HAPPY NEW YEAR. MAKE IT A YEAR OF LIGHT

2023

Year of knowledge

Let us put our knowledge to work

A candle can give only very little light, that may not be enough to see the entire field.

The same principle goes with the famous QMS Standard, ISO 9001 and the famous SPC system. Unfortunately, these two systems are so corrupted, investors are not benefited at all. You review some of the reports from Christopher Paris @ www.Oxibridge.com about the ISO auditors and fake certificates issued from the registrars. Our congress should investigate these systems and eliminate ISO 9001 requirements from the Government contracts, it is a serious matter.

OPEN YOUR EYES AND SEE WHAT IS HAPPENING AROUND THE WORLD

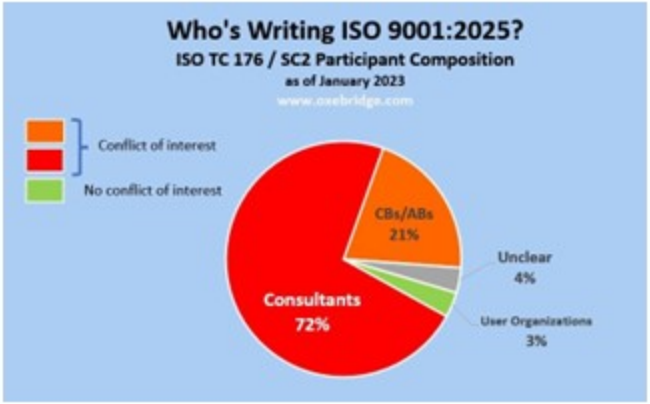
This is the time to strengthen our manufacturing base, because the world is transitioning to a different direction for good or bad, we make it good.

China's invasion with Balloon and shooting down of the same, may cause the relationship with China and the supply chain.

Russia and Ukraine war is another reason we must accelerate and strengthen our manufacturing base, train our people to do the right job and our schools and colleges should focus on industrial training to the students and they are the one leading our country to the next level higher and win the competition.

Labor shortage is another compelling factor, we should arise, awake and get in action to do the right thing, leave the politics behind.

Demand and supply is the main core of the business, we can do it with our consolidated effort, keeping in mind our families and children, above all strengthen our country's economical strength is our responsibility.



1. Our manufacturing industries are in big trouble; they are between the Rock and Hard spot unable to do their work freely. Freedom of operation always been hindered by policies and procedures.
2. There are two parasites sucking the resources of the company.
3. Number one is the famous ISO 9001 QM standard and the second is the Statistical gamblers, they tempt the management and sells their SPC, Cp. CpK, Six Sigma, Lean six sigma and many more from the same family.

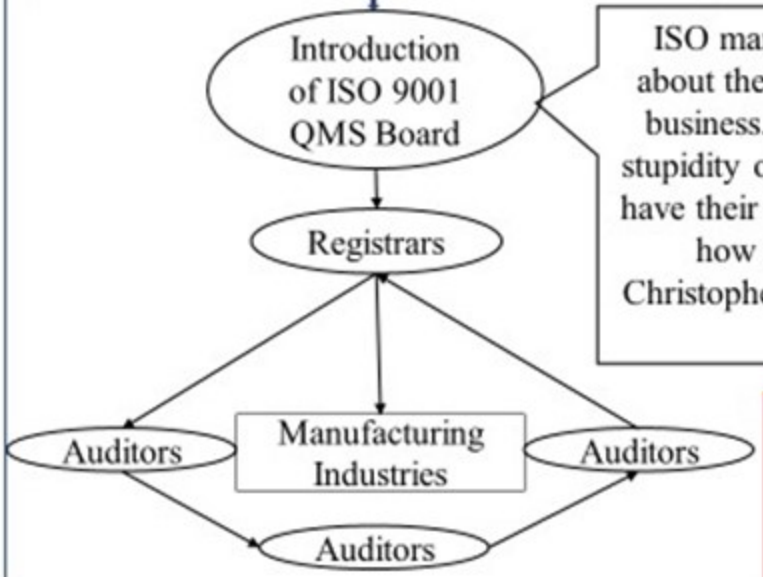
How ISO 9000 group makes their profit?

WHER IS QUALITY?

ISO 9000 families of QMS standards are the biggest Organized Scams existing in the world today. They milk the industries in a way pretending with the promise that they will clean up the issues and help to create a sound QMS for all the manufacturing industries. Diagram will explain the reality of their doings.
If that system is so sacred why all the quality problems with the product recalls, failures, risks and excessive cost of operation?

Most of the manufacturing industries were using QA Systems based on old MIL-Q-9858 standard. Failure to implement the system properly, foreign investors came in with their own standard, ISO 9001

Combined SPC/SQC and ISO-9001 it is a nightmare to our manufacturing industries, no matter what product they make and deliver to the customers, there is a hidden risk.

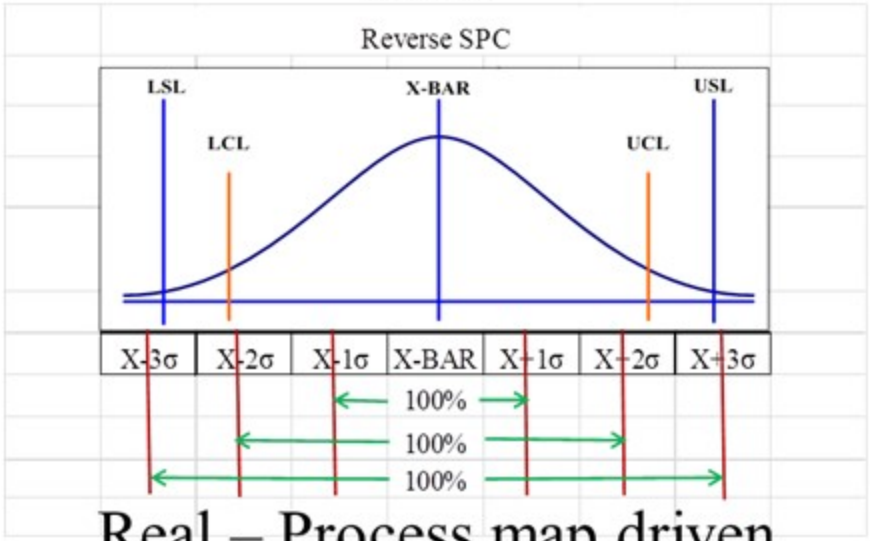


ISO management/Board are not concerned about the quality of your products, they need business. They built an empire knowing the stupidity of the management. ISO management have their own problems too, they do not know how to define quality. Worth reading Christopher Paris writings regarding ISO 9001 in LinkedIn.

Your only solution is this:-
1. Install Industrial Statistics and
2. Transformational Quality Management System. If not, you are wasting your time and money.

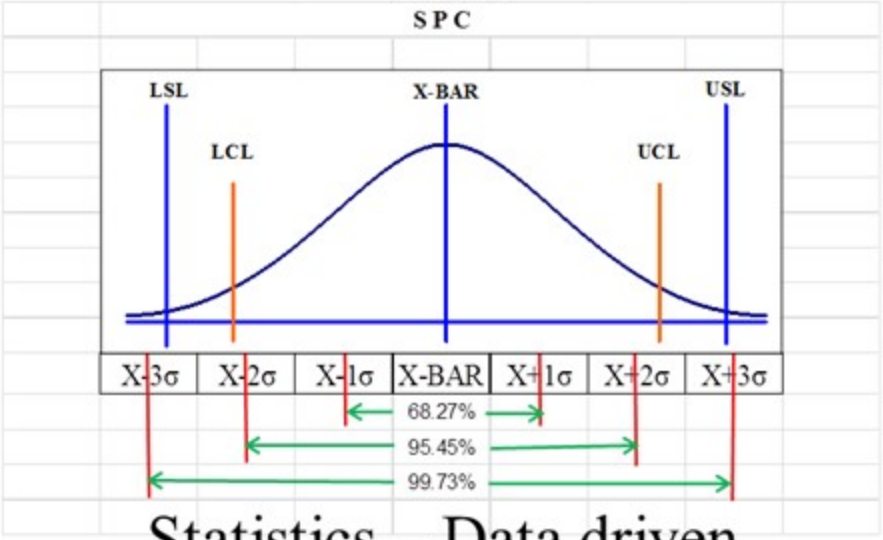
SAME BELL CURVE WITH TWO DIFFERENT PROPERTIES

NEW



Real – Process map driven

OLD



Statistics – Data driven

What you need is the New tools

Industrial Statistics &
Transformational Quality Management System.

Make valid system changes sooner and get back to business !!

1. Use new technology to work for excellence
2. Operational freedom to make Quality products
3. Reduce waste, cycle time and cost reduction, learn to save $$
4. Customer satisfaction
5. Return on investment

TRADITIONAL QUALITY CONTROL WITHOUT A QUALITY VISION

LOST THE KEY TO QUALITY

In statistics area under Normal Curve, according to the Empirical Rule or 68 -95-99 Rule, is **assumed** that the process is under control and normal, it is a cookie cutter application process.

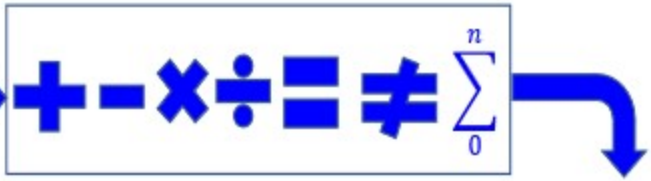
Reactive Quality system
Built on Statistical faith

This approach is not process healthy and no guarantee of quality products delivered & very expensive.

As the products come out: ISO, SPC Quality kicks in -Sampling inspection, Data analysis Cp, CpK Check, Hypothesis test, Six Sigma test, AQL & AOQL analysis and final destiny of the product: Accept or Reject or Scrap

This is your life saver, a game changer, no risks involved, transparent, customer focused.

Industrial Statistics is model used to plan the manufacturing process eliminates all the risks in the machining cycle.



