ADVANCED BIOMEDICAL EQUIPMENT MANAGEMENT

Level-IV

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

Module Title: **Configuring and Calibrating Biomedical Equipment**

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

- Observing OHS policies and procedures.
- Planning and preparing configuration and calibration
- Identifying configured and calibrated instrumentation and control devices
- Conditioning Biomedical Equipment according to plan or standards.
- Checking Biomedical Equipment for configuration and calibration
- Obtaining materials, tools, equipment and testing devices.

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

- Observe OHS policies and procedures.
- Plan and prepare configuration and calibration
- Identify configured and calibrated instrumentation and control devices
- Condition Biomedical Equipment according to plan or standards.
- Check Biomedical Equipment for configuration and calibration

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Read the information written in the “Information Sheets 1”.
3. After reading the information sheet, go to your instructor and get the copy of self-check.

4. Accomplish the “Self-check 1” Self-check 2, Self-check 3, Self-check 4, Self-check 5 in page 8,10,15,18,21,24

5. If you earned a satisfactory evaluation proceed to LO2. However, if your rating is unsatisfactory, see your teacher for further instructions.

6. Submit your accomplished Self-check. This will form part of your training portfolio.

Information Sheet-1	Observing OHS policies and procedures

1.1 Occupational Health and Safety

Occupational Health and Safety occupational Health and Safety or OHS deals with the safety, health and welfare of personnel in work environment. The objective of OHS is to put into practice the programs that will ensure a safe and a healthy working environment.

OHS must holistically include not only factory workers, but all other external persons who are affected by the work environment and activities. This includes visitors, vendors, customers and other stakeholders.

Occupational health and safety aims at preventing hazards at the Workplace. Activities at the workplace carry various risks which may lead to accidents, bodily injuries, hearing impairment, circulatory, musculoskeletal and respiratory diseases, stress-related disorders and even cancers. These are undesirable as the legal and moral responsibility is on the Organization's Top Management to provide a work environment that is safe and healthy.

Occupational Health and Safety as defined by World Health Organization

The World Health Organization (WHO) defines Occupational Health as below:

"Occupational health deals with all aspects of health and safety in the workplace and has a strong focus on primary prevention of hazards."

Benefits of establishing Occupational Health and Safety

By paying proper attention to the health, safety and welfare of the employees, organizations can benefit in terms of improved employee morale, reduced absenteeism, improved quality and enhanced productivity. These in turn helps in reducing the potential of work-related injuries and illnesses.

It can therefore be said that establishment of a sound health and safety practices helps organisations to sustain business in the long run.

Reasons for Injuries, accidents and ill health in Organizations

- There are various reasons that results in injuries, accidents and ill health in organizations. They are:
- Lack of awareness of safety aspects during work
- Lack of safety and health procedures
- Over exertion due to excessive work load
- Psychological stress and / or personal problems leading to loss of concentration at work
- Slips, trips or falls due to lack of safety planning and infrastructure
- Lack of safety equipment and personal protective equipment (PPE)
- Lack of insistence of regular medical check-ups
- Lack of assessment of work practices that are unsafe and / or spread diseases
- Lack of sanitation and hygiene

Use of equipment and / or materials that are unsafe and spread diseases

No learnings from “near misses” that could potentially become future accidents

Failure to identify occupational hazards and conduct risk assessment

Negligent house-keeping activity

Absence of a good and sound Occupational Health and Safety Management System

Industries / Occupations prone to accident and injuries

Even though almost all industries need to avoid accidents, injuries and ill health, there are specific industries that are prone to accidents, injuries and ill health. They are (not limited to) Mining, quarrying, agriculture, oil, gas, chemical, construction, machining, bio technology, etc.

Top Management Commitment towards Occupational Health and Safety

Top Management commitment and involvement in establishing an Occupational Health and Safety Management System is of paramount importance. It is the senior management who can provide a safe and healthy working environment and enforce safety practices in their

organization. It is their job to allocate resources and time to ensure planning and implementation of safety methods.

Failure on the part of the Top Management to prevent injuries, accidents or ill health could mean legal trouble and emotional problems.

Hence, the Top Management must do the following:

- Establish occupational health and safety committee or team
- Allocate safety resources and equipment
- Allocate manpower resources and finance for the Health and safety initiative
- Establish Occupational Health and Safety policy and objectives
- Ensure that the policy and objectives are communicated and understood within the organization
- Ensure that these OHS objectives are measurable
- Define and assign safety and health responsibilities across the organization structure
- Direct the middle management to monitor safety and health status of employees in their organization

Demand accountability from the lower management levels with regard to safety and health

Enforce safety practices as required by the applicable legislation as well as those deemed necessary for the organization

- Buy equipment with in-built safety features
- Institute employee wellness programs
- Review the effectiveness of the health and safety measures
- Employee Involvement

Involvement of employees in the implementation, maintenance and improvement of health and safety aspects are vitally important because:

Employees are the likely ones who are going to face safety and health related issues

Employees can visualize majority of the safety hazards at the workplace since they work hands-on with the devices and equipment.

Employees can bring in the group knowledge and ideas to deal effectively with health & safety is s only through employee involvement, better participation in health & safety programs can be expected

Self-Check -1	Written Test

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

Say true for the correct statement and false for wrong statement

1. All personnel working in laboratories must be trained in safe work practices and hazardous waste disposal.
2. Conductors and cable cores (EELP's Regulation) color code for neutral is white.
3. Control measures are not reasonably practicable to eliminate the hazards and associated risks.
4. Hazards are generally lower in research lab than in routine clinical labs.
5. Risk management is a proactive process that helps you responds to change and facilitate continuous improvement in your business

Note: **Satisfactory rating – 6 points** **Unsatisfactory - below 6 points**

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

Answer Sheet

Name: _____ date

Score = _____

Rating: _____

Information Sheet-2	Planning and preparing configuration and calibration

Personal Protective Equipment

Personal Protective Equipment Personal Protective Equipment (PPE) plays a key role in ensuring that the workers are protected while carrying out activities that have the potential to create injuries or harm to their body.

A range of personal protective equipment is available in the market which includes

Safety Helmet for head protection

Safety nose masks & respirators for protecting against dust, smoke and fumes released during certain work activities

Safety goggles and related eye wear that ensures the eyes are adequately protected against fast moving small particles and chemical / fluid splashes during work operations

- Safety Ear plug to prevent ears from excessive noises at the workplace
- Safety Aprons to prevent body from particles, chemicals, etc.
- Safety Shoes to prevent the feet from sharp chips and other particles

However above list is only partial since there are various other PPE such as body harness with ropes & tackles, gum boot, Visor (face safety), shields, ear muffs, safety cone, and many others.

Self-Check -2	MACTHING

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

A	B
1. Aprons	A. head protection
2. Safety Shoes	B. protect eyes
3. Helmet	C. prevent body from particles
4. Goggles	D. prevent the feet from sharp chips
5. Respirators	E. protecting against dust

Answer the following question!

Note: **Satisfactory rating – 5 points** **Unsatisfactory - below 5 points**

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

Name: _____ Date: _____

Score = _____

Rating: _____

Information Sheet-3	Identifying configured and calibrated instrumentation and control devices

3.1 Biomedical Equipment Control Systems, Instrument and device

Biomedical Equipment Control Systems, Instrument and device includes

- Sensors/ transducers
- analogue and digital systems
- Control valves
- Actuators
- Recorders
- Process switches
- PLC/Programmable Logic Control
- Pneumatics control systems
- Power Electronic control devices
- Electro-Pneumatic control systems

Electro- magnetic control

A control system is a device, or set of devices, that manages, commands, directs or regulates the behavior of other devices or systems. They can range from a home heating controller using a thermostat controlling a boiler to large Industrial control systems which are used for controlling processes or machines.

An automatic sequential control system may trigger a series of mechanical actuators in the correct sequence to perform a task. For example, various electric and pneumatic transducers may fold and glue a cardboard box, fill it with product and then seal it in an automatic packaging machine. Programmable logic controllers are used in many cases such as this, but several alternative technologies exist.

In the case of linear feedback systems, a control loop, including sensors, control algorithms and actuators, is arranged in such a fashion as to try to regulate a variable at

a set point or reference value. An example of this may increase the fuel supply to a furnace when a measured temperature drops. PID controllers are common and effective in cases such as this. Control systems that include some sensing of the results they are trying to achieve are making use of feedback and so can, to some extent, adapt to varying circumstances. Open-loop control systems do not make use of feedback, and run only in pre-arranged ways.

3.2 Open-loop and closed-loop control

There are two common classes of control systems, open loop control systems, and closed loop control systems.

In an open loop control system, the control action from the controller is independent of the "process output". A good example of this is a central heating boiler controlled only by a timer, so that heat is applied for a constant time, regardless of the temperature of the building. (The control action is the switching on/off of the boiler. The process output is the building temperature).

In a closed loop control system, the control action from the controller is dependent on the process output. In the case of the boiler analogy this would include a temperature thermostat to monitor the building temperature, and thereby feedback a signal to ensure the controller maintains the temperature set on the thermostat.

A closed loop controller therefore has a feedback loop which ensures the controller exerts a control action to give a process output the same as the "Reference input" or "set point". For this reason, closed loop controllers are also called feedback controllers.[

A valve is a device that regulates, directs or controls the flow of a fluid (gases, liquids, fluidized solids, or slurries) by opening, closing, or partially obstructing various passageways. Valves are technically fittings, but are usually discussed as a separate category. In an open valve, fluid flows in a direction from higher pressure to lower pressure.

Control valves are valves used to control fluid flow by varying the size of the flow passage as directed by a signal from a controller.

This enables the direct control of flow rate and the consequential control of process quantities such as pressure, temperature, and liquid level, according to the process design.

The opening or closing of automatic control valves is usually done by electrical, hydraulic or pneumatic actuators.

Normally with a modulating valve, which can be set to any position between fully open and fully closed, valve positioners are used to ensure the valve attains the desired degree of opening.

Modern control valves may regulate pressure or flow downstream and operate on sophisticated automation systems.

An automatic control valve consists of three main parts in which each part exist in several types and designs:

Valve actuator - which moves the valve's modulating element, such as ball or butterfly.

Valve positioner-which ensures the valve, has reached the desired degree of opening. This overcomes the problems of friction and wear.

Valve body - in which the modulating element, a plug, globe, ball or butterfly, is contained.

• **Sensor:**

Converts a physical parameter to an electrical output (a type of transducer, e.g. a microphone)

- **Transducer:**

A device that converts energy from one form to another

• Actuator:

Converts an electrical signal to a physical output (opposite of a sensor, e.g. a speaker)

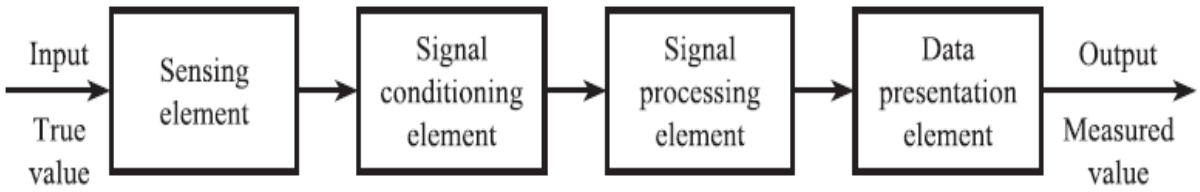


Figure 1 general instrumentation system

3.3 Sensing Elements: This is the front-end element which is in contact with the measurand and its function is conversion of the non-electrical input variable to

proportional electrical variable output suitable for further conditioning and processing in the subsequent electrical/electronic sub systems.

Measurand: Physical quantity, property, or condition that the system measures. These physical quantity includes:

- Bio potential
- Pressure
- Flow
- Dimension (imaging)
- Displacement (velocity, acceleration, and force)
- Impedance
- Temperature
- Chemical concentrations

Self-Check -3	MULTPLE CHOICE

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

1. A device that converts one form of energy into another is

A. sensor B. transducer C. Actuator D. Filter

2. The ability of an instrument to give the same output for equal inputs applied over some period of time is called

A. Reproducibility B. resolution C. accuracy D. precision

3. The process of sequentially reading the inputs, executing the program in memory, and updating the outputs, in PLC device is known as

A. timing B. scanning C. cycle time D. controlling

4. In an electro-pneumatic control, the signal control section is made up of

A. pneumatic component B. hydraulic component C. electrical components D. all

5. Process of adjusting instrument to meet the manufacturer specification is

A. calibration B. calibration standard C. calibration reference D. all

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

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

Answer Sheet

Name: _____ Date:

Score = _____

Rating: _____

Information Sheet 4	Conditioning Biomedical Equipment according to plan or standards

4.1 Tracking Instruments for Calibration Status

Each instrument should be labeled with the unique identifier (e.g. serial number, model number, location, etc.)

