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Issue 1

# WELMEC

European cooperation in legal metrology

## **Measuring Instruments Directive (2004/22/EC): Guide for generating sampling plans for statistical verification according to Annex F and F1 of MID 2004/22/EC**



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# WELMEC

European cooperation in legal metrology

WELMEC is a co-operation between the legal metrology authorities of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to Notified Bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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WELMEC Secretariat  
MIRS  
Grudново nabrežje 17  
SI – 1000 Ljubljana

e-mail : [secretary@welmec.org](mailto:secretary@welmec.org)  
Tel: +386 1 244 27 18  
Fax: +386 1 244 27 14

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# 1 General

Annex F of MID describes conformity assessment procedures, where a notified body chosen by the manufacturer carries out the appropriate examinations and tests, or have them carried out, to check the conformity of the instruments with the type as described in the EC-type examination certificate and the appropriate requirements of this Directive. Annex F1 of MID describes conformity assessment procedures, where a notified body carries out the appropriate examinations and tests, or have them carried out, to check the conformity of the instruments with the appropriate requirements of this Directive. Verification can be done by examination and testing of every instrument in accordance with MID Annex F, section 4 or Annex F1, section 6 or by statistical verification in accordance with MID Annex F, point 5 or Annex F1, point 7.

Typical applications for statistical verification are material measures (Annex MI-008) or electronic electricity meters (Annex MI-003). Statistical verification is based on sampling plans agreed between notified bodies and manufacturers taking into account the provisions given in MID, Annex F or F1.

This Guide is intended to support notified bodies when creating suitable sampling plans for conformity assessment acc. to Annex F and F1., statistical methods can also be used for Annexes A1<sup>1</sup> or for Annexes D, D1, E, E1, H and H1<sup>2</sup>.

The guide provides a practicable tool for the application of already existing documents and standards (in particular ISO 2859) with regard to MID conditions.

This Guide is intended to improve understanding and applicability of standards for non-professionals and does make no claim to be complete.

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<sup>1</sup> This annex requires product checks by the notified body. If appropriate the notified body may decide to create its sampling plans according to statistical methods.

<sup>2</sup> These annexes do not include specific requirements for final product inspection by the manufacturer. The decision whether to perform testing of every instrument, statistical control of the process or the product remains with the manufacturer. In the latter case the notified body has to evaluate the sampling plans.

## 2. Terms

### **Sampling plan**

combination of sample size(s) to be used and associated lot acceptability criteria

NOTE 1 A single sampling plan is a combination of sample size and acceptance and rejection numbers. A double sampling plan is a combination of two sample sizes and acceptance and rejection numbers for the first sample and for the combined sample.

NOTE 2 A sampling plan does not contain the rules on how to draw the sample.

NOTE 3 For the purposes of this part of ISO 2859, a distinction should be made between the terms sampling plan (3.1.17), sampling scheme (3.1.18) and sampling system (3.1.19).

[ISO 2859-1:1999 , 3.1.17]

### **Sampling scheme**

combination of sampling plans with rules for changing from one plan to another

[ISO 2859-1:1999 , 3.1.18]

### **Sampling system**

collection of sampling plans, or of sampling schemes, each with its own rules for changing plans, together with sampling procedures including criteria by which appropriate plans or schemes may be chosen

NOTE This part of ISO 2859 is a sampling system indexed by lot-size ranges, inspection levels and AQLs. A sampling system for LQ plans is given in ISO 2859-2.

[ISO 2859-1:1999 , 3.1.19]

### **Operating characteristic curve (OC curve)**

A curve showing, for a given sampling plan, the probability of accepting a lot, as a function of the quality level of the process from which the lots come; also as used for some types of plans, a curve showing the percentage of lots, or product items, that may be expected to be accepted as a function of the process quality level

NOTE: This type of operating curve is known as Type B. There are also operating characteristic curves of Type A and C.

