Ethiopian TVET-System

INDUSTRIAL ELECTRICAL MACHIN DRIVE TECHNOLOGY

Level-II

Based on May 2011 Occupational Standards

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Module Title: Applying Continuous Improvement Processes (Kaizen)

TTLM Code: EELEMD2TTLM1019

LG11: Satisfy quality system requirements in daily work installation

LG Code: EEL EMD2 M04 LO1-LG-11

LG12: Analyze opportunities for corrective and/or optimization action

LG Code: EEL EMD2 M04 1019LO2-LG-12

LG13: Recommend corrective and/or optimization actions

LG Code: EEL EMD2 M04 1019LO3-LG-13

LG14: Participate in the implementation of recommended actions

LG Code: EEL EMD2 M04 1019LO4-LG-14

LG15: Participate in the development of continuous improvement strategies

LG Code: EEL EMD2 M04LO5-LG-15

Instruction Sheet	LG11: Satisfy quality system requirements in daily work installation

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- Accessing information on quality system.
- Recording and reporting quality control data.
- Following quality control procedures.
- Recognizing and reporting non-conformances or problems.
- Conduct sustainable energy work practices

Promoting sustainable energy principles and work practices This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, you will be able to:**

- Access information on quality system requirements for own job function
- Record and report quality control data in accordance with quality system
- Follow ***quality control procedures*** to ensure products, or data, are of a defined quality as an aid to acceptance or rejection
- Recognize and report non-conformances or problems
- Conduct work in accordance with ***sustainable energy work practices***
- Promote sustainable energy principles and work practices to other workers

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the information Sheet
4. Accomplish the “Self-checks, in each information sheets**.**
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets and LAP Tests if any”. However, if your rating is unsatisfactory, ask your teacher for further instructions or go back to Learning Activity.

Information Sheet-1	Accessing information on quality system.

1.1. Introduction

many books and articles have been written to try to describe the nature of quality. But quality is like **love**. Everybody talks about it and everybody knows what he/she is talking about. Everybody knows and feels when there is love. Everybody recognizes it; when we try to define it, we are left standing empty -handed. The same counts for the concept of quality. There is no general consensus on the concept of quality. An absolute definition of quality does not exist because just like **beauty**, quality is in the eyes of beholder.

As a new staff member at Simulation Lab it is important that you understand the quality system used by Simulation Lab Don, the Simulation Lab Quality Officer, will spend time with you today explaining the concept of quality and how to access quality system requirements and apply them to your work.

The word 'quality' is used extensively today. For example, when people describe such things as cars, lifestyles and the services provided by tradespeople. Write down your answers to the following questions. You may wish to return later to see if your answers have changed! Which is the better quality vehicle - a Holden utility or a Rolls Royce saloon? Is the highest quality always the best quality?

Quality

Quality is a term that is often used inaccurately. The term can cause confusion because it has TWO related but different meanings:

- high grade, superior excellence
- a characteristic, property or attribute. (The Macquarie Dictionary)

It is the second meaning of quality that is used in the context of business, manufacturing, and commerce, or in this case, laboratory testing. Note that this second meaning does not specify whether the quality is high or low.

We do not always strive for the best product, service or result, instead we strive for the one that best suits our purpose. Similarly, we always strive for consistency of product. For instance, a hemoglobin measurement in blood is only required to one decimal place and therefore we strive for accuracy to one decimal point even when it is possible to attain greater accuracy. Attempting to measure hemoglobin to four decimal places would be more expensive and wasteful of time and resources.

Joseph M. Juran (one of the founders of quality management) summed up quality in the phrase:

'Fitness for purpose' W. Edwards Deming (another founder) said: **"Good quality does not necessarily mean high quality. It means a *predictable degree of uniformity and dependability at a low cost with quality suited to the market."***

1.2. Access information on quality system requirements for own job function - the Simulation Lab quality system

Now that you have an understanding of what quality means, we can examine what quality systems are and the part they play on the journey to quality.

Quality System

A quality system is formally described as 'the organizational structure, responsibilities, procedures, processes and resources for implementing the management of quality'. Said in a simpler way, a quality system concerns the way an enterprise goes about running its business to achieve its goals (effectively or otherwise!). The quality system would usually be documented and is often based around a quality manual that defines and embodies the system.

Many manufacturing and service enterprises have their quality systems certified against a recognised quality management standard, commonly one of the international ISO 9000 standards. Such standards lay down generic elements of good business practice that the enterprise must implement and follow in order to gain certification.

It is often the case today that organisations are required to be certified against a particular standard for contractual or regulatory reasons. Meat processing companies and nursing homes, for instance, must comply with government imposed standards in order to demonstrate that the processors produce food that is safe to eat and that the homes provide a caring environment for elderly people.

Having a certified quality system can inspire credibility in the eyes of customers and suppliers as well as helping the organisation to run more efficiently. However, it should be said that a quality system does not need to be certified for it to work well.

Independent bodies are specifically accredited to grant certification. Certification occurs after a thorough assessment or audit of the organization’s quality system and operations. Regular follow-up audits are necessary to demonstrate on-going compliance; otherwise certification may be withdrawn.

Simulation Lab would eventually like to apply for accreditation by NATA (National Association of Testing Authorities) against the ISO 17025 standard, 'General Requirements for the Competence of Testing and Calibration Laboratories'. Certification would give recognition to Simulation Lab that it was capable of performing nominated chemical analyses. Simulation Lab is currently working towards establishing a quality system that would satisfy requirements of the standard.

As Simulation Lab also does medical testing in the areas of biochemistry, immunology and microbiology, it is also required to be accredited by a national pathology body to do this type of work.

Simulation Lab's Quality System

For Simulation Lab to achieve 'quality' in its operations, it must be set up and run in such a way as to deliver it. Having an effective quality system, whether or not it is certified, is critical to achieve this outcome.

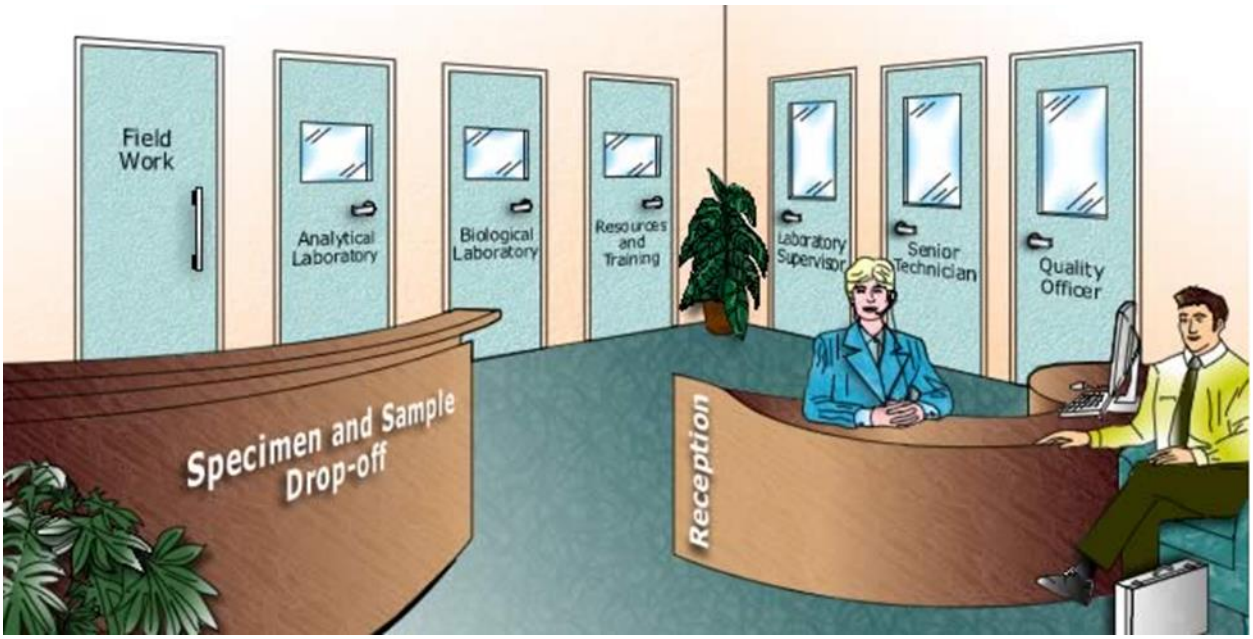
The documentation of Simulation Lab's quality system is currently being prepared by the Quality Officer to make it consistent with that specified in ISO 17025. Simulation Lab has a Quality Manual made up of 3 main parts:

1. Quality Policy Statement
2. Quality Policies
3. Quality Procedures.

Flowing from the Quality Manual are the Methods Manual, OHS Manual, Staff Manual, the MSDS folder (Material Safety Data Sheets) as well as related forms and records. Note that the Methods Manual contains the various standard laboratory methods used at Simulation Lab.

Locating parts of the Simulation Lab quality system

Simulation Lab Reception and then each office to locate the various manuals. Then go to the Resources and Training Room to locate where the MSDSs and Forms are held. While you are there click on each manual to see its Table of Contents.



Now that you have a general sense of where documents are located, you will be instructed to find some specific documents. Locate the Quality Policy Statement go to the Quality Officer's office. Select the **Quality Manual** on the shelf then choose the **Quality Policy Statement** and print it.

Now locate and read the Quality Policies: **Test Result Validation Policy** and **Internal Auditing Policy** in the **Quality Manual**. You will find these Quality Policies in the Quality Officer's office

For each Quality Policy there is a **Quality Procedure** in the **Quality Manual** located in the Quality Officer's office. Locate and read the quality procedures corresponding to the quality policies.

Now that you know where to find the documentation that supports SimuLab's quality system, you can assist in some problems that have arisen in the laboratory. As necessary you should refer to the appropriate manual to find the document that gives you the information that you need. Test what you have learned so far by doing the following activity, an activity to be sent to your tutor.

Quality System Requirements

The Krazy Kola Company has been having some problems with the development of syrups for their Krazy Kola. They have been developing mixed sugar syrups that contain sucrose, glucose and other unspecified sugars for a purpose that they have not disclosed. They have sent ten samples (labelled1-10) to Simulation Lab for stability testing, microbiological challenge testing and % w/v Glucose determination.


