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**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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## 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.

### 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.

**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:

- $A_c$  acceptance number;
- $A_{c_0}$  acceptance number for the corresponding single sampling plan;
- $A_{c_1}$  first acceptance number (for the double or multiple sampling plan);
- $A_{c_2}$  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.

**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.

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.

### 5.3.3 Double sampling plans for normal inspection

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

- a) Sampling plans with  $Ac_1 \geq 1$ :
- if the lot would have been accepted after the first sample if the AQL had been one step tighter, add 5 to the qualification score;
  - if the lot is accepted after the first sample but would not have been accepted if the AQL had been one step tighter, add 3 to the qualification score;
  - otherwise reset the qualification score to zero.
- b) Sampling plan with  $Ac_1 = 0$ ,  $Ac_2 = 1$  or 3 [ $Ac_0 = 1$  or 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 cumulative sample, add 1 to the qualification score;
  - otherwise reset the qualification score to zero.

### 5.3.4 Multiple sampling plans for normal inspection

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

- if the lot is accepted after the first sample, add 5 to the qualification score;
- if the lot is accepted after the second or the third sample, add 3 to the qualification score;
- otherwise reset the qualification score to zero.

Multiple sampling plans are permitted only when  $Ac_1 \geq 0$ .

### 5.3.5 Sampling plans for reduced inspection

**5.3.5.1** For all the single, double and multiple sampling plans for reduced inspection, the rules for the corresponding normal inspection shall apply, except for the following changes to the values to be added to the qualification score:

- 5 for normal inspection shall be replaced by 3 for reduced inspection;
- 3 for normal inspection shall be replaced by 1 for reduced inspection.

**5.3.5.2** For example, the rules for reduced inspection single sampling plans with  $Ac = 3$  are as follows:

- if the lot would have been accepted had the AQL been two steps tighter, add 3 to the qualification score;
- if the lot would have been accepted had the AQL been one step but not two steps tighter, add 1 to the qualification score;
- otherwise reset the qualification score to zero.

**NOTE** Under reduced inspection, 17 or more lots are necessary for qualification. For reduced inspection single sampling plans with  $Ac = 0$ , the qualification score addition is 1 per lot, and will never reach 50 within 20 lots [see 5.2.2 b)].

**5.3.6 Resetting of the qualification score**

If any of the following occurs, reset the qualification score to zero:

- any switching except for the switching from normal to reduced inspection;
- any state change (qualification, requalification or disqualification);
- any frequency shift.

**5.4 Example for product qualification**

The following is a numerical example for product qualification.

**Example 1:** In a product qualification period, normal or reduced inspection or a combination of normal and reduced inspection of ISO 2859-1 is applied [see 5.2.1 d)]. Suppose that a qualified manufacturer produces capacitors that satisfy the general requirements of 5.2.1 a) to d). In addition, assume the following:

- the requirements of an essentially continuous production have been satisfied [see 5.2.1 e)];
- the specified AQL is 0,65 % nonconforming;
- the agreed period of stability is 4 months [see 5.2.1 f)];
- the preceding 14 consecutive lots have been accepted on original normal inspection within the past 7 months;
- the inspection results for those lots are as given in Table 1.

**Table 1 — Example 1 results**

Lot No.	n	Ac	d	Acceptability	Qualification score	
					Add	Result
1	80	1	1	accepted	(+1)	1
2	80	1	0	accepted	(+5)	6
3	125	2	2	accepted	(reset)	0
4	125	2	1	accepted	(+3)	3
5	125	2	0	accepted	(+5)	8
6	80	1	0	accepted	(+5)	13
7	125	2	0	accepted	(+5)	18
8	125	2	0	accepted	(+5)	23
9	200	3	1	accepted	(+5)	28
10	200	3	1	accepted	(+5)	33
11	200	3	0	accepted	(+5)	38
12	200	3	2	accepted	(+3)	41
13	200	3	0	accepted	(+5)	46
14	200	3	0	accepted	(+5)	51

The qualification score exceeds 50 within 20 lots. The product thus meets the criteria of 5.2.2. The general requirements of 5.2.1 d) are satisfied at the same time, because 7 months of the production period exceeds the requisite 4 months period of stability. Therefore, the product will be qualified for skip-lot inspection after approval by the responsible authority.

## 6 Skip-lot sampling procedures

### 6.1 General

#### 6.1.1 Eligible period

When both the supplier and the product are qualified for skip-lot inspection, the qualification period terminates and the skip-lot eligible period begins. The applicable sampling plans, the lot selection and the inspection procedures during the skip-lot eligible period are shown in 6.4.

#### 6.1.2 Outline of skip-lot sampling procedures

The basic structure of the skip-lot sampling procedures in this part of ISO 2859 is outlined in Figure 1. There are three basic states for the procedures during two periods:

- a) State 1: lot-by-lot inspection state, (the qualification period);
- b) State 2: skip-lot inspection state, (the skip-lot eligible period);
- c) State 3: skip-lot interruption state (also the skip-lot eligible period), in which there is a temporary reversion to lot-by-lot inspection.

The skip-lot sampling procedures for a product start in State 1 (the qualification period), where lot-by-lot inspection is used. When both the supplier and the product are qualified for skip-lot inspection in accordance with 5.1 and 5.2, the procedure switches to State 2 (the skip-lot inspection state).

