

APPLY QUALITY CONTROL

NTQF LEVEL - III

LEARNING GUIDE -58

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| UNIT OF COMPETENCE: - | APPLY QUALITY CONTROL |
| MODULE TITLE: - | APPLYING QUALITY CONTROL |
| LG CODE: | HLT MLT M012 LO1-LG-58 |
| TTLM CODE: | HLT MLT TTLM 0919V1 |

LO1: Implement quality standards

This learning guide is developed to provide you the necessary information

regarding the following content coverage and topics –

- Quality standards and procedures
- Quality standards documents

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 –

- Acquire and confirm agreed quality standard and procedures
- Introduce standard procedures to organizational staff/personnel.
- Provide quality standard, procedures and documents to employees in accordance with the organization policy.
- Revise standard procedures.

Learning Instructions

1. Read the information written in the “Information Sheets”.

2. If you earned a satisfactory evaluation proceed to next module. However, if your rating is unsatisfactory, see your teacher for further instructions.

3. Read the “Operation Sheet” and try to understand the procedures discussed.

4. Practice the steps or procedures as illustrated in the operation sheet. Go to your teacher if you need clarification or you want answers to your questions or you need assistance in understanding a particular step or procedure

5. Do the “LAP test” (if you are ready). Request your teacher to evaluate your performance and outputs. Your teacher will give you feedback and the evaluation will be either satisfactory or unsatisfactory. If unsatisfactory, your teacher shall advise you on additional work. But if satisfactory you can proceed to the next Learning Guide

1.1.Acquiring and confirming agreed quality standard and procedures.

Quality standards are concise sets of evidence-based, measurable statements that provide guidance on important elements of high-quality health care in a specific topic area. Quality standards focus on areas where experts, patients, caregivers, and the public have identified a need for improvement in Ontario. They address standards of care for clinically defined populations (for example, adults with schizophrenia), service areas (for example, preoperative-operative testing), and health system issues (for example, care transitions). Each quality standard contains 5 to 15 quality statements. Each quality statement is a strong recommendation on high-quality practice for a specific aspect of care. Each quality statement is accompanied by one or more process, structural, or outcome indicators to help health care professionals and organizations measure their achievement of the practice outlined in the statement. Quality standards also include a small set of outcome indicators to measure the impact of the quality standard as a whole. Health Quality Ontario works with partner organizations to develop a multi stakeholder implementation plan for each quality standard to drive and support its adoption across the province. In another way the word quality, as you may already understand from the responses of different groups, is not understood uniformly. What constitutes health care quality is different for different people based on what is valued most. Due to this lack of standard understanding, quality particularly when applied to the health sector is not simple to define. With the greater emphasis given to quality of health care by patients, public health officials, funding agencies and governments during the last few decades,

different authors and organizations have tried to define it. In this lesson, we will see some of the most frequently used definitions.

Definition 1. Quality is the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. (*ISO 8402*)

Definition 2. Quality of health care is the application of medical science and technology in a way that maximizes its benefits to health without correspondingly increasing its risks. The degree of quality is, therefore, the extent to which care provided is expected to achieve the most favorable balance of risks and benefits. (*AvedisDonabedian*)

Definition 3. Quality health care is the proper performance (according to standards) of interventions that are known to be safe, that are affordable to the society in question, and that have the ability to produce an impact on mortality, morbidity, disability, and malnutrition. (M.I. Roemer and C. Montoya Aguilar, WHO)

Definition 4. Medical quality is the degree to which health care systems, services and supplies for individuals and populations increase the likelihood for positive health outcomes (*AmericanCollege of Medical Quality*)

Definition 5. The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. (*IOM of the National Academies*)

1.1.2 Benefits of Standards

- Ensure that products and services are safe, reliable and of good quality and also care environment.
- They are strategic tools that reduce costs by minimizing waste and errors, and increasing productivity.
- Help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.
- Frequently referenced by regulators and legislators for protecting user and business interests, and in support of government policies.

