CHM411 – QUALITY CONTROL

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What is quality?

- It is hard to give an-embracing definition of what quality or good quality means. Often it depends on each observer's view. Quality here is fitness for the required purpose and this is usually defined on the expense of the customer. The quality of a product is determined by how well it suits your needs.

- To define quality for practical purpose, we use some parameters which define the acceptability of the product which is called “product specification” This includes some parameters defining the quality of the materials and also that of the package of the finished product.

Definition

- In general, we may define quality as a measure to which a particular product satisfies the expectation of consumer with respect to certain tangible and intangible attributes inherent in the design of the product or service and its performance under normal use.
- [Reliability/durability/safety/maintainability/cost]

Obj. of Quality Control programmes

- Reduction of scrap or wastage rate
- Minimization of customer's complaint and products return rate
- Maintenance of the desired degree of conformance to product design
- Increasing the production of non-defective products going to customers
- Prevention of defective raw material from getting into production system
- Enhancing the conformance of product performance with customers' expectation

Roles of Quality Controller

- To ensure that the product of the company conforms to the product specification and time of delivery.
- To make sure that the product is produced at the right price, i.e. minimizing the cost by obtaining the specified product quality at the lowest possible cost.
- The quality control unit is also one of the policy units of any organization.

Quality control system

In most establishment, quality control starts from the planning stage of the product. To design a product, first step is to produce “master document” in which all the detailed description of the product is specified.

Master Document

These include:

- Product specification
- A list of the raw materials needed to be used and also for the packaging
- A complete list of all equipment to be used
- Step by step account of all the process by which the product will be made, including the way it is going to be packed and also where the product is to be delivered.

- The master document is very important and only few people have access to this document. From the master production document, a batch production document is produced and this gives a step by step account of how a batch is to be produced. Once this is obtained, production commences.

Phases of Quality Control

- To achieve the objectives of quality control, efforts must be built in from three different contexts as stated below; any attempt at controlling product or service quality must focus on the three perspectives.

A. Product or service quality design

Quality must be inherent in the design of the product.

- Once quality has been built into a product from the design stage, higher product quality can be enhanced in subsequent stages.

B. Production of manufacturing quality

- Efforts must be made to manufacture product with correct and specified process and with meticulous adherence to all the engineering details.
- The quality of the manufacturing process would be judged by the degree of conformance to this design specification.

C. Performance quality

- Performance quality is usually a function of the design and manufacturing quality.
- It relates to product's reliability, functionality and ease of maintenance and repair services.
- It is also a reflection of the extent to which the product's quality meets the customers' expectations.

Daily routine in a typical quality unit

- The function of any quality control department directly associates with getting out of product which is acceptable for consumers. The responsibility does not end with shipment of the products; it also follows product performance in the field.
- The following are some of the routine checks/roles in a quality control unit:

- Engineering model

  (conception of the idea).
- Verification & Standard of quality

  (this helps in the development of quality standards).
- Purchased material control (procurement of raw materials).

- Feeder section control; Assembling; Process control; Completed product & Inspection and testing (process control ensure that conditions for optimum performance of every process are maintained throughout, i.e. in terms of temperature, pressure, volume ratio, time etc. This process control is the work of production manager and not that of the quality control manager).

- Packaging; Design; Verification & Quality analysis (Quality analysis could be in any form, measurements, titration, IR, UV, NMR and GC etc.)
- Field performance (this is checking the products in the market to harvest opinion and see the changes with time).
- Product quality improvement (this is making recommendations based on field performance report, motivates the engineering department to re-design the product in order to improve its quality and the performance).

Areas concerned when changing production in an industry in order to improve quality

- Specifications
- Design
- Production
- Inspection
- Review of Specifications

See You Next Class & Keep Quality as your Watchword

Quality Control Procedures

Quality control procedures

- There are broadly three main approaches to quality control procedures in use. These include:

  - **Inspection methods** – it is either you accept/reject

  - **Acceptance sampling techniques**

  - **Process control procedures** - constantly examine input and output and refine process.

Inspection methods

- It involves checking or inspecting the quality of in-coming raw materials, process inventories or final outputs to ensure conformance with specified quality level.
- Inspection, therefore, is an integral part of the quality control system.

Decision variables

- Consequently, questions about many fundamental decision variables have been raised. These include:

  - What to inspect?
  - How many to inspect?
  - When to inspect?
  - Where to inspect?

What to inspect?

- The question as to what to inspect can be readily answered if efforts can be made to identify critical product or services characteristics, the nature of which is fundamental to our taking a decision as to whether that product or service is good or bad. Inspection is aimed at checking variability in product sizes, shapes and thickness from the prescribed standards.

What are some of the different ways to inspect processes?

- Gating - Only examine final product for pass/fail.
- Design of Experiments - Various process parameters can be varied (e.g. speeds, feeds) and the effects examined to determine the best settings for a process.

- Statistical Process Control (SPC) - Various measurements may be done on a part after processing, and the process can be adjusted to keep it within spec.
- Total Quality Management (TQM)- Try to improve employee attitude.