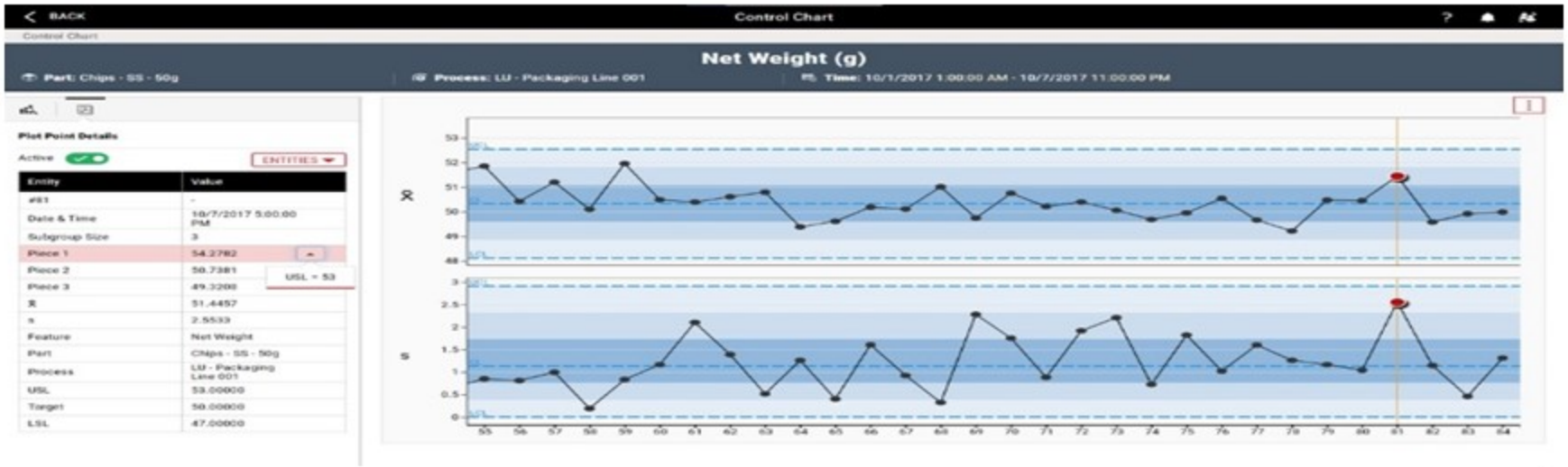
Quality Products delivered

TRADITIONAL QUALITY CONTROL WITHOUT A QUALITY VISION

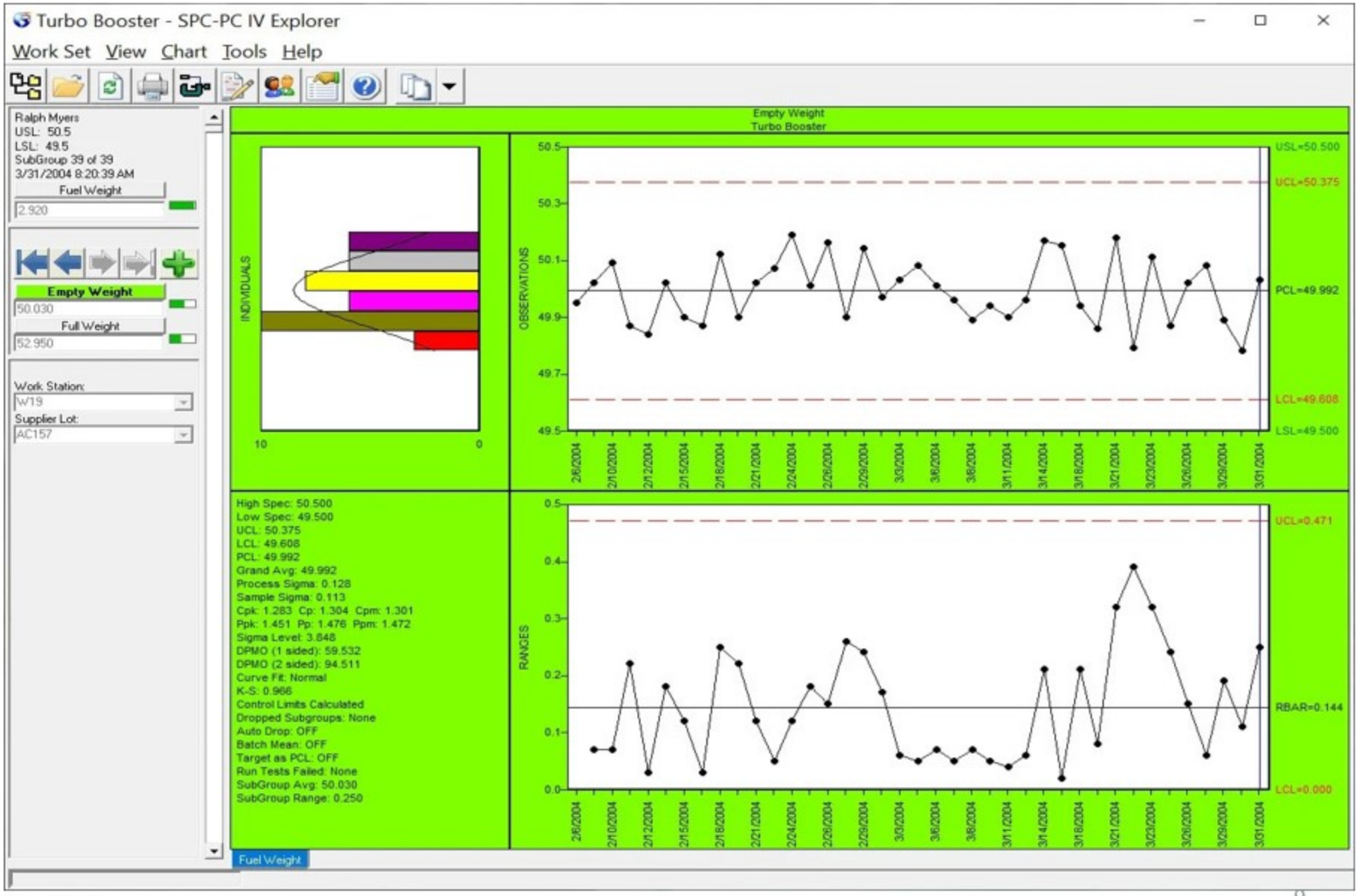
INSPECTION DATA SHEET SHOWN BELOW TO CREATE X-BAR, R-CHART

08:00 AM	0.9877	0.9876	0.9874	0.9876	0.9877
09:00 AM	0.9874	0.9876	0.9874	0.9875	0.9876
10:00 AM	0.9873	0.9874	0.9876	0.9875	0.9877
11:00 AM	0.9874	0.9876	0.9873	0.9874	0.9876
12:00 NOON	0.9877	0.9876	0.9874	0.9876	0.9875

Example: X-bar & R-bar charts shown below are created to show the data variations. This chart is from the web, shown for teaching purpose only.



Taken from the web: X-Bar, R-Chart created by different program



Taken from my SPC training class, years ago.

Typical Application of Statistics

In a precision manufacturing process, the diameter of Steel Shaft is normally distributed with the mean of 0.2508", and the Standard deviation is 0.0005. If the specification of the Shaft is 0.2500 + / - 0.0015", what percentage or fraction of the Shafts produced would conform to specification?

Answer = 91.92%

If we could adjust the manufacturing process by adjusting the machine to [0.0008"], so that the process mean is Exactly equal to 0.2500" then the process yield would be 99.73%

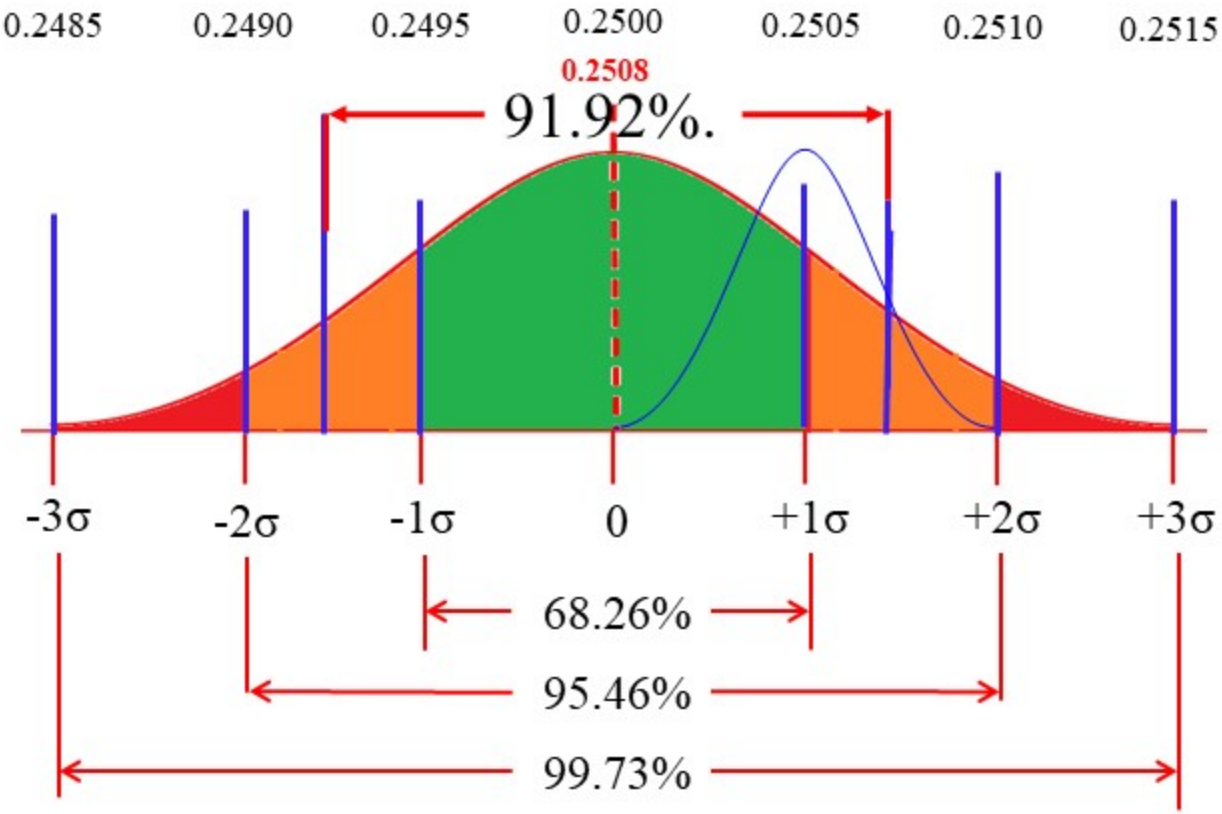
Detailed analysis is given in the next slide, pay attention.

TRADITIONAL QUALITY CONTROL WITHOUT A QUALITY VISION

Area under normal curve. Why is it called normal curve?. According to the Empirical Rule or 68-95-99 Rule, In statistics it is assumed that the process is under control & normal. In another words it is a "Cookie Cutter Process Application"

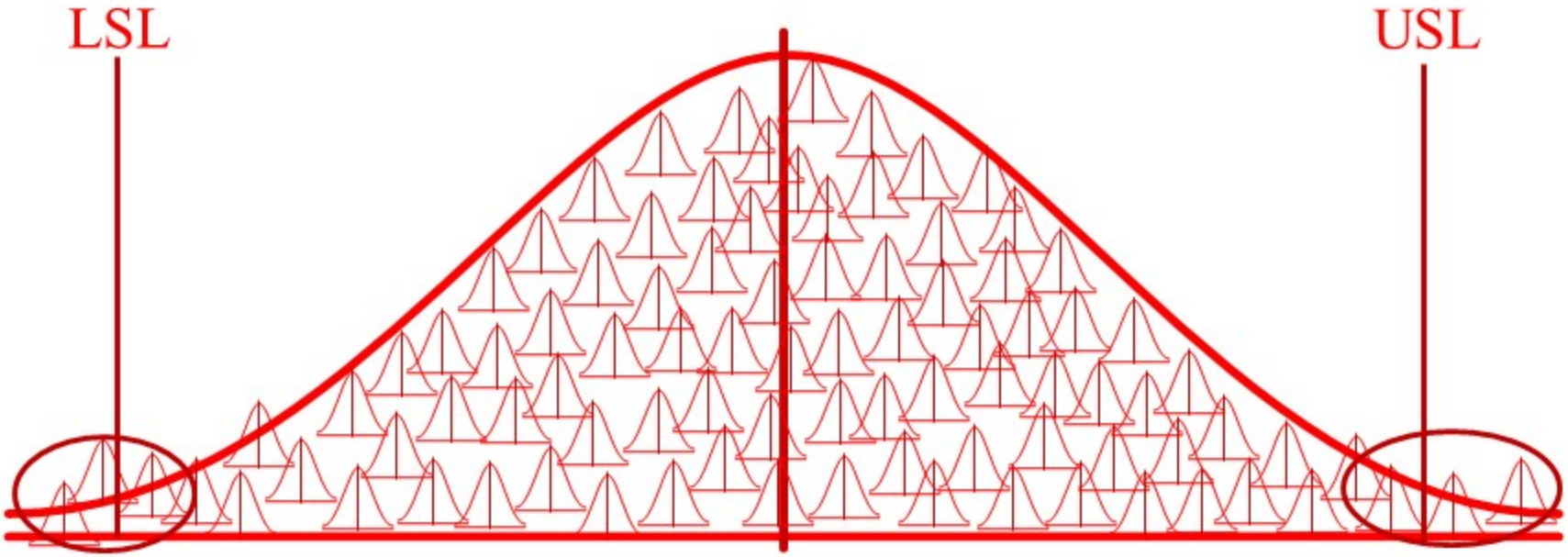
Specification. Shaft Dia. 0.2500 +/- 0.0015 and the Standard Deviation is 0.0005

Ambiguity, nonsense, senseless or Just fooling us.



Statistical Model – Data Driven – No Process knowledge.

