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Milk and milk products — Sampling — Inspection by variables in the presence of measurement error

Lait et produits laitiers — Échantillonnage — Contrôle par variables en présence d'erreur de mesure

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Foreword

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ISO 22110 | IDF 207 was prepared by Technical Committee ISO/TC 34, *Food*, Subcommittee SC 5, *Milk and milk products* and the International Dairy Federation (IDF). It is being published jointly by ISO and IDF.

This first edition of ISO 22110 | IDF 207 cancels and replaces the first edition of ISO 8197:1988, which is fully covered by this document.

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Foreword

IDF (the International Dairy Federation) is a worldwide federation of the dairy sector with a National Committee in every member country. Every National Committee has the right to be represented on the IDF Standing Committees carrying out the technical work. IDF collaborates with ISO and AOAC International in the development of standard methods of analysis and sampling for milk and milk products.

Draft International Standards adopted by the Action Teams and Standing Committees are circulated to the National Committees for voting. Publication as an International Standard requires approval by at least 50% of IDF National Committees casting a vote.

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All work was carried out by the Joint ISO/IDF Action Team on *Statistics of analytical data*, of the Standing Committee on *Quality assurance, statistics of analytical data and sampling,* under the aegis of its project leader, Dr. R. Crawford (NZ).

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Milk and milk products — Sampling — Inspection by variables in the presence of measurement error

1 Scope

This standard provides guidance in the selection of appropriate acceptance sampling schemes for the inspection of dairy products submitted for inspection in lots.

There are many situations in which product is transferred from one organisation to another. In these situations, either or both organisations may use sampling plans to satisfy themselves that the product is of acceptable quality.

Because testing of milk and milk products is usually destructive and costly, it is not feasible to test all product produced. Instead, samples are taken and tested. There is always uncertainty involved with sampling. In the case of acceptance inspection plans this means that there is a risk that product could be incorrectly classified, with downstream costs. This risk is not unique to milk and milk products, but is somewhat more noticeable than in some other commodities because of the inherent variability of milk and milk products, uncertainties in the test methods and the costs of testing.

The sampling plans in this standard are intended for using by receivers under the following conditions:

a) The inspection procedure is to be applied to a lot of product, supplied by one producer using one production process. Where product is transferred in consignments consisting of collections of lots, assessments should be made on an individual lot basis.

b) There is only a single quality characteristic under consideration. The plans can be applied to more than one characteristic but the individual risk profiles shall be adjusted to control the overall risk or items shall be classified as pass/fail and an attribute inspection plan used. It is recommended that a statistician be consulted.

c) The production process is stable.

d) The quality characteristic follows, or can be transformed to, a normal distribution.

e) The measurement process is stable and the measurement errors are normally distributed.

The lot of product may be packaged into discrete units, be unpackaged or be bulk packaged.

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, *Sampling procedures for inspection by attributes.*

ISO 3951:1989, *Sampling procedures and charts for inspection by variables for percent nonconforming.*

ISO 3534-1:1993, *Statistics — Vocabulary and symbols. Part 1. Probability and general statistical terms.*

ISO 5725 (all parts), *Accuracy (trueness and precision) of measurement methods and results.*

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ISO/TR 8550, *Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots*.

ISO 707 (IDF 50), *Milk and milk products — Guidance on sampling*.

ISO 5538 | IDF 113, *Milk and milk products — Sampling — Inspection by attributes*.

ISO 8197 (IDF 136), *Milk and milk products — Sampling — Inspection by variables*.

ISO 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in ISO 3534 and the following apply.

3.1
continuous result
result from a method that is a decimal number, e.g. the fat content of milk powder as measured by the Röse-Gottlieb method.

3.2
nominal result
result from a method that delivers a finite number of outcomes, such as pass/fail, present/absent, a number or letter on a limited scale, e.g. {A, B, C, D, E} or {1, 2, 3, 4}, or a colour on a colour chart.

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4 Types of inspection plans

An acceptance-sampling plan is intended for determining the acceptance or rejection of a lot (see ISO 3534). The plan stipulates the number of units (items) in the sample, to be drawn randomly from a lot for inspection against the product specification. The lot is then classified as "acceptable" or "not acceptable" according to how the inspection results compare with the criteria of the acceptance-sampling plan.