1
Krazy Kola
2
Krazy Kola
3
Krazy Kola
4
Krazy Kola
5
Krazy Kola

Self-Check -1	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1. _____ The organizational structure, responsibilities, procedures, processes and resources for implementing.

   A. Quality Procedures C. Quality system

   B. Quality D. Quality Policies

2. _____ Which one is not main part of Quality Manual made up.

   A. Quality Policy Statement

   B. Quality Policies

   C. Quality Procedures.

   D. None

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers

Information Sheet-2	Recording and reporting quality control data

A very important part of Simulation Lab's quality system is quality control. We shall now concentrate on this topic.

1.1. **Quality Control (QC)** is defined as being 'the operational techniques and activities that are used to fulfil the requirements for quality'. In effect, these operational techniques and activities mean:

- checking a process at appropriate stages to ensure it stays within defined limits (ie to produce the 'right' quality product)
- eliminating the causes of any unsatisfactory performance (ie reducing the rework and waste that otherwise cost companies money)
- removing or repairing any defective products before they get to the customer.

As this definition implies, QC is not a method of improvement of the quality of products, but rather a method of maintaining a consistent level of quality.

Activity: QC When?

Imagine that you manufacture Krazy Kola and that one processing, canning and packaging run costs a total of $150,500. At what steps in the process would QC be applied?

- ○ At the end when the Krazy Kola is canned and packaged.
- ○ At the beginning of the run ie checking raw materials and cans.
- ○ In the middle of the run ie checking all ingredients are added correctly.
- ○ At a number of critical points in the process.

What does QC mean for a laboratory organization like Simulation Lab where the 'product' is the analytical data that Simulation Lab reports to its customers? What are the QC activities that inform the analyst that the analytical process is operating within its defined limits (ie that the product is meeting quality standards or more simply, are the results? valid)?

The QC activities for laboratories such as Simulation Lab involve more than simply examining the end results of analysis. QC activities for Simulation Lab involve checks that

are performed at various stages of the laboratory processes. These include activities such as:

- Replicate analysis (checks for consistency)
- Standards analysis (correctness)
- Alternative methods (method validity)
- Control charts (abnormal trends)
- Comparison with other laboratories (independent cross-check).

The data generated from such QC checks is important and must be recorded, reported and stored for possible later reference during audits or if a query arises. This is a requirement of Simulation Lab's quality system.

Monitoring the validity of test results is a requirement of the laboratory standard, ISO 17025, and one that Simulation Lab must follow if it is to have confidence in the results it provides to its customers. We shall talk more about this subject shortly.

Document and Data Control Procedure

Document Control

1.The following constitute controlled documents used at Simulation Lab:

- All policies and procedures contained in the Quality Manual plus the Table of Contents and Amendment Record.
- Standard Operating Procedures (SOPs) and other relevant documents in the Methods Manual, OHS Manual and Staff Manual.

2. Each page of these documents shall contain the following information:
- Simulation Lab logo
- Controlled document name or number
- Version number
- Date of version.

3. Amendments to controlled documents shall be made as follows:
- Only the Quality Officer, Laboratory Supervisor or delegated senior staff are authorized to make amendments
- NO amendment is to be written onto a page
- Each amendment will result in the re-issue of the pages involved
- All copies of the document shall be amended at the one time
- A copy of amendments to manuals is to be recorded in the Amendment Record
- All superseded copies of controlled documents are kept in the History File.

4. Working documents such as Laboratory Test Sheets shall not be controlled documents but will use a standardized design.

Data Control

The control of results (both raw and final) and data is vital to the operations of Simulation Lab.

All results and data will be collated and stored as follows:

QC Data – Where an automated interface exists between an analyser and a computer, the QC data is to be stored on the hard drive of the computer and backup copies of the data made onto floppy discs or CD ROMs as appropriate on a daily basis.

Where data is extracted manually, the data is to be transcribed onto a **DATA - Running Sheet** and printouts, graphs etc attached to the running sheet. The running sheets are to be stored in the QC log for the test/machine.

Results - Are to be transcribed onto the **Results Data Sheet** and all calculations shown on this sheet. Printouts and graphs etc. are to be attached to the results data sheet. The data sheets are to be stored in the appropriate test folders.

Results are to be transcribed from the Results Data Sheet onto the Laboratory Test Sheet for promulgation to the customer.

Statistical Analysis - Is to follow established procedures for each of the tests performed and may be either

according to QC programs in commercially available statistics packages or via manual means. All calculations, graphs and validation results are to be stored on the computer hard drive (with daily backup copies) or in manual folders. Use the Document and Data Control Procedure to do the following activity.

Activity: QC Data Control:- Select whether the statements about QC data control are true or false.

Statement	True	False
QC is important at SimuLab.	○	○
Data Control is not important at SimuLab.	○	○
QC data is stored on hard drives.	○	○
QC data is stored as hard copy.	○	○
QC data may include graphs and charts.	○	○
Backups of QC data should always be made.	○	○
QC data should be destroyed after 12 months	○	○
Data Running Sheets are used to record manually extracted information.	○	○
The Quality Officer is responsible for data control.	○	○
I am responsible for QC.	○	○

It was discussed earlier that QC for Simulation Lab is about performing activities that give operators confidence that test results are valid and true. Monitoring of test result validity is an important aspect of the Simulation Lab quality system. If you have not kept a copy of the Test Result Validation Procedure, use the following link to obtain it. Print it for the following activity, to check you understanding of handling QC data.

Test Result Validation Procedure

The validity of test results is monitored by QC standardization protocols prior to the run and routine testing of standards during the run.

As appropriate, a range of check standards are used to cover low, medium and high ranges of the test samples being measured. This will monitor result accuracy. In addition, standards are employed to check for precision of results.

As relevant, the results of standards are displayed on statistical control charts where out-of-control situations are identified by trends and individual data points.

All out of control situations are investigated, the situation resolved and a record made. The requirement for re-analysis of test samples should be discussed with the Senior Technician.

Only certified or validated materials are used as standards. Instructions are provided in the standard operating procedures (SOPs) of the Methods Manual for the selection, maintenance and use of such standards.

Wherever possible, standards are diluted in substrates that are identical to, or approximate, real test samples. The SOPs provide instruction for standards preparation.

Interpretation of QC results on the Data Running Sheet is important for your complete understanding of the quality system at Simulation Lab. You will now complete the Data Running Sheet, given the Krazy Kola results, in the next activity, after which you will need to send it to your Tutor, together with your answers to some questions.

Self-Check -2	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

Instruction: If the statement is correct write true if the statement is in correct write false

1. _____ QC is important at simulation lab.
2. _____ the operational techniques and activities that are not used to fulfil the requirements for quality.
3._____ Statistical Analysis Is to follow established procedures for each of the tests.
4._____QC data may include graph and chart.
5._____the quality officer is not responsible for data control.

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answer

Information Sheet-3	Following quality control procedures

3.1. Follow quality control procedures to ensure products, or data, are of a defined quality as an aid to acceptance or rejection

In the previous step QC was defined as the checking of a process to ensure that it stays within defined limits in order to produce a product of the required quality. We also looked at some examples of how QC procedures are applied at Simulation Lab for the analysis of Krazy Kola samples.

In this step you will look more closely at QC procedures and, in particular, how the defined limits of quality determine acceptance or rejection.

QC procedures generally involve:

- measurement of a parameter
- the concepts of accuracy and precision regarding that measurement
- a range of acceptance (ie the defined limits of quality)
- recording of raw data, calculations and the decision to accept or reject (see info 2)
- recording of QC parameters to follow patterns over time (LO 2 - cont 1 and 3).

In this step, you will concentrate on the first three points, beginning with measurement of parameters.

Measurement of a Parameter

QC always involves the measurement of a parameter. Measurement methods range from very basic to highly sophisticated. For example, measurement of whether the paint on a Krazy Kola can is clean, shiny and unscratched as the can comes off the production line involves the simple method of a visual check by the human eye. Other measurement methods may involve basic measuring equipment, for example measuring whether a 24 can carton of Krazy Kola weighs within an acceptable variance. More sophisticated equipment and more complex procedures would be involved in determining, for example, the shelf life (stability) of Krazy Kola, or whether there is evidence of microbial contamination, or whether the concentration of glucose in Krazy Kola is acceptable.

There is also a range of different types of parameters. Although parameters are often physical, they may also be non-physical. For example, measurement of the percentage of 10 to 14-year-old males who like Krazy Kola is a measurement that uses opinion as a parameter.

Testing (ie measuring a parameter) may be non-destructive or destructive. For instance, checking the paint finish or weighing Krazy Kola does not damage the sample. On the other hand, chemical or microbiological testing of Krazy Kola makes it unsuitable for

further use. Other testing such as measuring the maximum load a seat belt can withstand before failure, or testing a rifle cartridge for detonation and accuracy under field conditions, leads to the destruction of the sample.

The Concepts of Accuracy and Precision

You will remember that in the glucose analysis of Krazy Kola we touched on the concepts of accuracy and precision. As stated earlier, the concepts of accuracy and precision regarding the measurement of parameters are an important part of QC procedures. These terms have different meanings and it is very important that you fully understand them before proceeding

The Difference between Accuracy and Precision

Consider the analogy of four archers who each take turns to shoot at a target using the same bow. Each archer performs quite differently

The most **accurate** archer is the one with shots landing in or near the middle ring of the target, the bullseye. Thus **accuracy** is the ability to get close to a **target** value, in this case the bullseye.

