The handbook for Quality Control Professionals

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The word “Quality” means much more than goodness or badness of a product. It refers to the qualities or characteristics of the things or process being studied.
The word “Control” means to “keep something within boundaries” or “to make something behave the way we want to behave”.

Taken together, the word “Quality Control” means we study the characteristics of our process in order to make it behave the way we want it to behave.

When we do this by the help of statistics (having to do with numbers and graphs) we then call it Statistical Quality Control (SQC).

In testing laboratory, we will tell “Quality Control is a statistical process used to monitor and evaluate the analytical process that produces the results”.

The two quality management system models most frequently used today are the ISO 9000 family of quality management system standards and Lean-Six Sigma.

In today’s world, quality is critical for an organization’s long-term sustainability, the individuals of the organization, and society as a whole.

The purpose of this book is not talk about ISO 9000 family, or Lean-Six Sigma or Quality Management System. Lots of excellent books are there (you can get the list of books at the end) written by masters. My purpose to write this to help the fresher to work from the day one with a systematic approach and basic knowledge to the things they are going to do on floor on day to day basis, so that they can understand what they are doing have some purposes and what are those purposes.

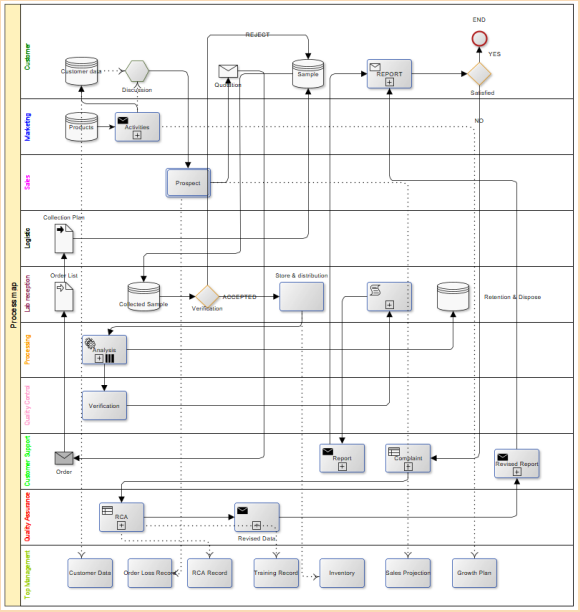
In testing laboratory, the quality of services (the product of laboratory is the test report) can be described and evaluated by following ways:

1. Performance – Will the test report be submitted on time? What is the lead time?
2. Serviceability – Will the laboratory help to overcome the problem observed after testing?
3. Precision and accuracy – Is the test report authentic and reliable?
4. Cost – Does the money spent for testing has value?
5. Conformance to standard – Does the test conducted as per national/international standard methods?
6. Aesthetics – How the report looks like? Can a lay man understand the report? Any important information shared with report?

5S

To start to focus on quality, start with 5S.

- Sort – Clearly distinguish needed items from unneeded items and eliminate the latter.
- Set in Order – Keep needed items in the correct place to allow for easy and immediate retrieval.
- Shine – Keep the work area clean.
- Standardize – Develop standardized work processes to support the first three steps.
- Sustain – Put processes in place to ensure that the first four steps are rigorously followed.
  Note: To do this you need to know the entire process flow chart (High Level Process Map).



Example of HPM of a testing laboratory

WORMPIT

We want to improve and maintain the quality for better profitability. To start this, need to reduce and control the wastage. To reduce the waste, WORMPIT is very successful policy.

- ***(W)*** *Waiting – Reduce waiting time due to lack of material, people, or equipment.*
- ***(O)*** *Over production – Stop to produce excess reagents, stock standards, excess media plates, sterilization of sample bottles.*
- ***(R)*** *Rework – Reduce defects, and correction.*
- ***(M)*** *Motion – Reduce unnecessary movement of people and equipment.*
- ***(P)*** *Over processing – Reduce/eliminate the activities or information which add no values.*
- ***(I)*** *Inventory – Reduce stocking materials for future use.*
- ***(T)*** *Transportation – Rearrange the materials in laboratory to reduce extra movement. Redesign the work flow and reassign the job distribution to avoid unnecessary movements.*
- ***(8th Waste)*** *Under utilization of talent – Identify the talent of each person and utilize it. Give them opportunity to utilize their hidden talent.*

How to do it:

1. Eliminate waiting
   a. Refer the HPM and break down each process/activity.
   b. Observe the process /activity and check where the waiting is more.
   c. Identify the reason of waiting.
   d. Eliminate the reason. To eliminate you may need to redesign the process step and may exclude or include a step. A very common reason in testing laboratory is the non-availability of reagent causes delay in analysis, which affects directly on customer satisfaction. To avoid this, the section should maintain

the minimum stock of reagent, purchase should circulate the lead time for each chemicals and the section should give requisition according to present stock, future expected load and lead time. The smart section head and organization, for this maintain primary and secondary stock.

Here the QC plays a vital role. They follow the trend of test load predict the future load. During morning discussion with team leaders, these information shared so that this waiting can be avoided.

Like that lots of small reasons are there which if can be identified and eliminated, the waiting can be avoided.

If you want to get help to identify the causes, you can contact on abhijit.bhar@outlook.com.

2. Eliminate over production

   Most of the laboratory produce excess reagents which never consumed and drained. CRM, which is costly, used to prepare calibration standard and not consumed 50% also and could not able to use due to loss of properties.

   a. Draw the flow chart of each test.
   b. Identify the chemicals and reagents.
   c. Estimate the shelf life of reagents.
   d. Calculate the test load expecting within the shelf life.
   e. Prepare the reagents accordingly.
   f. Evaluate the estimation and rework.
   g. Evaluate the shelf life periodically (once in a week is good practice).
   h. Smartly plan during CRM procurement. If the need of testing is to prepare standard from 1ppm to 50 ppm, then procurement of 99% pure is foolishness. Instead plan to procure CRM of 1000 ppm. If analytical need is ppb level, it is always better to procure CRM of 100 ppm. The required volume also is very important during planning. If you are making standard to use for GC, GCMS, you need 1 ul per injection. For HPLC, LCMS, then your requirement per injection ranges from 5 to 20 ul. For AAS or ICP-OES ranges from 2ml to 10 ml. So, the chemist should understand the requirement and plan accordingly. The QC should monitor the consumption.

3. Eliminate rework

   a. Evaluate the performance of the chemist (e.g., repeat test, spiked sample, analysis of retained sample).
   b. Participate in ILC/PT.
   c. Identify the deviation and plan training.
   d. Monthly evaluate the team competency.
   e. Plan to prepare second line. Multiple people should be competent for each activities, else the “Waiting” will increase.

4. Eliminate motion

   a. The manual, tools and consumables should be near the specific equipment. (I have seen in many laboratories that the manuals are kept in the section head’s cabin. This is meaning less. If needed, the section head can keep one copy with him, but the users need it more frequently and so it should be with equipment. Some consumables, which are costly, a portion of those can be kept separately and users will be accountable for the consumption).

   b. Many laboratory use a central printer. This is not a good option for the analytical section. People will be in queue (Waiting) or have to move multiple times to take the instrument output print. Instead, each instrument should have a separate printer.
   c. The gas panel should be at the same area of equipment, instead using a common gas panel area.
   d. The report to QC should go together at fix interval. It is always advisable to use LIMS nowadays.
5. Eliminate over processing
   a. Use control chart to monitor the response of instrument. The reanalysis will be done, if the value is out of control limit, else not needed. If the calibration R^2 >0.95 and it is acceptable as per Quality Manual, then chemist should not try to get >0.98 for regular analysis. This experiment is the part of QA to improve quality and separate project will be created for this.
   b. If the RPD of repeat analysis or controlled sample within (± 10%, which is normally acceptable) or within the limit specified by the Quality Manual, then do not repeat the test to get it better. Refer point 5.a.
6. Eliminate inventory
   a. Set the minimum stock level.
   b. Estimate the consumption per day/week/month.
   c. Identify the lead time.
   d. Do the vendor evaluation to understand their delivery performances.
   e. Keep a 10 days buffer.
   f. Check the shelf life of the product.
7. Eliminate transportation
   a. Fix an area at section entry for “Sample in” and “sample out”.
   b. Fix an area for “report in” and “report out”. The chemist can perform the test and keep the report in “report in” so that the supervisor can check it and can take necessary action. Chemist should not be waiting or moving multiple time to find out the supervisor.
   c. Allocate the responsibility to forward the report to QC on weekly/monthly basis.
   d. Use LIMS to avoid unnecessary waiting and movement.
8. Identify and utilize talent
   a. Identify the talent of each individual.
   b. Assign small project related to their talent.
   c. Guide them to do better.
   d. Give more opportunities to them according to talent.
   e. Make alternative for the current work they are doing to make them free to involve in activities as per their talent.

The variability in process increases the waste. Waste in terms of money, time, energy, and talent. Now you can understand why to follow WORMPIT.

For this you can make your check point for daily monitoring. I use my own “10 check point”, the copy of which enclosed.

