Mount Wachusett Community College

QUALITY SYSTEMS INTENSIVE WORKSHOP

40 hour (2 week, 5hr/day, 4-day)

Prepared by Gretchen Ingvason as part of NSF ATE Grant #1304474 - (National Science Foundation Advanced Technical Education)

QUALITY SYSTEMS INTENSIVE WORKSHOP

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MODULE 3
ANALYSIS

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ANALYSIS

Shop Math & Statistics Review

Analyzing the Data

Using Excel

Introduction to SPC

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REVIEW

- Inspection Types
  - Acceptance Sampling
- Sample Planning & Logistics
  - Traceability
  - When/where/who to sample
  - Collection methods
  - Quantity needed (Sample plans vs 100%)
- Inspection process:
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary

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SHOP MATH

- Inspection process:
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary

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SHOP MATH

- General math skills needed in production (service)

Universal
- Fractions
- Ratios
- Decimals
- Percentages
- Equations
- Conversions

~~Dimensional~~
- ~~Circles~~
- ~~Triangles~~
- ~~Perimeters~~
- ~~Areas~~
- ~~Angles~~
- ~~Volumes (solids)~~
- ~~Tapers~~

Outside the context of this course

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SHOP MATH

- Fractions
  - Adding / Subtracting
    - lowest common denominator
    - reducing

3/8 + 5/16 =

1/3 + 1/4 =

3/8 – 13/64 =

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SHOP MATH - Universal

- Fractions
  - Adding / Subtracting
    - lowest common denominator
    - reducing
  - Multiplying / Dividing

    6/32 * 1/4 =

    3/4 ÷ 3/8 =

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SHOP MATH - Universal

- Ratios

  70:30

  10:1

  4:1

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SHOP MATH - Universal

- Decimals
  - Places
  - 0.abcdef (etc.)

    A = 0.1 tenths
    B = 0.01 hundredths
    C= 0.001 thousandths
    D= 0.0001 ten thousandths (may also be called tenths)
    E = 0.00001 hundred thousandths
    F = 0.000001 millionths (also called parts per million ppm)
    …
    = 0.000000001 billionths (ppb parts per billion)
    …
    = 0.000000000001 trillionths (ppt parts per trillion)

SHOP MATH - Universal

- Decimals
  - Places
  - Fraction conversion

    1/16 =

    3/32 =

  - Multiplying/Dividing

    0.25 * 12

    12 ÷ 0.25

SHOP MATH - Universal

- Decimals
  - Places
  - Fraction conversion
  - Multiplying/Dividing
  - Converting Percentages to decimal (and vice versa)

14.17% = 0.

0.005 = %

SHOP MATH - Universal

- Decimals
  - Places
  - Fraction conversion
  - Multiplying/Dividing
  - Converting Percentages to decimal (and vice versa)
  - Scientific notation

2.5×10^5

2.5×10^{-4}

STATISTICS REVIEW

- Definition

  …science of collecting, organizing, analyzing and interpreting data in order to make decisions…
- Two Branches
  - Descriptive – organization, summarization & display of data
  - Inferential –uses sample to draw conclusions about a population
- Data Sets
  - Population: collection of ALL outcomes, measurements, etc.
  - Sample: subset or part of population

Quality Assurance & Quality Control are based on inferential

--- infer release of lot based on results of sample ---

The difference between the statistic inferred from the sample and the true population statistic is known as sampling error;

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STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous
    - All (continuum) values possible
    - Integers
    - Time sequence
    - Counts
    - Pass / Fail (go/no-go)

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STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative (variable vs attribute)
  - Discrete versus continuous
    - All (continuum) values possible
    - Integers
    - Counts
    - Pass / Fail (go/no-go)

STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
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STATISTICS REVIEW

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    - Integers
    - Counts
    - Pass / Fail (go/no-go)

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STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous
  - Sequenced
    - Time (hours)
    - Monthly
    - Manufactured order (1-100..)

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STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous
  - Sequenced

Descriptive Statistics

- Measures of central tendency
- Measures of dispersion
- Measures of shape

STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous

$\overline{x}$

STATISTICS REVIEW

- Measures of central tendency
  - Mean
    - Arithmetic average of the data

$(\sum x_1 + x_2 + \ldots) / n$ x = individual values, n = total number measured

Known as x-bar ( ) for the sample
Known as mu (μ) for population

  - Median
    - Middle number that separates the data

Example: 2 3 4 5 9 median is 4 (mean is 4.6)
2 3 4 5 6 9 median is 4.5 (mean is 4.8)

  - Mode
    - Number that appears most frequently

Example: 2 3 6 8 9 6 7 10 11 6 4 5 12

STATISTICS REVIEW

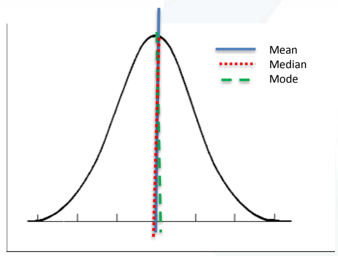
- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous
  - Measures of central tendency
    - Mean (arithmetic average)
    - Median (middle number of data set)
    - Mode (number that appears most frequently)

Example: 2 3 6 8 9 6 7 10 11 6 4 5 12

mean = 6.8 [(2+3+4+5+6+6+6+7+8+9+10+11+12)/13]
median = 6 (2 3 4 5 6 6 6 7 8 9 10 11 12)
mode = 6

STATISTICS REVIEW

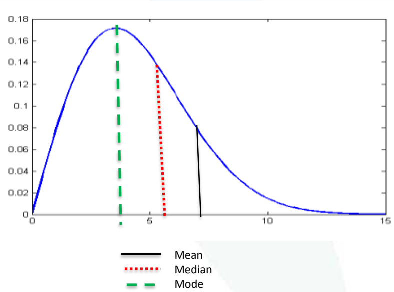
– Measures of central tendency
  - Mean (arithmetic average)
  - Median (middle number of data set)
  - Mode (number that appears most frequently)



When the distribution of the results is "normal" the mean, median and mode will be equal

STATISTICS REVIEW

– Measures of central tendency
  - Mean (arithmetic average)
  - Median (middle number of data set)
  - Mode (number that appears most frequently)



When the distribution is not normal, the median is the best indicator of central tendency – not affected by outliers.

STATISTICS REVIEW

Central Tendency	Advantage	Disadvantage
Mean (arithmetic average)	Center of gravity of the data	Extreme values may distort the picture
	Uses all data	May not be the actual value of any data point
	No sorting needed	
Median (middle number of data set)	Idea of where most data located	Data must be sorted/arranged
	Little calculation required	Extreme values may be important
	Insensitive to extreme values	Two medians cannot be averaged for combined median
		More variation between samples
Mode (number that appears most frequently)	Not influenced by extreme values	Data may not have a mode
	Is an actual value	
	Can be detected visually in plots	
	No calculating or sorting necessary	

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STATISTICS REVIEW

- Measures of Dispersion
  - Range
    - Difference between the largest and smallest value within the data set

    Example: 3 5 7 9 8 4 1 8 7
    Range is 8 (9-1)
  - Variance
    - Sum of the squared difference from the mean divided by the sample size

      Known as S^2 for the sample
      Known as σ^2 for the population

$$\sigma^2 = \frac{\sum (x - \mu)^2}{N} \qquad S^2 = \frac{\sum (x - X)^2}{n-1}$$

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STATISTICS REVIEW

- Measures of Dispersion
  - Range (difference between largest and smallest)
  - Variance (Sum of the squared difference from the mean divided by the sample size)
  - Standard Deviation
    - Square root of the variance

      Known as s for the sample
      Known as σ for the population

$\sigma = \sqrt{\sum (x - \mu)^2/N}$ $S = \sqrt{\sum (x - \bar{x})^2/n-1}$

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STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous
  - Measures of central tendency (mean, median, mode)
  - Measures of dispersion (range, variance, standard deviation)
  - Measures of shape
    - Continuous frequency distributions (variable data)
      - Normal
      - Exponential
      - Weibull

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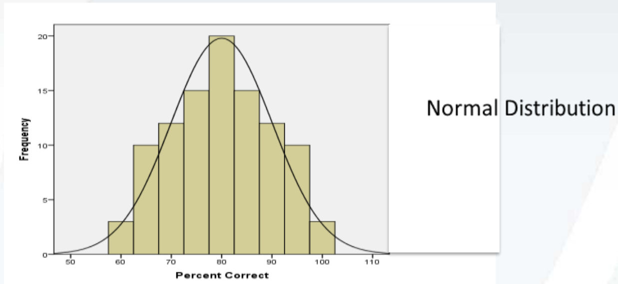
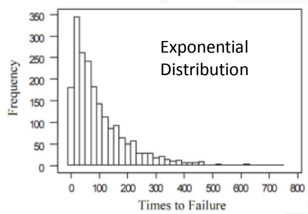
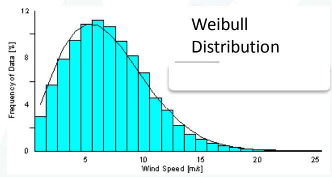
Continuous Frequency Distributions







STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous
  - Measures of central tendency (mean, median, mode)
  - Measures of dispersion (range, variance, standard deviation)
  - Measures of shape
    - Continuous frequency distributions (variable data)
      - Normal
      - Exponential
      - Weibull
    - Discrete frequency distributions (attribute data)
      - Poisson
      - Binomial
      - Hypergeometric

STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
  - Discrete versus continuous
  - Measures of central tendency (mean, median, mode)
  - Measures of dispersion (range, variance, standard deviation)
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    - Discrete frequency distributions (attribute data)

Quality Assurance & Quality Control are based on inferential
--- infer release of lot based on results of sample ---

The difference between the statistic inferred from the sample and the true population statistic is known as sampling error

STATISTICS REVIEW

- Understanding data
  - Quantitative vs qualitative
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  - Measures of central tendency (mean, median, mode)
  - Measures of dispersion (range, variance, standard deviation)
  - Measures of shape
    - Continuous frequency distributions (variable data)
    - Discrete frequency distributions (attribute data)

Quality Assurance & Quality Control are based on inferential
--- infer release of lot based on results of sample ---

The difference between the statistic inferred from the sample and the true population statistic is known as sampling error;

  - Large sample size = smaller sample error

Central Limit Theorem

- Central Limit Theorem

  "... the arithmetic mean of a sufficiently large number of iterates *(samples)* of independent random variables, each with a well-defined expected value and well-defined variance, will be approximately normally distributed, regardless of the underlying distribution.." wikipedia.com

  This can be achieved with 30 samples (50 in some statistics books).

