INTERNATIONAL STANDARD

ISO 28597

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Acceptance sampling procedures by attributes — Specified quality levels in nonconforming items per million

Règles d'échantillonnage par attributs en vue d'acceptation — Niveaux spécifiés de qualité en termes d'individus non conformes pour un million d'individus

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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 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: www.iso.org/iso/foreword.html.

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

This first edition of ISO 28597 cancels and replaces ISO 14560:2004, of which it constitutes a minor revision to change the reference number from 14560 to 28597.

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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	ISO 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.

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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

For processes that produce nonconforming items relatively rarely, it is advantageous to replace traditional methods of estimating and reporting quality levels by more suitable methods. For example, an estimated outgoing quality level reported as 10 nonconforming items per million items carries a more immediately comprehensible message than either 0,00001 nonconforming items per item or 0,001 nonconforming items per 100 items. This International Standard provides alternative methods that use nonconforming items per million items terminology in estimating and reporting quality levels.

This International Standard provides a means by which quality requirements, stated to be no worse than a given number of nonconforming items per million items, can be verified on a lot-by-lot basis. Procedures are also provided for estimation of the process quality level based on evidence from previous audit and/or lot acceptance samples. Additionally, guidance is given for presuming a process quality level so that the verification procedure can be used when prior sample data is inadequate or not available.

A key feature of this International Standard is that it provides incentives for suppliers to improve their quality. The lot acceptance portion of this specification requires larger sample sizes when quality declines, smaller sample sizes when quality improves. If a customer specifies the same quality requirements to multiple suppliers of a product, those suppliers with superior quality will require, on average, smaller samples for acceptance sampling.

This document is based upon the US Electronic Industries Alliance standards EIA-554 and EIA-555, which it consolidates and reorients to indicate that the procedures are generic and can therefore also be used in industrial or service applications not generally serviced by EIA.

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Acceptance sampling procedures by attributes — Specified quality levels in nonconforming items per million

1 Scope

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

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 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*

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3 Terms, definitions, symbols and abbreviated terms

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For the purposes of this document, the terms and definitions given in ISO 2859-1, ISO 3534-1 and ISO 3534-2, and the following symbols and abbreviated terms apply.

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

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

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

Ac acceptance number, representing the largest number of nonconforming items found in the sample that permits the acceptance of the lot, as given in the sampling plan

d number of nonconforming items observed

d_i number of nonconforming items found in the sample from the ith lot

LQL limiting quality level, in nonconforming items per million items (i.e. the actual quality level of a lot that corresponds to a probability of 21 % or less of lot acceptance for the sampling plan used)

L_P lower limit to the assessed process quality level for a given LQL and Ac, used for selecting a plan from Table 1

NOTE 1 L_P is the lowest actual quality level of a lot for which the probability of lot acceptance is 90 % or more for a sampling plan with the given acceptance number, but which is less than 90% for a sampling plan with the next smaller acceptance number for the same LQL.

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m total number of lots that are subjected to inspection

n number of items sampled from a lot

n_i number of items sampled from the ith lot

p quality level in fraction nonconforming items

$\hat{p}$ estimator of p

p_M quality level in nonconforming items per million items, $p_M = p \times 106$

$\hat{p}_M$ estimator of p_M

$P_{1,M}$ producer's risk quality level in nonconforming items per million items (i.e. the quality level that corresponds to a probability of lot rejection of 5 %)

$P_{2,M}$ consumer's risk quality level in nonconforming items per million items (i.e. the quality level that corresponds to a probability of lot acceptance of 10 %)

U_P upper limit to the assessed process quality level for a given LQL and Ac, used for selecting a plan from Table 1

NOTE 2 U_P is the highest actual quality level of a lot for which the probability of lot acceptance is 90 % or more for the sampling plan used.

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4 General principles

4.1 Objective

The objective of this International Standard is twofold: the quality assessment of product and the acceptance sampling of a lot when quality is high, as indicated by the fact that it is typically expressed in terms of numbers of nonconforming items per million items.

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4.2 Quality assessment of product

It is assumed that the product has been through its manufacture, inspection, test and final acceptance procedures, including procedures for eliminating unrepresentative lots.

When sampling from a consecutive series of lots, the assessment procedures in this International Standard are applicable when

a) the production process is in statistical control, and

b) the cumulative number of inspected items (audit and/or lot acceptance items) is 400 or more.

