# **INTERNATIONAL STANDARD**

# **ISO** 28598-1

First edition 2017-10

## Acceptance sampling procedures based on the allocation of priorities principle (APP)

# Part 1: Guidelines for the APP approach

Règles d'échantillonnage pour acceptation fondées sur le principe d'attribution de priorités (APP) — Ligne. Click to view

Partie 1: Lignes directrices relatives à l'approche APP



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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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 <a href="https://www.iso.org/patents">www.iso.org/patents</a>).

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

For an explanation on 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 the following URL: <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 5, *Acceptance sampling*.

This first edition of ISO 28598-1 cancels and replaces ISO 13448-1:2005, of which it constitutes a minor revision to change the reference number from 13448-1 to 28598-1.

With the view to achieve a more consistent portfolio, TC 69/SC 5 has simultaneously renumbered the following standards, by means of minor revisions:

Old reference	New reference	Title
ISO 2859-10:2006	150 28590:2017	Sampling procedures for inspection by attributes — Introduction to the ISO 2859 series of standards for sampling for inspection by attributes
ISO 8422:2006	ISO 28591:2017	Sequential sampling plans for inspection by attributes
ISO 28801-2011	ISO 28592:2017	Double sampling plans by attributes with minimal sample sizes, indexed by producer's risk quality (PRQ) and consumer's risk quality (CRQ)
ISO 18414:2006	ISO 28593:2017	Acceptance sampling procedures by attributes — Accept-zero sampling system based on credit principle for controlling outgoing quality
ISO 21247:2005	ISO 28594:2017	Combined accept-zero sampling systems and process control procedures for product acceptance
ISO 14560:2004	ISO 28597:2017	Acceptance sampling procedures by attributes — Specified quality levels in nonconforming items per million
ISO 13448-1:2005	ISO 28598-1:2017	Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 1: Guidelines for the APP approach
ISO 13448-2:2004	ISO 28598-2:2017	Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 2: Coordinated single sampling plans for acceptance sampling by attributes

Cross references between the above listed documents have been corrected in the minor revisions.

In addition, in <u>5.1</u> and <u>6.1.3</u>, the reference to ISO 2859 has been corrected to a reference to ISO 2859-1.

A list of all documents in the new ISO 28590 - ISO 28599 series of International Standards can be found on the ISO website.

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### Introduction

The ISO 28598 series provides a new acceptance sampling methodology in support of quality management. This could be beneficial for users of ISO 9001 or ISO 9004. This part of ISO 28598 gives guidance and explains the methodology, which is based on the "allocation of priorities principle" (APP). ISO 28598-2 provides attributes sampling plans. Development of ISO 28598-3, to provide variables sampling plans, is under consideration.

The procedures in the ISO 28598 series have considerable advantages under certain circumstances. A novel feature is the ability to use practically any type of prior objective and subjective information when determining the appropriate sampling plan. Examples of such information are inspection results for previous lots, certification of quality management systems as being in conformity with ISO 9001, quality control data and customers' subjective estimates of the supplier's capability to provide the desired quality, all of which may be summarized in a trust level. This allows a progressive reduction in sample size as the customer's trust in the producer increases.

Another advantage of the procedures arises when successive inspections of the same lot are carried out by different parties (i.e. customer, producer and/or a third party). In the past, it was generally accepted that the parties should use similar inspection plans or schemes. This could sometimes prove impossible, due to the parties having different resources and capabilities for inspection. Moreover, due to sampling variability, in up to 25 % of cases the use of similar inspection plans or schemes could result in contradictory results between two parties. This can lead to considerable effort being required to resolve disputes that could have been avoided from the very beginning. The APP enables each of the parties to organize inspection in accordance with its own resources and capabilities for inspection, thereby significantly reducing the probability of occurrence of contradictory results. The parties are not required to coordinate their sampling plans with each other, only with specific requirements of the sampling plans such as customer's or supplier's rights.

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# Acceptance sampling procedures based on the allocation of priorities principle (APP) —

### Part 1:

### Guidelines for the APP approach

### 1 Scope

This part of ISO 28598 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),
- 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.

NOTE Single sampling APP plans by attributes are given in ISO 28598-2.

The guidelines provided by this part of ISO 28598 may 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.

### 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 2859-1, Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

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

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

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

ISO 3951-1, 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 28591, Sequential sampling plans for inspection by attributes

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

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 28598-2:2017, Acceptance sampling procedures based on the allocation-of-priorities principle (APP) — Part 2: Coordinated single sampling plans for acceptance sampling by attributes

#### 3 Terms, definitions, symbols and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO 3534-2, ISO ISO 28598-2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <a href="http://www.iso.org/obp">http://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 3.1 Terms and definitions

#### 3.1.1

### normative quality limit

FUIL POF OF 150 limiting value of the lot quality level specified for the purpose of acceptance as a guaranteed lot quality level

Note 1 to entry: A limiting quality (LQ) may also be considered to be a guaranteed lot quality level although in that case the guarantee is assured only by a sampling plan that has a low probability of acceptance when the lot is of the LQ. Normally it requires large sample sizes, A specified NQL should be considered as a lot quality level guaranteed in part by a sampling plan and in part through supplementary evidence supporting the supplier's capability to satisfy the specified requirements. Asampling plan for LQ is utilized in the case of prior distrust in the lot quality. A sampling plan for a NQL depends on the level of trust in the lot quality and encourages a supplier to submit evidence other than the inspection data in support of the declared quality. In a variety of situations it allows a considerable decrease in the cost of inspection for both the supplier and the customer.

