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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.

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 14560 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 5, *Acceptance sampling*.

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.

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 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, *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: Statistical quality control*

3 Terms, definitions, symbols and abbreviated terms

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.

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.

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, $p_M = p \times 10^6$

$\hat{p}_M$ 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.

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.

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.

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.

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.

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

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

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

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

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):

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

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

then,

$$\sum_{i=1}^{5} d_i = 2; \sum_{i=1}^{5} n_i = 6\,500; \hat{p}_{\mathrm{M}} = \left(\frac{2 + 0{,}7}{6\,500 + 0{,}4} \right) \times 10^6 = 415{,}36$$ nonconforming items per million items.

5.6 Reporting results

5.6.1 Reporting fraction nonconforming in nonconforming items per million items

Results shall be reported in accordance with 5.3.

5.6.2 Period of data accumulation

The supplier is encouraged to retain as much data as is deemed appropriate for the estimation of the process quality level. The period over which the data may be accumulated for estimating the process quality level shall be defined by the manufacturer, but shall not exceed two years. When stating an estimated process quality level, the manufacturer shall state the time period over which the data were accumulated.

5.6.3 Reporting requirements of estimated quality levels

Customers may require periodic reporting of estimated quality levels, including the individual sampling results. The following shall be reported:

a) the total number of items inspected;

b) the total number of nonconforming items found.

5.6.4 Data exclusion options

The user of this International Standard may exclude data from the estimation of the process quality level when

a) the results of the current inspection lot satisfy Annex A, i.e. there is strong evidence that the process produced a non-representative (outlier, maverick) lot as compared to preceding lots produced by the process,

b) there has been a process change (e.g. improved statistical process control techniques have been implemented, new and better equipment/technology has been installed, better raw material has been obtained) which is thought to significantly improve quality, in which case all previous data may be excluded,

c) the process has been interrupted for a period of time which may cause the process quality level to change, in which case, all previous data may be excluded, or

d) the data is more than two years old.

6 Lot acceptance sampling requirements and procedures

6.1 Overview

When an objective assessment of the current process quality level is available, such as a recent estimate, the provisions of this International Standard may be used to verify that the LQL has not been exceeded for a particular lot.

When estimation of the process quality level, p, is not recommended because of a lack of sufficient prior sample data (see 4.3), a presumed process quality level may be used instead to select a suitable sampling plan from this International Standard. When presuming a quality level, the user is encouraged to consider the probabilities of lot acceptance given in Table 1 for the corresponding sampling plan. For each LQL, the better the presumed quality level, the higher the probability of accepting a lot with actual quality equal to the LQL. Conversely, the worse the presumed quality level, the lower the probability of accepting a lot of actual quality level equal to the LQL, but at the expense of a larger sample size. The user should presume a quality level based on practical user requirements, not on “rewarding” or “penalizing” the producer with smaller or larger sample sizes. This presumed value could also be based on knowledge of the quality level of similar products produced in a similar manner.

For lot inspection, Table 1 provides single sampling plans by attributes indexed by the LQL and by ranges including the estimated or presumed process quality levels in nonconforming items per million items. These sampling plans have the following properties:

a) the sample sizes are harmonious with those in ISO 2859-1, except that they are twice as dense and extend further;

b) when the actual quality level of a lot is equal to the LQL, the probability of lot acceptance does not exceed 21 %; and

c) when the actual quality level of a lot is between L_P and U_P inclusive, the probability of lot acceptance is 90 % or more.

For each sampling plan listed, Table 1 provides the following additional information:

d) the producer's risk quality level ($P_{1,M}$), i.e. the actual quality level of a lot for which there is a 5 % probability of lot non-acceptance;

e) the consumer's risk quality level ($P_{2,M}$), i.e. the actual quality level of a lot for which there is a 10 % probability of lot acceptance;

f) the specific probability of lot acceptance when the actual lot quality level is equal to the LQL.

6.2 Requirements and guidelines

Lot acceptance sampling shall be at the finished product stage.

When the quality level of a process has been assessed, users of this International Standard should be aware of the following.

a) In determining the number of nonconforming items in a sample, the entire sample shall be inspected even when the acceptance number of the sampling plan and/or the appropriate threshold number from Table A.1 has been exceeded.

b) While it is normally advantageous to have as many lots as possible averaged in the assessed process average (see 5.6.2), it is permissible to discard as much old data as the supplier deems appropriate (see 5.6.4).

