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Statistical Framework for Planning a Shelf Life Program

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Statistical Framework for Planning a Shelf Life Program

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Abstract

This document outlines a statistical framework for establishing a shelf-life program for components whose performance is measured by the value of a continuous variable such as voltage or function time. The approach applies to both single measurement devices and repeated measurement devices, although additional process control charts may be useful in the case of repeated measurements. The approach is to choose a sample size that protects the margin associated with a particular variable over the life of the component. Deviations from expected performance of the measured variable are detected prior to the complete loss of margin. This ensures the reliability of the component over its lifetime.

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NOMENCLATURE

ARL	Average Run Length
EWMA	Exponentially Weighted Moving Average
LCL	Lower Control Limit
UCL	Upper Control Limit

1. INTRODUCTION

This document outlines a statistical framework for establishing a shelf-life program for components whose performance is measured by the value of a continuous variable such as voltage or function time. The approach applies to both single measurement devices and repeated measurement devices, although additional process control charts may be useful in the case of repeated measurements. Shelf life plans for monitoring Pass/Fail data will be treated in another document.

The primary goal of these shelf life plans is to quickly detect a change that would threaten the component's ability to deliver the desired output within specifications over the required stockpile life of the component.

One type of deviation from nominal can be modeled as a **gradual linear drift**. This is performance that starts at nominal then gradually drifts out of specification as the component ages. Possible causes of linear drift include wear out, corrosion, or other aging phenomena. The purpose of a shelf life plan is to quickly detect unacceptable linear drift so that it can be mitigated before the component data falls outside of specification limits. Phenomena with non-linear drift can likely be bounded by a model with linear drift, so the methods here can be applied more broadly than simple linear drift.

The Model for Linear Drift assumes that the mean of the performance measure changes by an amount (Δ) between each sample. The figure below illustrates the hypothesized model for the mean with linear drift.

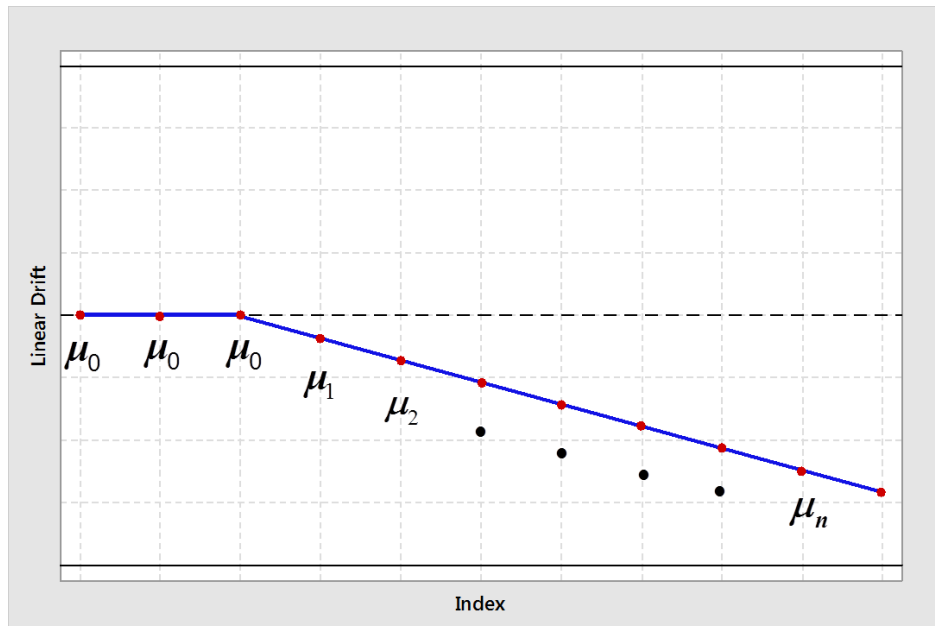


Figure 1. Linear Drift Model

In this figure μ_0 represents the nominal process mean, and μ_i represents the mean at stage i after the drift in the process mean has ensued.

A second type of deviation from nominal that will be treated in this document is a **sudden step change** in the mean. Possible causes of a step change include introduction of a new batch of raw materials during production, new operators, or a new tester. In this case the purpose of the shelf life plan is to quickly detect that a shift has occurred so that the cause of the shift can be identified and mitigated.

The model for a single step change assumes that the mean of the performance measure changes by an amount (Δ) in a single step, then remains at that new mean level. The figure below illustrates the hypothesized model for the mean with a single step change.

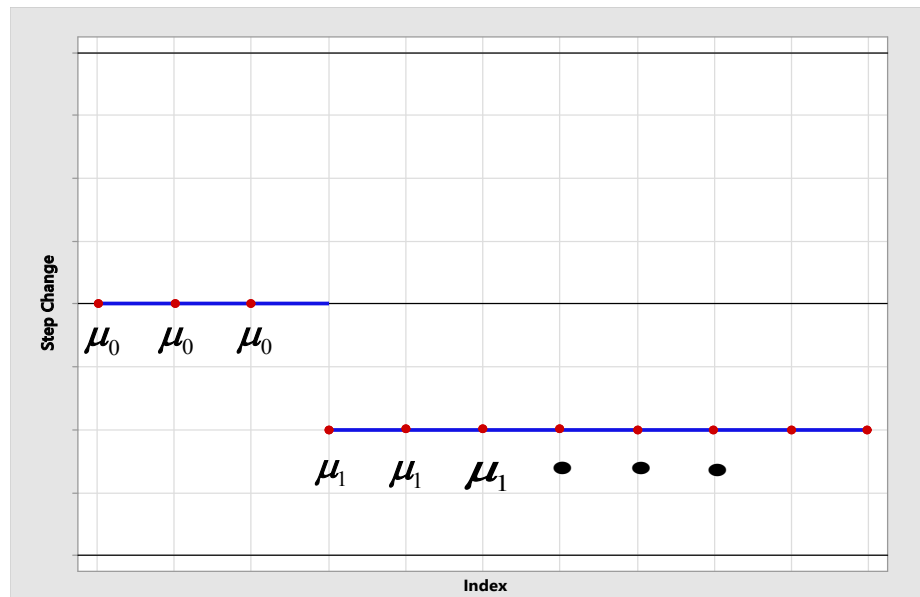


Figure 2. Step Change Model

In this figure μ_0 again represents the nominal process mean, and μ_1 represents the mean after the step change in the process mean has occurred. It is assumed that after the step change the process mean remains at μ_1 .

2. DESIGN STRATEGY

This section gives a straight forward approach to designing a shelf life program to detect either a linear drift or step change in the nominal process mean.

1. Evaluate initial (time zero) process performance (margin) relative to specification limits. Margin here is defined as how much the mean of the performance measure could shift (in multiples of σ) before the tail of the distribution falls outside of specification (see Figure 3). Specifications should thus be known and the required lifetime for the component should be known. If a precise quantitative measure of margin (C_{pk} or k-factor) is not readily available, engineering judgment should be used to determine a conservative bound.
2. Determine what magnitude of change must be quickly detected. Any amount of change (step change or linear drift) that would cause the performance measure to fall out of specification before the required lifetime is met should be detected quickly. This will depend on the amount of initial margin and the required lifetime of the component from Step (1). For example, for the linear drift problem, if the mean has an initial margin of 4σ , the maximum change that could be allowed over a 20-year lifetime requirement would be $(4\sigma/20) = 0.20\sigma$ per year. Thus, an annual change $\geq 0.20\sigma$ would be of concern. For the step change problem, a single step in the process mean $\geq 4\sigma$ at some point during the 20-year window would be of concern.