Chromatography solution

10 Point Checksheet (10P)

Navigating to Results

Process Area:	Purpose:	Reference:	Responsible:	Month:
Report Section	Keep area clean and organized			

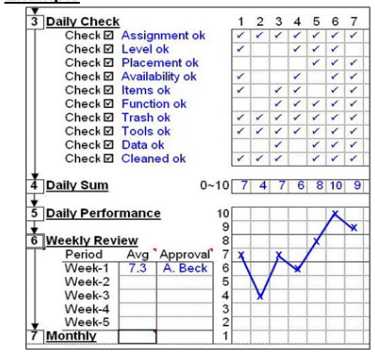
1 Setup

What? This list defines the acceptable standard, and measures conditions against the standard.
Why? Rules ensure a safe and efficient work-place by reducing waste and variability.
Who? The supervisor/manager is responsible for the standards and that people follow.
When? All work-days, no exceptions.

2 Rules

Rule-01: Assignment ok > all items have a defined place and correct label (number/description).
Rule-02: Level ok > quantity, fill-height or volume does not exceed the maximum level (record in file).
Rule-03: Placement ok > all items are placed in the their designated place.
Rule-04: Availability ok > all items are available when needed, no wait, nothing out of stock.
Rule-05: Items ok > all components, tools, papers etc are defined and known (no foreign objects).
Rule-06: Function ok > all systems, tools, machines, programs, lights etc are fully functional.
Rule-07: Trash ok > all bins are empty and cleaned at the end of day (empty at day-start).
Rule-08 Tools ok > all tools are available at their assigned place, nothing missing or broken.
Rule-09: Data ok > all plans updated: work-schedule, check-lists, daily action plan, job distribution etc.
Rule-10: Cleanliness ok > entire area cleaned-up at day-end and disinfected per weekly plan.

Example



3 Daily Check

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 Total

Check ☑ Assignment ok
Check ☑ Level ok
Check ☑ Placement ok
Check ☑ Availability ok
Check ☑ Items ok
Check ☑ Function ok
Check ☑ Trash ok
Check ☑ Tools ok
Check ☑ Data ok
Check ☑ Cleaned ok

4 Daily Sum 0~10

5 Daily Performance 10 9 8 7 6 5 4 3 2 1

6 Weekly Review

Period	Avg	Approval
Week-1		
Week-2		
Week-3		
Week-4		
Week-5		

7 Monthly

CTQ

Every product/service possesses a number of elements that jointly describe what the customer thinks of as quality. These are known as CTQ (Critical To Quality) or Quality Characteristics. It may be:

1. Physical
2. Sensory
3. Time orientation

If we translate these three for testing laboratory, we gets:

1. Physical – Sample collection kit, appearance of sample collector, sample collection protocol.
2. Sensory – Quality of paper of TRF (Test Request Form), report copy, sample collection container, communication from test enquiry to report submission.
3. Time orientation – Immediate response of each queries, continuous update of present status at each step, customer portal to track the test status (just think how you track your parcel in customer portal).

Considering all above, variability always will be there, but it should be within definite limit. As a QC person, our job is to ensure that the variations are within given limit, implement system/policies to stop the activity immediately whenever variations are out of limit. Variability can only be described in statistical terms, statistical methods play a central role in quality improvement efforts. For this we have to get data (attribute data, variable data). Variable data are usually continuous measurement (e.g., length, voltage, etc.) and attribute data on the other hand, are usually discrete data, often taking the form of counts (e.g., number of report delayed, number of customer lost, number of time repeat analysis performed, etc.).

7 basic Quality Tools

1. Cause and effect diagram
2. Check sheet
3. Control chart
4. Histogram
5. Pareto chart
6. Scatter diagram
7. Stratification

So, let's see some important tools……..

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Section and CTQ (prepare referring HPM)

Sr. No.	Section	CTQ	Type of data	Frequency
1	Marketing	Delay in response (target 5 minutes per enquiry)	Discrete	Every day
2	Marketing	Wrong test suggested (target 0)	Discrete	Everyday
3	Marketing	New customer on-board	Discrete	Weekly
4	Marketing	Revenue from new customer	Continuous	Monthly
5	Sales	Loss of customer	Discrete	Weekly
6	Sales	Order conversion ratio	Continuous	Every day
7	Labadmin	Delay in sample pick-up	Discrete	Every day
8	Labadmin	Delay in sample registration (target 5 minutes per sample)	Discrete	Every day
9	Labadmin	Sample cancellation (target 0)	Discrete	Every day
10	Labadmin	Sample forwarded to process 15 min. After received	Discrete	Every day
11	Chemistry	Delayed to submit test value (target 1 day)	Discrete	Every day
12	Chemistry	Test load	Discrete	Every day
13	Chemistry	RPD of repeat analysis	Continuous	Every day
14	Chemistry	RPD of spiked sample	Continuous	Every week
15	Chemistry	Control chart		Every day
16	Chemistry	Spiked sample by two chemist in duplicate	Continuous	Monthly
17	Chemistry	RPD of Retesting of retained sample	Continuous	Monthly
18	Chemistry	All related record updated on real time (Y/N)	Discrete	Every day
19	Microbiology	Delayed to submit test value (target 5 days)	Discrete	Every day
20	Microbiology	Test load	Discrete	Every day
13	Microbiology	RPD of repeat analysis	Continuous	Every day
14	Microbiology	RPD of spiked sample	Continuous	Every week
15	Microbiology	Control chart		Every day
16	Microbiology	Spiked sample by two microbiologist in duplicate	Continuous	Monthly
17	Microbiology	RPD of Retesting of retained sample	Continuous	Monthly
18	Microbiology	All related record updated on real time (Y/N)	Discrete	Every day

Sr. No.	Section	CTQ	Type of data	Frequency
19	Report section	Delay to prepare report (5 minutes per report)	Discrete	Every day
20	Report section	Received value on time (section wise)	Discrete	Every day
21	Report section	Received value after scheduled time (Section wise)	Discrete	Every day
22	Report section	On time report	Discrete	Every day
23	Report section	Reported after scheduled time	Discrete	Every day
24	Report section	Customer complaint	Discrete	Every day
25	Report section	Customer feed back	Discrete	Every day
26	Report section	Sample per day	Discrete	Every day
27	Report section	Revenue per day	Continuous	Every day
28	Report section	Report rejected	Discrete	Every day
29	Accounts	Pending payment	Continuous	Weekly
30	Admin	Late attendance	Discrete	Monthly
31	Purchase	Delay in procurement	Discrete	Weekly
32	Housekeeping	10 check point	Discrete	Every day

According to your organization and work flow, you can prepare the above chart.

Collect data for 1 month, and identify the base line (current situation). To gather data, you can use excel or any professional statistical software. As it is not possible to gather all data by your-self, so distribute the responsibilities. They will collect data in excel. Later you can transfer the data to professional software, if using any, which allows importing data from excel.

In this one month, when you are collecting data, you are also making the template ready for next step, making or getting test flow chart from the process floor, and identifying the people who are serious on work, focused, willing to learn and grow. They are going to be your back bone.

QC check-list

		Day																													
Sr. No.	**Description**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
A.	**DAILY**																															
1	Job allotment																															
2	Repeat analysis																															
3	Test method used verified																															
4	Test witnessing (at least 1 test)																															
5	Raw data verified																															
6	Pending test																															
7	Pending sample																															
8	Trend chart																															
9	Training conducted																															
10	Day sample load																															
11	Day test load																															
B.	**WEEKLY**																															
1	Competency record updated																															
2	Training record updated																															
3	Retained sample analysis																															
4	Spiked sample analysis																															
5	Market sample analysis																															
6	Environment monitoring record																															
C.	**MONTHLY**																															
1	Intermediate testing record																															
2	Preventive maintenance record																															
3	Monthly delayed in test																															
4	Monthly delayed in report																															
5	Team competency checked																															
6	Individual competency checked																															

Note: For each section and each person in the organization should use check-list for their activities. QC section can educate and motivate the people to use it.

Selection of tools

If you want to:							
Gather ideas	**Group ideas**	**Analyze**	**Sequence steps**	**Draw a picture of data**	**Track data over time**	**Prioritize or get group consensus**	**Show relationship**
Affinity diagram	Affinity diagram	Cause-and-effect diagram	Flowchart	Histogram	Check sheet	PICK matrix	Relations diagram
Cause-and-effect diagram	Cause-and-effect diagram	Forced-field analysis	Arrow diagram	Pareto chart	Run chart	Multivoting	Scatter diagram
Brainstorming		Relations diagram	Tree diagram	Run chart	Pareto chart	Normal group technique	
Forced-field analysis		Pareto chart		Scatter diagram	Control chart	Relations diagram	
Benchmarking		Five whys		Control chart		Decision matrix	
Audit							

SIPOC (Supplier-Input-Process-Output-Customer)

For each activity, there is a **supplier**, who is giving some **input**, using which the **process** is performing to give an **output** for a **customer**. For better understanding of the work process of your laboratory, you can use this chart.

Supplier	Input	Process	Output	Customer

Example 1: For a testing laboratory manager, the SIPOC is:

Supplier	Input	Process	Output	Customer
Food processor	Sample Test Method Limit	Performing the test for the given sample, following the method provided or specified by customer	Test report	Food processor

Note: Some times, the supplier and customer may same. In the organization each section is a different customer (internal). Customer may internal or external. There will be multiple steps. If you want to know further on SIPOC, you can contact on abhijit.bhar@outlook.com.