6.3 Lot acceptance procedure

The procedure is as follows.

a) Estimate the process quality level from past data in accordance with Clause 5, or presume a “process” quality level in accordance with 6.1.

b) Select the desired LQL in accordance with 6.1.

c) Determine the sample size n and acceptance number Ac by identifying the (L_P, U_P) interval in Table 1 for which the estimated (or presumed) process quality level falls for that LQL.

   If the estimated (or presumed) process quality level does not fall in a given (L_P, U_P) interval for that LQL, the sampling plan with Ac = 7 should be used. As compared to other sampling plans given, this plan will provide maximum consumer protection against accepting a lot whose actual quality level exceeds the LQL [see Table 1 together with the example provided in 6.4.2 when the quality level does not fall in a given (L_P, U_P) interval].

d) Randomly select from the lot a sample of size n and inspect each item in the sample to determine the number of nonconforming items.

If the number of nonconforming items in the sample is less than or equal to Ac, the sample provides evidence that the number of nonconforming items per million items does not exceed the LQL, and the lot shall be considered acceptable.

If Ac is exceeded, the sample has failed to demonstrate that the quality is better than the LQL, and the lot shall be considered non-acceptable.

6.4 Illustrated use of Table 1

6.4.1 Assessed process quality level falls in a given interval for the selected LQL

Suppose the estimated (or presumed) process quality level is 575 nonconforming items per million items and the selected LQL is 6 500 nonconforming items per million items. For this LQL, 575 falls in the (L_P, U_P) interval (422, 1 064). The indicated sampling plan is n = 500, Ac = 1. Inspection of the 500 items yields three nonconforming items. Since three exceeds Ac = 1, the sample has failed to demonstrate that the quality is better than the LQL of 6 500, and the lot is considered to be non-acceptable.

NOTE From Table 1, the sampling plan n = 500, Ac = 1 has the following properties. When the number of nonconforming items per million items in the entire lot is equal to:

a) 1 064 (i.e. U_p) or below, the probability of lot acceptance is 90 % or more;

b) 711 (i.e. $P_{1,M}$), the probability of lot acceptance is approximately 95 %;

c) 7 757 (i.e. $P_{2,M}$), the probability of lot acceptance is approximately 10 %;

d) 6 500 (i.e. the LQL), the probability of lot acceptance is approximately 16,4 %.

6.4.2 Assessed process quality level does not fall in a given interval for the selected LQL

Suppose that the estimated (or presumed) process quality level is 1 250 nonconforming items per million items and an LQL of 2 500 is desired. For this LQL, 1 250 does not fall in a (L_P, U_P) interval, because the largest value of U_P given is 931. Following the recommendation of 6.3 c), the sampling plan n = 5 000, Ac = 7 is selected.

Inspection of the 5 000 items yields six nonconforming items, which is below the acceptance number of Ac = 7. Thus, the sample does provide evidence that the LQL is not exceeded and the lot is considered to be acceptable.

NOTE From Table 1, the sampling plan n = 5 000, Ac = 7 has the following properties. When the actual number of nonconforming items per million items in the entire lot is equal to:

a) 931 (i.e. U_P) or less, the probability of lot acceptance is 90 % or more [at an assessed or specified quality level of 1 250, it can be shown that the probability of lot acceptance is only about 71 % (see Annex C)];

b) 796 (i.e. $P_{1,M}$), the probability of lot acceptance is approximately 95 %;

c) 2 353 (i.e. $P_{2,M}$) the probability of lot acceptance is approximately 10 %;

d) 2 500 (i.e. the LQL), the probability of lot acceptance is approximately 7 %.

7 Single sampling plans indexed by LQL in nonconforming items per million items

CAUTION — For the LQL and sampling plan selected, if the actual number of nonconforming items per million items in the entire lot and corresponding probabilities of acceptance given in Table 1 are considered unacceptable, then procedures in this International Standard should not be used.

Table 1 provides single sampling plans indexed by LQL and entered by a prior estimate of the process quality level in the case of a continuing series of lots, or indexed by LQL and entered by a presumed process quality level in the case of an isolated lot or the first few lots in a series (see 4.3). All quality levels given in the table are in nonconforming items per million items. Instructions for the use of this table are given in Clause 6.

