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Sample Size Determination for the Audit and Validation of an Industrial Process Control Outcome

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Abstract: This study is aimed at determining sample sizes at subgroup level and number of groups utilized in monitoring, evaluating and validating the reliability of an industrial process control output using a set of simulated data underlying the variable and attribute charts scenarios.

The methodology adopts sample size estimation procedure using $\bar{X}$ for the case of a variable control charts and $P, NP, \& C$ charts for the case of attribute control charts based on available information provided for the validation of reported quality control results.

Findings shows that the possibility of process validation using of diverse provided specific information. A sample subgroup sample size of 3 and sample group number of 20 were estimated provided UCL of 17.5 corresponding to total mean of 227.2 and grand total of 681.6 for an $\bar{x}$ control chart. Considering the attribute control chart for the proportion defective, a UCL of 0.801 yields an estimated subgroup sample size of 202 attributed to 0.773 overall proportion of defectives. A UCL of 11.08 resulted to an estimated sample size of 7 given a reported overall proportion of defective with attention drawn towards number of defectives all complemented by an estimation plot.

However, the result above proves the estimation procedure as best suited in the validation of the reliability industrial process or reports to ascertain inclusively the effectiveness and accuracy of the internal or assigned inspection team.

Keywords: *Quality Control, Industrial Process, Validation, Subgroup, Sample Number.*

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I. INTRODUCTION

The determination of subgroup sample size in quality control process is highly essential for the construction of required control charts towards defining the state of the industrial process accurately. However, knowing the subgroup sample size and number of subgroups will enhance proper planning of the experiments, monitoring, comparison and adequate evaluation of the process (Champ et al., 2003).

Notwithstanding, for the results of a control charts to be fully dependent and relied upon, it is of necessity of revalidate the outcome of the control chart via post-chart-construction audit. This audit process helps validates the information provided or reported about the underlying process using the control chart (Del Castillo, 2002).

This procedure tends to assess the entire process including the ability and degree of accuracy of the expert/inspector who has undergone the process evaluation using the control chart tools.

To validate the information provided, the process auditor/assessor is required to be provided some basic and relevant information upon which the subgroup sample size and number of subgroups could be estimated.

The information to be provided vary with respect to the type of control chart under assessment. In most cases, information about the upper and lower control limits (or any) and the centre lines.

In literature, less attention is drawn towards the post estimation of subgroup sample size and number of subgroups

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since majority of the firms and industries are barely well informed about industrial process audit. By and large, the sample size and number of sample group play essential role in ascertaining the reliability of the process. The technique help checkmate and identify errors or undue information about the process as those influenced by the inspection team or quality manager.

Industrial process audit and validation is very towards ensuring reliable, efficient process which comply with regulatory standards. This helps maintain quality standard, ensuring safety and improving operational efficiency. One of the main aspects of the audit is determining the sample size in closed form of the information used in establishing the control charts.

The role of industrial process audit is not limited but serve to assess the conformity of a manufacturing process to specified standards and regulatory requirements. These can be classified as either internal audits conducted within the company by her own personnel or external audits done by regulatory agencies or third parties (ISO, 2015).

To validate a process also entails confirming that an industrial process consistently produces a product that meets its specifications (FDA, 2011). This in industrials like pharmaceuticals, it is very critical to ensure that patient safety and product efficacy. Hence, statistical analysis to determine the sample size that will provide reliable insight without incurring irrelevant costs should be considered.

According to Cochran (1977), the sample size must be large enough and it is highly influenced by the limits (control limits) and the variability within the population. However, sample size determination is the corner stone of statistical quality control and thus essential for the accuracy of industrial audits and validations (Lind, et al, 2013).

The population of items or products is divided into subgroups, and samples are drawn from each. This technique is useful when the population is heterogeneous (which might be in time, operator or material related) and ensure that all subgroups are adequately represented (Thompson, 2012).

In a manufacturing facility, auditors used simplified sampling technique to evaluate the quality of products produced in different shifts. This technique ensured that any variability due to different operational conditions was captured. The auditors found that 50 units from each shift was sufficient to draw meaningful conclusions about the quality of the process (Smith, 2016)

II. DATA AND METHODS

The data for the study are simulated in line with the procedures associated with the data structure for the monitoring and evaluation of the state of industrial processes for a $3-\sigma$ using R Language statistical software.

