IEC 61193-3

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Quality assessment systems –
Part 3: Selection and use of sampling plans for printed board and laminate end-product and in-process auditing

Système d'assurance de la qualité –
Partie 3: Choix et utilisation de plans d'échantillonnage pour cartes imprimées et produits finis stratifiés et audits en cours de fabrication

IEC 61193-3:2013

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FOREWORD

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The text of this standard is based on the following documents:

FDIS	Report on voting
91/1061/FDIS	91/1080/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of the IEC 61193 series, under the general title *Quality assessment systems,* can be found on the IEC website.

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- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

A clear description in IEC standards and specifications and their reference to sampling plans in order to insure adherence to customer requirements is essential. All the details should be clear as to their implementation or adjustment for evaluation of the product to be shipped, the use of process control and SPC, or the applicability for using these principles in controlled experimentation. The general characteristics of these principles relate to a gradual reduction that might be needed in examining the product being manufactured. As such, they are sometimes referred to as the logical steps to process improvement. These steps are as follows.

a) STATISTICAL SAMPLING: where, when, and why

   - To determine a proper amount of examples from a given lot of product and using statistics to evaluate the occurrence of anomalies.

b) ZERO DEFECT STANDARDS: role of specifications

   - To adopt the role of attempting to achieve no defects in a production lot through the recommendations identified in standards or specifications that define the product requirements.

c) ECONOMICS: AQL versus cost of defects

   - To establishing the highest level of non-conforming product characteristics, determining the cost that is incurred when these are discovered or delivered accidentally to the customer (cost of quality) and establishing an acceptable quality assessment methodology in order to reduce these occurrences.

d) SPC REDUCED INSPECTION: rules for use and control

   - To create a process control program that is based on reject criteria, followed by controlled experimentation to improve the process and then using statistical analysis in order to determine that the process improvement has reduced the occurrences of these reject criteria.

The explosion of the electronics industry has led to a situation where the design of the printed board mounting structure or the material used to produce the product is so complex, that the quality level of these items delivered with known failures are no longer acceptable. The acceptable number of non-conforming products should be directed toward approaching zero in producer-customer contracts.

This has led to the development of new methods of quality assurance like the application of Statistical Process Control (SPC). The low number of permitted non-conforming product according to the AQL tables caused many to resort to 100 % testing or inspection.

At the same time the quality thinking has developed so that the idea to accept failures has become impossible, and the use of the AQL tables in the traditional way has been diminishing very rapidly.

QUALITY ASSESSMENT SYSTEMS –

Part 3: Selection and use of sampling plans for printed board and laminate end-product and in-process auditing

1 Scope

This part of IEC 61193 establishes sampling plans for inspection by attributes, including sample plan selection criteria and implementation procedures for printed board and laminate end-product and in-process auditing. The principles established herein permit the use of different sampling plans that may be applied to an individual attribute or set of attributes, according to classification of importance with regard to form, fit and function.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60194:2006, *Printed board design, manufacture and assembly – Terms and definitions*

IEC 62326-4:1996, *Printed boards – Part 4: Rigid multilayer printed boards with interlayer connections – Sectional specification*

ISO 9000:2005, *Quality management systems – Fundamentals and vocabulary*

ISO 14560:2004, *Acceptance sampling procedures by attributes – Specified quality levels in non-conforming items per million*

3 Terms and definitions

For purposes of this document, the terms and definitions given in IEC 60194:2006, ISO 9000:2005 and the following apply.

3.1
attribute
aspect or characteristic of a unit of a defined product in terms of actual requirement and allowable deviation

Note 1 to entry: An actual requirement signifies the following:

- a requirement that is stated as a measurement with an allowable more and/or less deviation;
- a requirement stated as an absolute desired condition with allowable anomalies;
- a requirement stated as an absolute without exception (go/ no-go).

