CQE Academy

CQE EXAM

Ultimate Study Guide

A complete study guide to help you crush the CQE Exam!

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Contents

Glossary

5S - A workplace organization tool meant to organize, clean and standardize a workplace. A common lean tool for visual control: Sort, Set, shine, Standardize, Sustain.

8D – A root cause analysis tool consisting of 8 Disciplines: Form a team, define the problem, implement containment actions, identify root cause, identify corrective actions, fully implement corrective actions, implement preventative actions, celebration

A

Acceptance quality limit (AQL) - Defined as the worst tolerable process average that is still considered acceptable, and is expressed in terms of percentage of non-conforming material.

Acceptance sampling - A practice whereby a sample is tested from a population (lot), and a decision to **accept or reject** that entire population (lot) is based on the test results of the sample.

Accuracy - The degree of agreement (closeness) between an observed (or measured) value and the true (or accepted) value. If a measurement system lacks accuracy, it is called biased.

Activity Network Diagram (AND or Arrow Diagram) – A Project Planning and Management tool that defines the sequential tasks requires to complete a complex project, and the critical path (CPM).

Affinity Diagram – A tool that facilitates the brainstorming of idea and organization of those ideas into common themes, relationships or characteristics.

Alternative hypothesis (H_a) – In hypothesis testing, this is the alternative hypothesis that the null hypothesis is tested against. This hypothesis takes the opposite sign (≠, >, <) of the null hypothesis.

American National Standards Institute (**ANSI**)-Oversees the development of voluntary consensus standards for products, services, processes, systems, and personnel in the United States. ANSI also represents the U.S. as the member body to ISO.

Analysis of variance (ANOVA)- A hypothesis test used to compare the means of 2 or more groups, that partitions variation into its sources.

Appraisal costs - Cost associated with any activity specifically designed to measure, inspect, evaluate or audit products to assure conformance to quality requirements. These are costs incurred to check & verify that product was built right the first time.

Assignable cause(s) - See special cause variation.

Assumptions - Expectations and conditions that are often assumed and must be true in order for a statistical procedure to be valid. Examples include: Assumption of Normality, Assumption of the Homogeneity of Variances, Assumption of Linearity.

Descriptive statistics

Descriptive (Enumerative) statistics is the process of describing, summarizing & displaying the basic features, properties or characteristics of a given data set.

Central Tendency and **Dispersion** are the most common **Descriptive Statistics**:

Central Tendency is a statistic that represents in some way, the **central value of a data set**:

- **The Mean -** the arithmetic **average**, which is calculated as the sum of all observations divided by the total number of observations.
- **The Median -** represents the **middle value** in a data set.
- **The Mode -** the **most frequently occurring value** in a data set.

$$mean = \frac{\sum x}{n} = \frac{Sum\ of\ all\ observations}{Totat\ number\ of\ observations}$$

Dispersion (Variation) reflects the spread (scatter) or dispersion of data around the central tendency. The 3 most common measurements of variation are:

- **The Range -** the smallest interval containing all the data.
- **The Variance** - the average squared difference of each individual value from the mean.
- **The Standard Deviation –** the square root of the variance.

$$\boldsymbol{Range} = \boldsymbol{R} = Max(x) - Min(x)$$

$$\boldsymbol{Sample\ Variance} = s^2 = \frac{\sum(x-\bar{x})^2}{n-1}$$

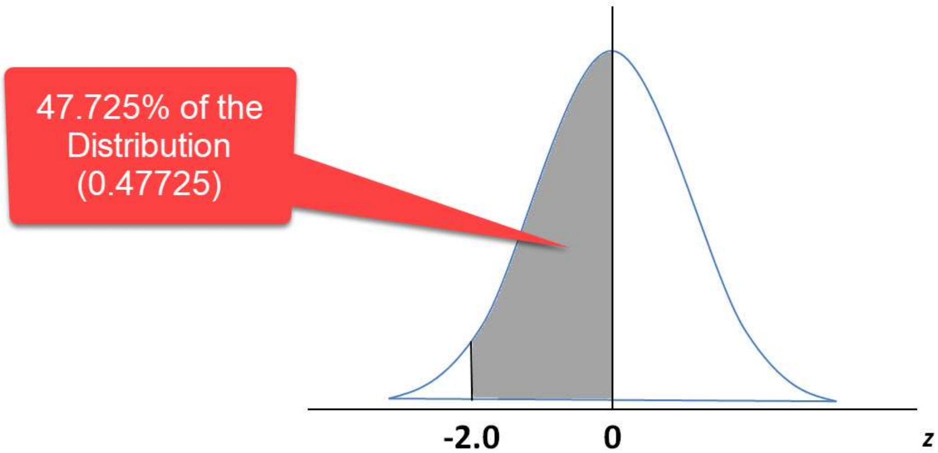
$$\boldsymbol{Population\ Variance} = \sigma^2 = \frac{\sum(x-\bar{\mu})^2}{N}$$

$$\boldsymbol{Sample\ Standard\ Deviation} = \boldsymbol{s} = \sqrt{Sample\ Variance} = \sqrt{s^2} = \sqrt{\frac{\sum(x-\bar{x})^2}{n-1}}$$

$$\boldsymbol{Population\ Standard\ Deviation} = \boldsymbol{\sigma} = \sqrt{Population\ Variance} = \sqrt{\sigma^2} = \sqrt{\frac{\sum(x-\bar{\mu})^2}{N}}$$

The Z-Transformation of the Normal Distribution

$$Z = \frac{X - \mu}{\sigma}$$



Area under the Normal Curve from 0 to X

X	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
0.0	0.00000	0.00399	0.00798	0.01197	0.01595	0.01994	0.02392	0.02790	0.03188	0.03586
0.1	0.03983	0.04380	0.04776	0.05172	0.05567	0.05962	0.06356	0.06749	0.07142	0.07535
0.2	0.07926	0.08317	0.08706	0.09095	0.09483	0.09871	0.10257	0.10642	0.11026	0.11409
0.3	0.11791	0.12172	0.12552	0.12930	0.13307	0.13683	0.14058	0.14431	0.14803	0.15173
0.4	0.15542	0.15910	0.16276	0.16640	0.17003	0.17364	0.17724	0.18082	0.18439	0.18793
0.5	0.19146	0.19497	0.19847	0.20194	0.20540	0.20884	0.21226	0.21566	0.21904	0.22240
0.6	0.22575	0.22907	0.23237	0.23565	0.23891	0.24215	0.24537	0.24857	0.25175	0.25490
0.7	0.25804	0.26115	0.26424	0.26730	0.27035	0.27337	0.27637	0.27935	0.28230	0.28524
0.8	0.28814	0.29103	0.29389	0.29673	0.29955	0.30234	0.30511	0.30785	0.31057	0.31327
0.9	0.31594	0.31859	0.32121	0.32381	0.32639	0.32894	0.33147	0.33398	0.33646	0.33891
1.0	0.34134	0.34375	0.34614	0.34849	0.35083	0.35314	0.35543	0.35769	0.35993	0.36214
1.1	0.36433	0.36650	0.36864	0.37076	0.37286	0.37493	0.37698	0.37900	0.38100	0.38298
1.2	0.38493	0.38686	0.38877	0.39065	0.39251	0.39435	0.39617	0.39796	0.39973	0.40147
1.3	0.40320	0.40490	0.40658	0.40824	0.40988	0.41149	0.41309	0.41466	0.41621	0.41774
1.4	0.41924	0.42073	0.42220	0.42364	0.42507	0.42647	0.42785	0.42922	0.43056	0.43189
1.5	0.43319	0.43448	0.43574	0.43699	0.43822	0.43943	0.44062	0.44179	0.44295	0.44408
1.6	0.44520	0.44630	0.44738	0.44845	0.44950	0.45053	0.45154	0.45254	0.45352	0.45449
1.7	0.45543	0.45637	0.45728	0.45818	0.45907	0.45994	0.46080	0.46164	0.46246	0.46327
1.8	0.46407	0.46485	0.46562	0.46638	0.46712	0.46784	0.46856	0.46926	0.46995	0.47062
1.9	0.47128	0.47193	0.47257	0.47320	0.47381	0.47441	0.47500	0.47558	0.47615	0.47670
2.0	0.47725	0.47778	0.47831	0.47882	0.47932	0.47982	0.48030	0.48077	0.48124	0.48169
2.1	0.48214	0.48257	0.48300	0.48341	0.48382	0.48422	0.48461	0.48500	0.48537	0.48574
2.2	0.48610	0.48645	0.48679	0.48713	0.48745	0.48778	0.48809	0.48840	0.48870	0.48899
2.3	0.48928	0.48956	0.48983	0.49010	0.49036	0.49061	0.49086	0.49111	0.49134	0.49158
2.4	0.49180	0.49202	0.49224	0.49245	0.49266	0.49286	0.49305	0.49324	0.49343	0.49361
2.5	0.49379	0.49396	0.49413	0.49430	0.49446	0.49461	0.49477	0.49492	0.49506	0.49520
2.6	0.49534	0.49547	0.49560	0.49573	0.49585	0.49598	0.49609	0.49621	0.49632	0.49643
2.7	0.49653	0.49664	0.49674	0.49683	0.49693	0.49702	0.49711	0.49720	0.49728	0.49736
2.8	0.49744	0.49752	0.49760	0.49767	0.49774	0.49781	0.49788	0.49795	0.49801	0.49807
2.9	0.49813	0.49819	0.49825	0.49831	0.49836	0.49841	0.49846	0.49851	0.49856	0.49861
3.0	0.49865	0.49869	0.49874	0.49878	0.49882	0.49886	0.49889	0.49893	0.49896	0.49900

