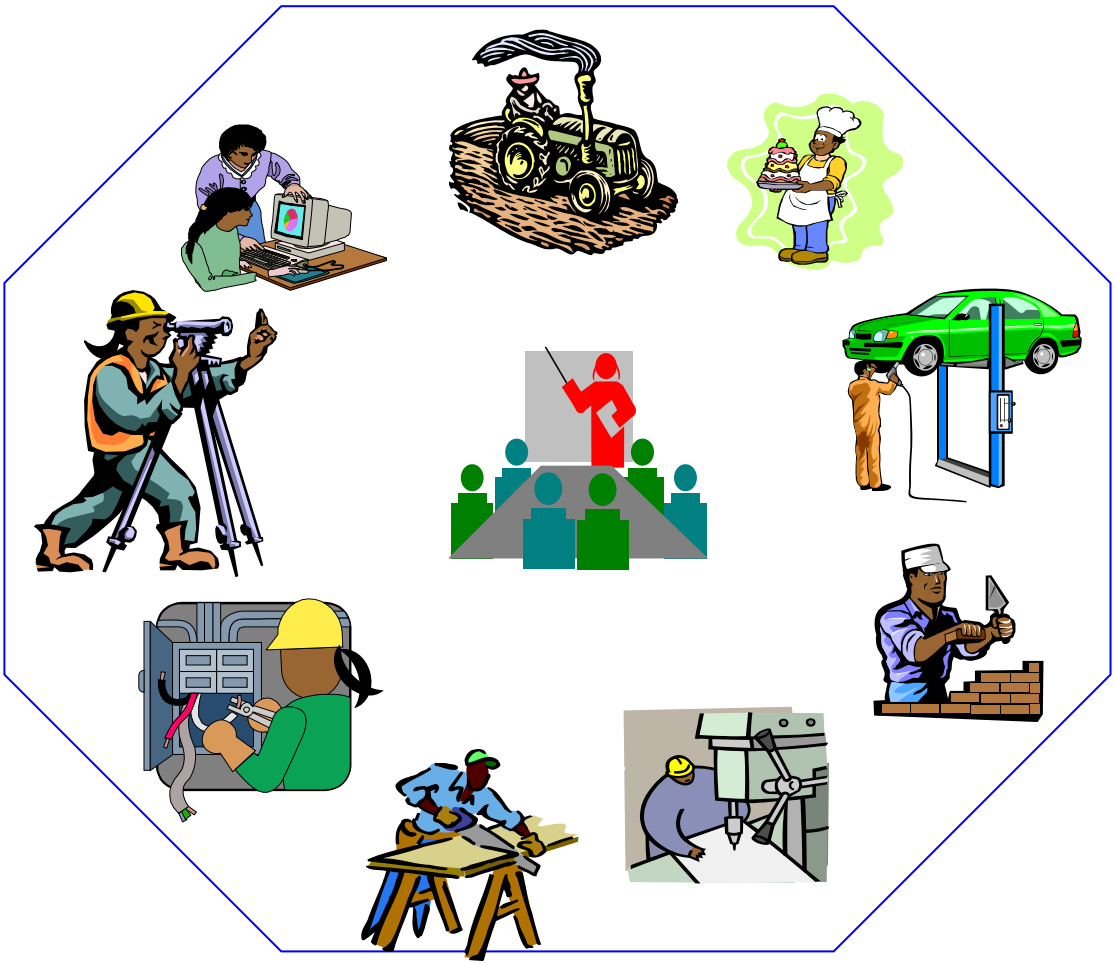
INTERMEDIATE BIOMEDICAL EQUIPMENT SERVICING- LIII

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



Module Title: Provide Technical Support in Equipment Acquisition

LG Code: EEL BES3 M03 LO (1-3) LG (13-15)

TTLM Code: EEL BES3 TTLM 0221v1

Feb 2021

Bishoftu, Ethiopia

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L #13	LO #1- Tracking technological development

Instruction sheet

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

- Assessing available technologies accessible sources
- Appropriate technology is selecting based on requirement
- Analyzing and recommend selected technology

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

- Assess available technologies accessible sources
- Appropriate technology is selected based on requirement
- Analyze and recommend selected technology

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
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Information Sheet 1- Assess available technologies accessible sources

Assess available technologies accessible sources

People Tracking Technologies generate actionable insights to increase conversation rates and profits of physical locations. Regardless of how you track people, the location position and time-based data quantify the In-Store Customer's Journey in retail stores, shopping malls, airports, stadiums, and smart cities.

To put it simply: By tracking people's behaviors in your physical location, you build a data-driven decision process and get more conversions, sales, and profits from the assets you already have.

People Tracking Technologies quantify human behaviors by location, time, and activity. The tracking solution can be interactive or anonymous. It could track objects, devices, or any "things" to capture the behaviors of a real person. The complexity of the tracking system depends on location positioning, recognition attributes, and precision parameters.

Trends in Tracking Technology

As a decision-maker, you should evaluate the tracking technology in context to your company's technical infrastructure, analytics skills, and market positioning.

Before diving deeper into the tracking technologies, you should ask –

- Is your intent marketing to customers or manage the store?
- How do the people tracking data fit the client's policies?
- Which Edge Sensors or Corporate/Cloud-Based Processing?

The advanced technologies expanded the ability to quantify behaviors beyond location and time. It includes facial sentiments, body motions such as gestures, and customer engagement with products. To sift between hype and value, evaluate the people tracking data by the quantity of training, the quality of the errors, and your business goals.

Most importantly, taken together, the massive shift to Cloud, 5G, and Internet of Things ecosystems has sped up the ability of retailers, malls, and other physical hubs to better track, understand and manage people in real life.

Guidelines and Standards

- **Web Content Accessibility Guidelines 2.1 (WCAG)**
  This is the latest version of the definitive web accessibility guidelines from the World Wide Web Consortium (W3C)
- **Web Content Accessibility Guidelines 2.0**
  This is the previous version of WCAG, updated in June 2018. WCAG 2.0 Level AA is still the standard supported by Washington State Policy #188 and the UW IT Accessibility Guidelines.
- **Accessible Rich Internet Applications (ARIA)**
  ARIA is a W3C specification that provides a way to make dynamic web applications and advanced user interface controls more accessible to people with disabilities.
- **WAI-ARIA Authoring Practices**
  This is an essential resource for anyone developing websites or web applications. It provides standard design patterns for dozens of common web widgets such as accordions, dialogs, and menus.

Browsers' Built-in Accessibility Tools

Modern versions of major browsers have their own accessibility tools built into their developer tools. For more information, see the documentation for the tools available in your preferred browser.

- **Chrome DevTools** Accessibility Reference.
- **Firefox Accessibility** Inspector
- **Microsoft Edge DevTools:** Accessibility

Third Party Accessibility Checkers & Browser Extensions

The following tools are listed alphabetically.

- **Accessibility Book mark lets**

  This suite of book mark lets can be used in any browser and work by visually highlighting specific accessibility features within a web page, including ARIA landmarks, headings, lists, and accessibility-related features of images and forms.
- **Accessibility Insights**

  This robust accessibility checker and educational tool from Microsoft is available as an extension for Chrome or Edge, or as downloadable software for checking Windows applications.
- **A Inspector WCAG Firefox Extension**

  This extension was developed from the same team at the University of Illinois who created the Functional Accessibility Evaluator (FAE), listed below.
- **axe**

  This accessibility testing toolkit from Deque (accessibility consultancy) is available as an API that can be integrated into automated testing processes for web development. It's also available as the axe Chrome Extension and axe for Android App.
- **Functional Accessibility Evaluator (FAE)**

  This is an online web accessibility evaluator from the University of Illinois. FAE is capable of crawling a website and providing a summary report, plus reports for each individual page.
- **Site improve Browser Extension**

  Site improve is a tool licensed by the UW for providing automated accessibility and quality assurance checking of university websites. For more information, see Site improve at UW. The Chrome browser extension can be used by anyone, with or without a Site improve account. (Note the Firefox version has been removed.)
- **WAVE**

  Developed by WebAIM, this online tool evaluates the accessibility of a web page and shows results using icons and indicators, embedded onto the original page.

It's available as a standalone website, or as the WAVE browser extension for both Chrome and Firefox.

- **Web Developer Extension for Firefox or Chrome**.
  This highly useful toolbar from Chris Pederick is packed with features, including many that help check web pages for accessibility features.

Mobile Development

- **Accessibility for Apple Developers**
  Apple's site includes a variety of resources for iOS developers.
- **Accessibility for Android Developers**
  includes a variety of resources that help developers to use the Android framework to make applications more accessible.

Assistive Technologies

When testing web pages and IT products with assistive technologies, it is important to be aware that no two assistive technology (AT) products are alike. Developers are cautioned to use these tools only as an approximate gauge of accessibility. What seems to work perfectly in Product A may be inaccessible in Product B. Therefore, developers should resist the tendency to develop sites and applications that work with a particular AT product, and focus instead on developing sites that comply with standards.

Some assistive technology vendors provide demo versions of their products, some of which can be used indefinitely but time-out after a few minutes of operation. Product licenses vary as to whether using these demo versions is permissible for testing and development purposes. For information about available products and license restrictions, contact the Access Technology Center.

Also, all major desktop operating systems are bundled with basic assistive technology utilities. For more information about these utilities in Windows and Mac OS X consult the Microsoft Accessibility and Apple Accessibility websites respectively.

In addition, the following assistive technologies can be useful for testing web pages.

