ELEMENTS OF ACCEPTANCE SAMPLING BY ATTRIBUTES

« Sampling is an instinctive process in humans. Often, opinions are formed, judgments are made, one behaves in one way or another, knowing a limited part of reality. The cook who decides whether to add salt to the roast, the teacher who ascertains the students' preparation, ..., take samples of the reality that surrounds them. »

(L. Fabbris, L'Indagine Campionaria, La Nuova Italia Scientifica, 1989

INDEX

INDEX *(cont.)*

BACKGROUND

- There are numerous definitions of **Quality Assurance (QA)**, *e.g.*:

  - A system of activities whose purpose is to provide to the producer or user of a product or a service the assurance that it meets definite standards of quality with a stated level of confidence

    (J.K. Taylor, Principles of Quality Assurance of Chemical Measurements, NBSIR 85-3105, Gaithersburg, USA)

  - The sum total of the organised arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use and that quality systems are maintained.

    (ICH Q7, Good Manufacturing Practice for Active Pharmaceutical Ingredients, November 2000)

BACKGROUND

- ***The inspection of incoming raw materials, process intermediates or finished products, namely the so-called SAMPLING, is an important part of Quality Assurance!***

- ***When the purpose of this inspection is to accept or reject a product based on whether or not it conforms to a predetermined standard, it is referred to as:***

ACCEPTANCE SAMPLING or **STATISTICAL ACCEPTANCE SAMPLING**

(the two terms are often used interchangeably!)

- ***Obviously, sampling can also be performed during production (or in process) and not only at the beginning or at the end of the manufacturing process !***

BACKGROUND

It must be clear from the outset that:

- ***The purpose of* ACCEPTANCE SAMPLING *is only to decide about the fate of a lot (approved / rejected) and not to evaluate its quality!***

  That is,* ACCEPTANCE SAMPLING *does not provide any direct form of Quality Control !

- **ACCEPTANCE SAMPLING** ***is, in fact, a tool to ensure that the output of a given process complies with the pre-established requirements !***

BACKGROUND

There is indeed a difference between:

ACCEPTANCE SAMPLING PLANS ***and*** ***ACCEPTANCE QUALITY CONTROL***

While the former, as mentioned, serve only to immediately accept or reject a given lot, the latter is a much more complex process that makes use of numerous statistical-probabilistic tools (*e.g.*, control charts, *etc*.) to intercept the signals sent by the process (drifts, trends, *etc*.) with the aim of improving its quality level.

BACKGROUND

So why do you need ACCEPTANCE SAMPLING?

- 100% control is inefficient while 0% control is risky
- Tests are often destructive
- Product compliance must be ensured while a Statistical Process Control (SPC) is being established
- The process is not under Statistical Control and therefore sampling is needed to evaluate the product
- The Client requests a sampling plan
- *etc.*

BACKGROUND

What is ACCEPTANCE SAMPLING done and how?

- The control is carried out on ***homogeneous batches of product*** (raw, semi-finished or finished), *i.e.* consisting of similar units.
- The control is carried out using three main « tools » namely:
  - ***sampling plan***
  - ***sampling scheme***
  - ***sampling system***

which are often combined with each other and generically called « sampling plan ».

In that case, one should more correctly speak of « SAMPLING SYSTEM ».

BACKGROUND

- a ***sampling plan*** is only a set of sample size (*i.e.*, number of sample units, *n*) + criterion for acceptance / rejection.

  Note that a sampling plan does not contain the rules by which to form the sample!

- a ***sampling scheme***, on the other hand, is a set of sampling plans with the rules that are used to move from one plan to another (***switching rules***).

- a ***sampling system***, on the other hand, is a sampling scheme completed by the instructions for conducting the sampling or sampling procedure.

BACKGROUND

What measures the QUALITY OF A LOT?

- The ***« measure of the quality of a lot »*** is given by the *percentage (or proportion) of non-conforming (or defective)* units* present in it.

- What exactly is meant by « non-compliant or defective unit »?
  - a unit that, ***assessed globally***, is not included in the established « specifications »
  - a unit that ***measured with respect to a given quantitative characteristic*** is not included in the tolerances imposed

(*) in practice, the terms non-conforming, non-compliant and defective are used interchangeably!

BACKGROUND

- Because of this classification we will therefore speak, respectively, of:
  - ***CONTROL BY ATTRIBUTES*** and
  - ***CONTROL BY VARIABLES***

To clarify the meaning of these definitions some clarifications are necessary!

BACKGROUND

In general terms it can be said that:

- each statistical unit (*e.g.*, an individual, an object, *etc.*) can be defined and identified by resorting to its ***characteristic properties*** or ***characters*** which can manifest themselves in the form of:
  - ***attributes → qualitative characters*** (*e.g.*, for an individual, the color of the eyes or hair)
  - ***measures → quantitative characters*** (*e.g.*, height or weight for an individual)
- ***qualitative characters*** are then divided into *ordinal* and *nominal* (depending on whether there is an order relationship or not)
- ***quantitative characters*** are then divided into *discrete* and *continuous*.

BACKGROUND

- ***Acceptance control methods by attributes*** are the ***most popular*** because they are ***cheaper and faster*** even if, generally, they require more observations than those by variables.
- From a general point of view, the ***attribute acceptance control methods*** are the methods of choice when the check is *destructive*.
- Alongside these concepts, the most important « conceptual tools » that will be used in the following are those that coming from

PROBABILITY THEORY

BACKGROUND

There are at least three definitions of what is meant by ***probability*** of a given *event E*.

According to the so-called classical definition, ***probability*** can be determined by dividing the number of desired events in which a given event can occur by the total possible number of equally probable outcomes.

$$P(E) = \frac{Number\ of\ ways\ E\ can\ successfully\ occur}{Total\ number\ of\ possible\ outcomes\ of\ the\ experiment} \quad (1)$$

The term *event* identifies any possible outcome of an experiment. An event can be *simple* if it consists of just one outcome or *compound* if it contains more than one outcome.

BACKGROUND

Faced with the occurrence of two or more events, it is first necessary to consider whether these are:

- ***Compatible*** (or *mutually non-exclusive*) or ***Non-Compatible*** (or *mutually exclusive*)

Additionally, *only compatible events* can be subsequently:

- ***Dependent*** or ***Independent***

The meaning and usefulness of these clarifications will be clear shortly!

BACKGROUND

Two or more events are mutually ***compatible*** (or ***mutually non-exclusive***) if they can occur simultaneously.

Instead, they are said to be ***incompatible*** (or ***mutually exclusive***) if they cannot occur at the same time

EXAMPLE:

If the event consists, for example, in establishing whether a tablet has flaws or is flawless, one possibility automatically excludes the other. Indeed, a tablet may indeed be defective or not.

BACKGROUND

The situation is different if, for example, the event consists in establishing the possible defects that a tablet could have (*e.g.*, *capping*, *chipping*, *etc.*).

In this case, in fact, the various possibilities are not mutually exclusive.

Capping

Chipping

BACKGROUND

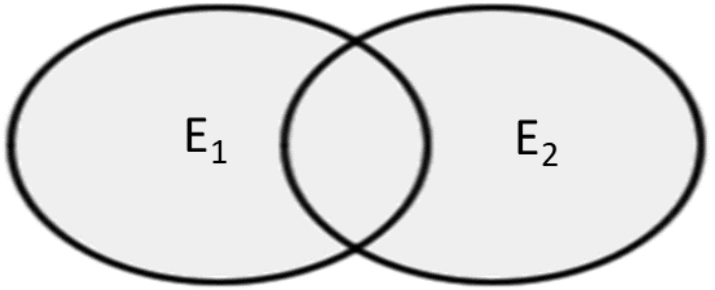
Two or more ***compatible and dependent events*** are those that can occur at the same time.

In this case, the probability of occurrence is the sum of the individual probabilities relating to each event minus the « overlap » between the two, that is:

$$\mathbf{P(E_1 \cup E_2) = P(E_1) + P(E_2) - P(E_1 \cap E_2)}$$

The logical connector $\cup$ stands for « ***or*** », while the connector $\cap$ stands for ***« and ».***

Using Venn diagrams:



BACKGROUND

Two ***incompatible events*** are those in which if one event occurs, the other cannot happen.

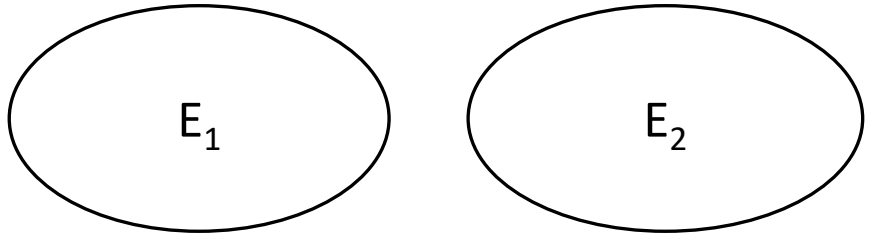
(Note: In this case the concepts of *dependent* or *independent* events do not apply!)

In this case, the probability of occurrence of two or more ***incompatible*** (or ***mutually exclusive***) ***events*** is the sum of the probabilities associated with each event.

$$\mathbf{P(E_1 \cup E_2) = P(E_1) + P(E_2)}$$

The logical connector $\cup$ stands for ***« or »***.

Using Venn diagrams:



BACKGROUND

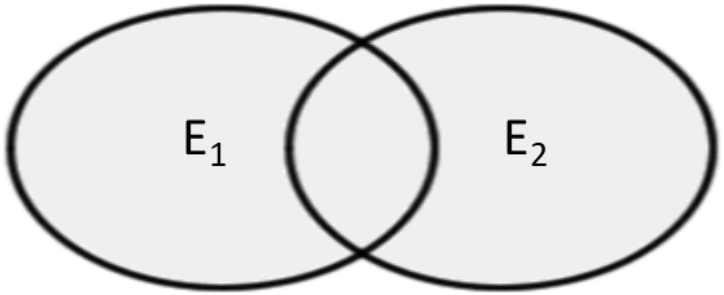
Two ***compatible and independent events*** are those in which the occurrence of one event does not affect the occurrence of the other.

In this case, the probability of occurrence of two independent events is the product of the individual probabilities associated with each event.

$$\mathbf{P(E_1 \cap E_2) = P(E_1) * P(E_2)}$$

The logical connector ∩ stands for ***« and »***.

Using Venn diagrams :



BACKGROUND

Another very important aspect is represented by the:

SAMPLING METHODS

which can be divided into two main groups:

- ***probabilistic methods***: for each statistical unit extracted the probability of inclusion in the sample is ***known***
- ***non-probabilistic methods***: for each statistical unit extracted the probability of inclusion in the sample is ***unknown***.

Since probabilistic sampling allows to obtain unbiased results for the population of interest, it would be advisable to <u>always</u> use this type of sampling.

BACKGROUND

- The most used ***types of probabilistic sampling*** are:
  - casual
  - systematic
  - stratified
  - cluster.
- ***simple random sampling***: the statistical units of the population are all equally likely to be selected for the sample.

  Therefore, if ***N*** is the population size and ***n*** the sample size, the probability that each element is selected at the first extraction is: ***1 / N***.

BACKGROUND

- The individual statistical units can then be sampled ***with or without replacement***.

  - **sampling with replacement :** after having extracted and observed a given unit, it is reinserted into the population again so that it still has the same probability as before it was extracted, that is: ***1 / N***

  - **sampling without replacement :** after having extracted and observed a given unit, it is not reinserted into the population so that it cannot be extracted again. Hence, the probability that a single unit will be selected in the second draw will be: ***1 / (N-1)***

BACKGROUND

The operational tools that allow to implement Acceptance Sampling (both for attributes and for variables) are the

SAMPLING PLANS

SAMPLING PLAN

SAMPLING PLAN

- ***What a sampling plan is*** we have already seen before and precisely:

  the set of sample size (*i.e.*, number of sample units, ***n***) + criterion for acceptance / rejection

- Now it is time to see ***what a sampling plan can look like***:

  - ***single*** : is a procedure in which a sample consisting of *n* units is randomly selected from the lot and the fate of the lot is established on the basis of the information contained in that single sample.

SAMPLING PLAN

- ***double*** : is a procedure for determining the fate of a lot that is based on two (2) samples taken randomly from the lot. Based on the first, it is possible to decide to accept the lot, reject it or take a second sample. If the second sample is used, the information resulting from the evaluation of the first and second samples is combined to decide whether to accept or reject the lot.

- ***multiple*** : it is an extension of the double sampling concept in the sense that, in this case, more than two samples may be required to reach a decision regarding the fate of the lot. The extremization of this concept is ***sequential sampling.***

SAMPLING PLAN

It should be noted that:

- The sample sizes in multiple sampling are generally smaller than those used for single or double sampling.
- Single, double, multiple or sequential sampling plans can be designed to produce equivalent results.
- Batches should be homogeneous and « large » ones are preferable to « small » ones.
- Sampling must be conducted randomly otherwise there is a risk of introducing a *bias*.

SAMPLING PLAN

- Given a batch consisting of ***N*** units, a ***single*** (or simple) ***sampling plan*** is defined by:
  - *sample size* ***n*** with $n < N$
  - *acceptance number* ***c*** (or maximum number of acceptable non-conforming units) with $c < n$
- Therefore:
  - from a lot consisting of ***N*** elements, of which ***D*** are non-conforming and ***N-D*** are conforming,
  - a random sample of numerosity ***n*** is extracted consisting of ***d*** non-conforming elements and ***n-d*** conforming elements
  - if $d \leq c$ → the lot is ***accepted***
  - if $d > c$ → the lot is ***rejected***

SAMPLING PLAN

- Example of a ***single sampling plan***:

$$\boldsymbol{N} = 10000 \quad \boldsymbol{n} = 89 \quad \boldsymbol{c} = 2$$

A random sample consisting of 89 units is taken and inspected from a lot of 10,000 pieces.

If the number of non-conforming (or defective) units ***d*** found following inspection of the sample is less than or equal to 2, the lot is accepted, if higher it is rejected.

This procedure is called a ***single (or simple) sampling plan*** since the lot is evaluated based on information obtained from a single sample of size ***n***.

SAMPLING PLAN

- From a ***probabilistic point of view***, the sampling problem is linked to the percentage of non-conforming (or defective) elements potentially present in the lot.

- The ***percentage of non-conforming units***, or defective units, ***P*** is defined as

$$P\ (percentage\ of\ non-conforming\ units) = \frac{d}{n} \times 100$$

d = number of non-compliant (or defective) units in the inspected sample

n = number of units that make up the sample.

Obviously, as the percentage of non-compliance increases, the probability that the lot will be accepted gradually decreases !

SAMPLING PLAN

An important measure of the performance of an acceptance sampling plan is represented by the

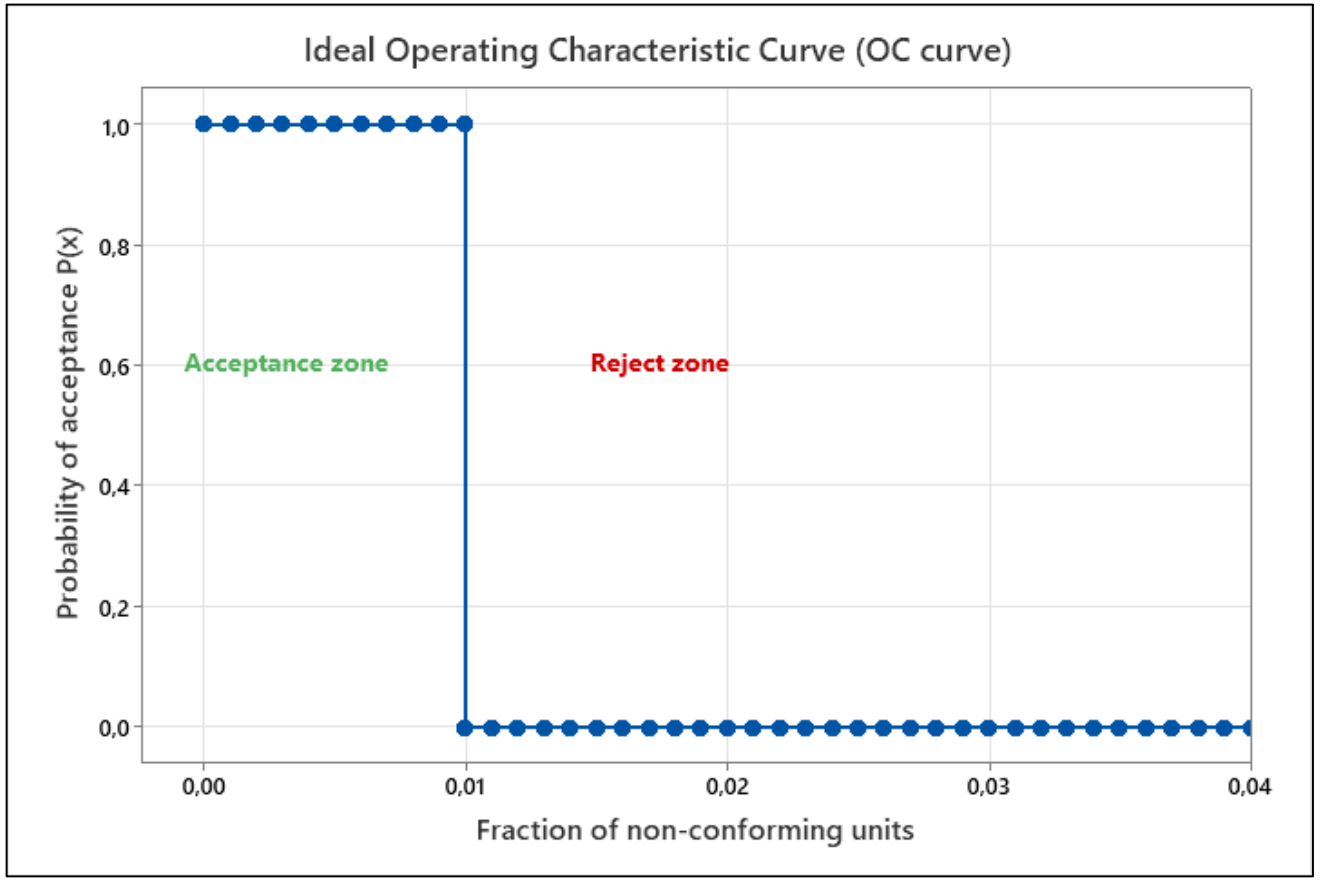
OPERATING CHARACTERISTIC CURVE or OC curve

This curve relates the ***probability of acceptance*** of the lot to the ***fraction of non-compliant or defective units.***

It shows the *« discriminatory power of a given sampling plan »* as it represents the probability that a batch has, with its non-compliant units, of passing or failing a specific inspection (*i.e.*, an inspection defined by a sample size and an acceptance criterion pre-established).