➢ *Variable Control Chart Sample-Size Determination*

To validity information about the mean level of an industrial process reported having constructed an $\bar{X}$ chart, there are two possibility of sample information required – those attributed to subsample and the sample group which could be estimated as follows using the control limits,

$$CL = \bar{X} \pm A_2\bar{R}$$

$3\sigma^2 = A_2\bar{R}$ (Montgomery, 2019).

The number of sample groups is estimated as

$$k_{\bar{X}} = \frac{1}{UCL + LCL}\sum_{i=1}^{k}\bar{x}_i$$

Where $\bar{x}_i$the individual subgroup is mean, UCL and LCL are upper and lower control limits for the industrial process mean level respectively. A_2 Is an arbitrary constant dependent on the subgroup sample size while $\bar{R}$ is the mean range of the subgroups.

However, the subgroup sample size is expressed as:

$$n_{\bar{X}} = \frac{2}{k(UCL + LCL)}\sum_{i=1}^{k}\sum_{j=1}^{n}x_{ij}$$

Where x_{ij} is the individual observation/value corresponding to sample group i in unit j, $\sum\sum x_{ij}$ account for the grand total for all the observations/ values reported.

In the case of the R – chart, the number of sample group can be expressed as

$$k_R = \frac{D_4}{UCL}\sum_{i=1}^{k}R_i$$

Where, D_4 is a constant relative to the sample group number and R_i is the range of individual subgroup.

➢ Attribute Control Charts Sample-Size Determination

- *Case I*

  P – Chart [Proportion defective]

The estimates of the subgroup sample-size for validating the results of P – chart varies with respect to the information provided or revealed with control specification limits expressed as:

$$SL = \bar{P} \pm 3\sqrt{\frac{\bar{P}(1-\bar{P})}{n}}$$

Type 1: If σ is known, then

$$n_p = \frac{\bar{P}(1-\bar{P})}{\sigma^2}$$

Type 2: If UCL and LCL are known,

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$$n_p = \frac{36\bar{P}(1-\bar{P})}{(UCL-LCL)^2}$$

Since $\sigma = (UCL - LCL)/6$

Type 3: If either UCL or LCL is known,

$$n_p = \frac{9\bar{P}(1-\bar{P})}{(UCL-\bar{P})^2} \equiv \frac{9\bar{P}(1-\bar{P})}{(\bar{P}-LCL)^2}$$

Where $\bar{P}$ is the proportion of defective (d_i) across all subgroups usually estimated as

$$\bar{P} = \frac{1}{mn}\sum_{i=1}^{m} d_i$$

- *Case II*

  NP – Chart [Number of Defective]

Like the P – chart, the estimation of the subgroup sample-size differs with respect to available or reported information with Control specification limits defined as:

$$SL = \bar{P} \pm 3\sqrt{n\bar{P}(1-\bar{P})}$$

Type 1: If σ is known,

$$n_{np} = \frac{\sigma^2}{\bar{P}(1-\bar{P})}$$

Type 2: If UCL and LCL are known,

$$n_{np} = \frac{(UCL-LCL)^2}{36\bar{P}(1-\bar{P})}$$

Type 3: If either UCL or LCL is known and the corresponding centre line

$$n_{np} = [2UCL + 9(1-\bar{P})]\bar{P} \pm \sqrt{\left[[2UCL + 9(1-\bar{P})]\bar{P}\right]^2 - 4\bar{P}^2 \times UCL^2}$$

$$\equiv [2LCL + 9(1-\bar{P})]\bar{P} \pm \sqrt{\left[[2LCL + 9(1-\bar{P})]\bar{P}\right]^2 - 4\bar{P}^2 \times LCL^2}$$

Considering type 1 and 2, it obvious that the subgroup sample-size for number of defectives is the reciprocal for proportion defective.

