Project of GUIDELINES FOR
BEST PRACTICES IN MEDICAL
DEVICE MANAGEMENT WITHIN
HEALTH FACILITIES

Medical Devices Sector
SAUDI FOOD & DRUG AUTHORITY
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<tr>
<td>AAMI</td>
<td>American Association of Medical Instrumentation</td>
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<tr>
<td>AI</td>
<td>Artificial Intelligence</td>
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<tr>
<td>BMET</td>
<td>Biomedical Engineer/Technician/Technologist</td>
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<td>CCTV</td>
<td>Closed-Circuit Television</td>
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<tr>
<td>CE mark</td>
<td>Conformité Européene (EU certificate of conformity)</td>
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<td>CD</td>
<td>Construction Documents</td>
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<td>CM</td>
<td>Corrective Maintenance</td>
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<td>CMMS</td>
<td>Computerized Maintenance Management System</td>
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<td>CPG</td>
<td>Clinical Practice Guidelines</td>
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<td>CR</td>
<td>Computed Radiography</td>
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<td>CSSD</td>
<td>Central Sterile Supplies Department</td>
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<td>CT</td>
<td>Computed Tomography</td>
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<td>DD</td>
<td>Design Development</td>
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<tr>
<td>DHCP</td>
<td>Dynamic Host Configuration Protocol</td>
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<td>ECG</td>
<td>Electrocardiogram</td>
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<td>ECR</td>
<td>Emergency Care Research Institute</td>
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<td>EHRs</td>
<td>Electronic Health Records</td>
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<td>EM</td>
<td>Equipment Management</td>
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<td>EU</td>
<td>European Union</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GMDN</td>
<td>Global Medical Device Nomenclature</td>
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<td>HR</td>
<td>Human Resources</td>
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<td>HTM</td>
<td>Health Technology Management</td>
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<td>IDF</td>
<td>The intermediate distribution frames</td>
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<td>ICDs</td>
<td>Implantable cardioverter-defibrillators</td>
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<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
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<td>IR</td>
<td>Interventional Radiology</td>
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<td>ISO</td>
<td>International Organization Standards</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>LDAP</td>
<td>Lightweight Directory Access Protocol</td>
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LIST OF DEFINITIONS

Acceptance Testing  The initial inspection performed on a piece of medical equipment prior to it being put into service. When the device first arrives in the health-care facility, it is checked to ensure it matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly. If a computerized maintenance management system (CMMS) is available, it is registered into the CMMS.

Medical Device Accessories  Products intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.

Assessment Process  Tool for determining medical device needs at the healthcare facility and detecting the gaps in the availability of medical devices by collecting
baseline information that can support recommendations for future planning.

Calibration
Some medical equipment, particularly those with therapeutic energy output (e.g. defibrillators, electrosurgical units, physical therapy stimulators, etc.), needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements (e.g. electrocardiographs, laboratory equipment, patient scales, pulmonary function analyzers, etc.) also require periodic calibration to ensure accuracy compared to known standards.

Certificate of Need (CON)
Planning tool used to support decision-makers in evaluating investments of highly specialized and expensive medical equipment, based on technical, epidemiological, and cost-benefit criteria in order to best optimize resources.

Clinical Engineer
A professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

Computerized Maintenance Management Systems
Computer-based software system that is used to automate issues related to technical support of medical devices and provide support to the management of the medical device inventory, corrective maintenance, preventive maintenance, contract management and provides a wide range of real time data reports on different issues related to the medical device lifecycle such as downtime, life cycle cost and inventory reports related to device type, location or selected manufacturers.

Corrective Maintenance (CM)
A process used to restore the physical integrity, safety and/or performance of a device after a failure. Corrective maintenance and unscheduled maintenance are regarded as equivalent to the term repair. This document uses these terms interchangeably.
Cybersecurity  Body of technologies, processes and practices designed to protect networks, computers, programs and data from attack, damage or unauthorized access.

Device Planning  Core component of hospital planning and design. Some medical devices require special architectural, electromechanical and infrastructure design in addition to the unique and specific utility and pre-installation requirements.

Failure  The condition of not meeting intended performance or safety requirements, and/or a breach of physical integrity. A failure is corrected by repair and/or calibration.

Global Medical Devices Nomenclature System (GMDNS)  List of generic names used to identify all medical devices to provide health authorities, regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and support patient safety.

The GMDNS is used for:

a) Data exchange between manufacturers, regulators and healthcare authorities

b) Exchange of post-market vigilance information
c) Supporting inventory control in hospitals
d) Purchasing and supply chain management

The GMDNS is recommended by the International Medical Device Regulators Forum (IMDRF) and is now used by over 70 national medical device regulators to support their activity. The GMDNS is managed by the GMDN Agency, a registered charity, which has a Board of Trustees, which represent regulators and industry.

Healthcare Needs Assessment  The identification and definition of prioritized requirements regarding medical devices.
Health Technology Management (HTM) / Clinical Engineering

The cost-effective and clinical effective management of all issues related to the medical device lifecycle. This may consist of a framework of standard policies and procedures designed to address all different components and issues related to medical devices. The term health technology management is used to describe the delivery structure required to manage the medical devices within healthcare systems.

Inspection

Scheduled activities necessary to ensure a piece of medical equipment is functioning correctly. It includes both performance inspections and safety inspections. These occur in conjunction with preventive maintenance, corrective maintenance, or calibration but can also be completed as a stand-alone activity scheduled at specific intervals.

Inspection and Preventive Maintenance (IPM)

IPM refers to all the scheduled activity necessary to ensure a piece of medical equipment is functioning correctly and is well maintained. IPM therefore includes inspection and preventive maintenance (PM). This is also referred as PPM (Planned Preventive Maintenance).

Medical Device

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: − Diagnosis, prevention, monitoring, treatment or alleviation of disease, − Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, − Investigation, replacement, modification, or support of the anatomy or of a physiological process, − Supporting or sustaining life, − Control of conception, − Disinfection of medical devices, − Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;
B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

| **Medical Device Nomenclature Systems** | Classification system to identify the type of medical devices by assigning a code to the type of device such as CT, MRI and implantable pacemakers. The classification system is needed for several HTM and regulatory issues. It must be part of any CMMS coding system to be able to identify and track certain parameters related to the different types of medical devices managed by the CMMS. |
| **Performance Inspections** | Activities designed to test the operating status of a medical device. Tests compare the performance of the device to technical specifications established by the manufacturer in their maintenance or service manual. These inspections are not meant to extend the life of the device, but merely to assess its current condition. Performance inspections are sometimes referred to as ‘performance assurance inspections.’ |
| **Preventive Maintenance (PM)** | PM involves maintenance performed to extend the life of the device and prevent failure. PM is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The procedures and intervals are usually established by the manufacturer. In exceptional cases the user may change the frequency to accommodate local environmental conditions. Preventive maintenance is sometimes referred to as ‘planned maintenance’ or ‘scheduled maintenance’. This document uses these terms interchangeably. |
| **Repair** | A process used to restore the physical integrity, safety, and/or performance of a device after a failure. Used interchangeably with corrective maintenance. |
| **Reuse** | Repeated use or multiple use of any medical device with reprocessing (cleaning, disinfection or sterilization) between uses. |
| **Safety Inspections** | Safety inspections are performed to ensure the device is electrically and mechanically safe. These inspections may also include checks for radiation safety or dangerous gas or chemical pollutants. When these inspections are done, the results are compared to country or regional standards as well as to manufacturer's specifications. The frequency of safety inspections may be different than planned maintenance and performance inspections, and are usually based on regulatory requirements. |
| **Single Patient Use Medical Device** | Medical devices that can be used for more than one episode of use on one patient only. The device shall be decontaminated between each use. |
| **Single Use Medical Device (SUMD)** | Medical device intended for use once, on an individual patient for a single procedure, and then should be discarded. |
| **Unique Device Identification Code (UDI)** | Unique device identification code using a globally accepted standard format which consist of series of numeric or alphanumeric characters and used as the key access to information stored in a UDI database. |
| **Universal Medical Devices Nomenclature System (UMDNS)** | Standard, free of charge, monthly updated, international nomenclature and computer coding system to help better manage classifying medical device types. UMDNS facilitates identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. The nomenclature is used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device databases. |
Chapter 1: Preambles

1.1 Introduction

1.1.1 Objective

- To develop standardized national guideline for best practices in medical device management throughout their life cycle within healthcare facilities.
- Enhance the efficiency and improve the management of medical devices, their operation and their rational use within healthcare facilities.
- Minimize the risks associated with the use of medical devices.
- Ensure the medical devices within the healthcare facility are:
  - utilized appropriately;
  - suitable for its intended purpose;
  - maintained in a safe and reliable condition;
  - operated in accordance with the manufacturer’s instruction by users and professionals who have obtained and maintained the correct level of knowledge and competency necessary, and disposed of appropriately at the end of its useful life.
- Periodically monitored for performance, leakage current, isolation, insulation, calibration, adverse events, risks, utilization and cost
- Perform one of the surveillance tasks that on the official order of SFDA system that mentions the “SFDA shall monitor the obligation of healthcare facilities with international standards of safety performance for medical devices” in accordance with these guidelines for management of health technology/medical devices within healthcare facilities.

In accordance with these guidelines, the SFDA is working with its partners to build a framework of regulatory procedures to support improving the quality of healthcare in the kingdom.
1.1.2 Scope
This guideline will apply to any medical device used as part of the routine care of patients. It will provide procedures and practices that will help ensure that a medical device is managed, operated and maintained as recommended by the manufacturer to ensure that its performance will be maintained throughout its lifetime. The procedures will cover the medical devices life cycle as following:

1. Planning phase: User requirements, safety, needs assessment, pre-installations requirements;
2. Procurement phase: Tender process, technical specifications, life-cycle cost, effective tender evaluation, pre-installation costs;
3. Installation phase: Pre-installation, inspection and commissioning, acceptance certificate, connectivity, operating and service manuals;
4. Operation phase: Effective lifecycle management of medical technologies; implementation of CMMS, preventive and corrective maintenance, calibration, training users, transport, and storage.
5. Disposal phase: Justification for scrapping, safety and hygiene, removal, dismantling and disinfection of medical device.

1.1.3 Stakeholders within healthcare facility
Medical device management requires the involvement of staff from many disciplines –technical, clinical, financial, administrative, etc. It is not just the job of managers; it is the responsibility of all members of staff who deal with healthcare technology\(^1\). This includes the departments of Biomedical Engineering, information technology, Nursing, Medical, Finance, Projects, General maintenance, Asset management …etc.