The first step in State 2 is to determine the initial inspection frequency (see 6.2 and Figure 2). During State 2, the inspection frequency may be shifted to another frequency (see 6.3 and Figure 3).

During State 2, skip-lot inspection may be temporarily interrupted (see 6.5), resulting in a switching to State 3 (the skip-lot interruption state). During State 3, the product may be requalified under less stringent conditions (see 6.6), resulting in a switching back to State 2 (the skip-lot inspection state).

During States 2 or 3 (the skip-lot eligible period), the product may be disqualified for skip-lot inspection (see 6.7), resulting in a switching back to State 1 (the lot-by-lot inspection state). In this case, the product shall require requalification in order to be able to return to skip-lot inspection.

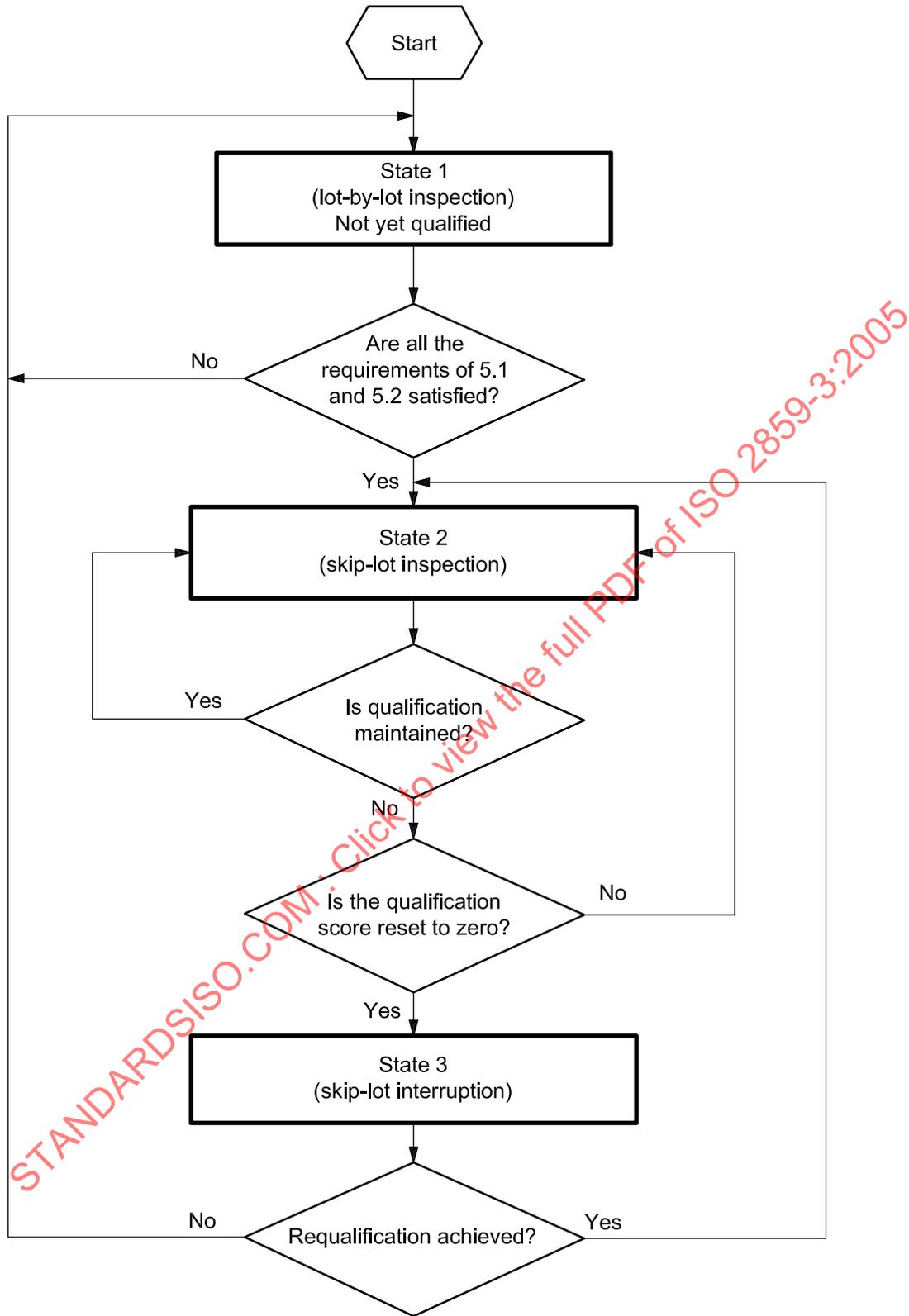


Figure 1 — Basic structure of the skip-lot sampling procedures

## 6.2 Initial inspection frequency and its determination

### 6.2.1 Initial inspection frequency

Authorized initial inspection frequencies for State 2 (the skip-lot inspection state) are as follows:

- a) 1 lot inspected in 2 submitted (1 in 2, i.e. 1/2);
- b) 1 lot inspected in 3 submitted (1 in 3, i.e. 1/3);
- c) 1 lot inspected in 4 submitted (1 in 4, i.e. 1/4).

### 6.2.2 Determining the initial inspection frequency

Figure 2 is a summary of the rules for determining the initial skip-lot inspection frequency. The number of lots that are needed for qualification shall be used for determining the initial inspection frequency. The data from the most recent 20 or fewer lots shall be used for qualification.

If 10 or 11 lots are needed for qualification, an initial inspection frequency of 1 in 4 shall be used.