Poisson Mean & Variance

When a random variable X follows the Poisson distribution the **mean** (expected value) and **standard deviation** can be calculated using the following equations:

- **Mean (Expected Value): μ = λ**
- **Standard Deviation:** $\boldsymbol{\sigma = \sqrt{\lambda}}$

The primary parameter associated with the Poisson distribution is **λ (Lambda)** and it represents the mean number of occurrences over a given interval of time. Within **reliability**, λ often represents the mean time to failure (**MTTF**) or the mean time between failures (**MTBF**).

Calculating Probability with the Poisson Distribution

To calculate the probability of occurrence when using the Poisson distribution, we use the following equation:

$$f(x) = P(X = x) = \frac{e^{-\lambda} * \lambda^{x}}{x!}$$

Where:

- e = natural log = 2.71828….
- λ = expected value = mean number of occurrences over time
- x = value of interest

Hypergeometric Distribution

In both of the discrete distributions above (Poisson & Binomial), one of the required conditions is that of **independence**.

Independence means that the result of each trial is not influenced by the result of the previous trial, however this is not always the case in Quality. In these instances, where Independence cannot be achieved, we must use the Hypergeometric distribution.

Calculating Probability with the Hypergeometric Distribution

You can use the following equation to calculate the probability of occurrence with the hypergeometric distribution:

$$f(x) = \frac{\binom{A}{x} * \binom{N-A}{n-x}}{\binom{N}{n}}$$

Where:

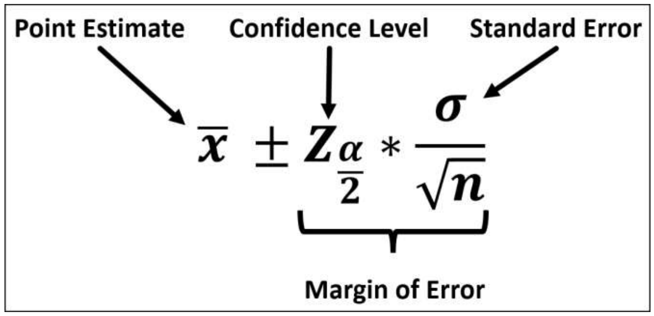
- N is the population quantity
- n is the sample quantity
- A is the number of nonconformances in the population
- x is the number of nonconformances in the sample

The hypergeometric distribution calculates the probability of exactly ***x*** defects when sampling ***n*** items from a population of size ***N*** which contains a total number of ***A*** defects.

The Confidence Interval Equation

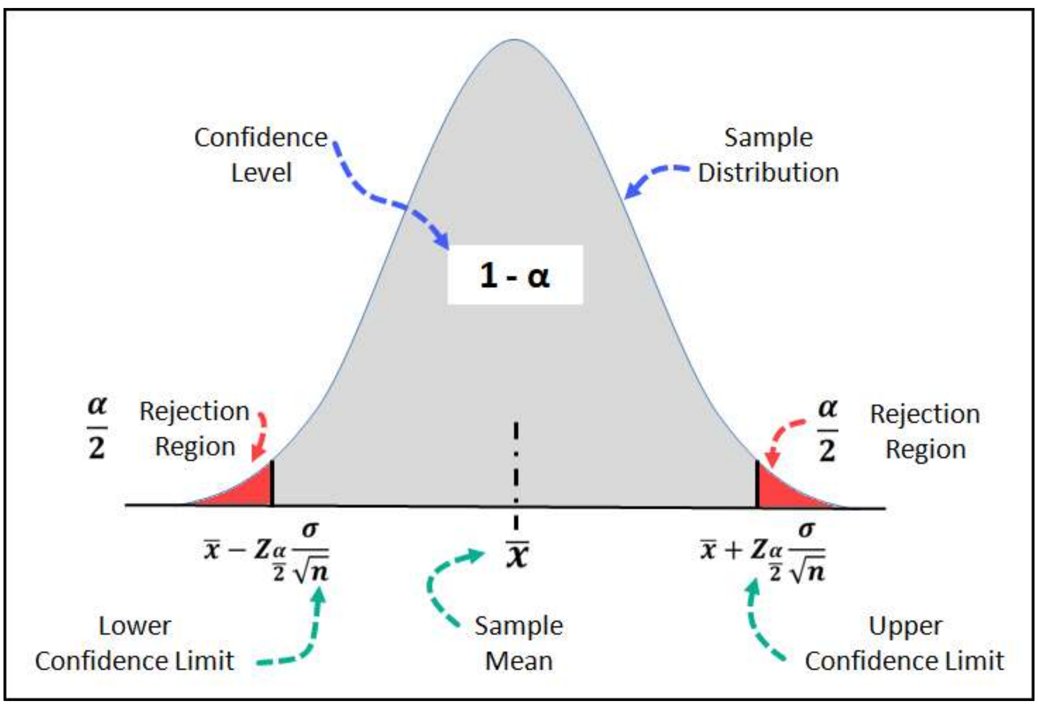
The confidence interval equation is comprised of 3 parts: **a point estimate (also sometimes called a sample statistic)**, **a confidence level**, and a **margin of error**.

The **point estimate**, or statistic, is the most likely value of the population parameter and the **confidence level & margin of error** represents the amount of uncertainty associated with the sample taken.



The Confidence Level & Z-Score

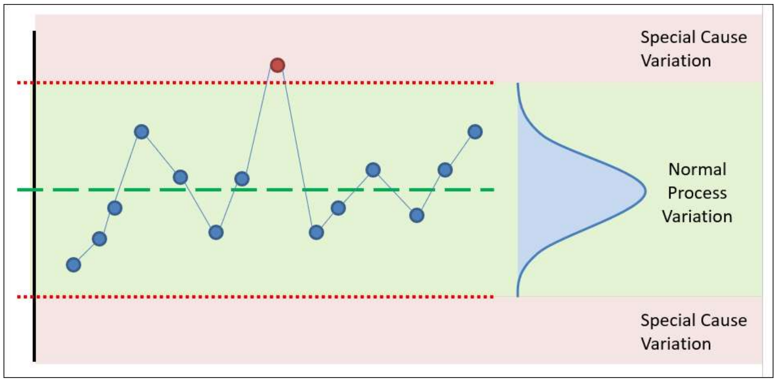
The confidence level above is expressed as a Z-score that also references the **alpha risk** (**Significance level**). *In this situation, we're using the Z-score because the distribution of sample means is normally distributed.*



On this graph you can see that the region shaded in gray in the middle captures a certain portion of the distribution, for example if your confidence level is 95%, it would capture 95% of the distribution.