#### satisfactory lot

lot for which the actual quality level is not worse than the specified NQL

### unsatisfactory lot

lot for which the actual quality level is worse than the specified NOL

#### 3.1.4

### customer's risk on supplier inspection

for an acceptance sampling plan fixed by the supplier, the maximum probability of a decision that classifies a lot as satisfactory when the actual lot quality level is worse than the specified NQL

### 3.1.5

#### supplier's risk on customer inspection

 $\alpha_0$ 

for an acceptance sampling plan fixed by the customer, the maximum probability of a decision that classifies a lot as unsatisfactory when the actual lot quality level is not worse than the specified NQL

#### 3.1.6

### schematic customer's risk at supplier inspection

 $\beta_a$ 

maximum probability of accepting the lot when the lot quality level in a sequence of lots is unsatisfactory and the sampling scheme specified by a supplier is used

Note 1 to entry: A schematic risk takes into account the probability of switching to inspection plans of differing severity.

#### 3.1.7

### schematic supplier's risk at customer inspection

 $\alpha_{2}$ 

maximum probability of non-acceptance of the lot when the lot quality level in a sequence of lots is satisfactory and the sampling scheme specified by a customer is used

Note 1 to entry: A schematic risk takes into account the probability of switching to inspection plans of differing severity.

#### 3.1.8

#### arbitration situation

situation which arises due to sampling variation when a customer rejects a lot which was accepted by the supplier on supplier inspection using the same quality level

#### 3.1.9

### arbitration characteristic curve

curve that provides a probability that a lot with a specific quality level will be classified as satisfactory by the sampling plan used by the supplier and as unsatisfactory by the sampling plan used by the customer

#### 3.1.10

### inspecting party

any party that organizes and conducts sampling inspection of the lot for the purpose of acceptance

Note 1 to entry: It may be the supplier, customer or a third party.

#### 3.1.11

#### trust level

customer's estimate of the weight of prior, supplementary and indirect evidence of the supplier's capability to fulfill the specified quality requirements

#### 3.1.12

#### supplier

organization or person that provides a product

[SOURCE: ISO 9000:2015, definition 3.2.5 – modified.]

#### 3.1.13

#### customer

organization or person that receives a product

[SOURCE: ISO 9000:2015, definition 3.2.4 – modified.]

#### 3.2 Symbols and abbreviated terms

Ac acceptance number

APP allocation of priorities principles

AQL acceptance quality limit

LQ limiting quality

NQL normative quality limit

**TQM** total quality management

sample size n

lot size N

trust levels T1 to T7

supplier's risk on customer inspection  $\alpha_0$ 

schematic supplier's risk at customer inspection  $\alpha_a$ 

customer's risk on supplier inspection  $\beta_0$ 

schematic customer's risk at supplier inspection  $\beta_a$ 

### General overview of quality

### **Quality measures**

31150285987.2011 The most common measures of quality are the percentage of nonconforming items and the number of nonconformities per 100 items of product. However, in general cases there may be other characteristics, especially in the inspection of friable, liquid, or linearly or spatially stretched kinds of product. The particular quality measure is specified in standards, specifications or contracts.

The inspections organized on the basis of these guidelines are treated not as an instrument for economic and psychological pressure upon the supplier to enhance quality of the lots, but as an instrument for information support and determination of the relations among the parties mentioned above in matters of lot quality. Each party has the opportunity to protect its interests and rights while still observing the interests and rights of the other parties. Thus, the ISO 28598 system reats the supplier, customer and third-party inspection plans as an integrated and coordinated system.

### Role of information on quality assurance

The efficiency resulting from using the principles stated in these guidelines increases with the degree of attention the supplier and customer pay to the quality assurance aspects of information. The efficiency depends on the amount and integrity of prior information (the more the amount of positive information and the greater its integrity the less the amount of sampling that is required). Prior information is taken into account in defining initial data for choosing sampling plans (first of all in defining the customer's risk on supplier inspection) and in constructing sampling schemes. These guidelines treat acceptance sampling as one of the elements in the information processes among the parties. In other words, sampling procedures are treated together with all data on quality.

Annex A gives the main aspects of the allocation of priorities principle (APP).

Annex B gives recommendations for choosing the customer's risk for supplier inspection.

#### Selection of a sampling system

### 5.1 Relations between sampling systems

The acceptance sampling system of the present guidelines supplement ISO 2859-1, ISO 3951-1, ISO 28591 and ISO 8423. The following information should be referred to for the selection from these International Standards.

### 5.2 Continuing series of lots

The sampling systems described in ISO 2859-1, ISO 2859-3, ISO 3951-1, ISO 28591 and ISO 8423 are beneficial in the following situations:

- a) a sampling inspection is conducted by a single party only (normally by the customer);
- b) a continuing series of lots is considered;
- c) the lots are inspected in the same sequence as those produced;
- d) two or more suppliers are in competition;
- e) the quality level is generally better than the AQL.

In this case, the switching rules given in ISO 2859-1, ISO 2859-3, ISO 3951-1, ISO 28591 and ISO 8423 can give the supplier a good incentive for improvement of the quality level, while purchasers can expect tolerable protection.

### 5.3 Separate lots

The ISO 2859-2 system is advantageous when:

- a) acceptance sampling is conducted by a single party only;
- b) a unique lot is produced or an isolated one inspected;
- c) it is impossible, for some reason, to use prior information on the supplier's capabilities in order to meet the quality requirements;
- d) a long-term business relationship between the producer and the customer is not presumed;
- e) large sample sizes are available.

In this case, ISO 2859-2 is reasonably supportive for the customer.

### 5.4 Features of the ISO 28598 sampling system

The ISO 28598 sampling system may assist when:

- a) inspection is first conducted by the supplier on final inspection and then, for the same lot, by the customer on incoming inspection (occasionally by a third party);
- b) there is a long-term relationship between the producer and the customer;
- c) prior information about the supplier's capabilities to meet specified requirements is available;
- d) the supplier's responsibility for a quality guarantee involving a sampling inspection was agreed upon in the contract;
- e) both parties are interested in reducing the cost of inspection.