How to organize a system of healthcare technology management \(^1\)
1.1.4 Background

Medical devices are for Diagnosis and Treatment. They play a crucial role in patient care and treatment. Once a device is in the market, its safety and performance depends on:

- Preservation of the integrity of the device through applying proper management procedures in storage, handling, transportation, delivery, installation and testing.
- Using the devices for the exact intended purpose as per the manufacturer's instruction.
- Operating them effectively and safely.
- Device characteristics change with time, therefore, continuous monitoring for safety and performance is essential to ensure that these changes don't have an impact on patient safety.
- Constant detection, investigation of unexpected incidents and possible adverse events.
- Proper preventive, corrective Maintenance, calibration and electrical safety tests to preserve its specified performance.
- Maintain proper documentation for all actions taken on the device including utilization, operation and maintenance cost.
- Decommission, disposing and replacing unsafe and obsolete items.
- Ensuring the staff have the right skills to optimally use the medical device.

Health technology management involves a cycle of activities in the life of equipment, as shown in (Figure 1.1).
1.2 Health Technology Management Department

Medical devices and supplies constitute a good percentage of hospital costs. They play a role in Diagnosing and treating patients in almost every department and ward within a healthcare facility. Managing these sensitive and fast evolving devices requires the availability of trained biomedical engineers and technicians who are capable of identifying and managing risks associated with the technology used within the hospital. Furthermore, most of the medical devices now share information with the hospital network to create and platform for information exchange and artificial intelligence.

In principle, no technology can be added or removed without the involvement of Health Technology Management/Clinical Engineering department in the process.

The recommended organizational structure of the HTM Department (sometimes called Clinical Engineering or Biomedical Department) depends mainly on the size and nature of services within the healthcare facility. The world health organization (WHO) published "HUMAN RESOURCES FOR MEDICAL DEVICES The role of biomedical engineers" as part of Medical Devices technical series to ensure access to quality and safe use of medical devices. The booklet details the responsibilities of the
HTM/Clinical Engineering department depending on the hospital size. The following shows some of the responsibilities of this department:

1. Planning for new technologies that includes (needs assessments, budgeting, cost analysis, pre-installation requirements … etc).

2. Purchasing process: Oversee the procurement cycle, putting specifications, tender processing, technical assessment, contracting, commissioning and acceptance testing.

3. Preventive and corrective maintenance of medical devices (in-house) and/or management of service contracts for devices categorized to be maintained by service providers (support the preparation, signing and supervising the implementation of contracts with manufacturers and local suppliers of medical devices, spare parts, chemicals, reagents and consumables).

4. Administrative support: Oversee the internal and external administrative communications, human resources and other administrative work related to medical devices.

5. OEM & 3rd party Contract Management, negotiations and administration

6. Quality control: Monitor the quality of technical support provided to medical devices, ensure safety to department staff, users and patients and monitor the overall performance of the HTM Dept, adverse events reporting, managing recalls on medical devices, incident reporting and investigations

7. Medical equipment retirement plan including decommissioning, disposing, and replacing unsafe & obsolete items. In order to ensure safe, accurate, and affordable technology in the hospital and to exclude obsolete, beyond repair and un-economical technology in the hospital.

2.1.2 Preventable medical errors

Significant percentage of preventable medical errors are caused by improper use of medical devices. In USA 440,000 patients are dying annually because of preventable medical errors\(^1\). The figure below illustrates errors related to medical devices. In another study, 59.5% of drug errors reported to USP from 570 HC facilities are due to implicate use of computers\(^2\).

It is the responsibility on clinical engineers when building their HTM system to have amandate to enhance the safety and performance of medical devices by monitoring the
performance of medical devices, detect any risk related to that devices and take all measures to minimize all adverse events related to medical devices.

In most Middle East countries, medical errors including those adverse events related to medical devices are not properly tracked. The role of HTM system and clinical engineers is to be part of any available initiative for tracking medical errors and adverse events related to medical devices and raise a “red flag” to hospital leaders such mechanism is not available.
Chapter 2: Planning

2.1 Introduction

2.1.1 Objective
To demonstrate how to conduct the medical devices planning through providing basic tools, references, and examples to do a proper planning and assessment of their current situation and future needs about medical devices.

2.1.2 Scope
This chapter applies to any healthcare facility whose planning for medical devices includes:
- New construction
- Renovation
- Device installation
to come up with a list of needs of medical devices and supplies from all healthcare providers departments with justifications that based on previous years utilizations, future needs and other objective parameters (product or service, quality, quantity, pre-installation, the condition and performance of current medical devices installed, including: device failures and issues; utilization, performance, maintenance; repair and calibration history).

2.1.3 Ownership
The involvement of Committee with minimum members as following:
- Healthcare provider administration.
- Finance department.
- Healthcare technology /Clinical engineering department.
- End-user department.
• IT department.
• Facility management department.
• Supply chain / procurement department.
• Project management department.

2.1.4 Background

Early engagement of all stakeholders in planning the technology needs for a new department or hospital is important to assure having a comprehensive view over the needs to make an educated decision on the proper technologies needed. The following diagram shows the steps involved in technology planning.

![Diagram showing the steps involved in technology planning](image)

**Figure 2.1: Pre-installation and Planning Processes Work Flow.**
2.2 Medical Devices Planning Process

Planning can be divided into four major phases:

- Healthcare needs assessment.
- Design.
- Construction.
- Occupancy.

2.1.5 Healthcare Needs Assessment

In this section, the required data collection and analysis steps that are required for specific medical devices needs assessment processes include:

- Health service requirements,
- Health service availability,
- Human resources Information,
- Budgeting
- Priority setting – local, regional and national

2.1.5.1 Health Service Requirements

The following should be considered to understand the overall requirements of the health services in the target area:

a. Epidemiological needs (disease priorities).
c. Anticipated level of utilization (how many times the devices will be used, is there a demand on advanced or just basic options, impact on quality of care for the patient)
d. Clinical program guidelines and protocols; national or local recommendations; and internationally recognized standards on diagnosis and treatment of different diseases relevant to this population.

Example: For a needs assessment for computed tomography (CT) imaging services, it is important to understand the needs for CT of the target population. To determine if more CT scanners are needed, the current region’s number of CT
scanners per 10,000 population can be compared to the average international and regional standards. The specifications for the CT scanner will also be influenced by the regional disease burden, the clinical scope of the healthcare facility and the availability of qualified human resources.

2.1.5.2 Health Services Availability

The following are the main types of information needed to be collected:

1) Healthcare provider infrastructure

- Type, size, and location of facilities, including the number and type of building(s).
- Availability and condition of water supply, connections and installation (e.g., Where does the water come from? What is the water quality?).
- Electrical power supply, electrical connections and installations (e.g., Is an emergency generator available?).
- Waste disposal system (e.g., How is waste handled, segregated, and disposed of?).
- Availability of tele-communication infrastructure.
- Assessment of electromagnetic compatibility (EMC).

2) Medical Devices

It is very important to understand and collect all relevant information associated with the current available medical devices. Normally, all needed information should be available in the healthcare facility’s CMMS reporting system and may include the following:

- Device type and available quantity.
- Manufacturer & model names.
- Average lifetime of medical devices identified by installation date.
- Location and distribution of medical devices identified by clinical departments, building number, floor level and room number.
- Working condition (operational, out of order, awaiting parts, etc.).
- Lifecycle costs information.
- Downtime information.
- Availability and consumption rate of spare parts.
- Supplier performance assessment.
- Any available incident reports.

2.1.5.3 **Human Resource (HR) Information**

Following are some HR related items to consider in the needs assessment process:

a. Availability of clinical staff with required qualifications. For example, qualified radiologists and radiographers are needed when considering the need for CT and X-ray systems.

b. The availability of outcome based continuing medical education programs (training based on manufacturer requirements) that include on the job training.

2.1.5.4 **Budgeting**

The following financial information are necessary:

a. Available budget, project or annual, for medical devices.

b. Estimated costs of the medical devices requested by the medical staff.

c. Estimated life cycle costs of the needed devices, such as spare parts, maintenance contracts, software licenses, other support costs, consumables, chemicals, training and disinfection.

d. The estimated costs for any additional infrastructure.

e. Does the device require consumables? Is it an open or closed system?

f. The estimated cost of any pre-installation and training requirements.

2.1.5.5 **Priority setting – local, regional and national and final needs assessment recommendations**

After data collection, perform a gap analysis as following:

- Interpretation of the collected information.
- Determine what similar technology is available in the local healthcare providers city (or region) and, where applicable, in the entire country based on the health services demand and overall population health and health delivery organization circumstances of the local area.

- Determine the available local, national and international standards.

- Consider the possible financial and human resource constraints, as well as prioritized epidemiological requirements.

The outputs of the gap analysis is a development of a prioritized needs list. (Table 2.1) outlines the questions to be asked, the data required to answer those questions, and the tools available to collect and evaluate the data.

There are several procedures available internationally to identify gaps in medical device availability. For example, a stepwise approach to identify gaps in medical devices (availability matrix and survey methodology) by the World Health Organization provides lists of recommended medical devices for various health screening and treatment processes.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Data Required</th>
<th>Tools</th>
<th>Results</th>
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<tbody>
<tr>
<td>1 What do we want/need in terms of health services?</td>
<td>- Population (target population, patient’s rate, density of population). - Health service provider availability - Epidemiological data (disease priorities…).</td>
<td>- “Certificate of need” process, see Appendix A - Clinical practice guidelines (CPG). - Survey questionnaires - Standards of level of care.</td>
<td>Appropriate health services delivery</td>
</tr>
<tr>
<td>2 What do we have? (Local conditions/ Limitations).</td>
<td>- Health service availability. - Lists of available medical devices. - Human resources availability.</td>
<td>- Service Availability Mapping (SAM) questionnaires? - Evaluation tools?</td>
<td></td>
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- infrastructure of medical devices management (electrical, water gases and IT system related to medical devices
- Inventory management tool.
- Computerized maintenance management system (CMMS).

3 Which standards/recommended best practices exist that could be applied or adapted?
- Standards/recommendations for health service delivery coverage.
- Standards/recommendations for medical devices
- Standards/recommendations for human resources required for operation/maintenance/management of medical equipment.
- (Essential) Medical device lists; i.e., per facility type and department, or per clinical procedure.

4 Overall Gap (2 – 3):
List of General Needs

5 What financial/human resources do we have?
(Constraints).
Budget (capital investment and operational)
Human resources.

6 Prioritized Needs (4 – 5):
Prioritized List of Needs

Table 2.1: Sample questions to be asked, data required to answer those questions, and the tools available to collect and evaluate the data.