The region in red is often called the **rejection region**, but I've shown it that way to demonstration the **alpha risk**. The alpha risk, 5% in this example, is **split in half** between the left and right tail of the sample distribution which is why the equation and the image show it as **α/2** .

Statistical Process Control



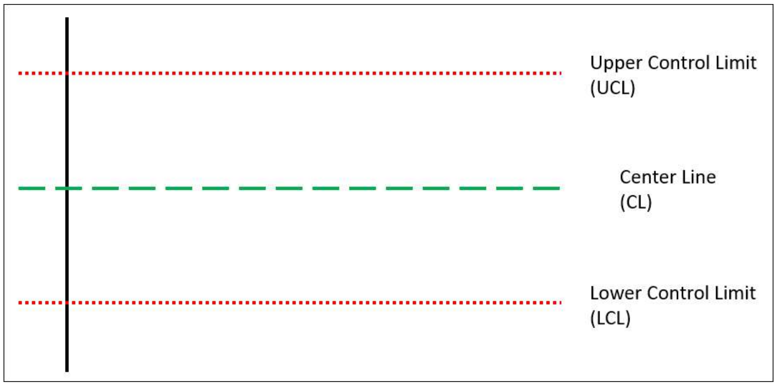
Statistical Process Control, or SPC, is a collection of tools that allow a Quality Engineer to ensure that their process is in control, using statistics.

The primary benefit of a control chart is its **unique ability to separate the normal variation within your process and the special cause variation.**

Common Cause Variation - Every process has a **normal, inherent level of variation**, often called **common cause variation** as the sources of these variation are common to the process and cannot be easily eliminated.

Special Cause Variation - is any type of variation that can be attributed to a special cause or situation that's influencing your process. These special causes impact your process in negative ways and result in instability and unpredictability.

A control chart has 3 key elements, the **Center Line**, the **Upper Control Limit** and the **Lower Control Limit**, that **allow the control chart to distinguish between common cause variation and special cause variation.**



Control limits are typically set at $\pm$ **3 standard deviations** away from the **mean** and reflect the common causes of variation with your process. These control limits are not associated with your specification limits or customer requirements.

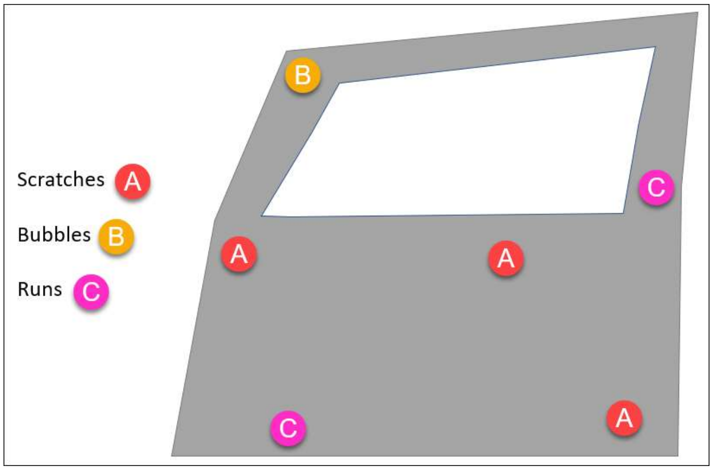
Selection of a Variable for Control Charts

Selecting the right variable for a control chart means understanding the difference between **discrete and continuous data**.

For **discrete data** it means understanding the difference between a **defect and a defective**.

A "**defective"** is an **entire unit** that fails to meet specifications. A "**defect"** is an **undesirable condition** within a unit. A **defective unit can have multiple defects** associated with it.

This single car door is a **"defective unit"** that could be trended, or each **individual defect** (scratches, paint runs, paint bubbles) can be trended.

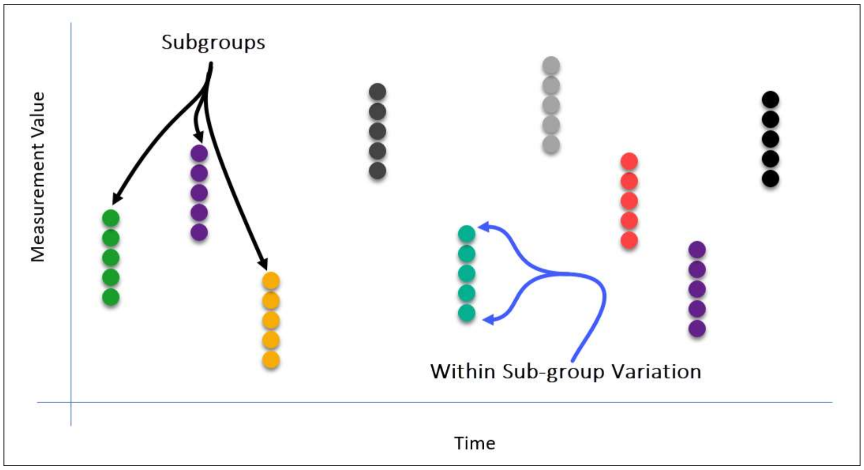


Rationale Subgrouping

A **rational subgroup** is defined as a collection of units that are all produced under the same conditions.

These samples should be as **homogenous** as possible, and any variation within these samples should only include the normal, **inherent process variation**.

Not having a properly defined **rational subgroup** can hide process changes or indicate process changes where in actuality none exist.



Variable Control Charts

If you're **rational sub-group size is a single value (1)**, then you'll use the **I-MR (Individual and Moving Range) Chart.**

If you're **rational sub-group size is between 2 – 10**, then you'll use the **X-Bar and R Chart.** When the sample size is less than 10, the **range** of the sample data is a better estimator of the **process variability** than the standard deviation.

If you're **rational sub-group size is greater than 10**, then you'll use the **X-Bar and S Chart.** When you've got 10 or more samples in a rational sub-group, then the **best estimator of the process variability is the sample standard deviation**.

X-bar & R Chart Equations

$$\textbf{The Grand Mean}: \bar{\bar{X}} = \frac{\sum \bar{X}_i}{k}$$

$$\textbf{X - bar Control Limits}: UCL_{\bar{X}} = \bar{\bar{X}} + A_2\bar{R} \qquad LCL_{\bar{X}} = \bar{\bar{X}} - A_2\bar{R}$$

$$\textbf{The Average Range} = \bar{R} = \frac{\sum R_i}{k} = \frac{Sum\ of\ Subgroup\ Ranges}{\#\ of\ Subgroups}$$

$$\textbf{The R Chart Control Limits}: UCL_R = D_4\bar{R} \qquad LCL_R = D_3\bar{R}$$

$$\textbf{Population Standard Deviation} = \hat{\sigma} = \frac{\bar{R}}{d_2}$$

X-Bar and R Chart				
Subgroup Sample Size	X-Bar Factor	Range Factors		Variance Factor
n	A_2	D_3	D_4	d_2
2	1.880	-	3.267	1.128
3	1.023	-	2.575	1.693
4	0.729	-	2.282	2.059
5	0.577	-	2.115	2.326
6	0.483	-	2.004	2.534
7	0.419	0.076	1.924	2.704
8	0.373	0.136	1.864	2.847
9	0.337	0.184	1.816	2.970
10	0.308	0.223	1.777	3.078
15	0.223	0.347	1.653	3.472
20	0.180	0.415	1.585	3.735
25	0.153	0.459	1.541	3.931

Process Capability Indices (C_p, C_{pk}, C_{pm}, C_r)

C_p

C_p is often described as a measure of the potential of the process as it represents what the process might be able to achieve if the process was centered.

