO 2859-1. The skip-lot procedures in this part of ISO 2859 can only be implemented if the ISO 2859-1 procedures are in use with normal or reduced inspection at general inspection levels I, II, or III. Multiple sampling plans may only be used during the qualification phase associated with normal inspection. It is strongly recommended that single sampling plans with an acceptance number of zero not be used in this part of ISO 2859. Skip-lot inspection may be used in the place of reduced inspection if it is more economical to do so and the responsible authority approves.

ISO 2859-3:2005 contains three annexes that summarize the options to be agreed upon prior to its use, techniques for random selection, and information to assist in making the decision between reduced and skip-lot inspection.

ISO 2859-4:2002 ***Sampling procedures for inspection by attributes — Part 4: Procedures for assessment of declared quality levels***

The procedures in ISO 2859-4 have been developed as a response to a growing need for sampling plans suitable for formal, systematic inspections such as reviews and audits. The procedures in ISO 2859 Parts 1 to 3 are provided for acceptance sampling purposes only, and are not suitable for the verification of a quality that has been declared for some entity. The sampling plans in ISO 2859-4 have been developed so that there is no more than a 5 % risk of contradicting a declared quality level that is satisfied, and no more than a 10 % probability of failing to contradict a declared quality level that is incorrect.

ISO 2859-5:2005 ***Sampling procedures for inspection by attributes — Part 5: System of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection***

Part 5 of ISO 2859 specifies sequential sampling plans and procedures for the case where lots consist of discrete items and where all the product characteristics involved in the assessment of quality are attributes. Sequential sampling plans are the only statistical procedures that satisfy a need to apply statistical procedures that require the smallest possible sample sizes. For lots of very good quality, the maximum savings for sequential sampling plans, in comparison to single sampling plans, may reach 85 %. ISO/DIS 2859-5 contains sampling plans indexed by percent nonconforming and by nonconformities per 100 items. It 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/FDIS 2859-10 ***Sampling procedures for inspection by attributes — Part 10: Introduction to the ISO 2859 series of attribute sampling standards***

ISO 2859-10 was developed to replace ISO 2859-0:1995. However, ISO 2859-0 contained a detailed discussion of the theory behind acceptance sampling by attributes and a description of ISO 2859-1. It is believed that this theory belongs in ISO/TR 8550, which is under revision, to include the theory behind all parts of ISO 2859 as well as a discussion of sampling by variables. ISO 2859-10 contains a brief summary of the application of attribute sampling and a summary of Parts 1 to 5 of ISO 2859. The purpose of ISO 2859-10 is to introduce each part in such a way that the user can make a logical decision regarding which sampling procedure is most appropriate. For detailed information on each part of ISO 2859, it is necessary for the user to obtain that part of ISO 2859.

ISO 3301:1975 [6] ***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 pre-assigned 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

6) Under revision.

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 3494:1976 [7] ***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 International 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/FDIS 3534-1 ***Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability***

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:

a) terms used in the theory of probability;

b) general statistical terms;

c) general terms relating to observations and test results;

d) 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/FDIS 3534-2 ***Statistics — Vocabulary and symbols — Part 2: Applied statistics***

This part of ISO 3534 defines terms in five areas of applied statistics: data generation and collection; statistical process management; specification, values and measurement and test results; inspection and general acceptance sampling; and sampling of bulk material. A list of standard symbols is also given. The entries are arranged thematically. Interrelationships between the different concepts are demonstrated by a number of concept diagrams. ISO 3534-1 is compatible with ISO 3534-2. In both parts, the mathematical level is restricted as far as possible to attain correct and concise definitions.

ISO 3534-3:1999 ***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:

a) general terms;

b) terms related to arrangements of experiments;

c) 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.

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7) Under revision.

ISO 3951:1989 [8] ***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 3951-1:2005 ***Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL***

ISO 3951 is being developed into a multi-part standard on single sampling by variables. Part 1 of ISO 3951 deals with a single normally distributed quality characteristic in a similar way to that in ISO 3951:1989, except that the discussion is confined to situations where there is only one AQL. It follows that it applies when there is a single upper or lower specification limit and where there are both, provided in the latter case that violation of either limit is of roughly the same seriousness. The preferred sample sizes in Part 1 of ISO 3951 have been changed from those in ISO 3951:1989 in order to provide a better match between the behaviour of the variables plans and the behaviour of the corresponding single sampling plans of ISO 2859-1. A lot is judged as unacceptable when sample measurements of the variable give grounds for believing that the proportion of the items emanating from the process 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/FDIS 3951-2 ***Sampling procedures for inspection by variables — Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics***

ISO 3951 is being developed into a multi-part standard on single sampling by variables. Part 2 of ISO 3951 deals with normally distributed quality characteristics in a similar way to that in ISO 3951:1989, but more generally than in ISO/DIS 3951-1, providing procedures for multiple quality characteristics and multiple AQLs. Part 2 can be applied to any number (including one) of independent quality characteristics that have any combination of single or double specification limits, and provides a single acceptance criterion. The preferred sample sizes in Part 1 of ISO 3951 have been changed from those in ISO 3951:1989 in order to provide a better match between the behaviour of the variables plans and the behaviour of the corresponding single sampling plans of ISO 2859-1. A lot is judged as unacceptable when sample measurements of the variable(s) give grounds for believing that the proportion of the items emanating from the process for which the variable(s) lies(lie) outside specification is at an unacceptably high level. Assessment of acceptability is made in terms of the sample mean(s) and the sample standard deviation(s) (or process standard deviation(s), if known) of the variable(s).

ISO/DIS 3951-3 ***Sampling procedures for inspection by variables — Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection***

ISO 3951-3 provides plans for double sampling by variables for lot-by-lot inspection of a continuing series of lots. These plans on average provide substantial savings of inspection effort in comparison with the corresponding single sampling plans by variables. The savings are achieved by first selecting from the lot and inspecting a random sample that is typically nearly 40 % smaller than that of the corresponding single sampling plan. If these inspection results satisfy an acceptance criterion, an immediate decision is made to accept the lot without further inspection. Alternatively, if the inspection results satisfy a non-acceptance criterion, an immediate decision not to accept the lot is made without further inspection. Thus, when quality is

8) ISO 3951:1989 will be replaced by ISO 3951-1 and ISO 3951-2.

very good or very poor, the saving in inspection effort can amount to nearly 40 %. Only when the inspection results from the first sample are equivocal is a second random sample, of the same size as the first, selected; the acceptability of the lot is then resolved by combining the results of the first and second samples and determining whether they satisfy a second acceptance criterion. However, the average total inspection effort for double sampling schemes is less than that of the corresponding single sampling plan at all, or at least nearly all, process quality levels.

ISO 3951-3 is indexed in terms of the acceptance quality limit (AQL). Schemes are provided for the case where the process standard deviation is known and for the case where it is unknown. (The process mean is generally unknown.) The schemes in the main text are for a single normally-distributed variable. The more complicated procedures for two or more independent normally-distributed variables are provided in annexes.

ISO/FDIS 3951-5 ***Sampling procedures for inspection by variables — Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation)***

Part 5 of ISO 3951 specifies sequential sampling plans and procedures for the case where lots consist of discrete items and where the product characteristic involved in the assessment of quality is a normally distributed variable with known (or precisely estimated) standard deviation. Sequential sampling plans are the only statistical procedures that satisfy a need to apply statistical procedures that require the smallest possible sample sizes. For lots of very good quality, the maximum average savings for sequential sampling plans, in comparison to single sampling plans, may exceed 80 %. Moreover, for lots of very good (or very bad) quality, the decision can be made after the inspection of only one item. ISO 3951-5 contains sampling plans indexed by percent nonconforming. It 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 5479:1997 ***Statistical interpretation of data — 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 International Standard, graphical methods, moment tests, regressions tests, and characteristic function tests are considered.