Calibration status of each instrument, the date of calibration, the next calibration date and the identification of person performing calibration should be readily available

4.2 MEDICAL DEVICE STANDARDS

Before a manufacturer can sell a medical device i, they must meet the requirements set out in several pieces of legislation:

Active implantable medical devices (covers all powered implants e.g. pacemakers) 90/385/EEC

In vitro diagnostic medical devices (covers any medical device which is intended for in vitro testing) 98/79/EC

Medical devices (covers most other medical devices) 93/42/EEC.

The legislation only requires that the medical device is 'safe'.

The technical interpretation of the legislation is left to (voluntary) Standards.

Manufacturers must meet the appropriate Standards, but may deviate from the their requirements as long as they can show that the overarching requirements of the legislation are met (i.e. that the device is ‘safe') - even though the Standard may not cover their particular technology.
This could apply to novel technologies, for example.
Harmonised Standards

To help manufacturers, some Standards are given a special status. They are 'harmonized' and compliance with relevant parts of the standard are deemed to give a 'presumption of conformity' to the legislation

How to Connect Standards to Legislation

As Standards do not usually cover a whole piece of legislation, a harmonized Standard also has. This aims to match up the various clauses of a Standard with the appropriate part of legislation that gave rise to it. If a harmonized Standard is based on International Standards (e.g. IEC-ISO), it will also have an 'EN' Foreword. This shows which versions of Standards are accepted.

Important Standards for Medical Device manufacturers

Reference	Title
EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects. Good clinical practice.
EN ISO 10993-XX	Biological evaluation of medical devices. Evaluation and testing within a risk management process

Table 1.standard of medical device manufacturer

Self-Check -4	SHORT ANSWEAR

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

1. List medical equipment standard

Note: **Satisfactory rating - 4 points** **Unsatisfactory – 4 points**

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

Answer Sheet

Name: _____ Date: _____

Score = _____

Rating: _____

Information Sheet 5	Checking Biomedical Equipment for configuration and calibration

Standard Operating Procedure

The elaborate test protocols for each equipment proposed in this work are described in 4 distinct steps which are described below (Additional steps may be proposed if desired by the manufacturer/ client.

Step 1- Relevant qualitative and quantitative tests should include the following:-

- Protection against mechanical risks
- Protection against risk of unwanted or excessive radiation
- Protection against risk of ignition of anesthesia mixtures
- Protection against excessive temperatures
- Abnormal operations and conditions of failure

Step 2- With relevant general rule, with the help of an appropriate electrical safety analyzer, and qualified person check/verify the following:-

- Current consumption
- Insulation Resistance
- Leakage current to the ground
- Leakage current through the Cabinet
- Leakage current through the patient
- Auxiliary current through the patient

The above measures include all tests that can be performed on electro medical equipment as prescribed by the general rule, and that meet the criteria established for this step and the previous one. The results of the tests mentioned above represent characteristics common to all electro medical equipment. Additionally, each equipment must observe compliance with their particular standard. The nature of the tests varies greatly according to the equipment to be tested; e.g., the tests applied in electrosurgical units are completely distinct from those applied in

infusion pumps. Through this methodology, test protocols developed for electrocardiographs, infusion pumps, syringe pumps, defibrillators and electrosurgical units are attached as suggestive tests.

Electro medical equipment in general the following tests should be applied:-

- Insulation resistance
- Leakage current to the ground
- Leakage current through the Cabinet
- Leakage current through the patient
- Auxiliary current through the patient

Self-Check -5	Multiple choice

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

1. Which of the following is relevant qualitative and quantitative tests

   A. Protection against mechanical risks

   B. Insulation resistance

   C. Leakage current to the ground

   D. Leakage current through the Cabinet

2 .Which of the following is Electro medical equipment test

   A. Current consumption

   B. Insulation Resistance

   C. Leakage current to the ground

   D. ALL

3. Which of the following is electrical safety analysis

   A. Insulation resistance

   B. Leakage current to the ground

   C. Leakage current through the Cabinet

   D. all

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

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

Answer Sheet

Name: _____

Score = _____

Rating: _____

Information Sheet 6	Obtaining materials, tools, equipment and testing devices.

5.1 Tools and device uses for calibration

Electrical safety analysers

An **Electrical safety analyzer** is a device designed to carry out a range of **electrical safety** tests in order to check that the device being tested complies with **electrical safety** requirements. The typical tests an **electrical safety analyzer** performs are: ground continuity test. Insulation test.

Patient monitor testers (simulators)

Fluke Biomedical ProSim **Vital Signs Simulators** transform physiological **simulation** by adding multi-parameter functionality (including ECG, SP02, temperature, respiration, NIBP, IBP, **cardiac** output, and fetal ECG/IUP) in a single **patient simulator** device, helping you meet your **patient monitor** testing and medical device.

Defibrillator / AED / pacemaker analysers

External defibrillation may still be necessary for a person with a pacemaker. If the implanted pacemaker delivers a low-energy shock while you are attempting to use an AED or another defibrillator, you simply wait for 30 to 60 seconds for the pacemaker to complete its therapy cycle before administering the shock

Infusion device analysers

Infusion Pump Tester and Analyzer is a multi-channel tester, providing comprehensive and immediate results that increase your productivity. It has built-in automation, allowing users to create custom test templates for testing of IV pump devices with minimal user intervention.

- Ability to test up to four infusion pumps simultaneously
- Provides real-time snap shots of flow and pressure for immediate issues recognition
- On-board and stand-alone automation for quick testing

- Easy data storage with Built-in memory

Electrosurgical unit testers

Electrosurgical analyzer measures ESU output and high-frequency leakage, allows verification tests on the return electrode contact quality monitors, and has an oscilloscope output for waveform viewing.

Ventilator / gas-flow analysers

The MaxO2 PLUS AE is an oxygen analyzer that measures the oxygen concentration in a flow of gas from a medical gas source or through a medical gas-flow device such as a ventilator or anesthesia system, or within an infant incubator. It is light-weight and rugged for portable use.

Pressure / flow meters

Differential Pressure flow meters measure the velocity of fluids by reading the pressure loss across a pipe constriction. These meters can contain laminar plates, an orifice, nozzle, or Ventura tube to create an artificial constriction. ... The higher the pressure drop, the higher the flow rate.

Self-Check -6	Short answer

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

1. List t materials, tools, equipment and testing devices.

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

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

Answer Sheet

Name: _____ date----------

Score = _____

Rating: _____

LG #43	LO #2**. Configure biomedical equipment**

Instruction Sheet

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

- Using appropriate PPE and OHS policies
- Check normal functioning systems and components.
- Diagnosing Fault/s or problem/s in the device.
- Configuring Biomedical Equipment
- Responding unplanned events or conditions.

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

- Use appropriate PPE and OHS policies
- Check normal functioning systems and components.
- Diagnose Fault/s or problem/s in the device.
- Configure Biomedical Equipment
- Responding unplanned events or conditions

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below 3 to 5.
3. Read the information written in the information “Sheet 1 Sheet 2, Sheet 3”sheet 4,sheet 5,sheet 6

4. ” Accomplish the “Self-check 1, Self-check 2,” Self-check 3 Self-check 4, Self-check 5,” in page -36,42 ,48,51 and 55

5. If you earned a satisfactory evaluation from the “Self-check” proceed to “Operation Sheet 1,” in page -56.

Information Sheet-1	Using appropriate PPE and OHS policies

1.1 Occupational Health and Safety procedures for a given work area

Occupational health and safety (OH&S) is the term used to describe the laws and processes that help to protect employees from death, disease and injury while at work.

What is hazard?

The Occupational Health and Safety Regulation 2001 define a hazard as 'anything (including work practices or procedures) that has the potential to harm the health or safety of a person'.

Hazard: is also a situation or thing that has the potential to harm a person. Hazards at work may include: noisy machinery, a moving forklift, chemicals, electricity, working at heights, a repetitive job, violence at the workplace etc.

Risk: is the possibility that harm (death, injury or illness) might occur when exposed to a hazard.

Hazards can be grouped into five broad areas:

- Physical k hazard e.g. noise, radiation, light, vibration
- Chemical hazard e.g. poisons, dusts
- Psychological hazard e.g. fatigue, violence
- Biological e.g. viruses, bacterial infection , parasites
- Mechanical/electrical hazard e.g. trips and falls, tools, electrical equipment (micro or macro shock).

Hazards can arise from: work environment use of machinery and substances poor work design inappropriate systems and procedures.

Risk management

Risk management is a proactive process that helps you responds to change and facilitate continuous improvement in your business. It should be planned, systematic and

cover all reasonably foreseeable hazards and associated risks. It involves four steps to set out hazards;

Identify hazards – find out what could cause harm.

Assess risks if necessary – understand the nature of the harm that could be caused by the hazard, how serious the harm could be and the likelihood of it happening.

Control risks – implement the most effective control measure that is reasonably practicable in the circumstances.

Review control measures-to ensure they are working as planned.

Step 1 – How to identify hazard

Identifying hazards in the workplace involves finding things and situations that could potentially cause harm to people. Hazards generally arise from the following aspects of work and their interaction: physical work environment equipment, materials and substances used work tasks and how they are performed work design.

- How to find hazards
- Inspect the work place
- Consult your workers
- Review available information's

Step 2 – How to assess risk

A risk assessment involves considering what could happen if someone is exposed to a hazard and the likelihood of it happening. A risk assessment can help you determine: how severe a risk is whether any existing control measures are effective what action you should take to control the risk how urgently the action needs to be taken.

STEP 3 – How to control risks

The most important step in managing risks involves eliminating them so far as is reasonably practicable, or if that is not possible, minimizing the risks so far as is reasonably practicable. The hierarchy of risk control. The ways of controlling risks are ranked from the highest level of protection and reliability to the lowest as shown in Figure below.

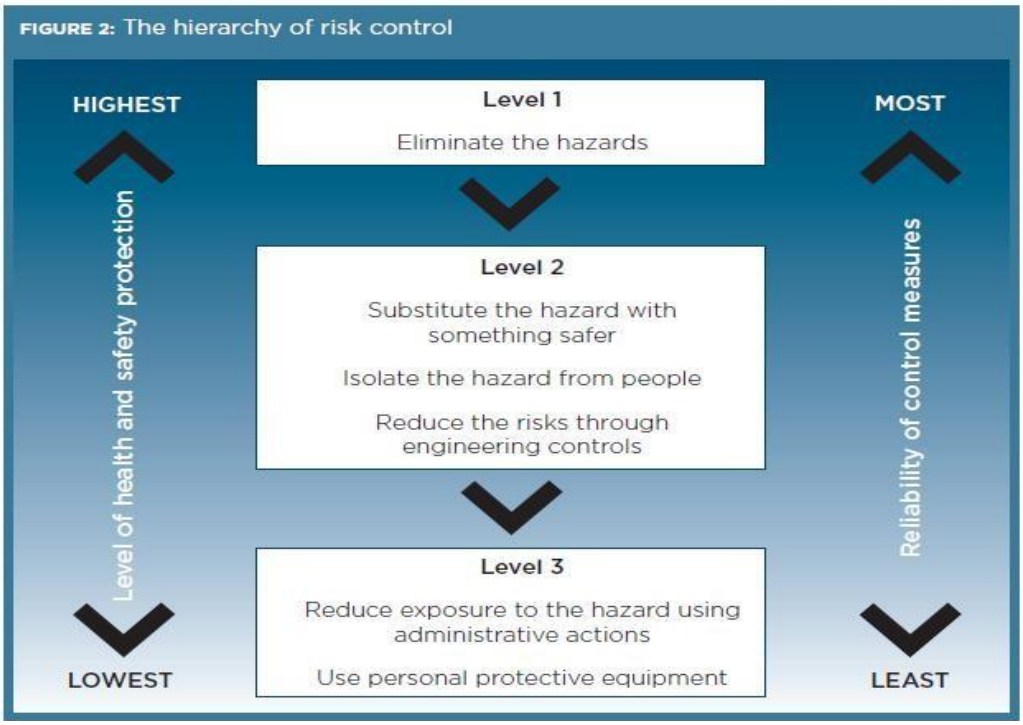


Figure 2 How to manage work health and safety risk

LEVEL- 1 Control measures

You must always aim to eliminate a hazard, which is the most effective control.

If this is not reasonably practicable, you must minimize the risk by working through the other alternatives in the hierarchy. The best way to do this is by, firstly, not introducing the hazard into the workplace. For example, you can eliminate the risk of a fall from height by doing the work at ground level.

LEVEL- 2 control measures

If it is not reasonably practicable to eliminate the hazards and associated risks, you should minimize the risks using one or more of the following approaches:

Substitute the hazard with something safer

For instance, replace solvent-based paints with water-based ones.

Isolate the hazard from people

This involves physically separating the source of harm from people by distance or using barriers. For instance, use remote control systems to operate machinery; store chemicals in a fume cabinet. Use engineering controls

An engineering control is a control measure that is physical in nature, including a mechanical device or process. For instance, use mechanical devices such as trolleys to move heavy loads; place guards around moving parts of machinery; install residual current devices (electrical safety switches); set work rates on a production line to reduce fatigue.