NOTE In instances when the required sample size is larger than the lot size, it will not be possible to check for compliance to the LQL unless the whole lot is inspected.

Table 1 — Single sampling plans indexed by LQL in nonconforming items per million items

LQL	L_P	U_P	Sample size n	Acceptance number Ac	Producer's risk quality level $P_{1,M}$	Consumer's risk quality level $P_{2,M}$	Probability of acceptance at LQL %
500	0	32	3 200	0	16	719	20,2
	33	81	6 500	1	55	598	16,5
	82	110	10 000	2	82	532	12,5
	111	152	16 000	4	123	500	10,0
	153	186	25 000	7	159	471	7,0
650	0	42	2 500	0	21	921	19,7
	43	106	5 000	1	71	778	16,5
	107	137	8 000	2	102	665	10,9
	138	194	12 500	4	158	639	9,3
	195	232	20 000	7	199	588	5,4
800	0	52	2 000	0	26	1 151	20,2
	53	132	4 000	1	89	972	17,1
	133	169	6 500	2	126	819	10,9
	170	243	10 000	4	197	799	10,0
	244	291	16 000	7	249	736	6,0

Table 1 *(continued)*

LQL	L_P	U_P	Sample size n	Acceptance number Ac	Producer's risk quality level $P_{1,M}$	Consumer's risk quality level $P_{2,M}$	Probability of acceptance at LQL %
1 000	0	65	1 600	0	32	1 438	20,2
	66	166	3 200	1	111	1 215	17,1
	167	220	5 000	2	164	1 064	12,5
	221	304	8 000	4	246	999	10,0
	305	372	12 500	7	319	941	7,0
1 250	0	84	1 250	0	41	1 840	20,9
	85	212	2 500	1	142	1 555	18,1
	213	275	4 000	2	204	1 330	12,4
	276	374	6 500	4	303	1 229	9,3
	375	465	10 000	7	398	1 177	7,0
1 600	0	105	1 000	0	51	2 300	20,2
	106	265	2 000	1	178	1 943	17,1
	266	344	3 200	2	256	1 662	11,5
	345	486	5 000	4	394	1 598	9,9
	487	582	8 000	7	498	1 471	6,0
2 000	0	131	800	0	64	2 874	20,2
	132	332	1 600	1	222	2 429	17,1
	333	440	2 500	2	327	2 128	12,4
	441	608	4 000	4	493	1 997	9,9
	609	716	6 500	7	613	1 810	5,4
2 500	0	162	650	0	79	3 536	19,7
	163	425	1 250	1	284	3 108	18,1
	426	551	2 000	2	409	2 659	12,4
	552	760	3 200	4	616	2 496	9,9
	761	931	5 000	7	796	2 353	7,0
3 200	0	210	500	0	103	4 595	20,1
	211	531	1 000	1	355	3 884	17,1
	532	688	1 600	2	511	3 323	11,5
	689	973	2 500	4	788	3 195	9,9
	974	1 164	4 000	7	996	2 941	6,0
4 000	0	263	400	0	128	5 740	20,1
	264	664	800	1	444	4 853	17,1
	665	881	1 250	2	654	4 252	12,4
	882	1 216	2 000	4	986	3 993	9,9
	1 217	1 455	3 200	7	1 245	3 676	6,0