### **Producer's risk**

For a given sampling plan, the probability of non-acceptance of a lot when the lot or process quality level (e.g. the fraction nonconforming) has a value stated by the plan as acceptable (e.g. an acceptable quality level, AQL)

### **Consumer's risk**

For a given sampling plan, the probability of acceptance of a lot or process when the quality level (e.g. fraction nonconforming) has a value stated by the plan as unsatisfactory (e.g. a limiting quality level, LQL)

### **Acceptance quality limit AQL** <sup>3</sup>

quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling

NOTE 1 This concept only applies when a sampling scheme with rules for switching and for discontinuation, such as in ISO 2859-1 or ISO 3951, is used.

NOTE 2 Although individual lots with quality as bad as the acceptance quality limit may be accepted with fairly high probability, the designation of an acceptance quality limit does not suggest that this is a desirable quality level. Sampling schemes found in International Standards such as this part of ISO 2859, with their rules for switching and for discontinuation of sampling inspection, are designed to encourage suppliers to have process averages consistently better than the AQL.

Otherwise, there is a high risk that the inspection severity will be switched to tightened inspection under which the criteria for lot acceptance become more demanding. Once on tightened inspection, unless action is taken to improve the process, it is very likely that the rule requiring discontinuation of sampling inspection pending such improvement will be invoked.

[ISO 2859-1:1999 , 3.1.26]

### **Limiting quality LQ** <sup>4</sup>

when a lot is considered in isolation, a quality level which for the purposes of sampling inspection is limited to a low probability of acceptance

[ISO 2859-1:1999 , 3.1.28]

**p** is the proportion of nonconforming items;<sup>5</sup>

**P<sub>a</sub>** probability of acceptance (in percent)

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<sup>3</sup> In MID analogous to „level of quality“

<sup>4</sup> In MID analogous to „limit quality“

<sup>5</sup> In MID analogous to „non-conformity“

### 3. MID-conditions for statistical verification

Requirements for statistical verification are given in Annex F, point 5 or Annex F1, point 7 respectively.

More specific requirements are laid down in Annex F, 5.3 or Annex F1, 7.3.

*The statistical control will be based on attributes. The sampling system shall ensure:*  
— a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;  
— a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

Explanations:

The sampling schemes agreed between notified body and manufacturer may only consist of sampling plans, that fulfil both conditions.

Both conditions refer to two specified points of the Operating characteristic (OC) curves of the sampling plan:

- $P_a(1\%) = 95\%$ ; (AQL)
- $P_a(7\%) = 5\%$ ; (LQ)

The first condition

$$P_a(\text{AQL}) = 95\%, p < 1\%$$

requires that AQL (related to a probability of acceptance  $P_a$  of 95 %) has to be smaller than 1 %, i.e. that a lot may only be accepted with a probability of 95 %, if it has less than 1 % non-conforming products.

As a consequence the manufacturer has to accept a producer's risk (risk that a lot with a smaller number of nonconforming products is not accepted) of 5 %.

The second condition

$$P_a(\text{LQ}) = 5\%, p < 7\%$$

requires, that LQ (related to a probability of acceptance  $P_a$  of 5 %) has to be smaller than 7 %, i.e. that a lot has to be refused with a probability of 95 %, if it has 7 % or more non-conforming products.

As a consequence the consumer's risk (risk that lots with too many non-conformities are accepted) equal to 5 %.

## 4. Creation of sampling plans fulfilling MID

The standard ISO 2859-1 can be used to create and evaluate sampling plans in accordance with MID. Up to the time of publication of this guide there is no standard covering the MID conditions to the full extent.

The following procedure is recommended:

- a) Clarify conditions for statistical verification, e.g.
    - homogeneity of the lot
    - Suitable procedure for taking samples
  - b) Define attributes
  - c) Agree on sampling procedure, e.g.
    - Single Sampling plan using ISO 2859-1
    - Double Sampling plan using ISO 2859-1
    - Sequential sampling plans using ISO 8422
  - d) Suggest suitable sampling plans, e.g.
    - ISO 2859-1, table 1 and 2 A for Single Sampling plan for inspection based on attributes
  - e) Check sampling plan for fulfilling conditions of MID by means of OC curves, e.g.
    - ISO 2859-1, table 10-H and 10-H-1 for Single Sampling plan for inspection based on attributes, or
    - with the help of computer applications (some freely available)
- Note: The OC curves have to be on the left hand side of the points mentioned in 3,  $P_a(1\%) = 95\%$  and  $P_a(7\%) = 5\%$
- f) Repeat d) and e) until sampling plan is completed.