LEVEL- 3 control measures

These control measures do not control the hazard at the source. They rely on human behavior and supervision, and used on their own, tend to be least effective in minimizing risks. Two approaches to reduce risk in this way are:

Use administrative controls

Administrative controls are work methods or procedures that are designed to minimize exposure to a hazard.

For instance, develop procedures on how to operate machinery safely, limit exposure time to a hazardous task, and use signs to warn people of a hazard.

Ethiopia Electrical Code

Function	Colour identification of core of rubber of PVC insulted
Earthling	White
Live of .c single - phase circuit	Green
Neutral of a.c single - phase or three - phase circuit	Black
Phase R of three - phase a.c circuit	Green
Phase S of three - phase a.c circuit	Yellow
Phase T of three - phase a.c circuit	Red

Table 2 Colour identification of bare conductors and cable cores (EELP's Regulation

Follow environmental protection legislation and regulations

MEDICAL CENTRES SAFETY PROGRAM

Safety includes a range of hazards including mishaps (an unlucky accident), injuries on the job, and patient care hazards.

The most common safety mishaps are “needle sticks” (staff accidentally stick themselves with a needle) or patient injury during care.

As a manager, ensure all staff and patients are safe within the facility.

Note: it’s everyone’s responsibility!

- Laboratory safety
- Laboratory Safety Comes First!
- Hand washing
- Standard (Universal) precautions
- Electrical Safety
- Fire Safety

Hand washing	Hair & Jewelry
Smoking	Eye Wash/Safety Showers
Food & Drink	Do Not Mouth Pipette
Eye & Face Protection	Good Housekeeping
Cosmetics	Sharp Objects
Shoes	Hair & Jewelry

Table 3 Basic Laboratory Safety Issues

Basic Rules of Bio Safety

The basic rules of Bio safety are essential to avoid occupational hazards when working in the laboratory.

Washing hands following all laboratory activities, following the removal of gloves and immediately after contact with infectious agents.

- Does not mouth pipette
- Use protective laboratory coats and gloves.
- Do not eat, drink, smoke or store food in the laboratory.
- Manipulate infectious agent carefully to avoid spills and the production of aerosols and droplets.
- Decontaminate work surface before and after use, and immediately after spills.
- Use needles, syringes and other sharps only absolutely necessary.

Rules of Environmental and Safety Compliance

All personnel working in laboratories must be trained in safe work practices and hazardous waste disposal.

- Maintain an accurate hazardous materials inventory.
- Properly label all hazardous materials.
- Segregate incompatible materials and place in safe storage locations.
- Use fume hood and other appropriate controls when using flammables, toxic or odorous vapors.
- Wear the appropriate protective equipment, such as a laboratory coat, gloves, and safety glasses.
- Use non-hazardous material instead of hazardous materials whenever possible.

There are several meeting that are medical equipment managers are required to attend as the organizations technical representative. The following are:

- Patient safety
- Environmental of Care
- Space Utilization Committee
- Equipment Review Board
- Infection Control (optional)

- Safety of our patient/staff is paramount to the success of our organizations mission.

Goals are developed by experts in patient safety nurses, physicians, pharmacists, risk managers, and other professionals with patient-safety experience in a variety of settings.

Patient safety is among the most important goals of every healthcare provider, and processes concerned with patient safety provides way for biomedical managers and clinical engineering departments to gain visibility and positively affect their workplace.

Electrical Safety

Electrical safety is the containment of limitation of hazardous such as, electrical shock, explosion, fire or damage to equipment and buildings.

Preventive maintenance programs reduce electrical hazards such as:

- The physiological effects of electricity.
- Leakage current
- Ground fault
- Electrical short hazard.

The use of proper power wiring distribution, and ground system in reducing electrical shock hazards.

- Specialized electrical safety test equipment
- Chemical Safety
- Laboratories use a lot of chemicals that caustic and corrosives
- Concentrated acids or bases, organic solvents that are noxious and flammable, eye irritants, mutagens, teratogens, etc.
- Spills are possible
- Wear gloves
- Clean the outside of the instrument
- Look for spill marks inside and clean these as well
- Ask lab personnel to help clean up the equipment, especially if you are taking to the shop

- Address any concerns to the Chemical Safety Officer

Biological Safety

A biomedical technician will be working with instruments that come in contact with infectious organisms or patient samples, both of which could be hazardous to one's health. All such samples, whether from healthy or sick, are to be considered hazardous

- Wearing proper protection such as lab coats, eye protection and gloves should be made a habit
- Instruments must be decontaminated by the lab personnel before repair is attempted, especially if moving the equipment to the shop
- Some of the instruments may be located within labs and unmovable
- Work with the biological safety officer to ensure your safety

Levels of Biological Safety

Depending on the hazard posed by the organism being cultured, different biological safety levels are mandated.

These safety levels, BSL 1 – BSL 4 specify containment and precautions, with level 1 being least restrained and 4 being highly contained.

Hazards are generally higher in research lab than in routine clinical labs

Know the biosafety officer and address questions

Biohazard Signs and Biosafety Levels

The source of bioelectric signals is the activity of single *excitable* neural or muscular cell. Indeed, the collective electrical activity of a large group of active cells in vicinity changes the properties of the electric field which propagates in the volume conductor consisting of the various tissues of the body. The changes in this electrical field is then indirectly monitored and measured by electrodes placed on the skin. In clinical practice, two electrode and multiple electrode recording configurations are commonly used. Multiple electrode configuration provides a spatial description of bioelectric phenomena whereas the two electrode setup is useful to study the time course of the electrical source. However, in both measurement configurations, the activity of neural or muscular cell (in unknown locations) transmitted through an inhomogeneous medium is monitored from a distance. Therefore, it is difficult to analyze the noninvasively collected information and to characterize the electrical source. In spite of these difficulties, analyzing the electric signals, recorded on the skin surface, plays a crucial role in clinical decision- making.

Biomedical signals are used primarily for extracting information on biological system under investigation

The sources of signals may originate in physiology, activities associated with living organ

Self-Check -1	True/false

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

Say true for the correct statement and false for wrong statement

1. All personnel working in laboratories must be trained in safe work practices and hazardous waste disposal.
2. Conductors and cable cores (EELP's Regulation) color code for neutral is white.
3. Control measures are not reasonably practicable to eliminate the hazards and associated risks.
4. Hazards are generally lower in research lab than in routine clinical labs.
5. Risk management is a proactive process that helps you responds to change and facilitate continuous improvement in your business

Note: **Satisfactory rating – 5 points** **Unsatisfactory - below 5 points**

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

Answer Sheet

Name: _____ date __

Score = _____

Rating: _____

Information Sheet-2	Check normal functioning systems and components.

Check normal functioning systems and components.

When it comes to identifying problems with medical devices, many techniques have been advanced as the best and quickest methods by various authors. This will also provide a structure for your troubleshooting process before you open the device's service manual. Presented in two parts, these steps will serve as a guide to assist in the troubleshooting and repair of medical equipment.

Before any repair or troubleshooting is started, one question has to be asked: "Was this device involved in a patient injury?" If so, stop all work and get approval from your risk manager before doing any work on the device.

Next, safety always comes first when working on equipment, so know the hazards that are associated with the device you are working on—whether electrical, mechanical, and chemical, gas, or bacterial. Take all the precautions needed, including personal protection such as gloves, etc. When in doubt as to a hazard, assume it is present.

You will also need to determine what the device is used for. While no longer a common problem, devices are sometimes used for other than their intended purpose. This can lead to a trouble call, which can be more political than technical. Look at the application before starting any work. If it is not the correct application for the device, you have got a problem that might take your manager to solve.

Rules of Engagement

There are nine rules and three thought processes used to troubleshoot engineered products—unfortunately, these do not work on people as they do on engineered products!

Below, you will find the nine rules:

- Look at the device/procedure/process.

- Listen to the user/device/procedure/process.
- Smell.
- Is the application correct for the device/procedure/process?
- Is there power?
- Is there an input?
- Is the processor/amplifier/etc. working?
- Is there an output?
- Is there a memory/program/system problem?
- The three thought processes are as follows:
- Look for the obvious.
- Think simple.
- Don’t overcomplicate the problem.

The thought processes above are best illustrated by this question: What is the end of time and space and the beginning of eternity? See the last page for the answer.

Rule 1) Look at the Device/Procedure/Process

Do not just look at the device/procedure/process but at all the information that may surround them. Are there any notes from the users? Is there a description of the problem, or is it just labeled “broken”? Is there a name of the person who found the problem? Is there an error log on the device? Is there evidence of a drop or spill, smoke, heat, or other damage?

If there is evidence of a spill, it must be considered hazardous and cleaned by someone trained to handle hazardous spills. Spills—even nonhazardous spills—are usually conductive and can cause shorts in the device circuitry. Solutions such as total parenteral nutrition, or TPN, are very thick and can act as glue that will overload motors on a pump. Always follow the universal precautions—the safety procedures established

by the Centers for Disease Control and Prevention—that are in use at the hospital when working on devices.

Next, look at any connectors, power cords, and input or output cables to be sure that they are in the correct positions and secure. Check the position of all switches and controls to be sure that they are correctly positioned and working.

Assuming that there are no signs of mechanical damage to the device, do a self-test or calibration on the device. This may also give you the error log on the device, which must be reviewed and problems noted. Unfortunately, all too many techs will stop the process if the self-test passes. There can be other problems present that are not part of the self-test process, so make sure to carry out complete the full troubleshooting before returning the device to use.

Next, remove the covers of the device and carefully look for dust buildup over fans or vent holes, fluid spills, loose hardware—or worse, floating hardware—cleaning and correcting as you proceed. Make sure all the chassis components are secure. Look for signs of heat, smoke, and burned components, and correct as needed.

Look at any fluids carefully. If they are oil-based, it may be an indication that a capacitor or transformer is leaking or failed. Generally, if this has happened, there will also be signs of heat damage around the failed component.

Next, move on to the circuit boards. Are they properly seated? Is there dust or spills on them? Are there signs of heat buildup? Are the components secured on the boards? Correct problems as you find them. You might look over the solder connections on the boards to be sure that there are no “cold” joints. You might also want to clean the connectors. You can use a white eraser; the pink erasers may leave a film on the contacts.

At some point, you should look at the manual and the device history to be sure that you have covered what needs to be done and to determine if the problem has occurred in the past. If it is a repeat problem, it may require changes in the PM or in-service training of the users

All these steps should be taken in conjunction with the three thought processes.

Rule 2) Listen, Listen, and Listen

Listen to the device/procedure/process for unusual sounds. These sounds can be electrical arcing, motor/fan sounds, pumps, or speakers/alarms that are or are not providing true tones. Does the mechanism require lubrication? If so, it should be cleaned first and then lubricated, as a buildup of lubricant can be the cause of the problem.

Listen to the user of the device to find out what they see as problems on the equipment, what has changed with the outputs or processes, and whether the device is still within normal ranges or not. Has the speed of the process changed? Has the use of consumables increased? Do not ask the users questions that they do not know the answers to. Keep the questions to the setup, controls, and outputs of the device/process. It is not unusual that a user or an operator will not know all the functions of a device/process. Sometimes, to avoid looking foolish, they will give bad answers to questions outside of their knowledge.

Seek out and listen to others who have worked on the same or similar devices or processes. They may have information that will help you correct the problem that was reported.

Rule 3) Smell

The sense of smell is often overlooked in troubleshooting methods. It is generally more useful in troubleshooting a process than a device. If a strong smell is present, it generally indicates that either the venting system is not working correctly or the input is being overloaded with a chemical. Sometimes it is an indication of a spill. Sometimes the users are so used to the smell in their area that they do not realize that the background levels have changed and something is not right. This may happen days before the problem that you are involved with has occurred. With processes or procedures, if a smell is present, look first at the ventilation or scavenging system, pumps, and then for leaks in the feed or waste lines.

On devices, overheated components, shorts, or fans that are blocked can cause smells. General rule: If it smells, there is a problem somewhere.

Remember that in the fall of the year when the building heats comes on you will often get calls about smells. In most cases, no devices or processes are involved with these smells; it is just dust on the heaters.

Rule 4) the Application of the Device/Procedure/Process

This is generally not a problem in most clinical areas, but using the wrong device, procedure, or process does happen in research areas and may happen in some clinical specialty areas. It is common in radiology and ultrasound when operators look for details that are not possible with

that particular device. It used to be common in the clinical laboratories when tests were done on a particular device, as opposed to now when multitasks are done with one device.

More of a problem than the misapplication of a device or procedure is using the wrong disposables on the device. This is a continuing education problem that everyone has to be involved with. Some clinical/biomedical engineers even go so far during preventive maintenance inspections or rounds as to remove any wrong disposables from the device. While this is a good preventive step, it requires the person doing the removal to replace the wrong items with the correct ones.

If disposables are the cause of the problem, it is a good idea to inform the materials management department about the issue and let them notify the supplier of the products. It may also require that a report be sent to the FDA under the requirements of the Safe Medical Devices Act of 1990.

If the wrong disposables are a constant problem, you need to notify the materials and risk management departments with your concerns. Documentation is critical to correct the issue, so document all failures, times, and expenses, as well as if patient care was compromised.

