

# Monitoring validated processes by using SPC

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## Monitoring validated process effectively

- Using SPC / Control charts to monitor processes
- Separating Signal from Noise

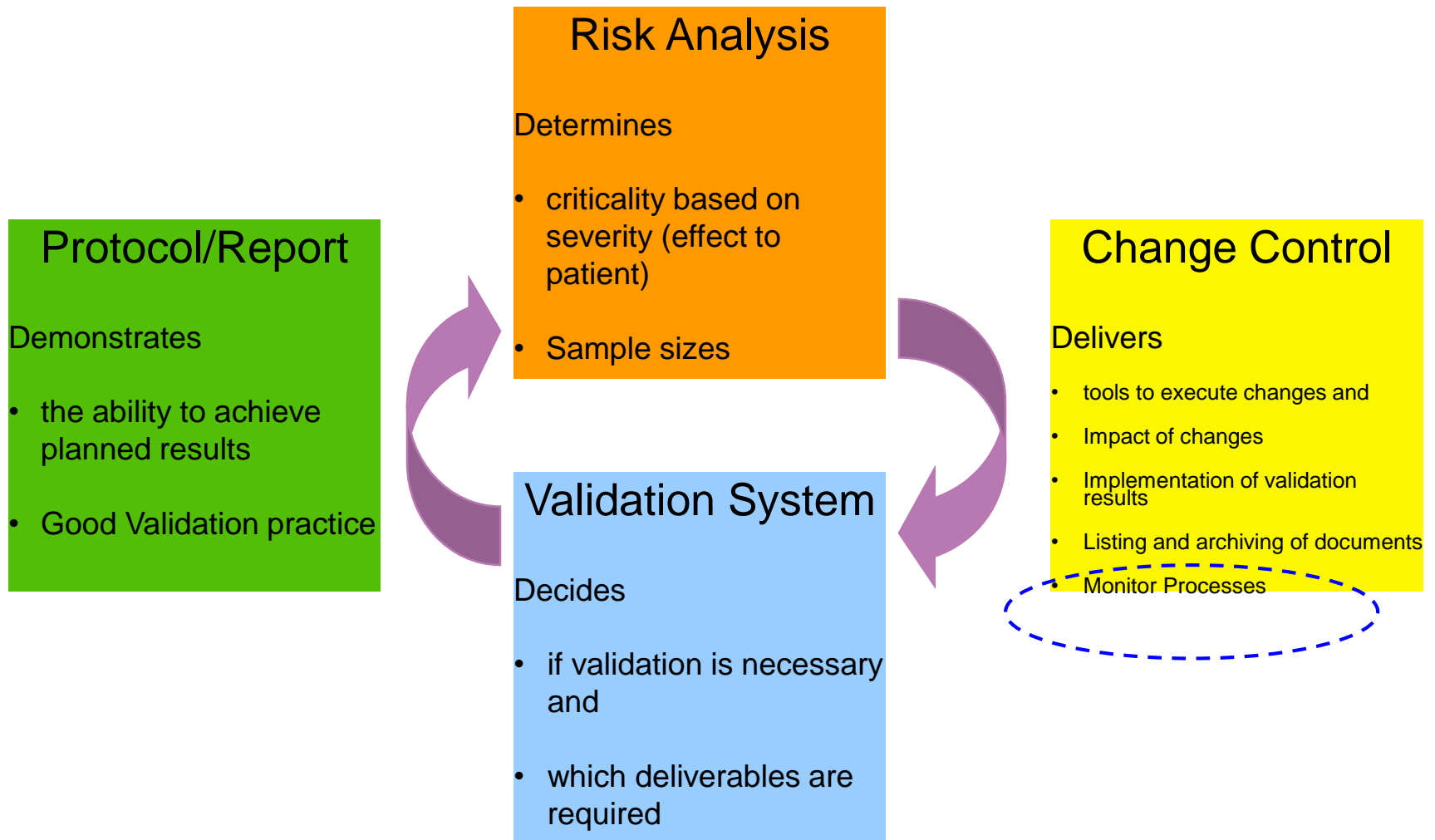
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# System Approach



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## Regulations

- 820.75 Process validation.
  - (a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.
  - (b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.
    - (1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).
    - (2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.
    - (c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

