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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 2859-1

Sampling procedures for inspection by attributes —

Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Règles d'échantillonnage pour les contrôles par attributs —

Partie 1: Procédures d'échantillonnage pour les contrôles lot par lot, indexés d'après le niveau de qualité acceptable (NQA)

ICS: 03.120.30

ISO/TC **69**/SC **5**

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

International Standard ISO 2859-1 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 5, *Acceptance sampling*.

This third edition cancels and replaces the second edition ISO 2859-1:1999 of which it constitutes a technical revision.

Significant changes in this edition include:

— a new procedure for switching from normal (or reduced inspection) to skip-lot inspection has been added.

— Guidance on the requirements for producer and product qualification for skip-lot sampling has been added.

— Guidance on the efficacy of implementing skip-lot sampling and some methods of randomly selecting lots to inspect or skip has been added.

— The operating characteristic (OC) curves for each plan have been removed in favour of sharing methods to create an individual plan's OC curve and Average Sample Number (ASN) curve, both of which are now included in Annex E.

A list of all parts in the ISO 2859 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

It is highly recommended that this part of ISO 2859 be used together with ISO 2859-0:1995, which contains illustrative examples.

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Introduction

This document specifies an acceptance sampling system of single, double, and multiple sampling plans for inspection by attributes. It is indexed in terms of the acceptance quality limit (AQL).

The objectives of the methods laid down in this document are to ensure that lots of acceptable quality have a high probability of acceptance and that the probability of not accepting inferior lots is as high as practicable. This is achieved by means of the switching rules which control the change from the initial normal inspection to tightened or reduced inspection and which provide the following:

a) An automatic protection to the consumer (by means of a switch to tightened inspection or discontinuation of sampling inspection) should a deterioration in quality (i.e. an increase in nonconformities) be detected.

b) An incentive (at the discretion of the responsible authority) to reduce inspection costs (either by means of a switch to a smaller sample size and/or to skip the inspection of randomly chosen lots) should consistently good quality be achieved.

In this document, the acceptance of a lot is implicitly determined from an estimate of the percentage of nonconforming items, or nonconformities per 100 items, in the process, based on a random sample of items from the lot.

This document is intended for application to a continuing series of lots of discrete products all supplied by one producer using one production process. If there are different producers or production processes, this document is applied to each one separately.

This document is intended for application to a single quality characteristic by either counting the number of nonconforming items in the sample (binomial distribution) or counting the number of nonconformities in a sample (Poisson distribution).

The choice of the most suitable attributes plan requires experience, judgement, and some knowledge of both statistics and the product to be inspected. Clause 5 of this document is intended to help those responsible for specifying sampling plans in making this choice.

The basic definitions and notations are provided in Clause 3 and Clause 4. The operational rules are contained in Clause 5 through Clause 11. Clause 12 provides further information on the monitoring of inspection results and the underlying process. Clause 13 provides information on the application of fractional acceptance number plans. The purpose of these plans is to provide a consistent progression from plans with acceptance number zero and plans with acceptance number one. All the tables needed for the sampling procedures can be found in Clause 15.

Five annexes are provided. Annex A is for information only and illustrates an example where the sampling plan applied is non-constant. Annex B shows five different sampling strategies. Annex C provides the procedures for random selection at the skip-lot frequency. Annex D provides a comparison between skip-lot and continuous sampling inspection in terms of average number of inspections, the producer's and the consumer's risks . Annex E details the construction of the Operating Characteristic (OC) and Average Sample Number curves.

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Sampling procedures for inspection by attributes —

Part 1:
Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

1 Scope

This part of ISO 2859 specifies sampling schemes indexed by acceptance quality limit (AQL) for inspection by attributes.

Its purpose is to induce the producer through the economic and psychological pressure of lot non-acceptance to maintain a process average at least as good as the specified acceptance quality limit, while at the same time providing an upper limit for the risk to the consumer of accepting the occasional poor lot.

Sampling schemes designated in this part of ISO 2859 are applicable, but not limited, to inspection of

— end items, such as complete products or sub-assemblies,

— components and raw materials,

— operations,

— materials in process,

— supplies in storage,

— maintenance operations,

— data or records, and

— administrative procedures.

1.1 Continuous Inspection

These schemes shall be used for a continuing series of lots, that is, a series long enough to allow the switching rules (9.3) to be applied. These rules provide:

a) a protection to the consumer (by means of a switch to tightened inspection or discontinuation of sampling inspection) should a deterioration in quality be detected.

b) an incentive (at the discretion of the responsible authority) to reduce inspection costs (by means of a switch to reduced inspection or the adoption of skip-lot sampling (see 1.2) should consistently good quality be achieved.