- **NVDA**

  NVDA (“Non-Visual Desktop Access”) is a free, open source screen reader for Windows. WebAIM publishes a handy guide on Using NVDA to Evaluate Web Accessibility.
- **Voice Over**

  Voice Over is Apple’s screen reader, which ships with Mac OS and iOS devices such as the iPhone and iPad. WebAIM publishes a handy guide on Using Voice Over to Evaluate Web Accessibility.
- **JAWS (not free)**

  Although not free, JAWS has been the most popular screen reader for many years (though is now being challenged by NVDA according to the most recent WebAIM Screen Reader User Survey). WebAIM also publishes a handy guide on Using JAWS to Evaluate Web Accessibility.

Web and IT Accessibility Resources from DO-IT

The DO-IT Center (Disabilities, Opportunities, Internetworking, and Technology) at the UW has worked tirelessly since 1991 to increase the participation of individuals with disabilities in challenging academic programs and careers. In doing so DO-IT has developed a number of resources related to IT accessibility, including the resources listed below.

- **30 Web Accessibility Tips**

  Practical tips based on common web accessibility issues encountered in higher education, developed as part of the Access Computing project, with funding from the National Science Foundation.
- **Accessible Technology**

  A collection of publications and videos on various aspects of assistive and accessible technology.

Self-Check -1	Written Test

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

PART I: Chose the correct answer (10point)

1. Which one of the following is not people behaviors technologies track development:
   A. Vision B. Facial Recognition C. Facial Demographics D. All E. None
2. People Tracking Technologies quantify human behaviors by
   A. Location B. Time C. Activity D. All
3. The complexity of the tracking system NOT depends on
   A. location positioning B. Time c. recognition attributes, d. precision parameters.
4. (WCAG) This is the latest version of the definitive web accessibility guidelines from the World Wide Web Consortium.
   A. (WCAG) B. WCAG 2.0 C. (ARIA) D. All
5. ARIA is a W3C specification that provides a way to make dynamic web applications and advanced user interface controls more accessible to people with disabilities.

   A. (WCAG) B. WCAG 2.0 C. (ARIA) D. All

PART I: Fill in the blank

1. List down the assistive technologies that can be useful for testing web pages(3pts)

   _____, _____, _____

   _____, _____, _____

   _____, _____, _____

2. List down the Browsers' Built-in Accessibility Tools **(2pts)**

   _____, _____, _____

   _____, _____, _____

Answer the following question!

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

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

Answer Sheet

Score = _____

Rating: _____

Information Sheet -2. Appropriate technology is selected based on requirement

Appropriate technology is selected based on requirement

Appropriate technology is defined as any object, process, ideas, or practice that enhances human fulfillment through satisfaction of human needs. A technology is deemed to be appropriate when it is compatible with local, cultural, and economic conditions (i.e., the human, material and cultural resources of the economy), and utilizes locally available materials and energy resources, with tools and processes maintained and operationally controlled by the local population.

Appropriate technology represents the social and cultural diversions of innovation. The essence of appropriate technology is that the usefulness or value of a technology must be consolidated by the social, cultural, economic, and political milieu in which it is to be used. Most of the groups working in the developing countries tend to view appropriate technology as the main tool in meeting the basic needs of hundreds of millions of people who have been largely left out of the development process.

MEDICAL TECHNOLOGY

Advancements in medical technology have allowed physicians to better diagnose and treat their patients since the beginning of the professional practice of medicine. Thanks to the continuous development of technology in the medical field, countless lives have been saved and the overall quality of life continues to improve over time

Medicine and Technology

In today's world, technology plays an important role in every industry as well as in our personal lives. Out of all of the industries that technology plays a crucial role in, healthcare is definitely one of the most important. This merger is responsible for improving and saving countless lives all around the world.

Medical technology is a broad field where innovation plays a crucial role in sustaining health. Areas like biotechnology, pharmaceuticals, information technology, the

development of medical devices and equipment, and more have all made significant contributions to improving the health of people all around the world. From “small” innovations like adhesive bandages and ankle braces, to larger, more complex technologies like MRI machines, artificial organs, and robotic prosthetic limbs, technology has undoubtedly made an incredible impact on medicine.

In the healthcare industry, the dependence on medical technology cannot be overstated, and as a result of the development of these brilliant innovations, healthcare practitioners can continue to find ways to improve their practice – from better diagnosis, surgical procedures, and improved patient care.

Information Technology and Medicine

Information technology has made significant contributions to our world, namely in the medical industry. With the increased use of electronic medical records (EMR), telehealth services, and mobile technologies like tablets and smart phones, physicians and patients are both seeing the benefits that these new medical technologies are bringing.

Medical technology has evolved from introducing doctors to new equipment to use inside private practices and hospitals to connecting patients and doctors thousands of miles away through telecommunications. It is not uncommon in today’s world for patients to hold video conferences with physicians to save time and money normally spent on traveling to another geographic location or send health information instantaneously to any specialist or doctor in the world.

With more and more hospitals and practices using medical technology like mobile devices on the job, physicians can now have access to any type of information they need – from drug information, research and studies, patient history or records, and more – within mere seconds. And, with the ability to effortlessly carry these mobile devices around with them throughout the day, they are never far from the information they need. Applications that aid in identifying potential health threats and examining digital information like x-rays and CT scans also contribute to the benefits that information technology brings to medicine.

Medical Equipment Technology

Improving quality of life is one of the main benefits of integrating new innovations into medicine. Medical technologies like minimally-invasive surgeries, better monitoring systems, and more comfortable scanning equipment are allowing patients to spend less time in recovery and more time enjoying a healthy life.

The integration of medical equipment technology and telehealth has also created robotic surgeries, where in some cases, physicians do not even need to be in the operating room with a patient when the surgery is performed. Instead, surgeons can operate out of their “home base”, and patients can have the procedure done in a hospital or clinic close their own hometown, eliminating the hassles and stress of health-related travel. With other robotic surgeries, the surgeon is still in the room, operating the robotic devices, but the technology allows for a minimally-invasive procedure that leaves patients with less scarring and significantly less recovery time.

Technology and Medical Research

Medical scientists and physicians are constantly conducting research and testing new procedures to help prevent, diagnose, and cure diseases as well as developing new drugs and medicines that can lessen symptoms or treat ailments.

Through the use of technology in medical research, scientists have been able to examine diseases on a cellular level and produce antibodies against them. These vaccines against life-threatening diseases like malaria, polio, MMR, and more prevent the spread of disease and save thousands of lives all around the globe. In fact, the World Health Organization estimates that vaccines save about 3 million lives per year, and prevent millions of others from contracting deadly viruses and diseases.

Self-Check -2	Written Test

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

PART I: Chose the correct answer (10pts)

1. A technology is deemed to be appropriate when it is
   A. compatible with local, cultural C. economic conditions
   B. Utilizes locally available materials and energy resources D. All
2. Appropriateness requires an optimum match between
   A. Availability of resources B. Local needs C. Applicable technology, D. All
3. Appropriate technology innovations are invariably introduced in practice within an organizational context is
   A. Money B. People C. Institutions, and equipment. D. All
4. ____ is the process by which people change a negative situation to an improved one
   A. Technology B. Innovations C. Development D. None
5. For an appropriate technology solution to work is not required.
   A. It addresses an identified and analyzed problem.
   B. It is technically sound.
   C. It is appropriate to the prevailing physical conditions.
   D. All
   E. None

. Answer the following question!

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

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

Answer Sheet

Score = _____
Rating: _____

Name: _____ Date: _____

Short Answer Question

Information Sheet 3. Analyze and recommend selected technology

Analyze and recommend selected technology

Computerized Maintenance Management Systems (CMMS)

The process of tracking medical equipment has become a more efficient process due to the implementation of computerized maintenance management systems (CMMS). A CMMS is a computer program that allows the biomed department to track each piece of equipment. Upon incoming inspection each piece of equipment is entered into the database.

The following information is recommended to be included in the database:

1. Hospital Equipment ID: Unique series of alphanumeric characters assigned to a piece of equipment.
2. Equipment Description: Device Type
3. Manufacturer
4. Model
5. Serial Number
6. Assigned Technician: Primary service provider (BMET or vendor)
7. Scheduled Maintenance information: interval, due date, procedure (each piece of equipment is to have a sticker showing PM information: last PM performed date, next PM due date, and tech identification)
8. Department Account: name and account code of owning department
9. Location: current location of the equipment (department or room if applicable)
10. Risk Category
11. Device Category: current status of equipment (active, inactive, storage, etc).
12. Vendor: provider of equipment and/or service if applicable
13. Purchase Order Number: Original PO# for purchase of equipment
14. Purchase Cost
15. Installation Date: date entered into service
16. Warranty Start and End Dates

The unique hospital identification is a sticker with the hospital name and an identification number. This sticker allows the equipment to be seen as a hospital asset and helps allow biomed to locate and verify equipment within the CMMS. Once the equipment is properly added to the database, biomed can track PM schedules and repairs. With each equipment work order the biomed techs can document all necessary information into the CMMS, such as parts used, performance verified that may include recorded information, and electrical safety information.

CMMS databases are very beneficial when reporting to agencies such as **Joint Commission (JC)**. It is not uncommon for JC to request equipment history when surveying hospitals. A CMMS database allows for quick and easy access to all equipment information.