There are two main categories of acceptance inspection schemes: inspection by variables sampling plans and inspection by attribute sampling plans. These differ primarily in the type of quality characteristic under assessment: continuous or nominal. This standard considers only the former, although, for completeness, this section, Section 4, describes inspection by attribute plans in general terms.

4.1 Inspection by variables schemes

Inspection by variables are methods which consists in measuring a quantitative characteristic of each item of a population or of a sample taken from this population (see ISO 3534). In practice these sampling schemes use measurements made on each sample to determine the acceptability of each lot of product. In an inspection by variables scheme, the sample average and the standard deviation are calculated. These are then used to assess the acceptability of the lot.

Most inspections by variables schemes are based on the assumption that the data are normally distributed or can be transformed so that they are normally distributed. Such sampling plans are described in detail in ISO 3951 when the test measurement uncertainty is negligible. However, ISO 3951 does not consider situations in which there is non-negligible measurement error. This standard expands upon the methods used in ISO 3951 to encompass situations where there is non-negligible measurement error.

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4.2 Inspection by attribute schemes

Inspection by attributes are methods which consists in taking note, for every item of a population or of a sample taken from this population, of the presence or absence of a certain characteristic (attribute) and in counting how many items have or do not have this characteristic (ISO 3534).
These schemes categorises each sampled item as either acceptable or not acceptable. The number of items in each category is used to assess the overall acceptability of each lot of product. However, note that nominal methods may also be subject to measurement error; consideration of these is outside the scope of this standard. Inspection by attribute sampling plans does not make assumptions about the distribution of the data and are therefore completely general. However, the cost of being completely general is that larger sample sizes are typically required to give the same level of confidence as would be obtained from the equivalent inspection by variables scheme. Suitable inspection by attribute plans is described in ISO 2859 and ISO 5538 | IDF 113.

5 Assessment of statistical risk and confidence

5.1 General

Sampling plans are designed to separate, with confidence, lots that contain acceptably low levels of non-conforming product from lots that contain unacceptably high levels of non-conforming product. Lots that contain very little non-conforming product should be accepted with high probability and lots with a high proportion of non-conforming product should have a low probability of being accepted.

For all acceptance-sampling schemes, it is possible to calculate the probability of accepting a lot based on the proportion of the lot that is non-conforming. A graph showing the probability of acceptance against the proportion of non-conforming product is called an operating characteristic (OC) curve. These OC curves summarise the statistical risk and confidence of the acceptance inspection scheme. A typical OC curve is shown in the figure 1.

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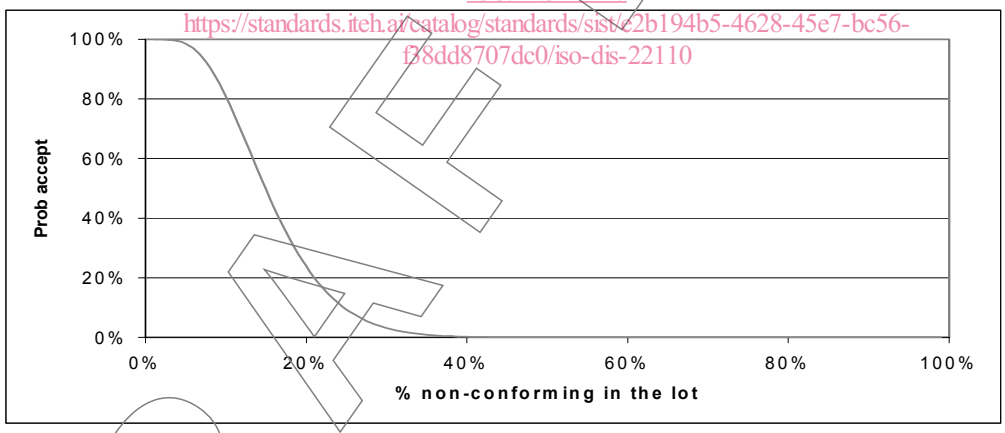

Figure 1 — Example of a typical OC curve

There are an infinite number of OC curves that can have a gradual slope or a steep slope. The overall shape of the OC curve determines the power of the acceptance inspection scheme to differentiate between lots of product of acceptable quality and lots of product that are not of acceptable quality.

