Statistical Issues in Quantitative Quality Programs

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1. Introduction

Quality programs such as statistical process control (SPC) and six sigma (6σ) aim at a reduction of process variation. SPC tries to make the process predictable or stable within certain limits by removing special causes, see Shewhart (1931). Stable processes show only process inherent or common cause variation, process influences that are constantly present. Six sigma tries to reduce process variation to a level of only 3.4 parts per one million parts non-conforming. One phase of 6σ, that investigates the process capability, categorizes the process state into a technology or control issue (or both). It is determined by the within and between subgroup variation and helps practitioners focus on improvement opportunities.

Ideally a rational subgroup is a sample in which all the items are produced under conditions in which only random effects are responsible for the observed variation, see Nelson (1988). The within subgroup variation is often referred to as short-term variation and the within and between subgroup variation together form the long-term variation. This terminology is used in SPC and in 6σ, see Nelson (1988) and Harry (1997), respectively. Typically, special causes influence between subgroup variation such as differences between raw material or differences in test conditions.

The tools that are used to investigate process control are control charts for SPC and Z_{shift} for 6σ. For SPC various signals in control charts indicate special causes and an out-of-control situation and for 6σ a large difference between short- and long-term performance (i.e. Z_{shift}) indicates a control problem. Next section discusses both approaches for two statistical models, after which the inflation factor, which serves as the basis for Z_{shift}, is discussed. This results in our view of the process state.

2. Process Control

The first model that describes a certain quality characteristic of a process is:

(1) $$Y_{ij} = \mu + \varepsilon_{ij}, \; \varepsilon_{ij} \sim N(0, \sigma_w^2), \; i = 1,2,...,k \;\text{ and }\; j = 1,2,...,n,$$

all variables independent, k the number of subgroups and n the number of items per subgroup. In view of SPC, process control is determined through either $\overline{X} - S$- or $\overline{X} - R$-charts. Control limits in the $\overline{X}$-chart are estimated with the pooled standard deviation and various tests will detect special causes that influence the process mean μ For the S- or R-chart, the control limits are estimated with the within subgroup standard deviation or ranges and signals outside the limits indicate special causes that influence the within group variation. If all implemented tests, that are related to potential disturbances, identify no signals, the process is called in statistical control. Practical problems arise since small changes of the process mean may not be detected quickly. Using signals outside the control limits only, the average run length is more than 15 subgroups for a process shift of at most $1.5\sigma_w/\sqrt{n}$. On the other hand, if small process shifts are expected, CUSUM, EWMA or larger samples n could be used.

In view of 6σ, a control problem is defined by a Z_{shift} larger than 1.5. Harry (1997) defines $Z_{shift} = Z_{st} - Z_{lt}$ with $Z_{st} = (U-L)/2\sigma_w$, $Z_{lt} = \min\{(U-\mu)/\sigma_t, (\mu-L)/\sigma_t\}$ and U and L the upper and lower specifications. For a process that is in statistical control σ_t is equal to σ_w. But for non-random shifts or drifts to the process mean, the process variation inflates. Assume that at subgroup i the new process mean is equal to $\mu + \mu_i$ as a results of non-random shifts or drifts. Hence, σ_w^2 increases with

$\sigma_{shift}^2 = \frac{1}{k}\sum_{i=1}^{k}(\mu_i - \bar{\mu})^2$, the variance due to shifts or drifts and $\bar{\mu} = \frac{1}{k}\sum_{i=1}^{k}\mu_i$ the average shift or drift of the process. Indeed, a randomly selected item from a randomly selected subgroup has variance $\sigma_t^2 = \sigma_w^2 + \sigma_{shift}^2$ and this is the variation that an individual consumer perceives. The Z_{shift} is equal to

(2) $$Z_{Shift} = Z_{st}(1-r) + |M - \mu - \bar{\mu}|/\sigma_t \text{, with } r = \sigma_w/\sigma_t \text{ and } M = (U-L)/2 .$$

A 6σ control problem is apparently determined by the sum of two process issues. One issue is the contribution of shifts or drifts to the total variation (i.e. *1-r*) multiplied with the short-term capability Z_{st}. It seems strange that process control is influenced by the short-term capability. Another issue is the distance from the process mean (the true process mean and the average shift or drift) to the middle of the specification area relative to the total variation. For a process that is in statistical control the Z_{shift} reduces to $|M-\mu|/\sigma_w$. This is more a "targeting" problem and does not contribute to process control. For instance, for the production of molded plastic parts the average dimension is determined by the dimension of the cavity and cannot be corrected during production anymore.

