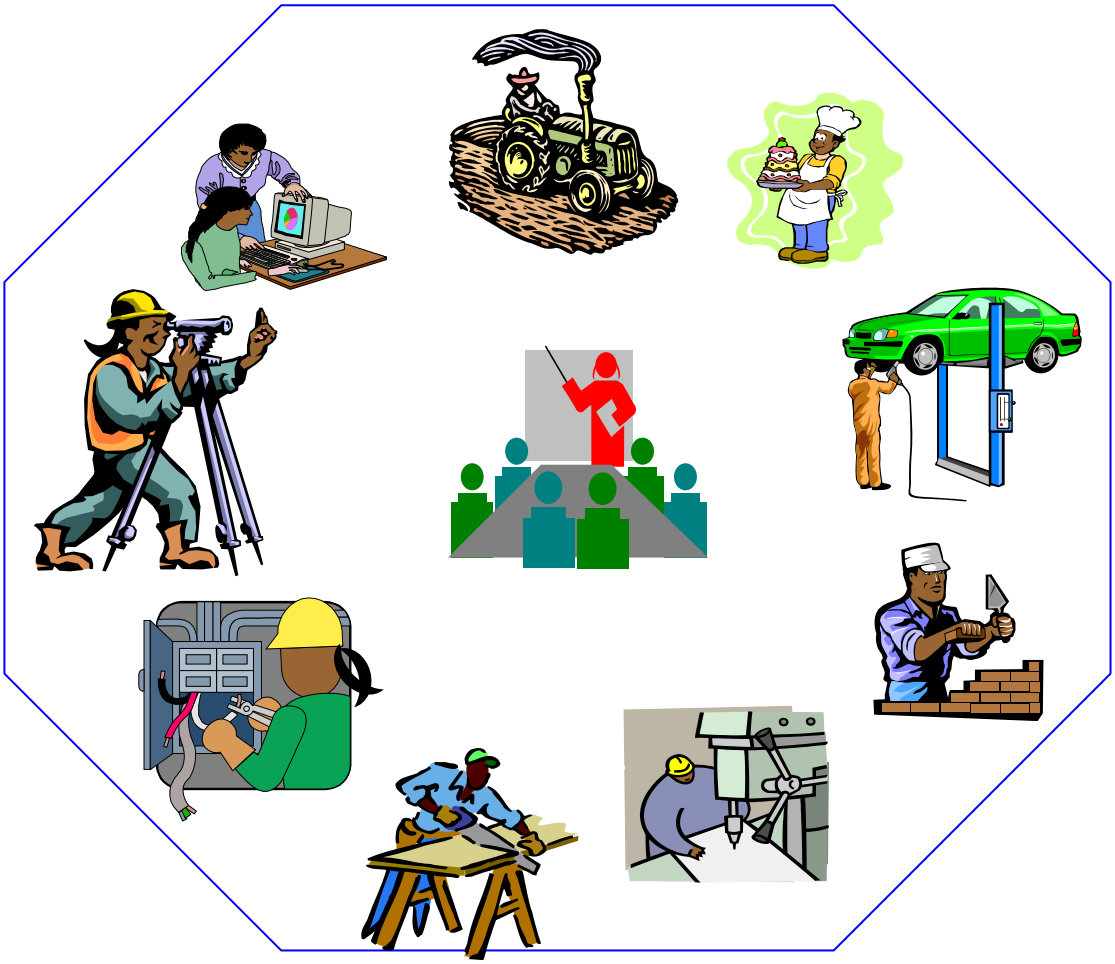
INTERMEDIATE BIOMEDICAL EQUIPMENT SERVICING

Based on May, 2011 Version 2 OS and Feb, 2021 Version 1 Curriculum



Module Title: Commission Biomedical Equipment

LG Code: EEL BES3 M04 LO(1-3) LG (16-18)

TTLM Code: EEL BES3 TTLM **0320v1**

Feb 2021

Bishoftu, Ethiopia

Table of Contents page

L #16	LO #1- Plan & prepare BME products & systems for commissioning

Instruction sheet

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

- Planning and preparing commissioning procedures.
- Consulting appropriate personnel.
- Checking commissioning procedures.
- Obtaining material to complete the work.
- Tools, equipment and testing devices.
- Checking preparatory work.

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:

- Plan and prepare commissioning procedures.
- Consult appropriate personnel.
- Check commissioning procedures.
- Obtain material to complete the work.
- Tools, equipment and testing devices.
- Check preparatory work.

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 you earned a satisfactory evaluation proceed to “Operation sheets
7. Perform “the Learning activity performance test” which is placed following “Operation sheets” ,
8. If your performance is satisfactory proceed to the next learning guide,
9. If your performance is unsatisfactory, see your trainer for further instructions or go back to “Operation sheets”.

Information Sheet 1- Planning and preparing commissioning procedures

Planning and preparing commissioning procedures.

Commissioning refers to the process of bringing an item into operation and ensuring that it is in good working order. On building projects, this refers primarily to building services.

Commissioning activities may include:

- Ensuring client access and providing client training and demonstrations.
- Completing operating and maintenance manuals, record drawings, software and test certification.
- Obtaining statutory approvals and insurance approvals.
- Manufacturers work testing.
- Component testing.
- Pre-commissioning tests.
- Set to work: this is the process of switching on (i.e. setting to work) items such as fans and motors to ensure that they are operating as specified (for example checking that fans are turning the right way).
- Balancing: this follows setting to work and involves looking at whole systems (rather than individual components) to ensure that they are properly balanced (ie water is coming out of all the taps at the correct pressure, air is coming out of the correct diffusers etc).
- Commissioning checks and performance testing.
- Post commissioning checks and fine tuning during occupancy.

A **commissioning plan** is a document used to outline the scope and define the responsibilities of the commissioning process as well as the activites, schedules and documentation required. It is part of the commissioning management process, intended to ensure the client receives an efficient, fully functioning building by the planned occupancy date. An effective commissioning plan can help ensure handover to the client is smoother and less troubleshooting and fine tuning is required.

The best commissioning process is one that is planned from the project's very inception. Designing in the ability to commission systems properly from the outset can provide huge benefits, especially on cost and performance.

The commissioning plan should be started early, and populated with detail as it becomes available. This approach calls on project professionals to plan, reality-check as they go along, prepare fully for handover, and follow through after occupation to fine-tune and resolve issues as they emerge.

According to BSRIA Guide BG 8/2009 Model Commissioning Plan, the plan should:

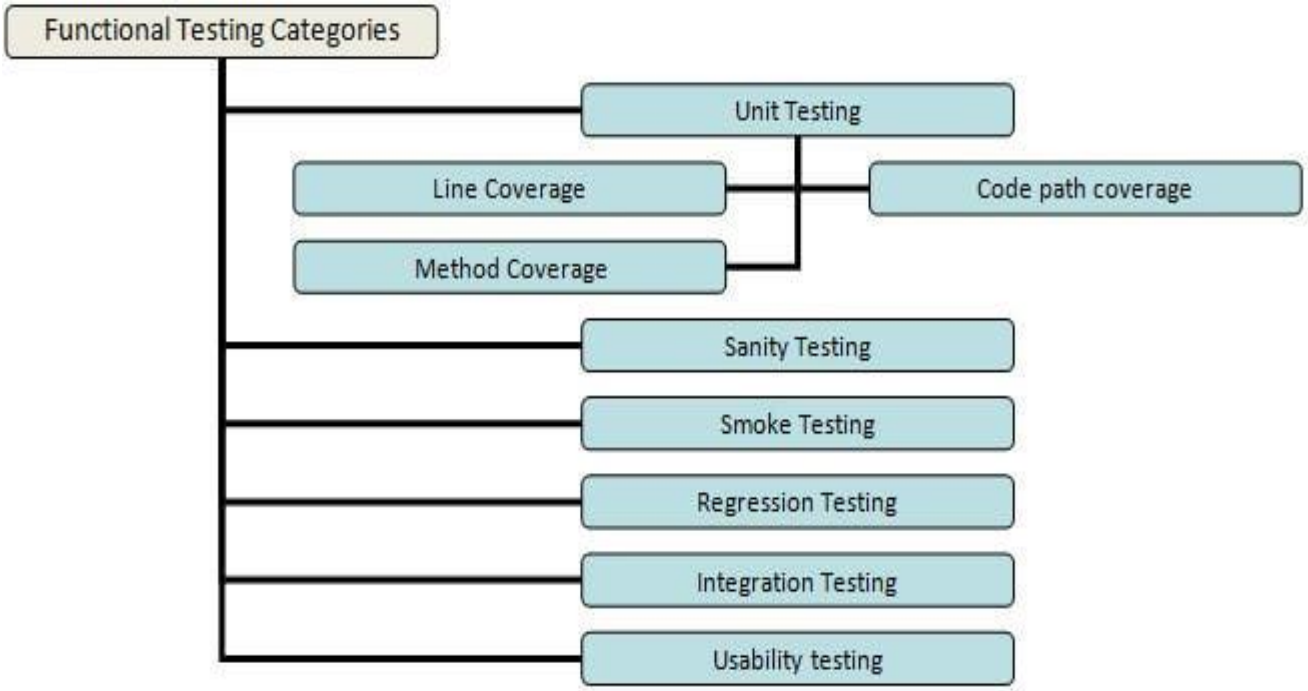
- Provide general information about the project.
- Identify the commissioning team members during each stage of the commissioning process.
- Define the roles and responsibilities for each commissioning team member.
- Identify the systems to be commissioned.
- Create a schedule of commissioning activities for each stage of the commissioning process.
- Establish documentation requirements associated with the commissioning process.
- Establish communication and reporting procedures for the commissioning process.

Functional testing

In the simplest words, functional testing checks an application, website or system to ensure that it is doing exactly what it is meant to.

In the planning stages, every project creates a document listing functional or requirement specifications. Essentially, it is a list of what the app/system/website is supposed to do, from a user's perspective.

Types of Functional Testing



Source: softwaretestinghelp.com

Unit Testing: This is performed by developers who write scripts that test if individual components/units of an application match the requirements. This usually involves writing tests that call the methods in each unit and validate them when they return values that match the requirements.