Using these first four rules will probably help you solve 75% of all your trouble calls. Medical devices do not have high failure rates, and the majority of all problems are of use origin. This use origin includes the application, cleaning (or lack thereof), poor airflow, poor PM, and operators that do not understand how to apply the device properly.

Self-Check -2	Short answer

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

List rule engagement to test normal function of medical equipment

Rule 1----------

Rule 2----------

Rule 3----------

Rule 4----------

Note: **Satisfactory rating - 4 points** **Unsatisfactory - below 4 points**

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

Answer Sheet

Name: _____date ----------

Score = _____

Rating: _____

Information Sheet-3	Diagnosing Fault/s or problem/s in the device.

3.1. Plan the tasks

The maintenance tasks are placed in daily and weekly checklists. This will help in planning time for them to be carried out. In most cases, for daily tasks the beginning of the working day will be best, but any time will suit as long as the job is done. For weekly tasks, it may be easier to allocate a different day for each type of equipment, in order to spread the load through the week. A simple timetable with the person responsible can be used as a reminder.

3.2. Display the lists

The maintenance checklists are designed to fit on a single page per section. This makes it easy to print or copy them and display them near the equipment. The lists will only be useful if they are easy to see, so placing them on the equipment or on a wall nearby will be best. Each page could be covered with plastic laminate or taped inside a plastic wallet. The same could be done with the troubleshooting checklists, or these could be stored nearby for when needed.

3.3. Record the work

It is normally helpful to have some way of recording when maintenance has been done. This

Will tell colleagues or the next shift that the daily check has been carried out, or remind the user themselves that the weekly job has been done. It can also be helpful to show supervisors and patients that care is being taken of equipment.

Recommended resources

The user should not be left on their own. Once a piece of equipment is installed, commissioned and accepted and once the user has been fully trained in operation, they will need these resources to carry out the use and maintenance of the equipment well:

Manuals in a fluent language

Operator manuals are essential and should be specified at time of purchase. It is often also possible to obtain service or technical manuals, which should be held by the maintenance department.

Scheduled Maintenance

A schedule of regular visits by qualified maintenance personnel will be needed. This might be managed by the maintenance department or senior hospital management.

Whether the maintenance is in-house or outsourced, a system of reminders to prompt the work will be needed.

Repair Services

The user will need to be able to call on a repair team when things break. Smaller items

Of equipment will be serviceable by the hospital team, whereas large scanners etc. will require specialist outside services.

Contract Management

The purchase contract should have details of what warranty services are available and contact details to call in these services. Either stores or administration should monitor performance against these contracts and plan for cover on expiry of any agreement.

Consumables supply

The needs for consumables should have been specified during the procurement process, so that necessary supplies are available from the start of equipment use. A schedule of

Restocking will need to be developed, so that there is never a gap in services.

Spares Supply

Technical advice will be required to decide which spares should be stocked on site and which should only be purchased when needed. As a general rule, it is recommended to

Keep spares likely to be needed for two years operation on site and to have these

Supplied with new equipment.

Effective Maintenance Strategy

It is essential that we plan the resources required for maintenance. Planning will need to be made for both repair work and also for planned preventive maintenance.

The following will also promote effective maintenance: User as well as service manuals

In procurement it should be made mandatory for the vendors to provide the following:

- Training to technicians and operators.
- Providing user/ operating manuals.
- Providing service / maintenance manuals
- Receipt and incoming inspection

Incoming equipment should be carefully checked for possible shipment damages; compliance with specifications in the purchase order; and delivery of accessories, spare parts and operating and service manuals.

Inventory and documentation

A proper entry should be made in the inventory register. The inventory record should contain the serial number and date of receipt as well as date of completed inspection.

Installation and final acceptance

Installation should be done by the vendor and training should be provided at this stage to the User as well as to the maintenance technicians.

Equipment history record

There should be an equipment history record sheet to track the performance of the equipment.

This sheet should note down the date of installation and commissioning, preventive as well as corrective maintenance records.

Maintenance

Proper maintenance of medical equipment is essential to obtain sustained benefits and to preserve capital investment. Medical equipment must be maintained in working order and periodically calibrated for effectiveness and accuracy.

Condemnation of old and obsolete equipment

The life cycle of medical equipment will vary from 5-10 years. If the equipment is declared obsolete by the vendor it may not be possible to get spare parts. Even if the parts are available it can become too expensive to obtain them and the equipment is no longer economical to repair. Condemnation of equipment should be well planned and the necessary steps should be taken in advance to arrange replacement.

Types and approaches to Maintenance of Medical Equipment:

There are two types of maintenance:

Corrective Maintenance (or Repair)

This is done to take corrective action in the event of a breakdown of the equipment. The equipment is returned repaired and calibrated.

Planned (or Scheduled) Preventive Maintenance

This work is done in a planned way before repair is required and the scheduled time for the work circulated well in advance. It involves cleaning, regular function / safety tests and makes sure that any problems are picked up while they are still small.

The choice of approach for Preventive and Corrective Maintenance depends on the complexity of equipment

Maintenance by in-house trained technicians

The majority of the problems are relatively simple and can be corrected by a trained technician. Simple repairs and inspections are less costly when done this way.

Vendors

Should provide training to in-house technicians at the time of installation and commissioning.

Maintenance by manufacturer or third party

For specialized and advanced equipment, the vendor should provide maintenance services

Through a combination of on-call services and a maintenance contract negotiated at the time of the purchase. It will rarely be economical to provide this level of service in-house.

Self-Check -3	True/false

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

1. The maintenance checklists are designed to fit on a single page per section
2. The majority of the medical equipment problems can be corrected by a biomedical engineer
3. Vendors should provide training to in-house technicians at the time of installation and commissioning.
4. The life cycle of medical equipment will vary from 5-10 years
5. Planning will need to be made for only repair work

Note: **Satisfactory rating – 5 points** **Unsatisfactory - below 5 points**

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

Answer Sheet

Name: _____ date

Score = _____

Rating: _____

Information Sheet-4	Configuring Biomedical Equipment

4.1 Configuration

Configuration is an arrangement of parts or elements in a particular form, figure, or combination.

While a competent, capable and expert team of staff members is the backbone of any hospital or healthcare facility, having up-to-date, functioning equipment can make it easier to provide extraordinary patient care. Technologically advanced equipment not only improves patient satisfaction, but also increases staff efficiency - both of which lead to more revenue. When you have ordered new medical equipment, how do you ensure that everything is set up properly and will be ready for immediate use? Here are five things to consider for the smoothest, most efficient equipment setup.

Proper Location

The first step of proper medical equipment setup is placing the equipment item(s) in the specified area of use. You need to have the equipment located in the area where it will be used, so a direct-to-site delivery process is extremely beneficial.

Inspection of Parts and Proper Assembly

The next step is inspection. You want to carefully inspect each piece of equipment for the following:

- Missing parts;
- Damaged parts;
- Mismatched parts.

Although it may seem simple and obvious, this is a crucial step for your hospital or healthcare facility. A quick check is not enough; you need a detailed inspection to avoid problems in the future.

What good is medical equipment if it isn't assembled correctly? Once you've inspected everything, be sure that the equipment gets assembled the right way. Even a small mishap could cause a malfunction and possibly damage your equipment. This means more time and money spent on equipment needs.

Test of Functionality

Once assembled, the medical equipment should be tested for functionality. Sometimes everything appears to be fine, but there may be a glitch that can't be seen. In addition to problems with the equipment itself, testing can uncover assembly mistakes before any permanent damage occurs.

Removal of Unnecessary Materials

The next step is to be sure all packing materials and other debris are removed from the medical equipment area. This helps ensure a clean, effective workspace for those employees who will be using the equipment on a regular basis. It also prevents contamination and other mishaps during work.

Self-Check -4	True/false

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

1. You want to carefully inspect each piece of equipment for:

A. Missing parts c. Damaged parts

B. Mismatched parts D. all

2. Once assembled, the medical equipment should be tested for

A. functionality c. Damaged parts

B. Mismatched parts D. all

3. ---------- is an arrangement of parts or elements in a particular form, figure, or combination

A. functionality c. Damaged parts

B. Configuration D. all

Answer the following question!

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

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

Answer Sheet

Name: _____ date

Score = _____

Rating: _____

Information Sheet-5	Responding unplanned events or conditions.

5.1 Overview unplanned events or conditions

Unplanned events are accidents or upset events or conditions that are not planned as a part of routine Project activities during any Project phase. Even with the planning and application of mitigation, accidents, malfunctions, and unplanned events could occur during any phase of the Project. These could occur as a result of abnormal operating conditions, wear and tear, human error, equipment failure, and other possible causes. Many accidents, malfunctions, and unplanned events are preventable and can be readily addressed or prevented by good planning, design, equipment selection, hazards analysis and corrective action, emergency response planning, and mitigation.

In this section, the potential accidents, malfunctions, and unplanned events that could occur during any phase of the Project and potentially result in significant adverse environmental effects are described, discussed, and assessed. The focus is on credible accidents that have a reasonable probability of occurrence, and for which the resulting residual environmental effects could be major without careful management.

It is noted that accidents, malfunctions, and unplanned events are evaluated individually, in isolation of each other, as the probability of a series of accidental events occurring in combination with each other is very minimal. These possible events, on their own, generally have a very low probability of occurrence and thus their environmental effects are of low likelihood. They have an even lower probability or likelihood of occurring together – thus their combination is not considered credible, nor of any measurable likelihood of occurrence.

Accidents, malfunctions, and unplanned event scenarios have been conservatively selected that represent higher consequence events that would also address the consequences of less likely or lower consequence scenarios. The accidents, malfunctions, and unplanned events that have been selected based on experience and professional judgment are as follows:

Worker accident: worker accidents may occur during either construction or operation, and may result in harm, injury, or death to one or more Project workers;

Fire: consists of a fire in a Project component. The focus is on the consequence, and not the mechanism by which it occurs;

- Electrical Hazardous materials spill:
- spills of fuel,
- petroleum products,
- chemicals used on site or in Project components; and

Inspect Electrical cords:

It better to keep an eye on electrical wires they shouldn't be cracked or damaged so check electrical cords once in a month.

Avoid binding and knotting cables: You need to avoid binding and knotting the wires because it may produce electric shocks which would be a hazard for your workplace.

Unused appliances need to be unplugged: Unused electrical items need to be unplugged until for further use. Because it will increase the electricity consumption

Avoid maintaining by yourself: You don't need to support this thing by yourself because it can be dangerous for you and it may produce electrical shocks. So you can have the assistance of Electricians Barrow in Furness or nearby areas who know all the safety measurements very well, and they will keep on guiding your employees for do's and don'ts.

Licensed electricians: You need to hire licensed electricians who should have proper information and qualification before playing with wires.

Don’t route power cords under the carpets: This is not suggested to install power cords under the rugs. Because employees are rolling the chairs here and there for work purpose and when chairs roll over them it would be risky for your employees.

Disconnect electrical equipment: If there are electrical equipment is malfunctioning, and you feel terrible smell then disconnect all the electrical equipment which is plugged

.

Self-Check -4	True/false

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

1. A fire at the Project location could interact with the atmospheric environment.
2. If there are electrical equipment is malfunctioning, and you feel terrible smell then you have allow all the electrical equipment which is plugged into a socket on urgent basis.
3. Power cord which is being considered to utilize must be of some renown brand, should be of high quality.
4. Prevent workplace accidents including Workplace Hazardous Materials Information System (WHMIS), first aid, and other applicable training programs.
5. Worker accidents may occur during either construction or operation, and may result in harm, injury, or death to one or more Project workers

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

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

Answer Sheet

Name: _____ date

Score = _____

Rating: _____

OPERATION SHEET #1	LEARNING GUIDE #43
Operation title	configure biomedical equipment electrical safety analyzer
Operation number	#01
purpose	Configure medical equipment test device and calibrator
Equipment, tools and materials	Electrical safety analysers
Conditions or situations for the operations	Dry room and clean environment. Concert room ,well organized biomedical workshop
Procedures	Put on gloves, masks Inspect tools are available and functional. Report any problems to the instructor. Prepare equipment according to correct standard. Arrange calibrating tools and equipment accordingly No Missing parts; No Damaged parts; No Mismatched parts Test the reading of test device
Precautions	Make Sure no physical damage on the equipment Wear Safety Glasses and Protective Clothing Always Test First
Quality criteria	All equipment should configured following service manual

LAP TEST 1

1. Configure reading value of calibrator
2. Measure resistance value did measure
3. does the reading value exceeds normal range

4.

LG #44	LO #3. **Calibrate biomedical equipment**

Instruction Sheet

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

- Using appropriate PPE.
- Checking normal functions of devices
- Conditioning biomedical equipment to be calibrated.
- Diagnosing fault/s or problem/s in the device.
- Calibrating and adjusting biomedical equipment
- Responding unplanned events or conditions.

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

- Using appropriate PPE.
- Check normal functions of devices
- Condition biomedical equipment to be calibrated.
- Diagnose fault/s or problem/s in the device.
- Calibrate and adjusting biomedical equipment
- Respond unplanned events or conditions.

