

*Microorganisms in Foods 8: Use of Data for
Assessing Process Control and Product Acceptance*

Verification of Process Control

by

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Discussion Topics

- Definition of **verification**
- Introduction of ICMSF sampling terms
- Purposes of microbiological testing
- Maximizing the value of verification data
- Some process engineering considerations

Definition: Verification

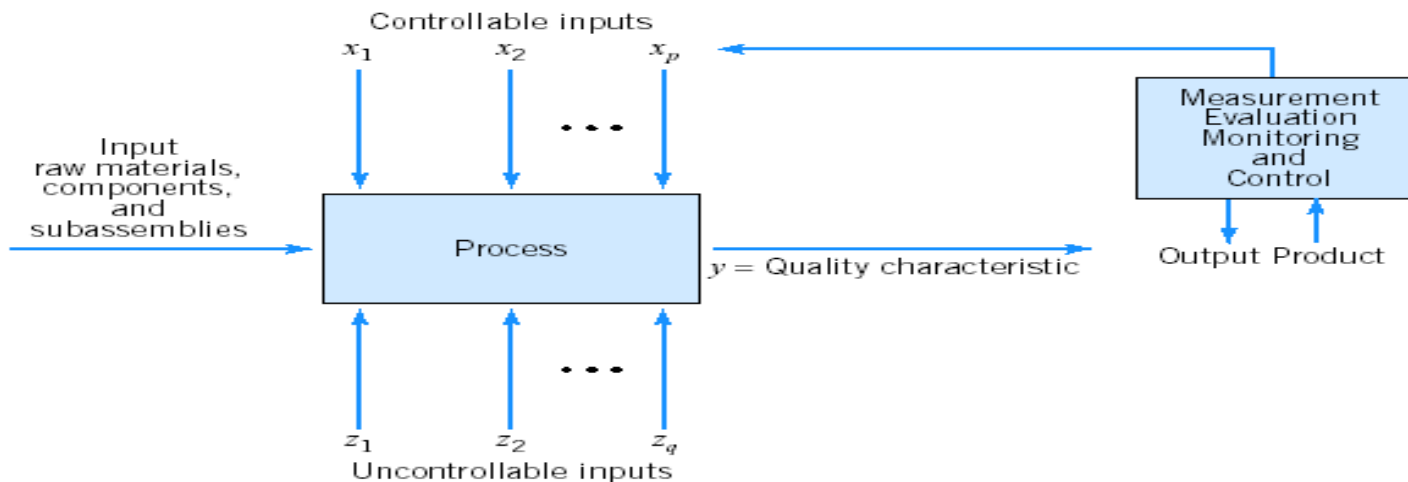
- The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.
 - Codex Alimentarius Commission
CAC/RCP 1-1069, Rev. 4-2003 - Annex

Potential Verification Procedures

- Validation of process effectiveness
- Calibration of equipment
- Review of records
- **Targeted sampling and testing**
- Visual inspection of equipment
- Environmental monitoring
- 2nd and 3rd party audits

Product Sampling and Testing

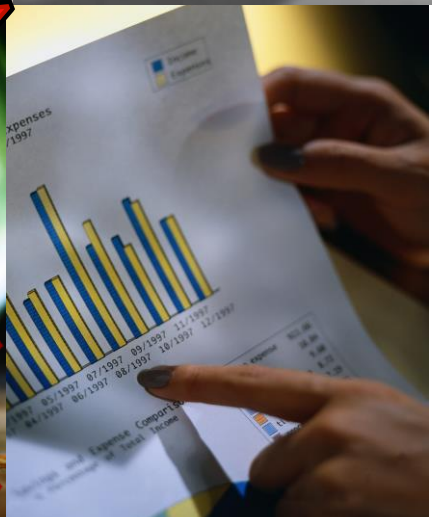
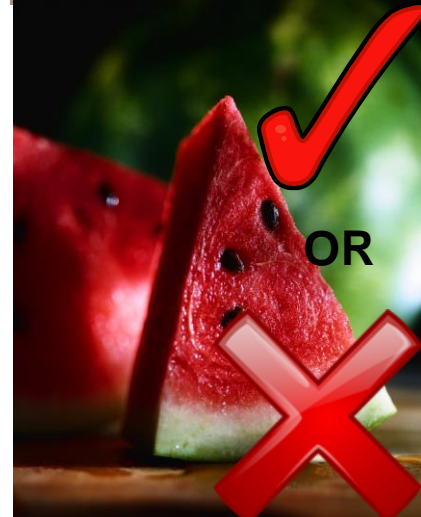
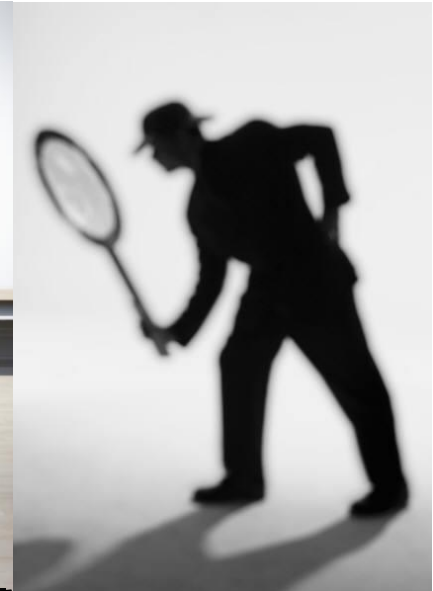
- Periodic verification **may** also include targeted sampling and laboratory testing of:
 - Ingredients
 - In-process materials
 - Finished products



Production process inputs and outputs.

Microbial Testing Means...

- Different things to different people:
 - Volumes of data to study
 - Detective game to identify unknown or causative agent
 - Product is either “good” or “bad”
 - Data as information to evaluate & verify process control & improvement



The Purpose of a Test Determines:

The target	Indicator or pathogen
The method	Time to results, accuracy, repeatability, etc.
The sample	Environment, line residue, end product, location collected, size/ number of samples
The frequency	Daily, weekly, monthly, etc. or event triggered
The interpretation	Investigational, routine, regulatory, etc.
The action	Rejection, process adjustment, recall, outbreak investigation, etc.

