Normalized Individuals (I_N) Control Chart

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Abstract: The only commonly used control chart that cannot be normalized is the Individuals (I) chart. A procedure called a Normalized Individuals (I_N) chart is provided for normalizing data associated with an I chart. The I_N chart works nearly identical to the Laney U' and P' charts for count data. The I_N chart has certain theoretical advantages as the estimates of the standard deviation remain unbiased in all situations where the process is stable. The I_N chart also has the advantage that it can be used for other applications not involving counts.

1.0 Introduction

$\bar{X}$-S, U, P, Laney U' and Laney P' control charts all allow the charts to be normalized based on the sample size or number of opportunities. The only commonly used control chart that cannot be normalized is the Individuals (I) chart. A procedure called a Normalized Individuals (I_N) chart is provided for normalizing data associated with an I chart. This chart has been implemented in Taylor (2017c), including an Excel spreadsheet.

Donald Wheeler (2011) recommends an I chart for handling count data, which he refers to as an XmR chart:

> "In contrast to this use of theoretical models which may or may not be correct, the XmR chart provides us with empirical limits that are actually based upon the variation present in the data. This means that you can use an XmR chart with count-based data anytime you wish. Since the p-chart, the np-chart, the c-chart, and the u-chart are all special cases of the chart for individual values, the XmR chart will mimic these specialty charts when they are appropriate and will differ from them when they are wrong."

David Laney (2002) points out that the I chart cannot be normalized to account for differences in sample size or opportunities, resulting in constant control limits. He provides the Laney U' and P' charts that address this issue for count data. The I_N chart works nearly identical to the Laney U' and P' charts for count data, so is equally effective at addressing the constant limits concern. The I_N chart has certain theoretical advantages as the estimates of the standard deviation remain unbiased in all situations where the process is stable.

The I_N chart also has the advantage that it can be used for other applications not involving counts. This includes control charts of lots with between lot variation and unequal sample sizes. It also includes control charts of stability data for out of trend values with unequal time periods.

The $\bar{X}$ and I_N control charts handle most needs, simplifying the selection of a control chart.

2.0 Individuals (I) Chart for the Normal Distribution

The I chart is the basis for the other procedures provided. Assume the values are represented by X_1, X_2, …, X_n, where the X_i are independent normal with common standard deviation σ. They may have different means.

$$X_i \sim N(\mu_i, \sigma)$$

The averages μ_i are subject to 1 or more shifts. This means $\mu_i = \mu_{i+1}$ in most cases except possibly for a small number of instances where a mean shift occurs.

ESTIMATING THE STANDARD DEVIATION

Because the average may shift 1 or more times, the total standard deviation of the X_i may overestimate σ. A more robust estimator of σ is based on $X_i - X_{i-1}$, which has distribution $X_i - X_{i-1} \sim N\left(\mu_i - \mu_{i-1}, \sigma\sqrt{2}\right)$. In most cases $\mu_i = \mu_{i-1}$, so:

$$\frac{X_i - X_{i-1}}{\sigma\sqrt{2}} \sim N(0,1)$$

As a result, $\frac{|X_i - X_{i-1}|}{\sigma\sqrt{2}}$ has the standard half-normal distribution with:

Mean:	$\sqrt{\frac{2}{\pi}}$
Median:	$\Phi^{-1}(0.75)$
Standard Deviation:	$\sqrt{1-\frac{2}{\pi}}$

When $\mu_i = \mu_{i-1}$, this results in the following unbiased estimates of the standard deviation σ:

$$S_i = \frac{\frac{|X_i - X_{i-1}|}{\sqrt{2}}}{\sqrt{\frac{2}{\pi}}} = \frac{\sqrt{\pi}}{2}|X_i - X_{i-1}| = \frac{R_i}{d_2}$$

where $R_i = |X_i - X_{i-1}|$ and the constant $d_2 = \frac{2}{\sqrt{\pi}} = 1.128379167$. This results in the following estimate of the standard deviation:

$$\bar{S} = \text{Average}(S_2, S_3, \cdots, S_n) = \frac{\bar{R}}{d_2} \quad \text{where} \quad \bar{R} = \text{Average}(R_2, R_3, \cdots, R_n)$$

$\bar{S}$ is an unbiased estimate of σ so long as no shifts occur. If shifts occur some of the S_i are biased. A more robust, but slightly less powerful, estimate of σ is:

$$\tilde{S} = \frac{\sqrt{\frac{2}{\pi}}}{\Phi^{-1}(0.75)} \text{Median}\left(S_2, S_3, \cdots, S_n\right)$$
$$= \frac{\sqrt{\frac{2}{\pi}}}{\Phi^{-1}(0.75)} \frac{\text{Median}\left(R_2, R_3, \cdots, R_n\right)}{d_2} = \frac{\text{Median}\left(R_2, R_3, \cdots, R_n\right)}{\sqrt{2}\,\Phi^{-1}(0.75)}$$