ISO 5725-1:1994 ***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 5725-2:1994 ***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***

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, 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 5725-3:1994 ***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 5725-4:1994 ***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 5725-5:1998 ***Accuracy (trueness and precision) of measurement methods and results — Part 5: Alternative methods for the determination of the precision of a standard measurement method***

Part 5 of ISO 5725 describes two experiments that may be used in circumstances where the experiment described in Part 2 would give biased estimates of repeatability and reproducibility standard deviations. One is appropriate when there is a risk that operators may allow the result of a measurement on one sample to influence the result of a subsequent measurement on another sample of the same material. The other is appropriate when the materials to be used in the experiment are such that one cannot be confident that identical samples can be prepared. Part 5 also describes “robust” methods of analysing the data obtained from the experiments described in Parts 2 and 5.

ISO 5725-6:1994 ***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/DIS 7870-1 ***Control charts — Part 1: General guidelines***

Every production, service, or administrative process contains a certain amount of inherent variability due to the presence of a large number of unavoidable, but usually minor, chance causes. The observed results from a process are, as a result, not constant. Control charts are used to study this variability to gain an understanding of its characteristics. Such information provides a basis for taking action on a process.

Part 1 of ISO 7870 presents an overview of the basic principles and concepts of control chart, and illustrates the relationship among various control chart approaches to aid in the selection of the most appropriate standard for given circumstances.

ISO/TR 7871:1997 ***Cumulative sum charts — Guidance on 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 7873:1993 [9] ***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 7966:1993 [10] ***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 8258:1991 ***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/FDIS 8422 ***Sequential sampling plans for inspection by attributes***

ISO 8422 specifies sequential sampling plans for the case where inspected lots consist of discrete items and where all the product characteristics involved in the assessment of quality are attributes. Sequential sampling plans are the only statistical procedures that satisfy a need to apply statistical procedures that require the smallest possible sample sizes. ISO/DIS 8422 contains sampling plans indexed by percent nonconforming and by nonconformities per 100 items. In contrast to ISO 2859-5, whose sampling plans have been designed to supplement the ISO 2859-1 acceptance sampling system for inspection by attributes, the sampling plans from ISO 8422 assure that both producer's and consumer's risks are under strict control. Therefore, they may be used when sampling is performed for regulatory reasons, the demonstration of quality of production processes or for statistical hypothesis testing.

ISO 8423:1991 [11] ***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 International 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.

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9) Under revision.

10) Under revision.

11) Under revision. ISO/FDIS 3951-5 replaces Annex A of ISO 8423:1991, which has been technically revised to improve its compatibility with the sampling systems in ISO 3951-1.

ISO/TR 8550:1994 [12] ***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 10576-1:2003 ***Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles***

This part of ISO 10576 sets out guidelines:

a) for drafting requirements that may be formulated as limiting values for a quantifiable characteristic; and

b) for checking conformity to such requirements when the test- or measurement result is subject to uncertainty.

This part of ISO 10576 is applicable whenever the uncertainty may be quantified according to the principles laid down in *Guide to the expression of uncertainty in measurement*. The term uncertainty is thus a descriptor for all sources of variation in the measurement result, including uncertainty due to sampling.

It is outside the scope of this part of ISO 10576 to give rules for how to act when an inconclusive result of a conformity test has been obtained.

ISO 10725:2000 ***Acceptance sampling plans and procedures for the inspection of bulk materials***

ISO 10725 specifies acceptance sampling plans by the determination of variables and use of acceptance inspection procedures for bulk materials. These sampling plans comply with specific operating characteristic curves at reasonable cost. This International Standard is applicable to the inspection where the lot mean of a single quality characteristic is the principal factor in the determination of lot acceptability, but it also gives special procedures for multiple quality characteristics. This International Standard is applicable to the cases where the values of standard deviations at individual stages of sampling are known or are imprecise.

ISO 10725 is applicable to various kinds of bulk materials, but is not always applicable to minerals such as iron ores, coals, crude petroleum, etc., where accurate estimation of the lot mean is more important than the determination of lot acceptability. For special cases when standard procedures are not always adequate and the measurement standard deviation is dominant, this International Standard specifies special acceptance sampling plans and procedures, such as in the case for liquids.

ISO 11095:1996 ***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 (RM). This International Standard applies to measurement systems for which reference materials are available. No distinction is made among the various types of RM and it assumes that the accepted values of the RM 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.

12) Under revision into three parts.

ISO 11453:1996 ***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 11462-1:2001 ***Guidelines for implementation of statistical process control (SPC) — Part 1: Elements of SPC***

Statistical process control (SPC) uses statistical techniques to increase knowledge about a process, to steer a process to behave in a desired way, to reduce variation of final-product parameters and/or in other ways improve its performance. This International Standard provides guidelines for an organization in planning, developing, executing and/or evaluating a statistical process control system. By implementing those guidelines deemed applicable and appropriate by customer and supplier, an organization may satisfy the requirement to adopt a comprehensive and effective SPC system.

ISO 11648-1:2003 ***Statistical aspects of sampling from bulk materials — Part 1: General principles***

Part 1 of ISO 11648 establishes general principles for sampling of bulk material from the aspects of application of statistical methods. It is applicable to general matters which apply to any form of bulk materials, and to statistical theory involved in bulk sampling

International standards dealing with the methods for sampling from bulk materials, such as solid fuels, iron ores, etc. have already been published and some of these are being revised in the responsible technical committees. This part of ISO 11648 provides a resource for technical terms and sampling techniques to types of bulk materials for which International Standards on sampling have not been written. This part of ISO 11648 may also act as a bridge for mutual understanding of terms and methods between technical committees.

This part of ISO 11648 also provides general guidance of application of statistical methods to sampling from bulk materials, such as how to estimate necessary variances for establishment of a sampling plan and how to check precision and bias when the average value of the checked quality characteristics is investigated. In addition, it gives information relating to the statistical analyses of serial data, such as variogram and correlogram.

ISO 11648-2:2001 ***Statistical aspects of sampling from bulk materials — Part 2: Sampling of particulate materials***

Part 2 of ISO 11648 provides basic methods for sampling particulate materials in bulk such as ores, mineral concentrates, coal, industrial chemicals in powder or granular form or agricultural products such as grain. Mechanical sampling from moving streams, manual sampling from moving streams, stopped-belt sampling, and sampling from stationary situations are considered. It describes the requirements that are to be met to provide samples for measuring one or more variables in an unbiased manner and with a known degree of precision.

ISO 11843-1:1997 ***Capability of detection — Part 1: Terms and definitions***

Part 1 of ISO 11843 specifies terms and definitions relating to the detection of a difference between an actual state of a system and its basic state. Thus in the case of chemical analysis, it is applicable when the object of analysis is to detect a difference between the concentration of an analyte in a material and the concentration of the analyze in a blank material.

ISO 11843-2:2000 ***Capability of detection — Part 2: Methodology in the linear calibration case***

Part 2 of ISO 11843 sets out the design of experiments that may be used to estimate the terms defined in Part 1, and describes how to calculate estimates of their values from the experimental data. In the section on the reporting and use of results, it contains the important requirement that results that fall below the critical value of the net state variable should not be reported as “zero” or “smaller than minimum detectable value” – in such cases the actual value should always be reported.

ISO 11843-3:2003 ***Capability of detection — Part 3: Methodology for determination of the critical value for the response variable when no calibration data are used***

Part 3 of ISO 11843 sets out the design of experiments that may be used to estimate the terms defined in Part 1, and describes how to calculate estimates of their values from the experimental data. The procedure given in Part 3 for the determination of the critical value of the response variable only is recommended for situations in which no calibration data are used. In the section on the reporting and use of the critical values, a convenient tabular form is described for setting out the required corresponding experimental parameters.

ISO 11843-4:2003 ***Capability of detection — Part 4: Methodology for comparing the minimum detectable value with a given value***

Part 4 of ISO 11843 provides a criterion for judging a requirement on the capability of detection and sets out the design of experiments that may be used for testing the conformity of this criterion. This assessment is valid without the assumptions necessary for the estimates according to Part 2.

ISO 13448-1:2005 ***Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 1: Guidelines for the APP approach***

The ISO 13448 series provides a new acceptance sampling methodology in support of quality management. This could be beneficial for users of ISO 9001:2000 or ISO 9004:2000. ISO 13448-1 gives guidance and explains the methodology, which is based on the “allocation of priorities principle” (APP). The procedures in the ISO 13448 series have considerable advantages under certain circumstances. A novel feature is the ability to use practically any type of prior objective and subjective information when determining the appropriate sampling plan. Examples of such information are inspection results for previous lots, certification of quality management systems as being in conformity with ISO 9001:2000, quality control data and customers' subjective estimates of the supplier's capability to provide the desired quality, all of which may be summarized in a trust level. This allows a progressive reduction in sample size as the customer's trust in the producer increases.