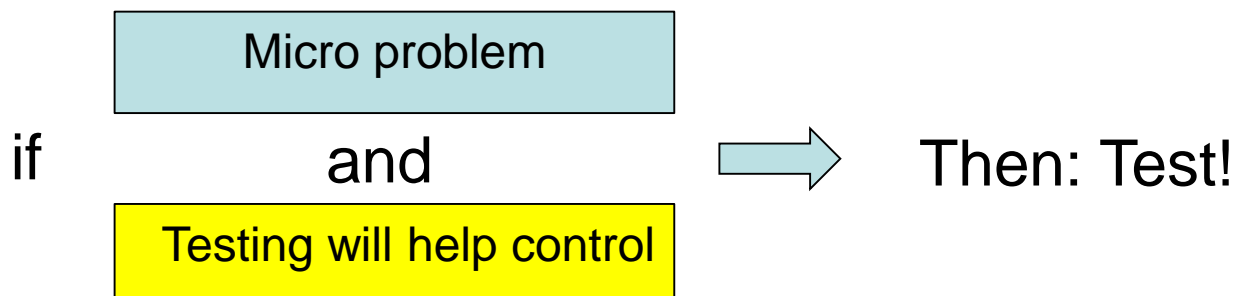


When & Where to Test for Food Safety Management

- ONLY: when there is good evidence that:
 - There is a microbiological problem
 - Food safety or quality
 - Historical or current

AND

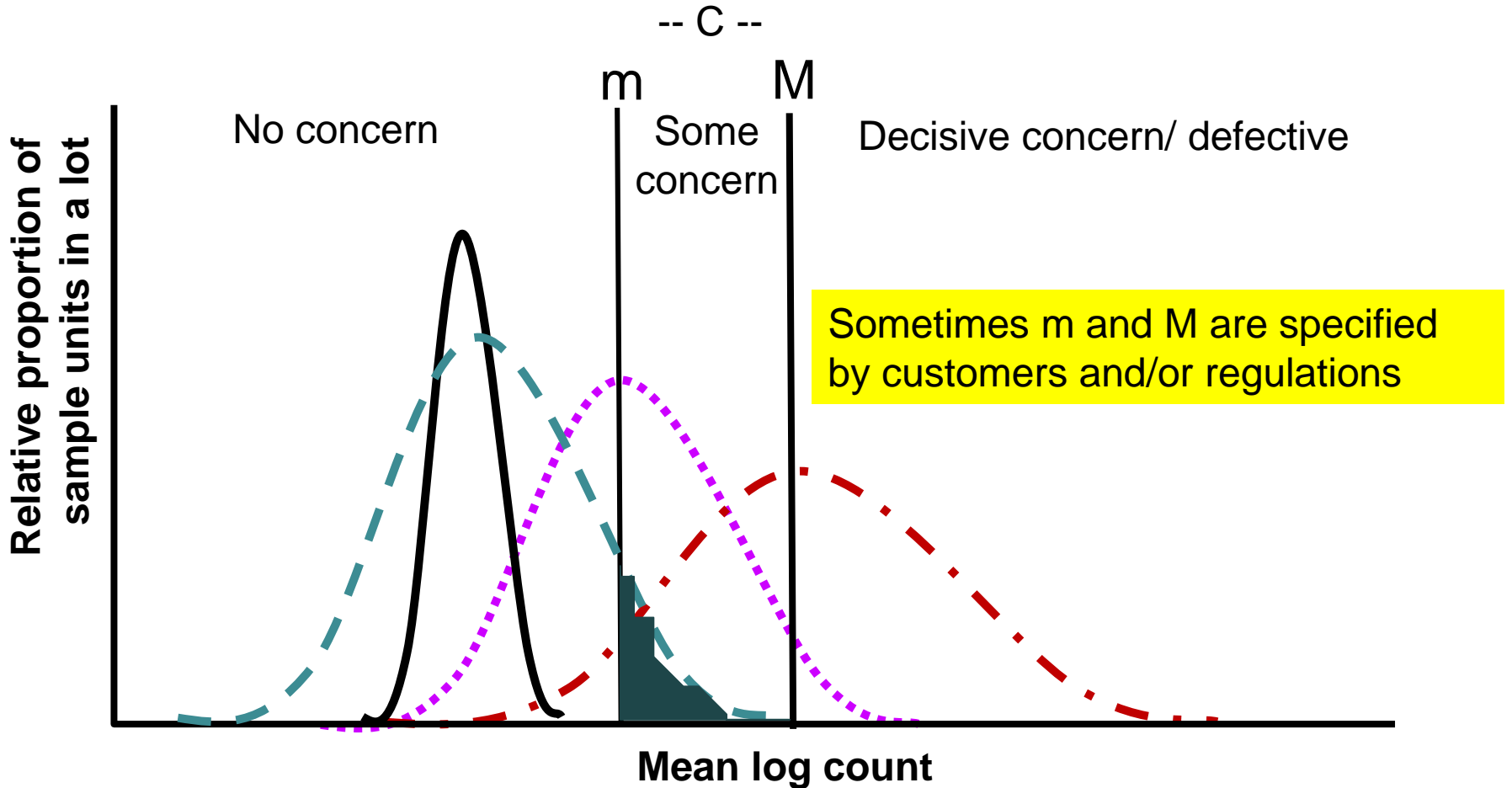
- Testing will help to control the problem



Key ICMSF Sampling Plan Terms

- n** Number of sample units to be analyzed
- c** Maximum number of sample units with marginal but acceptable results (i.e., between m and M)
- m** Concentration separating good quality or safety from marginally acceptable quality
- M** Concentration separating marginally acceptable quality from unacceptable quality or safety

