

# Process Change Notification (PCN) Supplier Perspective

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# PCN, a Supplier's Challenge

- PCN's are a time consuming, expensive undertaking for both Supplier and End User
  - As technology continues to drive innovation, the process windows shrink requiring tighter material requirements.
    - New materials aside, existing materials that worked on the prior generation, sometimes don't perform as well or at all, in the following generation.
      - This drives change through material studies..
      - This drives PCN's ..
  - As demand grows, expanding production to meet those needs to be accomplished and documented in a way to ensure the product hasn't changed.
    - Extensive product characterization is required



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# 4 Typical Reasons behind a PCN

- **Change in material / processing**
  - Raw material changes or improvements
  - Replacement of older, obsolescent equipment.
  - Addition of new synthesis / processing lines
  - Qualifying a back up supply for BCP
- **Change in metrology to improve capability**
  - Improved detection limits (no-one likes flat line data)
    - Replacement of older, obsolescent equipment
  - Validation of detection limits (MSA's, Gage R&R , LTS)
- **Change in the number of components being measured**
  - Driven by identification thru chemical fingerprinting
- **Data and Documentation**
  - CofA or eCofA changes
  - Identification and Transportation requirements
    - Labels, Bar codes, RFID



# Complexity of PCNs

- **PCN complexity increases as dimension shrink.**
  - The trend for more components being measured, increases yearly.
    - Hydrocarbons that had a six component analysis a few years ago, now have up to a 28 components analysis and a Chemical Fingerprint.
  - The need to have better characterization of the material
    - The drive to improve detection limits.
      - Establishing lower MDL's on more components.
    - Chemical fingerprints
      - Both raw and finished products to establish a baseline
      - No longer a simple statistical review.
- **Technology leaders drive the PCN's down to other customers**
  - As materials or metrology are required to improve, new standards are established which then become PCNs in the future for all other customers utilizing that material.
    - Utilizing a single best practice is better than supporting older / multiple methods for different customers.
      - Invites errors in processing.



# Additional Parameters Increases Probability of Rejecting Good Product (False Positive)

Number of Parameters	Pass Rate	Fail Rate
3	97%	3%
4	96%	4%
5	95%	5%
10	90%	10%
15	86%	14%
20	82%	18%

**Note that these calculations assume that the specification captures 99.73% and that the parameter distribution is normal. False positive failure rates significantly increase when specification limits are set at minimum detection limits and/or parameter distributions are not normal, which is the case for most contaminants.**

# Fab Requirements- Adding Complexity

- **Typical material PCN is 80-100 pages of data and statistics.**
  - Challenge: Different fabs want different formats:
    - Statistical Approach
      - Minimum number of samples
        - » Some fabs require 2-4 times the number of samples.
      - Two-Sample T-Tests vs. 1 Sample T-Tests
        - » Reworks the entire data pack.
    - Custom Formats
      - Same data, same results but transcribed into a custom format
      - Additional requirements
        - » Full Risk Analysis
        - » Operator Training Records

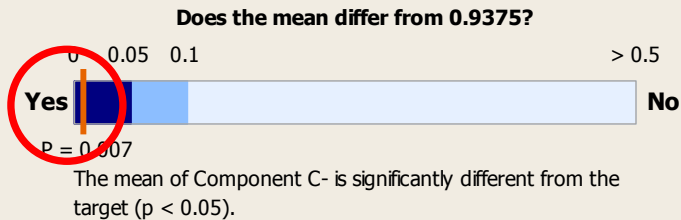
**Example to follow on analytical two similar test methods**



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# Example One vs Two sided T-Test

## 1-Sample t Test for the Mean of Component C- Summary Report

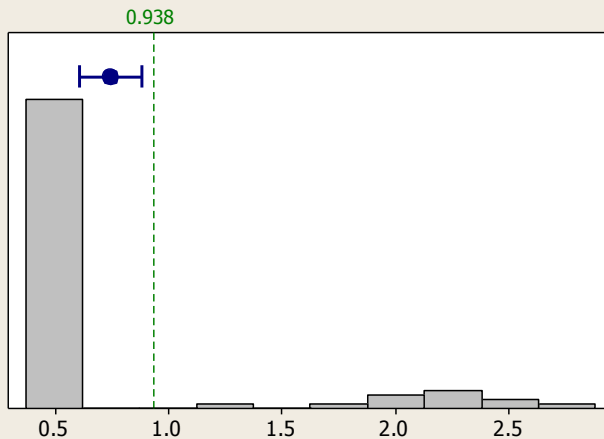


### Statistics

Sample size	79
Mean	0.74810
95% CI	(0.61163, 0.88458)
Standard deviation	0.60930
Target	0.9375

### Distribution of Data

Where are the data relative to the target?