In unit testing, code coverage is mandatory. Ensure that test cases exist to cover the following:
– Line coverage
– Code path coverage
– Method coverage

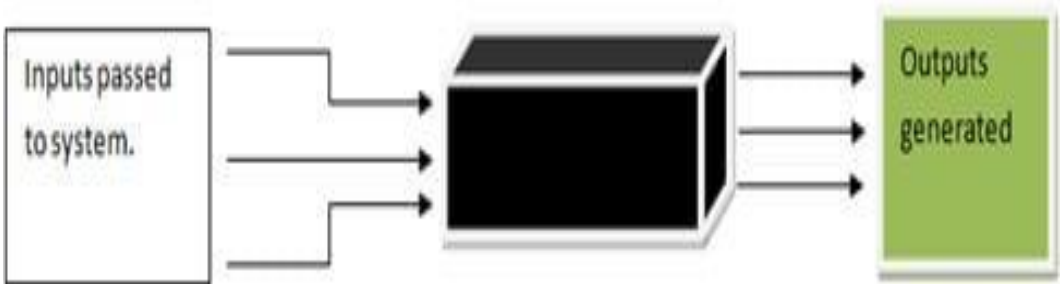
- **Smoke Testing**: This is done after the release of each build to ensure that software stability is intact and not facing any anomalies.
- **Sanity Testing**: Usually done after smoke testing, this is run to verify that every major functionality of an application is working perfectly, both by itself and in combination with other elements.

- **Regression Testing**: This test ensures that changes to the codebase (new code, debugging strategies, etc.) do not disrupt the already existing functions or trigger some instability.
- **Integration Testing**: If a system requires multiple functional modules to work effectively, integration testing is done to ensure that individual modules work as expected when operating in combination with each other. It validates that the end-to-end outcome of the system meets these necessary standards.
- **Beta/Usability Testing**: In this stage, actual customers test the product in a production environment. This stage is necessary to gauge how comfortable a customer is with the interface. Their feedback is taken for implementing further improvements to the code.

Process Workflow

The overview of a functional test includes the following steps:

1. Create input values
2. Execute test cases
3. Compare actual and expected output



Source: softwaretestinghelp.com

Generally, functional testing follows the steps below:

- Determine which functionality of the product needs to be tested. This can vary from testing main functions, messages, error conditions and/or product usability.
- Create input data for functionalities to be tested according to specified requirements.

- Determine acceptable output parameters according to specified requirements.
- Execute test cases.
- Compare actual output from the test with the predetermined output values. This reveals if the system is working as expected.

The Commissioning Procedure

For a newly purchased medical device, the medical device establishment shall be responsible to carry out the installation and test and commission of the medical device while the medical device owner shall be responsible for the acceptance processes of the medical device as detailed in this document.

Medical devices which are leased, on-loan, for trial evaluation, clinical investigation, transferred and undergone major upgrading, shall be installed, tested and commissioned before initial use.

Self-Check -1	Written Test

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

Part I: fill the blank space

1. _____ is a document used to outline the scope and define the responsibilities of the commissioning process as well as the activates, schedules and documentation required.

2. _____: is done after the release of each build to ensure that software stability is intact and not facing any anomalies.

3. List down the types of Functional Testing (5%)

_____,_____
_____,_____
_____,_____
_____,_____
_____,_____
_____,_____

Answer the following question!

Note: **Satisfactory rating – 5 and 10 points Unsatisfactory - below 8and 10points**

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

Answer Sheet

Name: _____ Date: _____

Score = _____
Rating: _____

Information Sheet 2- Consult appropriate personnel.

Consultation

Consultation is a legal requirement and an essential part of managing health and safety risks. A safe workplace is more easily achieved when everyone involved in the work communicates with each other to identify hazards and risks, talks about any health and safety concerns and works together to find solutions. This includes cooperation between the people who manage or control the work and those who carry out the work or who are affected by the work.

When to consult with workers

Many organizational decisions or actions have health and safety consequences for workers. For example, introducing new equipment into the workplace may affect the tasks your workers carry out, the timeframes for doing work, how they interact with each other and the environment in which they work.

A person conducting a business or undertaking must consult with workers when:

- identifying hazards and assessing risks arising from the work carried out or to be carried out
- making decisions about ways to eliminate or minimise those risks
- making decisions about the adequacy of facilities for the welfare of workers
- proposing changes that may affect the health or safety of your workers
- making decisions about procedures for consulting with workers; resolving health or safety issues; monitoring health of your workers; monitoring the conditions at the workplace and providing information and training for your workers.

What is effective consultation?

Consultation is a two-way process between you and your workers where you:

- talk to each other about health and safety matters
- listen to their concerns and raise your concerns

- seek and share views and information, and
- consider what your workers say before you make decisions.

Consultation requires that:

- relevant work health and safety information is shared with workers
- workers are given a reasonable opportunity to express their views and to raise health or safety issues
- workers are given a reasonable opportunity to contribute to the decision-making process relating to the health and safety matter
- views of workers are taken into account
- workers are advised of the outcome of any consultation in a timely manner.

How to consult with workers

Consultation with workers can be undertaken in various ways. It does not need to be a formal process and can be as simple as talking to them regularly and considering their views when making health and safety decisions.

Roles and Responsibilities

Members of the principal stakeholders will be included in and form a Commissioning Team that the Consultant shall identify in the Project Commissioning Plan.

The involvement of various members of the Commissioning Team shall be staged over the entire commissioning process and will conclude upon acceptance of the facility by the City Project Manager at the end.

Consultant Commissioning Scope and Organization

The Consultant has the responsibility and shall ensure that all commissioning activities are carried out according to the minimum requirements of the present document, culminating in the delivery of a fully operational plant compliant and complete in every respect.

The Consultant has the responsibility to deliver the Project Commissioning Plan, and subsequently to develop it. The Consultant is responsible for ensuring that the design requirements and objectives are properly translated into commissioning specifications

and objectives, for issue of procedures and for site activities, and for ensuring that commissioning records demonstrate compliance with the requirements.

In a general sense, the consultant shall prepare, put in action and control the whole commissioning process. All commissioning related items described in the present document are included in the Consultant scope unless otherwise specified.

Self-Check -2	Written Test

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

PART I. Say true or false (5point)

1. A person conducting a business or undertaking must consult with workers when making decisions about ways to eliminate or minimize risks.
2. Consultant has not the responsibility to deliver the Project Commissioning Plan
3. Consultation requires that relevant work health and safety information is shared with workers
4. Consultation not requires that the views of workers are taken into account
5. Consultation requires that relevant work health and safety information is shared with workers

PART II. Fill the blank space

1. List down the requirements of **Consultation**! (4pts)

   _____,_____
   _____,_____
   _____,_____

2. List down when to a person conducting a business or undertaking must consult with workers (6pts)

   _____,_____
   _____,_____
   _____,_____

. Answer the following question!

Note: **Satisfactory rating - 8 and 15 points Unsatisfactory - below 8 and 15 points**

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

Answer Sheet

Score = _____
Rating: _____

Name: _____ Date: _____

Short Answer Question

Information Sheet 3. Check commissioning procedures

Check commissioning procedures

The ever evolving role of technology in healthcare allows hospital to diagnose monitor and treat faster, with greater accuracy enabling better service and faster recovery. This is only possible provided medical equipment is safely commissioned in suitable environment, properly calibrated to provide accurate results, handled & maintained by trained staff.

Commissioning Checklist

A commissioning checklist is used to ensure the safety and functionality of new or modified systems in a facility. Efficiently validate the performance of HVAC, pumping, piping, and lighting systems using this comprehensive checklist. This checklist includes installation checks and testing, adjusting, and balancing (TAB) items.

Commissioning teams should take advantage of this mobile-ready checklist to easily perform the following:

- Specify the project details
- Check systems installation and operation
- Take/attach photos of compliance, detected failures, and more
- Assign corrective actions with a due date and priority level
- Sign off with digital signatures and auto-generate the commissioning report

This equipment commissioning checklist is used for the commissioning of burners/boilers in an industrial or commercial power plant. Easily customize or build your own checklist using iAuditor template editor to meet specific equipment design requirements and fulfill company needs. Each inspection item can also be set to “mandatory” to make sure that every detail about the equipment commissioning is checked.

Equipment Commissioning Checklist

Documentation & Requirements

Have all required legislated obligations been completed prior to installation?

Yes No N/A

Has all required licensing and testing been completed prior to or on installation?

Yes No N/A

Has all required specialist signage been installed?

Yes No N/A

Is baseline health surveillance required?

Yes No N/A

Is there an English language version of instruction/operating manual available?

Yes No N/A

Have all modifications been completed and approved by relevant authorities?

Yes No N/A

Does the equipment NOT create emissions or any other by-product which may impact the environment?

Yes No N/A

Has Safe Work Procedure (SWP) been completed for the equipment?

Yes No N/A

Are training, work practice and supervision changes required?

Yes No N/A

Have all staff who require training in the use of the equipment completed it prior to commissioning?

Yes No N/A

Are Staff training records completed and properly stored in the database?

Yes No N/A

Has the contractor company and individual workers completed the contractor induction?

Yes No N/A

Is a HAZOP required for this equipment? (Do it for high risk/complex equipment)

Yes No N/A

Has the Pressure Vessel Compliance Checklist been completed?

Yes No N/A

Are Specific Emergency Plan and relevant procedures/equipment in place?

Yes No N/A

If required, are health surveillance and testing programs in place?

Yes No N/A

Are machine guarding and emergency stops in place and working as designed?

Yes No N/A

Have all electrical wiring and supply issues been resolved?

Yes No N/A

Have all gas storage and supply issues been resolved?

Yes No N/A

Have all radiation sources storage, handling, and disposal issues been identified and resolved?

Yes No N/A

Has a maintenance plan and contract for scheduled maintenance and breakdown been arranged?

Yes No N/A

Self-Check 3	Written Test

Directions: Answer all the questions listed below.

I. Say true or false. (10point)

1. For the purchase of a new medical device purchase agreement/ tender document/ contract document/quotation;
2. For the purchase of a new medical device purchase order, test & commissioning date by the medical device establishment
3. General considerations when carrying out an acceptance check not include inspection of the packaging
4. Medical device establishment shall provide written notification of any specific installation and test and commissioning requirements.
5. For non-active device, only inspection, training and acceptance procedure is required.

. Answer the following question!

Note: **Satisfactory rating - 5 and 10 points Unsatisfactory - below 5and 10points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet 4- Obtain material to complete the work.

Obtain material to complete the work.

Documentation

The whole commissioning process needs to be well documented. Documents are prepared and issued during the progress of the commissioning activities in order to certify the performance of the tests and to provide the required authorizations for the continuation of the programme, in accordance with the procedures established by the Operating Organization.

The contract documents should define:

- Who is responsible for each aspect of commissioning and whether it will be witnessed.
- The methods that should be used.
- The standards that should be adopted.
- The documentation that is required.

Commissioning documents:

- Verify that systems have been commissioned correctly.
- Satisfy legal requirements.
- Provide a record for operations, maintenance and future works.
- Create a benchmark for future testing, maintenance and re-commissioning.

They might include:

- Manufacturer's literature.
- As-installed information.
- Inspection reports identifying functional, integration or operational issues.
- Test reports and certificates.
- Signed and witnessed commissioning schedules.
- Issue and resolution logs and reports, providing a record of problems and concerns raised by the commissioning team and the steps taken to resolve them.

