INTERNATIONAL STANDARD

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Third edition

Sampling procedures for inspection by attributes —

Part 4: Procedures for assessment of declared quality levels

Règles d'échantillonnage pour les contrôles par attributs —

Partie 4: Procédures pour l'évaluation des niveaux déclarés de qualité

PROOF/ÉPREUVE

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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.

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

This third edition cancels and replaces the second edition (ISO 2859-4:2002), which has been technically revised.

The main changes compared to the previous edition are as follows:

— xxx xxxxxxx xxx xxxx

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.

Introduction

The procedures in this document differ in their scope from the procedures in ISO 2859-1 to ISO 2859-3. The acceptance sampling systems specified in ISO 2859-1 to ISO 2859-3 are intended to be used in bilateral agreements between two parties. The acceptance sampling procedures are supposed to be used as simple, pragmatic rules for deciding on product release by inspection of only a limited sample of a consignment, and therefore the procedures do not make reference (either explicitly or implicitly) to any formally declared quality level.

Under acceptance sampling there is no sharp borderline between quality levels that should be considered acceptable and qualities that should be rejected by the procedure. For the procedures in ISO 2859-1, the two parties agree upon some acceptance quality limit (AQL) which is the worst tolerable process average when a continuing series of lots is submitted. The switching rules and the sampling schemes in ISO 2859-1 are designed to encourage the suppliers to have process averages consistently better than the AQL selected. In order to keep sample sizes moderate, the protection against accepting individual lots of inferior quality may be less than that provided by sampling plans targeted for sentencing individual lots. The procedures in ISO 2859-2, on the contrary, are designed to provide good protection against accepting individual lots of inferior quality (LQ), but at the expense of a possibly high risk of not accepting lots of qualities that both parties actually would consider to be acceptable.

The procedures in ISO 2859-1 to ISO 2859-3 are well suited for acceptance sampling purposes, but they should not be used in reviews, audits, systematic tests, etc. to verify a quality that has been declared for some entity. The main reason is that the procedures have been indexed in terms of quality levels that are relevant solely for the pragmatic purposes of acceptance sampling, and the various risks have been balanced accordingly in a pragmatic attitude.

The procedures in this document have been developed as a response to the growing need for sampling procedures suitable for formal, systematic inspections such as reviews or audits or systematic tests. When performing such a formal inspection, it is necessary both for the inspecting authority and for the body subject to inspection to consider the risks of reaching an incorrect conclusion. These risks have to be accounted for explicitly in the design of review/auditing/testing procedures.

This document provides guidance and rules to assist the user in accounting for the risks of incorrect conclusions in an informed manner.

The rules in this document have been devised such that there is only an acceptably small risk of contradicting the declared quality level when in fact the actual level conforms to the declared level.

If it were also desired that there should be a similarly small risk of not contradicting the declared quality level when in fact the actual quality level does not conform to the declared quality level, then it would be necessary to investigate a rather large sample. Therefore, in order to obtain the benefit of a moderate sample size, the procedures in this document have been devised in such a way that they allow a somewhat higher risk of failing to contradict the declared quality level when in fact the actual quality level does not conform to the declared quality level.

The wording of the result of the assessment should reflect this imbalance between the risks of reaching incorrect conclusions. For the levels I, II, and III, when the sample result contradicts the declared quality level, there is strong evidence of nonconformance to the declared quality level. When the sample result does not contradict the declared quality level, this should be understood as “we have not, in this limited sample, found strong evidence of nonconformance to the declared quality level”.

CAUTION — It should be noticed that, for sampling plans with very small sample sizes, one should be aware of the poor discriminatory power under such sample sizes by referring to the entries in Tables B.1, B.2, B.3 and B.4.

Sampling procedures for inspection by attributes —

Part 4: Procedures for assessment of declared quality levels

1 Scope

This document establishes single sampling plans for conformance testing, i.e., for assessing whether the quality level of a relevant audit population (lot, process, inventory, file etc) conforms to a declared value. Sampling plans are provided corresponding to four levels of discriminatory ability. The limiting quality ratio (LQR) (see Clause 4) of each sampling plan is given for reference. For levels I-III, the sampling plans have been devised so as to obtain a risk no more than 5 % of contradicting a correct declared quality level. The risk of failing to contradict an incorrectly declared quality level which is related to the LQR is no more than 10 %. The sample sizes for level 0 are designed in a way that the LQR factors of the sampling plans are compatible with the LQR factors for level I.

In contrast to the procedures in the other parts of the ISO 2859 series, the procedures in this document are not applicable to acceptance assessment of lots. Generally, this document mainly focuses on controlling type I error, which differs from the balancing of the risks in the procedures for acceptance sampling.

This document can be used for various forms of quality inspection in situations where objective evidence of conformity to some declared quality level is to be provided by means of inspection of a sample. The procedures are applicable to entities such as lots, process output, etc. that allow random samples of individual items to be taken from the entity.

The sampling plans provided in this document are applicable, but not limited, to the inspection of a variety of targets such as:

— end items;

— components and raw materials;

— operations;

— materials in process;

— supplies in storage;

— maintenance operations;

— data or records;

— administrative procedures;

— accounting procedures or accounting entries;

— internal control procedures.

This document considers two types of quality models for discrete items and populations, as follows.

i) The conforming-nonconforming model, where each item is classified as conforming or nonconforming, and where the quality indicator of a population of items is the proportion p of nonconforming items, or, equivalently, the percentage 100 p of nonconforming items.

ii) The nonconformities model, where the number of nonconformities is counted on each item, and where the quality indicator of a population of items is the average number λ of nonconformities found on items in the population, or, equivalently, the percentage 100 λ of nonconformities on items in the population.