This is a Statistical Model

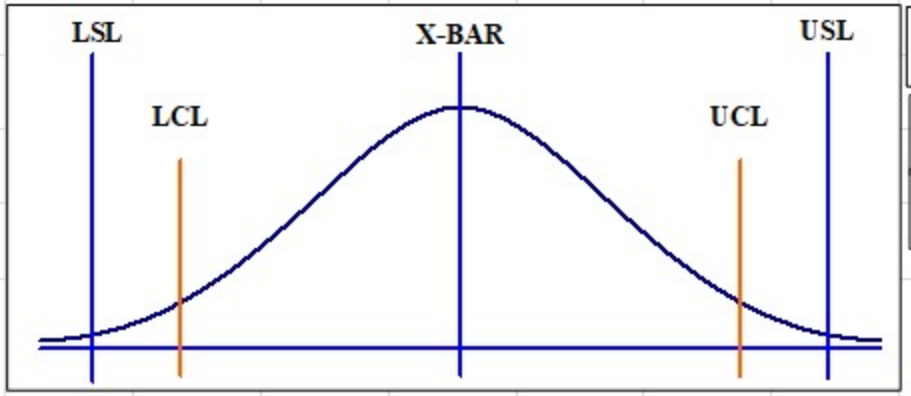


Statistical Failures inevitable, no matter how good you control your processes, product failure happens during the mission or some place during the final test of the product.

Birth defect of Statistics is, Uncertainty or Risk or Failure or margin of error.

Do not get fooled by Cp & CpK

Model of Cp & CpK. Spec = 12 +/- 6 & σ = 2



$$Cp = \frac{USL - LSL}{6s}$$

$$CpK = \frac{USL - \bar{x}}{3s}$$

$$CpK = \frac{\bar{x} - LSL}{3s}$$

X-3σ	X-2σ	X-1σ	X-BAR	X+1σ	X+2σ	X+3σ
LCL			Mean			UCL
LSL		Nominal				USL
6	8	10	12	14	16	18

What is Cp & CpK? What process capability they are talking about?

HERE IS THE PROOF

X-3σ	X-2σ	X-1σ	X-BAR	X+1σ	X+2σ	X+3σ
LCL			Mean			UCL
LSL			Nominal			USL
6	8	10	12	14	16	18

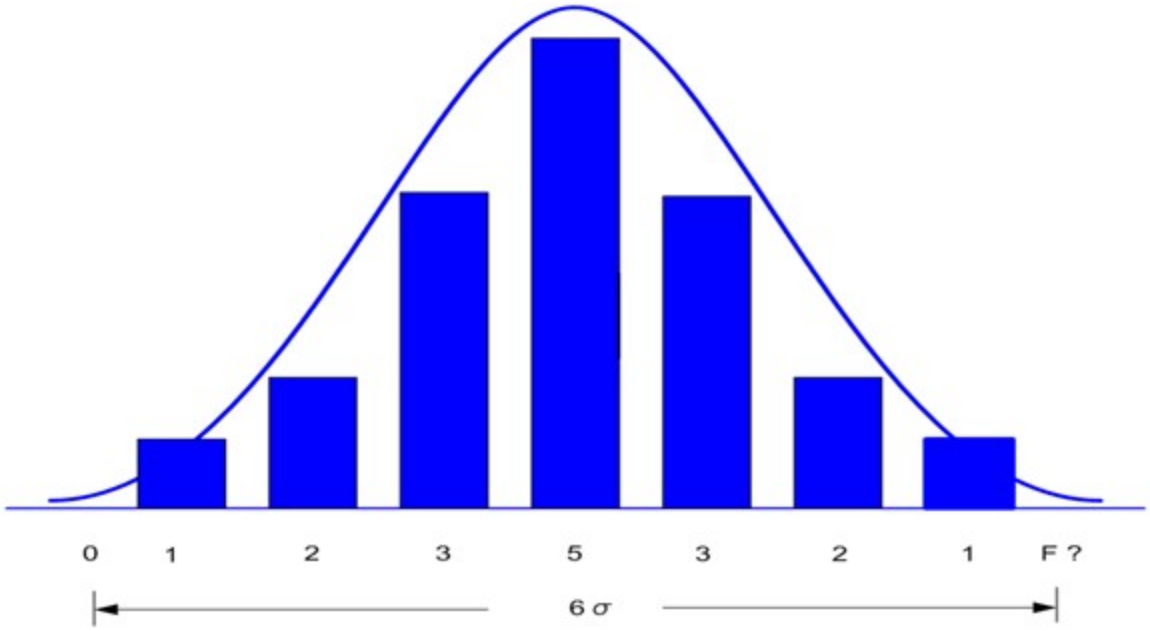
Specification. 12 +/- 6

LSL	X-BAR	USL	SDN	3 SDN	6 SDN	Cp	CpK L	CpK U	CpK
6	12	18	0.25	0.75	1.5	16	8	8	**8**
6	12	18	0.5	1.5	3	8.000	4	4	**4**
6	12	18	0.75	2.25	4.5	5.333	2.66667	2.66667	**2.66667**
6	12	18	1	3	6	4	2	2	**2**
6	12	18	1.3	3.9	7.8	3.076923	1.53846	1.53846	**1.53846**
6	12	18	1.5	4.5	9	2.666667	1.33333	1.33333	**1.33333**
6	12	18	2	6	12	2	1	1	**1**
6	17	18	0.1	0.3	0.6	40	36.6667	3.33333	**3.33333**
6	14	18	0.01	0.03	0.06	400	266.667	133.333	**133.333**
6	10	18	2	6	12	2	0.66667	1.33333	**0.66667**
6	14	18	2	6	12	2	1.33333	0.66667	**0.66667**
10	12	14	1	3	6	1.333333	0.66667	0.66667	**0.66667**
6	9	18	2	6	12	2	0.5	1.5	**0.5**
6	15	18	2	6	12	2	1.5	0.5	**0.5**
6	8	18	2	6	12	2	0.33333	1.66667	**0.33333**
6	16	18	2	6	12	2	1.66667	0.33333	**0.33333**
10	12	14	2	6	12	0.666667	0.33333	0.33333	**0.33333**
6	17	18	2	6	12	2	1.83333	0.16667	**0.16667**
6	6	18	2	6	12	2	0	2	**0**
6	18	18	2	6	12	2	2	0	**0**

Do not get fooled by Statisticians and their Tricks.

- Do not get fooled by Cp & Cpk
  - Conclusion from the experiment shown in the previous slide
    - As the standard deviation gets smaller , CpK value increases.
    - There is a correlation between Std. Dvn (Machine Capability) and CpK
    - Centering of the process at the Mean has nothing to do with the CpK.
    - It is wise to setup the process to get higher process yield, @ MMC/LMC
    - Process setup should be based on the capability of the machine, unstable machines should not be considered for close tolerance work.
    - When you can work with fundamentals, avoid Statistics & do not mix these two
    - Because Statistics is a process Blind & value neutral.
    - YOU know the process; Statistics do not know the process or product well.

Bank Loan & Payments



Bank Loan with interest $100,000.00

Made 17 payments of $5500.00 each = $ 93500.00 Balance = $ 6500

One day he goes to the Bank Manager & claimed that, look statistically I made all payments equal to 6 σ that is 99% of the bell curve and thank you for the help and this is the last payment **$1000.00 !**

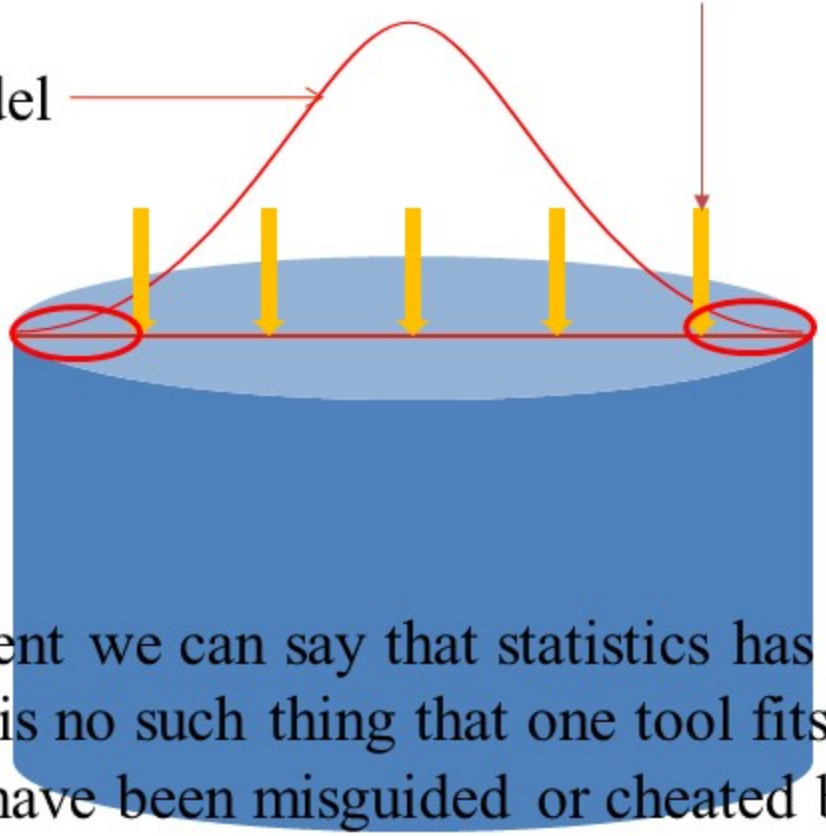
What do you think the reaction of the Bank Manager would be?

Water Tank: Purified drinking water

If you considered as Statistical Bell curve, does that mean water from the ends of the curve are bad?

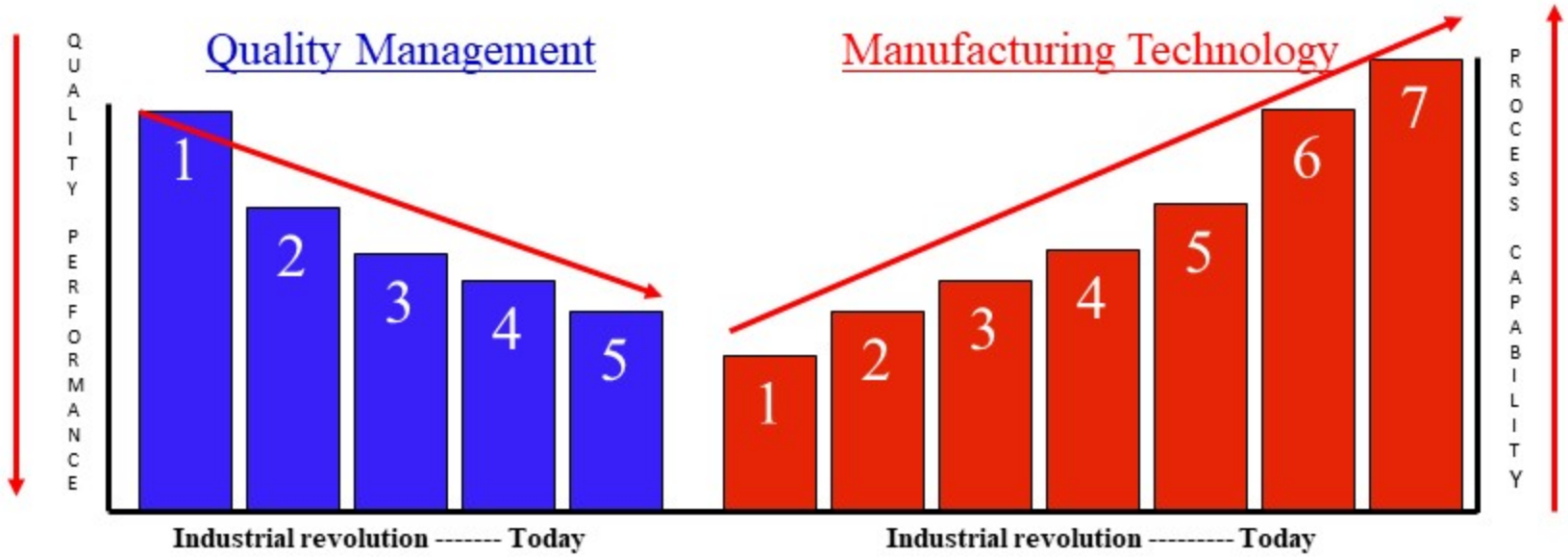
Mathematical Model

Water from any place in the tank has good quality.