5.2 Descriptors of OC curves

Two main descriptors are used to index OC curves: the acceptable quality level and the limiting quality.

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5.2.1 Acceptable quality level

The Acceptable Quality Level (AQL) a quality level which in a sampling plan corresponds to a specified but relatively high probability of acceptance (see ISO 3534). In practice this is the maximum percentage or proportion of nonconformities in a lot or batch that can be considered satisfactory as a process average.

Three OC curves with the same AQL are shown in the figure below. All three curves pass through the one point — (AQL with 10 % non-conforming product, 90 % probability of acceptance) — but they differ in their steepness. For a fixed AQL, acceptance inspection schemes using larger sample sizes have steeper OC curves. That is, as the sample size increases, the plans are better able to differentiate between product of acceptable quality (less than AQL non-conforming) and marginal product.

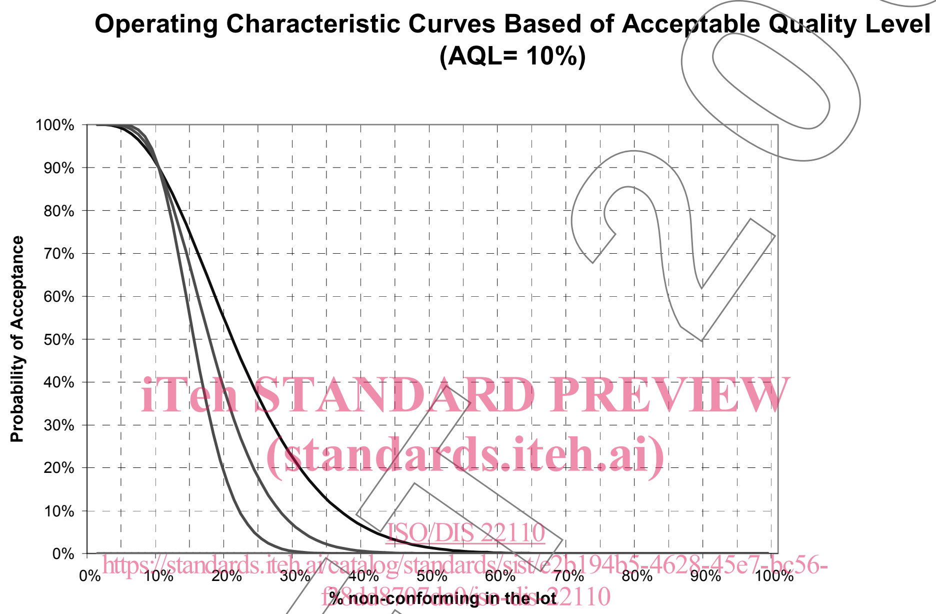

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Figure 2 — Operating Characteristic Curves based of Acceptable Quality Level (AQL= 10 %)

5.2.2 Limiting quality

The Limiting Quality (LQ) in a sampling plan is a quality level which corresponds to a specified and relatively low probability of acceptance (see ISO 3534). In practice the LQ is the quality level, when a lot is considered in isolation, which, for the purposes of acceptance sampling inspection, is limited to a low probability of acceptance. Quantitatively it is the percentage of non-conforming product for which there is approximately 10 % chance of acceptance.

The LQ defines the poorest level of marginal quality. LQ is sometimes referred to as lot tolerance percent defective (LTPD) and rejectable quality level (RQL). Four OC curves with the same LQ are shown in the figure below. All four OC curves pass through the one point (LQ 30 % non-conforming product, 90 % probability of rejection) but they differ in their steepness.

For a fixed LQ, acceptance inspection schemes with larger sample sizes have steeper OC curves. That is, as the sample size increases, the plans are better able to differentiate between marginal product (less than LQ non-conforming) and unacceptable product.