## 5. Examples

Example 1:

Inspection based on attributes:

Single sampling plan for normal inspection (General inspection level II)  
based on ISO 2859-1

Lot size N	Single Sampling plan n – c	Sample size code letter	AQL	p in % 1. requirement $P_a = 95\%$ ; $p < 1\%$	p in % 2. requirement $P_a = 5\%$ ; $p < 7$
51 - 500	50 – 0	H	0,25	0,103	5,82
501 - 1200	80 – 1	J	0,65	0,446	5,79
1201 - 3200	125 – 2	K	0,65	0,657	4,95
3201 - 10 000	200 – 3	L	0,65	0,686	3,83
10 001 - 35 000	315 – 5	M	0,65	0,833	3,31
35 001 - 150 000	500 – 7	N	0,65	0,799	2,61
150 001 - 500 000	800 – 10	P	0,65	0,773	2,11
500 001 and more	1250 – 14	Q	0,65	0,741	1,75

Abbreviations:

n = sample size

c = acceptance number

AQL = Acceptance quality limit

p = proportion of nonconforming items;

$P_a$  = probability of acceptance (in %)

Note:

50 – 0 is the smallest sampling plan of ISO 2859-1, that still fulfils MID. The smallest sampling plan calculated for inspection based on attributes with single sampling plans, that fulfils MID is 42 – 0.

Example 2:

Inspection by attributes:

Double sampling plan for normal inspection (General inspection level II)  
based on ISO 2859-1

Lot size N	Double Sampling plan $n - c_1/d_1 - c_{1+2}/d_2$	Sample size code letter	AQL	p in % 1. requirement $P_a = 95\%$ ; $p < 1\%$	p in % 2. requirement $P_a = 5\%$ ; $p < 7\%$
501 - 1200	50 - 0/2 - 1/2	J	0,65	0,446	5,79
1201 - 3200	80 - 0/3 - 3/4	K	0,65	0,657	4,95
3201 - 10 000	125 - 1/3 - 4/5	L	0,65	0,686	3,83
10 001 - 35 000	200 - 2/5 - 6/7	M	0,65	0,833	3,31
35 001 - 150 000	315 - 3/6 - 9/10	N	0,65	0,799	2,61
150 001 - 500 000	500 - 5/9 - 12/13	P	0,65	0,773	2,11
500 001 and more	800 - 7/11 - 18/19	Q	0,65	0,741	1,75

Abbreviations:

n = sample size

$c_1$  = acceptance number 1. sample

$c_{1+2}$  = acceptance number 1. and 2. sample

$d_1$  = rejection number 1. sample

AQL = Acceptance quality limit

p = proportion of nonconforming items;

$P_a$  = probability of acceptance (in %)

$d_2$  = rejection number 1. and 2. sample

Example 3:

Freely agreed sampling plan

Lot size N	Single sampling plan $n - c$	p in % 1. requirement $P_a = 95\%$ ; $p < 1\%$	p in % 2. requirement $P_a = 5\%$ ; $p < 7\%$
50 and more	50 - 0	0,103	5,82

Abbreviations:

n = sample size

c = acceptance number

p = proportion of nonconforming items;

$P_a$  = probability of acceptance (in %)

Note: This sampling plan (50 - 0) is applicable for every lot size and fulfils MID. However it involves a high producer's risk (approx 40%), in particular when avoiding big lot sizes. This sampling plan can be of use, in case where the manufacturer runs an effective production control or final product inspection delivering an only small amount of non-conformities.