3.1.1
critical attribute
attribute where a defect, that judgment and experience indicate, is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the product; or where a defect is likely to prevent performance or function of a major end item such as a ship, aircraft, computer, medical equipment, or telecommunication satellite

3.1.2
major attribute
attribute where a defect, other than critical, is likely to result in failure, or where a defect reduces the usability of the unit of a product for its intended purpose

3.1.3
minor attribute
attribute where a defect is not likely to reduce materially the usability of the unit of product for its intended purpose, or where a defect is a deviation from established standards having little bearing on the effective use or operation of the unit

3.2
acceptable quality level
DEPRECATED: AQL
maximum percent of defects that can be tolerated as a risk, stated for the purposes of sampling inspection

Note 1 to entry: Sample inspection with associated risk tolerance is employed only where all units of a product within an inspection lot is expected to completely conform to the specification requirements.

Note 2 to entry: See 3.3.

3.3
acceptance quality limit
lower than perfect quality level

Note 1 to entry: Revised term for AQL.

Note 2 to entry: The term is used to indicate a certain degree of risk in that some products may have non-conforming characteristics. However, they do not impact the final performance. These decisions are based on customer/supplier agreements.

Note 3 to entry: The use of the abbreviation AQL to mean "acceptable quality level" (refer to 3.2) is no longer recommended.

3.4
defective
unit of product that contains one or more defects

3.4.1
critical defective
unit of product that contains one or more defects of critical attributes, and that may also contain defects of major or minor attributes

3.4.2
major defective
unit of product that contains one or more defects of major attributes, and may also contain defects of minor attributes, but contains no defects of critical attributes

3.4.3
minor defective
unit of product that contains one or more defects of minor attributes, but contains no defects of major or critical attributes

3.5
inspection
process of measuring, examining, testing, or otherwise comparing the unit of product with the specified requirements

3.5.1
inspection by attributes
inspection of individual attributes (aspects or characteristics) of the unit of product per specified requirements, procedures, and/or instructions

3.5.2
inspection lot
collection of product units that are identified and treated as a unique entity from which a sample is drawn and inspected in order to determine conformance with acceptability criteria

3.5.3
inspection rate
number of features per unit of time that can be evaluated at specified false-alarm and escape-rate settings

3.6
risk management factor
RMF
maximum tolerable percentage of possible defects within a lot (group) of units, based on approximately 95 % confidence level

3.7
shipment-ready product
product shipped to the customer without having to meet any further acceptance criteria

3.8
unit of product
item(s) being inspected in order to determine conformance to specific requirements

Note 1 to entry: These requirements consist of the following:

- a single article, a pair, a set, a length, an area, an operation, a volume, a component of an end product, or the end product itself;
- may or may not be the same as the unit of purchase, supply, production or shipment.

4 Sampling methodologies

4.1 General

There is a considerable number of ISO standards on acceptance sampling (see Annex D for details). However, most of these standards contain plans that allow a lot to be accepted even when the sample from the lot contains one or more non-conforming items, although there are some exceptions (ISO 18414 and ISO 21247).

The zero acceptance number plans (c = 0) were originally designed and used to provide equal or greater consumer protection with less inspection than that required by corresponding sampling plans. The c = 0 plans are simple to use and administer since there is greater emphasis on zero defects and product liability prevention. The concepts stated herein provide a set of attribute plans for product lot inspection. The acceptance number in all cases is zero. This means that for some level of protection, a sample size is selected and if one or more non-conforming attributes are present, the lot will be withheld.

The terminology "withhold the lot" does not necessarily mean rejection. A lot is not automatically accepted or rejected if one or more non-conformances are found. It is only accepted if zero non-conformances are found in the sample.

Withholding the lot obliges engineering/management personnel to review the results and to withdraw the lot depending on the seriousness of the case. This relates to whether the attribute

was critical, major, or minor, or whether identifying the non-conformance to the requirements was defined as a critical, major, or minor defect.

The word "defective" is commonly used in quality control to describe a part, component, item, or any other unit of product that contains one or more defects. The word "defect" is commonly used to describe a particular non-conforming characteristic on a unit of product.

