



SLOVENSKI STANDARD
SIST ISO 2859-3:2006

01-april-2006

Postopki vzorčenja za kontrolo po opisnih spremenljivkah – 3. del: Postopki vzorčenja z izpuščanjem partij

Sampling procedures for inspection by attributes -- Part 3: Skip-lot sampling procedures

Règles d'échantillonnage pour les contrôles par attributs -- Partie 3: Procédures d'échantillonnage successif parties

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Ta slovenski standard je istoveten z: ~~SIST ISO 2859-3:2006~~ ISO 2859-3:2005

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ICS:

03.120.30	Uporaba statističnih metod	Application of statistical methods
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INTERNATIONAL
STANDARD

ISO
2859-3

Second edition
2005-05-01

**Sampling procedures for inspection by
attributes —**

**Part 3:
Skip-lot sampling procedures**

*Règles d'échantillonnage pour les contrôles par attributs —
Partie 3: Procédures d'échantillonnage successif partiel*
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Reference number
ISO 2859-3:2005(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 2859-3 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 5, *Acceptance sampling*.

This second edition cancels and replaces the first edition (ISO 2859-3:1991), which has been technically revised.

ISO 2859 consists of the following parts, under the general title *Sampling procedures for inspection by attributes*:

- *Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*
- *Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*
- *Part 3: Skip-lot sampling procedures*
- *Part 4: Procedures for assessment of declared quality levels*
- *Part 5: System of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection.*
- *Part 10: Overview of the ISO 2859 attribute sampling systems*

Sampling procedures for inspection by attributes —

Part 3: Skip-lot sampling procedures

1 Scope

This part of ISO 2859 specifies generic skip-lot sampling procedures for acceptance inspection by attributes. The purpose of these procedures is to provide a way of reducing the inspection effort on products of high quality submitted by a supplier who has a satisfactory quality assurance system and effective quality controls. The reduction in inspection effort is achieved by determining at random, with a specified probability, whether a lot presented for inspection will be accepted without inspection. This procedure extends the principle of the random selection of sample items already applied in ISO 2859-1 to the random selection of lots.

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

- a) end items, such as complete products or sub-assemblies,
- b) components and raw materials, and
- c) materials in process.

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2 Normative references

The following referenced documents are indispensable for the application 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 2859-1:1999, *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: Probability and general statistical terms*

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

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1, ISO 3534-1, ISO 3534-2 and the following apply. For ease of reference, some terms are quoted from these standards.

3.1.1

continuous production

production that is at a steady rate

NOTE Production is considered continuous if the production has been continued for a specified production period at a specified production frequency (see 5.2.1). Continuous production is considered a stabilizing factor of the manufacturing or assembly processes.

ISO 2859-3:2005(E)**3.1.2****disqualification**

failure to qualify for skip-lot sampling inspection (3.1.11)

3.1.3**inspection agency**

independent third party with the responsibility for lot inspection and qualification assessment

3.1.4**inspection frequency**

probability that a lot is inspected

NOTE Inspection frequencies specified in this part of ISO 2859 are 1/2, 1/3, 1/4 and 1/5.

3.1.5**interruption**

cessation of skip-lot sampling inspection (3.1.11), ending with a return either to skip-lot sampling inspection or to lot-by-lot inspection

3.1.6**lot-by-lot inspection**

inspection of products submitted in a series of lots

NOTE 1 In this part of ISO 2859, a sample (or samples) is (are) drawn from each lot and inspected using acceptance sampling procedures by attributes given in ISO 2859-1.

NOTE 2 In this part of ISO 2859, lot-by-lot inspection is used both in State 1 (qualification period) and State 3 (skip-lot interruption state) (see 5.1).

3.1.7**product qualification**

assessment of the product to determine its suitability for skip-lot sampling inspection (3.1.11)

3.1.8**qualification score**

running total derived according to given rules from the immediately preceding quality history, and used in making decisions regarding qualification, changes in inspection frequency (3.1.4), interruption (3.1.5), disqualification (3.1.2) and requalification (3.1.9)

3.1.9**requalification**

qualification for a resumption of skip-lot sampling inspection (3.1.11)

3.1.10**responsible authority**

person or group of people who has responsibility and authority to manage inspection systems appropriately

NOTE In this part of ISO 2859, the responsible authority has responsibility and authority to assess and verify supplier qualification, decide various criteria and judge switch inspection stages.