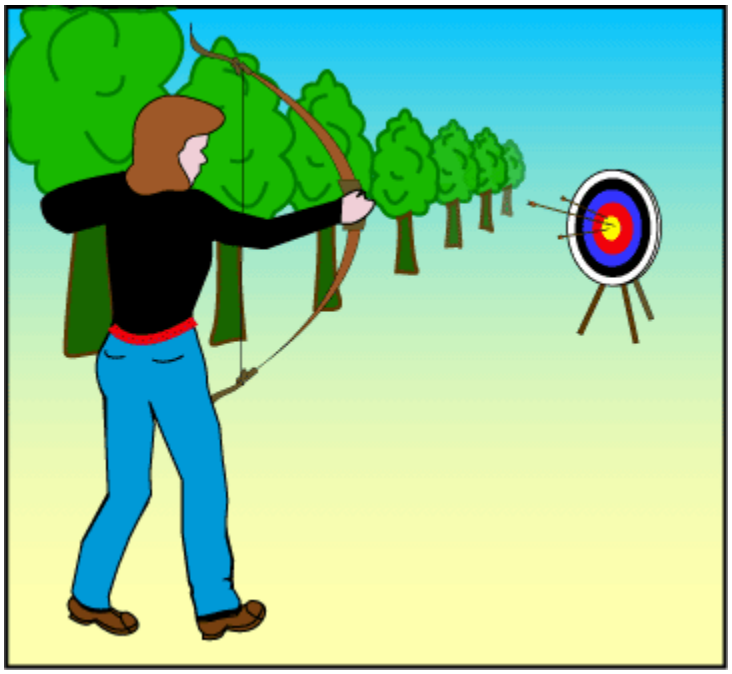


Fig 1 Accurate and precise

For the second archer, we see that the shots are also concentrated close together but away from the bullseye. This archer is not accurate because he hasn't hit the target however we can say that he is at least **precise. Precision** is about how results are grouped or **spread** or, said in another way, how repeatable they are

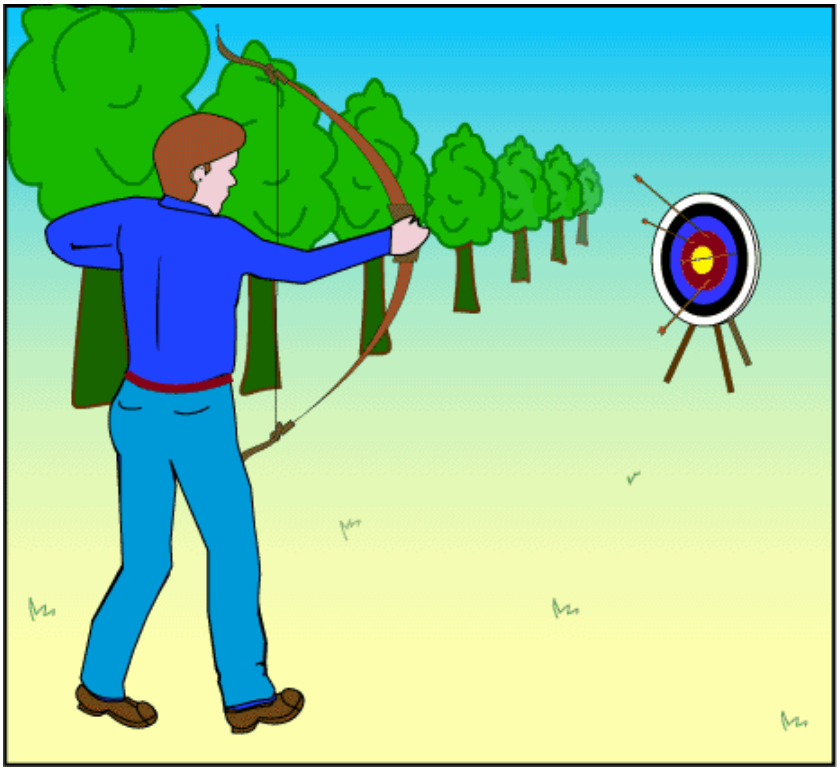


Fig 2. Precise but not accurate

The third archer is accurate overall but not precise. The average of his shots would lie close to the bullseye but the individual shots are spread out.

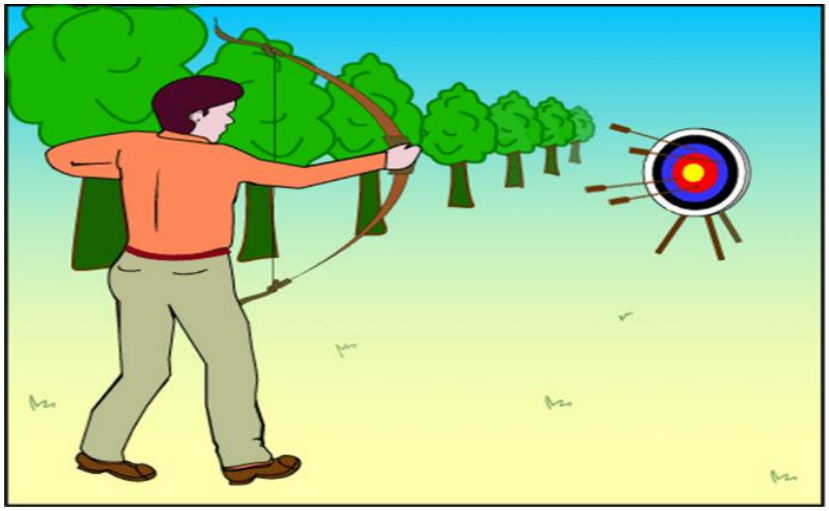


Fig 3. Accurate but not precise

The fourth archer is neither accurate nor precise because his shots are spread out and have landed away from the bullseye overall.

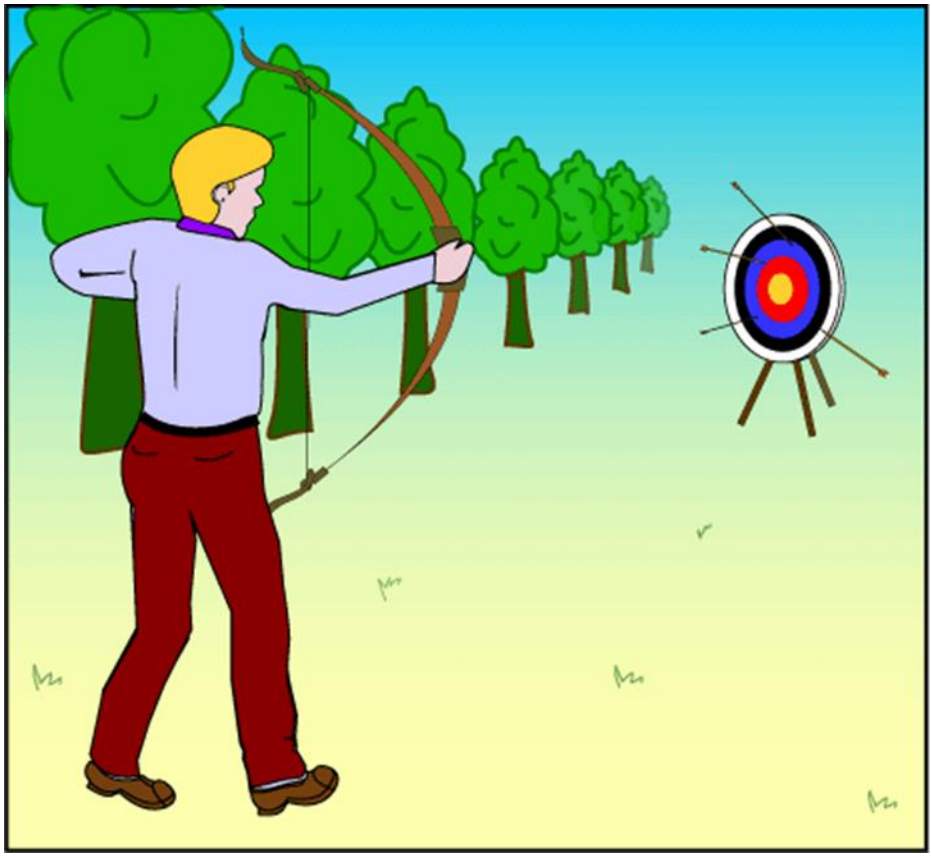


Fig 4. Not accurate and not precise

Imagine that the first archer in the Study Notes concerning accuracy and precision now uses a different bow with the result that her target looks like that of the second archer. How is it that she is no longer accurate yet she remains precise? The difference in performance can be attributed to some factor to do with the new bow. Perhaps the string was tighter, for example.

When results are precise but not accurate, as in our example above, we say that a bias exists, ie there is a consistent difference between the measured value and the target value. Bias is a measurement error that can come about as the result of human influences or other influences such as equipment that is set up incorrectly. Bias affects the accuracy of a measurement but not the precision.

Range of Acceptance

The third important part of QC procedures to be discussed is the **range of acceptance**. You will recall from the Krazy Kola work that each of the QC checks had 'defined limits'. These defined limits are known as the range of acceptance.

Range of Acceptance

The range of acceptance is defined as the limits that determine the quality of our analytical results. Figures falling within that range are accepted and figures falling outside the range will cause a run to be rejected.

For example, the Low Check Standard (CS) must give a value in the range 2.00% to 2.10% for the run to be accepted. There may be exceptions to this rule depending on circumstances. For example, if the Low CS was 1.88% (ie below the acceptable range) but the test samples were 30% to 50% and the other checks were satisfactory, then it could be argued that the run should be passed because the machine was shown to be accurate at the concentrations of the samples despite this not being the case at lower concentrations.

Such decisions about making exceptions to the rule would be left to the Senior Technician or the Quality Officer and may even be debated by the Quality Management Committee.

How is the range of acceptance for each CS determined?

One simple way is to analyze the CS a large number of times under conditions that are as close to ideal as possible. For example, using the Low CS we measure the % w/v glucose 100 times using good machinery and good operators. We then apply some basic statistics to the readings.

Firstly, we calculate the mean (the mean, also known as the **average**, can be found by adding the values of the individual readings and then dividing this by the number of readings). This figure is 2.05% glucose. Now we calculate the **standard deviation** which we find to be 0.025% glucose. Think of standard deviation as being a measure of how much the results are 'spread' - the wider apart our 100 results are spread, the greater will be the standard deviation. You can see from this that standard deviation is connected to precision - as standard deviation gets smaller, precision improves.