- Systems manuals providing the information needed for proper operation of the building systems.
- Training documentation to ensure operations and maintenance personnel have the expertise necessary for the operation and maintenance of the building systems.
- Plans for seasonal testing to ensure the optimization of systems during a range of different conditions.
- Final commissioning report, incorporating all the commissioning documentation.

Typical documentations in commissioning are:

For the purchase of a new medical device, documentation as listed (but not limited to) below shall be made available to medical device owner by medical device establishment prior to test & commissioning:

- Device registration certificate and Establishment License from MDA;
- Purchase agreement/ tender document/ contract document/quotation;
- Purchase order, test & commissioning date by the medical device establishment;
- Relevant licenses and certificates:

  i. Factory test certificate;

  ii. Software license (applicable only for software related medical device);

- List of equipment specialist responsible to carry out the T&C;
- Manuals (user, operation, service, spare part list, list of tool and test equipment required, circuit diagram, planned preventive maintenance manual and checklist as per manufacturer's requirement.);
- All approval document from regulatory body (where relevant); and as build drawing of site and facility where relevant.

For other than newly purchased medical devices such as leased, on-loan, for trial evaluation, clinical investigation, transferred, donated and medical device undergone major upgrading, documentation shall include (but not limited to):

- Device registration certificate and establishment license (if applicable) from MDA;

- Purchase agreement/leased agreement/tender document / quotation (where applicable);
- Purchase order, test & commissioning date by the medical device establishment (where applicable);
- Relevant licenses and certificates:

  i. Factory test certificate or equivalent certificate;

  ii. Software license (applicable only for software related medical device);and

  iii. Installation qualification, if applicable;

- list of equipment specialist and/or competent personnel responsible to carry out the test & commissioning
- Manuals (user, operation, service, spare part list, list of tools and test equipment required, circuit diagram, PPM Manual and checklist as per manufacturer requirement);
- All approval document from regulatory body (where relevant);
- As build drawing of site and facility where relevant;
- Maintenance history (include quality assurance test details where relevant);
- A clear statement that the equipment is being resold/donated; and
- Proof of decontamination.

Medical device establishment shall provide written notification of any specific installation and test and commissioning requirements.

For non-active device, only inspection, training and acceptance procedure is required.

For a designated device, all drawings, safety requirements & installation plan shall be submitted for approval to the relevant regulatory authority. The medical device establishment shall only commence with the installations of the designated device upon receiving the designated device permit from the regulatory authority.

Self-Check -4	Written Test

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

Part I fill the blank space

1. Listed down for the documentation shall include purchase of a new medical device! (5%)

_____,_____

_____,_____/_____

_____,_____

_____,_____,_____

2. Listed down for documentation shall include other than newly purchased medical devices! (5%)

_____,_____

_____,_____/_____

_____,_____

_____,_____,_____

Answer the following question!

Note: **Satisfactory rating 5 and 10 points Unsatisfactory below 5 and 10points**

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

Score = _____

Rating: _____

Answer Sheet

Name: _____ Date: _____

Information Sheet 5. Tools, equipment and testing devices

Tools, equipment and testing devices

Definitions:

Recognizing that there are multiple interpretations that exist for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of equipment, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with healthcare technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Medical equipment: Medical equipment requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment/equipment. Medical equipment excludes implantable, disposable or single-use medical equipment.

The following table shows tools and instruments which are appropriate to perform the electrical/electronic tasks given under this topic.

Table 1: tools and instruments

Tools	Test instrument & other equipments	Consumable materials
Different Pliers	Multimeter	Wire, Cable
Screw Drivers	Megger	Solder lead, Flux
Wrenches	Frequency meter	PCB
Pipe cutter	Inductance meter	
Steel rule	Oscilloscope	
	Power supply	
	Soldering gun	
	Digital IC Tester	

Measuring tools and instrument:- The electrician uses the following measuring tools and instruments to measure value of voltage, current and resistance, wire length, opening sizes of wire, conduit and other items.

Sawing and cutting tool. Two of the commonly used saw are:

***Figure 6**: tools and measuring instruments*

Self-Check 5	Written Test

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

I. Choose the best answer (each 2 point)

1. _____are used in handling and twisting wires.
   A. Pliers B. wrenches C. screw drivers D. hammers
2. Which of the following tool is used to make holes in building structure for passage of wires and conduit in both new and old installation, indoor or outdoor wiring
   A. Hammers B. wrenches C. drilling equipment D. soldering gun
3. _____ are used to drive and pull out nails.
   A. Pliers B. hammers C. wrenches D. screw drivers
4. _____ are used to drive and pull out screws.
   A. Pliers B. wrenches C. screw drivers D. hammers
5. Which of the following **is not** an example of instruments to measure electrical quantities
   A. Ammeter B. ohmmeter C. galvanometer D. pliers

. Answer the following question!

Note: Satisfactory rating 5 and 10points Unsatisfactory below 5 and 10 points

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

Answer Sheet

Score = _____
Rating: _____

Name: _____ Date: _____

Short Answer Question

Information Sheet 6. Check preparatory work.

Check preparatory work.

The Electronic and Biomedical Engineering (EBME) department should ensure processes are in place for acceptance testing. These processes will check that equipment meets safety standards, meets clinical requirements, and the procurement requirements of the Hospital from the day it arrives.

Preparation and approval of test

In particular, when the commissioning process works well, the preparation and approval of test documentation is a challenging activity if the commissioning programme is to proceed in an orderly and timely manner. Suitable preparations have to be made so that the stage completion and approval documents can be produced expeditiously.

To this end, reviews of test results need to be undertaken and test results need to be accepted at suitable times during the progress of testing within each stage. The end of each stage should include preparations for the start of the succeeding stage and a means should be arranged for the continual updating of documentation.

In addition, close liaison should be maintained with all participants in the commissioning programme, including personnel at the headquarters of the Operating Organization and personnel of the Regulatory Body.

Parallel to the commissioning and the related documentation activities, the plant documentation required as part of the plant handover process is also prepared. The plant documentation is usually transferred in system packages and over a reasonable period of time in order to allow the plant personnel to review each package comprehensively. This review often forms part of the operating group's activities during the commissioning process.

Implementation of checklist

Checklist was shared with clinical engineers and training/ implementation session on use of checklist was conducted. Most of the points are self-explanatory. They were informed about some of the points which may not be relevant to certain equipment like software license document for operating table & were asked to fill as not applicable. The

preventive maintenance related checklist and safe handling of equipment i.e. Do's & don't are also obtained. The service report is taken along with installation, performance and operating qualifications from service providers.

The companies were provided 28 point checklist along with **(RFP) request for proposal** so that they have time and clarity on documents expected at the time of installation /commissioning.

Checklist signed for accountability of the completion of documentation:

1. Prepared by
2. Supervised by
3. Reviewed by user department
4. Authorized by GM- Clinical Engineering
5. Final authorization by Medical Director

Self-Check 6	Written Test

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

Part I: Say true or false. (5point)

1. Electrical Safety Markings should be indicated on the device labels.
2. Electronic and Biomedical Engineering department should NOT be ensure processes are in place for acceptance testing.
3. The acceptance testing is completed The job number allocated from the database to this acceptance test
4. The acceptance testing is completed Any accessories that were delivered with the device must be listed and checked
5. Acceptance is not the order number for cross reference with the supplier

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

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Operation title -1: Filling equipment Commissioning Checklist

Burner/Boiler Commissioning

Is safe site access available and risk assessment completed?

Yes No N/A

Has a visual inspection been carried out to assess physical damage of components and cases?

Yes No N/A

Are all items packed in transit removed from combustion chamber?

Yes No N/A

Has boiler been assembled as per manufacturers instructions, including casing and baffles where appropriate?

Yes No N/A

Has boiler been pressure tested and certificated?

Yes No N/A

Are boiler filled with water and isolation valves open?

Yes No N/A

Is the burner to boiler fixings correct as per manufacturers instructions?

Yes No N/A

Are water pumps working to provide sufficient circulation/heating load?

Yes No N/A

Is the burner flame tube insulation sealing correct at appliance body as per manufacturers instructions?

Yes No N/A

Is there adequate clearance around Boiler and Burner for servicing?

Yes No N/A

Is the boiler door aligned and sealed correctly?

Yes No N/A

Is flue installation safe, fitted correctly and sealed to the appliance?

Yes No N/A

Does the permanent ventilation comply with current installation standards and regulations?

Yes No N/A

Are appliance electrical wiring checked for safety?

Yes No N/A

Is the wiring of the burner to appliance correct and according to manufacturers instructions?

Yes No N/A

Are external controls and interlocks connected and fully operational (BMS, fan flue, flow-switches, dampers, diverter valves, etc.)?

Yes No N/A

Are boiler thermostats fitted correctly to manufacturers instruction (on/off, high/low, high limit)?

Yes No N/A

Are modulating burners probes fitted and wired to manufacturers instructions?

Yes No N/A

Are all safety systems fitted and fully operational (e.g. pressure relief/safety valves etc.)?

Yes No N/A

Does the gas pipework safely fit and support with correct means of isolation?

Yes No N/A

Is the gas pipework tested for tightness and purged (certificates and fuel available)?

Yes No N/A

Is the gas booster or non-appliance specific gas valve safety interlocks connected?

Yes No N/A

Is the adequate access to the gas meter?

Yes No N/A

Are oil supply pipe(s) correctly fitted, purged and supported (check inline filter has been fitted)?

Yes No N/A

Is the oil pump set for the single or two-pipe system as applicable (fuel available)?

Yes No N/A

Is the rotation of 3 phase motors relative to burner/booster checked?

Yes No N/A

Completion

Additional Comments

All hazards and H&S issues have been identified and control measures have been initiated and/or implemented.

Inspector Name & Signature

Sign

Supplier/Installer Name & Signature

Sign

Manager/Supervisor Name & Signature

LG #16	LO #2- Commissioning

Instruction sheet

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

- Follow OH&S policies and procedures.
- Check and isolate circuits.
- Performed commissioning activities.
- Respond unplanned events or conditions.
- Obtain approval.

Undertake quality of the work 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:

- Following OH&S policies and procedures.
- Checking and isolate circuits.
- Performing commissioning activities.
- Responding unplanned events or conditions.
- Obtaining approval.
- Undertaking quality of the work

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Information Sheet 1 Follow OH&S policies and procedures.

Follow OH&S policies and procedures.

Planning to perform a certain task in a safe manner. When planning work practices with colleagues it is important to keep the health and safety of workers at the forefront of issues to be considered. In workplaces where potentially dangerous machinery is operated, or dangerous situations are encountered, this is not difficult. However, when the potential threat is not so obvious, the health and safety factors may be overlooked. Poorly designed furniture, inadequate lighting, unstable filing cabinets or screens, poor ventilation, inappropriate workloads and much more can become OHS issues. When planning work practices; use the "what if" principle. Try to think of all the things that could go wrong and then what could reasonably be done to prevent them. You are not expected to eliminate risk entirely; this is not possible.