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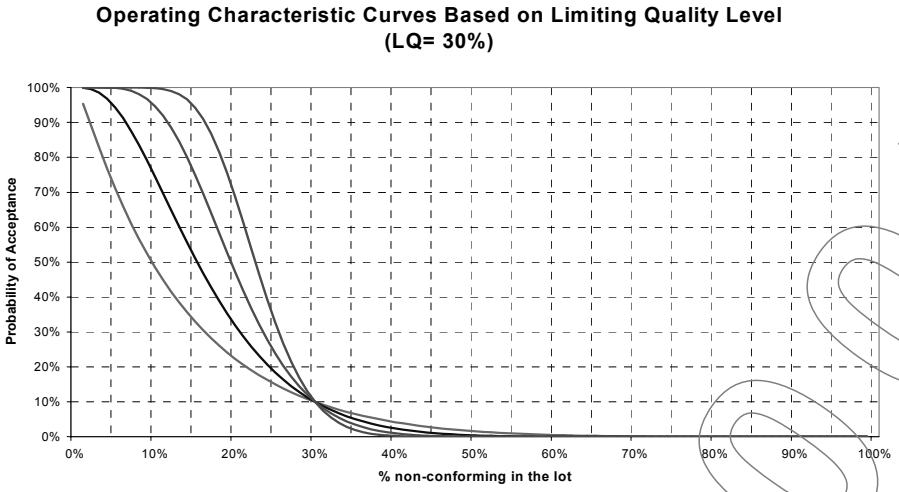

Figure 3 — Operating Characteristic Curves Based on Limiting Quality Level (LQ= 30 %)

5.2.3 Sample size

Traditionally, inspection-sampling plans have been applied only to lots consisting of discrete units. However, this constraint is unnecessary — inspection by variables sampling plans also apply to continuous product. In addition, previous standards have also tended to vary the sample size according to the lot size even though the sample size is, in the strict statistical sense, independent of the lot size.

The designers of the plans, however, such as those in ISO 3951, have deliberately chosen to relate sample size to lot size to force steeper OC curves upon larger lots, to reduce the chance of making an incorrect decision about larger lots. This approach is generally not appropriate for milk and milk products because, in many situations, the size of a packaged unit is arbitrary and not related to the quantity of product manufactured. For example, milk powder is usually packaged in either 25 kg bags or 900 kg bulk bins, but the customer typically purchases product by either the kilogram or the tonne, with neither basis related to the quantity of product manufactured. Relating the sample size to the number of units in the lot (as per ISO 3951) could produce overall risk for the same amount of product depending on how product units are defined.

This standard takes a different approach to the determination of sample size from that used in ISO 3951. This approach is fully described in annex D.

6 Classification of defects

The contract or specification shall clearly define and document all critical, major and minor defects in an unambiguous way, and define the inspection sampling plans. The following terms and definitions on defects applies:

6.1
critical defect
defect that is likely to make the product unacceptable.

6.2
major defect
defect that is likely to make the product unfit for sale to a consumer.

EXAMPLE A major defect could result in spoilage or contamination with an inhibitory substance.

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6.3
minor defect
failure to comply with a specification, but does not make the unit unfit for use or cause it to spoil.

EXAMPLE The chemical composition or net content falling outside, but close to, a specification limit would usually be considered to be a minor defect.

6.1 Choice of inspection and acceptable quality level

1. Sampling plans for major defects shall be selected using an AQL of not more than 6,5 %.

2. Sampling plans for minor defects shall be selected using an AQL of not more than 10 %.

3. The risk profile (B–N) is selected to control the risk of accepting a lot when more than the AQL is non-conforming.

4. Risk category B plans have the highest risk of wrongly accepting a lot when more than proportion AQL is non-conforming. These plans are more suitable for small lots.

5. Risk category N plans have the lowest risk of wrongly accepting a lot when more than proportion AQL is non-conforming.

7 Selection of sampling plans

The flow chart in figure 4 describes the process for selecting a sampling plan for a particular application from the options presented in this standard.

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The following outlines the basic procedure.

a) Determine the appropriate AQL using the guidelines in clause 6.