From the experiment we can say that statistics has a unique area of application, there is no such thing that one tool fits for all. For decades millions have been misguided or cheated by statistics. Our younger generation should be trained so that they should not be the slave or prey for statistics.

Look where quality is going as compared to manufacturing technology



Q 9858	TQM	AS 9100
S. Survey	SPC	ISO 9001
Approval	ISO 9000	GMP
Performance	QS 9000	Audits
Receiving Inspection	Audits	3 Sigma
MRB	Lean	6 Sigma
		Lean 6 Sigma
		SPC
		Green Belt
		Black Belt
		Gimba
		RCCA

Manufacturing in the primitive stage
Introduction of Automatic machines
Introduction of CNC machines
Introduction of multiple axes CNC machines
Introduction of CNC machines with MBD & DPD
Introduction of vision system built into CNC machines
Machines with more precision, accuracy, repeatability & stability
Addictive manufacturing & 3D Printing
Industrial Statistics
Artificial Intelligence.
And more to come.

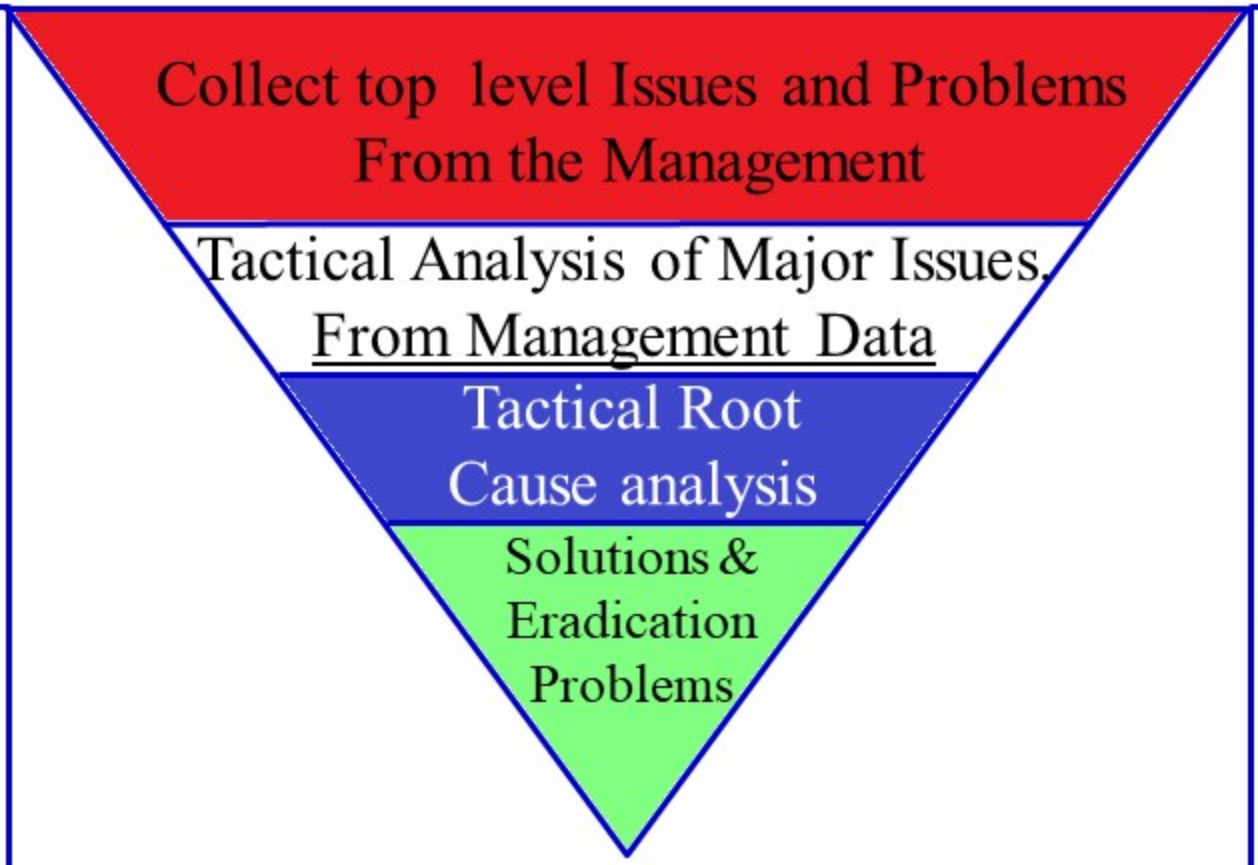
Solutions: to Recalls, Quality & Manufacturing Problems

Mining the problems and eradication

This is how you do Now. Expensive and less productive.

1. Look for data
2. Create data
3. Statistical analysis
4. SPC
5. Hypothesis test
6. Six sigma analysis
7. Check Cp & CpK
8. Unable to find root cause.
9. Deep dive to find operator error.
10. Operator error

REACTIVE PROCESS



Industrial Staatistics Make process easy & Cost saving.

1. Review problem
2. Understand issues
3. Evaluate issues
4. Check 5 M
5. Product definition
6. Tactical Root cause analysis
7. Process capability
8. Transparency
9. Implement solution
10. Eradicate the problem.

PROACTIVE PROCESS

Industrial statistics

Deep dive into the process
Follow me.

We need to do some homework

INDUSTRIAL STATISTICS. KEY THINGS YOU SHOULD REMEMBER & FOLLOW

Manufacturing engineering students should know the following thoroughly.

1. Review Customer requirements from contract
2. If you must design a new product, understand the specification requirements
3. Understand Engineering Drawing or Model
4. Understand GD&T [ASME Y-14.5M – 1994]
5. Review engineering drawing or model for accuracy & correct them
6. Serialize all variables and Important notes.
7. Learn Geometric Tolerances & their Properties [F,P,O,L,R – Page 3 & 42]
8. Learn General Tolerances [ASME Y 14.5M – Page 23]
9. Learn the types of Features; Linear, Range, Basic, True Position
10. Learn Plane Geometry, Trigonometry and Solid Geometry

KNOW YOUR MACHINES AND THEIR CAPABILITIES

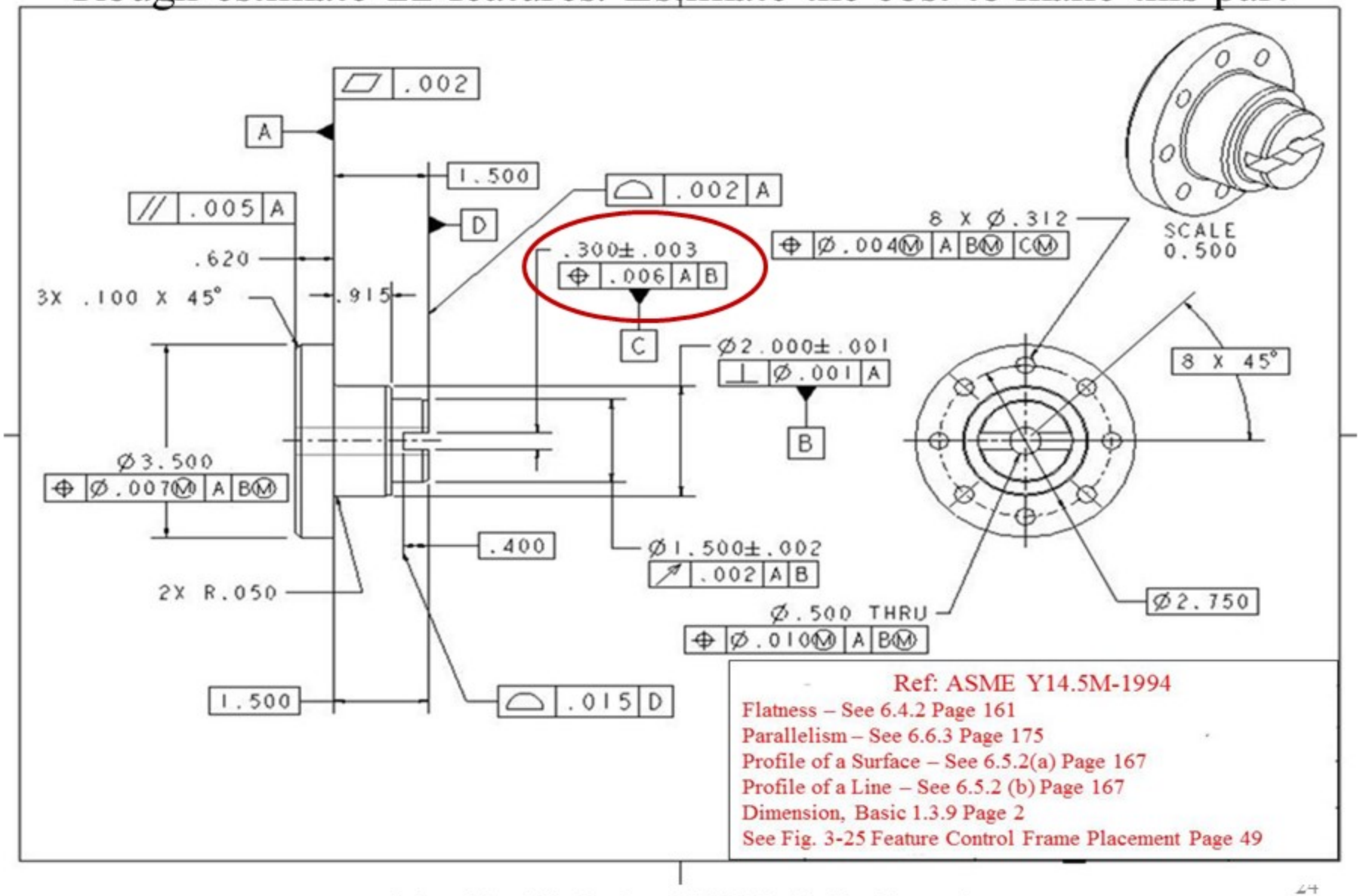
KEY FACTORS CANNOT BE IGNORED. IT IS VERY IMPORTANT MANUFACTURING ENGINEERING STUDENTS SHOULD KNOW THESE THINGS

1. Know your machine's capability, strength, repeatability
2. Capability to hold accuracy with Load and without Load
3. Keep the maintenance cycle
4. Manufacturers recommended service plan
5. Verify the accuracy of your machine in all the Axes
6. Identify each machine with its capability and post it on each machine
7. You take care of the machine, machine will take care of your work
8. Work holding Jigs and Fixtures are very important
9. Rigidity of the Fixture and work piece are very critical
10. Use proper cutting tool for the metal you are working on
11. Proper chip removal is equally important & right coolant
12. Burr removal is important to keep quality of the finished part
13. Avoid repeated inspection of the same part by different persons
14. Operators' inspection data is as good as the inspectors
15. Train the operator to use all precision measuring instruments
16. Protect finished products to avoid damage during transition.

Following are regarding Industrial Statistics Software R SPC. www.qem-inc.com

1. It is a web-based software program
2. If you want to buy any service, fill up the form completely – Buy – and send
3. When you get this program, change the password to your own
4. Read and understand the instructions & user guide completely
5. Identify each variables including Notes & any details from specification
6. Input each variable with tolerance in the right place
7. If any special instruction, please provide in the area for that instruction.
8. Save each variable input, upon completion, click View Master Data
9. See computer generated data displayed in +/- 3 standard deviations mode
10. Master Data displayed with Admin_XX number for each variable
11. Operator input sample inspection data
12. After all input of data, system generates X bar, R chart and a Bell curve chart
13. System displays Mean & Standard deviation Before & After the Process
14. Management can review these data any time to assure compliance.
15. Customers can also review the data for their satisfaction
16. Second party (Customer) audit and certification is the right thing to do.