Data relating to an effective quality system, statistical process control, preventative actions and other information may be considered by the customer for an approximate assessment of the strength of the lot quality guarantee and for specifying the degree of severity of supplier lot quality inspection to be performed.

### 6 Requirements for the quality of lots and relationships between the parties

### 6.1 Lot quality requirements

### 6.1.1 The form of lot quality requirements

Lot quality requirements should be specified in a contract and/or specification by agreement between the supplier and the customer.

The requirements should be specified in terms of the normative quality limits (NQLs).

If the requirements for lot quality levels are not specified in this way, the ISO 28598 sampling system is not applicable.

NOTE In non-contractual production, the requirements for the lot quality levels may be set in specifications and considered as supplier information about the quality of the lots produced.

### 6.1.2 Satisfactory and unsatisfactory lots

In compliance with the quality level set in a contract, the delivered production lots should be judged by the parties to be satisfactory lots (i.e. meeting specified requirements, see 3.1.2) or unsatisfactory lots (i.e. not meeting specified requirements, see 3.1.3). Thus any lot with a quality level better than the agreed NQL is considered to be a satisfactory lot. On the other hand, any lot with a quality level worse than the agreed NQL is considered to be an unsatisfactory lot.

### 6.1.3 Objectives

For individual and wholesale deliveries, the production lot becomes the object of relationships among the supplier, the customer and the third party and it is necessary to establish the criteria fixing the parties' relations regarding the lot of product. The allocation of priorities principle enables each party to make a free choice of sampling plans and schemes (see 8.3). Therefore, in the ISO 28598 sampling system, the lot quality criterion (NQL) should be specified regardless of the sampling plans, that is, applied for inspection of quality conformance. This is an essential distinction of the NQL from the AQL and the ISO 28598 sampling system from the ISO 2859-1 sampling system. NQL means that, in spite of the activities undertaken, including sampling and screening, the supplier cannot guarantee 100 % conformity of all items of product in a lot. However, the supplier guarantees that the actual quality level will not exceed the specified NQL. A complete guarantee is infeasible, not least due to sampling error and to errors inherent in the measurement and testing facilities and methods.

### 6.2 Relationships of the parties concerning lot quality

The supplier is obliged to deliver lots of satisfactory quality, i.e. corresponding to the specified requirements, with the submission of enough evidence of the adequacy of lot quality to satisfy the customer. On the other hand, the customer is not obliged to accept lots of unsatisfactory quality. On receipt of an unsatisfactory lot and after submission of the evidence to the supplier, the customer may return the whole lot or make the supplier undertake measures to ensure that the lot quality conforms to specified requirements.

It is wrong to believe that an NQL allows the supplier to deliver a percentage of the product that does not meet the requirements. The supplier is liable for the quality of each item of product. When a nonconforming item is found, the supplier should take every necessary measure to recompense the customer, including reclamation, repair or replacement of the nonconforming item even if the lot has been accepted.

#### 6.3 Preventative measures

Information about the NQL allows the customer, and/or a supplier, to establish measures for preventing potential losses. In particular, a customer may specify in a contract the delivery of extra quantities

of items if critical defects are found, establish the rules for introducing discounts depending on the NQL, or undertake other measures. Thus the NQL is the guaranteed information on lot quality for the customer and the basis for setting the relations among the parties.

### 7 Objective of the inspection conducted by supplier, customer and third party

#### 7.1 General

The contract or legislation may provide for a supplier's obligation to demonstrate that the lots are satisfactory by means of final inspection. The customer and third party may perform successive inspection in order to check the validity of supplier data on lot quality. The third party may perform inspection also in cases of arbitration or when supervising the quality of product.

These guidelines show that the main task of acceptance inspection is to confirm or repudiate the data on the lot quality, i.e. its purported conformity with specified requirements.

All non-statistical errors should be considered in favour of the opposite party

### 7.2 Objective of the inspection conducted by the supplier

Sampling inspection conducted by the supplier (supplier inspection) is treated as an instrument for demonstrating to the customer (or his representative) and/or third party the validity of information about the adequacy of lot quality.

Contractually specifying the NQL value, the supplier asserts by implication that the actual value of the quality level in the lots delivered is not worse than this value (see 6.1.3). The supplier inspection should be adequate to demonstrate that this information is true.

### 7.3 Objective of the inspection conducted by the customer

Sampling inspection conducted by the customer (customer inspection) may be regarded as a means of demonstrating inadequacy of the supplier's information concerning lot quality conformance with specified requirements in a potential claim situation. Normally when using the sampling system of ISO 28598 a customer inspection is not required. It is far more effective to audit a supplier's acceptance sampling and quality system.

### 7.4 Objective of the inspection conducted by a third party

An interpretation of sampling inspection performed by a third party reflects the interests of the inspecting party.

When an inspection is conducted in the interests of the supplier, it will be regarded as a means of demonstrating the validity of information about the compliance of lot quality with specific requirements.

When an inspection is conducted in the interests of a customer (e.g. certification of product, surveillance or product quality inspection with the possibility of making claims against the supplier or making the inspection results known), it is regarded as a means of demonstrating inadequate information about the compliance of lot quality with specific requirements.

NOTE In performing an inspection for arbitration purposes, the third party acts in accordance with the rules of the claimant.