## 6. Standards concerning Acceptance Sampling

- 1) ISO 2859-1:1999, Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
- 2) ISO 2859-1:1999/Cor 1:2001
- 3) ISO 2859-2:1985, Sampling procedures for inspection by attributes -- Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection

Can be used when the switching rules in ISO 2859-1 are not applied. Indexing is by a preferred series of limiting qualities with a consumer's risk usually below 10 % and always below 13 %. Procedures are provided to cater for two situations: Procedure A to be used when the supplier and the consumer both wish to regard the lot in isolation (shall be used unless there is a specific instruction to use procedure B), procedure B to be used when the supplier regards the lot as one of continuing series but the consumer considers the lot received in isolation.

- 4) ISO/CD 2859-2, Sampling procedures for inspection by attributes -- Part 2: Sampling plans indexed by limited quality (LQ) for isolated lot inspection

Revision of ISO 2859-2:1985

- 5) ISO 2859-3:2005, Sampling procedures for inspection by attributes -- Part 3: Skip-lot sampling procedures

ISO 2859-3:2005 specifies generic skip-lot sampling procedures for acceptance inspection by attributes. The purpose of these procedures is to provide a way of reducing the inspection effort on products of high quality submitted by a supplier who has a satisfactory quality assurance system and effective quality controls. The reduction in inspection effort is achieved by determining at random, with a specified probability, whether a lot presented for inspection will be accepted without inspection. This procedure extends the principle of the random selection of sample items already applied in ISO 2859-1 to the random selection of lots. The skip-lot sampling procedures specified in ISO 2859-3:2005 are applicable to, but not limited to, inspection of end items, such as complete products or sub-assemblies, components and raw materials, and materials in process.

- 6) ISO 2859-4:2002, Sampling procedures for inspection by attributes -- Part 4: Procedures for assessment of declared quality levels

ISO 2859-4:2002 establishes the sampling plans and the procedures that can be used to assess whether the quality level of an entity (lot, process, etc) conforms to a declared value. The sampling plans have been devised so as to obtain a risk of less than 5 % of contradicting a correct declared quality level. The risk is 10 % of failing to contradict an incorrect declared quality level that is related to the limiting quality ratio. Sampling plans are provided corresponding to three levels of discriminatory ability. In contrast to the procedures in the other parts of ISO 2859, the procedures in ISO 2859-4:2002 are not applicable to acceptance assessment of lots. Generally, the balancing of the risks of reaching incorrect conclusions in assessment procedures will differ from the balancing in the procedures for acceptance sampling. ISO 2859-4:2002 may be used for various forms of quality inspection in situations where objective evidence of conformity to some declared quality level is to be provided by means of inspection of a sample. The procedures are applicable to entities such as lots, process output, etc. that allow random samples of individual items to be taken from the entity. The sampling plans provided in ISO 2859-4:2002 are applicable, but not limited, to inspection of a variety of products such as end items, components and raw materials, operations, materials in process, supplies in storage, maintenance operations, data or records, and administrative procedures. The procedures are primarily intended to be used when the quantity of interest is the number or fraction of nonconforming items, for which the inspected items are classified as conforming or nonconforming. With minor changes, the procedures may also be used when the quantity of interest is the number of nonconformities or number of nonconformities per item. The necessary changes are the replacement of the "number of nonconforming items" by the "number of nonconformities" and the replacement of the "percent nonconforming items" by the "nonconformities per 100 items".

7) **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

ISO 2859-5:2005 contains sequential sampling schemes that supplement the ISO 2859-1 acceptance sampling system for inspection by attributes, whereby a supplier, through the economic and psychological pressure of lot non-acceptance, can maintain a process average at least as good as the specified acceptance quality limit, while at the same time provide an upper limit for the risk to the consumer of accepting the occasional poor lot. The sampling schemes defined in ISO 2859-5:2005 are applicable, but not limited, to the inspection of: end items, components and raw materials, operations, materials in process, supplies in storage, maintenance operations, data or records, and administrative procedures. These schemes are designed to be applied to a continuing series of lots, that is, a series long enough to permit the described switching rules to be applied. These switching rules provide: a) enhanced protection to the consumer (by means of tightened sampling inspection criteria or discontinuation of sampling inspection) should deterioration in quality occur; and b) an incentive, at the discretion of the responsible authority, to reduce inspection costs (by means of reduced sampling inspection criteria) should consistently good quality be demonstrated over time. The individual sampling plans are not designed to be applicable outside of the schemes in which they are presented. If lots are produced in isolation or in a series too short for ISO 2859-5:2005 to apply, the user is advised to consult ISO 2859-2 for appropriate sampling plans.