1.2 Skip-lot Inspection

This part of ISO 2859 also specifies optional 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 producer 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

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selection of lots. The skip-lot sampling procedures specified in this part of ISO 2859 are applicable to, but not limited to, inspection of

— end items, such as complete products or sub-assemblies,

— components and raw materials,

— operations,

— materials in process,

— supplies in storage,

— maintenance operations,

— data or records, and

— administrative procedures.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859-0:1995, *Sampling procedures for inspection by attributes — Part 0: Introduction to the ISO 2859 attribute sampling system*

ISO 3534-1:2006, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

ISO 3534-2:2006, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this part of ISO 2859, the terms and definitions given in ISO 3534-1:2006 and ISO 3534-2:2006 and the following apply.

NOTE For ease of reference, the definitions of some of these terms are quoted from ISO 3534-1:2006 and ISO 3534-2:2006, while others are redefined or newly defined.

3.1.1
acceptance quality limit
AQL
worst tolerable quality level

Note 1 to entry: 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 to entry: 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.

Note 3 to entry: 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 producers to have process averages consistently better than the AQL. If producers fail to do so, there is a high probability of being switched from normal inspection to tightened inspection where lot acceptance becomes more difficult. 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.

[SOURCE: ISO 3534-2:2006, 4.2.15, modified – original Note 4 to entry removed.]

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3.1.2
acceptance score
indicator that is used for fractional acceptance number plans to determine lot acceptability

Note 1 to entry: SEE: Section 13.2.1.2

3.1.3
average outgoing quality
AOQ
Expected average quality level of outgoing product for a given value of incoming product quality

Note 1 to entry: Unless otherwise specified, the average outgoing quality is calculated over all accepted lots plus all non-accepted lots after the latter have been inspected 100 % and the nonconforming items replaced by conforming items.

Note 2 to entry: The approximation used here is: "Average outgoing quality = incoming process quality × probability of acceptance". This formula is exact for accept-zero plans and overestimates otherwise.

[SOURCE: ISO 3534-2:2006, 4.7.1, modified - the original Note 2 to entry removed and Note 3 renumbered.]

3.1.4
average outgoing quality limit
AOQL
the maximum value that *AOQ* (3.1.3) can be, over all possible values of incoming product quality which might be submitted, for a given acceptance sampling plan, and with rectification of all non-accepted lots unless specified otherwise. It represents the maximum long run percentage nonconforming that the consumer can see under these circumstances.

[SOURCE: ISO 3534-2:2006, 4.7.2, modified – maximum long run percentage added.]

3.1.5
average sample number
ASN
average number of units in *sample* (3.1.31) inspected per *lot* (3.1.15) in reaching decisions to accept or not to accept when using a given acceptance *sampling plan* (3.1.33)

Note 1 to entry: ASN is dependent on the actual quality level of the submitted lots.

[SOURCE: ISO 3534-2:2006, 4.7.3, modified –Average Sample Number (ASN) is the preferred term and equivalent to the admitted term Average Sample SIze (ASSI) in the source]

3.1.6
consumer
The term consumer may be used to represent the user or buyer as appropriate. The consumer and the producer may even be different departments of the same company.

Note 1 to entry: See also *producer* (3.1.26)

3.1.7
consumer's risk quality
CRQ
lot or process quality level that in the sampling plan corresponds to a specified consumer's risk

Note 1 to entry: Consumer's risk is usually 10 %.

Note 2 to entry: See also limiting quality, *LQ* (3.1.14)

3.1.8
defect
non-fulfilment of a requirement related to an intended or specified use.

Note 1 to entry: The distinction between the concepts defect and *nonconformity* (3.1.20) is important as it has legal connotations, particularly those associated with product liability issues. Consequently, the term "defect" should be used with extreme caution.

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[SOURCE: ISO 3534-2:2006, 3.1.12, modified - Note 2 to entry removed.]

3.1.9
disqualification
failure to qualify for *skip-lot sampling inspection* (3.1.37)

3.1.10
inspection
activity such as measuring, examining, testing, or gauging one or more characteristics of a product or service, and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic.

[SOURCE: Source: ISO 3534-2:2006, 4.1.2, modified - "judgement" has been changed to "comparing results with required specification". The definition here includes the notion of establishing conformity on one or more characteristics.]

3.1.11
inspection by attributes
inspection whereby the presence or absence of one or more specified characteristics of each item in a *sample* (3.1.30) is observed to establish statistically the acceptability of a *lot* (3.1.15) or process.

Note 1 to entry: Inspection by attributes includes inspection for conformity of items as well as inspection for number of nonconformities per hundred items.

[SOURCE: ISO 3534-2:2006, 4.2.12, modified - Note 1 to entry added.]

3.1.12
interruption
cessation of *skip-lot sampling inspection* (3.1.36) ending with a return to continuous inspection.

3.1.13
item
Anything that can be described and considered separately.

EXAMPLE

— a physical item;

— a defined amount of bulk material;

— a service, activity or process;

— an organization, system, person; or

— some combination thereof.