Most statistical QC is based on the notion of a 95% confidence limit which basically means that 95% or 19 out of 20 measurements of the Low CS would be expected to fall within an acceptable range defined by the confidence limit.

The 95% confidence limit (acceptable range) is derived by subtracting and adding 2 standard deviations to the mean, as in the following example.

95% confidence limit = [2.05 - (2×0.025)] to [2.05 + (2×0.025)]

= [2.05 - 0.05] to [2.05 + 0.05]

= 2.00 to 2.10 = acceptance range

Think of the acceptance range in this way. If a CS result falls within the acceptance range, there is a good chance that the analytical process is operating well and that the test sample result is valid and can be accepted. On the other hand, if the CS result is outside the range, there is the possibility that something has gone wrong with the analysis. In this

case, follow up investigation is needed. **Can you see now how QC procedures help to give confidence to the analyst about the quality of the test results?**

Sometimes, even with a very effective quality system, things still go wrong. The next activity looks at a situation where Colin, the new laboratory trainee, has transcribed some Krazy Kola glucose results onto the Data Running Sheet.

Self-Check -3	Written Test

Name: _____ **Date:** _____

Instruction: Short Answer Questions

Directions: Answer all the questions listed below.

1._____QC procedures generally involve only measurement of a parameter.

2._____ the range of acceptance is defined as the limits that determine the quality of our analytical results.

3._____ quality control checking of a process to ensure that defined limits in order to produce a product of the required quality.

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-4	Recognizing and reporting non-conformances or problems

4.1. Introduction

In essence, a non-conformance occurs where a procedure in our quality system has not been followed in some way (ie you are not doing what you should be doing). There can also be times when a problem arises even though we appear to be doing everything correctly. In either case, quality or productivity may have jeopardized.

QC and Non-conformance

Crosby, another proponent on quality management, looks at quality from a slightly different perspective to Deming or Juran mentioned earlier. Crosby reasoned that the way to improve quality management was to measure the cost of doing things right (**the price of conformance**) against the cost of doing things wrongly (**the price of non-conformance**).

The price of conformance includes:

- **prevention costs -** the costs of reducing defects and non-conformances
- **appraisal costs** - at Simulation Lab the costs of running the quality system and any accreditations it holds.

The price of non-conformance includes:

- appraisal costs - detecting non-conformances (ie QC)
- internal failure costs - unsatisfactory quality detected within Simulation Lab
- external failure costs - costs associated with poor quality test results being detected outside the enterprise (ie by Simulation Lab's customers).

Crosby argued that reducing non-conformances would reduce the overall cost of quality. For example, reducing the number of failed runs at Simulation Lab from 5% to 1% would lead to significant savings in time, money and customer confidence as failed runs have to be repeated and this leads to delays and extra costs.

The ability to recognize and report non-conformances or problems at Simulation Lab will lead to better productivity and quality. The adage of 'a stitch in time saves nine' holds well here.

Non-conformances or problems occur right across the quality system and can result from issues to do with:

- People and personalities eg lazy habits
- Qc eg wrong sop used
- Equipment eg not calibrated
- Reagent and chemicals eg used after expiry date

- Training eg no employee induction
- Paperwork sops and instructions eg superseded documents used
- Communication eg client not notified
- Physical environment eg laboratory temperature too high.

Non-conformances or problems become known through various means such as:

- Customer complaints
- Internal audits
- Qc activities
- Instrument calibrations
- Staff observations or supervision
- Management reviews
- Checking of consumable materials.

Being able to recognize non-conformances or problems and report or rectify them in a timely manner is a key element to good QC. The following activity will develop your ability to reduce non-conformances in the workplace. Click on the link below to access this activity.

Self-Check -4	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1. _____the costs of reducing defects and non-conformances

A. Prevention costs C. Local resources

B. appraisal costs D. Services

2. _____The price of non-conformance includes:

A. appraisal costs C. external failure costs

B. internal failure costs D. All

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers

Information Sheet-5	Conduct sustainable energy work practices

The resources of the world are finite. We have only a limited amount of fossil fuels (gas, oil, coal), minerals and water. Resources such as water are recycled through the environment but there is only a finite amount that can be captured and used without affecting other aspects of the ecosystem. For example, consider the environmental problems associated with the Murray and Snowy Rivers.

Energy derived from fossil fuels is limited but energy from the sun is continuous and unlimited (for the next few million years anyway!). Theoretically, timber and plants are unlimited as they capture the sun's energy to grow. But famine still rules the world. Why?

The Western world uses more than its fair share of energy and resources. There is not much that Simulation Lab can do to help world poverty, apart from our sponsorship of relief programs, but Simulation Lab can have a direct effect on reducing the pollution of the environment.

Reduction in the use of energy and resources always leads to a reduction in waste, emission and pollution. At the same time this saves money. Simulation Lab has committed itself to employ sustainable energy practices.

One fundamental aspect of energy conservation is having an awareness of how energy use contributes to an increase in waste and pollution of the environment.

The audit is designed to identify and reduce energy use in premises of all sizes. Energy audits are investigations of energy use in a defined enterprise or in a defined area or site. The audit allows the measurement of energy use and costs, which leads to processes for better control of consumption.

Audits can be extremely complex, for example, imagine doing an energy audit at a car manufacturing plant! At Simulation Lab the audit will be relatively simple and based on common sense.

Self-Check -5	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1._____the audit is designed to identify and reduce energy use in premises of all sizes.

2._____Audits can be extremely complex.

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers

Information Sheet-6	Promoting sustainable energy principles and work practices

Promote sustainable energy principles and work practices to other workers

Conducting a safety audit and proposing ways to reduce energy and resource use is only half of the process. The other half involves promoting the acceptance of energy saving principles amongst the staff at Simulation Lab. This will involve some marketing and selling of the changes with the intention of changing the behavior of your workmates.

Self-Check -6	Written Test

Name: _____ Date: _____

Directions: Answer all the questions listed below.

1. _____ conducting a safety audit and proposing ways to reduce energy and resource.

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Instruction Sheet	LG12: Analyze opportunities for corrective and/or optimization action

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- Comparing current work practices with historical data records
- Recognizing variances that indicate abnormal
- Collecting and/or evaluating batch and/or historical records.
- Using appropriate quality improvement techniques

Promoting sustainable energy principles and work practices This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, you will be able to:**

- Compare current work practices, procedures and process or equipment performance with requirements and/or historical data or records
- Recognize variances that indicate abnormal or sub-optimal performance
- Collect and/or evaluating batch and/or historical records to determine possible causes for sub-optimal performance
- Use appropriate quality improvement techniques to rank the probabilities of possible causes

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the information Sheet
4. Accomplish the “Self-checks, in each information sheets.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets and LAP Tests if any”. However, if your rating is unsatisfactory, ask your teacher for further instructions or go back to Learning Activity.

Information Sheet-1	Comparing current work practices with historical data records

1.1. introduction

Improving quality is an interactive and proactive process. Your ability to analyses quality situations and to apply corrective actions to optimize procedures is important in your role as a Laboratory Technician. This unit of competency will check your ability to assess and apply quality principles.

1.2. Compare current work practices, procedures and process or equipment performance with requirements and/or historical data or records

Different charts are often used to enable a laboratory technician to monitor and compare processes with requirements, historical data and records. One of the simple statistical charts used to monitor processes is the run chart.

A run chart is simply a graphical means of depicting data in chronological order. This chart allows a visual means to see the performance of a particular test parameter and whether there are any trends developing. In this way problems can often be avoided before they occur.

As a Simulation Lab laboratory technician, you need to monitor processes and procedures for non-conformances. Today you will monitor the % w/v Glucose results for Krazy Kola over the last 20 runs and look at the performance of the Medium Check Standard. In reality the three check standards would be monitored at the same time but for simplicity you will only look at one here. Remember that the acceptance range for the Medium Check Standard is 19.74 - 20.02 and any values falling outside these limits will cause the run to fail QC. If this happens Simulation Lab cannot have confidence that the results for test samples will be valid.

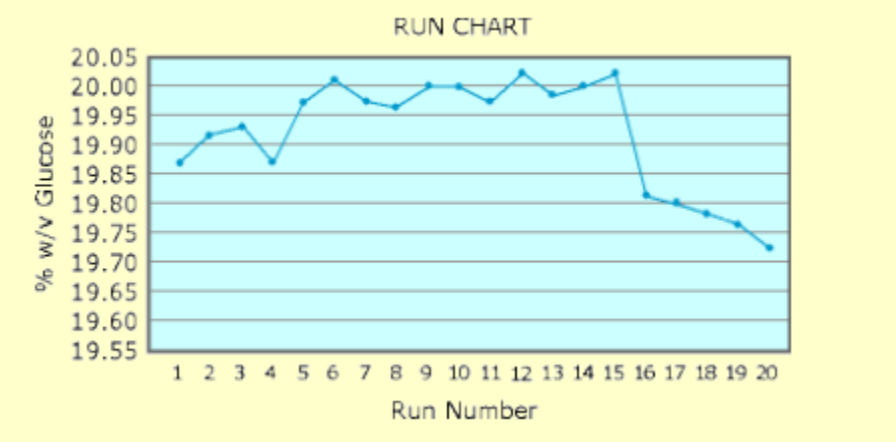
Run charts are useful because they show trends and problem-results however control charts can be even more useful. We will now consider control charts, which are an extension of run charts and are more effective in highlighting how QC data is behaving. Click on the following link to access information on control charts.

Control Charts

Remember that in **LO1**, **inf 3** we looked at the development of the range of acceptance and found that it was based on **2 standard deviations** on each side of the **mean** value. It was said that this represented the **95% confidence limits**, so named because 95% (or 19 out of 20) values will fall within this range under normal circumstances.

A control chart is like the run chart we saw earlier but it has the following features drawn in:

- a line denoting the mean value
- a line denoting mean plus 2 standard deviations, called the Upper Control Limit
- a line denoting mean minus 2 standard deviations, called the Lower Control Limit.



Self-Check -1	Written Test

Name: _____ Date: _____

Directions: Answer all the questions listed below.