If 12 to 14 lots are needed for qualification, an initial inspection frequency of 1 in 3 shall be used.

If 15 to 20 lots are needed for qualification, an initial inspection frequency of 1 in 2 shall be used.

### 6.2.3 Examples for determining the initial inspection frequency

The following example is a continuation of the example in 5.4.

**Example 2:** The number of lots needed for qualification is 14. Hence the initial inspection frequency is 1 in 3. If effective action for the improvement of the quality level was taken after the reset following lot number 3, then the number of lots needed for qualification can be considered to be 11 and the responsible authority can specify that the initial inspection frequency is 1 in 4.

## 6.3 Inspection frequency and shifting

### 6.3.1 Inspection frequency

Authorized inspection frequencies for State 2 (the skip-lot inspection state) are:

- a) 1 lot inspected in 2 submitted (1 in 2, i.e. 1/2);
- b) 1 lot inspected in 3 submitted (1 in 3, i.e. 1/3);
- c) 1 lot inspected in 4 submitted (1 in 4, i.e. 1/4);
- d) 1 lot inspected in 5 submitted (1 in 5, i.e. 1/5).

### 6.3.2 Shifting to the next lower inspection frequency

During State 2 (the skip-lot inspection state), if all of the following criteria are met, the inspection frequency shall be shifted to the next lower inspection frequency (e.g. from 1 in 3 to 1 in 4), except when the current inspection frequency is 1 in 5:

- a) the preceding 10 or more consecutive inspected lots have been accepted during the current State 2 (skip-lot inspection state) since the most recent qualification, frequency shift or requalification;
- b) the qualification score reaches or exceeds 50 within 20 consecutive inspected lots;
- c) the responsible authority approves the frequency shift.

During State 2, the qualification score shall be increased or reset only for inspected lots. If different AQL values are specified for two or more classes of nonconforming items or nonconformities, the above criteria shall be met in all the classes.

Figure 3 is a flowchart showing the procedures for frequency shift and skip-lot interruption (see also 6.5).