Having a CMMS is also extremely helpful when dealing with recalls. Most recalls are issued by the FDA and are easily accessed using **ECRI (Emergency Care Research Institute)**. Usually hospital staff that serve on the safety committee are member of the ECRI alert system, which is an online database. When new alerts or recalls are issued, ECRI will send out notifications that can be tracked on their website. Upon receiving a recall notice a properly maintained CMMS will make dealing with the recall very easy. Usually when a recall is issued the manufacturer, model, and list of serial numbers are included in the notice. Most CMMS systems will have equipment search options that will allow a user to input manufacturer, model, and serial number information. This will help directly pinpoint if the facility has any equipment affected by the recall without having to go and search for the equipment piece by piece.

A great asset to any hospital is a real time location system, also known as a RTLS. A RTLS can be very useful by providing real-time location of equipment. These systems can use radio frequency, ultrasound, or WiFi. The main setup of a RTLS system requires tags attached to equipment, antennas, and computer software. There are several companies that offer a form of this technology. Some systems may only give a general area in which the equipment is located.

Other systems can give accurate pinpoint locations and may also record other information such as temperatures. Temperature tracking is very useful for blanket and fluid warmers, also for laboratory freezers and refrigerators. Tracking temperatures of

these devices is required for regulatory compliance, and an RTLS system with this capability simplifies the process.

The idea of RTLS is to locate assets when needed either by clinical staff for patient use or biomed looking for equipment in need of preventative maintenance. This is the component that helps biomed departments ensure regulatory compliance. RTLS can prevent hospitals from purchasing or renting unneeded equipment by preventing loss of equipment. These location systems can be very expensive but can prove to be cost effective. Many RTLS systems are for more than just tracking equipment. They can also track patient flow and employee locations. With the addition of these features a RTLS system can be extremely effective in increasing productivity in all areas of the hospital.

Many equipment asset ID tags have barcodes on them that would allow a biomed to scan the equipment with a PDA (personal data assistant) and update various equipment profiles in real-time from any location. Some biomed departments are encompassing the technology of the Apple iPad and other wireless devices. With wifi and 3G, 4G, or LTE service, biomed can access the CMMS and even view service manuals for equipment. Randy Berlin, biomed manager at Southeast Alaska regional Health, has implemented iPads. He says, “We bought four iPads for less than the cost of two new laptops, and we have put a ton of PDF service manuals on the iPad”

Having access to service manuals out on the hospital floor will save time from having to return to the biomed shop and search for a manual creating a more efficient environment. Also this can possibly eliminate the need to remove the equipment from service allowing the tech to perform a simple repair on site significantly decreasing downtime. Tablet devices would also allow techs to search for phone numbers and equipment service contract information. Biomeds, by nature, are usually tech savvy allowing them to use emerging technology as a very effective time and resource management tool. Wireless tablet technologies will create an overall more efficient environment. Techs will no longer have to generate PM reports from their personal computers, print them out, keep up with clipboards, then enter all the data at a later time. With a tablet the tech will be able to open and close work orders in real time on the floor that will reduce if not eliminate paperwork that will greatly improve the efficiency of the technicians.

A CMMS can also be a very effective management tool allowing reports to be generated on PM completion rates, repair history, alert and recall history, equipment uptime, equipment turnaround time, and technician time use. CMMS systems can also help track trends and mean time before failure reports that will help mangers identify potential problems and create management strategies.

Self-Check 3	Written Test

Directions: Answer all the questions listed below.

PART I: Say true false

1. The process of tracking medical equipment has become a more efficient process due to the implementation of computerized maintenance management systems.
2. Once the equipment is properly added to the database, biomed can track PM schedules and repairs
3. RTLS can be very useful by providing real-time location of equipment

. Answer the following question!

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

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

. Prepare equipment and **material for** biomedical equipment specification

LG #14	LO #2- Prepare biomedical equipment specifications

Instruction sheet

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

- Identifying required information and specifications from:
- Studying and analyzing gathered data based on the approved requirement
- Determining capacity and working system
- Preparing equipment specifications

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

- Identify required information and specifications from:
- Study and analyze gathered data based on the approved requirement
- Determine capacity and working system
- Prepare equipment specifications

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Information Sheet- 1. Identifying required information and specifications.

Identifying required information and specifications

The development of a medical device, like any product, begins by defining the market. A company believes that they have an idea for a product that will solve a particular problem, for example providing a diagnostic or therapeutic treatment. The FDA requires that you show that the new device is safe and effective for its intended use.

The purpose of the product requirements document (PRD) or product spec is to clearly and unambiguously articulate the product's purpose, features, functionality, and behavior. Careful writing of the requirements can aid in a more rapid approval process. When writing the PRD and System requirements, each requirement should be testable and measurable

Another source of product and system level requirements is through the Risk Management process. When performing a System Risk Analysis or a FMEA, the mitigation to potential hazards or failure modes will become a requirement for the system. In turn, the mitigation requirements will be verified to prove their effectiveness at reducing the probability of occurrence.

Marketing Requirements Document (MRD)

This is an overview of Market Need, usually from the marketing perspective. It covers these things:

- **Market Need** - At an overview level why is your product needed?
- **Target User** - Who will use your product?
- **Target Purchaser** - Who will buy your product?

Product Requirements Document (PRD)

The PRD should clearly specify all product level requirements including:

- Functionality
- Usability
- User Interface System Interface
- Environmental
- Manufacturing

- Serviceability and Support
- Alarm and Annunciators
- Cleaning and Sterilization
- Performance
- Physical
- Reliability
- Security
- Quality
- Regulatory
- Safety
- Calibration
- Packaging
- Disposable
- Compatibility
- Internationalization and Globalization
- Price and Cost

For full example of a PRD see the PRD template at http://bit.ly/PRDtemplateGoogleDoc. Additionally, for products that are complex a system specification (Sys RS) further decomposes and allocates requirements into

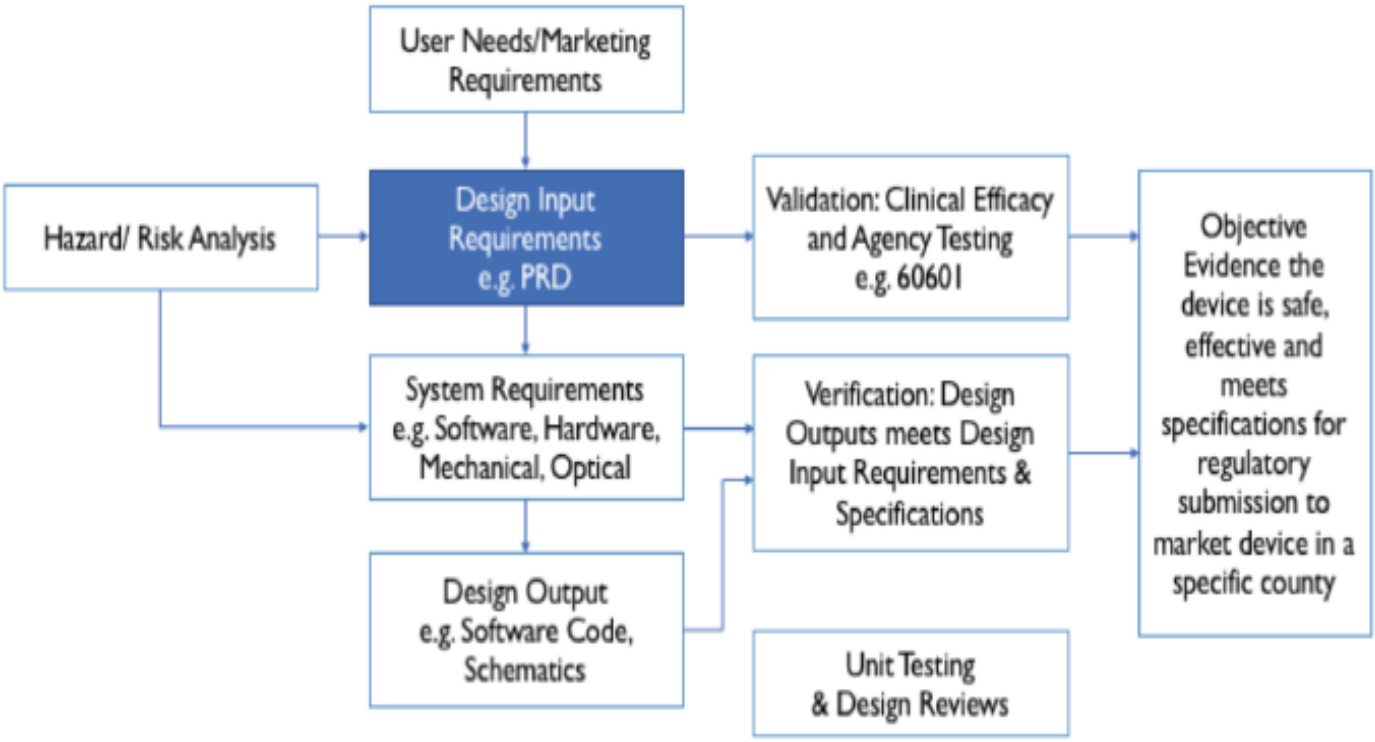
Additionally, for products that are complex a system specification (Sys RS) further decomposes and allocates requirements into subsystems such as mechanical, hardware, and software. For software only or software-intensive medical devices, a separate Software Requirement Specification (SRS) may be required to fully specify the device's operation.

Verifiable

The PRD and system requirements are used for two important processes. First you must prove the product meets the needs of your customer that is the product stands up to your marketing, clinical and regulatory claims. This is referred to as **validation**.