# 8 Requirements of the system of sampling inspection conducted by supplier, customer or third party

### 8.1 Common system requirements

If a contract or legislation provides for successive sampling inspection by various parties (supplier, customer or third party), then the system should satisfy a set of requirements on its inspection plans. First of all it should provide for flexibility of rules in choosing plans and schemes so as to provide for the differences in peculiarities, limitations and circumstances of each party. Moreover, the system should fix such requirements as necessary on the sampling plans to promote reproducibility of decisions obtained by the various parties on the basis of inspection results.

### 8.2 Reproducibility of decisions made by sampling inspection results

Due to the statistical nature of sampling, successive inspections at constant lot quality may give different results even if the inspection methodology is strictly observed. The most important example of this is when the supplier makes a positive decision and the customer, or the third party, makes a negative one due to the uncertainty inherent in random sampling, leading to an arbitration situation.

The system should provide for a low probability of occurrence of such cases.

For the non-reproducibility characteristic the guidelines consider the probability of both a positive decision at supplier inspection and a negative decision at customer inspection. For the analysis of successive inspection there is introduced the notion of an arbitration characteristic, i.e. the probability of an arbitration situation as a function of the lot quality level. Examples of arbitration characteristics are given in Annex A.

There is a widespread misconception that, to ensure the reproducibility of decisions, each party should use similar plans. However, their use may give high non-reproducibility of inspection results, up to a quarter of all cases, i.e. up to a value of the arbitration characteristic curve of 0,25. It is obvious that this is an extremely high value and with similar plans the parties may have to go to considerable trouble to resolve disputes, which should have been avoided when planning the inspection.

The supplier should endeavour to produce product that is considerably better than the NQL to avoid problems of conflicting acceptance at various stages of successive inspections.

The APP concept enhances the reproducibility of the decisions being made from inspection results and allows the assignment of any maximum value of the arbitration characteristic curve while still granting each party a high level of freedom in choosing from inspection plans and schemes.

# 8.3 System flexibility and the possibility to accommodate individual capabilities and interests of the inspecting parties

It is expedient for each party to have the opportunity to choose the inspection plans and schemes to suit their aims, capabilities and peculiarities. These guidelines limit the variety of inspection plans and schemes from which the parties may choose. These plans and schemes are referred to as permissible.

The criterion for an inspection plan or scheme to be permissible is a constraint on the risk of the other party. Each party has the complete freedom to choose any inspection plan or scheme from the variety of permissible plans without any coordination.

#### 8.4 Cost efficiency of inspection

The system should enable inspection costs to be minimized, and an inspection to be performed in due time and in amounts sufficient to provide for integrity of the decisions that will be based on the results. Inspection cost reduction is achieved by granting each party the right to choose optimal plans and schemes and also due to the opportunity to consider prior information, to adopt inspection plans and schemes for the current quality of the process and to acquire the latest prior information.

### 8.5 Types of information used when organizing inspection and in decision making

For organizing inspection and subsequent decision-making, the following information is used:

- prior information (see <u>Clause 9</u>);
- basic data, treated as requirements for product quality set up in a sampling plan or scheme, and for the integrity of a decision-making (see <u>Clause 10</u>);
- inspection data (see <u>Clause 11</u>).

#### 9 Prior information

### 9.1 Types of prior information

As a rule, before sampling inspection is undertaken, a great deal of prior information is available concerning the potential quality of lots. This includes a supplier's reputation quality history, data on statistical process control, performance data information about the supplier quality system including its certification or evaluation by a second party, inspection data from development and manufacturing, etc. It is rare for this information to be incorporated into acceptance sampling systems. However, neglecting this information may make sampling very expensive because of the large sample sizes that become necessary, or may fail to provide the required level of customer protection.

These guidelines provide a method for combining prior information, including information of a subjective nature, with inspection data, permitting a reduction in inspection effort while still maintaining the required level of customer protection.

Subjective prior information is considered by the customer in evaluating the probability of lots of satisfactory quality being submitted for inspection, and is used by the customer in setting his own risk on supplier inspection (see Annex B).

NOTE In practice, specialists are often in a position to estimate lot quality prior to carrying out sampling inspection. Most standards do not permit the subjective evaluation of lot quality to influence the determination of appropriate sampling plans or schemes. These guidelines enable the user to integrate those prior estimates.

### 9.2 APP approach for considering prior information

Prior information is integrated using an APP approach and, in particular, is the basis for evaluating the risks of the customer and the supplier (see <u>Annex B</u>).

Annex B presents the formula, which gives an assessment of the risk and enables the customer to consider prior information. In fact, he should estimate the probability of unsatisfactory lots being submitted for acceptance and, based on this estimate, set the customer's risk value on supplier inspection. In situations where his estimates of the probability of lots of unsatisfactory quality being submitted are low (for example, less than 0,1), then the customer may fix the value of his risk to be rather high, even close to or equal to 1. In the latter case the acceptance is carried out without inspection.

Suppliers may also use prior information to choose optimal sampling plans and schemes from permissible ones, in order to meet the customer's risk constraints. In an ideal situation, the supplier may have a very good estimate of the process quality level. In this case the supplier may use his own prior estimate of the lot quality level as an acceptable level corresponding to a high probability of lot acceptance. Calculated at this value of the quality level, the probability of acceptance is interpreted as its prior estimate.

### 9.3 Economic aspects of prior information

Use of prior information may provide considerable savings, as increases in the value of a customer's risk become possible, allowing a reduction in the amount of inspection and consequently a reduction in inspection costs.

Conversely, loss of credit by a supplier, and the lack of current prior information may force the customer to reduce the value of his own risk on supplier inspection and, as a consequence, to increase expenses and the cost of production.

On the whole, the approach enables each party to maximize use of available prior information and stimulates active data acquisition, accumulation and exchange.