How many to inspect? (3 ways)

No.1: 100% Inspection

Inspection may take the form of 100% inspection of all manufactured products. While this approach can greatly minimize the chances of passing defective items to the consumers, it is nevertheless, an expensive approach.

No. 2: Skip-Lot Inspection

- Instead of 100% inspection, a company may choose to inspect using the skip-lot inspection approach. For example, where there are 10 bags of an item to be inspected, the company may want to inspect only bags with serial numbers 1, 3, 5, 7 and 9.

No.3: Critical Parts Inspection

- Sometimes inspection may be limited to those critical components of the product or services on whose performance and reliability largely depends. For example, in a car manufacturing company, inspection efforts may be focused on such critical aspects such as the ignition and the electrical systems.

When to Inspect?

- This depends partly on the nature of the service or the product or its production process. In general, it is desirable:

  - When the cost of inspection per unit is minimal;

  - When the cost consequences of passing a defective output to the consumers is high; and

  - Whenever the process of inspection is not detrimental or destructive to the product.

Where to inspect?

- Generally, there are three established points of inspection:
  - ✓The point of entry of raw materials into the production systems;
  - ✓During manufacturing; and
  - ✓Prior to shipping the finished goods to the final consumers.

- However, there are many other critical points of inspection during the production process. These include the following:

✓ At a point before costly operations are embarked upon.

✓ At a point before the reversible operations.

✓ At a point before and after an operation which covers up defects.

✓ At a point before the finished goods are sent to the consumers.

Typical options when products fail inspection.

- Reworks (high cost)
- Scrap (high cost)
- Sell anyway (upset customers, poor reputation)
- Downgrade (lower returns), e.g. try to get largest chicken eggs, but when smaller eggs are produced, sell for less.

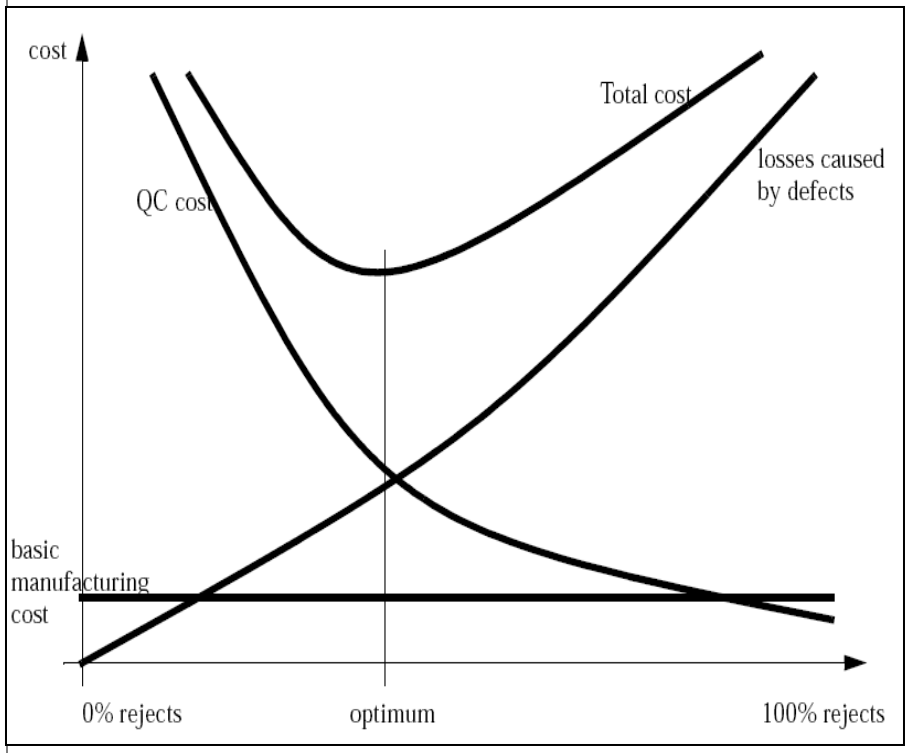
Does it cost more to inspect each process instead of the final product?

- The use of statistics allows small population samples to produce enough data for a process. And, it is much cheaper to adjust a process before problems occur, than it is to fix a completed product.