2.1.6 Design of new departments in hospitals
Once the healthcare needs assessment is reviewed and approved, preliminary design planning can begin:

Clinical Program Planning Process
Design starts with a detailed clinical program planning process.

a) Program planning process should describe the following:

- Clinical services that will be included in the proposed new or renovated building(s).
- Each clinical program’s general requirements (e.g. number of patient, exam and treatment rooms; number of operating rooms; space size needs)
within the constraints of the approved healthcare needs assessment (e.g.
overall building/remodel space size needs and budget estimate for the project).

**Note:** Clinical engineering technology assessments are useful at the program planning stage since generic device needs are one of several factors to be decided in the program planning phase (e.g. Do we need a CT scanner in this new building? Do we need basic CT scanner, intermediate, or advanced? What accessories do we need to add to address the clinical needs? Do we have trained staff to run the advanced options? What are the training needs? ). Clinical engineers should get involved in this program planning stage in translating clinical requirements and concerns into technical and facility requirements. At this stage, clinical engineers can provide technology assessments for major clinical systems as well as starting to develop a generic equipment list with generic requirements for required major systems (e.g. Radiology systems, OR rooms and lights) under consideration for each program. This is also the time to discuss in general terms required utilities for the programs and medical devices systems that will need to be installed or remodeled in the new building(s). Of course, even at this early stage, specific national and local regulatory requirements and governmental approvals need to be met and, if necessary, appropriate preliminary local and national regulatory agency approvals obtained.

b) For the next step in the Program planning process, a “schematic design” plan is drawn describing the program and space requirements for each department, their required support services and “adjacencies” (i.e. what other services need to be nearby).

**Example:** Once it is determined, that five operating rooms will be included in a new healthcare facility building then the Post Anesthesia Care Unit (PACU) or Recovery Room needs to be located adjacent and sized accordingly (e.g. 20+ beds). The Central Sterilization Department also needs to be designed in proximity to the operating rooms (ORs), or provisions made for the efficient movement of dirty and clean/sterile instruments back and forth from the ORs to that department.
c) The next step in the design phase is the development of detailed architectural and engineering drawings, often called design development (DD) drawings. The architectural and engineering teams develop detailed drawing sets including the following:
- Patient flow
- Floor plans.
- Interior elevations.
- Mechanical.
- Electrical.
- Plumbing.
- Fire prevention.
- Radiation Protection
- Medical Gasses
- Reception area
- Nursing station
- Changing rooms, utilities, restrooms, storage …etc.
- Special power requirements (3 phase, grounding, Uninterrupted power systems, backup generators, isolating service powerlines from medical equipment power lines, Intensive care unit and operating room electrical isolation …etc)
- Medical equipment loaded drawings.
- Tele-communication, including IT.
- Furnishings, finishes and other detailed drawings.

d) Simultaneously with the architectural design phase, a multidisciplinary team which include clinical engineers and clinical end-users shall develop a medical devices plan and incorporate the medical device plan into the architectural and engineering drawings showing medical devices locations and utility requirements (see: Table 9.1 of utilities). First priority, from an architectural planning standpoint, are the medical device systems that are fixed and therefore, require installation.
Technical requirements and selection of major system products based on the program plan, technology assessment reports, standards within the healthcare facility and the community, and the new facility design need to be developed.

**Note:** This is an iterative approach with input from the end-users and various support teams, including IT, and clinical engineers. Typically, a multidisciplinary formal drawing set review takes place at critical drawing development thresholds such as 50% completion, and 95% completion. After 100% DD drawing completion, healthcare executive leadership review and approval, funding approval, regulatory review and approval; final schedules and construction documents (CD) can be developed and construction contracts can be bid and let.

### 2.1.7 Construction

Once construction starts, clinical engineers need to be available to answer any questions that the design and/or construction teams have regarding device requirements.

**Note:** Change orders are expensive and need to be minimized. However, change orders often need to occur to accommodate the selected technologies that may not have been available or known about earlier in the new healthcare facility design process. Often changes in device requirements occur due to changes in technology, particularly when there is a long period of time between the design of the building and construction completion. For example, a plan for installing the magnet for an MRI machine needs to be in place since the magnet comes as one large piece and may require demolishing some walls to be placed in its place.

### 2.1.8 Occupancy Planning

As construction gets well underway, it’s time to finalize occupancy and device installation and commissioning planning. After finalizing the procurement phase (see chapter 3, Procurement), plans and schedules need to be developed for fixed device installation, fixed device moves (de-installation and re-installation), furniture
installation, and people and mobile medical device moves. Plans also need to be in place so that all medical devices get tested prior to first clinical use.

The medical devices requiring contractor installation get installed after their respective rooms and utilities are ready for these systems. As construction nears completion, and all building, fire and utility inspections and testing are complete, it’s time to continue medical devices installation and testing (some will call this milestone “Beneficial Occupancy”).

In addition, with the large amount of medical devices requiring IT connectivity, HTM shall coordinate with IT to install the manufacturer’s recommended IT requirements. After the IT infrastructure is installed and operational, network connected medical device installation and testing can be completed. Clinical end-users will require training on all new medical devices. Clinical engineers, along with clinical educators, both internal and supplier-provided, need to assure that as many clinical staff as possible complete training on all new technology prior to occupancy and first clinical use.

**Note:** HTM is responsible for the coordination of all medical device installation and testing.

### 2.1.9 Consideration of Emerging Technologies on Medical Devices

Several emerging technologies will impact future improvements in medical devices. For example, the increasing computerization of medical devices, and their interconnectivity has created a very large impact on medical devices. This integration and convergence of IT and Clinical Engineering is a recurring theme in many emerging technologies. Some of the challenges created by this convergence include the re-focus of Medical Devices resources (funds and staff) toward IT-related activities, medical device/IT security-related challenges for networked connected medical devices, and the need for the education of HTM and Clinical Engineering staff in IT technologies.
2.1.9.1 IT Security-related Challenges for Network-connected Medical Devices

Connected devices and cyber security are rapidly becoming critical topics for regulators as sophisticated IT technology integrates with medical devices. Connected devices’ generally refer to devices wired or wirelessly connected to other machines and those connected to the “Internet of Things” (IoT).

MD Specific Considerations: computerized medical devices can be vulnerable to security breaches and potentially impacting the safety & effectiveness of the device. This vulnerability escalates as medical devices are increasingly connected to the internet, hospital networks, and to any other medical device.

There are numerous sources of cybersecurity risk in medical devices and consideration must be given to all in order to ensure adequate protection which include but are not limited to the following:

1. Malware infections of devices that are network connected.
2. Unsecured or uncontrolled password distribution.
3. Failure to provide adequate software security updates.
4. Theft or loss of networked medical device.
5. Unauthorized access to hospital network or devices.
6. Off-the-shelf software that is not designed to prevent unauthorized access.
7. Denial-of-service (DoS) attack renders a device inaccessible to the authorized user.
8. Improper disposal of patient data or information.
9. Untested or defective software and firmware.
10. Misconfigured networks or poor security practices.
11. Saudi FDA cyber Security for Medical Devices requirements

Healthcare facilities need to take special precautions in order to safe-guard their network systems to attempt to reduce/eliminate potential attacks.

Ongoing Healthcare Facility Processes Required Regarding Cybersecurity:

The following may be used to help mitigate cybersecurity threats:

- Improve cybersecurity awareness.
- Evaluate shared networks.
- Build security requirements into contracts.
- Follow cybersecurity hygiene regimes during medical device deployment.
- Encourage collaboration and harmonize with network participants.
- Address healthcare facility IT process inconsistencies.

2.1.9.2 Education of HTM Professionals in IT-Related Skills

All HTM professionals (e.g. Clinical Engineers, BMETs) will need to obtain basic and more advanced training in IT-related topics. HTM professionals are often the only staff that understand a complex network-connected medical device system “end-to-end”. Training will have to occur at all HTM levels. Expertise will need to be developed in all areas of healthcare IT including networks, applications, operating systems, tools and troubleshooting. And most importantly, the HTM professional will have to learn to work closely with their peers in IT, who will continue to be the experts on the infrastructure (e.g. networks and data center), healthcare provider-wide IT services (e.g. LDAP, DHCP) and healthcare provider-wide applications such as the EHR.
### 2.3 Checklist

<table>
<thead>
<tr>
<th>No.</th>
<th>Check list item</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Availability of the needs assessment process incorporating a Health Technology Assessment review</td>
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<tr>
<td>2</td>
<td>Involvement of HTM and biomedical staff in the needs assessment</td>
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<tr>
<td>3</td>
<td>Availability of a medical device planning written procedure.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Availability of Group/Committee for Medical Devices/Health Technology Planning with involvement of all related parties in the ownership.</td>
<td></td>
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</tr>
</tbody>
</table>
Chapter 3: Procurement

3.1 Introduction

3.1.1 Objective

- To get satisfactory quality, service and price within a timely delivery schedule (right product or service of the right quality, right price and the right quantity, at the right place and time).\(^5\)

- To have effective procurement practice that leads to safe and high quality health care.

Other potential benefits of good procurement will include the following:

- The most economically advantageous terms for the medical devices acquired – not necessarily the lowest price obtained through tender, but the best deal for the organization’s needs.

- Timely delivery.

- Satisfactory and well-defined terms of delivery, installation, commissioning, training, payment, warranty and after-sales service.

- A greater interest from the suppliers in submitting offers in the future.

- To acquire a product that is safe, improves quality of care, is cost effective within the context of its application and is manageable (both support and training requirements) within the institution concerned.

- A product acquisition that fits within the strategic plan and the needs of the organization.

- A procurement process that follows national regulatory requirements with standardized structure that is transparent, auditable, effective and fair.

3.1.2 Scope

This process applies to the healthcare providers who will procure the medical devices and should include the following:

- Sourcing and solicitation of offers.

- Evaluation of offers.

- Review and award of contracts.
Contracting and all phases of contract administration until delivery of the products.

Requesting from suppliers that they provide accurate and transparent information in terms of product support and their understanding of a healthcare facility’s needs.

3.1.3 **Ownership**

The mechanism for procuring medical devices should be handled by committee with minimum members of:

- Purchasing.
- Legal.
- Finance.
- HTM department.
- End-users.
- IT.

