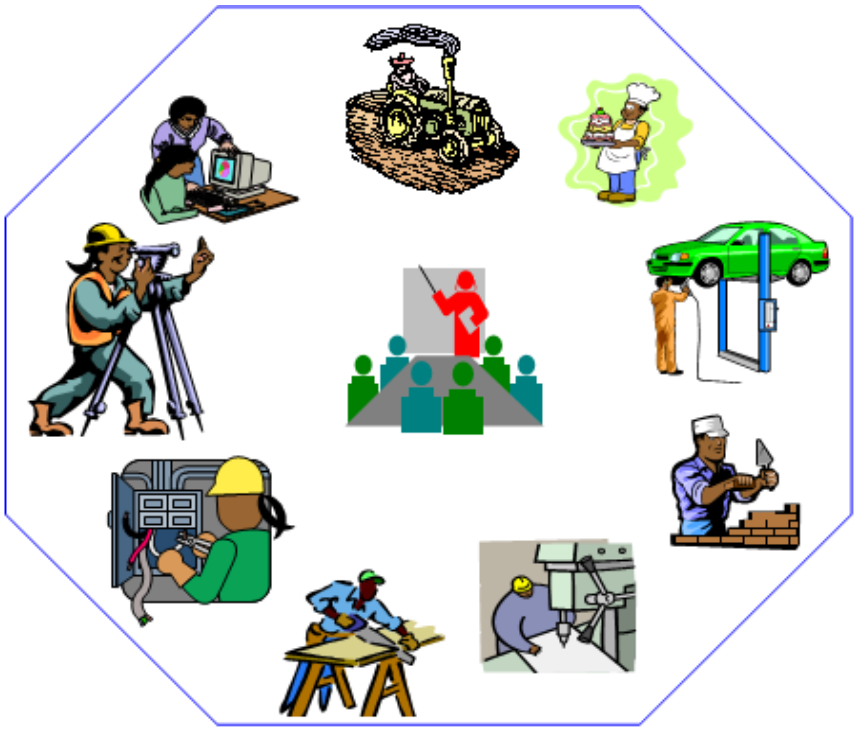
Dairy Products Processing

Level III

Based on Oct, 2019, Version 2 OS and March 2021, V1 Curriculum



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LG 64 #	LO #1- Implement quality standards

Instruction sheet 1

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

- Acquiring and confirming agreed quality standard and procedures
- Introducing standard procedures
- Providing quality standard and procedures documents
- Revising standard procedures.

This guide will also assist you to attain the learning outcomes stated in the cover page. Specifically, upon completion of this learning guide, you will be able to identify:

- Agreed quality standard and procedures
- Introduce Standard procedures
- Provide quality standard and procedures documents
- Revise Standard procedures

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 Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
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Information Sheet 1- Acquiring and confirming agreed quality standard and procedures

1.1 Acquiring and confirming agreed quality standard and procedures

Quality can be defined in the different ways:

- It is the standards of something as measured against other things of a similar kinds, the degree of excellence of something.
- It is the degree to which a commodity meets the requirements of the customer at the start of life.
- Is about making organizations perform for their stake holders from improving products , services, systems and processes to making sure that the whole organization is fit and effective.

Milk and milk products quality control is also defined as the use of various tests to ensure that milk and milk products are safe, healthy, and meet the standards for chemical composition, purity, and levels of bacteria and other microorganisms. Production of quality milk is a complicated process. It is the concern of different dairy value chain actors such as:

Milk producers: with a good quality control system, farmers can get a fair price in accordance with the quality of milk.

Milk processors: the milk processor who pays the farmer can be sure that the milk is of good quality and is suitable for making various dairy products.

Consumers: consumers will pay a fair price, e.g. moderate price for medium quality, high price for excellent quality.

Government agencies: with a good system, the government can protect the health of consumers, prevent contaminated and sub-standard products, and ensure that everyone pays or receives a fair price. NB: All this is possible only if proper system for quality testing and assurance, which conforms to national or internationally acceptable standards.

Table 1: compositional standard of quality milk

Constituent	Average%
Fat	3.7
Protein	3.3
Lactose	4.8
Mineral	0.7
Water	87.5

Table 2: physic- chemical properties of milk (cow milk)

Property	Range
Acidity	0.13-0.14%
PH	6.4-6.6
Specific gravity	1.028-1.03%
Freezing point	0.549^{o}c
Color	Yellow creamy white
Flavor	Sweat taste of lactose & salty taste

Source:

Factors affecting milk composition

All milks contain the same constituents but these vary in amounts thus making milks differ in their compositions with milk fats showing the greatest variation followed by proteins and lactose. The various factors that affect the composition of milk include:

Species: Each species of animal yields milk of different compositions.

Breeds: High yielding animals produce milk with lower fat percentage e.g. Friesian vs. Jersey cows.

Individual variation: There is variation between individual animals. Season: Variations are evident during the course of the year (especially fats being highest during dry seasons).

Age: The fat percentage increases up to 3rd lactation and afterwards decreases.

Milking interval: With longer intervals between milking, the yield is greater with a corresponding decrease in fat content and vice versa.

Completeness of milking: First milk contains less fat and last milk contains high fat. If the milking is not complete, the milk tests for less fat.

Irregularity in milking: Frequent changes in the milking timings, and frequent changes in milking intervals results less fat.

To acquire quality standard and procedures basic components needed are:

- Quality policy
- Responsibility and authority
- resource
- management representative
- quality system
- Quality assurance

Quality policy

Quality policy is a document jointly developed by management and quality experts to express the quality objectives of the organization, the acceptable level of quality and the duties of specific departments to ensure quality.

Quality policy should:

- State a clear commitment to quality.
- Recognize customer needs and expectations.
- Be actively supported by senior management.
- List the quality objectives that wanted to achieve.
- Be understood by everyone in the organization.
- Be consistent with organization's goals.
- Be maintained throughout organization.
- Be applied throughout organization.

Responsibility and authority

Define quality system responsibilities, give quality system personnel the authority to carry out these responsibilities, and ensure that the interactions between these personnel are clearly specified. And make sure all of this is well documented.

This requirement must be met for those who:

- Manage quality system work.
- Perform quality system work.
- Verify quality system work

Resources

Identify and provide the resources that people will need to manage, perform, and verify quality system work. Make sure that:

- Only trained personnel are assigned.
- Managers have the resources that need to verify work.
- Internal auditors have the resources it needs.

Management representative

Appoint a senior executive to manage quality system and give necessary authority. This senior executive must ensure that quality system is developed and implemented. This executive must:

- Monitor the performance of quality system.
- Control the performance of quality system.
- Report on the performance of quality system.
- Help improve the performance of quality system.
- Act as organization's spokesperson on quality.

Quality system

Develop a quality system and a manual that describes it. Quality system should ensure that products conform to all specified requirements.

Quality manual should:

- State quality policy.
- List quality objectives.
- Provide an overview of quality system.
- Describe the structure of organization.

- Discuss quality system procedures.
- Introduce quality documents and records.
- Teach people about quality system.
- Control quality system work practices.
- Guide the implementation of quality system.
- Explain how quality system will be audited.

Quality Assurance

Quality Assurance is a system of management activities involving planning, implementation, assessment, and reporting to make sure that the end product (i.e., environmental data) is of the type and quality needed to meet the needs of the user.

Self-check-1	Written test

Test item 1: Define the following terms

1. Quality control
2. Quality assurance
3. Quality policy
4. Basic components to acquire standards and procedures.

Information Sheet 2- Introducing standard procedures

2.1 Introducing standard procedures

Standards -are specifications for processes, procedures and product composition. It normally put together by national bureaus of standards for specific products and processes. Dairy industry standards thus form guidelines for the production of safe, wholesome and nutritious dairy products. Some standards are voluntary while others are compulsory. Food and Dairy Products Standards are mostly compulsory.

Procedures -are sets of practices specified by authorities or regulations. It may involve application for processes, permits and licenses returns as part of the conditions for conducting a specific business.

Aims of standards and procedures

The aim of policy, standards and codes of practice is to:

- Create harmony or agreement
- Standardize product quality and processes
- Promote fair play
- Meet safety requirements
- Avoid hazards and liabilities
- Enhance market access

When introducing standard procedures, managers can choose a number of different ways to organize and format. The goal is to create a document that is easy for the reader to understand and helpful for the work at hand.

Two factors determine type of Standard Procedures to use.

First, ways of decisions that the user need to make during the procedure.

Second, ways of steps and sub steps in the procedure, Routine procedures that are short and require few decisions can be written using the simple steps format. Long procedures consisting of more than ten steps, with few decisions, should be written in hierarchical steps format or in a graphic format. Procedures that require many decisions should be written in the form of a flowchart.

Hierarchical Steps - a dairy striving for very consistent work should use a more detailed and precise format for most Standards and Procedures.

The hierarchical steps format allows the use of easy-to read steps for experienced users while including more detailed sub steps as well. Experienced users may only refer to the sub steps when users need to, while beginners will use the detailed sub steps to help them learn the procedure.