Basic Manufacturing Cost

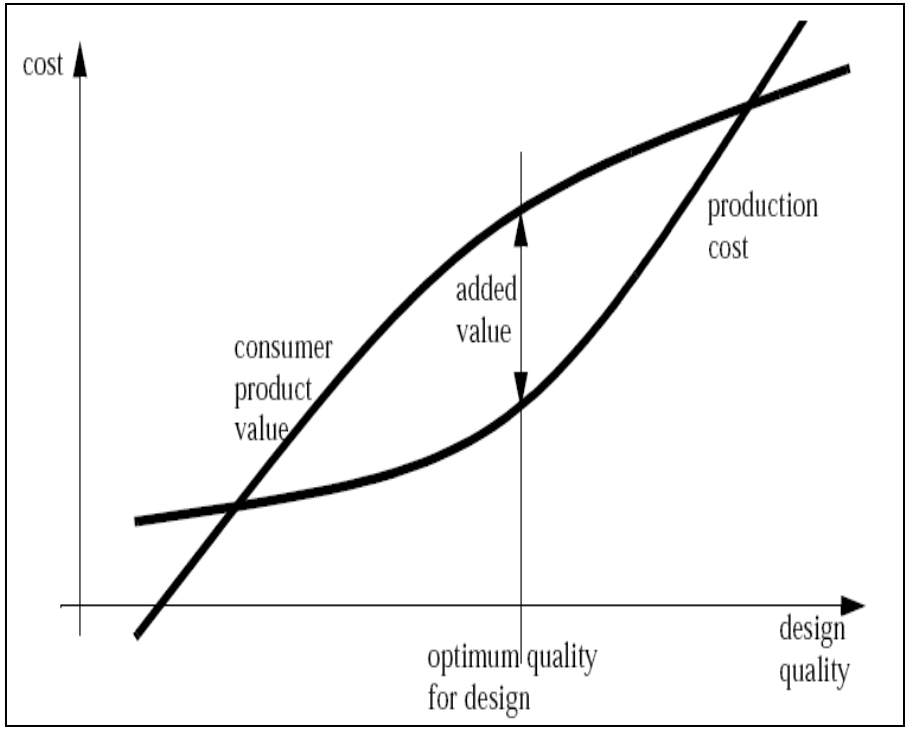
This is basic manufacturing cost per part associated with any piece. Considering quality levels; to improve quality to get 0% rejects (all parts good) costs rise significantly.

On the other hand if more rejects are produced, the economic losses rise. There is an optimal point to choose where the quality level of the product will give the optimal economic sense.



What about the cost of quality?

All products are the results of trade-offs - the most common factor is cost, others include size weight, etc. These vary between industries and products.



See You Next Class & Keep Adding Value to Your Quality to Enrich Your Future.

Statistical Quality Control

Statistical Quality Control

- Our discussion on statistical quality control will focus on two major concepts, namely:

❖The acceptance sampling and

❖The process control procedures.

Acceptance Sampling

In cases where inspection is not feasible like where inspection cost is high, or where inspection can be destructive, the use of acceptance sampling has been very prominent. Acceptance sampling is a "scheme for determining the acceptability of a lot based on sampling".

The procedure of acceptance sampling involves choosing a ***sample size*** from a ***lot*** of N items and comparing the number of ***defective items found*** in the sample against specified number of ***acceptable defects*** usually denoted by C.

The decision to accept or reject the lot from which sample came will depend on whether the **number of defects** found in the samples is **less or greater** than the stipulated and **acceptable number of defects.**

Thus, an acceptance plan with sample size **a** and acceptable detective items of size will enable us to reject lot whose number of defect items is greater than **c** and vice-versa.

From a lot with N= 1000 items. If from 20 drawn sample 7 defective items are found, the entire lot from where the sample came will be rejected. If, however, only 1 or 2 defective items are found, the decision will be to accept the lost as good.

Sampling Plans

There are three types of sampling plans in use; These are:

- The single sample plan;
- The double plan; and
- The sequential samples plan.

Single & Double Sample Plan

The single sample plan involves taking decision to accept or reject a lot on the basis of only one sample.

In the double samples plan, decision is based on the outcome of the two samples taken.

Sequential Sample Plan

In some cases, it may be necessary to take more than two samples. In such cases, the overall decision to accept or reject a lot is based on the aggregate outcome of the series (sequential) of samples that have been taken.

Acceptance Level

- In either of the sample plans, since “a finding of c or fewer defective items implies accepting the batch, c is often referred to as the acceptance level”.

It is possible that given an acceptance sampling plan (n,c); a good lot may be rejected and a bad lot may be accepted, particularly if the sample from which the lot is drawn is not representative of the whole lot.

Type I and Type II Errors

In statistical sampling theory, the risk of **rejecting a good lot** when it ought to have been accepted is referred to as Type I error (or the producer's risk).

On the other hand, the risk of **accepting a bad lot** as good is called Type II error (or consumer's risk).

The occurrence of these two types of error depends on how large the size of sample (n) is and how the acceptance level (c) has been chosen.

Usually, the larger the sample size (n) is, the greater the chances of minimizing these risks, i.e. the lesser the chances of committing these errors.

Discriminating Power of QC Curve

Based on fear of accepting an otherwise bad lot. It is clear that the **larger sample** has a much **higher probability of correctly accepting a good lot as good**.

Advantages of Large Sample Size

The larger the sample size, **the greater the reliability** of the result.

The larger sample is also better at **minimizing both risks** of accepting as good what is bad (Type II error) and rejecting as bad what is good (Type I error).

Process Control

Process Control

- Quality control efforts through sampling inspection procedure are largely a post-active effort. The focus is usually on finding out has many defects can be found in a lot or batch after the production process has been completed.

Process Control contd.

- Rather than wait to count how many bad units we have produced at the end of a production run, there is need to constantly monitor the production process periodically, say every two hours or so, with a view to determining whether the item that are being turned out meet the specifications or not.

