# WHO/UNFPA PREQUALIFICATION PROGRAMME

## Webinar – Control Charts for Quality Control

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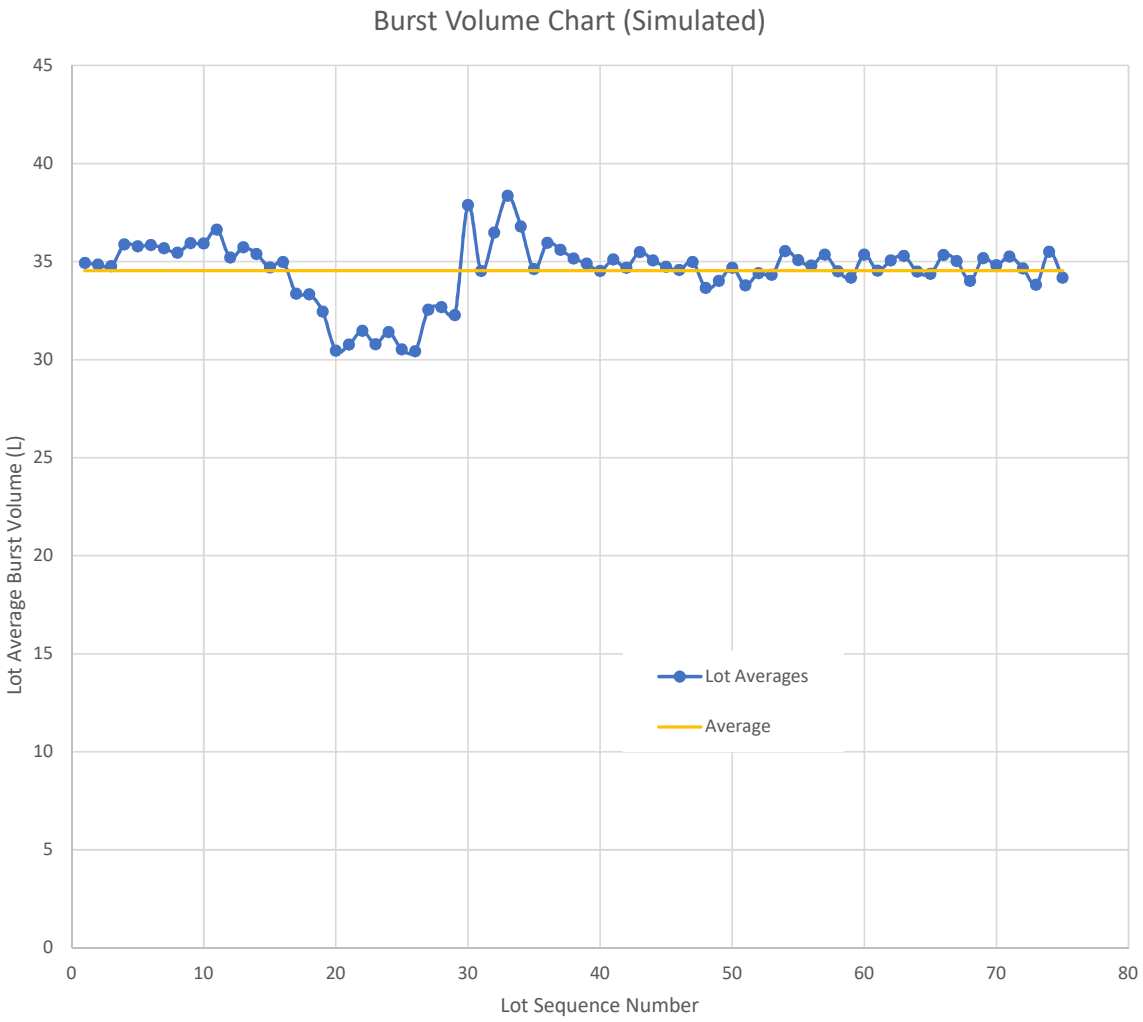
# Topics to be Covered

- Basic principles of control charts
- Constructing a simple chart
- Shewhart charts
- Control Limits
- CUSUM charts