It is typically done with clinical testing, such as animal tests. Second, your regulatory submission must show that the product was designed correctly. To prove this, it is good practice to assign high-level product requirements to sub-systems through requirement decomposition and allocation, and verify each subsystem design meets their respective

requirement. This is referred to as **verification**. It is done by testing every requirement in the lab. This is why specifying requirements must be done carefully. If you cannot test a requirement, you cannot verify its implementation is correct. If you have too many or conflicting requirements, the verification test will be hard (expensive) to do. Verification and Validation are often referred to as V&V. The diagram below illustrates the workflow.



Requirements for Verification and Validation diagram

Best Practices for Developing and Writing Requirements

All requirements must be testable and can fail when testing in a predictable way to prove implementation is correct.

- Make sure each requirement is complete. A requirement can reference other requirements if there are dependencies.
- Avoid duplicate requirements
- Avoid contradictory requirements
- It is preferred to write the requirement statement in positive terms. It is easier to prove a system can do something or has a characteristic than to prove it can't or doesn't.

- Use your cross-functional team to review requirements for testability. They will help you identify conflicting requirements within your documentation.

Requirements should be quantifiable and repeatable. Try to avoid qualitative requirements that add subjective decision making during implementation and verification.

Self-Check 1	Written Test

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

PART I: Say true or false (10pts)

1. Product Requirements Document should clearly specify all product level requirements including not functionality
2. All requirements must be testable and can fail when testing in a predictable way to prove implementation is correct avoid duplicate requirements
3. Product Requirements Document should clearly specify all product level requirements including environmental
4. Development of a medical device, like any product, begins by defining the market.
5. Product and system level requirements are through the Risk Management process.

. Answer the following question!

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

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

Score = _____
Rating: _____

Answer Sheet

Name: _____ Date: _____

Information Sheet- 2. Study and analyze gathered data based on the approved requirement

Study and analyze gathered data based on the approved requirement

In a developing country the doctors are busy with the patient workload and cannot spare time to develop generic specifications for purchasing medical equipment. Substantial time is wasted in framing individual specifications. The cycle from making an in dent to forming a committee and the vetting of the specification by experts is long.

Equipment specifications can also compromise on health and safety standards since biomedical engineers are either not available or are not involved in the process of framing specifications. This has given rise to serious problems like baby incubators catching fire since electrical safety checks were not complied with. In addition, the quality of procured equipment will be sub-standard if the specification is not thorough.

These difficulties cause the procurement cycle to be substantially delayed. Also, if the specifications are not generic there is the potential for litigation from the bidders and the bid may fail as a result. This severely affects the progress of healthcare programmes and patients will suffer.

Involvement of Empowered Procurement Wing (EPW)

The Empowered Procurement Wing then substantially revised the compendium of specifications with the following terms of reference:

1. Review the specifications and make them generic.
2. Make a uniform format for the specifications and incorporate all health and safety requirements, engineering inputs, environmental issues like electromagnetic compliance, all the documentations required, power supply requirements and warranty and post warranty commitments including after sales service.
3. Involve biomedical engineers as well as teams of doctors to bring the compendium up to international standards.
4. Make this a dynamic, web-based system and involve IT Consultants to link to the Procurement Management Information System (PROMIS)
5. To incorporate UMDNS (Universal Medical Device Nomenclature System, ECRI Institute, Plymouth Meeting, USA) nomenclature and coding. To also examine

the feasibility of incorporating the UNSPSC (United Nations Standard Products and Services Code, www.unspsc.org) coding system.

6. To coordinate funding from DFID for assisting with manpower and resources required.

Template for specifications

Biomedical engineers from Empowered Procurement Wing (EPW) and Fishtail Consulting (Marshfield, UK) finalized the template to be used for every specification. It was based on a published format, was modified several times and finally is as given below:

1. **Description of the function**. In this block a brief function of the equipment is provided.
2. **Operational Requirements**. In this block a brief description of the operational requirement is given, like portability, microprocessor controlled system etc.
3. **Technical Specifications**. Generic technical specifications were filled up in this block. This is the major section, with all the parameters like dimensions and technical requirements.
4. **System configuration and accessories**. Under this block all the accessories along with the quantities required are filled up. This will enable the equipment to be supplied with all the accessories in suitable quantities so as not to miss any important items which are required to make the equipment fully functional.
5. **Environmental Conditions**. In this block the operating requirements as well as storage conditions with respect to temperature and humidity conditions are specified. Also the electromagnetic compliance (EMC) ratings wherever required is added.
6. **Power Supply**. Under this block the requirement of power source was specified, like 220V single phase supply or battery operation etc. Also specified is any requirement of voltage stabilizer and UPS or battery backup etc.
7. **Standards, Safety and Training**. Under this block international standards like FDA approval, CE marking or Bureau of Indian Standard markings are specified. Also specified are requirements for electrical safety and for critical devices such as ventilators as per standards of the International Electro technical Commission and ISO. Also specified are end user training requirements for effective usage of

the equipment. Comprehensive warranty and annual maintenance contracts can also form a part of this block, although the tender documents will normally spell these out in more detail.

8. **Documentation**. Under this block, requirements such as inspection and calibration certificates, operating and service/ maintenance manuals, spare parts list, list of available service equipment required for preventive and corrective maintenance, log book etc are specified.

Resources

Funding for the project, including subscriptions to the material detailed below, was provided by the Department for International Development, UK. This included a team of local consultant biomedical engineers, procurement experts and IT specialists based in the Empowered Procurement Wing of the Ministry. An external consultant biomedical engineer was also contracted

Self-Check 2	Written Test

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

PART I: Chose the correct answer

1. _____ is block a brief function of the equipment is provided.
   A. Operational requirements B. Description C. Specifications D. None
2. _____is block a brief description of the operational requirement is given, like portability, microprocessor controlled system etc.
   A. Operational requirements B. Description C. Specifications D. None
3. _____is the major section, with all the parameters like dimensions and technical requirements.
   A, Operation B. Description C. Technical Specifications D. All
4. _____is block the operating requirements as well as storage conditions with respect to temperature and humidity conditions are specified.
   A, Operation B. Description C. Specifications D. Environmental Conditions
5. _____is any requirement of voltage stabilizer and UPS or battery backup etc.
   A, Power Supply B. Description C. Specifications D. Environmental Conditions

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

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

Answer Sheet

Score = _____

Rating: _____

Information Sheet -3. Determine capacity and working system

Determine capacity and working system

Medical devices are essential for safe and effective prevention, diagnosis, treatment and rehabilitation of illness and disease.

The WHO Department of Essential Medicines and Health Products (EMP), particularly the Diagnostic Imaging and Medical Devices Unit (DIM), aims to ensure improved access, quality and use of safe and appropriate medical devices. Specifically, it requests that the secretariat, WHO, “establish and update regularly an evidence and web-based health technology database to serve as a clearing house which will provide guidance on appropriate medical devices according to level of care, setting, environment, and intended health intervention, tailored to the specific needs of the country or region.

One of the important elements of this health technology database is the Technical Specifications (TS) for medical devices. Technical specifications are required for the procurement and acquisition process of medical devices.

Technical specifications:

1. Technical specifications should be tailored appropriately by users according to the specific situation, especially: Local standards and legislation; local regulations and conditions; languages; installation conditions, technological levels, electrical range, capacities, utility environment, clinical procedures, personnel (users) experience and other local specific conditions.
2. Technical characteristics of WHO technical specifications indicate basic, appropriate, standard equipment for low- and middle- income countries. If you are interested in purchasing more advanced equipment, you should consider optional functions depending on your needs.
3. The number of accessories, consumables, spare parts and other components indicates usual and/or ideal number and is not a mandatory quantity. The user can determine this quantity according to a product’s characteristics and frequency of use in your hospital.

4. For tender purposes, you should consider not only medical equipment itself, but also related services in order to be able to use the equipment.
5. for services associated with purchasing medical equipment.

Complements

1. **Who are the TS (Technical specifications) intended for?**

   Technical health workers in a hospital such as biomedical engineers, hospital managers, planning officers, procurement officers, and other health related stakeholders such as ministry of health, regulators, manufacturers, NGOs, and UN agencies

2. **How to use WHO technical specifications (WHO TS**)?

   For tendering, procurement, and purchasing of medical equipment, you can search for appropriate equipment according to “technical characteristics, physical characteristics, utility requirement, warranty and maintenance, documentation” of WHO TS.

The different requirements for good technical specifications depending on the levels of health care are summarized below.

Table: The different requirements for good technical specification

User	Required from technical specifications	How to increase usability?
Planner	Guide on options available	Fit well with intervention Simplicity of access Different levels of technology
Medical staff	Understandable Guide as to what is appropriate	Simple language Local names Searchable Linked with intervention Different levels of technology
Biomedical engineer	Reference for internal TS development	Simple to cross reference with other formats Clear, consistent format
Procurement department	Reference use for bids Adaptable for local use	Not too many options to choose Simple contents
Maintainer of database	Easy to keep up	Manageable quantity of devices Simple, relational database
Industry	Benchmarking of products Marketing	Open access Facility to comment and object

The different requirements for good technical specifications depending on the levels of health care are summarized below.