3.1.4 **Background**

In order to provide safe, effective and high quality patient care, healthcare facilities need to have well-defined medical device acquisition and management programs. Not all devices are created equal, and not all devices are suitable for all healthcare environments. Therefore, it is essential that any new acquisition be thoroughly evaluated to ensure that it is an appropriate choice for a given facility and application. This includes soliciting feedback from a variety of personnel, such as end users and clinical engineers. Multiple devices should be reviewed and compared on predetermined key features listed in technical specifications, which are created by "clinical, technical, and end-user groups" to ensure that the needs of these groups are met (Willson et al.)

The adoption of a value analysis based approach to procurement is also relevant and addresses the need to consider the benefits to quality of care and service delivery using a multidisciplinary, evidence based systematic approach.
3.2 Procurement Procedures

3.3.1 Pre-procurement Procedures

Before reaching the point of procurement, as stated in earlier chapters of this document, it is important to use the planning information described in the previous chapter.

After that, procurement can move forward and enable a process which includes:

- Sourcing and solicitation of offers.
- Evaluation of offers.
- Review and award of contracts,
- Requesting from suppliers to provide accuracy and transparency in terms of product support and understanding of a healthcare facility’s needs.
- Contracting and all phases of contract administration until delivery of the product.

Ethical and transparency principles need to be adopted in the process, all stakeholders must avoid any perceived conflict of interest. Involved parties must declare any conflict of interest and avoid participating in decisions related to favoring one party over the other.

Figure 3.1: Purchasing Process.

Tender Requirements:
Prepare the tender to obtain the following:

- Technical specifications from HTM department.
- Clinical application/specifications from the end users department.
- Pre-installation requirements from engineering (e.g. architects, physical plant).
- Governmental/Legal requirements and tender submission procedure from logistics/procurement.
- Regulatory requirements (License for the distributor, Market authorization for the device)
- Transparency and conflict of interest policy associated with the tender
- Tender evaluation process and important dates.
- Process of obtaining further information related to the tender.
- Pre-installation requirements request.
- Choose your key performance indicators that are going to be used for approving payments (warranty, spare parts, time to respond to service request, required up time, maximum allowed down time, delivery time, installation time, spare parts requirements, length of warranty, training of user, training of biomed in hospital, accessories, availability of an engineer on site, service and operation manual, preventive maintenance requirements, Electrical safety tests required, Calibration tests requirements ...etc)
- Any other requirements associated with the medical device (e.g. radiation safety, chemical, medical gases, central supply and sterilization/cleaning requirements).

3.3.2 Technical Specification Development of Tender Document, General Considerations:

- Clearly identify the previously identified clinical needs for the device.
- Suppliers need to understand whether you need a product with simple, moderate of advanced options.
- Establishing unbiased technical specifications for the technology requested.
- It is vital that a Clinical Engineer is involved in the development of the technical specifications to be included in any tender for the medical device under consideration.
- The tender evaluation will depend on the specifications, requirements and performance levels, therefore, be very specific and clearly identify your needs.
- Avoid adding specifications that would exclude certain suppliers over the other unless there is a clearly identified clinical need.
- Request device upgrade and update policy
- Technology evolving is fast and quick, therefore, healthcare facilities need to have a mechanism to constantly develop and update technical specifications for medical devices in all modalities (Radiology, different laboratory departments, Intensive care, operating rooms, oncology ..etc). Such committees need to include biomedical engineers, clinicians, and technologists. They need to remain up to date with the developments, recalls issued, and assessments done in their areas.

### 3.3 Operation Costs Consideration

The full costs of ownership of the technology includes:
- Training (both initial and ongoing) for the operator, clinician and Biomedical engineers.
- Software updates.
- Maintenance and installation costs, which are effectively identified prior to execution of any agreement.
- Running costs (ex: Daily expenses to operate the equipment. This might include the reagent cost, detergent cost, cession cost, etc.)
- Preventive maintenance cost if some parts need regular replacements
- Extended warranty cost
- Agreement that if at a later date it is necessary to move the device to another location, cost of supplementary reinstallation.
- Any medical device that is ‘donated’ or ‘gifted’ to a healthcare facility also requires a thorough life cycle costing analysis prior to acceptance even though there may be no initial capital outlay for the device itself.

### 3.4 Methods of Acquisition

The suppliers of medical devices to hospitals and healthcare organizations in the Kingdom of Saudi Arabia is for the most part provided by local vendor representatives of the manufacturers. The process of acquiring/selling medical devices follows the International standards under three (3) known methods:
1) The direct purchase/sale form is used for the medical devices which are owned by the hospitals in general.

2) Leased medical devices are owned by the vendors and installed in hospitals according to agreements for the purchase of medical consumables or laboratory reagents as per the consumption by the leased medical devices used/consumed for a certain period of time.

3) The third type of acquiring medical devices is through agreements known as “Guaranteed Price Per Reportable Results (GPPRR). In this kind of agreement the device remains the property of the vendor and medical/laboratory consumables are provided by the supplier free of charge while the hospital pays only for reportable test results in compliance with the terms of the agreement.

3.5 Tender Contents

A generic template of tender should be designed and subsequently customized to incorporate the specific technology/medical device core requirements. Typical tender items of a generic nature include:

- Distributor Qualification requirements (licenses, bank guarantees, previous experience, SFDA establishment license, Market authorization for devices …etc)
- General condition of the contract (sometimes referred to as Terms & Conditions).
- Contract specification (sometimes referred to as scope of work) which will include the technical specifications of the technology required.
- Pricing schedule (this enables potential suppliers to present their pricing within a standard layout enabling comparisons to be made during the evaluation process).
- Proposal evaluation criteria and matrix
- Tender processing time lines, and
- Process for seeking further information (all suppliers must have access to the same level of information so that no one has more advantage over the other)
- Site visiting arrangements process (suppliers need to visit the site, ask clarification questions about the clinical and technical needs, ,etc).
- Administrative instructions (this will cover matters such as return of tender documents, delivery, application procedure, closure date, mechanism of asking questions …etc.).

Announce the tender shall include the following:
- List of medical devices with quantities and specifications,
- Performance characteristics like accuracy… etc.
- Ability to upgrade medical devices if needed.
- Interoperability requirements
- Safety requirements.
- Regulatory requirements (SFDA establishment license (MDEL) No. for the establishment, SFDA Medical Devices Market Authorizations (MDMA) No. of requested devices...etc.)
- Warranty period required.
- Extended warranty
- Training needs.
- Maintenance costs.
- Known risks associated with the device(s).
- Supplier evaluation criteria.
- Pre-purchase questioner.
- Compatibility of the operating/environmental conditions of the place where the device will be used.
- Manuals (user, operation, instructions for use (IFU), service, spare part list, lists of tool and test equipment required, circuit diagram, planned preventive maintenance manual and checklist as per manufacturer’s requirements).
- Decontamination, cleaning, disinfection and sterilization procedures, ensuring the healthcare facility is able to reprocess in line with the manufacturer’s instructions (e.g. by trained technicians). The infection control & CSSD team and should be consulted.
- Disposal instructions.

3.6 Ethical Considerations

An integral component of any procurement process is a mandatory need to ensure that all ethical considerations are observed. These are as follows:

- Transparency, confidentiality and fairness
  - All suppliers should be treated fairly and evenhandedly at all stages of the procurement process.
• Avoid any perceived conflict of interest between members involved in the tender evaluation and the suppliers. Any such conflict of interest must be declared. (Example: supplier is a relative of one of the decision makers in the tender, one of the tender evaluation committee members have previously benefited from the supplier or may benefit from the current tender, supplier is funding a project running by one of the committee members …etc)

• **Use of power**
  Buyers should discourage the arbitrary or unfair use of purchasing power or influence.

• **Corruption**
  Buyers must not tolerate corruption in any form.

• **Declaring an interest**
  All personal interests should be declared.

• **Business gifts and hospitality**
  No prospective supplier business gifts or hospitality should be tolerated in the procurement cycle.

• **Payment terms**
  Payment terms should be objective with clear milestones. Late payments undermine an organization’s credibility.

• **Supplier relationships and competition**
  Relationships with suppliers, regardless of duration, should be managed professionally.

• **Encouraging small businesses**
  Buyers should, wherever possible, be aware of opportunities to support the local community and SMEs, whilst maximizing opportunities for global sourcing.

• **Employment relationship**
  Employees should have legal contracts.

• **Wages and working hours**
  Living wages are paid.

• **Treatment of employees**
  No harsh or inhumane treatment is allowed.

• **Health and safety**
  Working conditions are safe and hygienic.

• **Discrimination**
  No discrimination is practiced.
Apply the predetermined evaluation criteria for all suppliers after receiving and evaluating the bidders' proposals based on the below criteria (supplier competency) per the following:

- Service support (Availability of hotline and quick response time, quick delivery of spare parts).
- Time to deliver.
- Adhering to the regulatory requirements (establishment license, no issued alerts/recalls, MDMA as applicable).
- Cost.
- Installation cost included or not?
- Freight included or not?
- Risk of device:
  - Patient safety – is there a risk of patient harm with this technology?
  - Risk and clinical effectiveness – will patient outcome be impacted negatively?
  - Patient experience – will this be better or worse with the provision of this technology?
  - Risk to health and safety.
- Accessories need.
- Maintenance costs.
- Warranty period.
- Cost of consumables.
- Lifetime cost.
- Meets specification requirements
- Meets standards
- Review of published hazard and recall data to identify any ongoing technology issues.
- Examine the evidence base (documentation, clinical trials data, etc.) for any manufacturer claims cited in the submitted documentation.
- Consideration of the use of market trend and price benchmarking systems to identify significant pricing trends and discrepancies.
- Supplier Capability:
  - Staffing structure.
  - Availability of experienced staff.
  - Have a system to measure customer satisfaction.
  - Experience in the industry.
3.8 Compliance Checking

- Prioritize the above evaluation criteria (i.e. is this requirement specified a ‘high’, ‘medium’ or ‘low’ priority)
- Assign weight for all criteria
- Compare and rank the suppliers responses

3.9 Contract with Supplier.

3.10 Payments Scheduling.

3.11 Storage Requirements:

See tables (9-6) and (9-7) in the appendices for more details.