Causes of Variation

- Variations may be attributed to **two major causes**.
- (1) **usual or chances variations**, which sometimes are unexplainable and uncontrollable, and
- (2) **assignable causes**, which are usually due to such factors as machine or tools, wear, faulty material and operator's fatigue.

- Whatever the causes of product or service variability, and given the fact that the process is out of control, one can, through control, initiate immediate corrective actions.
- Such actions may take the form of, for example, adjustment of the machine, oiling of some tools or changing to a new batch or raw materials.

Process Control Charts

- These are charts used in process to monitor the extent of variability in the quality standard of the finished items from a predetermined standard. It is chiefly used to discover very quickly when the process is going out of control.

- When such signal is received, the operations manager can act to prevent more sub-standard products from being produced by taking some corrective actions.
- Generally in quality control, attention is focused on controlling two types of product characteristics; the attributes and the variables.

Attributes

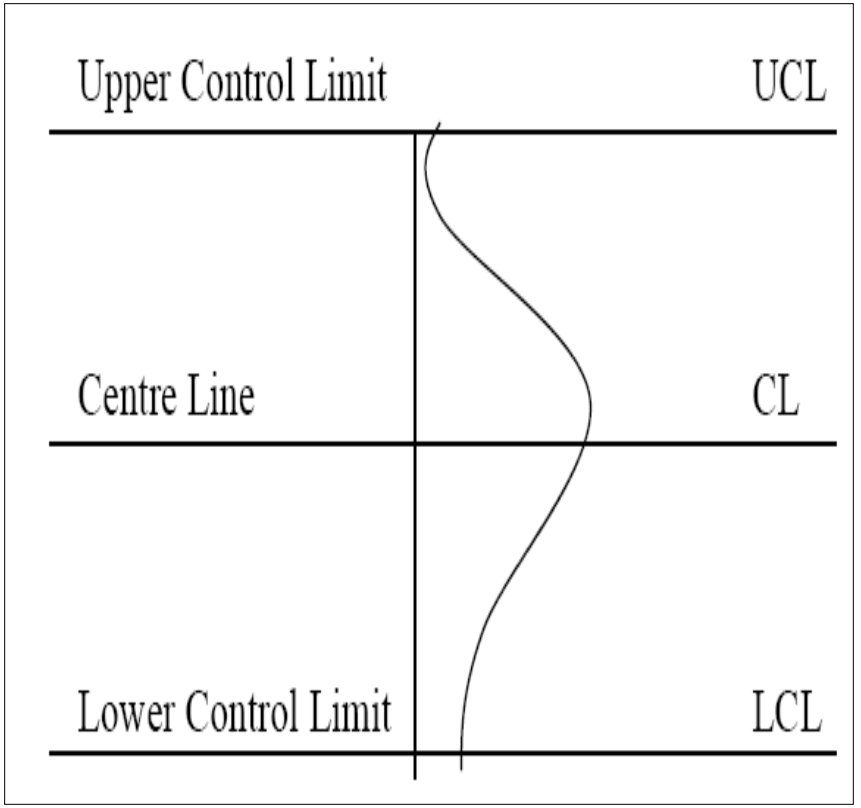
- Attributes are binary characteristics that are either present or not in a product and which basically determine the functionality of that product. They usually indicate whether a product is good or bad. E.g, the quality of an electric bulb is usually measured by its attributes; it either lights up or it does not. If it lights up then it is good, otherwise, it is rejected.

Variables

- On the other hand, variables are product characteristics that are usually subject to some variability, e.g in weight, size diameter, length, colour, etc.

Process Control Chart

- A process control chart has a central line, an upper control limit and a lower Control limit as shown in Figure beside:



Control Chart for Variables

- These are charts that are used to monitor and check variability in such product characteristics is weight, thickness, length, etc. periodically, samples are drawn from populations of products that are coming out of the system and are tested or measured to see the extent of variability from the required standard. Basically, there are two types of control charts for variables. **These are the X (or mean chart) and the R (or range chart)**

The $\overline{X}$ charts

- The mean or X chart is used to identify changes in the process average by way or finding out whether the means of the periodic samples taken at regular intervals fall within the control limits by
- Computing the mean of the sample means (center line)
- Computing the values for the upper and lower control limits (UCL and LCL)
- Plot the means of the various samples and see if all or most of the sample means fall within the control limits.