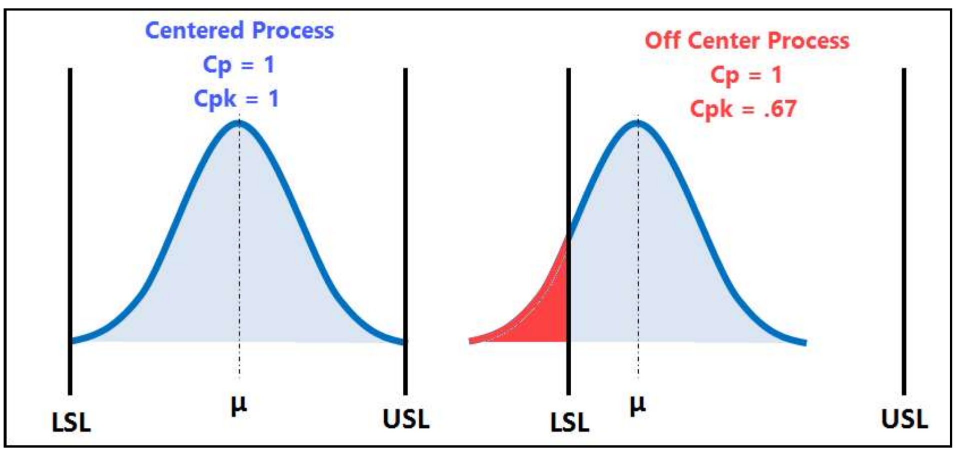
$$C_p = \frac{USL - LSL}{6\sigma}$$

Remember this is because C_p only takes variability into account and ignores the location of the central value of the process.

C_{pk}

While C_p only considered the variation within your process, C_{pk} takes into account both the variability & and centrality of the process and therefore reflects the actual performance of the process.

$$C_{pk} = Min(C_{p,Lower}, C_{p,Upper}) = Min\left(\frac{USL - \bar{x}}{3s}, \frac{\bar{x} - LSL}{3s}\right)$$



C_{pm}

C_{pm} is referred to as the Taguchi index, and (similar to Cpk) is designed to penalize processes that are not centered around the process Target Value (T).

$$C_{pm} = \frac{USL - LSL}{6\sqrt{s^2 + (\bar{x} - T)^2}}$$

C_r

C_r represents the proportion of the process tolerance that is consumed by the design specification, while C_p represents how much of the design space (product tolerance) is filed up by the process variation.

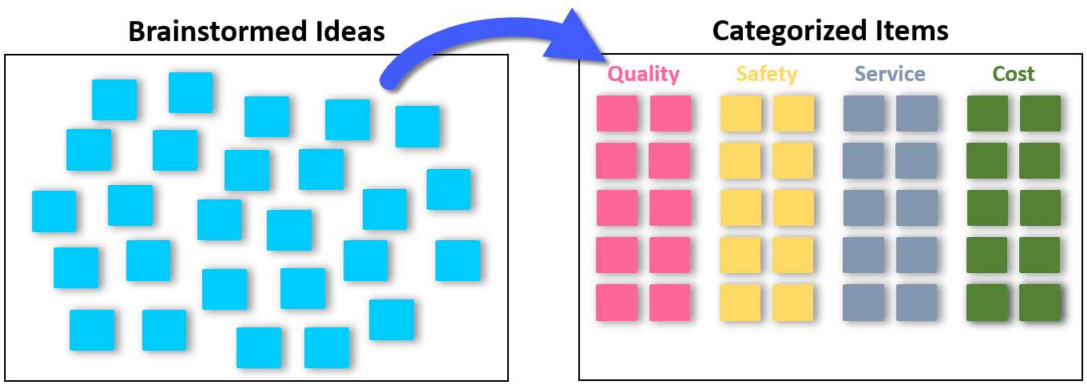
$$C_r = \frac{1}{C_p}$$

Tool 1 - Affinity Diagrams

When two items have an **Affinity**, it means they have **a similarity of characteristics** which suggests a potential relationship.

The **Affinity Diagram** is a tool that **facilitates brainstorming** and **organizes facts and data** into **themes or groups of common characteristics**.

Brainstorming a problem, and then analyzing those facts and data for topics that have an affinity with each other, can **make complex problems simple**.



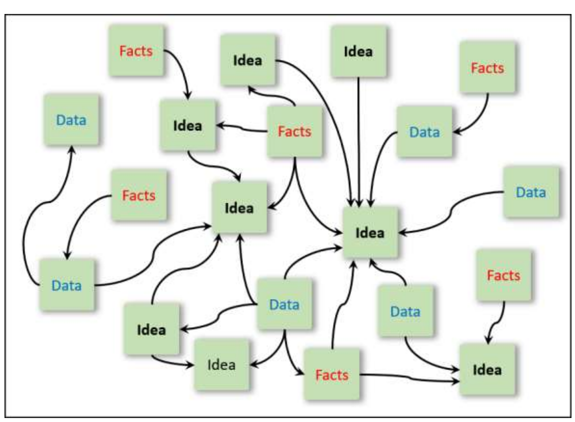
Tool 2 - Interrelationship Digraphs

The interrelationship digraph is another tool you can use to **analyze a complex problem** to **identify the cause and effect relationships** that exist between **disparate facts**.

The primary purpose of this tool is to help you **uncover, visualize and communicate the natural cause and effect relationships** that exist **within a complex project or problem**.

This cause & effect analysis can be used directly after creating an affinity diagram to reveal the relationships between ideas.

The tool uses **relationship arrows** between ideas to identify the **specific cause and effect relationships** between these seemingly disparate facts. With the **relationship arrow** leaving the “causal” topic, and ending at the “effectual” topic.

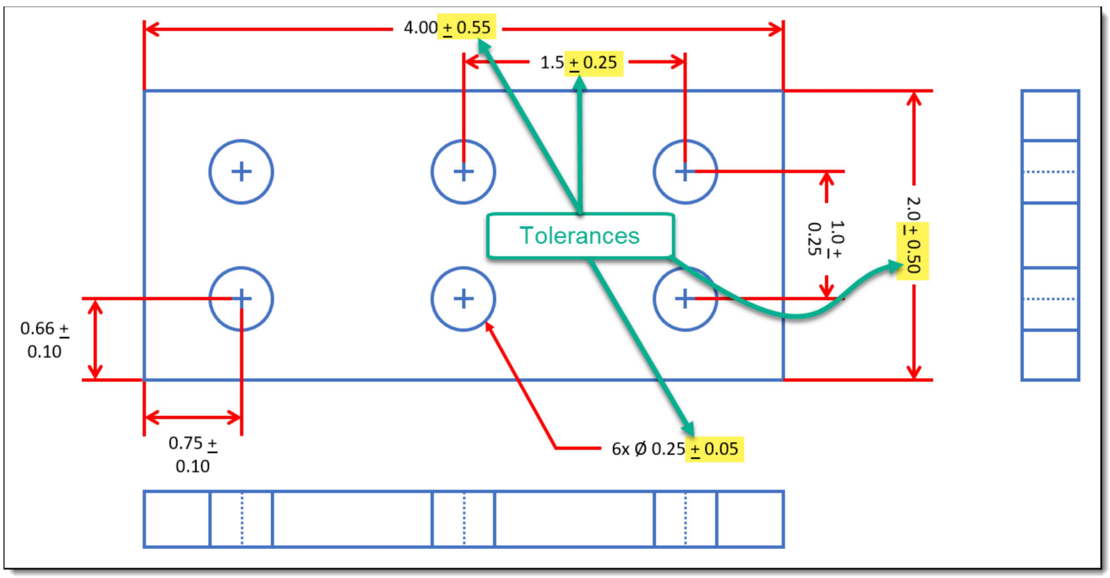


Tolerances

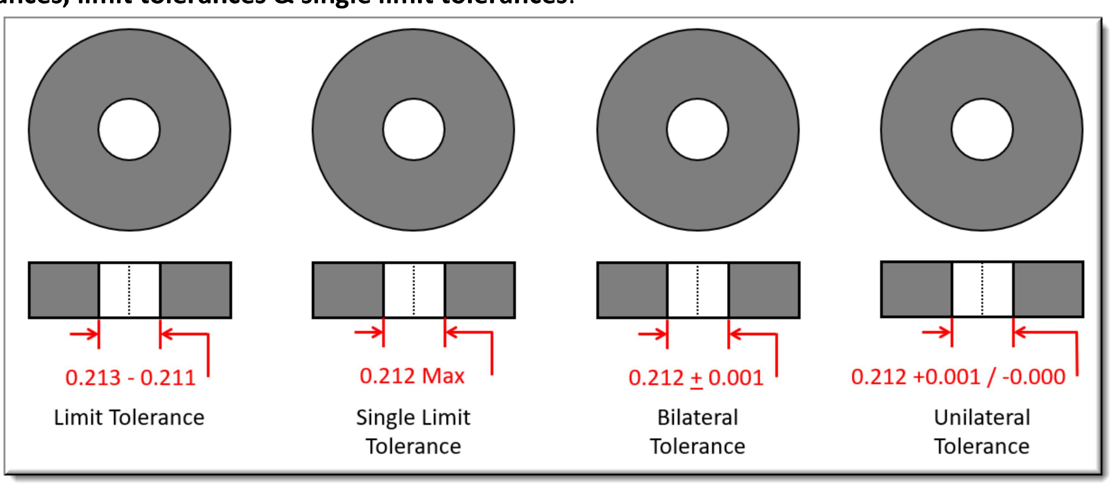
According the ASME Y14.5, **A tolerance is defined as the total amount that a specific dimension is permitted to vary.** This total amount is considered the difference between the maximum and minimum limits.