4.3 Acceptance sampling of a lot

Sampling procedures are provided to verify that the quality is no worse than the limiting quality level (LQL). An estimate of the process quality level in nonconforming items per million items, based on previous data, is used to select the appropriate sampling plan. Presumption (rather than estimation) of the process quality level is permitted when determining sampling plans for the first few lots in a series or for isolated lots, unless and until enough data is available to form a valid estimate. It is recommended that estimation of the process quality level commence when the total number of inspected items (audit and/or lot acceptance items) from one or more consecutive lots is 400 or more; otherwise, continue to presume the process quality level (see 6.1). The sampling plans in this International Standard are indexed by the LQL and the estimated (or presumed) process quality level.

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Suppliers are encouraged to not only drive their processes to a state of statistical control, but also to employ continuous improvement techniques to raise the quality of their products. As quality levels improve, suppliers can then benefit from this International Standard's provision for reduction in acceptance sample size.

Acceptance sampling procedures given in this International Standard can be used when processes have actual nonconforming quality levels of up to 37 606 nonconforming items per million items. However, selecting a small LQL may result in a prohibitively large sample size (see Table 1). For large LQLs, existing sampling plans in other international standards (e.g. ISO 2859-1) may be more appropriate depending upon user requirements.

5 Estimation of quality levels in nonconforming items per million items

5.1 Prerequisites

Users of this document should confirm that all of the following are met for the products whose quality level is being reported:

a) processes meet the assumptions of 4.2;

b) attribute sampling inspection for the characteristics being reported is conducted for product that has completed production;

c) when products are manufactured at more than one location, product from each line or system of production is considered separately.

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5.2 Data sources

The estimation of process quality levels is based on

a) past results from audit samples that are drawn at random from the population, and/or

b) past lot acceptance data.

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Data from lots that fail the lot acceptance procedure, whether audit sample data or lot acceptance data, may be excluded from the calculations only if the conditions of Annex A are met. Inspection lots of products which fail acceptance criteria are either assumed to be 100 % inspected with all nonconforming items being removed from the lot, or are removed from consideration for shipment and discarded.

5.3 Estimation of p_M, the process quality level

This is as follows.

a) When sample results from only a single lot are available, from which d nonconforming items have been found in a sample of size n, p_M is estimated using the formula

$$\hat{p}_M = \left(\frac{d + 0,7}{n + 0,4} \right) \times 10^6 \quad (1)$$

A mathematical justification for Equation (1) is presented in Annex B.

b) When sample results from a series of lots are available, Equation (1) is modified to take into account evidence from more than one lot. In this case, the process quality level in nonconforming items per million items is estimated using the formula

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$$\hat{p}_M = \left(\frac{\sum_{i=1}^{m} d_i + 0,7}{\sum_{i=1}^{m} n_i + 0,4} \right) \times 10^6 \quad (2)$$

where

$\sum_{i=1}^{m} d_i$ is the total number of nonconforming items found in the m lots;

$\sum_{i=1}^{m} n_i$ is the sum of the sample sizes from the m lots.

5.4 Sampling requirements and guidelines

These are as follows.

a) The sample size, n, and the number of nonconforming items observed, d, are determined when performing the audit or lot acceptance of a lot before it is shipped to a customer. The items shall be selected randomly.

b) All sample evidence from lots 1 through m shall be included, except as provided by 5.1, 5.2, 5.4 d), and 5.6.4.

c) Although, strictly speaking, re-estimation of the process quality level p_M should be carried out whenever new sample results become available, in general it is sufficient only to re-estimate p_M periodically. This periodic re-estimation should occur, as a minimum, whenever the total number of items from which the previously estimated process quality level was determined increases by 20 %.

d) Although it is normally advantageous to have many lots averaged, it is permissible to discard as much old data as the supplier deems appropriate when a process change occurs [see 5.6.4 b].

5.5 Examples of estimation of the quality level

5.5.1 Example for single data source

Suppose that eight nonconforming items have been found in samples totalling 100 000 items in all. An estimate of the process quality level is required. From Equation (1):

$$\hat{p}_M = \left(\frac{8 + 0,7}{100\ 000 + 0,4} \right) \times 10^6 = 87 \text{ items per millions items}$$

5.5.2 Example for multiple data sources

Given sample data from m = 5 lots as follows,

i	1	2	3	4	5
d_i	0	1	0	0	1
n_i	1 000	1 500	1 000	1 500	1 500

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