### 10 Choosing sampling plans and schemes

#### 10.1 General

These guidelines enable the parties concerned to abandon the use of similar plans and schemes for successive inspection. Use of the ISO 28598 sampling system gives the parties the autonomy to choose specific plans and schemes. It is necessary to agree only upon some initial requirements of the integrity of the decisions to be made.

### 10.2 Characteristics of sampling plans and schemes

The difference between the objectives of the inspection conducted by the supplier, customer and/or the third party dictates the discrimination between the measures to protect the interests of the opposite party. The protection of the other party's interests is achieved by introducing constraints on the sampling plans and schemes on which decisions on lot conformity are made. These constraints are formulated in terms of constraints on the risk of the other party. Thus, the supplier's inspection plans and schemes are characterized by the customer's risk on supplier inspection, and the customer's inspection plans and schemes by the supplier's risk on customer inspection. If the decision rules use confidence limits (intervals, regions), then the corresponding constraints for confidence levels are introduced. Constraints for confidence levels and constraints for the risks may be calculated from each other.

### 10.3 Rights of the parties in choosing sampling plans and schemes

An inspecting party should choose sampling plans and schemes subject only to providing protection of the other party's interests:

- for supplier inspection a given constraint on the customer's risk on supplier inspection should be provided;
- for customer inspection a given constraint on the supplier's risk on customer inspection should be provided.

The third party should organize inspection in accordance with the rules of either the supplier or the customer (see 7.4).

### 10.4 Permissible sampling plans and schemes

#### 10.4.1 General

Permissible sampling plans and schemes are those that satisfy either the constraints of type I as defined in 10.4.2, or the constraints of type II as defined in 10.4.3.

### 10.4.2 Constraints of type I

These are the constraints on customer's risks on supplier inspection and constraints on the supplier's risks on customer inspection.

Due to these constraints, all possible inspection plans are divided into those that are permissible and those that are not permissible. For the supplier, the permissible plans are those which meet the constraint on the customer's risk on supplier inspection. For a customer, the permissible plans are

those which meet the constraint on the supplier's risk on customer inspection. The sets of permissible plans for each party are different.

A supplier should choose a sampling plan and a scheme from among the permissible ones only with regard to his own optimality criteria.

A customer should choose a sampling plan with regard to his own objectives and his own optimality criteria observing the constraint on the supplier's risk on customer inspection.

A third party, if any, should follow the rules of supplier (or customer) inspection depending on the objective of the inspection, in accordance with 7.4.

### 10.4.3 Constraints of type II

These are the constraints on confidence levels when decision rules involve confidence limits (intervals, regions) for the lot quality levels.

Different parties (supplier, customer, the third party) choose sampling plans with regard to their own objectives, abilities and optimality criteria, observing decision rules that are based on the confidence intervals (regions).

Protection of the opposite party's interests is conditioned by the decision rules structure, which automatically provides for the constraints on relevant risks (sec 10.6.3).

### 10.5 Setting the constraints for risks and confidence levels

### 10.5.1 Constraints of type I

### 10.5.1.1 Supplier inspection

### **10.5.1.1.1** For separate lots

Standard values of customer's risk on supplier inspection are fixed by the customer from the range: [0,1; 1]. The upper value of 1 corresponds to the acceptance by trust without supplier inspection. The selection of this value should depend on the degree of the customer's trust in the supplier's capabilities to meet the specified requirements. These guidelines recommend seven levels of prior trust in the supplier's capabilities, each corresponding to a different constraint on the customer's risk on supplier inspection. However, in specific situations the supplier and the customer may use a greater number of levels of trust. Recommendations for setting a customer's risk on supplier inspection are given in Annex B.

The customer has the right to change the values of the customer's risks on supplier inspection within the limits specified in this International Standard, depending on the degree of his trust in the information about the quality of the product manufactured by the supplier, up to the values corresponding to lot acceptance without performing any inspection.

#### 10.5.1.1.2 For a continuing series of lots

When inspecting a sequence of lots, sampling schemes may be used with rules for switching between plans of various severity corresponding to various risks. An inspecting party chooses the scheme in accordance with constraints prescribed by the schematic risk for the opposite party. The minimal value of the schematic customer's risk on supplier inspection is equal to 0,1. Recommendations for establishing the schematic customer's risk on supplier inspection are given in Annex B.

NOTE 1 Sampling schemes can be used by the customer for incoming inspection if the succession of lots submitted is produced by one and the same producer for fixed requirements for the lot quality of product. If the production lots are submitted by different producers on incoming inspection, then the customer inspects each lot as a single lot, not as a sequence of lots for which inspection schemes may be used.

The customer may increase the value of the schematic customer's risk on supplier inspection up to the value 1, depending on his degree of trust in the supplier information about the quality of product. The value 1 corresponds to customer acceptance without supplier inspection, reflecting the customer's total trust in the supplier.

NOTE 2 Skip-lot sampling is a specific case of an inspection scheme. When calculating the average customer's risk it should be borne in mind that, for lots accepted without inspection, the value of the customer's risk on supplier inspection is equal to 1. However, the schematic customer's risk on supplier inspection is defined for the purpose of the relevant plan.

These guidelines cover the common approaches of the parties to the decision-making, should either a sampling plan or a sampling scheme be used. It should be noted that, for both sampling plans and schemes, the decision is made with regard to separate lots. However, when applying sampling schemes, i.e. a number of inspection plans with rules for switching between them, and in making decisions concerning a particular single lot, use is actually made of prior information in terms of inspection data on the preceding lots using relevant switching rules. In all situations when there is trust in manufacturing stability, it is important to use sampling schemes because they can provide for lower inspection costs and greater efficiency.

### **10.5.1.2** Customer inspection

The standard value of the supplier's risk on customer or third-party inspection (normally 0,01; 0,05 or 0,1) should be specified in the contract and is not subject to alteration. If the value of a supplier's risk on customer inspection is not specified in a contract, then the value 0,05 should be used.