CONTROL LIMITS FOR THE INDIVIDUALS (I) CHART

Control limits are the average plus and minus 3 standard deviations of the values being plotted. For an I chart the values X_i are plotted. The estimated average of the X_i is:

$$\bar{X} = \frac{X_1 + X_2 + \ldots + X_n}{n}$$

Using the estimates of σ from the previous section:

$$CL = \bar{X} \pm 3\,\bar{S}$$
$$= \bar{X} \pm 3\,\frac{\bar{R}}{d_2} = \bar{X} \pm 2.659574468\,\bar{R}$$

$$CL = \bar{X} \pm 3\,\tilde{S}$$
$$= X \pm 3 \frac{\text{Median}\left(R_2, R_3, \cdots, R_n\right)}{\sqrt{2}\,\Phi^{-1}(0.75)} = \bar{X} \pm 3.145074248\,\text{Median}\left(R_2, R_3, \cdots, R_n\right)$$

CONTROL LIMITS FOR THE MOVING S CHART

For the Moving S chart S_i are plotted. S_i has:

$$E\left\{S_i\right\} = \sigma \qquad SD\left\{S_i\right\} = \sigma \frac{\sqrt{1-\frac{2}{\pi}}}{\sqrt{\frac{2}{\pi}}} = \sigma\sqrt{\frac{\pi}{2}-1}$$

$$UCL\left\{S_i\right\} = \left(1 + 3\sqrt{\frac{\pi}{2}-1}\right)\bar{S} = 3.266531919\,\bar{S}$$

$\tilde{S}$ can be substituted for $\bar{S}$ in the above equation.

Table 1: Control Limits for Individuals (I) Chart

Type of Chart	Estimator	Formulas
Individuals Chart: Plot of values X_i Uses: $\bar{X} = \frac{X_1 + X_2 + ... + X_n}{n}$	$\bar{S}$	$\bar{S} = \text{Average}(S_2, S_3, \cdots, S_n)$ $CL = \bar{X} \pm 3\,\bar{S}$
	$\tilde{S}$	$\tilde{S} = \sqrt{\frac{2}{\pi}} \frac{1}{\Phi^{-1}(0.75)} \text{Median}(S_2, S_3, \cdots, S_n)$ $CL = \bar{X} \pm 3\tilde{S}$
	$\bar{R}$	$\bar{R} = \text{Average}(R_2, R_3, \cdots, R_n)$ $CL = \bar{X} \pm \frac{3\sqrt{\pi}}{2}\,\bar{R} = \bar{X} \pm 2.659574468\,\bar{R}$
	$\tilde{R}$	$\tilde{R} = \text{Median}(R_2, R_3, \cdots, R_n)$ $CL = X \pm 3\frac{\tilde{R}}{\sqrt{2}\,\Phi^{-1}(0.75)}$ $= \bar{X} \pm 3.145074248\,\tilde{R}$
Moving S Chart: Plot of $S_i = \frac{\sqrt{\pi}}{2}\lvert X_i - X_{i-1}\rvert$	$\bar{S}$	$UCL = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\bar{S} = 3.266531919\,\bar{S}$
	$\tilde{S}$	$UCL = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\tilde{S} = 3.266531919\,\tilde{S}$
Moving Range Chart: Plot of $R_i = \lvert X_i - X_{i-1}\rvert$	$\bar{R}$	$UCL = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\bar{R} = 3.266531919\,\bar{R}$
	$\tilde{R}$	$UCL = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\frac{\sqrt{\frac{2}{\pi}}}{\Phi^{-1}(0.75)}\tilde{R} = 3.864128973\,\tilde{R}$

Note that the Moving S and Moving R charts differ by a factor of d_2 and provided essentially the same information. However, the estimates $\bar{S}$ and $\tilde{S}$ are handier for other applications including estimating process capability, so the Moving S chart is preferred.

CONTROL LIMITS FOR THE MOVING R CHART

For the Moving R chart $R_i = d_2 S_i$ are plotted. The control limits are similarly scaled by d_2:

$$UCL\{R_i\} = d_2 UCL\{S_i\} = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\bar{R} = 3.266531919\,\bar{R}$$

$$UCL\{R_i\} = d_2 UCL\{S_i\} = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\sqrt{\frac{2}{\pi}}\frac{1}{\Phi^{-1}(0.75)}\text{Median}\left(R_2, R_3, \cdots, R_n\right)$$
$$= 3.864128973\,\text{Median}\left(R_2, R_3, \cdots, R_n\right)$$

The lower control limits of the moving S and R charts are negative.

3.0 Normalized Individuals (I_N) Chart for the Normal Distribution

The Normalized Individuals (I_N) chart assumes instead:

$$X_i \sim N\left(\mu_i O_i, \sigma\sqrt{O_i}\right)$$

The I chart is a special case of the I_N chart with $O_1 = O_2 = \cdots = O_n = 1$. The O_i represent the sample size or number of opportunities that the X_i are based on. The relationship between the average and standard deviation above is based on the effect of addition. Assume $X = Y_1 + Y_2 + Y_3 + \cdots + Y_O$. Assuming the Y's are independent, regardless of the distribution of the Y's, $\mu_X = \mu_Y O$ and $\sigma_X = \sigma_Y \sqrt{O}$. $\mu_i = \mu_{i-1}$ in most cases, except possibly for a small number of instances where a mean shift occurs.