SAMPLING PLAN

In the ***« ideal case »*** shown on the side (which however does not exist in practice and is not feasible!) the OC curve, and therefore the sampling plan associated with it, would express the ***maximum of the discriminatory power*** as it would allow to accept all the lots under a certain level of defects (*e.g.*, 1%) and reject all the others.



SAMPLING PLAN

- ***The shape of the Characteristic Curve depends on the sampling « conditions » !***
- In fact, there are two « typical situations », namely:
  - the case in which the sample is taken all together from a separate lot (*e.g.*, a lot stored in the warehouse) and each unit, once examined, is discarded. This situation can be traced back to the classic example of the « extraction of balls from an urn ***without replacement*** ». Since the possibilities are only two "compliant piece" or "non-compliant piece" (*e.g.*, black and white balls), the probability of obtaining ***x*** non-conforming elements among the ***n*** extracted all together from a box containing ***N*** is described by the **HYPERGEOMETRIC DISTRIBUTION** (OC Curve Type A) namely:

SAMPLING PLAN

$$P_a(x) = \sum_{x=0}^{c} \frac{\binom{Np}{x} \times \binom{Nq}{n-x}}{\binom{N}{n}}$$

where:

N = lot size

p = proportion of non-conforming units in the lot, ***p*** = 0, 1/*N*, 2/*N*, 3/*N*, .., 1

q = proportion of conforming units in the lot, ***q*** = 1 – ***p***

n = sample size

x = number of non-conforming units, ***x*** = 0, 1, 2,…, ***n***

SAMPLING PLAN

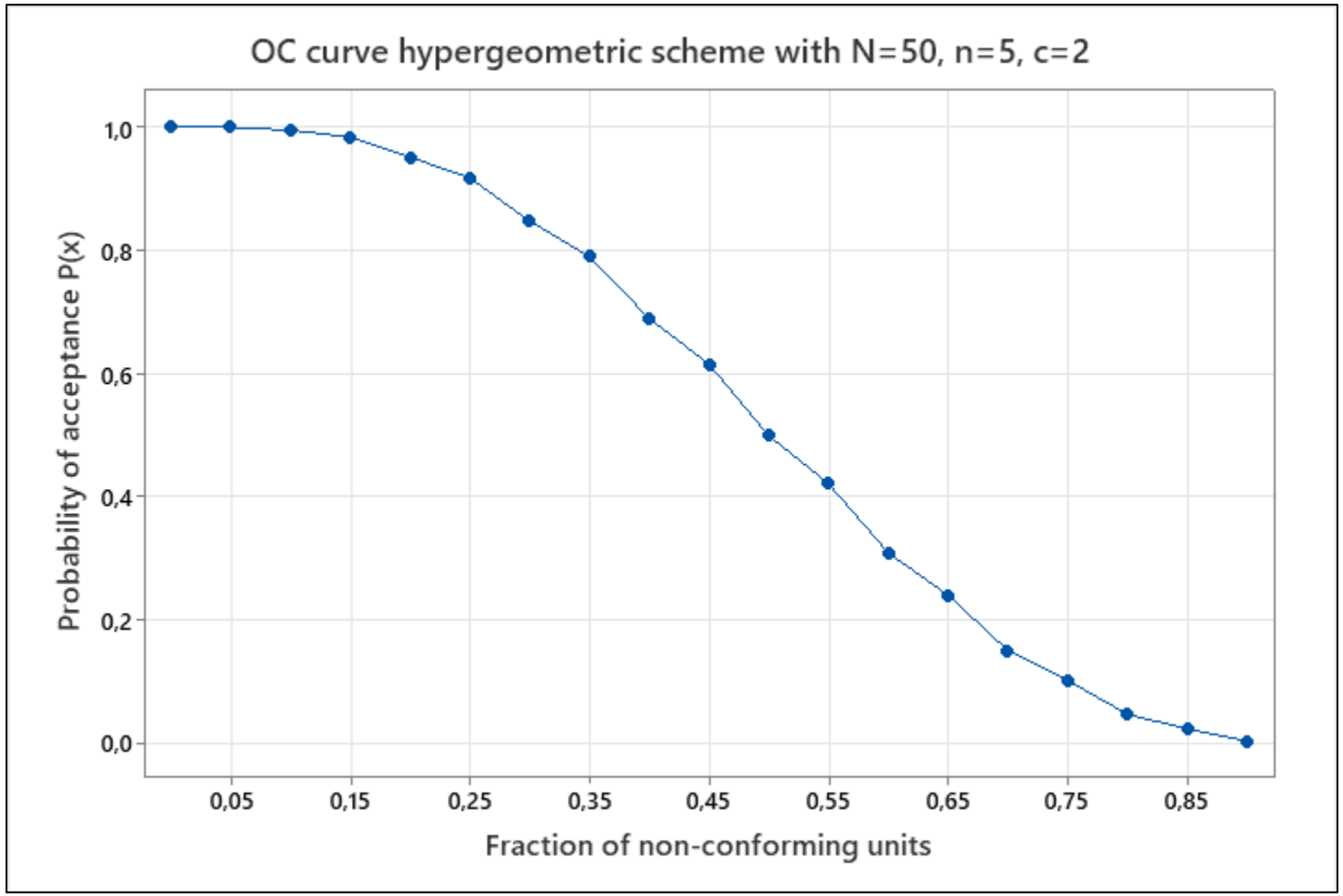
Here is an example of construction of the Characteristic Operating Curve in the Hypergeometric case:

$$\boldsymbol{N} = 50 \quad \boldsymbol{n} = 5 \quad \boldsymbol{c} = 2$$

$$P_a(x=2) = P_a(x=0) + P_a(x=1) + P_a(x=2) = \sum_{x=0}^{2} \frac{\binom{50p}{x} \times \binom{50(1-p)}{5-x}}{\binom{50}{5}}$$

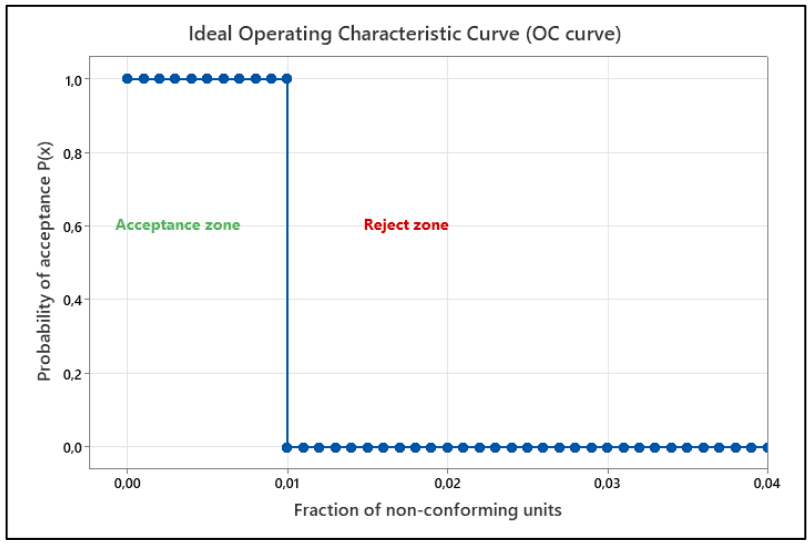
x	0.00	0.10	0.20	0.30	0.40	0.50	0.60	0.70	0.80	0.90
Pa(x)	1	0.9952	0.9517	0.8483	0.6900	0.5	0.3040	0.1517	0.0483	0.0048

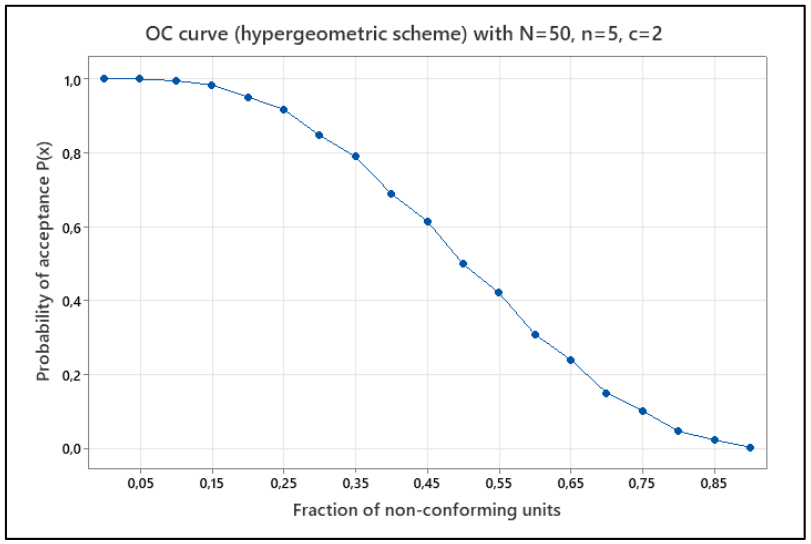
SAMPLING PLAN

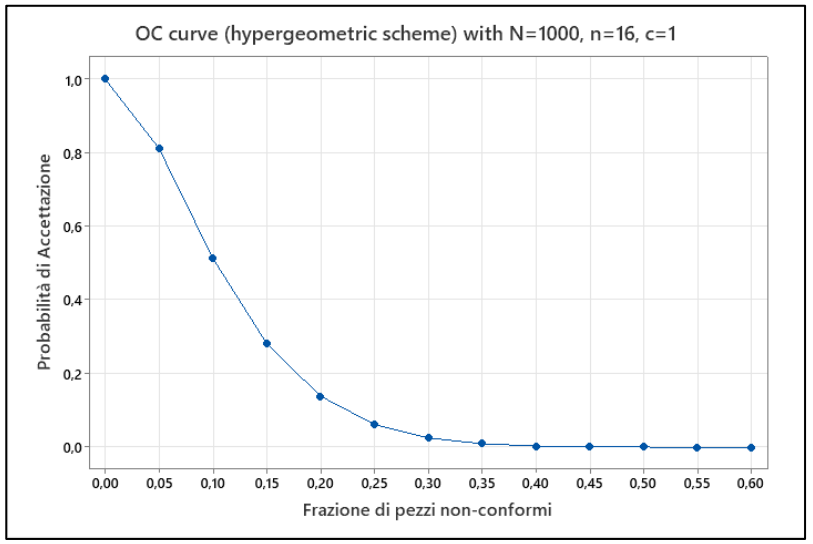


SAMPLING PLAN

From what we can see the « effective curve » looks very different from the « theoretical curve » shown above. However, keep in mind, and we will see it later, that by acting on some parameters even the « effective curve » can tend to the theoretical one assuming the trend sometimes called "heron neck".

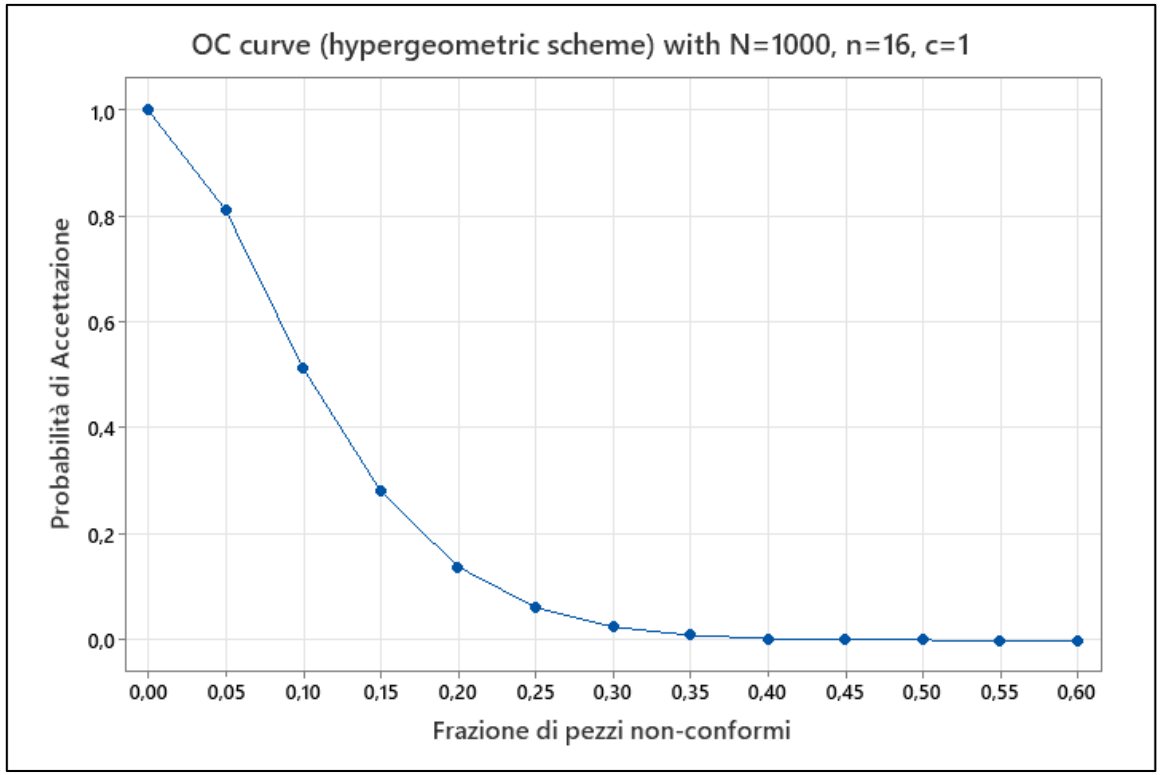






SAMPLING PLAN

..... precisely ... «heron neck» ☺



SAMPLING PLAN

- the other « typical situation » that occurs is that of:
  - the case in which the sample is taken «from an infinite lot» (or in process) or that each unit, once examined, is reintegrated. This situation is attributable to the classic example of the "extraction of balls from a box ***with replacement***". Since the possibilities are only two, "compliant piece" or "non-compliant piece" (black and white balls), the probability of obtaining ***x*** non-conforming elements among the ***n*** extracted all together from an urn containing ***N*** is described by the **BINOMIAL DISTRIBUTION** (OC curve Type B) namely:

SAMPLING PLAN

$$P_a(x) = \sum_{x=0}^{c} \binom{n}{x} \times p^x \times q^{n-x}$$

where:

n = sample size

p = proportion of non-conforming units in the lot, $0 < p < 1$

q = proportion of conforming units in the lot, $q = 1 - p$

x = number of non-conforming units, $x = 0, 1, 2, \ldots, n$

SAMPLING PLAN

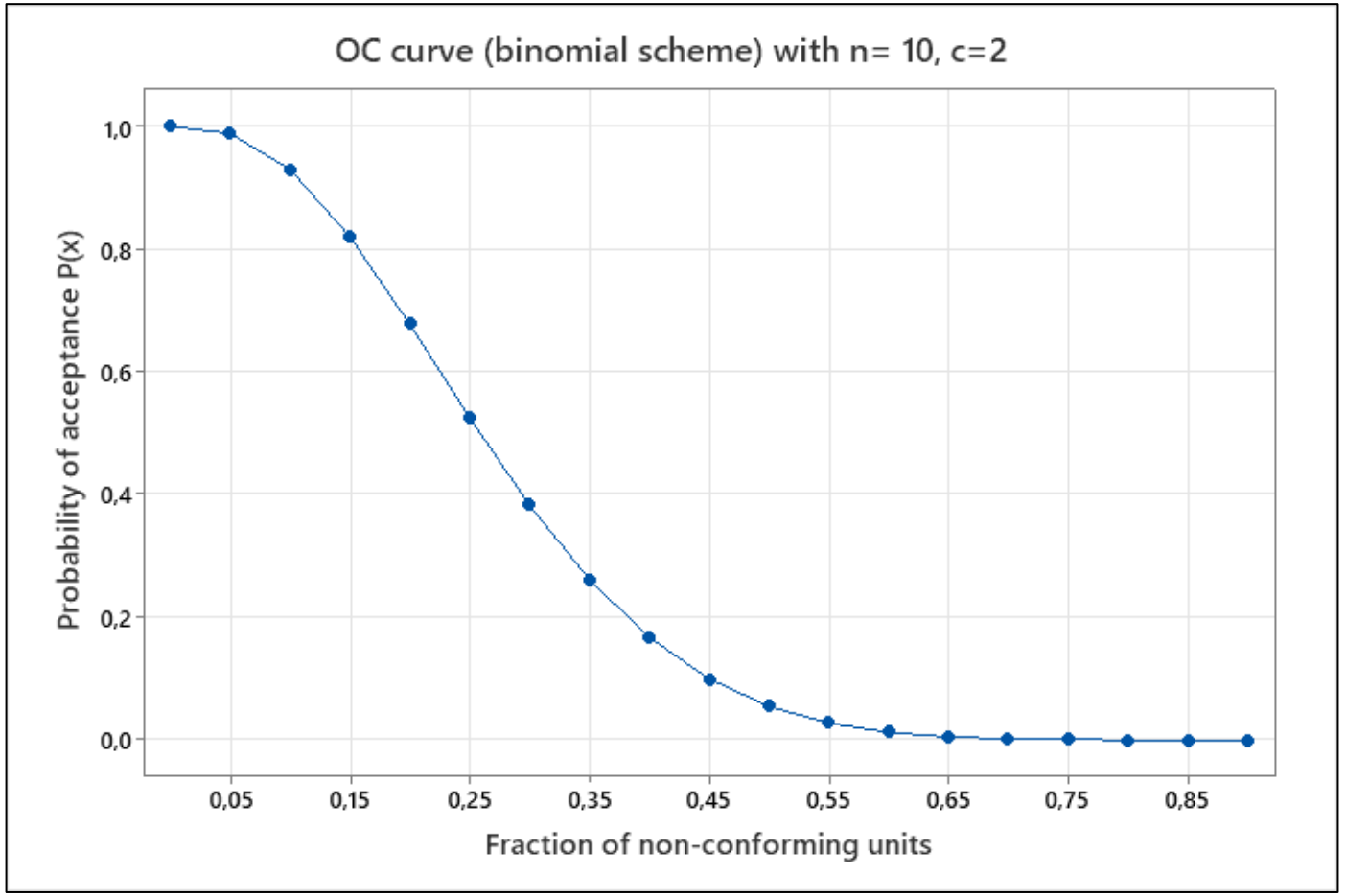
Here is an example of construction of the Characteristic Operating Curve in the Binomial case:

$$\boldsymbol{N} = 100 \quad \boldsymbol{n} = 10 \quad \boldsymbol{c} = 2$$

$$P_a(x) = \sum_{x=0}^{2} \binom{10}{x} \times p^x \times q^{10-x} = \sum_{x=0}^{2} \binom{10}{x} \times p^x \times (1-p)^{10-x}$$

x	0.00	0.10	0.20	0.30	0.40	0.50	0.60	0.70	0.80	0.90
Pa(x)	1	0.9298	0.6778	0.3828	0.1673	0.0547	0.0123	0.0016	0	0

SAMPLING PLAN



SAMPLING PLAN

In the case where ***N*** is large and ***p*** is small, the Binomial scheme can be approximated by the Poissonian one according to:

$$P_a(x) = \sum_{x=0}^{c} \frac{e^{-np} \times (np)^x}{x!}$$

where:

n = sample size

p = proportion of non-conforming units in the lot, $0 < p < 1$

x = number of non-conforming units, $x = 0, 1, 2, \ldots, n$

SAMPLING PLAN

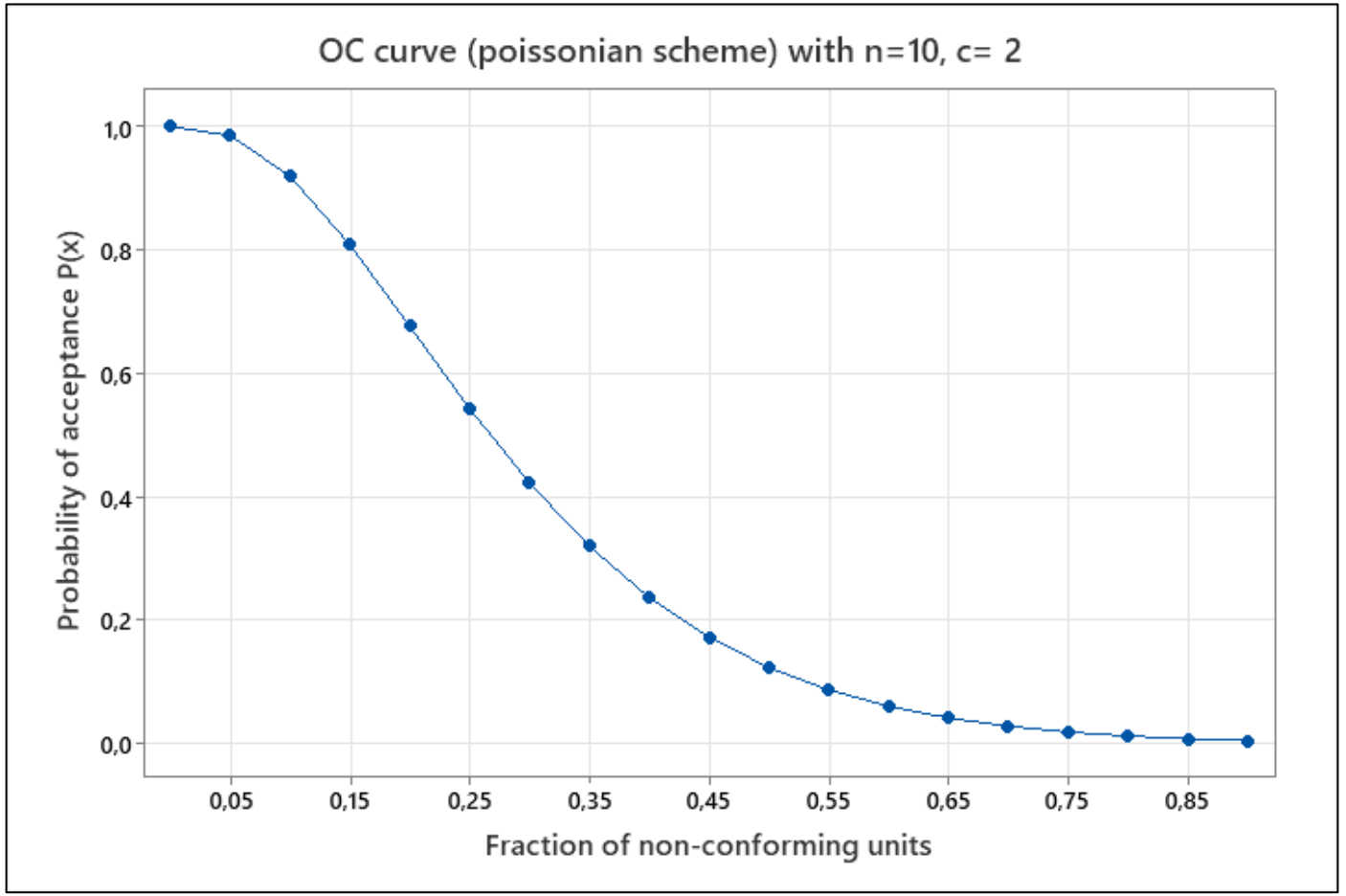
Here is an example of construction of the Characteristic Operating Curve in the Poissonian case:

$$\boldsymbol{N} = 100 \quad \boldsymbol{n} = 10 \quad \boldsymbol{c} = 2$$

$$P_a(x) = \sum_{x=0}^{2} \frac{e^{-10p} \times (10p)^x}{x!}$$

x	0.00	0.10	0.20	0.30	0.40	0.50	0.60	0.70	0.80	0.90
Pa(x)	1	0.9197	0.6767	0.4232	0.2381	0.1247	0.0620	0.0296	0.0138	0.0062

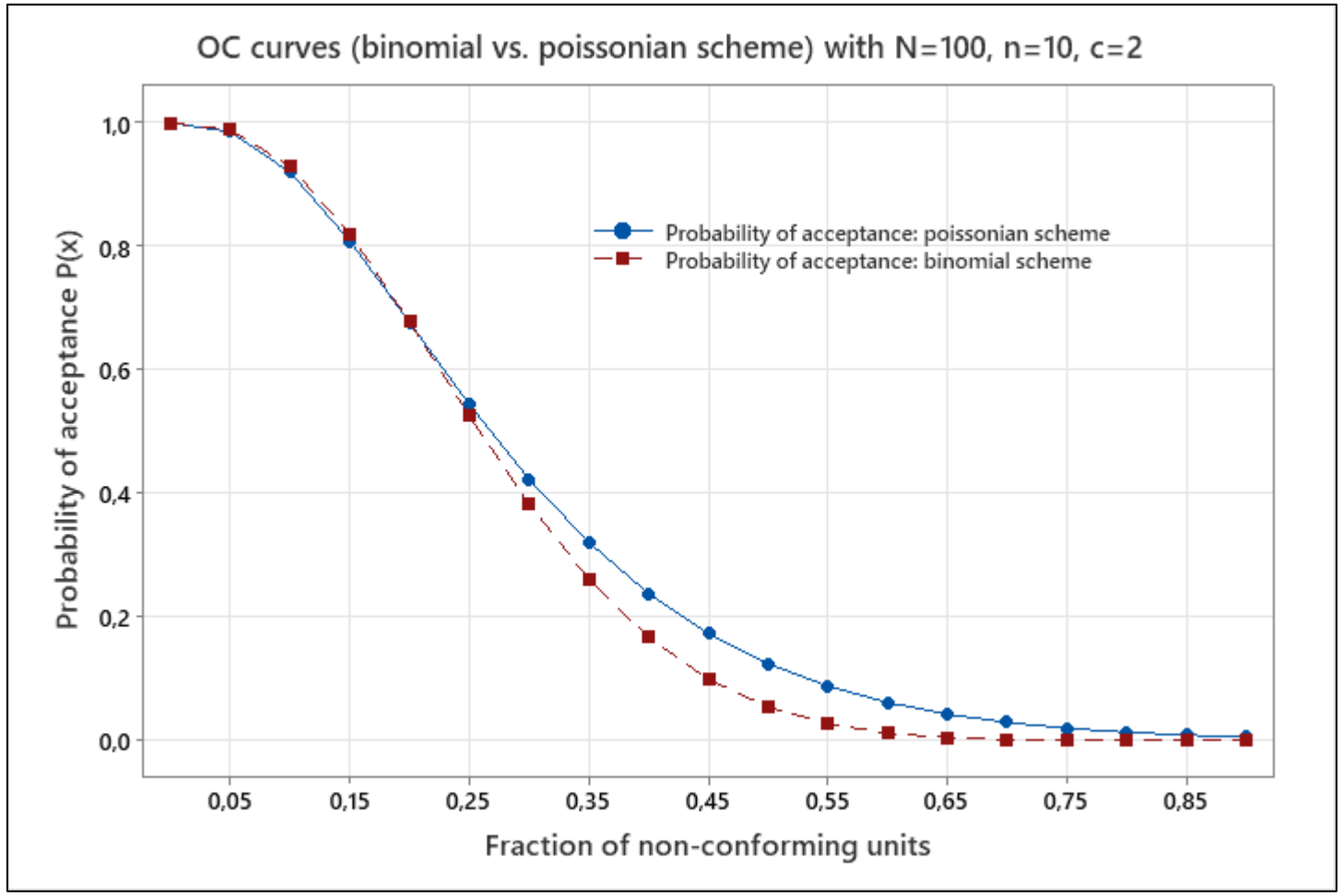
SAMPLING PLAN



SAMPLING PLAN

The fact that in general the Poissonian scheme represents a good approximation for the Binomial one is well highlighted in the graph on the side.

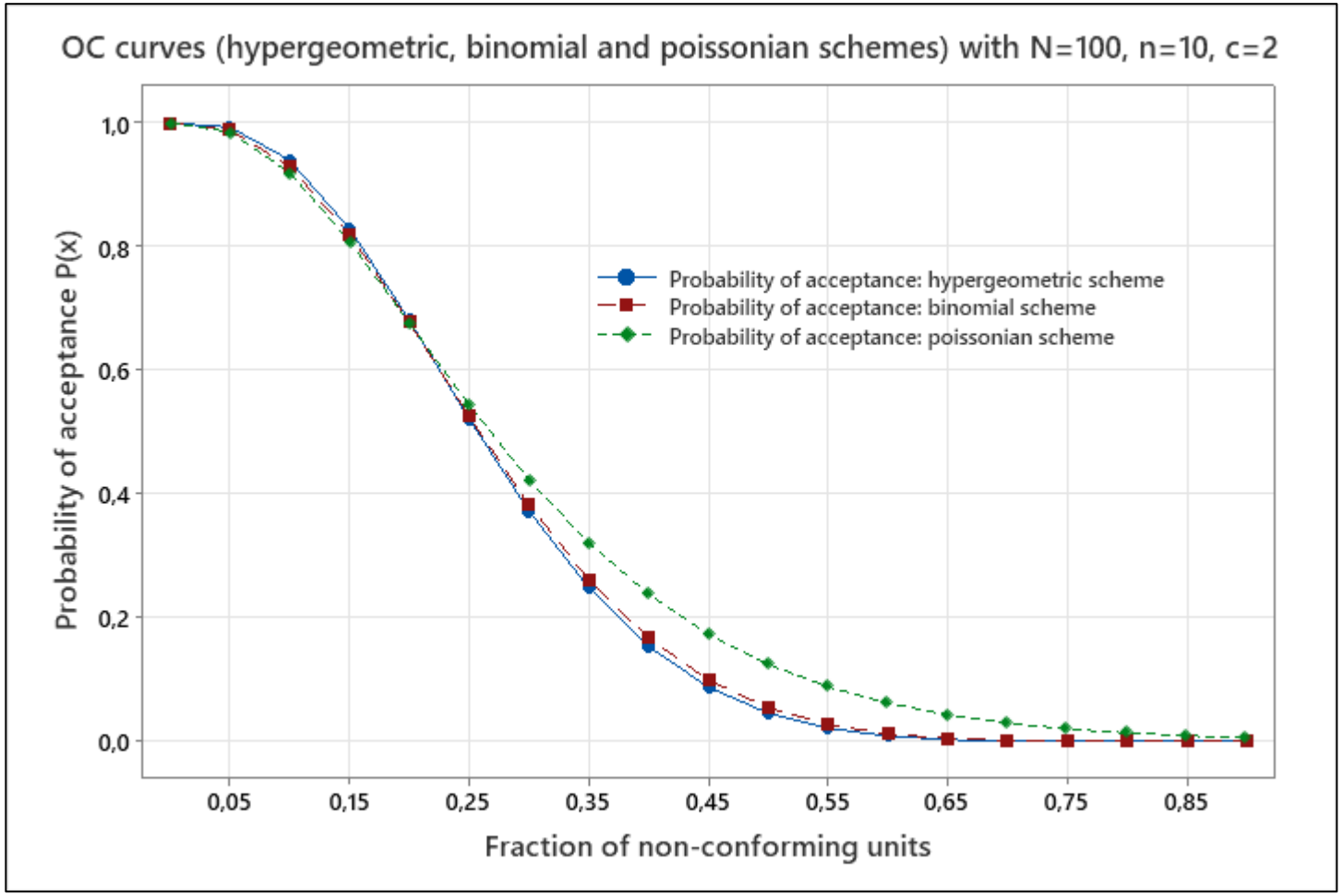
Note: the lot size N is intentionally reported even if it does not enter the calculation!



SAMPLING PLAN

However, it is worth noting that, in general, there are no major differences between the three schemes, at least for lots of normal practical interest.

Note: the difference is very small for N large and p small.



SAMPLING PLAN

What is shown graphically in the previous slide is nothing more than the practical consequence of the fact that in the equation that describes the Hypergeometric random variable, that is:

$$P_a(x) = \sum_{x=0}^{c} \frac{\binom{Np}{x} \times \binom{Nq}{n-x}}{\binom{N}{n}}$$

N affects P relatively little and, in any case, for very large values of N, the function becomes equivalent to the corresponding Binomial random variable:

$$P_a(x) = \sum_{x=0}^{c} \binom{n}{x} \times p^x \times q^{n-x}$$

Note how the lot size, N, appears neither in the Binomial nor in the Poisson formula !