Note 1 to entry: Object is a deprecated term.

[SOURCE: ISO 3534-2:2006, 1.2.11, modified - "process" and "organisation" added. Note 1 to entry removed and Note 2 renumbered.]

3.1.14
limiting quality
LQ
quality level which is the limit of an unsatisfactory process average when a continuing series of lots is considered.

Note 1 to entry: 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

Note 2 to entry: See also consumer's risk quality, *CRQ* (3.1.7)

[SOURCE: ISO 3534-2:2006, 4.2.14, modified - Notes 1 and 2 to entry added.]

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3.1.15
lot
definite amount of some product, material or service, collected together

Note 1 to entry: This definition differs from that in ISO 3534-2:2006, 1.2.4.

Note 2 to entry: An inspection lot may consist of several batches or parts of batches.

3.1.16
lot size
number of items in a lot

3.1.17
nonconforming item
item (3.1.12)with one or more nonconformities

Note 1 to entry: See notes to *nonconformity* (3.1.20)

[SOURCE: ISO 3534-2:2006, 1.2.12, modified - Note 1 to entry added.]

3.1.18
nonconformities per 100 items in a sample
one hundred times the number of *nonconformities* in the sample divided by the sample size, viz:

$$100\frac{d}{n}$$

where:

— d is the number of nonconformities in the sample

— n is the sample size

3.1.19
nonconformities per 100 items in a population or lot
one hundred times the number of *nonconformities* in the population or lot divided by the population or lot size, viz:

$$100p = 100\frac{D}{N}$$

where

— p is the number of nonconformities per item

— D is the number of nonconformities in the population or lot

— N is the population or lot size

Note 1 to entry: An item may contain one or more nonconformities.

3.1.20
nonconformity
non-fulfilment of a requirement

Note 1 to entry: See notes to *defect* (3.1.8)

Note 2 to entry: Nonconformity will generally be classified according to its degree of seriousness such as:

— Class A: those nonconformities of a type considered to be of the highest concern; in acceptance sampling such types of nonconformities will be assigned a very small acceptance quality limit value.

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— Class B: those nonconformities of a type considered to have the next lower degree of concern; therefore, these can be assigned a larger acceptance quality limit value than those in class A and smaller than in class C, if a third class exists, etc.

Note 3 to entry: Adding characteristics and classes of nonconformities will generally affect the overall probability of acceptance of the product.

Note 4 to entry: The number of classes, the assignment into a class, and the choice of acceptance quality limit for each class, should be appropriate to the quality requirements of the specific situation.

[SOURCE: ISO 3534-2:2006, 3.1.11, modified - Notes 2, 3, and 4 added.]

3.1.21
normal inspection
use of a *sampling plan* (3.1.33)with an acceptance criterion that has been devised to secure the producer a high probability of acceptance when the *process average* (3.1.25)of the lot is better than the *acceptance quality limit* (3.1.1).

Note 1 to entry: Normal inspection is used when there is no reason to suspect that the *process average* (3.1.24)differs from an acceptable level.

Note 2 to entry: This definition differs from that in ISO 3534-2:2006, 4.1.10.

[SOURCE: ISO 3534-2:2006, 4.1.12, modified - Note 1 to entry added.]

3.1.22
original inspection
inspection (3.1.10) of a *lot* (3.1.15), or other amount, not previously inspected.

Note 1 to entry: This is in contrast, for example, to inspection of a lot which has previously been designated as not acceptable and which is submitted again for inspection after having been further sorted, reprocessed, etc.

[SOURCE: ISO 3534-2:2006, 4.1.16]

3.1.23
percent nonconforming in a sample
one hundred times the number of *nonconforming items* (3.1.17) in the sample divided by the sample size, viz: $\frac{d}{n} \times 100$ where:

— d is the number of nonconforming items in the sample

— n is the sample size

3.1.24
percent nonconforming in a population or lot
one hundred times the number of *nonconforming items* (3.1.17) in the population or lot divided by the population or lot size, viz: $100p = 100\frac{D}{N}$ where

— p is the proportion of nonconforming items

— D is the number of nonconforming items in the population or lot

— N is the population or lot size

Note 1 to entry: In this part of ISO 2859 the terms *percent nonconforming* (3.1.23) in a sample and *percent nonconforming* (3.1.23) in a population or lot or *nonconformities per 100 items* in a *sample* (3.1.18) and *nonconformities per 100 items* in a population or *lot* (3.1.19) are mainly used in place of the theoretical terms "proportion of nonconforming items" and "nonconformities per item" because the former terms are the most widely used.

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3.1.25
process average
process level averaged over a defined time period or quantity of production

Note 1 to entry: In this part of ISO 2859 the process average is the quality level (percent nonconforming or number of nonconformities per hundred items) during a period when the process is in a state of statistical control.