Choosing m and M

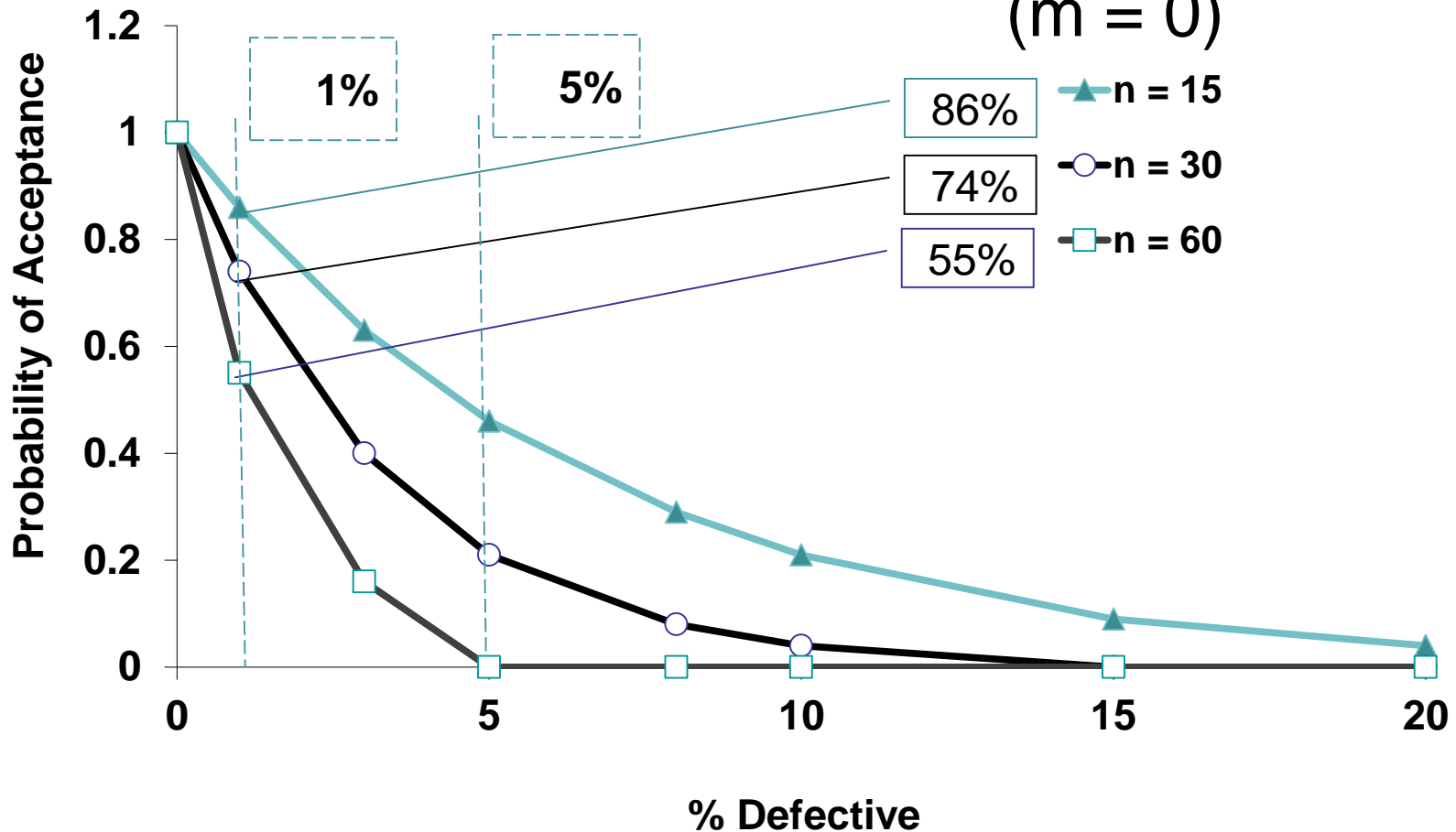


ICMSF Sampling Plans

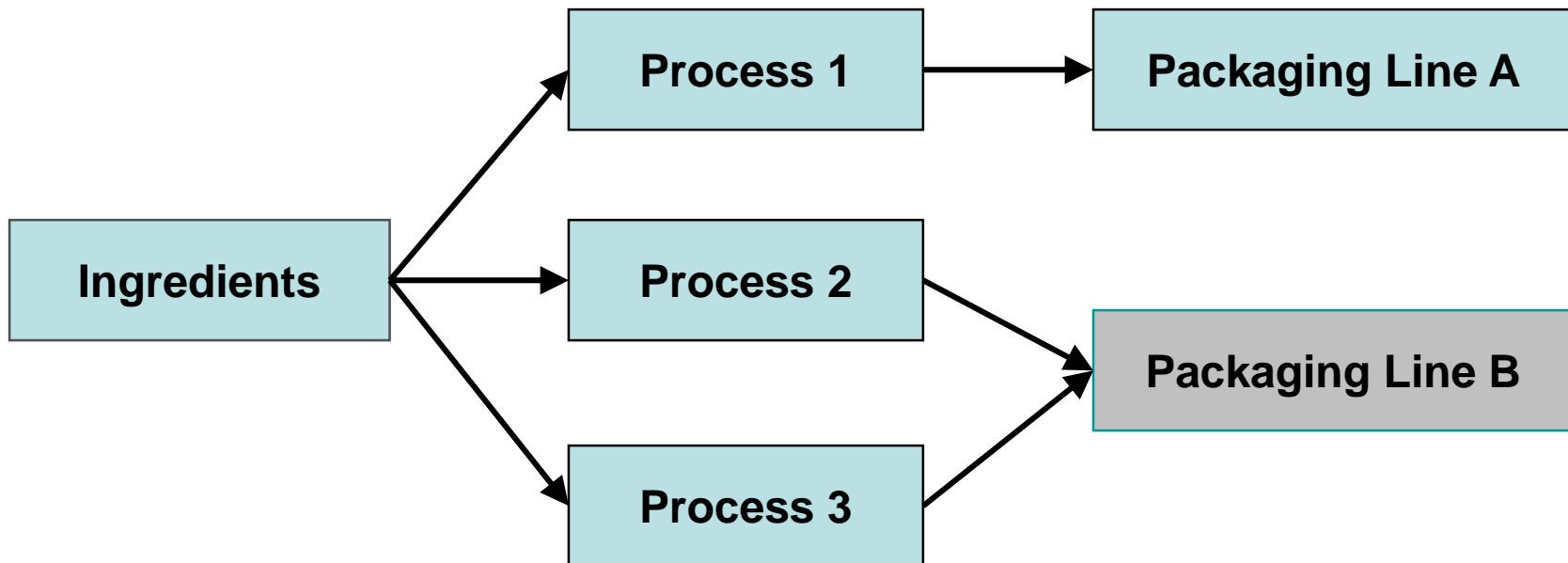
- ICMSF sampling plans apply when:
 - Information indicates a potential for contamination
 - OR
 - Production conditions and history are not known
- These are “within-lot” testing approaches