Assume $\mu = M$, a non-random shift of size $a\sigma_w$ occurs at subgroup $t_0 + 1$ and the shifted process remains at the new level for all subsequent subgroups. Then the Z_{shift} may be determined mathematically, but instead we have listed some approximate values in Table 1 for different sizes a, for different moments t_0 and for $Z_{st} = 6$.

	Shift sizes a						
Moments $(k-t_0)/k$	**0.25**	**0.5**	**0.75**	**1**	**1.5**	**2**	**5**
0.10	0.04	0.11	0.22	0.35	0.67	1.05	3.15
0.25	0.09	0.25	0.47	0.72	1.31	1.92	4.63
0.50	0.16	0.40	0.72	1.08	1.87	2.65	6.01
0.75	0.21	0.48	0.81	1.18	2.00	2.84	6.93
0.90	0.23	0.50	0.79	1.12	1.82	2.58	6.98

Table 1: Approximate Z_{shift} values for a shift of size $a\sigma_w$ at moments t_0 and $Z_{st} = 6$.

Clearly, Z_{shift} larger than 1.5 only occurs for relatively large shifts. However, for n at least 4, a shift of size $0.75\sigma_w$ will be detected by a $\bar{X}$-chart, but it is not always a control problem in view of 6σ. Note that Z_{shift} becomes even lower for processes that have a technology problem (i.e. $Z_{st}<6$). For model (1) the criterion 1.5 for Z_{shift} is not appropriate to indicate out-of-control. For stable processes, the Z_{shift} only indicates how much the process average is away from the center.

The second model is:

(3) $$Y_{ij} = \mu + X_i + \varepsilon_{ij}, \quad X_i \sim N(0,\sigma_b^2), \quad \varepsilon_{ij} \sim N(0,\sigma_w^2), \quad i = 1,2,\ldots,k \text{ and } j = 1,2,\ldots,n,$$

with all variables independent. This model arises from model (1) if subgroup shifts are random. Some batch wise processes have between subgroup (read batch) variation that is inherent to the process. For instance, a tea or a pharmaceutical factory produces large batches of granulate from which smaller items (tea bags or tablets) are manufactured. The average size of the granulate between batches result in weight averages of the items. Due to the set-up and the natural resources involved in the granulate process, differences may not be reduced to zero completely.

SPC investigates process control for model (3) with two control charts. An individuals control chart for the subgroup average and a S- or R-chart for the within subgroup variation. The moving average of the subgroup averages is used to determine the control limits for the individuals chart. These limits include inherent differences between the subgroups. Non-random shifts to the process average or special causes that influence σ_b will be detected with this chart. Unfortunately, the individuals control chart could also show signals of special causes that influence s_w. Such signals depend on the change in s_w, the ratio $r^2 = s_w^2/(s_b^2 + s_w^2)$ and the sample size *n*. Control charts for variance components models are given in Yashchin (1994) or Does, Roes and Trip (1999).

Again, 6σ calculates Z_{shift} which is equal to formula (2) with $\overline{m} = 0$ and s_{shift} replaced by s_b. For $m = M$, Z_{shift} reduces to $Z_{st}(1 - r)$, with $r^2 = s_w^2/(s_b^2 + s_w^2)$. Values of Z_{shift} larger then 1.5 will occur for processes that have relative high differences between subgroup means and high short-term process capability. However, the process may be in statistical control and 6σ indicates a control problem that is not present according to SPC. This becomes even worse for processes that do not have a process average in the middle of the specification. Further, non-random shifts or drifts of subgroup means contribute to larger between subgroup variation, but Z_{shift} does not distinguish between non-random or random shifts.

3. The inflation factor

Harry (1997) derived the Z_{shift} value from the inflation factor that was used by other researchers, such as Evans (1975). They proposed to multiply s_t with 1.5, to compensate for non-random shifts or drifts in calculating the proportion non-conforming. For model (1) the inflation factor is $c = s_t/s_w$ and it clearly shows the contribution of non-random shift to the process variation. For a shift of size $a s_w$ at subgroup $t_0 + 1$, the inflation factor is listed in Table 2. Harry (1997) states that most values of the inflation factor c are in between 1.4 and 1.8, but this is only true for model (1) with large shifts. To inflate the standard deviation with 1.5 seems more than enough to compensate for shifts.