3.1.26
producer
The term producer may be used to represent the seller, supplier, vendor, manufacturer or producer as appropriate for the situation. The producer and the consumer may even be different departments in the same company.

Note 1 to entry: The producer is important in this part of the ISO 2859 standard as it depends on the operation of the switching rules in response to changes in quality level. Only the producer is in a position to do this.

Note 2 to entry: See also *consumer* (3.1.6)

3.1.27
producer's risk
PR
probability of nonacceptance when the quality level has a value stated by the plan as acceptable

Note 1 to entry: Quality level could relate to fraction nonconforming and be acceptable to AQL.

Note 2 to entry: Interpretation of the producer's risk requires knowledge of the stated quality level.

[SOURCE: ISO 3534-2:2006, 4.6.4.]

3.1.28
product qualification
assessment of the product to determine its suitability for *skip-lot sampling inspection* (3.1.36).

3.1.29
reduced inspection
inspection less severe than *normal inspection* (3.1.21) to which the latter is switched when inspection results of a predetermined number of lots indicate that the quality level achieved by the process is better than that specified.

Note 1 to entry: The discriminatory ability under reduced inspection is less than under *normal inspection* (3.1.21).

Note 2 to entry: Reduced inspection may be invoked when the inspection results of a predetermined number of consecutive lots indicate that the *process average* (3.1.25)is better than the *AQL* (3.1.1).

[SOURCE: ISO 3534-2:2006, 4.1.11, modified - Notes 1 and 2 to entry added.]

3.1.30
responsible authority
concept used to maintain the neutrality of this part of ISO 2859 (primarily for specification purposes), irrespective of which party is invoking or applying it.

Note 1 to entry: The responsible authority may be:

a) the *producer* (3.1.26)

b) the *consumer* (3.1.6)

c) an independent verification or certification authority;

d) any of a), b) or c), differing according to function (see Note 2) as described in a written agreement between two of the parties, for example a document between producer and consumer.

Note 2 to entry: The duties and functions of a responsible authority are outlined in this part of ISO 2859 (see 5.2, 6.2, 7.2, 7.3, 7.5, 7.6, 9.1, 9.3.3, 9.4, 9.5, 10.1, 10.3, 13.1).

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3.1.31
sample
set of one or more items taken from a lot and intended to provide information on the lot

Note 1 to entry: This definition differs from that in ISO 3534-2:2006, 1.2.17.

3.1.32
sample size
number of items in the sample

Note 1 to entry: This definition differs from that in ISO 3534-2:2006, 1.2.26.

3.1.33
sampling plan
plan which states the sample size(s) to be used and the associated criteria for lot acceptance

Note 1 to entry: A single sampling plan is a combination of sample size and acceptance and rejection numbers. Double and multiple sampling plans are a combination of two or more sample sizes and associated acceptance and rejection numbers for the first sample and for subsequent combined samples.

Note 2 to entry: A sampling plan does not contain the rules on how to draw the sample.

Note 3 to entry: For the purposes of this part of ISO 2859, a distinction should be made between the terms *sampling plan* (3.1.33),*sampling scheme* (3.1.34) and *sampling system* (3.1.35)

[SOURCE: ISO 3534-2:2006, 4.3.3, modified - Notes 1, 2 and 3 to entry added.]

3.1.34
sampling scheme
combination of sampling plans with switching rules for changing from one plan to another

Note 1 to entry: SEE: Section 9.3

[SOURCE: ISO 3534-2:2006, 4.3.2.]

3.1.35
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 1 to entry: 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.

Note 2 to entry: This definition differs from that in ISO 3534-2:2006, 5.4.1.

3.1.36
skip-lot sampling inspection
inspection in which some lots in a series are accepted without inspection, when the sampling results for 10 immediately preceding lots meet the stated criteria

Note 1 to entry: The lots to be inspected are chosen randomly in accordance with the skip-lot inspection frequency of 2 in 5.

[SOURCE: ISO 3534-2:2006, 4.2.5, modified - "a stated number of" changed to 10 and Note 1 to entry added.]

3.1.37
switching score
indicator that is used under *normal inspection* (3.1.20)to determine whether the current inspection results are sufficient to allow for a switch to *reduced inspection* (3.1.28)

Note 1 to entry: SEE: Section 9.3.3.2

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3.1.38
tightened inspection
inspection more severe than normal inspection , to which the latter is switched when inspection results of a predetermined number of lots indicate that the quality level achieved by the process is poorer than that specified

Note 1 to entry: Tightened inspection is invoked when the inspection results of a predetermined number of consecutive lots indicate that the *process average* (3.1.24)might be poorer than the *AQL* (3.1.1).