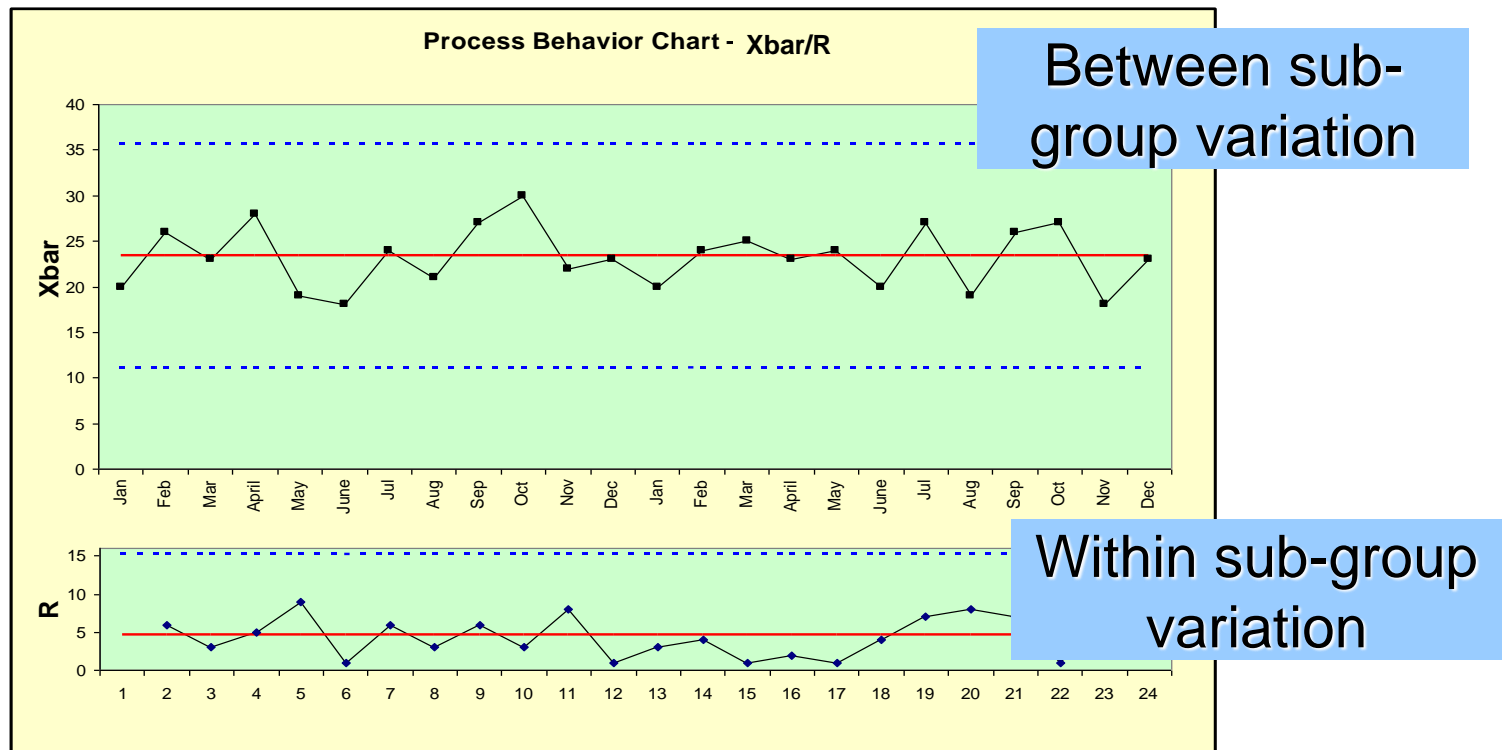
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# Sources of Variation