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below 3 to 6.
3. Read the information written in the information “Sheet 1, Sheet 2, and Sheet 3”. Sheet 4, Sheet 5, and Sheet 6”.

4. Accomplish the “Self-check 1, Self-check t 2, Self-check 3” Self-check 4, Self-check 5, Self-check 6 in page 64, 71, and 73, 76,81, 86 respectively.

Information Sheet-1 Using appropriate PPE

1.1 personal protective equipment (PPE)

Definition: Devices used to protect employees from injury or illness resulting from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards.

The need for PPE and the type of PPE used is based on hazard present; each situation must be evaluated independently. Examples of PPE include ear muffs, respirators, face masks, hard hats, gloves, aprons and protective eyewear. PPE limits exposure to the harmful effects of a hazard but only if workers wear and use the PPE correctly.

Information about suitable controls for many common hazards and risks can be obtained from:

1.2 Codes of practice and guidance material

Manufacturers and suppliers of plant, substances and equipment used in your workplace.PPE is used as a last resort to avoid risk in work place.

The use of PPE signifies that the hazard could not be controlled by other methods, such as: administrative controls, engineering or industrial hygiene controls. The use of PPE signals that the hazard still exists in the workplace unprotected individuals in the same area will be exposed.

Failure of PPE means that the worker will be exposed. PPE type depends on hazard to be protected.

- Eye and Face protection Common Uses:
- Impact Protection

- Chemical Hazards
- Radiation Protection
- Eye and Face Protection device
- welder’s goggles
- laser goggles
- UV
- Infrared

Safety glasses are used to protect the eyes from flying objects.

Chemical splash goggles protect against fluids by sealing tightly against the face

Face shields provide highest level of protection

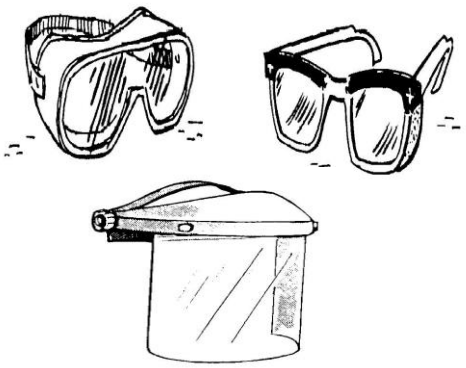


Figure 3 Hearing Protection

Noise induced hearing loss can occur with exposures >90 dB. All hearing protection devices should have a Noise Reduction Rating (NRR) of decibels they will reduce noise levels.

Types

Ear Plugs - less expensive, disposable, good ones have fairly high NRRs - sometimes difficult to tell if employees are wearing them

Ear Muffs - more expensive, more durable, typically higher NRRs than plugs, more obvious.

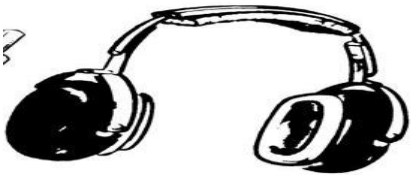


Figure 4 Arm and Hand protection

Gloves - Typical Uses Chemical protection Biohazard protection Friction protection

Protection from extremes of heat and cold.

Types

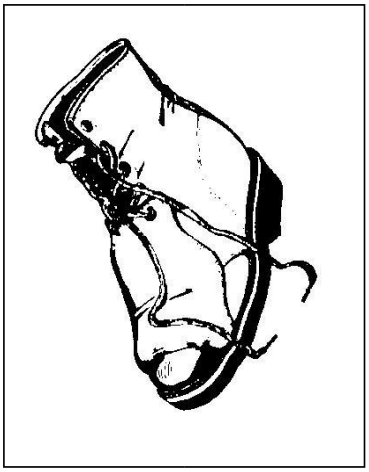
Surgical gloves

Electrical gloves

Figure 5 Foot and Leg protection

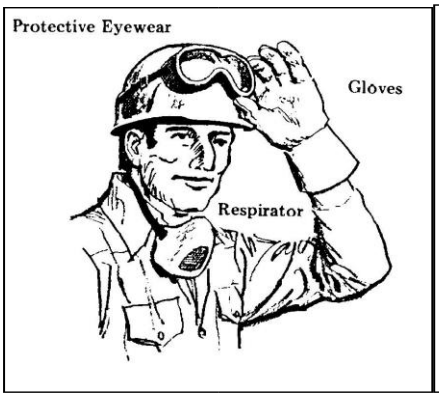
Steel-toed footwear, preferably with metatarsal guards, is used to protect feet from crushing injuries caused by heavy objects

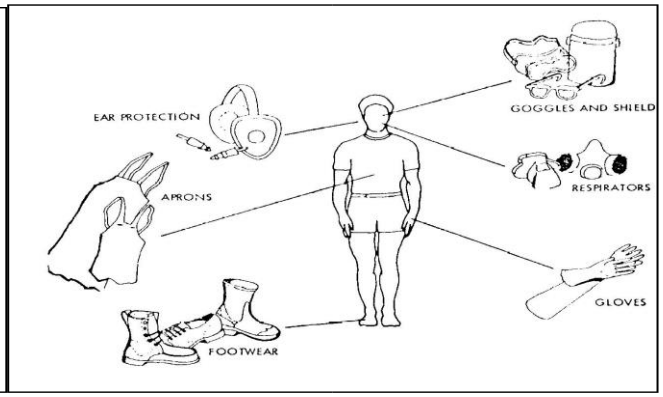
Rubber boots are often used to protect feet from exposure to liquids.



Respiratory protection

Protects users by removing harmful materials that may enter the body via the lungs. Inhalation is one of the quickest, most efficient ways to introduce lethal levels of hazardous materials into the body





Selection and Use of Chemical Disinfectants Alcohols (ethanol, isopropanol)

Ethanol or isopropanol in concentrations of 70% - 95% are good general-use disinfectants. They are most effective against lipophilic viruses, less effective against non-lipid viruses, and ineffective against bacterial spores. Because of their quick evaporation rate, it may be difficult to achieve sufficient contact time.

Disinfectants Defined: - Disinfecting agents are registered by the Environmental Protection Agency (EPA) as “antimicrobial pesticides” and are substances used to control, prevent, or destroy harmful microorganisms (i.e., bacteria, viruses, or fungi) on inanimate objects and surfaces. These antimicrobial products have traditionally included sanitizers, disinfectants, and sterilant

Self-Check -1	Written Test

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

1. What are the common uses of Eye and Face protection are

   A. Impact Protection C. Radiation Protection

   B. Chemical Hazards D. All

2. …… Uses Chemical protection, Biohazard protection, Friction protection from extremes of heat and cold?

   A. Glove C. Hearing Protection

   B. Head protection D. Eye and Face protection

3. PPE used to protect employees from injury or illness resulting from contact with, electrical, mechanical, or other workplace hazards.

   A. Chemical C. physical

   B. Radiological D. All

4. One of the following is not the protective device?

   A. welder's goggles C. laser goggles

   B. Infrared D. None

5. Which one of the following are the types of Hearing Protection?

   A. Ear Plugs C. Ear glove

   B. Ear Muffs D. A & B

Answer the following question!

Note: **Satisfactory rating – 5 points** **Unsatisfactory - below 5 points**

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

Answer Sheet

Name: _____

Score = _____

Rating: _____

Information Sheet-2 Check normal functions of devices

2.1 normal functions of devices

Medical devices are highly regulated by multiple regulatory bodies and compliances. On the other hand, end users expect exceptional performance, effectiveness, and safety from the device they are using. This compels medical device manufacturers to define and implement medical device testing strategy that turns to be effective throughout the development cycle — starting from the concept and design phase to production stage.

A medical device testing strategy must incorporate compliance processes and technical testing strategies for better performance and effectiveness of medical devices. Manufacturers need to have a strong testing strategy in place right from the design stage, as performing an exhaustive testing of a produced device is ineffective and inefficient.

For e.g. A medical device manufacturer needs to test each functionality of the medical device right from the design stage for a better test coverage. If they test manufactured devices for the functionalities and find issues with the device, it will be very costly and time consuming to go back to the design phase and find appropriate solutions for the issues

2.2 Revising an effective medical device testing strategy

Testing team should utilize design team as a source of knowledge. Design input can help to derive the test structure that matches with the hardware, software or other technical requirements. The design class modes, effects, and criticality analysis (FMECA) can be used to derive test requirements of the device for risk mitigation.

An effective medical device testing strategy needs several sets of test requirements.

These test requirements are based on the component specification, manufacturing process, and other critical functional specifications of the device. Test requirements define and describe setup conditions, actions, and expected response constraints for each experiment defined in the test steps.

These sets of requirements are required to smoothen test implementation as tests are carried out continuously at different stages of the complete manufacturing process, from component selection to a final assembly of a medical device, and each stage has different requirements and different parameters to be satisfied.

Medical Instruments/Equipment's used in Pathology / Microbiology / Bio chemistry laboratories & various depts. Of Hospitals e.g.; ICU/OT/OPD/ Pediatrics / Gynecology / Physiotherapy/X ray etc. are being tested in Medical Laboratory, equipped with state of the art Bio Medical Test equipment's/ simulators.

Thermometers, Blood Pressure apparatus, Pipettes, weighing scale, Auto clave, Blood storage/Refrigerators, Analyzers, RF based equipment's, Monitors, etc. are being calibrated/Tested in Medical Laboratory.

The Medical Laboratory is equipped with state of the art; Oxygen analyzer, Ultrasound Transducer leakage tester, Parameter tester, Multi-channel Infusion device analyzer, Electrical safety analyzer, Ventilator analyzer, Fetal simulator, X ray test device, CR Plate Reader (Tester), Patient simulator, Rigid endoscope tester, Electro surgery analyzer, Incubator analyzer, Pulse ox meter simulator etc.

2.3 Applying medical device testing strategy

The highest level of medical device test strategy takes the production testing of components, sub-assemblies, and the finished product into account for technical testing. Specific hardware and software requirements for each test stages are considered with the measurement methods and expected output in the test strategy.

An effective test strategy is a product level activity that brings a complete test set into account for each stage of the product development. It considers defects in a test model at each stage and correlates defects to optimize the overall performance of the device. The desired output for each stage is defined by the strategy to ensure overall effectiveness.

In the validation process, the system is divided into small blocks without losing the traceability to the original test strategy and then the testing starts with specified requirements for each block in the system. Validation methods for each block are customized based on risk-based analysis for better fitting of the test strategy. The high-

level test strategy provides a strong reference for technical reviews of the device and its validation.

2.4 Microprocessor testing

In order to perform testing to the highest standards, medical devices must undergo solid electronic testing. Most of class II and III medical devices have microprocessor at its core. Hence, medical device testing starts with a microprocessor testing.

For an effective testing of transistors inside a microprocessor, it must provide access to their interconnections. However, the catch is, the testing team should carry out microprocessor chips' testing before installing it into a printed circuit board (PCB) for an increased testing effectiveness.

Tests for integrated circuits consider their logic gate functions and interconnection between them. Well-suited test methods can be selected from several industry-used test methods based on the requirements.

After attaching all the components to the PCB, testing of mounting and interconnection process is the next priority. In this phase, the testing team should use common defect of an assembly model where they try to identify the wrong component, missing component, open interconnect, shorted interconnect, etc., in the PCB assembly process.

Modern test equipment delivers the physical access to the PCB and allows the direct measurements of components in small groups. It is important to ensure that these small groups of components in the PCB do not affect the functioning of the system as a whole. Hence, functional testing is crucial for all the functions, which can be influenced by parameters of other components. Similar PCBs are allowed for functional testing, but it is insufficient for finding common manufacturing defects. Hence, additional troubleshooting may be required to identify specific repairs.

2.5 Automating the test

A test automation system is an electronic system developed with the purpose and consists of a computer, instruments and a software to carry and control test process. There are certain commercial test automation systems available in the market in

accordance with industry standards. However, the testing team can use a customized test system based on the need and requirements.

While using test automation system, the testing team may need to change the strategy based on the available test options for each stage of medical device development. It may restrict the testing team with constraints by limiting the implementation methods.

In case of testing complex medical devices with extremes of voltage and current requirements, the testing team may face challenges in the test automation environment due to the limited ability to generate test cases and measuring the accuracy of the test. Ideally, automated test implementation is a matter of simultaneous hardware and software design. The test set for a certain stage in the manufacturing process flow is defined in the test strategy by the test specifications allocated for that particular stage. We need to break down those test specifications into software and hardware requirement specifications according to the test system software and interface hardware, respectively.

Normally, system specifications are derived from medical device design stage, but there are certain specifications that we need to derive from the production test environment like compliance with security and data integrity. Mechanical design, coding and electrical design of test system result from all those specifications. For an established facility, where several medical devices have been designed, manufactured and tested, common blocks of hardware and software are re-used to simplify the process.

2.6 Validation process

Once everything is in place, the medical device test system must be validated, including software and hardware. The process of software and hardware validation for medical devices must be detail specific. The purpose of validation is to test if the device meets specific user needs or not. Hence, the structure and approach are very crucial to apply validation methodology.