### Comments

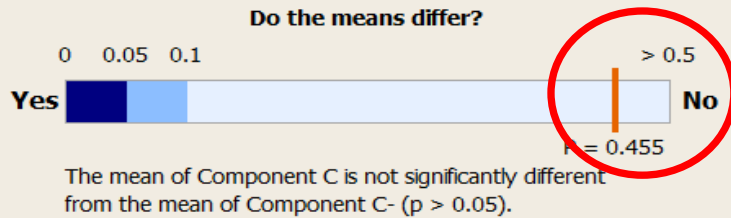
- Test: You can conclude that the mean differs from 0.9375 at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the mean from sample data. You can be 95% confident that the true mean is between 0.61163 and 0.88458.
- Distribution of Data: Compare the location of the data to the target. Look for unusual data before interpreting the test results.



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# Example One vs. Two sample T-Test

## 2-Sample t Test for the Mean of Component C and Component C- Summary Report

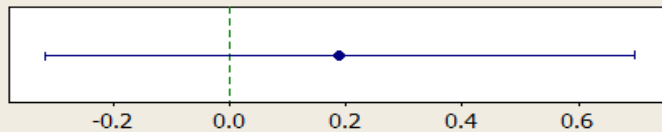


Statistics	Component C	Component C-
Sample size	32	79
Mean	0.9375	0.74810
95% CI	(0.4453, 1.430)	(0.61163, 0.88458)
Standard deviation	1.3652	0.60930
Difference between means*		0.18940
95% CI		(-0.31941, 0.69820)

\* The difference is defined as Component C - Component C-.

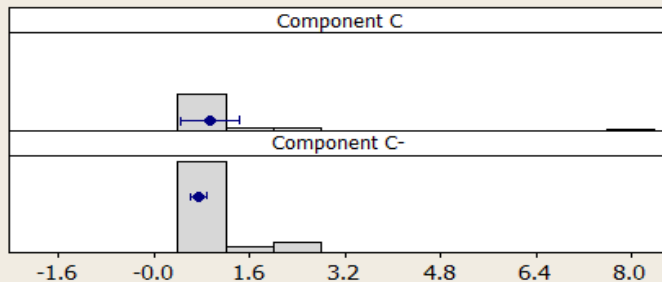
### 95% CI for the Difference

Does the interval include zero?



### Distribution of Data

Compare the data and means of the samples.



### Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 95% confident that the true difference is between -0.31941 and 0.69820.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.



# Sample Test

- **Same material, two independent distillation columns, same laboratory equipment but depending upon which test is used, it either fails (statistically different) or finds no statistical difference.**
  - **Standardizing on a single approach will provide a consistent approach to material reviews.**
  - **It will accelerate the implementation of the PCN by eliminating delays in approval(s).**