- To compute the means of the sample means, we first find the value for the respective sample means as follows:

$$\bar{X}_1 = \frac{X_{11} + X_{12} + X_{13} + \ldots X_{1n}}{n}$$

$$\bar{X}_2 = \frac{X_{21} + X_{22} + X_{23} + \ldots + X_{2n}}{n}$$

$$= \text{“}$$

$$= \text{“}$$

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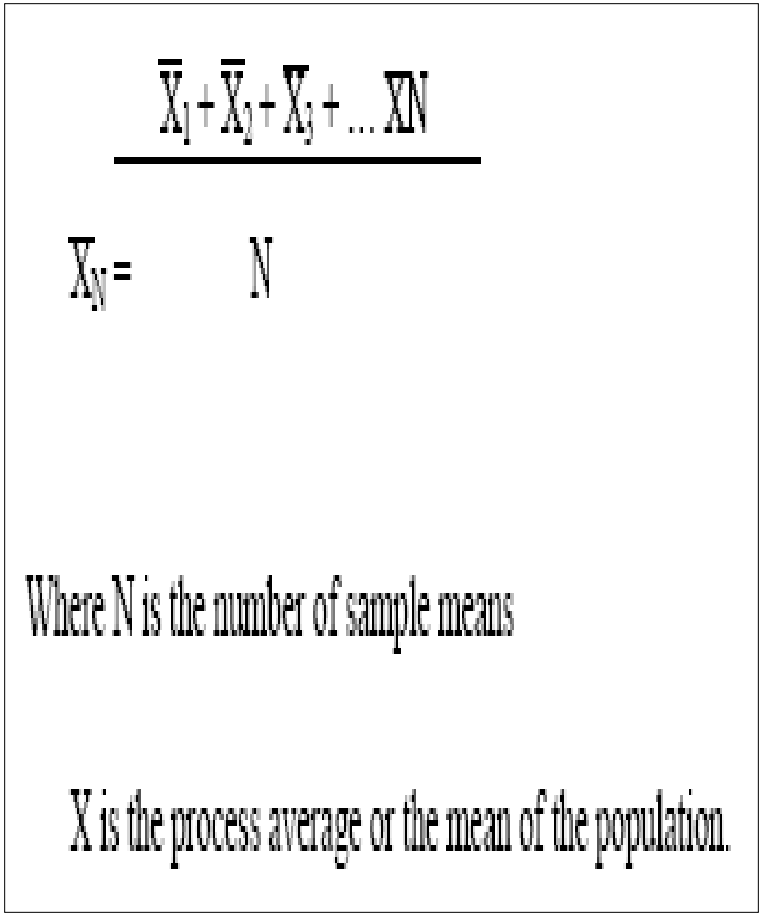
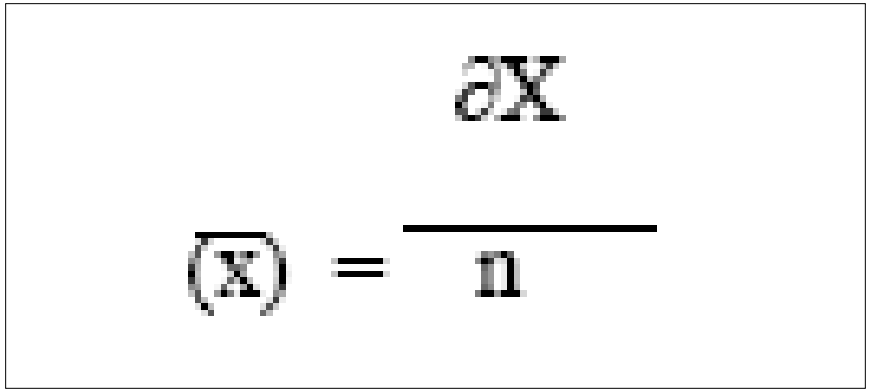
$$\bar{X}_N = \frac{X_{N1} + X_{N2} + X_{N3} + \ldots + X_{NN}}{n}$$

n = number of observations in the sample;

- Having found the means of the n sample, we now find the means of the sample means (X) as follows