3.1.11**skip-lot sampling inspection**

sampling inspection procedure in which some lots in a series are accepted without inspection when the sampling results for a stated number of immediately preceding lots meet stated criteria

NOTE The lots to be inspected are chosen randomly in accordance with a stated (skip-lot) inspection frequency. An inspection frequency of 1 in 2, for example, means that the long run average proportion of lots inspected is 1/2.

3.1.12

supplier qualification

assessment of the supplier's competence to implement skip-lot sampling inspection (3.1.11)

3.2 Symbols and abbreviated terms

The symbols and abbreviated terms used in this document are as follows:

- Ac acceptance number;
- Ac₀ acceptance number for the corresponding single sampling plan;
- Ac₁ first acceptance number (for the double or multiple sampling plan);
- Ac₂ second acceptance number (for the double or multiple sampling plan);
- d* number of nonconforming items or nonconformities in the sample;
- k* number of lots used for inspection frequency (the inspection frequency is 1 in *k*; i.e. 1/*k*);
- n* sample size.

4 General requirements

4.1 Skip-lot inspection may only be used when both the supplier and the product are qualified. The requirements for qualification are specified in Clause 5.

NOTE The skip-lot sampling procedures specified in this part of ISO 2859 should be distinguished from Dodge's skip-lot sampling plans. See [1], [2] and [3] in the Bibliography.

4.2 This part of ISO 2859 is intended to supplement the ISO 2859-1 sampling system, and may be used together with ISO 2859-1. Unless otherwise specified in this part of ISO 2859, the provisions of ISO 2859-1 shall apply. ISO 2859-10 provides useful information concerning the use of the standards in the ISO 2859 series.

4.3 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.

4.4 Skip-lot sampling may be used instead of reduced inspection if it is more cost effective to do so (see 9.2 and Annex C), but its application and switching rules are different from those of reduced inspection in ISO 2859-1.

4.5 There are some limitations to the use of skip-lot sampling procedures (see 9.1).

4.6 When different acceptance quality limit (AQL) values are specified for two or more classes of nonconforming items or nonconformities, special care should be taken to ensure correct application of the standard (see 5.2.2 to 6.6 and 10.2).

4.7 Inspection may take place at the supplier's or purchaser's locations, or at an interface between operations of a production process.

4.8 As every product has its own environment and characteristics, options are provided so that the supplier and the responsible authority may select the appropriate options to meet the specifics of the product and its environment. All choices as a result of this tailoring should be specified in a written document.

4.9 When specified by the purchaser, this part of ISO 2859 may be referenced in a purchasing or specification contract, inspection instruction, or other contractual documents.

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4.10 The responsible authority and the inspection agency are to be designated in one of the above documents. This part of ISO 2859 assumes that both lot inspection and qualification assessment are conducted by an inspection agency, being an independent third party. However, the purchaser may conduct both. It is necessary to replace the term "inspection agency" by "purchaser's inspector" or "assessing team" as occasion demands (see 5.1.2, 5.2.3 and Clauses 7 and 8).

5 Supplier and product qualification**5.1 Supplier qualification****5.1.1 Requirements for supplier qualification**

The requirements for supplier qualification are as follows.

- a) The supplier shall have implemented and maintained a documented system for controlling product quality and design changes. It is assumed that the system includes inspection by the supplier of each lot produced and the recording of inspection results.
- b) The supplier 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 supplier'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 supplier shall not have experienced any change that might adversely affect quality.

5.1.2 Assessment for supplier qualification

An assessment team may be dispatched for the assessment for supplier qualification. When the assessment is conducted by the inspection agency, a typical example of what is to be examined and how functions and responsibilities are shared is shown in Clause 8.

When the purchaser conducts the assessment for supplier qualification, the functions and responsibilities of the assessment team are similar to those of the inspection agency.