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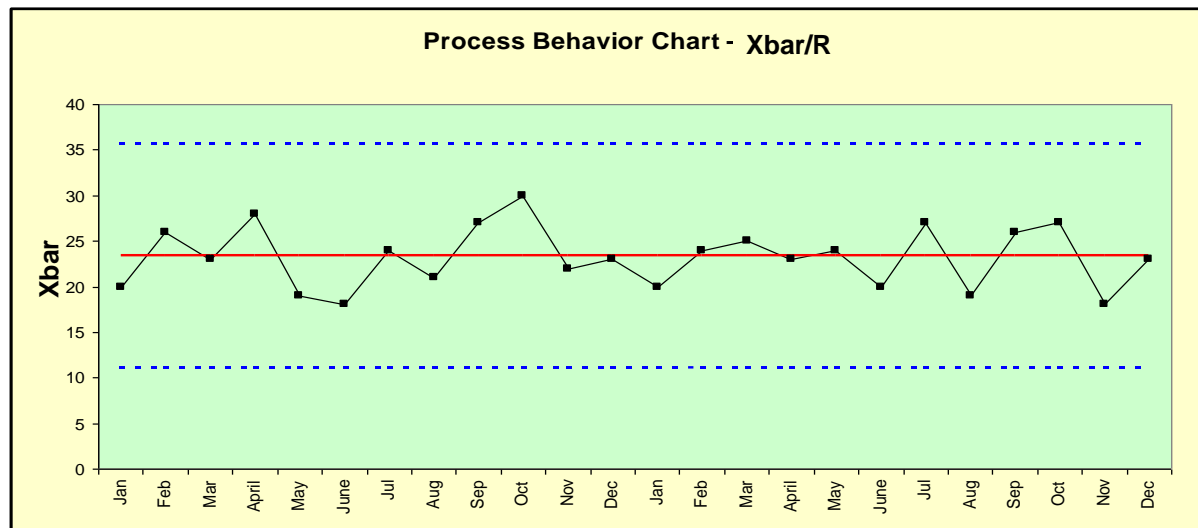
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# Sources of Variation

## Robustness



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- Noise is the random natural variation of a process
- Peaks and troughs are acceptable and are a natural part of the process
- Signals are deviations from natural variation and indicate a change in the process
- Signals include single points and combinations of points called trends

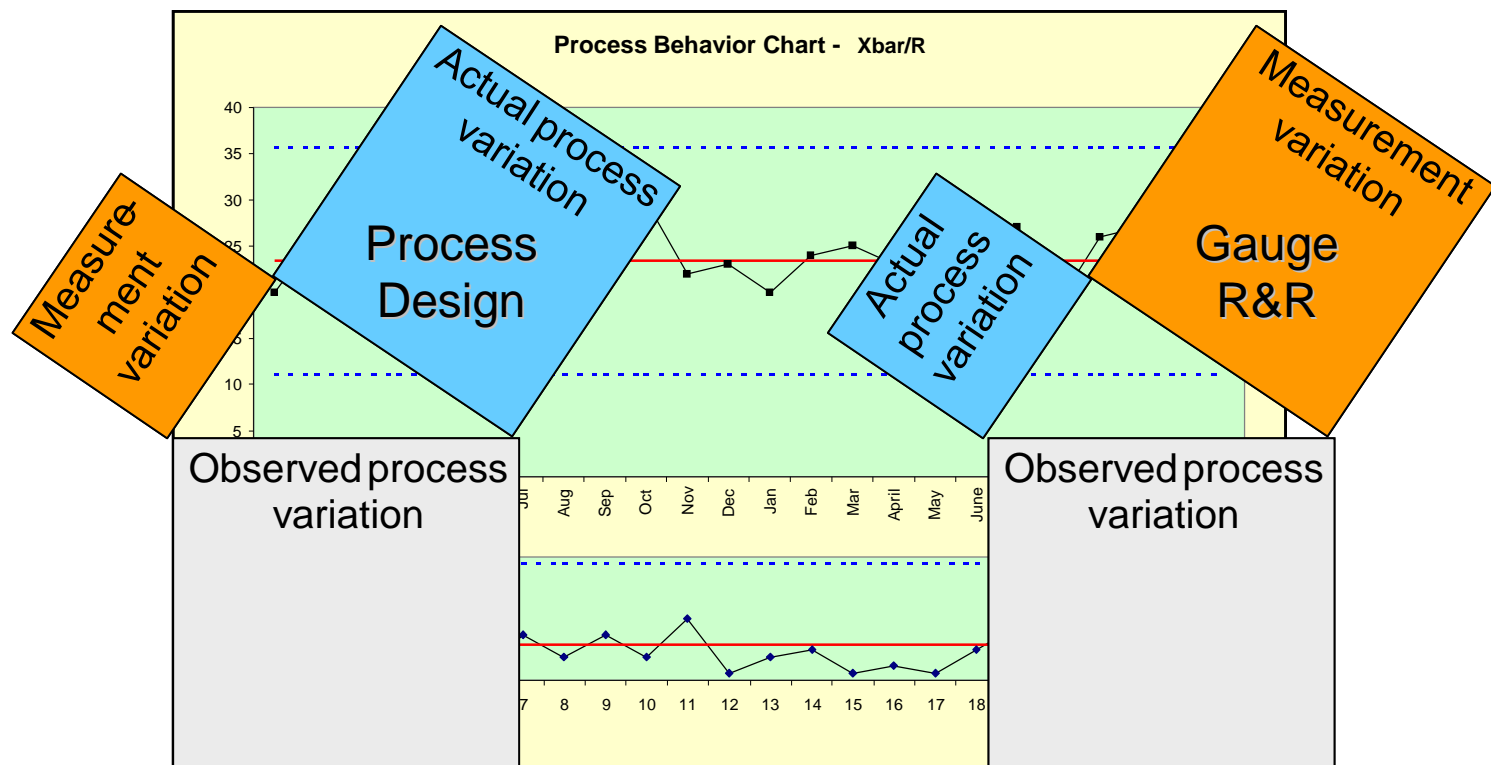
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## Sources of process variation