SAMPLING PLAN

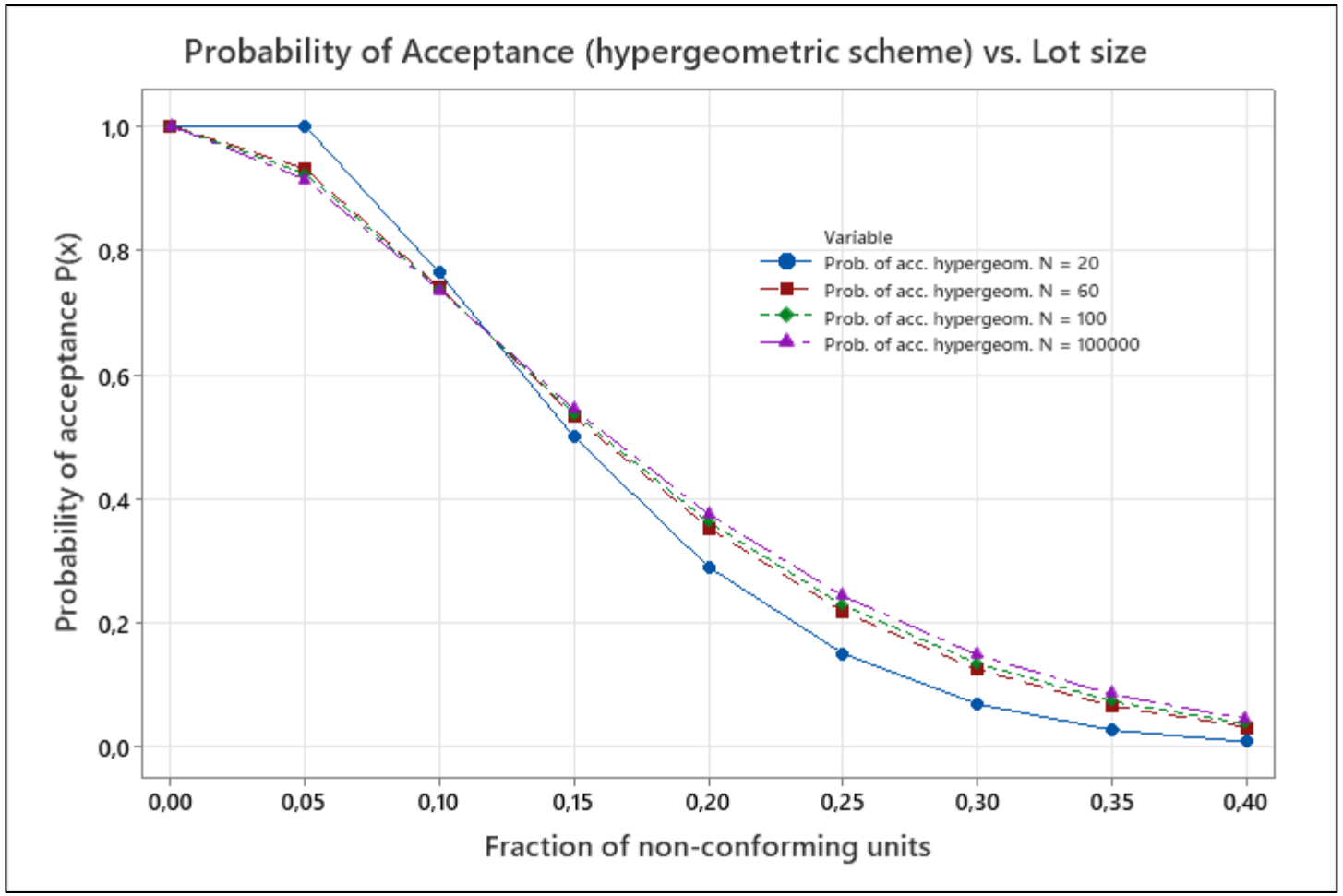
The table on the side shows the Probability of Acceptance (P_a) values calculated using the hypergeometric scheme in the case n = 10 and c = 1 with N (lot size) ranging from 20 to 100000 (∞).

Fraction of non-conforming units	Pa hypergeom. N = 20	Pa hypergeom. N = 60	Pa hypergeom. N = 100	Pa hypergeom. N = 100000
0.00	1.000	1.000	1.000	1.000
0.05	1.000	0.931	0.923	0.914
0.10	0.763	0.741	0.738	0.736
0.15	0.500	0.533	0.538	0.544
0.20	0.291	0.354	0.363	0.376
0.25	0.152	0.219	0.229	0.244
0.30	0.070	0.126	0.136	0.149
0.35	0.029	0.067	0.075	0.086
0.40	0.010	0.033	0.039	0.046

SAMPLING PLAN

In the graph, the values in the previous table clearly show how the effect of the lot size, ***N***, on the OC curve is minimal when a small portion of it (for example ***n*** <10%) is used as a sample.

Here, then, is how it is possible to approximate with the Binomial that does not contain N in its expression !



SAMPLING PLAN

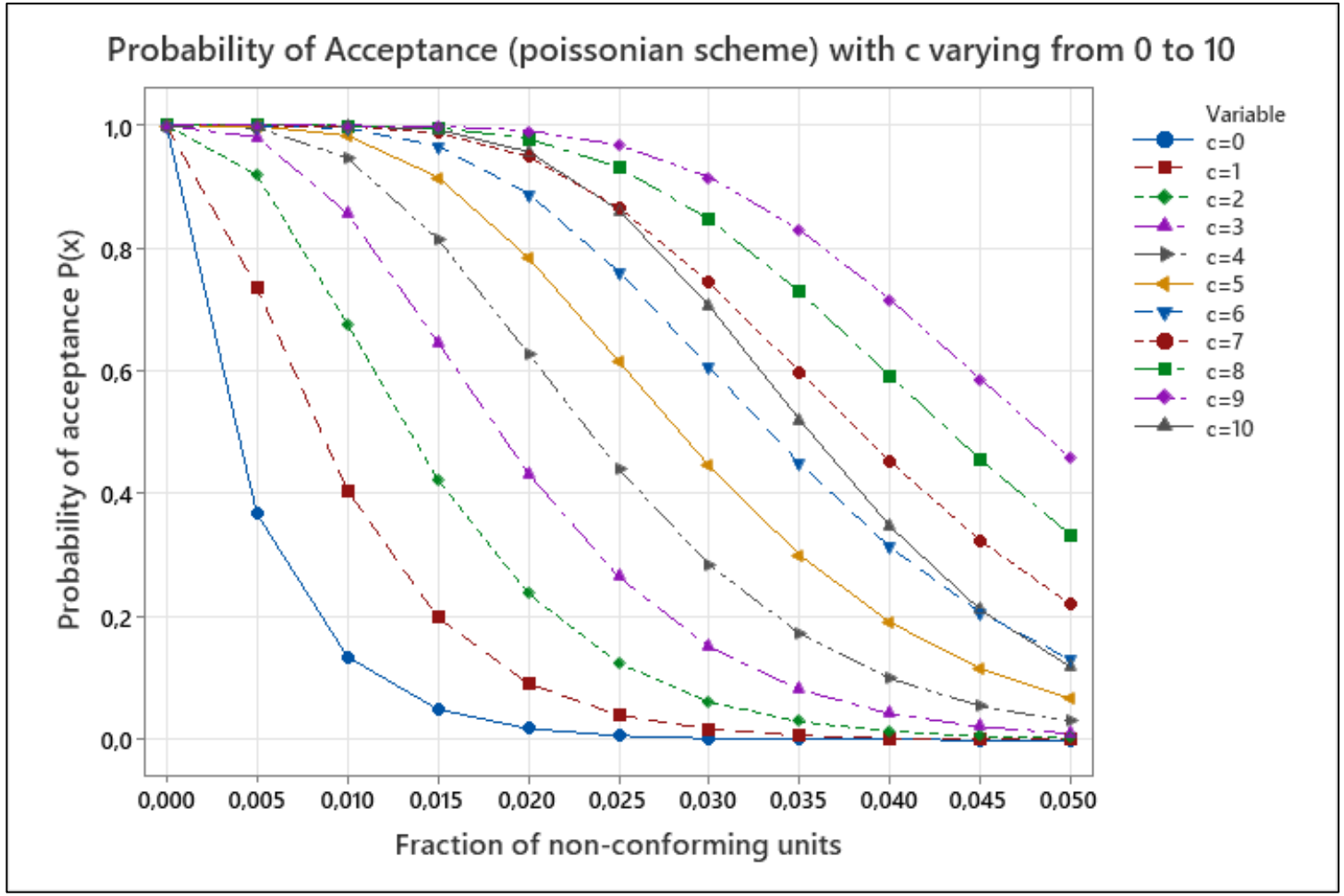
Hence, if ***n*** is large (> 50) and ***p*** small, such that ***np*** <10 and p (1-p) ~ p, then the Binomial random variable can be approximated with a Poissonian random variable where $\boldsymbol{\lambda = np}$

$$P_a(x) = \sum_{x=0}^{c} \frac{e^{-np} \times (np)^x}{x!}$$

and this explains why most of the sampling plans for the control by attributes are based on the Poisson Distribution.

SAMPLING PLAN

A practical application of what has just been stated is provided on the side. Imagine a batch of 10,000 vials and a single sampling plan with a normal inspection level. According to ISO 2859-1 the *code letter* is «L» to which Table 2-A associates a sample size ***n*** = 200 pieces.



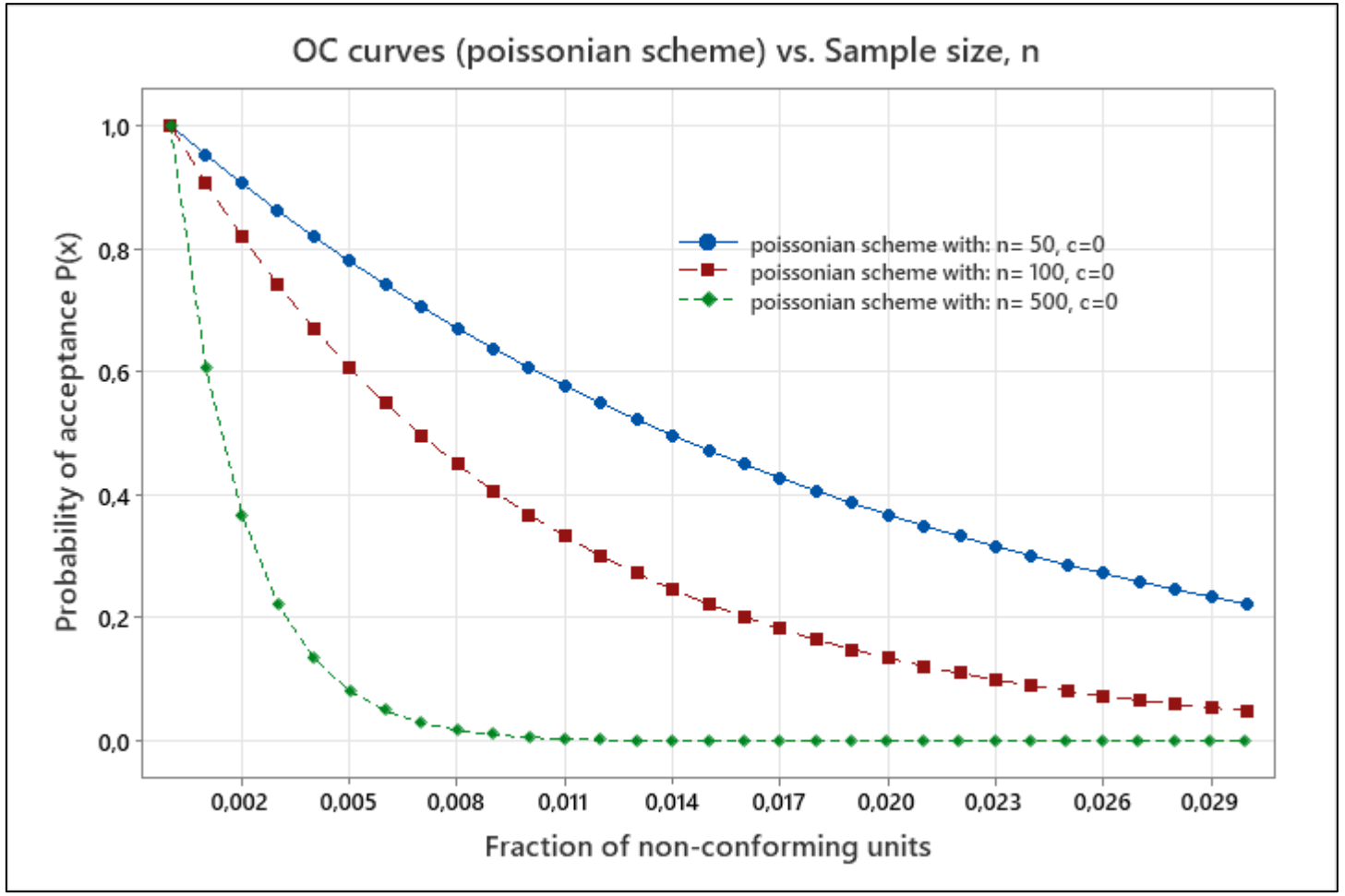
SAMPLING PLAN

- If these vials have only one cosmetic defect, they are discarded.
- Imagine that you inspect the 200 vials for acceptance and assume that you accept the lot according to the criterion c = 3, *i.e.*, that the maximum number of defective pieces allowed is equal to 3.
- In about 2 out of 100 cases the batch would be rejected with 0.5% of non-compliant units, while about 27 times out of 100 a batch with 2.5% of non-compliant units would be accepted.

SAMPLING PLAN

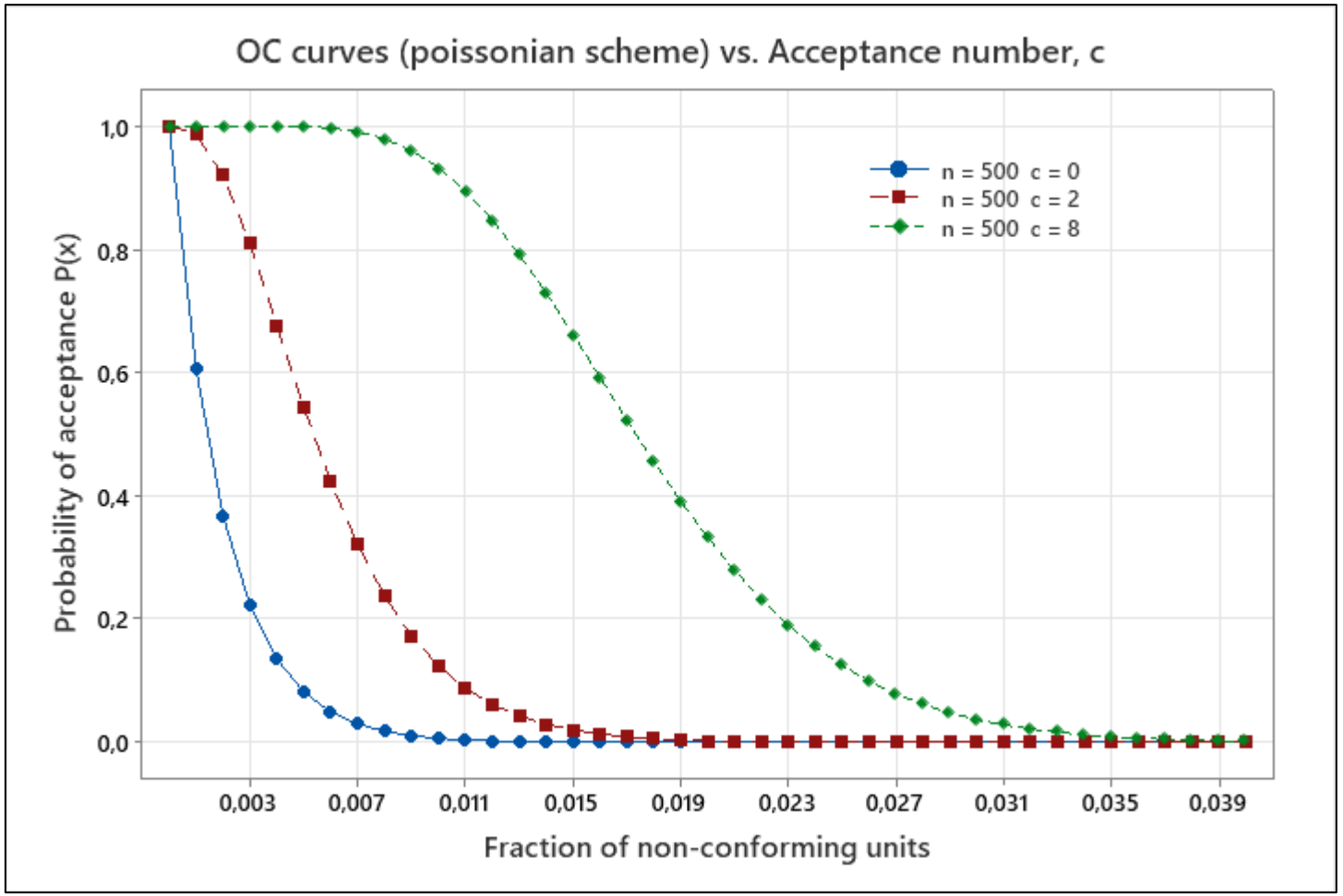
The graph on the side shows how ***as the sample size increases***, while ***N*** and ***c*** remain constant, ***the OC curve becomes increasingly steep*** tending to the maximum value reached for ***n*** = ***N*** (*i.e.*, 100% inspection).

As obvious, the discriminatory power of the sampling plan increases as n increases !