4.2 Attribute sampling plans

4.2.1 General

The following subclauses provide an overview of lot size description attribute plans while relating them to other plans. Two broad categories of sampling exist and these are

a) continuous;

b) production lot.

4.2.2 Continuous sampling

Continuous sampling is often used when product units are submitted one at a time. This can apply to production processes where a product moves through various steps. Product moving along a conveyor can also be thought of as being a candidate for continuous sampling. Industry has moved away from inspecting quality at the end of the line; thus, in-process inspection or sampling is a way in which many companies maintain statistical process controls.

The continuous sampling plan may call for frequency checks, i.e. one unit out of five. Even if the products are good, this frequency check is maintained. If, however, a unit is non-conforming, 100 % inspection is reverted to until the specified number of consecutive conforming products result. At that point, the process returns to frequency inspection.

As an example, a quality decision for continuous sampling would be to examine five samples, within a particular hour, out of a total of thirty products passing through a process. Based on the characteristics being inspected (i.e., solder bridging on a particular part) nothing is observed in a certain number of hours, the time can be increased without changing the sample size. At this point, the sample taken represents a larger portion of an amount of products being processed. The samples are then monitored for a longer period of time before reducing to fewer samples again, or to increase the allotted time in which the samples are randomly selected.

4.2.3 Production lot attributes

Production lot size descriptions involve units of products that are presented in a group, batch, or lot for inspection, as opposed to being presented one at a time. In these cases, a sample of a specified quantity is drawn and compared with some acceptance criteria. In the past, sampling plans allowed a certain quantity of defectives in the sample; the c = 0 plan does not. In c = 0 plan, the attributes evaluated either conform or do not conform. Go/no go type gauges are often used in attribute plans.

4.2.4 Production lot variables

Another production lot sampling procedure involves the analysis of measured characteristics where the attributes vary with respect to their requirements. Variable sampling compared with attribute sampling essentially involves the inspection of a smaller sample size to obtain the same protection afforded by an attribute plan. The economics of these smaller sample sizes, however, are quite often offset by the calculation involved and the need to obtain and record measurements. In addition, the essential difference between variables and attributes sampling is not the relative sample sizes, but that variables sampling is based on measurements whereas attributes sampling is based on classifications.

Where variables' data is required from an inspection operation, variables' plans shall definitely be considered. The use of variable plans is necessary when the distribution of the variable data can significantly improve the process. It may also be important to establish an upper and lower characteristic so that the customer is aware of the changes that might be necessary to bring the two limits closer together in a manner that meets the customers' requirement (target). By the manufacturer retaining the records regarding meeting the target value of a particular requirement, the data can indicate when the process is starting to become out-of-control due to the distribution of measurements within the specified upper and lower acceptance limit. In variables' production lot sampling, the information is collected primarily to help assure the manufacturing of acceptable products by indicating the distance from the target that the lot inspection provides.

4.3 Non-statistical sampling plans

There are cases where zero defects can visually be assured, although the sample size cannot logically be defined in terms of statistical risks. Such sample sizes are generally exceptionally low for the more important attributes and, therefore, knowledge of the process and the control factors is essential. The drilling of printed circuit boards might use first article inspection as a methodology to determine that the automated tools creating the number of holes in the board meet the criteria of the requirements. No further inspection of the product is carried out. However, to ensure that the production process is still under control, a sampling may be made regarding the number of uses of a drill, any changes in speed or feed characteristics, or other features of the automated process that might impact the quality that was approved by the first article.

In order to avoid any confusion in justifying such sample sizes on inspection plans, specific notations should be used to avoid any tie-in with statistical risks. The reason for such a selection should be noted, either directly in the plan or in the quality engineering standards.