Graphic Procedures When writing procedures for very long activities, managers should consider using a graphic format. The graphic format breaks long processes into shorter sub processes that consist of only a few steps. Workers can learn several short sub processes more easily than one long procedure. Another possibility for the graphic format is to use photographs and diagrams to illustrate the procedure. Many producers and most of their advisers have access to computers with powerful graphic capabilities. Digital cameras are now relatively inexpensive and simple to operate. Use these tools to design creative Standards and Procedures that combine helpful pictures with explanatory text. Pictures truly are worth a thousand words, and it is helpful regardless of the literacy level or native language of a worker.

Flow charts

Procedures that require many decisions should be presented as a flowchart. Flowcharts are simply a graphic way to present the logical steps in a decision-making process. While normal milking procedures are quite straightforward and repetitive, deciding what to do about a cow with abnormal milk certainly is not. Many different factors such as mastitis or an injury may cause the abnormal milk. The appropriate response to each situation may be dramatically different. A flowchart provides an easy-to-follow mechanism for walking a worker through a series of logical decisions and the steps that should be taken as a result.

Self-check-2	Written test

Test item I. Define the following terms.

1. Standard
2. procedure

Test item II short answer

1. Write the ways how do procedure mentioned.
2. Write aims of standard and procedures.

Information Sheet 3- Providing quality standard and procedures documents

3.1 Providing quality standard and procedures documents

The documents of standards and procedures includes:

Cleaning standards

(1) A milk house must contain

(a). one or more sinks with concave bottoms for washing equipment,

(b). a separate sink for washing hands,

(c). he necessary materials for washing and drying hands, and

(d). Cup boards, stands or shelves of non-corrosive material located off the floor to hold the materials and equipment used in the production and handling of milk or farm-separated cream.

(2) All sinks referred to in subsection

(a) Must be drained by a pipe equipped with a trap connected to a wastewater drainage system.

(3) If a milk house is provided with a laboratory, the laboratory must

(a) not open directly into the milk house working area, and

(b) be maintained in a clean and sanitary condition

Storage of hazardous products

(1) All containers of detergents or sanitizers and all other cleaning materials used in the production and handling of milk or farm-separated cream that are stored in a milk house must be in a location and stored in a manner that prevents contamination of the milk or farm-separated cream.

(2) No pesticides, or other toxic products, other than those that are directly related to the operation of a milk house, must be stored in a milk house.

(3) All veterinary drugs stored in a milk house must be kept in a cupboard or refrigerator in a manner that prevents contamination of the milk and farm-separated cream

Hose port

(1). A milk house must be equipped with a hose port that

(a). is located at least 40 cm above the milk house floor,

(b). is not more than 15 cm in diameter, and

(c). is kept closed when not in use to prevent the entry of pests.

(2). A milk house must have (a) outside the milk house and directly below the hose port, a concrete apron

(I). that is connected to the main entrance of the milk house by a concrete walkway, and

(II) that is large enough so that the hose of the milk transport vehicle cannot contact ground other than the concrete walkway,

(a). a grounded exterior electrical outlet adjacent to the hose port and controlled by a bipolar switch located on the interior wall of the milk house in a location accessible to the bulk milk grader, and

(b). a window in the milk house that permits the bulk milk grader to observe the transfer pump compartment of the milk transport vehicle's tank from inside the milk house

Equipment

(1) When located in a milk house, the refrigeration compressor, water heater and water pump must be installed and operated in a manner that does not contaminate the milk.

(2) A milk house must be equipped with a separate and adequately drained and well maintained equipment room for the vacuum pumps.

Milk and Cream Handling Equipment

Equipment in contact with milk

The surfaces of materials and equipment that come into contact with milk or farm-separated cream must be:

(a). constructed of non-corrosive material,

(b). smooth and free of cavities, open seams and loose particles,

(c). non-toxic and resistant to damage by cleansers and sanitizers,

(d). unaffected by milk or farm-separated cream, and

(e). Manufactured so as not to affect milk and farm-separated cream.

Equipment maintenance - All equipment used to handle, store or transport milk or farm-separated cream must be:

(a). kept clean,

(b). installed and maintained in accordance with the manufacturer's instructions,

(c). maintained in working order, and

(d). used only for the purposes of collecting, cooling, holding and transferring milk or farm-separated cream

Tank standards

(1) The owner of a milk transport vehicle must ensure that the milk transportation tank and related equipment conform:

(a). insulated so that the temperature of the milk cannot rise more than 2ºC in 24 hours, and

(b). Equipped with a sufficient number of spray balls to allow for proper cleaning.

(2) The milk transportation tank and related equipment of the milk transport vehicle must be cleaned and sanitized at least once a day in a manner that prevents contamination of the milk.

(3) If more than one shipment is collected in one day in a milk transport vehicle, the pump, hoses and fittings of the milk transport vehicle must be washed between shipments.

(4) On a milk transport vehicle, the inner wall of the milk transportation tank and any equipment that comes into contact with milk, and any container used for the transportation of farm-separated cream, must be

(a). constructed of non-corrosive material, and manufactured in such a manner as not to affect milk or farm-separated cream,

(b). smooth and free of cavities and loose particles, and

(c). Non-toxic and resistant to damage from cleansers and sanitizers.

Plant standards

The dairy plant must meet the following requirements: a floor

(i). made of a hard, washable and waterproof material, and be rounded at the intersections with the walls in order to prevent any accumulation of water or dirt,

(ii). free of indentations, cracks and crevices,

(ii). inclined toward the drains so as to prevent the accumulation of liquids, and

(iv). provided with a wastewater drainage system that includes devices for preventing the contamination of the facilities by pests and odours;

the walls and ceilings must be

(I). covered with a hard, smooth, washable and waterproof material, and

(II). free of indentations, pitting, cracks and flaking; doors, windows and any other openings to the exterior must be kept closed or have screens or other devices to prevent pests from entering the dairy plant.

Dairy plant water system:

(1) The dairy plant must have hot and cold pressurized running water and soap for the washing of hands, with equipment for drying and disinfecting hands.

(2) The dairy plant must have hot and cold running potable water under pressure, with pipes and nozzles installed and arranged in a way that facilitates the cleaning of the facilities and equipment.

(3) The dairy plant must have a drainage system for wastewater that separates the floor wastewater from the sewage wastewater until the wastewater leaves the dairy plant, and includes an inspection hole, flush mechanisms, drainage siphons, protection grids and a solid matter interceptor.

(4) The drainage system for a dairy plant's washing water must be separate from the sanitary drains for the toilets, urinals and sinks.

(5) The washroom facilities of a dairy plant must

(a). have hot and cold running potable water under pressure, and equipment for cleaning and drying hands, and

(b). Not lead directly into the dairy product handling areas.

Hygiene standards

(1) Entry to the processing, manufacturing, reprocessing, packing and repacking areas of a dairy plant must be restricted to personnel authorized by the processor.

(2) A processor must follow sanitary practices and require all workers in the dairy plant and visitors to the dairy plant to comply with those practices in order to ensure the sanitary processing of dairy products.

(3) The dairy plant and its material and equipment must be kept clean.

(4) The workers at a dairy plant must

(a). wear work apparel that shows dirt easily, and that has no pockets or buttons above the waist,

(b). wear a head covering or a hairnet and beard-cover in order to completely cover the hair while working in the dairy plant,

(c). change clothing before moving from a high potential cross-contamination area to a lower potential area,

(d). ensure that watches and jewellery are not worn within the dairy product handling areas, and

(e). be properly trained for the duties being performed.

(5) Tobacco may not be used and food and drink may not be consumed within

(a). the dairy product handling areas,

(b). the dairy product equipment cleaning facilities area, or

(c). the areas for the storage of dairy products and supplies to be used in processing dairy products of a dairy plant.

(6) Dairy products may be handled in a dairy plant only by

(a) a person who does not have a communicable disease at an infectious stage, or who does not have an infected sore or wound,

(b) a person who is not a carrier of pathogens that could contaminate dairy products, and

(c) a person who, if that person has an open sore, is wearing a waterproof protection on the wound that prevents contamination of the dairy products and of ingredients or surfaces with which the dairy products come into contact.

(7) A processor must ensure that there is an effective pest control program that prevents the entry of pests into and eliminates pests from the dairy plant.

(8) Waste, garbage and refuse of any kind in a dairy plant must be deposited in impermeable containers that

(a). are made of a material that is washable and unaffected by disinfectants,

(b). have tight-fitting covers that will not detach when opened, and

(c). are properly identified and kept clean.

(9) Waste containers must be taken to the main waste area or compartment at the end of the daily operations or if they become full during the course of daily operations.

(10) Waste must be managed so that the dairy products handling facilities and equipment are not contaminated, and there is no risk of contamination of the potable water supply.

Operation requirements

(1) A processor must ensure that all equipment used in the processing of dairy products is designed, constructed, installed and operated to ensure that there is no contamination of pasteurized dairy products by any other product.