The figure below gives an example of how to compute the initial margin. In this example, the reliability requirement is $R = 0.98$, so when the 98th percentile of the distribution exceeds the specification limit, the requirement is no longer being met. The initial margin is thus defined as the distance (in units of σ) from the 98th percentile of the initial distribution to the specification limit. In Figure 3, the initial margin is approximately 2.5σ .

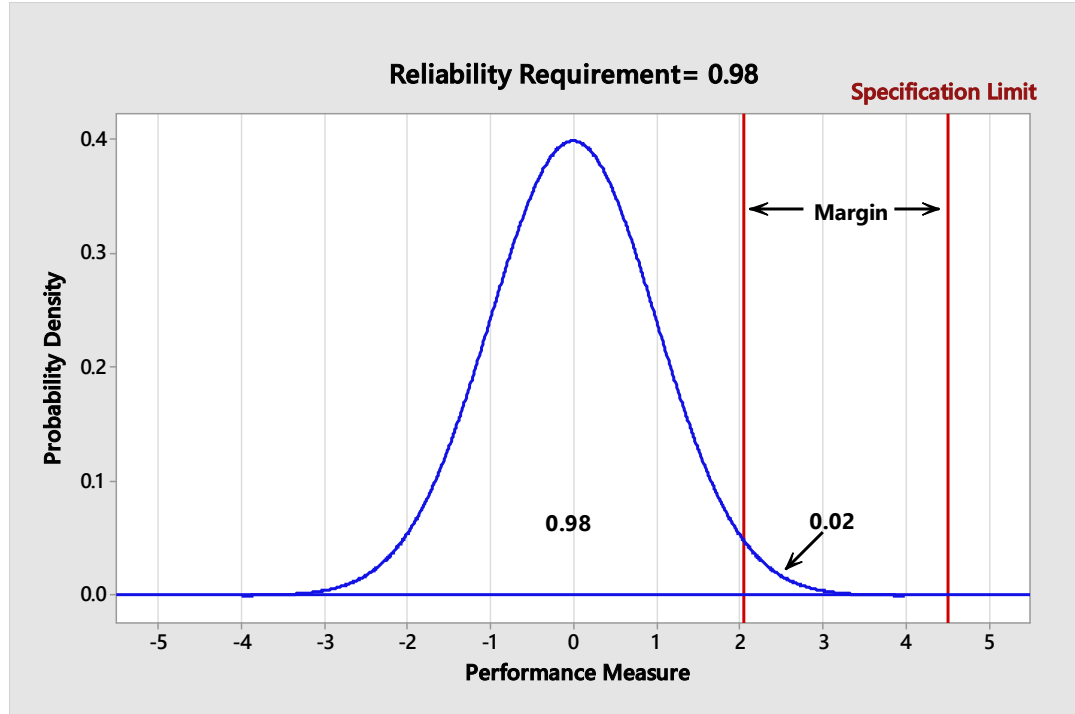


Figure 3. Calculate Initial Margin

A control chart is designed and implemented to monitor the performance measure of interest and quickly detect when an unacceptable shift or linear trend in the mean has occurred. The control chart proposed for this problem is the exponentially weighted moving average (EWMA, See references 1-3). This control chart has been shown in the literature to detect both step changes and linear drift changes more quickly than competing control charts, given the same sample size.

The form of the control chart is given by the expression below. The EWMA at time t , E_t , is a weighted average of the most recent sample average, \bar{y}_t , and the previous value of the EWMA, E_{t-1} .

$$E_t = \lambda \bar{y}_t + (1 - \lambda)E_{t-1} \quad 0 < \lambda \leq 1 \quad t = 1, 2, 3, \dots$$

$$= \lambda \bar{y}_t + (1 - \lambda)\lambda \bar{y}_{t-1} + (1 - \lambda)^2 \lambda \bar{y}_{t-2} + \dots + (1 - \lambda)^{t-1} \lambda \bar{y}_1 + (1 - \lambda)^t E_0$$

The expanded form of the EWMA shows that the most recent data receives the most weight, and the weights decrease exponentially going back in time. The control chart has a center line at the nominal mean, μ_0 , with control limits at the lower control limit (LCL) and upper control limit (UCL) defined as follows:

$$LCL = \mu_0 - L \cdot \frac{\sigma}{\sqrt{n}} \cdot \sqrt{\frac{\lambda}{(2 - \lambda)}}$$

and

$$UCL = \mu_0 + L \cdot \frac{\sigma}{\sqrt{n}} \cdot \sqrt{\frac{\lambda}{(2 - \lambda)}} .$$

The parameters μ_0 and σ are assumed known, and n is the size of each sample. The user chooses the values (λ, L, n) to obtain a specific EWMA performance. The metric of performance for the EWMA is the Average Run Length (ARL), the expected number of samples before the control chart produces a signal (the EWMA falling outside the control limits). As a general rule, small values of λ are used to detect small changes in the mean, and large values of λ are used to detect large changes. The multiplier L is chosen to control the false alarm rate (the ARL when the mean is at nominal) and the sample size n is chosen to improve sensitivity to changes.

Tables of ARLs can be constructed for various choices of (λ, L, n) using simulation techniques. These values can then be used to design the control chart. Tables of ARLs have been constructed for both the step-change problem and the linear drift problem. The tables for the linear drift problem are presented first.

For example, Table 1 below gives ARLs for $(\lambda, L) = (0.20, 1.81)$ and values of n ranging from 1 to 30. These values for λ and L were chosen to result in a nominal false alarm rate of $ARL = 30$. The value $\lambda = 0.20$ is recommended because it is known to provide quick detection of relatively small changes in the mean. The ARL values in the table are then used as described below in the design of the EWMA control chart for linear drift.

