WHO/UNFPA Prequalification Programme

Joint UNICEF – UNFPA –WHO meeting

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Quality Monitoring Strategies

Scope

- Use of basic statistics
- Charts and trend analysis
- Discussion and questions

Basic Statistics

- Use basic statistics when reporting and analysing results
  - Use t-tests to determine if means of two sets of results are statistically significantly different
  - Use ANOVA when comparing means from three or more sets of results
  - Use Chi (χ) Squared or Fisher Exact test when comparing attribute results
  - Use linear correlation methods to assess trends
- All of the above tests are available in Excel (except Fisher Exact Test)
- Simple statistical package
- All are available as online calculators

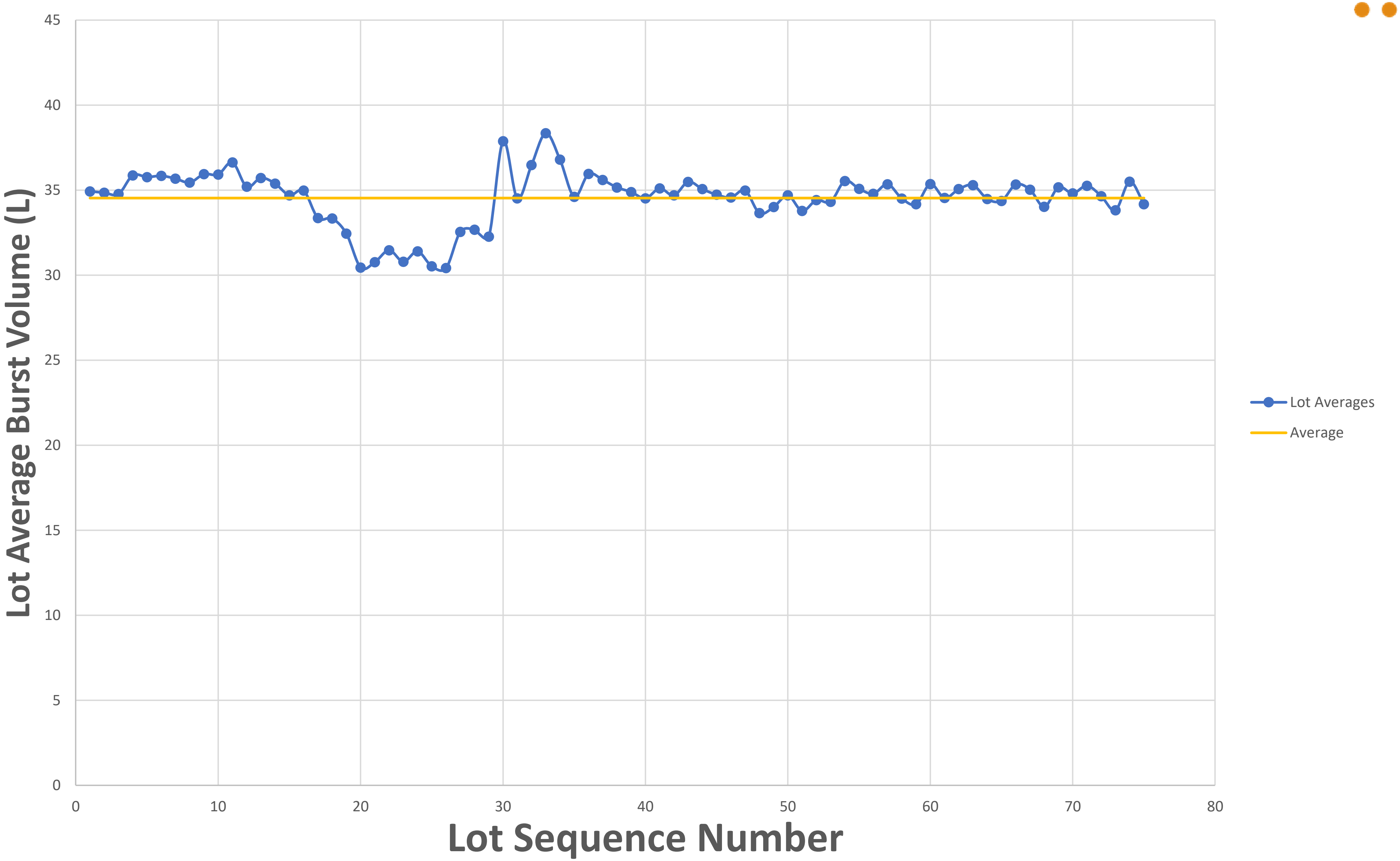
Charts and Trend Analysis

- Charts provide a very powerful method of monitoring processes and trends