# Variables Charts (Xbar Charts)

- Plot results for lot averages against appropriate reference
- Reference can be time, date, lot ID number, sequence number, etc
- Very easy to generate in excel using line charts or scatter charts options
- Many statistical software packages have procedures for plotting charts

| Lot Sequence Number | Average Burst Volume (L) |
|---|---|
| 1 | 34.93 |
| 2 | 34.85 |
| 3 | 34.77 |
| 4 | 35.87 |
| 5 | 35.77 |
| 6 | 35.84 |
| 7 | 35.68 |
| 8 | 35.45 |
| 9 | 35.94 |
| 10 | 35.92 |
| 11 | 36.63 |
| 12 | 35.2 |
| 13 | 35.72 |
| 14 | 35.38 |
| 15 | 34.7 |
| 16 | 34.97 |
| 17 | 33.36 |
| 18 | 33.33 |
| 19 | 32.44 |
| 20 | 30.45 |
| 21 | 30.77 |



# Shewhart Charts

- Add control limits to a basic chart
- Allows statistically significant shifts in properties to be identified
- Action limits are set at ± 3 standard errors from the mean (capture about 99.7% of all results)
- Warning limits (if used) are set at ± 2 standard errors from the mean (capture about 95% of results)
- Often just the action limits are used

# Determining the Standard Error

- If there is no appreciable between sample variation the standard error is determined from an estimate of the within sample standard deviation
- Three methods of determining the estimate of the within sample standard deviation:
- From the average of the ranges for each lot

$$\sigma = \frac{\bar{R}}{d_2}$$

- From the average of the standard deviations for each lot

$$\sigma = \frac{\bar{s}}{c_4}$$

- From the pooled standard deviation across all lots
- In all cases the standard error (SE) is given by:

SE = $\sigma/\sqrt{N}$ where N is the sample size per lot

# Calculating the Pooled Standard Deviation and Standard Error

For equal sample sizes the following equation can be used:

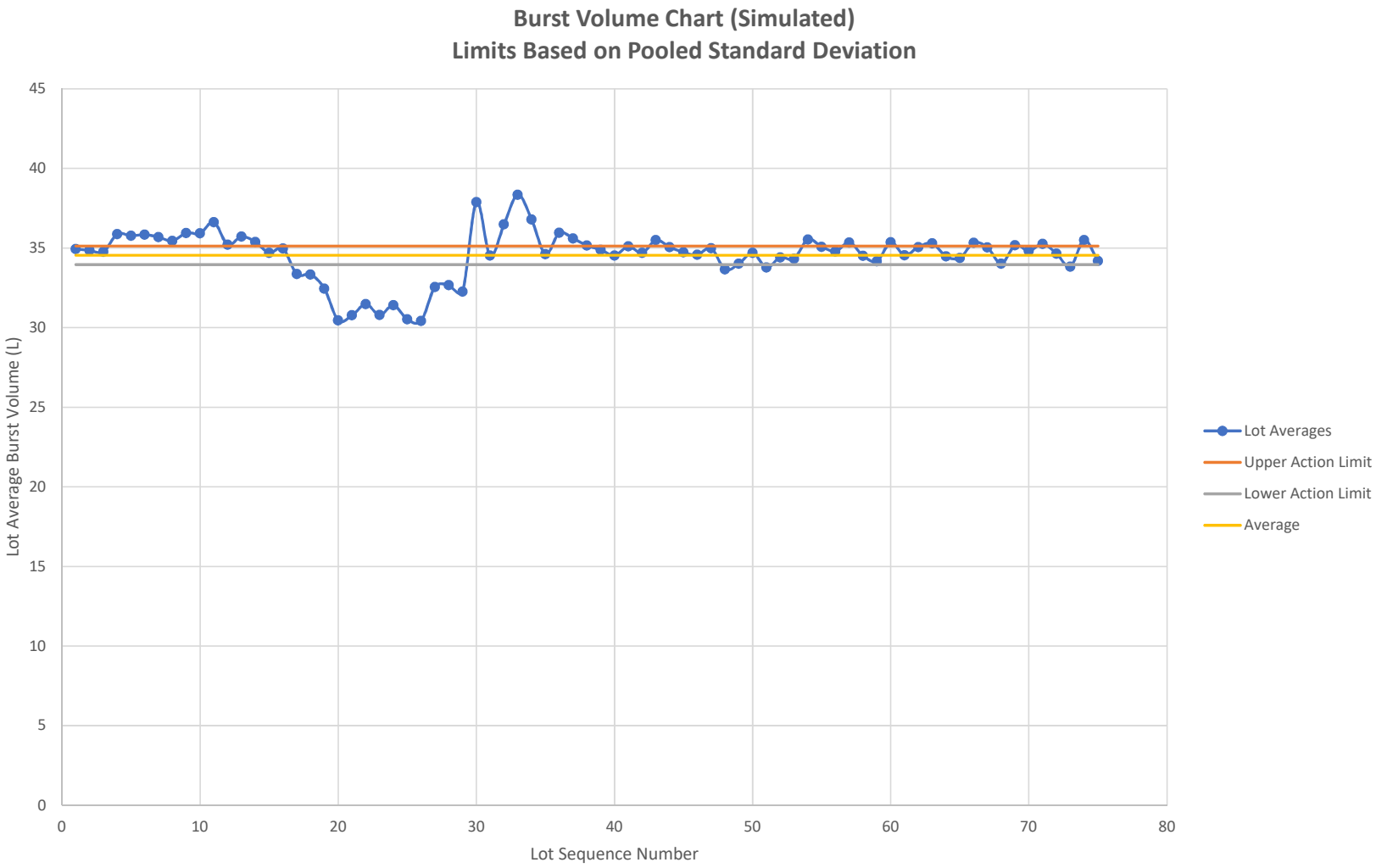
$$s_{pooled} = \sqrt{\frac{s_1^2 + s_2^2 + \ldots + s_k^2}{k}}$$