The normalized values are then:

$$N_i = \frac{X_i}{O_i} \sim N\left(\mu_i, \frac{\sigma}{\sqrt{O_i}}\right)$$

The normalized values N_i are plotted on the I_N chart.

ESTIMATING THE STANDARD DEVIATION

Because the average may shift 1 or more times, the total standard deviation of the N_i will overestimate σ if there are shifts in the average. A more robust estimate of σ is based on:

$$N_i - N_{i-1} \sim N\left(\mu_i - \mu_{i-1}, \sigma\sqrt{\frac{1}{O_i} + \frac{1}{O_{i-1}}}\right)$$

In most cases $\mu_i = \mu_{i-1}$, so:

$$\frac{N_i - N_{I-1}}{\sigma\sqrt{\frac{1}{O_i}+\frac{1}{O_{i-1}}}} \sim N(0,1)$$

$$\frac{\left|N_i - N_{I-1}\right|}{\sigma\sqrt{\frac{1}{O_i}+\frac{1}{O_{i-1}}}}$$ has the standard half-normal distribution

When $\mu_i = \mu_{i-1}$, this results in the following unbiased estimates of the standard deviation σ:

$$S_i = \sqrt{\frac{\pi}{2}}\frac{\left|N_i - N_{I-1}\right|}{\sqrt{\frac{1}{O_i}+\frac{1}{O_{i-1}}}}$$

This results in the following estimate of the standard deviation:

$$\bar{S} = \text{Average}\left(S_2, S_3, \cdots, S_n\right)$$

$\bar{S}$ is an unbiased estimate of *σ* so long as no shifts occur. If shifts occur some of the S_i are biased. A more robust, but slightly less powerful, estimate of σ is:

$$\tilde{S} = \sqrt{\frac{2}{\pi}}\frac{\text{Median}\left(S_2, S_3, \cdots, S_n\right)}{\Phi^{-1}(0.75)}$$

CONTROL LIMITS FOR THE NORMALIZED INDIVIDUALS (I_N) CHART

Control limits are the average plus and minus 3 standard deviations of the statistic being plotted. For the I_N chart the values N_i are plotted. The estimated average of the N_i is:

$$\bar{N} = \frac{X_1 + X_2 + \ldots + X_n}{O_1 + O_2 + \ldots + O_n}$$

Using the estimates of σ from the previous section the control limits for the i^th point are:

$$CL_i = \bar{N} \pm 3\frac{\bar{S}}{\sqrt{O_i}} \qquad \text{or} \qquad CL_i = \bar{N} \pm 3\frac{\tilde{S}}{\sqrt{O_i}}$$

CONTROL LIMITS FOR THE NORMALIZED MOVING S CHART

For the Normalized Moving S chart S_i are plotted. S_i has:

$$E\{S_i\} = \sigma \qquad SD\{S_i\} = \sigma\sqrt{\frac{\pi}{2}-1}$$

$$UCL\{S_i\} = \left(1+3\sqrt{\frac{\pi}{2}-1}\right)\bar{S} = 3.266531919\,\bar{S}$$

$\tilde{S}$ can be substituted for $\bar{S}$ in the above equation. The lower control limits of the normalized moving S chart are negative. Based on:

$$\frac{S_i}{\sigma}\sqrt{\frac{2}{\pi}} \sim \text{Half-normal}(0,1) \text{ with distribution function } F(x) = 1-2\Phi(-x)$$

$$\left(\frac{S_i}{\sigma}\sqrt{\frac{2}{\pi}}\right)^2 \sim \chi_1^2$$

Exact control limits using $\Phi(-3)$ = 0.0013498980316301 and $\Phi(3)$ = 0.99865010196837 percentiles are:

$$LCL\{S_i\} = -\Phi^{-1}\left(\frac{1-\Phi(-3)}{2}\right)\sqrt{\frac{\pi}{2}}\,\bar{S} = \sqrt{\chi_1^{2^{-1}}(\Phi(-3))}\sqrt{\frac{\pi}{2}}\,\bar{S} = 0.00212041588119265\,\bar{S}$$

$$UCL\{S_i\} = -\Phi^{-1}\left(\frac{1-\Phi(3)}{2}\right)\sqrt{\frac{\pi}{2}}\,\bar{S} = \sqrt{\chi_1^{2^{-1}}(\Phi(3))}\sqrt{\frac{\pi}{2}}\,\bar{S} = 4.01706597427291\,\bar{S}$$

$\tilde{S}$ can be substituted for $\bar{S}$ in the above equation.