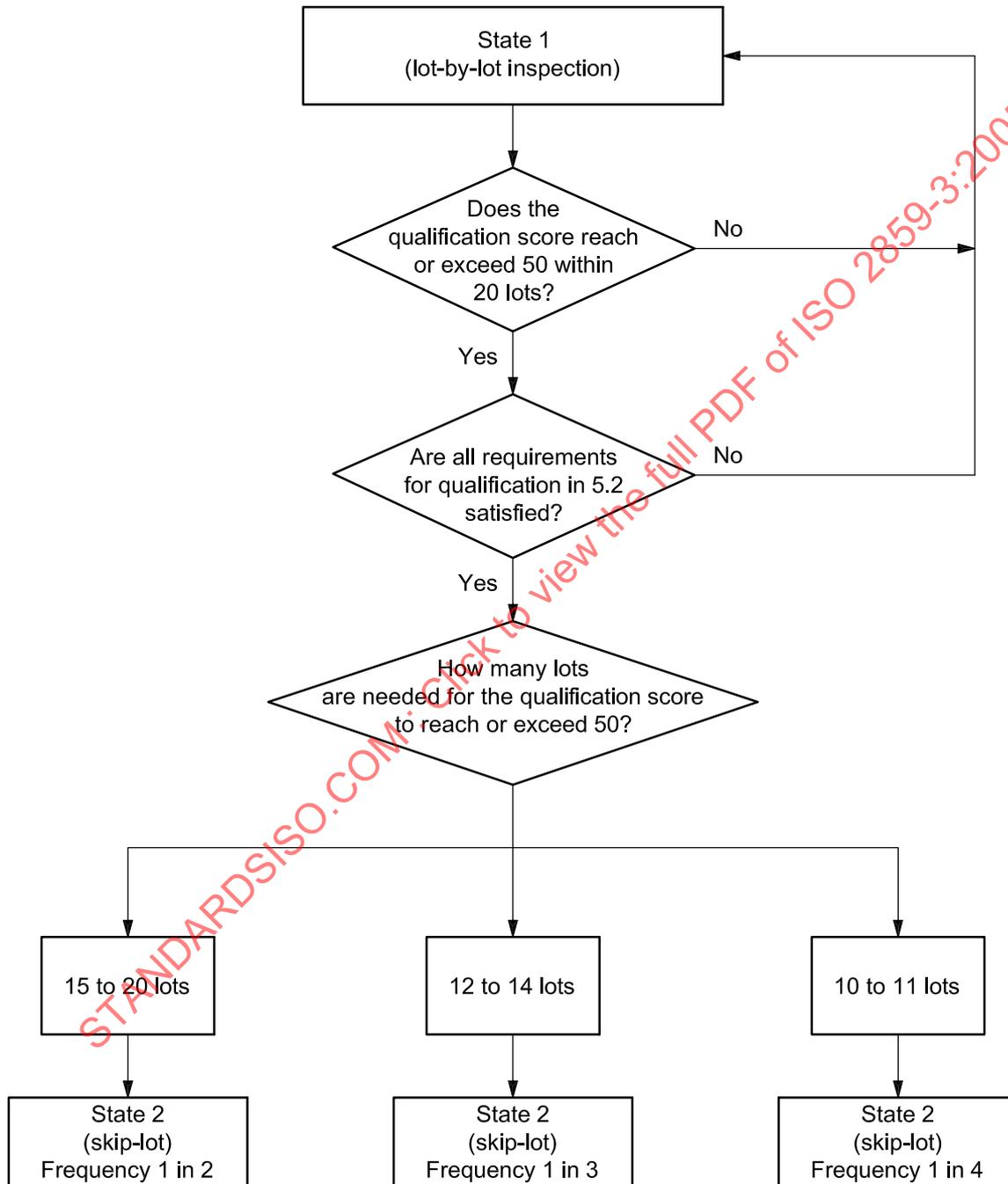


Figure 2 — Determination of the initial inspection frequency

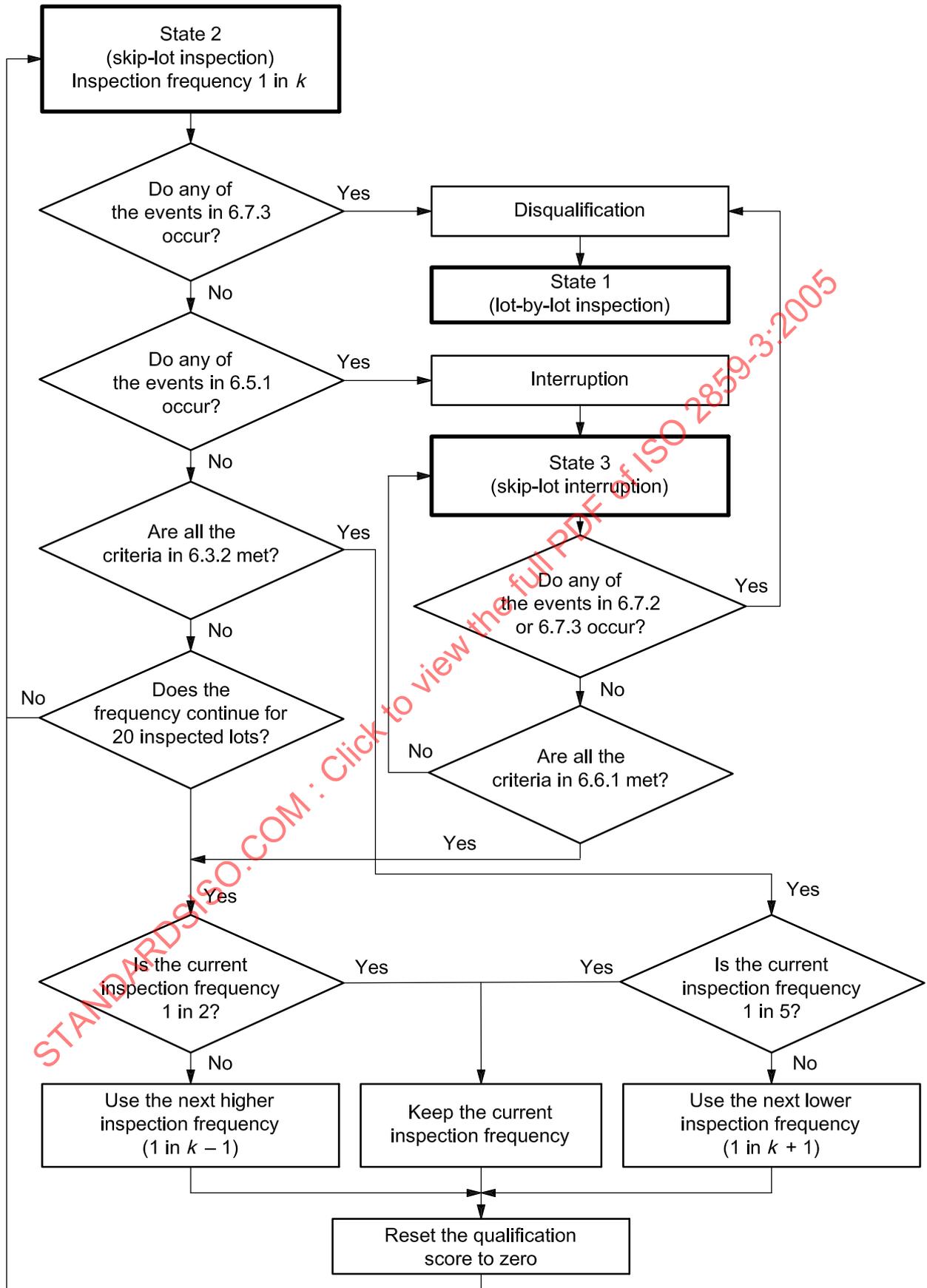


Figure 3 — Frequency shift, interruption and disqualification

**6.3.3 Shifting to the next higher inspection frequency**

During State 2 (skip-lot inspection state), if the qualification score does not reach 50 within 20 consecutive inspected lots of the most recent qualification, frequency shift or requalification, the inspection frequency shall be shifted to the next higher inspection frequency (e.g. from 1 in 4 to 1 in 3), except when the current inspection frequency is 1 in 2 (see 6.6).

**6.3.4 Example for shifting to the next lower inspection frequency**

The following example is a continuation of the examples in 5.4 and 6.2.3.

**Example 3:** In a period of skip lot inspection, only normal inspection according to ISO 2859-1 is applied. The initial inspection frequency is 1 in 3. Suppose that 14 lots have been inspected and accepted with the results given in Table 2.