Table 1. ARLs for various linear drift values with nominal ARL= 30 ($\lambda= 0.20$, $L= 1.81$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
0.05	12.3	10.3	9.41	8.74	8.23	6.91	6.23	5.75	5.43	5.17
0.10	8.75	7.35	6.56	6.10	5.74	4.79	4.29	3.99	3.75	3.58
0.15	7.10	5.93	5.33	4.95	4.63	3.85	3.47	3.21	3.02	2.89
0.20	6.11	5.10	4.58	4.24	3.97	3.31	2.97	2.76	2.60	2.49
0.25	5.45	4.52	4.05	3.75	3.54	2.94	2.64	2.46	2.32	2.21
0.30	4.92	4.10	3.68	3.42	3.20	2.66	2.41	2.24	2.11	2.03
0.35	4.55	3.77	3.38	3.13	2.95	2.48	2.24	2.07	1.97	1.89
0.40	4.23	3.51	3.14	2.92	2.76	2.31	2.07	1.95	1.86	1.80
0.45	3.96	3.31	2.97	2.75	2.59	2.16	1.97	1.86	1.79	1.71
0.50	3.74	3.13	2.80	2.60	2.47	2.06	1.89	1.78	1.69	1.61
0.55	3.57	2.98	2.67	2.48	2.34	1.98	1.82	1.71	1.60	1.50
0.60	3.41	2.84	2.54	2.37	2.25	1.90	1.76	1.62	1.50	1.40
0.65	3.26	2.73	2.45	2.28	2.15	1.85	1.69	1.55	1.41	1.30
0.70	3.15	2.61	2.35	2.19	2.08	1.80	1.62	1.46	1.31	1.21
0.75	3.03	2.53	2.27	2.11	2.01	1.74	1.54	1.37	1.23	1.13
0.80	2.92	2.44	2.20	2.04	1.94	1.69	1.47	1.28	1.16	1.09
0.85	2.84	2.37	2.14	1.99	1.89	1.63	1.39	1.21	1.11	1.04
0.90	2.75	2.29	2.07	1.95	1.87	1.57	1.33	1.16	1.07	1.03
0.95	2.68	2.24	2.02	1.91	1.83	1.50	1.25	1.12	1.04	1.02
1.00	2.60	2.17	1.97	1.87	1.79	1.44	1.19	1.07	1.02	1.01

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

As an example, a change of magnitude 0.25, with n=4 measurements per sample, has ARL= 3.75. This means that the average number of samples to detection using this EWMA is 3.75. If no change in the mean occurs, a signal will occur approximately every 30 samples (ARL= 30).

Tables of average run lengths for the linear drift problem are included in Appendix A for EWMAs with nominal ARLs 20, 30, 50 and 100, and sample sizes from n=1 to n=30. This will allow some flexibility if the nominal ARL= 30 is not appropriate. A tradeoff is that as the nominal ARL increases, the average number of samples to detection also increases.

Values from Table 1 are displayed graphically below, for changes of size 0.05, 0.25, 0.50, 0.75, and 1.00. This range of values covers what would reasonably be expected in stockpile components. This graph shows a significant decrease in time to detection (ARL) as the sample size increases from 1 to 15, but there is not great improvement from 15 to 30 for these changes. This is seen in the leveling off of each curve beyond sample size fifteen.

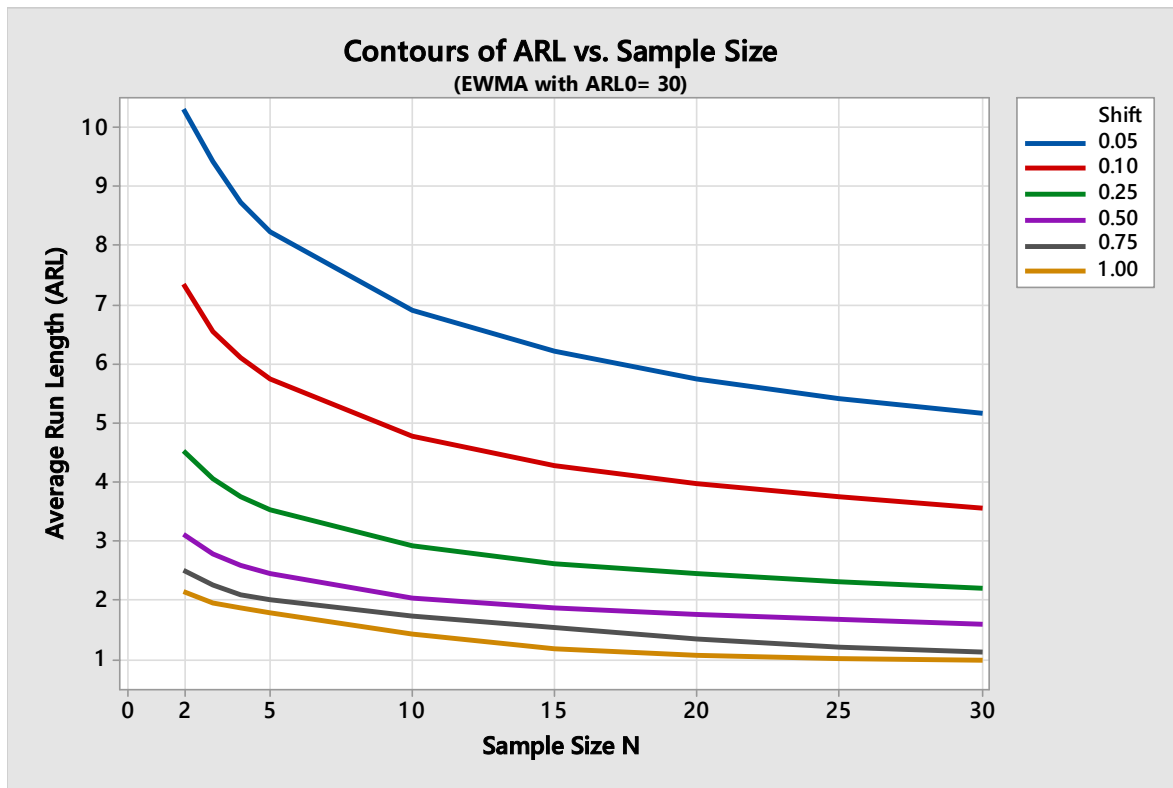


Figure 4. Contours of ARL as a Function of Sample Size – Linear Drift Model

The planning for the linear drift case continues as follows:

3. Choose the appropriate combination of (λ, L, n) . Based on the need to have the Nominal ARL much greater than 20 (assuming sampling is done every year) for stockpile components, a choice of $(\lambda, L) = (0.20, 1.81)$ is recommended. This results in a Nominal ARL of 30, with a high probability that the run length will exceed 20 when the mean is at nominal.
4. Choice of sample size n will depend on the value of Δ that must be detected quickly. In the example above in Step 2, the value $\Delta = 0.20\sigma$ was considered of great importance. In Table 1 above, the time to detection for this value of Δ ranges from ARL= 6.11 ($n=1$) to ARL= 2.49 ($n=30$). Since $n=30$ units per sample will probably not be feasible, a compromise must be made. The choices of $n=3$ and $n=5$ reduce the ARL from 6.11 to 4.58 and 3.97 respectively, and represent a reasonable compromise between time to detection and cost.
5. Based on the above analysis, the EWMA with $(\lambda, L, n) = (0.20, 1.81, 5)$ is recommended. Assuming that sampling is done every year, this means that a change in the mean of $\Delta = 0.20\sigma$ each year will be detected in approximately 4 years. If this is not acceptable, more units must be sampled each year at additional cost.

The control chart design strategy for the single step change case is now presented. Suppose that the initial margin, as defined above, is $\Delta = 0.50\sigma$. Then it is desired to quickly detect any step change of that magnitude or greater.

The table below gives ARLs for $(\lambda, L) = (0.20, 1.81)$ and values of n ranging from 1 to 30. These values for λ and L were chosen because they result in a nominal false alarm rate of $ARL = 30$. The value $\lambda = 0.20$ is again recommended to provide quick detection of relatively small changes in the mean. These values are then used in the design of the EWMA control chart for a single step change.