Example 2: SIPOC for Chemistry section:

Supplier	Input	Process	Output	Customer
Labadmin	Sample TRF	Sample entry	Test list	HOD, Chemistry
HOD, Chemistry	Test list Competency matrix	Test allotment	Job sheet	Chemist
Chemist	Stock status	Consumption calculation	Purchase requisition	Purchase
Chemist	Job sheet	Analysis	Raw data	HOD, chemistry
HOD, Chemistry	Raw data	Verification	Approved raw data	Report section
QC	QC sample	Analysis	Raw data	QC

Note: You can break down the activities further as per your company HPM.

Example 3: SIPOC for testing laboratory:

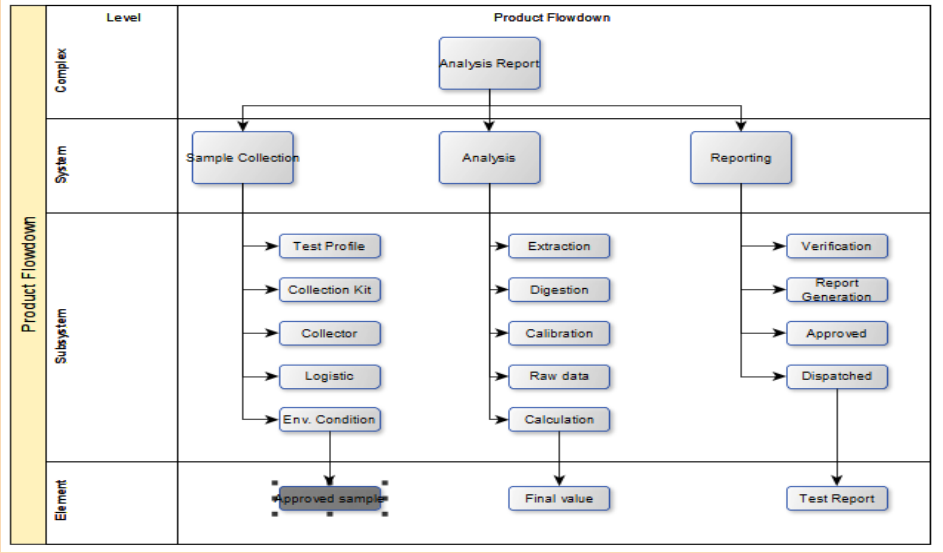
Supplier	Input	Process Requirement	Process	Output	Customer Requirement	Customer
Marketing Head	Sector details, profile and test details. (Measure the requirement received earlier and if it is a new test introducing in the market, then what is the return projected)	1. Sector details 2. Sector wise profile 3. Information to be printed in catalogue 4. If any pre-selected lay out by customer	1. Take required information 2. Select suitable pictures 3. Design and print 4. Send to customer for approval	Sector wise catalogue	1. Sector wise catalogue 2. Required information 1) Profile and test 2) Why to do test 3) Govt. regulation 4) Why from us 3. Pictures 4. Price	Marketing team
Marketing Team	Customer data base (Measure weekly addition of new customer in data base and customer feedback received)	1. Customer list 2. Soft ware to send promotional mails 3. Client meeting plan and reporting format 4. Facility visit plan for customer	1. Update customer data base 2. Link the document for each sector 3. Send mails 4. Contact customer and fix appointment 5. Visit customer 6. Understand their requirement 7. Prepare visit report	1. Increase customer data base 2. Customer requirement understood and shared with management 3. Competitor's activities	1. Business prospect	Sales Team
Sales Team	Business prospect from marketing team (Monitor total enquiry, enquiry sector wise, lost cases with reasons)	1. Test profile and cost 2. Prospects 3. Our advantage details	1. Send quotation against mail received form customer 2. Visit customer to close the deal 3. Special price approval from management 4. Customer visit plan to laboratory if needed 5. Send order to logistic team	1. Order received 2. List of orders 3. List of new customer addition 4. Order lost details with reasons 5. New test request from customer to management 6. Competitor's activities	Clean order (Proper test profile, clear payment terms, if discounted then copy of management approval, agreed TAT)	Logistic team
Logistic team	Client order from logistic team	1. Collection agent network along with contact details 2. Sample collection kit 3. Transportation net work	1. Client order 2. Identify the nearest and readily available collection agent 3. Talk to client and fix collection date and time 4. Pass on the information to collection agent 5. Ensure collection agent have collection kit 6. Co-ordinate with client and collection agent till sample received in lab	1. Sample collection instruction 2. Sample collection plan	1. Customer address 2. Sample collection instruction 3. Sample collection kit 4. Sample drop location	Sample collection agent
Sample collection agent	Sample with test request	1. Sample 2. Test Request 3. Codification system 4. LIMS	1. Do the entry in inward register 2. Do entry in Sample entry register 3. Assign lab code 4. Erase other Ref. No.	Sample list for the day	1. Clear information of test to be conducted 2. Clearly mention the sample matrix 3. Clearly mention the last date for report submission 4. Clearly mention the	Lab Admin

			5. Check test request form 6. Do physical verification 7. Create job sheet 8. Send sample and job sheet to process		customer address 5. Details information of reference of quotation	
Lab Admin	Sample list for the day Test request form	1. Bar code scanning 2. LIMS software	1. Create job sheet as per details in sample register 2. Use Labcode to trace the sample, henceforth 3. Give the sample and job sheet to processing team 4. Retain the sample if cannot give to process today, maintain the document.	Job sheet	1. Sample matrix 2. Test to be performed 3. Due date for report submission	Processing team
Processing team	Job sheet with sample	1. Job sheet and sample received 2. Job sheet entry 3. Job distribution 4.	1. Job sheet and sample received before 10:00am 2. Job sheet entered in register 3. Job equally distributed	Work plan	1.	Processing team members
Processing team members	Work plan with job sheet and sample	1. Instrument 2. Chemicals & reagents 3. Glass parts 4. Accessories 5. CRM/RM 6. Methods	1. Check instrument performance 2. Ensure preventive maintenance done. 3. Ensure CRM available 4. Ensure COA available 5. Ensure all glass parts are calibrated 6. Perform analysis 7. Perform analysis of one known sample every after 10 samples 8. Ensure to update data in trend chart 9. Ensure raw data updated 10. Ensure sample analyzed as per TAT	Analysis result. Trend chart. Consumption record.	1. Error free result. 2. Supporting raw data and record 3. Records including instrument record, calculation record	QC
QC	1. Blind QC 2. Intermediate sample 3. Retest request 4. Retained sample for analysis	1. QC sample 2. CRM 3. Retained sample	1. Give QC sample as unknown 2. Give CRM for intermediate testing 3. Give one sample for repeat analysis Give one retained sample as unknown to process	1. Analysis result of QC sample 2. Analysis result of CRM 3. Analysis result of retained sample 4. Analysis result of a sample in duplicate	1. Result of QC sample within ± 10% of actual value. 2. Result of CRM sample within ± 10% of actual value. 3. Result of retained sample analysis within ± 10% deviation with earlier result. 4. Result within ± 10% deviation.	QC
QC	Analysis result	Raw data obtained from analysis. Approval from authority.	1. Check all data and verify if result within acceptable range. 2. Approve to prepare report. 3. Check the CCV trend chart, if	Final value in job sheet to lab-admin to prepare report	All parameters of QC activities to be satisfied to release report.	Lab-Admin