4.0 Comparison to Laney U' Chart

The Laney U' chart has control limits:

$$CL_i = \bar{N} \pm 3\,\sigma_Z\sqrt{\frac{\bar{N}}{O_i}}$$

The resulting estimate of the standard deviation is:

$$\hat{S} = \sigma_Z\sqrt{\bar{N}} = \sqrt{\bar{N}}\frac{\sum_{i=2}^{n}\left|\frac{N_i-\bar{N}}{\sqrt{\frac{\bar{N}}{O_i}}} - \frac{N_{i-1}-\bar{N}}{\sqrt{\frac{\bar{N}}{O_{i-1}}}}\right|}{d_2(n-1)} = \frac{\sqrt{\pi}}{2}\frac{\sum_{i=2}^{n}\left|\frac{N_i-\bar{N}}{\sqrt{\frac{1}{O_i}}} - \frac{N_{i-1}-\bar{N}}{\sqrt{\frac{1}{O_{i-1}}}}\right|}{(n-1)}$$

Compare this to the estimate of the standard deviation for the I_N chart:

$$\bar{S} = \frac{\sum_{i=2}^{n} S_i}{(n-1)} = \sqrt{\frac{\pi}{2}}\frac{\sum_{i=2}^{n}\frac{|N_i-N_{i-1}|}{\sqrt{\frac{1}{O_i}+\frac{1}{O_{i-1}}}}}{(n-1)}$$

Table 2: Control Limits for Normalized Individuals (I_N) Chart

Type of Chart	Estimator	Formulas
Normalized Individuals Chart: Plot of $N_i = \frac{X_i}{O_i}$ Uses: $\bar{N} = \frac{X_1 + X_2 + \ldots + X_n}{O_1 + O_2 + \ldots + O_n}$	$\bar{S}$	$\bar{S} = \text{Average}\left(S_2, S_3, \cdots, S_n\right)$ $CL_i = \bar{N} \pm 3\frac{\bar{S}}{\sqrt{O_i}}$
	$\tilde{S}$	$\tilde{S} = \frac{\sqrt{\frac{2}{\pi}}}{\Phi^{-1}(0.75)}\text{Median}\left(S_2, S_3, \cdots, S_n\right)$ $CL_i = \bar{N} \pm 3\frac{\tilde{S}}{\sqrt{O_i}}$
Normalized Moving S Chart: Plot of $S_i = \sqrt{\frac{\pi}{2}}\frac{\left\|N_i - N_{I-1}\right\|}{\sqrt{\frac{1}{O_i} + \frac{1}{O_{i-1}}}}$	$\bar{S}$	$UCL = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\bar{S} = 3.266531919\,\bar{S}$
	$\tilde{S}$	$UCL = \left(1 + 3\sqrt{\frac{\pi}{2} - 1}\right)\tilde{S} = 3.266531919\,\tilde{S}$

When the O_i are all equal, the two estimates are equivalent.

$$\bar{S} = \hat{S} = \frac{\sqrt{\pi}}{2}\sqrt{O}\,\frac{\sum_{i=2}^{n}\left|N_i - N_{i-1}\right|}{(n-1)}$$

The two estimates differ with how they handle a changing number of opportunities.

$\bar{S}$ is an unbiased estimate, as previously shown. $\hat{S}$ can be biased. This is due to the fact that the correction factor d_2 assumes the two items subtracted are independent of each other. They are not independent because they include the common term $\bar{N}$. For larger sets of data, the estimate $\bar{N}$ is more precise and the two parts are nearly independent.

Table 3 shows the performance of the following two estimators for the case where the standard deviation is 1. Different combinations of O_1, O_2 and O_3 are shown. O_3 is the number of opportunities for all the other data points combined.

Laney: $\hat{S}_2 = \frac{\sqrt{\pi}}{2}\left|\frac{N_2 - \bar{N}}{\sqrt{\frac{1}{O_2}}} - \frac{N_1 - \bar{N}}{\sqrt{\frac{1}{O_1}}}\right|$ Taylor: $\bar{S}_2 = \sqrt{\frac{\pi}{2}}\frac{|N_2 - N_1|}{\sqrt{\frac{1}{O_2} + \frac{1}{O_1}}}$

Table 3: Comparison of Laney and Taylor Estimators of the Moving Standard Deviation

			$\hat{S}_2$		$\bar{S}_2$	
O_1	O_2	O_3	Average	SD	Average	SD
1	1	1	1.000	0.756	1.000	0.756
1	10	1	0.897	0.658	1.000	0.756
1	1	10	1.000	0.756	1.000	0.756
1	10	10	0.943	0.712	1.000	0.756
1	1	100	1.000	0.756	1.000	0.756
1	10	100	0.989	0.748	1.000	0.756
1	1	1000	1.000	0.756	1.000	0.756
1	10	1000	0.999	0.755	1.000	0.756

Table 3 was generated using simulations of 100,000,000 trials each, giving 4 digits of precision. Only 3 digits are shown. Table 1 confirms:

- $\bar{S}_2$ is unbiased.
- $\hat{S}_2$ = $\bar{S}_2$, and thus unbiased when $O_1 = O_2$.
- $\hat{S}_2$ is biased when $O_1 \neq O_2$. However, this bias is 1% or less when $O_1 \neq O_2 << O_3$.