(2) The surfaces of the materials and equipment that come into contact with dairy products must be

(a). made of non-corrosive material,

(b). smooth and have no crevices or loose parts,

(c). non-toxic and of a type suitable for cleaning and disinfecting operations,

(d). unaffected by the dairy products, and be constructed so that they do not alter the characteristics of the dairy products, and

(e). free of components or residue that may contaminate dairy products.

(3) Steam introduced directly into dairy products or that comes into direct contact with the surfaces of dairy product processing equipment must be from potable water and be free of harmful substances.

(4) The materials and equipment that come into contact with dairy products must be cleaned at the end of the dairy plant's daily operations, and must be sanitized immediately before use and every time they are contaminated.

(5) Non-metallic materials must be used when hand cleaning equipment and utensils.

Self-check -3	Written test

Item I Give short answer

1. Write at least 5 standards that are contained in plant documents.

Information Sheet 4- Revising standard procedures

4.1 Revising standard procedures

To revise the standard procedures quality management plan would be applied.

Quality Management Plan (QMP)

A QMP is a formal plan that documents an entity's management system for the environmental work to be performed. The QMP is an "umbrella" document which describes the organization's quality System in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces with those planning, implementing, and assessing all environmentally related activities conducted.

Quality system procedures

Develop and implement quality system procedures that are consistent with quality policy.

- Develop procedures for all areas of quality system.
- Document procedures, and keep them up to date.
- Each procedure should:
  - ✓ Specify its purpose and scope.
  - ✓ Describe how an activity should be carried out.
  - ✓ Describe who should carry out the activity.
  - ✓ Explain why the activity is important to quality.
  - ✓ Describe when and where it should be carried out.
  - ✓ Explain what tools and equipment should be used.
  - ✓ Explain what supplies and materials should be used.
  - ✓ Explain what documents and records should be kept.
- Procedures may also refer to detailed work instructions that explain exactly how the work should be done.

Quality planning

Develop quality plans that show how somebody intend to fulfill quality system requirements. It is expected to develop quality plans for products, processes, projects, and customer contracts.

- Quality plans should list the quality objectives intend to achieve, and the steps intend to take to achieve these objectives.
- When constructing quality plan, consider the following terms:
    - ✓ need to purchase any new equipment or instruments, or any new inspection and test tools
    - ✓ need to carry out any special training in order to fulfill all quality system requirements
    - ✓ need to improve design, production, testing, inspection, installation, or servicing procedures
    - ✓ Need to improve your quality measurement and verification procedures
    - ✓ need to develop any new measurement methods or instruments
    - ✓ need to clarify your organization's standards of acceptability
    - ✓ Need to develop any new documents, forms, reports, records, or manuals
    - ✓ need to allocate more resources in order to achieve the required levels of quality

Quality management standards

Quality management system (QMS) standards establish a framework for how a business manages its key processes. It can help whether the business offers products or services and regardless of your size or industry. It can also help new businesses start off on the right foot by ensuring processes meet recognized standards, clarifying business objectives and avoiding expensive mistakes.

To comply with the standard somebody first need to implement a QMS. Implementing a QMS can help the business to:

- achieve greater consistency in the activities involved in providing products or services

- reduce expensive mistakes
- increase efficiency by improving use of time and resources
- improve customer satisfaction
- market your business more effectively
- exploit new market sectors and territories
- manage growth more effectively by making it easier to integrate new employees
- constantly improve your products, processes and systems

For example, the quality system of a manufacturing business might include looking at more efficient manufacturing processes or speeding up distribution.

The **ISO 9000 series** of standards is the main set of International Standards applying to the management of quality systems. It includes ISO 9001, the key internationally agreed standard for a QMS. Businesses can be certified against this standard when it meet its requirements.

The ISO 9001:2008 standard

ISO 9001:2008 is the key internationally agreed standard for quality management systems. It is used by over 951,000 businesses in 175 countries worldwide (source: British Standards Institution (BSI), 2010).

The ISO 9001:2008 standard has four elements:

- **management responsibility** - ensuring top level management shows commitment to the quality system and develops it according to customers' needs and the business' objectives
- **resource management** - ensuring the people, infrastructure and work environment needed to implement and improve quality systems are in place
- **product realization** - delivering what customers want, looking at areas such as sales processes, design and development, purchasing, production or service activities
- **measurement, analysis and improvement** - checking whether you have satisfied customers by carrying out other measurements of your system's effectiveness

The advantages of ISO 9001:2008 for the business can include:

- greater efficiency and less waste
- consistent control of major business processes, through key processes lists

- regulation of successful working practices
- risk management
- increased customer satisfaction
- greater consistency in the quality of products and services through better control of processes
- differentiation of business from its competitors
- increased profits
- exploitation of new markets

However, business man should also be aware of some of the **disadvantages** to implementing the standard. These can include:

- the cost of getting and keeping the certification
- the time involved
- overcoming opposition to implementing change from within the business

The standard is adaptable to business' needs and resources, though any one may need the help of a consultant.

The ISO 9004:2009 standard

ISO 9004:2009 goes beyond ISO 9001:2008 and provides guidance on how some one can continually improve your business' quality management system. It also contains information on managing for sustained success. This can benefit not only ones' customers but also:

- employees
- owners
- suppliers
- society in general

By measuring these groups' satisfaction with your business, you'll be able to assess whether you're continuing to improve.

The ISO 9000 series, which includes 9001 and 9004, is based around eight quality management principles that senior managers should use as a framework for improvements to the business:

- **Customer focus** – it must understand and fulfill customer needs.

- **Leadership** – leaders should demonstrate strong leadership skills to increase employee motivation.
- **Involvement of people** - all levels of staff should be aware of their responsibilities within the business and the importance of providing what the customer requires.
- **Process approach** - identifying your essential business activities and considering each one as part of a process.
- **System approach to management** - managing processes together as a system, leading to greater efficiency and focus. Some could think of each process as a cog/ component in a machine, helping it to run smoothly.
- **Continual improvement** - this should be a permanent business objective.
- **Factual approach to decision-making** - senior staff should base decisions on thorough analysis of data and information.
- **Mutually beneficial supplier relationships** - managers should recognise that business and its suppliers depend on each other.

Self-check-4	Written test

Test item I. define the followings

1. Quality management plan
2. Resource management
3. Advantages of quality system

LG 65#	LO #2- Assess quality of service delivered

Instruction sheet 2

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

- Checking quality services against standards and specifications.
- Evaluating service using the appropriate evaluation quality parameters
- Identifying causes of any faults and taking corrective actions

This guide will also assist you to attain the learning outcomes stated in the cover page. Specifically, upon completion of this learning guide, you will be able to identify:

- Check quality services against standards and specifications
- Evaluating service using the appropriate evaluation quality parameters
- causes of any faults and taking corrective actions

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6. You are to get the key answer only after you finished answering the Self-checks).
7. If your performance is satisfactory proceed to the next learning guide,

Information Sheet 1- Checking quality services against standards and specifications

1.1 Checking quality services against standards and specifications

To assess the quality of services, three elements or types of measures needed to be considered:

- structure measure
- process measures
- out comes measures

Structures measures- refer to the organization and elements of the system of care.

Process measures-examines how the care is provided.

Outcome measures- related to the ultimate effect or results of the care deliver.

Deliver- means to cause and to become, to show, to perform, to give back or to make something. In addition delivering is the process generating an image from model, by means of program.

Evaluating service delivered

Quality refers to excellent of a product or a service, including it's' attractiveness, lack of defects reliability and long term durability.

Quality check may include:

- visual inspection
- physical measures
- Check against design/specifications.

Physical measurement/inspection

I) Measuring devices are needed to provide evidence of conformity of product to determined requirements.

Darkened fat column containing black specks at the base is due to:

- Temperature of milk-acid mixture too high.
- Acid too strong.
- Milk and acid mixed too slowly.
- Too much acid used.

- Acid dropped through the milk.

II) A documented procedures outlines the process used to ensure that monitoring and measurement to be carried out in a manner that is consistent with the monitoring and measurement requirements.

III) Calibrated or verified at specific intervals, or prior to use against measurement standards traceable to international or national standards.

IV) Adjusted or re-adjusted as necessary

V) Identified to enable the calibration status to be determined

Safeguarded from adjustments that woul invalidate the measurement results

Protected from damage and deterioration during handling, maintenance and storage.

check against specifications/preferences

Quality specification may include:

- finish (comparing with final products standards)
- fit
- material
- alignment
- size color
- durability
- product
- variation
- damage and imperfection,
- Fabrication and etc.

Measuring techniques of materials, component parts or products

- measure includes those measurements which may be taken by the employee in the work place/ at their work station
- the characteristic of the materials to be used for specific product must be:

Good quality- this is the most important factor when choosing materials to buy. Products with good quality are long lasting and safe to use we know that it follows certain standards before being commercialized.

Reliable- means that the product be sure that will perform its well, will operate safely and give the best.