If the supplier has been qualified for another similar product, the responsible authority may consider this fact in determining the degree of additional assessment for supplier qualification.

The responsible authority shall determine whether the supplier is eligible for skip-lot inspection after reviewing the assessment results (see 8.2).

Assessment and registration of the supplier 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.

5.1.3 Verification of supplier qualification

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

The method of verification is similar to the method of assessment, but it may be simplified so that the review may be conducted by an inspector in place of an assessment team (see 8.2).

5.2 Product qualification

5.2.1 Generic 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 AQL(s) shall be at least 0,025 %. The specified inspection level(s) shall be general inspection levels I, II or III (see ISO 2859-1).
- d) The product shall have been on normal or reduced inspection or a combination of normal and reduced inspection (see ISO 2859-1) 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.

Both the minimum production period and the minimum production frequency should be specified, based on the agreement between the supplier and the responsible authority (see Annex A).

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 supplier and the responsible authority.

- f) The product quality shall have been maintained at the AQL or better (see ISO 2859-1) for a period of stability mutually agreed to by both the supplier and the responsible authority. If no period is specified, the period shall be 6 months.

5.2.2 Specific requirements for product qualification

5.2.2.1 The specific requirements for the product qualification are that the following criteria shall be met:

- a) 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;
- b) the qualification score (see 5.3) reaches or exceeds 50 within 20 consecutive lots; if the qualification period exceeds 20 lots, use the qualification score recalculated for the last 20 lots.

5.2.2.2 There are the following limitations on applicable sampling plans:

- a) fractional acceptance number sampling plans (see ISO 2859-1:1999, Clause 13) shall not be used;
- b) multiple sampling plans are permitted only when the first acceptance number is a numerical value.

5.2.3 Assessment for product qualification

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

The product qualification assessment shall be conducted by an assessment team, an inspector or an inspection agency. When the assessment is conducted by an inspection agency, a typical example of what is to be examined and how functions and responsibilities may be shared is shown in Clause 8 and Annex A.

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When the assessment for product qualification is conducted by the purchaser the functions and responsibilities of the assessment team or the inspector are similar to those of the inspection agency. The responsible authority shall determine whether the product is eligible for skip-lot inspection after reviewing the assessment results (see 8.3). Product qualification assessments should always be performed, even in the case of a supplier with a quality management system certified to be in conformity with ISO 9001.

5.2.4 Verification of product qualification

Product qualification shall be verified at a frequency agreed to by both the supplier 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 supplier qualification.

The method of verification is similar to the method of assessment, but it may be simplified (see 8.3).

5.3 Qualification score**5.3.1 General**

The qualification score is used not only for qualification, but also for making decisions regarding a change in frequency, interruption of the procedure, requalification and disqualification. The rules given shall be applied in the same manner to each state.

In the case of inspection for nonconformities per 100 items, the term “nonconforming item” in the following rules shall be replaced by “nonconformity”.

5.3.2 Single sampling plans for normal inspection

The rules for calculating the qualification score for normal inspection, single sampling plans are as follows:

- a) Sampling plans with $Ac \geq 3$:
- if the lot would have been accepted had the AQL been two steps tighter, add 5 to the qualification score;
 - if the lot would have been accepted had the AQL been one step but not two steps tighter, add 3 to the qualification score;
 - otherwise reset the qualification score to zero.
- b) Sampling plan with $Ac = 2$:
- if the lot is accepted with no nonconforming item in the sample, add 5 to the qualification score;
 - if the lot is accepted with one nonconforming item in the sample, add 3 to the qualification score;
 - otherwise reset the qualification score to zero.
- c) Sampling plan with $Ac = 1$:
- if the lot is accepted with no nonconforming item in the sample, add 5 to the qualification score;
 - if the lot is accepted with one nonconforming item in the sample, add 1 to the qualification score;
 - otherwise reset the qualification score to zero.
- d) Sampling plan with $Ac = 0$:
- if the lot is accepted, add 3 to the qualification score;
 - otherwise reset the qualification score to zero.