### 10.5.2 Constraints of type II

The use of the decision rules described in 10.6.3 provides for a customer's risk on supplier inspection equal to  $\gamma_0$  = 0,75, where  $\gamma_1$  is the confidence level used for building confidence intervals from the supplier inspection results. The supplier's risk on customer inspection is equal to  $\alpha_0$  = 1- $\gamma_2$ , where  $\gamma_2$  is the confidence level used in processing the customer inspection data.

### 10.6 Decision-making rules

### 10.6.1 Decision-making with respect to supplier and customer inspection

### 10.6.1.1 Supplier inspection

A decision that a lot is satisfactory (positive decision) means that the supplier in the course of inspection has demonstrated the integrity of his information showing product conformity with specified requirements. A decision that lot quality is unsatisfactory (negative decision) means that the supplier failed to demonstrate this integrity.

#### **10.6.1.2** Customer inspection

A decision that a lot is unsatisfactory (negative decision) means that the customer in the course of inspection demonstrated the lack of integrity of the supplier information about lot quality conformity with specified requirements.

A decision that lot quality is satisfactory (positive decision) means that the customer failed to repudiate the supplier assertion that the product conformed to specified requirements.

### 10.6.1.3 Third-party inspection

On third-party inspection, the decision is made either according to the supplier's or the customer's rules depending on the interests concerned.

### 10.6.2 Constraints of type I

For type I constraints, decisions are made on the basis of the rules included in the specifications of the permissible inspection plans and schemes.

NOTE For example, when applying a single inspection plan by attributes, the decision is made by comparing the number of nonconforming items or nonconformities in a sample with the acceptance number. If the number of nonconforming items or nonconformities does not exceed the acceptance number, then a positive decision is made. On the other hand, when the acceptance number is exceeded, a negative decision is made. The inspection plans on supplier and customer inspection for the same NQL will be different. This means that the decision rules are also different. The coincidence of acceptance numbers is possible, but the sample sizes will be different.

### 10.6.3 Constraints of type II

For type II constraints, each party establishes different decision rules, as specified below.

### a) **On supplier inspection**

The decision that the lot is satisfactory is made if a confidence interval (one-sided) or a confidence region is included within the required interval (region) of lot quality values. The decision that the lot quality is unsatisfactory is made if at least one point of the confidence interval (region) is found to be outside the required interval for the lot quality level.

### b) On customer inspection

The decision that the lot is satisfactory is made if at least one point of the confidence interval (region) is found inside the requirements for lot quality levels. The decision that the lot is unsatisfactory is made if all the points of the confidence interval (region) lie outside the required interval for the lot quality level.

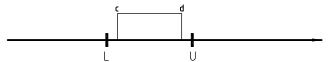
The decision rules are illustrated in Figure 1.

NOTE The application of decision rules in this form has certain advantages. First, the illustrations show clearly that disputable situations are always resolved in favour of the opposite party. Second, the matters of choosing inspection plan parameters and setting decision rules are separated. The decision rules are the object of the agreement between the parties or of the regulation by the authorized body, and the selection of inspection amounts (considering each stage of inspection) becomes completely independent for each party.

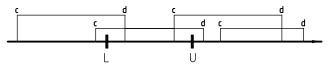
### 11 Re-submission of previously non-accepted lots on supplier inspection

The supplier and customer may specify in the contract the rules for reducing the customer's risks on supplier inspection for lots repeatedly submitted for inspection after previous non-acceptance, down to the minimal risk values.

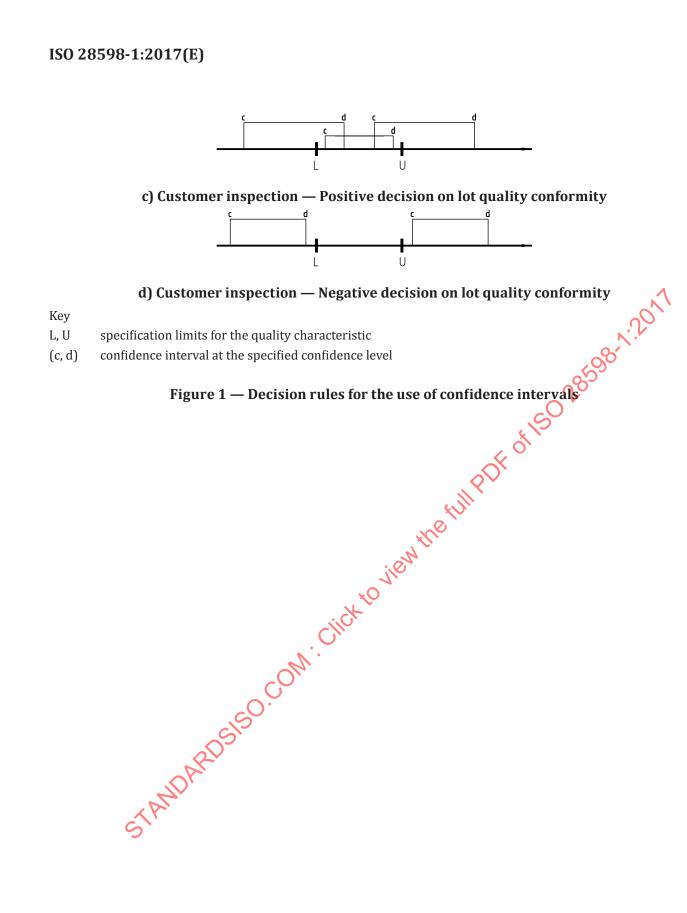
The supplier may resubmit the lots for inspection after they have undergone some activities: complete inspection, replacement or restoration of nonconforming items of product.



a) Supplier inspection — Positive decision on lot quality conformity



b) Supplier inspection — Negative decision on lot quality conformity





**14** 

### Annex A

(informative)

### Allocation of priorities principle

#### A.1 General

ISO 9001[1] can be used by independent third-party certification bodies to assess an organization's ability to meet customer, regulatory and the organization's own requirements.