ISO 13448-2:2004 ***Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 2: Coordinated single sampling plans for acceptance sampling by attributes***

Part 2 of ISO 13448 provides attributes single sampling plans for inspection of lots. All subjective and objective information of the supplier's capability to provide the desired quality, including any certification of its quality management system to ISO 9001 or an equivalent standard, may be taken into account by the customer or a third party when deciding on his sampling plan, thus allowing smaller sample sizes when the information is favourable.

Part 2 of ISO 13448 also provides for the case where successive sample inspections are performed on the same lot by different parties (i.e. producer, customer and/or a third party), allowing each party independence of choice of sampling plan, needing only to coordinate their sampling plans with specific requirements such as customer's or producer's risks. This feature enables each party to organize inspection in accordance with its own resources and significantly reduces the chance of different parties obtaining conflicting results due to sampling variability.

ISO 13528:2005 ***Statistical methods for use in proficiency testing by interlaboratory comparisons***

This International Standard provides detailed descriptions of sound statistical methods to use to analyse the data obtained from proficiency testing schemes, and gives recommendations on their use in practice by participants in such schemes and by accreditation bodies. It is intended as a companion to ISO/IEC Guide 43, *Development and operation of laboratory proficiency testing.*

ISO 14560:2004 ***Acceptance sampling procedures by attributes — Specified quality levels in nonconforming items per million***

This International Standard uses nonconforming items per million items in its estimating and reporting of quality levels and in its indexing of sampling plans. Sampling plans are provided for verifying that the quality level of a given lot does not exceed a stated quality level. Procedures are also provided for estimating product or process quality levels. A key feature of this International Standard is that it provides incentives for suppliers to improve their quality by requiring larger sample sizes for lot acceptance when quality declines and smaller sample sizes when quality improves. The sampling plans by attributes in this International Standard are listed with various quality levels and their corresponding producer's and consumer's risk levels.

ISO 16269-6:2005 ***Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals***

This International Standard describes procedures for establishing statistical tolerance intervals that include at least a specified proportion of the population with a specified confidence level. Both one-sided and two-sided statistical tolerance intervals are provided, a one-sided interval having an upper or a lower limit while a two-sided interval has both upper and lower limits. Two methods are provided, a parametric method for the case where the characteristic being studied has a normal distribution and a distribution-free method for the case where nothing about the distribution except that it is continuous. Extensive tables are provided to determine the intervals.

ISO 16269-7:2001 ***Statistical interpretation of data — Part 7: Median — Estimation and confidence intervals***

The median of a population is a numerical value such that the numbers in the population lying on either side of it are equal. This International Standard specifies procedures for establishing a point estimate and confidence intervals for the median of a population, based on a random sample of size n from that population.

ISO 16269-8:2004 ***Statistical interpretation of data — Part 8: Determination of prediction intervals***

This International Standard describes procedures for establishing a range of values of a characteristic from a random sample of a given size (n) from a population, such that the range can be asserted with a given level of confidence to include all but at most r of a further m sample values of the characteristic from the same population. Two methods are provided, a parametric method for the case where $r = 0$ and the characteristic being studied has a normal distribution, and a distribution-free method for $r = 0, 1, \ldots, 10$ for the case where nothing is known about the distribution except that it is continuous. The parametric case further subdivides into the case where the standard deviation is known and the case where it is estimated. Extensive tables are provided of the factors required to determine the intervals.

Prediction intervals are a valuable tool wherever it is desired or required to predict the results of a future sample of a given number of discrete items from the results of an earlier sample of items produced under identical conditions. They are of particular use to engineers who need to be able to set limits on the performance of a finite number of manufactured items. This is of increasing importance with the trend to shift back to small-scale production in some industries.

ISO/FDIS 18414 ***Acceptance sampling procedures by attributes — Accept-zero sampling system based on credit principle for controlling outgoing quality***

For lot-by-lot inspection of a continuing series of lots where the inspection is by attributes and is non-destructive, ISO 18414 provides an efficient method for guaranteeing any user-specified average outgoing quality limit (AOQL) using single sampling plans. All the sampling plans have an acceptance number of zero, i.e. no lot is accepted if the sample from it contains one or more nonconforming items. Thus, only the sample size may change for each successive lot. Based on the "credit" accumulated from the previous lots, the sample size for the next lot is determined from a simple rule, tending to progressively decrease while no nonconforming items are found in the samples. However, as soon as one or more nonconforming items are found, the sample size reverts to a larger value, which provides an incentive for the producer to maintain a nonconformity-free process in order to keep inspection costs to a minimum.

ISO 18414 has an advantage over other AOQL-indexed systems in that 100 % inspection of large lots can be avoided without compromising the AOQL.

ISO 18414 can be suitable for regulatory purposes, as control of the expected quality of items reaching the market-place is achieved with the smallest possible sample sizes. It can be used by suppliers/producers, buyers/consumers and regulatory agencies to provide control of the expected quality of the totality of accepted product of each type from each source.

ISO 21247:2005 ***Combined accept-zero sampling systems and process control procedures for product acceptance***

This International Standard provides a set of sampling plans and procedures to assess conformance to specified requirements. These plans do not permit any nonconformances in the samples taken for acceptance. Plans are provided for sampling by attributes, sampling by variables, or continuous sampling by attributes. This International Standard also permits and, in fact, encourages the use of alternative methods for acceptance in lieu of acceptance by its tables.

ISO/FDIS 21747 ***Statistical methods — Process performance and capability statistics for measured quality characteristics***

Calculated statistical values are used for the evaluation of manufacturing processes, in order to describe the basic quality characteristics of the processes. This norm describes procedures for the determination of these statistical values.

ISO/TS 21748:2004 ***Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation***

ISO/TS 21748 provides an appropriate and economic methodology for estimating measurement uncertainty associated with the results of standard test methods subjected to collaborative study according to Part 2 of ISO 5725, *Accuracy (trueness and precision) of measurement methods and results*. Without a quantitative assessment of uncertainty, it is impossible to decide whether observed differences between results reflect more than experimental variability, whether test items comply with specifications, or whether laws based on limits have been broken. The methodology complies fully with the relevant principles of the *Guide to the Expression of Uncertainty in Measurement*, published by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, whilst taking account of method performance data obtained by collaborative study.

ISO/TS 21749:2005 ***Measurement uncertainty for metrological applications — Repeated measurements and nested experiments***

ISO/TS 21749 provides guidance on the evaluation of the uncertainties associated with the measurement of test items, for instance as part of ongoing manufacturing inspection. Such uncertainties contain contributions from the measurement process itself and from the variability of the manufacturing process. Both types of contribution include those from operators, environmental conditions and other effects. In order to assist in separating the effects of the measurement process and manufacturing variability, measurements of check standards are used to provide data on the measurement process itself. The guidance complies with the principles of the *Guide to the Expression of Uncertainty in Measurement*, published by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML.

ISO/TR 22971:2005 ***Accuracy (trueness and precision) of measurement methods and results — Practical guidance for the use of ISO 5725-2:1994 in designing, implementing and statistically analysing interlaboratory repeatability and reproducibility results***

The primary purpose of this document is to provide users with practical guidance to the use of ISO 5725-2:1994, *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*. Information is presented in a simple step-by-step procedure for the design, implementation, and statistical analysis of inter-laboratory studies for assessing the variability of a standard measurement method and on the determination of repeatability and reproducibility of data obtained in inter-laboratory testing.

It is recommended that this guidance document is read in conjunction with ISO 5725-2.

A.2 Technical abstracts of ISO/TC 69 standards

ISO Guide 33:2000 ***Uses of certified reference materials*** **(Developed jointly by REMCO and ISO/TC 69)**

Certified Reference Materials (CRM) 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 CRM. It pertains only to CRM characterized to be homogeneous as described in ISO Guide 35. The use of the CRM is essential for assessment of trueness and optional for assessment of precision;

— Section 3 discusses the use of CRM for the definition and realization of conventional measurement.