Validation must be carried on an initial production unit. In other words, a device for validation has to be built into the production environment. The process requires involving the end-user and it should be tested either under simulated use or under the actual use.

Validation tests are required to validate that the medical device functions as expected and meets the users' needs.

The initial approach for validation should start with unit testing of a set of stages in the process and then a complete system could be validated as a whole. Considering the complexity of the system, it is an overwhelming task for most of the automation systems. In that case, a divide and conquer validation approach is a better choice.

Integration testing involving complete system is a necessary practice, which should be a culmination of a coordinated validation protocol and not the entire plan.

A functional testing of a medical device consists of testing different functional blocks such as operating system, instruments, hardware etc., which must be validated for their intended use. The process starts with manufacturer's specifications or a subset of specifications that can be applied to each block from design and test team.

The testing team should work with the manufacturing team to validate those specifications and then testing and verification of the performance of individual block should be done to document the result, which should be then reviewed. The functional block test comes handy for validation of custom developed hardware or software for medical devices.

2.7 Verification testing

Verification is a process to confirm whether the examination and provision of objective evidence that specified requirements of the device have been fulfilled. Verification process starts with clear and well-defined product requirements. These product requirements must be measurable in order to verify. We must know what the answer should be as verification is not an experiment.

The process follows several formal protocols. It suggests comparing current product requirements with the requirement of an already approved product. The verification process must contain full methodology or a reference to standard methodology, statistical justification for sample size, statistical plan for data analysis and more. It also needs to specify details on acceptance criteria and procedure to follow in case of the failed verification.

If a verification is failed, it must go through a further investigation to determine the requirement, which could not be verified and whether that requirement is valid or achievable in the current design or not. Further investigation may provide information whether the product requirement can be updated and re-verified.

A strongly defined and implemented medical device testing strategy can save dollars for manufacturers and ensure that devices meet the end user expectations. It also decreases the risk of devices recall. From the business standpoint, it is advisable to collaborate with organizations having domain expertise in testing as it decreases the overall risk and time required for testing.

Self-check 2	Multiple choice.

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

1. Which of the following is being calibrated/Tested in Medical Laboratory

   A. Analyzers,

   B. RF based equipment's

   C. Monitors

   D. .all

2. --------- is a process to confirm whether the examination and provision of objective evidence that specified requirements of the device have been fulfilled

   A. microprocessor testing

   B. verification testing

   C. calibration

   D. commissioning

3. ---------- is an electronic system developed with the purpose and consists of a computer, instruments and a software to carry and control test process

   A. microprocessor testing

   B. verification testing

   C. calibration

   D. Automating the test

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

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

Answer Sheet

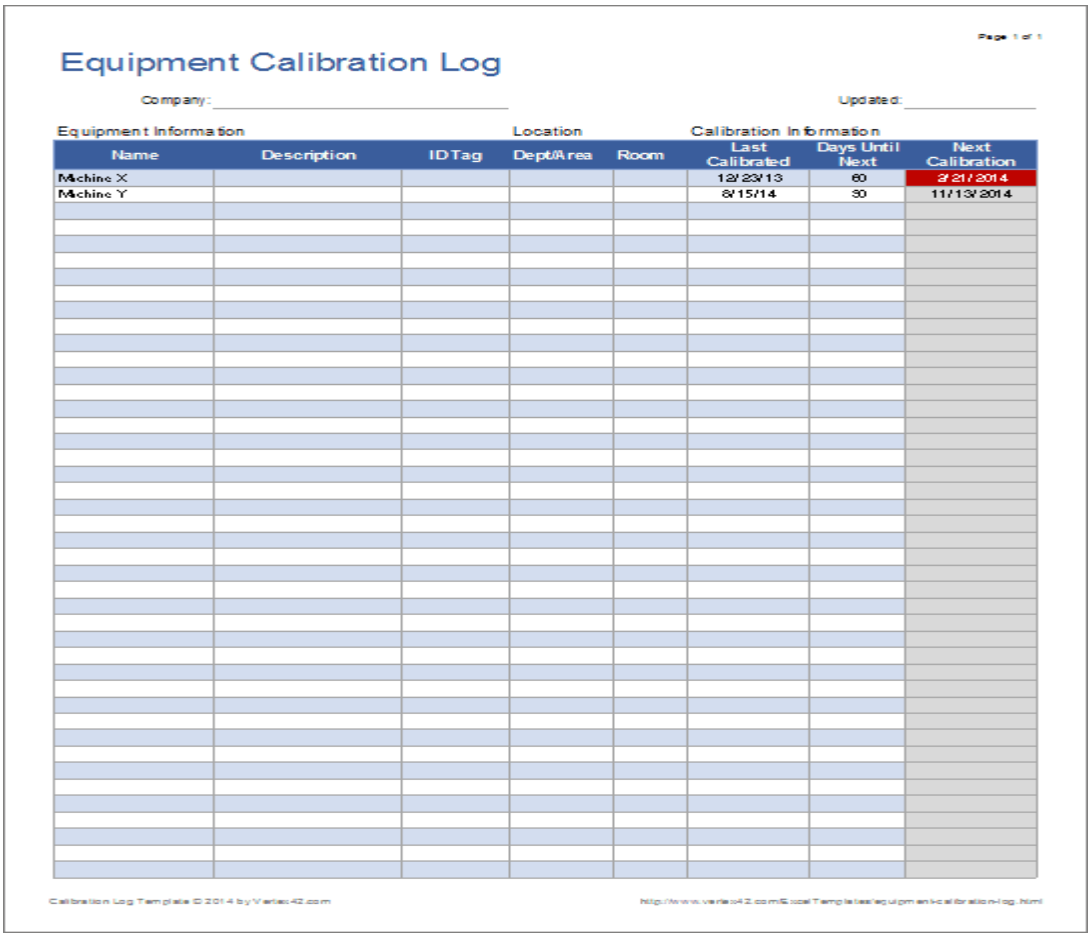
Name: _____

Score = _____

Rating: _____

3.2 Tracking Instruments for Calibration Status

Each instrument should be labeled with the unique identifier (e.g. serial number, model number, location, etc.)Calibration status of each instrument, the date of calibration, the next calibration date and the identification of person performing calibration should be readily available



Equipment Calibration Log

Company: _____ Updated: _____

Equipment Information			Location		Calibration Information		
Name	Description	ID Tag	Dept/Area	Room	Last Calibrated	Days Until Next	Next Calibration
Machine X					12/23/13	60	3/21/2014
Machine Y					8/15/14	30	11/13/2014

Calibration Log Template © 2014 by Vertex42.com http://www.vertex42.com/ExcelTemplates/equipment-calibration-log.html

Table 4 Equipment calibration logo

Self-check 3	short answer

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

1. list Unique identifier uses for calibration

Note: **Satisfactory rating 6 points** **Unsatisfactory - below 6 points**

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

Answer Sheet

Name: _____

Score = _____

Rating: _____

Information Sheet-4 Diagnosing fault/s or problem/s in the device

4.1 Troubleshooting faults in medical equipment Approach:

- Have knowledge of principle of operation of equipment
- Know equipment history from the user and maintenance records
- Use service manuals, test equipment and correct tools
- Use correct trouble-shooting techniques (see further on)
- Perform root cause analysis
- Record equipment details in workshop receiving book. Note date, serial number etc.

When should you have your equipment calibrated?

You should seek to have your medical equipment tested and calibrated when:

You purchase a new or second-hand instrument, since you cannot be sure that just because it's new, it is properly calibrated.

When a specific time period is elapsed, since not every piece of equipment lasts as long as others.

When a specific amount of usage (or hours used) has elapsed, for instance it may be wise to test a defibrillator every time it is used.

When an instrument has had a shock or vibration which could have knocked it out of sync. This is especially important in portable devices, or new devices that might have been shipped or traveled long distances.

Whenever observations appear questionable. Common sense comes into play with this – if it look damaged or like it's giving off readings, there's a good chance it could be.

4.2 Correct troubleshooting techniques

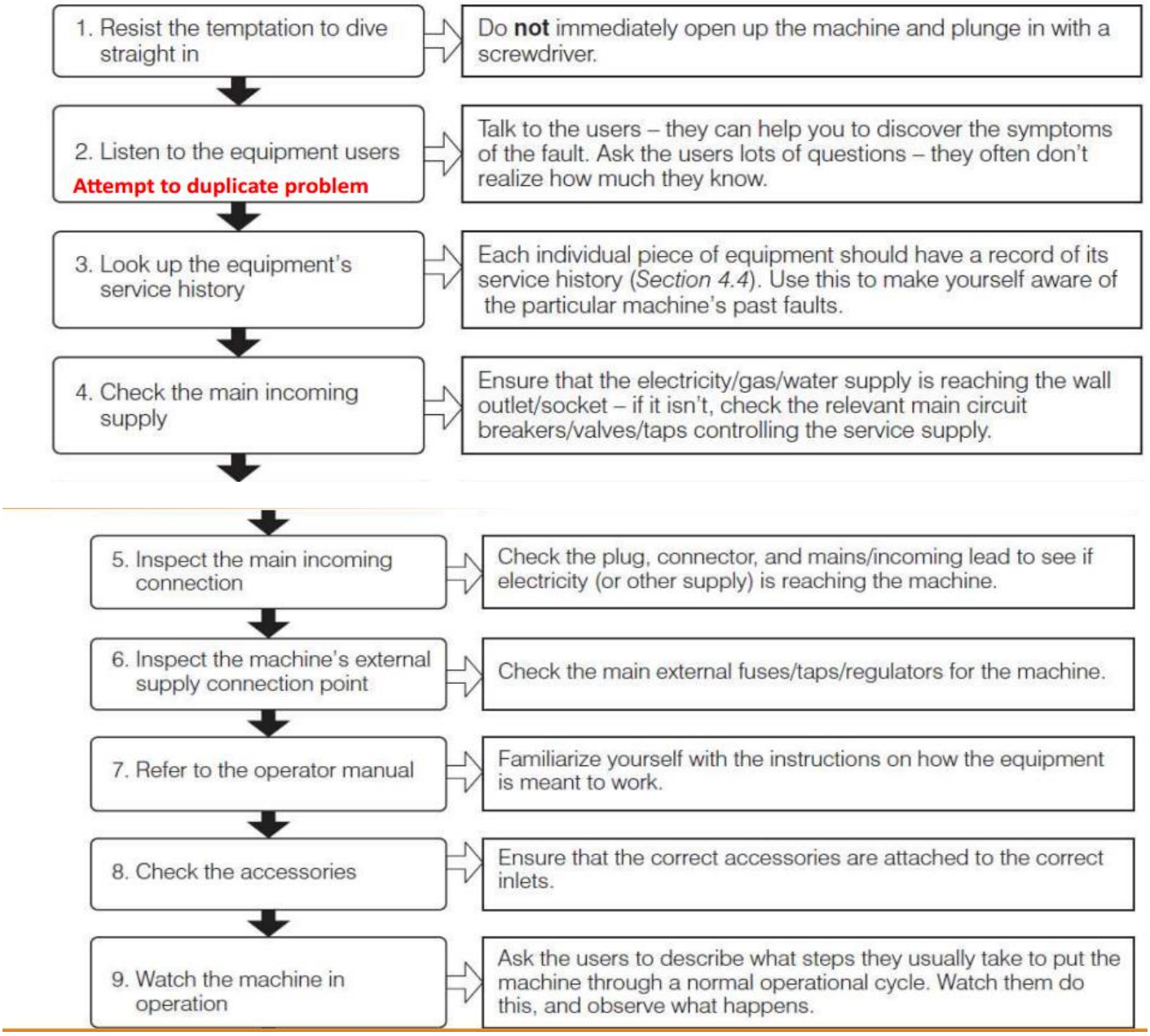


Figure 6 Correct troubleshooting techniques

Self-check -4	Multiple choice and short answer

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

1.which of the following is Troubleshooting faults in medical equipment Approach:

A. Have knowledge of principle of operation of equipment

B. Know equipment history from the user and maintenance records

C. Use service manuals, test equipment and correct tools

D. All

2. List correct approaches of troubleshooting techniques

Note: **Satisfactory rating – 10 points** **Unsatisfactory - below 10 points**

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

Answer Sheet

Name: _____date____

Score = _____

Rating: _____

Information Sheet-5 Calibrating and adjusting biomedical equipment

5.1 Medical Equipment Calibration

Medical Equipment Calibration is the process of ensuring the output quality of said equipment is at par with the industry defined standards. This is done to ensure that the functionality of the item, as well as the result/reading it provides, is accurate at the point of delivery.

Why Does Medical Equipment Need Regular Calibration?

Medical equipment like any other equipment is prone to wear and tear over time which directly impacts its performance accuracy. And the only way to retain the equipment's effectiveness and minimize risks or uncertainty is through regular calibration. This is especially important as the accuracy provided by such medical equipment is crucial to the overall output, with respect to both quality and profitability. Apart from this, regular calibration of medical equipment is also required to receive the necessary certifications and licenses from regulatory authorities.