- Can be used proactively to control processes (control charts)
- Can be used retrospectively to review results and trends
- Can be used to monitor both variables (averages and standard deviations) and attributes (number of nonconforming items)
- Easy to set up in Excel or appropriate commercial statistical packages

Chart Types

- Basic
  - Plot averages and standard deviations or number of nonconformities over time or by lot sequence
- Shewhart Charts
  - Add limits to basic charts to identify when statistically significant changes occur
  - Warning limits (95%) typical set at 2 standard errors (SE) above and below the mean
  - Action limits (99.7%) typical set a 3 standard errors above and below the mean
  - Control limits – same as action limits (USA practice)
- Advanced Charts
  - CUSUM charts
  - G-Charts

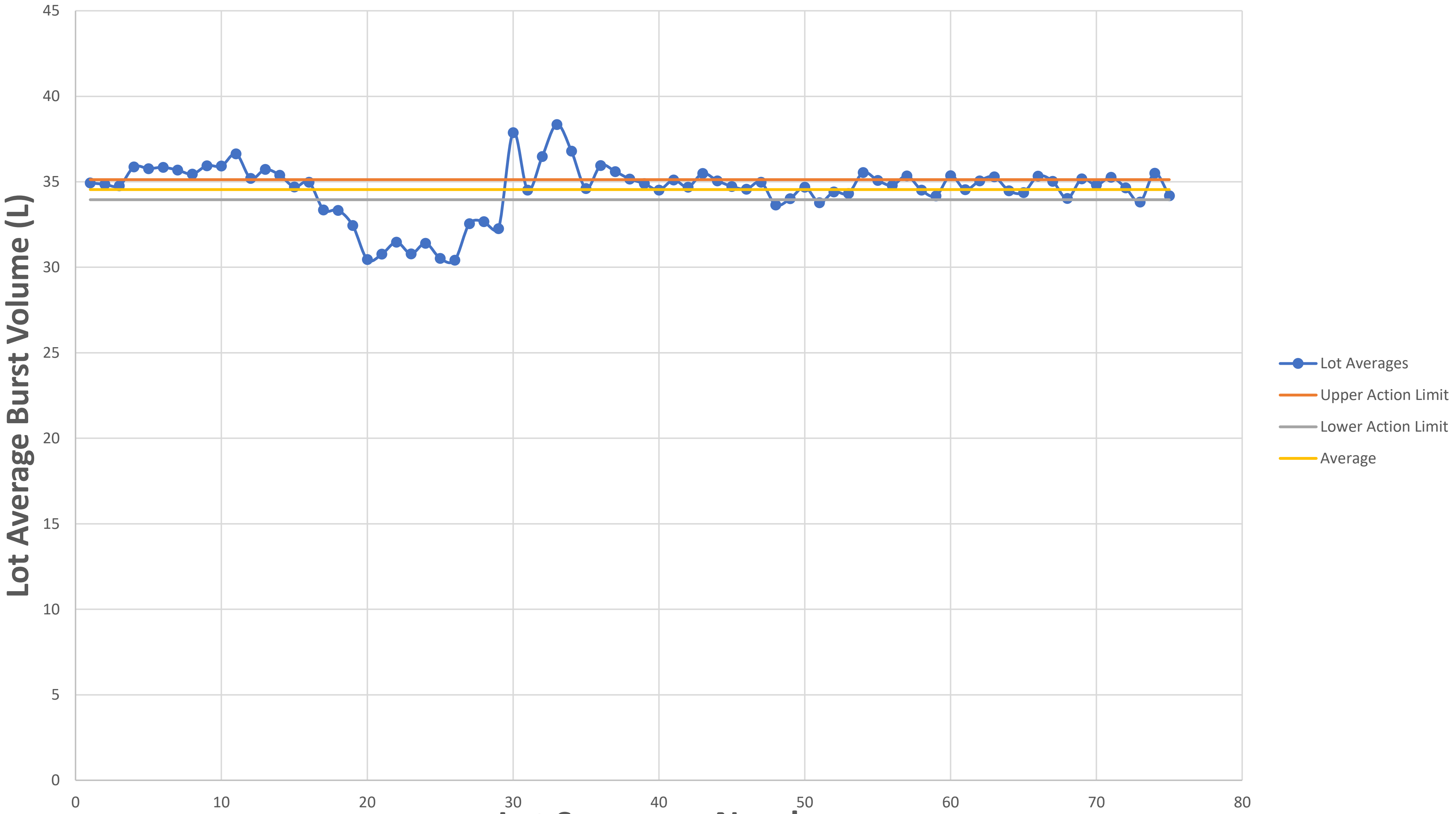
Burst Volume Chart (Simulated)