Instruction: If the statement is correct write true if the statement is in correct write false

1._____One of the simple statistical charts used to monitor processes is the run chart.

2. _____Different charts are often used to enable a laboratory technician to monitor and compare processes

3._____ a control chart is like the run chart a line denoting the mean value

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-2	**Recognizing variances that indicate abnormal**

2.1. Recognize variances that indicate abnormal or sub-optimal performance

Variances and Variability

Remember in LO1, inf 3 you investigated the concepts of **accuracy and precision** with the archers. You also should know that **measurements** can never be perfectly accurate and precise: there is always variability.

Variability, Accuracy and Precision If we could measure with perfect accuracy down to the molecular level we would be able to determine, for example

This perfect value is called the True Value. Needless to say, the true value is not measurable as we are unable to measure down to the molecular level for many reasons. We strive for measurement of the Accepted Value, which approximates the true value and is accurate enough for our purposes. In this case the machine measured 29.98% w/v, which is more than accurate enough for our purposes, as we are only required to give the answer to one decimal place.

If the Accepted Value is close enough to the True Value for our purposes, then we say that the answer is Accurate (just like an archer hitting the bullseye). We check accuracy in a run by using Check Standards that have a verified concentration. We then compare the measurement of the check standard with their verified value (accepted value) and if close enough, the accuracy of the run has been established.

Notice that although it was the same sample, the same run, the same machine and the same operator, there are small differences in the values obtained each time the check was measured. This range of values reflects the Precision of the run. The larger the range of values the lower the precision and the smaller the range of values the higher the precision.

To recap: Accuracy reflects how close we have come to measuring the true value. Accuracy might also be thought of as correctness.

Precision shows how close a number of replicate measures are to each other, in other words how the individual values are spread or grouped.

Errors and Variation

Every time a measurement is taken there is a difference between the True Value (not achievable) and the actual measurement. This difference is called an **Error** and errors lead to **Variation** in a product or service.

For example, think of the Krazy Kola assays. What factors would lead to errors in the measured % w/v Glucose? Click on the following link to do an activity to test your understanding of factors leading to errors.

Errors lead to variability. They can be **systematic** or **random.**

Systematic errors remain constant or vary in a specific manner. For example, the thermometer might always read 1oC too high or the pipette might deliver 5% below a given volume. Systematic errors are said to arise from a **BIAS** in the measurement system leading to inaccuracy.

Note that operators can introduce bias, for example, a technician may use a burette in exactly the same manner every time but may be using it incorrectly. Similarly, a technician may not know how to round up/round down correctly.

Random errors are unpredictable and lead to imprecision.

Variability is caused by the sum of the errors in a process.

Self-Check -2	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

Instruction: If the statement is correct write true if the statement is in correct write false

1._____ True Value for our purposes then we say that the answer is Accurate
2._____ Variability errors are unpredictable and lead to imprecision.
3._____ Random is caused by the sum of the errors in a process.
4._____ Errors lead to variability. They can be systematic or random.
5._____ Systematic errors remain constant or vary in a specific manner

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points**

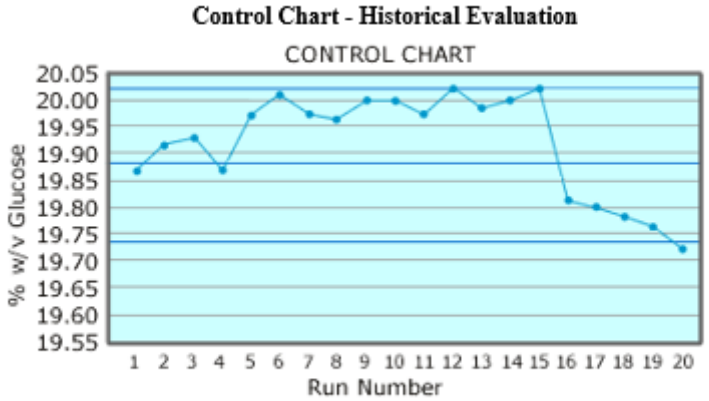
You can ask you teacher for the copy of the correct answers.

Information Sheet-3	Collecting and/or evaluating batch and/or historical records.

3.1. Collect and/or evaluate batch and/or historical records to determine possible causes for sub-optimal performance

In LO 2, inf 1 a control chart was set up for the % w/v Glucose Medium Check Standard using the mean (19.88) and 95% confidence limits (19.74 to 20.02) as the Upper and Lower Control Limits (20.02 and 19.74 respectively) .

You will now use the completed control chart to evaluate historical records. The chart contains % w/v Glucose results for the Medium Check Standard collected over the last 20 runs of Krazy Kola (same data used in the run chart in LO2, inf 1).



It is obvious from the control chart that only one measurement (# 20) falls outside the control region and would be rejected. But the control chart tells us much more. Can you see what is happening?

There are a number of situations where the measurement system may not be in control even though all check results lie within the Upper and Lower Control Limits. In these situations, the check results show abnormal behavior indicating that the results for the test samples may not be valid.

Examples of this sort of behavior include:

- a run of consecutive values on one side of the mean (values should fall around the mean on a random basis)
- sharp drops or increases from one value to the next
- a run of consecutive values increasing or decreasing.

Guidelines, referred to as Westgard Rules, have been established to assist the operator to determine whether check results are normal or not. The exact set of rules used will vary between applications and institutions.

The control chart just investigated has yielded some valuable information about the glucose analysis. Even though only the last of the twenty values for the Medium Check Standard was outside the range of acceptance, the control chart has highlighted three regions where there were problems.

One way to investigate these problems is to go through an exercise to arrive at the root cause (ie the one underlying factor that caused the variation). There are a number of avenues to investigate the root causes, looking at the:

- past performance of the glucose analyser instrument
- maintenance history of the analyser
- calibration of the analyser
- QC program
- Glucose Reagent used for the test
- stability of the Glucose Reagent
- operators using the analyser.

As you can see there are various sources of information that can be used to investigate the cause of the poor performance of the glucose test. Before you can undertake this investigation you need to access and print out some relevant laboratory documents.

Self-Check -3	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

Instruction: If the statement is correct write true if the statement is in correct write false

1. _____you will now use the completed control chart to evaluate historical records.
2. _____The check results show abnormal behavior indicating that the results for the test samples may not be valid.
3. _____The control chart has highlighted five regions where five were problems.

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-4	Using appropriate quality improvement techniques

4.1. Use appropriate quality improvement techniques to rank the probabilities of possible causes

The use of the glucose analysis scenario in the last step involved significant statistical analysis and some detective work to get to the root causes of the problems that were indicated by the Medium Check Standard values.

Some basic errors were made during these runs and the answers were relatively obvious.

Unfortunately, life is not always so easy. Often the problems associated with variability are subtle and numerous but nonetheless significant. Often they do not necessarily arise from operator error or machine failure (Special Causes) but are part of the overall system (Common Causes). Special Causes and Common Causes are discussed in more detail in LO3, inf1.

There are a number of techniques to enable us to identify and rank possible causes in a process. We will look at two of these techniques.

- Brainstorming
- Ishikawa Charts (also known as Fishbone Charts, or Cause and Effect Diagrams).

Brainstorming a Solution

Brainstorming is defined as 'a technique used in groups where everyone contributes ideas without any self- or group evaluation of validity'

Read and print out the following guidelines for brainstorming, as you will need them for the next activity.

- To begin with, a problem or question must be clearly formulated, for example, 'What is causing browning of the apple pulp during pie production?'
- Several people must be involved (between six and twelve participants is preferable).
- Brainstorming should be undertaken in a comfortable and supportive environment.

- Each person in turn calls out a possible cause or reason.
- A 'scribe' writes the reason on a whiteboard or a piece of butcher's paper.
- There is to be ABSOLUTELY NO evaluation of answers or comments on answers - there must be free-flowing thought.
- The process continues until the answers run out.
- The reasons are then grouped into similar categories, and duplicates are eliminated.
- The group then votes in order to rank the reasons from the MOST probable to the LEAST probable.
- The group then proposes solutions for the three 'most probable' reasons.
- Management implements the solutions and the success (or otherwise) of the solutions is monitored.
- The process may be repeated until success is achieved (note that very complex problems may require a number of rounds of this process).

Self-Check -4	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1._____ a technique used in groups where everyone contributes ideas without any self- or group evaluation of validity'

A. evaluation C. cause

B. Brainstorming D. reason

2._____ there is a number of techniques to enable us to identify and rank possible causes in a process.

A. Brainstorming C. evaluation

B. Ishikawa Charts D. A$B E. None

3._____Ishikawa Charts (also known as

A. Fishbone Charts,
B. Cause Diagrams
C. Effect Diagrams
D. All
E. None

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Instruction Sheet	LG13: Recommend corrective and/or optimization actions

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- Analyzing to decide on the appropriate actions.
- Identifying required changes to standards and procedures and training
- Reporting recommendations to designated personnel inspecting workplace.

Promoting sustainable energy principles and work practices This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, you will be able to:**

- Analyze causes to predict likely impacts of changes and decide on the appropriate actions
- Identify required changes to standards and procedures and training
- ***Report*** recommendations to designated personnel

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the information Sheet
4. Accomplish the “Self-checks, in each information sheets.

5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets and LAP Tests if any”. However, if your rating is unsatisfactory, ask your teacher for further instructions or go back to Learning Activity.

Information Sheet-1	**Analyzing to decide on the appropriate actions**

1.1. **Analyze cause(s) to predict likely impacts of change(s) and decide on the appropriate actions(s)**

You know that variability (inaccuracy, imprecision, mistakes etc) contributes to a reduction of quality in the workplace but who or what is responsible for this variability? Is it the fault of sloppy workers, inflexible management, Acts of God or what?

In this task we will investigate the 'big picture' causes of variability.

We will start by considering **Defective Goods and Poor Service.** These are what the customer usually sees when variation is uncontrolled. Click on the link below to access an activity on defective goods and poor customer service.