1.1.2 Introduction to Quality Control

QC is the operational techniques and activities that are used to satisfy quality requirements or a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer an important part of the quality control is the Quality assessment. The system of activities to verify if the quality control activities are effective in other words: an evaluation of the products themselves. Quality control monitors activities related to the examination (analytic) phase of testing. The goal of quality control is to **detect, evaluate, and correct errors** due to test system failure, environmental conditions, or operator performance, before patient results are reported.

1.1.2.1 Types of QC

Internal quality control: a set of procedures for continuously assessing laboratory work and the emergent results. This can range from routine checking of equipment, having a co-worker go over another employee's data analysis, or running standards and controls on a regular basis.

External quality control: a process of checking a quality of test/product by external examiner. It is to verify results by sent to an outside lab (Proficiency Testing [PT]) or provided by an external source such as your regional reference laboratory (Spatial testing [ST])/rechecking and onsite evaluation.

1.1.2.2 Quality control procedures

QC consists of the procedures used to detect errors that occur due to

- test system failure,
- adverse environmental conditions
- variance in operator performance,
- variance in the monitoring of the accuracy and precision of the test performance over time.
- There's no *one* rule or one *set* of rules that's right for *all* tests and methods.

Some methods have better precision than others; therefore, different QC procedures should be used. The most cost-effective operation is possible when the QC procedures are selected for the individual tests on the basis of the quality required for the test and the performance observed for the method.

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|---------------------|-------------------|
| Self-Check 1 | True/false |
|---------------------|-------------------|

Name: _____ Date: _____

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

I-True or False: Write TRUE if the statement is correct and write FALSE if the

statement is wrong. (5pts. Each)

1. Quality standards are concise sets of evidence-based, measurable statements that provide guidance on important elements of high-quality health care in a specific topic area
2. Quality of health care is the application of medical science and technology in a way that minimizes its benefits to health without correspondingly increasing its risks.
3. Each quality standard contains 5-15 quality statement's

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

I- True/false:

1. _____
2. _____
3. _____

1.2. Introducing standard procedures to organizational staff/personnel.

Policies and Procedures are two words frequently heard in the business world and there is often confusion between the two concepts.

What is an Organizational Policy?

A Policy defines an outcome; it is a premeditated rule set by a business to guide organizational direction, employees and business decisions, and to regulate, direct and control actions and conduct. Policies can range from a broad philosophy to a specific rule. They are the direct connection between a company's Vision and its daily operations and the underpinnings to a company's culture.

What is an Organizational Procedure?

A procedure is a means to an end. Procedures are step by step instructions, prescribing an exact sequence of action. A procedure explains how to and who (which position) will implement the policy. Procedures are specific, factual and succinct. They may include timelines, specific forms to be used and template forms. Procedures assist in eliminating common misunderstandings which can result in costly mistakes.

What is the difference?

Together Policies and Procedures empower a process by providing clear and concise direction necessary for consistent operation. The essential differences are outlined below:

Policies

- General in nature
- Identify company rules
- Explain why rules exist
- Explain when the rule applies
- Describe to whom (what position) it applies
- Explain how it is enforced
- Describe consequences
- Provide guidance for managerial thought and action
- Flexible - allows for discretion

Procedures

- Identify specific and alternative actions
- Explain when to take actions
- Describe emergency procedures
- Include warnings and cautions
- Give examples
- Show how to complete a specific form
- Prescribe how to carry out the action through step by step instruction
- Less flexible - concise and exact sequence of activities

Why does a company need Organizational Policies?

Policies and Procedures (P&Ps) are essential when a company requires consistency in its daily operations. They provide clarity and direction re: accountability. P&Ps assist companies in meeting legal requirements set out by the Employment Standards Act, the Human Rights Code, the Occupational Health and Safety Act and numerous other compliance requirements. A properly written policy and/or procedure allows employees to understand their roles and level of responsibility and conduct their job by making decisions within predefined boundaries. By implementing P&Ps, management can provide guidance to employees without needing to micromanage, freeing managers to focus on strategic thought. P&Ps allow the workforce to not only understand the accountabilities and responsibilities of their own position, but also that of their co-workers, which can foster a cooperative work environment.