An example might be a sampling operation where just the first and last item from a lot, are inspected dimensionally. This is also accomplished where the first and last time a drill bit is used, it is drilled into an inspection coupon. This permits the first and last characteristics of the drilled hole to be examined and determined that all holes drilled in between are of a good quality. Another example might be evaluating a number of products during a particular time sequence. If the products are different, the technique can be normalized by evaluating the amount of unit area being processed along a conveyor over a particular time. In this case, a variety of products can be measured and evaluated. The system then would be judged in or out of control, depending on non-conformance per unit area over specific time sequences.

The higher index values in the $c = 0$ plans are also used where favourable process control has been demonstrated and just an audit is required. Although the statistical risks seem high, the risks from a practical standpoint would be exceptionally low.

4.4 Defining $c = 0$ plans

There are many plans that have used the $c \geq 0$ concepts. These plans are acceptable quality level (AQL) oriented. Essentially, the AQL is a specified percent that is considered to be good quality. In any sampling plan, an operating characteristic curve can be generated to define the risk of accepting lots with varying degrees of percent non-conforming or defective. These plans went out of favour in the late 1980's, due to the misunderstanding that it was good practice to release shipment-ready products with known, non-conforming attributes.

When the AQL concept is used, a high probability of acceptance associated with the AQL percentage exists. Normally, this is in the order of a 0,90 to 0,98 probability of acceptance level. The risk of rejecting this AQL percentage is in the order of 0,10 to 0,02 probability level. This rejection risk is called the "producer's risk."

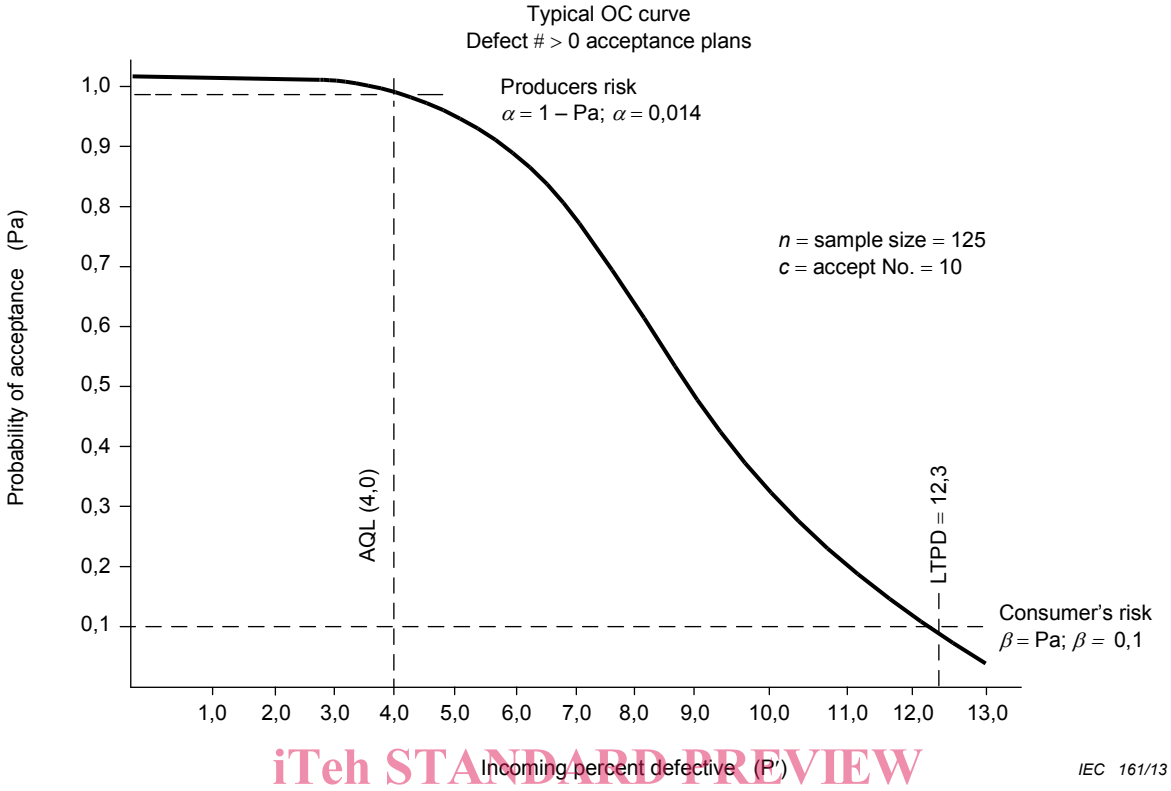
The assumptions in employing the AQL concept, is that some agreement has been reached between the producer and the consumer. Although the term 'quality' is implied by the initials AQL, selecting this method is the worst tolerable quality level, since non-conforming products