In cooperation with international experts in the field and experts from other UN organizations, WHO has developed

a medical device technical specifications template (as seen in above) that can be downloaded by interested parties and serve as a guideline in acquisition processes. The topics to be filled-out on the template are the following:

- Name, category, and coding
- Purpose of use
- Technical characteristics
- Physical/chemical characteristics
- Utility requirements
- Accessories, consumables, spare parts, other components
- Packaging
- Environmental requirements
- Training, installation, and utilization
- Warranty and maintenance

Self-Check .3	Written Test

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

Say true or false

1. Important elements of health technology database are the technical specification for medical devices.
2. Technical specifications are not required for the procurement and acquisition process of medical devices.
3. “Medical devices are essential for safe and effective prevention, diagnosis, treatment and rehabilitation of illness and disease
4. Technical specifications should not be tailored appropriately by users according to the specific situation, especially local standards and legislation;
5. Technical specifications should be tailored appropriately by users according to the specific situation, especially local regulations and conditions.

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

Answer Sheet

Answer Sheet

Score = _____

Rating: _____

Information Sheet 4. Prepare equipment specifications

Prepare equipment specifications

This section should demonstrate the Bidder's responsiveness to the specification by identifying the specific components proposed, addressing the requirements, as specified, point by point; providing a detailed description of the essential performance characteristics proposed; and demonstrating how the proposed bid meets or exceeds the specifications.

- **Scope of Supply**: Please provide a detailed description of the goods to be supplied, indicating clearly how they comply with the technical specifications required by the ITB (see below table); describe how the organization/firm will supply the goods and any related services, keeping in mind the appropriateness to local conditions and project environment.

- **Technical Quality Assurance Mechanisms:** The bid shall also include details of the Bidder's internal technical and quality assurance review mechanisms, all the appropriate quality certificates, export licenses and other documents attesting to the superiority of the quality of the goods and technologies to be supplied.
- **Reporting and Monitoring:** Please provide a brief description of the mechanisms proposed for this project for reporting to the UNDP and partners, including a reporting schedule.
- **Subcontracting:** Explain whether any work would be subcontracted, to whom, how much percentage of the work, the rationale for such, and the roles of the proposed sub-contractors. Special attention should be given to providing a clear picture of the role of each entity and how everyone will function as a team.
- **Risks / Mitigation Measures:** Please describe the potential risks for the implementation of this given to providing a clear picture of the role of each entity and how everyone will function as a team. Letters of commitment from partners and an indication of whether some or all have successfully worked together on other previous projects is encouraged.

- **Anti-Corruption Strategy (Optional):** Define the anti-corruption strategy that will be applied in this project to prevent the misuse of funds. Describe the financial controls that will be put in place.
- **Statement of Full Disclosure:** This is intended to disclose any potential conflict in accordance with the definition of “conflict” under Section 4 of this document, if any.
- **Other:** Any other comments or information regarding the bid and its implementation. project that may impact achievement and timely completion of expected results as well as their quality. Describe measures that will be put in place to mitigate these risks.
- **Implementation Timelines:** The Bidder shall submit a Gantt Chart or Project Schedule indicating the detailed sequence of activities that will be undertaken and their corresponding timing.
- **Partnerships (Optional):** Explain any partnerships with local, international or other organizations that are planned for the implementation of the project. Special attention should be

Format of WHO technical specification

Medical devices specification

(Including information on the following where relevant/appropriate, but not limited to)

		Instructions and examples
I	*Version No.*	(Rows i - v and 1 are completed and managed by WHO)
Ii	*Date of initial version*	
Iii	*Date of last modification*	
Iv	*Date of publication*	
V	*Completed / submitted by*	Usually name of Institution / Organization / UN agency
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	
2	Generic name	Name of the medical device as commonly used (e.g. anaesthesia machine).

3	Specific type or variation (optional)	Characteristics of the device that distinguish it from other similar devices or devices of the same generic name (e.g. handheld, bench-top, portable, digita adult/paediatric/neonatal, consumable/disposable, single-use, etc.)
4	GMDN name	Name as produced and maintained by the Global Medical Devices Nomenclature (GMDN) Agency, e.g. *Anaesthesia unit, mobile*. (NB: Access to GMDN Agency nomenclature system may be restricted - see http://www.gmdnagency.com/ for further information).
5	GMDN code	Comments as for [9]; GMDN code for 'Anaesthesia unit, mobile' is *47769* (all GMDN device codes have 5 digits)
6	GMDN category	Comments as for [9]; GMDN category for 'Anaesthesia unit, mobile' is '*02 Anaesthetic and respiratory devices*'.
7	UMDNS name	Name as produced and maintained by the ECRI institute, e.g. *Anaesthesia Units* (NB: Access to ECRI nomenclature system may be restricted - see https://www.ecri.org/Products/Pages/UMDNS.aspx for further information).
8	UMDNS code	Comments as for [12]; ECRI code for 'Anaesthesia Units' is *10134* (all ECRI device codes have 5 digits).
9	UNSPSC code (optional)	United Nations Standard Products and Services Code [see http://www.unspsc.org/]. This coding system uses a hierarchy of Family-Class-Commodity. For an anaesthesia unit, which comprises a number of functional modules, there are a number of corresponding Commodity codes and titles listed under more than Class; e.g. **Commodities** *42272501* '*Gas anaesthesia apparatus*' and *42272502* '*Absorber units for gas anaesthesia apparatus*' are included under **Class** *42272500* '*Anaesthesia apparatus and accessories and supplies*' in the **Family** *42270000 'Respiratory and anaesthesia and resuscitation products*'.
10	Alternative name/s (optional)	Name/s set by a regional or national authority, local names (e.g. Boyle's machine) or synonyms of formal nomenclature (e.g. anaesthesia apparatus or system).

11	Alternative code/s (optional)	Corresponding code/s set by a regional or national authority.
12	Keywords (optional)	Specific area / disease related to the device (e.g. anaesthesia, intra-operative care, etc.).
13	GMDN/UMDNS definition (optional)	Definitions produced and maintained by the GMDN Agency and ECRI Institute, respectively.
PURPOSE OF USE		
14	Clinical or other purpose	A description of the essential clinical or other objective/s associated with the device's utilisation, e.g. anaesthesia units (allow the anaesthetist to) dispense a mixture of gases and vapours and vary the proportions thereof to control a patient's level of consciousness and/or analgesia during surgical procedures.
15	Level of use (if relevant)	The level of healthcare service delivery at which the device is to be used, or is typically used. [NB: Since the level of skill/s required of the device user/s should also be considered, and the levels of service delivery are not globally standardised, this level may vary from country to country.] Home use should also be considered as a level of care. For our example, the anaesthesia unit would typically be used at district, regional and tertiary hospitals.
16	Clinical department/ward (if relevant)	The usual service area / functional department in which the device would be used, e.g. Operating room, Intensive Care Unit, Paediatric ward, Outpatient department). Home use should also be considered as a level of care.
17	Overview of functional requirements	General description of the device's function, e.g. for anaesthesia unit this would include gas/vapour delivery platform; ventilator with patient breathing circuit; scavenging system to capture and exhaust waste

		gases; physiological and multi-gas monitors, etc.
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	The required characteristics and specific/critical functional requirements. e.g. modules, components, measured and/or delivered parameters and associated values and ranges, compatibility / inter-operability requirements, etc.
19	Display parameters (if relevant)	User interface information requirements (e.g. display of pressure, volume, flow, status indicators, inspiration and expiration times, etc.) and format (continuous waveform display, digital, trends, etc.).
20	User adjustable settings (if relevant)	Device functional parameters, alarms, language, etc. that should be adjustable at the discretion of the user/s.

Self-Check 4	Written Test

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

Say true or false

1. The bid shall NOT include details of the Bidder's internal technical and quality assurance review mechanisms,
2. Please provide a brief description of the mechanisms proposed for this project for reporting to the UNDP and partners, including a reporting schedule.
3. Special attention should NOT be given to providing a clear picture of the role of each entity and how everyone will function as a team.
4. Anti-corruption strategy that will be applied in project to prevent the misuse of funds.
5. Bidder shall submit Project Schedule indicating the detailed sequence of activities that will be undertaken and their corresponding timing.

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

Answer Sheet

Answer Sheet

Score = _____

Rating: _____

Operation title: - Preparing Technical Specifications of Electrocardiograph 3 channels

Purpose	To acquire the trainees with Preparing biomedical equipment *Technical Specifications and Standards*
Equipment ,tools and materials	Materials and equipment needed or useful for *Technical Specifications* include these: • Marketing Requirements Document • Product Requirements Document • Verifiable • Computer • Soft ware application • Internet
Conditions or situations for the operations	• All tools, equipment's and materials should be available on time when required.
Procedures	1. Define the Document's Purpose. ... 2. Identify the Scope. ... 3. Provide a Software Overview. ... 4. Outline the Infrastructure Requirements. ... 5. Define the Functional Requirements. ... 6. Define the Non-functional Requirements. ... 7. Provide any References and Appendices
Precautions	Preparing materials, tools and equipment are according to inseminator command.
Quality criteria	Did trainees the Standards Biomedical devices Technical Specifications

LAP Test	Practical Demonstration

Name: _____ **Date:** _____

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

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

Task 1. Preparing Technical Specifications of Anesthesia machine

2. Request your teacher for evaluation and feedback

LG #15	LO3. Evaluating technical document of bids

Instruction sheet

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

- Acquiring technical proposals of the bid
- Evaluating and compare specifications against declared requirements
- Identifying correct and best offer based on approved criteria
- Documenting and submitting report of evaluation and recommendations

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

- Acquire technical proposals of the bid
- Evaluate and compare specifications against declared requirements
- Identify correct and best offer based on approved criteria
- Document and submit report of evaluation and recommendations

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets
7. Perform “the Learning activity performance test” which is placed following “Operation sheets” ,
8. If your performance is satisfactory proceed to the next learning guide,
9. If your performance is unsatisfactory, see your trainer for further instructions or go back to “Operation sheets”.