Table 1 *(continued)*

LQL	L_P	U_P	Sample size	Acceptance number	Producer's risk quality level	Consumer's risk quality level	Probability of acceptance at LQL
			n	Ac	$P_{1,M}$	$P_{2,M}$	%
5 000	0	329	320	0	160	7 170	20,1
	330	818	650	1	547	5 971	16,4
	819	1 102	1 000	2	818	5 313	12,4
	1 103	1 521	1 600	4	1 232	4 990	9,9
	1 522	1 863	2 500	7	1 593	4 704	6,9
6 500	0	421	250	0	205	9 168	19,6
	422	1 064	500	1	711	7 757	16,4
	1 065	1 378	800	2	1 023	6 639	10,8
	1 379	1 947	1 250	4	1 577	6 385	9,2
	1 948	2 329	2 000	7	1 992	5 878	5,3
8 000	0	526	200	0	256	11 447	20,1
	527	1 330	400	1	889	9 689	17,0
	1 331	1 696	650	2	1 259	8 167	10,8
	1 697	2 434	1 000	4	1 972	7 978	9,9
	2 435	2 912	1 600	7	2 490	7 346	5,9
10 000	0	658	160	0	321	14 288	20,0
	659	1 663	320	1	1 112	12 101	17,0
	1 664	2 206	500	2	1 637	10 609	12,3
	2 207	3 043	800	4	2 466	9 967	9,8
	3 044	3 728	1 250	7	3 189	9 399	6,9
12 500	0	842	125	0	410	18 252	20,8
	843	2 129	250	1	1 423	15 469	17,9
	2 130	2 758	400	2	2 047	13 251	12,3
	2 759	3 746	650	4	3 036	12 260	9,1
	3 747	4 661	1 000	7	3 987	11 743	6,9
16 000	0	1 053	100	0	513	22 763	19,9
	1 054	2 662	200	1	1 780	19 309	16,9
	2 663	3 448	320	2	2 560	16 546	11,3
	3 449	4 872	500	4	3 948	15 923	9,8
	4 873	5 828	800	7	4 985	14 670	5,8
20 000	0	1 316	80	0	641	28 372	19,9
	1 317	3 328	160	1	2 226	24 092	16,8
	3 329	4 416	250	2	3 279	21 148	12,2
	4 417	6 093	400	4	4 938	19 884	9,7
	6 094	7 176	650	7	6 139	18 043	5,2

Table 1 *(continued)*

LQL	L_P	U_P	Sample size	Acceptance number	Producer's risk quality level	Consumer's risk quality level	Probability of acceptance at LQL
			n	Ac	$P_{1,M}$	$P_{2,M}$	%
25 000	0	1 619	65	0	789	34 804	19,3
	1 620	4 262	125	1	2 850	30 760	17,8
	4 263	5 522	200	2	4 101	26 391	12,1
	5 523	7 620	320	4	6 176	24 824	9,7
	7 621	9 334	500	7	7 986	23 430	6,7
32 000	0	2 104	50	0	1 025	45 007	19,7
	2 105	5 330	100	1	3 565	38 339	16,7
	5 331	6 907	160	2	5 130	32 921	11,1
	6 908	9 761	250	4	7 913	31 719	9,6
	9 762	11 674	400	7	9 990	29 252	5,7
40 000	0	2 630	40	0	1 282	55 939	19,5
	2 631	6 667	80	1	4 460	47 752	16,5
	6 668	8 848	125	2	6 573	42 016	12,0
	8 849	12 211	200	4	9 901	39 570	9,5
	12 212	14 604	320	7	12 499	36 510	5,6
50 000	0	3 287	32	0	1 602	69 428	19,4
	3 288	8 211	65	1	5 495	58 527	15,8
	8 212	11 070	100	2	8 226	52 345	11,8
	11 071	15 279	160	4	12 393	49 338	9,4
	15 280	18 712	250	7	16 021	46 635	6,5
65 000	0	4 205	25	0	2 050	87 989	18,6
	4 206	10 686	50	1	7 154	75 581	15,5
	10 687	13 854	80	2	10 298	65 160	10,1
	13 855	19 584	125	4	15 891	62 931	8,5
	19 585	23 419	200	7	20 057	58 153	4,9
80 000	0	5 254	20	0	2 561	108 749	18,9
	5 255	13 374	40	1	8 957	93 797	15,9
	13 375	17 704	65	2	12 696	79 812	9,9
	17 075	24 520	100	4	19 906	78 348	9,0
	24 521	29 318	160	7	25 120	72 472	5,3
100 000	0	6 563	16	0	3 201	134 036	18,5
	6 564	16 743	32	1	11 219	116 195	15,6
	16 744	22 243	50	2	16 552	102 959	11,2
	22 244	30 712	80	4	24 947	97 441	8,8
	30 713	37 606	125	7	32 241	92 371	6,0

Annex A
(normative)

Data exclusion

A.1 Threshold number

This is a number, as given in Table A.1 which, if exceeded by the number of nonconforming items in a sample, signals to the user that an assignable cause might be present, and that the product represented by a sample may be from a population different from earlier product.