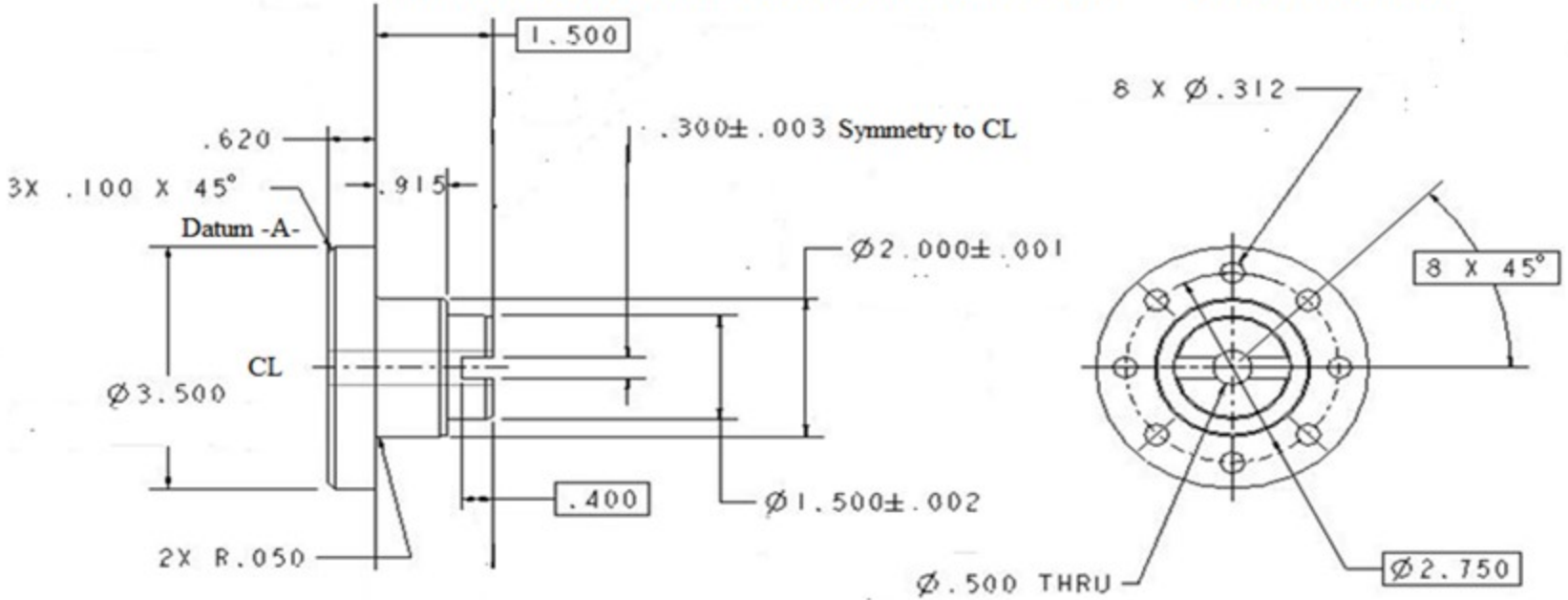
Rough estimate 22 features. Estimate the cost to make this part



Ref: ASME Y14.5M-1994
Flatness – See 6.4.2 Page 161
Parallelism – See 6.6.3 Page 175
Profile of a Surface – See 6.5.2(a) Page 167
Profile of a Line – See 6.5.2 (b) Page 167
Dimension, Basic 1.3.9 Page 2
See Fig. 3-25 Feature Control Frame Placement Page 49

15 Variables after revision Estimate the cost to make this part

This dimension can be re defined as 1.500 +/- 0.001 or 0.0005



This dimension can be re defined as 0.400 +/- 0.001 or 0.0005

Benefits = % of Variables reduction = cost reduction and quality enhancement.

PROCESS MAPPING
(Starts from the component level)

MATRIX

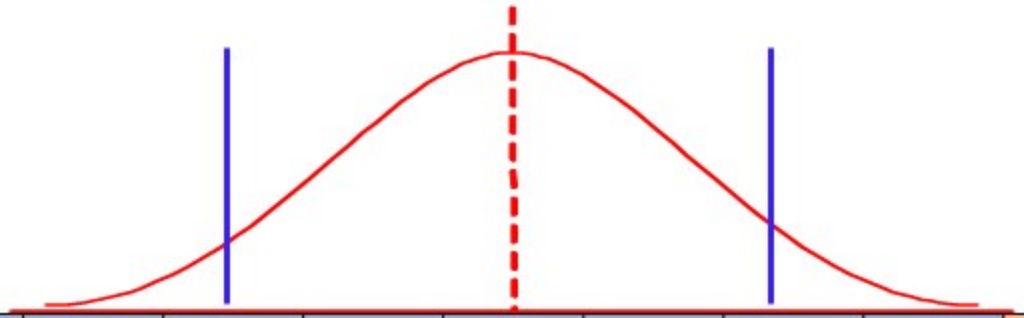
Project #	Project Name	Item number/Pt. Number	Item Name	Customer Name	Address	Phone #	Email address
Drg. #	Model #	Serial #	Process #	Process Supplier	Purchased from	Approved Processor. Yes / No	Machine #
Machine Capability	CNC Program # & Revision #	Machine Stability	Theoretical Std. Dvn. From QDC Form	QDC Matrix data	QDC Matrix #	QDC Matrix Revision	Measuring Instrument used
Temperature	Pressure	Humidity	Calibration Control	Employees trained			

Operation #	Description	Control Parameters	Set up proofed	Operator Check	Measuring devices Used with accuracy
10	Turning OD	OD. 0.975 +/- 0.002"	1st piece qualified	0.9762"	0 -1" Micrometer, 0.0001"

View of Master Data from the R SPC Software Program

Entry ID	Customer	Project	Drawing Number	Creation	Revision	Process No	Dimension Type	Linear Dimension	Linear Plus	Linear Minus	Range High	Range Low	True Basic	True Position	Lot Number	Serial	Item Number	Process ID	Description	Machine	Notes	Derived Dim	Derived Tolerance ±	Machine/ Process- Repeatability/Capability/Stability. Capability	X-3	X-2	X-1	X	X+1	X+2	X+3	Actual Std Dvn from 25 Samples
101	Bob		1	1	7/28/2012 0:00	7/28/2012 0:00	1	L	0.75	0.005	-0.005	0	0	0	0	1	1	1	Turning	Valve	No1	This is acritical pa	0.7515	0.0045	0.0015	0.7470	0.7485	0.7500	0.7515	0.7530	0.7545	0.7560	0.0004
102	Bob		102	1234567	8/17/2012 0:00	8/17/2012 0:00	2	R	0	0	0	0.85	0.844	0	0	2	2	2	Turning	Lathe	Customer had issu	0.847	0.0030	0.0010	0.8440	0.8450	0.8460	0.8470	0.8480	0.8490	0.8500	0.0001
103	Bob	5X		1234567	8/17/2012 0:00	8/17/2012 0:00	3	T	0	0	0	0	0	0.95	0.018	3	3	3	5	Milling	Mill 3	Hole drilling is slo	0.95	0.0064	0.0021	0.9437	0.9458	0.9479	0.9500	0.9521	0.9542	0.9563	0.0004
104	106		2012	1234567	9/23/2012 0:00	9/23/2012 0:00	106	L	0.987	0.012	-0.005	0	0	0	0	12	12	1001	92312	Milling	Milling machine	Take extreme care	0.9915	0.0075	0.0025	0.9840	0.9865	0.9890	0.9915	0.9940	0.9965	0.9990	0.0009
105	106		107	1234567	9/23/2012 0:00	9/23/2012 0:00	105	T	0	0	0	0	0	0.875	0.014	10	11	12	15	Shaft	Mill - 2	Use T P Gage to	0.875	0.0050	0.0017	0.8699	0.8716	0.8733	0.8750	0.8767	0.8784	0.8801	0.0004
106	106		106	8765832	9/23/2012 0:00	9/23/2012 0:00	106	R	0	0	0	0.987	0.975	0	0								0.981	0.0060	0.0020	0.9750	0.9770	0.9790	0.9810	0.9830	0.9850	0.9870	0.0003

Master data runs from A through AG. We are looking the main features from Q – Z as shown below and added actual Std. Dvn from 25 samples for analysis and training purpose only.



Derived Dim	Derived Tolerance ±	Machine/ Process- Repeatability/Capability/Stability. Capability	X-3 σ - 3	X-2 σ - 2	X-1 σ - 1	X σ	X+1 σ + 1	X+2 σ + 2	X+3 σ + 3	Actual Std Dvn from 25 Samples
0.7515	0.0045	**0.0015**	0.7470	0.7485	**0.7500**	0.7515	0.7530	0.7545	0.7560	**0.0004**
0.847	0.0030	**0.0010**	0.8440	0.8450	0.8460	0.8470	**0.8480**	0.8490	0.8500	**0.0001**
0.95	0.0064	**0.0021**	0.9437	0.9458	0.9479	**0.9500**	0.9521	0.9542	0.9563	**0.0004**
0.9915	0.0075	**0.0025**	0.9840	**0.9865**	0.9890	0.9915	0.9940	0.9965	0.9990	**0.0009**
0.875	0.0050	**0.0017**	0.8699	0.8716	0.8733	0.8750	0.8767	**0.8784**	0.8801	**0.0004**
0.981	0.0060	**0.0020**	0.9750	0.9770	**0.9790**	0.9810	0.9830	0.9850	0.9870	**0.0003**

QUALITY CONTROL WITH A QUALITY MISSION

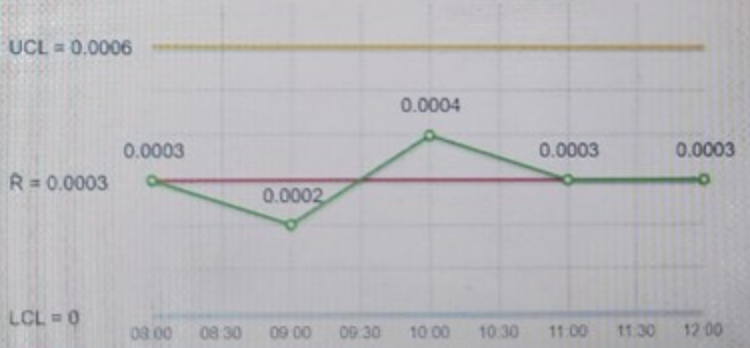
Not secure www.processmaps.net

Sample Data ADMIN_57_85_10_06_2022 Add Edit Delete

Time	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
08:00	0.9877	0.9876	0.9874	0.9876	0.9877
09:00	0.9874	0.9876	0.9874	0.9875	0.9876
10:00	0.9873	0.9874	0.9876	0.9875	0.9877
11:00	0.9874	0.9876	0.9873	0.9874	0.9876
12:00	0.9877	0.9876	0.9874	0.9876	0.9875

X Bar Chart

R Bar Chart



Standard Deviation (After the Process)