Information Sheet -1. Acquire technical proposals of the bid

Acquire technical proposals of the bid

Definition

- **"Bid"** refers to the Bidder's response to the Invitation to Bid, including the Bid Submission Form, Technical Bid and Price Schedule and all other documentation attached thereto as required by the ITB.
- **"Bidder"** refers to any legal entity that may submit, or has submitted, a Bid for the supply of goods and provision of related services requested by UNDP.
- **"Contract"** refers to the legal instrument that will be signed by and between the UNDP and the successful Bidder, all the attached documents thereto, including the General Terms and Conditions (GTC) and the Appendices.
- **"Country"** refers to the country indicated in the Data Sheet.
- **"Data Sheet"** refers to such part of the Instructions to Bidders used to reflect conditions of the tendering process that are specific for the requirements of the ITB.
- **"Day"** refers to calendar day.
- **"Goods"** refer to any tangible product, commodity, article, material, wares, equipment, assets or merchandise that UNDP requires under this ITB.
- **"Government"** refers to the Government of the country where the goods and related services provided/rendered specified under the Contract will be delivered or undertaken.
- **"Instructions to Bidders"** refers to the complete set of documents which provides Bidders with all information needed and procedures to be followed in the course of preparing their Bid
- **"ITB"** refers to the Invitation to Bid consisting of instructions and references prepared by UNDP for purposes of selecting the best supplier or service provider to fulfill the requirement indicated in the Schedule of Requirements and Technical Specifications.

- **"LOI"** (Section 1 of the ITB) refers to the Letter of Invitation sent by UNDP to Bidders.
- **"Material Deviation"** refers to any contents or characteristics of the bid that is significantly different from an essential aspect or requirement of the ITB, and

I. substantially alters the scope and quality of the requirements;
II. limits the rights of UNDP and/or the obligations of the offer or; and
III. adversely impacts the fairness and principles of the procurement process, such as those that compromise the competitive position of other offerors.

- **"Schedule of Requirements and Technical Specifications***"* refers to the document included in which lists the goods required by UNDP, their specifications, the related services, activities, tasks to be performed, and other information pertinent to UNDP's receipt and acceptance

Technical Specification for Medical Devices

In countries there is a significant need for counseling regarding minimum specifications and requirements that should be considered before starting a process of purchase or donation of medical devices. Having this type of specification allows improving access to medical devices of high quality, safety and efficacy, as well as planning adequately the financial, infrastructure and human resources, among others, to be considered in the implementation, functioning and decommissioning of the devices. WHO technical specification (TS) for medical devices can provide guidelines in procurement and acquisition process of medical devices.

Request for Technical Proposal (RTP)

A Request for Technical Proposal (RTP) is a solicitation document used in two-step sealed bid. Normally in letter form, it asks only for technical information; price and cost breakdowns are forbidden.

The request must include, as a minimum, the following:

- A description of the supplies or services required.
- A statement of intent to use the two-step method.
- The requirements of the technical proposal.
- The evaluation criteria, to include all factors and any significant sub factors.

A statement that: the technical proposals shall not include prices or pricing information.

The date, or date and hour, by which the proposal must be received

A statement that:

- In the second step, only bids based upon technical proposals determined to be acceptable, either initially or as a result of discussions, will be considered for awards, and,
- Each bid in the second step must be based on the bidder's own technical proposals.

A statement that:

- Offer or's should submit proposals that are acceptable without additional explanation or information,
- The Government may make a final determination regarding a proposal's acceptability solely on the basis of the proposal as submitted; and
- The Government may proceed with the second step without requesting further information from any offer or; however, the Government may request additional information from offer or's of proposals that it considers reasonably susceptible of being made acceptable, and may discuss proposals with their offer or's.

A statement that: a notice of unacceptability will be forwarded to the offer or upon completion of the proposal evaluation and final determination of unacceptability.

A statement either that only one technical proposal may be submitted by each offer or or that multiple technical proposals may be submitted. When specifications permit different technical approaches, it is generally in the Government's interest to authorize multiple proposals.

Self-Check 1	Written Test

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

Part 1: Chose the correct answer

1. A Request for Technical Proposal must include, as a minimum, is:
   A. A description of the supplies or services required.
   B. A statement of intent to use the two-step method.
   C. The requirements of the technical proposal.
   D. All
2. _____ refers to any legal entity that may submit, or has submitted, a Bid for the supply of goods and provision of related services requested by UNDP.
   A. Goods B, Country C. Bidder D. Bid
3. _____ refers to the legal instrument that will be signed by and between the UNDP and the successful Bidder.
   A. Goods B, Contract C. Bidder D. Bid
4. _____ refers to such part of the Instructions to Bidders used to reflect conditions of the tendering process that are specific for the requirements of the ITB.
   A. Goods B. Contract C. Bidder D. Data Sheet

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

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

Answer Sheet

Score = _____

Rating: _____

Information Sheet-2. Evaluate and compare specifications against declared Requirements

Bid Evaluation

Bid evaluation is the organized process of examining and comparing bids to select the best offer in an effort to acquire goods, works and services necessary to achieve the goals of an organization. The best offer recommended as a result of bid evaluation is referred to as the lowest responsive evaluated bid.

Bid evaluation is the responsibility of a body known as the Bid Evaluation Panel. How this panel is called depends on the organization. Synonymous terms are quotation review panel, bid review board or tender review committee, to name a few. Most procurement Legal and Regulatory Frameworks require it to be an ad-hoc body with at least three members knowledgeable in Procurement, with technical expertise in the specific item being procured and a representative of the user entity. Prior to evaluation of bids, the evaluation criteria are predefined and included in the bidding documents. The bid evaluation panel evaluates bids based on the predefined criteria only and recommends award to the lowest responsive evaluated bid.

Evaluation criteria

Evaluation criteria are the standards against which bids are evaluated. Generally, evaluation criteria can be categorized into three categories including (i) mandatory criteria, (ii) weighted criteria and (iii) weighted criteria with mandatory elements.

I. **Mandatory criteria** are used in straightforward bid evaluation methods where they are rated as pass/fail, responsive/non-responsive or comply/non-comply. They are usually used in evaluation for goods procurement, but may also be used for the procurement of services and infrastructure works. The mandatory criteria are the first criteria against which bids are evaluated in order to eliminate bids that do not conform to these requirements (UNDP, 2016).

II. **Weighted criteria** are criteria which can be measured in terms of degree of responsiveness. The scale used to measure the degree of responsiveness depends on the procurement method and category of procurement. Usually this applies to the evaluation of services.

III. **Weighted criteria with mandatory elements** are criteria that have mandatory minimum requirements defined and are measured above that minimum requirement (UNDP, 2016); for example, a requirement may be set for a consultant to be fluent in at least two international languages and a rated score may be assigned for persons with additional international language capabilities, if the additional language adds value to the requirement.

Stages of the Bid Evaluation Process

We will classify the bid evaluation process into four basic stages including (1) preliminary examination for responsiveness to formal qualification requirements, (2) evaluation for compliance with technical requirements, (3) price/financial evaluation and (4) post qualification/due diligence.

I. **Preliminary Examinations for Responsiveness to Formal Qualification Requirements:** During preliminary examination, bids are examined to ensure they are from eligible companies or countries, that the bid is submitted with all requirements, that bid securities (when required) are valid, and that tax and other legal and commercial requirements are met. All bids determined non-responsive at this stage are not considered for the next stage.

II. **Evaluation for Compliance with Technical Requirements:** At this stage, the panel evaluates for compliance with specified quality (specifications). They also look at issues such as the bidder's experience, delivery schedule, compliance with quantity specified, works schedule, after sale services, warranty and other requirements specified in the bidding documents. These are, however, not fixed but predetermined based on the particular case. Bids that do not comply with the technical requirements are not considered for price/financial evaluation. Before price evaluation, all bids that are not responsive would be listed and clear reasons recorded for their not being eligible for further evaluation.

III. **Price/Financial Evaluation:** At this stage, the panel examines the offered price for computational errors and, depending on the procurement type (goods, services or work), takes into consideration factors such as provisional sums and discounts, etc. Where bids are priced in more than one currency, all currencies are converted to a single currency for evaluation based on exchange rate from a specified

source, as stated in the bidding documents. The corrected/evaluated prices are then compared and bids ranked in order beginning with the lowest responsive evaluated bid. A price reasonableness analysis is also done to ascertain that the price of the recommended bidder is fair given the prevailing market conditions.

Post Qualification/Due Diligence: This activity applies to the lowest responsive evaluated bid. For some organizations, where prequalification of bidders was done, verification is done on the lowest responsive evaluated bidder to ascertain that such bidder still complies with the prequalification requirements. Where prequalification was not done, post qualification is done based on criteria specified in the bidding documents

Self-Check 2	Written Test

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

Part I: Fill the black space

1. _____ are criteria that have mandatory minimum requirements defined and are measured above that minimum requirement (UNDP, 2016); :(2pts)
2. _____ are used in straightforward bid evaluation methods where they are rated as pass/fail, responsive/non-responsive or comply/non-comply (2pts)
3. _____ are criteria which can be measured in terms of degree of responsiveness. (2pts)
4. _____ is the organized process of examining and comparing bids to select the best offer in an effort to acquire goods, works and services necessary to achieve the goals of an organization(2pts)
5. Mention the four basic stages the bid evaluation process classify:(5pts)

_____,_____

_____,_____

_____,_____

. Answer the following question!