8) **ISO 2859-10:2006**, Sampling procedures for inspection by attributes -- Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes

ISO 2859-10:2006 provides a general introduction to acceptance sampling by attributes and provides a brief summary of the attribute sampling schemes and plans used in ISO 2859-1, ISO 2859-2, ISO 2859-3, ISO 2859-4 and ISO 2859-5, which describe specific types of attribute sampling systems. ISO 2859-10:2006 also provides guidance on the selection of the appropriate inspection system for use in a particular situation.

9) **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 3951-1:2005 specifies an acceptance sampling system of single sampling plans for inspection by variables, in which the acceptability of a lot is implicitly determined from an estimate of the percentage of nonconforming items in the process, based on a random sample of items from the lot. ISO 3951-1:2005 is primarily designed for application under the following conditions: where the inspection procedure is to be applied to a continuing series of lots of discrete products all supplied by one producer using one production process; where only a single quality characteristic  $x$  of these products is taken into consideration, which must be measurable on a continuous scale; where the measurement error is negligible, i.e. with a standard deviation no more than 10% of the process standard deviation; where production is stable (under statistical control) and the quality characteristic  $x$  is distributed according to a normal distribution or a close approximation to the normal distribution; where a contract or standard defines an upper specification limit  $U$ , a lower specification limit  $L$ , or both; an item is qualified as conforming if and only if its measured quality characteristic  $x$  satisfies the appropriate one of the following inequalities:  $x$  greater than or equal to  $L$  (i.e. the lower specification limit is not violated);  $x$  greater than or equal to  $U$  (i.e. the upper specification limit is not violated);  $x$  greater than or equal to  $L$  and  $x$  less than or equal to  $U$  (i.e. neither the lower nor the upper specification limit is violated). The first two inequalities are called cases with a single specification limit, and the third a case with double specification limits. If double specification limits apply, it is assumed in ISO 3951-1:2005 that conformance to both specification limits is equally important to the integrity of the product; in such cases it is appropriate to apply a single AQL to the combined percentage of product outside the two specification limits. This is referred to as combined control.

10) **ISO 3951-2:2006**, 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 3951-2:2006 specifies an acceptance sampling system of single sampling plans for inspection by variables, indexed in terms of the Acceptance Quality Limit (AQL). ISO 3951-2:2006 is primarily designed for use under the following conditions: where the inspection procedure is to be applied to a continuing series of lots of discrete products all supplied by one producer using one production process; where the quality characteristics of the items of product are measurable on a continuous scale; where the measurement error is negligible (i.e. with a standard deviation no more than 10 % of the corresponding process standard deviation); where production is stable (under statistical control) and the quality characteristics are distributed, at least to a close approximation, according to normal distributions; where, in the case of multiple quality characteristics, the characteristics are independent of one another, at least approximately; where a contract or standard defines an upper specification limit, a lower specification limit, or both on each of the quality characteristics.

11) ISO 3951-3:2007, Sampling procedures for inspection by variables -- Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