Safety Rules

There will undoubtedly be a safety program to follow for the shop or area in which you will be working. The following general safety rules are furnished as a guide.

- SUPPORT your local safety program and take an active part in safety meetings.
- INSPECT tools and equipment for safe conditions before starting work.
- ADVISE your supervisor promptly of any unsafe conditions or practices.
- LEARN the safe way to do your job before you start.
- THINK safety, and ACT safety at all times.
- OBEY safety rules and regulations-they are for your protection.
- WEAR proper clothing and protective equipment.
- CONDUCT yourself properly at all times-horseplay is prohibited.
- OPERATE only the equipment you are authorized to use.
- REPORT any injury immediately to your supervisor.

Purpose of OH &S

A health and safety policy ensures that the employer complies with the Occupational Safety and Health. Act and relevant state legislation. It provides guidelines for

establishing and implementing programs that will reduce workplace hazards, protect lives and promote employee health.

An OHS Policy

An OHS Policy is simply a method of stating how you, your employees, contractors and visitors are expected to behave when they are on Company property or performing Company related activities. As an employer or responsible contractor, you are required by law to provide a safe system of work.

Self-Check 1	Written Test

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

I. **Say true or false** (each 2 point)

1. Goal of OHS programs NOT include fostering a safe and healthy work environment

2. Planning to perform a certain task in a safe manner

3. INSPECT tools and equipment for safe conditions before starting work.

4. ADVISE your supervisor promptly of any unsafe conditions or practices.

. Answer the following question!

Note: Satisfactory rating 5 and 10 points Unsatisfactory below 5 and 10 points

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

Score = _____

Rating: _____

Answer Sheet

Name: _____ Date: _____

Information Sheet 2 Check and isolate circuits.

Check and isolate circuits

To help verify the functionality and safety of medical devices, electrical safety standards have been established in the United States, European countries, and other parts of the world. The standards differ in criteria, measurements, and protocol. The International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC) organizations based in Europe provide standards worldwide in partnership with the World Trade Organization. These include standards for electro-medical equipment. There are general and specific standards for medical device electrical safety. IEC60601 AAMI/NFPA 99 The primary standard for medical devices is IEC 60601. General requirements for protection against electric shock hazards are covered in IEC 60601.1, Section 3.

In this standard, each instrument has a class:

- Class I—Live part covered by basic insulation and protective earth
- Class II—Live part covered by double or reinforced insulation
- Class IP—Internal power supply

Each patient applied part or patient lead has a type:

- Type B—Patient applied part earthed
- Type BF—Patient applied part floating (surface conductor)
- Type CF—Patient applied part floating for use in direct contact with the heart

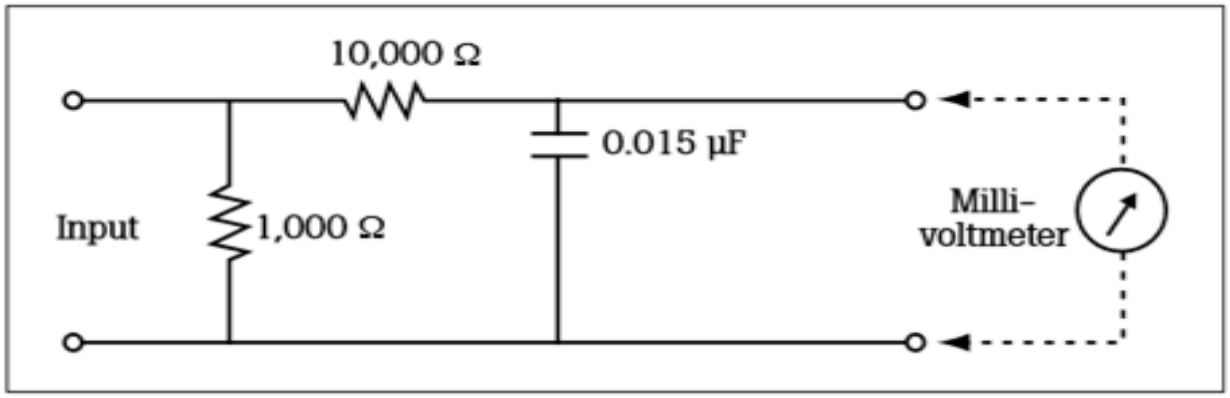
Leakage measurement limits have been developed for equipment types and measurements

- NC—normal conditions
- SFC—single fault conditions

The terminology used in IEC 60601.1 3rd Edition includes:

- Protective earth resistance
- Earth leakage current
- Touch current (formerly enclosure leakage current)
- Patient leakage current
- Patient auxiliary current
- Mains on applied part (MAP)

Leakage current (μA)		Earth leakage current mA	Touch current (μA)	Patient leakage current AC (μA)	Patient leakage current DC (μA)	Patient leakage current mains on applied (μA)	Patient auxiliary current (μA)	Patient auxiliary current (μA)	Patient auxiliary current (μA)
Type B	NC	5	100	100	10	–	100	10	100
	SFC	10	500	500	50	–	500	50	500
Type BF	NC	5	100	100	10	–	100	10	100
	SFC	10	500	500	50	5000	500	50	500
Type CF	NC	5	100	10	10	–	10	10	10
	SFC	10	500	50	50	50	50	50	50



The figure above represents the impendence of a patient test load. Leakage current measuring devices use this impedance circuit for measurements.

Additional important points regarding IEC 60601.1 include:

1. The use of up to 25 amperes ac for protective earth testing (this is a type-test and generally suitable for manufacturers)
2. Leakage current is measured at 100 percent of mains voltage
3. Performance of dielectric strength/insulation testing is measured at 110 percent of mains voltage.

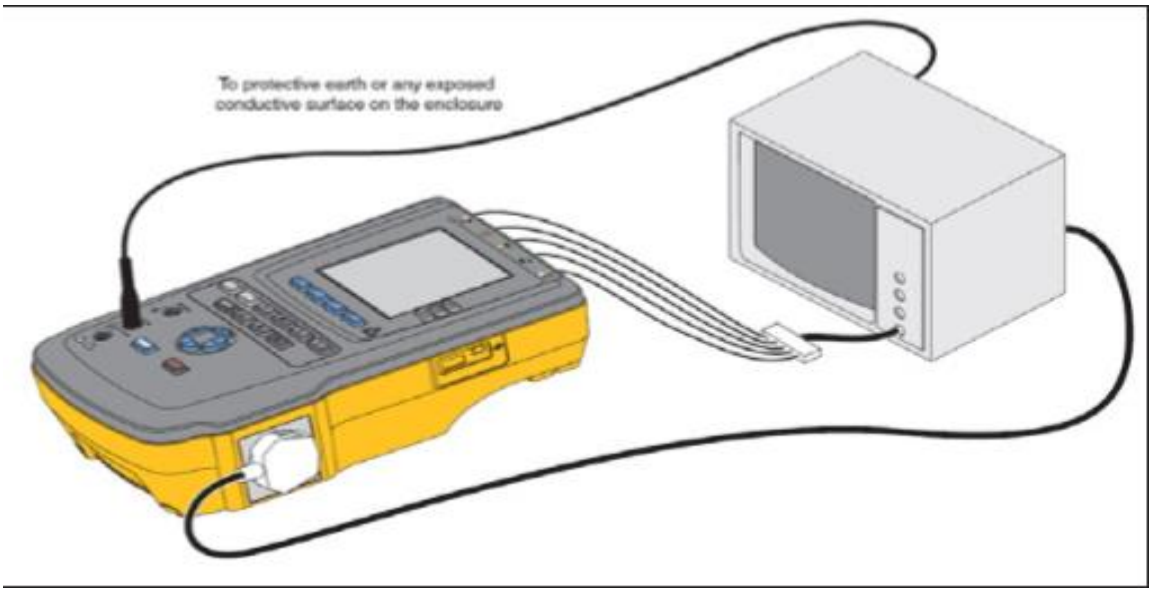
A new IEC standard, IEC 62353, is used for medical device testing in hospitals. IEC 62353 was developed because IEC 60601.1 is a type-testing standard with no risk management criteria and is impractical for testing in the hospital environment.

IEC 62353 tests are performed on equipment prior to use on patients, during schedule periodic testing, and after repair. Thus, this standard is for field (hospital) testing and

does not address equipment design. In Annex E of the document, the manufacturer is requested to provide information on testing interval and procedure based on risk, typical usage, and device history. The minimum testing requirement for life support and other critical equipment is every 24 months.

Electrical safety testing

Testing requirements and sequence according to IEC 62353. Only measurement equipment that meets IEC 61010-1 should be used. The sequence outlined in the figure below should be followed. For example, protective earth resistance should be measured prior to leakage current measurements



General connections to an electrical safety analyzer (ESA) are shown in Figure. Consult the operational manual for specifics for your electrical safety analyzer. Documentation requirements for IEC 62353 include:

- Identification of the testing group (hospital department, independent service organization, manufacturer)
- Names of the person(s), who performed the testing and evaluation(s)
- Identification of the equipment/system (e.g. type, serial number, inventory number) and the accessories tested
- Tests and measurements
- Date, type, and outcome/results of:

- Visual inspections
- Measurements (measured values, measuring method, measuring equipment)
- Functional testing
- Concluding evaluation
- Date and signature of the individual who performed the evaluation

Computerized record-keeping systems are greatly preferred for data storage, search, review, and analysis. Note the device fields must be standardized.

The ESA609 integrates all functions needed to test medical devices when patient lead testing is not required:

- Line (mains) voltage
- Ground Wire (or protective earth) resistance
- Equipment current
- Ground wire (earth) leakage
- Chassis (enclosure) leakage
- Direct equipment leakage
- Point to point leakage and resistance

Self-Check 2	Written Test

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

I. **Say true or false** (each 1 point)

1. Leakage current is measured at 100 percent of mains voltage
2. Performance of dielectric strength/insulation testing is measured at 100 percent of mains voltage.
3. protective earth resistance should be measured prior to leakage current measurements
4. Computerized record-keeping systems are greatly preferred for data storage, search, review, and analysis
5. NOT standards differ in criteria, measurements, and protocol.

. Answer the following question!

Note: Satisfactory rating 5 and 10 points Unsatisfactory below 5 and 10 points

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date_____

Information Sheet 3. Performed commissioning activities

Performed commissioning activities

Needs identification usually starts from users of technology, i.e. the medical staff (physicians and nurses).Indeed, the need to acquire a medical device may be due to one or a combination of the following reasons:

- Provide a new service
- Improve service efficiency
- Improve clinical outcomes
- Improve cost benefits
- Meet specific standards
- Reduce a risk.

In general, tendering process takes place to purchase medical equipment based on the required specifications. In tendering, all vendors are allowed to bid under a competitive and fair evaluation. Moreover, it gives a good opportunity for hospitals to select the best possible medical equipment. It is worthy to mention that technical specifications should include general requirements such as the warranty, technical services, technical documents, and any other necessary requirements for equipment operation.