Causes of Variability

We discussed previously how errors lead to variability and how errors can be classified into two types ie **systematic and random.**

Systematic errors remain constant or vary in a specific manner, for example, a particular thermometer may always read 1°C too high or a particular pipette may always deliver 5% below a given volume. Systematic errors arise from a bias somewhere in the measurement system and lead to inaccuracy. Bias can be introduced by operators as

well as by equipment. For example, a technician may consistently use a pipette in exactly the same incorrect manner.

Random errors are unpredictable and lead to imprecision.

Variation or variability is the cumulative sum of all the errors (systematic and random) in a process. The Root Causes of variation can be broken down into two types called **Common Causes** and **Special Causes.**

Common Causes are part of the system and lead to the normal variation you would expect to see in results. As they are part of the system the technician cannot fix them (without fundamental changes to the system). For example, the owner may decide to use the cheapest pipettes available; despite extreme care in their use, the cheap pipettes are inaccurate and deliver incorrect volumes.

Special Causes are generally one-off causes and are assignable to a particular person or event. Special causes lead to variation in results which are not normal. For example, a momentary power failure causes the QC program on the analyser to reset to last year's parameters. This is not noticed until the end of the week and consequently 300 specimens have to be redone. Special causes can be identified and removed.

Activity: Common and Special Causes of Variation

Think about the examples of defective goods and poor service from the previous activity. Try your hand at estimating the general proportion of quality problems that are due to common causes and the proportion that are due to special causes.

Type the percentage due to common causes in the box below and press check. Keep guessing until you arrive at the correct answer - you will obtain feedback.

Does the answer amaze you? What does this suggest to you?

Initiating Change

If 85% of variability is due to common causes, then 85% of the corrective effort should be directed at the Management System. Is this what usually happens?

NO - in reality we often direct 85% of our effort to solving special causes (sloppiness, mistakes, personality conflicts etc) even though we are doomed to only achieving a maximum of 15% improvement in variability even if we can solve 100% of the special causes (which in itself is an impossibility).

It stands to reason that the major effort should always be directed to changing the SYSTEM (through continuous improvement etc).

Self-Check -1	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1. _____remain constant or vary in a specific manner

A. Systematic errors. C. Special Causes

B. Random errors D. None

2._____are generally one-off causes and are assignable to a particular person or event

A. Systematic errors C. Special Causes

B. Random errors D. Initiating Change

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-2	**Identifying required changes to standards and procedures and training**

2.1. Identify required change(s) to standards and procedures and training

Good quality management requires the ability to identify the changes required to improve methods, procedures and training.

A lot of the approaches to Quality Management are common sense and it is easy to identify how to do things better. However, other factors, such as costs, may impinge on your ability to identify required changes.

For example, one way of solving the variation associated with the % w/v Glucose analysis is the purchase of a fully automated system that comes with full software integration and single-use aliquot reagents and controls. But the system costs $275,896 and Simulation Lab only does $30,000 of soft drink glucose testing per year. Would you change to the new system?

Identifying and making changes is not always as straightforward as deciding when to purchase new equipment. It may involve correction and amendment of current documents, and checks to determine if current documents fulfil current objectives.

Click on the following link to access a draft SOP for disposal of Krazy Kola samples. This SOP is being developed due to a sudden increase in the volumes of Krazy Kola being received for additional and specialized testing.

Self-Check -2	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

Instruction: If the statement is correct write true if the statement is in correct write false

1. _____Quality Management are common sense and it is difficult to identify how to do things better.
2. _____Identifying and making changes is not always as straightforward as deciding when to purchase new equipment.

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-3	**Reporting recommendations to designated personnel inspecting workplace**

3.1. Report recommendations to designated personnel

There are four major steps to quality improvement:

1. Identifying the problem(s)
2. Deciding on an appropriate course of action
3. Reporting recommendations to the decision makers in such a way that a decision to change is more likely than less likely
4. Implementation, monitoring outcomes and adjustments.

For very minor matters often all that is needed is a 'word in the boss's ear' to get the OK to move ahead. In other cases, a written submission is required. Written submissions often cause panic amongst those who do not write them often.

In this step we will look at a 'Submission Model' that takes all the worry out of writing a report. Let's look at a couple of recent submissions at SimuLab. Which recommendation would you support?

Activity: Colin and Trevor's Submissions

Colin's submission:

We hafto get the distilled water from the back lab and it is a real bore. We reckon that the boss should put in a water supply umit if the front lab four us.

Colin, Trainee Technician

The following is Trevor's submission, with notes of explanation given.

Quality Memorandum

(Trevor uses a Standard Format - You Can Use it too!)

TO: Senior Technician
CC: Laboratory Supervisor **(CC means copy to**)
FROM: Trevor, Technician - Biological Laboratory
SUBJECT: Carrying of Distilled Water from Analytical Laboratory to the Biological Laboratory (**Clear identification of the problem**)

DATE: 31/12/01
Max

(Succinct Introduction)

There is no distilled water unit in the Biological Laboratory. Biology technicians have to access the unit in the Analytical Laboratory and then carry it back to the Biological Laboratory. We have recently increased our usage of distilled water due to the extra Krazy Kola contract.

(Negatives of the current system)

This has a number of consequences:

- Analytical Lab staff are often interrupted by the daily ritual of water collection
- There is risk to the backs of the biology men - the women refuse to carry the heavy 20 L container
- Use of a trolley is difficult due to the hallway steps and the differing heights of the benches in the two labs
- Water is often spilled in the corridor leading to a slipping risk
- Twice Colin has jammed his fingers on the lab door jamb
- We estimate that the procedure wastes 20 minutes per day

(Recommendation of change and costings)

I have contacted Cool Waters Purifiers Ltd and they have quoted a price of $1,209.00 fully installed (inc GST). The reduction of lost time of 20 minutes per day would mean that

the unit was paid for in a little over 12 weeks with the added benefit of reducing our injury risks.

(Countering of possible objection)

Running costs are less than for the current analytical unit so there would be some savings made there.

(Call for action and a timeline)

I strongly recommend that the unit be purchased ASAP. Can we discuss this on Friday?

Regards,

Trevor

Self-Check -3	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below. Use the Answer sheet provided in the next page:

1._____which one is not correct major steps to quality improvement.

A. Identifying the problem(s)

B. Deciding on an appropriate course of action

C. Reporting recommendations

D. Implementation, monitoring outcomes and adjustments.

E. All

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Instruction Sheet	LG14: Participate in the implementation of recommended actions

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- Implementing approved actions and monitor performance.
- Implementing changes to systems and procedures to eliminate possible causes
- Communicate to relevant personnel

Promoting sustainable energy principles and work practices This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, you will be able to:**

- Implement approved actions and monitor performance following changes to evaluate results
- Implement changes to systems and procedures to eliminate possible causes
- Document outcomes of actions and communicate them to ***relevant personnel***

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the information Sheet
4. Accomplish the “Self-checks, in each information sheets**.**
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets and LAP Tests if any”. However, if your rating is unsatisfactory, ask your teacher for further instructions or go back to Learning Activity.

Information Sheet-1	Implementing approved actions and monitor performance

1.1. Introduction

In your workplace you will be asked to become involved in workplace change. How you approach these tasks may be vital to your career. In this task, we will investigate some common quality approaches to implementation of change.

1.2. Implement improved actions(s) and monitor performance following change(s) to evaluate results

One of the common tools used for the implementation of change is the **PDCA** or **Deming Circle** developed by W Edwards Deming, one of the founders of Total Quality Management (TQM) and the quality movement. The Deming circle represents the problem analysis process and the quality improvement cycle and provides focus on defect correction as well as d efect prevention.

P PLAN the change
D DO implement the change
C CHECK that the change is having the desired effects
A ACT to follow up and make adjustment based on outcomes to date.

Planning involves:

- determining the goals and targets of what needs to be done to make the change happen
- determining the methods for reaching goals

Doing involves:

- Educating, training and informing relevant people of what is going to happen and who is doing what
- Implementing the changes.

Checking involves:

- checking the effects of implementation to see that the change is happening as required.

Acting involves:

- taking appropriate action to make amendments, if required, to make the change happen as planned.


Plan
Do
Act
Check

Self-Check -1	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

Instruction: If the statement is correct write true if the statement is in correct write false

1. _____PDCA or Deming Circle One of the common tools used for the implementation of change.
2. _____Planning determining the goals and targets of what needs to be done to Make the change happen.

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-2	Implementing changes to systems and procedures to eliminate possible causes

1.2. Implement change(s) to systems and procedures to eliminate possible causes

In LO 2, inf 3 you constructed a Cause and Effect Diagram (Ishikawa or Fishbone Chart) relating to a problem from your own experience. In your answer you included:

- the Cause and Effect Diagram
- a description (two to three lines) of the problem or variation
- the top three causes (in your opinion)
- an explanation of how you would reduce the variation, linked with these causes.

8 Steps to Implementing Change

1. **Management Support for Change: -** Employees develop a comfort level when they see management supporting the process.
   It is critical that management shows support for changes and demonstrates that support when communicating and interacting with staff.
   There is nothing worse than sending a mixed message to employees. If you can't support the change 100%, don't even think about making it. Employees will know it and it will self-destruct.
2. **Case for Change: -** No one wants to change for change sake, so it is important to create a case for change. A case for change can come from different sources. It can be a result of data collected on defect rates, customer satisfaction survey, employee satisfaction survey, customer comment cards, business goals as a result of a strategic planning session or budget pressures.
   Report this ad Using data is the best way to identify and justify areas that need to improve through change initiatives.
3. **Employee Involvement: -** All change efforts should involve employees at some level. Organizational change, whether large or small, needs to be explained and communicated, specifically changes that affect how employees perform their jobs. Whether it is changing a work process, improving customer satisfaction or finding ways to reduce costs, employees have experiences that can benefit the change planning and implementation process.
   Since employees are typically closest to the process, it is important that they understand the why behind a change and participate in creating the new process.
4. **Communicating the Change: -** Communicating change should be structured and systematic. Employees are at the mercy of management to inform them of changes. When there is poor communication and the rumor mill starts spreading rumors about change, it can create resistance to the change.
   Being proactive in communications can minimize resistance and make employees feel like they are part of the process.