  Why is this important?

  - *Quality Assurance & Quality Control are based on inferential statistics; determine release of lot based on results of sample*
  - *Large sample size = smaller sample error*
  - *When the distribution of the results is "normal" the mean, median and mode will be equal*

  Therefore $x \cong \mu$ (sample mean approximates population mean)

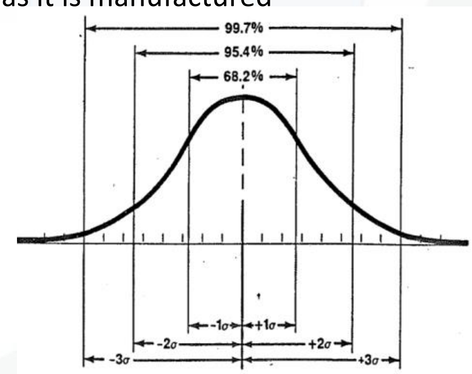
  and $s \cong \sigma$ (sample standard deviation approximates population standard deviation)

HOW STATISTICS USED

- Two Branches
  - Descriptive – organization, summarization & display of data
  - Inferential –uses sample to draw conclusions about a population
- Understanding data
  - Measures of central tendency
    - mean, median, mode
  - Measures of dispersion
    - range, variance, standard deviation
  - Measures of shape
    - Variable Data = Normal, weibull, etc.

HOW STATISTICS USED

- Understanding data
  - Measures of central tendency (mean, median, mode)
  - Measures of dispersion (range, variance, standard deviation)
  - Measures of shape (variable data = normal, etc.)
- Standard deviation is used to predict whether product remains within specification as it is manufactured
  - Often referred to as sigma
  - 1 sigma = 68.2% of results
  - 2 sigma = 95.4%
  - 3 sigma = 99.7%



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STATISTICS REVIEW

Quality Assurance & Quality Control are based on inferential
--- infer release of lot based on results of sample ---
-- comparison of products, machines, etc. --

- Hypothesis testing
  - Statistical hypothesis testing can also be known as confirmatory data analysis
  - Used for making informed decisions
    - Product pre- and post- change, is it the same?
    - Material vendor A versus vendor B, are they equivalent?
    - Marketing decisions
    - New treatments (medicine, therapies, etc.)

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STATISTICS REVIEW

Quality Assurance & Quality Control are based on inferential
--- infer release of lot based on results of sample ---
-- comparison of products, machines, etc. --

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    - Product pre- and post- change, is it the same?
    - Material vendor A versus vendor B, are they equivalent?
    - Marketing decisions
    - New treatments (medicine, therapies, etc.)
- Comparison of means or variation?

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STATISTICS REVIEW

- Comparison of means or variation?
  - Is there a difference in the spread (variation) of the data between the "sample" and previous population?

Comparing the risks of having an accident among several groups of people

Are there fewer reported side-effects from the new drug versus the old drug?

Are the two samples statistically different?

data driven decision rather than "gut" feel

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STATISTICS REVIEW – Hypothesis Testing

- Comparison of means or variation?
- Statistical inference using data
  - "Statistically significant" when predicted as unlikely to have occurred by chance alone
    - There is a significance (confidence) level

Example 95% confident that Vendor B is the same as current Vendor (A).

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STATISTICS REVIEW – Hypothesis Testing

- Comparison of means or variation?
- Statistical inference using data
  - "Statistically significant" when predicted as unlikely to have occurred by chance alone
    - There is a significance (confidence) level.
  - Reject the null hypothesis
    - Is there enough data to cast doubt on conventional wisdom

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HYPOTHESIS TESTING

- Statistical inference using data
  - "Statistically significant" when predicted as unlikely to have occurred by chance alone
    - There is a significance level.
  - Reject the null hypothesis
    - Is there enough data to cast doubt on conventional wisdom
- How to:
  - State null hypothesis and alternate hypothesis

    Example: Person in the court system is considered innocent until proven guilty

    null hypothesis (H_0) = not guilty

    alternate hypothesis (H_1) = guilty

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HYPOTHESIS TESTING

- Statistical inference using data
  - "Statistically significant" when predicted as unlikely to have occurred by chance alone
  - Reject the null hypothesis
- How to:
  - State null hypothesis and alternate hypothesis
  - Select significance level
    - Probability below which null hypothesis will be rejected
    - Typically 5% or 1% (0.05 or 0.01)

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HYPOTHESIS TESTING

- Selecting significance level
  - Type I (α) error
    - Rejecting the null hypothesis when it is true
    - Post-change lot considered different when it was equivalent
  - Type II (β) error
    - Accepting the null hypothesis when it is false
    - Post-change lot was considered equivalent when it was different.

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HYPOTHESIS TESTING

- Selecting significance level
  - Type I (α) error
    - Rejecting the null hypothesis when it is true
  - Type II (β) error
    - Accepting the null hypothesis when it is false

Example: Person in the court system is considered innocent until proven guilty

null hypothesis (H_0) = not guilty
alternate hypothesis (H_1) = guilty

	H_0 is true Truly Not Guilty	H_1 is true Truly Guilty
Accept the Null Acquittal	Right decision	Wrong decision **TYPE II (β) error**
Reject the Null Conviction	Wrong decision **Type I (α) error**	Right Decision

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HYPOTHESIS TESTING

- Selecting significance level
  - Type I (α) error
    - Rejecting the null hypothesis when it is true
  - Type II (β) error
    - Accepting the null hypothesis when it is false

Example: Vendor A product has average diameter 0.055”
new Vendor (B) has average diameter 0.050”
Should we switch to Vendor B because they’re better?

null hypothesis (H_0) = better
alternate hypothesis (H_1) = not better

	H_0 is true Truly Better	H_1 is true Truly Not Better
Accept the Null Switch to Vendor B	Right decision	Wrong decision **TYPE II (β) error**
Reject the Null Stay with Vendor A	Wrong decision **Type I (α) error**	Right Decision

HYPOTHESIS TESTING

- Selecting significance level
  - Type I (α) error
    - Rejecting the null hypothesis when it is true
      example: Post-change lot considered different when it was equivalent
  - Type II (β) error
    - Accepting the null hypothesis when it is false
      example: Post-change lot was considered equivalent when it was different.

5% (p_α = 0.05) means 5% of the time the process change may be rejected when it was actually acceptable

1% (p_α = 0.01) means 1% of the time the process change may be rejected when it was actually acceptable

HYPOTHESIS TESTING

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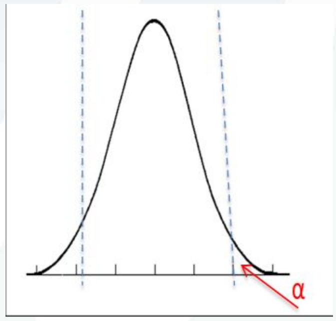

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HYPOTHESIS TESTING

- Statistical inference using data
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- How to:
  - State null hypothesis and alternate hypothesis
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    - Typically 5% or 1% (0.05 or 0.01)
  - Consider statistical assumptions (i.e. is the data normally distributed, values independent, etc.)

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HYPOTHESIS TESTING

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    - Probability below which null hypothesis will be rejected
    - Typically 5% or 1% (0.05 or 0.01)
  - Consider statistical assumptions (i.e. is the data normally distributed, values independent, etc.)
  - Select relevant test statistic
    - Student's t
    - Z-Test

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HYPOTHESIS TESTING

- Selecting relevant test statistic
  - Student's t (comparing means)
    - Use when
      - Sample size < 30
      - Independent samples
      - Variances do not have to be equal
      - Normal distribution
  - *z* test (comparing means)
    - Assumptions
      - Sample size > 30
      - Independent samples
      - Variances equal

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HYPOTHESIS TESTING

- Selecting relevant test statistic
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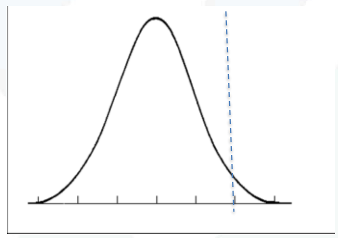
One-sided testing

One sided: is the result larger (smaller)than the original



HYPOTHESIS TESTING

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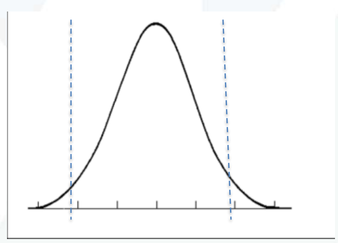
      - Variances do not have to be equal
      - Normal distribution
  - *z* test (comparing means)
    - Assumptions
      - Sample size > 30
      - Independent samples
      - Variances equal

One-sided testing versus Two-sided testing

- One sided: is the result larger (smaller) than the original
- Two sided: is the result different than the original



HYPOTHESIS TESTING

- Statistical inference using data
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- How to:
  - State null hypothesis and alternate hypothesis
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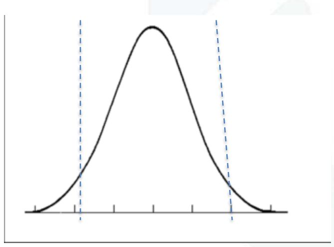
  - Select significance level
    - Probability below which null hypothesis will be rejected
    - Typically 5% or 1% (0.05 or 0.01)
  - Select relevant test statistic
    - Student's t
    - Z-Test
  - Compute the test statistic from the observed values

HYPOTHESIS TESTING

One-sided testing versus Two-sided testing

- One sided: is the result larger (smaller) than the original
- Two sided: is the result different than the original



- Student's t (comparing means)
  - Looking at differences (before/after)

$\overline{X}$ = sample mean
μ_0 = target value or population mean
s = sample standard deviation
n = number of test samples

$$t = \frac{\overline{X} - \mu_0}{s / \sqrt{n}}$$

$$s_d = \sqrt{\sum (x - \overline{X})2/n - 1}$$

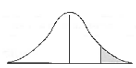
Compare calculated "t" with table value for α

HYPOTHESIS TESTING

- Statistical inference using data
  - "Statistically significant" when predicted as unlikely to have occurred by chance alone
  - Reject the null hypothesis
- How to:
  - State null hypothesis and alternate hypothesis
  - Consider statistical assumptions (i.e. is the data normally distributed, values independent, etc.)
  - Select significance level
    - Probability below which null hypothesis will be rejected
    - Typically 5% or 1% (0.05 or 0.01)
  - Select relevant test statistic
    - Student's t
    - Z-Test
  - Compute the test statistic from the observed values
  - Compare result with test statistic table values