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- SPC is a method of monitoring an ongoing process
- It involves tracking data (readings or results) over time and using the data to find out information about the process.
- SPC can be performed
  - Manually (pen paper and a calculator if necessary)
  - or
  - Electronically (excel or specific software)
- Can be used anywhere (continuous) data is collected

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- It is used to
  - Observe the process behaviour over time
  - Identify the occurrence of Out of Control Conditions
  - Identify the occurrence of Control in a previously Out of Control process
- It Does Not Control the process
  - It highlights the process behavior and supports the Engineer/Operator in deciding if special cause action is required
- It is a powerful technique when used properly

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## SPC is used to

- Gain a better understanding of our process
- Knowing if our process improvement attempts are working
- Supporting the prioritization of areas for continuous improvement
- To be proactive rather than re-active
- Validated processes need to be monitored to show that they are in a state of control
- Reacting to a test fail can be expensive in terms of both man hours and scrapped material

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- It is used both 'in the office' and 'on the line' in cases of continuously collected data
- On the line
  - Operators will enter data on the line
- In the office
  - Managers and Engineers will use the data to get information about the process
  - Data will be used to support the decision making process

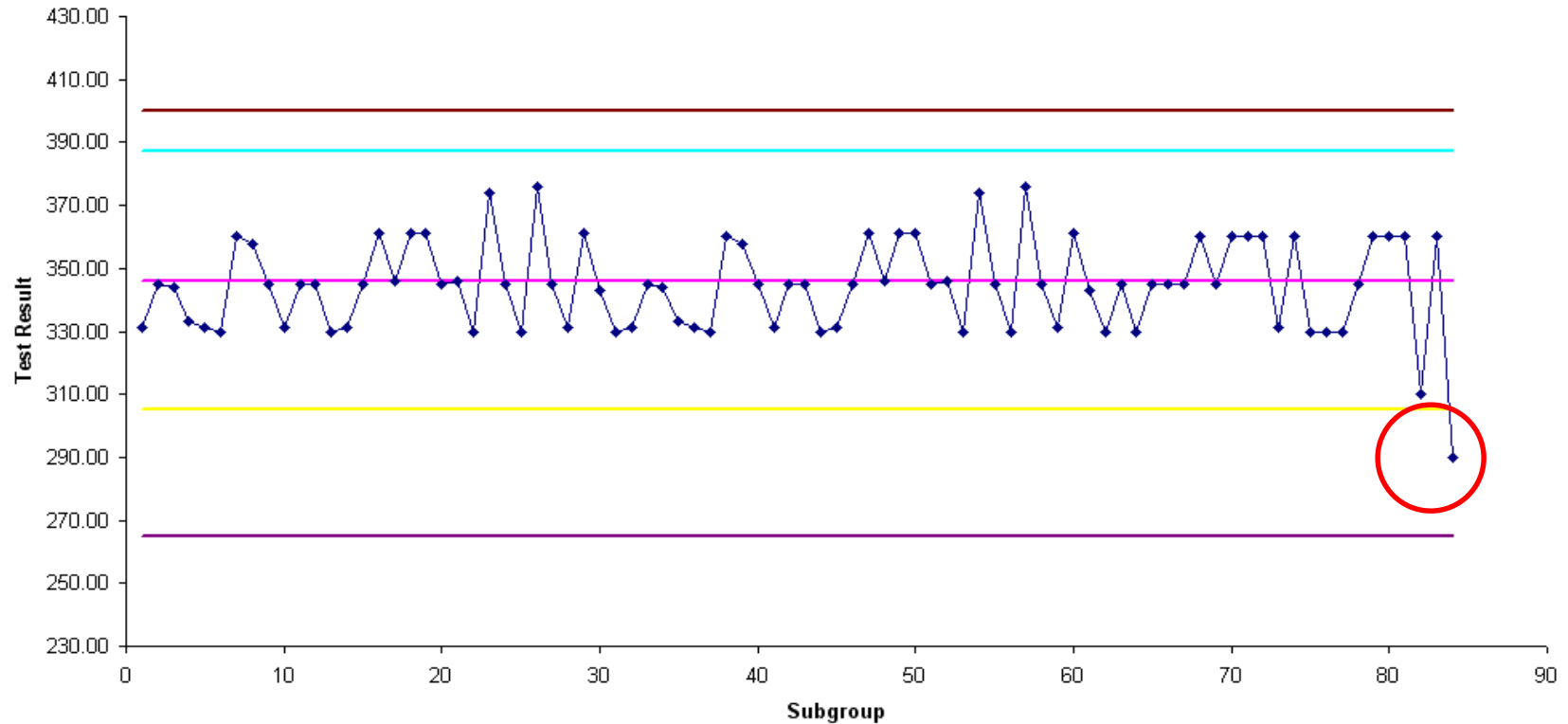
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## Out side Control Limit