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

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet -3. Identify correct and best offer based on approved criteria

A prequalification procedure

A prequalification procedure is, in principle, required for selecting potential contractors and suppliers for large scale contracts or contracts with complex and highly specialized services.

The objectives of prequalification are:

- To ensure that invitations to bid are extended only to technically and financially qualified bidders, and to prevent unqualified bidders from winning the bid as a result of superficial evaluation;
- To enable prospective bidders, who may be insufficiently qualified on their own, to avoid the expense of bidding; to give an incentive for these potential bidders to form a joint venture that may give them a better chance of success; and
- To limit the number of bidders, in advance, to a manageable size for the Procuring Entity in conducting bidding procedure and evaluation, when a large number of bidders are expected to participate..

Eligibility

In accordance with the Procurement the following describes the mandatory principles in establishing the qualifications of suppliers and contractors .Those that are considered appropriate include:

a) technical competence, financial resources, facilities, reliability, experience and reputation of product and personnel to perform the contract
b) legal capacity
c) solvency
d) fulfillment of tax and social security obligations
e) absence of criminal record
f) satisfactory past performance

Evaluation Criteria of Prequalification

The Prequalification Criteria for judging the qualifications of the applicant should be established as the minimum requirements in respect of experience, technical qualifications, financial resources, proven performance of any equipment etc in a manner which would result in a yes or no answer to whether an applicant meets

the criteria. It is desirable that the Prequalification Criteria are prepared at the same time as the Prequalification Documents are prepared. The Criteria not be changed during the Prequalification Evaluation process.

Prequalification documents should enlarge on the information provided in the notification advertisement and contain a description of:

a) the scope and description of the proposed procurement;
b) the estimated value of the contract and major quantities of work;
c) location of the work;
d) eligibility requirements including, eligibility requirements for domestic preference (if applicable);
e) procurement scheduling of goods or works to be procured;
f) abbreviated specifications and conditions of contract;
g) main quantities to be procured;
h) delivery or implementation schedules;
i) requirements for bid and performance securities;
j) the source of financing of the procurement; the contract conditions and at least the following if full contract conditions are not yet developed
k) payment terms;
l) price adjustment provisions;
m) the language and governing law of the contract;
n) other information in sufficient detail to enable bidders, suppliers or contractors to assess their interest and respond appropriately; and
o) the name and address of the PE and of the PE's official in charge of the
p) Procurement with a statement of their roles.

Evaluation Procedure

Stage-1, "Preliminary Examination", is to assess the document formality required in the Prequalification Documents, for each bidder with pass-or-fail criteria. It is necessary to confirm one by one, whether the submitted documents and its format are in conformity with the requirement.

Stage-2, "Qualification Evaluation" is to examine whether submitted documents comply with the qualification requirement by using pass-or-fail criteria. If the level of

qualification requirement is too high, it tends to limit the number of bidders, and in the reverse case it tends to allow unqualified bidders to be passed through for the bidding The evaluation work must be done by following the criteria set up beforehand, and the method must be based on absolute evaluation, not by comparative evaluation. The following items are to be noted in setting up criteria and conducting evaluation.

General Experience

- The Prequalification Documents usually indicate the minimum qualification requirements for
  - ✓ Annual turnover
  - ✓ Successful project experience of similar nature and complexity
- **Personnel Capabilities**
  - ✓ Experience of prime candidate and alternative for key management and specialist positions
- **Equipment Capabilities**
  - ✓ Type, characteristics, minimum number and availability of key equipment
- **Financial Positions**
  - ✓ Cash flow capacity Soundness of financial position
- **Litigation History**
  - ✓ Accurate information on any litigation or arbitration resulting from contracts completed or under execution

Evaluation of Joint-Venture,

Special conditions apply when the applicant for prequalification is a joint venture formed by two or more firms. It is essential that the prequalification documents state clearly the conditions applying to joint ventures, and to any change in its membership after prequalification and to subsequent bidding by the joint venture. each partner in the joint venture must submit the complete documentation required of a firm applying for individual prequalification;

a) the prequalification application must confirm that if after prequalification the applicant should submit a bid, then: that bid as well as (in case of an award) the resulting contract would be signed so as to be legally binding on all partners jointly and severally, and, a joint venture agreement providing that joint and

several liability of all partners in respect to the contract would be submitted together with the bid.

b) the application must include a description of the proposed participation and responsibilities of each partner of the joint venture for execution of the contract;

c) the application must include a statement of proposed financial contribution of each partner, • the percentage participation in the joint venture of each of its members (in terms of the corresponding value of the contract) must not exceed each member's capacity in terms of each of the qualifying criteria; and

d) the application must designate one of the partners, as the lead firm or partner in charge through whom any correspondence between the applicant and the PE will be channeled.

"Slice and Package" Contracts Evaluation

Applicant shall be prequalified for the maximum number and types of contracts for which the Applicant meets the appropriate aggregate requirements of such contracts. The applicant should be asked in the prequalification documents to indicate the specific contracts for which it wishes to be considered.

Prequalification with Conditionality

In principle, no bidder should be prequalified with conditionality.

Limiting the Number of Bidders

It is not permissible to set a limit on the number of successful Applicants prior to the evaluation of prequalification. All Applicants meeting the prequalification criteria specified shall be allowed to bid.

Prequalification Evaluation Report

The report should address each of the pass–fail criteria set in the documents. Disqualification of Applicants who fail to meet the criteria should be explained.

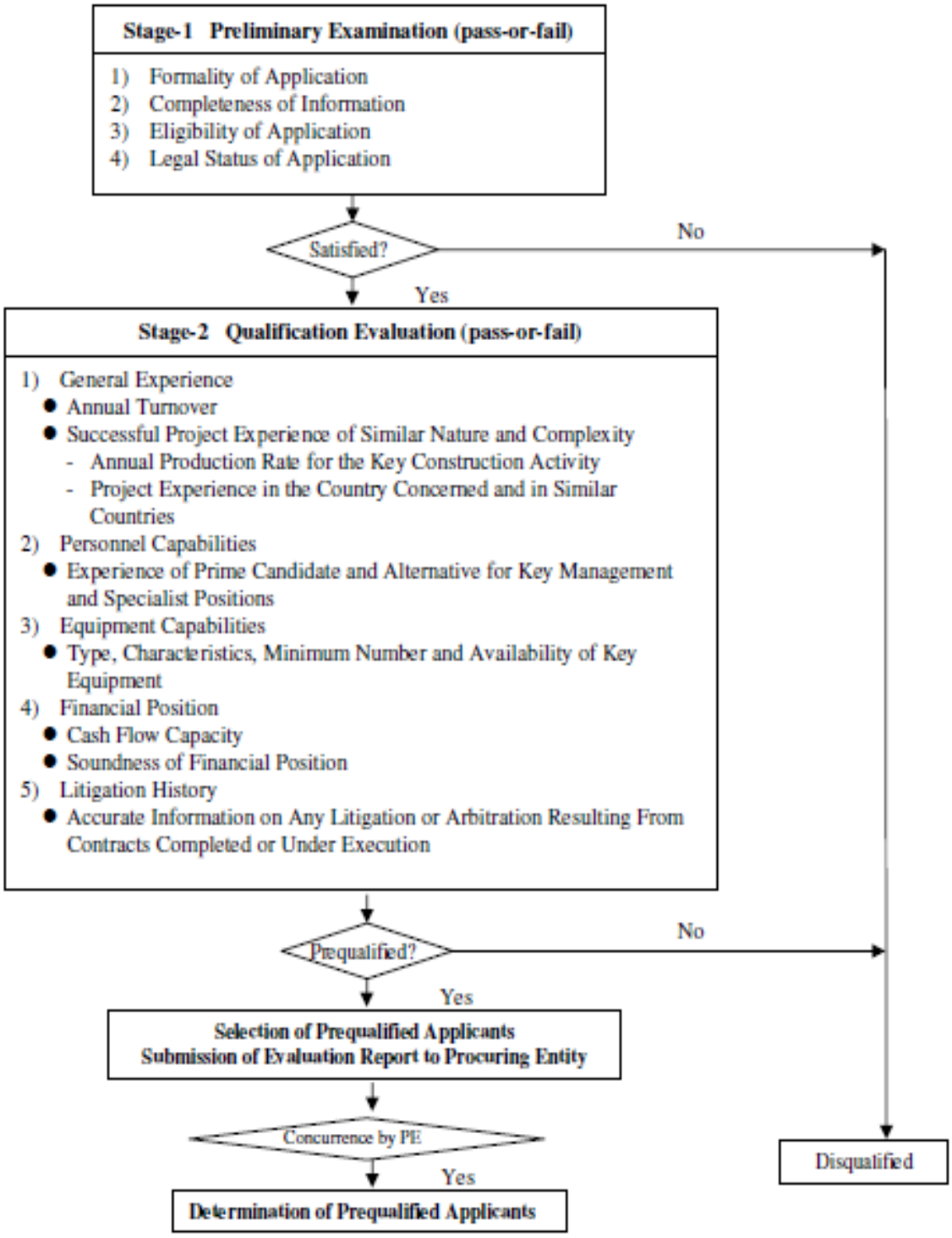
Notification to Applicants

According to the Procurement the PE shall promptly notify each supplier or contractor who participated, whether or not it has been prequalified and shall make available to any member of general public, upon request, the names of all who have been prequalified. Promptly after the notification of the results of the prequalification the PE shall invite bids from all the Applicants that have been prequalified.