- *Case III*

  C – Chart [Number of Conformities]

The number of conformities of defects per unit of an industrial process is detected using the C – chart. However, the sample size is estimated as:

$$n_c = \frac{1}{\bar{C}}\sum_{i=1}^{n} c_i$$

Given that the total number of conformities per unit is known and the centre line, $\bar{C}$ is specified. c_i is the number of conformities or defect per unit with control specification limits defined as:

$$SL = \bar{C} \pm 3\sqrt{\bar{C}}$$

III. RESULTS AND DISCUSSION

Table 1 Variable Control Charts

R – Chart	Sim. No.	D	TR	UCL	k	$\bar{X}$ – Chart	TM	GT	LCL	UCL	k	n
	1	2.115	12	6.345	4		101.43	405.72	7.62	15.02	9	4
	2	1.864	120	22.368	10		227.2	681.6	5.2	17.5	20	3
	3	2.004	75	25.05	6		191.38	956.9	4.89	22.45	14	5
	4	1.716	11	1.2584	15		105.985	317.955	6.26	13.01	11	3

Upon simulation, Table 1 gives the estimates of number of subgroups and subgroup sample-size considering R and $\bar{X}$ control charts. It is shown based on the first simulation that if the lower and upper control limits for an $\bar{X}$ – chart are reported to be 5.2 and 17.5 respectively associated with a grand total value of 681.6 resulting to a total mean of 227.2, the estimated number of subgroups is 20 while each subgroup has sample-size of 3. For R – chart, an estimated number of subgroups is obtained to be 4 given that the reported upper control limit is 6.345 based on a total range of 12 across subgroups attributed to $D = 2$.

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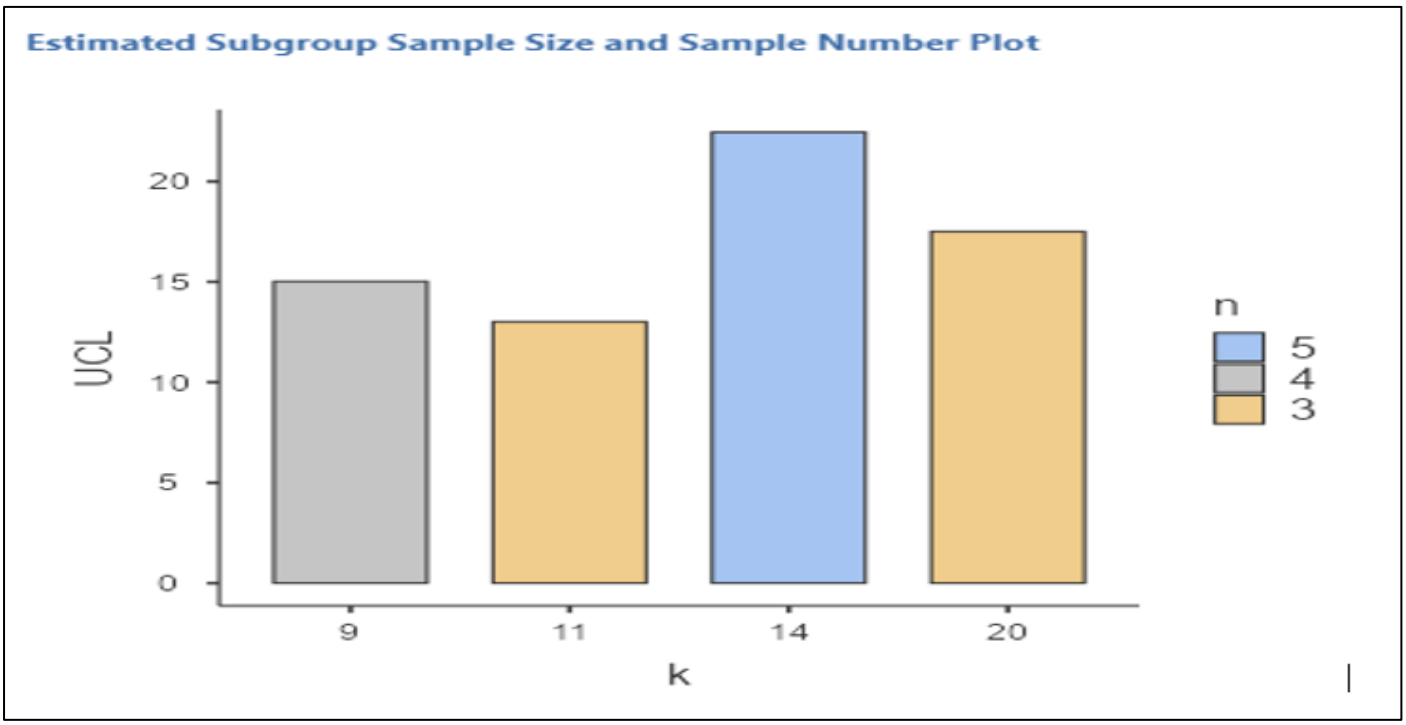

Fig 1 $\bar{X}$ Estimated Subgroup Sample Size And Sample Number Given UCL.