The results of such assessments should be in addition to the evidence submitted by the supplier concerning the assurance of product quality conformity to specific requirements. The acceptance quality inspection and the acceptance and certification of products are supplemented by the guarantees obtained by assessing internal manufacturing processes, as well as the quality and control assurance performed by the supplier. This widens the concept of acceptance sampling.

Final sampling should be treated as only one of the supplier's means of proving its abilities to ship products of specific quality. The requisite sampling intensity should depend on the degree of customer confidence formed by the totality of evidence offered.

If the customer has a favourable impression of the supplier quality system and (or) the certificates granted by the third party are available, the role of acceptance sampling inspection (testing) as such may not be as important as it would be otherwise. This approach treats acceptance sampling inspection as a means for the supplier to demonstrate the validity of the information about the quality of product populations released by it, and also as a means for the customer or the third party to check the validity of this information.

Statistical parameters, such as customer's and supplier's risks and confidence levels, are the quantitative characteristics of the integrity of decisions made on the basis of the acceptance sampling inspection results.

When organizing acceptance quality inspection, the relevance of the subjective element is frequently underestimated. A high price is paid if an inspector will not take anything on trust except for "objective" inspection data.

### A.2 Use of quality information

Traditional acceptance sampling procedures take into account no data other than the inspection data. It goes without saying that this approach leads to a relatively large inspection effort.

Furthermore, it is possible to reward the producer who achieves higher trust levels with financial incentives provided from the savings due to inspection cost reduction.

When substantial positive subjective information is available, it becomes unprofitable for the customer to place his trust solely in direct inspection results. Moreover, it becomes profitable for both parties to exchange data on quality and to study product manufacturing and operation processes.

The system allows the accommodation of the level of customer trust in data on the quality of products, and provides the possibility of controlling the amount and the validity of sampling inspection depending on this level of trust. Inspection costs can be considerably reduced in maintaining quality assurance of products.

### A.3 Reproducibility of decisions

The system provides for reproducibility of decisions obtained by various parties whilst giving them maximum freedom to choose inspection plans and schemes. This almost eliminates the occurrence of arbitration situations caused by sample to sample variability.

The arbitration characteristic curve may be calculated using the following formula:

$$A(p) = L_s(p) \lceil 1 - L_c(p) \rceil$$

where

- A(p) is the probability of an arbitration situation for a supplier and customer sampling system for lot quality level p;
- $L_{\rm s}(p)$  is the probability of accepting a lot for a sampling plan on supplier inspection, for lot quality level p;
- $L_{\rm c}(p)$  is the probability of accepting a lot for a sampling plan on customer inspection, for lot quality level p;
- *p* is the lot quality level.

NOTE The formula is based on the assumption that the lot quality is the same for the supplier and the customer, i.e. that the lot quality is not affected by the supplier's inspection, by the delivery or by the storage of the lot.

For similar supplier and customer inspection plans, the maximum probability of a lot disposition requiring arbitration is equal to 0,25. Examples of the arbitration characteristic curve are shown in Figure A.1.

The basis of these guidelines are the allocation of priorities principle (APP) [6], [7].

It can be proved that the APP provides for the maximum value of the arbitr]ation characteristic curve to be no higher than  $\min\{\alpha_0,\beta_0\}$  where  $\alpha_0$  and  $\beta_0$  are the supplier's risk on customer inspection and the customer's risk on supplier inspection respectively.

### A.4 APP principles

### A.4.1 Rights of individual parties

Following the guidance given in the APP:

- a) the supplier and customer have the right to establish inspection plans and schemes unilaterally subject to fulfilling a limitation for the opposite party's risk, i.e. for the probability of a false decision affecting the opposite party's interests;
- b) the customer has the right to fix his risk on supplier inspection; the supplier's risk on customer inspection is specified by the standard or the contract and cannot be modified;
- c) the third party performs an inspection
  - 1) from the supplier's point of view, if the supplier ordered an inspection for the purposes of certification, or
  - 2) from the customer's point of view, if the customer ordered the inspection; or if he carries out an inspection independently with the purpose of surveillance, for example at certification, and also when the results are to be published or a claim is to be made on the supplier.

### A.4.2 Features of APP acceptance sampling system

A supplier, customer and third party acceptance sampling inspection system indexed by the above principles provides

- a) a methodological basis for acceptance sampling as a means of confirming the validity of decisions on product conformity or nonconformity to the specified requirements,
- b) coordination between the establishment and methodology of acceptance sampling with ISO 9001:2015 provisions and the implementation of the offered system together with the quality assessment, and certification and attestation of the manufacturing processes,
- c) the inclusion of acceptance sampling into a mechanism of data exchange concerning the quality of products,
- d) control of the amount of inspection in accordance with the degree of the customer's trust, considerably reducing the amount if the customer develops more trust in the supplier's information about the quality of products. Transfer to acceptance without inspection (i.e. indirect inspection) is possible on reaching complete confidence. And conversely, loss of customer confidence leads to tightening of inspection and an increase in inspection costs,
- e) the optimization and adaptation of inspection plans and schemes for particular and changing conditions of the parties,
- f) an almost complete elimination of disputes caused by the variable nature of sample inspection results.
- g) for correct arbitration solutions of disputes concerning process quality.