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

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

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

3 Terms, definitions, symbols and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 3534-2 and ISO 9000 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
non-rejection number
c
largest number of nonconforming items or nonconformities, respectively, found in the sample from the population under investigation that does not lead to contradiction of the declared quality level

3.1.2
quality ratio
QR
ratio of the actual quality level to the declared quality level of the entity under investigation

3.1.3
limiting quality ratio
LQR
value of the quality ratio that is limited to a small risk of failing to contradict an incorrect declared quality levelNote 1 to entry: In this document, the risk of failing to contradict an incorrect declared quality level is no more than 10 %.

3.1.4
audit population
totality of items under audit inspection

3.1.5
audit population conformance
state of the audit population fulfilling imposed requirements

3.2 Symbols and abbreviated terms

c non-rejection number of a sampling plan

d number of nonconforming items or, respectively, nonconformities in the sample

n sample size of a sampling plan

DQL declared quality level

LQR limiting quality ratio

QR quality ratio

4 Sampling and decision procedure

4.1 Identifying a sampling plan

A single sampling plan (*n, c*) with sample size *n* and non-rejection number *c* is identified from Table 1 by two characteristics:

a) the DQL, ranging from 0,01 percent to 10,00 percent;

b) the LQR level, ranging over 0, I, II, III.

Except a few exceptions for very small and very large DQL, the non-rejection numbers are constant under each LQR level, with *c* = 0 under level 0, *c* = 1 under level I, *c* = 2 under level II, and *c* = 3 under level III.

If the declared quality level is not one of the tabulated values, then the next higher tabulated value of DQL shall be used to select the plan.

NOTE This results in an LQR that is somewhat higher, and to a probability of falsely contradicting a correct declared quality level that is somewhat lower than the values given in Tables 2 to 5 (see 8.2).

EXAMPLE If an LQR level II is chosen with a DQL of 0,65 % nonconforming items, Table 1 yields a sampling plan with a sample size *n* of 127, and a non-rejection number of nonconforming items *c* of 2, which provides an LQR of 6,45 (see Table 4).

4.2 Drawing of samples

The sample shall be selected by simple random sampling or, where appropriate, by stratified or other methods of random sampling from the entity.

When stratified sampling is used, the number of items from each stratum shall be selected in proportion to the size of strata of the entity under investigation. The sub-sample from each stratum shall be selected by simple random sampling from that stratum.

When sampling from a lot or a consignment, stratified sampling may be used with strata corresponding to identifiable sub-lots.

When sampling from a process, stratified sampling may be used with strata corresponding to identified sources of variation, for example tools, operators, shifts, etc.

If the sample size exceeds the size of the entity under investigation, then all items of the entity shall be inspected.

EXAMPLE If, in the example considered in 4.1, the entity under investigation is the computer records of administrative transactions during five business days, and the number of transactions each day are approximately equal, then the total sample of n = 127 transactions are selected as five sub-samples, three consisting of 25 transactions and two consisting of 26 transactions, selected by simple random sampling from the transactions on each of the five days.

4.3 Decision objective

The audit population is considered as *conforming* if the population quality indicator (percentage of nonconforming units, or percentage of nonconformities per item, respectively) is smaller or equal to the DQL. Otherwise, the audit population is considered as *nonconforming*. The inspection objective shall decide on the conformance of the population by taking one of two mutually exclusive decisions: i) *rejection*, i.e., contradict the quality declaration expressed by the DQL and classify the population as nonconforming; ii) *non-rejection* or *acceptance*, i.e., do not contradict the quality declaration expressed by the DQL and classify the population as conforming.

4.4 Decision by sampling

Each of the n items in the sample shall be inspected, and the total number d of nonconforming items or, respectively, of the nonconformities on items in the sample shall be determined.

— If d is less than or equal to the non-rejection number c, the decision is *non-rejection*, i.e., the declared quality level is not contradicted.

— If d exceeds the non-rejection number c, the decision is *rejection*, i.e., the declared quality level is contradicted.

EXAMPLE Assume that, in the situation considered by the Example in 4.1, two or fewer nonconforming items are found in the sample of 127 items. Then the sample result does not contradict the DQL of 0,65 % nonconforming items. If three or more nonconforming items are found, the sample evidence contradicts the DQL.

4.5 Disposition of nonconforming items

Any nonconforming items or items exhibiting nonconformities found in the sample shall not be returned to the rest of the items unless the nonconforming items are brought to a conforming condition and applicable administrative rules are followed.

Examples for the use of the sampling and decision procedure in industrial practice are provided in Annex A.

5 Principles

Any assessment procedure based on sampling is subject to *sampling risk*, i.e., the risk of taking an erroneous decision due to the limited information conveyed by a sample. In the present context, there are two types of erroneous conclusions on an audit population:

a) rejection although the population is actually conforming, i.e., the population quality indicator (percentage of nonconforming units, or percentage of nonconformities per item, respectively) is actually smaller or equal to the DQL;

b) non-rejection although the population is actually nonconforming, i.e., the population quality indicator (percentage of nonconforming units, or percentage of nonconformities per item, respectively) is actually exceeding the DQL.

The corresponding error risks are expressed by the respective error probabilities, namely a) the probability of rejecting an actually conforming population; b) the probability of not rejecting an actually nonconforming population. The latter two risks shall be balanced by the design of the sampling plans.