HYPOTHESIS TESTING

XII. APPENDIX - TABLES



t_α

Table V t Distribution

d.f.	$t_{0.100}$	$t_{0.050}$*	$t_{0.025}$**	$t_{0.010}$	$t_{0.005}$	d.f.
1	3.078	6.314	12.706	31.821	63.657	1
2	1.886	2.920	4.303	6.965	9.925	2
3	1.638	2.353	3.182	4.541	5.841	3
4	1.533	2.132	2.776	3.747	4.604	4
5	1.476	2.015	2.571	3.365	4.032	5
6	1.440	1.943	2.447	3.143	3.707	6
7	1.415	1.895	2.365	2.998	3.499	7
8	1.397	1.860	2.306	2.896	3.355	8
9	1.383	1.833	2.262	2.821	3.250	9
10	1.372	1.812	2.228	2.764	3.169	10
11	1.363	1.796	2.201	2.718	3.106	11
12	1.356	1.782	2.179	2.681	3.055	12
13	1.350	1.771	2.160	2.650	3.012	13
14	1.345	1.761	2.145	2.624	2.977	14
15	1.341	1.753	2.131	2.602	2.947	15
16	1.337	1.746	2.120	2.583	2.921	16
17	1.333	1.740	2.110	2.567	2.898	17
18	1.330	1.734	2.101	2.552	2.878	18
19	1.328	1.729	2.093	2.539	2.861	19
20	1.325	1.725	2.086	2.528	2.845	20
21	1.323	1.721	2.080	2.518	2.831	21
22	1.321	1.717	2.074	2.508	2.819	22
23	1.319	1.714	2.069	2.500	2.807	23
24	1.318	1.711	2.064	2.492	2.797	24
25	1.316	1.708	2.060	2.485	2.787	25
26	1.315	1.706	2.056	2.479	2.779	26
27	1.314	1.703	2.052	2.473	2.771	27
28	1.313	1.701	2.048	2.467	2.763	28
29	1.311	1.699	2.045	2.462	2.756	29
Inf.	1.282	1.645	1.960	2.326	2.576	Inf.

There is only a 5% probability that a sample with 10 degrees of freedom will have a t value greater than 1.812.

* one tail 5% α risk ** two tail 5% α risk

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HYPOTHESIS TESTING

- How to:
  - State null hypothesis and alternate hypothesis
  - Consider statistical assumptions (i.e. is the data normally distributed, values independent, etc.)
  - Select significance level
  - Select relevant test statistic
  - Compute the test statistic from the observed values
  - Compare result with test statistic table values

    IF the calculated value is > (greater than) the table value
    accept the alternate hypothesis

    IF the calculated value is < (less than) the table value
    accept the null hypothesis

HYPOTHESIS TESTING

- How to:
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  - Consider statistical assumptions (i.e. is the data normally distributed, values independent, etc.)
  - Select significance level
  - Select relevant test statistic
  - Compute the test statistic from the observed values
  - Compare result with test statistic table values

    IF the calculated value is < (less than) the table value
    accept the null hypothesis
    There is not enough evidence to say there's a statistical difference

    IF the calculated value is > (greater than) the table value
    accept the alternate hypothesis
    There is enough evidence to say there's a statistical difference

HYPOTHESIS TESTING

– Compare result with test statistic table values
  IF the calculated value is > (greater than) the table value
  accept the alternate hypothesis
  IF the calculated value is < (less than) the table value
  accept the null hypothesis

Example:
A new process generated products with the following weights (g)
0.46 0.61 0.52 0.57 0.54
To be profitable an average weight > 0.50g is required
With 95% confidence, is the new process recommended

Null (H_0) = average $\leq$ 0.50g
Alternate (H_1) = average > 0.50g

HYPOTHESIS TESTING

Example:
- A new process generated products with the following weights (g)
  0.46 0.61 0.52 0.57 0.54
- To be acceptable an average weight > 0.50g is required

With 95% confidence, is the new process recommended

- Student's t (comparing means)
  – Looking at differences (before/after)

$\overline{X}$ = sample mean
μ_0 = target value or population mean
s = sample standard deviation
n = number of test samples

$$t = \frac{\overline{X} - \mu_0}{s / \sqrt{n}}$$

$$s_d = \sqrt{\sum (x - \overline{X})2/n - 1}$$

Compare calculated "t" with table value for α

HYPOTHESIS TESTING

Example:

- A new process generated products with the following weights (g)
  0.46 0.61 0.52 0.57 0.54
- To be acceptable an average weight > 0.50g is required

With 95% confidence, is the new process recommended

$\bar{X} = 0.54$
$\mu_0 = 0.50$
$s = 0.056$
$n = 5$
One tailed test because “>”

$\alpha = 0.05$
$df = 4$

- Student’s t (comparing means)
  - Looking at differences (before/after)

$\bar{X}$ = sample mean
μ_0 = target value or population mean
s = sample standard deviation
n = number of test samples

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HYPOTHESIS TESTING

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Example:
A new process generated products with the following weights (g)
0.46 0.61 0.52 0.57 0.54
To be acceptable an average weight > 0.50 g is required
With 95% confidence, is the new process recommended

Calculated t = 1.597 Table t = 2.132

calculated value < table value;
therefore, insufficient evidence to recommend the new process
difference not statistically significant (or improvement)

HYPOTHESIS TESTING

Statistical Difference (Significance)
vs.
Practical Difference (Significance)

With large sample sizes (i.e. 10,000 data points) may find a statistical difference, but when looked at from business standpoint may not matter

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HYPOTHESIS TESTING

Statistical vs. Practical Difference (Significance)

With large sample sizes (i.e. 10,000 data points) may find a statistical difference, but when looked at from business standpoint may not matter

Example:
Comparing product from 2 plants
Product specification = 1.34 – 2.34
Look at 6 months worth of data
300 lots, 20,000 data points, 4 different raw material lots

Plant 1: average = 1.78 range = 1.48 - 2.21
Plant 2: average = 2.01 range = 1.51 – 2.25

Statistically different, but not distinguishable at customer

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ANALYSIS

Shop Math & Statistics Review
Analyzing the Data
Using Excel
Introduction to SPC

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QUALITY SYSTEMS

- Quality is a product (or service) with the *features and characteristics* which determine *desirability* and can be *controlled* to *meet certain basic requirements.*

- Quality System
  - Say what you do (documents)
  - Do what you say (training)
  - Record what you did (write it down, quality records)
  - **Check the results (analysis)**
  - Act on the difference (improvement)

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ANALYZING THE DATA

- Picture vs Numbers in a table
- Statistical analysis
  - what is the data telling us
  - Decision making

SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Charts
4. Cause and Effect Diagram (a.k.a. Ishikawa or Fishbone)
5. Histogram
6. Pareto Chart
7. Scatter Plot (Diagram)

HISTOGRAM

- Demonstrates frequency of measurement
  - Shows how often each value from a data set occurs
- Similar to a bar chart
  - Key difference
    - Bar chart depicts categories
      Example: flowers, trees, vegetables, fruits
    - Histogram depicts frequency of occurrence
      Example: number of businesses with revenue ranges

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HISTOGRAM

- Demonstrates frequency of measurement
  - Shows how often each value from a data set occurs
- When to use a histogram
  - Data is numerical (not pass/fail)
  - Determine whether process distribution is normal
  - Determine whether process meets customer requirements
  - Measuring supplier process output
  - Are two process outputs the same
- Shape of the graph can provide clues

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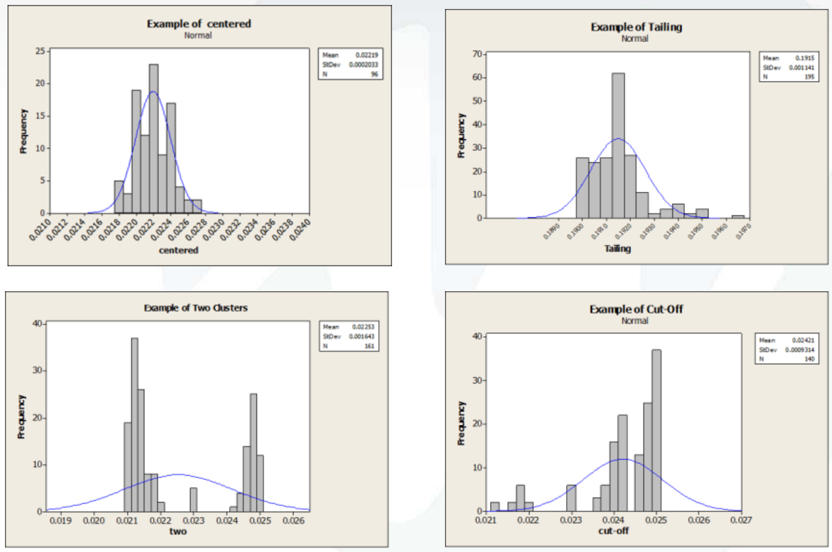
HISTOGRAM EXAMPLE



HISTOGRAM

- Demonstrates frequency of measurement
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- When to use a histogram
  - Data is numerical (not pass/fail)
  - Determine whether process distribution is normal
  - Determine whether process meets customer requirements
  - Measuring supplier process output
  - Are two process outputs the same
- Shape of the graph can provide clues

Four previous graphs were within specification.

However, what the customer see’s with each shipment or lot would be different.