Shewhart Charts for Variables

- Add limits to detect when statistically significant changes occur
- No appreciable lot to lot variability (e.g. IUD frame dimensions)
  - *SE = SD/√N* where *SD* is an estimate of the within lot standard deviation and *N* in the sample size per test
  - The *SD* can be estimated from the average range for the lots, the average standard deviation for the lots or the pooled standard deviation of the lots
    - $SD = \frac{\overline{R}}{d_2}$ where $\overline{R}$ is the average range per set of test samples per lot and d_2 is an unbiasing constant
    - $SD = \frac{\overline{S}}{C_4}$ where $\overline{S}$ is the average standard deviation per set of test samples per lot and C_4 is an unbiasing constant
    - $SD_{(pooled)} = \sqrt{\frac{S_1^2+S_2^2+S_3^2+\cdots}{k}}$ where S_1, S_2, S_3, … are the within lot standard deviations and k is the total number of standard deviations used to determine the pooled standard deviation (assumes sample size is the same for all samples)

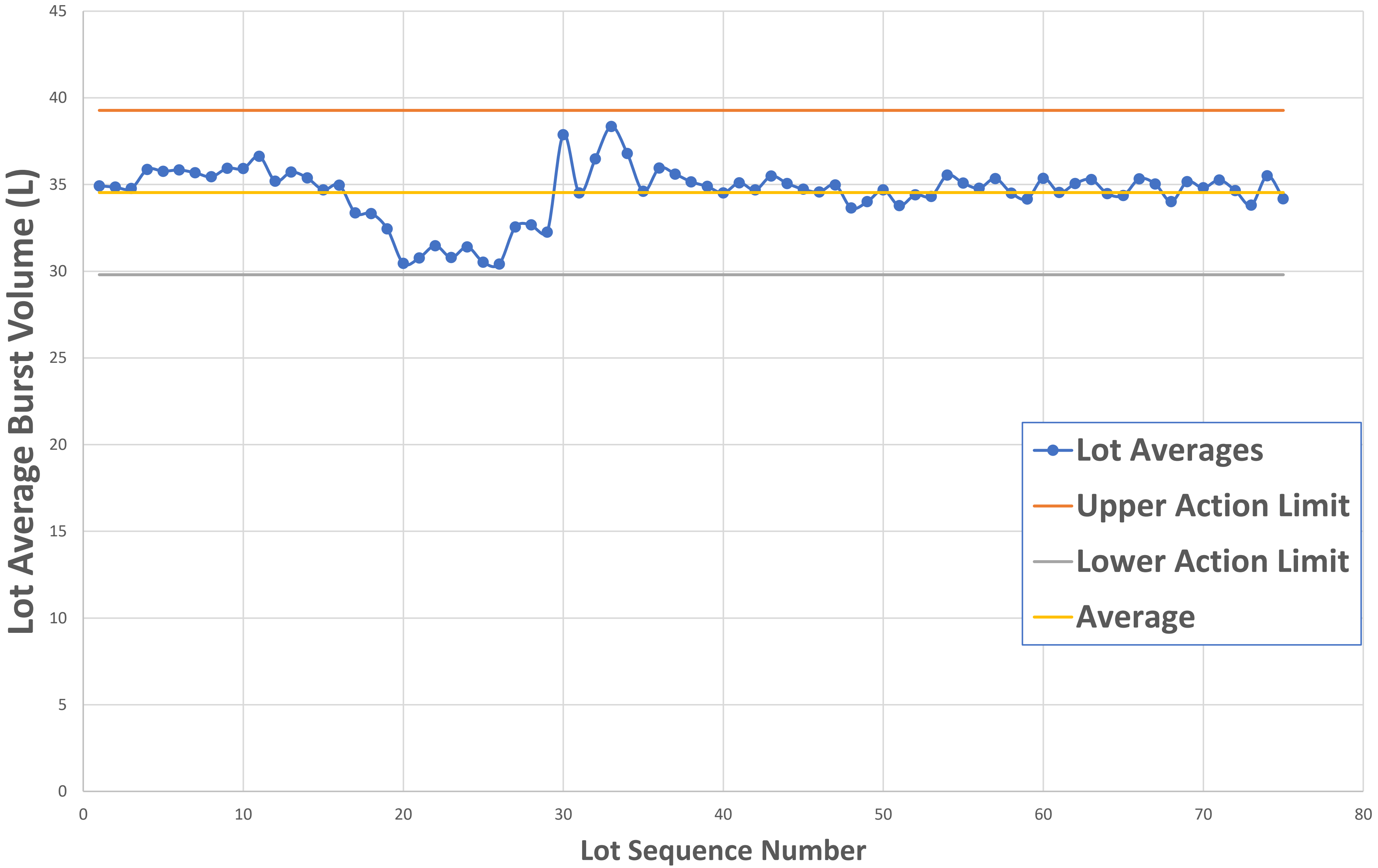
Burst Volume Chart (Simulated)
Limits Based on SE Based on Pooled Standard Deviation