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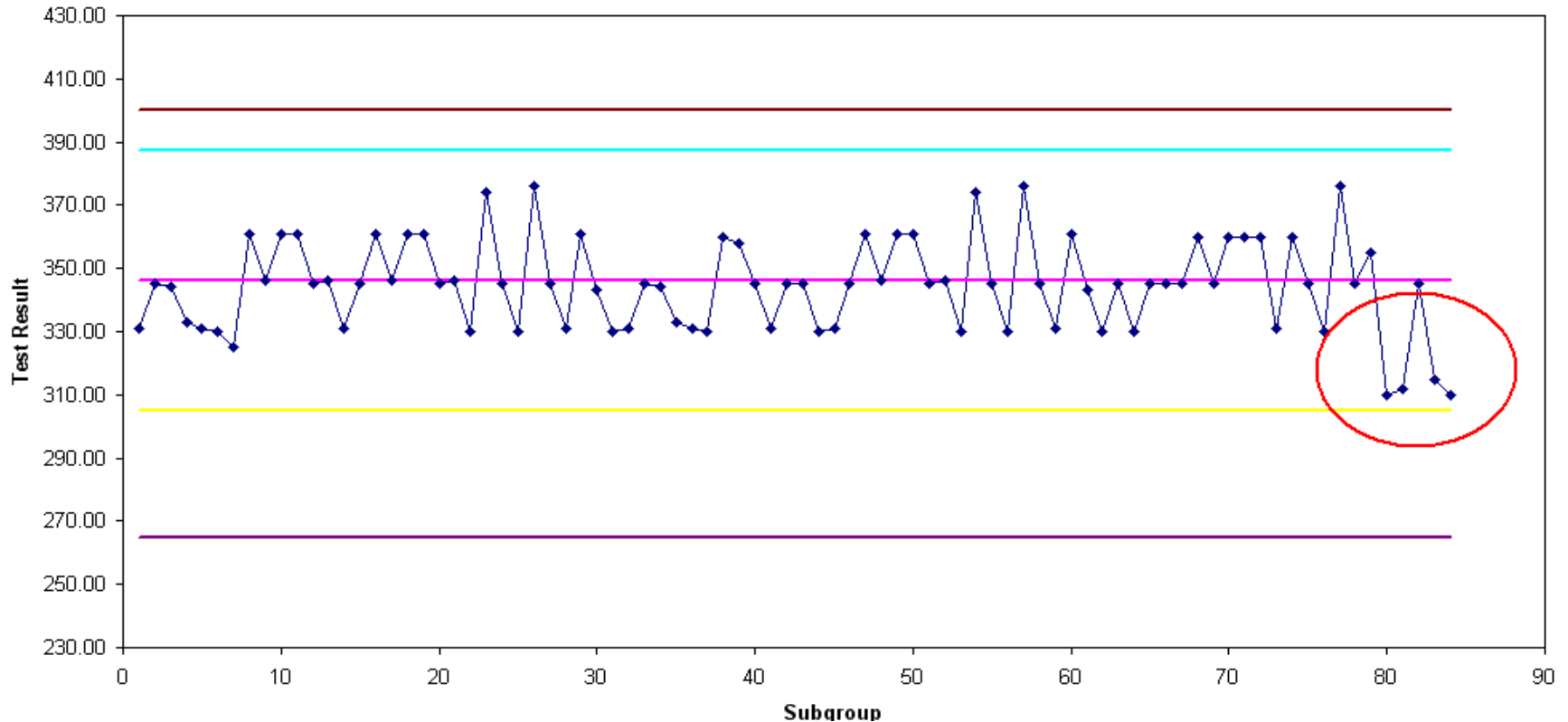
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# Usage of SPC