ISO Guide 35:—[13)] ***Reference materials — General and statistical principles for certification*** **(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 (RM) and also to help potential users to better define their technical requirements. The Guide should be useful in establishing the full potential of certified RM 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 RM. It deals with two of the most important technical considerations in the certification of RM: 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.

13) To be published. (Revision of ISO Guide 35:1989, *Certification of reference materials — General and statistical principles*)

ISO 2602:1980 [14] ***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 2854:1976 [15] ***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 2859-0:1995 [16] ***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 2859-1:1999 ***Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality level (AQL) for lot-by-lot inspection***

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:

a) 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;

b) 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.

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14) Under revision.

15) Under revision.

16) Under revision as ISO 2859-10.

ISO 2859-2:1985 [17] ***Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection***

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 2859-3:2005 ***Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures***

Part 3 of ISO 2859 is intended to supplement the ISO 2859-1 sampling system and should be used together with that system. The skip-lot sampling procedures specified in this part of ISO 2859 are intended only for a continuing series of lots. All lots in the series are expected to be of a similar quality and there should be reason to believe that the lots not inspected are of the same quality as those inspected. Skip-lot sampling procedures may be used instead of reduced inspection but its application and switching rules are different from those for reduced inspection in ISO 2859-1. The supplier using this procedure must be qualified by a quality management standard such as ISO 9001. The product must be of a stable design. The AQL(s) must be at least 0,025 percent. The product shall have been on normal or reduced inspection during the period in which it is qualified. A qualification score, similar to that used for reduced inspection in ISO 2859-1, is used to qualify the product for skip-lot inspection. Inspection frequencies of 1 in 2, 1 in 3, 1 in 4, and 1 in 5 are used, depending on the qualification score and the quality of lots inspected during the skip-lot stage. Procedures are also available for switching between inspection frequencies and a return to inspection of each lot.

ISO 2859-4:2002 ***Sampling procedures for inspection by attributes — Part 4: Procedures for assessment of declared quality levels***

Procedures in ISO 2859 Parts 1, 2 and 3 are well suited for acceptance sampling purposes, but they should not be used in reviews or audits to verify a quality that has been declared for some entity. The main reason for this is that the procedures have been indexed in terms of quality levels that are relevant solely for the pragmatic purposes of acceptance sampling, and the various risks have been balanced accordingly. The procedures in this part of ISO 2859 have been developed as a response to the growing need for sampling procedures suitable for formal inspections such as reviews or audits. When performing such formal inspections, it is necessary for the responsible authority to consider the risks of accepting nonconforming entities or not accepting conforming ones, and to take these risks into account in the planning and execution of these inspections. This part of ISO 2859 provides guidance and rules to assist the user in taking these risks into account in an informed manner.

17) Under revision.

ISO 2859-5:2005 ***Sampling procedures for inspection by attributes — Part 5: System of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection***

This part 5 of ISO 2859 is a sampling system indexed by lot-size ranges, inspection levels and AQLs and specifies sequential sampling plans and procedures for inspection by attributes of discrete items. It contains sampling plans for sequential sampling indexed by percent nonconforming and nonconformities per 100 items. ISO 2859-5 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 2859-5 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.

The statistical characteristics of sampling plans in ISO 2859-5 are approximately the same as the characteristics of the equivalent sampling plans from ISO 2859-1. Therefore, the sampling system from ISO 2859-5 may be used instead of the sampling system from ISO 2859-1 when a user needs to decrease sampling costs, and accepts more complicated rules of sequential sampling plans.

ISO/FDIS 2859-10 ***Sampling procedures for inspection by attributes — Part 10: Introduction to the ISO 2859 series of attribute sampling standards***

The purpose of ISO 2859-10 is to provide the user with enough information regarding Parts 1 to 5 of ISO 2859 to enable a decision to be made as to which part would be most appropriate. The standard contains a general introduction to acceptance inspection by attributes. The sampling schemes and plans in the various parts of ISO 2859 are introduced along with an example of the use of each part. The reasons for avoiding sampling procedures that are not based on the mathematical theory of probability are presented along with a brief summary of the advantages of using the schemes and plans in the series. Details of the use of each part are found in the standards themselves. The use of each part in this International Standard is illustrated by means of examples.

ISO 3301:1975 [18] ***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 pre-assigned 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 3494:1976 [19] ***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 International 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.

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18) Under revision.

19) Under revision.

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

This (draft) 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 contains general statistical terms;

— the third section contains general terms relating to observational and test results; and

— the fourth contains 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/FDIS 3534-2 ***Statistics — Vocabulary and symbols — Part 2: Applied statistics***

This (draft) International Standard defines coherent sets of concepts and the terms expressing these concepts in five different areas of applied statistics: data generation and collection; statistical process management; specification, values, and measurement and test results; inspection and general acceptance sampling; and sampling of bulk material. These terms may be used in drafting of other International Standards. For each area, the different concepts are arranged thematically in a conceptual framework in accordance with normative terminology practice by means of several concept diagrams which describes in detail the interrelationships between the different concepts and thus provide a deeper understanding of the individual concepts. A list of standard symbols and abbreviations is also given. Alphabetical indexes are included. ISO 3534-1 and ISO 3534-2 are intended to be compatible. They share the common goal of restricting their respective mathematical levels to the minimum levels necessary to attain correct and concise definitions.

ISO 3534-3:1999 ***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 3951:1989 [20] ***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 AQL and is complementary to ISO 2859-1. The two International 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

20) ISO 3951:1989 will be replaced by ISO 3951-1 and ISO 3951-2.

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 3951-1:2005 ***Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL***

ISO 3951 is being developed into a multi-part standard on single sampling by variables. Part 1 of ISO 3951 deals with a single normally distributed quality characteristic in a similar way to that in ISO 3951:1989, except that the discussion is confined to situations where there is only one AQL. It follows that it applies to the control of a single specification limit or to the combined control of double specification limits. The preferred sample sizes in Part 1 of ISO 3951 have been changed from those in ISO 3951:1989 in order to provide a better match between the operating characteristic (OC) curves of the variables plans and the OC curves of the corresponding attributes single sampling plans of ISO 2859-1. A lot is judged as unacceptable when sample measurements of the quality characteristic indicate that the process fraction nonconforming is at an unacceptably high level. The acceptability criterion is a function of the sample mean and the sample standard deviation (or process standard deviation, if known) of the quality characteristic. A choice is available between equivalent numerical and graphical acceptance criteria.

ISO/FDIS 3951-2 ***Sampling procedures for inspection by variables — Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics***

ISO 3951 is being developed into a multi-part standard on single sampling by variables. Part 2 of ISO 3951 provides the means to formulate a single acceptance criterion for a class of any number of independent, normally distributed quality characteristics, to which a single AQL applies. Within a class, some quality characteristics may require control of a single specification limit while others may require combined control of double specification limits. A quality characteristic requiring separate or complex control of double specification limits will therefore appear in two classes. For multiple classes, the lot is acceptable if and only if the acceptance criterion for every class is satisfied.

The preferred sample sizes in Part 2 of ISO 3951 have been changed from those in ISO 3951:1989 in order to provide a better match between the operating characteristic (OC) curves of the variables plans and the OC curves of the corresponding attributes single sampling plans of ISO 2859-1. Assessment of acceptability is based on an implicit or explicit estimate of the process fraction nonconforming, determined as a function of the sample mean(s) and the sample standard deviation(s) (or process standard deviation(s), if known) of the quality characteristic(s).

ISO/DIS 3951-3 ***Sampling procedures for inspection by variables — Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection***

This part of ISO 3951 specifies an acceptance sampling system of double sampling schemes for lot-by-lot inspection by variables for percent nonconforming. It is indexed in terms of the acceptance quality limit (AQL). Schemes are provided for the case where the process standard deviation is known and for the case where it is unknown. It is assumed that all quality characteristics to which this part of ISO 3951 is applied are normally distributed.

The schemes provided in this part of ISO 3951 have operating characteristic (OC) curves that are matched as closely as possible to the OC curves of the corresponding single sampling plans of ISO 2859-1, subject to the first and second sample sizes being equal.