While $\bar{S}_2$ is the theoretically better estimator, for all practical purposes the two estimators perform the same. Either can be used.

One nice feature of the Laney U' chart is that σ_Z is a useful measure of overdispersion. A value close to 1 suggests a U chart could be used. For an I_N chart, σ_Z could be defined as below for applications involving normalized count data:

$$\sigma_Z = \frac{\bar{S}}{\sqrt{\bar{N}}}$$

It is common practice to use a pair of charts to show the average and variation ($\bar{X}$-S, I-MSD). Similarly, a Laney U' or P' chart can be paired with a moving σ_Z chart.

5.0 Examples of Applications

COMPLAINT DATA

The first set of data is the complaint data shown in Table 4. There are 20 values. The sales volume, representing the number of opportunities, steadily increases. The data is overdispersed relative to the Poisson distribution with about half the points falling outside the control limits on a U-chart.

Table 4: Example Complaint Data

Month	Complaints (X_i)	Sales Volume (O_i)	Normalized Complaints Rates (N_i)
1	426	90000	0.004733333
2	543	110000	0.004936364
3	428	90000	0.004755556
4	67	40000	0.001675
5	303	60000	0.00505
6	481	70000	0.006871429
7	304	90000	0.003377778
8	718	120000	0.005983333
9	681	150000	0.00454
10	1030	210000	0.004904762
11	704	190000	0.003705263
12	1062	250000	0.004248
13	1085	220000	0.004931818
14	1311	210000	0.006242857
15	1309	230000	0.005691304
16	1342	220000	0.0061
17	1740	310000	0.005612903
18	1468	330000	0.004448485
19	1364	320000	0.0042625
20	1824	330000	0.005527273

Figure 1 shows the Laney U' Chart and Figure 2 shows the I_N chart of this data. They are nearly identical and result in the same conclusion that the complaint rate is unchanged. SigmaZ values are also shown, which are similar. The two charts use different estimators of the standard deviation, so there will be slight differences between the 2 charts for each individual set of data. The I_N chart can be used anytime a Laney U' or P' chart can be used.

A Normalized Moving S chart is shown in Figure 3. A Moving σ_z chart can be added to a Laney U' chart. Figure 4 shows a moving σ_z chart for the complaint data. It looks nearly identical to the Normalized Moving S chart in Figure 3, except for the scale. The

I_N chart also has an option of using the median rather than average to estimate the standard deviation. This option can also be extended to the Laney U' chart.