Where S1, S2, etc are the sample standard deviations for lot and k is the number of lots sampled

The standard error (SE) is then given by:

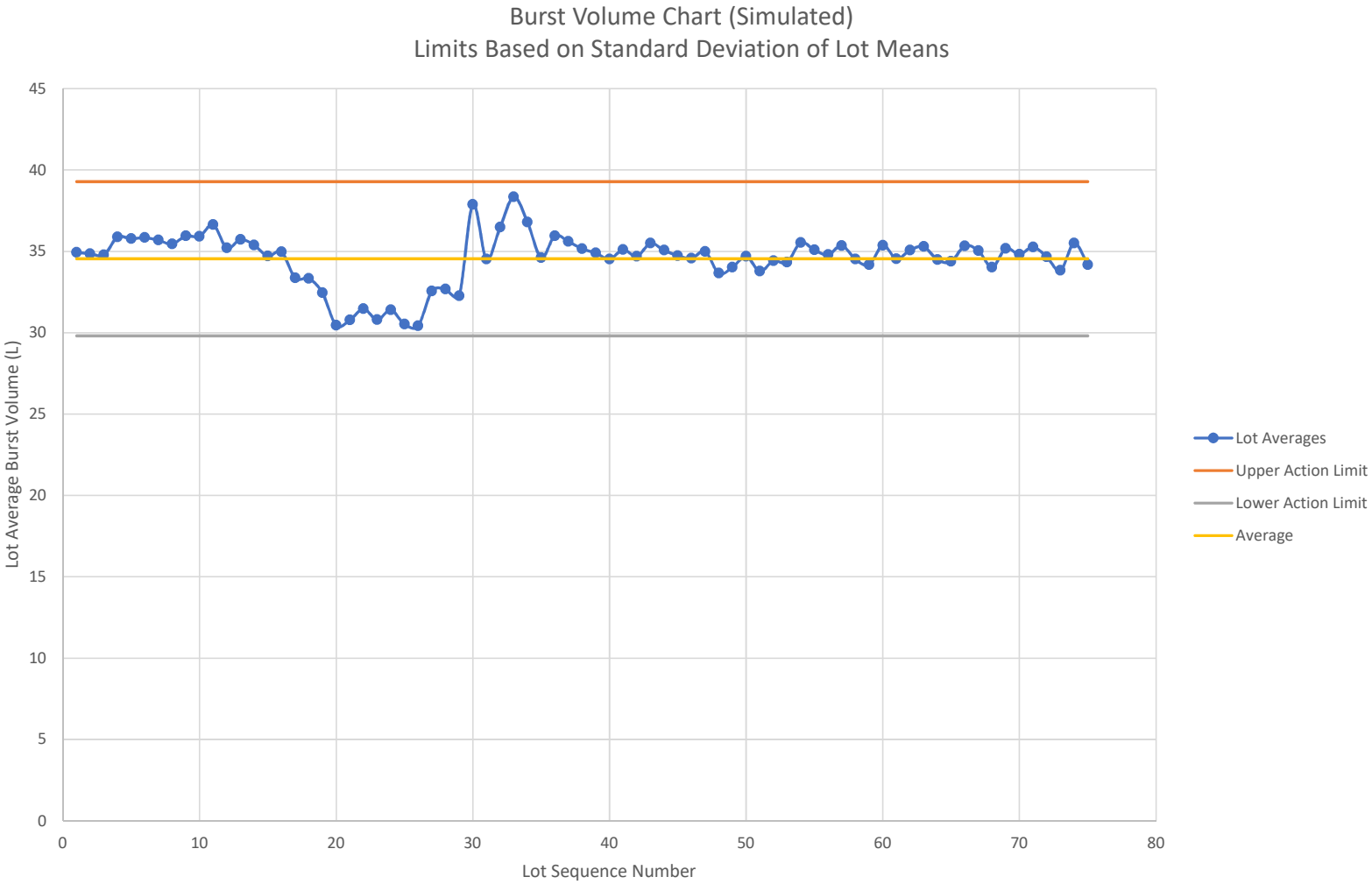
$$SE = Spooled/\sqrt{N}$$

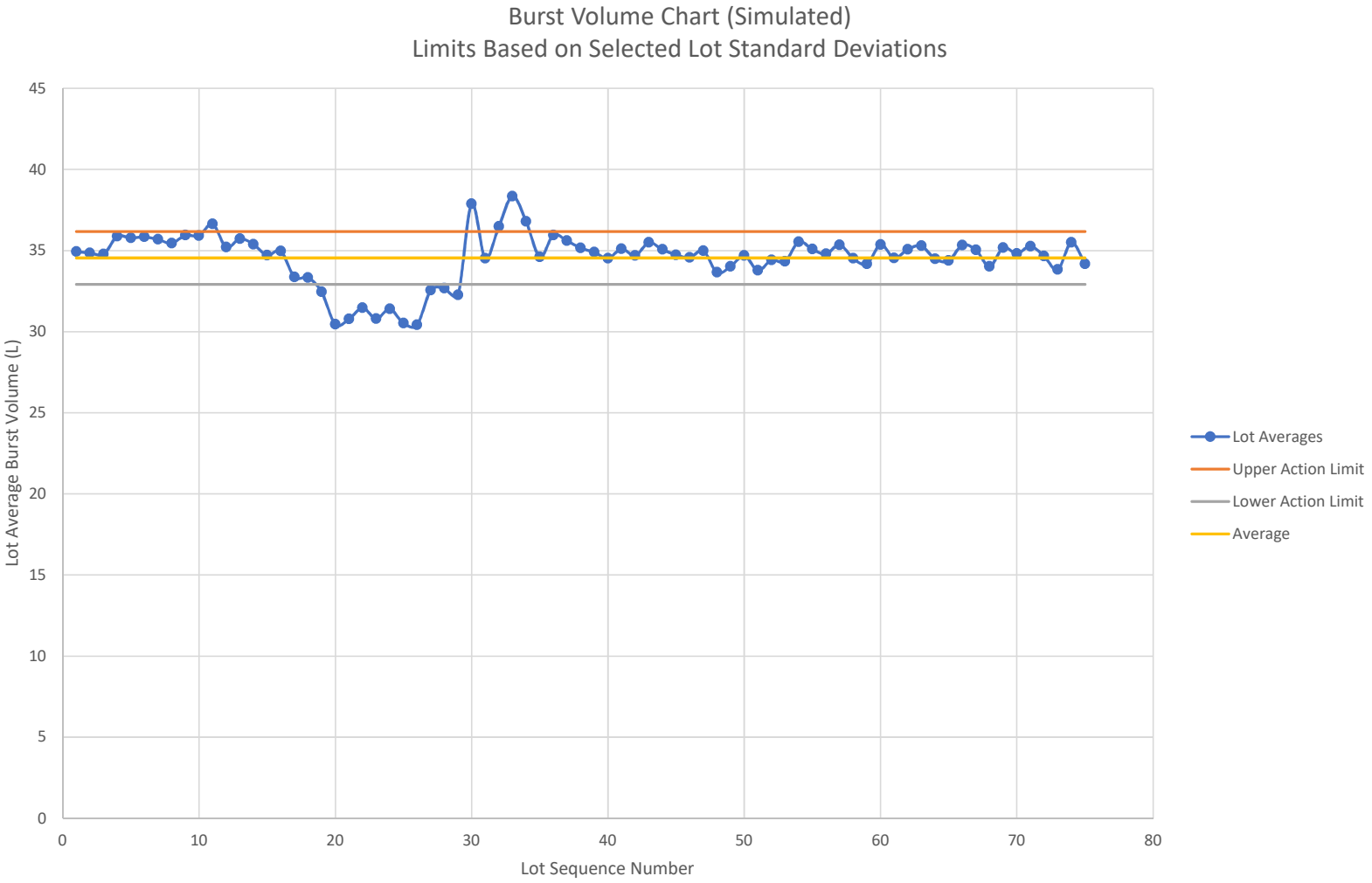
Where N = number of samples tested in each lot