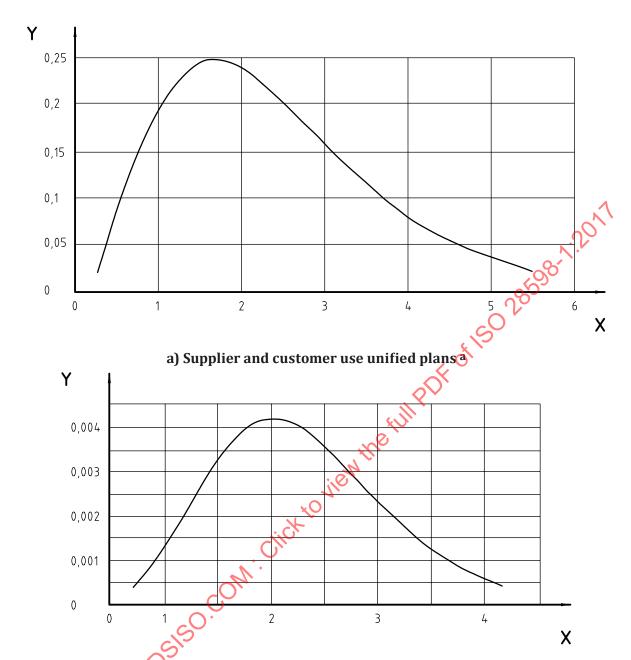
### A.4.3 Interpretation of the APP

<u>Figure A.2</u> shows the interpretation of the APP in terms of the operating characteristic curve.

Each party may choose any inspection plan (scheme).

However, the relevant supplier operating-characteristic curve should not pass above the point ( $p_{NQL}$ ,  $\beta_0$ ) i.e. the value of the operating characteristic should not exceed  $\beta_0$  at  $p_{NOL}$ .

The relevant customer operating-characteristic curve should not pass below the point ( $p_{NQL}$ ,  $1 - \alpha_0$ ), i.e. the value of the operating characteristic curve should not be less than  $1 - \alpha_0$  at  $p_{NOL}$ .

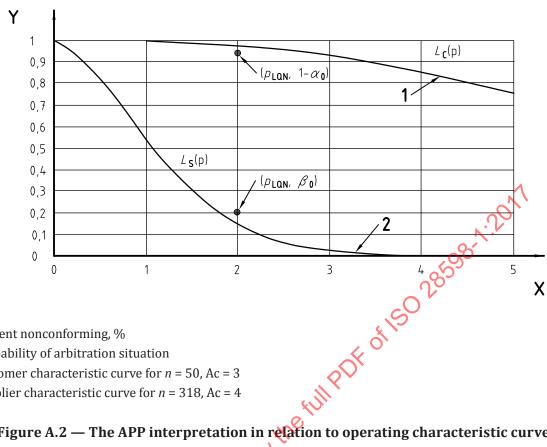


b) Supplier inspection plan meets limitation for the customer's risk on supplier inspection and customer inspection plan meets limitation for the supplier's risk on customer inspection b

#### Key

- X percent nonconforming, %
- Y probability of arbitration situation
- a Supplier n = 100, Ac = 1; customer n = 100, Ac = 1.
- b Supplier n = 318, Ac = 4; customer n = 50, Ac = 3.

Figure A.1 — Arbitration characteristic curves of supplier and customer sampling procedures



X percent nonconforming, %

Key

- probability of arbitration situation
- customer characteristic curve for n = 50, Ac = 3 1
- supplier characteristic curve for n = 318, Ac = 4

on in reconstruction of the state of the sta Figure A.2 — The APP interpretation in relation to operating characteristic curves

### Annex B

(informative)

### Recommendations for setting customer's risks on supplier inspection

### B.1 Meaning of customer's risk on supplier inspection

Taking into account all available prior information about products being shipped, the customer can estimate the prior probability *P* of submission of nonconforming production lots for supplier inspection:

$$P(p > p_{NQL})$$

where

is the lot quality level; р

is the lot quality level equal to the NQL.

Full PDF of 150 28t. The inequality sign in  $P(p > p_{NOL})$  implies that good quality corresponds to small values of p. An NOTE example of such a parameter is represented by the percent of nonconforming items.

For the customer's risk  $eta_{
m b}$  , which represents the probability of accepting the population of products not meeting its quality requirements with regard to the prior information available, the following inequality obtains:

$$\beta_{\rm b} \le \beta_0 P (p > p_{\rm NQL})$$

where  $\beta_0$  is the customer's risk on supplier inspection, i.e. the value of the operating-characteristic curve at lot quality level  $p_{NQIC}$ 

This inequality depends neither on the nature of the prior distribution function, nor on the type of operating-characteristic curve. The inequality is true for any types of prior distribution function and operatingcharacteristic curve. The value of  $\beta_0 P(p>p_{\mathrm{NQL}})$  may be several times larger than the value of  $\beta_{\mathrm{b}}$ . This should be taken into consideration when using the formulae resulting from the inequality as they may give a grossly over-guaranteed result.

If the value  $P(p>p_{NQL})$  is considerably lower than 1, for example less than 0,1, the customer may increase the value of the risk  $oldsymbol{eta}_0$  whilst still maintaining a reasonably small value of the customer's risk

Thus, if the customer is oriented to a certain actual value of risk  $\beta_{\rm b}$  (for example,  $\beta_{\rm b}$  = 0,01 or  $\beta_{\rm b}$  = 0,05), the value of  $\beta_{\rm 0}$  may be obtained from the formula

$$\beta_0 = \begin{cases} \beta_b / P(p > p_{\text{NQL}}) & \text{if } \beta_b / P(p > p_{\text{NQL}}) < 1\\ 1 & \text{otherwise} \end{cases}$$
(B.1)