**Table 2 — Example 3 results**

Lot No.	n	Ac	d	Acceptability	Qualification score	
					Add	Result
15	125	2	0	accepted	(+5)	5
16	125	2	0	accepted	(+5)	10
17	200	3	0	accepted	(+5)	15
18	200	3	1	accepted	(+5)	20
19	200	3	0	accepted	(+5)	25
20	200	3	2	accepted	(+3)	28
21	315	5	0	accepted	(+5)	33
22	315	5	3	accepted	(+3)	36
23	315	5	1	accepted	(+5)	41
24	315	5	2	accepted	(+5)	46
25	315	5	0	accepted	(+5)	51

NOTE In a period of skip-lot sampling inspection, only normal inspection plans from ISO 2859-1 are applied.

The qualification score exceeds 50 within 20 inspected lots, and the criteria of 6.3.2 are met without any interruption. Therefore, the inspection frequency should be shifted to 1 in 4 subject to the approval of the responsible authority.

**6.4 Sampling plans, lot selection and inspection procedures (States 2 and 3)**

**6.4.1 Sampling plans (States 2 and 3)**

During the skip-lot eligible period, the sampling plans applied to individual lots are those given in ISO 2859-1:1999, Table 2-A (single sampling plans), Table 3-A (double sampling plans) or Table 4-A (multiple sampling plans) for the specified AQL(s) on normal inspection.

Single sampling plans with  $Ac = 0$  are not recommended for use during the skip-lot eligible period because of their inadequate switching characteristics; plans with  $Ac = 1$  should be used instead (see Annex C). When a sampling plan with  $Ac = 0$  is used for one of the AQLs, special note should be taken of these poor switching characteristics. Fractional acceptance number sampling plans may not be used. Multiple sampling plans are permitted only when there is a first acceptance number.

**6.4.2 Lot selection and inspection procedures (States 2 and 3)**

The lot(s) to be inspected during State 2 (the skip-lot inspection state) shall be selected in accordance with an established organizational procedure for random lot selection (see Annex B). During State 2, the lots shall be selected for inspection with a probability equal to the current inspection frequency ( $1/k$ ). It is important that the

supplier does not know which of the lots will be inspected until the lots have been offered for acceptance inspection.

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

#### 6.4.3 Inspection procedures (States 2 and 3)

The average size of lot submitted during State 2 and State 3 (the skip-lot interruption state) should be approximately the same as the average lot size during State 1 (the qualification period).

It is assumed that the supplier's quality assurance system includes the internal inspection of each lot produced and the recording of inspection results. These results, for all lots produced (including the lots not inspected at acceptance inspection), shall be made available to the responsible authority and/or the inspection agency.

A running record of the number of items inspected and the number of nonconforming items or nonconformities found in each sample for all lots during the supplier's internal inspection while in States 2 and 3 shall be kept in a skip-lot log.

Acceptance or non-acceptance of lots that the supplier considers non-acceptable during internal inspection shall not affect the skip-lot status. For example, the responsible authority may accept a lot after rectification without acceptance inspection, or ad-hoc acceptance inspection may be made. The results of internal inspection and *ad hoc* acceptance inspection shall be neglected for the purposes of the procedures of this part of ISO 2859, as are the results of resubmitted lots.

### 6.5 Skip-lot interruption

#### 6.5.1 Skip-lot interruption procedures

When either of the following occurs on original inspection during State 2 (skip-lot inspection state), State 3 (the skip-lot interruption state) shall be instituted and lot-by-lot inspection shall be temporarily applied:

- the last lot inspected is not accepted (and the qualification score is reset to zero); or
- the last lot inspected is accepted, but the qualification score is reset to zero.

If different AQL values are specified for two or more classes of nonconforming items or nonconformities, and if either of the above occurs for one or more classes, then State 3 shall be instituted for all the classes.

#### 6.5.2 Example for skip-lot interruption

The following example is a continuation of the examples in 5.4 and 6.2.3.

**Example 4:** In a period of skip-lot interruption, only normal inspection according to ISO 2859-1 is applied. The current state is State 2 and the current inspection frequency is 1 in 3. Assume that an inspected lot is accepted, but that the qualification score is reset to zero, as shown in Table 3.

**Table 3 — Example 4 results**

Lot No.	$n$	Ac	$d$	Acceptability	Qualification score	
					Add	Result
15	125	2	0	accepted	(+5)	5
16	125	2	0	accepted	(+5)	10
17	200	3	3	accepted	(reset)	0

NOTE In a period of skip-lot interruption, only normal inspection plans from ISO 2859-1 are applied.

Skip-lot inspection is therefore interrupted and State 3 (the skip-lot interruption state) is to be instituted.

**6.6 Requalification**

**6.6.1 Requalification procedure**

If both of the following criteria are met during State 3 (skip-lot interruption state), the product may be requalified and State 2 (skip-lot inspection state) may be resumed:

- a) 4 to 6 consecutive lots have been accepted on original inspection during State 3; and
- b) the qualification score reaches or exceeds 18 within 6 lots.

If different AQL values are specified for two or more classes of nonconforming items or nonconformities, the product shall meet the above criteria in all the classes.

The inspection frequency shall be shifted to the next higher inspection frequency (e.g. from 1 in 4 to 1 in 3), except when the inspection frequency prior to interruption was 1 in 2.

**6.6.2 Example for requalification**

The following example is a continuation of the example in 6.5.2 (see also examples in 5.4 and 6.2.3).