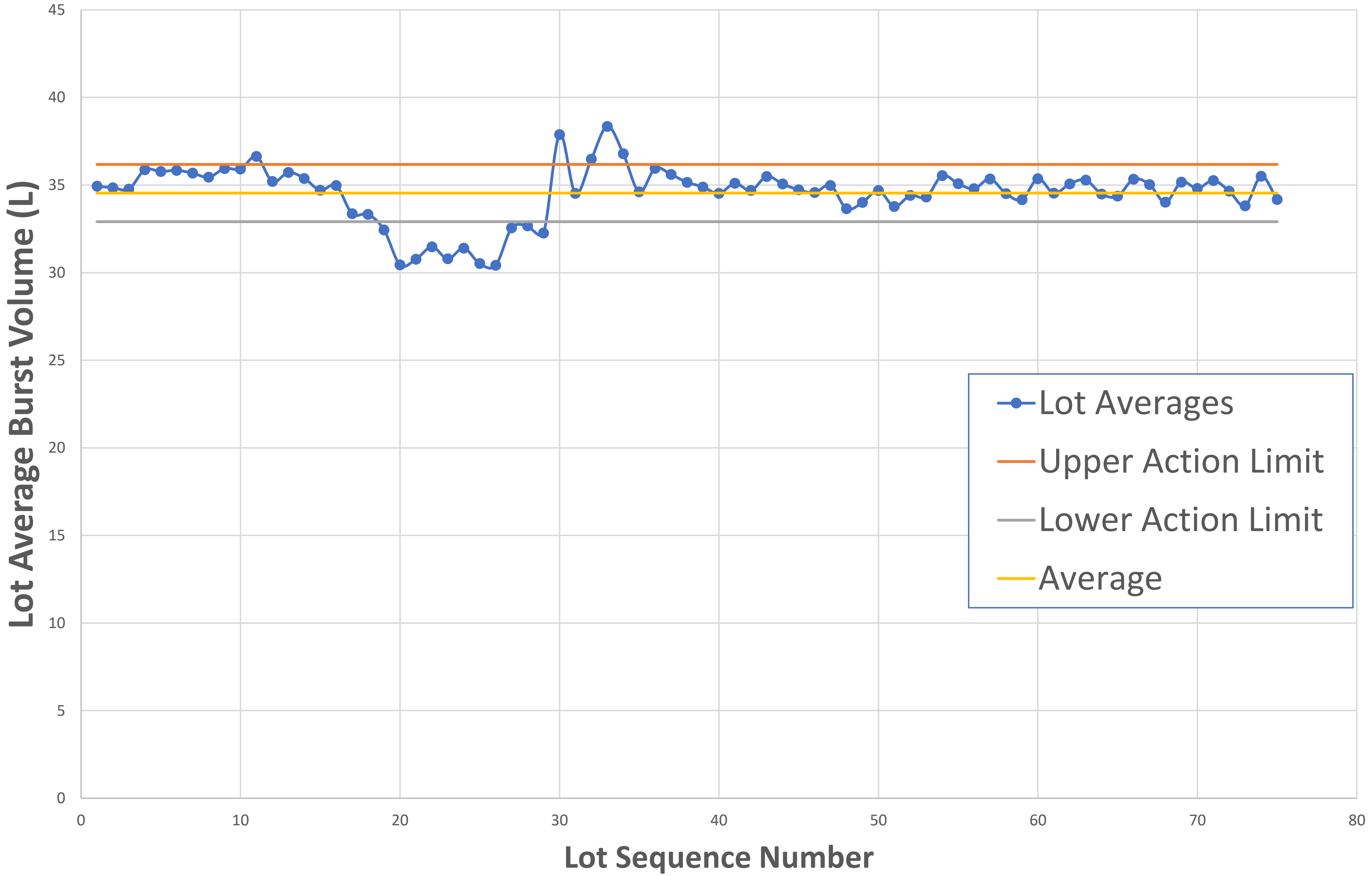
Shewhart Charts for Variables (continued)