	Shift sizes *a*						
Moments $(k - t_0)/k$	**0.25**	**0.5**	**0.75**	**1**	**1.5**	**2**	**5**
0.10	1.00	1.01	1.03	1.04	1.10	1.17	1.80
0.25	1.01	1.02	1.05	1.09	1.19	1.32	2.38
0.50	1.01	1.03	1.07	1.12	1.25	1.41	2.69
0.75	1.01	1.02	1.05	1.09	1.19	1.32	2.38
0.90	1.00	1.01	1.03	1.04	1.10	1.17	1.80

Table 2: Inflation factor c for shifts of size $a s_w$ at moments t_0.

In practice we have to deal with estimates that show sampling variation. For model (1), typical estimates are the overall average as an estimate for m, the pooled standard deviation for $ó_w$ and the total standard deviation for $ó_t$. In formula the estimates are

$$(4) \qquad \overline{\overline{Y}} = \frac{1}{k}\sum_{i=1}^{k}\overline{Y}_i, \; s_p = \sqrt{\frac{1}{k}\sum_{i=1}^{k}s_i^2} \; \text{ and } \; s_t = \sqrt{\frac{1}{nk-1}\sum_{i=1}^{k}\sum_{j=1}^{n}\left(Y_{ij} - \overline{\overline{Y}}\right)^2},$$

with $\overline{Y}_i$ and s_i the average and standard deviation of subgroup *i*. The inflation factor may be estimated with $\hat{c} = s_t/s_p$ and hypothesis testing gives us the critical value (or inflation factor) for rejecting the null-hypothesis: "No shifts or drifts have occurred in model (1)". For $a = 0.05$, the inflation factor is listed in Table 3 for different numbers of subgroups and items per subgroup. It shows that the inflation factor is larger than 1.5 only for small number of samples. For model (1) it is more appropriate to use $\overline{X}$-charts and inflation factors of Table 3 to judge an out-of-control situation.

For model (3) non-random shifts or drifts and the (process inherent) random shifts may not be separated easily (and certainly not using the estimates in (4)), since the between subgroup variance is

$s_b^2 + s_{shift}^2$. For a stable and centered process ($m = M$) with no technology problem ($Z_{st} \geq 6$), the inflation factor $c = s_t / s_w$ must be less than 1.3 for a proportion non-conforming less than 3.4 ppm.

	Number of subgroups								
Number of items	**2**	**3**	**4**	**5**	**10**	**15**	**20**	**25**	**30**
2	2.61	2.10	1.84	1.69	1.40	1.30	1.25	1.21	1.19
3	1.53	1.43	1.36	1.31	1.20	1.15	1.13	1.11	1.10
4	1.31	1.26	1.22	1.20	1.13	1.10	1.09	1.08	1.07
5	1.22	1.19	1.16	1.14	1.10	1.08	1.07	1.06	1.05
10	1.09	1.08	1.07	1.06	1.04	1.04	1.03	1.03	1.02

Table 3: Estimates of the inflation factor for model (1) that is in statistical control.

Table 4 shows the critical value of the estimated inflation factor $\hat{c}$ if c =1.3. For smaller values of c the results in Table 4 will be smaller too. Note that the values of Table 4 do not depend on the short-term performance, only the criterion 1.3 does. For model (3), we may use the inflation factor of Table 4 to show either a control problem (non-random shift or changes to s_b) or to find out that the between subgroup variation is too large even if the short-term variation reaches the value 6 and the process is centered. In addition, control charts help understanding the process state.

	Number of subgroups								
Number of items	**2**	**3**	**4**	**5**	**10**	**15**	**20**	**25**	**30**
2	3.92	3.11	2.70	2.46	1.98	1.82	1.73	1.67	1.63
3	2.35	2.17	2.03	1.94	1.72	1.63	1.58	1.55	1.53
4	2.02	1.93	1.85	1.79	1.64	1.57	1.53	1.51	1.49
5	1.88	1.82	1.77	1.72	1.60	1.54	1.51	1.49	1.47
10	1.67	1.66	1.63	1.61	1.53	1.49	1.46	1.45	1.44

Table 4: Estimates of the inflation factor for c=1.3 and model (3) in statistical control.

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RESUME

The criterion 1.5 for Z_{shift} does not coincide with the view of process control according to SPC and the Z_{shift} is a mix of the inflation factor, the short-term process capability and a fixed distance of the process average to the center of the specification area. The inflation factor is more transparent to judge out-of-control, but we recommend its use additional to control charts. The criteria for the inflation factor depend on the statistical model that describes the process and on the sample size. For processes with between subgroup variation inherent to the process, goals on the short-term capability and the process centering should be formulated first before a criterion for the inflation factor may be set.