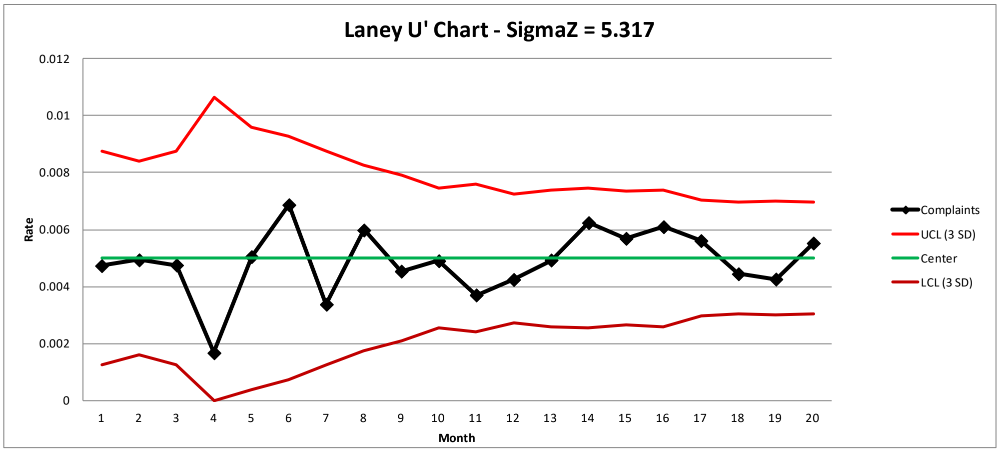

Figure 1: Laney U' Chart of Complaint Data

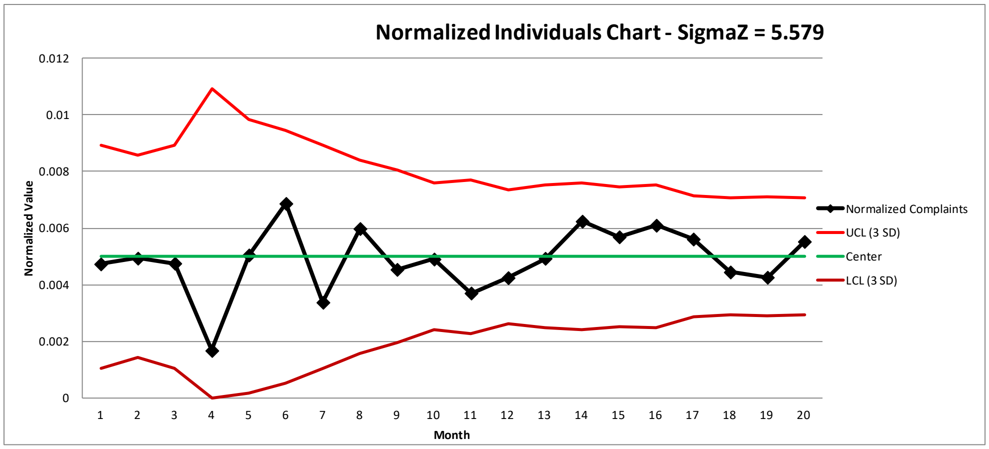

Figure 2: I_N Chart of Complaint Data

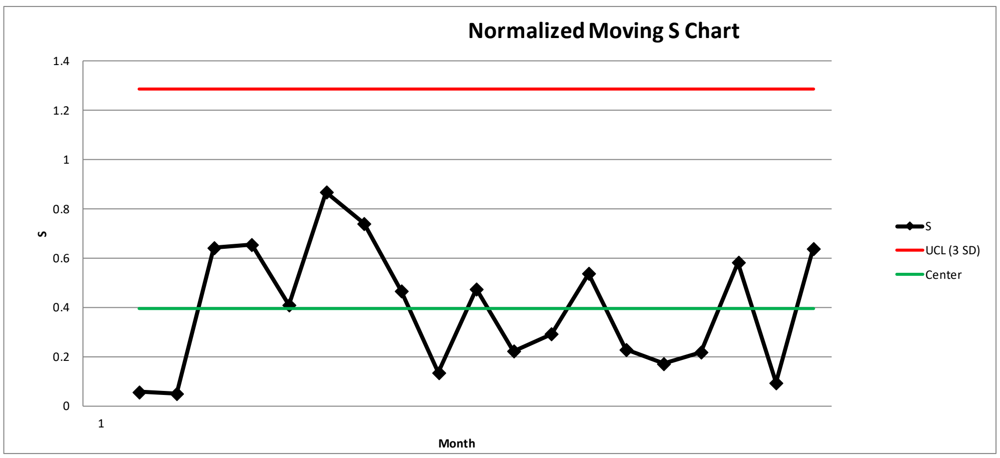

Figure 3: Normalized Moving S Chart of Complaint Data

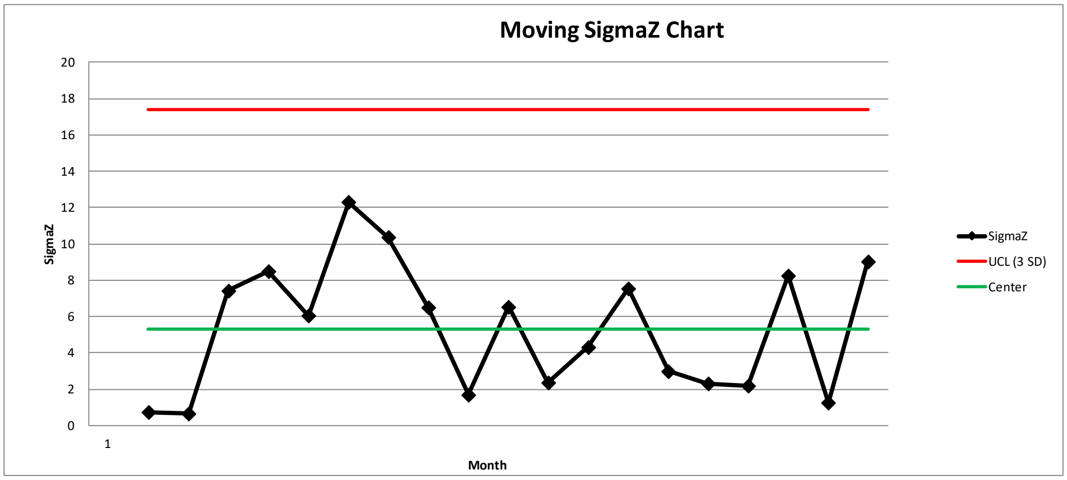

Figure 4: Moving SigmaZ Chart of Complaint Data

BETWEEN/WITHIN LOT VARIATION

While for count data the Laney U' and I_N charts are interchangeable, there are many other applications of the I_N chart to non-count data where only the I_N chart is applicable.

For example, the $\overline{X}$ chart assumes there is a single source of variation. An alternative model better fitting some processes is the between/within lot variation model. This model assumes there are two sources of variation, one for the lot averages and one for individual units within a lot around the lot average. An I chart of the lot averages is recommended in this case. However, if the sample size varies from lot-to-lot, an I_N chart is more appropriate. Table 5 shows an example set of data. Figure 5 shows an I_N chart of lot averages where some averages are based on 5 samples and other 13.