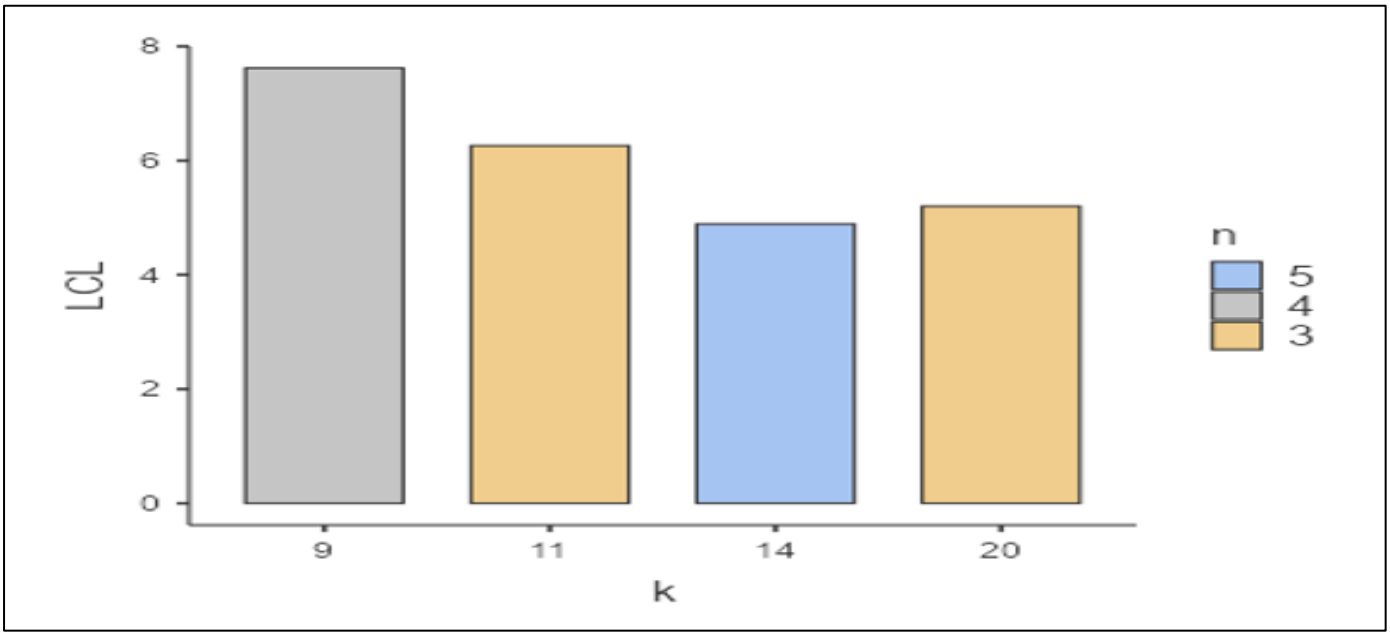

Fig 2 $\bar{X}$ Estimated Subgroup Sample Size And Sample Number Given LCL

Table 2 Attribute Control Charts

P – Chart	Sim. No.	$\bar{P}$	σ	LCL	UCL	n_p	NP – Chart	$\bar{P}$	σ	UCL	n_{np}
		0.261	0.062	0.075	0.447	50		0.261	1.521	10.54	3, 12
		0.06	0.142	-0.0112	0.1312	100		0.146	0.999	12.456	2, 8
		0.773	0.030	0.745	0.801	202		0.346	2.127	16.00	6,20
		0.18	0.134	-0.22	0.581	9		0.566	2.377	11.08	7,23

C – Chart											
Sim. No.	1	2	3	4	5	6	7	8	9	10	11	12
TC	70	36	75	48	105	104	64	72	25	78	55	81
AC	7	4	3	4	5	4	8	12	5	13	5	9
n_c	10	9	25	12	22	26	8	6	5	6	11	9

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Table 2 shows the estimates of the subgroup sample sizes for attribute control chart with attention drawn to proportion of defective, number of defective and number of conformities. It is revealed that if for instance a claim is made that the overall proportion of defective in an industrial process is 0.18 corresponding to an upper control limit of 0.581, the validity of the actual sample size used is only true if and if it is proven to be 9. Also, in the case of the number of defective, a valid sample size to justify the report of an industrial process output with 0.146 proportion of defective and 12.456 is asymptotically 8 as the higher the sample size the better the reliability of the estimates.