3.12 Tender Award Process and Payment Processing

A tender award is often initially provided through a letter confirming supplier status followed by the issuing of a purchase order document from the institution. This may also be supplemented for large value items with a contract document.
The following shall be considered before tender awarding or payment processing:

- Any contract documentation generated should include the information and terms and conditions originally specified in the invitation to tender documentation.
- Any advanced payment for a selected technology should be resisted and payment should be specifically tied to successful acceptance testing, completion of delivery, installation and all training aspects for the product. On large projects, partial payments based on objective milestone completions, may be appropriate.
- Any contracts generated should be duplicated for the “Buyer” and “Supplier” and forwarded to the Supplier for signature in the first instance. Once signed off by both parties the contract will be in force.
- Unsuccessful suppliers who participated in the tendering process should be entitled to a debrief including identification of the areas of weakness established during the evaluation process.
- Any meetings should be held and coordinated by the Procurement Department supported by Clinical/ biomedical Engineering Department in conjunction with the End-user Medical Department also involved.
- Any comparisons with other tender responses received should be avoided, as tenders will have been submitted on a confidential basis.
- Any such meetings should be documented.
Checklist

The table below represents a best practice checklist. Its purpose is to serve as a tool for evaluating procurement activities and assist in the development of process improvements.

<table>
<thead>
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<th>No.</th>
<th>Check list item</th>
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<th>Comments</th>
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<tbody>
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<td>1</td>
<td>Availability of purchasing committee members as indicated in the ownership</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>Availability of written procurement procedure</td>
<td></td>
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<tr>
<td>3</td>
<td>Availability of tender format</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Recognize method of acquisition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Availability of code of ethics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Evaluation Criteria are applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Availability of acceptance process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Availability of purchasing committee members as indicated in the ownership</td>
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<td>10</td>
<td>Availability of tender format</td>
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</tbody>
</table>
Chapter 4: Installation & Commissioning

4.1 Introduction

4.1.1 Objective

- Ensure the medical device supplied matches the specification of the device indicated in the Supplier’s invitation to tender response.
- Ensure the medical device is in good condition and fully functional after commissioning.

4.1.2 Scope

This process applies to the healthcare provider who will install and commission the medical devices that will include the following:

- Checking the supplied medical device with related manuals, catalogues, accessories & official documentation.
- Ensure the medical device is in good condition and fully functional.
- Checking the Calibration, performance and electrical safety tests.
- Getting the related training (both user and technical).

4.1.3 Ownership

The mechanism for installation of medical devices should be handled by committee with minimum members of:

- Warehouse Department.
- HTM Department.
- End-users Department.
- Assets management.
- Purchase Department.
- Project management department.
4.1.4 Background

Pre-installation Requirements, Receipt and Acceptance

- Following completion of the tender process, the Supplier will be responsible for the delivery of the medical device.
- Prior to delivery and installation, any site preparation work shall be completed.

Note: Pre-installation checks should apply to all medical devices installed into a healthcare setting, whether they are leased, donated, on trial or purchased.

![Diagram of Installation & Commissioning processes.](image)

4.2 Delivery

- The healthcare provider shall check for external damage to the package or its contents. (physical checks).
- The medical device delivered matches the original tender acquisition specification.
- The healthcare facility should ensure the medical device supplied matches the specification of the device indicated in the Supplier’s invitation to tender response.
- The medical device has been supplied with the appropriate original medical device manufacturer recommended accessories and consumables.
• All necessary information and documentation, including instructions for use have been provided.
• Ensure that manufacturers transport and storage requirements are met. Many chemical reagents lose their effectiveness because they were not transported or stored properly.

4.3 Medical Device Installation & Commissioning

• The device is configured in an appropriate manner.
• Installed according to the original medical devices manufacturer’s recommendations and located where required with oversight of this process by the Clinical Engineering department.
• Delivery has been achieved with the technology/medical device in good condition and fully functional.
• Manufacturer’s and regulatory authorities’ Health & Safety requirements during the installation process are considered and met.
• The availability of disinfection and sterilization contract or competent personnel tools and spaces.
• Data has been captured and stored on the organizations Computerized Maintenance Management System (CMMS) for asset tracking purposes.
• Formal training needs according to the manufacturer requirements have been identified and implemented and data captured for inclusion in training databases for ongoing needs.
• In the case of reusable devices, maintenance requirements have been identified and scheduled.
• Information about proper storing and transporting.
• Involvement of HTM and End-user departments during the installation and acceptance process. The entire process should be coordinated by clinical/ biomedical department which should liaise with other groups as required.
• Report signed from the responsible clinical/biomedical engineer and end user explaining that the medical device is installed, in good condition and fully functional.
• Confirmation that all documentation has been delivered including local configurations, as-built drawings, and IT information for connected devices.
• A control number will be assigned and labelled, placed on the unit, along with any other appropriate labels (e.g. warrant expiration date, loaned device.)
• In case the delivered medical device failed to comply with healthcare facility’s identified requirements in the tender, the Procurement Department shall be responsible for liaising
with the medical device supplier in the event of damaged or inappropriately delivered or unrepairable medical device.

**Note**: Medical devices must not be put into use before acceptance check processes have been performed.
4.4 Checklist

The table below represents a best practice checklist. Its purpose is to serve as a tool for evaluating procurement activities and assist in the development of process improvements.

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<tbody>
<tr>
<td>1</td>
<td>HTM Supervise/ Perform the installation and commissioning stage with the related parties</td>
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<tr>
<td>2</td>
<td>All testing and commissioning activities are documented</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>All Devices have passed the relevant safety and performance tests</td>
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<tr>
<td>4</td>
<td>User and service manual exist</td>
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<tr>
<td>5</td>
<td>Completion of pre-installation work and analysis prior to delivery of the technology.</td>
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<tr>
<td>6</td>
<td>Installation and acceptance testing completion including all necessary training.</td>
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</table>
Chapter 5: Operations

5.1 Introduction

5.1.1 Objectives:

- Effective maintenance plans of the medical devices in order to increase the lifetime and decrease the breakdown of medical devices.
- Documentation of medical device history.
- Maintaining the safety and effectiveness of the medical devices.
- Ensuring that the medical device’s users are trained and have the required skills/knowledge to operate the devices.
- Effective reprocessing of medical devices.

5.1.2 Scope:

This chapter covers all operational activities of medical devices as follows:

- Tracking the medical devices.
- Maintenance of medical devices (i.e. CM, PPM).
- Management of spare parts.
- Calibration.
- Safety inspection.
- Reprocessing.
- Transfer of medical devices.
- Managing the field service notifications (FSNs), recalls and alerts and reporting any adverse events.

5.1.3 Ownership:

- HTM/Clinical Engineering Department.
- End-user Medical Departments.
- Quality Department.
- CSSD.
After the medical devices acceptance phase has been satisfactorily completed, the device can be used safely and the device is now in the operations phase.

**Figure 1.1: Operations processes.**
5.2 Operation Activities

The healthcare facility shall do the following:

5.2.1 Create Device History Record

An asset management software (e.g. CMMS) shall be used to manage the medical devices. The software shall include—but not be limited to—the following information:

**Device General Information**

- Includes: device category, device type (according to GMDN, description, model name & number, manufacturer, supplier, serial number and asset number, SFDA MDMA number, warranty period, purchasing costs, device location, assigned HTM/Clinical Engineering employee and service contract information if applicable, acceptance date, type of procurement (this could be: lease, reagent rental, deferred payment, loan, etc.), life expectancy of the medical device and risk class of device, accessories requirements if any.

**Periodic Preventive Maintenance (PPM)**

- Includes: Frequency of periodic preventive maintenance (PPM), procedure of PPM, calibration requirements and spare parts used for PPM.

**Test equipment required**

The characteristics of all measuring or energy delivering devices even the best designed ones change with time. Meaning if the device is showing a reading of (10), as the device is used more frequently, the deviation from the actual value increases. Therefore, special test devices need to be used regularly by a trained biomedical engineer/technician to verify the level of deviation in the operation of the devices. All devices having a deviation higher than the acceptable range identified by the manufacturer must be removed from service and the supplier must re-calibrate them. Some of the test devices include (patient simulator, infusion pump tester, defibrillator tester, Xray KV mater, artificial lung, laser power meter, and more.)
Examples:

- The anesthetic sets up the anesthesia machine for a certain gas and air percentage, certain gas volume and expects the machine to deliver the amounts indicated on the machine. The actual delivered parameters by the machine would change with time, and this requires using an artificial lung with calibrated sensors to verify that the actual delivered parameters match the machine settings. If not, the machine should be removed from service.

- Kilovolt (KV) and milli-ampere-second (mAs) meters need to be frequently used on X-ray machines to ensure that the dose delivered from an X-ray tube matches the machine settings, if not, the machine needs to be removed from service.

- All devices connected to patients must be checked for leakage current, insulation resistance, ground resistance and more electrical parameters to ensure that no excessive currents leading to possible heart failures enters into the body from that machine.

The supplier needs to identify the processes for:

- Preventive maintenance procedures and frequency
- Calibration verification procedure and frequency
- Test equipment needed for functional tests for the device
- Regular replacement parts needed for the machine

Device History

Includes:

- PPM history: date of each PPM, PPM kits & parts used, who completed the work, and time spent performing PPM.
- Corrective Maintenance (CM) history: date of failure, failure description, spare parts used, time duration of maintenance.
- related FSNs/recalls
- The history record of a new device shall be generated when a new device is ready for clinical operation (installed, tested, and tagged).
5.2.2 Plan for PPMs, Spare Parts Inventory and Electrical Safety Tests

Periodic Preventive Maintenances (PPMs) and safety tests are performed to maintain the basic safety and essential performance of medical devices according to the manufacturer requirements. In addition, performing PPM will reduce the chance of breakdown of the device which will increase the device’s utilization and reduce repair cost during the device’s life cycle.

When performing PPM, the following points should be considered:

- The PPM frequency and procedures shall be in line with the manufacturer requirements.
- The PPM frequency is usually indicated by time periods (interval-based), or as per device’s operation hours (meter-based), or both.
- Only trained personnel shall perform the PPM.
- For some devices, the PPM procedure requires replacing some parts or PPM kits. In this case, an adequate number of PPM kits shall be kept in stock, and periodically re-stocked, depending on the number of devices used in the facility and frequency of PPMs.

**Note:** If the PPM procedure includes using test equipment for performance or calibration checks, the test equipment shall be tested and calibrated by the manufacturer or a certified body.

- Before performing PPM, the device shall be clean, decontaminated (if needed), and working in a good condition.
- After performing PPM, a device’s performance and function tests shall be carried out.
- In all cases, this should include a safety test and safety inspection as part of the PPM.
- The PPM details (date, PPM kits, etc.) shall be recorded in the device’s history in the CMMS. Data shall be filed for a minimum of five years.
- All PPMs must be signed off by the end-user and clinical engineer/contractor performing the service. In addition, the device shall be tagged after PPM. The tag shall contain at least the date of last performed PPM, the due date for the next PPM, and responsible the engineer or technician.