SAMPLING PLAN

The graph on the side instead shows how, while ***N*** and ***n*** remain constant, ***as c increases, the OC curve moves more and more to the right assuming and accentuating the sigmoid shape***. ***Obviously, the discriminatory power of the sampling plan decreases as c increases !***



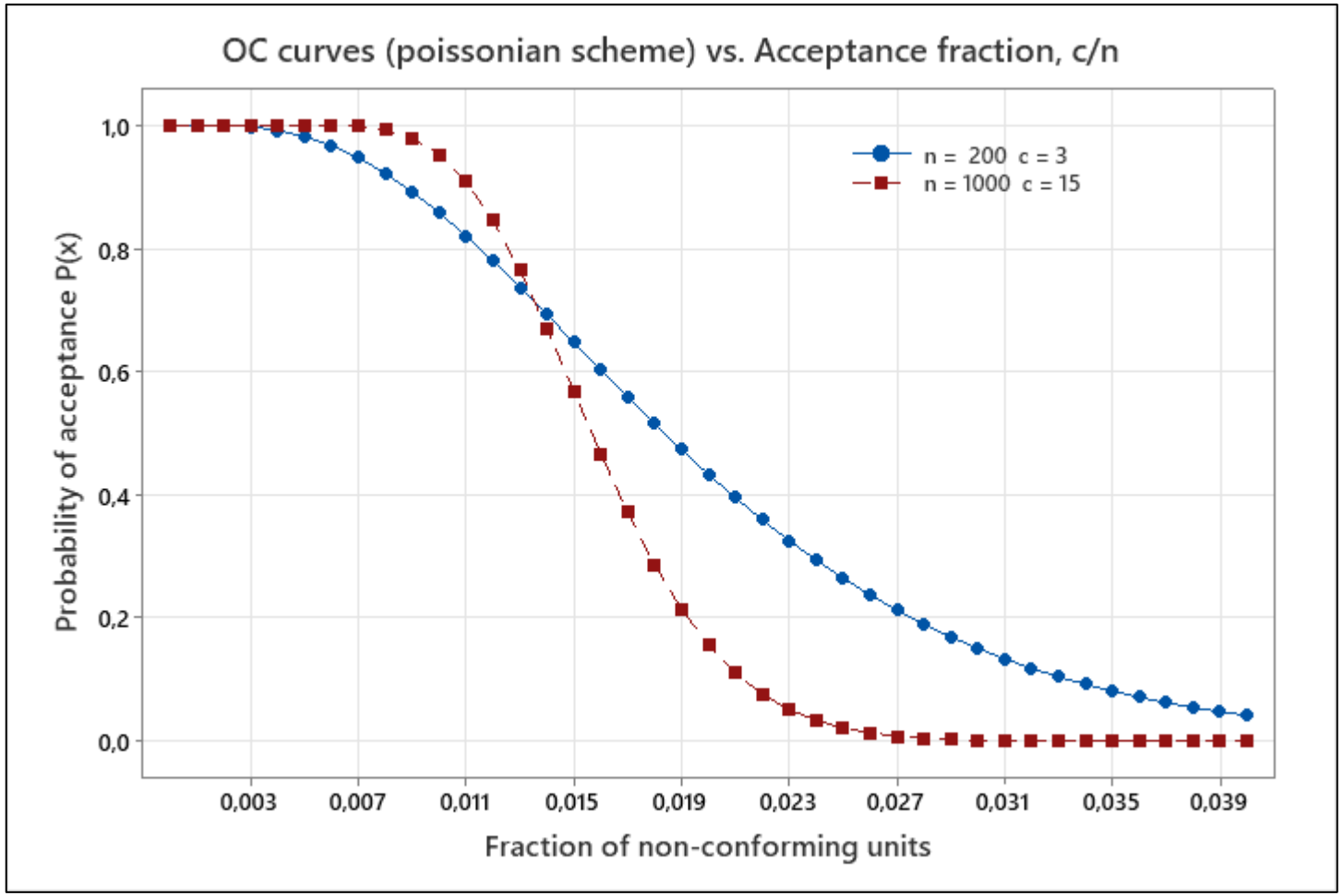
SAMPLING PLAN

What is highlighted in the previous slide deserves particular attention because it is very significant.

In fact, later, speaking of ISO 2859-1, it will be observed how the procedure, passing from a given inspection level to a more severe one, does not necessarily involve an increase in the sample size, but only a reduction in the acceptance number ***c***, just as shown in the previous slide.

SAMPLING PLAN

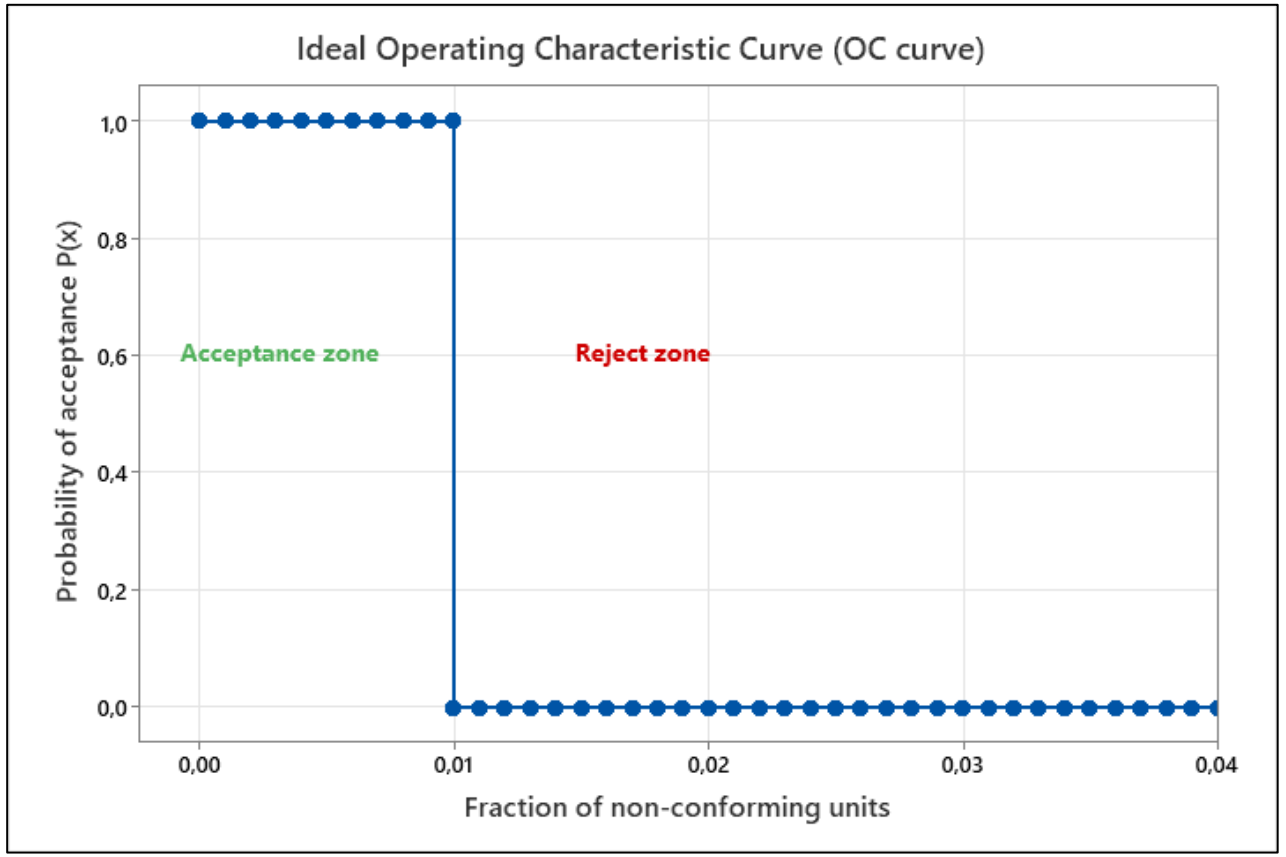
The graph on the side shows how, by increasing ***n*** and ***c*** to keep their ratio unchanged, ***the OC curve becomes steeper and steeper and tending to the heron neck: the discriminatory power of the sampling plan increases!***



SAMPLING PLAN

What we have seen so far indicates that:

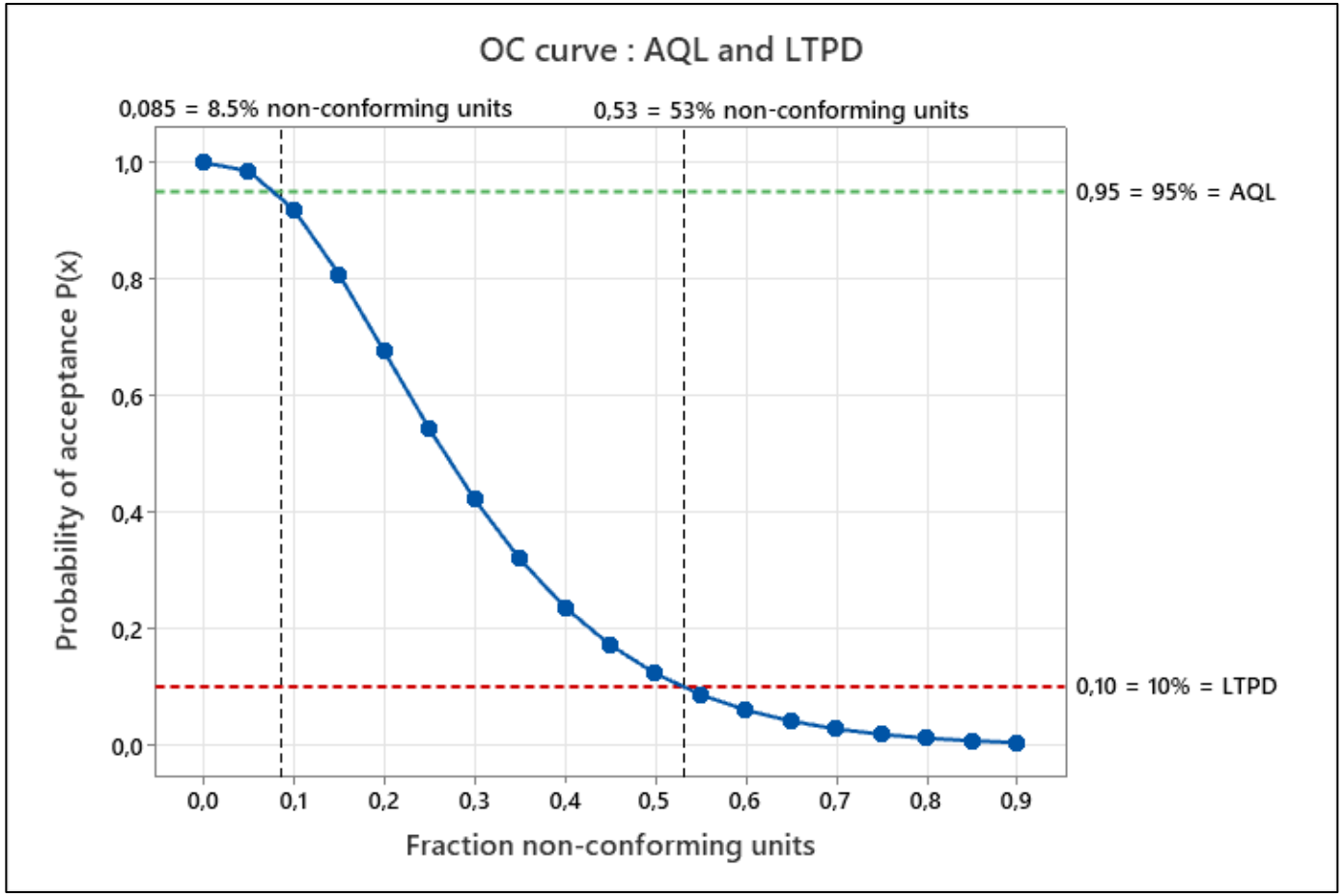
- the discriminatory power of a sampling plan varies according to the sample size, ***n*** and the acceptance number, ***c***
- moreover, as already said, the «ideal» OC curve of the type shown here on the side does not exist in practice. In fact, it could only take place in the case of a 100% and error-free inspection.



SAMPLING PLAN

As seen, however, the OC curves with which, on the other hand, we are dealing in practice are of the sigmoid type shown on the side. On them, conventionally, two fundamental points are identified, known as:

- **AQL**: Acceptance Quality Level
- **LTPD**: Lot Tolerance Percent Defective



SAMPLING PLAN

- The term ***AQL*** commonly corresponds to the ***95% of the Probability of Acceptance*** even if, often, it is understood more as a "high" probability of acceptance rather than a specific value

- ***In practice, AQL represents the level of defects that the Customer still considers acceptable in the long term or, as they say, « on average ».***

- Still from a practical point of view, the AQL tells us what is the percentage of rejects in the lot that will ensure that it, on average, **exceeds** the control required by the sampling plan.

  Sampling plans are in fact designed precisely in such a way that they accept a batch of product at AQL in most cases.

SAMPLING PLAN

- The ***AQL*** therefore represents ***a fundamental requirement for the Manufacturer*** who wants the batches produced to have as ***« average quality »*** a level of nonconformity (or defects) such as to ensure that they are accepted by the Customer in most cases.

- ***AQL is a feature of the Supplier's production process and not of the sampling plan !***

SAMPLING PLAN

- The ***LTPD, Lot Tolerance Percent Defective, corresponds to 10% probability on the OC curve*** and it ***represents the lowest level of quality that the Customer is available to accept in a single lot.***

- The LTPD, in practice, tells us what is the percentage of waste in the lot that will ensure that, on average, it does not pass the control provided for in the sampling plan.

- Also, the *Tolerated Defect Percentage for the Lot* is not a characteristic of the sampling plan, but a specification set by the Customer.

SAMPLING PLAN

- In summary: **AQL** and **LTPD** are both associated with waste rates, but while **AQL** is associated with a ***low waste rate***, **LTPD** is associated with a ***high waste rate***.

- In fact, the OC curve « merges » AQL and LTPD even if the nature of this relationship is seen in terms of a ***« Supplier / Customer competition »***.

  Indeed, the Producer would like the «good lots» to be accepted while the Customer would like the «bad lots» to be definitely rejected. From this perspective, we can therefore think of a:

  - ***Producer's Quality Level*** (PQL) and to a ***Producer's Quality Risk o PR*** (α) associated with it

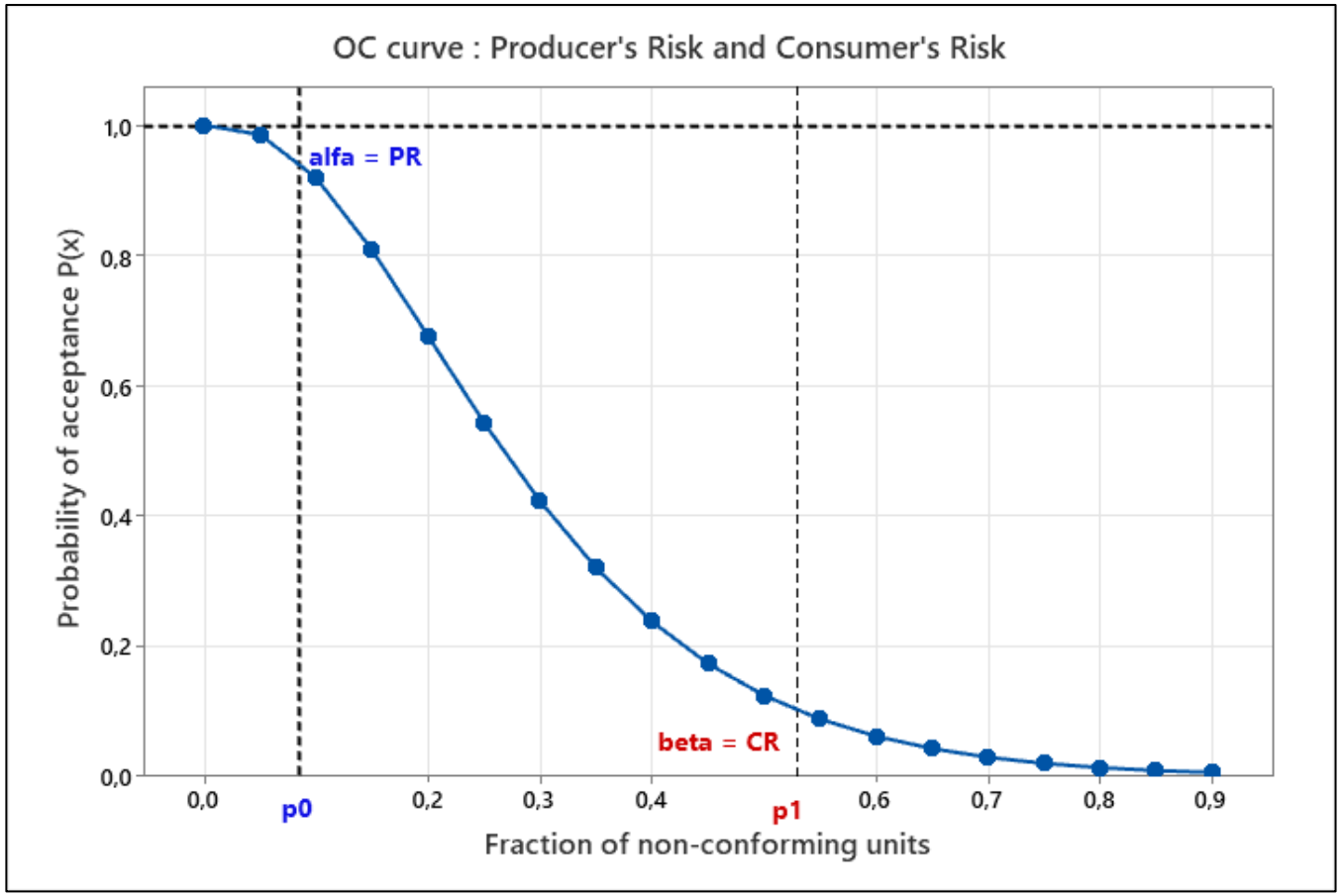
  and of a:

  - ***Consumer's Quality Level*** (CQL) and to a ***Consumer's Quality Risk o CR*** (β) associated with it.

SAMPLING PLAN

- The Producer wishes that batches with defects on average not exceeding p_0 are accepted in most cases and therefore with their own risk not exceeding α, or *Producer's Risk* (**PR**).

- The Consumer, on the other hand, wants bad quality batches, *i.e.*, with non-conformities greater than p_1, to be rejected in most cases and therefore have a low probability, not exceeding β, or *Consumer's Risk* (**CR**), of being accepted.