Sample Size Influence on Probability of Acceptance

($m = 0$)

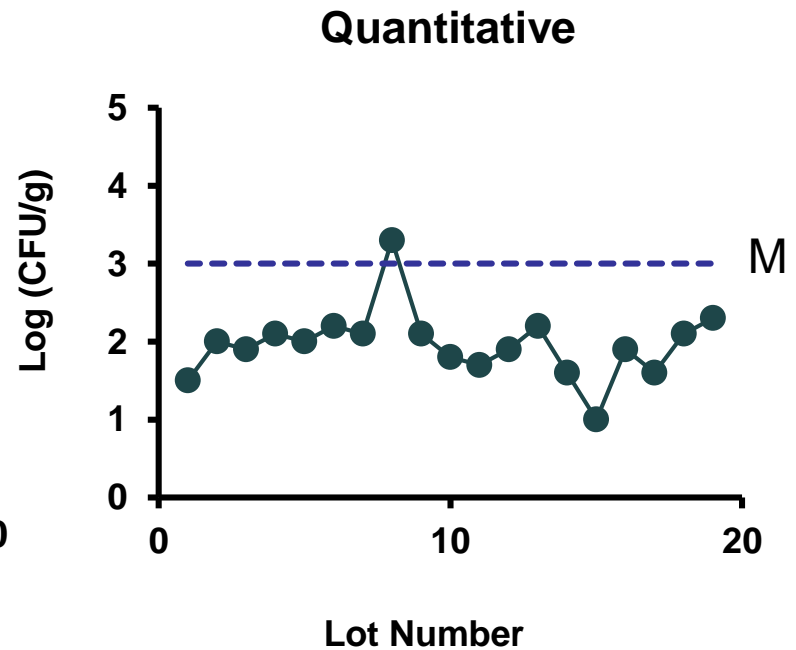
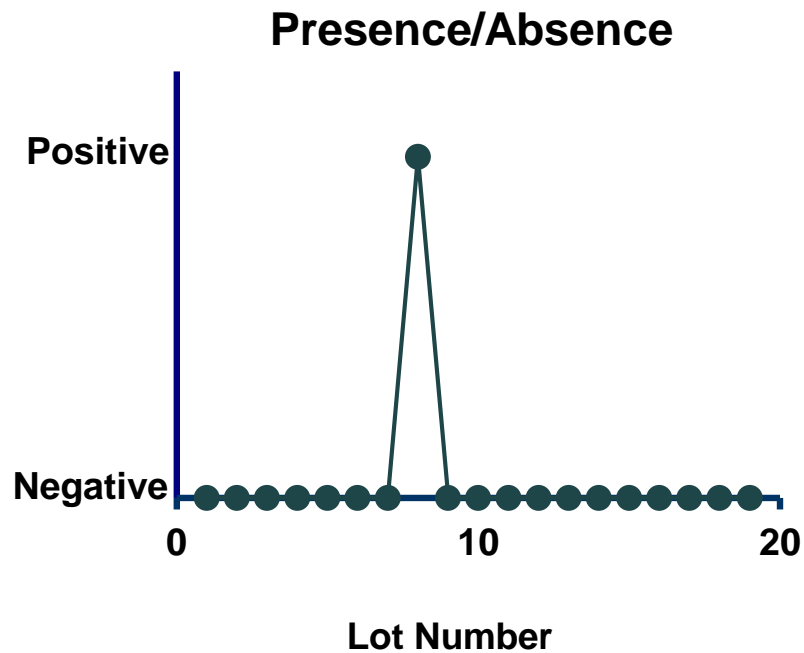