5.3 Corrective Maintenance Management

If a device has a malfunction, the user shall do the following:

- Inform the HTM/Clinical Engineering department immediately.
A work order shall be generated and contain –at least- the following information:

- Device’s description and asset number.
- Location of the device.
- Description of the problem.
- Requestor’s contact details.

• The work order should be assigned to the responsible clinical engineer/technician who shall have proper training, qualifications, and tools to repair the device.
• After repairing the device, the assigned clinical engineer/technician shall update the work order by entering details of the used spare parts, time consumed in repairing the device, and corrective action details. Then close the work order.
• All CM order must be signed off by the end-user and Clinical Engineer/Contractor performing the service and the device is working as intended by the manufacturer.
• On all electrical medical devices, a test/safety Inspection shall be conducted as part of the CM.
• Function and calibration tests shall be conducted after installation, any major replacement and modification.
• If applicable, the device shall be calibrated after the corrective maintenance, as per manufacturer requirements.

Note: If the CM procedure includes using test equipment for performance or calibration checks, the test equipment shall be tested and calibrated by the manufacturer or a certified body.

5.4 Transfer and storage procedures

• When transferring a device to be used in another location or department, a transfer form shall be filled. The form should contain at least the device description and asset number, present location, new location, date of transfer.
• A copy of the (transfer form) must be sent to the HTM/Clinical Engineering Department to update the device’s record in order to keep track of the device for the purpose of the device’s maintenance, utilization, and future needs assessments.
In case the device need to disassembled and reassembled in different location, qualified engineer according to the manufacturer recommendations shall conduct this task. In case the device needs to be stored, it must be stored in accordance with the manufacturer's storage instructions such as the device’s shelf life, storage room temperature and humidity requirements (See: tables (9.6) and (9.7) in the appendixes for more details).

5.5 Reusable Medical Devices Reprocessing

5.5.1 Steps of the Reprocessing

![Reprocessing steps diagram]

The reprocessing process includes several steps and sub-processes. These apply depending on the risk classification of the medical device, which imply the aimed goal whether it is disinfection or sterilization. The process of reprocessing includes the following:

1. Pretreatment (to eliminate obvious stains):
   a) Collecting.
   b) Pre-cleaning.
   c) Disassemble.

2. Disinfection:
Disinfection can be manual or machine accomplished (e.g. washer-disinfectors machines according to ISO 15883 standards). The process includes the following subprocesses:

a) Cleaning and rinsing: To eliminate the residual blood, secretion or tissue before disinfection.

b) Disinfection: To eliminate bacteria, fungus and virus

c) Final rinsing and drying

d) Check for cleanliness and integrity

e) Assembly

f) Visual inspection

3. Functionality check (at the end of disinfection).

4. Sterilization: To eliminate prion pathogens:

a) Packaging (per ISO 11607)

b) Sterilization: (using one of the methods listed below based on manufacturer requirements):

i. Moist heat sterilization (ISO 17665).

ii. Dry heat sterilization (ISO 20857).

iii. Sterilization through radiation (ISO 11137).


c) Labeling:

i. Device name and model.

ii. Release date.

iii. Devices expiration date.

iv. Sterility expiration date.

v. Time of use limit and the current time of use.

vi. Assign a lot-number to each reprocessed medical device.

5. Documentation and release or reprocess.

6. Change the lot-number after each validation and any update on the process and maintain records for 5 years.

7. Transport and store (Disinfected medical devices shall be stored under clean-room conditions and sterile medical devices shall be stored under the recommended conditions of the manufacturer of the packaging material.

5.5.2 General Consideration for Reprocessing
1. All parts and external and internal components of the medical devices shall be exposed to the effect of each process.
2. Follow all manufacturer recommendations.
3. Check after each step for any residual stains or degradation of the medical devices.
4. Use desalinated water for rinsing.
5. Maintain checklist and clear comprehensible SOPs for each process.

5.5.3 Risk Classification
Considerations for the risk classification and choosing the reprocessing method:
1. Design, material, technical and functional properties of the device.
2. The risk of the to-be-disinfected medical device can be defined based on:
   a) The expected adverse effect as a result of:
      i. The usage preceding the disinfection process
      ii. The preliminary disinfection process that preceded the main disinfection.
      iii. The transport and the stage of the medical devices.
   b) The type of usage following the reprocessing.
3. The amount and typical types of pathogens expected to be on the device’s surfaces after use and their resistance to the proper disinfection process.

5.5.4 Risk Classes
1. Uncritical:
   Medical devices that only come into contact with intact skin.
2. Semi-critical:
   Medical devices that come into contact with mucous membranes or diseased skin.
   a) Medical devices without reprocessing special requirements (A).
   b) Medical devices with more stringent reprocessing requirements (B) if:
      i. The judgment of the efficacy of reprocessing is not possible by simply inspection,
ii. The fully avoidance of influential factor on the use or functional safety of the devices, as a result of reprocessing or transporting of the medical devices, is not guaranteed, or

iii. The number of uses or the reprocessing-cycle are limited as per manufacturer's instructions.

3. Critical:

Medical devices for the application of blood, blood products or other sterile drug or sterile medical devices, and medical devices which, as intended, penetrate the skin or mucous membrane and are used in contact with blood, or internal tissues or organs, including wounds

a) Medical devices without reprocessing special requirements (A):
   i. The medical device is thermostable (can be sterilized by steam sterilizer under 134 degrees C).

b) Medical devices with higher reprocessing requirements (B): If the device is thermostable (can be sterilized by steam sterilizer under 134 degrees C) and:
   i. The judgment of the efficacy of reprocessing is not possible by simply inspection,
   ii. The fully avoidance of influential factor on the use or functional safety of the devices, as a result of reprocessing or transporting of the medical devices, is not guaranteed,
   iii. The number of uses or the reprocessing-cycle are limited as per manufacturer's instruction, or

c) Medical devices with special high reprocessing requirements (C) if:
   i. The medical device is thermolabile (not to be sterilized by steam steam).
5.5.5 Requirements for Each Class

<table>
<thead>
<tr>
<th>Class</th>
<th>Processes</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncritical</td>
<td>• Cleaning</td>
<td>• Manual process.</td>
</tr>
<tr>
<td>Semi Critical A</td>
<td>• Disinfection</td>
<td>• Quality Management.</td>
</tr>
<tr>
<td></td>
<td>• Optional:</td>
<td>• SOPs and validation.</td>
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<td></td>
<td>• Pre-treatment</td>
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<td></td>
<td>• Sterilization</td>
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</tr>
<tr>
<td>Semi Critical B</td>
<td>• Pretreatment</td>
<td>• Automated cleaning and disinfection.</td>
</tr>
<tr>
<td></td>
<td>• Disinfection</td>
<td>• Quality Management.</td>
</tr>
<tr>
<td></td>
<td>• Optional:</td>
<td>• SOPs and validation.</td>
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<tr>
<td></td>
<td>• Sterilization</td>
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<tr>
<td>Critical A</td>
<td>• Disinfection</td>
<td>• Automated cleaning and disinfection.</td>
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<tr>
<td></td>
<td>• Sterilization</td>
<td>• Moist Heat Sterilization.</td>
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<tr>
<td></td>
<td>• Optional:</td>
<td>• Quality Management.</td>
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<tr>
<td></td>
<td>• Pre-treatment</td>
<td>• SOPs and validation.</td>
</tr>
<tr>
<td>Critical B</td>
<td>• Pretreatment</td>
<td>• Evidence of accredited training.</td>
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<tr>
<td></td>
<td>• Disinfection</td>
<td>• Automated cleaning and disinfection.</td>
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<td></td>
<td>• Sterilization</td>
<td>• Moist Heat Sterilization.</td>
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<td></td>
<td>• Optional:</td>
<td>• Quality Management.</td>
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<td></td>
<td>• Labeling</td>
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<tr>
<td>Critical C</td>
<td>• Pretreatment</td>
<td>• Proper Sterilization process</td>
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<tr>
<td></td>
<td>• Disinfection</td>
<td>• Certification of the Quality Management Process</td>
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<tr>
<td></td>
<td>• Sterilization</td>
<td>• according to ISO 13485.</td>
</tr>
<tr>
<td></td>
<td>• Labeling</td>
<td>• Risk Management according to ISO 14971</td>
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<tr>
<td></td>
<td></td>
<td>• SOPs and validation.</td>
</tr>
</tbody>
</table>

Table 5.1: Sterilization and Disinfection Risk Classes Requirements.

5.6 Computerized Maintenance Management System (CMMS)

A computerized maintenance management system (CMMS) is a software application that provides the documentation and management tools used by healthcare technology management (HTM) programs to collect, store, organize, analyze, and report medical device data for healthcare facility.

Sophisticated CMMSs support medical devices throughout the entire device lifecycle; from pre-procurement, acquisition, commissioning, device inventories, corrective maintenance (CM or unplanned repair) and planned maintenance management, field safety notices/ recalls and adverse events management, to device “end-of-life” management, replacement analysis and disposal.
Each healthcare facility shall have a CMMS for the following reasons:

- Track the medical devices within its institution
- Monitor the performance of medical devices during its life cycle in the healthcare facility.
- Calculate the operational costs of medical devices during their life cycle in the healthcare facility.
- Contract Management – management of outsourced maintenance to manufacturers/vendors or third party sources
- Parts management.
- Forecasting demand for future medical device acquisitions
- Providing history database for all installed medical devices.
- Staffing requirements to support the medical device—both directly and indirectly through external support (vendors, third party providers etc.)
• Present the responsible engineer for each devices and trained end-users.
• Document reprocessing process.

5.7 Data integrity

Without accurate and complete data, a CMMS is not going to be of much use to the HTM department. All HTM staff is responsible for assuring that the data they enter and update are complete and accurate. Incomplete and inaccurate data make it difficult to report useful information, which can lead to poor decision-making.

Good data quality depends on several factors, including the following:

• **Availability of HTM-relevant data sources:** Source data needs to be available to the HTM staff. For example, medical device acquisition cost data, which should be included on every asset record, require a purchase order or invoice information in order to accurately capture the device’s price.

• **HTM employee accountability:** Documentation quality begins at the source, the employees. CMMS training and documentation expectations and guidelines should be provided to every HTM employee. Assessment of documentation quality should be included in employee performance appraisals.