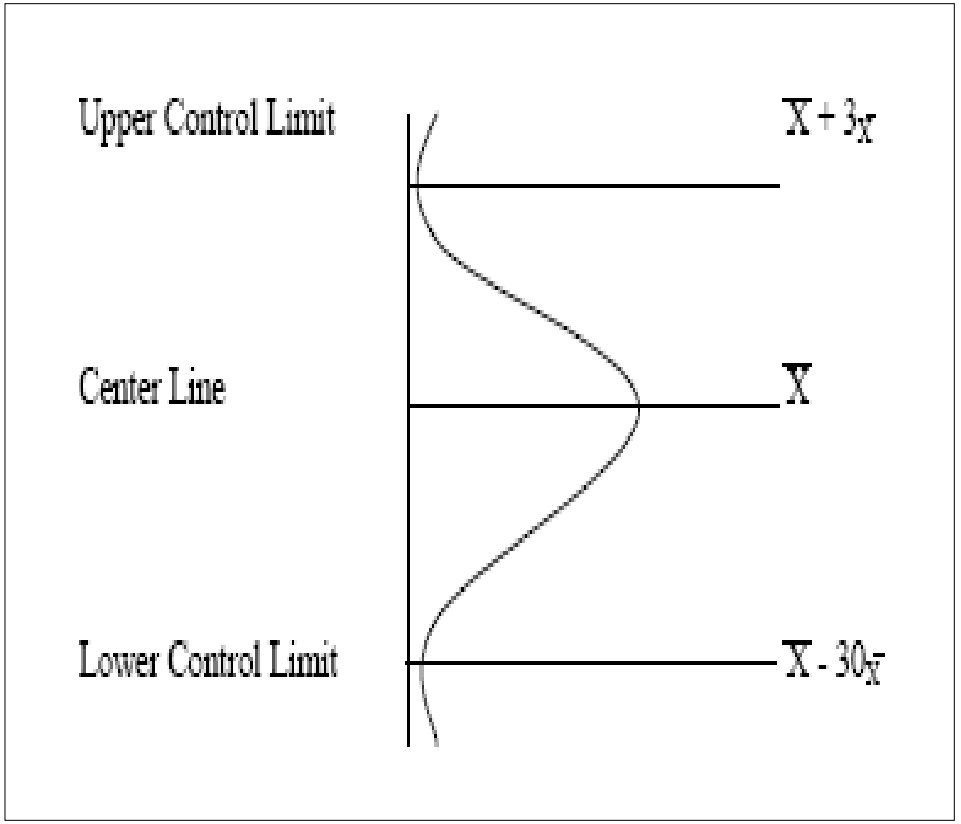


- **To compute both the UCL and the LCL, we need to find the standard deviation of the population. From the normal sampling theory, the variability of our sampling plan can be expressed in terms of the standard error of the mean which can be expressed as**



Process Control Limits

- The upper and the lower control limits will then be 3 away from the central line as shown in Figure by the side



- If we assume that we have a sample size n = 5, whose standard deviation = 0025, then

$$(\bar{X}) = \bar{X} = \frac{0.0025}{\sqrt{n}} = \frac{0.0011}{\sqrt{5}}$$

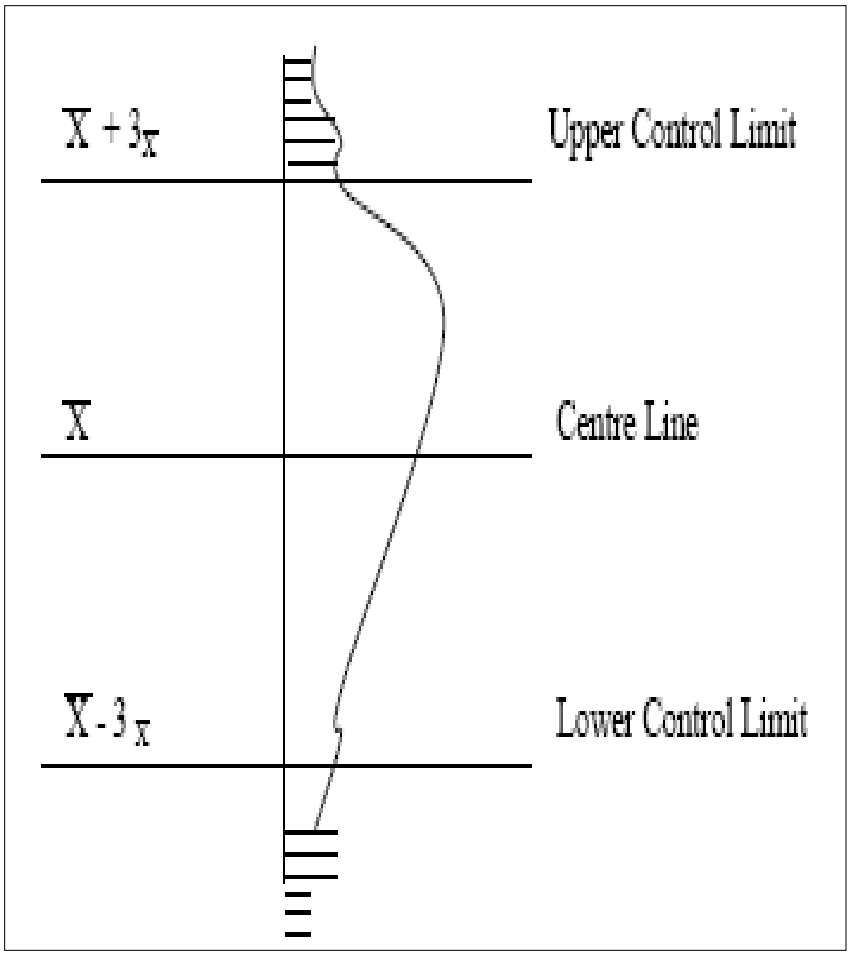
The control limits for the X – chart can therefore be written as follows:

$$\text{UCl} = \bar{X} + 3_{\bar{X}}$$

$$\text{Centre Line} = \bar{X}$$

$$\text{LCL} = \bar{X} - 3_{\bar{X}}$$

- Then the process control chart for the process will look like this figure



In control

- Having determined the control limits, a periodic sample of the outputs of the process is taken and the means are plotted on the control chart. If all means fall within the upper and lower control limits, we will conclude that the process is in control.