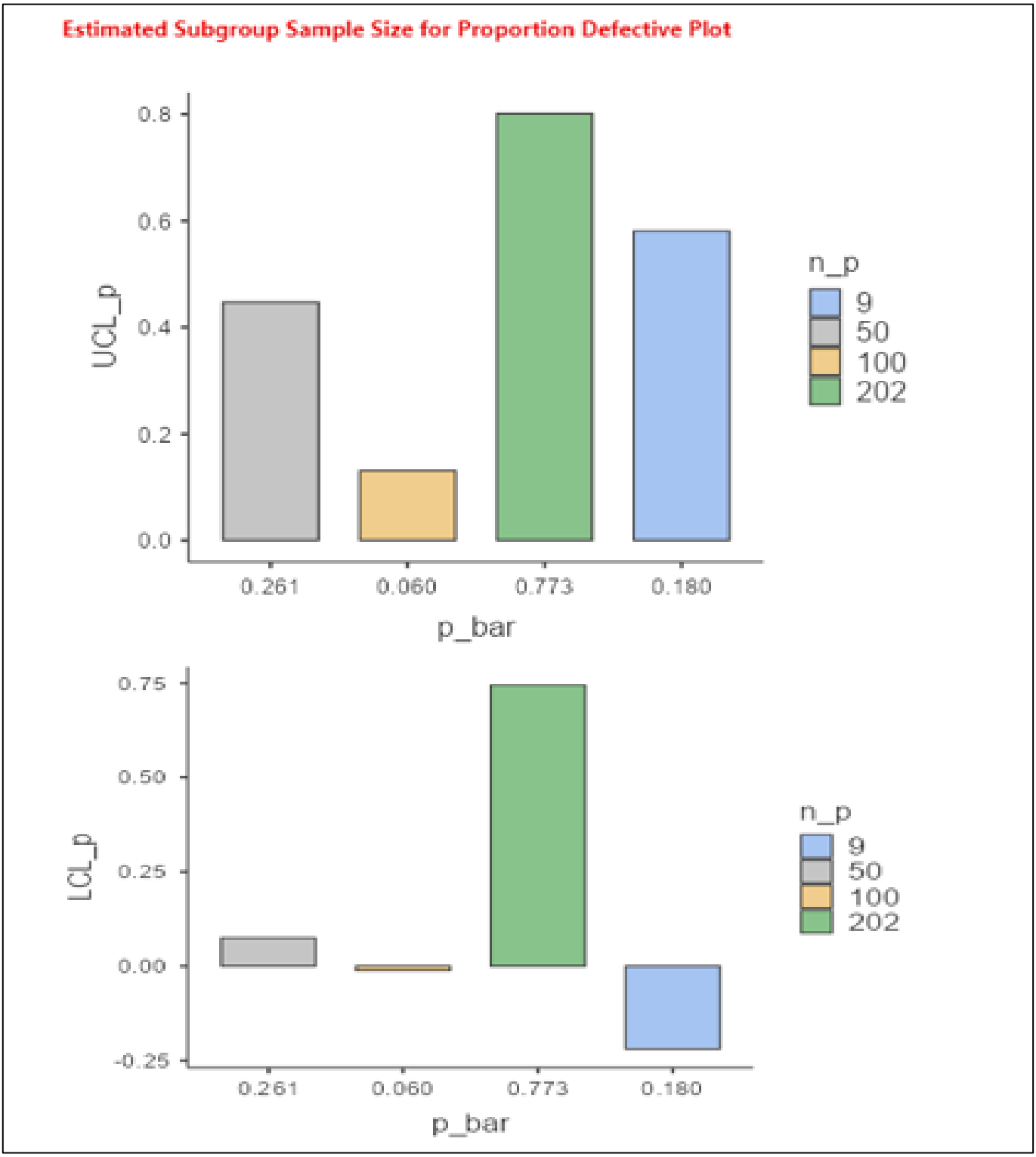

Fig 3 Estimated Subgroup Sample Size Given UCL/LCL And $\bar{P}$.