5. **Implementation: -** Once a change is planned, it is important to have good communication about the roll-out and implementation of the change.
   A timeline should be made for the implementation and changes should be made in the order of its impact on the process and the employees who manage that process.
   For instance, if your organization is upgrading its software program, employee training should be done before the software is installed on their computers.
   An effective timeline will allow for all new equipment, supplies or training to take place before it is fully implemented.
   Implementing without a logical order can create frustration for those responsible for the work process.
6. **Follow- up: -** Whenever a change is made it is always good to follow-up after implementation and assess how the change is working and if the change delivered the results that were intended. Report this ad Sometimes changes exceed target expectations but there are occasions that changes just don't work as planned. When this is the case, management should acknowledge that it didn't work and make adjustments until the desired result is achieved.
7. **Removing Barriers: -** Sometimes employees encounter barriers when implementing changes.
   Barriers can be with other employees, other departments, inadequate training, lacking equipment or supply needs. Sometimes management also needs to deal with resistant or difficult employees.
   It is management's responsibility to ensure that employees can implement change without obstacles and resistance.
   It is unfortunate but there are times when employees simply can't accept a change. In these rare cases, employees simply need to move on in order to successfully implement a needed change. These are difficult but necessary decisions.
8. **Celebrate: -** It is important to celebrate successes along the way as changes are made. Celebrating the small changes and building momentum for bigger changes are what makes employees want to participate in the process.
   When employees understand why a change is made and are part of the process for planning and implementing the change, it allows for a better chance for successful implementation.
   If you would like to learn more about managing change in your organization, John Kotter has a great book, Leading Change, with a New Preface, that I highly recommend. Filed Under: Quality Management, Small Business Management

Self-Check -2	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. _____Employees develop a comfort level when they see management supporting the process
2. _____ Removing Barriers Sometimes employees encounter barriers when implementing changes.
3. _____ All change efforts should NOT involve employees at some level.
4. _____Celebrate is important to celebrate successes along the way as changes are made.
5. _____Communicating change should be structured and systematic.

Note: **Satisfactory rating - 3 and 5 points** **Unsatisfactory - below 3 and 5 points** You can ask you teacher for the copy of the correct answers

Information Sheet-3	Communicate to relevant personnel

3.1. Working relationships and communication

The standard for inspection work is: Each inspection organization should seek to facilitate positive working relationships and effective communication with those entities being inspected and other interested parties.

The Offices of Inspectors General (OIG) and the Department/Agency should strive to:

- Foster open communication at all levels. With limited exceptions, primarily related to investigative-type work, the OIG should keep the Department/Agency advised of its work and its findings on a timely basis and strive to provide information helpful to the Department/Agency at the earliest possible stage. Surprises are to be avoided.
- Interact with professionalism and respect. OIGs should act in good faith.
- Recognize and respect the mission and priorities of the Department/Agency. Each OIG should work to carry out its functions with a minimum of disruption to the primary work of the Department/Agency.
- Be thorough, objective, and fair. The OIG must perform its work thoroughly, objectively, and with consideration to the Department's/Agency's point of view and should recognize Department/Agency successes in addressing challenges or issues.
- Be engaged. While maintaining OIG statutory independence of operations and recognizing that OIGs need to conduct work that is self-initiated, congressionally requested, or mandated by law, OIGs should interact with Department/Agency management to identify any specific needs or priorities management may have regarding the reviews to be conducted by the OIG.
- Be knowledgeable. The OIG will continually strive to keep abreast of Department/Agency programs and operations, and Department/Agency management should be kept appropriately informed of OIG activities and concerns being raised in the course of OIG work.
- Provide feedback. OIGs should implement mechanisms, both formal and informal, to ensure prompt and regular feedback.

During an inspection, inspectors should appropriately communicate information about the process and the nature of the inspection to the various parties involved to help them understand such things as the inspection objective(s), time frames, data needs, and reporting process. Inspectors should use their professional judgment and comply with their respective organizations' policies and procedures to determine the form, content, and frequency of communication. Communication should be appropriately documented in the associated inspection records.

Following on from inf 2 we now need to consider the implications of your three changes in terms of documentation and communication.

Activity: Assignment - Quality Actions and Outcomes

How would you document the changes you decided were needed in the Assignment - Cause and Effect Diagram, Implementing Change and how would you communicate the changes to staff (and customers if appropriate)? Provide clear, concise and detailed answers to these questions (above) and be sure to include the following:

1. the names of new or altered documents required
2. a full example of one document (choose the shortest one)
3. a list of changes that may need to be made to other documents, for example the creation of a new fire safety SOP may need to be referred to in another SOP
4. how and why you would communicate the changes to staff (and others if appropriate).

Self-Check -3	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1. _____ Inspectors should appropriately communicate information about the process and the nature of the inspection.
2. _____ Communication should be appropriately documented in the associated inspection records.
3. _____ Provide feedback should implement mechanisms, only informal, to ensure prompt and regular feedback.

Note: **Satisfactory rating - 3 and 5 points Unsatisfactory - below 3 and 5 points**

You can ask you teacher for the copy of the correct answers

Instruction Sheet	LG15: Participate in the development of continuous improvement strategies

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- Identifying possible contributing factors.
- Identifying options for removing or controlling the risk
- Assessing the adequacy of current controls, quality methods and systems
- Identifying opportunities to continuously improve performance
- Developing recommendations for continual improvements

Consult with appropriate personnel to refine recommendations Promoting sustainable energy principles and work practices This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, you will be able to:**

- Review all relevant features of work practice to identify possible contributing factors leading to sub-optimal performance
- Identifying options for removing or controlling the risk of sub-optimal performance
- Assessing the adequacy of current controls, quality methods and systems
- Identifying opportunities to continuously improve performance
- Developing recommendations for continual improvements of work practices, methods, procedures and equipment effectiveness
- Consulting with appropriate personnel to refine recommendations before implementation of approved improvement strategies

Documenting outcomes of strategies and communicate them to relevant personnel

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the information Sheet
4. Accomplish the “Self-checks, in each information sheets.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets and LAP Tests if any”. However, if your rating is unsatisfactory, ask your teacher for further instructions or go back to Learning Activity.

Information Sheet-1	Communicate to relevant personnel

1.1. Participate in the development of continuous improvement strategies

To be recognized as competent in this unit you must be assessed in both the knowledge content and the workplace skills. The assessment is in two parts, part one is a knowledge assessment and part two is a practical assessment.

Introduction

Total Quality Management (TQM) is a philosophy for managing the quality of an enterprise at every level and on a continuous basis. Remember, there is no such thing as a perfect process it can always be improved.

Important aspects of TQM

- Quality and Competition
- Continuous Improvement
- Strong Customer Focus (both internal and external)
- Variability Reduction} Last two are linked aspects
- Employee Participation in Problem Solving

TQM looks at the three components in the creation of goods or services:

- Customer
- Producer
- Supplier.

TQM strives to delight the customer with outstanding service. The customer is defined as anyone that relies on you for information or a product and includes External Customers (people who purchase goods or services from SimuLab) or Internal Customers (your fellow workmates at SimuLab).

Colin, the trainee technician, asks you if you will help him set up the QC for the Glucose Analyser. He is now your customer as he is relying on you for help and information. You should provide him with timely and effective service. If you do not, then the external customer who is relying on Colin to provide them with the Krazy Kola results will not be given outstanding service and the reputation of Simulation Lab (and maybe the bottom line) will suffer.

Continuous Improvement - you will now concentrate on the implementation of continuous improvement procedures but remember that the needs of the customer (both external and internal) and variability reduction are also significant parts of the process and must be considered in your activities.

Click on the link below if you would like to refresh yourself or extend your understanding of quality and its principles.

More on Quality!

Terminology

The following Quality Management terms must be understood to fully appreciate the Simulation Lab quality system.

Quality

Quality is a term that is often used inaccurately. The term can cause confusion because it has TWO related but different meanings:

- high grade, superior excellence
- a characteristic, property or attribute (The Macquarie Dictionary).

It is the SECOND meaning of quality that is used in the context of business, manufacturing, and commerce, or in this case, laboratory testing. Note that this second meaning does not specify whether the quality is high or low.

Quality Control (QC)

Quality control involves checking the product to ensure that it complies with given parameters. QC can never improve a product - it just removes or repairs defective products before they get to the customer.

Quality Assurance (QA)

This is the task of overseeing the quality function. This includes planned, systematic actions leading to adequate confidence the goods or services will satisfy given requirements. QA improves the product by putting in place systems and procedures that lead to a better product.

Total Quality Management (TQM)

This is an on-going strategy that changes the culture of an organization. A philosophical approach that concentrates on the needs of the customer and strives to give outstanding customer service, and uses continuous improvement whilst maintaining 'fitness for purpose'.

History

The history of the quality movement is complex and lengthy, stretching as far back as ancient times. The following is a brief summary.

Roman Empire

Bridge engineers were directly responsible for the quality of their work. Poor quality often resulted in death!

Before the Industrial Revolution

Craftsmen dealt directly with purchasers (fitness for purpose was very important).

Industrial Revolution

Foremen assumed responsibility for QC. Craftsmen/workers now not necessarily in contact with the customer.

1925

Bell Telephone Company established modern concepts of QC and QA - used sampling, inspection and testing, and 'do it right first time'.

1940s (World War Two)

USA led a massive quality training effort including the use of statistical research.

1950s - 1970s

The Western world became complacent about Quality; standards remained the same or slipped.

1950s

Deming and Juran went to Japan (post-war reconstruction of Japanese industry) leading to a massive turnaround in quality of products and many innovative approaches to design and manufacture, for example:

- Quality Control Circles
- Kanban (Just in Time)
- Kaizen (Continuous Improvement).

1970s - Present

Others in the Western world caught up with Japan. Strong emphasis on TQM. Development of standards such as the ISO 9000 series and ISO 17025 for Laboratory Operations.

Continuous Improvement

Continuous Improvement is a never-ending process of searching for ways to improve a process or product. Steps may be small, incremental and time-consuming, but the philosophy is for steady improvement to be made. Ideas for improvement are solicited from staff and customers.