Out of control

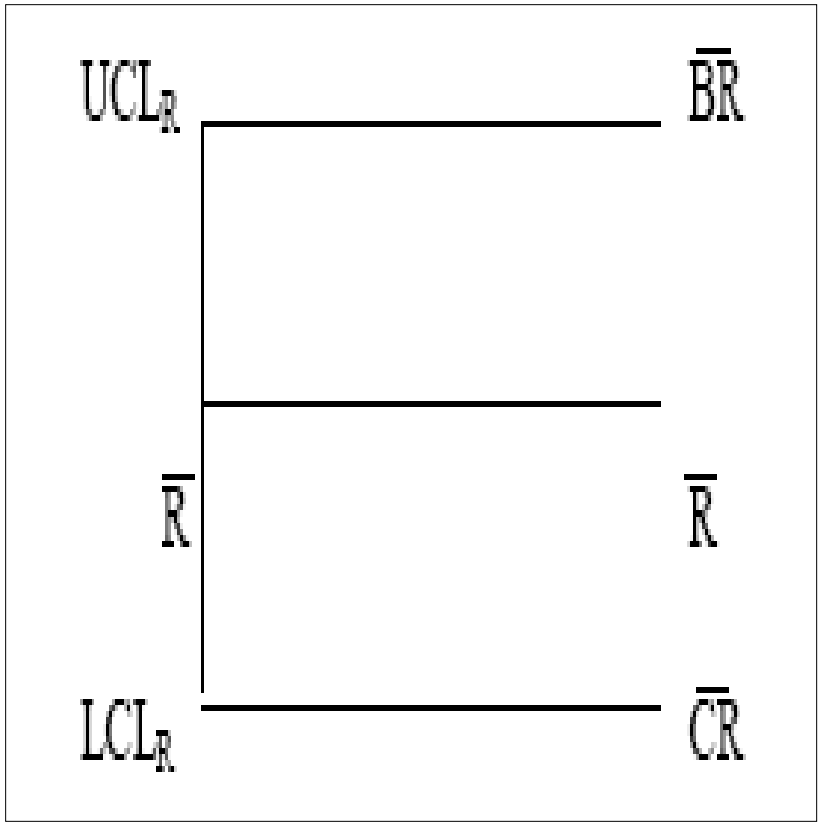
- However, if a reasonable number of them fall outside the control limits, then the conclusion is that the process is out of control and it will be stopped immediately in order to find out the cause of the problem.

The R (or Range) Chart

- This is a chart used mainly to control the range of product quality variability or to control the precious of the process. A range is normally defined as the difference between the largest and the smallest values in a sample. The R-chart is useful in monitoring product quality ranges so as to ensure that the variability is kept within acceptable limits.

Process Range Control Limits

- As it is with X chart, the UCL and the LCL are three standard deviations away from the mean of the sample ranges as shown in Figure



Typical Example

- **Suppose we are interested in controlling the variability in the diameter of a motor shaft. Three samples of size n = 5 were taken and the diameters were recorded as shown in the upper part of Table besides.**

Observations	Sample 1	Sample 2	Sample 3
1	1.026	1.010	1.040
2	1.019	1.018	1.039
3	1.020	1.012	1.029
4	1.030	1.024	1.028

- The sample averages as well as the ranges are calculated as shown in the lower part of the Table.

Observations	Sample 1	Sample 2	Sample 3
1	1.026	1.010	1.040
2	1.019	1.018	1.039
3	1.020	1.012	1.029
4	1.030	1.024	1.028
5	1.018	1.019	1.035
Average (X)	1.023	1.016	1.034
Range (R)	0.012	0.014	0.012

$$\bar{X} = \frac{1.023 + 1.016 + 1.034}{3} = 1.024$$

Thank You & See U next Class

INDUSTRIAL HEALTH AND SAFETY

INDUSTRIAL HEALTH AND SAFETY

- Industrial health and safety hazard may mean condition that causes legally compensable illness or any condition in the work place that impaired health of employees enough to make them loose time from work or to work at less than full efficiency.

Basic accident prevention activities

- Elimination of hazards, at the source from the machine, method, materials or plant structure.

- Control of the hazards by shielding, enclosing, or guarding it.

Basic accident prevention activities – contd.

- Training of the employees to recognize and be aware of the hazards.
- Specification of the proper types of personnel protective equipment of employees to shield them against hazards.

SYSTEM SAFETY APPROACH

- A system is an orderly arrangement of a component that are interested and that act and interacts to perform some task or functions in a particular environment.

- **Hazard identification**
- **Hazard elimination**
- **Hazard protection**
- **Determination of maximum possible financial loss**
- **Determination of acceptable loss retention**

ENVIRONMENTAL FACTORS/STRESSES

- Chemical Hazards
- Physical Hazards
- Biological Hazard
- Ergonomic hazard

CHEMICAL STRESS

- Chemical compounds in the form of liquids, gases, mists, dusts, fumes and vapours may cause problems by **skin absorption** (though direct contact with the skin), by **ingestion** (eating or drinking) or by **inhalation** (breathing).

THRESHOLD LIMIT VALUES

- This refers to limit published by a committee of American Conference of Governmental Industries Hygienist (ACGH). Threshold limit values apply to air – borne concentration of substance and respective conditions under which it is believed that nearly all workers may be repeatedly exposed without adverse effect.