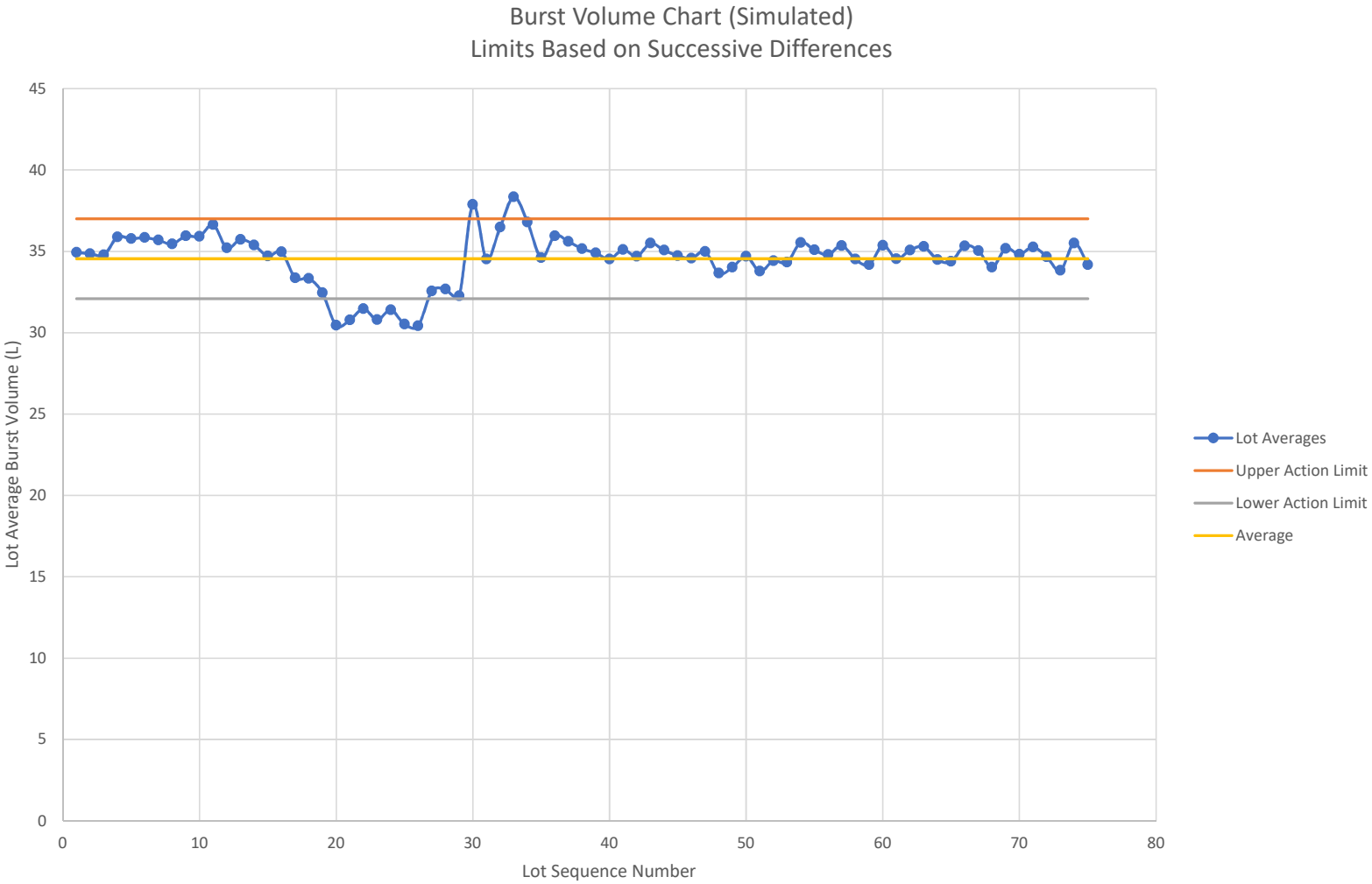

Burst Volume Chart (Simulated)
Limits Based on Pooled Standard Deviation
Lot Average Burst Volume (L)
Lot Sequence Number
0
5
10
15
20
25
30
35
40
45
0
10
20
30
40
50
60
70
80
Lot Averages
Upper Action Limit
Lower Action Limit
Average

# Allowing for Between Lot Variability

- Two options
- Use the standard deviations of the lot means
  - Very easy to implement in Excel
  - Appears to work well for condom burst properties
  - Recommended method
- Use sum of squares of successive differences between the lot means
- $$SE = \sqrt{\frac{1}{2(g-1)} \sum_{j=1}^{g-1} \left(y_j - y_{j+1}\right)^2}$$
- Where g is the number of lots and yj are the lot means


Burst Volume Chart (Simulated)
Limits Based on Standard Deviation of Lot Means
Lot Average Burst Volume (L)
Lot Sequence Number
0
5
10
15
20
25
30
35
40
45
0
10
20
30
40
50
60
70
80
Lot Averages
Upper Action Limit
Lower Action Limit
Average


Burst Volume Chart (Simulated)
Limits Based on Selected Lot Standard Deviations
Lot Average Burst Volume (L)
Lot Sequence Number
0
5
10
15
20
25
30
35
40
45
0
10
20
30
40
50
60
70
80
Lot Averages
Upper Action Limit
Lower Action Limit
Average