Tolerances are intended to create boundaries for the design, which create the design space associated with your product. Your product should be capable of functioning as intended throughout the entire tolerance range of your product.

Your tolerances should be created to account for the variation in your value stream (manufacturing process) which can never be fully eliminated, and which can originate from many different sources.



There are 4 different types of tolerances that we need to discuss, these are **bilateral tolerances, unilateral tolerances, limit tolerances & single limit tolerances**.



As shown, **Limit Tolerances** show both a maximum and minimum dimension allowable for the feature. A **Single Limit Tolerance** only defines one limit dimension, normally either the **maximum or minimum value** for a feature or dimension.

The **Bilateral Tolerance** shows the nominal dimension (0.212) and the allowable tolerance in either direction ± .001. The **Unilateral Tolerance** shows the nominal dimension (0.212) and a tolerance in only one direction +0.001.

Another method for tolerancing your dimensions is the usage of **standard tolerances**. For example, many drawings are created with a note that reads like this:

Unless otherwise specified, dimensions are in inches:

- **Angles: +/- 0.5 degrees**
- **.XX: +/- 0.01"**
- **.XXX: +/- 0.005"**

This allows the designer to put the nominal dimension on the drawing and then let the drawing control the tolerance. For example, the designer can show a dimension of 1.45" and the implied tolerance is 0.01" because the nominal dimension was specified to two decimal places X.XX.

Had the dimension been specified to the third decimal place (1.450"), then the implied dimension would be 0.005".

Tolerancing Rules

Similar to dimensions, there are a handful of important rules associated with Tolerance found within ASME Y14.5-2009 that you should know:

1. All dimensions must have a tolerance - unless they are specified as minimum, maximum or reference only.
2. Tolerances [and Dimensions] shall completely define the nominal geometry allowable variation
3. Tolerances [and Dimensions] apply only at the drawing level where they are specified
4. Tolerances [and Dimensions] should be arranged for optimum readability
5. Tolerances [and Dimensions] are assumed to apply to the full length, width and depth of a feature unless stated otherwise

Sequential Sampling Plans

The sequential sampling plan is a further extension of the multiple sampling plan where sampling can go on indefinitely until the entire lot is inspected.

ANSI/ASQ Z1.4 - The Attribute Sampling Plan

The ANSI/ASQ **Z1.4 standard** is acceptance sampling for **attribute data** and originated as **Military Standard 105**. This standard applies to processes that are continuous in nature, and do not apply to processes that operator infrequently or irregularly.

The Z1.4 standard allows the user to choose between **single, double, or multiple sampling plans**, and then assists the user in setting up their **sampling scheme**.

Since we've already discussed the nuances of the single, double, multiple and sequential plans, let's focus now on the **sampling schemes** and **switching rules** within the **ANSI/ASQ standard**.

A **sampling scheme** is a set of sampling plans that are used along with **switching rules** that govern with sampling plan should be used. These various sampling plans include **normal sampling, heightened sampling** and **reduced sampling**.

These switching rules are integral to the standard.

Many people simply use various sampling plans with no switching rules. This is not the intention of the standard.

The intention of the standard is to be used as a system that uses the switching rules. **If you're not using the switching rules, you're not inspecting per ANSI Z1.4.**

These sampling schemes are meant to reward vendors who have demonstrated a stable, **high quality process** with **reduced sampling**, and **encourage continuous improvement** for poorly performing vendors with **heightened sampling**.

The ANSI standard has **3 general inspection levels (I, II and III)**, and **4 special inspections**, which you can see below.

The **special inspection levels** should only be used when small sample sizes are necessary due to high inspection costs. These small sample sizes naturally **result in large sampling risks** for both the producer and consumer. Using these special plans must come with an assessment, and acceptance of those risks.

We're going to focus mainly on the **general inspection levels within the standard**.

Normal sampling starts with **General Inspection Level II**, this should be the default starting point for any sampling plan or scheme.

Lot or Batch Size			Special Inspection Levels				General Inspection Levels		
			S-1	S-2	S-3	S-4	I	II	III
2	to	8	A	A	A	A	A	A	B
9	to	15	A	A	A	A	A	B	C
16	to	25	A	A	B	B	B	C	D
26	to	50	A	B	B	C	C	D	E
51	to	90	B	B	C	C	C	E	F
91	to	150	B	B	C	D	D	F	G
151	to	280	B	C	D	E	E	G	H
281	to	500	B	C	D	E	F	H	J
501	to	1200	C	C	E	F	G	J	K
1201	to	3200	C	D	E	G	H	K	L
3201	to	10000	C	D	F	G	J	L	M
10001	to	35000	C	D	F	H	K	M	N
35001	to	150000	D	E	G	J	L	N	P
150001	to	500000	D	E	G	J	M	P	Q
	>	500001	D	E	H	K	N	Q	R

As you can see in the table above, **moving between inspection level I, II and III changes the sample size code letter**, which **changes the number of samples associated with a sampling plan**.

For example, if your lot size is 100,000 units, here are the sample size code letters and sample sizes:

- Level I translates to a sample size code letter **L**, which has a sample size of 200
- Level II translates to a sample size code letter **N**, which has a sample size of 500
- Level III translates to a sample size code letter **P**, which has a sample size of 800

While these different inspection levels might all have the same AQL, inspecting more samples always reduces the **consumers risk of accepting a bad lot**.

So **General Inspection Level I** may be used when more risk can be tolerated, and **General Inspection Level III** may be used when less risk can be tolerated.

Sample Size Code Letter	Sample Size	AQL (Acceptance Quality Limit) for Normal Inspection																									
		0.25		0.4		0.65		1		1.5		2.5		4		6.5		10		15		25		40		65	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2	↓		↓		↓		↓		↓		↓		↓		0	1	↓		↓		1	2	2	3	3	4
B	3	↓		↓		↓		↓		↓		↓		0	1	↕		↓		1	2	2	3	3	4	5	6
C	5	↓		↓		↓		↓		↓		0	1	↕		↕		1	2	2	3	3	4	5	6	7	8
D	8	↓		↓		↓		↓		0	1	↕		↕		1	2	2	3	3	4	5	6	7	8	10	11
E	13	↓		↓		↓		0	1	↕		↕		1	2	2	3	3	4	5	6	7	8	10	11	14	15
F	20	↓		↓		0	1	↕		↕		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22
G	32	↓		0	1	↕		↕		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑	
H	50	0	1	↕		↕		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑		↑	
J	80	↕		↕		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑		↑		↑	
K	125	↕		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑		↑		↑		↑	
L	200	1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑		↑		↑		↑		↑	
M	315	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑		↑		↑		↑		↑		↑	
N	500	3	4	5	6	7	8	10	11	14	15	21	22	↑		↑		↑		↑		↑		↑		↑	
P	800	5	6	7	8	10	11	14	15	21	22	↑		↑		↑		↑		↑		↑		↑		↑	
Q	1250	7	8	10	11	14	15	21	22	↑		↑		↑		↑		↑		↑		↑		↑		↑	
R	2000	10	11	14	15	21	22	↑		↑		↑		↑		↑		↑		↑		↑		↑		↑	

The Average & Range Method for MSA

The **average and range** method is capable of separating **repeatability** from **reproducibility** when analyzing the total measurement system variation but requires more effort and calculation than the range method.

