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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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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

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

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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.

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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.

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

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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

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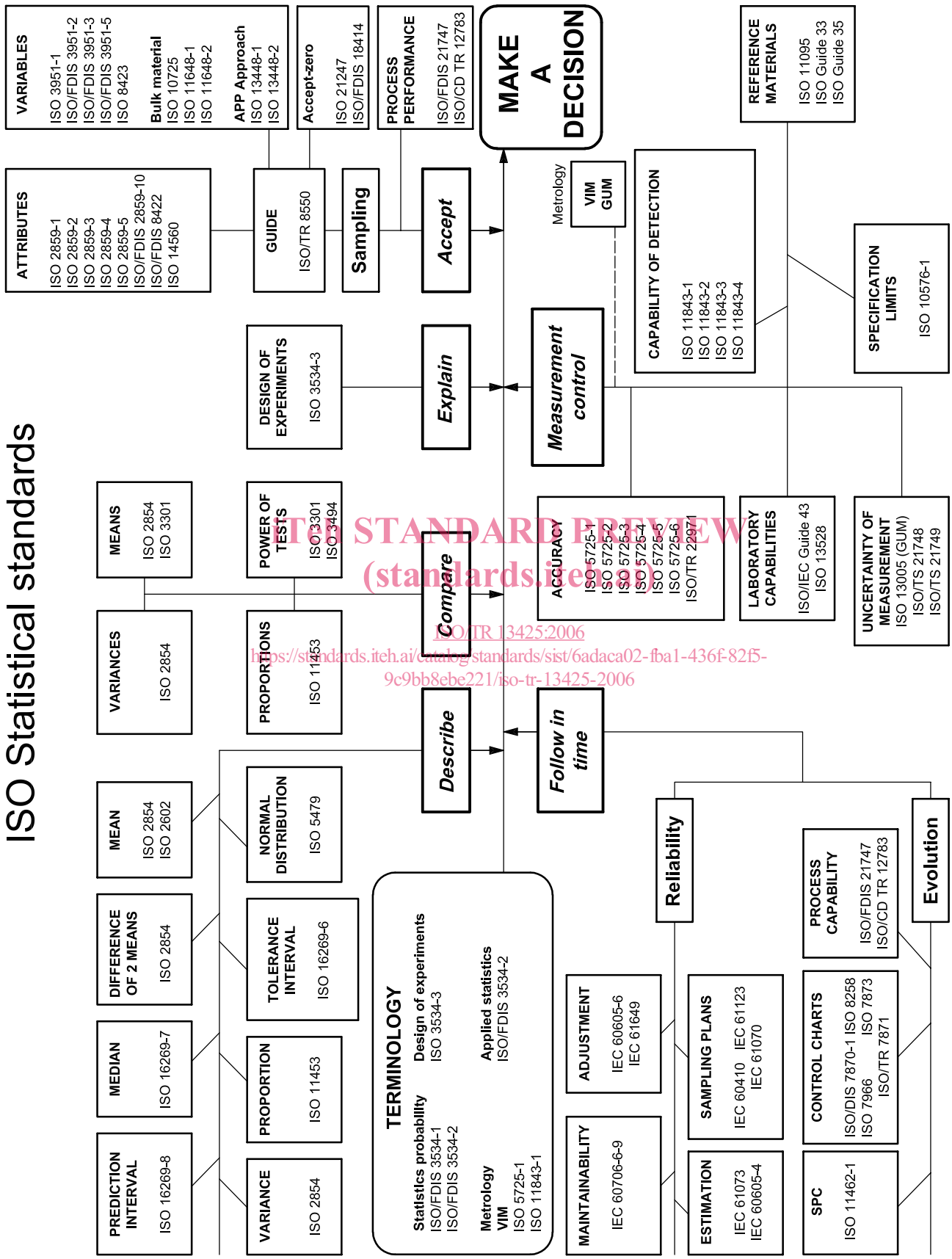
2 Cartography



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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.

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ISO Guide 35:—[1] ***Reference materials — General and statistical principles for certification*** **(Developed jointly by REMCO and ISO/TC 69)**

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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).

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

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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.

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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

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3) Under revision.

4) Under revision as ISO 2859-10.

5) Under revision.

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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***

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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.

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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.

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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.

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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.

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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.

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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***

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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.

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