Tools of Quality

There are many tools that are used to measure, evaluate and improve quality. Some of these include:

- **PDCA** (Plan, Do, Check, Act) - cycle for improvement
- **Ishikawa Charts, Fishbone Charts and Cause and Effect Diagrams** - for evaluation of processes
- **Pareto Charts and analysis** - to determine how inputs are related to products or results
- **SWOT Analysis** (Strengths, Weaknesses, Opportunities, Threats) - used to evaluate a process, product or business in terms of these four interrelated parameters
- **Run Charts, Control Charts, Histograms and Scatter grams** - used to represent QC data in a logical and readable form
- **Brainstorming** - for continuous improvement purposes and problem solving.

TQM Concepts

Total Quality Management is an all-encompassing philosophy that includes the concepts of QC, QA and Statistical QC, as well as the following concepts:

- Quality & Competition
- Continuous Improvement
- The concept of Internal and External Customers
- Variability Reduction
- Employee Participation in problem solving.

Customer Complaints

The handling of customer complaints is an important aspect of the SimuLab quality system (and it's also a requirement in the laboratory competency standard, ISO 17025).

At SimuLab all customer complaints are to be:

- Treated as an opportunity to improve
- Logged in the customer complaint folder
- Investigated and acted upon
- Recorded
- In all but the most extreme circumstances, resolved to the customer's satisfaction.

1.1. Review all relevant features of work practice to identify possible contributing factors leading to sub-optimal performance

W Edwards Deming distilled his decades of quality experience into two sets of helpful hints:

- Deming's 14 TQM Points
- Deming's Seven Deadly Diseases

DEMING'S 14 TQM POINTS

1. Create constancy of purpose towards service improvement.
2. Adopt the new philosophy (TQM).
3. Cease dependence on inspection to achieve quality (QC).
4. End the practice of awarding business solely on the price tag (our suppliers).
5. Constantly improve the process of planning production and service.
6. Institute training on the job.
7. Institute leadership for people and systems improvement.
8. Drive out fear in order to encourage employees to work together.
9. Break down barriers between departments and work areas.
10. Eliminate slogans, exhortations and production targets.
11. Eliminate numerical quotas for management and the workforce.
12. Remove barriers to pride of workmanship (empowerment).
13. Institute a vigorous program of education and self-improvement for everyone in the organization.
14. Put everyone in the organization to work accomplishing the transformation (everyone is responsible for quality!)

DEMING'S SEVEN DEADLY DISEASES

1. Lack of constancy of purpose to improve products and services by providing resources for long-range planning, research and training.
2. An emphasis on short-term profits and the quarterly dividend.
3. Individual performance evaluations through merit ratings and annual reviews.
4. Managers who are highly mobile, hopping from company to company.
5. Use by management of numbers and figures that are visible and available, with no thought of what information may be needed but unknown or hidden.
6. Excessive medical costs.
7. Excessive legal liability costs, swollen by lawyers who work on contingency fees.

In previous examples you have concentrated on the processes themselves, the science and human errors. We will now concentrate on the systems, procedures and policies that impact on quality delivery.

Remember that 85% of causes of variation are common causes that are part of the system installed by management. TQM and Continuous Quality Improvement (CQI) are tools for improving the system.

Self-Check -1	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1._____ a philosophy for managing the quality of an enterprise at every level and on a continuous basis.

A. Quality C. Management

B. Total Quality Management D. None

2. _____TQM looks at the three components in the creation of goods or services:

A. Customer C. Supplier

B. Producer D. All E. None

3._____ used to evaluate a process, product or business in terms of these four interrelated parameters

A. SWOT Analysis C. Continuous Improvement

B. Tools of Quality D. Brainstorming

4._____ involves checking the product to ensure that it complies with given parameters.

A. Equality control C. Quality Assurance

B. Producer D. Supplier

5._____ used to represent QC data in a logical and readable form

A. Run Charts, C. Histograms and Scatter

B. Control Charts, D. All

Information Sheet-2	Identifying options for removing or controlling the risk

1.1. Identify options for removing or controlling the risk of sub-optimal performance

Whenever an example of a factor contributing to sub-optimal performance is identified there are a number of factors to consider.

- The how, why, what, where and when of change
- Up-front costs and possible long term savings
- Personnel implications, for example, training, resistance, numbers, changes in management
- Customer implications, for example, improved service, increased cost, turnaround time
- Supplier implications, for example cost, availability, supplier's quality system
- Documentation
- Flow on changes to other aspects of the workplace.

This range of factors will lead to the generation of a number of options including:

- do nothing (too expensive, customer does not need it, supplier cannot supply)
- do it all at once ('crash through' approach)
- do it over time (often easier to gain staff acceptance this way)
- remove the risks completely (eg replace machine, replace staff, pull out of this testing)
- control the risks (better QA, more sensitive QC).

Self-Check -2	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1. _____there is no Factor contributing to sub-optimal performance is identified there are a number of factors to consider

Note: **Satisfactory rating - 3 points** **Unsatisfactory - below 3 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-3	Assessing the adequacy of current controls, quality methods and systems

7.3. Assess the adequacy of current control, quality methods and systems

Philip Crosby is often described as the 'evangelist' of quality management. He wrote a book called 'Quality is Free' which expounds his contention that Quality actually saves money and is therefore free. His view is that the price of getting things wrong (price of non-conformance) always outweighs the cost of getting things right (price of conformance). Thus **'Quality is Free'**.

Crosby's view intermeshes with many of Deming's Points.

Crosby's philosophy has three main points:

- Quality is free: poor quality is expensive
- do things right the first time
- 'zero defects' is the only legitimate goal of a quality program.

Self-Check -3	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below. Use the Answer sheet provided in the next page:

1._____which one of the following is main points of Crosby's philosophy.

A. Quality is free: poor quality is expensive

B. do things right the first time

C. Zero defects' is the only legitimate goal of a quality program.

D. All

Note: **Satisfactory rating - 3 points** **Unsatisfactory - below 3 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-4	Identifying opportunities to continuously improve performance

4.1. Identify opportunities to continuously improve performance

Quality is one aspect of SimuLab's activities. We have discussed quality at length to define it, manage it and improve it. Another aspect of SimuLab's activities is **performance.**

Obviously performance is related to quality and the two are sometimes discussed as being the same thing. But performance comes out of the quality system and of course quality is related to how we perform.

Sound confusing? Put simply, performance is what we do (for example, doing glucose measurements on 30 samples of Krazy Kola by 3.00 pm today) and quality is how well we do it (for example QC, meet the deadline, minimise wastage, report results correctly with appropriate units).

The US Joint Commission on Accreditation of Healthcare Organisations (JCAHO) has developed nine **Dimensions of Performance** and these are listed below.

- Efficacy (ability to produce the desired effect)
- Appropriateness
- Availability
- Timeliness
- Effectiveness (producing the intended or expected result)
- Continuity
- Safety
- Efficiency (competently)
- Care and Respect

NOTE: efficacy, effectiveness and efficiency have different meanings. To illustrate these different meanings, we will consider the scenario concerning the measurement of glucose levels in Krazy Kola:

- The test procedure is efficacious if it is able to measure the glucose level
- You are effective if you have the ability to produce accurate glucose levels
- You are efficient if you can do it by 3.00 pm.

Self-Check -4	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. _____ another aspect of SimuLab's activities is performance.
2. _____ Obviously performance is related to quality and the two are sometimes discussed as being the same thing
3. _____effectiveness and efficiency have the same meanings

Note: **Satisfactory rating - 3 points** **Unsatisfactory - below 3 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-5	Developing recommendations for continual improvements

5.1. Develop recommendations for continual improvements of work practices, methods, procedures and equipment effectiveness

Continual improvements or Continuous Quality Improvement (CQI) sounds very useful in theory but the practice sometimes requires hard work.

The Japanese car industry has an approach to CQI that works well because of the structure of Japanese society.

- Each and every employee is required to make a certain number of quality improvement suggestions per month (say one per month, twelve per year)
- Management evaluates all suggestions and puts in place all viable suggestions
- The worker receives workplace admiration and respect for the great idea and sometimes a monetary reward.

This is a relatively simple process (but a potential personnel relations nightmare - imagine telling Australian workers that it was mandatory to come up with 12 suggestions per year!).

The results are evident in the excellent (and relatively cheap) Japanese cars on the market today.

Self-Check -5	Written Test

Name: _____ Date: _____

Directions: Answer all the questions listed below.

1.____Continual improvements or Continuous Quality Improvement sounds very useful.

2.____Management not evaluates all suggestions and puts in place all viable suggestions

Note: **Satisfactory rating - 3 points** **Unsatisfactory - below 3 points**

You can ask you teacher for the copy of the correct answers.

Information Sheet-6	Consult with appropriate personnel to refine recommendations

10.1. Consult with appropriate personnel to refine recommendations before implementation of approved improvement strategies

Quality Improvement in the workplace is fine when outlined on paper. It may take a lot of work but we can collect data, review quality systems, institute automated QC data management, purchase better equipment and even move to a new building BUT we cannot do any of these things without

CONSULTATION.

Consultation means:

- Meeting for deliberation
- Seeking information or advice from someone who knows more than we do
- Taking counsel
- Taking suggestions into consideration.

Whenever you consult always keep these points in mind. You need to:

- Meet, talk and listen
- Seek advice
- Talk to the right people.

Self-Check -6	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below.

1._____Consultation means.

A. Meeting for deliberation

B. Seeking information

C. Taking counsel

D. Taking suggestions into consideration.

E. All

2._____ whenever you consult always keep these points in mind.

A. Meet, talk and listen C. Talk to the right people.

B. Seek advice D. All

Note: **Satisfactory rating - 3 points** **Unsatisfactory - below 3 points**

You can ask you teacher for the copy of the correct answers.

Reference

1. Electrical-Quality-Control-Plan-Sample
2. Manual on Quality Assurance for Installation and Commissioning of Instrumentation, Control and Electrical Equipment In Nuclear Power Plants
3. NPP—. Quality Assurance Manual
4. International standard on quality control
5. Methods and techniques for implementing the quality assurance programmer

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