**Example 5:** In a period of requalification, only normal inspection according to ISO 2859-1 is applied. The current State is State 3. The inspection frequency prior to interruption was 1 in 3. Assume that the first 5 lots have been accepted during State 3, and the qualification score reaches or exceeds 18 within 6 lots (see the data in Table 4).

**Table 4 — Example 5 results**

Lot No.	n	Ac	d	Acceptability	Qualification score	
					Add	Result
18	200	3	2	accepted	(+3)	3
19	200	3	0	accepted	(+5)	8
20	315	5	3	accepted	(+3)	11
21	200	3	0	accepted	(+5)	16
22	315	5	1	accepted	(+5)	21

NOTE In a period of requalification, only normal inspection plans from ISO 2859-1 are applied.

The criteria of 6.6.1 are met. Therefore, the product is requalified and State 2 may be resumed. The inspection frequency shall be shifted to 1 in 2 from the prior frequency of 1 in 3.

**6.7 Product disqualification**

**6.7.1 General**

When any one of the events given in 6.7.2 or 6.7.3 occurs during State 2 (the skip-lot inspection state) or State 3 (the skip-lot interruption state), the product shall be disqualified for skip-lot inspection and State 1 (the lot-by-lot inspection state) shall be resumed.

The reason(s) for product disqualification shall be documented.

When the product is disqualified and State 1 (the lot-by-lot inspection state) is resumed, requirements for product qualification (see 5.2) shall be applied again.

### 6.7.2 Product disqualification during State 3

When any one of the following events occur on original inspection during State 3, the product shall be disqualified for skip-lot inspection:

- a) a lot is not accepted during State 3 (and the qualification score is reset to zero);
- b) a lot is accepted, but the qualification score is reset to zero; or
- c) requalification is not achieved within 6 lots.

If different AQL values are specified for two or more classes of nonconforming items or nonconformities, and if any one of the above occurs for any one or more classes, then the product shall be disqualified and State 1 shall be resumed.

### 6.7.3 Product disqualification during States 2 or 3

When any one of the following events occurs during State 2 or State 3, the product shall be disqualified from skip-lot inspection:

- a) there is no production activity during a period agreed to by both the supplier and the responsible authority; if no period is specified, the period shall be 2 months; or
- b) the supplier deviates significantly from the written and approved quality control procedures, or violates other requirements given in 5.1.1 or 5.2.1; or
- c) the responsible authority wishes to resume lot-by-lot inspection (e.g. a customer complaint is received, validated and determined to have a serious effect on the quality of the product, or the procedures shift between States 2 and 3 more than once during a short time period).

### 6.7.4 Example for product disqualification

The following example is another continuation of Example 4 given in 6.5.2 (see also Example 1 in 5.4, Example 2 in 6.2.3 and Example 3 in 6.3.4).

**Example 6:** The current state is State 3. Assume that the first 3 lots have been accepted, but the fourth one is not. The product is disqualified and State 1 (the lot-by-lot inspection state) is resumed.

## 6.8 Supplier disqualification and suspension

When the product is disqualified in accordance with 6.7, the supplier qualification should be suspended pending effective corrective action. If effective corrective action is not made within a reasonable period, the supplier shall be disqualified for skip-lot inspection.

When the original supplier qualification was based on certification in accordance with ISO 9001, but the supplier has failed to maintain the certification, both the supplier and the product shall be disqualified for skip-lot inspection and State 1 (the lot-by-lot inspection state) shall be resumed.

The reason(s) for the supplier disqualification shall also be documented.

## 7 Supplier responsibilities

**7.1** The supplier should aim at keeping quality levels better than the relevant AQLs, by means of the quality assurance system and the quality control activities. When required by the inspection agency for supplier qualification assessment, the following information shall be provided, by the supplier, to the inspection agency:

- a) a summary and/or details of the supplier's quality assurance system; and
- b) a summary and/or details of the supplier's quality control activities.

7.2 When required by the inspection agency for product qualification assessment, the following information shall be provided, by the supplier, to the inspection agency:

- a) a summary of the quality history;
- b) the production period and the production frequency;
- c) an outline of the production method, production equipment and tools; and
- d) a summary and/or details of the quality control procedures for the product, including the supplier's methods of inspection and tests to control all characteristics.

7.3 For verification of product qualification, the supplier shall provide the inspection agency with similar but simplified information.

The supplier shall make available to the inspection agency the documents on which the above information is based, for either qualification assessment or review.

If the supplier qualification is based on certification in accordance with ISO 9001, the supplier responsibilities for qualification should be limited to reporting the current certification including the date and results of the verification.

7.4 The supplier shall notify the inspection agency whenever the product is produced for the first time to a new list number, drawing number or specification.

The supplier shall notify the inspection agency of any change in the method of production or inspection, of any modification of tools, gauges, or material related to the production of the product, or of any changes in specifications.

7.5 The supplier shall immediately notify the inspection agency whenever they find a non-acceptable lot and arrangements shall be taken under established organizational procedures. The lot shall be held pending approval for acceptance by the responsible authority in accordance with established organizational procedures. Lots accepted under these procedures instead of inspection by the inspection agency shall be neglected for the purpose of the skip-lot sampling procedures (see 6.4).

7.6 The supplier shall make available to the inspection agency the inspection data for all lots shipped, whether or not they are inspected by the inspection agency.