3.2 Symbols and abbreviations

The symbols and abbreviations used in this part of ISO 2859-1 are as follows:

Ac	acceptance number
AQL	acceptance quality limit (in percent nonconforming items or in nonconformities per hundred items)
AOQ	average outgoing quality (in percent nonconforming items or in nonconformities per hundred items)
AOQL	average outgoing quality limit (in percent nonconforming items or in nonconformities per hundred items)
CRQ	consumer's risk quality (in percent nonconforming items or in nonconformities per hundred items)
d	number of nonconforming items (or nonconformities) found in a sample from a lot
D	number of nonconforming items in a lot
LQ	limiting quality (in percent nonconforming items or in nonconformities per hundred items)
N	lot size
n	sample size
p	process average
p_x	quality level for which the probability of acceptance is x, where x is a fraction
P_a	probability of acceptance (in percent)
Re	rejection number

NOTE The symbol n may be accompanied by a subscript. Numerical subscripts 1 or 2 denote the first or second sample, respectively. In general, n_i is the size of the ith sample in double or multiple sampling.

4 Expression of nonconformity

4.1 General

The extent of nonconformity shall be expressed either in terms of percent nonconforming (see 3.1.23 and 3.1.24) or in terms of nonconformities per 100 items (see 3.1.18 and 3.1.19). Table 14 and Table 17 are based on the assumption that nonconformities occur randomly and with statistical independence. If it is known that one nonconformity in an item could be caused by a condition also likely to cause others, the items shall be considered just as conforming or not and multiple nonconformities ignored

4.2 Classification of nonconformities

Since most acceptance sampling involves evaluation of more than one quality characteristic, and since they may differ in importance in terms of quality and/or economic effects, it is often desirable to classify the types of nonconformities according to agreed classes as defined in 3.1.18. The number of classes, the

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assignment of nonconformities into classes, and the choice of AQL for each class should be appropriate to the quality requirements of the specific situation.

5 Acceptance quality limit (AQL)

5.1 Use and application

The AQL, together with the sample size code letter (see 10.2), is used for indexing the sampling plans and schemes provided in this part of ISO 2859

When a specific value of the AQL is designated for a certain nonconformity or group of nonconformities, it indicates that the sampling scheme will accept the great majority of the lots submitted, provided the quality level (percent nonconforming or nonconformities per 100 items) in these lots is no greater than the designated value of AQL. The sampling plans provided are so arranged that the probability of acceptance at the designated AQL value depends upon the sample size for a given AQL, being generally higher for large samples than for small ones.

The AQL is a parameter of the sampling scheme and should not be confused with the process average that describes the operating level of the manufacturing process. It is expected that the process average will be better than the AQL to avoid excessive rejections under this system.

NOTE The designation of an AQL shall not imply that the producer has the right knowingly to supply any nonconforming item.

5.2 Specifying AQLs

The AQL to be used shall be designated by the responsible authority. Different AQLs may be designated for groups of nonconformities considered collectively or for individual nonconformities as defined in 3.1.18. The classification into groups should be appropriate to the quality requirements of the specific situation. An AQL for a group of nonconformities may be designated in addition to AQLs for individual nonconformities, or subgroups, within that group. When the quality level is expressed as percent of nonconforming items (3.1.21 and 3.1.22), AQL values shall not exceed 10 % nonconforming. When the quality level is expressed as number of nonconformities per 100 items (3.1.17), AQL values up to 1 000 nonconformities per 100 items may be used.

5.3 Preferred AQLs

The series of values of AQLs given in the tables are known as the preferred series of AQLs. If, for any product, an AQL is designated other than one of these values, these tables are not applicable.

6 Submission of product for sampling

6.1 Formation of lots

The product shall be assembled into identifiable lots, or in such other manner as may be laid down (see 6.2). Each lot shall, as far as is practicable, consist of items of a single type, grade, class, size and composition, manufactured under uniform conditions at essentially the same time.

6.2 Presentation of lots

The formation of the lots, the lot size and the manner in which each lot shall be presented and identified by the producer shall be designated or approved by, or according to, the responsible authority. As necessary, the producer shall provide adequate and suitable storage space for each lot, equipment needed for proper identification and presentation, and personnel for all handling of product required for drawing of samples.

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7 Acceptance and non-acceptance

7.1 Acceptability of lots

Acceptability of a lot shall be determined by the use of a sampling plan or plans.

The term "non-acceptance" is used in this context for "rejection" when it refers to the result of following the procedure. Forms of the term "reject" are retained when they refer to actions the consumer may take, as in "rejection number."

7.2 Disposition of non-acceptable lots

The responsible authority shall decide how lots that are not accepted will be disposed of. Such lots may be scrapped, sorted (with or without nonconforming items being replaced), reworked, re-evaluated against more specific usability criteria, or held for additional information, etc.

7.3 Nonconforming items

If a lot has been accepted, the right is reserved to not accept any item found nonconforming during inspection, whether that item formed part of a sample or not. Items found nonconforming may be reworked or replaced by conforming items, and resubmitted for inspection with the approval of, and in the manner specified by, the responsible authority.