Suitable for application/purposes- choose the materials which are very nessecery to make the project possible making a list of product is good treat of wise consumer. The products which are not used must be crossed out.

low cost- it does not mean that always buy less expensive one and exclude the quality Low cost means someone afford to buy not the material does not hurting the pocket assue of better quality.

Self-check-1	Written test

Test item I write short answers for the following questions.

1. Write at least 5 quality specifications.
2. Write 3 elements to assess quality services.

Information Sheet 2- Evaluating service using the appropriate evaluation quality parameters

2.1 Evaluating service using the appropriate evaluation quality parameters

Evaluating quality parameters are used to determine:

- Potential or existing quality problems.
- Types of variation in quality
- Report variation and potential problems

a. Potential or existing quality problems

The following are methods by which a worker use to identify problems in the quality of products (milk, cheese, butter and cream) which can be used for employees to report the problems and variations to the supervisor and furthermore, to reduce food safety hazards.

Milk test

Any employee in milk processing plant should check and report the quality of milk and its product before they use it for consumption. To check it use the following mechanism.

Organoleptic test like (taste and smell)

Organoleptic test means test by our sense organ such as nose, mouth and eye.

By using our sense we can determine the freshness, storage time and other deviation of milk. The following are example of detecting flavor defect.

Acid or Sour Milk

Description Acid or sour is detected by both the senses of taste and smell. The tip of the tongue is sensitive to the "peeling" or "tingling" sensation. A general feeling of "cleanliness" and enhanced ability to taste is part of the sensation.

Cause Acid or sour milk is a result of bacterial action on lactose converting it to Lactic acid. It can be produced by culture organisms such as *Lactococcus lactis* ssp. *lactis* or *Lactococcus lactis* ssp. *Cremoris.*

Adulteration test

There are several ways in which milk may be adulterated, e.g. by adding water to increase the quantity of milk delivered and by adding an alkali to reduce the acidity of the milk with the intention to mislead with regard to its freshness.
A milk supplier may also skim off a portion of the cream layer and retain it for domestic purposes. Sophisticated equipment and techniques are required to precisely determine the degree and type of adulteration but the results of fat, titratable acidity and specific gravity tests may give strong indications of fraudulent behavior by the milk supplier.

If a lower than normal fat test is obtained combined with a high (1.035) specific gravity then milk skimming should be suspected. If a lower than normal fat test is obtained combined with a low (1.020) specific gravity then the addition of water should be suspected. A lower than normal titratable acidity, e.g. 0.10% lactic acid suggests the addition of an alkali such as sodium hydroxide or sodium bicarbonate.

Specific gravity is the relation between the mass of a given volume of any Substance and that of an equal volume of water at the same temperature.
Since 1 ml of water at 4°C weighs 1 g, the mass of any material expressed in g/ml and its specific gravity (both at 4°C) will have the same numerical value. The specific gravity of milk averages 1.032, i.e. 1 ml of milk weighs 1.032 g at 4°C.

Since the mass of a given volume of water at a given temperature is known, the volume of a given mass or the mass of a given volume of milk, cream, skim milk etc can be calculated from its specific gravity. For example one liter of water at 4°C has a mass of 1 kg, and since the average specific gravity of milk is 1.032, one liter of average milk will have a mass of 1.032 kg.
Defect in creams defect in cream flavor may be due to different factors as described in the table below

Table: 4

Possible flavor defect in cream	Possible reasons	Possible solution
Cooked taste	excessive heating	Proper pasteurization
Tallow /oily	Fat oxidation	Use proper container to prevent light(dark bottle)
Rancidity	Fat hydrolysis	Inactivate lipase via pasteurization
Barny smell	Poor ventilation	Proper ventilation or immediate removal of milk
Bitter taste	Ingestion of bitter weeds	Selective grazing
Cheesy taste	Increased activity of proteolytic bacteria	Store cream at< $5^{o}C$

b. **Types of variation in quality**

In addition to defect identification methods, the employees should know the change and cause of variability's of products. Any worker in milk processing area must understand the cause of variation of milk and its change after milking by different factors and should report the variation to the supervisor according to industry quality assurance requirement.

Freshly drawn milk is not always the same. The variability in composition has been studied best, but also the structure (e.g., the size of the fat globules) varies.

In a qualitative sense, cows' milk is fairly constant in composition.

The following are the main factors affecting composition and properties of milk.

A) **Species, breed, and individual**—in other words, genetic factors. Milk of individual cows within a breed varies over a wide range both in yield and in the content of the various constituents.

The potential fat content of milk from an individual cow is determined genetically, as are protein and lactose levels. Thus selection for breeding on the basis of individual performance is effective in improving milk compositional quality. Herd recording of total

milk yields and fat and solids-not-fat (SNF) percentages will indicate the most productive cows, and replacement stock should be bred from these.

B. Stage of lactation (this has a considerable effect; colostrum's differs greatly from normal milk),, estrus, and gestation, i.e., physiological factors. The fat, lactose and protein contents of milk vary according to stage of lactation.

Solids-not-fat content is usually highest during the first two to three weeks, after which it decreases slightly.

Fat content is high immediately after calving but soon begins to fall, and continues to do so for 10 to 12 weeks, after which it tends to rise again until the end of the lactation. The high protein content of early lactation milk is due mainly to the high globulin content.

C. Illness of the cow, mastitis in particular and age. As cows grow older the fat content of their milk decreases by about 0.02 percentage units per lactation while the fall in SNF content is about 0.04 percentage units. Both fat and SNF contents can be reduced by disease, particularly mastitis.

D. Feed, climate. Underfeeding reduces both the fat and the SNF content of milk, although SNF content is the more sensitive to feeding level.

Fat content and fat composition are influenced more by roughage (fiber) intake. The SNF content may fall if the cow is fed a low-energy diet, but is not greatly influenced by protein deficiency, unless the deficiency is acute.

E. Method of milking: The first milk drawn from the udder contains about 1.4% fat while the last milk (or stripping) contains about 8.7% fat. Thus, it is essential to milk the cow completely and thoroughly mix all the milk removed before taking a sample for analysis.

The fat left in the udder at the end of a milking is usually picked up during subsequent milking, so there is no net loss of fat. Milk is not a system in equilibrium. It changes, even while in the udder. This is partly because different components are formed at various sites in the mammary secretary cell and come into contact with one another after their formation.

Furthermore, several changes can occur due to the milking, the subsequent lowering of the temperature, and so on.

Changes may be classified as follows:

I) **Physical changes** can occur. For instance, air is beaten in during milking. Because of this, additional dissolution of oxygen and nitrogen occurs in milk. Moreover, a new structural element is formed: air bubbles.

Milk contains many surface-active substances, predominantly proteins; this can become attached to the former air–water interface. Furthermore, by contact with the air bubbles, fat globules may become damaged, i.e., lose part of their membrane.

Fat globules may cream. Creaming is most rapid at low temperature because the globules aggregate to large flocks during the so-called cold agglutination. On cooling, part of the milk fat starts to crystallize, the more so as the temperature is lower.

But even at 0^{o}C part of the fat remains liquid. The presence of fat crystals can strongly diminish the stability of fat globules toward (partial) coalescence.

II. **Chemical changes** may be caused by the presence of oxygen. Several substances can be oxidized. In particular, light may induce reactions, often leading to off-flavors.

III. **Biochemical changes** Milk contains many enzymes that can be active. Examples are lipase, which causes lipolysis; protease, which causes Proteolysis; and phosphates, which cause hydrolysis of phosphoric acid esters.

IV. Microbial changes are often the most conspicuous. The best-known effect is production of lactic acid from lactose, causing an obvious decrease in ph. numerous other changes, such as lipolysis and proteolysis, may result from microbial growth.

v. Processing of course, changes composition and properties of milk. It is intended to do so. But it often has undesirable effects. For example, high-heated milk has been markedly changed in protein composition.

After identifying the defected and non-conformance product the employee should report the problems to the supervisor according to enterprise procedure

C. Report Variation and Potential Problems

The following minimum information should be recorded during reporting work problem:

✓ Date month and year----------

- ✓ Name of reporting organization--------
- ✓ Address:----------

Title of the report

1. Problems encountered (brief description of the incident)----------
   ---
   ---
2. Possible solutions (actions) which is taken on the work site by different bodies --
   ---

   -----
3. Required support from the institution will listed ----------
   ---

Possible copies

1. **To ----------**
2. **To----------**
3. **To----------**

Each address must include

- Signature of quality controller/supervisor
- The names of the persons who investigated the incident.

Self-check -2	Written exam

Test item I short answer

1. Write quality tests discussed in the above content covered.
2. Write the advantages of evaluating quality parameters.

Information Sheet 3- Identifying causes of any faults and taking corrective actions

3.1 Identifying causes of any faults and taking corrective actions

The best way to determine causes of any quality faults in industry is implementing root cause analysis.