SEVEN QUALITY TOOLS

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2. Check Sheet
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5. Histogram
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SCATTER PLOT (DIAGRAM)

- Graphic display of data points useful for determining relationships between two variables
  - Independent variable (inputs)
  - Dependent variable (outputs)
- Shapes or trends can provide clues

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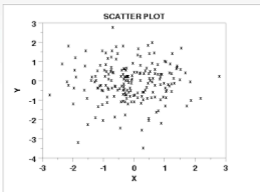
SCATTER PLOT (DIAGRAM)



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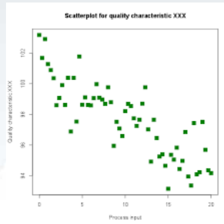
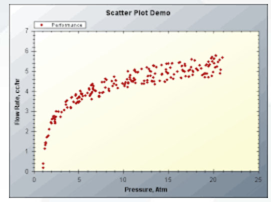
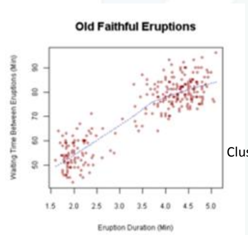


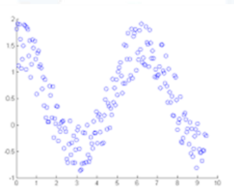
Negative linear



Positive non-linear



Clusters



Cyclic

ANALYZING THE DATA

- Picture vs Numbers in a table
- Statistical analysis
  - *what is the data telling us*
  - *decision making*
  - Software
    - Minitab®
    - Statistica ®
    - Statgraphics ®, etc.
  - Excel
  - Calculator’s

ANALYZING DATA – Using Excel

- Descriptive Analysis
  - Average
  - Standard Deviation
  - Variance
  - Range

ANALYZING DATA – Using Excel

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  - Average
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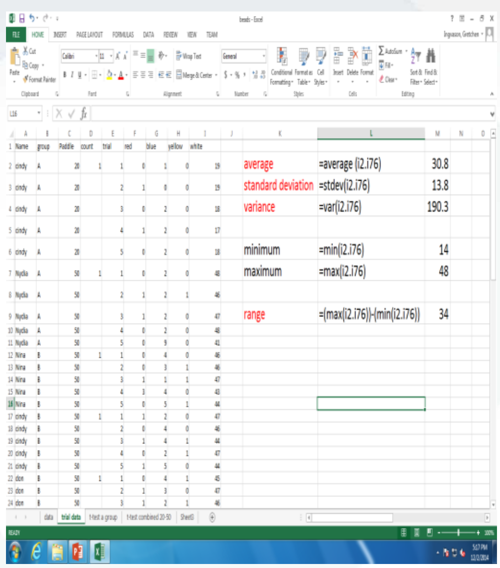
  - Range

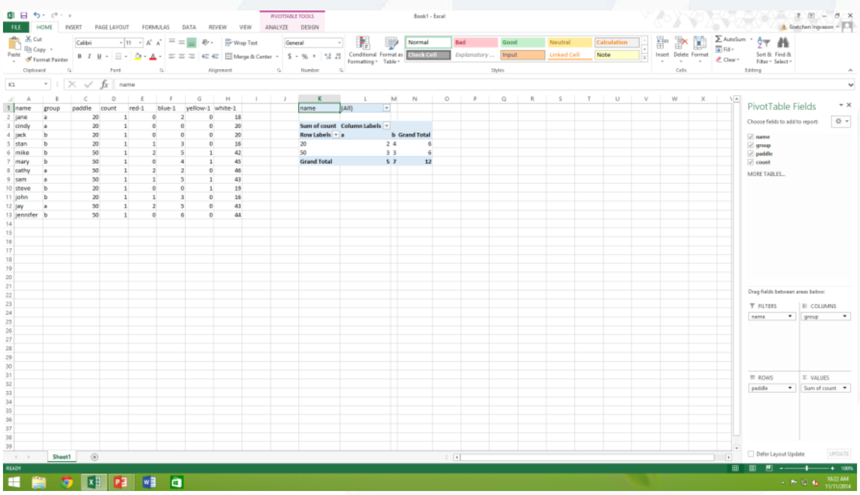


ANALYZING DATA – Using Excel

- Descriptive Analysis
- Pivot Tables
  - Method for organizing columns into tabular format

ANALYZING DATA – Using Excel

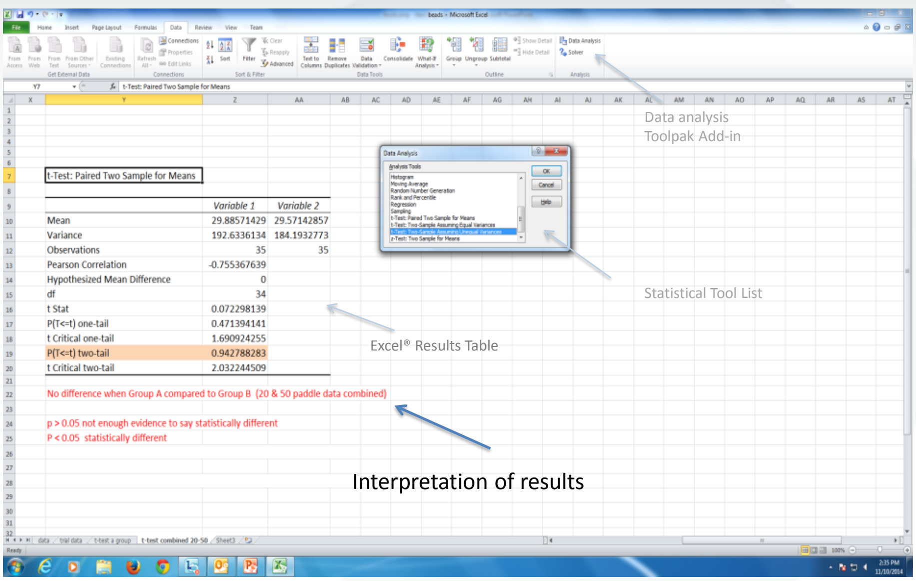
- Pivot Tables
  - Method for organizing columns into tabular format



ANALYZING DATA – Using Excel

- Descriptive Analysis
- Pivot Tables
  - Method for organizing columns into tabular format
- Hypothesis testing
  - Student t

BEAD EXPERIMENT



ANALYSIS

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ANALYSIS – Statistical Process Control (SPC)

- *Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.*
- Inspection process:
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary

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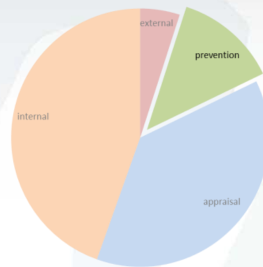

- Internal
  - Scrap, Rework
- Appraisal
  - Material Receipt
  - In-process/Final Inspection
- Prevention
  - Improvement, Planning

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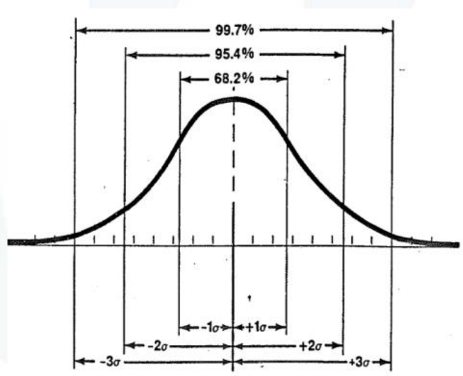
STATISTICAL PROCESS CONTROL (SPC)

- Measure of process stability or variability
  - Standard deviation is a measure of dispersion or spread of the data
    - Statistical calculation assumes normality
- Standard deviation is used to predict whether product remains within specification as it is manufactured
  - Often referred to as sigma
  - 1 sigma = 68.2% of results
  - 2 sigma = 95.4%
  - 3 sigma = 99.7%



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STATISTICAL PROCESS CONTROL (SPC)

- Measure of process stability or variability

  "… SPC is applied in order to monitor and control a process. Monitoring and controlling the process ensures that it operates at its full potential. At its full potential, the process can make as much conforming product as possible with a minimum (if not an elimination) of waste (rework or scrap)…"

  wikipedia.com

- Internal
  - Scrap, Rework

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STATISTICAL PROCESS CONTROL (SPC)

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  wikipedia.com

- A process under statistical control is predictable.

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CONTROL CHARTS

- Analyze variation in processes (manufacturing or administrative)
  - Walter Shewart (1931), "*The Economic Control of Quality of Manufactured Product*"
  - Line graphs that display dynamic process behavior

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SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Charts
4. Cause and Effect Diagram (a.k.a. Ishikawa or Fishbone)
5. Histogram
6. Pareto Chart
7. Scatter Plot (Diagram)

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CONTROL CHARTS

- Control chart types
  - Variable
    - X-bar / R (Average – Range)
    - Run charts (Single point data)
    - X / MR (Individual – Moving Range)
    - CuSum (Cumulative Sum)
    - EWMA (Exponentially Weighted Moving Average)

    Most commonly used on production floor
  - Attribute
    - p chart (percent defective)
    - np chart (number defective)
    - c chart (number of defects)
    - u chart (number defects per unit)

    Used widely for metrics and measures of overall effectiveness

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CONTROL CHARTS

- Control chart types
  - Variable
    - **X-bar / R (Average – Range)**
    - Run charts (Single point data)
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CONTROL CHARTS – "X-Bar / R"

CONTROL CHARTS – "X-Bar / R"

- Product Data
  - Specification Limits
    - Provided by Customer
  - Control Limits
    - Calculated and used by Manufacturer
- Machine (Process) Data
  - Specification Limits
    - Determined by Manufacturer in design/validation
    - Edges of manufacturing acceptable product

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CONTROL CHARTS – “X-Bar / R”

- Product Data
  - Specification Limits
    - Provided by Customer
  - Control Limits
    - Calculated and used by Manufacturer

    Used to ensure product released meets Customer requirements

    Prevent manufacturing scrap or rework
- Machine (Process) Data
  - Specification Limits
    - Determined by Manufacturer in design/validation
    - Edges of manufacturing acceptable product
    - *Product testing to establish limits ensures product released meets Customer requirements*
  - Control Limits
    - Calculated by Manufacturer

  Prevent manufacturing scrap or rework.

  Machine control rather than having to inspect or test.

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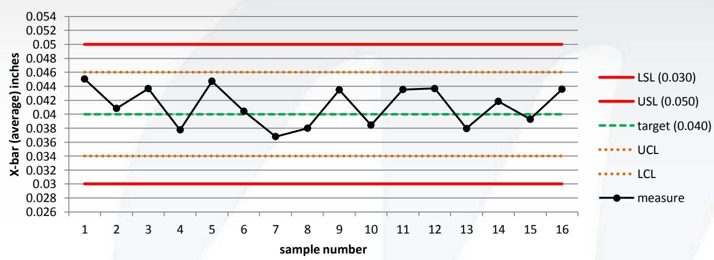
CONTROL CHARTS – "X-Bar / R"

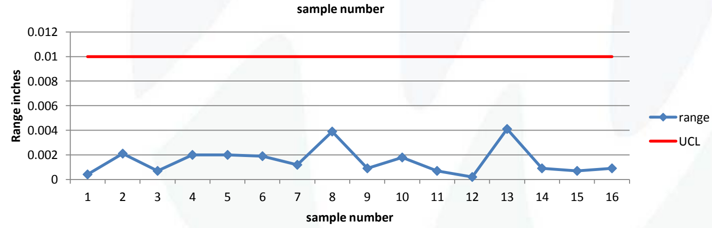
- Product Data
  - Specification Limits
    - Provided by Customer
  - Control Limits
    - Calculated and used by Manufacturer
- Machine (Process) Data
  - Specification Limits
    - Determined by Manufacturer in design/validation
    - Edges of manufacturing acceptable product
  - Control Limits
    - Calculated by Manufacturer

Prevent manufacturing scrap or rework.