7.4 Classes of nonconformities or nonconforming items

Specific assignment of nonconformities or nonconforming items to two or more classes requires using a set of sampling plans. In general, the set of sampling plans have a common sample size, but different acceptance numbers for each class having a different AQL, such as in Table 2 and Table 5.

7.5 Special reservation for critical classes of nonconformities

Some types of nonconformities may have critical importance, for example they will result in hazardous conditions to those using a product. This subclause specifies the special provisions for critical nonconformities. At the discretion of the responsible authority, every item in the lot may be required to be inspected for critical nonconformities. The right is reserved to inspect every item submitted for critical nonconformities and to not accept the lot immediately if a critical nonconformity is found. The right is also reserved to sample, for critical nonconformities, every lot submitted by the producer and to not accept any lot if a sample drawn from it is found to contain one or more critical nonconformities.

7.6 Resubmitted lots

All parties shall be immediately notified if a lot is found not acceptable. Such lots shall not be resubmitted until all items are re-examined or retested and the producer is satisfied that all nonconforming items have been removed or replaced by conforming items, or all nonconformities have been corrected. The responsible authority shall determine whether normal or tightened inspection shall be used on re-inspection and whether re-inspection shall include all types or classes of nonconformities or only the particular types or classes of nonconformities which caused initial non-acceptance.

8 Drawing of samples

8.1 Sample selection

8.1.1 General

The items selected for the sample shall be drawn from the lot by simple random sampling (as given in ISO 24153). However, when the lot consists of sub-lots or strata, identified by some rational criterion,

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stratified sampling shall be used in such a way that the size of the subsample from each sublot or stratum is proportional to the size of that sublot or stratum (for further details see ISO 2859-10:2006).

NOTE Some sampling strategies are provided in Annex D

8.1.2 Skip-lot

The lot(s) to be inspected during the skip-lot inspection shall be selected in accordance with an established organizational procedure for random lot selection (see Annex B). The lots shall be selected for skip-lot inspection with a probability of 0,4 (2 in 5). It is important that the producer does not know which of the lots will be inspected until the lots have been offered for acceptance inspection.

However, at least one lot shall be inspected during a period agreed to by both the producer and the responsible authority. If no period is specified, the period shall be 2 months.

8.2 When to draw the samples

Samples may be drawn after the lot has been produced, or during production of the lot. In either case, the samples shall be selected according to 8.1.

8.3 Double or multiple sampling

When double or multiple sampling is to be used, the subsequent sample shall be selected from the remainder of the same lot.

9 Normal, tightened, reduced and skip-lot inspection

9.1 Start of inspection

Normal inspection shall be carried out at the start of inspection, unless otherwise directed by the responsible authority.

9.2 Continuation of inspection

Normal, tightened or reduced inspection shall continue unchanged on successive lots, except where the switching procedures (see 9.3) require the severity of the inspection to be changed. The switching procedures shall be applied to each class of nonconformities or nonconforming items independently.

9.3 Switching rules and procedures (see Figure 1)

9.3.1 Normal to tightened

When normal inspection is being carried out, tightened inspection shall be implemented as soon as two out of five (or fewer than five) consecutive lots have been non-acceptable on original inspection (that is, ignoring resubmitted lots or batches for this procedure).

9.3.2 Tightened to normal

When tightened inspection is being carried out, normal inspection shall be re-instated when five consecutive lots have been considered acceptable on original inspection.

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9.3.3 Normal to reduced

9.3.3.1 General

When normal inspection is being carried out, reduced inspection may be implemented provided that all of the following conditions are satisfied:

a) the current value of the switching score (see 9.3.3.2) is at least 30; and

b) production is at a steady rate; and

c) reduced inspection is considered desirable by the responsible authority.