The supplier shall provide the inspection agency with a list containing the specification numbers, list or drawing numbers, contract and/or purchase order numbers, customer, destination and quantity shipped. For those lots released without inspection by the inspection agency, the supplier shall record the dates of shipment and stamp the shipment to indicate that the product was shipped under skip-lot procedures without inspection by the inspection agency.

## 8 Inspection agency and responsible authority responsibilities

### 8.1 General

This clause gives a typical example of the responsibilities of the inspection agency and of the responsible authority, based on the following assumptions:

- both lot inspection and qualification assessment are conducted by the inspection agency; and
- the purchaser has all the functions of the responsible authority.

However, in practice, it is to be preferred that some of the functions of the responsible authority are assigned to the inspection agency, especially details connecting to conducting inspection.

If the purchaser conducts both lot inspection and qualification assessment, it is not always necessary to divide the responsibilities (see 5.1 and 5.2).

## 8.2 Responsibilities on supplier qualification

When appropriate, the inspection agency shall assess whether or not the supplier satisfies the requirements for supplier qualification given in 5.6. The inspection agency shall provide written notification to the responsible authority. The following information should be included:

- a) a summary of the supplier's quality management system;
- b) a summary of the supplier's quality control activities; and
- c) overall evaluation of the supplier's ability for quality assurance.

The responsible authority shall review the provided information and shall determine whether the supplier is eligible for skip-lot inspection.

The inspection agency shall verify the supplier's qualification at the specified frequency (see 5.1.3). If shortcomings exist, the responsible authority shall be notified through organizational channels. The responsible authority shall decide whether or not the supplier is disqualified because of the shortcomings.

NOTE Supplier qualification is useful not only for skip-lot inspection but also for reduced inspection.

## 8.3 Other responsibilities

**8.3.1** When appropriate, the inspection agency shall assess whether or not the product satisfies the requirements for product qualification given in 5.2.1 and 5.2.2. The inspection agency shall also review all factors of production, inspection and product failure for the following purposes:

- a) to assess whether the supplier's quality assurance system and quality control activity will cover the product concerned; and
- b) to determine whether skip-lot inspection is more cost effective than reduced inspection (see Annex C for a discussion of the factors that favour skip-lot inspection over reduced inspection).

**8.3.2** When it is determined that the product is eligible and that skip-lot inspection is preferred to reduced inspection, the inspection agency shall provide written notification to the responsible authority. The following information should be included:

- a) a summary of the quality history;
- b) the production period and the production frequency;
- c) an outline of the production equipment and tools;
- d) a summary of the quality control system for the product, including the supplier's methods of inspection, testing and the ability to control all characteristics;
- e) an overall evaluation of the supplier's ability to control all the quality characteristics of the product;
- f) the date desired to switch to State 2 (skip-lot inspection state); and
- g) the determined inspection frequency.

**8.3.3** The responsible authority shall review the information provided, the end use of the product and its safety aspects, and shall determine whether the product is eligible for skip-lot inspection. The responsible authority shall decide on the starting date of skip-lot inspection.

When specified, the inspection agency shall verify the product qualification at the specified frequency (see 5.2.5). If shortcomings exist, the responsible authority shall be notified through organizational channels. The responsible authority shall decide whether or not the product is disqualified because of the shortcomings.

In-process inspection is sometimes necessary for assuring the quality of the final product. When the supplier and the responsible authority agree that this is the case, in-process inspection shall be periodically conducted by the inspection agency.

## **9 Compatibility with ISO 2859-1**

### **9.1 Limitations**

Although this part of ISO 2859 is intended to supplement the ISO 2859-1 sampling system, there are some limitations, such as the following:

- a) the product shall be of stable design (see 5.2.1);
- b) the product shall not have any critical classes of nonconforming items or nonconformities (see 5.2.1);
- c) the specified AQL(s) is at least 0,025 %. The specified inspection level(s) should be general inspection level I, II or III (see 5.2.1);
- d) tightened inspection is not compatible with skip-lot inspection (see 5.2.1);
- e) reduced inspection may be used during State 1 (qualification period), but sampling plans for reduced inspection may not be used during State 2 (skip-lot inspection state) and State 3 (skip-lot interruption state) (see 5.2.1 and 6.4.1);
- f) multiple sampling plans are permitted only when there is a first acceptance number (see 5.2.2 and 6.4.1);
- g) fractional acceptance number sampling plans shall not be used (see 5.2.1 and 6.4.1);
- h) sampling plans with  $A_c = 0$  should not be used during States 2 and 3; plans with  $A_c = 1$  should be used instead (see 6.4.1 and 10.2).

### **9.2 Relation to reduced inspection**

The skip-lot sampling procedures in this part of ISO 2859 may be used instead of reduced inspection if it is more cost effective to do so (see Annex C).

The requirements for supplier qualification and product qualification given in 5.1 and 5.2 might seem to be rather different from the switching rules of ISO 2859-1 from normal to reduced inspection. The latter also contain the element of supplier qualification, although this is not immediately evident.

The specific requirements for product qualification given in 5.2.2 correspond to the requirements for the switching score in ISO 2859-1, but the former are somewhat tighter than the latter.

On the other hand, this part of ISO 2859 is more advantageous than reduced inspection in that it gives the producer a greater incentive to aim for and maintain a better quality level.

## 10 Additional information

### 10.1 Design basis

The skip-lot procedures are designed to protect against acceptance of a significant quantity of nonconforming items. They were developed under the assumption that the process quality level is at or better than one-half of the AQL value in order to qualify for skip-lot inspection. The statistical characteristics of the skip-lot procedures are described in 10.2.