ISO 3951-3:2007 specifies an acceptance sampling system of double sampling schemes for inspection by variables for percent nonconforming. It is indexed in terms of the acceptance quality limit (AQL). The objectives of the methods laid down in ISO 3951-3:2007 are to ensure that lots of acceptable quality have a high probability of acceptance and that the probability of non-accepting inferior lots is as high as practicable. This is achieved by means of the switching rules, which provide automatic protection to the consumer (by means of a switch to tightened inspection or discontinuation of sampling inspection) should a deterioration in quality be detected, and an incentive (at the discretion of the responsible authority) to reduce inspection costs (by means of a switch to a smaller sample size) should consistently good quality be achieved. In ISO 3951-3:2007, the acceptability of a lot is implicitly or explicitly 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. ISO 3951-3:2007 is primarily designed for use under the following conditions: where the inspection procedure is to be applied to a continuing series of lots of discrete products all supplied by one producer using one production process; where the items of product have a single quality characteristic; where the quality characteristic is measurable on a continuous scale; where the measurement error is negligible (i.e. with a standard deviation no more than 10 % of the corresponding process standard deviation); where production is stable (under statistical control) and the quality characteristic is distributed, at least to a close approximation, according to a normal distribution; where the possibility of having to select and inspect a second sample is administratively acceptable; and where a contract or standard defines an upper specification limit, a lower specification limit, or both on the quality characteristic. The procedures in ISO 3951-3:2007 are not suitable for application to lots that have been screened previously for nonconforming items.

12) ISO/WD 3951-4, Sampling procedures for inspection by variables -- Part 4: Procedures for assessment of declared quality levels

Under development

13) ISO 3951-5:2006, Sampling procedures for inspection by variables -- Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation)

ISO 3951-5:2006 specifies a system of sequential sampling plans (schemes) for lot-by-lot inspection by variables. The schemes are indexed in terms of a preferred series of acceptance quality limit (AQL) values, ranging from 0,01 to 10, which are defined in terms of percent nonconforming items. The schemes are designed to be applied to a continuing series of lots. ISO 3951-5:2006 is designed for use under the following conditions: where the inspection procedure is to be applied to a continuing series of lots of discrete products all supplied by one producer using one production process; where only a single quality characteristic of these products is taken into consideration, which must be measurable on a continuous scale; where the uncertainty of the measurement system is negligible with respect to the production process standard deviation; where production is stable (under statistical control) and the quality characteristic is distributed according to a normal distribution (or a close approximation to the normal distribution) or a distribution which may be mathematically transformed to a normal distribution; where the standard deviation of the quality characteristic is known; and where a contract or standard defines an upper specification limit, a lower specification limit or both.

14) ISO 8422:2006, Sequential sampling plans for inspection by attributes

ISO 8422:2006 contains sequential sampling plans and procedures for inspection by attributes of discrete items. The plans are indexed in terms of the producer's risk point and the consumer's risk point. Therefore, they can be used not only for the purposes of acceptance sampling, but for a more general purpose of the verification of simple statistical hypotheses for proportions. ISO 8422:2006 provides procedures for sequential assessment of inspection results that may be used to induce the supplier, through the economic and psychological pressure of non-acceptance of lots of inferior quality, to supply lots of a quality having a high probability of acceptance. At the same time, the consumer is protected by a prescribed upper limit to the probability of accepting lots of poor quality. ISO 8422:2006 provides sampling plans that are applicable, but not limited, to inspection of different fields, such as: end items, components and raw materials, operations, materials in process, supplies in storage, maintenance operations, data or records, and administrative procedures. The sampling plans from ISO 8422:2006 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 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%). In the case of the acceptance sampling of continuing series of lots, the system of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection published in ISO 2859-5 should be applied.

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

16) ISO 8423:1991, Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)

Applies if all of the following conditions are satisfied: a) inspected are continuing series of lots of discrete items supplied by one producer from one production process; b) only a single quality characteristic  $x$  is taken into consideration; c) production is stable and  $x$  has a known standard deviation; d) an upper or lower limit (or both) is defined.

17) ISO 8423:1991/Cor 1:1993

Amends values in table 1 and subclause C.2.3 and equations in subclauses 3.2.2.1 and 3.2.3.1.

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

Describes the selection process, general considerations influencing a selection, making a comparison of the methods for sampling inspection, other methods sometimes adopted in practice, market and production conditions - effect on the selection process, the final selection. Is applicable to a wide variety of inspection situations including end items (e.g. complete products or sub-assemblies), components and raw materials, services, materials in process, supplies in storage, maintenance operations, data or records.