Root cause analysis (RCA) or environmental assessment, is defined as a retrospective investigation method used to identify why an incident occurred. An incident can be an outbreak, an event that could have caused microbial, chemical, or physical contamination, a processing failure, or a food safety system failure. The goal of this type of investigation is to determine the factor(s) underlying the problem and identify actions that can be taken to eliminate the problem, prevent its recurrence, and ultimately reduce the risk of foodborne illness. To accomplish these goals, the investigation team should take the necessary steps to identify the actual root causes, or environmental antecedents, of the problem and not just the contributing factors.

Root cause analysis (also called environmental assessment): a retrospective investigative tool used to determine the underlying reason(s) that caused an incident and what actions can be done to eliminate the problem, prevent recurrence, and reduce risk. Investigation is used synonymously with root cause analysis in this document.

Root cause (also called environmental antecedent): the underlying reasons that resulted in a system breakdown. If the root cause had not occurred, the event would not have occurred or would have been of significantly lower impact.

Contributing factors: the physical, biological, behavioral, or attitudinal factors that directly or indirectly resulted in an outbreak or other incident.

A. The difference between a contributing factor and a root cause

Distinguishing between root causes and contributing factors is crucial to ensuring that the investigation has been sufficiently thorough to arrive at the root causes. A contributing factor is ***what*** went wrong, whereas a root cause is ***why*** it went wrong. Oftentimes, contributing factors are also violations of food safety regulations (such as improper holding

temperature). Inspections or incident investigations should continue after food safety violations are identified to determine why the violation occurred. Root cause findings may or may not be clear regulatory violations; however, ending investigations at violations or contributing factors will diminish the prevention power of the RCA approach.

Control of contributing factors without addressing the underlying reason why it present can result in a repetitive cycle of short-term correction followed by gradual loss of food safety controls and recurring problems. Making this distinction encourages prevention of the problem rather than just mitigation of the effects of an incident.

Situations an RCA can be performed

Because of its broad origins in a variety of industries, RCAs can be used to investigate a wide range of adverse events affecting safety or quality from singular, unusual events to patterns of recurrences in a variety of food industry settings. An RCA can be helpful any time a food company or regulatory agency needs to know why a foodborne illness outbreak or other incident occurred and how to prevent it from recurring. There is no event too big or too small for which an RCA cannot be performed; however, it is important that the investigation techniques and approaches be appropriately tailored to match the scope and significance of the event. To be most effective in preventing food safety failures, RCAs should be integrated within a self-evaluating organizational culture and linked with existing continuous process improvement initiatives

Advantages of performing an RCA

Advantages

The findings from RCAs are critically important for understanding what went wrong in a food safety operation so that corrective actions can be implemented. Findings from RCAs should also indicate what went right, such as where safety measures and other aspects of the production system were operating as intended and prevented or mitigated the impact of an event.

- Companies may also benefit from incorporating RCA in their food safety systems in the following ways:
- Preventing future product recalls and foodborne outbreaks, protecting the health of customers, and minimizing loss of consumer confidence.

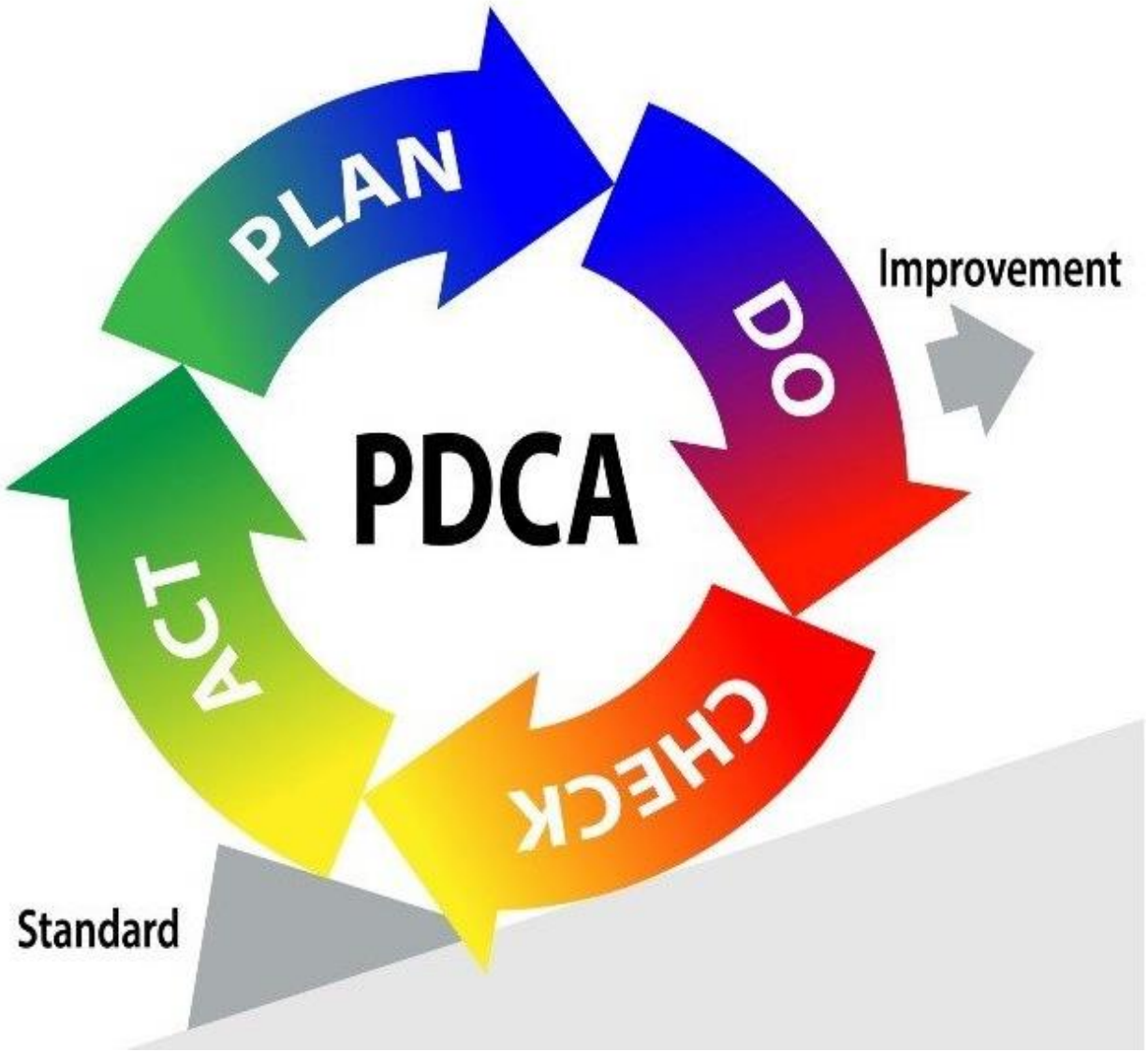
- Gaining potentially positive public perception and brand recognition, and improved customer trust, that could lead to greater profits.
- Demonstrating food safety commitment to supply-chain partners and consumers.
- Encouraging employee engagement in improving company food safety systems.
- Fostering employee pride and engagement.
- Strengthening self-evaluation, continuous process improvement, and quality assurance capacities within the company or organization's culture.

Outbreak-related information was initially grouped into five broad categories of contributing factors:

1. Improper holding temperatures of food.
2. Improper cooking temperatures of food.
3. Using contaminated utensils and equipment.
4. Poor health and hygiene of food handlers.
5. Obtaining food from unsafe sources

Corrective and preventive action (CAPA) In order to understand the usefulness of CAPA, manufacturers and workers must first introduce the PDCA cycle. The Plan-Do-Check-Act (PDCA) cycle is a four-step quality management process that was introduced by Dr. W. Edwards Deming. A graphical representation of the Deming wheel is represented below. This model is commonly used by project teams and is at the core of all food safety/quality management systems and continuous improvement initiatives.

Figure



1

Corrective Action/Preventive Action, CAPA for short, is a tool that enables the systematic investigation of a non-conformance in order to identify its true root cause(s). In a second phase, a corrective (preventative) action plan is developed to eliminate the source of the issue and prevent its recurrence.

CAPA is a tool that can be utilized during the “Check” and “Act” stages of the PDCA cycle. Without a robust CAPA problem, there would be no process improvement.

Self chek-3	Written test

Instruction 1: explain the following terms

1. Root cause analysis(RCA)
2. Corrective and preventive action(CAPA)

LG#66	LO3- Record information

Instruction sheet: 3

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

- Recording basic information on the quality performance
- Maintaining records of work quality

This guide will also assist you to attain the learning outcomes stated in the cover page.

Specifically, upon completion of this learning guide, you will be able to identify:

- Record of basic information on the quality performance
- Maintain records of work quality

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 Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, ask your trainer for further instructions or go back to training.

Information Sheet 1- Maintaining records of work quality

1.1 Maintaining records of work quality

Quality Record is the sytem of documentation of all occurrences in sequences to enhance work quality.