How big should a company be to consider implementing Policies and Procedures?

With as few as six employees there will be recurring issues. Productivity and efficiencies both from a legal and operational standpoint can be gained through the implementation of P&Ps.

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HR-Fusion's Hamilton, Ontario location is uniquely positioned to provide services to Brantford, Burlington, Oakville, and the surrounding Niagara region. HR requirements outside the immediate geographic area are handled through the HR-Fusion partner network and provides coast to coast coverage as required.

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| Self check 2 | Written test |
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Name: _____ Date: _____

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

I-Essay: Explain briefly:

1. What is an organizational procedure? (5pts.)
2. What is quality? (5pts.)

Note: Satisfactory rating above- 5 points Unsatisfactory below -5 points

You can ask your teacher or trainer for the copy of the correct answers.

Answer Sheet

Score = _____

Rating: _____

Name: _____

Date: _____

I- Essay:

1. _____

2. _____

| | |
|----------------------------|-------------------------------------------------------------|
| Information sheet 3 | Providing quality standard and procedures documents. |
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1.3.Providing quality standard and procedures documents

Quality standards are useful for several audiences:

- Patients, caregivers, and the public can use quality standards to understand what excellent care looks like and what to ask for when receiving treatment.
- Health care professionals can use quality standards to guide and measure evidence-based quality improvement, and to support continuing professional development.
- Local health integration networks and government agencies can use quality standards to inform regional improvement strategies and performance measurement.
- Government can use quality standards to identify provincial priority areas, inform new data collection and reporting initiatives, and design performance indicators and funding incentives

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| Self test 3 | Written test |
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Directions: Answer all the questions listed below. Use the answer sheet provided in the next page.

I-Essay: Explain briefly:

1. Write use of giving quality standards(3pt)

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

You can ask your teacher or trainer for the copy of the correct answers.

Answer Sheet

Score = _____

Rating: _____

Name: _____

Date: _____

I- Essay:

1. _____

Information sheet 4

Revising / updating standard procedures.

1.4.Revising / updating standard procedures.

Changes to Standard Operating Procedures (SOPs) follow a specific method that a company's Quality and Regulatory Affairs department establishes. Start documenting requested changes to an SOP as soon as relevant personnel consider the revision. Keep a list of conversations regarding these changes by date and participants. Then, include this record as part of your initial request to change an SOP. So now life is good: You have an SOP manual, a more knowledgeable staff, consistency of services, a great tool for performance measures, regular training, etc.

You didn't think you were done, did you?

SOPs should be reviewed by all staff, department supervisors and the director at least once each year, and suggestions from staff should always be considered for changes of process. The consequences of not having SOPs in good working order are far more serious than the inconvenience of keeping them updated.

Part I of this series explains why SOPs matter and presents strategies for creating them. These strategies are also useful for updating existing SOPs. Part II discusses ways to implement SOPs in your organization.

Organizations need to develop a comprehensive system to ensure that all policies, procedures and training programs are continually reviewed and

updated, in practice as well as in writing. Making such a review part of supervisor job descriptions, and making time for it on the calendar help ensure that your organization keeps the information current and functional.

Do Your SOPs Still Do the Job?

Here are some questions to ask as you consider whether your existing SOPs are in use throughout your organization and are still working as you intended them to.

STAFF AWARENESS

Where are the SOPs kept? Is the "centralized" copy really still available?

Does everyone have a copy? Do new staff get a copy right away? Is there someone responsible for assuring this? Do all of the staff know more than vaguely what you are talking about when you ask about policies?

USEFULNESS OF CURRENT SOPS

Do you hear consistent grumbling from staff regarding any particular procedures?