Process Example

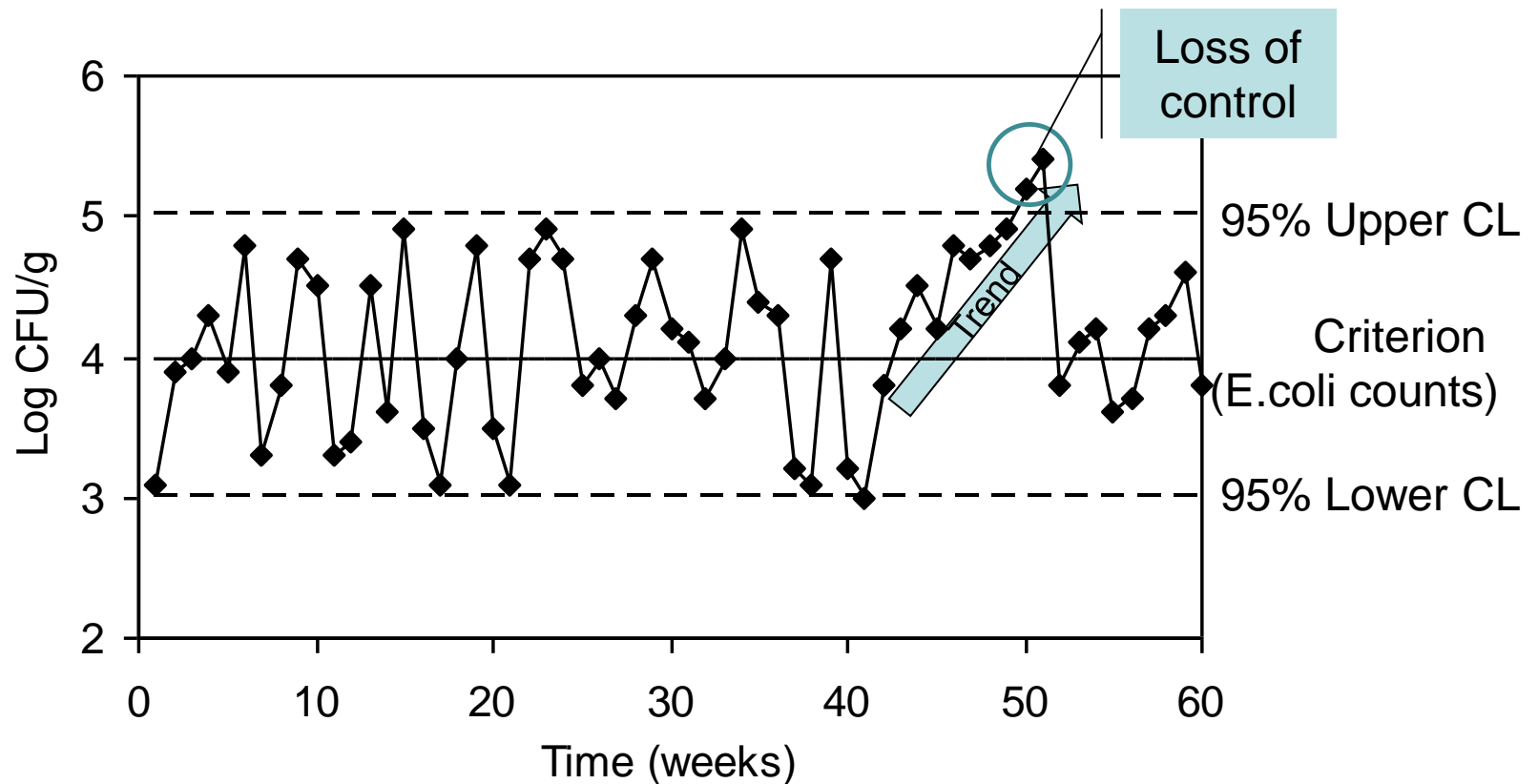


What action do you take when an unacceptable result is found on Line B?

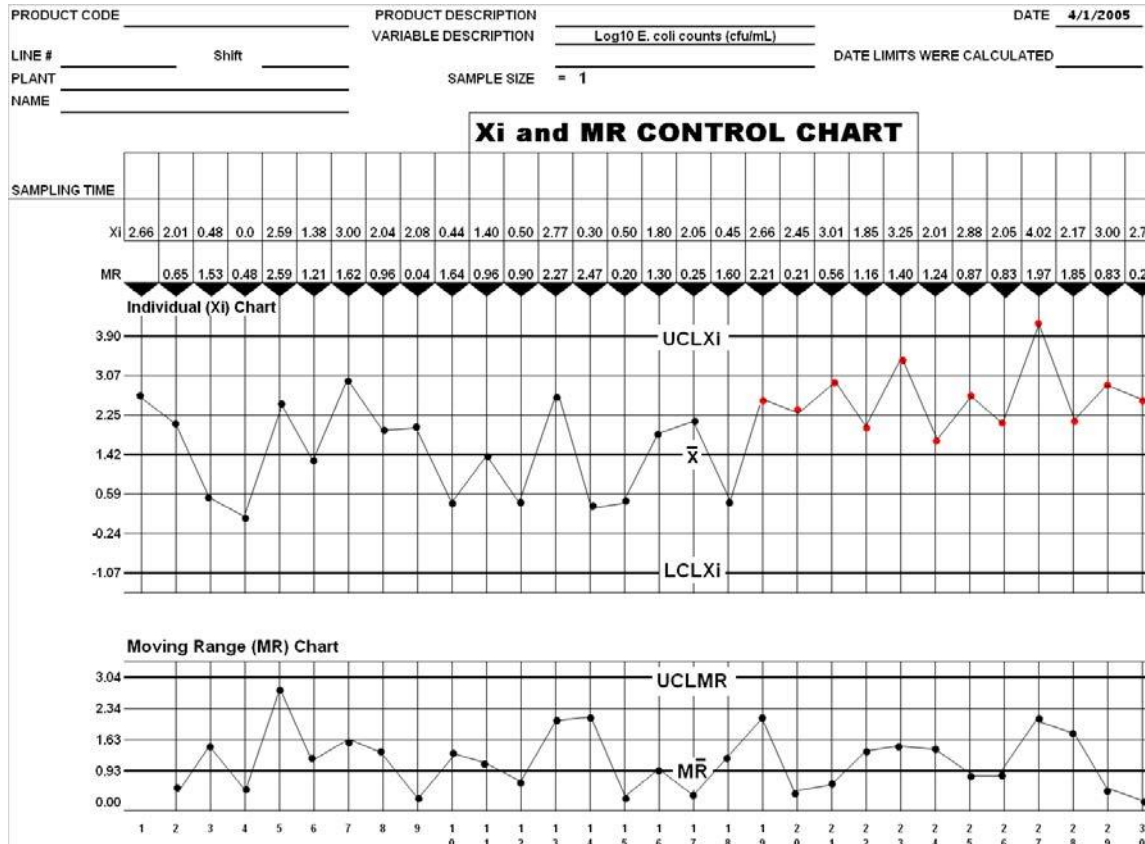
Result Format Influences Information Provided