Identifying the hazards

Some factors in the workplace may increase the risk of an injury occurring. These hazards can be identified in different ways:

- Walk through the workplace and look for potential hazards.
- Talk over risk factors with workers.
- Check through injury records to help pinpoint recurring problems.
- Regularly monitor and update risk identification.

Assessing the risks

The next step is to assess which factors are contributing to the risk of injury.

Typical risk factors include:

- **Type of work** – working in a fixed posture for a prolonged period of time can increase the risk of injury.
- **Layout of the workspace** – a cramped or poorly designed workspace can increase the risk of injury by forcing people to assume awkward postures, such as bending or twisting.
- **Weight of an object** – a heavy load may be difficult to lift and carry and can increase the risk of injury.
- **Location of an object** – heavy objects that have to be lifted awkwardly, for example above shoulder height or from below knee level, can increase the risk of injury.
- **Duration and frequency** – increasing the number of times an object is handled or the length of time for which it is handled can increase the chance of injury.
- **Condition of an object** – more effort may be required to manipulate badly designed or poorly maintained equipment

- **Awkward/ uncomfortable loads** –loads that are difficult to grasp, slippery or an awkward shape can increase the risk of injury.
- **Handling a live person or animal** – lifting or restraining a person or animal can cause sprains and other injuries.

Reducing or eliminating the risk

After identifying workplace hazards and controlling the risks, you can do several things to reduce the risk of manual handling injuries. These tips can help reduce injury at home as well as at work.

Safety suggestions include:

- **Change the task** -does this task need to be carried out? If so, does it have to be done this way?
- **Change the object** – for example, repack a heavy load into smaller parcels.
- **Change the workspace** – for example, use ergonomic furniture and make sure work benches are at optimum heights to limit bending or stretching.
- **Use mechanical aids** – like wheelbarrows, conveyor belts, cranes or forklifts.
- **Change the nature of the work** – for example, offer frequent breaks or the chance to do different tasks.
- **Offer proper training** – inexperienced workers are more likely to be injured.

Protecting back

The back is particularly vulnerable to manual handling injuries. Safety suggestions include:

- Warm up cold muscles with gentle stretches before engaging in any manual work.
- Lift and carry heavy loads correctly by keeping the load close to the body and lifting with the thigh muscles.
- Never attempt to lift or carry loads if it is too heavy.
- Pushing a load will be less stressful on body than pulling a load.
- Use mechanical aids or get help to lift or carry a heavy load whenever possible.
- Organize the work area to reduce the amount of bending, twisting and stretching required.
- Take frequent breaks.
- Cool down after heavy work with gentle, sustained stretches.
- Exercise regularly to strengthen muscles and ligaments.

- Lose any excess body fat to improve fitness.

Professional advice

Workplace occupational health and safety coordinator can give advice about managing the risks associated with manual handling.

Where to get help

- manager or supervisor
- elected Health and Safety Representative and workplace occupational health and safety coordinator
- doctor

Things to remember

- Changing workplace design is an effective way to prevent manual handling injuries.
- There are organizations that can offer information and advice on modifying the workplace or work practices.

Importance of workplace inspections

Workplace inspections help prevent injuries and illnesses. Through critical examination of the workplace, inspections identify and record hazards for corrective action. Joint occupational health and safety committees can help plan, conduct, report and monitor inspections. Regular workplace inspections are an important part of the overall occupational health and safety program.

The purpose of inspections

As an essential part of a health and safety program, workplaces should be inspected. Inspections are important as it allow one to:

- listen to the concerns of workers and supervisors
- gain further understanding of jobs and tasks
- identify existing and potential hazards
- determine underlying causes of hazards
- monitor hazard controls (personal protective equipment, engineering controls, policies, procedures)
- recommend corrective action

Workplace Elements

Look at all workplace elements - the environment, the equipment and the process. The environment includes such hazards as noise, vibration, lighting, temperature, and ventilation. Equipment includes materials, tools and apparatus for producing a product or a service. The process involves how the worker interacts with the other elements in a series of tasks or operations.

Summary of Inspection Information Requirements

- Basic layout plans showing equipment and materials used
- Process flow
- Information on chemicals
- Storage areas
- Work force size, shifts and supervision
- Workplace rules and regulations
- Job procedures and safe work practices
- Manufacturer's specifications
- Personal Protective Equipment (PPE)
- Emergency procedures - fire, first aid and rescue
- Accident and investigation reports
- Maintenance reports, procedures and schedules
- Monitoring reports (levels of chemicals, physical or biological hazards)
- Reports of unusual operating conditions
- Names of inspection team members and any technical experts assisting

Self-check-1	Written test

Test item short answer

1. Write advantages of work place specification.
2. Write at least Inspection Information Requirements

Information Sheet 2- Recording basic information on the quality performance

Documentation is any written text document used to explain some attributes of an object, procedure or process. Documentation is an essential part of the quality assurance system. It provides the control measures and actions that need to be implemented and also documents the various activities undertaken in the production of a good or service, their inter-relationship, characteristics and operating parameters.

The Quality Assurance Manual (QAM): Is the first level of documentation in a Quality Assurance System. The QAM clearly identifies the product and the processes that affect the quality of the product. The manual also describes:

- The farm or business
- The scope of the quality assurance system
- The industry quality policies and commitment to produce quality products
- Environmental guidelines to industry
- The product and its specifications
- The processes involved in the production of the product

The QAM for a dairy farm will among other things provide a brief profile of the farm or business, the commodity addressed (raw milk), the product quality objectives and the processes involved in production of raw milk.

Quality Assurance Procedures (QAP) are vital in quality management system. It establish processes that identify the activity, establish what to look for in that activity based on a certain reference, acceptance criteria and the records to keep. They are simplified step-by-step sequence of activities or course of action that must be followed in the same order to correctly perform a task In a dairy farm and industry.

QAP are required for the following actions among others;

- Sourcing of farm inputs
- Dairy plant management

- Cleaning and sanitization
- Control of non-conforming products
- Control of records

Standard Operating Procedures (SOP): Are step-by-step instructions compiled to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance. SOP's in milk production ensure personnel follow the correct procedures and cover the following activities among others.

- Operation of machine
- Milking
- Cleaning of equipment, containers and utensils

Quality Records: Are the documented evidences that processes are executed according to the quality assurance plan and requirements. Such records in a dairy products include:

- Milk production records
- Operation records
- Equipment maintenance records
- Pest management records
- Staff training records

Self-check -2	Written test

Test item I Elaboration

1. Write document records in dary industry.
2. Quality assurance manual

LG #67	LO #4- Study causes of quality deviations

Instruction sheet-4

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

- Investigating causes of deviations from final outputs or services
- recommending suitable preventive action on quality standards and Identifying causes of deviation from specified quality standards

This guide will also assist you to attain the learning outcomes stated in the cover page. Specifically, upon completion of this learning guide, you will be able to identify:

- Investigate causes of deviations from final outputs or services
- Recommend suitable preventive action on quality standards and Identifying causes of deviation from specified quality standards

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 Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, ask your trainer for further instructions or go back to training.

Information Sheet 1- Investigating causes of deviations from final outputs or services

1.1 Investigating causes of deviations from final outputs or services

An efficient deviation handling system, should implement a mechanism to discriminate events based on its relevance and to objectively categorize them, concentrating resources and efforts in good quality investigations of the root causes of relevant deviations. A strong corrective action and preventive action (CAPA) system requires this efficient deviation handling system which evaluates the event according to the **associated risk, categorizes it and acts accordingly in a timely manner, and verifies the effectiveness** of the actions taken. As a formal or informal tool, Quality Risk Management (QRM) has always been part of the analysis process linked to the handling of events and deviations in operations.

This guidance document proposes a possible strategy to differentiate non-significant events which actually do not affect the product's quality or violate any norm or defined procedure, from actual deviations which could impact on the product´s quality. Deviation handling Quality Risk Management was mainly designed to be used prospectively when manufacturing operations are defined and validated. Therefore, potential deviations are identified and avoided by implementing risk control measures and preventive actions. Quality risk management is based on the identification of product attributes and operational parameters which are critical to manufacturing operations in order to identify in advance their associated risks.

The guidance document describes how the information may be used as criteria for the categorization and treatment of events, and eventually, deviations. The application of risk management in dealing with deviations is not only practical but provides a framework for a decision-making process based on a scientifically sound and objective approach, while also enabling decisions to be confidently upheld before the regulatory authorities.

Under this approach, a sequence of steps may be identified when handling events and possible deviations:

- Event Detection
- Decision Making Process / Deviation Categorization
- Deviation Treatment
- Root cause investigation

Event detection: The manner on how personnel react when in presence of an event is the first challenge to the system, and it largely depends on their level of training, qualification, commitment, and support form upper management.

As a basic requirement, personnel are expected to be alert and aware of possible undesirable events and clearly know what to do in terms of documenting and communicating them. The way personnel react and make decisions can be systemized and improved by the use of a decision tree to initially screen events based on their risk and impact on the product in order to categorize, record, and investigate it as needed.