Is the manual truly comprehensive? Have you noticed any gaps?

Are the SOPs still realistic? Efficient? Effective? Is there now a better way?

When did you last really read them?

INTEGRATION WITH YOUR OPERATIONS

Are staff still involved in conversations that arise about needed updates?

Are you open to changes and improvements, even though you worked so hard to get what you have now?

Is your training still linked to procedures, and successful at helping staff understand what it is they need to accomplish?

What Needs to Change?

The answers to the questions asked above should guide the kinds of changes that may be needed. For example:

If awareness is the issue, you may need to produce and distribute the procedures and ask supervisors to remind staff about them.

If the information is out of date, you can use the process outlined in Part I to identify and make necessary changes to the SOPs.

If there's a lack of acceptance of the SOPs, do some digging to find out why:

Is the use of the SOPs included in job descriptions, employment policies, performance objectives, and training?

Are the SOPs too cumbersome to use? Are they unnecessarily complicated or too far removed from day-to-day reality?

Do your supervisors believe in their value and insist on their use? If not, why?

Do line staff resist following the SOPs? If so, why?

Identifying where the gaps between the procedures and their acceptance occur means that you can focus on a response that addresses the real issues and involves the right people.

How to Make the Changes?

Designate only one person to actually enter changes in the master document. This person could be your director of operations, manager, executive director—based on what's best for your agency. Here is a suggested process for identifying and implementing changes to your SOPs:

Include SOPs on the agenda of regular department staff meetings if there are any suggestions for change, deletions, or additions that need to be discussed. After discussion with the entire department, the department supervisor advises the director of operations of his/her team's suggestions or needed clarification. The director of operations evaluates the requested change and if necessary discusses it with the executive director or leader.

If the Director of Operations and the ED agree to make the change, that section of the master SOP manual (both electronic and physical copy) is updated with the new wording and instruction. A memo then goes out to the entire staff with a summary of the update, and the page and section number that was updated. Each staff person also receives a printed copy of the new revised section for the staff member to update their own manual.

Keeping SOPs a Priority

Development of SOPs and keeping them up to date and used must be a priority of an agency. To go through this process to say "Yes, we have 'em" is a waste of time. Agencies who are most successful with following SOPs have made it someone's main task to:

keep the SOPs current,

Ensure training is taking place based on the SOPs, and prevent SOPs from falling to the bottom of the priority list. Many agencies are understaffed, and yours may be one of them. If you are thinking you can't devote staff time to SOPs, think again about all of the aspects of your operation that will run more smoothly, more safely, and more reliably when everyone follows a good set of

SOPs. SOPs are the core of your entire operation, and therefore critical to the internal and external success of your program.

Finding an SOP Advocate

Who should take charge of SOPs in your organization? Look for a staff person who:is organized,does not "have an agenda,"likes people, and understands the importance of this project and document.

When you find this individual, see where you can make some changes so this person has the time and energy to take on your SOPs.

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| Self check 4 | Written test |
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Directions: Answer all the questions listed below. Use the answer sheet provided in the next page.

I-Essay: Explain briefly:

1. Write different methods that used in order to revise or update SOPs ?

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

You can ask your teacher or trainer for the copy of the correct answers

Answer Sheet

| |
|---------------|
| Score = _____ |
| Rating: _____ |

Name: _____ Date: _____

I- Essay:

1. _____

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|--------------------------|-----------------------------------|
| Operation Sheet-1 | Quality control procedures |
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Techniques for-maintaining quality

Step 1- Decide which specific standards the product or service must meet.

Step 2- Determine the extent of QC actions (for example, the percentage of units to be tested from each lot).

Step 3- Collect real-world data (for example, the percentage of units that fail)

Step 4- Report the results to management personnel

Step 5-Decide and take corrective action (for example, defective units must be repaired or rejected and poor service repeated at no charge until the customer is satisfied).