In this part of ISO 3951, the acceptability of a lot is implicitly (i.e. the Form k method) or explicitly (i.e. the Form p* method) determined from an estimate of the percentage of nonconforming items in the process, based on either one or two random samples of items from the lot. The main text presents univariate schemes, but multivariate independent procedures are also provided, in informative annexes. No procedures are provided for two or more dependent quality characteristics. Measurement error is assumed to be negligible.

ISO/FDIS 3951-5 ***Sampling procedures for inspection by variables — Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation)***

Part 5 of ISO 3951 is a sampling system indexed by lot-size ranges, inspection levels and AQLs, and specifies sequential sampling plans and procedures for inspection by variables of discrete items. It is assumed that the product characteristic involved in the assessment of quality is a normally distributed variable with known (or precisely estimated) standard deviation. ISO 3951-5 contains sampling plans for sequential sampling indexed by percent nonconforming. It 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 3951-5 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. The continuing series of lots should be of sufficient duration to allow the switching rules to be applied.

The statistical characteristics of sampling plans in ISO 3951-5 are approximately the same as the characteristics of the equivalent single sampling plans from ISO 3951-1, but the average sampling effort, while using the sampling plans from ISO 3951-5, is much smaller in comparison to that of ISO 3951-1. For lots of very good quality, the maximum average savings for sequential sampling plans, in comparison to single sampling plans, may exceed 80 %. Moreover, for lots of very good (or very bad) quality, the decision can be made after the inspection of only one item. Therefore, the sampling system from ISO 3951-5 may be used instead of the sampling system from ISO 3951-1 when a user needs to decrease sampling costs, and accepts more complicated rules of sequential sampling plans.

ISO 5479:1997 ***Statistical interpretation of data — Tests for departure from the normal distribution***

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 International 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-test), and characteristic function tests (Epps-Pulley-test) are considered.

ISO 5725-1:1994 ***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 5725-2:1994 ***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***

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 5725-3:1994 ***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 5725-4:1994 ***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 5725-5:1998 ***Accuracy (trueness and precision) of measurement methods and results — Part 5: Alternative methods for the determination of the precision of a standard measurement method***

Part 5 of ISO 5725 describes two experiments that may be used in circumstances where the experiment described in Part 2 would give biased estimates of repeatability and reproducibility standard deviations. One experiment is the split-level design, which is appropriate when there is a risk that operators may allow the result of a measurement on one sample to influence the result of a subsequent measurement on another sample of the same material. (If the uniform level design is used in this situation, the repeatability standard deviation may be reduced but the between-laboratory variation increased). The other experiment is the design for a heterogeneous material, which is appropriate when the materials to be used in the experiment are such that one cannot be confident that identical samples can be prepared. (If the uniform-level experiment is applied with such materials, variation between the samples will inflate the estimate of the reproducibility standard deviation). Part 5 also describes "robust" methods of analyzing the data obtained from the experiments described in Part 2 and 5. These methods do not require data that are found to be outliers to be excluded from the calculations, and will be more suitable with a new measurement method that gives rise to many outliers, or in the context of proficiency testing. Examples are given of all of the methods.

ISO 5725-6:1994 ***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. 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/DIS 7870-1 ***Control charts — Part 1: General guidelines***

This (draft) International Standard presents key elements and philosophy of the control chart approach, and identifies a wide variety of control charts, including those related to the Shewhart control chart and those stressing process acceptance or on-line process adjustment.

ISO/TR 7871:1997 ***Cumulative sum charts — Guidance on quality control and data analysis using 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 7873:1993 [21] ***Control charts for arithmetic average with warning limits***

This International 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 8258. 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 annex, the theoretical principles underlying this International Standard are outlined.

ISO 7966:1993 [22] ***Acceptance control charts***

The acceptance control chart is a graphical method for evaluating if a process is in a "state of statistical control" with respect to sample or subgroup variation, and if it can be expected to satisfy product or service specifications for the characteristic(s) being measured. In contrast to control charts of the Shewhart type (see ISO 8258), the basic assumption for acceptance control charts is that the process can remain in control any level within a zone of acceptable process levels not only at a single level. Above and below this zone there is a zone of rejectable process levels. Between these zones there are indifference zones.

Four elements are required for the definition of an acceptance control chart:

a) an border-line acceptable process level (APL) with an alpha-risk for rejecting an acceptable process;

b) a border-line rejectable process level (RPL) with a beta-risk for accepting an unacceptable process;

c) an action criterion or acceptable control limit;

d) the sample size n. For both APL and RPL, there might be upper and lower levels.

The specification of any two of the defining elements APL, RPL, acceptance control limit, or sample size of an acceptance control chart system determines the remaining two values. The standard explains the construction of charts on the basis of any pair of these specifications. The procedures are illustrated by several examples. Nomograms are given for the design of acceptance control charts.

ISO 8258:1991 ***Shewhart control charts***

This is a guide to the use and understanding of the Shewhart control chart approach to statistical process control and limited to only this type of control charts. (A general description of control chart methods is given in ISO 7870.) This chart requires data obtained by sampling subgroups of items from the process at regular intervals, each subgroup consisting of the same product or service with the same measurable units and the same subgroup size. From each subgroup, one or more subgroup characteristics are derived, e.g. subgroup average and subgroup range or subgroup standard deviation. A Shewhart control chart is a graph of the values of a given subgroup characteristic versus the subgroup number. It consists of a central line located at a reference or target value of the characteristic and of two statistically determined control limits, each on either side of the central line. There are two basic types of Shewhart control charts: those with standard values given and those without any. Types of variables and attributes control charts are discussed. The different stages from preliminary considerations to the construction of the chart are described and discussed together with control procedures and interpretations of the control charts. Illustrative examples are given of different types of Shewhart control charts. Control charts with warning limits are discussed in ISO 7873.

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21) Under revision.

22) Under revision.

ISO/FDIS 8422 ***Sequential sampling plans for inspection by attributes***

ISO 8422 specifies sequential sampling plans for the case where inspected lots consist of discrete items and where all the product characteristics involved in the assessment of quality are attributes. The sampling plans from ISO 8422 should primarily be used for the analysis of samples taken from processes. For example, they may be used for the acceptance sampling of lots taken from a process that is under statistical control. However, they may be also be used for the acceptance sampling of an isolated lot when its size is large, and the expected fraction nonconforming is small (significantly smaller than 10 %). Sequential sampling plans are the only statistical procedures that satisfy a need to apply statistical procedures that require the smallest possible sample sizes.

ISO 8422 contains sampling plans indexed by percent nonconforming and by nonconformities per 100 items. The sampling plans are indexed by two parameters: producer's risk quality (with the producer's risk set to 5 %) and consumer's risk quality (with the producer's risk set to 10 %). Thus, in contrast to ISO 2859-5, whose sampling plans have been designed to supplement the ISO 2859-1 acceptance sampling system for inspection by attributes, the sampling plans from ISO 8422 assure that both producer's and consumer's risks are under strict control. Therefore, they may be used when sampling is performed for regulatory reasons, the demonstration of quality of production processes or for statistical hypothesis testing.

ISO 8423:1991 [23] ***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 under sequential sampling for percent nonconforming when inspection is by variables, and the standard deviation may be considered to be known. A sequential sampling procedure is a procedure where items are selected and subjected to inspection 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. The standard provides a general method for constructing sequential sampling plans with given consumer's and producer's risks. Tables of sampling plans having specified the producer's risk to 5 %, and the consumer's risk to 10 % are given. An annex of the standard provides sequential sampling plans that may be used to substitute the sampling plans in ISO 3951.

ISO/TR 8550:1994 [24] ***Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots***

The primary purpose of ISO/TR 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.

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23) Under revision. ISO/FDIS 3951-5 replaces Annex A of ISO 8423:1991, which has been technically revised to improve its compatibility with the sampling systems in ISO 3951-1.

24) Under revision into three parts.

ISO 10576-1:2003 ***Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles***

Conformity testing is a systematic examination of the extent to which an entity conforms to a specified criterion. The objective is to provide assurance of conformity, either in the form of a supplier's declaration, or of a third party certification (see ISO/IEC Guide 2:1996). A specification is usually formulated as a single limiting value, LV, or as a set of (upper and lower) limiting values for a measurable characteristic. When the specification refers, e.g. to health related characteristics, the limiting values are sometimes termed *threshold limit value* TLV, or *permissible exposure limits*, PEL.