This method is also more accurate in estimating the error or variation within a measurement system.

In this method, 2 or 3 operators (appraisers) measure a minimum of 10 parts. More parts can be measured, which only increases the accuracy of the analysis.

Then, each sample part is measured by each operator 2 or 3 times (replicate measurements). Remember, these measurements should be taken randomly to avoid any bias in the data.

Appraiser	Replicate Measurements	Samples										
		1	2	3	4	5	6	7	8	9	10	Averages
A	1											
	2											
	3											
	Average											
	Range											
B	1											
	2											
	3											
	Average											
	Range											
C	1											
	2											
	3											
	Average											
	Range											

Repeatability Calculation (Equipment Variation – EV)

Repeatability (Equipment Variation) is estimated using **R-double bar**, which is the average value of the range measured within each operator and within each part.

$$Equipment\ Variation\ (EV) = \sigma_{Repeatability} = \frac{\bar{\bar{R}}}{d_2}$$

In this calculation **d_2** depends on m = (# of replicates, usually 2 or 3), and n = (# of parts) * (# of operators). The value of n should equal the number of range values used to calculate the average range (R-bar) value.

When the value of n is greater than 16, you can use d^*_2.

Reproducibility Calculation (Appraiser Variation – AV)

Reproducibility (Appraiser Variation) is determined by analyzing the variation between the average of the individual technicians for all parts.

You'll notice below that to calculate the reproducibility (appraiser variation), we must subtract the repeatability as the equipment variation would otherwise overinflate the estimate of appraiser variation.

Cost of Quality

When it comes to Quality & Cost, there are 4 different Categories that can be utilized to capture your quality related costs, these are:

- **Prevention Cost -** costs associated with activities specifically designed to prevent poor quality in products.
- **Appraisal Cost -** costs associated with activities specifically designed to measure, inspect, evaluate or audit products to assure conformance to quality requirements.
- **Internal Failure Cost -** costs incurred when a product fails to conform to a quality specification before shipment to a customer.
- **External Failure Cost -** costs incurred when a product fails to conform to a quality specification after shipment to a customer.

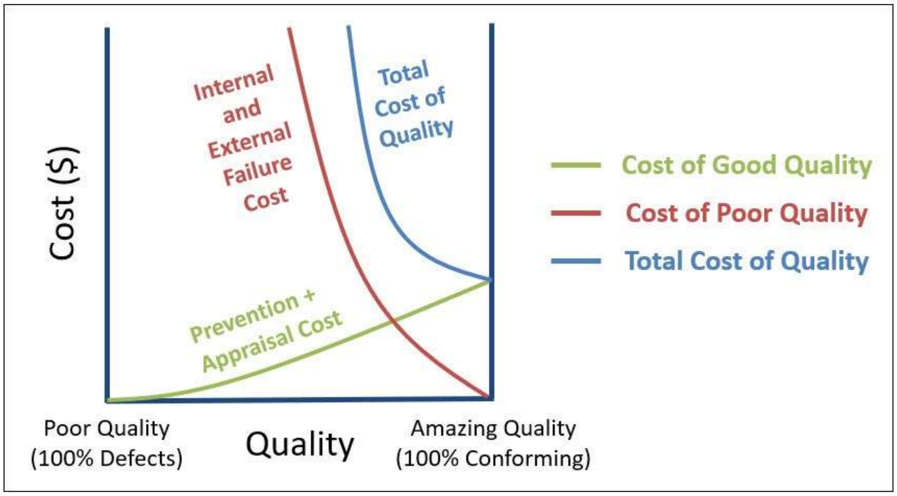
The **Total Quality Cost** then is simply the sum of all these cost categories; Prevention, Appraisal, & Failure Costs (Internal & External).

As you can see, there are two "good" quality cost categories (Prevention & Appraisal) and two "bad" categories (Internal Failures & External Failures).

These cost categories can also be re-stated from the "Right the First Time" perspective. All you need to do is to ask yourself is "If all our processes produced the correct result the 1^{st} time, would this cost still be here?"

For example, Prevention & Appraisal costs ensure that a task was conducted right the first time, and Failure Costs, both internal & external, occur when a task is not performed right the first time.

The Quality Cost Curve below which shows the relationship between **good quality**, **poor quality** and the **total cost of quality**.



As you move from 0% conformance to 100% conformance the Prevention & Appraisal Costs increase linearly. Similarly, the Failure Costs (Internal + External) begin decreasing sharply.

Then, the Total CoQ (Cost of Quality), which is a sum of these two other curves also decreases sharply.

Prevention Cost

Prevention Costs are those costs or activities that are specifically designed to prevent poor quality in products. These costs ensure that product is built right the first time by preventing or reducing errors from occurring.

As we say above, investments in this category result in a lower total COQ over time always have the best Return on Investment (ROI). Prevention costs should be viewed as an investment in cost-avoidance.

Prevention Activities (Costs)	
Design Qualification Testing	FTA, FMEA & FMECA
Market Research	Field Evaluation or Testing for New Products
Prototype Testing & Iteration	New Product Design Review & Analysis
Design Review Meetings	Design Validation & Verification
Equipment Fixture Design	Defect Proofing (Poke-Yoke)
Supplier Evaluation	New Supplier Qualification
Supplier Capability Surveys	Supplier Reviews, Ratings & Quality Planning
Supplier Scorecard	Supplier Quality Agreements
New Employee Screening	New Employee Training & Education
Controlled Storage	Internal Process Capability Evaluations
Developing a Process Control Plan	Predictive Equipment Maintenance
Quality Planning	Quality Education & Training
Quality Improvement Projects	Process Qualification, Validation & Verification
Procedure Writing	Implementation of a Quality Data System
Quality System Audits	Development of Quality Control Plans

Risk Management

Risk Management is the seventh & final pillar of the CQE Body of Knowledge and contains 4 chapters **Risk Oversight, Risk Assessment, Risk Control and Risk Management Tools.**

Risk Oversight

What is Risk (Severity & Likelihood)

From a very generic perspective, Risk can be thought of as the *effect of uncertainty* on our desired *goal*.

It's important to remember though that uncertainty can work both ways. It can have either negative or positive impact on our goals. You can have good luck or bad luck. For example, if you were to look at the integration of risk management into project management, you may experience uncertainty that works in your favor. Most often however, especially in the world of quality, **we generally think of the consequences being a negative event.**

Therefore, the definition of risk as it relates to Quality Management has been more narrowly defined as the combination of the probability of occurrence (likelihood) of a negative event and the severity of that event.

$$Risk = Severity \times Occurrence$$

That negative event can be as small as a non-obvious cosmetic issue or as severe as death or serious injury to your customer.

Below is a Risk Ranking Matrix that shows the relationship between the **Risk** value (Numbers in the matrix) and the **Severity** of Occurrence (Y Axis) and the likelihood of **Occurrence** (X-Axis).

This matrix assumes that the scales of your Risk Analysis for both Severity & Occurrence are a 10x Scale from 1 - 10; with 1 being the least severe or least likely value and 10 being the highest; however, this scale is arbitrary.