Process Control Example



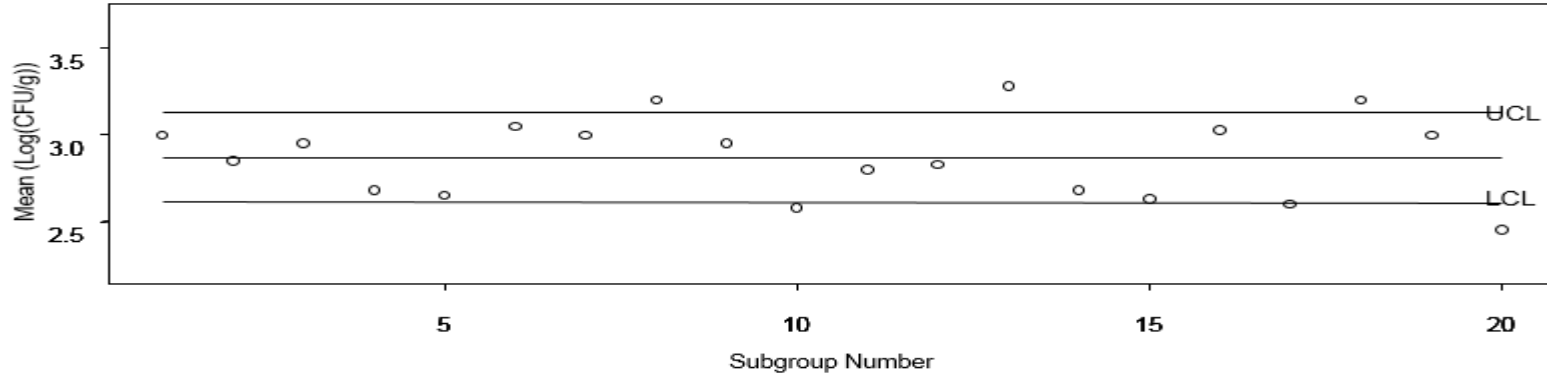
Control Chart Example



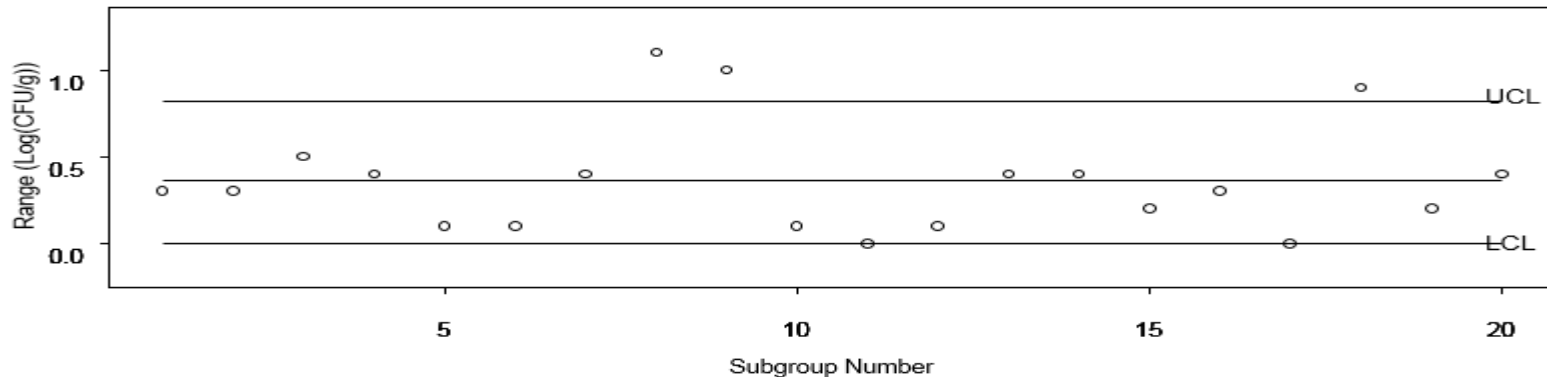
Example: Figure X. Log(10) *E. coli* counts illustrating an increase in CFU per ml (From AOAC methods, Appendix F. SPC, 2006)

Control Chart Example

Mean-Chart

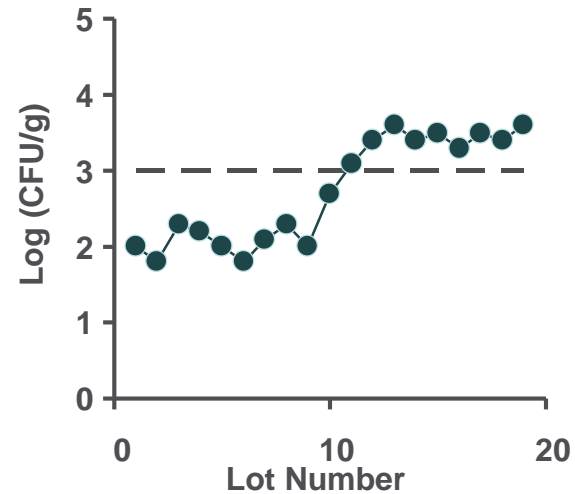
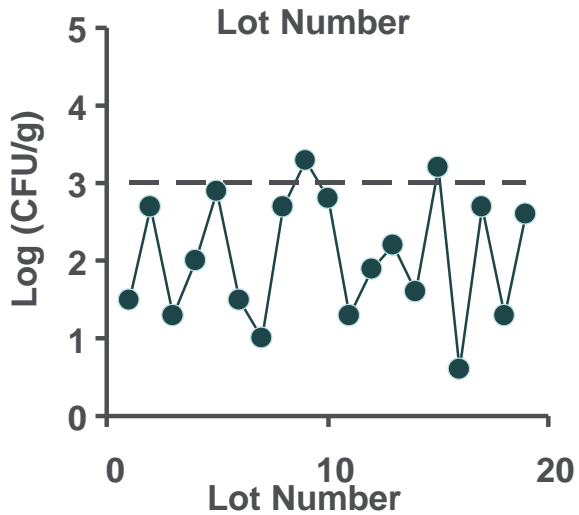
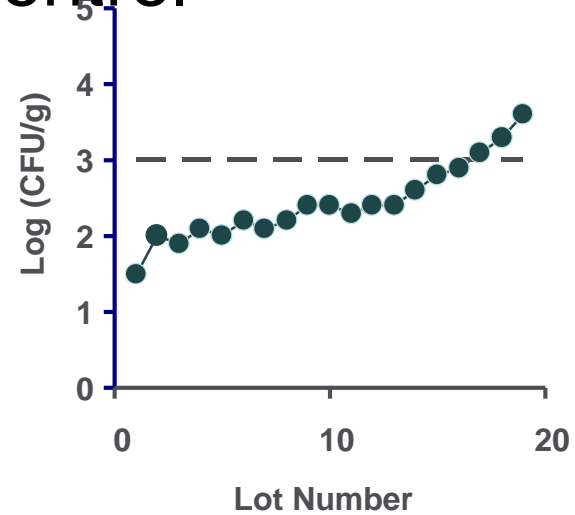
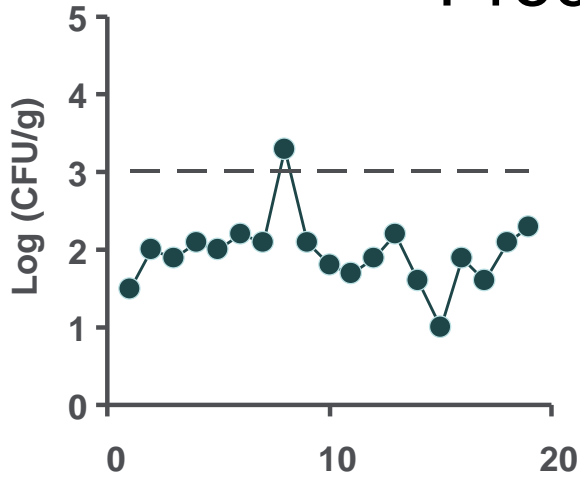