In the evaluation process, the purchased medical equipment should be evaluated from three different angles:

- Technical,
- Clinical, and
- Financial.

The purpose of technical and financial evaluations is to check the proposed technology, and to ensure the performance of the devices meets the desired outcomes. On the other hand, financial evaluation considers only the costs of the proposed technology. Both technical and clinical evaluations are carried out using either scoring or accept/reject

approaches, whereas financial evaluation regards the lowest price among accepted vendors.

After making the selection, an award must be issued to acquire the device. A purchase contract document is prepared by the purchasing department and it must cover all terms and conditions that have been agreed upon by the vendor and the hospital.

Delivery and incoming inspection

Clinical engineering department ensures an incoming inspection on equipment includes verification of accessories, manuals, and electrical safety and operation in accordance with all applicable policies. Incoming equipment should be carefully checked for possible shipment damage and compliance with specifications in the purchase order. One role of clinical engineer is to ensure an incoming inspection on medical equipment by verifying the following:

- Accessories existence
- Manuals existence
- Electrical safety
- Compliance with specifications
- Possible shipment damage

Inventory and documentation

Medical device inventory and documentation is an assistive stage in the life cycle. It provides information to support medical equipment management in different stages. Upon completion of the incoming inspection, a device record file should be created and it should be active throughout the useful life span of the device. Each device is identified and tracked by a unique number called equipment record number. The device record file should contain the following data:

- An Equipment Control Number (ECN)
- A generic description of the equipment
- The equipment manufacturer, model, and serial number
- The owner department and the location of the equipment
- The purchase order number and date

- The equipment's acquisition cost
- The supplier's name, address, and telephone number
- The warranty conditions and expiration date
- An abbreviated description of the inspection and preventive maintenance requirements and intervals
- An abbreviated service history
- Information regarding any applicable service contract
- The location of the equipment's user and service manuals.

Installation and commissioning

Installation and commissioning can be carried out by in-house technical staff if they are familiar with a given item of equipment. If the installation and commissioning are needed from the suppliers, in-house technical staff should monitor this process. In general, installation process should be compatible with standard policies for medical equipment installation.

User Training

To reduce the possibility of equipment malfunction following service or repair, all personnel involved in maintaining and servicing equipment must be trained to appropriate standards for the work they are carrying out. Operator error is a leading cause of device malfunctioning, especially in developing countries. Incorrect usage of medical equipment will also greatly increase maintenance problems. Therefore, training of users should be regularly monitored from the vendor to ensure an appropriate skill level that is required for equipment operation. In fact, training should include all of the user staff as needed, such as clinical and technical staff. In addition, it should cover all aspects of medical equipment usage.

Monitoring of use

One common mistake in MEM is to believe that the warranty period is covered by the supplier, so no in-house technical attention is necessary. In-house technical staff should become the link between user and supplier and should observe any supplier's technical staff. This also will provide a learning opportunity for the in-house technical personnel.

This performance should be also documented in the service history of the device by in-house technical staff.

Maintenance

Equipment maintenance involves all activities related to providing an adequate level of service and limiting downtime of medical devices. Maintenance or service activity is required in order to ensure the devices are kept functioning within the limits imposed by the test criteria and to return devices to the required level of functioning after breakage or other failure. The primary goal of maintenance activity is to reduce, or, if possible, to eliminate the need of repairs.

Traditionally, equipment maintenance is categorized as Preventive Maintenance (PM) and Corrective Maintenance (CM). Preventive maintenance procedures are actions that are necessary or desirable in order to extend the operational intervals between failures to extend the life of equipment or to detect and correct problems that are not apparent to the user. On the other hand, corrective maintenance procedures are any services that involve medical equipment repair, in addition to any specific service include repairs performed under a service contract or repairs performed by vendors during the warranty period.
It could be extended in case of a hazard notification or user error. In summary, PM aims keep the device as new as possible whereas CM aims to keep the device as good as prior to failure as possible.

Indeed, PM procedures are based on manufacturer's requirements, individual experience, and equipment service history, whereas CM procedures are mainly based on manufacturer's recommendations. Forward planning of maintenance calls for knowledge of maintenance requirements and the resources that are required in order to perform maintenance. These resources include labor, parts, materials, tools, and costs. PM should be performed based on the frequency and the procedure. Frequency of maintenance is based on the manufacturer’s recommendation and the equipment history. The maintenance procedure includes all actions that should be carried out on a device. It should be written down for each device as a check list and reviewed regularly.

In CM, a response is carried out due to a service request. In this request, a summary of problem symptoms should be identified. Regardless of a technical service type, a set of factors can influence effectiveness of CM. These include experience, information, device complexity level, availability of spare parts, service manual existence, and equipped workshop. In this context, service modalities that provide CM are classified into four main classes; in-house service, contracted service, maintenance insurance, and contracted technology management. In-house service refers to maintaining the equipment by engineers and technicians in the clinical engineering department. The service contract is the most popular method for maintenance of medical equipment. Different options of this type are available based on labor and spare parts. In maintenance insurance, by its name, a hospital chooses to pay an insurance company instead of a service supplier. The insurance company then calls an appropriate service provider to support medical equipment. The last type is contracted technology management, in which all activities are completely assigned to management provider. In addition, a manager or a service provider is stationed in the hospital.

Replacement

Replacement is the last stage of medical equipment's life cycle. All medical devices reach the point in their life where the cost-benefit ratio goes to the negative because of decreased reliability, increased downtime, safety issues, compromised care, increased operating costs, changing regulations, or simply obsolescence

Disposal of equipment must follow safety procedures in order to protect people and the environment. The ideal healthcare technology replacement planning system should be facility wide, and cover all clinical equipment employing accurate objective data for analysis. Moreover, it should be futuristic and include strategic planning relating to clinical marketplace trends and the hospital’s strategic initiatives relating to technology. The plan should encompass factors relating to cost-benefit analysis, safety, expected life span, standardization, and clinical benefits. In application, decontamination requirements should be regarded prior to disposal. Furthermore, many benefits can be obtained by utilizing scrapped equipment as listed below:

- Use spare parts with similar equipment
- Replace with new ones with the same vendors
- Donate them to charity clinics after operation verification
- Dummies in internal training
- Use in research labs
- Save them for museums.

In fact, most of hospital planning processes tend to focus on current or short-term needs with little or no consideration of future replacement of medical equipment. An equipment replacement plan will help to guide the hospital on potential future spending obligations relating to medical devices. Different approaches are used for replacement of medical equipment. These approaches are either qualitative or quantitative. In qualitative approach, a combination of different criteria is regarded to approve replacement decision; whereas in quantitative approach, a mathematical model is proposed to determine replacement thresholds which lead to a realistic replacement decision.

Self-Check .3	Written Test

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

Part I: Say true or false (each 1pts)

1. Tendering process takes place to purchase medical equipment based on the required specifications
2. Financial evaluation considers the costs of the proposed technology
3. Disposal of equipment must follow safety procedures in order to protect people and the environment
4. Replacement is the last stage of medical equipment's life cycle.
5. Installation and commissioning can be carried out by in-house technical staff if they are familiar with a given item of equipment.

Part II Fill the black space

1. List down the three different angles in the evaluation process, the purchased medical equipment should be evaluated (3pts)

_____,_____

_____,_____

_____,_____

2. Mentions the date device record file should contain: (5pts)

_____,_____

_____,_____

_____,_____

. Answer the following question!

Note: Satisfactory rating 7 and 13 points Unsatisfactory below 7 and 13 points

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Respond unplanned events or conditions

Many accidents, malfunctions and unplanned events are, however, preventable and can be readily addressed or prevented by good planning, design, emergency response planning, and mitigation. By identifying and assessing the potential for these events to occur, North cliff can also identify and put in place prevention and response procedures to minimize or eliminate the potential for significant adverse environmental effects, should an accidental event occur.

Unplanned events are episodes that are not expected to occur during the Project's normal Construction and Operational Phase activities, such as accidents. The Project follows safety and engineering design criteria that aim to avoid unplanned events that could lead to adverse environmental, socio-economic or health and safety impacts Installing single Phase system, resulting in an Unplanned Event (Commissioning and Operational Phase)

Unplanned learning occurs when an event occurs that causes a learning activity to be undertaken or carried out without any prior thought or planning (e.g. through reading a journal, undertaking an activity or task, or a discussion with a colleague owing to an interaction during your normal working day)

Table : Unplanned Event (Commissioning and Operational Phase)

Activity	Event	Receptors	
Installing single phase system		Environmental	Socio Economic & Health
	short circuit	X	X
	Fires and explosions	X	X
	Shock & injury		X
	Death		X

Based on these considerations, the potential accidents, malfunctions and unplanned events that were considered by the Study Team for the Sisson Project are:

- Loss of Containment from Tailings Storage Facility (TSF)
- Erosion and Sediment Control Failure
- Pipeline Leak
- On-Site Hazardous Materials Spill
- Release of Off-Specification Effluent from the Water Treatment Plant
- Failure of a Water Management Pond
- Failure of a Water Management Pond Pump
- Off-Site Trucking Accident
- Vehicle Collision

- Uncontrolled Explosion
- Fire

On-Site Hazardous Material Spill

An On-Site Hazardous Material Spill is a spill of materials associated with the Project that is considered to be hazardous due to its inherent physical or chemical properties, or because of its toxicity, flammability, corrosiveness, or explosiveness.

The following measures will be in place to reduce or eliminate the potential for a major release arising from an on-site hazardous material spill:

- The storage of liquid hazardous materials within buildings, in secure Contained areas;
- the provision of impermeable containment berms (or other forms of secondary containment);
- placement of protective barriers as appropriate;
- sitting of such facilities in locations that represent a relatively low risk and afford an opportunity
- for containment during emergency response;
- provision of alarms on secondary containment measures;
- careful implementation of fuel transfer operations; and
- Provision of an emergency response plan for the immediate isolation and clean-up of a release.

Self-Check 4	Written Test

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

Part I Say true or false (5point)

1. Unplanned events are episodes that are expected to occur during the Project's normal Construction and Operational Phase activities
2. One of an example of unplanned event is accident.
3. The Project follows safety and engineering design criteria that aim to avoid planned events.
4. impossible to respond to unplanned events or conditions
5. Electrical fires and explosions could lead to adverse environmental, socio-economic or health and safety impacts

. Answer the following question!

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

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet 5. Obtain approval

Obtain approval.

Commissioning Completion Assurance is conducted to provide objective evidence that the commissioning has been accomplished. The Commissioning Completion Assurance provides confidence that all commissioning activities are complete. Commissioning Completion Assurance documentation includes the planned measures to resolve all outstanding items and deficiencies.