Minor Deviations - When the deviation does not affect any quality attribute, a critical process parameter, or an equipment or instrument critical for process or control, it would be categorized as Minor, and treated as such by the applicable procedure.

Possible examples of minor deviations are given below: -

- Skip of FEFO principle (first expired-first out) in raw material handling
- Balance out of tolerance used to determine gross weight of raw materials upon reception
- Pressure differential out of established limits in class washing area.
- Inadequately trained personnel to perform warehouse cleaning activities

Major Deviations- When the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to patients (or personnel/environment) is unlikely, the deviation is categorized as Major requiring immediate action, investigation, and documented as such by the appropriate SOP.

Possible examples of major deviations are given below:

- Use of unapproved reference standard to test product.

- Inadequately trained personnel to perform quality tests
- Production started without line clearance.
- Filter integrity test has been carried out using equipment with no documented installation qualification completed.
- Gross misbehavior of staff in a critical aseptic process.
- Pressure differential out of established limits in aseptic fill areas.
- Operational parameter out of range for a parameter defined as non-critical.
- Untrained personnel responsible for segregating the approved and rejected raw material in the warehouse.

Critical Deviations - When the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to patients (or personnel or environment) is highly probable, including life threatening situation, the deviation is categorized as Critical requiring immediate action, investigated, and documented as such by the appropriate SOP. Possible examples of critical deviations are given below:

a) Expired or rejected component used
b) Sterilization record of product-contact material used in aseptic filling process not available or unacceptable
c) Incomplete inactivation stage of fermentation.
d) Temperature out of control limit during detoxification stage.

Note 1: Deviations need to be analyzed based on objective and justified criteria avoiding the natural bias from different people or groups.

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Self-check-1	Written test

Test item I. writes short answer

a. Write examples of minor deviation

b. Write causes of deviation

c. Explain types of deviation with examples.

Information Sheet 2- Recommending suitable preventive action on quality standards and deviation from specified quality standards

2.1 Recommending suitable preventive action on quality standards and Identifying causes of deviation from specified quality standards

Deviation- an unplanned event that has been assessed as having a potential to impact material or product in terms of quality, patient/customer safety and regulatory compliance.

- Any occurrence that is not in-conformance with established Standard operatin procedures, Master Batch Records, regulatory fillings, test methods, specifications or other standards, that may affect the purity, potency, quality, efficacy or safety of products or components.

Deviation prevention action

A pre-existent Quality control will contribute to determine the categorization of the deviation. If Quality control has not been performed, it may be carried out at this time as part of the impact assessment in order to determine the criticality of the process parameters involved, and the risk to the patient.

Minor Deviations may be treated as follows:

Item

1. Description
2. Correction
3. Efficacy and Conclusion

Data base record

An adequate description of the deviation requires documented objective evidence written in a concise and clear way stating time, location and person that found the deviation when possible.

Minor deviations are normally addressed by Corrections which are taken to correct and contain the problem (including immediate actions), based on sufficient documented evidence.

Corrections are immediate actions taken based on a simplified analysis of the deviation. It should be quality control approved before implemented if possible, and if this is not feasible, the authorized and qualified responsible personnel may approve and carry out the correction, and approved by quality assurance as soon as possible.

Corrections associated to manufacturing lots need to be quality assurance approved before release. Minor deviations do not necessarily require an investigation aimed at identifying the root causes of the problem as major and critical deviations do. Some corrections could require a change control.

Efficacy of the corrections is normally verified based on the immediate outcome of the actions, and this should be documented. The result of the documented evaluation of the correction/s has to be stated under Conclusions. The information may be recorded in any form of data base where it can be retrieved later during quality reviews or investigations.

Major or Critical Deviations may be treated as follows:

1. Description
2. Correction
3. Efficacy of Correction
4. Batch disposition, if applicable
5. Root Cause Investigation
6. Corrective and preventive action(CAPA)
7. Efficacy of Corrective Action
8. Conclusion

Data base record Major or critical deviations usually require an enhanced, thorough and objective description which needs to be documented.

An adequate description associated to the deviation is essential in order to perform a meaningful investigation. Major or critical deviations would be typically first addressed by corrections, which would need quality assurance approval as mentioned above.

An investigation is then initiated on the root causes of the deviation, followed by the corresponding corrective actions. If a minor deviation is repeated a significant number of times, it could turn into a major deviation, and must be treated as such. The investigation of the deviation should also determine the reason why the implemented corrective actions were not successful.

Based on the same rationale, repetitions of one same incident can turn it into a minor deviation. Note 1: These activities may take place in a sequence or fashion that could differ from the described above, however, the main analysis and criteria would be essentially the same.

Note 2: The term “planned deviation” is frequently used to describe a decision to carry out a process in a different way from which it is established in a SOP, Method or Manufacturing Batch Record (e.g., a reprocess) due to an unforeseen event. Planned deviations need to be fully documented and justified. Usually, planned deviations associated to onetime events, and change control to permanent changes.

Root cause investigation

Root Cause Investigation is a powerful tool used for quality improvement. Among the different tools available for Root Cause Investigation.

The impact on the affected process, equipment, system or product should be assessed regarding other similar situations that could be taking place or will occur. A “vertical” analysis to identify the root cause should always be accompanied by a “horizontal” analysis on the possible events that could be avoided in the future by extending the scope of the investigation to evaluate the possible impact of the deviation on other lots of the same product or on other similar manufacturing processes. It is reasonable to assume that often there will be deviations for which the root cause cannot be readily and clearly determined, and that a probable cause will not be determined.

Also, in certain cases, the deviation will be attributed to unpredictable circumstances beyond control. In any case, conclusions and rationale should always be well supported and well documented. It is fundamental that investigations on root causes of deviations be carried out in a systematic and professional manner following an approved procedure, and conducted by adequately trained personnel. When well-managed, it provides an excellent opportunity to have departments communicate between them and to improve process understanding. Investigations should be based on historical data and accumulated knowledge.

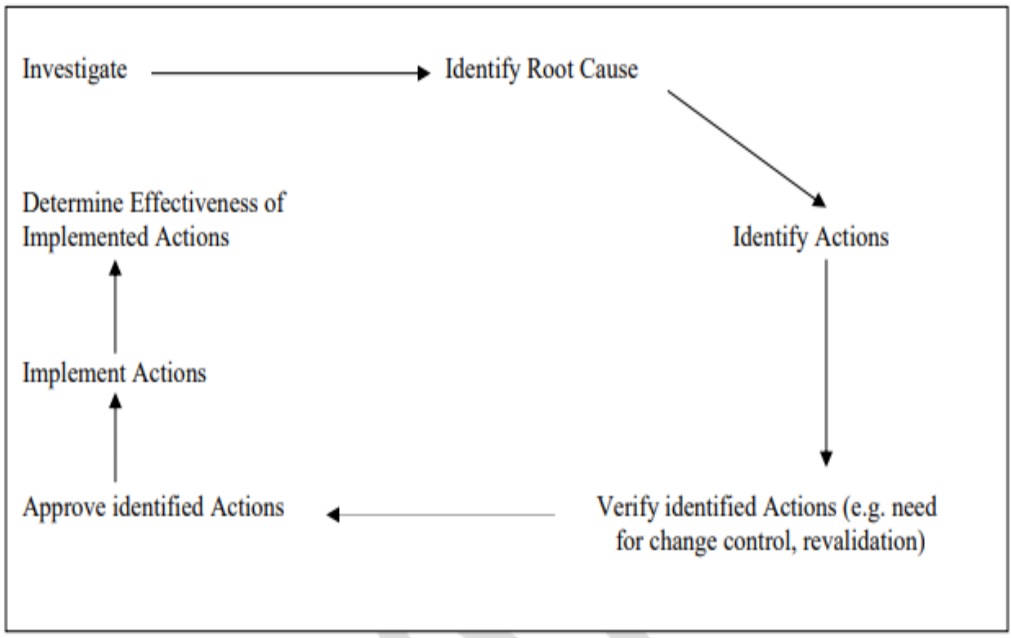
Corrective and Preventive Actions (CAPA)

The root cause investigation process is a key step in handling major and critical deviations as it will provide objective evidence to implement corrective and possibly preventive actions as part of the CAPA system. Corrective Actions are taken to eliminate the root causes of deviations, and should be based on good quality investigations.

Corrective actions should be quality approved before implemented and its efficacy verified in a documented manner, activity that could require a significant period of time.

Corrective actions could be transferred to an independent CAPA system to avoid unnecessary delay for deviation closure. This independent CAPA system should include tracking of all actions required by a pre-approved CAPA plan and effectiveness check. Not all corrective actions will have associated preventive actions. Corrective actions are “reactive” in nature and are triggered in response to detected deviations and could generate preventive actions as well. These preventive actions (linked originally to nonconformities) will act on similar processes, manufacturing lines or different sites, where there has not been yet a deviation.