Machine control rather than having to inspect or test.

SPC: X-Bar / R Charts

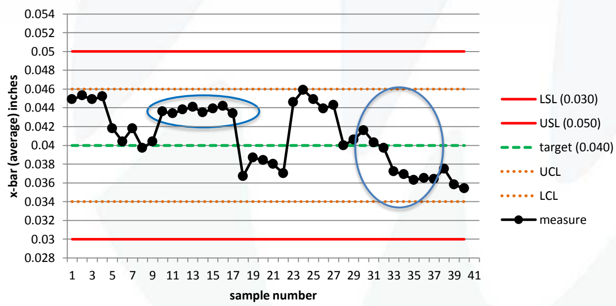




Rule of thumb for X-bar: UCL = Xbar + 3s   LCL = Xbar – 3s
using mean (Xbar) and standard deviation established during process validation (capability) studies

SPC RULES

- Five Common
  1. Trends
     - 7 or more consecutive points on one side of the center (target) line
     - 7 or more consecutive points increasing or decreasing



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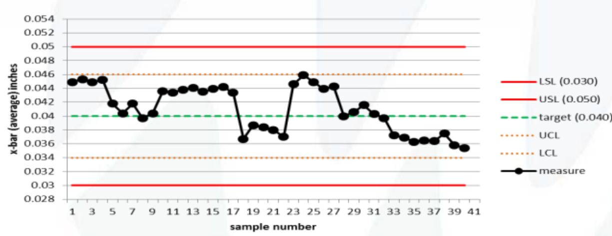
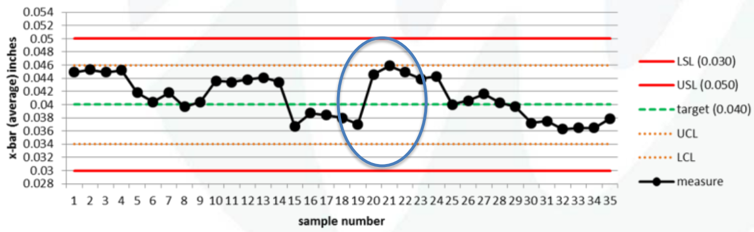


- Xbar - Machine wear; tool wear; tired operator
- R – change in operator skill, change in incoming material quality

SPC RULES

- Five Common
  1. Trends
  2. Jumps in Process Level
     - X-bar - Modification of production method or process
     - Change in inspection device or method
     - New operator or machine
     - R- material / method / operator / inspection change



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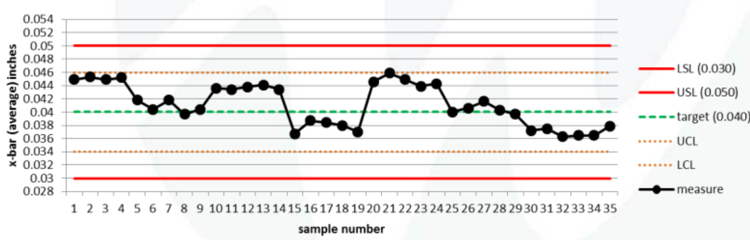
SPC RULES

- Five Common
  1. Trends
  2. Jumps in Process Level
  3. Recurring Cycles
     - X-Bar – environment (temp/humid, Ashift/Bshift), regular rotation of machine or operator
     - R- scheduled maintenance; tool wear



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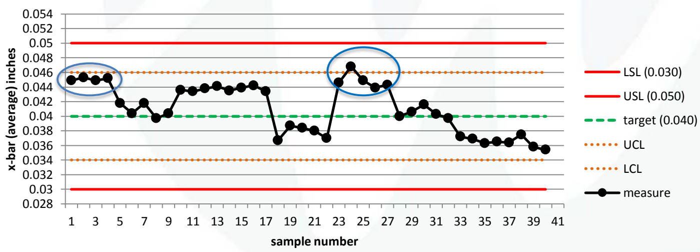
SPC RULES

- Five Common
  1. Trends
  2. Jumps in Process Level
  3. Recurring Cycles
  4. Points near or outside limits
     - X-bar – over control, large systematic difference in material quality/test method/equipment
     - R – mixed quality of distinctly different materials



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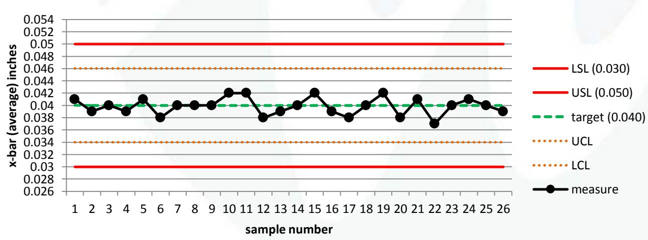
SPC RULES

- Five Common
  1. Trends
  2. Jumps in Process Level
  3. Recurring Cycles
  4. Points near or outside limits
  5. Lack of Variability
     - X-Bar- incorrect calculation of control limits; improvements since calculation
     - R – widely differing lot measurements; improvement since calculation



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PROCESS MEASURES

- SPC is measure of process stability or variability
  - A process under statistical control is predictable.
- Understanding process suitability for specifications
  - Machines equivalent
  - Effect of adjustments
  - Material variability
- Process Measures
  - Process Performance (Pp)
  - Process Capability (Cp)

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PROCESS MEASURES

- Process Measures
  - Process Performance (Pp)
  - Process Capability (Cp)

Often are discussed interchangeably, however the calculation of the values IS different.

The difference lies in how the standard deviation is handled.

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PROCESS MEASURES

- SPC is measure of process stability or variability
  - A process under statistical control is predictable.
- Understanding process suitability for specifications
  - Machines equivalent
  - Effect of adjustments
- Process Measures
  - Process Performance (Pp)
  - Process Capability (Cp)

Assumptions for conducting performance (capability) studies:

1. process is "stable" (in statistical control); allowing for predictive behavior.
2. both measures are calculated based on normal distribution

   If the data are non-normal, it is either transformed or measures are calculated based on the alternate distribution.

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PROCESS PERFORMANCE

- Process Measures
  - Process Performance (Pp)
    - How well is the process running?

$$Pp = \frac{USL - LSL}{6\ \sigma}$$

Note: The standard deviation is calculated based on the square root of the variance

$$\sigma = \sqrt{\sum (xi - X\text{-}bar)^2 / n{-}1}$$

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PROCESS PERFORMANCE

- Process Measures
  - Process Performance (Pp)
    - How well is the process running?
    - Process Performance Index (Ppk)
      - Is the process centered on target or running at one of the specification limits

Ppk = min(PPU, PPL)

PPU (process performance index upper)
PPL (process performance index lower)

$$PPU = \frac{USL - xbar}{3\,\sigma}, \quad PPL = \frac{xbar - LSL}{3\,\sigma}$$

Ppk > 1.33 ideal

PROCESS MEASURES

- Process Measures
  - Process Performance (Pp)
    - How well is the process running?
  - Process Capability (Cp)
    - Measures ability to meet specifications
  - Studies conducted to evaluate process
    - Do nothing – process limits well within specifications
    - Change the specifications - may be unrealistic, Customer negotiation
    - Center the process – bring bulk of product into specification (reduce risk)
    - Reduce Variability – consistency of delivery to customer
    - Accept the Losses – short term solution, rework/scrap efficiency

PROCESS CAPABILITY

- Process Measures
  - Process Capability (Cp)
    - Does the process produce product meeting specification?

$$Cp = \frac{USL - LSL}{6\ \sigma_\omega}$$

Note: standard deviation is estimated using the average range of the data set and an unbiasing constant.

$$\sigma_\omega = \frac{R}{d_2}$$

Unbiasing Constants can be calculated, but this is rarely done and can either be looked up in a reference table or Cp values are calculated using software.

PROCESS CAPABILITY

- Process Measures
  - Process Capability (Cp)
    - Does the process produce product meeting specification?
    - Process Capability Index (Cpk)
      - Is the process centered on target or running at one of the specification limits

Cpk = min(CPU, CPL)

CPU (process capability index upper)
CPL (process capability index lower)

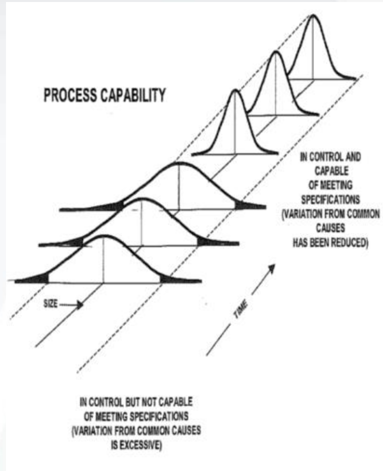
$$CPU = \frac{USL - xbar}{3\ \sigma_\omega}, \quad CPL = \frac{xbar - LSL}{3\ \sigma_\omega}$$

For Customers

Cpk $\geq$ 1.33 typically
Cpk $\geq$ 1.67 for CTQ

Check the Results

- Process Measures
  - Process Performance
  - Process Capability



Check the Results

		Statistical Control	
		In-Control	Out-of-Control
Capability	Acceptable	Case 1	Case 2
	Unacceptable	Case 3	Case 4

- Case 1: process capable and-in control (stable)
  - Ideal for Customer, predictably provide product within specification
- Case 2: process capable but out-of-control
  - Generally not acceptable due to unpredictability
- Case 3: process not capable, but in-control
  - Can be accepted based on control of process, but special cause variation needs to be reduced (process stable, but can be out-of-specification)
- Case 4: process not capable and out-of-control
  - Not acceptable due to unpredictability and inability to meet specifications.