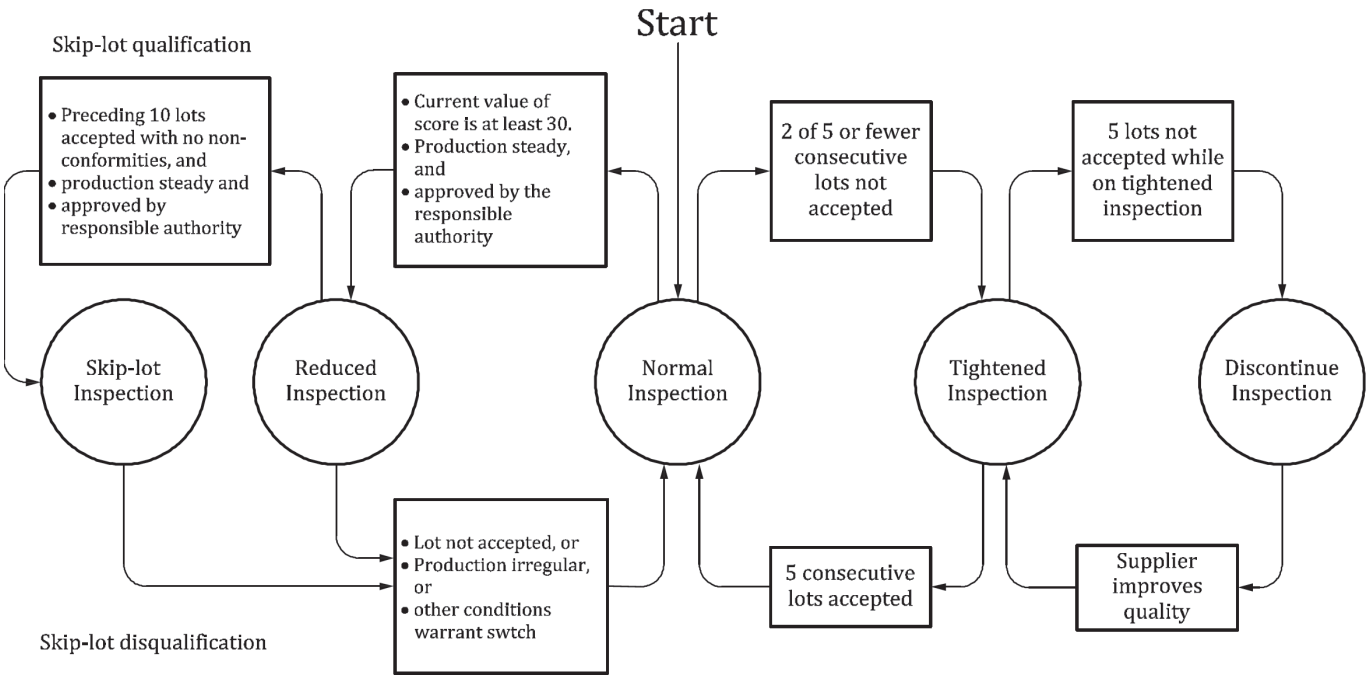


Figure 1 — Outline of the switching rules (see 9.3)

9.3.3.2 Switching score

The calculation of the switching score shall be initiated at the start of normal inspection unless otherwise specified by the responsible authority.

The switching score shall be set at zero at the start and updated following the inspection of each subsequent lot on original normal inspection.

a) Single sampling plans:

   1) when the acceptance number is 2 or more, add 3 to the switching score if the lot would have been accepted if the AQL had been one step tighter; otherwise reset the switching score to zero;

   2) when the acceptance number is 0 or 1, add 2 to the switching score if the lot is accepted; otherwise reset the switching score to zero.

b) Double and multiple sampling plans:

   1) when a double sampling plan is used, add 3 to the switching score if the lot is accepted after the first sample; otherwise reset the switching score to zero.

   2) when a multiple sampling plan is used, add 3 to the switching score if the lot is accepted by the third sample; otherwise reset the switching score to zero.

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NOTE The application of the switching score is illustrated in Annex A.

9.3.4 Reduced to normal

When reduced inspection is being carried out, normal inspection shall be re-instated if any of the following occur on original inspection:

a) a lot is not accepted; or

b) production becomes irregular or delayed; or

c) other conditions warrant that normal inspection shall be re-instated at the discretion of the responsible authority.

9.3.5 Skip-lot to normal

When skip-lot inspection is being carried out, normal inspection shall be re-instated if any of the following occur on original inspection:

a) a lot is not accepted; or

b) production becomes irregular or delayed; or

c) other conditions warrant that normal inspection shall be re-instated at the discretion of the responsible authority.

9.3.6 Reduced to skip-lot

When reduced inspection is being carried out, skip-lot inspection may be implemented provided that all of the following conditions are satisfied:

a) The previous 10 lots have been accepted with zero nonconforming items (zero nonconformities)

b) production is at a steady rate; and

c) Both the producer and product are qualified to do so (see 9.5.2)

d) skip-lot inspection is considered desirable by the responsible authority.

9.4 Discontinuation of inspection

If the number of lots not accepted in a sequence of consecutive lots on original tightened inspection reaches 5, the acceptance procedures of this part of ISO 2859 shall not be resumed until action has been taken by the producer to improve the quality of the submitted product or service, and the responsible authority has agreed that this action is likely to be effective. Tightened inspection shall then be used as if 9.3.1 had been invoked.

9.5 Skip-lot sampling

9.5.1 General requirements

The lot-by-lot inspection in this part of ISO 2859 may be replaced by skip-lot sampling when the requirements are fulfilled. Skip-lot inspection may only be used when both the producer and the product are qualified. The requirements for qualification are specified in Clause 9.5.2

The skip-lot sampling procedures specified in this part of ISO 2859 are intended only for a continuing series of lots and shall not be used for isolated lots. All lots in the series are expected to be of a similar quality and there should be reason to believe that lots not inspected are of the same quality as the ones inspected.