Range-Chart

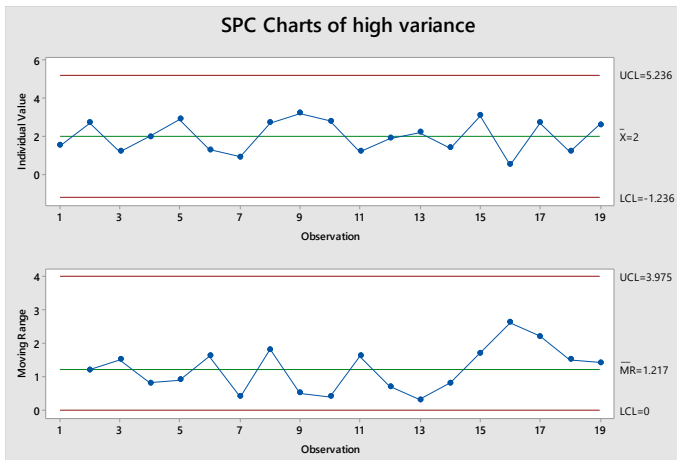
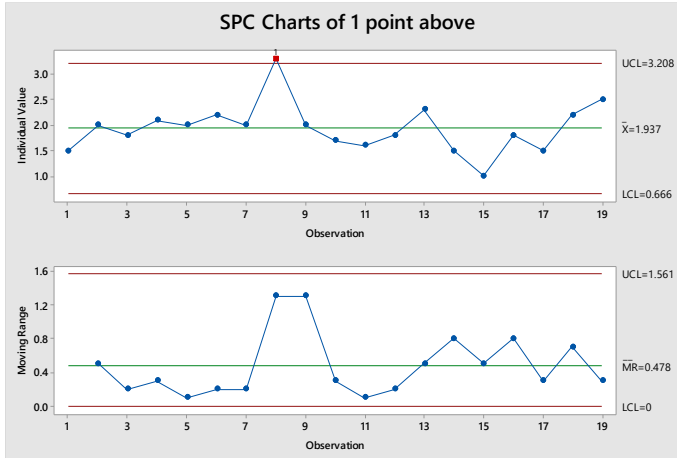
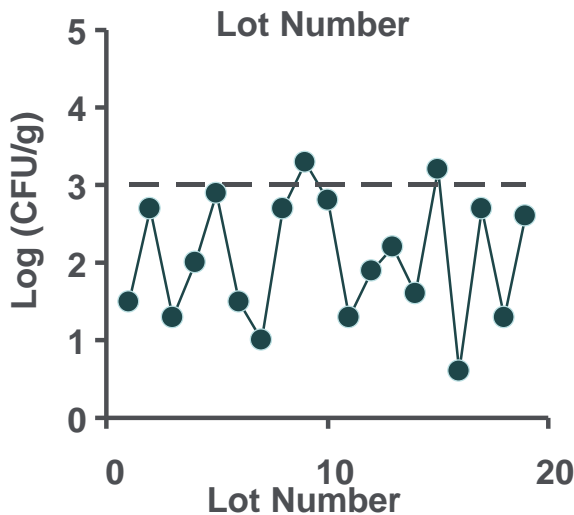
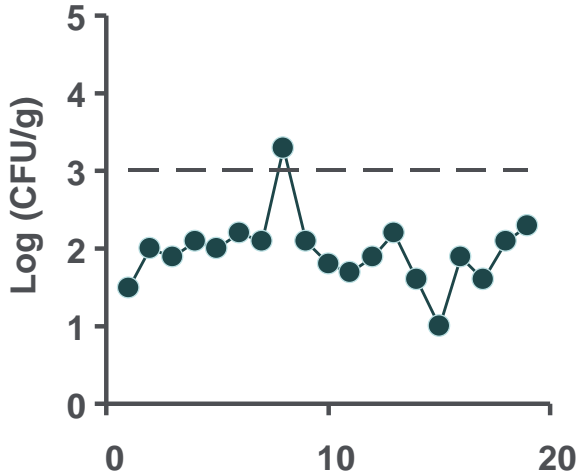


Example: Hypothetical example of x-bar and R control charts using a process capability study that measured “Total Aerobic Plate Count” for 20 data subgroups each with 4 replicates. (Note: On these companion charts the middle solid line represents the target value the flanking lines are the +/- 3σ lines)