QUALITY OPERATIONS

Incoming Inspection
Product Release
Professional Practices

Developed as part of NSF ATE Grant #1304474

QUALITY SYSTEM

- Quality Department
  - Voice of the Customer
  - Support function
  - Regulatory review
- Basic Premise
  - Say what you do
  - Do what you say
  - Record what you did
  - Check the results
  - Act on the difference

- Inspection process:
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary

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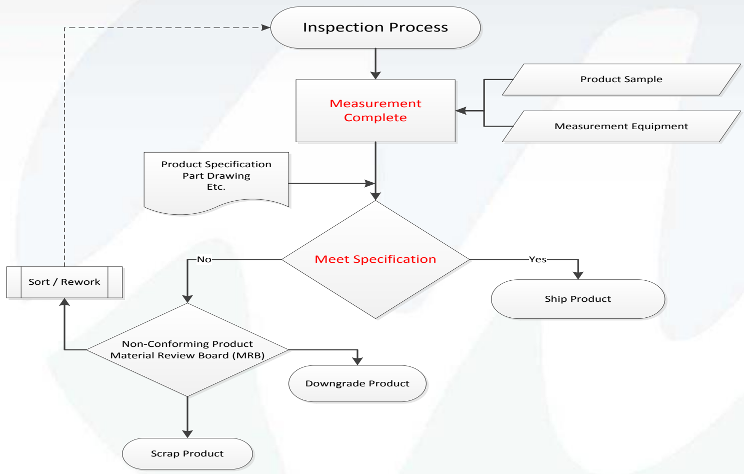
CHECK THE RESULTS



CHECK THE RESULTS

21CFR 211.22 Responsibilities of quality control unit.

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company…

CHECK THE RESULTS

21CFR 820.80 Receiving, in-process, & finished device acceptance.

… (b) *Receiving acceptance activities.* …Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

… (c) *In-process acceptance activities.* …in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.

… (d) *Final acceptance activities.* … Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:

(1) The activities required in the DMR are completed;

(2) the associated data and documentation is reviewed;

(3) the release is authorized by the signature of a designated individual(s); and

(4) the authorization is dated.

CHECK THE RESULTS: Product Release

- Meet Specifications – Yes
- Ship the Product
  - Certificate of Analysis
  - Certificate of Conformance

Product Release

- Ship the Product
  - CERTIFICATE OF ANALYSIS

    Document issued by Quality Assurance confirming that a product meets its product specification.

    They commonly contain the actual results obtained from testing performed as part of quality control of an individual batch of a product.

HONSO PHARMACEUTICAL CO., LTD
本草製薬株式会社
HONZOU BLDG.,3F 6-21, 3-CHOME, MARUNOUCHI, NAKA-KU, NAGOYA, JAPAN
名古屋市中区丸の内3丁目6－21（ホンゾウビル3F）〒461-0002
FAX(052)951-0679
TEL(052)951-0626 http://www.honso.com

Certificate of Analysis

Sample described as	:	Minor Bupleurum Formula
Lot no.	:	E10913
Date of manufacture	:	14/DEC/2001
Period of analysis	:	14/DEC/2001~25/DEC/2001
Date of report	:	25/DEC/2001

Result of Analysis		Test Result		Specification
Description	:	Light-Yellow-Brown Granules		
			—	Complies
Identification	:	Pass	—	Complies
Purity				
Heavy metals	:	Pass	—	less than 30ppm
Arsenic	:	Pass	—	less than 2ppm
Loss on drying	:	6.66%	—	less than 10.0%
Total ash	:	4.55%	—	2.0~6.0%
Acid-insoluble ash	:	0.03%	—	less than 1.0%
Extract content				
Dilute ethanol-soluble extract	:	83.19%	—	70.0~96.0%
95% Ethanol-soluble extract	:	27.57%	—	17.0~34.0%
Assay				
Glycyrrhizin	:	38.03mg/day	—	24.7~46.0mg/day
Baicalin	:	154.13mg/day	—	110.6~205.6mg/day
Saikosaponin	:	13.58mg/day	—	6.5~19.7mg/day
Microbial Limit Test				
Total Plate Count	:	25	—	less than 1000/g
Yeast & Mold	:	0	—	less than 100/g
E.Coli	:	Negative	—	Complies

We hereby certify that the above mentioned is true and correct.

HONSO PHARMACEUTICAL CO., LTD.
Hiroyasu Ishi[illegible]
Hiroyasu [illegible]
Manager of Quality Control Dept.

Product Release

- Ship the Product
  - CERTIFICATE OF CONFORMITY:
    generally state that it conforms to one or a combination of the following:
    - Drawings
    - Specifications
    - Approved Instructions
    - Company standards

Product Release

- Ship the Product
  - CERTIFICATE OF CONFORMITY:
    generally state that it conforms to one or a combination of the following:
    - Drawings
    - Specifications
    - Approved Instructions
    - Company standards
  - They are issued by a manufacturer
    - Stating that the part conforms to some of the subjects cited above
    - They are signed by a person 'authorized' by the manufacturer
      - Authorized is typically Quality, but could be different department

DAYTON T. BROWN INC.

CHURCH STREET • BOHEMIA, LONG ISLAND, NEW YORK 11716

23 January 2008
DTB04C08-0074
410035-00-000

Certificate of Conformance for Freight Container Mechanical Seal Testing

Customer: OneSeal A/S
Vibe Alle 2
2980 Kokkedal
Denmark

Attention: Mr. Lars Berenth

Purchase Order No.: LBJ-118
Test Item: Bolt Seal
Part No.: 79T06
Serial No.: 000001 through 000025
Specification No.: ISO/PAS 17712:2006(E)
Test Dates: 11 January 2008 through 23 January 2008

Dayton T. Brown Inc. certifies that 25 samples, 5 for each test, of Bolt Seals P/N 79T06 were subjected to the following tests.

Test Name	Paragraph Number	Classification Rating
Tensile Test	6.2	High Security
Shear Test	6.3	High Security
Flex Test	6.4	High Security
Impact Test @ room temp	6.5	High Security
Impact Test @ reduced temp	6.5	High Security

Results: The above listed tests were completed with no discrepancies noted.

The test results contained herein pertain only to the specimens listed in this report. This report shall not be reproduced, except in full, without the written approval of Dayton T. Brown, Inc.

Prepared by: J. Benincasa

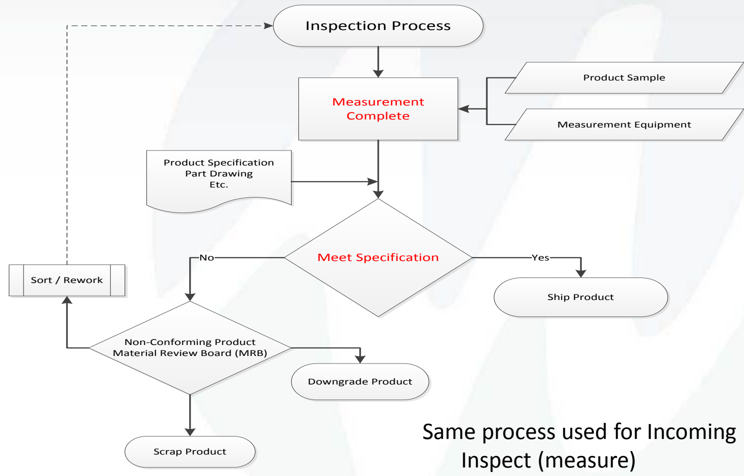
Engineer: G. Hyland

Quality Department: M. DiAris

Product Release

- Ship the Product
  - Certificate of Analysis
    - Contains actual test results, demonstrating specifications
    - Issued and signed by Quality
  - Certificate of Conformance
    - No actual results, states that it conforms (meets) specification
    - Typically signed by Quality, but may not be

CHECK THE RESULTS



Same process used for Incoming Materials –
Inspect (measure)
Meet Specifications – yes/no
Release or Return

Developed as part of NSF ATE Grant #1304474

CHECK THE RESULTS

- Meet Specifications – YES
- Ship the Product or Use Incoming Material

Developed as part of NSF ATE Grant #1304474

CHECK THE RESULTS

- Meet Specifications – Yes
- Ship the Product or Use Incoming Material

OR

- Meet Specifications – NO
- Nonconformance Process
  - Material Review Board

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CHECK THE RESULTS

21CFR 211.22 Responsibilities of quality control unit.

(a)There shall be a quality control unit that shall have the responsibility and authority to approve or reject … and the authority to review production records to assure that no errors have occurred or, **if errors have occurred, that they have been fully investigated.** …

21 CFR 211.165 Testing and release for distribution.

…(f) Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria…

Guidance for Industry, Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

B. Reprocessing (14.2)

..reprocessing by repeating a crystallization step or other appropriate chemical or physical manipulation steps …is generally considered acceptable… should be **preceded by careful evaluation** to ensure that the quality … is not adversely affected due to the potential formation of by-products and over-reacted materials.

C. Reworking (14.3)

Before a decision is taken to rework batches … **an investigation into the reason for nonconformance** should be performed… documentation to show that the reworked product is of equivalent quality to that produced by the original process. Concurrent validation …….

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CHECK THE RESULTS

21CFR 820.90 Nonconforming product.

(a) *Control of nonconforming product.* … The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

(b) *Nonconformity review and disposition.*

(1) … procedures that define the **responsibility for review and the authority for the disposition of nonconforming product**. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications…

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CHECK THE RESULTS

ISO 9001:2008(E) 8.3 Control of Non-Conforming Product
ISO 13485:2003

"… organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure….

… organization shall deal with non-conforming product by one or more of the following ways:

a)… take action to eliminate detected non-conformity

b)…authorizing its use, release or acceptance under concession …

[9001 … concession by relevant authority or customer]

[13485 …concession only if regulatory requirements are met..]

a)..take action to preclude its original intended use or application

…when nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity…."