Severity of the Event											
	10	10	20	30	40	50	60	70	80	90	100
	9	9	18	27	36	45	54	63	72	81	90
	8	8	16	24	32	40	48	56	64	72	80
	7	7	14	21	28	35	42	49	56	63	70
	6	6	12	18	24	30	36	42	48	54	60
	5	5	10	15	20	25	30	35	40	45	50
	4	4	8	12	16	20	24	28	32	36	40
	3	3	6	9	12	15	18	21	24	27	30
	2	2	4	6	8	10	12	14	16	18	20
	1	1	2	3	4	5	6	7	8	9	10
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
		Probability of Occurrence of the Event									

Types of Quality Risks to Manage

From a quality perspective, we have to manage the risks that might prevent us from achieving our goal of a high-quality product, hence the name **Quality Risk**. These risks to quality come in a few different forms and are categorized based on the impacted stakeholder:

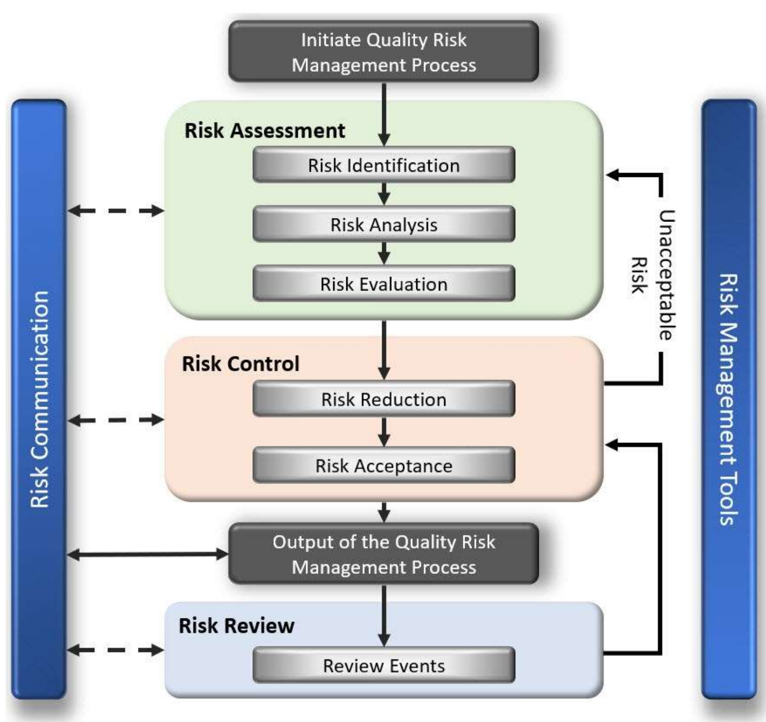
- **User Safety Risk** - This area of risk is generally the most severe and can include things like personal injury or death to your customers.
- **Product/Reliability Risk** - This area of risk captures any event that has an impact your product and its quality, functionality or reliability, which implies a reduction in performance or quality over time.
- **Compliance/Regulatory Risk** - This area of risk captures any event (decision or action) that could be associated with a perception that your organization is out of compliance with a regulatory requirement.

As you can see the stakeholders associated with these areas of risk are your customers, and for those who work in regulated industries; the regulatory bodies themselves.

The other type of risk here that's worth mentioning is the idea of **Business Risk** where there is a quality related event that can have a negative impact on your business and its financial or competitive performance.

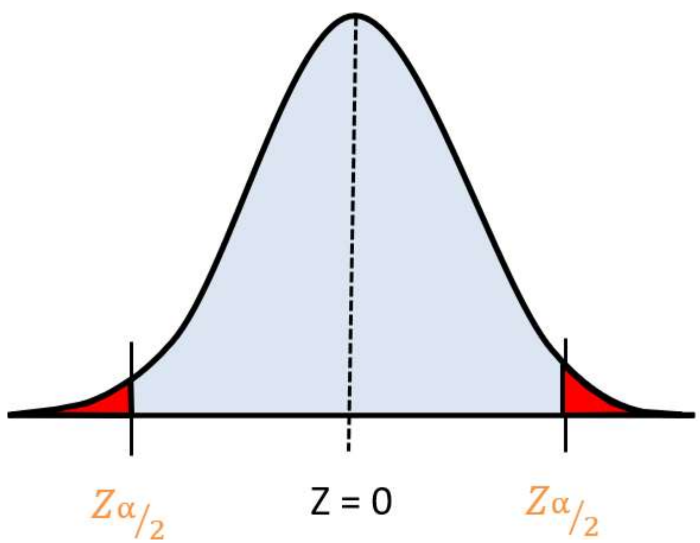
The Quality Risk Management Process

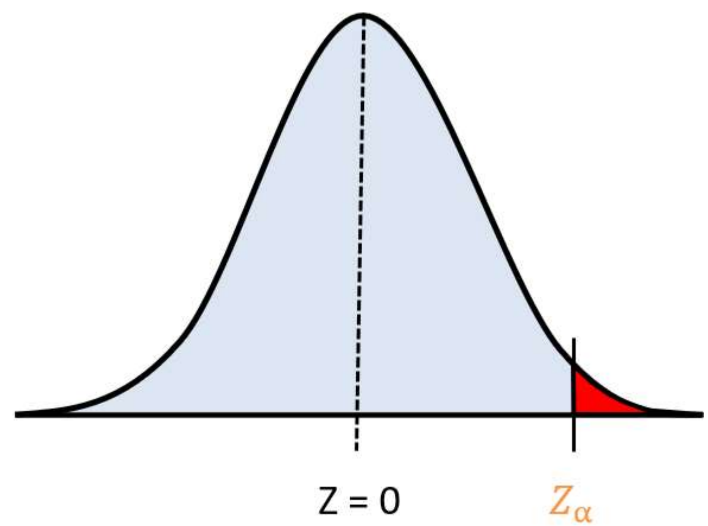
Risk Management *is defined as the systematic application of management policies, procedures & practices to the tasks of assessing, controlling, monitoring, communicating & reviewing risk throughout the lifecycle of a product or service.*



Continuous Data Distribution

Distribution	Cumulative Probability	Central Tendency	Dispersion	Parameters
The Normal Distribution	$Z = \frac{X - \mu}{\sigma}$	$\mu = \frac{\sum X}{N}$	$\sigma = standard\ deviation$	**μ** is the mean value **σ** is the standard deviation
The Uniform Distribution	$P(X_1 < x < X_2) = \frac{(X_1 - X_2)}{(b - a)}$	$\mu = \frac{a + b}{2}$	$\sigma^2 = \frac{(b - a)^2}{12}$	***a*** is the minimum value in the distribution ***b*** is the maximum value in the distribution
The Exponential Distribution	$R(t) = e^{-\lambda t}$	$\theta = \frac{1}{\lambda}$		$\lambda = Failure\ Rate$
The Weibull Distribution	$R(t) = e^{-\left(\frac{t}{\theta}\right)^{\beta}}$			**β(Beta)** - the Weibull **Shape** or Slope Parameter **θ(Theta)** - the Weibull **Scale** Parameter **Δ(Delta)** - The Weibull **Location** Parameter (Not shown in equation)





Significance Level (α)	Confidence Level (100 – α)	Two-tailed Sign. Level ($\alpha/2$)	$Z_{\alpha/2}$
0.01	99%	0.005	2.575
0.05	95%	0.025	1.960
0.10	90%	0.05	1.645

Significance Level (α)	Confidence Level (100 – α)	Z_{α}
0.01	99%	2.33
0.05	95%	1.65
0.10	90%	1.28

Confidence Intervals

Parameter of Interest	Equation	Parameters	Use When
The Population Mean (μ)	$\bar{x} \pm Z_{\frac{\alpha}{2}} * \frac{\sigma}{\sqrt{n}}$	$\bar{x}$ is the sample mean, **σ** is the population standard deviation, **n** is the sample size, $Z_{\frac{\alpha}{2}}$ is the z-statistic associated with the confidence level	The population variance is known and the sample size (n) is greater than 30
The Population Mean (μ)	$\bar{x} \pm t_{\frac{\alpha}{2}} * \frac{s}{\sqrt{n}}$	$\bar{x}$ is the sample mean, **s** is the sample standard deviation, **n** is the sample size, $t_{\frac{\alpha}{2}}$ is the t-statistic associated with the confidence level	The population variance is unknown or the sample size (n) is less than 30
The Population Variance	$\frac{(n-1)s^2}{X^2_{1-\alpha/2}} < \sigma^2 < \frac{(n-1)s^2}{X^2_{\alpha/2}}$	**n** is the sample size, **s²** is the sample variance, $X^2_{1-\alpha/2}$ and $X^2_{\alpha/2}$ are the critical chi-squared values associated with the confidence level	Creating a confidence interval for the population variance when the sample variance is known.
The Population Standard Deviation	$\sqrt{\frac{(n-1)s^2}{X^2_{1-\alpha/2}}} < \sigma < \sqrt{\frac{(n-1)s^2}{X^2_{\alpha/2}}}$	**n** is the sample size, **s²** is the sample variance, $X^2_{1-\alpha/2}$ and $X^2_{\alpha/2}$ are the critical chi-squared values associated with the confidence level	The square root of variance.
The Population Proportion	$p \pm Z_{\frac{\alpha}{2}}\sqrt{\frac{p*(1-p)}{n}}$	**p** is the sample proportion, **n** is the sample size, and $Z_{\frac{\alpha}{2}}$ is the z-statistic associated with the confidence level	Creating a confidence interval for the population proportion when the sample proportion is known.