• **CMMS data standardization:** Operation of a high-data-quality CMMS depends on multiple levels of data field standards. These include fields defined by the CMMS supplier, fields defined within the healthcare facility, and fields that use nationally or internationally published “standardized” definitions. Policies should indicate which data definitions HTM staff should use. For example, fields that indicate which department “owns” a medical device can use the organization’s own chart of accounts. Device type fields can use the Global Medical Device Nomenclature (Global Medical Device Nomenclature, 2017) or Universal Medical Device Nomenclature System (UMDNS, 2017). HTM supervisory personnel or the CMMS database administrator should be responsible for managing (adding, deleting, and updating) these and other foundation data tables (e.g. department, building, medical device type, manufacturer and vendor lists).

• **Referential integrity:** For the foundational data, both the underlying database structure and the CMMS application error-checking capability, are important to ensure high data quality. The database should include appropriate referential integrity in order to make sure that related fields do not have any “orphan” data. For example, every medical device
record should have a manufacturer’s reference, and every manufacturer reference should have a manufacturer name, address, and so on.

- **Field definitions**: Each CMMS field should have a written definition so every HTM staff member uses the field the same way. Without field definitions, individual staff may interpret a single field in different ways. For example, for a network-connected medical device, what is the definition of the “Port” field on the IT data section of the asset record in (Figure 5.4)? Is it the physical data port where the Ethernet cable plugs into the wall or the virtual port used for HL-7 data communication with the electronic medical record? Both “ports” are important data, but they serve different purposes.

![Port](image)

**Figure 5.4**: all fields need to be defined. For example, is the “port” field a data port in the wall or a logical port for HL-7 data or?

- **Maintenance activity coding**: Where sharing or comparison of maintenance data is desirable or required, maintenance activities must be consistently and accurately coded. Dropdown lists and other coding techniques help standardize data, although sometimes at the expense of detail. Definitions are paramount to make sure “apples to apples” comparisons can be made. For example, what does the checkbox field “PM-preventable mean” (Figure 5.5)? Does it only apply to CM workorders, or can it be used to indicate a change is needed in a PPM procedure? How will the aggregated data from this field be used?

![PM Preventable](image)

**Figure 5.5**: “PM-Preventable” is an example of a field that needs to be defined. When should technicians check this box?

### 5.7.1 Error Checking

Certain fields in the CMMS are always required (e.g. Asset Control Number). Other fields may be required by Healthcare Facility/HTM policy and the CMMS should allow these to be configurable (e.g. Downtime).
The CMMS should provide a robust set of configurable error checks. For example:

- **Data types**: The CMMS should automatically ensure that each field has the appropriate data type entered (e.g., string, number, dollar amount, date).

- **Range constraints**: Most fields have logical ranges, so constraints can be configured to make sure that data entry is stopped, or a warning issued, if a value is out of the expected range. For example, a range check for a vendor hourly rate field could be set for a minimum of $50 USD to a maximum of $999 USD per hour to catch an obviously erroneous data entry.

- **Date checks**: Dates (and times) need to have a consistent format throughout the CMMS. Some dates (e.g., next PPM due date) must be in the future when initially entered. Most other dates should be current or in the past when entered (e.g., work order completion date).

- **Multiple-field error checking**: Multiple-field error checking is more complex and often requires special CMMS configuration or customization. For example, suppose that downtime is a required field when an asset is a “critical system,” but optional if it is not. Multiple-field error checking would be configured so that downtime is always required on critical system repair work orders.

- **HTM business rules**: A healthcare provider may have internal requirements that mandate certain rules in the CMMS. For example, local business rules may authorize different levels of purchasing authority for parts and services for different levels of HTM personnel, based on the cost of the order (e.g., a staff BMET is allowed to place parts orders up to $1,000 USD without additional approval, whereas a BMET supervisor is allowed to place an order up to $5,000 USD).

In addition to automatic error checking, periodic audits are necessary to maintain data quality. Some data problems that require data aggregation cannot be immediately caught at data entry.

**Example**: For a specific BMET, or group of staff, an audit could recognize that an insufficient number of labor hours have been documented on work orders compared to payroll system-related data (e.g., time card entries). Sampling audits by supervisors can also check for problems that are difficult to automate, such as verification that work orders are accurate and documented in sufficient detail.

For a CMMS to be effective it needs to be easy to use. Modern CMMSs allow the use of smart phones, tablets, and laptops. Pick lists, autocomplete text entry, voice to text, and other modern
data entry techniques make them easier to use. Reports can be set up to run at regular intervals and dashboards can provide near-real-time feedback on ongoing activities (see: section 9.1.3).

5.8 Considerations in selecting a new or replacement CMMS

Suppliers offer a wide variety of CMMS applications at a wide variety of price points. With such wide availability, it is not recommended that HTM departments try to develop their own CMMS. Modern CMMSs are complex software applications, that take a lot of time to write and can be difficult to update and maintain. Most healthcare facilities will already have some kind of CMMS in place so the rest of this section will focus on CMMS replacement selection and implementation. If there is no CMMS currently available, and there are no, or very little, funds available for a CMMS, there are low cost, or even free (with restrictions) CMMSs available, although they are not typically HTM focused (Hoppe, 2017).

CMMS Software Evaluation and Selection

The evaluation and selection process should be as follows:

1. Assess your current CMMS system for its features that are working well and its deficiencies. Also, as you assess deficiencies of your current system, take into consideration that some of those deficiencies might be data related, and poor quality data are poor quality data regardless of the CMMS features. You don’t want to import bad data into your new CMMS, so a data clean-up project may also be appropriate.

2. Develop a high-level list of your CMMS needs, including key required and desirable features, for a new system.

3. Consider the proposed physical location of the new system (cloud-based vs local), taking into account security considerations, data ownership, hardware, support model, and cost.

Note: Commercial CMMS suppliers offer vendor-hosted, cloud-based CMMS software that runs from a web browser and is compatible with a variety of web-enabled devices (e.g. laptops, tablets and smart phones).
4. Invite vendors to provide an on-line demonstration of their software.

**Note:** To optimize everyone’s time, focus on your requirements list by providing the suppliers in advance of their demonstrations with a draft high-level list of your requirements and, if possible, a few scenarios that they can use to show how their products might meet your requirements. (e.g. demonstrate a COSR report for all imaging systems, show a dashboard of pending work for today or for this week). From these demonstrations, and the other information you gather, you can develop a more formal and final requirements document and pursue your selection process through RFI (Request for Information) and/or tender/RFP/RFQ (Request for Proposal/Quotation) processes depending on your healthcare facility’s procurement process requirements. The result should be a written response from each vendor to each of your requirements and a written pricing proposal. You may also want to prioritize each specification item (e.g. mandatory, preferred, desirable).

5. Review the supplier’s written responses and see which products meet which specifications—both “out of the box” and through customization.

**Note:** Pay particular attention to supplier responses that require customizations: What will the customizations cost? How long will they take to complete? Contact references and, if needed, schedule additional demonstrations.

6. Limit the number of suppliers to your top candidates based on pricing and features. Limit the demonstrations to exactly what you want to see so you can clearly evaluate their responses. Features can be “scored” by your evaluation team based on how well they meet your requirements. Pricing comparisons should include both initial pricing and support and licensing pricing for a period of time (e.g. 5 years, 10 years) so you can evaluate pricing based on life cycle costs. Then determine which product comes closest to meeting both feature requirements and budget.

7. Once you decide on a single product, the next step is to negotiate a final price, schedule, and terms and conditions with the vendor. Get all the vendor promises in writing. Be clear about the deliverables, responsibilities, expectations, and schedules, particularly customization and data imports, which sometimes are problematic and can take a long time. Then start getting ready for the implementation-planning phase.
### 5.9 Reporting adverse events to SFDA

It is a moral responsibility for users, patients and all those using a medical device or accessory to report adverse events. There are multiple numbers of the same device being used by other patients in other hospitals and reporting the incident will save others from facing the same accident (reporting is saving).

Accidents or injuries on patients or users caused by a Medical device or accessory must be reported to SFDA national center for medical device reporting (NCMDR) to protect patients in other hospitals from facing the same incident (reporting is saving). The center investigates the accident and a recall, warning, or field safety notice for the device may result from this investigation. The released statement will include a corrective actions required to be implemented on the device to avoid the re-occurrence of the incident in other hospitals.

Corrective actions include but not limited to the following:

- Removing the device from service
- Replacing or adjusting some parts
- Advising nursing on proper method for using the device.
- Regular warning

SFDA requires that manufacturers and distributors track the devices they sold within Saudi. When a recall is issued, the National center for medical device reporting forces the manufacturer's representative in Saudi to conduct whatever corrective action needed on all the similar devices available in Saudi to protect patients and users in other hospitals from facing the same accident.

It is important to note that recalls on Medical devices and equipment take place within the best brands, best manufacturers and best devices. Sometimes, a manufacturing problem temporarily takes place, so all batches of devices manufactured during that design problem need to be removed from service or fixed. Manufacturers must report such problems to SFDA, in addition, design problems, false claims, wring instructions for use, faults that have caused or may cause harm to patients or users must be reported to SFDA so that an investigation and root cause analysis is done. If the investigation results in an action against the device, SFDA will request the list of customers who bought the device from the manufacturer and follow up with manufacture or its representative to perform the desired action to avoid causing harm to other patients.
5.9.1 How to report an adverse event?

Report adverse events by calling 19999 or by visiting the NCMDR web portal: [https://ncmdr.sfda.gov.sa/](https://ncmdr.sfda.gov.sa/), where the adverse event can be reported and followed up.

What should be reported?

1. An event has occurred

Typical events are:

a) A malfunction or deterioration in the characteristics or performance.

A malfunction or deterioration should be understood as a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

The intended purpose means the use for which the device is intended, according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials.

b) An inadequate design or manufacture.

This would include cases where the design or manufacturing of a device is found deficient.

c) An inaccuracy in the labeling, instructions for use and/or promotional materials.

Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.

d) A significant public health concern.

This can include an event that is of significant and unexpected nature, such that it becomes alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD).

e) Use error.

- Use Error Resulting in Death or Serious Injury/ Serious Public Health Concern.
- Use error related to medical devices, which did result in death or serious injury or serious public health concern, should be reported to the SFDA.
- Use errors becoming reportable: Use errors become reportable to the SFDA when you:
- Note a change in trend (usually an increase in frequency), or a change in the pattern of an issue that can potentially lead to death or serious injury or public health concern.
- Initiate corrective action to prevent death or serious injury or serious public health concern.

2. The Event Led to One of the Following Outcomes

  a) Death of a Patient, User or Other Person

  b) Serious Injury of a Patient, User or Other Person.

  Serious injury (also known as serious deterioration in state of health) is either:
  - Life threatening illness or injury,
  - Permanent impairment of a body function or permanent damage to a body structure.