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b) Select an appropriate risk profile for the application – see clause 6.

c) Determine the type of result associated with the quality parameter under consideration; that is, are the data continuous or nominal?

d) If the data are nominal, then an attributes sampling plan is required. Select an appropriate plan from ISO 2859 or ISO 5538 | IDF 113 or use a three-class sampling plan.

e) If the data are continuous but neither normally distributed nor transformable to normality, then results should be coded as acceptable/not acceptable with respect to some threshold value, and an attributes sampling plan from ISO 2859 or ISO 5538 | IDF 113 should be used.

f) If the data are continuous and are normally distributed, or can be transformed to normality, then the following should be used.

   1. If the measurement error is negligible, then the ISO 3951 standard may be used. Equivalently, depending on whether the process standard deviation is known or unknown, the tables in annexes A and B, respectively, can be used with $\gamma = 0$. Statistical details are explained in annexes E and F.

   2. If the *between-laboratory* measurement error is not negligible, then there is no valid inspection by variables sampling plans for isolated lots and a verification scheme must be used instead. Refer to Section 9 and annex 9.

   3. If the *between-laboratory* measurement error is negligible but there is non-negligible (known) *within-laboratory* measurement error (as measured by the repeatability standard deviation), and if the process standard deviation is known, then the tables in annex A (known process standard deviation) should be used to determine the sampling plan, i.e. the sample size and the acceptability constant.

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4. If the *between-laboratory* measurement error is negligible but there is non-negligible *within-laboratory* measurement error (as measured by the repeatability standard deviation), and if the process standard deviation is unknown but the ratio γ of the within-laboratory standard deviation to the process standard deviation is known, then the tables in annex B (unknown process standard deviation, known ratio) should be used to determine the sampling plan. Note that the ratio of the repeatability standard deviation to the process standard deviation, γ, need be known only approximately.

5. If the *between-laboratory* measurement error is negligible but there is non-negligible *within-laboratory* measurement error (as measured by the repeatability standard deviation), and if the process standard deviation is unknown, then the tables in annex C (unknown process standard deviation, known within-laboratory measurement error) should be used to determine the sampling plan.