Whenever conformity testing involves measurement- or sampling uncertainty, it is common practice to invoke elements from the theory of statistical hypothesis testing to provide a formal procedure. With the knowledge of the measurement procedure and of its behaviour with regard to the uncertainty of its outcomes it is possible to estimate and minimize the risk of making erroneous declarations of conformity or non-conformity to the specifications. An operational way of formulating requirements of assurance is to require that whenever an entity has been declared to be conforming, this status should not be altered by subsequent measurements on the entity, even using more precise measurements (e.g. a better measurement method or technology). Alternatively, in terms of risks, the risk of (erroneously) declaring a non-conforming entity to be conforming shall be small. Consequently, it is necessary to tolerate a (large) risk that an entity, which only marginally conforms, will fail to be declared as conforming. Applying a two-stage procedure instead of a one-stage procedure will in general decrease this risk.

When a test for non-conformity is performed, similar considerations are valid.

ISO 10725:2000 ***Acceptance sampling plans and procedures for the inspection of bulk materials***

ISO 10725 specifies acceptance sampling plans by the determination of variables and use of acceptance inspection procedures for bulk materials. These sampling plans comply with specific operating characteristic curves at reasonable cost. This International Standard is applicable to the inspection where the lot mean of a single quality characteristic is the principal factor in the determination of lot acceptability, but it also gives special procedures for multiple quality characteristics. This International Standard is applicable to the cases where the values of standard deviations at individual stages of sampling are known or are imprecise.

ISO 10725 is based on the assumptions of known and stable standard deviations. In order to judge stability of each standard deviation, a special type of control charts are used, and the values of the factor for obtaining upper control limit are tabulated for large degrees of freedom. It is equivalent to an extended F-test.

The sampling plans can be adjusted to the quality level of the supplied material, though switching rules are not provided.

Annex C provides theoretical background for "known standard deviations", such as the following:

a) mathematical aspects of the assumptions,

b) mathematical models for a single characteristic,

c) mathematical models for multiple characteristics, and

d) brief description for the procedures of design calculation.

e) Annex C also provides brief description for "imprecise standard deviations".

Annex D provides both theoretical information and practical methods for calculation of OC curves.

The subject of ISO 10725 locates on the border line between bulk sampling and acceptance sampling, and attention has been paid for consistency with other International Standards prepared by ISO/TC 69/SC 3 and SC 5, including ISO 11648-1.

ISO 11095:1996 ***Linear calibration using reference materials***

This International Standard has three purposes:

— first, to outline the general principles to calibrate a measurement system and to maintain that "calibrated" measurement system in a state of statistical control;

— second, to provide a basic method to estimate a linear calibration function under either one of two assumptions relating to the variability of measurements, to check the assumption of linearity of the calibration function and the assumptions on the variability of the measurements, and to estimate the value of a new unknown quantity by transforming the measurements made on that quantity with the calibration function;

— third, to provide a control method for extended use of a calibration function to detect when the calibration function needs to be updated, and to estimate the uncertainty of the measurements after transformation with the calibration function.

Two alternatives are provided to the basic method under special conditions. An example is given to illustrate the basic method and the control method.

ISO 11453:1996 ***Statistical interpretation of data — Tests and confidence intervals relating to proportions***

This International Standard provides procedures for estimation of the proportion p of items with a specific characteristic from a sample of n items from a population. As well procedures for point estimation as one- and two-sided confidence intervals are given. Furthermore, significance tests on the proportions p are given for comparisons of a proportion with a given value p_0 and for comparisons of two proportions, and procedures for determining samples sizes for these tests to have a specified power are also provided. It is essential that the drawing of samples does not have any appreciable effect on the population. If the sample drawn at random is less than 10 % of the population, this is usually satisfactory; but if the sample is greater than this, reliable results can be obtained by the procedures given in this International Standard only by replacing each item sampled before drawing the next item at random from the population. The different procedures are set up in three different forms, and their use are illustrated by numerical examples.

ISO 11462-1:2001 ***Guidelines for implementation of statistical process control (SPC) — Part 1: Elements of SPC***

This International Standard provides guidelines for the implementation of a statistical process control (SPC) system. These guidelines are aimed primarily at increasing production efficiency and inherent capability for a given amount of resource input. This International Standard integrates the traditional definitions of statistical process control, algorithmic process control, and model-based control methods. It also extends the definition of the term "parameter" to apply to a process parameter or a product parameter; and to recognize that a product parameter can be either an in-process parameter or a final-product parameter. It is intended that elements of this International Standard be selected based on their applicability and appropriateness to a specific process. The selection of SPC elements, the order in which an organization implements these elements, and the extent to which the elements are applied and adopted by an organization all depend on factors including: customer needs, market being served, nature of product or service, technology, and the nature and speed of production and transaction processes. These SPC guidelines are complementary (not alternative) to technical specified requirements and quality system requirements. They are generic, independent of any specific process, industry or economic sector. It is not the purpose of these SPC system guidelines to enforce uniformity of statistical process control systems.

ISO 11648-1:2003 ***Statistical aspects of sampling from bulk materials — Part 1: General principles***

ISO 11648-1 also gives guidance for the application of statistical methods. For example, different methods of bias testing are specified in the above International Standards and the users of them can not judge which is better. ISO 11648-1 attempts to provide a basis for bias testing, introducing direct estimation of error variances by duplicate measurements of each member of paired data. This leads more accumulation of knowledge about error variances than any of the methods ever proposed for bias testing.

The necessity of study on application of serial data analysis, e.g. variogram method, to establishment of sampling plan from bulk materials has been suggested recently. ISO 11648-1 gives further information of applications of serial data analysis to the various kinds of data rather than a standard, because the technique is developing now.

ISO 11648-2:2001 ***Statistical aspects of sampling from bulk materials — Part 2: Sampling of particulate materials***

Part 2 of ISO 11648 provides basic methods for sampling particulate materials in bulk such as ores, mineral concentrates, coal, industrial chemicals in powder or granular form or agricultural products such as grain.

Mechanical sampling from moving streams, manual sampling from moving streams, stopped-belt sampling, and sampling from stationary situations are considered. It gives a mathematical model to describe the various sources of error that influence the outcome of sampling, and describes how the variances associated with these sources of error may be estimated. It gives the performance criteria that are to be met if bias is to be avoided, and methods for calculating the number of sampling increments and the sample mass required to achieve a chosen degree of precision. It also describes practical methods for preparing test samples from gross samples.

ISO 11843-1:1997 ***Capability of detection — Part 1: Terms and definitions***

Part 1 of ISO 11843 specifies terms and definitions relating to the detection of a difference between an actual state of a system and its basic state, including the critical value of the net state variable. According to these definitions, the estimated value of a net state variable will exceeds its critical value with only a small probability when the system is in its basic state. Hence when this critical value is exceeded it may be concluded, with a small probability of being incorrect, that the system is not in its basic state. In the case of chemical analysis, when the measured concentration exceeds the minimum detectable value, it may be concluded, with a small probability of being incorrect, that the concentration of an analyte exceeds that in the blank material.

ISO 11843-2:2000 ***Capability of detection — Part 2: Methodology in the linear calibration case***

Part 2 of ISO 11843 sets out the design of experiments that may be used to estimate the terms defined in Part 1, and describes how to calculate estimates of their values from the experimental data. It is applicable when the calibration function that relates the state variable to the response variable is linear, and when the repeatability standard deviation is either constant or linearly related to the net state variable. It contains formulae for the computation of the calibration function, the critical value of the net state variable, and the minimum detectable value, and includes an Annex giving some numerical examples of these calculations.

ISO 11843-3:2003 ***Capability of detection — Part 3: Methodology for determination of the critical value for the response variable when no calibration data are used***

Part 3 of ISO 11843 sets out the design of experiments that may be used to estimate the terms defined in Part 1, and describes how to calculate estimates of their values from the experimental data. The procedure given in Part 3 for the determination of the critical value of the response variable only is recommended for situations in which no calibration data are used. The distribution of data is assumed to be normal or near-normal. The procedure is recommended for situations in which it is difficult to obtain a large amount of the actual states although a large amount of the basic state can be prepared. It contains formulae for the computation of the critical value of the response variable, and includes an annex giving some numerical examples of the calculation.