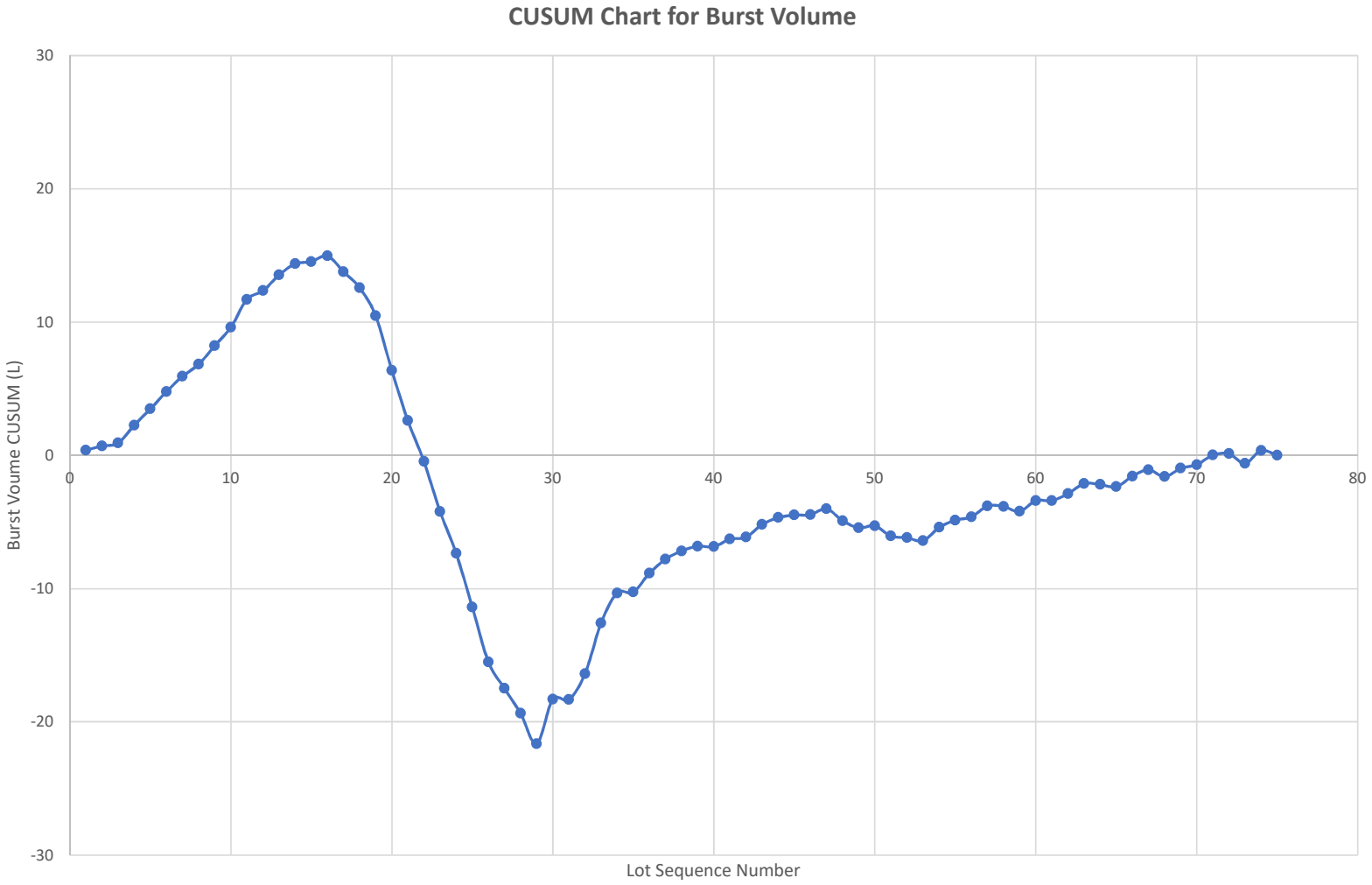

Burst Volume Chart (Simulated)
Limits Based on Successive Differences
Lot Average Burst Volume (L)
Lot Sequence Number
0
5
10
15
20
25
30
35
40
45
0
10
20
30
40
50
60
70
80
Lot Averages
Upper Action Limit
Lower Action Limit
Average

# Other Kinds of Charts

- Range charts
- Standard deviation charts
- Counts:
  - Number or percentage of nonconforming condoms in burst test
  - Number or or percentage of nonconforming condoms in freedom from holes test
  - Number or percentage of leaking packages in package integrity test
- CUSUM charts

# CUSUM Charts

- Plot the cumulative sum of the difference between each lot mean and a target value for the property being plotted
- Can be used for burst volumes and burst pressures (Variable CUSUM charts)
- Can be used for numbers of nonconforming condoms in burst test, freedom from holes test and package integrity test (Attribute CUSUM charts
- Advantage
  - flag up a statistically significant shift in process average faster than other charts
- Disadvantages
  - more difficult to understand and interpret
  - more challenging to set up


CUSUM Chart for Burst Volume
Burst Voume CUSUM (L)
30
20
10
0
-10
-20
-30
0
10
20
30
40
50
60
70
80
Lot Sequence Number

# References

ISO 7870-1:2014 Control charts — Part 1: General guidelines

ISO 7870-2:2013 Control charts — Part 2: Shewhart control charts

ISO 7870-3:2012 Control charts — Part 3: Acceptance control charts

ISO 7870-4:2011 Control charts — Part 4: Cumulative sum charts

ISO 7870-5:2014 Control charts — Part 5: Specialized control charts

ISO 7870-6:2016 Control charts — Part 6: EWMA control charts

ISO 7870-8:2017 Control charts — Part 8: Charting techniques for short runs and small mixed batches

ISO/DIS 7870-9 Control charts — Part 9: Control charts for autocorrelated processes (under development)

# Discussion and Questions