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CHECK THE RESULTS: Nonconforming

- Quality is not just Quality's Responsibility
  - Marketing / Sales
  - Engineering (design, process, manufacturing)
  - Manufacturing/Production
  - Procurement / Purchasing
  - Storage / Warehouse
  - Packaging / Shipping
  - Field Service

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CHECK THE RESULTS: Nonconforming

- Policy and Procedure for non-conforming
  - Segregation and Containment
    - ✓ Status labels
    - ✓ Quarantine
  - Non-conformance documentation
    - ✓ Part number, lot number, in-process/final, test result
    - ✓ Test results / specification
    - ✓ Lab OOS investigation
  - Investigation process
    - ✓ What happened
    - ✓ Special cause
    - ✓ One batch / multiple / recurring
  - Disposition
    - ✓ Material Review Board

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MATERIAL REVIEW BOARD (MRB)

- Key Members: Quality, Production, Purchasing
  - Additional Members: Marketing/Sales, Engineering, R&D
- Review non-conforming material and provide disposition
  - Rework (sorting)
  - Reprocess (perform additional steps)
  - Scrap
  - Downgrade
  - Use as is - requires written Customer agreement
- Meeting frequency dependent on Company SOP

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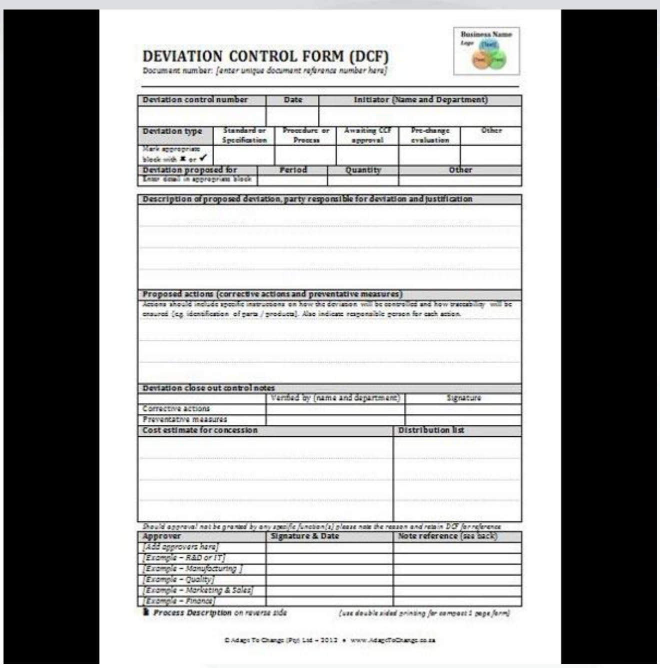

Business Name
Logo

DEVIATION CONTROL FORM (DCF)

Document number: *[enter unique document reference number here]*

Deviation control number	Date	Initiator (Name and Department)

Deviation type	Standard or Specification	Procedure or Process	Awaiting CCF approval	Pre-change evaluation	Other
Mark appropriate block with ✖ or ✔					

Deviation proposed for	Period	Quantity	Other
Enter detail in appropriate block			

Description of proposed deviation, party responsible for deviation and justification

Proposed actions (corrective actions and preventative measures)

Actions should include specific instructions on how the deviation will be controlled and how traceability will be ensured (e.g. identification of parts / products). Also indicate responsible person for each action.

Deviation close out control notes

	Verified by (name and department)	Signature
Corrective actions		
Preventative measures		

Cost estimate for concession	Distribution list

Should approval not be granted by any specific function(s) please note the reason and retain DCF for reference

Approver	Signature & Date	Note reference (see back)
[Add approvers here]		
[Example – R&D or IT]		
[Example – Manufacturing]		
[Example – Quality]		
[Example – Marketing & Sales]		
[Example – Finance]		

***Process Description** on reverse side* *(use double sided printing for compact 1 page form)*

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CHECK THE RESULTS: Status Labeling

- GMP Requirement / ISO traceability
- Visible Factory – production floor and warehouse
  - Raw Material
  - Work-in-Progress (WIP)
  - Finished Goods
- Non-Conforming Quarantine
  - ISO requires segregated area
  - GMP requires segregated <u>and locked</u> (limited access)
  - Electronic Systems

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CHECK THE RESULTS: Status Labeling

- Universal Colors
  - Green for ACCEPTANCE
  - Yellow or Orange for HOLD
  - Red for REJECTED

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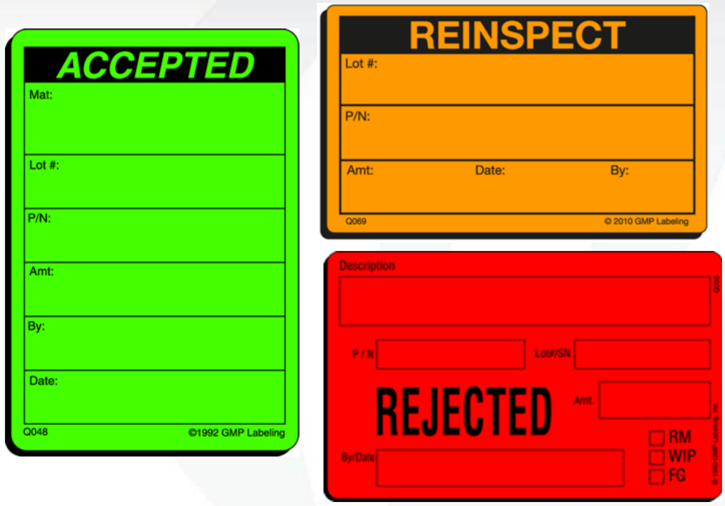
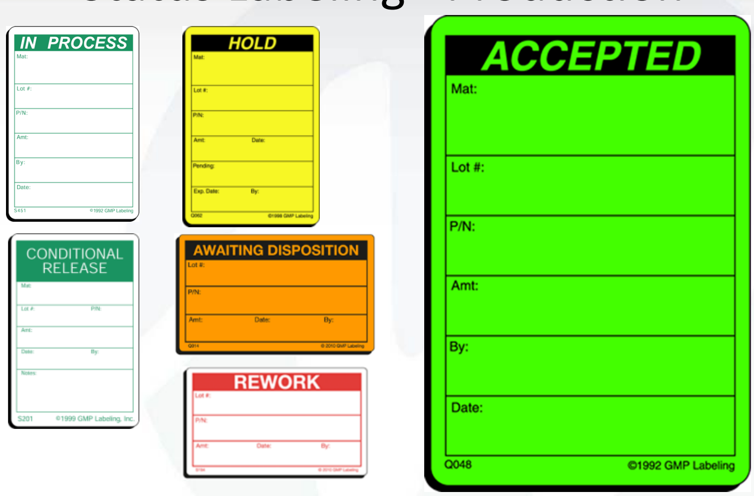
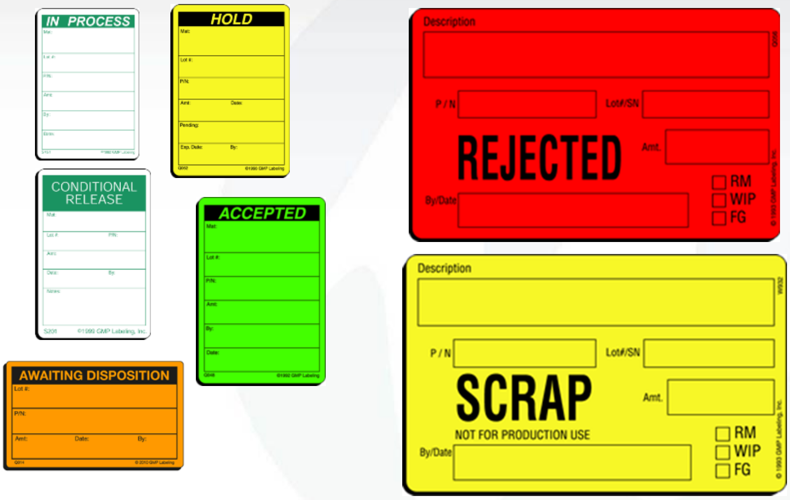
Status Labeling – Incoming (Receiving)



Status Labeling - Production



Status Labeling - Production



Status Labeling - Warehouse

CHECK THE RESULTS: Status Labeling

- Material Flow
  - Receipt : on-hold until inspection complete
  - Raw Material to production floor must have green acceptance
  - Work-In-Progress (WIP)
    - Labeled as "acceptable" moving through process
    - Hold if work stopped due to non-conformance
      - Rework if to move forward
      - Reject / Scrap
  - Final Inspection: on-hold until inspection complete
  - Finished goods to warehouse must have green acceptance

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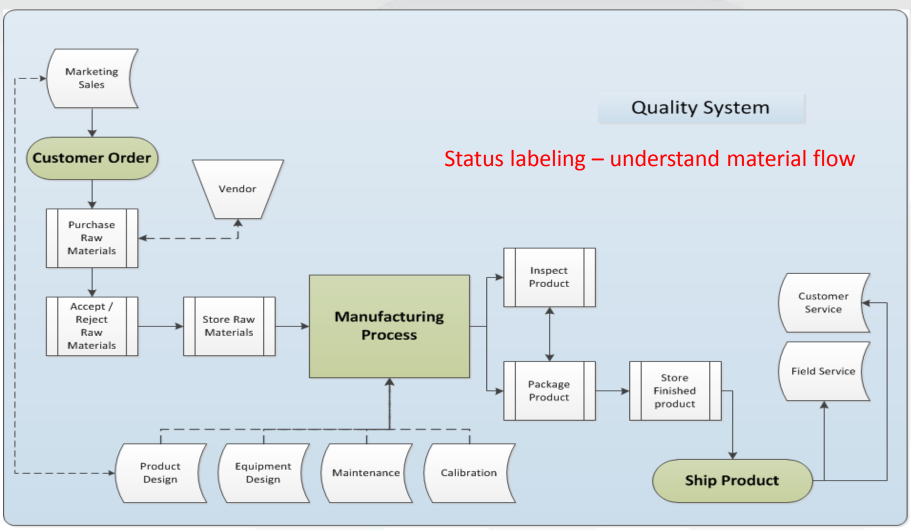

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PROFESSIONAL PRACTICES

Ethics
Confidentiality
Teamwork (Conflict Resolution)
Communication

Developed as part of NSF ATE Grant #1304474

QUALITY OPERATIONS

- Quality Assurance & Quality Control
  - Voice of the Customer
    - Is the product manufactured properly?
    - Does the product function as expected?
    - Was the product manufactured using the correct materials
  - Regulatory review
    - Does the product/service meet the Regulatory requirements (i.e. government, UL, etc.)
    - Does the product meet the Customer regulatory expectations?
  - Support function
    - Work with manufacturing, purchasing, etc. to meet Customer and Regulatory requirements
    - Incoming Materials / Product Release

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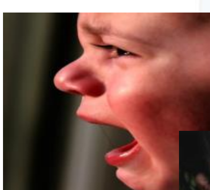
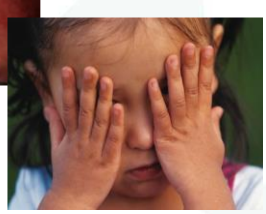
CODES OF PROFESSIONAL PRACTICE

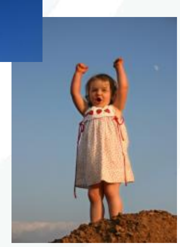
- Honesty
  - Follow procedures, record data accurately, report issues when they occur, etc.
- Integrity
- Transparency
- Accountability
- Confidentiality
- Objectivity
- Respectfulness
  - Everyone there for common purpose
- Obedience to the Law
  - Manufacture goods, provide service, conduct among peers