ISO 11843-4:2004 ***Capability of detection — Part 4: Methodology for comparing the minimum detectable value with a given value***

Part 4 of ISO 11843 provides a criterion for judging whether the minimum detectable value is less than a given value of the net state variable and sets out the design of experiments that may be used for testing the conformity of this criterion. In contrast to Part 2, it is not necessary to assume that the calibration function that relates the state variable to the response variable is linear, and that the repeatability standard deviation is either constant or linearly related to the net state variable. Formulae for testing the conformity of the criterion are presented and in an annex, a numerical example is given.

ISO 13448-1:2005 ***Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 1: Guidelines for the APP approach***

Part 1 of ISO 13448 is a guidance document, not a source of sampling plans and schemes. It specifies the organizational principles of successive acceptance sampling performed by different parties: the supplier, the consumer and the third party.

It is designed for inspection of populations of any product supplied or delivered in discrete items in lots. It is applicable to those situations where the supplier unilaterally, or the supplier and the consumer contractually, specify lot quality criteria against which the lots are considered to be satisfactory.

Part 1 of ISO 13448 describes the common rules for decision-making and setting the constraints for the parties' risks and confidence levels based on subjective and objective information about supplier capability to meet quality requirements. These constraints are represented by appropriate trust levels. The ISO 13448 system extends on interpretation of the allocation-of-priorities principle, and contains tables for the levels of trust in a priory information including the evidence of ISO Family 9000 implementation by a supplier.

ISO 13448-2:2004 ***Acceptance sampling based on the allocation of priorities principles (APP) — Part 2: Coordinated single sampling plans for acceptance sampling by attributes***

Part 2 of ISO 13448 is a sampling system indexed by the allocation-of-priorities principle trust levels and normative quality limits (NQLs). It outlines attributes sampling procedures and single sampling plans for successive independent inspections of the same lot conducted by the supplier, consumer and/or the third party. It extends on suitable environments for applying ISO 13448, ISO 2859, and ISO 8422, contains supplier and consumer sampling procedures. It also includes tables of single sampling APP plans by attributes and rules for choosing them.

This part of ISO 13448 also provides for the case where successive sample inspections are performed on the same lot by different parties (i.e. producer, consumer, and/or a third party), allowing each party independence of choice of sampling plan, needed only to coordinate their sampling plans with specific requirements such as consumer's or producer's risks. This feature enables each party to organize inspection in accordance with its own resources and almost eliminates the chance of different parties obtaining conflicting results due to sampling variability.

Part 2 of ISO 13448 provides a catalogue of single sampling plans indexed in terms of the normative quality level (NQL).

ISO 13528:2005 ***Statistical methods for use in proficiency testing by interlaboratory comparisons***

This International Standard provides detailed descriptions of sound statistical methods to use to analyse the data obtained from proficiency testing schemes, and gives recommendations on their use in practice by participants in such schemes and by accreditation bodies. It is intended as a companion to ISO/IEC Guide 43, *Development and operation of laboratory proficiency testing*. It describes several methods for the determination of the assigned value and its standard uncertainty, and several methods for determining the standard deviation for proficiency assessment, and includes a robust method of calculating the assigned value from the results reported by some or all of the participants in a round of a proficiency test. It provides guidelines to use to limit the uncertainty of the assigned value and to choose the number of replicate measurements. It describes the use of a number of performance statistics, including the z-score, and provides appropriate graphical methods that may be used to present the results of one or more rounds of a proficiency test in terms of these performance scores.

ISO 14560:2004 ***Acceptance sampling procedures by attributes — Specified quality levels in nonconforming items per million***

This International Standard uses nonconforming items per million items in its estimating and reporting of quality levels and in its indexing of sampling plans. Sampling plans are determined by indexing tables with a selected limiting quality level (LQL) and either an estimated or a presumed quality level. Procedures are also provided for estimating product or process quality levels. A key feature of this International Standard is that it provides incentives for suppliers to improve their quality by requiring larger sample sizes for lot acceptance

when quality declines and smaller sample sizes when quality improves. The acceptance sampling plans in this International Standard are based upon a maximum producer's risk of 10 % and a maximum consumer's risk of 20 %. Also tabulated for each plan are the quality levels that correspond to a 5 % producer's risk and a 10 % consumer's risk. When estimating a process quality level, procedures are provided for excluding data from an audit or lot acceptance sample under certain conditions.

ISO 16269-6:2005 ***Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals***

This part of ISO 16269 describes procedures for establishing statistical tolerance intervals that include at least a specified proportion p of the population with a specified confidence level. Procedures for both one-sided and two-sided statistical tolerance intervals are provided, a one-sided interval having an upper or a lower limit while a two-sided interval has both upper and lower limits. Two types of tolerance intervals are considered: parametric and distribution-free. The parametric approach assumes that the characteristic being studied has a normal distribution, and the distribution-free that nothing is known about the distribution except that it is continuous. Procedures are given for the parametric case for the following two situations: unknown mean and known variance and unknown mean and unknown variance. Extensive tables, giving exact values of the factors, are provided for a number of entrance values for confidence levels from 50 % to 99,9 %, for the proportion p from 0,50 to 0,999 and for sample sizes from 2 to 1 000. For one-sided and two-sided distribution-free statistical tolerance intervals, tables of required sample sizes are provided for commonly used values of the proportion p and the confidence level. The methods are illustrated by several examples.

ISO 16269-7:2001 ***Statistical interpretation of data — Part 7: Median — Estimation and confidence intervals***

This part of ISO 16269 specifies procedures for establishing a point estimate and confidence intervals for the median of any continuous probability distribution, based on a simple random sample of size n from that population. Procedures are provided for both one-sided and two-sided confidence intervals. The procedures are based on order statistics and are distribution-free, i.e. they do not require knowledge of the family of distributions to which the distribution belongs. As the exact procedures for determining distribution-free confidence intervals require inequalities to be solved, an approximation is provided that gives exact results for sample sizes up to more than 280 000. The procedures are illustrated by two numerical examples.

ISO 16269-8:2004 ***Statistical interpretation of data — Part 8: Determination of prediction intervals***

This part of ISO 16269 describes procedures, based on an initial random sample of n items from a population, for establishing an interval on a quality characteristic that, with a specified confidence level, will include the measured value of the characteristic on all but at most a specified number r of a further m items randomly drawn from the same population. Procedures for both one-sided and two-sided prediction intervals are provided, a one-sided interval having an upper limit $\bar{x} + ks$ or a lower limit $\bar{x} - ks$ while a two-sided interval has both, where $\bar{x}$ is the sample mean for the initial random sample and s is its standard deviation. Two types of prediction interval are considered, parametric and distribution-free. The parametric approach assumes that the characteristic being studied has a normal distribution, and the distribution-free that nothing is known about the distribution except that it is continuous.

For the parametric case, procedures are given for unknown mean and known variance and also for unknown mean and unknown variance. Extensive tables provide values of the required factor k for 6 confidence levels ranging from 90 % to 99,9 %, for 44 initial sample sizes n ranging from 2 to infinity, and for 32 sample sizes m ranging from 1 to one million for the further sample to which the prediction is applied, all for the case r = 0.

For distribution-free one-sided and two-sided prediction intervals, the intervals are based on the largest and/or the smallest order statistics and tables of required sample sizes n are provided for the same six confidence levels and the same 32 values of m as above, for r = 0, 1, …, 10.

The methods are illustrated by 10 examples.

ISO/FDIS 18414 ***Acceptance sampling procedures by attributes — Accept-zero sampling system based on credit principle for controlling outgoing quality***

ISO 18414 specifies a system of single sampling schemes for lot-by-lot inspection by attributes, for use when inspection is non-destructive and the probability of misclassifying the state of a product's quality characteristic(s) is negligible. All sampling plans are of the accept-zero form, i.e. no lot is accepted if the sample from it contains one or more nonconforming items. The schemes depend on a suitably defined average outgoing quality limit (AOQL), the value of which is chosen by the user; no restrictions are placed on the choice of the value of the AOQL or on the sizes of successive lots in the series. The methodology ensures that the overall average quality reaching the customer or market-place will not exceed the AOQL in the long run.