- Appreciable lot to lot variability (e.g. condom burst properties)
  - Limits based on within lot standard errors are too tight and generate many out of specification alerts
    - Use the standard deviation of the lot means as the SE to calculated the limits
    - The standard deviation over a selected range when the process is considered to be in an acceptable level of control should be used
    - Calculate the standard error from sequential differences in lot means using the equation $SE = \sqrt{\frac{1}{2(g-1)} \sum_{j=1}^{g-1} (y_j - y_{j+1})^2}$ where g is the number of lots used in the calculation and the y_j are the lot means

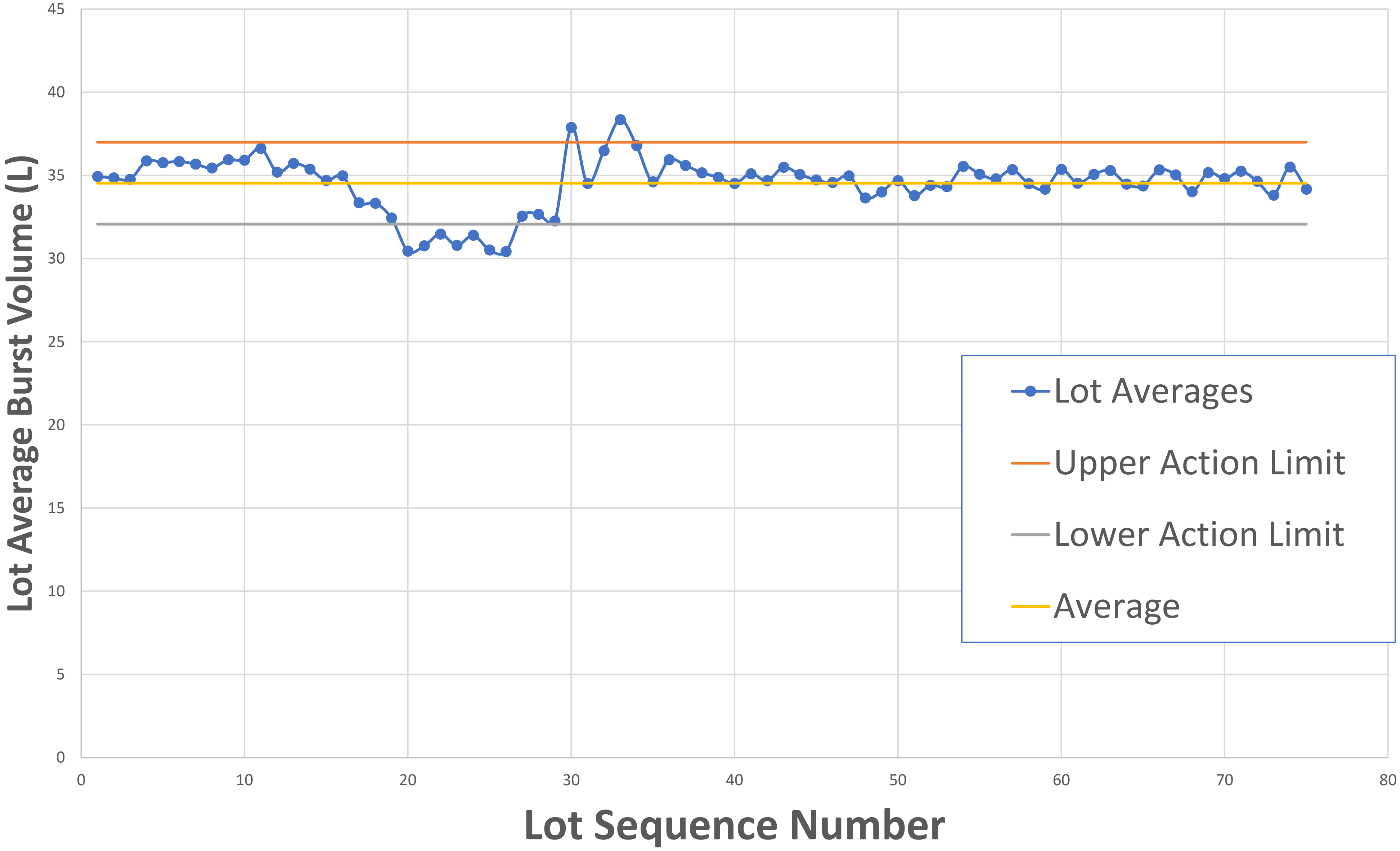
Burst Volume Chart (Simulated)
Limits Based on Standard Deviation of Lot Means