4 out of 5 are closer to limit than average



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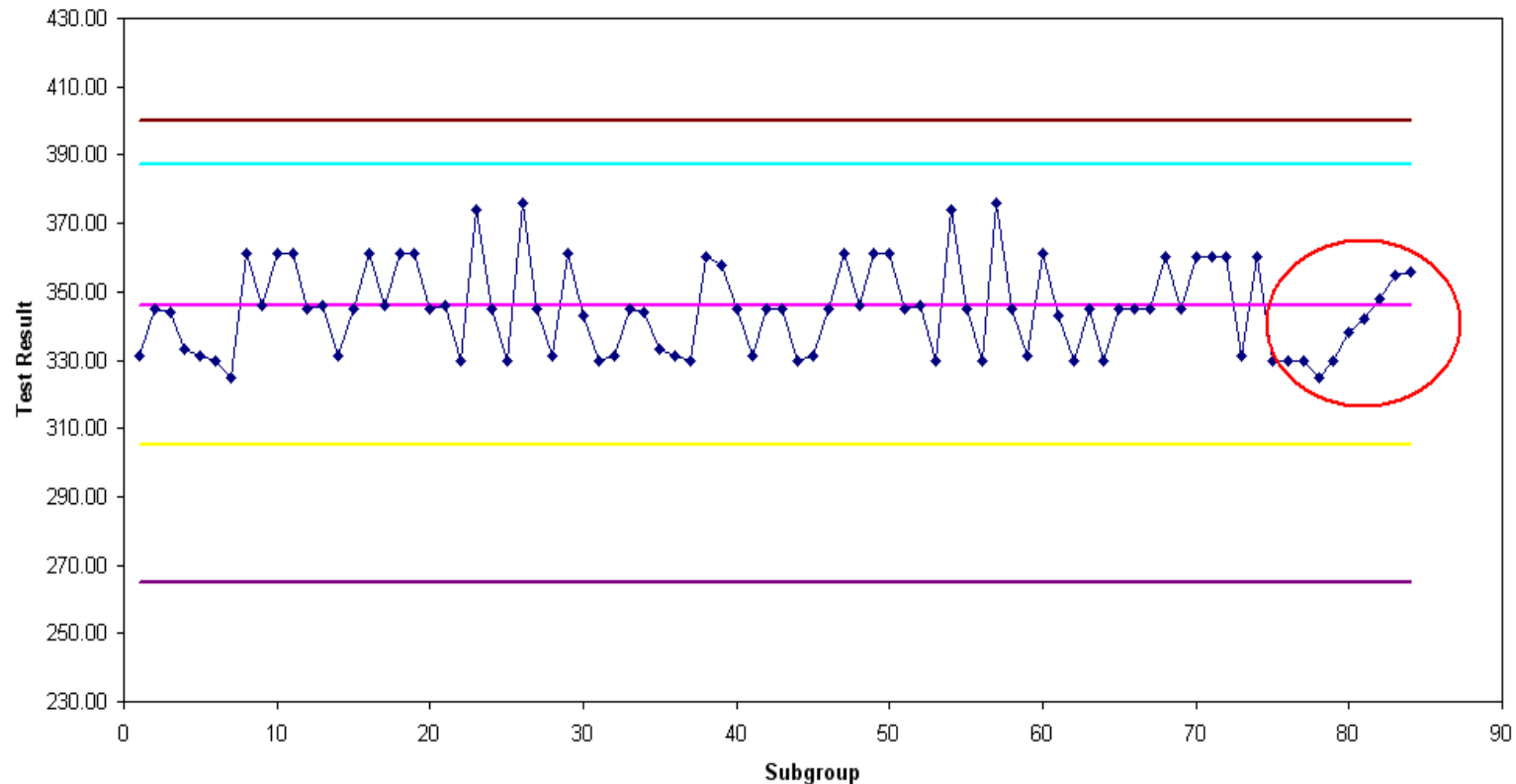
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# Usage of SPC