19) ISO/TR 8550-1:2007, Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots -- Part 1: Acceptance sampling

ISO TR 8550-1:2007 gives general guidance on the selection of an acceptance sampling system, scheme or plan. It does this principally in the context of standards that either already exist or are presently under development. The guidance is confined to acceptance sampling of products that are supplied in lots and that can be classified as consisting of discrete items (i.e. discrete articles of product). It is assumed that each item in a lot can be identified and segregated from the other items in the lot and has an equal chance of being included in the sample. Each item of product is countable and has specific characteristics that are measurable or classifiable as being conforming or nonconforming (to a given product specification). Standards on acceptance sampling are typically generic, as a result of which they can be applied to a wide variety of inspection situations. These include, but are not limited to, the following: end items, such as complete products or sub-assemblies; components and raw materials; services; materials in process; supplies in storage; maintenance operations; data or records; and administrative procedures. Although ISO TR 8550-1:2007 is written principally in terms of manufacture and production, this should be interpreted liberally, as it is applicable to the selection of sampling systems, schemes and plans for all types of products and processes as defined in ISO 9000.

20) ISO/TR 8550-2, Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots -- Part 2: Sampling by attributes

ISO/TR 8550-2:2007 provides guidance for acceptance sampling of products that are supplied in lots and that can be classified as consisting of discrete items (i.e. discrete articles of product). Each item in a lot can be identified and segregated from the other items in the lot and has an equal chance of being included in the sample. Each item of product is countable and has specific characteristics that are measurable or classifiable as being conforming or nonconforming (to a given specification). Standards on acceptance sampling by attributes are applicable to a wide variety of inspection situations. These include, but are not limited to, the following: end items, such as complete products or sub-assemblies; components and raw materials; services; materials in process; supplies in storage; maintenance operations; data or records; administrative procedures. Although ISO/TR 8550-2:2007 is written principally in terms of manufacture and production, it is applicable to the selection of sampling systems, schemes and plans for all types of product and processes as defined in ISO 9000.

21) ISO/TR 8550-3:2007, Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots -- Part 3: Sampling by variables

ISO/TR 8550-3:2007 provides guidance for acceptance sampling of products that are supplied in lots and that can be classified as consisting of discrete items (i.e. discrete articles of product). Each item in a lot can be identified and segregated from the other items in the lot and has an equal chance of being included in the sample. Each item of product is countable and has specific characteristics that are measurable on a continuous scale. Each characteristic has, at least to a good approximation, a normal distribution or a distribution that can be transformed so that it closely resembles a normal distribution. Standards on acceptance sampling by variables are applicable to a wide variety of inspection situations. These include, but are not limited to, the following: end items, such as complete products or sub-assemblies; components and raw materials; services; materials in process; supplies in storage; maintenance operations; data or records; administrative procedures. Although ISO/TR 8550-3:2007 is written principally in terms of manufacture and production, it should be interpreted liberally as it is applicable to the selection of sampling systems, schemes and plans for all types of product and processes as defined in ISO 9000.

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

ISO 13448-1:2005 provides guidelines specifying the organizational principles of acceptance sampling in situations where the contract or the legislation provides for successive inspection to be carried out by different parties: the supplier, the customer and/or a third party. These guidelines are designed for inspection of populations of any product supplied or delivered in discrete items in lots. They are applicable to supplier inspection (final inspection, product certification upon supplier's request), customer inspection (incoming inspection, audit inspection, acceptance sampling), and third-party inspection (certification of product, inspection and supervision for observance of International Standard requirements, quality inspection carried out at the supplier, and/or customer, request), where the quality levels and the lot acceptability criteria are specified unilaterally by the supplier or contractually by the supplier and the customer. These guidelines are also applicable to situations when only one sampling inspection is actually needed. The guidelines provided can be applied in developing standards on acceptance sampling for standard inspection models, specific items or quality levels, as well as in developing contracts, specifications and instructions. In contractual use of the APP, the parties concerned should acknowledge in the contract that they approve of its principles (also by referring to the present guidelines). The parties may also provide for the use of the APP in disputes and arbitration.