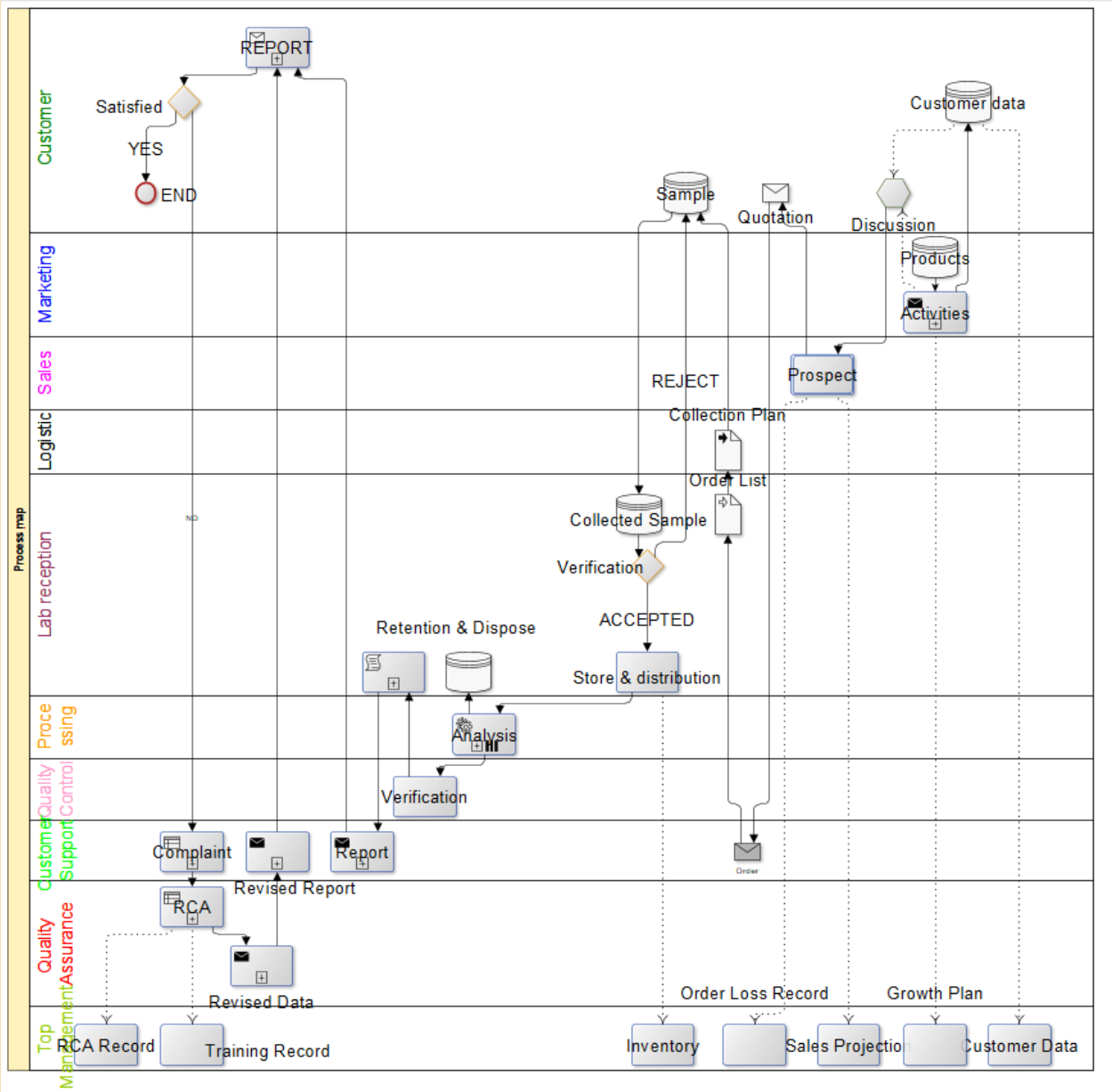
			not within range, send sample back to process for repeat analysis. 4. Check blind QC report, if not satisfied, do RCA. Sample to be reprocessed. 5. Check intermediate report, if not satisfied, verification needed. Stop analysis and resolve the problem. Inform lab-admin about the delay of reporting. 6. Check repeat analysis report, if not satisfied, do RCA. Reprocess of sample needed. 7. Check report of analysis of retained sample. If not satisfied, do RCA, hold the report.			
Lab-Admin	Final value of analysis	Final value of analysis with approval	1. Prepare the report. 2. Get signature from signing authority. 3. Send report to customer.	Analysis Report	1. Report on time. 2. Error free report. 3. Reliability. 4. Traceability. 5. Suggestion/remark if needed or requested.	Customer

Now you have understood how to prepare and what is the benefit.

Prepare Product Flow Down Chart:

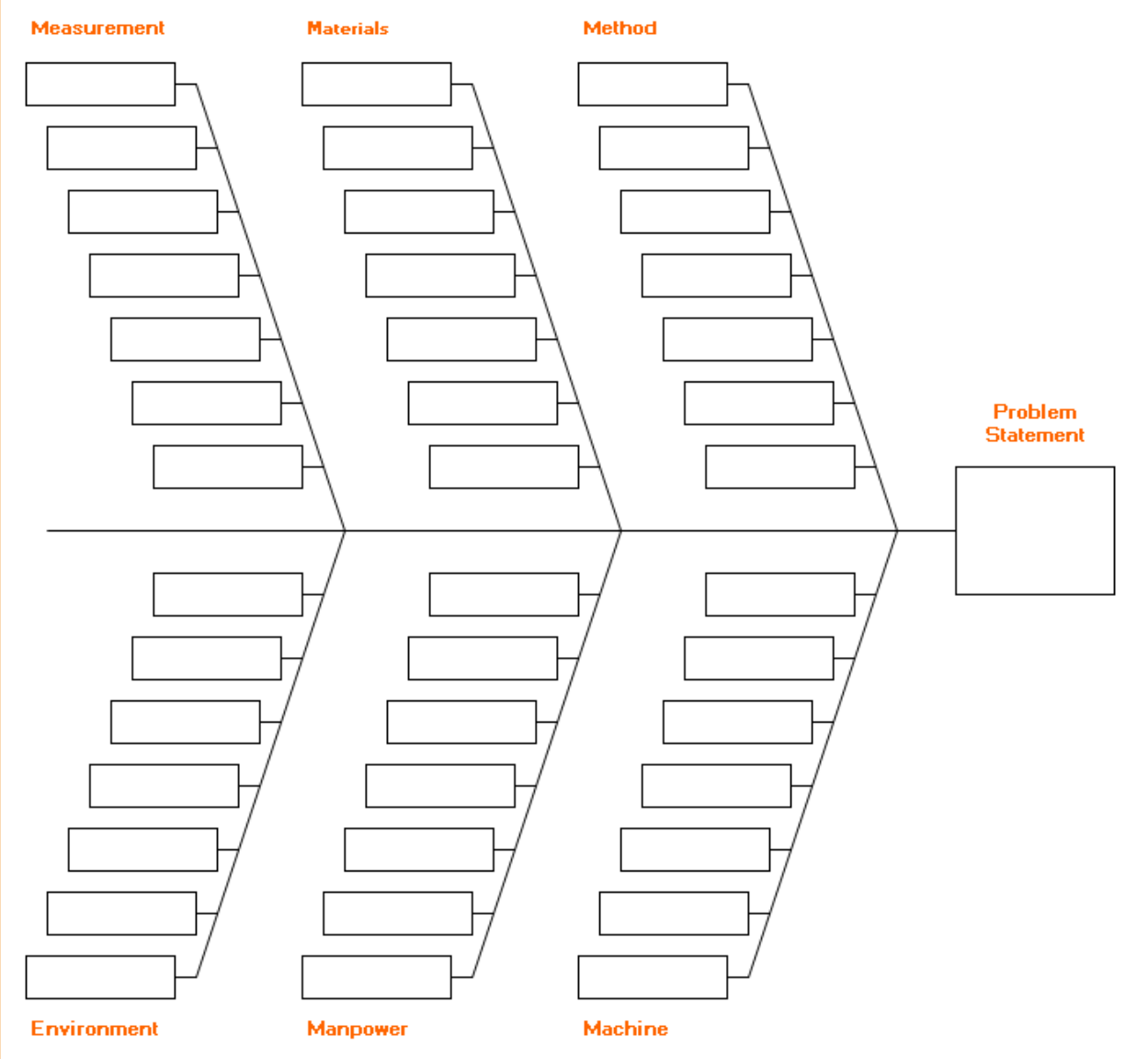


Prepare HPM (High level Process Map):



Note: HPM will give the better visual presentation to understand the flow of work and check point. These check points are more crucial to monitor, evaluate, and plan for improvement (PDCA cycle).

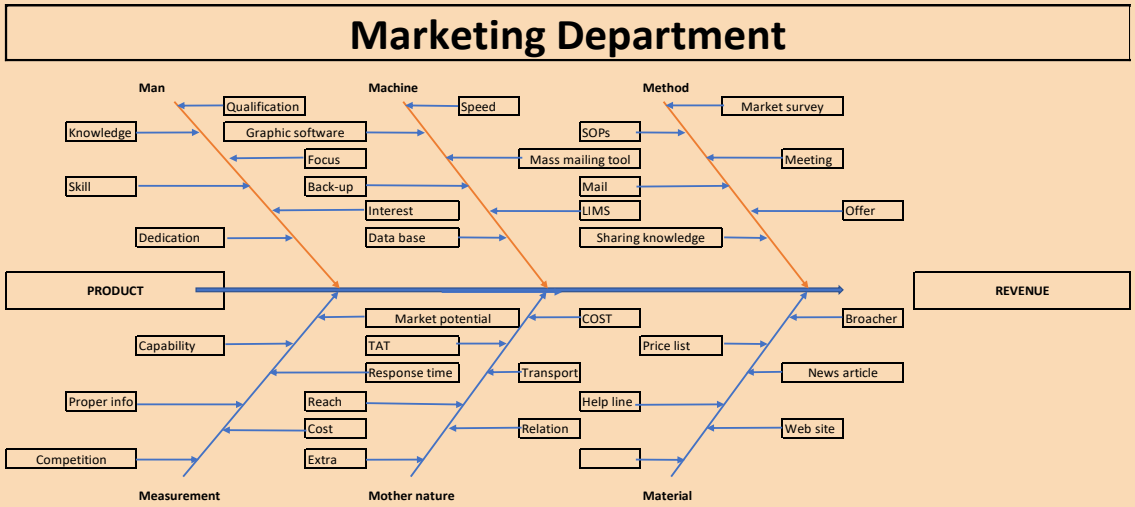
Prepare Cause and effect diagram



Note: For each activity prepare the diagram, this is the most important to start to find out the area to consider to focus for control and improvement.