How Often Should You Calibrate Your Medical Equipment?

When it comes to frequency of equipment calibration, each one has different requirements based on its scope and scale of use. The best way to ensure equipment calibration is done regularly is by creating a calibration schedule, for which you must also consider the following aspects:

Manufacturer Recommended Frequency

In most cases, medical equipment and tools come with manufacturers recommendations with respect to calibration frequency. However, you must also factor in the nature of its use while doing so. For instance, tools that are used to perform critical measurements may require different intervals.

The science of measurements is called Metrology. Measurement is the process or the result of determining the ratio of a physical quantity, such as a length or a mass, to a unit of measurement, such as the meter or the kilogram.

Calibration is a comparison between measurements, one is set (standard) value and the other measured (practical) value that leads to process of corrective actions when results are out of limits.

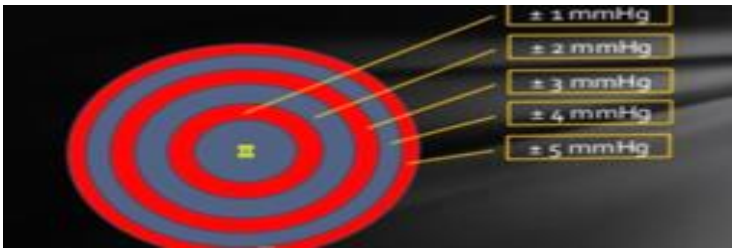
The accuracy of a measurement system is the degree of closeness of measurements of a quantity to that quantity's true value.

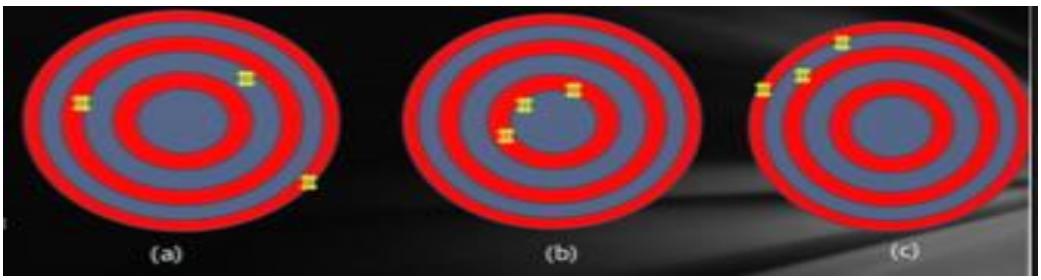
Precision of measurement system or reproducibility, is the degree to which repeated measurements under unchanged condition show the same result.

A measurement system is designated to valid if it's both accurate and precise

Example:

NIPB measurement supposed to be within tolerance of 5mmHg, therefore by performing the test 3 times





We notice all the readings within the tolerance but the following points are reasonable

Figure 7(a) with low accuracy and precision are acceptable and requires calibration

Figure 8 (b) high accuracy and precision, calibration not required

Figure (c) high precision and low accuracy close to the limit

Purpose of measurement

The purpose of measurement is to provide information about quantity of interest of measurand. Example the measurand might be the flow rate, potential difference, or energy…etc.

No measurement is exact. When quantity is measured, the outcome depends on

- The measuring system
- The measurement procedure

Calibration Process

Written calibration procedures that use traceable calibration standards and/or calibration equipment. Qualified individuals (having the appropriate education, training, background and experience) responsible for calibrating & maintaining instrumentation .Second person check of all calibration tests

Qualified individuals responsible for monitoring the calibration Ensure the calibration program and procedures are reviewed and approved by the Quality Assurance Department

Only a few equipment's have been listed below for illustration

Equipment	Parameters
Defibrillators	- Electrical Safety tests - Biphasic energy measurement - ECG, performance and arrhythmia simulation

	- Charge and discharge time test - Waveform simulation
Pulse Oxymeter	- Electrical safety tests - O2 Saturation - Heart rate - Pulse amplitude - Selectable pigmentation and ambient light condition
Infusion pump	- Electrical safety tests - Flow rate - Occlusion alarm tests - Pressure
Patient Simulators	- Electrical safety tests - ECG - Blood pressure - Cardiac Output - Respiration - Temperature - Pacemaker recognition
Ventilators	- Tidal Volume - Inspiratory Peak flow - Inspiratory peak pressure - Peep pressure - Minute volume - I/E ratio - Oxygen level - Inspiratory hold
Fetal monitor	- Electrical safety tests - Fetal ECG - Maternal ECG - Uterine activity - TOCO simulation

Table 5 Calibrating parameter of medical equipment

Self-check 5	Matching

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

A	B
1. Pulse Ox meter	A. Uterine activity
2. Fetal monitor	B. Respiration
3. MECHANICAL Ventilators	C. Flow rate
4. Defibrillators	D. Inspiratory hold
5. Infusion pump	E. O2 Saturation
6. Patient Simulators test	F. Charge and discharge time

Note: **Satisfactory rating – 6 points** **Unsatisfactory – 6 points**

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

Answer Sheet

Name: _____ Date: _____

Score = _____

Rating: _____

Information Sheet-6 Responding unplanned events or conditions.

6.1 Worker accident

A worker accident has the potential to interact with communities as it may result in harm, injury, or death to workers. All workers will be properly trained in practices to prevent workplace accidents including Workplace Hazardous Materials Information System (WHMIS), first aid, and other applicable training programs. These procedures are designed to prevent serious injury to staff and the general public as well as to minimize the occurrence of unplanned events and minimize any potential damage to the environment.

Interactions between a worker accident and communities will be mitigated by compliance with health and safety legislation, safety by design, and implementation of environmental management measures aimed at protecting human health. Safety risks to workers will be reduced by complying with the requirements of various governing standards including the federal Canada Labour Code, the federal Transportation of Dangerous Goods Act.

Workplace Health and Safety Act and all associated regulations. Adherence to public safety codes and regulations will help the Project to be carried out in a safe manner to protect workers and the public.

With the application of, and compliance with, these acts, regulations, and standards, including the application of safety and security measures that are known to effectively mitigate the potential environmental effects, the potential environmental effects of a worker accident on communities during construction and operation and maintenance of the Project are assessed as minor.

6.2 Fire

A fire at the Project location could interact with the atmospheric environment (smoke emissions), infrastructure and services (stress on services) communities (potential safety risks to workers), land use and property (potential for substantive loss or damage

to property of resources), and the aquatic, wildlife and natural vegetation environments (potential contamination with sediment-laden water used in extinguishing the fire).

A fire may arise from Project heavy equipment or from natural causes such as a lightning strike. In the unlikely event that a fire occurred, the immediate concern for a fire would be for human health and safety. Local air quality conditions may deteriorate through the duration of the fire.

Personnel will take the necessary precautions to prevent fire hazards when at the work site and will keep the site free of all flammable waste. Manitoba Hydro will ensure that personnel are trained in the use of fire-extinguishing equipment. In the unlikely event of a fire, local emergency response will be able to reduce the severity and extent of damage.

The emissions from a fire would likely consist mainly of smoke (particulate matter) and CO2 but could also include CO, NO2, SO2, and other products of incomplete combustion. A large fire could create particulate matter levels greater than the ambient air quality standard over distances of several kilometers, but such situations would be of short duration, infrequent, and are not expected to occur because of planned mitigation and prevention measures. The potential residual environmental effects of a fire are therefore assessed as minor.

6.3 Electrical Hazardous

Safety measurements are not limited to your residential places you have to keep these parameters sustain in your office area too. Various electric appliances are being used already in your place where printers, monitors, and other electronic applications are plugged into the non-efficient power cord. This kind of practice can be dangerous. Multiple numbers of employees need to have the proper training to prevent their self and fellows. Numerous accidents are taken place due to faulty equipment or some of the material which is missing. In this blog, I am going to let you know how to keep your workplace safe from severe kind of electrical hazards suggested by Electrical Safety Foundation International. Let’s have a look

Power Cord should be of High quality:

Power cord which is being considered to utilize must be of some renown brand, should be of high quality. Purchase your product from reputable retailer

Installation place:

You need to install power strips in such location where air passage should be at best to scatter heat because too much heat may cause short circuits in wiring that's why this is suggested to keep away from the heating area.

Avoid overloading in outlets:

Usually, you may have seen in your workplace where high voltage appliances are plugged into one outlet, so it is suggested to avoid too much overloading

Inspect Electrical cords:

It better to keep an eye on electrical wires they shouldn't be cracked or damaged so check electrical cords once in a month.

Avoid binding and knotting cables:

You need to avoid binding and knotting the wires because it may produce electric shocks which would be a hazard for your workplace.

Unused appliances need to be unplugged:

Unused electrical items need to be unplugged until for further use. Because it will increase the electricity consumption

Avoid maintaining by yourself:

You don't need to support this thing by yourself because it can be dangerous for you and it may produce electrical shocks. So you can have the assistance of Electricians Barrow in Furness or nearby areas who know all the safety measurements very well, and they will keep on guiding your employees for do's and don'ts.

Licensed electricians:

You need to hire licensed electricians who should have proper information and qualification before playing with wires.

Don’t route power cords under the carpets:

This is not suggested to install power cords under the rugs. Because employees are rolling the chairs here and there for work purpose and when chairs roll over them it would be risky for your employees.

Disconnect electrical equipment:

If there are electrical equipment is malfunctioning, and you feel terrible smell then disconnect all the electrical equipment which is plugged into a socket on urgent basis.

These are all the essential safety parameters which you should follow because you are spending probably 7–8 hours daily and some avoidance will put your life at risk. On the other hand, you must ensure your electrics PAT testing from Barrow in Furness for your life safety. Major incidents are figured out due to such dodging acts from the organization, and they take these measurements for granted. So keep your workplace risk free at any cost.

Self-Check -6	Written Test

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

Say True or False for the following question

1. A fire at the Project location could interact with the atmospheric environment.
2. If there are electrical equipment is malfunctioning, and you feel terrible smell then allow all the electrical equipment which is plugged into a socket on urgent basis.
3. Power cord which is being considered to utilize must be of some renown brand, should be of high quality.
4. Prevent workplace accidents including Workplace Hazardous Materials Information System (WHMIS), first aid, and other applicable training programs.
5. Worker accidents may occur during either construction or operation, and may result in harm, injury, or death to one or more Project workers;

Note: **Satisfactory rating – 5 points** **Unsatisfactory - below 5 points**

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

Answer Sheet

Name: _____ Date: _____

Score = _____

Rating: _____

OPERATION SHEET #2	LEARNING GUIDE #44
Operation title	Calibrating oxygen test for anesthesia machine
Operation number	#02
purpose	Performing calibration of oxygen sensor for check quality of oxygen
Equipment, tools and materials	Electrical safety analysers Oxygen sensor Oxygen cylinder Hose
Conditions or situations for the operations	Dry room and clean environment. Concert room ,well organized biomedical workshop, Room temperature
Procedures	1. Put on gloves, masks 2. Inspect tools are available and functional. Report any problems to the instructor. 3. Inspect specifications for tools with correct standard. 4. Arrange all calibrating tools accordingly 5. Check for • No Missing parts; • 6.Perform calibration 6. .close APL vale 7. .change ventilation mode to bag mode 8. .open oxygen sensor and exposed to atmosphere for few minute 9. return oxygen sensor to normal position 10. deliver high pressure of oxygen by using oxygen flush and wait for few minute
Precautions	Make Sure no physical damage on the equipment

	Wear Safety Glasses and Protective Clothing Always Test First
Quality criteria	All equipment should return the standard value given on tools manual(refer service manual of equipment)

LAP TEST NO 2

1. Calibrate 21 percent calibration?
2. Calibrate 100 percent calibration

LG #45	LO #4.**Inspect and test configured and calibrated biomedical equipment**
Instruction Sheet	

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

- Inspecting configured and calibrated devices for accurateness
- Undertaking final inspections
- Checking biomedical equipment to ensure safe operation
- Preparing report

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

- Inspect configured and calibrated devices for accurateness
- Undertake final inspections
- Check biomedical equipment to ensure safe operation
- Prepare report

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below 3 to 4
3. Read the information written in the information “Sheet 1, Sheet 2,”sheet 3, sheet 4.
4. Accomplish the “Self-check 1, Self-check 2, Self-check 3, and Self-check 4 in page 92, 96, 99, 102 respectively.
5.

Information Sheet-1 Inspecting configured and calibrated devices for accurateness

1.1 Inspect biomedical equipment

All calibration records must be retained as per document retention procedures which should include;

1. “As found” measurements, results of adjustments and appropriate review & approval of all results
2. Tolerance or limit for each calibration point
3. Identification of standard or test instrument used
4. Identification of persons performing the work and checking the results with dates

1.2 After Calibration

Review must ensure the approved activities have been completed and all results have passed the established acceptance criteria

Actions to be taken if machines are out of calibration (e.g. contact appropriate service people, label and remove from service)

Record all calibration & maintenance activities

Periodic review of historic calibration & maintenance data to evaluate appropriateness of established frequencies

Testing and calibration of equipment ensures accuracy, effectiveness and long life of equipment's, which ultimately enables one to achieve the highest degree of quality control Extremely important in achieving quality control of the highest standard in medical equipment Is done with the help of specialized testing and calibrating equipment. Should be done at least once a year Can be done as per a range of national and international standards

including – IEC606.1, EN60601.1, EN60601.2.4, EN61010, VDE0751, MDADB9801, HE 95, ANSI/AAMI and more.