Commissioning Completion Assurance shall be accomplished by the following means:

- Completion of all commissioning activities and reports
- Meetings held, as required by the respective commissioning phases
- A Commissioning Completion Assurance document has been completed by the Consultant and ready for sign-off by the Project Manager and other stakeholders.

Following sign-off of the Commissioning Completion Assurance, commissioning records shall be compiled into a Commissioning History file and included in the Commissioning Completion Assurance documentation. Each commissioned system shall have a distinct Commissioning History sub-file and submitted in electronic format and hard copies. Electronic copies will be stored in the DMS for the life of the facility.

Commissioning Records

The Commissioning Team Leader must ensure full and accurate sign off records are kept of the tests carried out during commissioning. The Commissioning Team shall complete the requisite commissioning quality records and confirm completeness utilizing a comprehensive Commissioning Completion Assurance (CCA) checklist, previously issued by the consultant and approved by the Project Manager.

The following records, as a minimum, shall be uploaded to the DMS in addition to required hard copy records:

- Commissioning reports including settings
- Commissioning plans and procedures
- Evidence of commissioning verification
- Deficiency reports and corrective actions taken
- Training reports

- Other commissioning documents

Final compilation is organized according to Commissioning Completion Assurance (CCA) and Commissioning history files.

The Consultant shall include all Commissioning Records in the projects' turnover document package within one months of achieving Commissioning Control Point. Complements and updates will be introduced after performing the last Phase tests.

Assurance of Test and commissioning Certificate

Test and commissioning certificate shall be issued by medical device establishment once **test and commissioning** process is successfully completed.

The certificate shall be signed by:

a) Medical device establishment;
b) Medical device owner; and
c) Competent technical personnel

Self-Check 5	Written Test

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

Part I: Say true or false

1. CCA is conducted to provide objective evidence that the commissioning has been accomplished
2. A CCA document has been completed by the Consultant and ready for sign-off by the Project Manager and other stakeholders.
3. Final compilation is organized according to (CCA) and Commissioning history files.
4. The Commissioning Team Leader must ensure full and accurate sign off records are kept of the tests carried out during commissioning.

Part II: Fill the black space

1. List down the means commissioning Completion Assurance shall be accomplished (6pts)

_____,_____

_____

_____

. Answer the following question!

Note: Satisfactory rating 5 and 10 points Unsatisfactory below 5 and 10 points

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

Answer Sheet

Score = _____
Rating: _____

Name: _____ Date: _____

Information Sheet 6 Undertake quality of the work..

Quality

Within healthcare, there is no universally accepted definition of ‘quality’. However, the following definition, from the US Institute of Medicine, is often used:

Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

The Institute of Medicine has identified six dimensions of healthcare quality.

These state that healthcare must be:

- safe
- effective
- patient-centered
- timely
- efficient
- equitable.

The dimensions of quality

Safe

Avoiding harm to patients from care that is intended to help them.

Timely

Reducing waits and sometimes harmful delays.

Effective

Providing services based on evidence and which produce a clear benefit.

Efficient

Avoiding waste.

Person-centered

Establishing a partnership between practitioners and patients to ensure care respects patients' needs and preferences.

Equitable

Providing care that does not vary in quality because of a person's characteristics.

Important Principles

Acceptance testing occurs at two times: 1) Immediately after the equipment is installed (before commissioning); and 2) About one month before the end of the warranty period. The second acceptance test assures that the equipment meets the specifications at the time of purchase *before* the warranty expires. This provides sufficient time to notify the vendor or manufacturer and have the issues resolved at no cost.

During acceptance it is essential that the medical physicist work with the service engineers doing the installation so problems can be resolved as they are discovered. This will lead to a faster installation and assure that the equipment is performing to specification when the installation is complete.

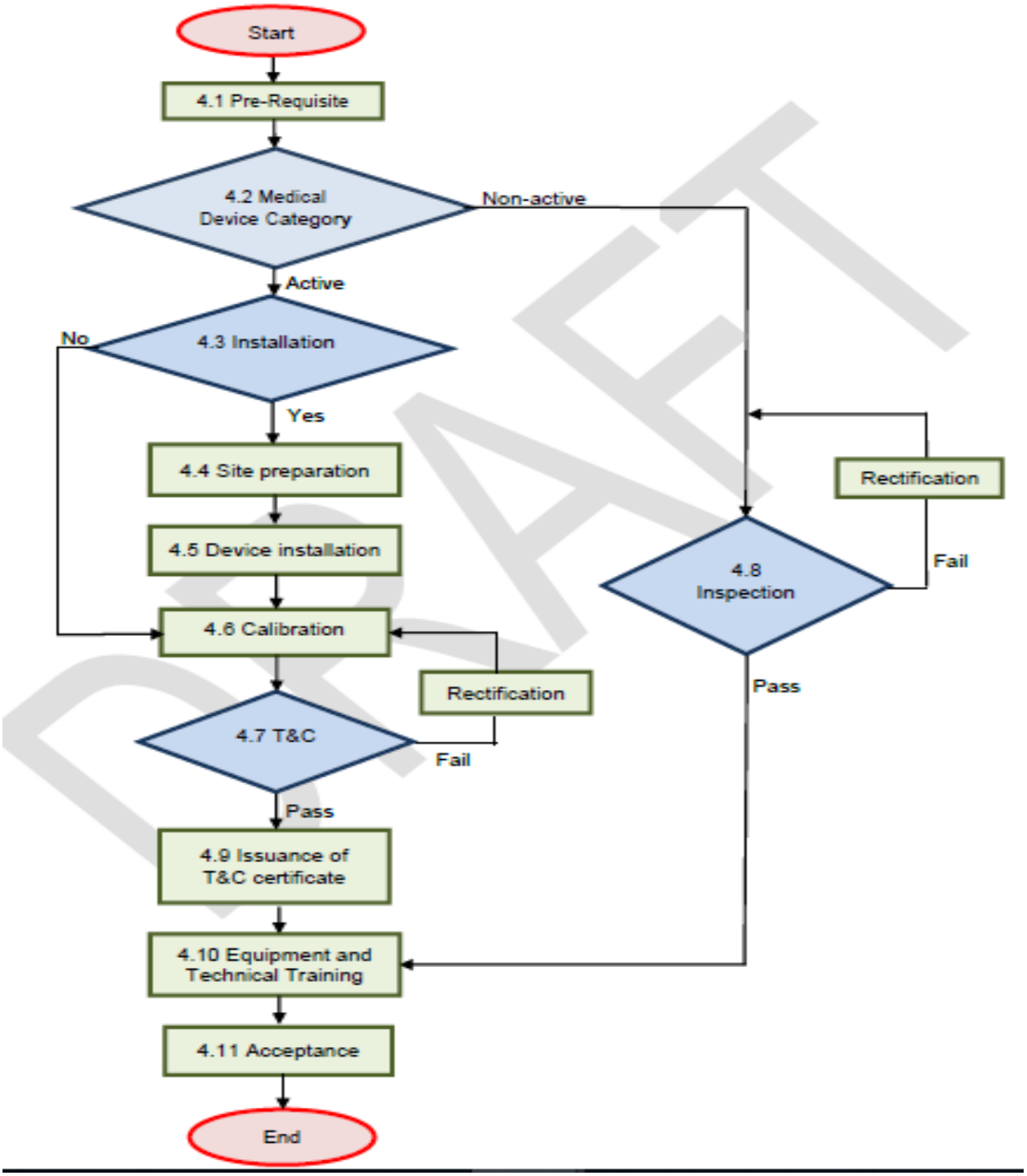
During commissioning the medical physicist provides information necessary for clinical operation of the equipment, e.g., establishes scan protocols for a CT scanner. If vendor provided protocols are to be used, the medical physicist must assure that the image quality and patient dose are optimized with these protocols.

Base line values are established during commissioning against which performance will be compared in the future as part of the ongoing quality control program.

Introduction to References

References for acceptance and commissioning may be somewhat dated. However, even older documents provide the general view of what must be tested, although specifications may have changed (improved).

Maintaining a working relationship with vendors and manufacturers is important and addressed in the Supplemental References.


Start
4.1 Pre-Requisite
4.2 Medical Device Category
Non-active
Active
No
4.3 Installation
Yes
4.4 Site preparation
4.5 Device installation
4.6 Calibration
Rectification
4.7 T&C
Fail
Pass
4.9 Issuance of T&C certificate
4.10 Equipment and Technical Training
4.11 Acceptance
End
Rectification
Fail
4.8 Inspection
Pass

Self-Check 6	Written Test

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

Part I: Say true or false (4pts)

1. References for acceptance and commissioning may be somewhat dated.
2. During commissioning the medical physicist provides information necessary for clinical operation of the equipment.
3. Acceptance testing occurs before commissioning and about one month before the end of the warranty period.
4. Within healthcare, there is universally accepted definition of ‘quality.

Part I: Fill the black space

1. List down the six dimensions of healthcare quality identified by the Institute of Medicine: **(6pts)**

_____

_____

_____

_____

_____

_____

.Answer the following question!