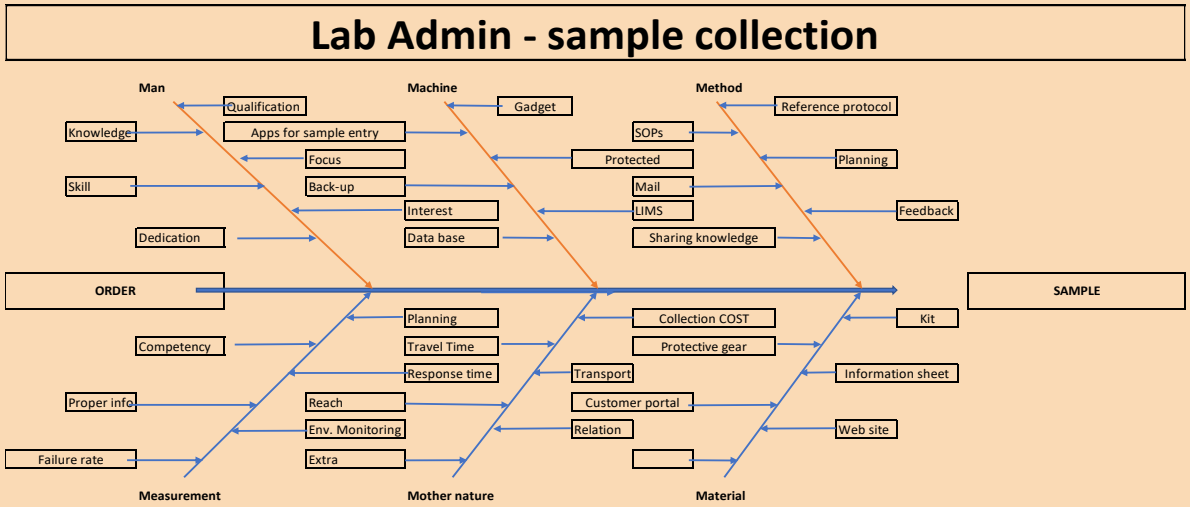
In next page some examples has been given to refer.

Examples of Cause-and-effect (fish-bone, Ishikawa) diagram:



Quantitative data of each CTQ:

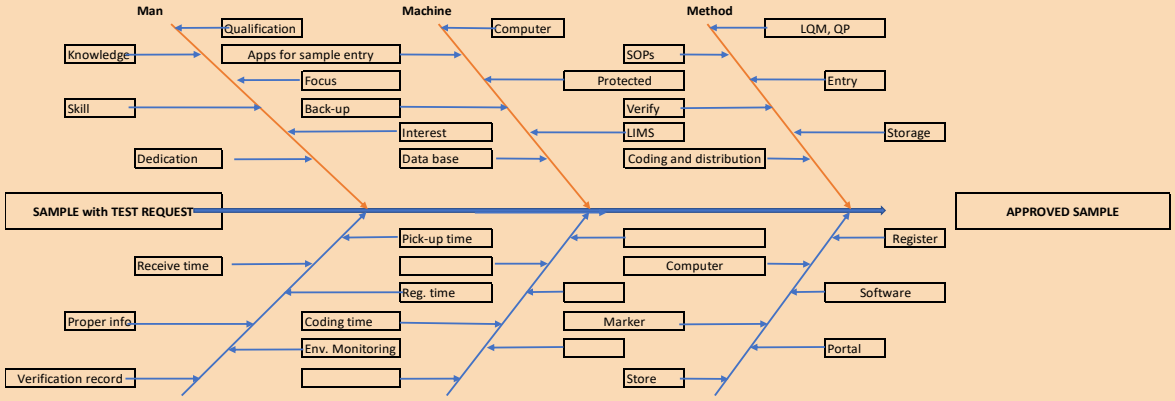
Sr. No.	CTQ	Discrete data	Continuous data
1	Qualification of marketing personnel is up to the mark (Y/N)		
2	Knowledge of marketing personnel is up to the mark (Y/N)		
3	Marketing personnel have focus (Y/N)		
4	Marketing personnel have skill to identify the market (Y/N)		
5	Marketing personnel have interest to the job (Y/N)		
6	Marketing personnel have dedication to work and company (Y/N)		
7	How many reply to customer taken more than 5 minutes		
8	How many promotional material created in the month		
9	How many mails sent to customer in the month		
10	How many enquiry received in the month		
11	How many customer feedback received in the month		
12	How many data generated in the month		
13	How many complaint received in the month		
14	How many complaint are unresolved in the month		



Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	Qualification of sample collector is up to the mark (Y/N)		
2	Knowledge of sample collector is up to the mark (Y/N)		
3	Number of Evaluation of sample collector done per month		
4	Number of controlled sample checked during transportation per month		
5	Number of incomplete TRF for sample details per month		
6	Number of incomplete TRF for customer details per month		
7	How many times single customer attended per trip per month		
8	How many days per month was idle		
9	How many times sample reached laboratory after 4pm		
10	How many sample rejected per month due to loss of sample integrity during transportation		

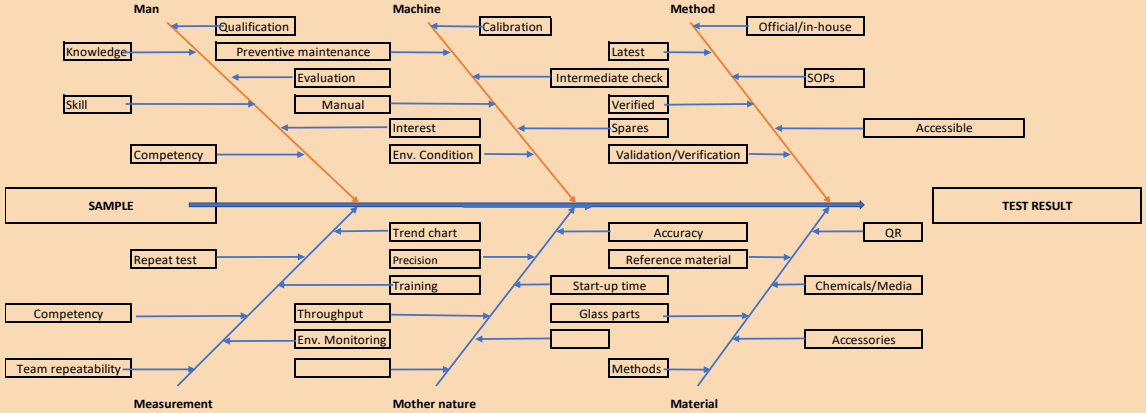
Lab Admin - sample registration



Quantitative data of each CTQ:

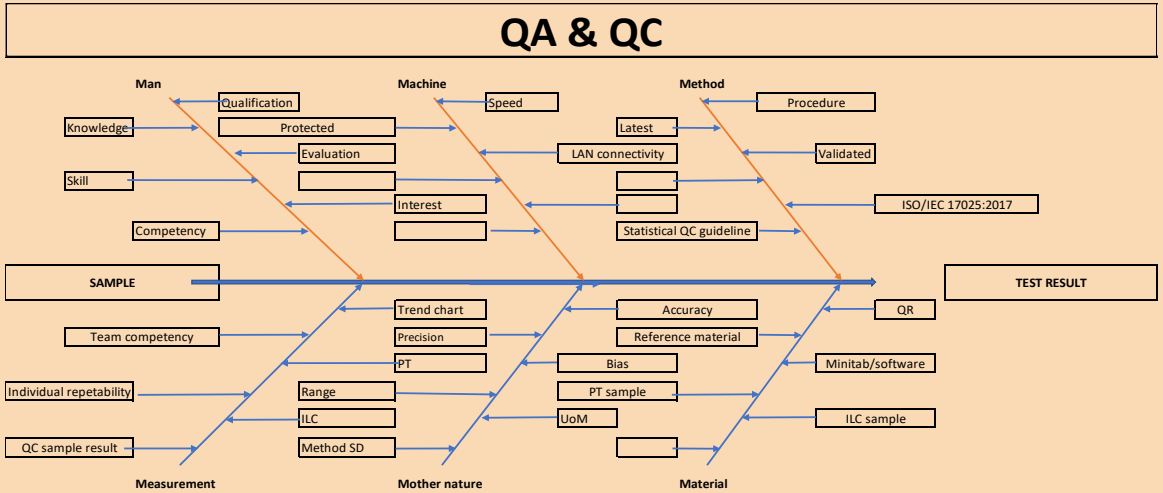
Sr. No.	CTQ	Discrete data	Continuous data
1	How many incomplete TRF		
2	How many delayed in collection		
3	How many times sample integrity fails during transportation		
4	How many samples failed in physical verification		
5	How many entry has errors in data entry		
6	How many sample registration took times more than 5 minutes		
7	How many samples forwarded to process after 15 minutes from sample receive time		
8	How many sample entry is without date and time		
9	How many incomplete jobsheet issued		
10	How many sample retained but no record available		

Processing - Chemistry & Microbiology



Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	Number of sample rejected from process		
2	Number of sample received 15 minutes after inward time		
3	Number of days process did not receive forecast		
4	Number of repeat analysis due to problem with reagent		
5	Number instrument for which calibration date expired		
6	No. of training conducted per person		
7	No. of training conducted against which has no improvement observed		
8	Instrument preventive maintenance record available (Y.N)		
9	Intermediate testing record available (Y/N)		
10	No. of instrument without service contract		
11	No. of records without verification		
12	No. of test failed in QC		
13	No. of repeat test not within acceptable tolerance		
14	No. of days where value out of the control limit in trend chart		



Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	Number of sample cancelled/month		
2	Number of sample delayed to issue/month		
3	No. of sample delayed to report/month		
4	No. of repeat analysis conducted per month		
5	No. of repeat test out of limit/month		
6	No. of test for retained sample analyzed per month		
7	No. of repeat test for retained sample out of limit/month		
8	No. of test failed during team repeatability check/month		
9	"Z" score of test out of limit/ILC		
10	"Z" score of test out of limit/PT		
11	ILC participated per month		
12	PT participated per month		
13	No. of Error in TRF Vs. total TRF		
14	No. of report with error per month		

Note: Besides each fish-bone diagram, the CTQ chart given. Identify the CTQ to be monitored and write them. Gather data and write in proper column for discrete or continuous data.