may be found in the sample size and yet the production lot is still delivered to the customer, see Table 1. Since sampling is used, the producer assumes a risk of having a lot rejected, although the actual percentage defective in the lot is equal to or less than specified in the AQL.

It is also important that a clear distinction be made by either the customer or the requirements of the specification regarding the characteristics of the non-conforming attribute. Many printed board or laminate standards identify some characteristics as a process indicator and allow these to be delivered since they do not impact the performance of the product. The sampling plan, therefore, allows a lower inspection number and uses the occurrences of the process indicators as something that needs to be improved. Scratches on copper conductors are an example of such an indicator. Other attributes are defined as defects since they do impact performance and, therefore, impact the entire production line.

If no prior AQL agreement exists, and sampling is to be performed simply because 100 % inspection is impractical, then over-inspection is usually the result. Also, when 100 % sampling is impractical, the producer is encouraged to inspect a small number of units of product on less critical attributes. To illustrate the concept, if the $c \geq 0$ plan were used, a 1,0 % AQL might be used for critical attributes and a 4,0 % AQL might be used for major attributes. The technique for sample selection under an Acceptable Quality Limit would correlate to a $c = 0$ plan which would allow no non-conforming product in the sample size.

It is a statistical fact that zero accept number ($c = 0$) plans provide equivalent statistical assurance than do plans associated with defect acceptance ($c \geq 0$). This can be verified by examining the operating characteristics (OC) curves, which should normally be provided with sampling plans. Figure 1 shows a typical OC curve from a $c \geq 0$ plan. There is a probability scale on the Y-axis and an incoming defective possibility scale on the X-axis. The curve is generated through probability calculations based on a sample size of 125 with an acceptable number of 10. Also shown is the producer's risk, which is a risk of rejecting a good lot of product and the associated consumer's risk, which is the risk of accepting a bad lot of product.



NOTE 1 Values come from Poisson distribution analysis. (α is 0,013 7 by Poisson distribution and is 0,011 9 by binomial distribution; β is 0,101 3 by Poisson distribution and is 0,086 8 by binomial distribution.)

NOTE 2 For typical OC curve refer to ISO 2859-1.

Figure 1 – Typical OC curve for $c \geq 0$ plan

In addition to the AQL and producer's risk, there is a parameter called the lot tolerance percent defectives (LTPD). This LTPD is considered poor quality, and is sometimes identified as consumer's risk quality. Several sampling plans can have OC curves pass through the same AQL/producer's risk point. For each of these plans, however, there will be a different LTPD at some constant probability of acceptance level. This probability of acceptance level corresponding to the LTPD is usually low with a 0,10 being widely accepted. This probability level is called the "consumer's risk".

The user of sampling plans shall select the plan that will provide reasonably good protection against accepting lots with percent defectives not a lot greater than the AQL. With the AQL/producer's risk point fixed, the closer the LTPD gets to the AQL, the larger the sample size and the acceptance number becomes. Figure 2 is a comparison of the $c \geq 0$ OC curve and an equivalent OC curve from the zero defect $c = 0$ plan. This example illustrates that the $c = 0$ curve with a small sample of 18 and an accept number of 0 is equivalent or better than the $c = 0$ plan with a relatively large sample of 125 and an acceptance number of 10. The producer's risk probability may be greater at certain levels with the $c = 0$ plan.