Table 2. ARLs for various step changes with Nominal $ARL = 30$ ($\lambda = 0.20, L = 1.81$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
0.05	29.0	28.9	28.3	27.9	27.7	24.7	22.7	21.7	20.4	18.9
0.10	27.5	25.7	23.9	23.1	21.4	17.0	14.2	12.3	10.8	9.96
0.15	25.5	22.3	19.8	17.5	16.3	11.6	9.3	7.80	6.75	6.13
0.20	23.0	18.1	15.5	13.7	12.4	8.35	6.45	5.51	4.83	4.38
0.25	19.9	15.4	12.6	10.8	9.48	6.43	5.00	4.29	3.73	3.38
0.30	17.6	13.1	10.4	8.90	7.68	5.11	4.03	3.44	3.03	2.75
0.35	15.6	10.9	8.77	7.34	6.41	4.27	3.39	2.91	2.58	2.37
0.40	13.8	9.45	7.53	6.32	5.52	3.70	2.95	2.54	2.27	2.09
0.45	12.2	8.31	6.51	5.51	4.78	3.24	2.60	2.25	2.03	1.87
0.50	10.8	7.36	5.72	4.85	4.24	2.88	2.33	2.05	1.83	1.67
0.55	9.75	6.51	5.10	4.31	3.82	2.60	2.13	1.87	1.68	1.53
0.60	8.89	5.83	4.61	3.88	3.44	2.39	1.96	1.70	1.54	1.41
0.65	8.12	5.35	4.19	3.57	3.15	2.21	1.81	1.59	1.42	1.28
0.70	7.34	4.87	3.88	3.31	2.93	2.05	1.70	1.47	1.32	1.21
0.75	6.92	4.55	3.57	3.06	2.72	1.92	1.59	1.38	1.23	1.14
0.80	6.30	4.17	3.35	2.86	2.54	1.81	1.50	1.29	1.16	1.08
0.85	5.91	3.91	3.12	2.67	2.39	1.71	1.40	1.21	1.11	1.05
0.90	5.41	3.63	2.93	2.53	2.26	1.62	1.33	1.16	1.07	1.02
0.95	5.17	3.43	2.77	2.39	2.14	1.54	1.26	1.10	1.04	1.01
1.00	4.82	3.26	2.62	2.27	2.03	1.45	1.20	1.07	1.02	1.01

¹Change is defined as the change in the mean in a single step. The change in the mean is expressed in units of the standard deviation. It is assumed the mean continues at the new value until the process is adjusted back to nominal. Step change values greater than 1.0 could occur, but in that case the change will be detected quickly with any reasonable sample size.

As an example, a change of magnitude 0.50, with $n=4$ measurements per sample, has $ARL = 4.85$. This means that the average number of samples to detection using the EWMA is 4.85. If no change in the mean occurs, a signal will occur approximately every 30 samples (false alarm rate is $ARL = 30$).

Tables of average run lengths for the step change problem are included in Appendix B for EWMA's with nominal ARLs 20, 30, 50 and 100, and samples sizes from $n=1$ to $n=30$. This will

allow some flexibility if the nominal ARL= 30 is not appropriate. A tradeoff is that as the nominal ARL increases, the average number of samples to detection also increases.

Values from Table 2 are displayed graphically below, for changes of size 0.05, 0.25, 0.50, 0.75, and 1.00. This range of values covers what would reasonably be expected in stockpile components. This graph shows a significant decrease in time to detection (ARL) as the sample size increases from 1 to 15, but there is not great improvement from 15 to 30 for these changes.

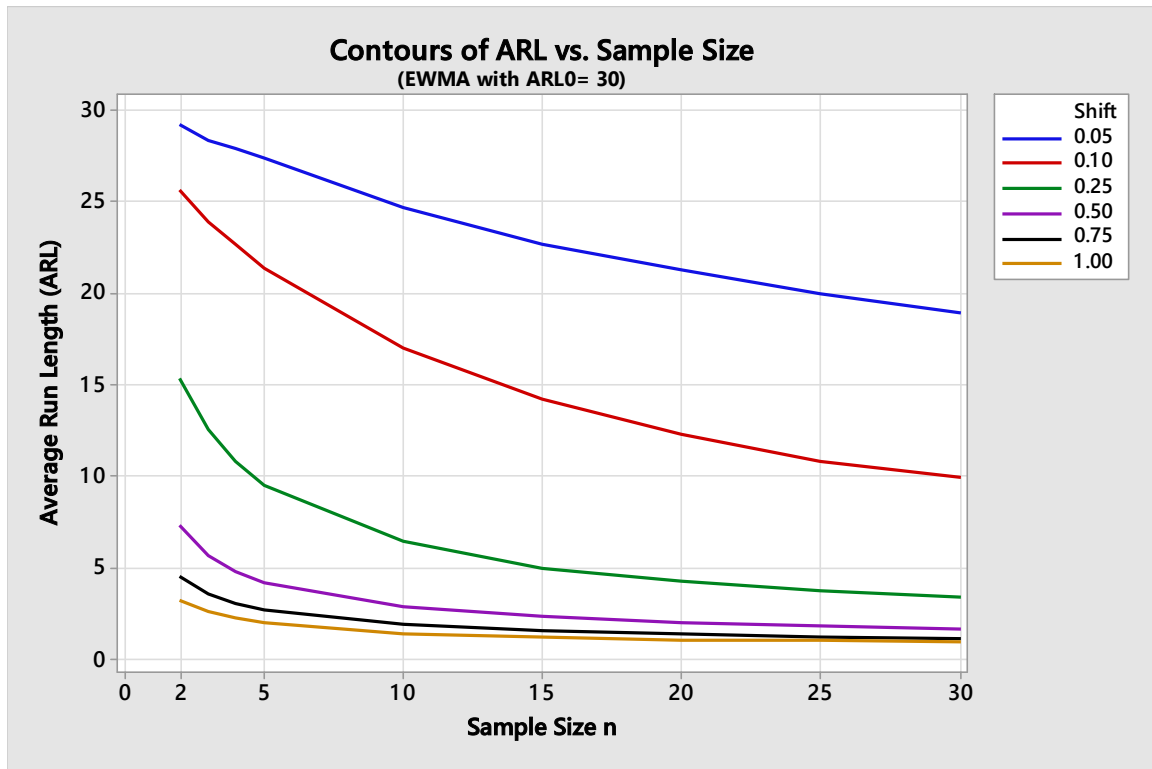


Figure 5. Contours of ARL as a Function of Sample Size – Step Change Model

Following the same Steps (1) and (2) as for the linear drift problem, the planning for the step change problem continues as follows:

3. Choose the appropriate combination of (λ, L, n) . Based on the need to have the Nominal ARL much greater than 20 (assuming sampling is done every year) for stockpile components, a choice of $(\lambda, L) = (0.20, 1.81)$ is recommended. This results in a Nominal ARL of 30, with a high probability that the run length will exceed 20 when the mean is at nominal.
4. Choice of sample size n will depend on the value of Δ that must be detected quickly. In the example above in Step 2, the value $\Delta = 0.50\sigma$ was considered of great importance. In Table 1 above, the time to detection for this value of Δ ranges from ARL= 10.8 ($n=1$) to ARL= 1.67 ($n=30$). Since $n=30$ units per sample will probably not be feasible, a compromise must be made. The choices of $n=3$ and $n=5$ reduce the ARL from 10.8 to 5.72 and 4.24 respectively, and represent a reasonable compromise between time to detection and cost.