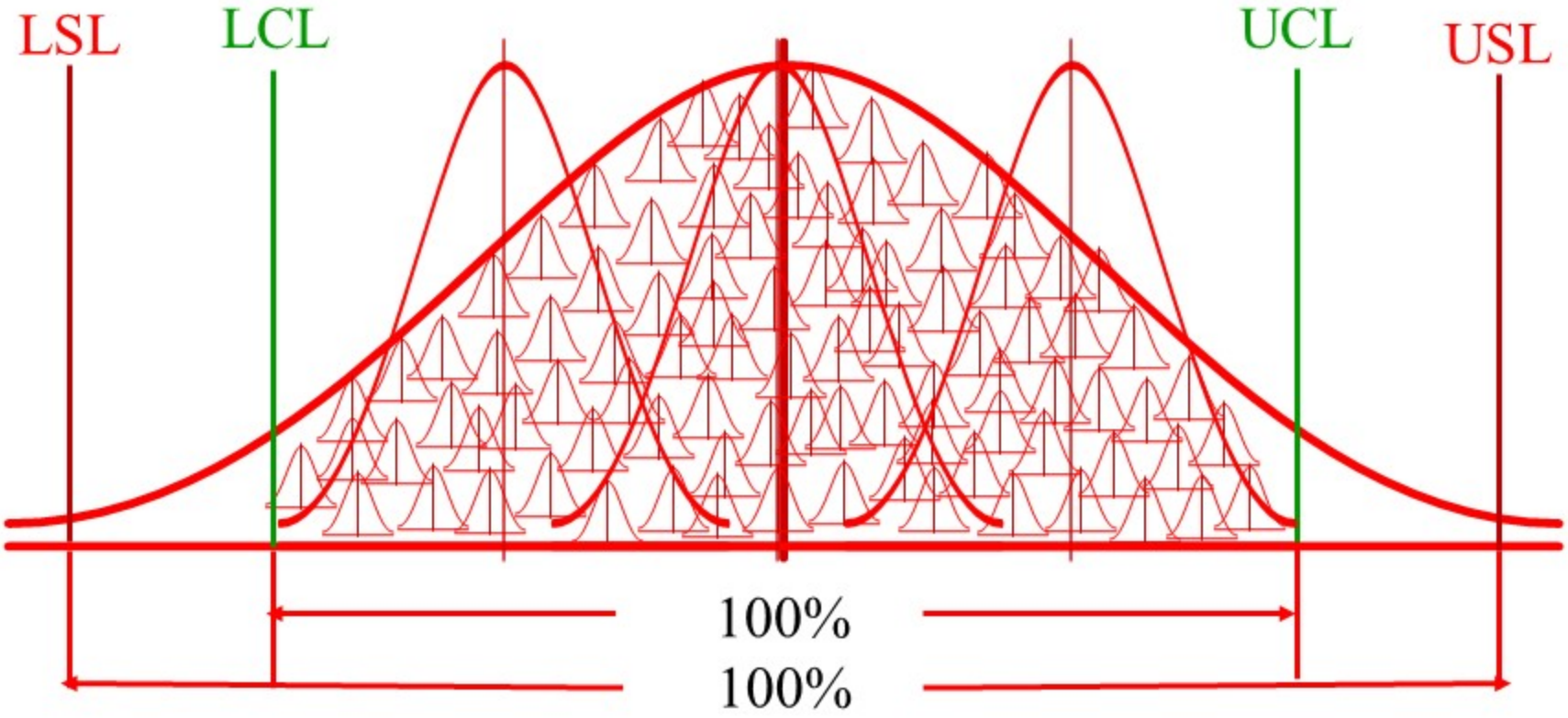
0.0001

Mean (X) (After the Process)

0.9875

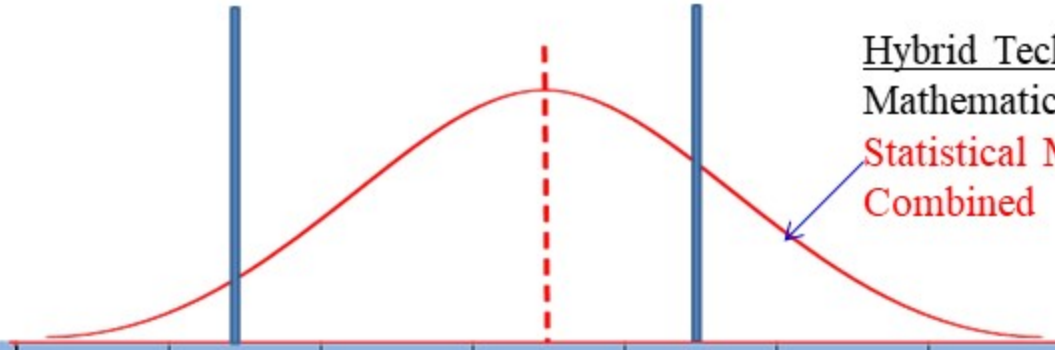
Bell Curve

This is a Mathematical Model



Because Industrial Statistics helps you to define and control each variable to the MMC or LMC or in between based on fit, form & function of the part in the next assembly or process.

Important part of Master Data from the R SPC Software Program

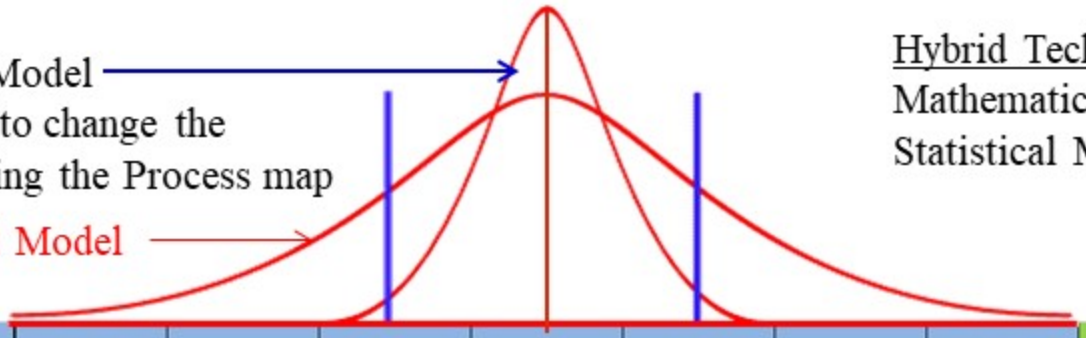


Hybrid Technology:
Mathematical Model &
Statistical Model
Combined

Features	Limits	Machine / Process - Repeatability/Capability/Stability. Capability	X-3	X-2	X-1	X	X+1	X+2	X+3	Actual Std Dvn from 25 Samples (Sigma)	Calculated Std Dvn = R-bar/d2. (Sigma)
Linear	Plus/ Minus	**0.0010**	0.6000	0.6800	0.7000	0.7500	0.8000	0.9000	0.9500	**0.001**	**0.0020**

This is the Statistical & Mathematical Model where the data are displayed in +/ - 3 Std. Dvn and between X-2 and X+1 format.
With Mathematical model targeting the process is possible.

Important part of Master Data from the R SPC Software Program



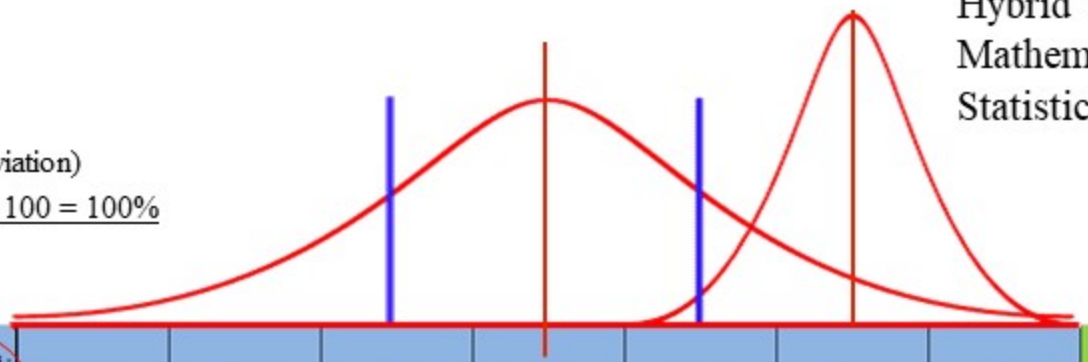
Hybrid Technology:
Mathematical Model &
Statistical Model

Features	Limits	Machine / Process - Repeatability/Capability/Stability. Capability	X-3	X-2	X-1	X	X+1	X+2	X+3	Actual Std Dvn from 25 Samples (Sigma)	Calculated Std Dvn = R-bar/d2. (Sigma)
Linear	Plus/ Minus	**0.0010**	0.6000	0.6800	0.7000	0.7500	0.8000	0.9000	0.9500	**0.001**	**0.0020**

This is the Statistical & Mathematical Model where the data are displayed in +/ - 3 Std. Dvn and between X-1 and X+1 format.
With Mathematical model targeting the process is possible that yields 100%

Important part of Master Data from the R SPC Software Program

Calculate the Yield.
Process Yield = PC/St. D * 100
(Process Capability/ Standard Deviation)
Process Yield = (0.0010/0.0010)* 100 = 100%



Hybrid Technology:
Mathematical Model &
Statistical Model

Features	Limits	Machine / Process - Repeatability/Capability/Stability. Capability	X-3	X-2	X-1	X	X+1	X+2	X+3	Actual Std Dvn from 25 Samples (Sigma)	Calculated Std Dvn = R-bar/d2. (Sigma)
Linear	Plus/ Minus	**0.0010**	0.6000	0.6800	0.7000	0.7500	0.8000	0.9000	0.9500	**0.001**	**0.0020**

This is the Statistical & Mathematical Model where the data are displayed in +/ - 3 Std. Dvn and between X+1 and X+3 format.
With Mathematical model targeting the process is possible that yields 100%

Data from Master data sheet created by the R SPC software program for analysis purpose

Process capability selected prior to the process.	COMPARISON OF CALCULATED SIGMA (using SPC) AND ACTUAL SIGMA FROM QDC FORM							
	CALCULATED SIGMA (using SPC) = R-bar / d_2. Where d_2 = 2.326 For Sub group 5.							
	CALCULATED SIGMA σc					ACTUAL SIGMA FROM QDC FORM		
	TEST #	R-bar	d_2	σ_c		MinYield		Actual σ_a
0.0015	101	0.0014	2.326	0.0006		100%		0.0004
0.0010	102	0.0017	2.326	0.0007		100%		0.0001
0.0021	103	0.0013	2.326	0.0006		100%		0.0004
0.0025	104	0.0044	2.326	0.0019		100%		0.0009
0.0017	105	0.0013	2.326	0.0006		100%		0.0004
0.0020	106	0.0034	2.326	0.0015		100%		0.0003
0.0010	107	0.0007	2.326	0.0003		100%		0.0001
0.0005	112	0.001	2.326	0.0004		100%		0.0003

Process Capability before process

This is the new Hybrid technology

Use of new technology can boost the quality & productivity significantly.

Data from Master data sheet created by the R SPC software program for analysis purpose

Process capability selected prior to the process.	COMPARISON OF CALCULATED SIGMA (using SPC) AND ACTUAL SIGMA FROM QDC FORM							
	CALCULATED SIGMA (using SPC) = R-bar / d_2. Where d_2 = 2.326 For Sub group 5.							
	CALCULATED SIGMA σc					ACTUAL SIGMA FROM QDC FORM		
	TEST #	R-bar	d_2	σ_c		MinYield		Actual σ_a
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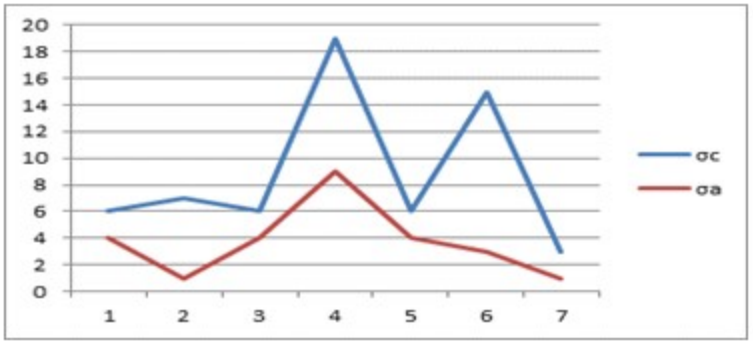
0.0010	102	0.0017	2.326	0.0007		100%		0.0001
0.0021	103	0.0013	2.326	0.0006		100%		0.0004
0.0025	104	0.0044	2.326	0.0019		100%		0.0009
0.0017	105	0.0013	2.326	0.0006		100%		0.0004
0.0020	106	0.0034	2.326	0.0015		100%		0.0003
0.0010	107	0.0007	2.326	0.0003		100%		0.0001
0.0005	112	0.001	2.326	0.0004		100%		0.0003



Correlation Analysis of the process before and after

No more Cp, CpK, Six Sigma calculations. That is a trap to entice you to stay addict to the system.
We give training to the students and your organization, walk you through the process.
Contact us.