Table: Example of Preliminary Examination

Bidder	Verification	Eligibility	Bid Security	Completeness of Bid	Substantial Responsiveness	Acceptance for Detailed Examination
Bidder A	Yes	Yes[1]	Yes	Yes	Yes	Yes
Bidder B	No[2]	Yes	Yes	Yes	Yes[3]	Yes
Bidder C	Yes[4]	Yes	Yes	Yes	Yes	Yes
Bidder D	Yes	Yes	No[5]	No[6]	Yes	No
Bidder E	Yes	No[7]	No[8]	Yes	Yes	No
Bidder F	Yes	Yes	Yes	Yes	Yes	Yes
Bidder G	Yes	Yes	Yes	Yes	Yes	Yes
Bidder H	Yes	Yes	Yes	Yes	Yes[9]	Yes

Prequalification Procedure for Contracts



Self-Check	Written Test

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

Say true or false

1. To enable prospective bidders, who may be insufficiently qualified on their own, to avoid the expense of bidding;
2. The objectives of prequalification are to limit the number of bidders,
3. Prequalification documents should enlarge on the information provided in the notification advertisement and contain a description of: location of the work
4. The Prequalification documents usually indicate the minimum qualification requirements for Annual turnover
5. Special conditions apply when the applicant for prequalification is a joint venture formed by only two firms.

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

Answer Sheet

Answer Sheet

Score = _____

Rating: _____

Information Sheet- 4. Document and submit report of evaluation & recommendations

Document and submit report of evaluation and recommendations

This format is intended specifically to assist in reporting the results of the evaluation of the applications for prequalification. The Evaluation Committee should evaluate the applications received in accordance with the criteria specified in the Prequalification document and prepare a detailed analysis of them. A summary report of this analysis should be submitted for review to the approving authority/ financial institution funding the contract. The summary should address each of the pass–fail criteria set in the prequalification document. Disqualification of the Applicants who fail to meet the criteria should be clearly explained.

Details of the individual evaluation of those. Applicants who were not prequalified or were conditionally prequalified should be furnished clearly with necessary additional attachments. References to pertinent clauses in the prequalification documents should be given as necessary.

The summary should make special mention of Joint Venture Applicants in regard to the completeness of their documentation, eligibility requirements including domestic bidder price preference, sharing provisions, and liability of the JV partners.

In case the prequalification evaluation includes “slice and package” requirements, the summary should mention the procedure used in the evaluation and show the aggregate total of contract value for which Applicants are considered as prequalified.

A checklist for the evaluation summary is given at the end of this document.

SAMPLE TABLE OF CONTENTS

SAMPLE FORMS

Table 1: Identification

Name of project	
Source of Financing	
Procuring Entity a) name b) address	
Contract number (identification	
Description of the Works	
Cost estimate	
Method of procurement (check one)	ICB _____ NCB _____ Other _____
Domestic preference allowed	Yes _____ No _____
Proposed contract type	Ad-measurement with BOQ _____ Lump-sum price _____ Others (please specify) _____
Co-financing, if any: a) agency name b) percent financed by agency	_____ _____

Table 2: Bid Opening Checklist

Bid Opening Checklist	
Contract Reference.	
Bid Opening Date:	
Time:	
Number of bids submitted:	
Name of Bidder:	
CHECKLIST	
Is outer envelope of bid sealed?	
Is bid form completed and signed?	
Expiration date of bid:	
Is documentary authority for signing enclosed?	
Amount of bid security (if required) (state currency) :	
Describe any “Substitution,” “Withdrawal,” or “Modification” submitted	
Describe any alternative bid made:	
Describe any discounts or modifications offered:	
Additional comments:[10]	
Name of bidder or representative present:	
Total bid price (list currencies and amounts or percentages)[11] :	
Signature of responsible official for the bid opening:	
Date:	

Table 3: Bidding Identification

1.1	Name of Borrower	_____
1.2	Loan/Grant number	_____
1.3	Date of effectiveness	_____
1.4	Closing date	_____
(a)	original	_____
(b)	revised	
1.5	Name of project	_____
1.6	Purchaser (or Employer)	
(a)	name	_____
(b)	address	_____
1.7	Name of Contract	_____
1.8	Contract number (identification)	_____
1.9	Contract description	_____
1.10	Cost estimate[12]	_____
1.11	Method of procurement (check one)	ICB _____ LIB _____ Other _____
1.12	Prior review required[13]	Yes _____ No _____
1.13	Domestic preference allowed	Yes _____ No _____
1.14	Regional preference allowed	Yes _____ No _____
1.15	Fixed price contract	Yes _____ No _____
1.16	Co-financing, if any:	
(a)	agency name	_____
(b)	per cent financed by agency	_____

Table 4: Bidding Process

2.1General Procurement Notice first issue date	_____
2.2 Prequalification, if required	_____
(a) number of firms prequalified	_____
(b) date of Bank's no-objection	
2.3 Specific Procurement Notice	
(a) name of national newspaper	_____
(b) issue date	_____
(c) name of international publication	
(d) issue date	_____
(e) address of the Web site(s)	_____
(f) issue date	_____
	_____
2.4 Standard Bidding Document	
(a) title, publication date	_____
(b) date of Bank's no-objection	_____
(c) date of issue to bidders	_____
2.5 Number of firms issued documents	_____
2.6 Amendments to documents, if any	
(a) list all issue dates	1. _____ 2. _____ 3. _____
(b) date(s) of Bank's no-objection	1. _____ 2. _____ 3. _____
2.7 Date of pre-bid conference, if any	_____
2.8 Date minutes of conference sent to bidders and Bank	_____
3.1 Bid submission deadline	
(a) original date, time	_____

(b)	extensions, if any	_____
3.2	Bid opening date, time	_____
3.3	Record of bid opening, date sent to Bank	_____
3.4	Bid validity period (days or weeks)	
(a)	originally specified	_____
(b)	extensions, if any	_____
		_____

Self-Check 4	Written Test

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

Say true or false

1. The Evaluation Committee should not evaluate the applications received in accordance with the criteria specified in the Prequalification document.
2. The summary should address each of the pass–fail criteria set in the prequalification document.
3. Applicants who were not prequalified or were conditionally prequalified should be furnished clearly with necessary additional attachments.
4. In case the prequalification evaluation not includes “slice and package” requirements
5. The summary should mention the procedure used in the evaluation.

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

Answer Sheet

Answer Sheet

Score = _____

Rating: _____

Operation title: - Bidding evaluation for Electrocardiograph 3 channels

Purpose	To acquire the trainees bidding evaluation Technique of biomedical equipment
Equipment ,tools and materials	Materials and equipment needed or useful for bidding evaluation • *Table 1*. Identification, *Table 2*. Bidding Process and *Table 3*. Bid Submission and Opening. • The bidders submit bids envelope • Marketing Requirements Document • Product Requirements Document • Verifiable • Computer • Soft ware application
Conditions or situations for the operations	• All equipment's and materials should be available on time when required. • Appropriate table, working area bidding evaluation practice.
Procedures	1. "**Preliminary Examination**", • Formality of Application • Completeness of Information • Legal Status of Application 2. "**Qualification Evaluation**" • Eligibility of Applicants ✓ Applicant's Nationality ✓ Conflict of Interest ✓ Ineligibility • Historical Contract Non-performance ✓ History of Non-performing Contracts ✓ Pending Litigation • Financial Situation ✓ Financial Performance ✓ Average Annual Turnover • Experience ✓ General Experience ✓ Specific Experience
Precautions	• Preparing materials, tools and equipment are according to inseminator command.
Quality criteria	• Did trainees bidding evaluation Technique of BME

LAP Test	Practical Demonstration

Name: _____ **Date:** _____

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

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

Task 1. Bidding evaluation for anesthesia machine with ventilator and monitor

2. Request your teacher for evaluation and feedback

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AKNOWLEDGEMENT

We wish to extend thanks and appreciation to the many representatives of TVET instructors and respective industry experts who donated their time and expertise to the development of this TTLM.

We would like also to express our appreciation to the TVET instructors and respective industry experts of Regional TVET Bureaus, TVET College/ Institutes, and Federal Technical and Vocational Education and Training Agency (FTVET) who made the development of this curriculum with required standards and quality possible.

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Answer Key for self-check
Module Title: Provide Technical Support in Equipment Acquisition

LO #1- Tracking technological development
Answers for self-check 1 **PART I: Chose the correct answer** 1. E 2. D 3. B 4. D 5. D **Answers for self-check 2** **PART I: Chose the correct answer** 1. D 2. D 3. D 4 .D 5. E **Answers for self-check 3** **PART I: Say true false** 1. T 2. T 3. F
LO #2- Prepare biomedical equipment specifications
Answers for self-check 1 **Say true or false** 1. F 2. T 3. T 4. T

Answers for self-check 2

Fill the blank

6. Description of the function
7. Operational Requirements
8. Technical Specifications
9. Environmental Conditions
10. Power Supply

Answers for self-check 3

Say true or false

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

Answers for self-check 4

Say true or false

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

LO3. Evaluating technical document of bids

Answers for self-check 1

Part 1: Chose the correct answer

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

Answers for self-check 2

Fill the blank

6. Weighted criteria with mandatory elements
7. Mandatory
8. Weighted
9. Bid Evaluation

Answers for self-check 3

Say true or false

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