CT (Critical To) Matrix

CT Matrix										
Product Tree Complex Level / Process Tree Subsystem Level										

Note: Refer next page for one example on how to use CT Matrix.

Critical To Matrix will be used for:

1. CTP – Critical To Process
2. CTQ – Critical To Quality
3. CTS – Critical To Satisfaction
4. CTD – Critical To Delivery
5. CTC – Critical To Cost

Example of CT Matrix

CT MATRIX (Critical To)

Product Tree Complex Level / Process Tree / Subsystem Level	Need sample collection at the earliest	Need regional laboratory	Need accredited laboratory	Need cost 30% lower than competition	Need report within 3 days	Need to know sample status	Need reliable report	Need interpretation	Need solution	
Logistic										
* Pre-defined test profile	X								X	2
* Sample collection kit	X	X		X		X				4
* Sample trasportation	X	X			X				X	4
Processing										
* Barcoded	X	X			X	X				4
* Automated analyzer				X	X	X	X			4
* Statistical QC				X	X		X	X	X	5
* LIMS interface	X			X	X	X	X	X	X	7
Customer support										
* Food technologist	X							X	X	3
* Customer portal	X				X	X	X	X	X	6
* Auto report preparation				X	X	X	X	X		5
* Report traceability			X		X	X	X	X	X	6
* Contracts	X	X	X	X	X	X		X	X	8
Administrative Process										
* Finance/Budget	X	X	X	X	X				X	6
* HR relations	X									1
* Strategic plan & communication	X		X	X	X	X		X	X	7

C&E Matrix (Cause and Effect):

This can be used after prepared the Fish-Bone diagram.

C&E (Cause & Effect) Matrix

	Rating of Importance to Customer (1 - 10)																
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Process Inputs	Process Outputs																Total
1																	0
2																	0
3																	0
4																	0
5																	0
6																	0
7																	0
8																	0
9																	0
10																	0
Total Column Score		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Note: To use this, write the process output from left to right, right the process input from top to bottom. Give ranking for each process output at "Rating" column. Now give "X" mark where you feel that process input relates to the process output. Then total the score. This will tell which process input need to focus more.

Trend Chart (Run Chart)

Trend chart (run chart) allow to study observed data for trends or patterns over a specified of time.

A trend chart

- Monitors the performance of one or more processes over time to detect trends, shifts or cycles.
- Allows to compare a performance measure before and after implementation of a solution, to measure its impact.
- Focuses attention on truly vital changes in the process.
- Tracks useful information for predicting trends.

How to do it

1. Decide on the process performance measure.
2. Gather data (generally 20-25 data points should be collected to detect meaningful patterns).
3. Create a graph with a vertical line (y axis) and a horizontal line (x axis).
    a. On the vertical line (y axis), draw the scale related to the variable being measured.
        i. Arrange the y axis to cover full range of the measurements and then some (e.g., $1^{1/2}$ times the range of data).
    b. On the horizontal line (x axis), draw the time or sequence scale.
4. Plot the data
   Look at the data collected. IF there are no obvious trends, calculate the average. Draw a horizontal line at the average value.
   Tip: Do not redraw this average line every time new data is added. Only when there has been a significant change in the process or prevailing conditions should the average be recalculated and drawn, and then only the using the data points after the verified change.

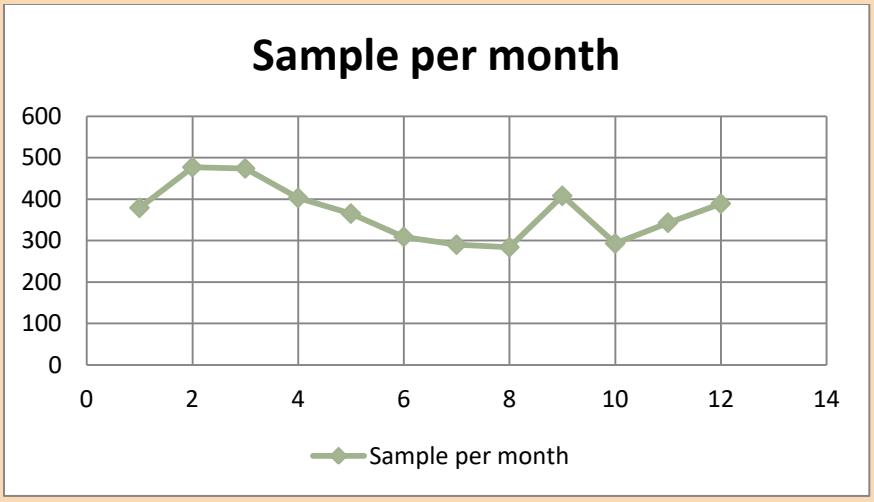
5. Interpret the chart
   Note the position of the average line. Is it where it should be relative to a customer need or specification? Is it where the organization wants it to be, relative to the business objective?
   Tips: A danger in using a Run Chart is the tendency to see every variation in data as being important. The trend chart should be used to focus on truly vital changes in the process. Simple tests can be used to look for meaningful trends and patterns.

Where it can be used

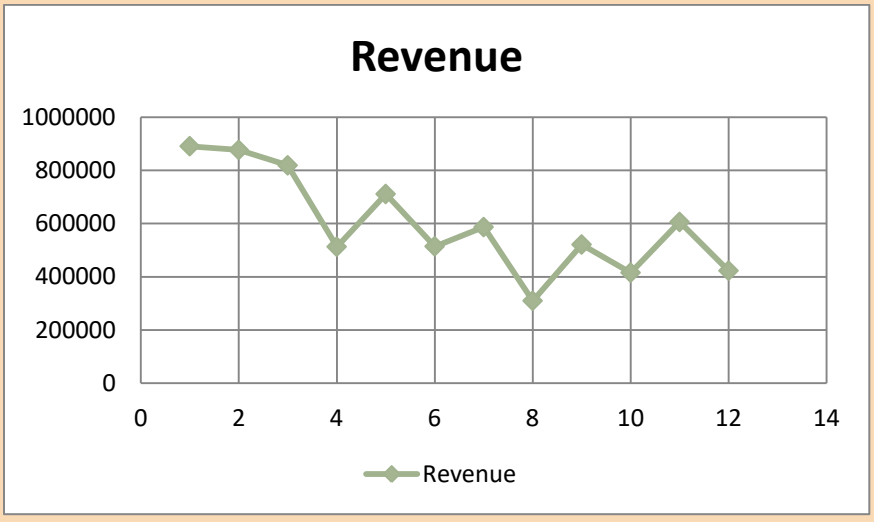
If you are in stock market, you have observed that the investor monitor the trend of the market by the trend chart. There is no limit for the market for maximum rise or fall for the day. But from the trend the investor decides when to invest and when to sale it off.

In laboratory, the trend chart successfully using by marketing, finance and accounts section. The processing section using trend chart for costly consumables and reagents. There are lots of applications of trend chart in laboratory and more you will work on it, more opportunity you will explore.

Below are few examples of different sections:

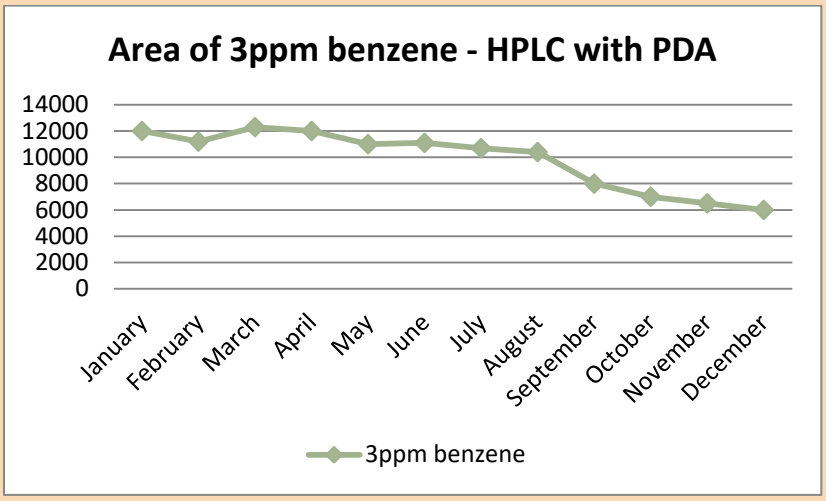


Note: We can see there is decrease of sample load in the laboratory and it is alarming.



Note: We can see the revenue also has reduced month over month, but interesting part is that the pattern is not same as of sample quantity. Means, there are requirements of different test which influencing the revenue. So, the

management should focus on the test which gives high return and should explore the strategy to increase the demand of those tests.



Note: Pattern of area of 3ppm Benzene month over month. From here lots of factors can be identified to focus. First is that, as area is reducing, means the sensitivity is reducing, which may not impact the precision and accuracy, but definitely will impact on sensitivity / detectivity and so it will affect the quality of test. Second, is that why the response decreasing? Where to focus – the lamp energy, or the optics? Needs service or need to change the parts?