Improvement process diagram



In addition, manufacturers are strongly recommended to identify **preventive actions** which are proactive in nature and are defined and implemented independently from the occurrence of deviations (i.e. preventive actions act on potential deviations). In other words, “The manufacturer may encounter situations that have not actually caused a nonconformity, but may do so in the future. Such situations may call for preventive action . In order to achieve this, the quality management system has to establish the different sources of information to be followed and trended as part of a systematic, periodic and documented evaluation, usually steered by quality assurance.

As part of the CAPA and improvement process, activities like product and QMS review (e.g. Annual Product Review) give the opportunity to summarize the accumulated information, findings and trends on an annual basis in order to identify systemic actions to improve the QMS. Examples of information sources to identify preventive actions regarding production process, equipment or facilities would include:

a) Manufacturing in-process control or Quality Control analytical trend data indicating that control or alert limits are being approached.

b) Preventive actions could include actions planned to return process performance to nominal values from the edges of the process control range.

c) Supplier Qualification Program data (e.g. % rejected materials, external audit findings) :

- Product quality related Complaints
- Production yield variations (e.g. caused by materials defects)
- Stability trend data
- Internal audit findings
- Preventive Maintenance reports (e.g. equipment break down, spare parts usage)
- Revalidation data (e.g. autoclave temperature profile shift while still within acceptable range)
- Environmental and Water monitoring

Note: The amount of work related to the improvement activities is dependent on the risk and significance of the deviation or potential deviation.

Self-check -2	Witten test

Test item I say true or false

1. Discuss process improvement system
2. Define deviation and discuss corrective and preventive action.

LG #68	LO #5- Complete documentation

Instruction Sheet-5

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

- Recording Information on quality and indicating service performance
- Recording all service processes and outcomes

This guide will also assist you to attain the learning outcomes stated in the cover page. Specifically, upon completion of this learning guide, you will be able to identify:

- Record Information on quality and indicate service performance
- Record all service processes and outcomes

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 Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, ask your trainer for further instructions or go back to training.

Information sheet 1- Recording Information on quality and indicating service performance

1.1 Recording Information on quality and indicating service performance

Quality Performance

Performance measures designed to move associates toward business goals can be a powerful method for action. Because "some one get what he/she measure," it is important to think through how and what somebody measure so some can achieve the desired results. And measuring profitability is attractive because it goes straight to the heart of every builder's existence.

Performance measures of profitable builders are as varied as their business strategies. A good place to start is examining your own business goals and tune-up your measures at the company level. Then proceed to create department measures that align with company goals. Ones organization will be the winner.

The six – factor model of personality in the work place

The following are the five-factor model with job performance and other job-related activities.

Motivation, deviation, absences, and job satisfaction are related to the five factors.

Work place motivation

Motivation is the driving force by which humans achieves their goals. The motivation is said to be intrinsic. The term is generally used for humans but it can also describe the cause of animal behaivour as well. According to various theory, motivation may be rooted in a basic need to minimize physical pain and maximize pleasure, or it may include specific needs such as eating and resting or a desired object, goal, state of being ,ideal, or it may be attributed to less apparent reasons such as selfishness, morality or avoiding mortality.

Job Satisfaction

Job satisfaction has been defined as a pleasurable emotional state resulting from the consideration of one's job; an affective reaction to one's job; and an attitude towards one's job. Weiss (2002) has argued that job satisfaction is an attitude but points out that researchers should clearly distinguish the objects of cognitive evaluation which are affect (emotion), beliefs and behaviors.

Departure in the work place

Workplace deviance occurs when an employee voluntarily pursues a course of action that pressures the well-being of the individual or the organization.

Employees who had a positive perception of their workplace were less likely to pursue deviant behavior. Research indicates that personality acts as a moderating factor: workplace deviance was more likely to be endorsed with respect to an individual when both the perception of the workplace was negative and emotional stability.

Performance in the Workplace

Of the five factors, the single factor of carefulness is the most predictive of job performance.

Absences

Job absence is very much part of job performance: employees are not performing effectively if they do not even come to work. Shy, careful employees are much less likely to be absent from work, as opposed to extraverted employees who are low on carefulness.

Teamwork

Often times in the workplace the ability to be a team player is valued and is critical to job performance. Although this strengthen the case that job performance is related to the five-factor model via increased cooperativeness among coworkers, the role of personality by implying that actual job performance (task performance) is related to cognitive ability and not to personality .

Using 5S to Increase Performance in the Workplace

5S is the name of a workplace organization methodology that uses a list of five Japanese words which are **seiri** (Sorting), **seiton** (Straightening or setting in order / stabilize), **seiso**

(Sweeping or shining or cleanliness / systematic cleaning), **seiketsu** (Standardizing) and **shitsuke** (Sustaining the discipline or self-discipline). Translated into English, they all start with the letter "S". The list describes how to organize a work space for efficiency and effectiveness by identifying and storing the items used, maintaining the area and items, and sustaining the new order. The decision-making process usually comes from a dialogue about standardization which builds a clear understanding among employees of how work should be done. It also instills ownership of the process in each employee. One common error by senior management is never being visible on the factory floor.

5S provides the foundation for improving performance through continuous improvement. It focuses on:

Increasing quality by removing waste from the workplace.

Provide reduction in operating costs by reducing non value added activities.

Improving delivery by simplifying processes and removing obstacles

Improving safety through improved housekeeping and identification of hazards

Provide an environment where continuous improvement is embraced through workers problem solving and suggestions, thereby improving morale.

Simply put, 5S works best if the implementation of the program is based on the 5S Performance Improvement Formula:

P=Q+C+D+S+M

Where;

- **P** - Increase productivity.
- **Q** - Improve product quality.
- **C** - Reduce manufacturing costs.
- **D** - Ensure on-time delivery.
- **S** - Provide a safety working environment
- **M** - Increase worker morale.

Generally, Job performance and personality (as measured in the Six-factor model) are related. It appears that the relation between job performance and the five factors (QCDSM) is more a consequence of the social aspects of the workplace than of ability. Cognitive ability is more strongly correlated with task performance than any of the six factors are correlated with task performance. The Six factors are strongly correlated with cooperating

with others and enjoying the overall workplace experience, which are key components of long-term job success. Being absent from work or working as a team are correlates of personality that directly affect whether one will succeed in the workplace, and they are strongly correlated with the Big six and not with cognitive ability.

Cognitive ability may allow an employee to complete a specific task, but the ability to work with others and to stay motivated is aspects of personality. The six-factor model is a valid predictor of workplace performance. Personality is an indispensable consideration for employers looking for quality employees.

Making sure that everyone keeps up the daily 5S discipline is a management problem. It may be the responsibility of the 5S team leader, but it is also driven and supported by the auditing and tracking system that is used to measure conformance to the 5S process. The structure of the QCDSM process ensures a disciplined approach is carried out on every shift day in and day out

Self-check-1	Written test

Test item I explaination

1. Explain briefly Work place performance.
2. Write five s' s used to increase work place performance.

Information Sheet 2- Recording all service processes and outcomes

2.1 Recording all service processes and outcomes

Production process

The production process is concerned with transforming a range of inputs into those outputs that are required by the market. The transforming resources include the food and beverages, machinery, and people that carry out the transforming processes. The transformed resources are the raw materials and components that are transformed into end products.

Any production process involves a series of links in a production chain. At each stage **value** is added in the course of production. Adding value involves making a product more desirable to a consumer so that they will pay more for it. Adding value therefore is not just about manufacturing, but includes the marketing process including advertising, promotion and distribution that make the final product more desirable.

It is very important for businesses to identify the processes that add value, so that they can enhance these processes to the ongoing benefit of the business.

Types of process

There are three main types of process: **job, batch and flow production**.

Job production

Job or (make complete) production is the creation of single items by either one operative or a team of operative. Job production is unique in the fact that the project is considered to be a single operation, which requires the complete attention of the operative before every body passes on to the next job.

Batch production

The term batch refers to a specific group of components, which go through a production process together. As one batch finishes, the next one starts. For example on Monday, Machine A produces a type 1 engine part, on Tuesday it produces a type 2 engine part, on

Wednesday a type 3 and so on. All engine parts will then go forward to the final assembly of different categories of engine parts.

Flow production

Batch production is described as (intermittent) production and is characterized by irregularity. If the rest period in batch production disappeared it would then become flow production. Flow production is therefore a continuous process of parts and sub-assemblies passing on from one stage to another until completion.

Finally, record whole process and out come by preparing fomat or formats. Formats may be prepared in different ways for production, quality, technical, finance and storage.

Example for production some body can use the following table. (table 6)

R/no	Days	Raw material received (unit)		Expected production	Real production	Waste/loose (daviation)	Production per shift	Total production
1	Day I	Shift I						
		Shift I						
2	Day II	Shift I						
3	Day III	Shift I						
4	Day IV	Shift I						
5	Day v	Shift I						
6	------	--------						

Remark (deviation/loose): ----------

Recorded by: ---------- signature:……

Self-check-2	Written test

Test item I write short answer.

1. Production process
2. Types of production

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