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9.5.2 Producer and product qualification

9.5.2.1 Requirements for producer qualification

a) The producer shall have implemented and maintained a documented system for controlling product quality and design changes. It is axiomatic that the system includes inspection by the producer of each lot produced and the recording of inspection results.

b) The producer shall have instituted a system that is capable of detecting and correcting shifts in quality levels and monitoring process changes that may adversely affect quality. The producer's personnel responsible for the application of the system shall demonstrate a clear understanding of the applicable standards, systems and procedures to be followed.

c) The producer shall not have experienced any change that might adversely affect quality.

d) Assessment and registration of the producer in accordance with the third-party assessment standards given in ISO 9001 for the group of products containing the product concerned should be considered in determining eligibility for skip-lot inspection.

9.5.2.2 Assessment for producer qualification

The responsible authority shall determine whether the producer is eligible for skip-lot inspection.

9.5.2.3 Verification of producer qualification

Producer qualification shall be verified at a frequency agreed to by both the producer and the responsible authority. The purpose of this verification is to determine whether or not the producer is still able to understand and follow the quality control procedures.

9.5.2.4 Requirements for product qualification

Generic requirements for the product qualification are as follows:

a) The product shall be of stable design.

b) The product shall not have any critical classes of nonconforming items or nonconformities.

c) The specified inspection level(s) shall be general inspection levels I, II or III.

d) The product shall have been on normal or reduced inspection or a combination of normal and reduced inspection during the qualification period. A product that has been on tightened inspection at any time during the qualification period is ineligible for skip-lot inspection.

e) The product shall have been produced on an essentially continuous basis for a specified production period at a specified production frequency.

f) Both the minimum production period and the minimum production frequency should be specified, based on the agreement between the producer and the responsible authority . If no minimum production period is specified, the period shall be 6 months. Whenever production is held pending sample approval, only the time period after approval and resumption of production shall be included. If no minimum production frequency is specified, the minimum production frequency shall be once per month, or at least one lot shall be submitted each month. Products of a similar nature shipped to other parties may be considered in the determination of "essentially continuous", if agreed to by both the producer and the responsible authority.

g) The product quality shall have been maintained at the AQL or better for a period of stability mutually agreed to by both the producer and the responsible authority. If no period is specified, the period shall be 6 months.

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9.5.2.5 Assessment for product qualification

An assessment for product qualification shall not be made prior to the assessment for producer qualification, although both assessments may be made at the same time.

The responsible authority shall review the assessment information provided, the end use of the product and its safety aspects and shall determine whether the product is eligible for skip-lot inspection.

Product qualification assessments should always be performed, even in the case of a producer with a quality management system certified to be in conformity with ISO 9001.

9.5.2.6 Verification of product qualification

Product qualification shall be verified at a frequency agreed to by both the producer and the responsible authority. The purpose of this verification is to determine whether or not the quality control procedures for the product continue to be followed. The verification should be made together with the verification for producer qualification.

The method of verification is similar to the method of assessment.

9.5.2.7 Specific requirements for product qualification

The specific requirement for the product qualification are that the preceding 10 or more consecutive lots have been accepted on original inspection; the term "on original inspection" means that the results of resubmitted lots shall not be included. There is the following limitation on applicable sampling plans; fractional acceptance number sampling plans shall not be used.

9.5.3 Qualification and disqualification

9.5.3.1 Qualification

9.5.3.1.1 Single sampling plans for normal inspection

The rule for skip-lot qualification for normal inspection single sampling plans is the same for all sampling plans i.e. for sampling plans with Acceptance numbers of 0 to 56 inclusive: The current value of the switching score is at least 30, production is steady, the optional switch to skip-lot inspection is approved by the responsible authority and the preceding 10 lots have been accepted with zero nonconformities.

9.5.3.1.2 Single sampling plans for reduced inspection

The rule for skip-lot qualification for reduced inspection single sampling plans is the same for all sampling plans i.e. for sampling plans with Acceptance numbers of 0 to 26 inclusive: The criteria for reduced inspection is maintained, i.e. during reduced inspection all inspected lots have been accepted, production is steady, no other conditions warrant the switch away from reduced inspection, and the preceding 10 lots have been accepted with zero nonconformities.

9.5.3.2 Disqualification

Skip-lot inspection shall be interrupted if an inspected lot is not accepted, production is irregular, other conditions warrant the switch away from skip-lot inspection.

Inspection shall return to normal inspection.

9.5.3.3 Requalification

The Skip-lot qualification period can resume immediately. If the interruption was due to non-acceptance of an inspected lot then a further sequence of 10 lots, under lot by lot normal inspection would need to be accepted with zero nonconforming items (or nonconformities) before requalification for skip-lot inspection is achieved.

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