Now you understood, instead of looking after value on paper, it is always more presentable and understandable quickly through the graph and where and how this trend chart can be utilized.

Pareto Chart

From the trend chart, we now know the trend. Then we evaluate if the trend is in our favor or not. If in favor, then now have to know what the factors help to improve are and if failed, then what are the reason to fail. To do this we will take the help of Pareto Chart.

A Pareto chart focuses efforts on the problems that offer the greatest potential for improvement by showing their relative frequency or size in a descending bar graph.

A Pareto chart:

- Helps to focus on those causes that will have the greatest impact if solved.
- Is based on the proven Pareto principle: 20% of the sources cause 80% of any problem.
- Displays a relative importance of problems in a simple, quickly interpreted, visual format.
- Helps prevent “shifting the problem” where the “solution” removes some causes but worsens others.

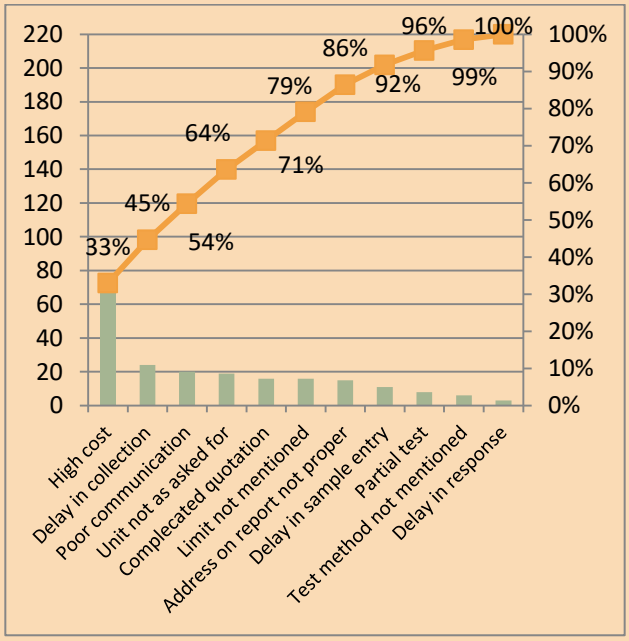
- Measures progress in a high visible format that provides incentive to push on for more improvement.

How to do it

1. Decide which problem to focus on.
2. Using brainstorming or existing data, choose the causes or problems that will be monitored, compared, and rank-ordered.
3. Choose the most meaningful unit of measurement such as frequency or cost.
   Sometimes it is difficult to know before the study is done which unit of measurement is best. Be prepared to do both frequency and cost.
4. Choose the time period for the study.
   Choose a time period that is long enough to represent the situation. Longer studies don't always translate to better information. Look first at volume and variety within the data.
   Make sure the scheduled time is typical in order to take into account seasonality or even different patterns within a given day or week.
5. Gather the necessary data on each problem category either by "real time" or reviewing historical data.
6. Compare the relative frequency or cost of each problem category.
7. List the problem categories on a horizontal line and frequencies on a vertical line.
8. Draw the cumulative percentage line showing the portion of the total that each problem category represents.
9. Interpret the results.

Example:

Problem category	Frequency	Cumulative %
High cost	68	33%
Delay in collection	24	45%
Poor communication	20	54%
Unit not as asked for	19	64%
Complicated quotation	16	71%
Limit not mentioned	16	79%
Address on report not proper	15	86%
Delay in sample entry	11	92%
Partial test	8	96%
Test method not mentioned	6	99%
Delay in response	3	100%



As I know now some basic tools to monitor the process, now I have to know some common calculation which I need to use to understand how my process behaves before improvement steps and after improvement steps.

The following minimum calculation I have to know:

1. Average (mean), median and mode
2. Estimate the standard deviation for a sample and population
3. Defect per million opportunities (DPMO)
4. Process capability (Cp and Cpk)
5. 'z' score

Let's start:

Mean, Median and Mode

A water sample analyzed 9 times for the determination of chloride content for a known concentration of 20mg/L. Data obtained as follows:

Run No.	Value obtained, mg/L
1	18
2	17
3	21
4	17
5	19
6	17
7	21
8	19
9	17
Total =	166
Mean (total/no. of observation) =	18.44

If we arrange the data from lowest to highest then it looks like:

17, 17, 17, 17, 18, 19, 19, 21, 21

Here the "18" is the middle one and both of this side have 4 readings. So, the median is 18.

Now, if the data are as follows:

17, 17, 17, **17**, **18**, 19, 19, 21

Then, we can see there are 8 values and which one will be the median? In this case, we have to take the average of two mid values (here average of 17 & 18, shown above in "bold"). So, the median will be (17+18)/2 or 17.5.

Now if we see the values in the above, we can see "17" has obtained 4 times, "18" one time, "19" two times and "21" two times. Value "17" has obtained maximum times, hence Mode is "17".

Standard deviation

Standard deviation we calculate to see the deviation of observations from a target value or a process mean. This calculation can be done for entire population (all values of analysis) or a sample (some of the values from entire population). For better understanding, suppose in a production unit, throughout the day they are producing pencils which has fixed length and diameter. Now I can measure all the pencils length and diameter which has produced for the day and can calculate the deviation on length and diameter. This is population. Now, this is not possible. So, I can taken one pencil from the production from a fixed time interval (e.g., after every 30 minutes) and then end of the day I can calculate the deviation. This is sample.

Standard deviation for a population:

Calculation	Formula	Notes
Population Standard Deviation	$\sigma = \sqrt{\frac{\sum(Xi - \mu)^2}{N}}$	μ = population average X = individual values in population N = count of values in population
Sample Standard Deviation	$S = \sqrt{\frac{\sum(Xi - \bar{X})^2}{n-1}}$	$\bar{X}$ = sample average X = individual value of sample N = count of individual values in sample

Note: For population mean we use μ and population standard deviation as σ. For sample mean we use $\bar{X}$ and sample standard deviation as S.

In the next page the values of 90 readings for chloride estimation in water given. For those values, now we will calculate the standard deviation for population and sample.

Total 90 values collected, as mentioned below (unit = mg/L)

A	B	C
Value	(A-mean)	B^2
10	0.042	0.0018
10.2	0.242	0.0587
9.8	-0.158	0.0249
10.3	0.342	0.1171
9.7	-0.258	0.0664
9.9	-0.058	0.0033
10.3	0.342	0.1171
9.8	-0.158	0.0249
9.6	-0.358	0.1280
10.3	0.342	0.1171
10.2	0.242	0.0587
10.4	0.442	0.1956
9.8	-0.158	0.0249
9.9	-0.058	0.0033
9.7	-0.258	0.0664
9.8	-0.158	0.0249
10.2	0.242	0.0587
10.3	0.342	0.1171
10	0.042	0.0018
10.2	0.242	0.0587

A	B	C
Value	(A-mean)	B^2
9.7	-0.258	0.0664
9.9	-0.058	0.0033
10.2	0.242	0.0587
10.3	0.342	0.1171
10.1	0.142	0.0202
10.1	0.142	0.0202
9.6	-0.358	0.1280
9.9	-0.058	0.0033
10.1	0.142	0.0202
10.1	0.142	0.0202
9.9	-0.058	0.0033
10.2	0.242	0.0587
9.9	-0.058	0.0033
9.9	-0.058	0.0033
10.3	0.342	0.1171
10.1	0.142	0.0202
10	0.042	0.0018
10.2	0.242	0.0587
9.6	-0.358	0.1280
10.1	0.142	0.0202

A	B	C
Value	(A-mean)	B^2
9.9	-0.058	0.0033
10.1	0.142	0.0202
9.8	-0.158	0.0249
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9.9	-0.058	0.0033
10.2	0.242	0.0587
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9.8	-0.158	0.0249

A	B	C
Value	(A-mean)	B^2
9.9	-0.058	0.0033
9.6	-0.358	0.1280
10.1	0.142	0.0202
10.2	0.242	0.0587
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10.3	0.342	0.1171
9.8	-0.158	0.0249
10.3	0.342	0.1171
10.1	0.142	0.0202
9.8	-0.158	0.0249
9.8	-0.158	0.0249
10	0.042	0.0018
10.2	0.242	0.0587
9.7	-0.258	0.0664
9.7	-0.258	0.0664
10.2	0.242	0.0587
9.9	-0.058	0.0033
10.2	0.242	0.0587
9.8	-0.158	0.0249

	A	B	C
	Value	(A-mean)	B^2
	10.2	0.242	0.0587
	9.6	-0.358	0.1280
	9.8	-0.158	0.0249
	10.2	0.242	0.0587
	9.8	-0.158	0.0249
	9.6	-0.358	0.1280
	9.7	-0.258	0.0664
	9.8	-0.158	0.0249
	9.9	-0.058	0.0033
	9.9	-0.058	0.0033
Total =	896.2		4.3996
Mean (μ)=	9.96		
Std. Dev. (σ) =	0.22		0.22
	Through Excel		By calculation

Total sample, N = 90
Mean (μ) = 9.96
Std. Dev. (σ) = 0.22
Xi = Individual value = Column A
Xi - μ = Individual value – Mean = Column B
$(Xi - \mu)^2$ = Square of (individual value – mean) = Column C

Formula for standard deviation for population

$$\sigma = \sqrt{\frac{\sum(Xi - \mu)^2}{N}}$$

So,

$$\sigma = \sqrt{\frac{\sum(Xi-\mu)^2}{N}} = \sqrt{\frac{4.3996}{90}} = 0.22$$

Note: Same we are getting in excel. All 90 values have been given here so that you can practice.