Note: Satisfactory rating 5 and 10 points Unsatisfactory below 5 and 10 points

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

Answer Sheet

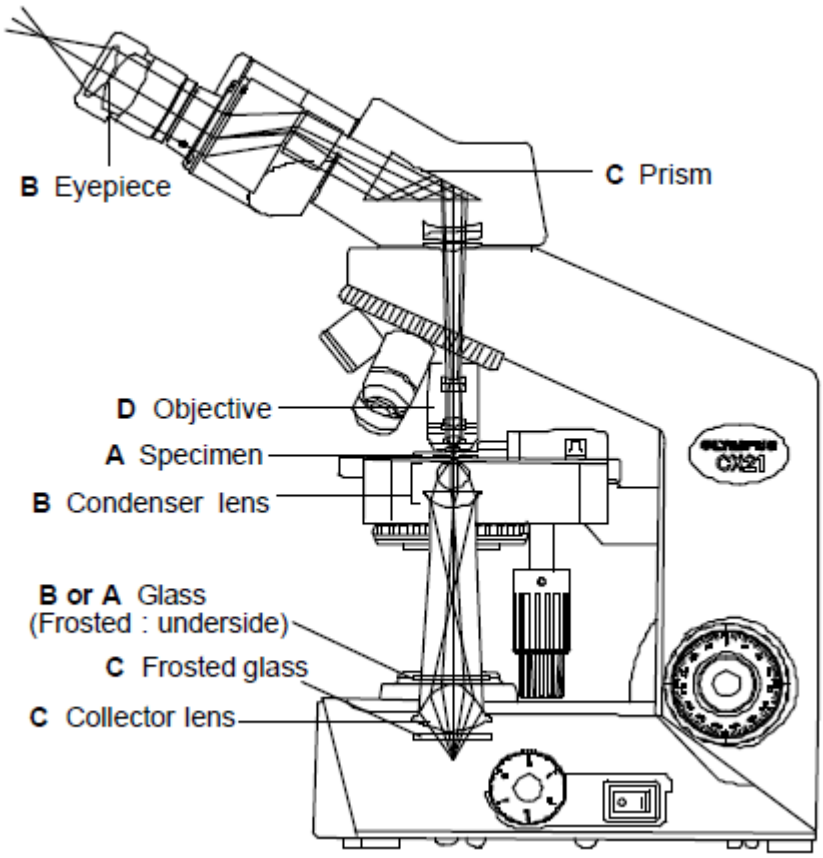
Score = _____

Rating: _____

Name: _____ Date: _____

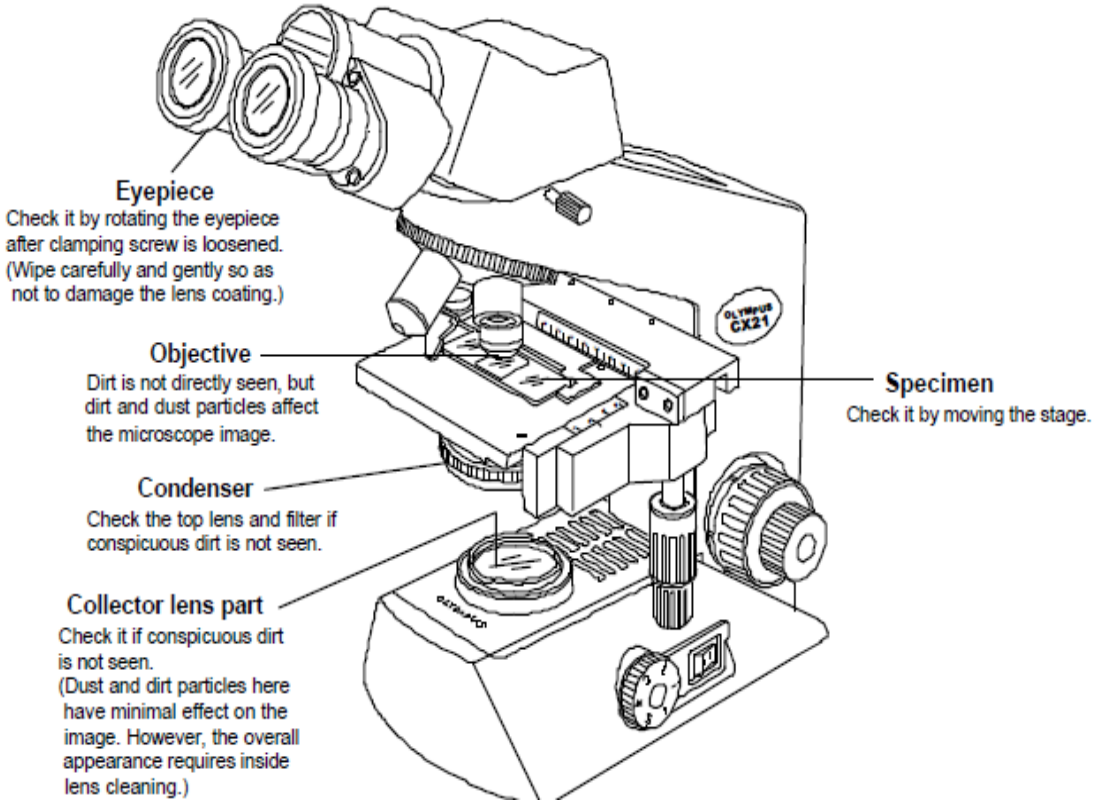
Operation title: - Checking Performance of Microscope

Purpose	To acquire the trainees Checking Performance of Microscope operation
Equipment ,tools and materials	Tools and equipment needed or useful for Checking Performance of Microscope operation include these: • Special cleaner for optical lenses • Special optical cleaning cloths • Lens tissue Neutral • detergent (For plastic part or frame) • Cleaning solution (For lens or filter etc.) • Cotton swab or tweezers etc. • Blower Silicon cloth (For finishing) • Sealing materials • Screws (assorted) • Wire tie • Table • Electric power • Electric cable • Table • Raw milk
Conditions or situations for the operations	• All tools, equipment's and materials should be available on time when required. • Appropriate table, working area/ workshop to assembling microscope practice.
Procedures	1. Check the electrical unit, mechanical and optical performance. 2. Checking Dirty Portion • Image influence caused by dirt on each component ✓ The following figure shows the influence of image on each optical component if stains or dust is adhered to that portion. In general, the microscope image is largely affected by dirt adhered on the nearer portion to a specimen and image surfaces. Therefore, the optical components should be kept clean and dust-free.



A: Dirt is clearly seen.
B: Blurred contours of dirt is seen.
C: Dirt is seen when the aperture iris diaphragm is stopped down.
D: Dirt is not directly seen, but contrast of image deteriorates

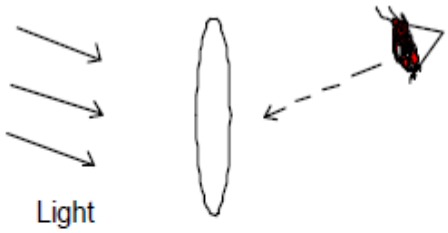
- **How to find dirty portion through observation**
  - ✓ Close the aperture iris diaphragm. (When the aperture iris diaphragm is closed, it facilitates finding the dirt particles because the depth of focus increases and the dirt position bring into focus. However, very small dirt particle may not be found in this method.)
  - ✓ Observe a specimen through the eyepiece.
    If dirt is seen by observing it, look for the portion where stains or dust is adhered by following the description below.

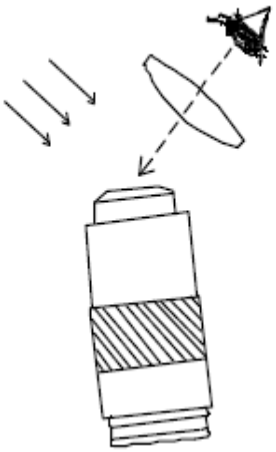
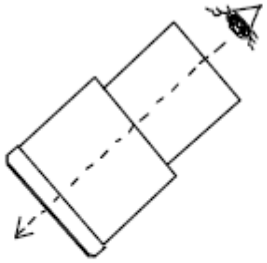


Note: If dirty portion cannot be identified in the above, it is assumed that internal lens and prism are contaminated.

In this case, please contact your Authorized Olympus dealer

- **How to check cleaning condition**
  - ✓ When a large lens is checked, look at the lens while putting it toward bright side or breathe on the lens and observe the condition that the haze on the whole surface of the lens disappears evenly.

<table>
<tr><td></td><td>



Dust becomes conspicuous when looking at it with the lens inclination changed.
If there is a dirty part or a remained part that is not cleaned completely, the haze of this part will disappear slower than that of the other part.
✓ For a small lens such as top lens of objective, check it by magnifier.


An eyepiece can be substituted for magnifier by turning the eyepiece upside down.
</td></tr>
<tr><td>Precautions</td><td>• Care should be taken while connecting with electric power, assembling and adjusting the Microscope
• Preparing materials, tools and equipment are according to inseminator command.</td></tr>
<tr><td>Quality criteria</td><td>• Did personal protective equipment worn while Checking Performance of Microscope
• Did trainees Checking Performance of Microscope
• The microscope functional for properly</td></tr>
</table>

LAP Test	Practical Demonstration

Name: _____ **Date:** _____

Time started: _____ **Time finished:** _____

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

Task 1 - Checking Performance of Microscope operation

LG #17	LO3. Inspecting and document completion of work

Instruction sheet

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

- Undertaking final inspections.
- Document and reporting Work completion

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:

- Undertake final inspections.
- Document and report Work completion

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 you earned a satisfactory evaluation proceed to “Operation sheets
7. Perform “the Learning activity performance test” which is placed following “Operation sheets” ,
8. If your performance is satisfactory proceed to the next learning guide,
9. If your performance is unsatisfactory, see your trainer for further instructions or go back to “Operation sheets”.

Information Sheet 1. Undertake final inspections

Records

The first task is to ensure records are taken that can be entered into the equipment management database once the acceptance testing is completed.

- The generic equipment type, for example 'defibrillator'
- The Equipment number from (or to be entered into) the equipment database
- The model of the device (as shown on the manufacturers label)
- The job number allocated from the database to this acceptance test
- Any accessories that were delivered with the device must be listed and checked
- The order number for cross reference with the supplier
- The serial number
- The cost of the device with accessories
- The name of the manufacturer, and supplier (if different)
- The telephone contact details for the supplier
- The date of acceptance into the hospital
- The date of warranty expiry
- The signature of the technician who carried out the acceptance testing
- Location of the technical documents
- Location of the equipment (Ward or Dept)
- Person within the ward or department responsible for that device (Departmental equipment controller)

Acceptance Checks

When carrying out acceptance testing, not all tests are valid for all devices but the form must be an assessment tool for all. With every device the individual checks should be recorded as a 'Pass', 'Fail', or not applicable 'N/A'. If a device has any minor failures that can be easily rectified, any remarks and faults corrected must be recorded on the acceptance form and database.

General considerations when carrying out an acceptance check include inspection of the packaging, whether the equipment arrived intact (as specified in the order) with the correct accessories and documentation. The documentation must include a user manual and it would be good practice to ask for this in pdf format to allow it to be placed on the Hospital intranet. This allows easy access to all users, and as the NHS now has a goal to be paperless by 2017, we need to find ways to achieve this.

Technical inspections should firstly ensure that the equipment is complete and undamaged. All the control knobs and fuses etc are intact. If the device contains chemicals or liquids, these should be inspected to ensure that they are correct. If the device has Wheels, or castors ensure they roll freely and the brakes work. All labelling should be inspected to ensure it is in the correct language, and meets expectations. All medical devices should carry a CE mark with a four digit code to indicate compliance with: EU Council Directive 93/42/EEC of 14 June 1993 concerning medical devices / OJ L 169 of 12 July 1993

Electrical Safety Markings should be indicated on the device labels. I.e. Class I or II, Type B, BF, CF or Type AP, APG. Record Class and type on the acceptance form and on the database. You should be aware of the current electrical safety regulations regarding the device being tested.

It is important to check the mains connection, paying attention to the condition and type of cable, whether the plug is intact, the plug terminal connections are terminated properly with correct cable colour code, cord grip is attached, fuses are correct and in accordance with the rating stated on the device, or in the technical documentation. The equipment Protection is in accordance with current requirement, for example, some laser equipment will be terminated with a special interlocking electrical supply socket. Voltages are set to the correct value for the mains supply. Earth terminal symbol is correct (if applicable to the device).

Once the equipment classification and type have been determined, you then need to ensure the device meets the safety requirements by carrying out the electrical measurements that will determine a pass or fail for earthing of the equipment, earthing of accessories, insulation resistance, earth leakage current, enclosure leakage current,

and patient leakage current where applicable to the device. (This will usually be carried out using an automated electrical safety analyser.)