**"I've learned that
people will forget what you said,
people will forget what you did, but
people will never forget how you made them feel."**

Maya Angelou







CODES OF PROFESSIONAL PRACTICE

- Honesty
- Integrity
- **Transparency**
- **Accountability**
- Confidentiality
- **Objectivity**
- Respectfulness
- Obedience to the Law

Developed as part of NSF ATE Grant #1304474

PROFESSIONAL PRACTICES

- Quality Assurance / Quality Control personnel
  - Are not
    - “policemen”
    - “looking over their shoulder”
    - “naysayers”
  - Are
    - Voice of the Customer
    - Regulatory review
    - Support function

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PROFESSIONAL PRACTICES

- Quality Assurance / Quality Control personnel
  - Voice of the Customer, Regulatory review, Support function

- **Transparency**, Objectivity, Accountability,
  - Procedures
  - Methods
  - Notifying immediately
- Transparency, **Objectivity**, Accountability,
  - Data driven
  - Regulations / Standards
- Transparency, Objectivity, **Accountability**
  - Verify results
  - Notify immediately
  - Assist when asked, support production

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PROFESSIONAL PRACTICES

- Quality Assurance / Quality Control personnel
  - Voice of the Customer, Regulatory review, Support function

- Transparency, Objectivity, Accountability
  - Teamwork
  - Conflict Resolution
  - Time / Project Management
  - Communication

Developed as part of NSF ATE Grant #1304474

TEAMWORK

- Types of Teams
- Membership
- Stages
- Conflict, groupthink, barriers
- Decision-Making

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TEAMWORK

- Teams have become universal
  - Cross functional daily operations
- Types of Teams
  - Process / Continuous Improvement
  - Work Groups (Workcells)
  - Self-Managed

Developed as part of NSF ATE Grant #1304474

TEAMWORK

- Types of Teams
  - *Work Groups (Work Cells)*: layout of workstations facilitate process step sequence, all operators within cell are cross-trained on tasks
  - Departments can also be referred to as work groups/teams
    - Example: Operations may encompass several product lines, each product line has a designated area and support staff (Engineering, QA/QC, Mechanics, Production Associates, etc.)
  - *Self-Managed*: directly manage day-to-day operation of process (department), have authority to make decisions
    - Set goals
    - Allocate assignments
    - Ownership of process

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TEAMWORK

- Types of Teams
  - Work Groups
  - Self-Managed
  - *Process Improvement*: focus on improving or developing specific business processes
    - Cross-functional
    - Achieve specific goal
    - Management Sponsor (resource availability)
    - Project plan with start/end targets

Developed as part of NSF ATE Grant #1304474

TEAMWORK

- Membership
  - Roles & Responsibilities
    - Champion = initiates concept or idea for change/improvement
    - Sponsor = supports plans, activities and outcomes
    - Team Leader = Directs member efforts, coaches, communicates to management
    - Member(s) = participants, subject matter experts
  - Team meetings may also include
    - Facilitator = observes process and suggests changes to move forward; assists team leader in closing discussion; may provide training as needed
    - Scribe = designated note taker
    - Timekeeper = keeps meeting on track

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TEAMWORK

- Stages
  - **Forming:** team comes together and begins process of understanding other members

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TEAMWORK

- Stages
  - **Forming**: team comes together and begins process of understanding other members
    - Review the project
    - Establish roles (assigning task categories – contribution)
    - Determine meeting times (frequency)
    - Evaluate that all functions represented
  - **Storming:** team members adjusting to working as a team rather than individually
    - Project may be different than anticipated or more difficult
    - Conflict resolution

TEAMWORK

- Stages
  - Forming: team comes together and begins process of understanding other members
  - Storming: team members adjusting to working as a team rather than individually
  - **Norming:** agree on mutually accepted ideas to move forward
    - Some work gets accomplished
    - Trust is building
    - Share ideas and work products without hesitation
  - **Performing:** members working together to reach common goal
    - Diagnose and solve problems
    - Large amount of work is accomplished

TEAMWORK

- Stages
  - Forming: team comes together and begins process of understanding other members
  - Storming: team members adjusting to working as a team rather than individually
  - Norming: agree on mutually accepted ideas to move forward
  - Performing: members working together to reach common goal
  - **Closing (Adjourning)**: results shared, loose ends tied up, team disbanded
  - **Recognition:** contribution acknowledge and celebrated

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TEAMWORK

- Types of Teams
- Membership
- Stages
- Barriers
  - Groupthink
  - Conflict
  - Logistics
  - Agendas
  - Training

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TEAMWORK

- Barriers
  - Group-Think

    " Group members try to minimize conflict and reach a consensus decision without critical evaluation of alternative viewpoints, by actively suppressing dissenting viewpoints, and by isolating themselves from outside influences.

    Loyalty to the group requires individuals to avoid raising controversial issues or alternative solutions, and there is loss of individual creativity, uniqueness and independent thinking…"
    (wikipedia.com)

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TEAMWORK

- Barriers
  - Group-Think
  - Conflict
    - Five Dysfunctions (P. Lencioni, "The Five Dysfunctions of a Team")
    - 10 Problems (PR Scholtes, "The Team Handbook")

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TEAMWORK

- Barriers
  - Group-Think
  - Conflict
    - Five Dysfunctions (P. Lencioni, "The Five Dysfunctions of a Team")

      Absence of trust
      Fear of conflict
      Lack of commitment
      Avoidance of accountability
      Inattention to results

Developed as part of NSF ATE Grant #1304474

TEAMWORK

- Barriers
  - Group-Think
  - Conflict
    - Five Dysfunctions (P. Lencioni, "The Five Dysfunctions of a Team")
    - 10 Problems (PR Scholtes, "The Team Handbook")

      Floundering –can't start/stop
      Member influence based on position
      Talker
      The one who won't speak up
      Opinions stated as facts
      Rushing to solution
      Digression/tangents – unfocussed discussion
      Explain others motives
      Ignoring or ridiculing other's responses
      Personal Conflict

Developed as part of NSF ATE Grant #1304474

CONFLICT RESOLUTION

- Exercise (pushing hands)

Developed as part of NSF ATE Grant #1304474

TEAMWORK

- Barriers
  - Group think
  - Conflict
  - Logistics
    - 3 Shift operation
    - Multiple sites
    - Different departments
  - Agenda
    - hidden
  - Training
    - Root Cause Tools
    - Professional conduct skills

Developed as part of NSF ATE Grant #1304474

TEAMWORK

- Types of Teams (Work Groups, Self-Managed, Process/Continuous Improvement)
- Membership (Champion, Sponsor, Leader, Members)
- Stages (forming, storming, norming, performing, closing)
- Barriers (conflict, group-think)
- Decision-Making
  - Consensus vs Majority

Developed as part of NSF ATE Grant #1304474

TIME MANAGEMENT

- Time Management
  - Telephone
  - Email
  - Meetings
  - Daily Activities

Developed as part of NSF ATE Grant #1304474

TIME MANAGEMENT

- Multi-tasking Exercise

PROFESSIONAL PRACTICES

Ethics
Confidentiality
Teamwork (Conflict Resolution)
Time / Project Management
Communication

COMMUNICATION

COMMUNICATION

- The exchange of information between people by
  - Speaking
  - Writing
  - Using common systems of signs or behavior

- 5 types
  - Intrapersonal
  - Interpersonal
  - Small Group
  - Public
  - Mass Communications

COMMUNICATION

- Delivering your message
  - Direct Language
  - Factual and relevant details
  - Repetition / reiteration
  - Be aware of non-verbal message
  - Check often for understanding
- Email, Phone, Face-to-Face

Developed as part of NSF ATE Grant #1304474

COMMUNICATION

- Barriers
  - Attitude
    - negative prevent adapting to change
    - overly optimistic miss what actually occurring
  - Experience
    - Oversharing
    - Newbie wanting to prove
  - Mood
    - when grumpy may not listen
    - when joyful interrupt others
  - Noise Level
    - Hearing all the messages
  - Non-Verbal Messages
  - Subject Knowledge
  - Wording

Developed as part of NSF ATE Grant #1304474

COMMUNICATION

- Barriers
  - Attitude (negative versus overly optimistic)
  - Experience (oversharing versus newbie)
  - Mood (grumpy versus joyful)
  - Noise Level (hearing all the messages?)
  - Non-Verbal Messages
    - Demonstrate engagement (i.e. eye contact, relaxed)
    - Back to the person indicates not interested
  - Subject Knowledge
    - The know-it-all
    - pretending loses credibility & erodes trust
  - Wording
    - be non-ambiguous,
    - get to the point,
    - maybe a quick greeting will break the ice (i.e. email salutation)
    - English as second language

COMMUNICATION

LISTENING

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LISTENING

- Listening is hard work
  - Listen intentionally for people's names
  - Listen with interest
  - Try to get rid of your assumptions
  - Listen for what isn't said

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LISTENING SKILLS

- Listening is hard work
  - Listen intentionally for people's names
  - Listen with interest
  - Try to get rid of your assumptions
  - Listen for what isn't said
- Active Listening
  - Try to understand from speaker's point of view

Versus

- Hearing
  - Physical process of eardrum and brain

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LISTENING SKILLS

- Listening is hard work
- Active Listening Skills

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LISTENING SKILLS

- Listening is hard work

- Active Listening Skills
  - Make the decision to listen.
  - Don't interrupt.
  - Keep your eyes focused on the speaker and your ears tuned to their voice.
  - Ask a few questions throughout the conversation.
  - Summarizing statements

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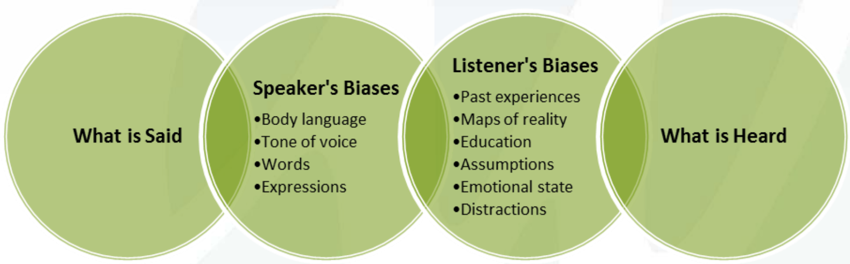
LISTENING SKILLS

- What is Said and what is Heard.



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