Now, we will calculate the standard deviation for a sample. Data will be taken from above table with a fixed interval (in the example, I have taken data after every 5).

If you see the data, you will see that a particular value has obtained multiple times, but interval is not same. So, when we take the sample from a population, if it does not represent more closely to population, there will always be chances to get wrong prediction. If data's are normally distributed, we will get results of samples close to the population. So, selecting the sampling method is very important when we are going to assume about population by analyzing sample data.

Let's see what we get result after taking sample interval of 5.

Sampling after each 5 values:

	A	B	C
Sr. No. of earlier table	Value	(A-mean)	B^2
1	10	0.094	0.0089
6	9.9	-0.006	0.0000
11	10.2	0.294	0.0867
16	9.8	-0.106	0.0111
21	9.7	-0.206	0.0423
26	10.1	0.194	0.0378
31	9.9	-0.006	0.0000
36	10.1	0.194	0.0378
41	9.9	-0.006	0.0000
46	9.7	-0.206	0.0423
51	9.9	-0.006	0.0000
56	10.2	0.294	0.0867
61	9.9	-0.006	0.0000
66	9.7	-0.206	0.0423
71	9.8	-0.106	0.0111
76	9.7	-0.206	0.0423
81	10.2	0.294	0.0867
86	9.6	-0.306	0.0934
Total =	178.3		0.6294
Mean ($\bar{X}$)=	9.91		
Std. Dev. (S) =	0.192		0.192
	Through Excel		By calculation

Total sample, n = 18
Mean (μ) = 9.96
Std. Dev. (σ) = 0.22
Xi = Individual value = Column A
Xi - $\bar{X}$ = Individual value – Mean = Column B
$(Xi - \bar{X})^2$ = Square of (individual value – mean) = Column C

Formula for standard deviation for population

$$S = \sqrt{\frac{\sum(Xi - \bar{X})^2}{n - 1}}$$

So,

$$\mathcal{S} = \sqrt{\frac{\sum(Xi-\bar{X})^2}{n-1}} = \sqrt{\frac{0.6294}{18-1}} = 0.192$$

Note: Same we are getting in excel. All 18 values have been given here so that you can practice. You should practice this by selecting different values form the first 90 values.
You can see that instead on "n-1", if you take "n", which are 18, then the value for S will be 0.187.

Now we can see, there is a difference of standard deviation of a population and sample. This variation depends on the each individual value pooled from population with a **pre-defined frequency**.

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DPMO (Defect Per Million Opportunities)

For every work there are multiple opportunities to do things wrong. As a QC person, it is our responsibilities to find out those parameters, monitor those parameters and inform the respective section/person to reduce those errors. To find out those parameters (known as CTQs, Critical To Quality) we can use different tools (e.g., process map, Ishikawa diagram, work flow chart, FMEA, etc.). Once we know the parameters, we monitor, gather data and calculate the defect rate in terms of DPMO.

To calculate DPMO, the data may be defect and defective.

To calculate the DPMO, we have to know the total defects, from how many samples defect identified and opportunity for error for each sample and then calculate the DPMO using following table:

Example: A sample request form has provision to enter 14 information to write by the customer and all are mandatory. It is the responsibility of the front office to ensure that Walk-In customer has filled-up the form and entered all 14 fields. The QC has verified 200 forms and found there are 284 empty fields. So,	
Defects	284
Sample	200
OFE (Opportunity for Error)	14
TOEF (Total Opportunity for Error)	2800 (sample x OFE)
DPO (Defect Per Opportunity)	0.10 (defects/TOFE)
DPMO (Defect Per Million Opportunity)	101429 (DPO x 10^6)

Now, refer below examples for defective %:

Example: The evaluate the slant preparation by a microbiologist, the HOD asked him to prepare 200 slants. Once prepared, the HOD checked the angle of the slant for each slant and found 40 slants are not with desired slope (remember what written earlier, the CTQ to be decided before each evaluation). So,	
Defective	40
Sample	200
Yield (%)	80 [(passed/sample)*100]
Defect (%)	20
DPMO (Defect Per Million Opportunity)	200000 [Defect%/100) x 10^6]

Means, if the microbiologist, with present competency, prepares 1milion slant, then 200000 slants will be rejected. So, these DPMO calculation will help to understand where to focus. Lesser the DPMO, better the process performance. It can be used to monitor those performances where defect can be calculated.

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Process capability (Cp and Cpk)

Before we control the process/quality, we have to understand first what the present performance is and that is the capability of process – whether it is throughput or variation.

Cp and Cpk, commonly referred to as process capability indices, are used to define the ability of a process to produce a product that meets requirements. To understand Cp and Cpk we must have an understanding of the following terms:

- Specifications: Specifications define product requirements. In other words, they define what is expected from an item for it to be usable. Specifications are normally defined in terms of nominal (+/-) tolerances or ranges (low to high). A specification for a piston ring, for example, might specify that the diameter be 74mm +/- 0.05mm. The upper specification limit (USL) is the upper limit of the specified range. Similarly the lower specification limit (LSL) is the lower limit of the specified range. In testing laboratory, when we perform any test, we set LSL and USL for a given concentration for that test. As for example, to estimate vitamin by HPLC, we perform CCV (Continuous Calibration Verification) after a periodic interval and set a limit within which the value should come (the limit normally we set at 2 or 3 standard deviation, which again decides by repeated analysis during method validation/verification).
- Standard deviation: Explained earlier.
- Mean: Explained earlier.

The Cp index is calculated using specification limits and the standard deviation only. This index indicates, in general, whether the process is capable of producing products to specifications. No information on the ability of the process to adhere to the target value is included in this index.

The formula for Cp is as follows:

$Cp = (\text{Upper spec} - \text{lower spec}) / 6\sigma = (USL-LSL)/6\sigma$

The Cpk index is calculated using specification limits, the standard deviation, and the mean. The index indicates whether the process is capable of producing within specification and is also an indicator of the ability of the process to adhere to the target specification.

The formula for Cpk is as follows:

$Cpk = \min(CpU, CpL)$; where $CpL = (\text{Mean} - LSL)/3\sigma$ and $CpU = (USL - \text{Mean})/3\sigma$

Cpk is more widely used than Cp, since it takes into account the mean and the standard deviation in its calculation. Please note that the difference between Cp and Cpk is an indicator of how far the average of the process is from the target specification. When the average of the process approaches the target value, the gap between Cpk and Cp closes. When the average of the specification is equal to the target value, then Cpk is equal to Cp. Cpk can never exceed Cp.

Case 1	
USL	24
LSL	18
Mean	21
σ	0.5
Cp	(24-18)/6*0.5 = 2
CpL	(21-18)/3*0.5 = 2
CpU	(24-21)/3*0.5 = 2
Cpk	2

Case 2	
USL	24
LSL	20
Mean	21
σ	0.5
Cp	(24-20)/6*0.5 = 1.33
CpL	(21-20)/3*0.5 = 0.66
CpU	(24-20)/3*0.5 = 2.66
Cpk	0.66

Case 3	
USL	24
LSL	18
Mean	21
σ	1.5
Cp	(24-18)/6*1.5 = 0.66
CpL	(21-18)/3*1.5 = 0.66
CpU	(24-21)/3*1.5 = 0.66
Cpk	0.66

Case 4	
USL	24
LSL	20
Mean	21
σ	1.5
Cp	(24-20)/6*1.5 = 0.44
CpL	(21-20)/3*1.5 = 0.22
CpU	(24-20)/3*1.5 = 0.88
Cpk	0.22

Some common interpretation:

1. *In both Cp and Cpk, the higher the value, the better.*
2. *The Cp value does not change as the process is being centered to target unless something in the process changes.*
3. *The Cp and Cpk values will be equal if the process is perfectly centered.*
4. *Cpk is always equal to or smaller than Cp.*
5. *If the Cpk value becomes negative number, then the process average is outside one of the specification limits.*

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'z' score

A z-score describes the position of a raw score in terms of its distance from the mean, when measured in standard deviation units. The z-score is positive if the value lies above the mean, and negative if it lies below the mean.

Simply put, a z-score (also called a standard score) gives you an idea of how far from the mean a data point is. But more technically it's a measure of how many standard deviations below or above the population mean a raw score is.

It is also known as a standard score, because it allows comparison of scores on different kinds of variables by standardizing the distribution. A standard normal distribution (SND) is a normally shaped distribution with a mean of 0 and a standard deviation (SD) of 1.

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

Where, x = value obtained, μ = mean, σ = standard deviation

Suppose, the mean of results obtained for chloride content for a water sample, which has been analyzed by 10 different chemists is 74 mg/L and standard deviation observed is 4. Your result is 70 mg/L. Then what will be your z-score?

Here, x = 70 mg/L, μ = 74 mg/L, σ = 4

$Z = (x-\mu)/\sigma = (70-74)/4 = -1$

Note: A z-score close to 0 says the data point is close to average.