CORRELATION ANALYSIS		
	σ_c	σ_a
	6	4
	7	1
	6	4
	19	9
	6	4
	15	3
	3	1
	4	3
Average	8	4
CORRELATION		1

QUALITY CONTROL WITH A QUALITY MISSION

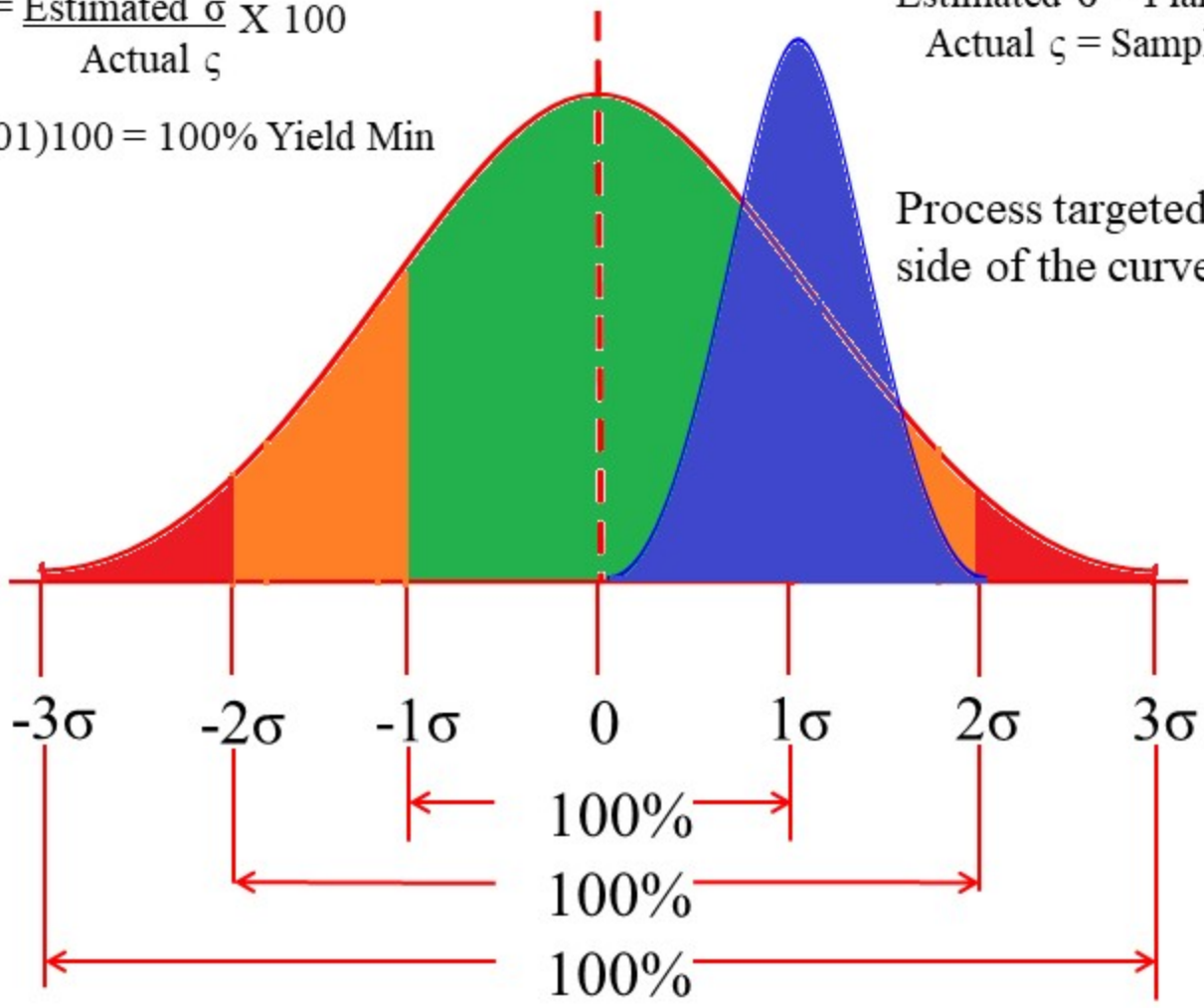
Industrial Statistics is based on Mathematical Model of a Bell Curve, with that targeting the process is easy.
In the Mathematical Model Area Under the Normal Curve is 100%

Process Yield = $\frac{\text{Estimated } \sigma}{\text{Actual } \varsigma} \times 100$

Ex: (0.001/ 0.001)100 = 100% Yield Min

Estimated σ = Planned σ
Actual ς = Sample ς

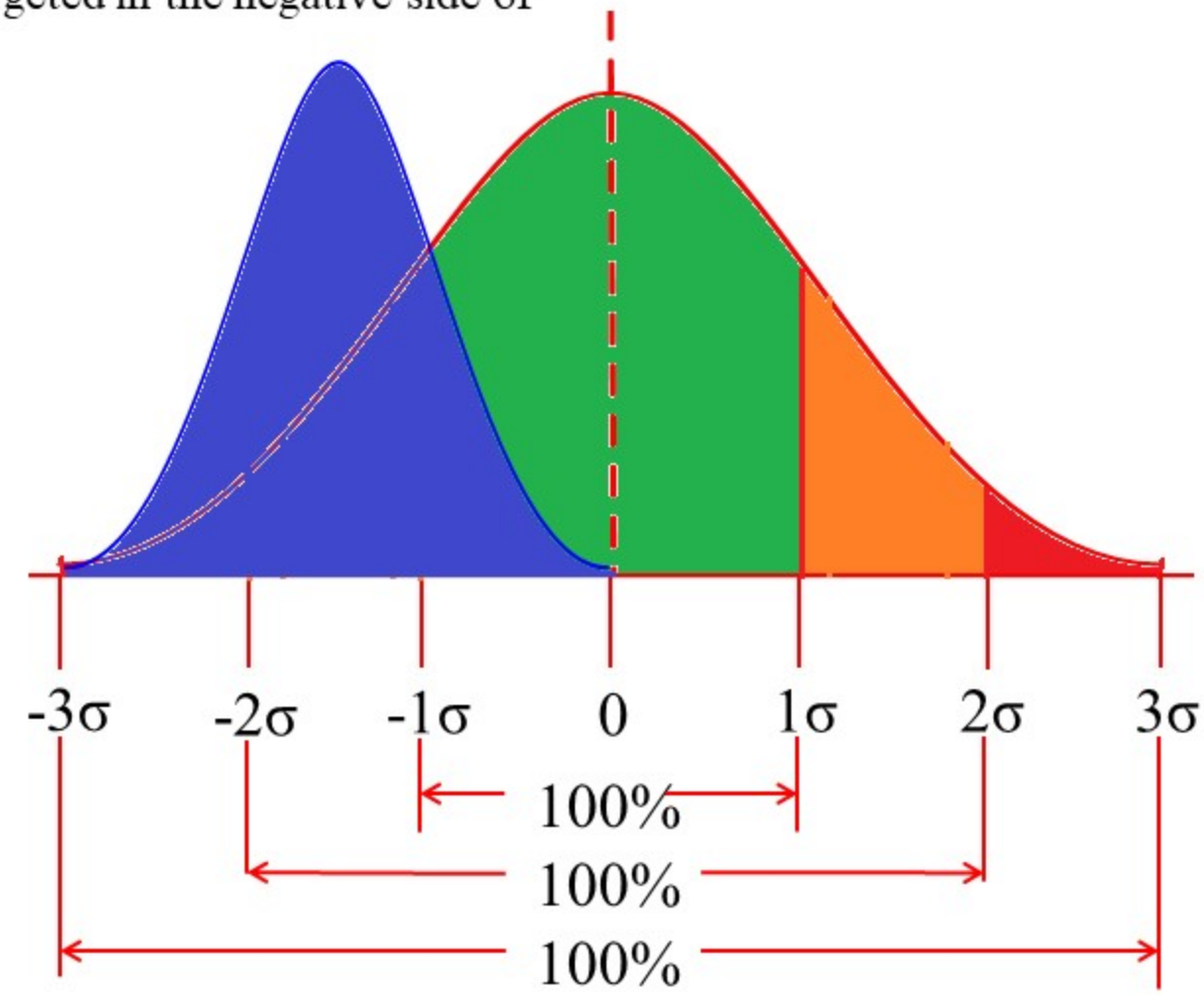
Process targeted in the positive side of the curve



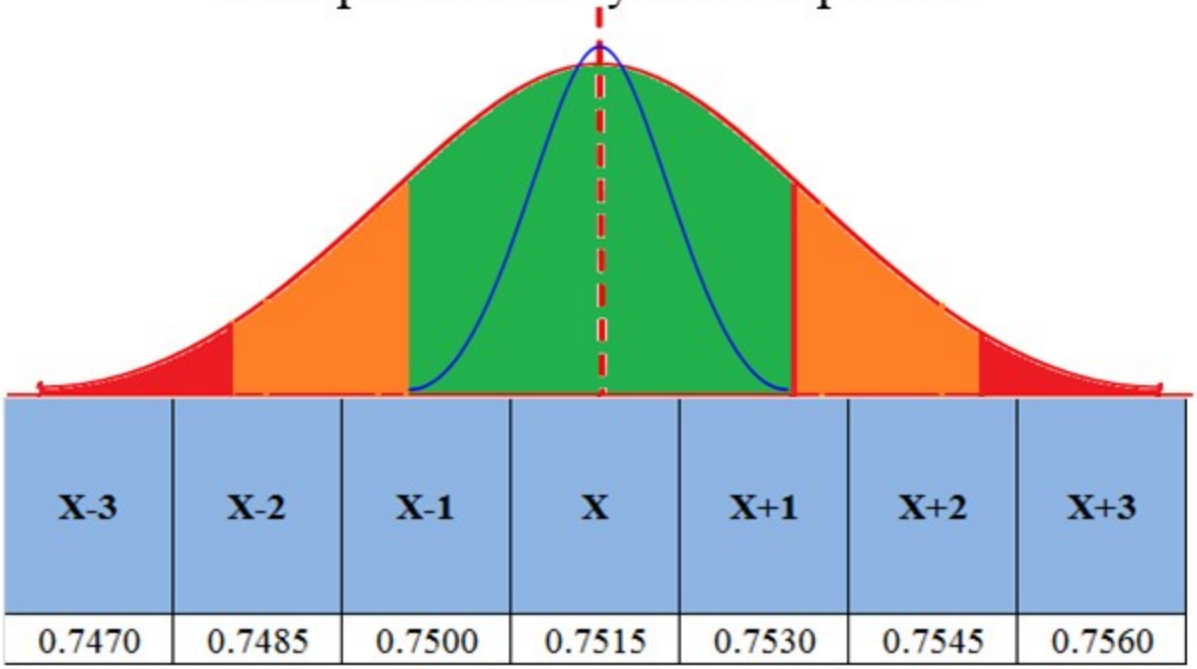
QUALITY CONTROL WITH A QUALITY MISSION

Industrial Statistics is based on Mathematical Model of a Bell Curve, with that targeting the process is easy.
In the Mathematical Model Area Under the Normal Curve is 100%

Process targeted in the negative side of the curve



Important part of Master Data from the R SPC Software Program.
Example: Process yield comparison