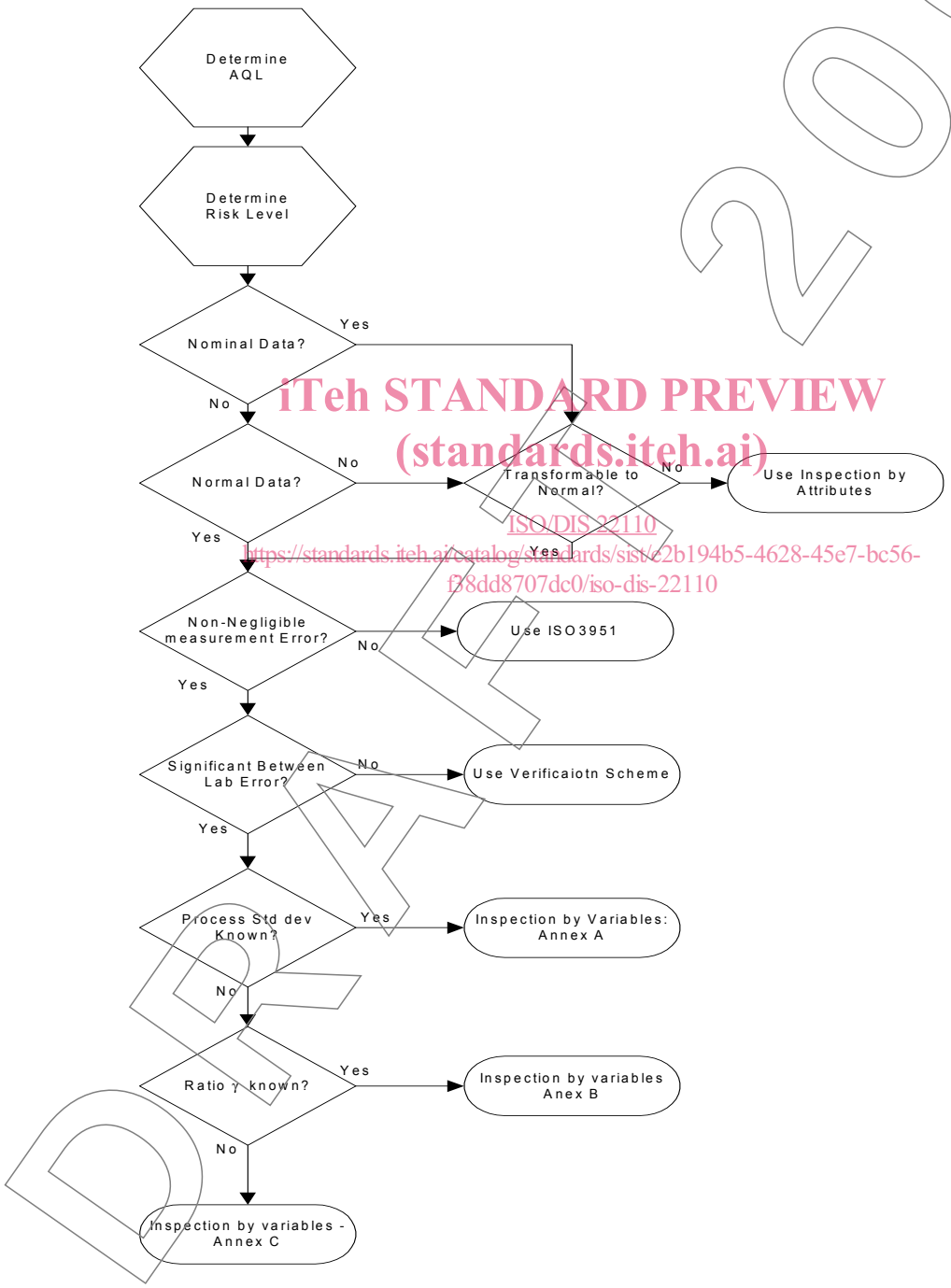

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Figure 4 — Flow chart

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NOTE The measurement error can be considered to be non-negligible if the total measurement error standard deviation exceeds 30 % of the process standard deviation. The total measurement error standard deviation includes both within-laboratory and between-laboratory variation.

It is possible to reduce the effective measurement uncertainty by performing analyses in replicate and utilising the average result for each physical sample because the measurement error standard deviation of the average is, by the central limit theorem, $\sigma_r / \sqrt{n_2}$ where σ_r is the measurement error standard deviation of individual results and n_2 is the number of replicate analyses performed on each individual sample.

8 Sampling and inspection procedures

8.1 Method of sampling

Samples should be taken at random from throughout the lot to be assessed using the sampling procedures outlined in ISO 707 | IDF 50.

8.2 Procedure with known ratio of measurement error standard deviation to process standard deviation

Inspection by variables in the presence of non-negligible within-laboratory measurement error — known ratio of measurement error standard deviation to process standard deviation

This clause describes the procedure for selecting an inspection by variables sampling plan when:

a) the measurement error is non-negligible, i.e. the total measurement error standard deviation is greater than 30 % of the process standard deviation;

b) the between-laboratory measurement error is negligible;

c) the within-laboratory measurement error, represented by the repeatability standard deviation σ_r, is known; an estimate of σ_r can be obtained using the methods described in ISO 5725;

d) the ratio of σ_r to σ, $\gamma = \sigma_r/\sigma$, is known. Producers can provide that ratio from their production records. It is evident from examination of the tables in annexes A and B that the value of γ need be known only approximately.

Appropriate values of the sample size (n^*) and the acceptability constant (k^*) can be obtained from tables (see annex A or annex B) for a selected AQL and risk profile for values of γ likely to be encountered in practice. For other values of γ, n^* and k^* can be calculated using the formulae in annex E or annex F.

Procedure:

Take a sample of n^* items at random from the lot. Calculate the arithmetic mean $\bar{x}$ of the n^* results using the formula

$$\bar{x} = \frac{1}{n^*} \sum_{i=1}^{n^*} x_i$$

where

x_i is the result obtained for the i^{th} item in the sample (i = 1, 2, …n), and

n^* is the number of items in the sample.

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