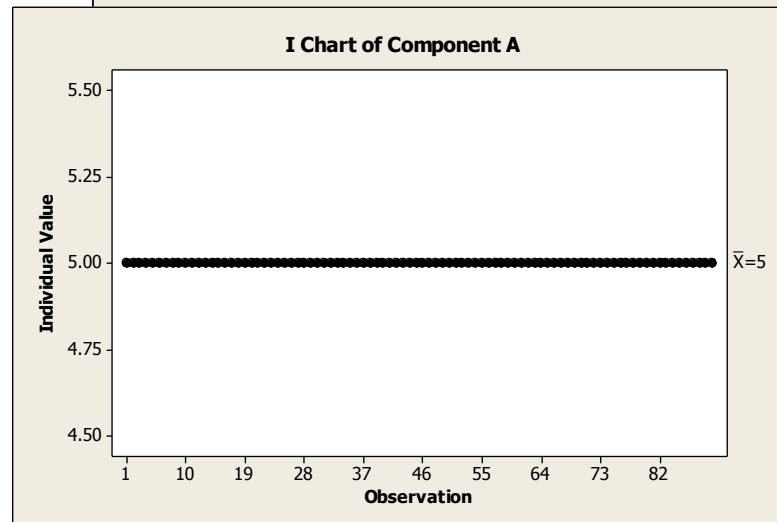
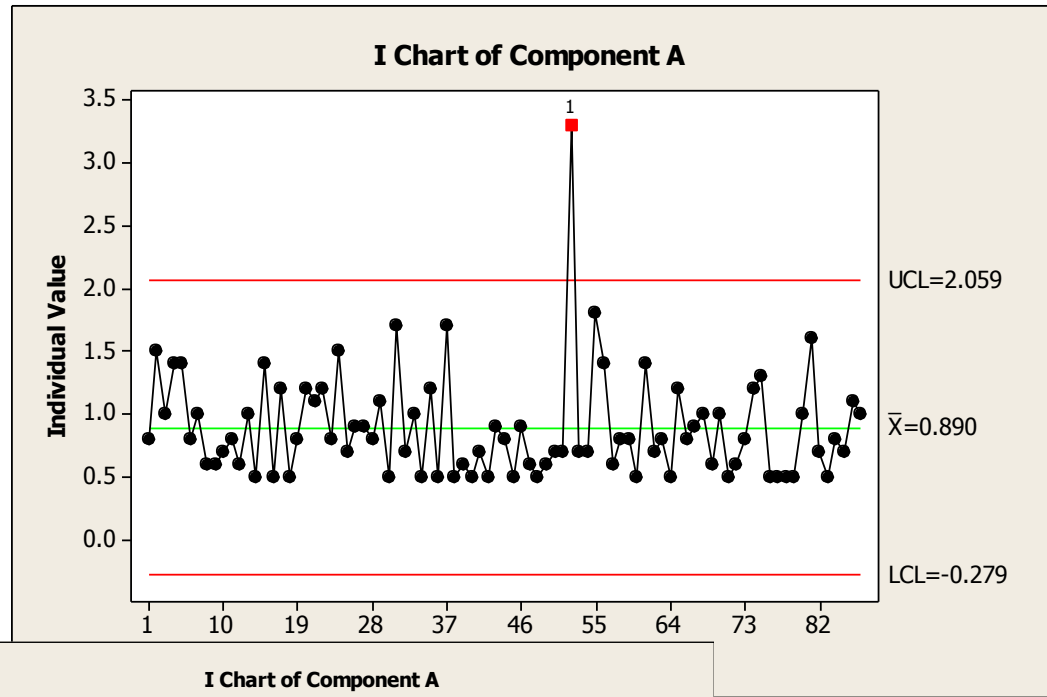
# Metrology PCN Challenges

- **Metrology PCNs have additional challenges:**
  - Obsolescent technology may not have the detection limits of new metrology.
    - The result is they will statistically fail T-Tests especially when the old metrology results are highly or fully truncated.
      - This will delay the approval of the PCN as it isn't "the same".
  - Metrology is highly dependent upon the Method used requiring:
    - Gage R&R (addresses: Linearity Bias & Precision and Accuracy)
    - MSA (Measurement System Analysis)/ MDL (Method Detection Limit)
      - Older reporting methods typically were using "detection limit"
  - Gas Mixtures have the added complexity of Mix Tolerance and post-fill measurements



# Example, which is better?

- The bottom I-Chart is truncated at 5 ppmv detection limit.
- The top I-Chart is new metrology that shows the variability, all below 3.5 ppmv.
- Same material, different metrology.
  - Statistically different.



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# Impact of Diverse PCN Requirements

- The General PCN will cover 70-80% of the fabs with little issue.
- The fabs that have unique formats or requirements will receive their PCN later due to the time required to rework the document.
  - This has the impact of delaying the PCN with potentially the same end point (shortening the approval window).
- Metrology PCNs can turn into emergency PCNs if the tool dies.
  - Often there is a long window to qualify the tool even on the POR material.



# Summary..

- No one wants PCNs but we understand the necessity to document changes and qualify the change.
  - Moving through a PCN quickly is beneficial financially to both Fabs and suppliers.
    - Having a comprehensive PCN document aides in the review process.
    - Having all the customers approve a PCN in the shortest period of time reduces costs and risks.
- Wish List:
  - A single format that all fabs would agree on utilizing:
    - The preferred tests methods, content:
      - Run charts
      - Process Capability Analysis
      - Statistical tests (e.g. T-Tests, other)
    - Sample requirements (minimum)
    - Analytical requirements (Fingerprints, LTS)