Step 6- If too many unit failures or instances of poor service occur, a plan must be devised to improve the production or service process

Step7 - The plan must be put into action.

Step 8 - Finally, the QC process must be ongoing to ensure that remedial efforts, if required, have produced satisfactory results and to immediately detect recurrences or new instances of trouble.

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| Operation Sheet-2 | Performing IQC for newly opened reagents |
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PURPOSE

The purpose of this activity is to enable you to practice those skills necessary to perform IQC for serological test reagents, and to achieve competency in these skills.

INSTRUCTIONS

This activity should be conducted in a skill laboratory/healthy facility. Learners should review Learning Guide for performing IQC for serological test newly opened reagents before beginning the activity. The teacher should demonstrate the steps/tasks in each learning guide one at a time. Under the guidance of the teacher, learners should then work in groups and practice the steps/tasks in the Learning Guide for IQC procedure and observe each other's performance; while one learner/group doing the activity, another learner/group should use the Learning Guide to observe performance. Learners should then rotate roles. Learners should be able to perform the steps/tasks before skills competency is assessed using the Checklist for IQC performance.

CONDITIONS OR SITUATION FOR THE OPERATIONS

This activity could be done in skill laboratory or in healthy facility

RESOURCES (Equipment and Materials)

- Laboratory coat
- Gloves
- Laboratory request form
- Water and soap
- Permanent Marker
- IQC Log book
- SOP
- Stationery

Precaution: When a IQC is being performed , adequate safety precautions must be taken to prevent contamination .

Standard Precautions

Always wash hands before and after obtaining and handling specimens

- Cover cuts and lesions with waterproof dressing
- Wear disposable aprons and appropriate gloves .
- Use PPE

Procedure-Learning guide/Checklist

LEARNING GUIDE 1:

Performing IQC/EQA for different test

(To be completed by **Participant/students**)

Rate the performance of each step or task observed using the following rating scale:

- 1. Needs Improvement:** Step or task not performed correctly, out of sequence (if necessary), or is omitted
- 2. Competently Performed:** Step or task performed correctly in proper sequence (if necessary) but participant/student does not progress from step to step efficiently
- 3. Proficiently Performed:** Step or task performed efficiently and precisely in the proper sequence (if necessary)

| Performing IQC/EQA for different laboratory tests (Some of the following steps/tasks should be performed simultaneously) | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------|----------|----------|----------|---------------|
| STEP/TASK | 1 | 2 | 3 | Remark |
| Getting ready | | | | |
| • Wearing the Laboratory coat | | | | |
| • Washing your hand with soap | | | | |
| • Wearing the gloves | | | | |

| Performing IQC/EQA for different laboratory tests (Some of the following steps/tasks should be performed simultaneously) | | | | |
|-----------------------------------------------------------------------------------------------------------------------------|---|---|---|--------|
| STEP/TASK | 1 | 2 | 3 | Remark |
| • Preparing the necessary equipment | | | | |
| • Preparing newly opened working reagents | | | | |
| • Prepare negative and positive control inserted | | | | |
| 7. Follow the instruction procedure inserted | | | | |
| 8. Mix reagents with negative and positive control | | | | |
| HISTORY (ASK/CHECK RECORD) | | | | |

| LAP Test | Practical Demonstration |
|----------|-------------------------|
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Name: _____ Date: _____

Time started: _____ Time finished: _____

Instructions: Given necessary templates, tools and materials you are required to perform the following tasks within 3-4 hour.

Task 1. Perform quality control procedures

Task 2. Performing IQC for newly opened reagents

| |
|------------------------------------|
| List of reference materials |
|------------------------------------|

1.Claire capon (2000) **understanding organizational context**,
Pearson
education.

2.Elizabeth Chell. (2001) **Entrepreneurship: globalization,
innovation and
development.**

Thomson learning.

3.**Trainer guide manual**, (Micro enterprise creation, small business
management, business growthstrategies), 2002.