It Can be done for almost the entire range of medical equipment's – including Defibrillators, Pulse Oximetry, Infusion pumps , Patient Simulators, ventilators , Fetal Monitors, Patient monitors etc. Should be carried out by trained engineers. Should be concluded by documenting the test results and issuing a calibration report.

SELF CHECK 1	TRUE/FALSE

1. All calibration records must be retained as per document retention procedures

2. Review must ensure the approved activities have been completed and all results have passed the established acceptance criteria
3. Testing and calibration of equipment ensures accuracy, effectiveness and long life of equipment's,
4. calibration is done for almost few of medical equipment’s

Note: **Satisfactory rating 4 point** **Unsatisfactory - below 4 points**

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

Answer Sheet

Name: _____ Date----------

Score = _____
Rating: _____

Information Sheet-2 Undertake final inspections

2.1 inspections

The initial test for a new piece of equipment prior to the use in patient care is called the Inspection. This inspection serves to ensure the equipment passes all performance and safety requirements prior to use. This is typically the most rigorous test performed of all inspections. A test form should be used to document test results. Incoming inspections should be done on all medical equipment, regardless of whether owned, rented, leased, loaned, or on demonstration equipment. Each device should be evaluated per the Device Inclusion Worksheet to determine the inventory classification. All medical equipment determined to be on a management program needs to receive a performance and safety test prior to patient use. Working with clinical staff is required to ensure all medical equipment receives an incoming inspection, including demo equipment brought in by vendors. If the equipment passes the inspection, the device should be entered into the hospital's inventory. Inspection labels, warranty labels, and battery labels are also placed on the device when appropriate. The equipment can now be placed into service. If the device does not pass the inspection, it is not placed into service and the deficiencies are noted. Many devices receiving an incoming inspection are covered under warranty. In this case, the vendor should be contacted to either exchange or repair the equipment. The equipment should not be placed into service until it can successfully pass the incoming inspection.

2.2 Vendor Safety Certification Form

Medical equipment often is provided to facilities for use as loaners, demonstration, rental or lease. It is sometimes not possible for the hospital or its biomedical equipment agent to adequately test these devices before they are used clinically. As a prerequisite to patient use of devices that cannot be fully tested by the hospital, the hospital requires the vendor to provide a certification that the device(s) is/are safe for use at the facility for a specific period of time or under specific circumstances of use.

Clinical Use Prohibited Without This Certification

Hospital:_____

Department:_____

Manager: _____Date: _____

Device Description: _____

Vendor: _____

Contact: _____

Serial Numbers of All Devices:_____

Intended Use of the Device: _____

Dates of Use: Start: _____ Stop: _____

Vendor completes this part:

_____This vendor certifies this device is provided to the facility in safe and useable condition, and is FDA approved for the intended clinical procedure(s). This vendor has or will test the device for proper function prior to clinical use, but after arrival at the facility. Training will be provided to staff on safe use and potential risks.

_____This device is an investigational device for which FDA approval does not exist as of yet. The device will not be used clinically until all hospital investigational review board approval is received.

Training will be provided on safe use and potential risks.

_____This equipment is provided repeatedly to the hospital and is maintained by the vendor. It is checked between assignments to different facilities, and records of maintenance are provided

Annually to the facility. Ongoing performance and safety testing is provided, and the vendor certifies that the device is safe for use as provided at delivery.

_____ Non-hospital employees who will be delivering and/or operating the equipment are appropriately trained and qualified to be transporting, setting up, and operating the equipment.

Note any special conditions:

_____

_____

Vendor Signature: _____Date: _____

Facility Signature: _____ Date: _____

Self-check -2	Checking biomedical equipment to ensure safe operation

1. The initial test for a new piece of equipment prior to the use in patient care is called---------

   A. calibration

   B. testing

   C. commissioning

   D. inspection

2. Medical equipment often is provided to facilities for use as

   A. loaners

   B. demonstration,

   C. Rental or lease.

   D. All

3. Many devices receiving an incoming inspection are covered under.

   A. warranty

   B. license

   C. maintenance

   D. all

4. The equipment should not be placed into service until it can successfully pass the incoming inspection

   A. true

   B. false

Note: **Satisfactory rating – 4 points** **Unsatisfactory - below 4 points**

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

Answer Sheet

Name: _____ **Date ----------**

Score = _____

Rating: _____

Information Sheet-3 Checking biomedical equipment to ensure safe operation

3.1 medical equipment safety

A hazard is any biological, chemical, mechanical, environmental or physical agent that is reasonably likely to cause harm or damage to humans, other organisms, or the environment in the absence of its control. Most hazards are dormant or potential, with only a theoretical risk of harm; however, once a hazard becomes "active", it can create an emergency. A hazardous situation that has come to pass is called an incident. Hazard and possibility interact together to create risk

Following use on a patient or when requiring inspection or service, all medical devices must be checked for visible evidence of contamination by the user/clinician; however, as contamination is not always visible, all equipment must be cleaned following patient use. Every attempt must be made by the user to adequately decontaminate the equipment prior to transfer for repair or servicing. If it is not possible to decontaminate, then the equipment must be safely contained and clearly identified as ‘contaminated’ until advice is obtained from the Infection Prevention and Control Team and the Medical Electronics Department.

3.2 Considerations for Safety Analysis

- Time required to obtain results
- Ways and means for getting the information to subcontractors
- Format and degree of detail of end result of data
- Type of information needed before performing the study
- Time frame for the study (review, update, submission, and completion)

3.3 Safety Analysis Tools

- Techniques and Methods
- Preliminary Hazard Analysis (PHA)
- First analysis preformed

- Identify critical areas, safety design criteria, and evaluate hazards
- Operating Hazards Analysis (OHA)
- Focuses on hazards from the task by the operating system as the device is stored, transported, or used.
- Provide a basis for operations safety, warnings, and emergency procedures.

Self-check -3	Short answer

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

1. List Considerations for Safety Analysis
2. List Safety Analysis Tools

Answer the following question!

Note: **Satisfactory rating – 8 points** **Unsatisfactory - below 8 points**

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

Answer Sheet

Name: _____date

Score = _____

Rating: _____

Information Sheet-4 Preparing report

4.1 Documentation

There must be two copies of the instructions manual and a service manual with the equipment. Instructions manual should be with the equipment, and the other filed with the person responsible in department of the health unit. Service Manual must be obtained for each equipment, in order to provide technical information needed by the clinical engineer for maintenance. This should be a mandatory item in the technical specifications during procurement of equipment as well. IEC 60601-1 determines that all equipment must be accompanied by a description of technique, supplied by the manufacturer

Sample Report Format

Defibrillator Report Format

MANUFACTURER: _____MODEL: _____
SERIAL NO: _____ TEST CARRIED ON: _____
Reference Equipment's Used:

Electrical Safety Analyzer & Defibrillator Analyzer Equipment details

Equipments Details	Model/Make/ Serial No.	Calibration Valid till
Electrical Safety Analyzer		
Defibrillator Analyzer		

DEFIBRILLATOR CALIBRATION PARAMETERS				
S. No.	Quantity Measured	Range/Frequency	CMC(±)	Remarks
	Heart Rate Accuracy	±5%		
	Output Accuracy	±15%		
	Output Accuracy Multiple	±15%		
	Output Energy at Max Setting for 10 Chg cycle (Battery Power)	±15%		
	Charge time after 10 discharge cycles (Battery Power)	≤ 15 sec		
	Energy after 60 sec of full charge	≥ 85%		
	Synchronizer Operation	≤ 60 msec		
	Pacer Output Accuracy	±10%		
	Pacer Rate Accuracy	±5%		

**Defibrillator performance for 'Verify units on battery' is verified for its operational integrity.*

Figure 9 documentation format

Self-check -4	True/false

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

1. There must be two copies of the instructions manual and a service manual with the equipment.

2. Service Manual must be obtained for all equipment,

3. IEC 60601-1 determines that all equipment must be accompanied by a description of technique, supplied by the suppliers

Note: **Satisfactory rating – 6 points** **Unsatisfactory - below 6 points**

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

Answer Sheet

Name: _____ Date: _____

Score = _____

Rating: _____

Reference

1. https://www.wrla.org/sites/wrla_01/files/health_and_safety_manual_sample.pdf

2. https://www.hse.gov.uk/toolbox/ppe.htm
3. https://www.pdfdrive.com/biomedical-instrumentation-e38621649.html
4. The Global Harmonization Task Force: www.ghtf.org
5. https://www.who.int/medical_devices/publications/en/MD_Regulations.pdf
6. “Ethiopian Building Code Standard, ELECTRICAL INSTALLATION OF BUILDINGS; EBCS-10 1995.
7. https://24x7mag.com/maintenance-strategies/alternative-equipment-maintenance/prevailing-attitudes/troubleshooting-medical-equipment/
8. https://www.who.int/management/organize_maintenance_healthcare.pdf
9. https://www.einfochips.com/blog/implementing-medical-device-testing-strategies-a-high-level-overview/
10. http://qi.nhsrcindia.org/sites/default/files/Testing%20%26%20Calibration%20of%20Bio%20Medical%20Equipment.pdf
11. http://qi.nhsrcindia.org/sites/default/files/Testing%20%26%20Calibration%20of%20Bio%20Medical%20Equipment.pdf
12. https://apps.who.int/iris/bitstream/handle/10665/44587/9789241501538_eng.pdf?sequence=1
13. https://www.who.int/management/organize_maintenance_healthcare.pdf

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This TTLM is developed from respective EOS by: ⬇⬇⬇

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ANSWER SHEET OF ALL LEARNING GUIDE (**LG42 – LG45)**

Key to Corrections (for Learning Guides)

Learning Guide #42
Answers for self-check 1 1. TRUE 2. FALSE 3. FALSE 4. FALSE 5. TRUE **Answers for self-check 2** 1. C 2. D 3. A 4. B 5. E **Answers for self-check 3** 1. B 2. A 3. D 4. D 5. A **Answers for self-check 4**

Reference	Title
EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects. Good clinical practice.
EN ISO 10993-XX	Biological evaluation of medical devices. Evaluation and testing within a risk management process

Answers for self-check 5

1. **B**
2. **D**
3. **D**

Answers for self-check 6

1. Electrical safety analysers
2. Patient monitor testers (simulators
3. Defibrillator / AED / pacemaker analysers
4. Infusion device analysers
5. Electrosurgical
6. Pressure / flow meters l unit testers

Learning Guide 43

Answers for self-check 1

1. TRUE
2. TRUE
3. FALSE
4. FALSE
5. TRUE

Answers for self-check 2

Rule 1) Look at the Device/Procedure/Process

Rule 2) Listen, Listen, and Listen

Rule 3) Smell

Rule 4) the Application of the Device/Procedure/Process

Answers for self-check 3

1. TRUE
2. FALSE
3. TRUE
4. TRUE
5. FALSE

Answers for self-check 4

1. **D**
2. **D**
3. **B**

Answers for self-check 5

1. TRUE
2. TRUE
3. TRUE
4. TRUE
5. TRUE

Learning Guide #44

Answers for self-check 1

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

Answers for self-check 2

1. D
2. C
3. D

Answers for self-check 3

1. serial number
2. model number
3. location
4. power input
5. uses
6. type

Answers for self-check 4

1. D

2.

1. Have knowledge of principle of operation of equipment
2. • Know equipment history from the user and maintenance records
3. • Use service manuals, test equipment and correct tools
4. • Use correct trouble-shooting techniques (see further on)
5. • Perform root cause analysis
6. • Record equipment details in workshop receiving book. Note date, serial number etc.

Answers for self-check 5

1. E
2. A
3. D
4. F
5. C
6. B

Answers for self-check 6

1. TRUE
2. TRUE
3. TRUE
4. TRUE
5. TRUE

Learning Guide #45

Answers for self-check 1

1. TRUE
2. TRUE
3. TRUE
4. FALSE

Answers for self-check 2

1. D
2. D
3. B
4. B

Answers for self-check 3

1.

A. Time required to obtain results

B. Ways and means for getting the information to subcontractors

C. Format and degree of detail of end result of data

D. Type of information needed before performing the study

E. Time frame for the study (review, update, submission, and completion)

2.

- Techniques and Methods
- Preliminary Hazard Analysis (PHA)
- First analysis preformed
- Identify critical areas, safety design criteria, and evaluate hazards
- Operating Hazards Analysis (OHA)
- Focuses on hazards from the task by the operating system as the device is stored, transported, or used.
- Provide a basis for operations safety, warnings, and emergency procedures.

Answers for self-check 4

1. TRUE
2. TRUE
3. TRUE