SAMPLING PLAN

EXAMPLE

- Previously we saw how most of the sampling plans for the acceptance control by attributes are based on the Poisson distribution described by:

$$P_a(x) = \sum_{x=0}^{c} \frac{e^{-np} \times (np)^x}{x!}$$

- Suppose you have agreed to the following for the purchase of a batch of 10,000 vials:
  - α (Producer's risk) = 5%
  - β (Consumer's risk) = 10%
  - p_0 = 1% (*i.e.*, fraction of pieces not conforming to 95%= 0.01)
  - p_1 = 5% (*i.e.*, fraction of pieces not conforming to 10% = 0.05)

SAMPLING PLAN

From the data it appears that:

$p_1/p_0 = 0.05/0.01 = 5$

This value corresponds to approximately

c = 3 and therefore the sample size will be:

$n_0 = np_0 / p_0 = 1.35/0.01 = 135$

$n_1 = np_1 / p_1 = 6.65/0.05 = 133$

Therefore, the specifications of this sampling plan can be summarized as follows:

n (sample size) = 135 pieces

c (acceptance number) = 3

c	np0	np1	np1 / np0
0	0.05	2.30	46.00
1	0.35	3.85	11.00
2	0.80	5.30	6.63
3	**1.35**	**6.65**	**4.93**
4	1.95	7.95	4.08
5	2.60	9.25	3.56
6	3.25	1.50	3.23
7	3.95	1.75	2.97
8	4.70	1.95	2.76
9	5.40	14.20	2.63
10	6.15	15.40	2.50
11	6.90	16.60	2.41
12	7.70	17.75	2.31
13	8.45	18.95	2.24
14	9.25	20.10	2.17
15	10.05	21.25	2.11

AVERAGE OUTGOING QUALITY

AVERAGE OUTGOING QUALITY

- As already mentioned, the application of the sampling plan leads to the acceptance or rejection of the batch.
- In general, when the batch is rejected, it is 100% inspected, or « *sieved* », and the defective items replaced by the Manufacturer → ***sampling plan with rectification.***
- The ***Average Outgoing Quality*** returns, in practice, the average fraction of non-compliant elements that should be obtained when applying a sampling plan with rectification.

AVERAGE OUTGOING QUALITY

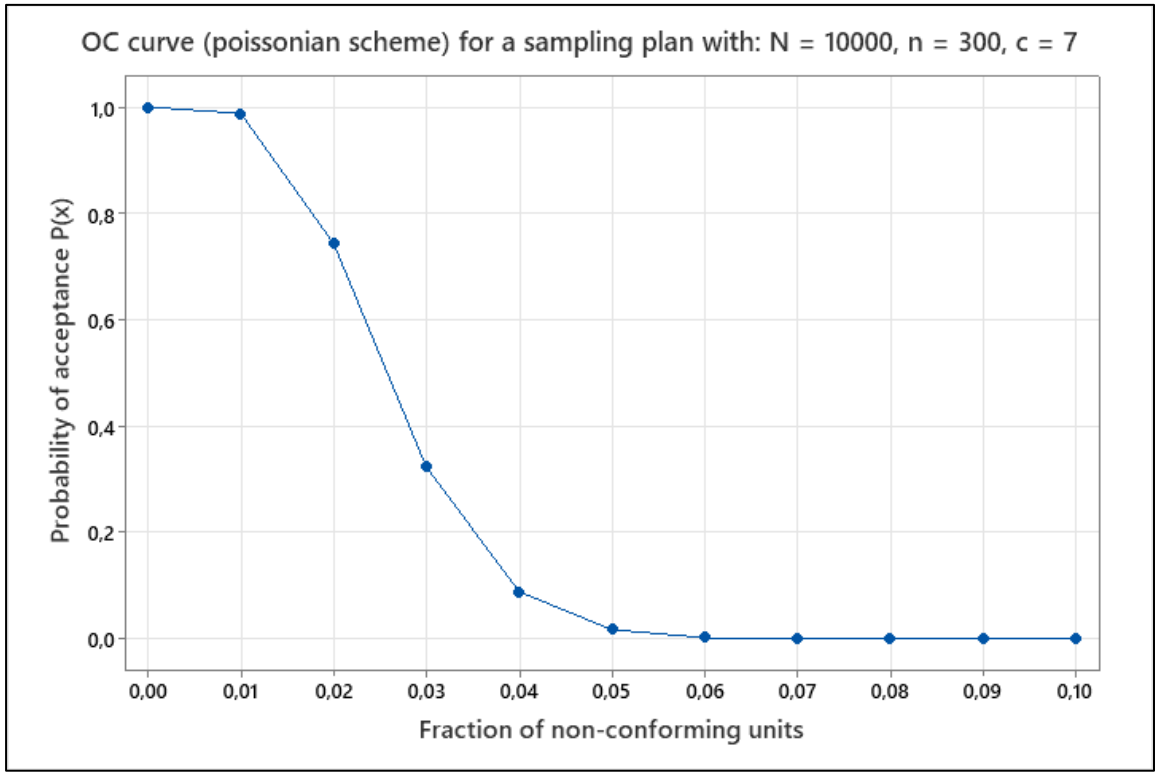
- Starting from the Operating Characteristic Curve, it is possible to calculate the Average Outgoing Quality by applying the formula:

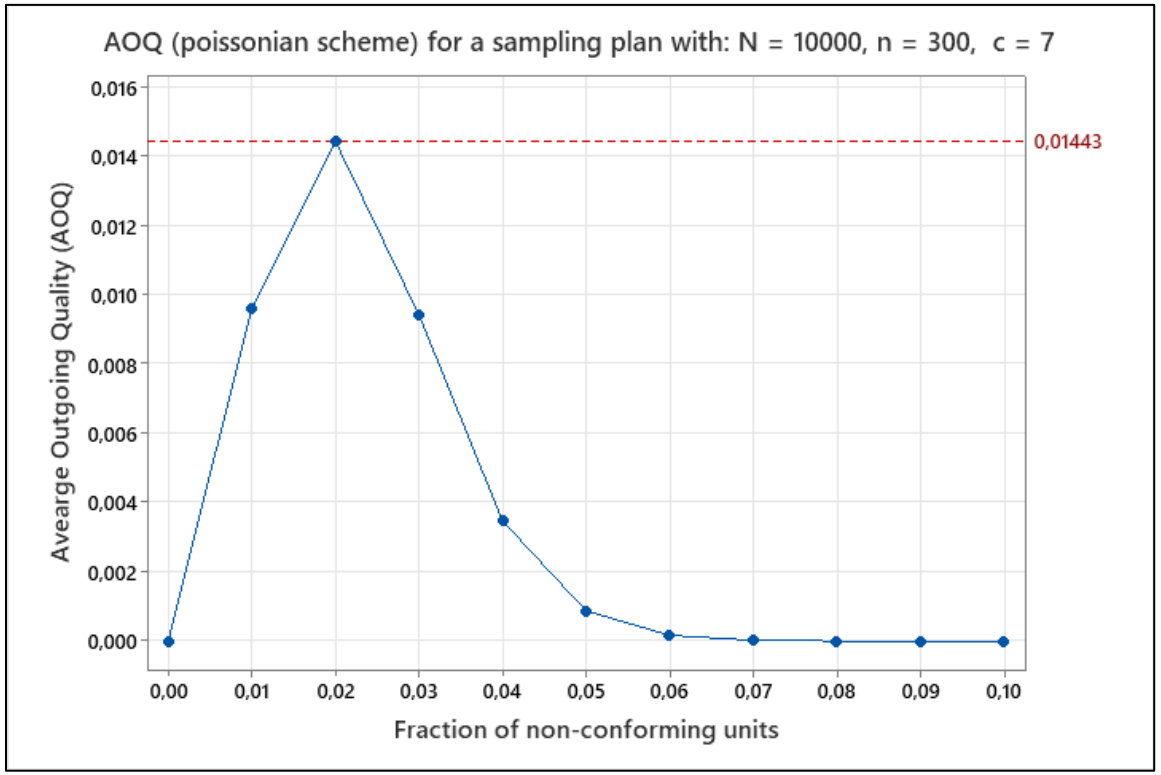
$$\boldsymbol{Average\ Outgoing\ Quality} = \frac{(\boldsymbol{N} - \boldsymbol{n}) \times \boldsymbol{p} \times \boldsymbol{P_a}}{\boldsymbol{N}}$$

where:

- $\boldsymbol{N}$ = lot size
- $\boldsymbol{n}$ = sample size
- $\boldsymbol{p}$ = fraction of non-conforming (or defective) elements
- $\boldsymbol{P_a}$ = probability of acceptance

AVERAGE OUTGOING QUALITY





AVERAGE OUTGOING QUALITY

- The maximum of the AOQ curve represents the worst quality that can be expected based on the sampling plan adopted: ***Average Outgoing Quality Limit (AOQL)***.

  This quantity is important for practical purposes as it allows you to choose between different sampling plans based on their AOQL values.

- In the example shown in the previous slide AOQL = 0.01443 equal to approximately 1.44%.

AVERAGE NUMBER OF INSPECTION

AVERAGE NUMBER OF INSPECTION

- The ***Average Number of Inspection (ANI)*** represents the *expected* number of units to be inspected overall after having 100% checked a series of rejected lots.
- In the case of a simple sampling plan, it is calculated as the expected value of a random variable that assumes the following values with the corresponding probabilities:

Quality	*Probability*
n	**P(p)**
N	**1 - P(p)**

$$ANI = n + (N - n) \times [1 - P(p)]$$

AVERAGE NUMBER OF INSPECTION

- The ***Average Number of Inspection (ANI)*** represents the *expected value* of the number of units to be inspected overall after having 100% checked a series of rejected lots.

- Let's consider, for example, the case of a company that buys medical devices in batches consisting, on average, of about 500 pieces each. For each lot 25 pieces are randomly sampled each time and the number of defects is determined on them.

  The defect data (absolute, fractional and percentage values) relating to 10 different supplies are summarized in the following table.

AVERAGE NUMBER OF INSPECTION

On the basis of these historical data and knowing that the maximum number of acceptable defective elements is $c = 0$, it is possible to determine the Average Number of Inspection (ANI), for example in the case in which the lot consists of 400, 500 or 600 pieces.

Lot No.	Lot size, N	Sample size, n	No. of defects found in sample	Defects in sample (fraction)	Defects in sample (percentage)
1	530	25	2	0.0800	8.00
2	575	25	1	0.0400	4.00
3	460	25	0	0.0000	0.00
4	410	25	3	0.1200	12.00
5	570	25	1	0.0400	4.00
6	600	25	0	0.0000	0.00
7	515	25	8	0.3200	32.00
8	508	25	2	0.0800	8.00
9	430	25	0	0.0000	0.00
10	440	25	1	0.0400	4.00

AVERAGE NUMBER OF INSPECTION

The calculation can be done simply by using the formula:

$$ANI = n + (N - n) \times [1 - P(p)]$$

in which the different values of ***P*(*p*)** are determined using the hypergeometric scheme and the historical data represented in the previous table as follows:

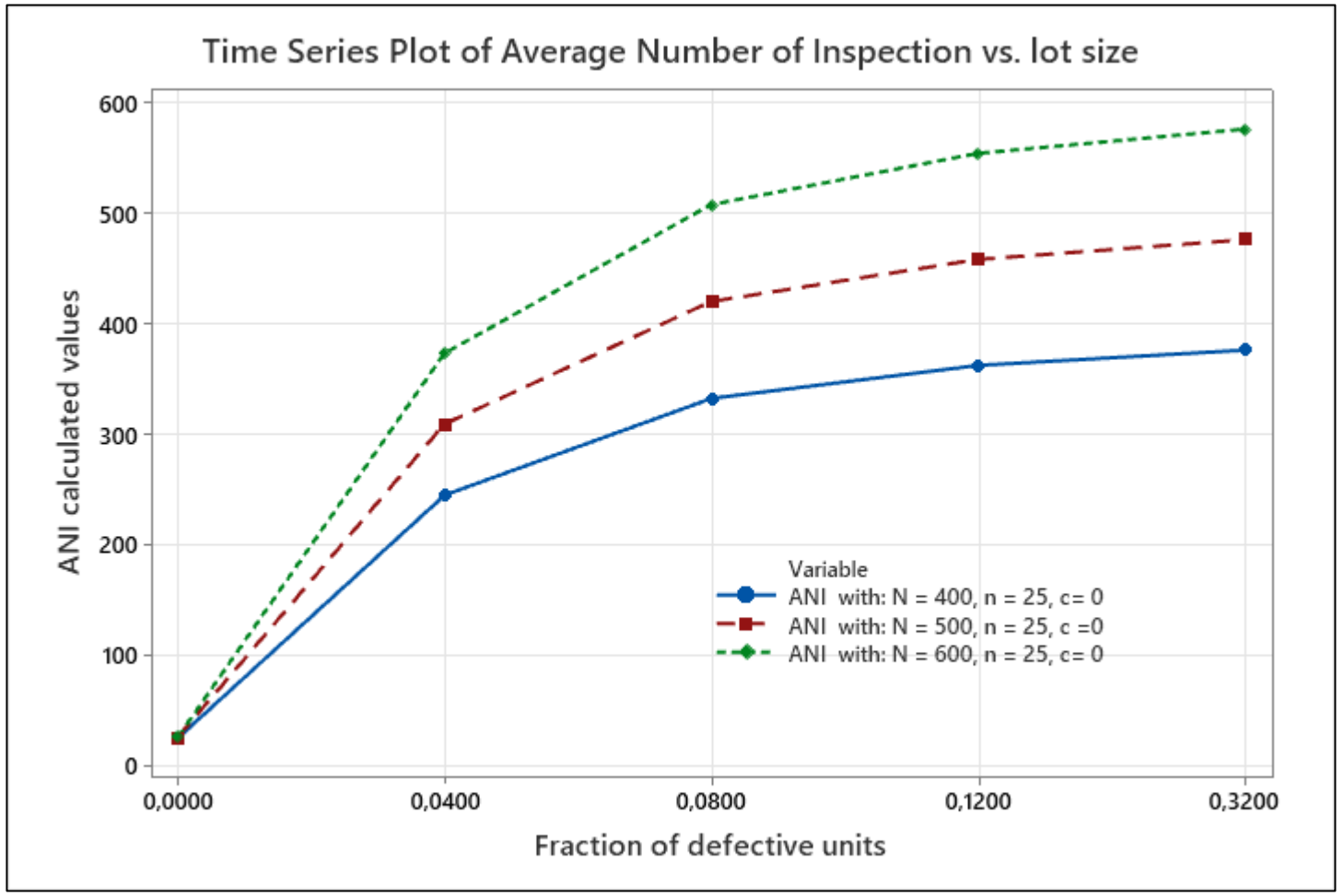
Defects in sample (fraction)	P(p) hypergeom. N= 400, n= 25, c = 0	P(p) hypergeom. N= 500, n= 25, c = 0	P(p) hypergeom. N= 600, n= 25, c = 0	ANI (N= 400, n= 25, c = 0)	ANI (N= 500, n= 25, c = 0)	ANI (N= 600, n= 25, c = 0)
0.0000	1.00000	1,0000	1.0000	**25**	**25**	**25**
0.0400	0.34883	0.3512	0.3528	**244**	**308**	**372**
0.0800	0.11617	0.1178	0.1189	**331**	**419**	**507**
0.1200	0.03678	0.0376	0.0382	**361**	**457**	**553**
0.3200	0.00004	0.0000	0.0001	**375**	**475**	**575**

AVERAGE NUMBER OF INSPECTION

It is evident from the graph on the side how the number of units to be inspected increases as the size of the lot size increases.

This function is therefore useful for determining a sampling plan.

Moreover, it also allows you to estimate the costs associated with the selection of a given sampling plan.



AVERAGE NUMBER OF INSPECTION

Considering everything we have seen so far,

what can we say about the process ?

AND THE PROCESS ?

AND THE PROCESS ?

- Even if taken for granted, what we have seen so far leads to the conclusion that:

The normal production process also produces non-compliant or defective units!

- Therefore, by taking random samples of the same size from a stable process, a similar "stability" is expected in the production of non-compliant units.

This aspect is very important and can be easily verified using a simple control chart in which the fraction of non-conforming units is monitored instead of the common quantitative variables that are usually used to build a control chart (e.g., yields, assay values , etc.).

AND THE PROCESS ?

Simplifying, it can be said that in the context of « control by attributes » the main control charts that are used to monitor the stability of processes are:

- ***p or np-charts***: they are used to monitor the fraction of non-conforming elements when they can be categorized into two distinct groups, *e.g.*, pass / fail (BINOMIAL MODEL). They are equivalent if the subgroups (or *areas of opportunity*) are the same, otherwise the *p-chart* is the one that best applies.

- ***c or u-charts***: they are used to monitor the number of defects when each element can have more than one (POISSONIAN MODEL). They are equivalent if the subgroups (or *areas of opportunity*) are equal otherwise the *u-chart* is the one that best applies.

AND THE PROCESS ?