### 10.2 Statistical characteristics of the skip-lot procedures

#### 10.2.1 General

The statistical characteristics shown in 10.2.2 to 10.2.4 are for single sampling plans for a single class of nonconformity. Tables 5, 6 and 7 provide the probability of switching ( $Pr$ ) in percent, and the average run length (ARL) in lots.

These tables show that sampling plans with  $Ac = 0$  have poor switching characteristics, which is why such plans should not be used.

The switching characteristics of a double sampling plan are not always close to those of the corresponding single sampling plan, in spite of the equivalent OC curve, but they are similar to those for the single sampling plan having a one step smaller sample size. If different AQLs are specified for two or more classes, the switching characteristics may be less satisfactory. In such a case it is recommended to use sampling plans with acceptance numbers of 2 or more.

#### 10.2.2 Qualification

Table 5 provides the switching characteristics of qualification during State 1 on normal inspection. For example, if  $Ac = 3$  and the quality level is at 0,4 times the AQL value (i.e. at the two-step tighter AQL), the probability of qualifying for skip-lot inspection is about 96 % and the average period for qualification is about 11 lots.

**Table 5 — Switching characteristics of qualification**

P/AQL	Ac = 0		Ac = 1		Ac = 3		Ac = 10	
	Pr	ARL	Pr	ARL	Pr	ARL	Pr	ARL
0,400	42,39	17,00	80,86	11,89	95,73	11,16	99,95	10,21
0,631	25,83	17,00	58,66	12,75	78,30	12,23	96,40	11,31
1,000	11,70	17,00	26,30	13,81	31,99	13,36	35,43	13,91
1,585	3,34	17,00	3,82	14,82	1,62	13,78	0,01	14,67

#### 10.2.3 Frequency shift and interruption

When the skip-lot procedures are in State 2 (the skip-lot inspection state), the probability of shifting to the next lower inspection frequency before interruption is very similar to that of qualification. The probability of shifting to the next higher inspection frequency is negligible. Table 6 provides the switching characteristics of interruption during State 2. For example, if  $Ac = 3$  and the quality level is at twice the AQL value, the probability of interruption before frequency shift is nearly 100 % and the average period until interruption is about 2,2 inspected lots.

**Table 6 — Switching characteristics of interruption**

P/AQL	Ac = 0		Ac = 1		Ac = 3		Ac = 10	
	Pr	ARL	Pr	ARL	Pr	ARL	Pr	ARL
0,400	57,61	7,80	19,14	6,32	14,58	5,68	1,14	5,57
1,000	88,30	6,18	73,65	6,05	81,11	4,77	81,94	4,78
2,000	98,63	4,25	99,32	3,65	99,96	2,16	100,00	1,28
3,000	99,84	3,15	100,00	2,25	100,00	1,37	100,00	1,02

**10.2.4 Requalification and disqualification**

Table 7 provides the switching characteristics of disqualification during State 3. For example, if Ac = 3 and the quality level is at twice the AQL value, the probability for disqualification is about 94,5 % and the average period until disqualification is about 1,9 lots. Conversely, the probability for requalification is about 5,5 %.

**Table 7 — Switching characteristics of disqualification**

P/AQL	Ac = 0		Ac = 1		Ac = 3		Ac = 10	
	Pr	ARL	Pr	ARL	Pr	ARL	Pr	ARL
0,400	26,13	3,35	8,85	3,16	5,82	2,50	0,45	2,50
1,000	53,10	3,14	45,46	3,37	46,04	2,45	46,96	2,48
2,000	78,01	2,79	88,24	2,80	94,48	1,90	99,96	1,27
3,000	89,69	2,48	98,36	2,12	99,82	1,36	100,00	1,02

**10.2.5 Operating characteristic curve**

The operating characteristic curves of the normal inspection plans (see ISO 2859-1) apply to all individual lots selected for inspection during States 2 and 3. The average probability of acceptance is very closely approximated by the OC curves of the normal inspection plans.

## Annex A (normative)

### Optional requirements to be agreed prior to product qualification

#### A.1 General

This part of ISO 2859 provides the following options so that the supplier and the responsible authority may select the appropriate ones. This annex gives examples of the provisions to be incorporated into appropriate documents.

#### A.2 Essentially continuous production for product qualification (see 5.2.1)

##### A.2.1 Minimum production period

The product shall have been produced on an essentially continuous basis for a period determined by both parties.

##### A.2.2 Minimum production frequency

At least .... lot(s) shall be submitted for acceptance inspection every .... month(s).

##### A.2.3 Inclusion of similar products

Products of a similar nature shipped to other parties shall/shall not (as appropriate) be considered in the determination of essentially continuous production.

#### A.3 Other options

##### A.3.1 Minimum period of stability

The minimum period of maintaining the AQL or better product quality is an option for product qualification (see 5.2.1).

The product quality shall have been maintained at or better than the AQL for a period of ..... months.

##### A.3.2 Minimum frequency of inspection

The minimum frequency of inspection is an option for lot selection (see 6.4).

At least 1 lot shall be inspected during each ..... month(s) period.

##### A.3.3 Maximum period of inactivity

The maximum period of inactivity is an option for product disqualification (see 6.7).

The product shall be disqualified for skip-lot inspection and State 1 (lot-by-lot inspection state) shall be resumed when there is no production activity during any period of ..... month(s).