5. Based on the above analysis, the EWMA with $(\lambda, L, n) = (0.20, 1.81, 5)$ is recommended. Assuming that sampling is done every year, this means that a single step change in the mean of $\Delta = 0.50\sigma$ will be detected in approximately 4 years. If this is not acceptable, more units must be sampled each year at additional cost.

3. SHELF LIFE PLANS FOR COMPONENTS WITH REPEATED MEASURES

Some components such as electronic neutron generators (ELNGs) placed in a shelf life study can be measured repeatedly over time, leading to fewer overall units needed than with single measurement devices. The methodologies and tables presented earlier still apply, but the EWMA control chart in this case is based on averages of measurements made on the same devices year after year. The overall standard deviation in this case is comprised of separate variance components that can be estimated as described in Appendix C.

Referring to the sample size sensitivity analyses in Figures 4 and 5 above, it is clear that the point of diminishing returns (flat part of the curves) begins in the range of 10-20 samples. Thus, if the cost of an individual component is great, a minimum of 10 units is recommended. For less expensive components, sample size 20 is recommended. In either case, the units are measured every year for the duration of the shelf life program. A control chart for variance components (See reference 4) can be constructed if multiple measurements are made on each device each year (see Appendix C).

In the linear drift example given earlier, the value $\Delta = 0.20\sigma$ was considered to be of great importance. For single measurement devices, the recommendation was to use an EWMA with $(\lambda, L, n) = (0.20, 1.81, 5)$. This meant that a change in the mean of $\Delta = 0.20\sigma$ each year would be detected in approximately 4 years, assuming sampling once a year. With sample size 10 each year, the ARL=3.3 and with sample size 20 each year, the ARL=2.8, modest improvements over sample size 5 each year. In this case the cost of components and the cost of testing could be used to determine an appropriate sample size between 10 and 20.

Several cautions must be made, however, with respect to control charting with repeated measures and a limited number of samples.

1. It will be very difficult to detect deviations from a simple linear drift model in cases where other aging models are more appropriate.
2. The control chart is designed to detect changes in the mean of a continuous measurement variable. There may not be enough data to detect changes in the failure rate based on pass/fail data.
3. Changes during production may result in changes in performance and the appearance of sub-populations. A small sample of components measured over time is less likely to be representative of the entire population and such changes may not be reflected in the shelf life units.
4. Repeated measurements may degrade the performance of the component over time.
5. The small sample size cannot accommodate the potential need for experimental units outside the shelf life study.
6. Fewer units will be available for reliability estimation. This problem may be compounded by the desire to reduce testing quantities in the future.

The major caution associated with the repeated measures control chart is that the smaller total sample size will potentially result in a less representative sample of the entire population. The

samples taken for the shelf life program should be sampled throughout the production years, to make them as representative as possible.

4. CONCLUSIONS

Shelf life planning should begin with an assessment of the initial (time zero) critical performance measures with respect to specifications. Performance measures with little margin will need more frequent monitoring and larger sample sizes. Those with a great deal of margin will need less frequent monitoring and smaller sample sizes. In case of multiple critical performance measures, the shelf life program should be based on the performance measure with the least margin. Other considerations for testing frequency include the need to periodically exercise the measurement equipment.

The exponentially weighted moving average (EWMA) control chart is recommended to monitor key performance measures and should be designed to quickly detect linear trends or step changes considered important. A strategy for the design of the EWMA has been presented here. The design consists of choosing (λ, L, n) . Values of λ and L have been recommended to control the nominal ARL, and a strategy for choosing n has been recommended to control the time to detection when the mean is no longer at nominal.

For single measurement devices, an annual sample size of 4-6 units is recommended, while for repeated measures devices, a sample of size 10-20 units (measured each year) is recommended. In most cases these numbers will be sufficient.

In cases where the analysis recommends a sample size that is not economically feasible, the tables presented here will show the risk associated with a reduced sample size.

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APPENDIX A: TABLES OF ARLs FOR THE LINEAR DRIFT MODEL

Table A1. ARLs for various linear drift values with nominal ARL= 20 ($L= 1.50$, $\lambda= 0.15$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
0.05	10.7	9.24	8.44	7.89	7.49	6.34	5.78	5.37	5.09	4.86
0.10	7.95	6.70	6.06	5.67	5.39	4.50	4.09	3.77	3.57	3.41
0.15	6.49	5.54	4.98	4.62	4.39	3.67	3.30	3.06	2.90	2.76
0.20	5.68	4.79	4.32	4.02	3.78	3.18	2.86	2.66	2.50	2.40
0.25	5.09	4.28	3.83	3.58	3.37	2.83	2.57	2.37	2.24	2.14
0.30	4.67	3.89	3.50	3.27	3.07	2.59	2.33	2.17	2.05	1.97
0.35	4.29	3.59	3.23	3.01	2.85	2.38	2.15	2.00	1.92	1.85
0.40	4.02	3.35	3.03	2.83	2.64	2.22	2.01	1.90	1.82	1.75
0.45	3.76	3.16	2.84	2.65	2.50	2.11	1.93	1.81	1.73	1.65
0.50	3.56	2.99	2.71	2.51	2.37	2.00	1.84	1.74	1.64	1.54
0.55	3.39	2.86	2.58	2.40	2.27	1.92	1.77	1.65	1.55	1.43
0.60	3.26	2.72	2.46	2.28	2.16	1.86	1.70	1.57	1.44	1.34
0.65	3.13	2.62	2.36	2.20	2.08	1.80	1.63	1.48	1.34	1.24
0.70	3.01	2.52	2.27	2.12	2.01	1.74	1.55	1.38	1.26	1.16
0.75	2.92	2.44	2.20	2.05	1.95	1.68	1.48	1.31	1.18	1.10
0.80	2.80	2.36	2.12	1.99	1.90	1.62	1.41	1.23	1.12	1.06
0.85	2.71	2.29	2.07	1.94	1.86	1.56	1.32	1.17	1.08	1.04
0.90	2.65	2.22	2.02	1.90	1.81	1.51	1.26	1.12	1.05	1.02
0.95	2.57	2.16	1.97	1.85	1.77	1.44	1.21	1.09	1.03	1.01
1.00	2.51	2.11	1.92	1.83	1.74	1.37	1.15	1.06	1.01	1.00