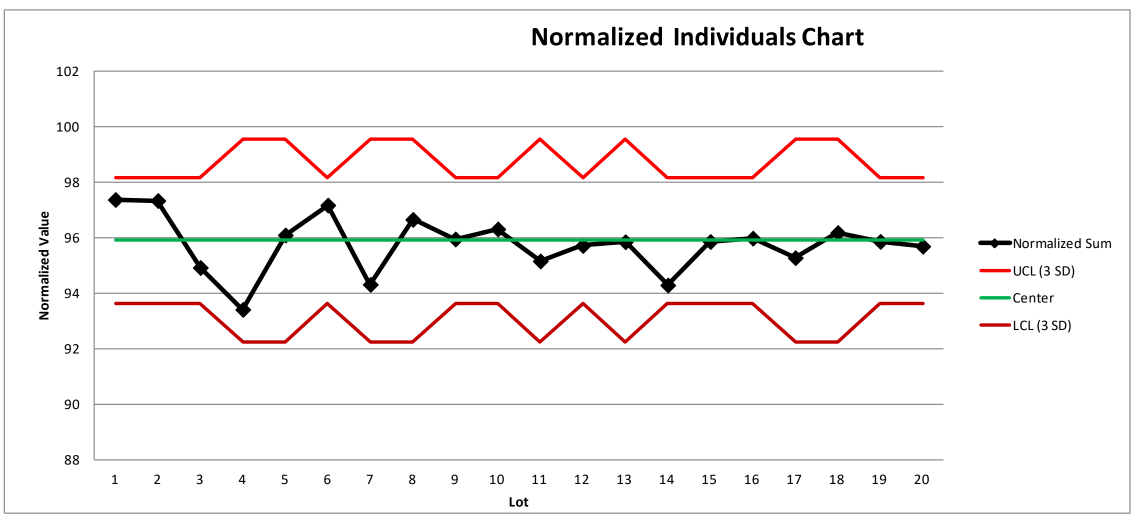

Figure 5: I_N Chart of Lot Averages with Unequal Sample Sizes

Table 5: Example Between Lot Variation Data

Lot	Value (Sum)	N	Normalized Value (Average)
1	1265.983327	13	97.38333286
2	1265.494062	13	97.34569709
3	1234.095432	13	94.93041783
4	467.0938368	5	93.41876736
5	480.5207487	5	96.10414975
6	1263.362522	13	97.18173242
7	471.6089798	5	94.32179597
8	483.3272231	5	96.66544462
9	1247.482101	13	95.96016158
10	1252.155511	13	96.31965468
11	475.8327811	5	95.16655622
12	1244.424527	13	95.72496359
13	479.2992493	5	95.85984986
14	1225.883257	13	94.29871211
15	1246.284863	13	95.86806642
16	1247.863834	13	95.98952569
17	476.4285921	5	95.28571841
18	480.9507213	5	96.19014427
19	1246.33594	13	95.8719954
20	1244.075692	13	95.69813015

Table 6: Example Stability Data

Month	Value
0	100.8281
3	99.8719
6	99.16905
9	98.08248
12	98.12253
18	94.95572
24	93.00887
36	88.96801
48	85.21958

LINEAR TRENDS WITH UNEQUAL INTERVALS

Another application is when there is a linear trend over time but values are collected at unequal intervals. An example is the detection of out of trend (OOT) values during a stability study where data is collected at times 0, 3, 6, 9, 12, 18, 24, 36 and 48 months. Table 6 shows an example set of data.

Figure 6 shows a linear regression of the data. The twelve-month data point appears to be higher than expected, however, falls within the 95% prediction interval. Flagging a point outside the 95% prediction interval is a poor approach to detecting OOT values. It would result in a false signal for around 5% of the stability points. This translates to close to 50% of stability studies signaling an OOT point. Further, the OOT value has widened the prediction interval so it does not fall outside them. Robust regression estimators could solve the second issue but not the first.