NOTE Exceeding the threshold number is one of the conditions necessary for applying the exclusion rule, which allows for such sample evidence to be excluded when estimating a process quality level in nonconforming items per million items.

A.2 Provisions for data exclusion

All nonconforming items confirmed during the initial submission for final acceptance inspection shall be included in the calculation of $\hat{p}_{\mathrm{M}}$. However, after a prior estimate has been made of the process quality level in nonconforming items per million items, data from an audit or lot acceptance sampling may be excluded from the data accumulation on condition that all of the following conditions are met:

a) the number of nonconforming items in the sample shall exceed the appropriate threshold number shown in Table A.1, and as explained in A.3;

b) an assignable cause shall have been identified and appropriate corrective action taken;

c) the product represented by the sample shall not be accepted;

d) the consumer shall be in agreement;

e) the preceding ten lots shall all have been within the threshold limits;

f) a log shall be maintained of all lots excluded and this log shall include, as a minimum,

   1) the excluded sample result (sample size, number of nonconforming items found, and lot size),

   2) the assignable cause determined, and

   3) the corrective action taken.

Table A.1 — Threshold numbers for excluding data

Lower limit on $n\hat{p}$	Upper limit on $n\hat{p}$	Threshold number
0	0,214 69	1
0,214 70	0,567 20	2
0,567 21	1,016 23	3
1,016 24	1,529 52	4
1,529 53	2,089 14	5
2,089 15	2,684 09	6
2,684 10	3,307 11	7
3,307 12	3,953 11	8
3,953 12	4,618 34	9
4,618 35	5,300 01	10
NOTE $\hat{p}$ represents the previously estimated process quality level.		

A.3 Probability of exceeding the threshold number

If the previously assessed process quality level, $\hat{p}$, coincides with the actual quality level of the present lot, then the probability that the number of nonconforming items in a given sample of size n will exceed the threshold number is at most 0,02. Therefore, if the threshold number is exceeded for a given sample, it may be presumed that the sample represents a population significantly different from the base population. If the conditions of A.2 are met, the data from this sample shall be excluded from future assessments of the process quality level.

A.4 Underlying theory for derivation of lower and upper limits in Table A.1

The following illustrates that, whether an $n\hat{p}$ is near the upper or lower limit for a given threshold number, the probability of exceeding that threshold number will be at most 0,02.

By example and for the upper limit, suppose that p_M has been assessed, in accordance with Clause 5, as 208 nonconforming items per million items. Expressed as a fraction nonconforming, $\hat{p} = 0{,}000\ 208$.

For a sample of size 10 000, for example, the expected (average) number of nonconforming items is then $n\hat{p}$ = (10 000) × (0,000 208) = 2,08 and the corresponding threshold number is 5.

The probability of six or more nonconforming items, using the Poisson approximation with mean 2,08 is equal to 1,0 minus the probability of finding five or fewer nonconforming items, or:

$P_{\geqslant 6}$ = 1,0 − [P_0 + P_1 + P_2 + P_3 + P_4 + P_5]

$P_{\geqslant 6}$ = 1,0 − [0,124 930 + 0,259 855 + 0,270 249 + 0,187 373 + 0,097 434 + 0,040 532]

$P_{\geqslant 6}$ = 1,0 − 0,980 373 = 0,019 627, which is less than 0,02

This shows that on the high end of the interval the probability of exceeding the threshold number is < 0,02.

Now, for the lower limit, suppose that p_M has been assessed as 153 nonconforming items per million items. For a sample of size n = 10 000 and fraction nonconforming $\hat{p}$ of 0,000 153, the expected number of nonconforming items is 1,53. The probability of six or more nonconforming items is now

$P_{\geqslant 6}$ = 1,0 – [0,216 536 + 0,331 300 + 0,253 444 + 0,129 257 + 0,049 441 + 0,015 129]

$P_{\geqslant 6}$ = 1,0 – [0,995 105] = 0,004 895, which is less than 0,02.

The highest value of $n\hat{p}$ in a particular exclusion interval will always have the highest probability of exceeding the threshold number for any value of $n\hat{p}$ in that interval. Furthermore, that probability will never exceed 0,02.