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

Table A2. ARLs for various linear drift values with nominal ARL= 30 (L= 1.81 λ = 0.20)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
0.05	12.3	10.3	9.41	8.74	8.23	6.91	6.23	5.75	5.43	5.17
0.10	8.75	7.35	6.56	6.10	5.74	4.79	4.29	3.99	3.75	3.58
0.15	7.10	5.93	5.33	4.95	4.63	3.85	3.47	3.21	3.02	2.89
0.20	6.11	5.10	4.58	4.24	3.97	3.31	2.97	2.76	2.60	2.49
0.25	5.45	4.52	4.05	3.75	3.54	2.94	2.64	2.46	2.32	2.21
0.30	4.92	4.10	3.68	3.42	3.20	2.66	2.41	2.24	2.11	2.03
0.35	4.55	3.77	3.38	3.13	2.95	2.48	2.24	2.07	1.97	1.89
0.40	4.23	3.51	3.14	2.92	2.76	2.31	2.07	1.95	1.86	1.80
0.45	3.96	3.31	2.97	2.75	2.59	2.16	1.97	1.86	1.79	1.71
0.50	3.74	3.13	2.80	2.60	2.47	2.06	1.89	1.78	1.69	1.61
0.55	3.57	2.98	2.67	2.48	2.34	1.98	1.82	1.71	1.60	1.50
0.60	3.41	2.84	2.54	2.37	2.25	1.90	1.76	1.62	1.50	1.40
0.65	3.26	2.73	2.45	2.28	2.15	1.85	1.69	1.55	1.41	1.30
0.70	3.15	2.61	2.35	2.19	2.08	1.80	1.62	1.46	1.31	1.21
0.75	3.03	2.53	2.27	2.11	2.01	1.74	1.54	1.37	1.23	1.13
0.80	2.92	2.44	2.20	2.04	1.94	1.69	1.47	1.28	1.16	1.09
0.85	2.84	2.37	2.14	1.99	1.89	1.63	1.39	1.21	1.11	1.04
0.90	2.75	2.29	2.07	1.95	1.87	1.57	1.33	1.16	1.07	1.03
0.95	2.68	2.24	2.02	1.91	1.83	1.50	1.25	1.12	1.04	1.02
1.00	2.60	2.17	1.97	1.87	1.79	1.44	1.19	1.07	1.02	1.01

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

Table A3. ARLs for various linear drift values with nominal ARL= 50 ($L= 2.05$, $\lambda= 0.20$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	50.0	50.0	50.0	50.0	50.0	50.0	50.0	50.0	50.0	50.0
0.05	14.0	11.7	10.4	9.65	9.10	7.59	6.75	6.26	5.88	5.60
0.10	9.69	8.04	7.18	6.66	6.24	5.17	4.64	4.30	4.02	3.83
0.15	7.74	6.44	5.76	5.35	5.03	4.14	3.71	3.43	3.23	3.08
0.20	6.63	5.51	4.91	4.53	4.27	3.54	3.17	2.93	2.78	2.66
0.25	5.88	4.86	4.35	4.03	3.78	3.13	2.81	2.61	2.48	2.34
0.30	5.33	4.40	3.92	3.66	3.44	2.85	2.57	2.39	2.25	2.13
0.35	4.89	4.04	3.62	3.35	3.16	2.63	2.36	2.19	2.07	1.99
0.40	4.55	3.75	3.38	3.13	2.94	2.45	2.21	2.05	1.97	1.91
0.45	4.27	3.53	3.17	2.93	2.77	2.31	2.08	1.96	1.89	1.83
0.50	4.01	3.34	2.99	2.77	2.61	2.18	1.99	1.89	1.82	1.75
0.55	3.83	3.17	2.85	2.63	2.49	2.09	1.93	1.84	1.75	1.66
0.60	3.65	3.03	2.73	2.53	2.38	2.01	1.88	1.77	1.66	1.55
0.65	3.49	2.91	2.61	2.42	2.28	1.94	1.81	1.69	1.56	1.44
0.70	3.36	2.79	2.51	2.33	2.19	1.90	1.76	1.62	1.47	1.33
0.75	3.23	2.69	2.44	2.25	2.12	1.86	1.69	1.52	1.37	1.24
0.80	3.14	2.62	2.34	2.17	2.06	1.81	1.63	1.44	1.28	1.16
0.85	3.02	2.53	2.27	2.10	2.00	1.76	1.54	1.35	1.20	1.11
0.90	2.94	2.44	2.19	2.05	1.96	1.71	1.47	1.27	1.14	1.07
0.95	2.86	2.38	2.14	2.01	1.93	1.67	1.41	1.21	1.09	1.03
1.00	2.77	2.32	2.09	1.96	1.90	1.61	1.32	1.15	1.06	1.02

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

Table A4. ARLs for various linear drift values with nominal ARL= 100 (L= 2.36, $\lambda= 0.20$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	100	100	100	100	100	100	100	100	100	100
0.05	16.1	13.3	11.9	11.0	10.2	8.35	7.46	6.85	6.45	6.45
0.10	10.8	8.98	7.94	7.34	6.87	5.65	5.03	4.65	4.36	4.36
0.15	8.62	7.05	6.31	5.83	5.45	4.49	4.01	3.72	3.50	3.50
0.20	7.29	5.98	5.35	4.94	4.65	3.83	3.42	3.19	2.99	2.99
0.25	6.44	5.30	4.72	4.37	4.11	3.39	3.03	2.82	2.66	2.66
0.30	5.79	4.78	4.27	3.95	3.71	3.09	2.77	2.56	2.41	2.41
0.35	5.34	4.42	3.90	3.63	3.41	2.84	2.57	2.36	2.21	2.21
0.40	4.94	4.08	3.67	3.37	3.18	2.64	2.37	2.18	2.07	2.07
0.45	4.63	3.82	3.41	3.17	2.98	2.48	2.21	2.06	1.99	1.99
0.50	4.37	3.62	3.24	2.99	2.83	2.34	2.09	1.99	1.93	1.93
0.55	4.14	3.43	3.07	2.84	2.69	2.22	2.02	1.94	1.89	1.89
0.60	3.94	3.27	2.94	2.72	2.56	2.12	1.97	1.90	1.82	1.82
0.65	3.77	3.13	2.81	2.61	2.45	2.05	1.93	1.85	1.74	1.74
0.70	3.63	3.01	2.70	2.51	2.36	1.99	1.89	1.79	1.67	1.67
0.75	3.49	2.90	2.61	2.41	2.26	1.96	1.85	1.72	1.57	1.57
0.80	3.37	2.80	2.53	2.32	2.19	1.93	1.79	1.64	1.48	1.48
0.85	3.27	2.71	2.44	2.24	2.11	1.90	1.75	1.55	1.38	1.38
0.90	3.16	2.63	2.36	2.18	2.06	1.87	1.67	1.47	1.29	1.29
0.95	3.07	2.57	2.28	2.11	2.02	1.82	1.60	1.38	1.20	1.20
1.00	2.99	2.49	2.23	2.08	1.99	1.78	1.53	1.29	1.15	1.15