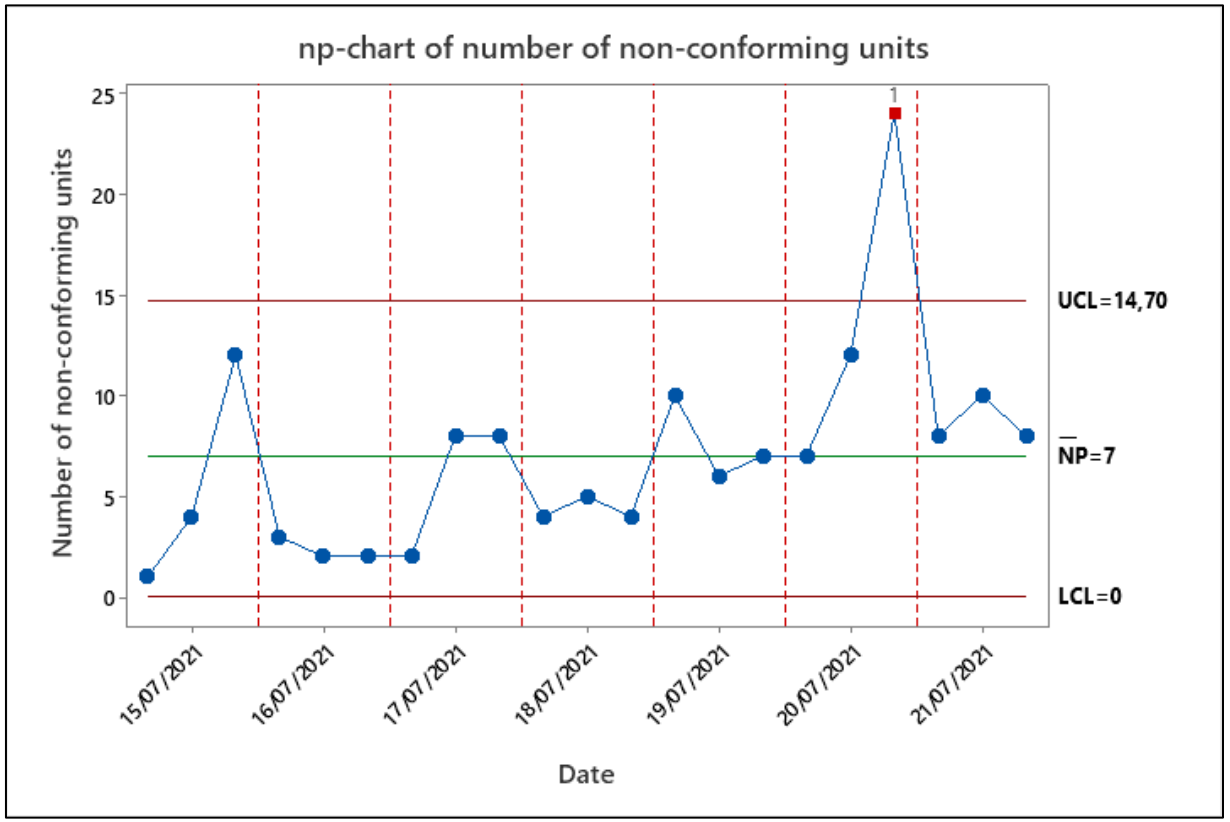
EXAMPLE:

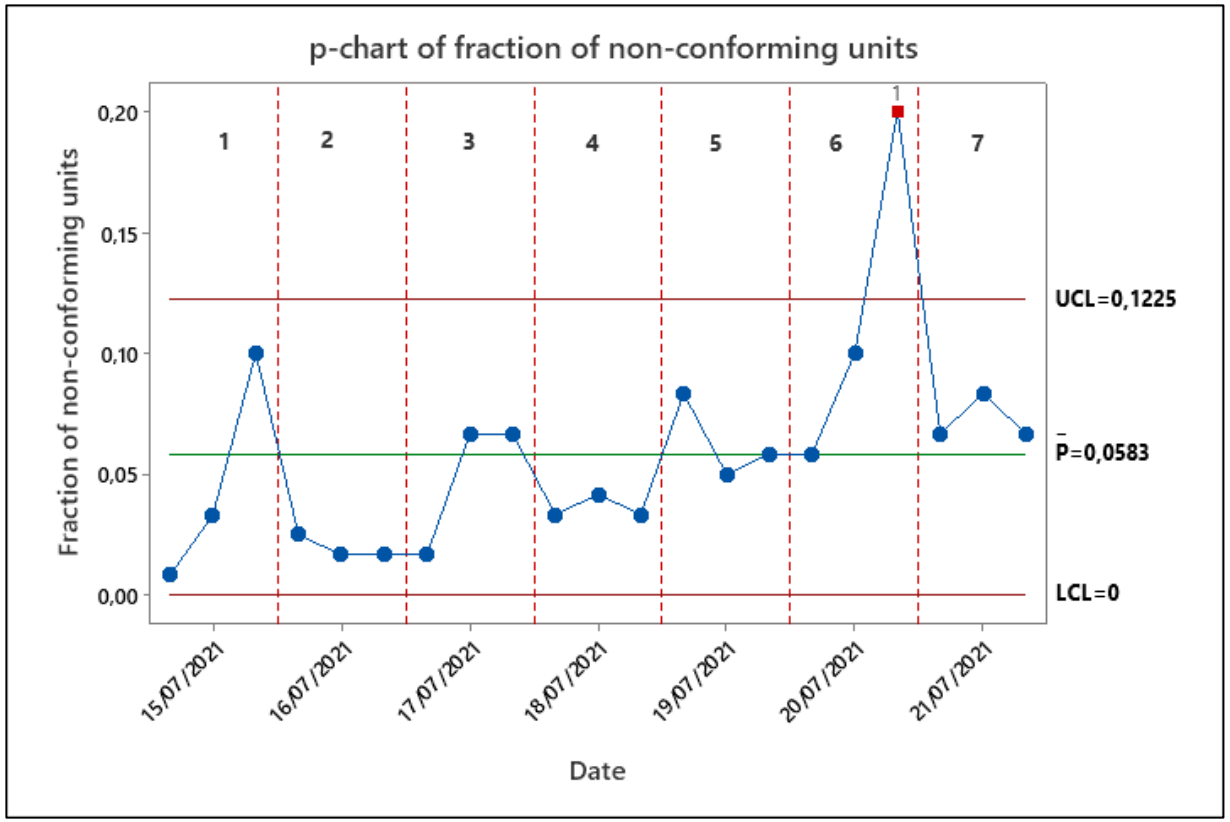
Let's consider the case summarized in the table to the side which reports the number of non-conforming units detected over seven days and three shifts for a given process. 120 sample units were used for each control.

Date	Shift	No. of non-conforming units	No. of inspected units
July 15, 2021	1	1	120
	2	4	120
	3	12	120
July 16, 2021	1	3	120
	2	2	120
	3	2	120
July 17, 2021	1	2	120
	2	8	120
	3	8	120
July 18, 2021	1	4	120
	2	5	120
	3	4	120
July 19, 2021	1	10	120
	2	6	120
	3	7	120
July 20, 2021	1	7	120
	2	12	120
	3	24	120
July 21, 2021	1	8	120
	2	10	120
	3	8	120

AND THE PROCESS ?

The data in the table are summarized below in the two *np* and *p-charts*.





AND THE PROCESS ?

- As expected, the two control charts display the same profile regardless of the references used in the two cases: non-conforming units or fraction of non-conforming units
- An upward trend is evident which indicates a tendency, increasing over time, to the appearance of non-conforming units: ***the process is therefore unstable and the defective units it expresses are not under control !***
- An investigation will therefore be required to identify the causes of this and eliminate them.
- ***The study of defects is therefore an indicator of the status of the process from which it originates !***

AND THE PROCESS ?

The alternative use of *np* and *p-charts* applies as long as the subgroups are all identical as in the previous case.

Instead, let's consider the data in the table here on the side where the number of non-conforming units was detected on different days and each time on a different sample basis.

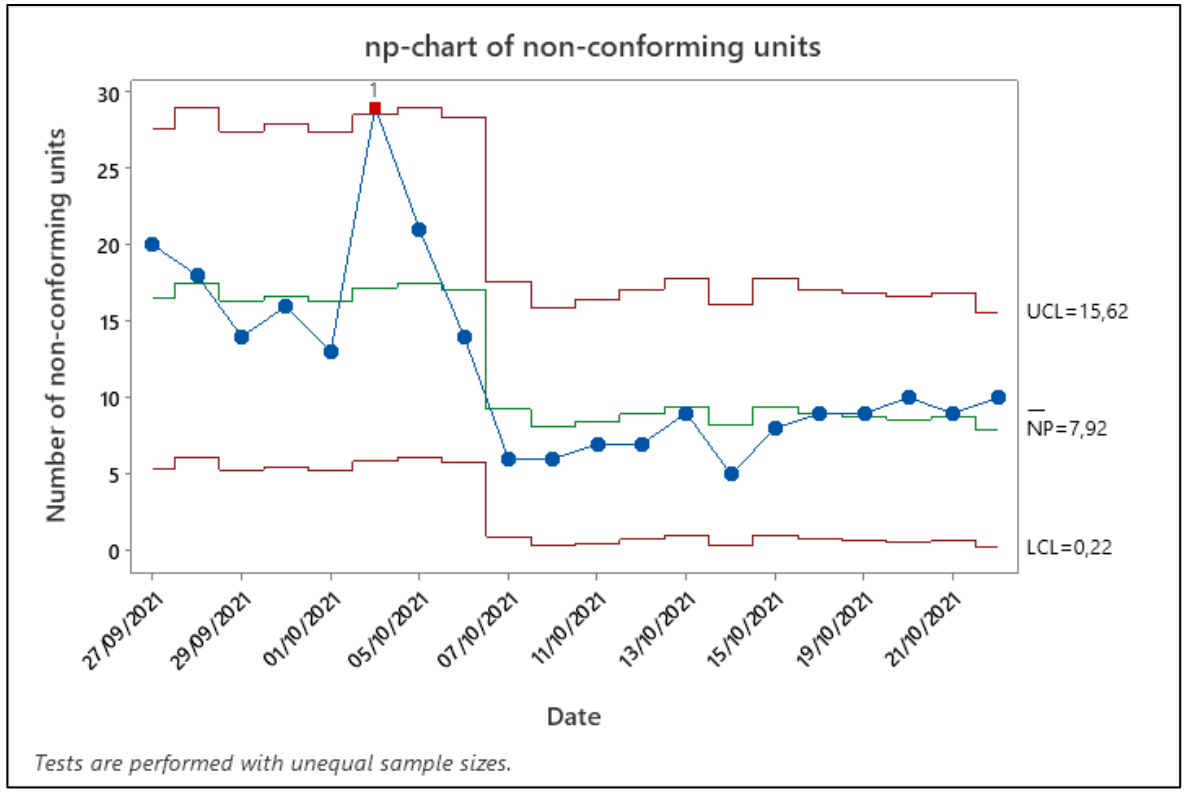
Date	No. of non-conforming units	No. of inspected units
September 27, 2021	20	98
September 28, 2021	18	104
September 29, 2021	14	97
September 30, 2021	16	99
October 1, 2021	13	97
October 4, 2021	29	102
October 5, 2021	21	104
October 6, 2021	14	101
October 7, 2021	6	55
October 8, 2021	6	48
October 11, 2021	7	50
October 12, 2021	7	53
October 13, 2021	9	56
October 14, 2021	5	49
October 15, 2021	8	56
October 18, 2021	9	53
October 19, 2021	9	52
October 20, 2021	10	51
October 21, 2021	9	52
October 22, 2021	10	47

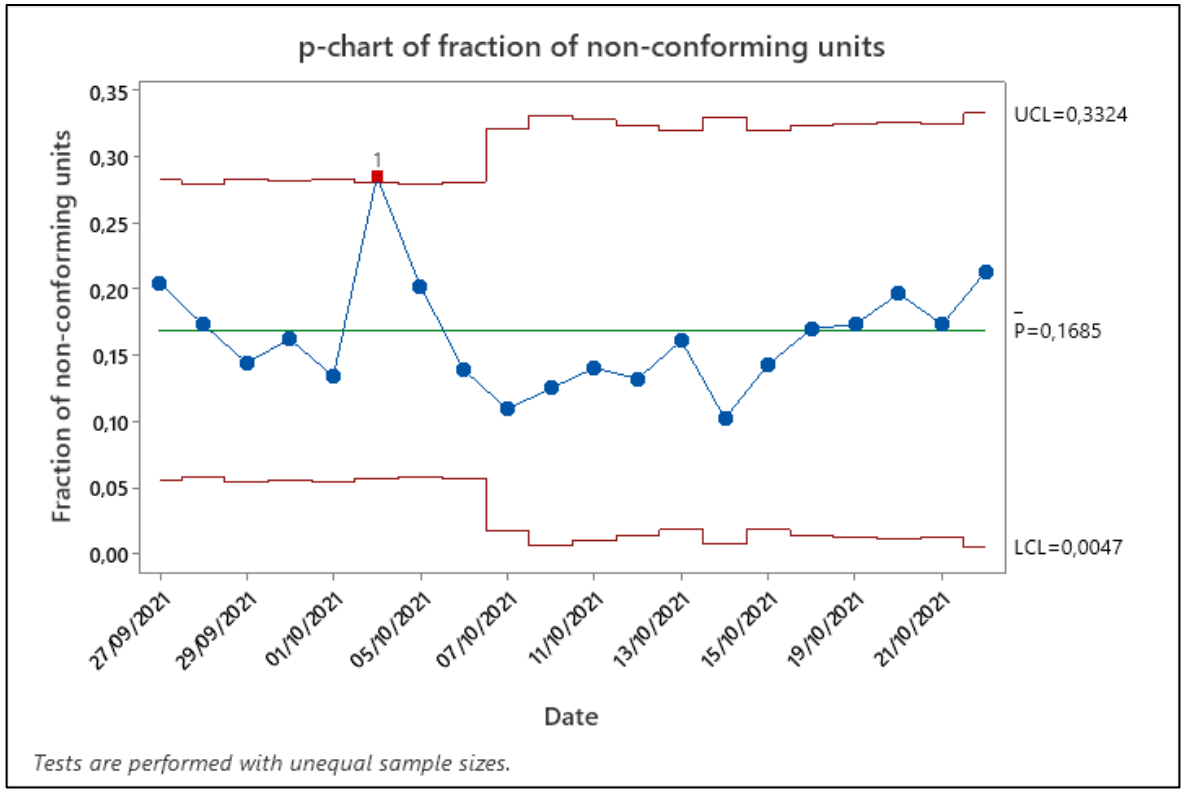
D. J. Wheeler, D.S. Chambers, Understanding Statistical Process Control, 2nd Ed., SPC Press, Knoxville, 1992

AND THE PROCESS ?

The data in the previous table are shown here below using *np* and *p-charts*.

In this case, the better readability of the p-chart than the np-chart is evident !





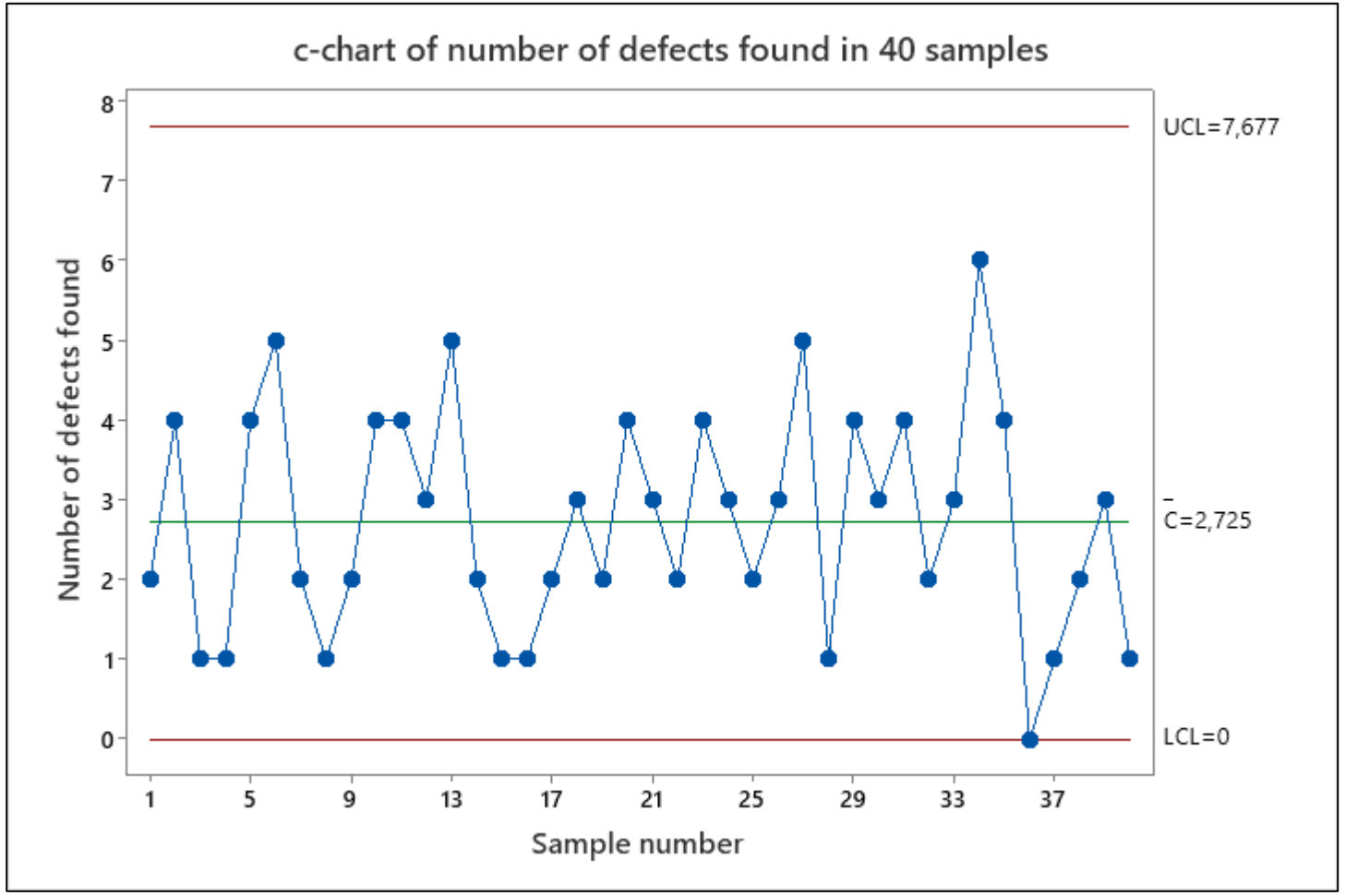
AND THE PROCESS ?