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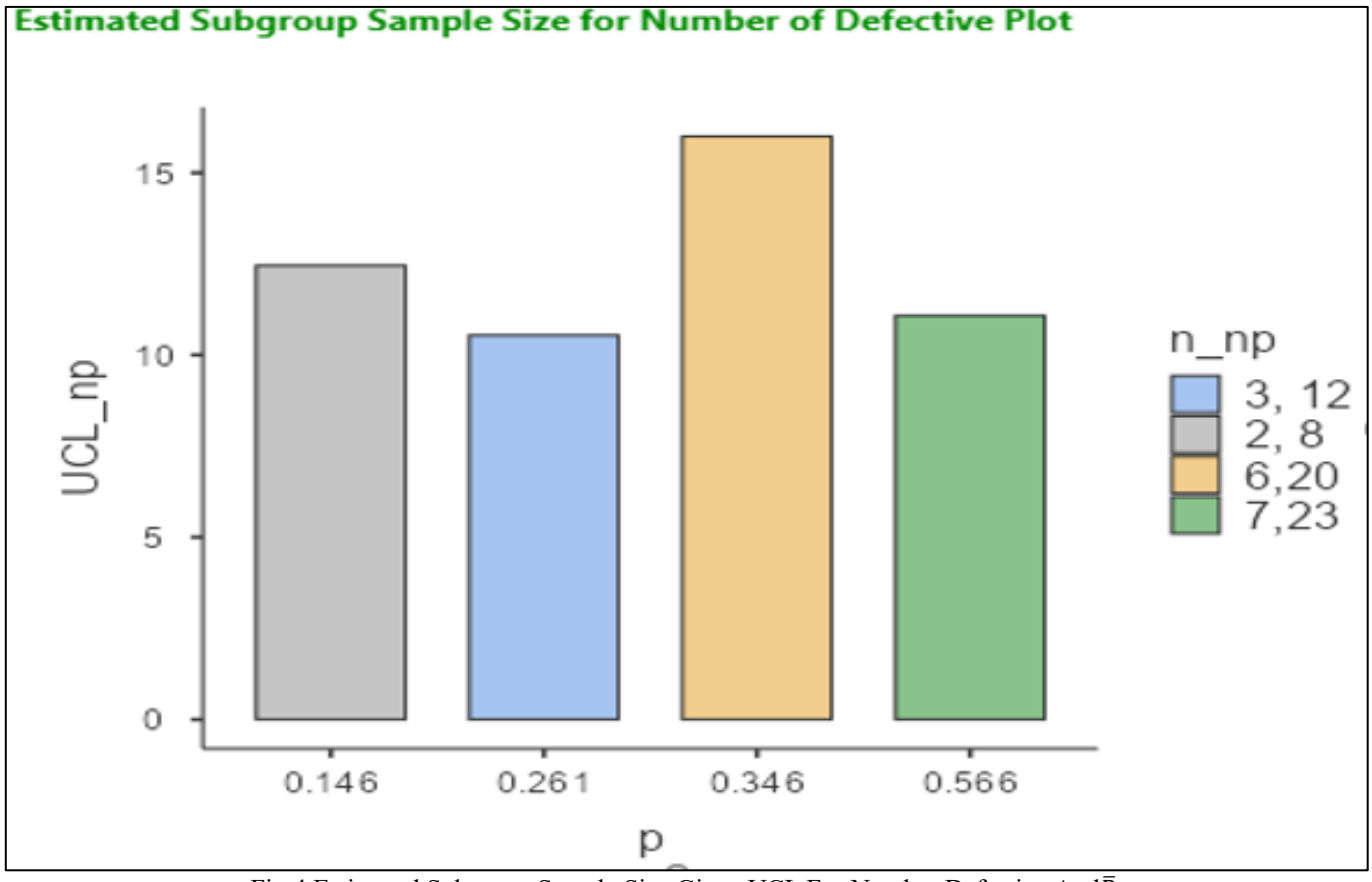

Fig 4 Estimated Subgroup Sample Size Given UCL For Number Defective And$\bar{P}$.