The schemes are intended to induce a supplier, through the economic and psychological pressure of lot non-acceptance and consequent loss of accumulated credit, to attempt to maintain a nonconformity-free process, while assuring, by means of the lowest practicable sample sizes, that the long-term percentage of nonconforming items delivered to the customer or market-place does not exceed the AOQL. This objective is achieved by a progressive reduction in the sample size in response to good quality history.

The schemes are designed to be applied to a series of lots from each supplier. The credit principle provides automatic protection to the customer should a deterioration in quality be detected, by means of a total loss of accumulated credit and reversion to a relatively large sample size whenever a nonconforming item is found, and 100 % inspection of the first lot if it is not accepted, or of any non-accepted lot that immediately follows a non-accepted lot. ISO 18414 has the advantage over other AOQL-indexed systems in that 100 % inspection of large lots can be avoided without compromising the AOQL. The credit principle also provides an incentive to reduce sampling costs (by means of a progressive reduction in required sample size) should consistently good quality be achieved.

ISO 18414 can be suitable for regulatory purposes, as control of the expected quality of items reaching the market-place is achieved with the smallest possible sample sizes, and long-term control of the realized, or actual quality level in the market-place is achieved with certainty, regardless of how long or short individual suppliers' series may be. ISO 18414 can be used by suppliers/producers, buyers/consumers and regulatory agencies to provide control of the expected quality of the totality of accepted product of each type from each source.

ISO 21247:2005 ***Combined accept-zero sampling systems and process control procedures for product acceptance***

This International Standard provides a set of sampling plans and procedures to assess conformance to specified requirements. These plans are not AQL-based and do not permit any nonconformances in the samples taken for acceptance. Matched plans are provided for sampling by attributes, sampling by variables, or continuous sampling by attributes. All of these plans allow for switching among normal, tightened and reduced inspection severities. This International Standard also permits and, in fact, encourages suppliers to develop their quality systems to the point where they can be used for acceptance of product in lieu of sampling tables.

ISO/FDIS 21747 ***Statistical methods — Process performance and capability statistics for measured quality characteristics***

This (draft) International Standard provides a framework for estimating the quality capability/performance of industrial processes for an array of standard processes. These standard processes are categorized by the stability of the first and second distributional moments, as to whether they are constant, change systematically, or randomly. As such, the quality capability/performance can be assessed for very differently shaped distributions with respect to time.

ISO/TS 21748:2004 ***Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation***

ISO/TS 21748 provides a methodology for estimating measurement uncertainty associated with the results of standard test methods subjected to collaborative study according to ISO 5725-2, *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*. The general approach used requires the following.

— Values for the repeatability, reproducibility and trueness of the test method in use, as described in Part 2 of ISO 5725, are available from published data about the method. These estimate the within- and between-laboratory variance components, and the uncertainty associated with the trueness of the method.

— The laboratory confirms that its implementation of the test method is consistent with the established performance of the method, by checking its own bias and precision, and hence that the data are applicable to the results it obtains.

— Influences on the measurement results that were not adequately covered by the collaborative study are identified and the associated variances quantified.

An uncertainty estimate is made by combining the variances in the manner prescribed by the *Guide to the Expression of Uncertainty in Measurement*, published by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML.

ISO/TS 21749:2005 ***Measurement uncertainty for metrological applications — Repeated measurements and nested experiments***

ISO/TS 21749 provides guidance on the evaluation of the uncertainties associated with the measurement of test items, for instance as part of ongoing manufacturing inspection. Such uncertainties contain contributions from the measurement process itself and from the variability of the manufacturing process. The approach adopted is based on the results of an experiment designed by the test or calibration laboratory concerned to assess effects such as the operator, the environment and time. The form of experimental design addressed permits the application of the Analysis of Variance (ANOVA) to estimate the variances associated with the various effects. Other sources of uncertainty such as the measurement configuration, material inhomogeneity and bias are addressed. The use of measurements of check standards is also covered, as a means to provide quantitative information on the measurement process itself. The guidance complies with the principles of the *Guide to the Expression of Uncertainty in Measurement*, published by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML.

ISO/TR 22971:2005 ***Accuracy (trueness and precision) of measurement methods and results — Practical guidance for the use of ISO 5725-2:1994 in designing, implementing and statistically analysing interlaboratory repeatability and reproducibility results***

The document is divided into four sections, which include:

— organization of an inter-laboratory program;

— critical examination of data;

— estimation of repeatability and reproducibility standard deviations; and

— worked examples using statistical software.

The first section deals with the organization of the inter-laboratory test and covers the roles of the convenor, laboratory personnel, and statistician in preparing for and administering the test; the choice of materials and levels of interest for the test; and the selection of laboratories. It also describes how the number of replicate measurements (to be made on each sample) is to be statistically treated and the manner in which the resulting data are to be reported.

The second section deals with data using graphical and numerical procedures. Guidance is given as to when data are anomalous; i.e. if they are inconsistent with other data from the study, and outlier tests (like Cochran's Bartlett's Levene's Hartley's or Grubb's) are used, even when the data are unbalanced, to identify the presence or absence of anomalous data. The data which have been identified as statistical outliers are reported to the convenor who shall undertake an appropriate investigation to ascertain whether to retain, reject or modify any data.

The third section deals with the estimation and interpretation of repeatability and reproducibility standard deviations. Also included is a comparison of the relative contributions of the repeatability and reproducibility standard deviations to the total variability of the test method. Several examples illustrate the method.

The fourth section deals with worked examples that highlight various techniques that can be used. This section illustrates the extent to which graphs and statistics can be derived automatically using statistical software programs. The objective is not to advertise or endorse specific packages, but to emphasize the major advantages of automatic computation, namely accuracy, speed and the ability to use procedures that might not be possible with the use of a pocket calculator alone.

Annex B
(informative)

List of committee drafts and working drafts in ISO/TC 69 work program

B.1 Committee drafts

ISO/CD 8423, *Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)*

ISO/CD 8550-1, *Guide to the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 1: General guide to acceptance sampling*

ISO/CD 8550-2, *Guide to the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 2: Guide to sampling by attributes*

ISO/CD 8550-3, *Guide to the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 3: Guide to sampling by variables*

ISO/CD 13700, *Machine performance studies — Measured data — Discrete parts*

ISO/CD TR 18532, *Guidance on the application of statistical methods to quality and standardization*

ISO/CD 22514-1, *Capability and performance — Part 1: General principles and concepts*

ISO/CD 24153-1, *Random sampling procedures — Part 1: Quality control and designed experiment applications*

B.2 Working drafts

ISO/NP 7870-4, *Control charts — Part 4: Process adjustment control charts*

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

ISO/WD 11462-2, *Guidelines for implementation of statistical process control (SPC) — Part 2: Catalogue of tools and techniques*

ISO/NP 11843-5, *Capability of detection — Part 5: Methodology in the non-linear calibration case*

ISO/CD TR 12783, *Process capability and performance measures*

ISO/WD 24153-2, *Random sampling procedures — Part 2: Monte Carlo simulation applications*

Annex C
(informative)

Index

Standard	Page of the abstract	
	Non-technical	Technical
ISO 7873	10	25
ISO 7966	10	25
ISO 8258	10	25
ISO 8422	10	26
ISO 8423	10	26
ISO 8550	11	26
ISO 10576-1	11	27
ISO 10725	11	27
ISO 11095	11	28
ISO 11453	12	28
ISO 11462-1	12	28
ISO 11648-1	12	28
ISO 11648-2	12	29
ISO 11843-1	12	29
ISO 11843-2	13	29
ISO 11843-3	13	29
ISO 11843-4	13	29
ISO 13448-1	13	30
ISO 13448-2	13	30
ISO 13528	14	30
ISO 14560	14	30
ISO 16269-6	14	31
ISO 16269-7	14	31
ISO 16269-8	14	31
ISO 18414	15	32
ISO 21247	15	32
ISO 21747	15	32
ISO/TS 21748	15	33
ISO/TS 21749	15	33
ISO/TR 22971	16	33

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