The table on the side shows the absolute number of defects found on forty (40) different samples examined. In this case the reference control chart is the *c-chart* as the subgroups (or *areas of opportunity*) are of the same size: each time 1 sample.

Sample number	No. of defects	Sample number	No. of defects
1	2	21	3
2	4	22	2
3	1	23	4
4	1	24	3
5	4	25	2
6	5	26	3
7	2	27	5
8	1	28	1
9	2	29	4
10	4	30	3
11	4	31	4
12	3	32	2
13	5	33	3
14	2	34	6
15	1	35	4
16	1	36	0
17	2	37	1
18	3	38	2
19	2	39	3
20	4	40	1

AND THE PROCESS ?

In this case, apart from a value at the lower limit, no particular trend is noted.



E. Belluco, Guida allo Statistical Process Control per Minitab, FrancoAngeli, 2013

AND THE PROCESS ?

The situation is different if the number of defects is determined on different subgroups, for example a different number of samples.

At that point, as already seen in the case of *p-charts* compared to *np-charts*, in order to be able to compare the values, it is necessary to switch from the initial absolute integer values (of the real *counts*) to ratios. In fact, every single "counts" is related to its own subgroup (or *area of opportunity*) to which it belongs.

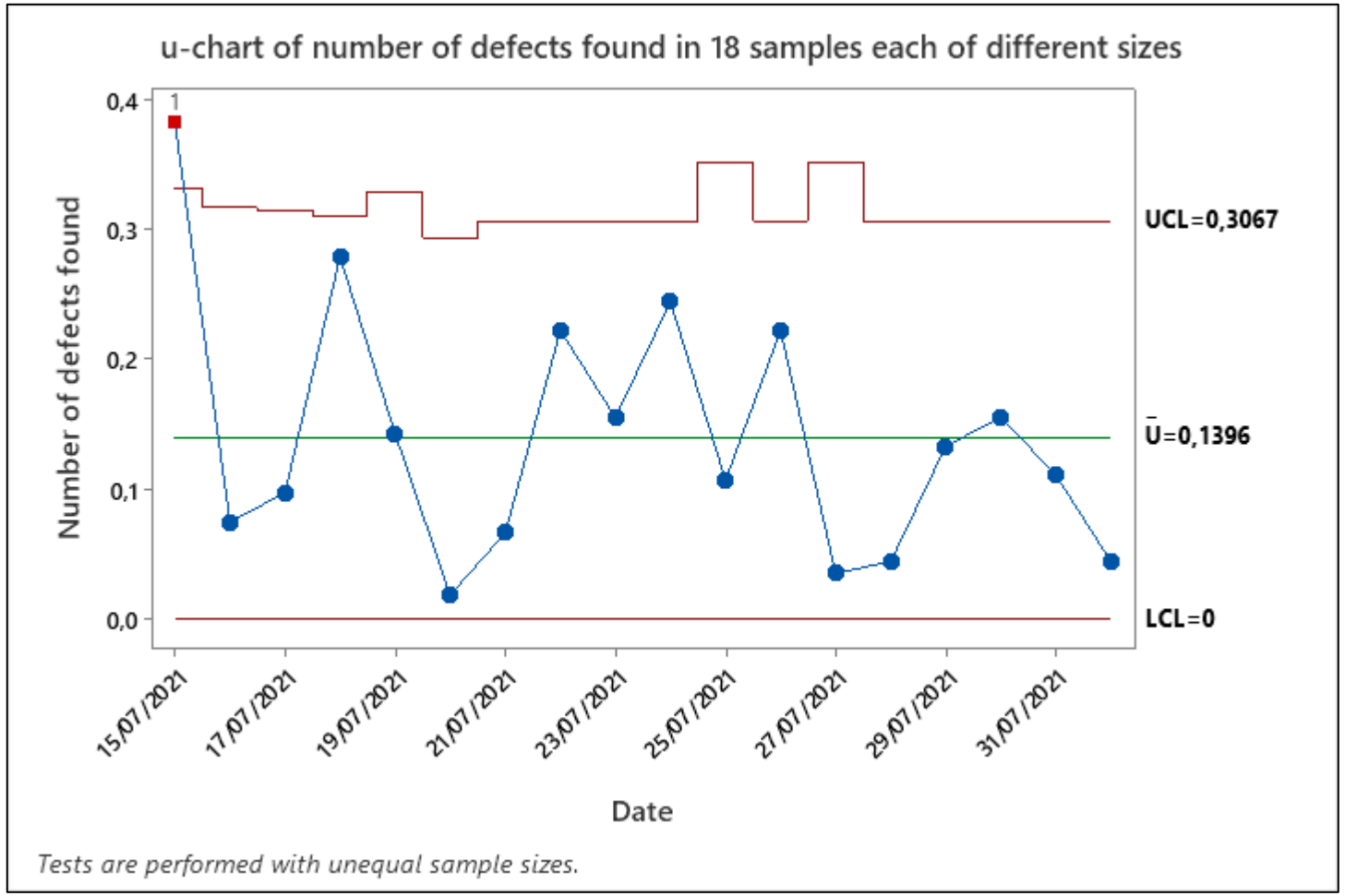
AND THE PROCESS ?

The table on the side shows the absolute number of defects found on different days on a different number of samples examined each day.

Date	No. defects found	No. inspected units
July 15, 2021	13	34
July 16, 2021	3	40
July 17, 2021	4	41
July 18, 2021	12	43
July 19, 2021	5	35
July 20, 2021	1	53
July 21, 2021	3	45
July 22, 2021	10	45
July 23, 2021	7	45
July 24, 2021	11	45
July 25, 2021	3	28
July 26, 2021	10	45
July 27, 2021	1	28
July 28, 2021	2	45
July 29, 2021	6	45
July 30, 2021	7	45
July 31, 2021	5	45
August 1, 2021	2	45

AND THE PROCESS ?

In this case the reference control chart is the *u-chart* as the subgroups (or *areas of opportunity*) are of different sizes.



D. J. Wheeler, D.S. Chambers, Understanding Statistical Process Control, 2nd Ed., SPC Press, Knoxville, 1992

AND THE PROCESS ?

A very important aspect that should never be overlooked when working with control charts of this type, that is, which are based on « counts » and not on « measures », is that

THIS TYPE OF DATA, DUE TO THEIR « DISCRETE » NATURE, MUST BE DISAGGREGATED TO BECOME INFORMATIVE ABOUT THE PROCESS FROM WHICH THEY ORIGINATE.

If kept « merged », the data only return an overall information of how things are, but they say nothing about where the problems lie and therefore do not allow the process itself to be improved !

ISO 2859-1

ISO 2859-1

- The sampling procedures for the purpose of an inspection by attributes were developed during WWII and among them the most used was the MIL-STD-105, the latest version of which (*i.e.*, E) was published in 1989.
- The ISO 2859 procedure is a sort of « civil equivalent » of the procedure for military use and like that has as its main focus the concept of AQL.
- There are different « schemes » for ISO 2859 which cover different situations: isolated batch (ISO 2859-2), inspection of only a part of the batches subjected to inspection or skip-lot (ISO 2859-3), *etc*.
- ***Only ISO 2859-1 will be considered below.***

ISO 2859-1

- ISO 2859-1 proposes sampling schemes for the inspection of batches indexed by ***AQL*** and ***« sample size code letter ».*** It is often said that the standard is ***«AQL oriented»***

- The purpose of the procedure is to maintain a *process average level* no worse than the specified AQL and to provide the Customer with an upper limit for the risk of occasionally accepting a low-quality batch.

ISO 2859-1

- It must be clear that AQL is a parameter of the sampling scheme and should not be confused with the *process average* that describes the operational level of the production process. The process average is expected to be better than the AQL in order to avoid an excessive number of rejections given these conditions !

- The ISO 2859-1 standard considers three types of sampling plan (*i.e.*, single, double and multiple sampling) each of which is associated with a different « discriminatory power » that is a different slope of the OC curve

ISO 2859-1

- sample sizes are predetermined: 2, 3, 5, 8,13, 20, 32, 50, 80, 125, 200, 315, 500, 1250 and 2000

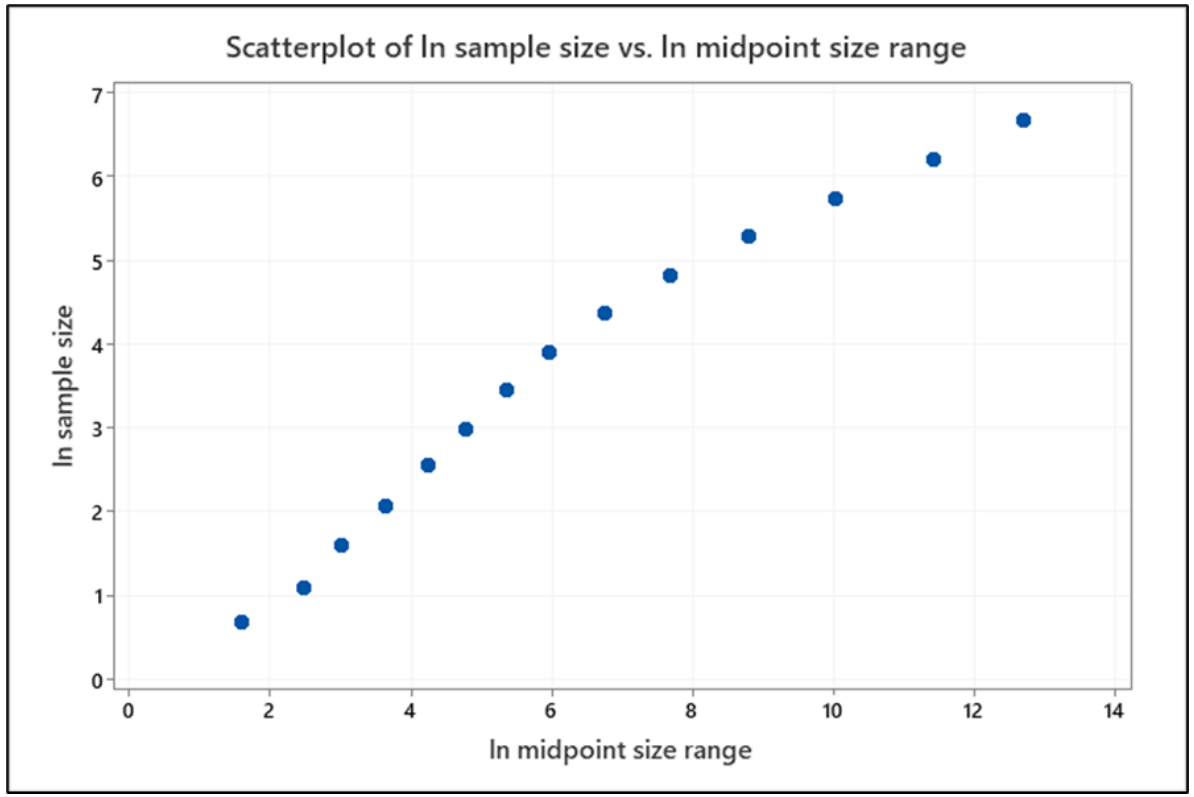
   not all sample sizes are considered.

- sample sizes are related to batch sizes according to a logarithmic law.

  In particular, the natural logarithm of the sample size (*ln sample size*) is in an approximately linear relationship with the natural logarithm of the central value of each interval relating to the size of the lots (see next slide).

ISO 2859-1

Lot size interval	Lot size midpoint	ln Lot size midpoint	Sample Size	ln Sample Size
2 – 8	5.0	1.6094	2	0.69315
9 – 15	12.0	2.4849	3	1.09861
16- 25	20.5	3.0204	5	1.60944
26 – 50	38.0	3.6376	8	2.07944
51 – 90	70.5	4.2556	13	2.56495
91 – 150	120.5	4.7916	20	2.99573
151 -280	215.5	5.3730	32	3.46574
281 – 500	390.5	5.9674	50	3.91202
501 – 1200	850.5	6.7458	80	4.38203
1201 – 3200	2200.5	7.6964	125	4.82831
3201 – 10000	6600.5	8.7949	200	5.29832
10001 - 35000	22500.5	10.0213	315	5.75257
35001 – 150000	92500.5	11.4350	500	6.21461
150001 - 500000	325000.5	12.6916	800	6.68461
500000 -	….	…	…	…



ISO 2859-1

- There are three inspection levels for each type of sampling:
  - ***Normal (II)***: is what is usually used at the beginning of the inspection activity
  - ***Tightened (III)***: it is what is adopted when the recent quality of the Supplier has deteriorated
  - ***Reduced (I)***: it is what is adopted when the recent quality of the Supplier is excellent.

- To these three levels are added four ***Special Levels: S-1, S-2, S-3 e S-4*** all of which use small samples.

  Special levels are used when small samples are needed or when such sampling risk can be tolerated!

ISO 2859-1

Some criteria for passing from one inspection level to another (or ***switching rules***) are, for example:

- ***Normal → Tightened*** : 2 to 5 consecutive lots were rejected
- ***Tightened → Normal***: 5 consecutive lots are accepted
- ***Normal → Reduced***: 10 consecutive batches are accepted or Production proceeds under « stationary conditions » and the sampling authority deems a reduced inspection desirable.
- ***Reduced → Normal***: 1 batch rejected or irregular production.

ISO 2859-1

- ***Primary focus of ISO 2859-1 is, as initially seen, the AQL.***
- The AQL is usually fixed in the contract with the Customer, and you can have different AQLs for different defects.

  However, the definition of an AQL does not authorize the Manufacturer to knowingly supply non-compliant units!
- It is common to adopt:
  - **AQL = 1%** for **MAJOR DEFECTS** and
  - **AQL = 2.5%** for **MINOR DEFECTS**.
- ***In the presence of critical defects, the lot is rejected. Critical defects are not acceptable!***

ISO 2859-1

Practical operation

- based on *lot size* and *Inspection Level* (I, II, III or S) to be adopted, the appropriate ***Sample Size Code Letter*** (A, B, C ...) is identified using Table 1
- In light of:
  - type of sampling plan (single, double, multiple) and
  - option (normal, tightened, reduced)

  established, the relevant Master Table (from 2A to 4C) is identified.
- In the Master Table, using the fixed AQL and the Code Letter previously obtained, are then identified:
  - Sample Size and
  - Acceptance criteria (Ac/Re)

ISO 2859-1

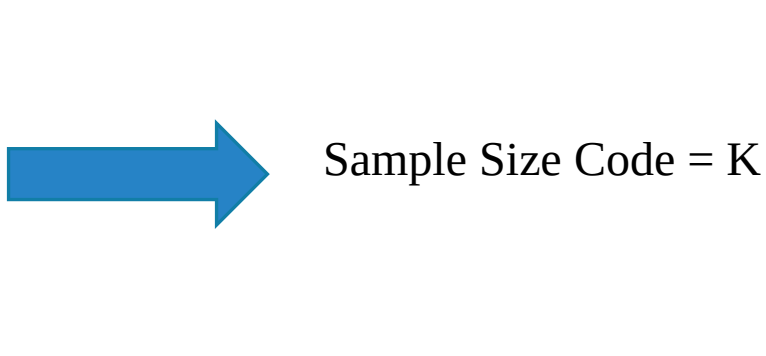
EXAMPLE:

Lot size = 2000 units

AQL = 0.65%

Inspection level = Normal (II)

Sampling plan = Single



Sample Size Code = K

ISO 2859-1

- Sampling plan single /Inspection level Normal (II) : K = 125 units (***n***) e ***c*** = 2
- Sampling plan single /Inspection level Tightened (III) : K = 125 units (***n***) e ***c*** = 1
- In this case, given ***N***= 2000, ***AQL***=0,65 and sampling plan “single”, changing the inspection level, the sample size remains the same while changes the value of c which from Normal to Tightened is reduced from 2 to 1.
- ***This « general strategy» is used throughout the norm going from Normal to Tightened.***

CONCLUSIONS

CONCLUSIONS

During the presentation we saw how:

- the need to verify whether the material supplied by a producer to a consumer, or by a department to another of the same company, corresponds to pre-established requirements, requires a set of statistical techniques that are called *acceptance control*
- the *acceptance control* is mainly used to establish whether the batches subjected to the control can be accepted or rejected and not to determine their quality level
- as part of the *acceptance control*, the quality of the lot is measured by its percentage of defects

CONCLUSIONS

- inspection by attributes is the « *inspection whereby the item is classified simply as conforming or nonconforming with respect to a specified requirement or set of specified requirements, or the number of nonconformities in the item is counted* »

- the ISO 2859-1 standard is the « *part of ISO 2859 which specifies an acceptance sampling system for inspection by attributes. It is indexed in terms of acceptance quality limit (AQL)* »

ISO 2859-1, 2nd Ed.,1999

CONCLUSIONS

However, the best synthesis of the concepts exposed in the presentation lies in what follows:

« *Sampling plans cost money to design and implement. They can be used to perform more than a police function. The information generated is invaluable; it is regrettable that these results are often simply filed away or never recorded. The institution of a sampling plan should have associated with it effective procedures for the feedback and utilization of the data resulting from the plan.* »

E.G. Schilling, D.V. Neubauer, Acceptance sampling in Quality Control, 3rd Ed., CRC Press, 2017

Thank you very much for your attention!

http://riccardobonfichi.it