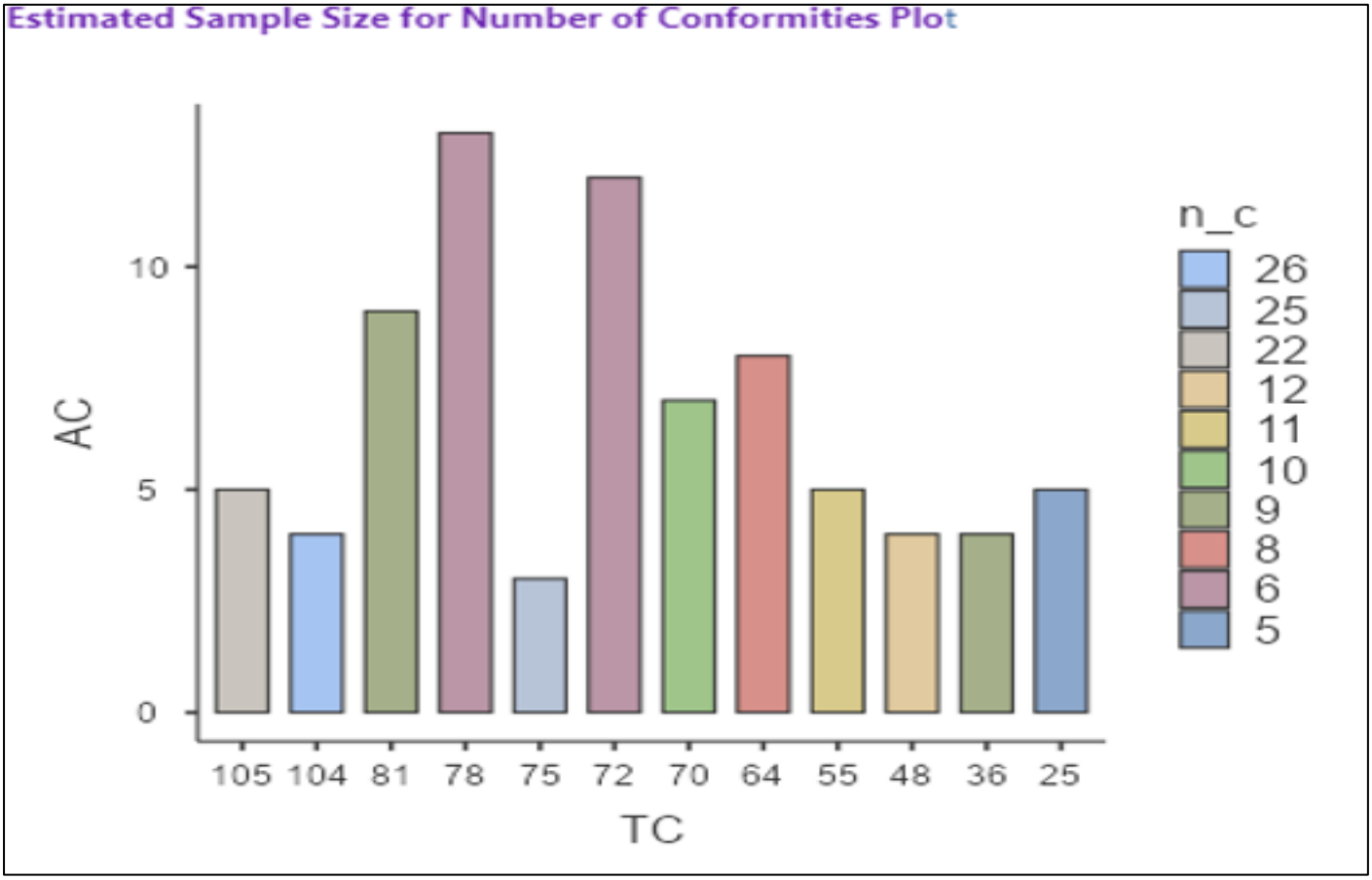

Fig 5 Estimated Subgroup Sample Size For Number Of Conformities Given $\bar{C}$ And Total Number Of Conformities.

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Figure 1-5 complement the results presented in Tables 1, 2. This inline gives an insight to the implication associated with the distance produced between the UCL and LCL at arriving at the same sample size regardless a close form to the information provided.

IV. CONCLUSION

Industrial process audit is a post-estimation technique that checkmates accuracy in industrial process output outcome for a control chart and the inspection team. It serves as a corrective measure to eradicate or reduce uncertainty associated with the outcome reported in relation to the sample size claimed to have used. It is a single blind approach as the full information is made available to industrial stakeholder but validating the truth value of the information warrant a release of a part as evidence to ascertain the true state of the report given by the inspection team.

RECOMMENDATION

It is of concern that much attention should be drawn to sample size estimation among other measures and validation elements to verify the true states of a process in comparison to those provided by an internal inspection/audit team. This should include other complex industrial process control charts such as U-chart, CUSUM Chart, etc.

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