Installation and Operational tests must ensure the equipment functions correctly. This should be done through the user carrying out tests, or the supplier carrying out tests. Once the equipment user has received adequate training to use the device safely, they should decide whether or not the device is operating correctly in the clinical environment and inform the technician once they are happy that everything operates as expected. In the UK, since 2010 it has become a regulatory requirement that devices are maintained correctly and used safely. The regulatory auditors from the Care Quality Commission have a 3 year target to inspect all public and private organizations against regulation 16, outcome 11 between 2012 and 2015.

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Self-Check 1	Written Test

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

Part I: Say true or false. (5point)

1. When carrying out acceptance testing, all tests are valid for all devices but the form must be an assessment tool for all.
2. Installation and Operational tests must ensure the equipment functions correctly.
3. Technical inspections should firstly ensure that the equipment is complete and undamaged.
4. The acceptance testing is completed Any accessories that were delivered with the device must be listed and checked
5. General considerations when carrying out an acceptance check include inspection of the packaging.

Part II: Fill the black space

1. Write the down appropriate shutdown procedure for Dairy equipment (5%)

_____,_____

_____,_____

_____,_____

2. Explain the producers taken when **cleaning** the slicing machine (4%)

_____,_____

_____,_____

_____,_____

. Answer the following question!

Note: Satisfactory rating 5 and 9 points Unsatisfactory below 5 and 9 points

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-2. Document and report Work completion

Document and report Work completion

Commissioning report today deals with an important aspect of commissioning activity. In any industry and business today, everybody is expected to write a commissioning report on what he/she performed in commissioning. Because, it is in the main means of communication between suppliers and receiving agents.

In commissioning report, people express what they performed, analysed, the procedure and material used, summaries of work and some recommendations.

Thus, commissioning report writing is a process of producing reports, which comprises of the above components.

Anybody who produces commissioning report should know how to communicate with people to get reliable data, interpret data, analyse data and it is expected to know what medium of communication used to exchange data, how to document this data and generate the final report about the occurrence. So commissioning report writing is a practical repetitive activity of employees as part of jobs in commissioning activities.

Commissioning report writing has three basic purposes:

- To inform (receive and transfer items, activities done, procedures used, result of work)
- To instruct (give directions for performing duties, provide commissioning support, descriptions of items…. etc)
- To persuade (to tell reason why does follow rules/procedures, convince work to be done, to inform bottlenecks of the process).

Types of Report

There are many ways to classify commissioning reports using subject matter, functions, frequency of issuance, type and formality of formats, …but, traditionally there are two descriptive categories

- Informational report and

- Analytic report

The Informational Report

Presents information without criticism, evolution and recommendation

It provides

- Detailed account of activities
- No attempt to provide solution to problems
- Information on present and past events

Example inventory report, sales report, progress report

The Analytic Report

It is a report goes beyond informational reports since it presents an analysis and interpretation of the fault in addition to the facts.

The conclusion and recommendations are the most important and interesting parts of the report. The analytical report serves as bases for the solution of an immediate problems or a guide to future happenings.

It is valuable and commonly used instruments for all types of activities to report by applying different techniques

Procedures Of Report Writing

Report writing is reconstruction of written form of purpose full performances of commissioning.

Report writing goes through 4 steps of doing

1) Preliminary planning
2) Jotting work procedures
3) Gathering of data about the activities and situations
4) Organizing data and
5) Develop report

General Format

Technical Reports have an organized format because a majority of your audience may not read the entire report in one reading. This specific format allows readers to quickly locate the information they need.

Most technical reports include the parts listed below. However, you may be required to include or exclude specific sections. Be sure to check with your instructor before using the format outlined here.

Transmittal Letter

Transmittal letters often accompany reports and inform readers of a report's context. Typically, the letter includes information not found in the report. For example, the letter contains information about the particular project and/or due dates. A Transmittal Letter is a business letter and should be formatted accordingly; that is, you should include the recipient's address, your address, a salutation and closing. Depending on the project, you may also need to include contact information. Always check with your instructor to determine whether or not you should attach a transmittal letter to your report.

Title Page

A technical report should always include a title clearly identifying the report. A title should be descriptive and accurate, but not wordy, verbose or too terse.

Abstract

The Abstract is extremely important because it helps readers decide what to read and what to pass over. The idea of the Abstract is to give readers an honest evaluation of the report's content, so they can quickly judge whether they should spend their valuable time reading the entire report. This section should give a true, brief description of the report's content. The most important purpose of the Abstract is to allow somebody to get a quick picture of the report's content and make a judgment.

Since an Abstract is a brief summary of your report, its length corresponds with the report's length. So, for example, if your report is eight pages long, you shouldn't use

more than 150 words in the Abstract. Generally, Abstracts define the report's purpose and content.

Executive Summary

Typically, Executive Summaries are written for readers who do not have time to read the entire technical report. An executive summary is usually no longer than 10% of the report. It can be anywhere from 1-10 pages long, depending on the report's length. In the executive summary, you should summarize the key points and conclusions from your report. You might include anexecutive summary with your report, or the summary can be a separate document.

Some reports only include an abstract while others include an executive summary. Always check with your instructor to determine which to include or if you should include both.

Table of Contents

A Table of Contents includes all the headings and subheadings in your report and the page numbers where each of these begins. When you create a Table of Contents, one of the most important decisions you have to make involves design. A good Table of Contents distinguishes headings from subheadings and aligns these with the appropriate page numbers. This also means you should pay attention to capitalization, spacing, and indentation.

List of Figures & List of Tables

These two separate lists assist readers in locating your photos, drawings, tables, graphs and charts. Like the Table of Contents, you need to present both of these in an organized, appealing format. Typically, you can shorten a figure or table's title when you create these lists.

Report Body

In a technical report, the body typically presents an Introduction, various other sections, depending on your topic, and a Conclusion. Throughout the body, you should include text (both your own and research from other sources), graphics, and lists. Whenever you

cite information or use graphics from another source, you must credit these sources within your text. Check with your instructor to know which reference style to use.

References

Whenever you cite information (this includes graphics) from another source, you must credit the source in your References. Always check with your instructor to determine which reference style to use.

Appendices

Appendices include information that is too large to fit within your report, yet information necessary to your report. For example, large graphics, computer print-outs, maps, or sample codes are best placed in Appendices. When making decisions about what to place in an Appendix, consider whether or not the material interrupts the reading flow. For instance, six pages of calculations would obviously cause readers to loose their train of thought. Appendices always appear at the end of a report.

Example Technical Report

As you read the example, keep in mind that this technical report was a requirement for CE208 at Colorado State University. The course instructor, Dr. Tom Siller, commented on this document. Other instructors or job situations may have different opinions or require a different format.

Transmittal Letter

December 12, 1996

Dr. Tom Siller
Colorado State University
Fort Collins, CO 80524

Dear Mr. Siller:

We are submitting to you the report, due December 13, 1996, that you requested. The report is entitled CSU Performing Arts Center. The purpose of the report is to inform you of our design decisions for the center. The content of this report concentrates on the

structural and acoustical aspects of the CSU Performing Arts Center. This report also discusses cable-stayed technology. If you should have any questions concerning our project and paper please feel free to contact Mike Bridge at 491-5048.

Sincerely,
Mike Bridge
Lead Engineer

Self-Check 2	Written Test

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

PART I: Say true or false. (5point)

1. Informational report presents information without criticism, evolution and recommendation.
2. Commissioning report today deals with an important aspect of commissioning activity
3. Typically, Executive Summaries are written for readers who do not have time to read the entire technical report.
4. Abstract is extremely important because it helps readers decide what to read and what to pass over.
5. Conclusion and recommendations are the most important and interesting parts of the report.

. Answer the following question!

Note: Satisfactory rating 5 and 9 points Unsatisfactory below 5 and 9 points

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

References

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Answer Key for self-check

LO 1: Planning and preparing for commissioning

Answers for self-check 1

Part II fill the blank space

1. **Commissioning plan**
2. **Smoke Testing**
3. List down the **types of Functional Testing** (5%)
   - Unit Testing
   - Smoke Testing
   - Sanity Testing
   - Regression Testing
   - Integration Testing

Answers for self-check 2

Say true or false

1. T
2. F
3. T
4. F
5. T

Fill the blank space

3. List down the requirements of Consultation! (4pts)

   - Relevant work health and safety information is shared with workers
   - workers are given a reasonable opportunity to express their views and to raise health or safety issues
   - workers are given a reasonable opportunity to contribute to the decision-making process relating to the health and safety matter
   - views of workers are taken into account
   - workers are advised of the outcome of any consultation in a timely manner

4. List down when to a person conducting a business or undertaking must consult with workers (6pts)

   - identifying hazards and assessing risks arising from the work carried out or to be carried out

- making decisions about ways to eliminate or minimise those risks
- making decisions about the adequacy of facilities for the welfare of workers
- proposing changes that may affect the health or safety of your workers
- making decisions about procedures for consulting with workers; resolving health or safety issues; monitoring health of your workers; monitoring the conditions at the workplace and providing information and training for your workers

Answers for self-check 3

Say true or false

1. T
2. T
3. F
4. T
5. T

Answers for self-check 4

Part I fill the blank space

3. Listed down for the documentation shall include purchase of a new medical device! (5%)
    - Device registration certificate and Establishment License from MDA;
    - Purchase agreement/ tender document/ contract document/quotation;
    - Purchase order, test & commissioning date by the medical device establishment;
    - Relevant licenses and certificates etc
4. Listed down for documentation shall include other than newly purchased medical devices! (5%)
    - Device registration certificate and establishment license (if applicable) from MDA;
    - Purchase agreement/leased agreement/tender document / quotation (where applicable);
    - Purchase order, test & commissioning date by the medical device establishment (where applicable);
    - Relevant licenses and certificates etc

Answers for self-check 5

Multiple chose question

1. A
2. B
3. C
4. C
5. D

Answers for self-check 6

Say true or false

1. T
2. F
3. T
4. T
5. F

LO #2- Commissioning

Answers for self-check 1

Say true or false

1. F
2. T
3. T
4. T

Answers for self-check 2

Say true or false

1. T
2. F
3. T
4. T
5. F

Answers for self-check 3

Say true or false

1. T

2. F

3. T

4. T

5. T

Answers for self-check 4

Say true or false

1. T

2. T

3. T

4. F

5. T

Answers for self-check 5

Say true or false

1. T

2. T

3. T

4. T

Answers for self-check 6

Say true or false

1. T

2. T

3. T

4. F

LO3. Inspecting and document completion of work

Answers for self-check 1

Say true or false

1. F
2. T
3. T
4. T
5. T

Answers for self-check 2

Say true or false

1. T
2. T
3. T
4. T