A.5 Examples of use of Table A.1

A.5.1 Example when sample data cannot be excluded

Suppose that adequate prior data have been collected so that the process quality level can be estimated, and that the estimate is 1 000 nonconforming items per million items (i.e. $\hat{p}_M$ = 1 000 or $\hat{p}$ = 0,001). Suppose that the acceptance sampling plan in use calls for a sample size of 250 for the next lot, and that, during the inspection of these 250 items, two nonconforming items are found. Enter in Table A.1 with the product of n = 250, the sample size and, with 0,001, the calculated value of $\hat{p}$; the product $n\hat{p}$ is equal to 0,250. From Table A.1, the threshold number is two when $n\hat{p}$ equals 0,250. Since the threshold number is not exceeded, the test data cannot be excluded and must be added into the equation if the method in Clause 5 is used, with two being added to the numerator and 250 to the denominator. The new value of $\hat{p}$ should now be used to calculate a new value of $n\hat{p}$, when $n\hat{p}$ is to be recalculated [see 5.4 c)].

A.5.2 Example when sample data can be excluded

Again, suppose that enough prior data has been collected for the process quality level in nonconforming items to be estimated using the method given in Clause 5. Suppose that the estimate is again 1 000 nonconforming items per million items, or $\hat{p}$ = 0,001. Suppose also that the sampling plan calls for a sample size of 160 and that two nonconforming items are found in the sample. Again, Table A.1 is entered with the product $n\hat{p}$ = 160 × 0,001 = 0,160. For this value, Table A.1 gives a threshold number of 1. As two nonconforming items have been found, the threshold number has been exceeded, so the data may be excluded from use in subsequent estimates of the process quality level, provided that all the conditions of A.2 are met.

Annex B
(informative)

Underlying theory for generating point estimates of quality level in fraction nonconforming

B.1 Estimate of p, the process fraction nonconforming

When sample sizes are less than 10 % of lot sizes, the binomial distribution is an acceptable approximation of the hypergeometric distribution for determining sampling probabilities. However, if this is not the case, the producer's and consumer's risks are less than those given in this International Standard, and thus smaller sample sizes could have been used to achieve the producer's and consumer's risks than that reported in the present document.

Assuming that d, the number of nonconforming items in a sample of n items, follows a binomial distribution, the Clopper–Pearson upper confidence limit, C_U, on p is the value of p satisfying:

$$C_U = \left[1 - \sum_{i=0}^{d} \binom{n}{i} \times \hat{p}^{\,i} \times (1 - \hat{p})^{n-i} \right] \times 100\ \% \tag{B.1}$$

It can also be shown that this cumulative binomial expression can be expressed in terms of the F-distribution. Setting C_U = 50 % will result in an expression which is used for arriving at the upper 50th percentile of the fraction nonconforming:

$$\hat{p} = \frac{1}{1 + \left(\frac{n-d}{d+1} \right) \times F_{0,50}(2n - 2d, 2d + 2)} \tag{B.2}$$

where $F_{0,50}(2n - 2d, 2d + 2)$ denotes the 50th percentile of an F-distribution with $(2n - 2d)$ degrees of freedom in the numerator and $(2d + 2)$ degrees of freedom in the denominator.

A practical approximation for p is given by

$$\hat{p} \approx \frac{d + 0{,}7}{n + 0{,}4} \tag{B.3}$$

It can be shown by substituting the expression in Equation (B.3) into Equation (B.1) that under a wide variety of conditions, i.e. for d/n < 0,5 when $d \geqslant 1$, and for d = 0 when $n \geqslant 6$, that this approximation lies between the upper 50 % and 51 % confidence limits.

B.2 Example of estimating p

Using n = 500, d = 2, $F_{0,50}(996, 6)$ = 1,12 in Equation (B.2) yields

$$\hat{p} = \frac{1}{1+\left(\frac{498}{3}\right)\times(1{,}12)} = 0{,}005\ 35$$

That is, with 50 % confidence it can be said that the actual lot quality in fraction nonconforming is no more than 0,00535.

Using the approximation of Equation (B.3) yields

$$\hat{p} \approx \frac{d+0{,}7}{n+0{,}4} = \frac{2+0{,}7}{500+0{,}4} = 0{,}005\ 4$$

NOTE Equation (B.1) may be used to show that this estimate corresponds to a confidence level of between 50% and 51%, viz.:

C_U = [1 – (0,066 72 + 0,181 11 + 0,245 33)] 100 % = (1 – 0,493 16) 100 % = 50,7 %

That is, with 50,7 % confidence it can be said that the actual lot quality in fraction nonconforming is no more than 0,005 4.