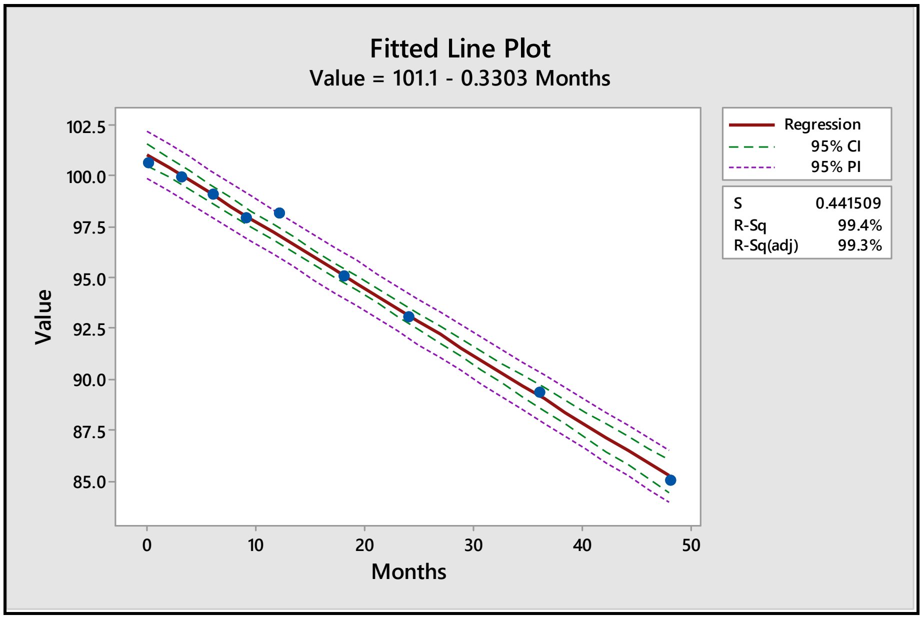

Figure 6: Linear Regression of Stability Data

Before trending the data on an I_N chart, the differences between consecutive values must be calculated as shown in Table 7. When this is done, the normalized values are the slopes.

Table 7: Changes and Slopes of Example Stability Data

Month	Change	Length Interval	Normalized Change (Slope)
3	-0.65563532	3	-0.218545106
6	-0.85848342	3	-0.286161138
9	-1.17796488	3	-0.392654961
12	0.193200231	3	0.064400077
18	-3.09996878	6	-0.516661463
24	-1.98809354	6	-0.331348924
36	-3.72314215	12	-0.310261846
48	-4.31874831	12	-0.359895693

Figure 7 shows the resulting I_N chart. The median standard deviation estimator was used to avoid any OOT point inflating the estimated variation and widening the control limits. It shows the 12-month point is OOT.

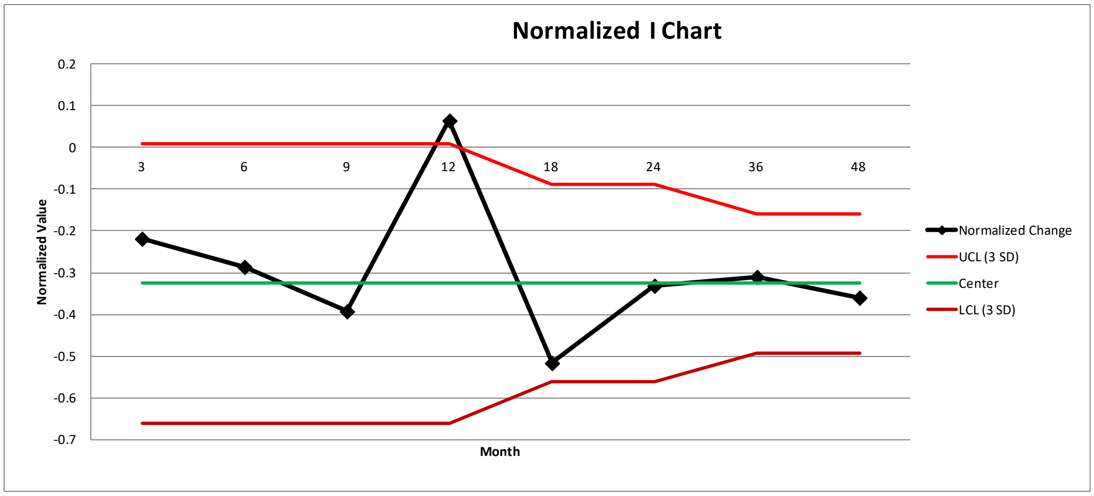

Figure 7: I_N Chart of Changes to Detect Out-Of-Trend Point

It is clear that the assumption $X_i \sim N\left(\mu_i O_i, \sigma\sqrt{O_i}\right)$ applies to the complaint and between lot data. Both are additive sets of data for which this assumption is assured to be met. It is not as clear it is met for the stability data. There are numerous sources of variation including measurement error, variation in the starting values for each unit and variation in the slopes for each unit. Some of these are constant and some grow linearly with time. Combining all these sources of variation results in something somewhere in between, making the assumption reasonable.

6.0 Conclusions

Based on the methods and comparisons presented, the following recommendations are made relative to control charting practice:

- The I_N chart handles count and pass/fail data where a Laney U' or P' chart might be used. It also handles many other situations involving non-count data where a Laney U' or P' chart do not apply.
- The I_N chart can replace the I, U, C, P, NP, Laney U' and Laney P' charts. The $\bar{X}$ and I_N charts handle most needs, simplifying the selection of a chart. These are the only 2 charts needed in most cases. The decision between them is based on whether there are multiple values per time period or not.
- The exception to this rule is nonnormal data. One such case is when counts are low and follow the binomial or Poisson distributions. In this case U and P charts with adjusted control limits should be used as described in Taylor (2017a, b).
- If the Laney U' or P' chart is used, consider accompanying it with a moving σ_Z chart. It is inconsistent to show $\bar{X}$-S, and I-Moving S charts, but not to do the

same for a Laney U' or P' chart, as they are all based on a time-ordered series of estimates of the standard deviation.

- S and moving S charts are preferable to R and Moving R charts because the estimates $\bar{S}$ and $\tilde{S}$ are useful for other applications including estimating process capability.

7.0 References

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