X-3	X-2	X-1	X	X+1	X+2	X+3
0.7470	0.7485	0.7500	0.7515	0.7530	0.7545	0.7560

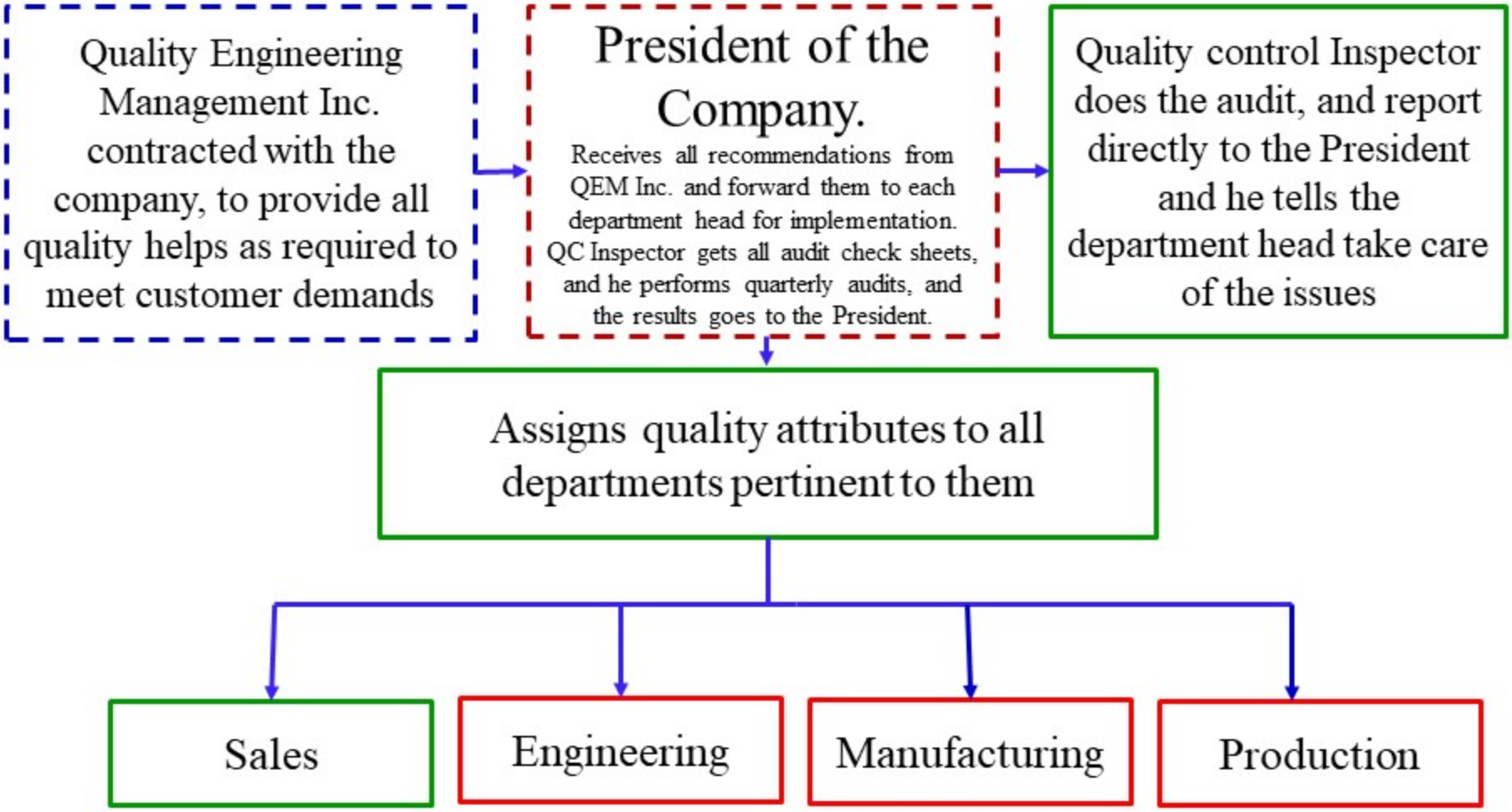
Actual Std Dvn from 25 Samples (Sigma)	Estimated Std Dvn = R-bar/d2. (Sigma)
0.0004	0.0006

$$\text{Process Yield} = \frac{\text{Estimated } \sigma}{\text{Actual } \varsigma} \times 100$$

Process Yield Throughput = (0.0006/0.0004) X 100 = 150%

Is it not better than 6Sigma yield 99.73%?

Quality without Quality Department.
Quality functions in the hands of Manufacturing Professionals!!



MANUFACTURING CORPORATION HAS TWO WINGS

Corporate Quality managements are responsible to create quality procedures and instructions to manage and control quality of the products. They believe ISO 9001 & SPC would do a pretty good job of controlling quality of the products manufactured.
Remember they have no product and process knowledge, but management have full confidence with their MRB system.

Manufacturing arm of the corporation are fully equipped with state of the art of all sorts of machineries to make products to meet the customers requirements.
Manufacturing management knows the capability, stability, repeatability of their machines.
The biggest problem they face is the communication with quality management. Matter of fact a knowledge gap between manufacturing and quality, that is two different cultures.

Eliminate third party certification totally.

Go for second party certification. That means you are dealing with your customers directly; they know your capability and you know what they need, a direct interaction with your customers is more productive.

Taking into consideration of the pitfalls of the system ISO 9001, SPC etc. this is the time to invest something that produces quality products in real time.

What we need is a working systems and they are:

1. Transformational Quality Management System
2. Industrial Statistics

You heard that "A bad workman quarrels with his tools"
Transformational Quality Management System is based on the Model of old MIL-Q-9858 standard.
Nothing wrong with this standard at all, but the upper management was not capable to make the system put to work efficiently and economically to produce quality products and deliver it on time to their customers.

IT IS EASY TO MAKE TRANSITION.

Transformational Quality Management System

1. Revise Corporate Systems to meet your products need
2. Install Model based Process Maps Driven Process control
3. Initiate a Proactive risk mitigation system
4. If your Company is planning to move forward, then just make minor changes to the system and take the lead.
5. Do not invest money on these: Six Sigma, SPC, Cp, CpK, Black Belt, Green Belt, Hypothesis testing and all statistical tools. This does not fit in your manufacturing process. Statistical tools comes with an error or margin of error. If we are trying to error proof the process, statistical tool is a wrong choice.

TRANSFORMATIONAL QUALITY MANAGEMENT SYSTEM MODEL

[BASED ON MIL-Q-9858A, 16 DECEMBER 1963]

1.0 **SCOPE**
1. APPLICABILITY
2. CONTRACTUAL INTENT
3. SUMMARY
4. RELATION TO OTHER CONTRACT REQUIREMENTS
5. RELATION TO MIL-I-45208. INSPECTION SYSTEM REQUIREMENTS

2.0 **SUPERSEDING, SUPPLEMENTATION AND ORDERING**
1. APPLICABLE DOCUMENTS
2. AMENDMENTS AND REVISIONS
3. ORDERING GOVERNMENT DOCUMENTS

3.0 **QUALITY PROGRAM MANAGEMENT**
1. ORGANIZATION
2. INITIAL QUALITY PLANNING
3. WORK INSTRUCTIONS
4. RECORDS
5. CORRECTIVE ACTION
6. COSTS RELATED TO QUALITY

4.0 **FACILITIES AND STANDARDS**
1. DRAWINGS, DOCUMENTATION AND CHANGES.
2. MEASURING AND TESTING EQUIPMENT
3. PRODUCTION TOOLING USED AS MEDIA OF INSPECTION
4. USE OF CONTRACTOR'S INSPECTION EQUIPMENT
5. ADVANCED METROLOGYREQUIREMENTS

5.0 **CONTROL OF PURCHASES**

1. RESPONSIBILITY
2. PURCHASING DATA

6.0 **MANUFACTURING CONTROL**

1. MATERIALS AND MATERIAL CONTROL
2. PRODUCTION PROCESSING AND FABRICATION
3. COMPLETED ITEM INSEPECTION AND TESTING
4. HANDLING, STORAGE AND DELIVERY
5. NONCONFORMING MATERIAL
6. STATISTICAL QUALITY CONTROL AND ANALYSIS
7. INDICATION OF INSPECTION STATUS

7.0 **COORDINATED GOVERNMENT/CONTRACTOR ACTIONS**

1. GOVERNMENT INSPECTION AT SUBCONTRACTOR OR VENDOR FACIITY
2. GOVERNMENT PROPERTY
    1. GOVERNMENT FURNISHED MATERIAL
    2. DAMAGED GOVERNMENT FURNISHED MATERIAL
    3. BAILED PROPERTY

8.0 **NOTES**

1. INTENDED USE
2. EXEMPTIONS
3. ORDER DATA.

Do not feed the DOG (DOcument Gamblers)

Who are they?

1. ISO Quality standard creators

2. Registrars

3. Auditors

4. Statisticians and their SPC expertise.

5. Problem solvers (SPC Driven) Six Sigma, Black Blet, Green Belt, Cp & Cpk.

6. SPC Magicians: They trick you Infront of your very own eyes (Showing Bell curve exercise and more)

7. Hypothesis testers.

Big problem – Big picture

1. Significant proportion of device recalls were attributed to faulty **design** of product

2. FDA found that approximately 44% of the quality problems that led to voluntary recall actions during the 6year period were due to lack of **design** control.

3. A subsequent study of software-related recalls from 1983 – 1991 indicated that over 90% of all software related failures were due to **design** related errors both hardware and software.

Let us review CFR Title 21, Part 820 Quality System Requirements:-

CFR – CODE OF FEDERAL REGULATIONS TITLE 21
PART 820 QUALITY SYSTEM REGULATION

Sec. 820.20 Management responsibility

(a) Quality policy.

(a) *Quality policy.* Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

(b) *Organization.* Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.

(1) *Responsibility and authority.* Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

(2) *Resources.* Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

(3) *Management representative.* Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and

(ii) Reporting on the performance of the quality system to management with executive responsibility for review.

(c) *Management review.* Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals

(d) Quality Planning.

(e) Quality system procedure

Sec. 820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedure for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability and product characteristics.

FDA-PRODUCT RECALLS-DESIGN ISSUES-QUALITY

Following is copied from The Safe Medical Devices Act of 1990, to explain the critical issues our Medical Devices Manufacturers are facing to make and deliver quality products.

Your report says: (1) Device recalls caused by faulty design. (2) 44% of the recalls were caused by faulty design of the products. (3) Over 90% of the product recalls were caused by due to design related issues.

[The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), enacted on November 28, 1990, amended section 520(f) of the act, providing FDA with the authority to add preproduction design controls to the CGMP regulation. This change in law was based on findings that a significant proportion of device recalls were attributed to faulty design of product. Specifically, in January 1990, FDA published the results of an evaluation of device recalls that occurred from October 1983 through September 1989, in a report entitled ``Device Recalls: A Study of Quality Problems'' (Ref. 1). (See 55 FR 21108, May 22, 1990, where FDA announced the availability of the report.) FDA found that approximately 44 percent of the quality problems that led to voluntary recall actions during this 6-year period were attributed to errors or deficiencies that were designed into devices and may have been prevented by adequate design controls. These design-related defects involved both noncritical devices (e.g., patient chair lifts, in vitro diagnostics, and administration sets) and critical devices (e.g., pacemakers and ventilators). Also in 1990, the Department of Health and Human Services' Inspector General conducted a study entitled ``FDA Medical Device Regulation From Premarket Review to Recall'' (Ref. 2), which reached similar conclusions. With respect to software used to operate medical devices, the data were even more striking. A subsequent study of software-related recalls for the period of fiscal year (FY) 1983 through FY 1991 indicated that over 90 percent of all software- related device failures were due to design-related errors, generally, the failure to validate software prior to routine production (Ref 3).]

Our manufacturers are facing a very big problem today, that is – Engineering Design problem – This is a critical issue, this problem must be addressed in the higher level and a training program should be initiated at the earliest and remove the use of Statistics and use of sampling plans from the CFR where appropriate.

Sec. 820.250 Statistical techniques.

(b) Sampling plans, when used, shall be written, and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.
Source: 61 FR 52654, Oct. 7, 1996, unless otherwise noted.

FAA

3. Quality System Requirements

11. Quality Manual

Section 21.138 requires each Production Certificate applicant to provide a quality manual describing its quality system to the FAA for approval. This requirement also applies to PMA and TSO approval holders. The quality manual must address the quality system requirements of the subpart under which the applicant seeks production approval. The quality manual should also address changes to the quality system, revisions to the manual, and a means of tracking revisions to the manual.

Federal Register :: Production and Airworthiness Approvals, Part Marking, and Miscellaneous Amendments

21.137 Quality System.

The Bottom line is that, teach our growing younger generation the earned values of practical Manufacturing Engineering fundamentals and the basics.
Creativity starts from there.

Question and Answers or an inhouse training program Contact

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Message: 714-783-8911
Email: bmatthewbob@gmail.com
Visit: www.qem-inc.com