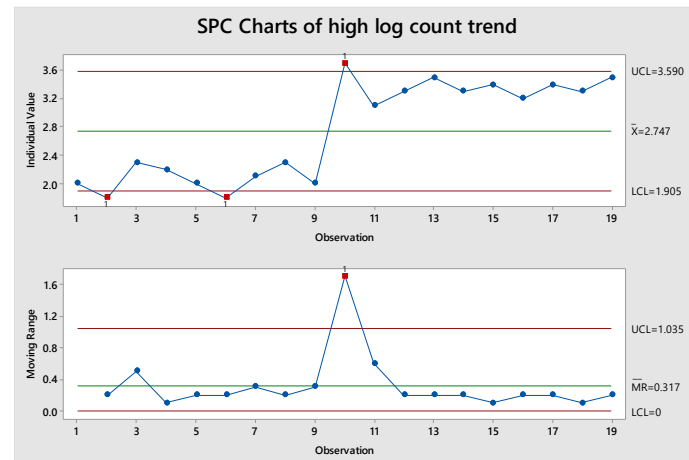
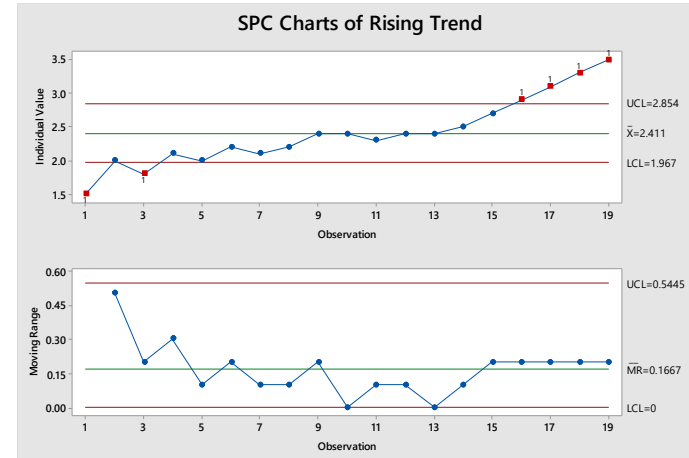
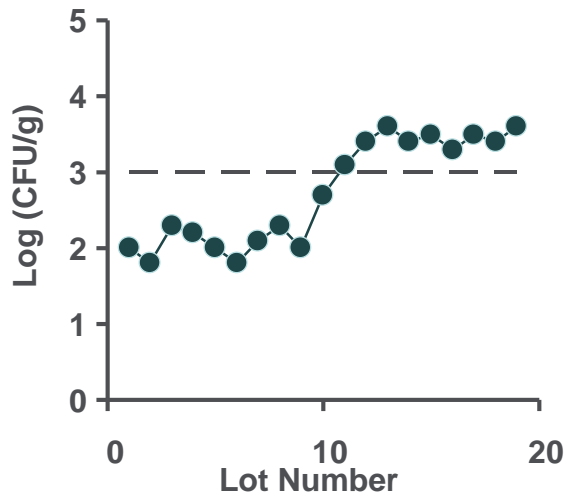
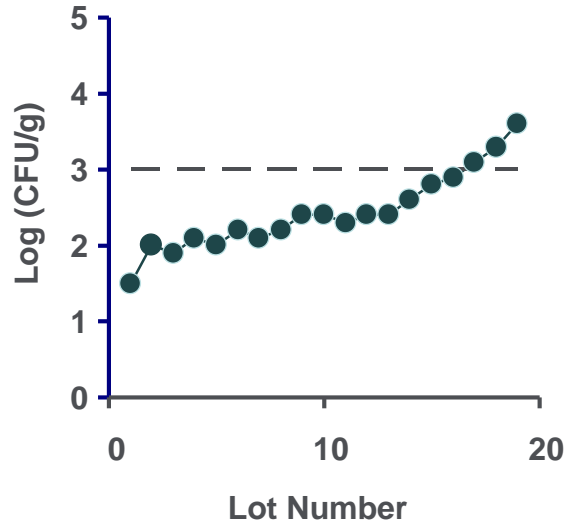
Trend Analysis Can Inform Process Control



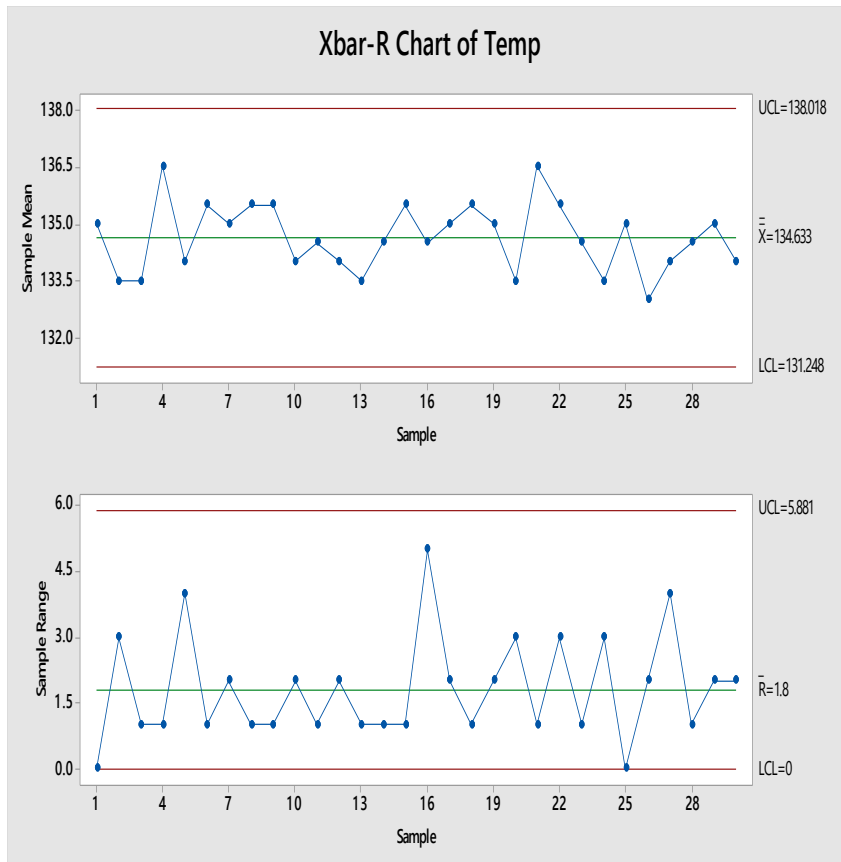
Trend Analysis Can Inform Process Control – SPC Charts #1



Trend Analysis Can Inform Process Control – SPC Charts #2



STATISTICAL PROCESS CONTROL Charts



- Verification can be supported by SPC charting of other (non-microbial) system parameters, e.g.:
 - Temperature (cooking)
 - Moisture (e.g., A_w)
- Monitoring these and examining trends can be helpful in establishing process control and be investigative

Verification Summary

- Testing is recommended to generate meaningful data
 - Validation of controls for quality or safety
 - Verification of controls to direct corrective action
- Process verification data are most often more informative than end-product testing
- ***Statistical process control techniques can be used with quantitative data to continually monitor food systems and aids in investigations of overall processing systems level issues – determining root causes***
- Expertise is essential for reliable decisions