Burst Volume Chart (Simulated)
Limits Based on Selected Lot Standard Deviations



Burst Volume Chart (Simulated)
Limits Based on Successive Differences



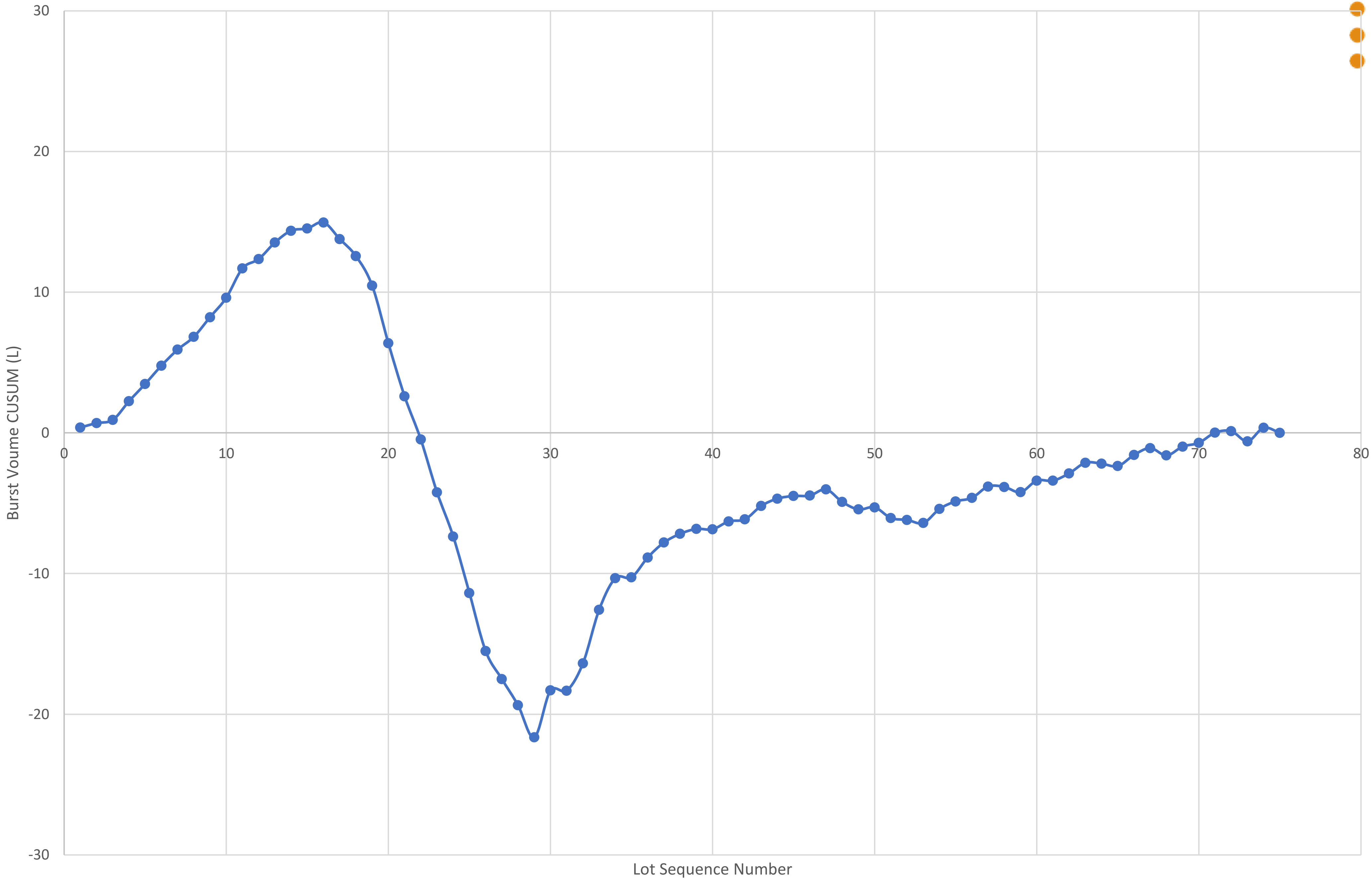
Shewhart Charts for Attributes

- Attributes, e.g. nonconforming condoms with respect to freedom from holes
- Plot number of nonconforming condoms per test (np-chart)
  - Sample size has to be constant per lot
- Plot proportion/fraction or percentage of nonconforming per sample (p-chart)
  - Permits different sample sizes to be used per lot
- Control limits are set using the standard error as for variable charts
  - $SE = \sqrt{n\overline{p}\,(1-\overline{p})}$ for np-charts where n = sample size and $\overline{p}$ is the average proportion of nonconforming items for lot
  - $SE = \sqrt{\frac{\overline{p}(1-\overline{p})}{n}}$ for p-charts

Other Types of Charts

- Cumulative Sum (CUSUM) Charts
  - More complex to set up and plot than Shewhart charts
  - Less intuitive to understand
  - Permit the more rapid detection of statistically significant shifts in properties than Shewhart Charts
  - The CUSUM value for a specific set of results is calculated by subtracting a target value and adding the CUSUM value for the previous set of data.
    - If the current process average is running higher than the target the CUSUM will increase
    - If the current process average is running lower than the target the CUSUM will decrease