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

APPENDIX B: TABLES OF ARLs FOR THE STEP CHANGE MODEL

Table B1. ARLs for various step changes with Nominal ARL= 20 ($L= 1.50$, $\lambda= 0.15$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
0.05	19.7	19.5	19.3	18.8	18.8	17.4	16.5	15.5	14.6	13.9
0.10	18.9	17.9	16.8	16.3	15.3	12.6	10.9	9.68	8.70	8.04
0.15	17.7	15.7	14.5	13.3	12.4	9.18	7.55	6.49	5.77	5.20
0.20	16.3	13.8	12.0	10.6	9.70	6.90	5.58	4.81	4.23	3.88
0.25	14.6	11.9	10.1	8.74	7.90	5.48	4.41	3.80	3.34	3.07
0.30	13.2	10.1	8.40	7.41	6.40	4.46	3.64	3.12	2.79	2.58
0.35	11.9	8.86	7.15	6.23	5.46	3.79	3.10	2.66	2.42	2.22
0.40	10.7	7.76	6.33	5.42	4.77	3.28	2.70	2.35	2.12	1.95
0.45	9.78	6.80	5.53	4.74	4.21	2.93	2.42	2.10	1.91	1.74
0.50	8.80	6.13	5.01	4.18	3.78	2.65	2.18	1.92	1.73	1.60
0.55	8.04	5.58	4.49	3.84	3.40	2.42	2.00	1.75	1.59	1.45
0.60	7.27	5.07	4.07	3.50	3.10	2.23	1.85	1.63	1.46	1.34
0.65	6.66	4.64	3.74	3.23	2.90	2.07	1.72	1.49	1.34	1.25
0.70	6.22	4.30	3.47	2.98	2.64	1.93	1.60	1.41	1.25	1.16
0.75	5.76	4.02	3.24	2.79	2.51	1.82	1.51	1.31	1.19	1.11
0.80	5.37	3.77	3.02	2.61	2.36	1.70	1.42	1.24	1.12	1.06
0.85	5.08	3.51	2.86	2.48	2.22	1.62	1.34	1.17	1.08	1.03
0.90	4.73	3.26	2.69	2.34	2.13	1.53	1.26	1.13	1.05	1.02
0.95	4.49	3.14	2.54	2.23	2.00	1.46	1.21	1.08	1.03	1.01
1.00	4.27	2.98	2.42	2.11	1.91	1.39	1.15	1.06	1.02	1.00

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

Table B2. ARLs for various step changes with Nominal ARL= 30 (L= 1.81 λ = 0.20)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
0.05	29.0	28.9	28.3	27.9	27.7	24.7	22.7	21.7	20.4	18.9
0.10	27.5	25.7	23.9	23.1	21.4	17.0	14.2	12.3	10.8	9.96
0.15	25.5	22.3	19.8	17.5	16.3	11.6	9.3	7.80	6.75	6.13
0.20	23.0	18.1	15.5	13.7	12.4	8.35	6.45	5.51	4.83	4.38
0.25	19.9	15.4	12.6	10.8	9.48	6.43	5.00	4.29	3.73	3.38
0.30	17.6	13.1	10.4	8.90	7.68	5.11	4.03	3.44	3.03	2.75
0.35	15.6	10.9	8.77	7.34	6.41	4.27	3.39	2.91	2.58	2.37
0.40	13.8	9.45	7.53	6.32	5.52	3.70	2.95	2.54	2.27	2.09
0.45	12.2	8.31	6.51	5.51	4.78	3.24	2.60	2.25	2.03	1.87
0.50	10.8	7.36	5.72	4.85	4.24	2.88	2.33	2.05	1.83	1.67
0.55	9.75	6.51	5.10	4.31	3.82	2.60	2.13	1.87	1.68	1.53
0.60	8.89	5.83	4.61	3.88	3.44	2.39	1.96	1.70	1.54	1.41
0.65	8.12	5.35	4.19	3.57	3.15	2.21	1.81	1.59	1.42	1.28
0.70	7.34	4.87	3.88	3.31	2.93	2.05	1.70	1.47	1.32	1.21
0.75	6.92	4.55	3.57	3.06	2.72	1.92	1.59	1.38	1.23	1.14
0.80	6.30	4.17	3.35	2.86	2.54	1.81	1.50	1.29	1.16	1.08
0.85	5.91	3.91	3.12	2.67	2.39	1.71	1.40	1.21	1.11	1.05
0.90	5.41	3.63	2.93	2.53	2.26	1.62	1.33	1.16	1.07	1.02
0.95	5.17	3.43	2.77	2.39	2.14	1.54	1.26	1.10	1.04	1.01
1.00	4.82	3.26	2.62	2.27	2.03	1.45	1.20	1.07	1.02	1.01

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

Table B3. ARLs for various step changes with Nominal ARL= 50 (L= 2.05, $\lambda= 0.20$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	50.0	50.0	50.0	50.0	50.0	50.0	50.0	50.0	50.0	50.0
0.05	47.3	46.3	46.2	44.1	42.9	38.6	34.7	31.7	29.1	26.4
0.10	45.7	40.5	37.1	34.4	31.7	23.5	18.9	16.1	13.8	12.4
0.15	39.9	32.9	28.1	25.1	22.3	14.8	11.5	9.62	8.34	7.26
0.20	34.2	26.1	21.4	18.2	15.8	10.4	7.86	6.57	5.68	5.06
0.25	29.2	21.2	16.6	13.9	12.0	7.71	5.93	4.97	4.35	3.86
0.30	24.7	17.0	13.2	11.0	9.50	6.10	4.74	3.95	3.47	3.14
0.35	21.2	14.2	11.0	9.03	7.80	5.00	3.91	3.29	2.92	2.67
0.40	18.3	12.0	9.16	7.53	6.54	4.26	3.35	2.85	2.55	2.31
0.45	15.8	10.2	7.90	6.45	5.65	3.71	2.93	2.51	2.25	2.06
0.50	13.8	8.94	6.86	5.65	4.90	3.31	2.64	2.28	2.04	1.88
0.55	12.4	7.87	6.04	4.99	4.39	2.95	2.40	2.08	1.87	1.71
0.60	11.1	7.02	5.38	4.56	3.96	2.69	2.19	1.91	1.72	1.58
0.65	9.83	6.30	4.87	4.09	3.59	2.47	2.03	1.79	1.59	1.45
0.70	9.16	5.74	4.48	3.75	3.31	2.32	1.89	1.65	1.47	1.34
0.75	8.16	5.27	4.13	3.49	3.06	2.13	1.78	1.54	1.38	1.25
0.80	7.65	4.87	3.80	3.24	2.88	2.01	1.67	1.45	1.28	1.17
0.85	7.08	4.52	3.55	3.03	2.69	1.91	1.57	1.35	1.21	1.11
0.90	6.46	4.25	3.34	2.85	2.53	1.80	1.49	1.27	1.15	1.07
0.95	6.07	3.94	3.10	2.69	2.40	1.73	1.40	1.20	1.09	1.04
1.00	5.70	3.70	2.96	2.55	2.28	1.64	1.32	1.14	1.06	1.02

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

Table B4. ARLs for various step changes with Nominal ARL= 100 (L= 2.36, $\lambda= 0.20$)