MONITORING HAZARDS

- Monitoring implies an awareness of potential health hazard and a continuing assessment of the adequacy of control measures being used.
- The four types of monitoring system generally used in occupational health surveillance are **personal, environmental, biological and medical**.

CONTROLS

- It is best to introduce control measures to minimize hazard when an industrial facility is being designed so that they can be integrated into the building and operations.

General Control Methods

- There is no single measure which guarantees the safe use of all hazardous material since safe use depends on a combination of many controls.

The methods are:

- *substitution,*
- *process alteration,*
- *enclosure,*
- *Isolation,*
- *use of wetting agent,*
- *special ventilation,*
- *designs and protective devices.*

ADMINISTRATIVE CONTROL

- When an employee's exposure cannot be reduced to permissible safe levels through engineering controls, an effort should be made to limit the employee's exposures through administrative controls.

Tips in administrative control

- Management of work schedules and the related duration of exposures so that employees are minimally exposed to health hazards.
- Transferring employees who have reached this upper permissible limit of exposure
- Assigning many individual to a job to keep the exposure of each within permissible limits

HOUSE KEPING AND MAINTAINANCE

- Good house keeping plays a key role in the control of occupational health hazards. Immediate clean up of any spills of toxic material is a very important control measure. Dust should be removed before it can become air-borne by traffic, vibration and random air current.

WASTE DISPOSAL

- Trained individuals should use established methods for the safe disposal of hazardous toxic residues, other contaminated waste, and containers of chemicals that are no longer needed. The disposal of hazardous materials in sewage systems can create many problems.

See You Next Class
&
Prepare for Test 2

QUALITY CONTROL OF PHARMACEUTICALS

QUALITY CONTROL OF PHARMACEUTICALS

- Pharmaceuticals are medicinal products which are prescribed by practitioners and dispersed through pharmacies and hospitals. Techniques used to determine that pharmaceuticals conform to specified standards of identity of strength, quality and purity is called pharmaceutical testing.

Quality Control: headings

- Q.C of raw material
- Q.C in manufacturing procedures
- Q.C of finished products
- Q.C of identity

Q.C of raw material

- **Physical specification**: This includes such characteristics as bulk density, mesh size, colour, odour, extraneous contamination such as fibres and homogeneity.

- **Chemical specification**: Chemical or physiological potency, melting point and boiling point ranges, optical rotation, moisture, heavy metal content, chemical identity, solubility and presence of chemical contaminations.

Quality Control in Manufacturing Procedures

- Pharmaceutical manufacturers must make products in conformance with the Good Manufacturing Practices as prescribed by the FDA.

Batch-production records

- This describe each manufacturing step in detail.
- Exact processing temperature, specific mixing times, designated equipments and precise details of operations, such as mixing sequence, filtration or compression are carefully specified on the batch-production records.

In-process Assays

- These are used to ensure homogeneity of mixing or completeness of a reaction in the manufacturing process.
- There must be adequate in-process controls, such as weights checking; tablets disintegrating time; the fill of liquids; the adequacy of mixing; the homogeneity of suspensions and the clarity of the solution.

Biological or Chemical assay

- Representative samples of the pharmaceutical are taken by inspectors and submitted to the chemical or biological testing laboratory for final assay.

Quality Control of Finished Product

Accordingly, each batch of a pharmaceutical must satisfy five requirements:

- The label claim for potency
- Homogeneity Standards
- Standards of pharmaceuticals elegance
- Identity specifications
- Regulatory standards if they are applicable to the specific pharmaceuticals.

Potency Assay

- Biological products must meet analogous standards for potency. Some special types of pharmaceuticals require additional complex tests.
- All products, intended for injection, must meet sterility requirements. Tests are frequently required on these products for absence of pyrogens and for safety (toxicity).

Stability tests

- Theses are more complex and specific than the production potency tests.
- It ensures the effectiveness and safety of the product during normal shelf-life. At the same time, confirms the absence of any harmful degradation substances.
- As a result of these tests, many pharmaceuticals have a full-effectiveness expiration date on the label.

Packaging tests

- Suitable specifications, test methods and cleaning and sterilization procedures must be used to assure that containers, closures and other component parts of drug packages are suitable for their intended use.

Packaging tests – contd.

- They must not be reactive, additive or absorptive to any extent that significantly affect the identity, strength, quality or purity of the drug and must furnish adequate protection against its deterioration or contamination.

Pharmaceutical Elegance Test

- This refers to the physical appearance of the dosage units. These standards include inspection to ensure that solutions are sparkling clear, tablets are not capped or chipped, and coloured products are of the right shade.
- These standards govern physical quality.

Quality Control of Identity

- This is proper labeling i.e., that the right product is in the right bottle with the right label.
- To maintain the identity of the product, extensive checks are made throughout the manufacturing operations and very rigid controls are applied to printing, storage and application of labels on finished pharmaceuticals.

Thanks for Listening
&
Wish you the best in the examination