  - Statistical shifts are detected using a V-mask or by tabulating the positive and negative trends in the CUSUM separately

CUSUM Chart for Burst Volume (Target Set at Overall Average Burst Volume)



Process Capability Assessment

- Assessment of how well a process performs against specification
  - Compare the mean of the process with the mean of the specification
  - Compare the width of the specification with the 99.7% confidence interval
- Two types of indices, C and P
  - C process capability indices – based on the within samples standard deviation
  - P process performance indices – based on the overall standard deviation
- Cp and Pp
  - Cp is the ratio of the specification tolerance divided by 6 x within sample standard deviation
  - Pp is the ratio of the specification tolerance divided by 6 x overall standard deviation
- If Cp or Pp is greater than 1 then the process is potentially capable

Why Potentially Capable – Depends on Centring

To Assess Centring Use Cpk or Ppk

- Cpk also assess how well the process is centred
- Cpk is the smallest value of
  - (Mean – LSL)/3 x SD (Cpl)
  - (USL – Mean)/3 x SD (Cpu)
- Target values for Cpk

Cpk < 1 trouble ahead – process is not capable of

Cpk = 1 barest minimum value – risk of occasional lot rejections

Cpk = 1.33 regarded as the minimum acceptable value

Cpk ≥ 2 quality standard required to claim 6-sigma status

Discussion

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Questions

Thank you for your attention