## 7 in a row



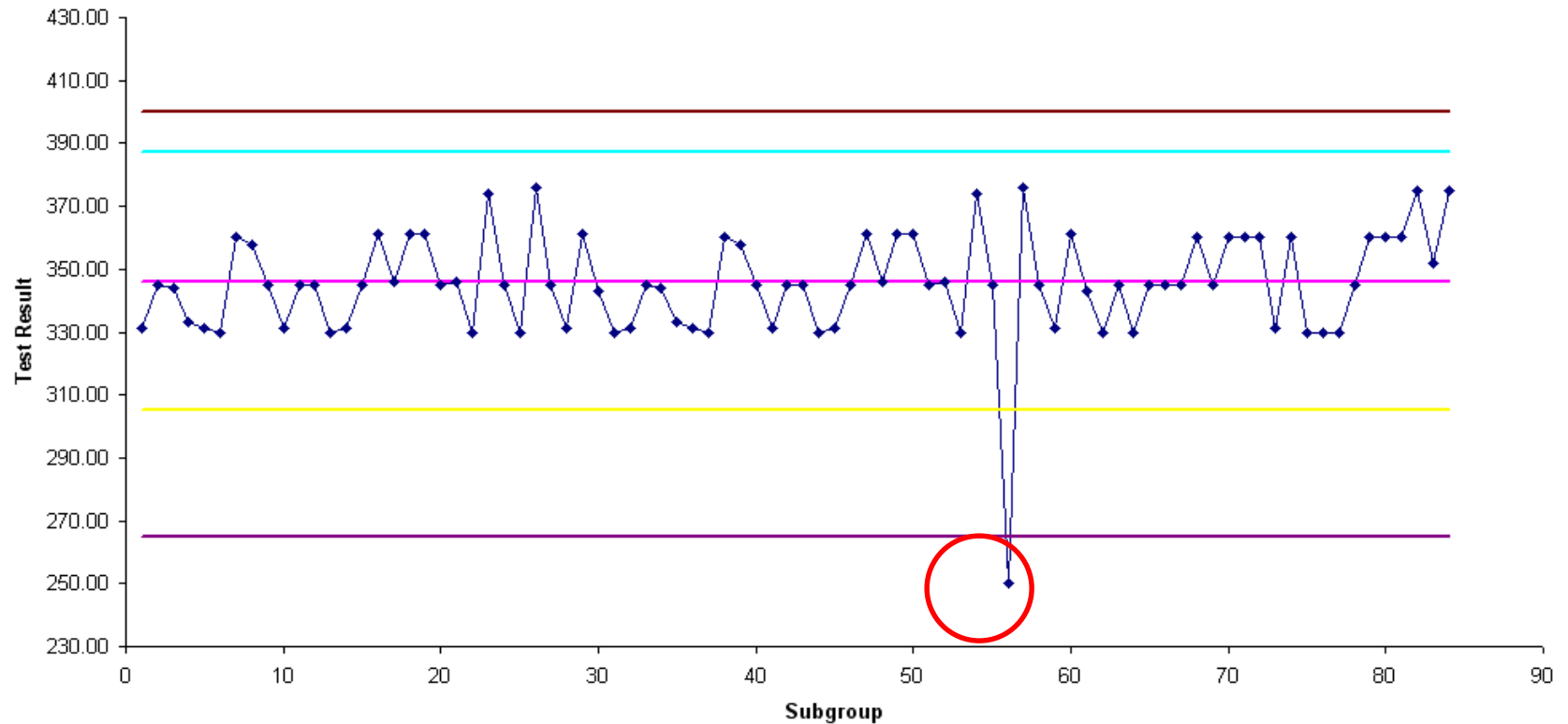
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## Failure – Out of Spec



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- SPC – useful in decision making process
- Importance of Data Collection
- Importance of investigating ‘Out of Control’ Conditions
  - Investigations to be full and thorough
- Data not to be misrepresented – full understanding needed before decisions can be made
- Various Conditions to identify signals, not all of them are in use
  - Hugging the control limits / center line
  - ....

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