¹ Change = $\frac{\Delta}{\sigma}$	n=1	n=2	n=3	n=4	n=5	n=10	n=15	n=20	n=25	n=30
0.00	100	100	100	100	100	100	100	100	100	100
0.05	95.8	92.9	87.0	84.5	80.7	70.3	60.3	52.7	48.2	43.0
0.10	85.2	73.3	65.8	58.7	53.6	37.3	28.4	22.9	19.3	16.8
0.15	72.6	56.3	46.1	39.6	33.8	20.9	15.6	12.7	10.5	9.24
0.20	58.9	42.1	32.5	27.0	22.8	13.6	9.98	8.13	7.02	6.11
0.25	47.8	31.6	23.9	19.2	16.5	9.80	7.25	5.96	5.16	4.57
0.30	39.4	24.9	18.5	14.6	12.5	7.50	5.67	4.72	4.08	3.65
0.35	32.1	19.8	14.5	11.7	9.83	6.07	4.65	3.86	3.39	3.05
0.40	27.0	16.3	11.9	9.56	8.14	5.06	3.92	3.28	2.92	2.65
0.45	22.6	13.6	9.97	8.08	6.89	4.42	3.38	2.90	2.58	2.35
0.50	19.5	11.6	8.56	7.01	6.05	3.83	3.04	2.61	2.33	2.13
0.55	17.2	10.1	7.48	6.08	5.24	3.42	2.74	2.36	2.11	1.95
0.60	15.1	8.77	6.64	5.42	4.74	3.08	2.49	2.17	1.96	1.81
0.65	13.3	7.81	5.91	4.89	4.25	2.84	2.30	2.01	1.82	1.68
0.70	11.8	7.11	5.33	4.45	3.90	2.64	2.15	1.89	1.70	1.55
0.75	10.5	6.43	4.92	4.08	3.56	2.44	2.01	1.78	1.58	1.44
0.80	9.65	5.85	4.53	3.77	3.33	2.29	1.90	1.67	1.49	1.34
0.85	8.83	5.42	4.19	3.50	3.07	2.16	1.80	1.56	1.38	1.24
0.90	8.12	5.00	3.89	3.29	2.89	2.06	1.71	1.47	1.29	1.16
0.95	7.51	4.70	3.63	3.09	2.74	1.96	1.62	1.38	1.21	1.10
1.00	7.00	4.39	3.45	2.91	2.60	1.87	1.53	1.29	1.14	1.06

¹Change is defined as the change in the mean between each sample. The change is expressed in units of the standard deviation. Values as high as 1.0 are not likely, but are included for completeness.

APPENDIX C: CONTROL CHARTS FOR VARIANCE COMPONENTS

When the units placed in the shelf life study can be measured repeatedly over time, additional analysis may be performed.

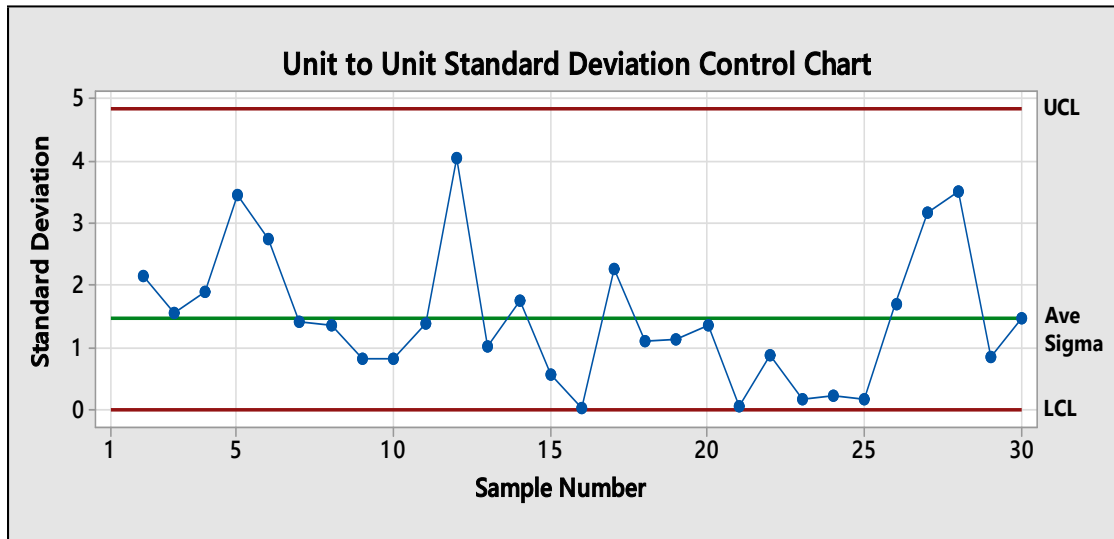
The model for the observed data, y_{ij} , the j^{th} measurement of unit i can be expressed as

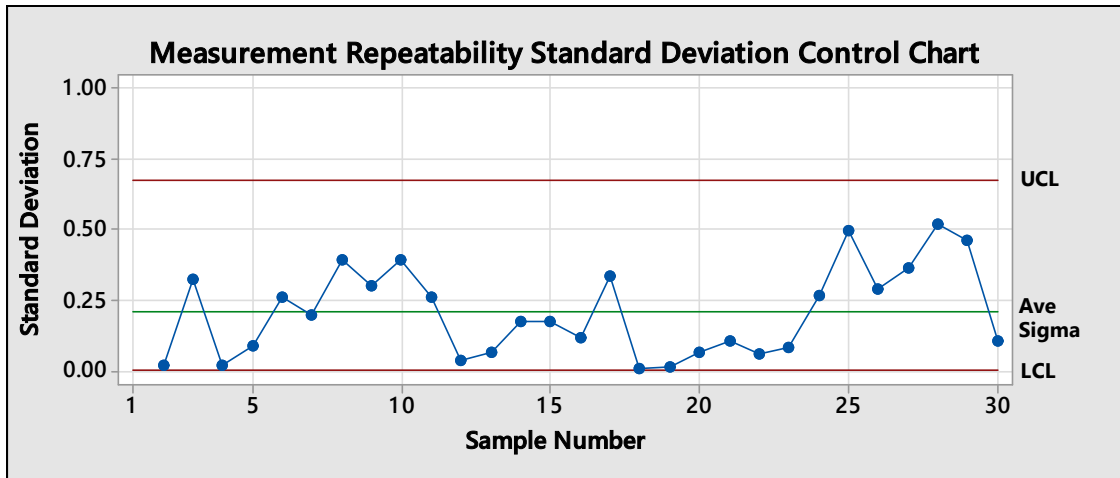
$$y_{ij} = \mu_0 + \alpha_i + \varepsilon_{ij} .$$

In this expression μ_0 is the nominal mean, α_i is the random effect associated with unit i , and ε_{ij} is the random measurement error associated with the j^{th} measurement of unit i . It is further assumed that the random effects are independent and normally distributed with $\alpha_i \sim N(0, \sigma_\alpha^2)$ and $\varepsilon_{ij} \sim N(0, \sigma_\varepsilon^2)$. The α_i terms contribute to the initial unit-to-unit differences.

The initial parameters μ_0 , σ_α , and σ_ε are assumed known, although in practice the parameters σ_α and σ_ε would need to be estimated from a small measurement experiment prior to selecting units for the shelf life program.

If multiple measurements are made on each unit each year, control charts can be constructed to monitor the separate components of variation. Standard statistical packages such as Minitab can be used to generate control charts for both the unit-to-unit standard deviation and the measurement error standard deviation. Examples of the form of these two charts appear below.





The unit-to-unit standard deviation chart would be used to detect an anomaly between units that increases the estimated standard deviation. The measurement repeatability standard deviation control chart would be used to detect an increase in tester variability. Formulas used to compute the standard deviations and the associated control limits can be found in Minitab's Gage R&R documentation.

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