Hypothesis Testing

Parameter of Interest	Equation	Parameters	Use When
Population Mean	$z = \frac{\bar{x}-\mu}{\frac{\sigma}{\sqrt{n}}}$	$\bar{x}$ is the sample mean, **μ** is the population mean, **σ** is the population standard deviation**,** **n** is the sample size	The population variance is known and the sample size (n) is greater than 30
Population Mean	$t - statistic = \frac{\bar{x}-\mu}{\frac{s}{\sqrt{n}}}$	$\bar{x}$ is the sample mean, **μ** is the population mean, **s** is the sample standard deviation**;** **n** is the sample size	The population variance is unknown or the sample size (n) is less than 30
Population Variance	$X^2 = \frac{(n-1)s^2}{\sigma^2}$	**n** is the sample size, **S²** is the sample variance, **σ²** is the population variance	Comparing a sample variance against a population variance
Population Variance	$F = \frac{s_1^2}{s_2^2}$	**(S₁)²** is the first sample variance **(S₂)²** is the second sample variance	Comparing two population variances against each other
Population Proportions	$Z_O = \frac{\hat{p}-p_O}{\sqrt{\frac{p_O(1-p_O)}{n}}}$	p_O = the hypothesized population proportion , $\hat{p}$ is the sample proportion, **n** is the sample size,	Comparing a sample proportion against a population proportion

Attribute Data Control Charts

The p Chart

$$\boldsymbol{\bar{p}} = Centerline = \frac{\sum np}{\sum n} = \frac{Sum\ of\ All\ Defectives}{Sum\ of\ Subgroup\ Quantity}$$

$$\boldsymbol{UCL_{\bar{p}}} = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{\bar{n}}} \qquad \boldsymbol{LCL_{\bar{p}}} = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{\bar{n}}}$$

$$\bar{n} = Average\ Sample\ Size = \frac{\sum n}{k} = \frac{\sum subgroup\ quantity}{\#\ of\ subgroups}$$

The np Chart

$$\boldsymbol{n\bar{p}\ Centerline} = \frac{\sum np}{k} = \frac{Sum\ of\ All\ Defectives}{\#\ of\ subgroups}$$

$$\boldsymbol{UCL_{np}} = n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})} \qquad \boldsymbol{LCL_{np}} = n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}$$

$$\boldsymbol{\bar{p}} = \%\ Defective = \frac{\sum np}{\sum n} = \frac{Sum\ of\ All\ Defectives}{Sum\ of\ Subgroup\ Quantity}$$

The u Chart

$$\boldsymbol{\bar{u}} = Centerline = \frac{\sum \boldsymbol{c}}{\sum \boldsymbol{n}} = \frac{Sum\ of\ All\ Defects}{Sum\ of\ units\ inspected}$$

$$\boldsymbol{\bar{n}} = Average\ \ of\ Samples\ per\ Subgroup = \frac{\sum \boldsymbol{n}}{\boldsymbol{k}} = \frac{\text{Sum of units inspected}}{\text{Number of subgroups}}$$

$$\boldsymbol{UCL_u} = \bar{u} + 3\sqrt{\frac{\bar{u}}{\bar{n}}} \qquad \boldsymbol{LCL_u} = \bar{u} - 3\sqrt{\frac{\bar{u}}{\bar{n}}}$$

The c Chart

$$\boldsymbol{\bar{c}} = Centerline = \frac{\sum c}{k} = \frac{Sum\ of\ All\ Defects}{\#\ of\ Subgroups}$$

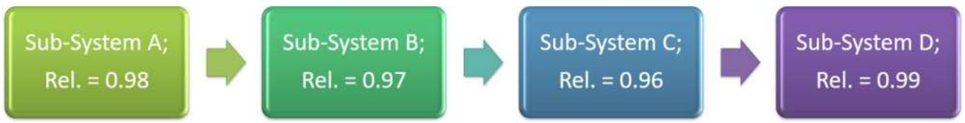
$$\boldsymbol{UCL_c} = \bar{c} + 3\sqrt{\bar{c}} \qquad \boldsymbol{UCL_c} = \bar{c} - 3\sqrt{\bar{c}}$$

		Sample Size	
		Constant	**Variable**
Type	**Defect**	c Chart	u Chart
	Defectives	np Chart	p Chart

Reliability and Fault Tree Equations

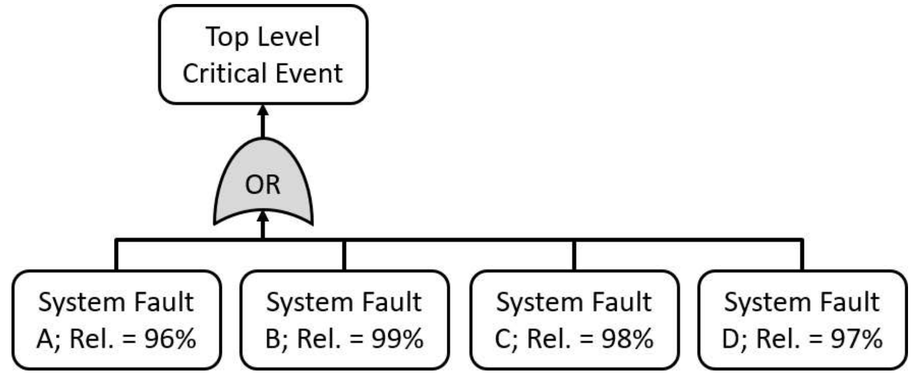
Series System Reliability

$$Series\ System\ Reliability = R_{system} = R_1 \times R_2 \times R_3 \times R_4 \times \ldots\ldots R_n$$



Fault Tree Reliability (OR GATE)

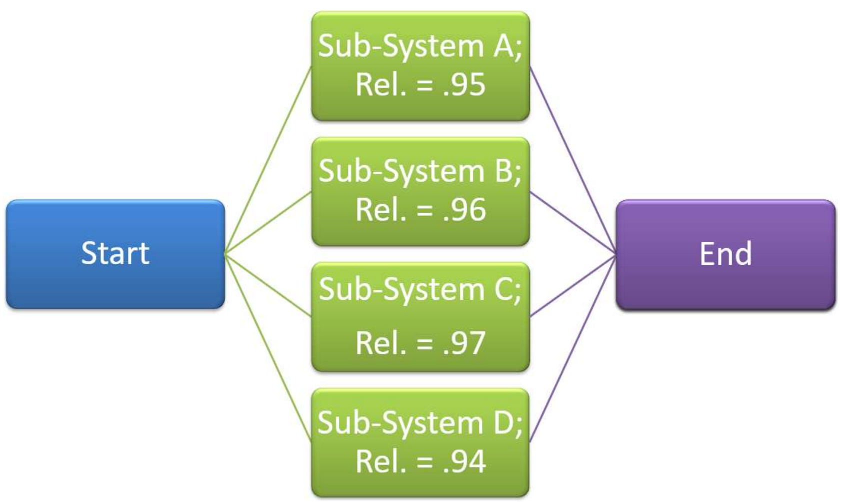
$$Reliability\ of\ OR\ Gate:\ R_{OR\ Gate} = R_1 \times R_2 \times R_3 \times R_4 \times \ldots\ldots R_n$$



Parallel System Reliability

$$Parallel\ System\ Reliability = 1 - (U_1 \times U_2 \times U_3 \times U_4 \times \ldots\ldots U_n)$$

$$Where\ U_1 = 1 - R_1$$



Fault Tree Reliability (AND GATE)

$$AND\ GATE\ System\ Reliability = 1 - (U_1 \times U_2 \times U_3 \times U_4 \times \ldots\ldots U_n)$$

$$Where\ U_1 = 1 - R_1$$