23) 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

ISO 13448-2:2004 provides attributes sampling procedures and single sampling plans for successive independent inspections of the same lot conducted by the supplier, consumer and/or a third party. ISO 13448-2:2004 addresses supplier inspection (final inspection, product certification upon supplier's request), consumer inspection (incoming inspection, surveillance, acceptance sampling), and third party inspection. ISO 13448-2:2004 may also be applicable when only one inspection is needed. A catalogue of single sampling plans is given, indexed by the normative quality limits (NQLs). ISO 13448-2:2004 provides sampling procedures for finished product, components and discrete items, operations; discrete items and the processes that produce them, and data and records. Attributes sampling procedures are provided for inspection of an isolated lot or a continuing series of lots of a discrete product. These procedures are applicable when a normative quality limit (NQL) is given expressed in terms of percent nonconforming or nonconformities per 100 items. ISO 13448-2:2004 provides a co-ordinated system of supplier, consumer and third party acceptance sampling procedures. It is also applicable to the case where a supplier individually, or on agreement with a consumer, in a contract, specifies a lot quality criterion expressed in terms of an NQL. In either case, it provides a coherent methodology for designating lots as satisfactory or unsatisfactory for shipment and proposed use.

24) ISO 14560:2004, Acceptance sampling procedures by attributes -- Specified quality levels in nonconforming items per million

ISO 14560:2004 specifies, for quality levels expressed as nonconforming items per million items, procedures for estimating the quality level of a single entity (e.g. a lot) and, when the production process is in statistical control, for estimating the process quality level based on evidence from several samples. Procedures are also specified for using this information when selecting a suitable sampling plan so as to verify that the quality level of a given lot does not exceed a stated limiting quality level (LQL). For the case where no prior sample data is available, guidance is given for presuming a process quality level in selecting a plan.

25) ISO 18414:2006, Acceptance sampling procedures by attributes -- Accept-zero sampling system based on credit principle for controlling outgoing quality

ISO 18414:2006 specifies a system of single sampling schemes for lot-by-lot inspection by attributes. All the sampling plans of the system are of 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. ISO 18414:2006 is designed for use under the following conditions: 1) where the inspection procedure is to be applied to a series of lots of discrete items that are intended to be identical, and which are all supplied by one producer using one production process; 2) where one or more quality characteristics of these products are taken into consideration, which must all be classifiable as either conforming or nonconforming; 3) where the inspection error involved in classifying the state of a product's quality characteristic(s) is negligible; and 4) where inspection is non-destructive. ISO 18414:2006 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 18414:2006 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.

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

ISO 21247:2005 provides a set of accept-zero sampling systems and procedures for planning and conducting inspections to assess quality and conformance to specified requirements. In addition, ISO 21247:2005 provides requirements for alternative acceptance methods proposed by the supplier. Such alternative methods would be based upon establishing and implementing an internal prevention-based quality management system as a means of ensuring that all products conform to requirements specified by the contract and associated specifications and standards. ISO 21247:2005, when cited in contract, is applicable to the supplier and extends to subcontractors or vendors. The quality plans are to be applied as specified in the contract documents, and deliverables may be submitted for acceptance if the requirements of ISO 21247:2005 have been met. Sampling systems and procedures in ISO 21247:2005 are applicable, when appropriate, to assess conformance to requirements of end items; components or basic materials; operations or services; materials in process; supplies in storage; maintenance operations; data or records; administrative procedures. The sampling systems and procedures of ISO 21247:2005 are not intended for use with destructive tests or where product screening is not feasible or desirable. In such cases, the sampling systems to be used will be specified in the contract or product specifications.

27) ISO/DIS 24153, Random sampling and randomization procedures

28) ISO/CD 28801, Sampling by attributes -- Double sampling plans with minimal sample sizes indexed by producer's risk quality (PRQ) and consumer's risk quality (CRQ)

29) ISO 3534-2:1993: Statistics – Vocabulary and symbols – Part 2

30) Draft IEC 62058-11