Annex C
(informative)

Statistical theory and calculation of Table 1

In Table 1, the L_P, U_P, n and Ac values were derived (as indicated below) by using a producer's risk of 10 % and a consumer's risk of 21 %. Had the conventional producer's risk of 5 % and consumer's risk of 10 % been used, the resulting sample sizes would have been considered too large for practical purposes. It is customary, however, when presenting a producer's risk quality level and consumer's risk quality level of the sampling plan, to use 5 % and 10 %, respectively, as has been done in Table 1.

To comply with the maximum producer's risk of 10 %, the following must be satisfied:

$$\sum_{i=0}^{\mathrm{Ac}} \binom{n}{i} p^i (1-p)^{n-i} \geqslant 0{,}9 \qquad \text{(C.1)}$$

To comply with the maximum consumer's risk of 20 %, the following must be satisfied:

$$\sum_{i=0}^{\mathrm{Ac}} \binom{n}{i} p^i (1-p)^{n-i} \leqslant 0{,}21 \qquad \text{(C.2)}$$

These two equations were solved in the following manner to find L_P and U_P and the minimum sample size, n, for given values of Ac, LQL and p.

a) It was decided that the sample sizes should be restricted to the set of preferred values 16, 20, 25, 32, 40, 50, 65, 80, 100, 125, 160, 200, 250, 320, 400, 500, 650, 800, 1 000, 1 250, 1 600, 2 000, 2 500, 3 200, 4 000, 5 000, 6 500, 8 000, 10 000, 12 500, 16 000, 20 000, 25 000. This set of sample sizes is in accordance with that of ISO 2859-1 except that it is twice as dense and extends further.

NOTE Each sample size is derived by multiplying the previous sample size by approximately the 10th root of 10.

b) It was also decided that the acceptance numbers Ac should be restricted to the set of preferred values 0, 1, 2, 4 and 7.

c) The preferred sample size was found such that the left side of Equation (C.2) at the given LQL and Ac would be $\leqslant$ 21 %. In addition, the probability of accepting a lot with the actual quality level equal to the LQL should be monotonically decreasing as the presumed quality level increases. This is preferable so that the consumer's risk decreases as the presumed quality level gets worse. The actual consumer's risk at the LQL for each plan is shown in Table 1.

d) With LQL and Ac given, and n now known, Equation (C.1) is then solved to find the worst quality level such that the left side of this equation is greater than or equal to 90 %. In other words, the worst quality level, p, is found such that the probability of observing Ac or fewer nonconforming items in a sample of size n will be at least 90 % if the actual quality level is at that quality level. This worst quality level is then converted to U_P by multiplying by 10^6.

   Then, for Ac = 0, L_P = 0, and for Ac > 0, L_P is one more than the U_P value in the previous row of Table 1.

e) The probability of acceptance at the LQL was computed using the cumulative binomial with p = LQL $\times$ 10^{-6} and then converted to a percentage.

$$\sum_{i=0}^{\text{Ac}} \binom{n}{i} p^i (1-p)^{n-i} = \text{probability of acceptance}$$

f) The probability of acceptance at any given p can be found using the cumulative binomial in e) above. In the example of 6.4.2, the LQL equals 2 500 and the estimated process quality level, $\hat{p}_{\text{M}}$, is equal to 1 250 nonconforming items per million items. Table 1 yields the sampling plan n = 5 000, Ac = 7. To calculate the probability of accepting the lot when the actual p_{M} = 1 250, the binomial is summed from i = 0 to Ac = 7, with n = 5 000 and p = $\hat{p}_{\text{M}} \times 10^{-6}$ = 1 250 $\times$ 10^{-6} = 0,001 250.

$$P_{\leqslant 7} = P_0 + P_1 + P_2 + P_3 + P_4 + P_5 + P_6 + P_7$$

$P_{\leqslant 7}$ = 0,001 922 9 + 0,012 033 3 + 0,037 643 6 + 0,078 490 9 + 0,122 721 9 + 0,153 471 5 + 0,159 906 1 + 0,142 780 5 = 0,708 970 7, which is approximately 0,71.

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