  The term "permanent" means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage.

  Medical intervention is not in itself a serious injury. It is the reason that motivated the medical intervention that should be used to assess the reportability of an event.

  c) No Death or Serious Injury Occurred, but the Event Might Lead to Death or Serious Injury of a Patient, User or Other Person if the Adverse Event Recurs.

  All events do not lead to a death or serious injury. The non-occurrence of such a result might have been due to circumstances or to the timely intervention of health care personnel.

  The event is considered "adverse" if in the case of recurrence, it could lead to death or serious injury.

  This applies also if the examination of the device or a deficiency in the information supplied with the device, or any information associated with the device, indicates some factor which could lead to an event involving death or serious injury.

  Include relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in this report.
3. The Manufacturer's Device is Associated with the Event

In assessing the link between the device and the event, the manufacturer should take into account:

a) The opinion, based on available information, from a healthcare professional
b) Information concerning previous, similar events
c) Other information held by the manufacturer

This judgment may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that all factors, including the device, be associated with the event.

5.9.2 Dealing with FSNs/Recalls.

Field Safety Correction Action

A field safety corrective action is taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device. Such action should be notified via a field safety notice.

Field Safety Notice (FSN)/Recall

A notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.

SFDA classifies medical device recalls into three categories, representing the potential risk to public health:

- Class I High risk.
- Class II Medium risk.
- Class III Low risk.

FSNs/Recalls Weekly Report
The NCMDR staff is sending an updated list of recalls on a weekly basis to healthcare officers. The report contains information such as the manufacturer name, affected device model and description, and affected lot/batch/serial numbers.

When the health care officer receives the recalls weekly report, he/she shall:
- Ensure that the healthcare facility removes from use any affected device/product mentioned in the FSNs/Recalls.

If the healthcare facility has any affected device then the officer shall:
- Communicate with the NCMDR Team and Authorized Representative of the manufacturer to ensure the implementation of the necessary corrective actions.
- If the FSN requires the user to stop using the device, then the officer shall take the necessary actions to ensure that the affected device(s) are not in use until a corrective action is done.

5.10 Special requirements for specific medical devices

Safety of all medical devices for both patients and medical practitioners can be enhanced by providing user training. However, some especially high risk, medical devices need additional training to reduce their risk for the following medical devices:

1. Non-implantable active medical devices for:
   a. generation and application of electrical energy to directly affect the function of nerves and / or muscles or the heart activity including defibrillators,
   b. intracardiac measurement of electrical quantities or measurement of other quantities using electrically operated probes or sensors in blood vessels or on exposed blood vessels,
   c. Generation and application of any energy for immediate coagulation, tissue destruction or destruction of deposits in organs,
d. direct introduction of substances and fluids into the bloodstream under potential pressure build-up, where the substances and fluids can also be processed or specially treated endogenous substances whose introduction is directly coupled to a removal function,
e. mechanical ventilation with or without anesthesia,
f. diagnosis using imaging techniques based on the principle of nuclear magnetic resonance
g. therapy with pressure chambers
h. therapy by means of hypothermia

2. Infant incubators
3. external active components of active implants

The healthcare provider shall not operate or use these high risk medical devices without assigning an in-house medical device clinical educator for each type of high risk medical device. The Medical Devices Clinical Educator shall be trained by the manufacturer or his representative on the correct and safe handling, use and operation of the medical device and their accessories and if the device is subject to be combined and operate with other devices or within system, the training scope shall be extended to include the whole combined devices and system. This training shall be based on the IFU and related safety and maintenance information. This training shall qualify the Medical Devices Clinical Educator to train the other users of the device and this shall be included in the manufacturer certification. The healthcare provider shall document this training.

The Medical Devices Clinical Educator’s obligations toward all medical devices assigned to him are the following:
- Attend the training provided by the manufacturer
- Organize and conduct training for other users of the same medical device from the same manufacturer in their healthcare provider.
- Document all the training activities that have been executed on the related medical device and share it with the HTM department.
- Assure the availability of the IFU of this medical device and make it accessible for all users at all working hours.
- Monitor the compliance/adherence to the requirement of safety and calibration checks and periodic preventive maintenance.
- Organize on a regular basis discussions to address safety issues regarding the use and operation of these medical devices with the users, SFDA-Officer, manufacturer or his authorized representative and the HTM Department and all parties involved in the operation of these medical devices. Apply corrective action where appropriate. These discussions shall be documented.
- Update users with and all parties involved in the operation of these medical devices with all safety issues and recalls issued by the SFDA or the manufacturer.
- Support the SFDA-Officer in case of reporting adverse events, applying SFDA medical devices recall procedures and manufacturer procedures.

5.11 Special safety requirements

Safety of medical devices for both patients and medical practitioners can be enhanced by providing proper user training and proper device maintenance. However, some medical devices need special safety requirements to eliminate their risk.

5.11.1 Medical Laser Devices

The laser is used in several different applications in healthcare facilities including dermatology, surgery, and ophthalmology.

When using a laser device, the following precautions should be taken:

• Use of proper protective eyewear for both health practitioner and the patient to protect the eyes from direct and reflected laser energy.
• Laser warning signs in Arabic and English should be placed on the door of each procedure room to prevent personnel from entering without wearing protective eyewear.
• Ventilation of airborne contaminants to protect personnel from inhaling noxious fumes.
• Quick operating procedures for using laser equipment shall be posted in each clinic.
• The operator and/or dermatologist shall be licensed by Saudi Commission for Health Specialties in relevant specialty.
• The patient shall sign a consent form that acknowledges procedure hazards and declare patient's history and physical state, and it should be updated at each visit.
• Operators shall be trained on laser emergency incidents, laser safety training and operating laser equipment. (Training certificate shall be kept on file).

• The eyewear wavelength shall match and cover the device wavelength.

• Eyewear shall be in good condition (Operators shall not use broken eyewear).

• Adequate number of eyewear (at least 3) shall be provided.

• Any reflecting object of the laser beam such as mirrors, metal and any other reflecting objects shall be covered or removed to avoid inadvertent exposure to direct or scattered laser radiation.

5.11.2 Ionizing Radiation

Ionizing radiation is a form of energy that acts by removing electrons from atoms and molecules of materials that include air, water, and living tissue. Ionizing radiation can travel unseen and pass through these and most other materials.

The main exposure to ionizing radiation is through the use of diagnostic medical exams. Medical exams that use ionizing radiation include: X-ray, CT scan, PET scan, Fluoroscopy, and Nuclear Medicine procedures.

The following actions can help reduce the exposure to and risk of harm from diagnostic ionizing radiation by:

• Checking to see if a test that does not use ionizing radiation can provide similar information.

• Making certain the least possible amount of radiation needed to obtain a good quality image is used.

• Using protective lead shielding to prevent exposing other areas of the body to radiation.

• Performing functional tests of quality assurance to ensure that the device is not deviating from the proper use (KV, mAs, tests, collimator alignment tests, …etc)

5.12 Inventory Accuracy
The inventory accuracy shall be maintained so that all devices & spare parts can be tracked after acquisition by the hospital. All additions, deletions, changes should be made promptly. The inventory accuracy shall be periodically verified, at least the existence of identification number, manufacturer and description, with a statistically significant sample each year.

Inventory should include:

- Location of the device.
- Department owning the device.
- Service provider.
- Acceptance date.
- Additional useful information.
- Spare parts.

5.12.1 A Sample Statistical Model for Evaluating Inventory Accuracy

The values chosen below reflect the minimum sample quantities necessary to ensure that the inventory is at least 85% accurate. A more accurate inventory would require less sampling. The numbers are derived from the equation:

\[ s = \sqrt{\frac{p(1-p)(N-n)}{nN}} \]

where \( s \) is the standard error of the sample, \( p \) is the mean accuracy of the inventory, \( n \) is the sample size, and \( N \) is the population size.

To derive the numbers used here, a mean accuracy for the inventory was assumed to be 90%, with a standard error of 5%. In this way, the following statement can be made with 95% confidence: Based upon the sample, if the accuracy of the selected sample is 90% or greater, then the mean accuracy of the entire population is the same as the accuracy of the sample +/- 5%. This assumes that the selected samples are truly randomly selected.

For example, to find the sample size required, this equation can be rewritten as:

\[ n = \frac{Np(1-p)}{Ns^2 + p(1-p)} \]

If the total number of items in the inventory is 100 items, then:
\[ n = \frac{(100)(0.9)(1 - 0.9)}{(100)(0.5)^2 + 0.9(1 - 0.9)} \]

\[ n = 26.47 \]

This number is then rounded up to the next highest integer. The typical sample sizes used for accuracy check are:

- < 100 items the audit shall be 27 randomly selected items.
- >100 but < 500 items, the audit shall be 34 randomly selected items.
- 500 but < 1000. The audit shall be at least 35 randomly selected items.
- 1000 the inventory shall consist of 36 randomly selected items.

The accuracy is expected to be > 95\%.²

For more details please refer 2013 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI EQ56:2013

### 5.13 Warranty Management

Warranty Management deals with management of all technical services related to medical devices that are within their warranty period. During this period, the type, quality and performance of the medical device, as well as the quality of services and technical support provided by the supplier, is assessed. The responsibility for the device’s technical performance is primarily with the supplier, and the healthcare facility and HTM program is responsible for documenting and notifying the supplier of all quality and performance issues so they can get them rectified free of charge during the pre-agreed-upon warranty period.

- Warranty management procedures shall ensure that all faults of the device occurring within the contracted warranty period are reported and fixed, and bring the device to its original working condition.
- The warranty provisions and scope of coverage, are recommended by the HTM/Clinical Engineering and the device’s clinical department, and based on the device’s purchase agreement. This would include all warranties provided by manufacturers, local suppliers and third-party providers. This could include Planned Preventive Maintenance, Corrective Maintenance, Emergency services, inclusion/exclusion of spare parts, etc. HTM/Clinical Engineering has to monitor the performance – both in terms of quality of repairs and
support response - and ensure that all these activities are in conformance with the purchase agreement and other procurement documentation.

- All warranty services must be recorded in the CMMS system. Warranty registers must be continuously monitored for performance. All reports shall be available in the CMMS which is used for management of all warranty work orders and other activities.

- HTM/Clinical Engineering must monitor all technical services provided during the warranty period for appropriate responses, quality and types of repairs and turnaround time. They must ensure that supplier performance is continuously assessed, and the related clinical department is informed. Supplier performance management and ratings are key indicators and should be factored during future procurement activity.

- HTM/Clinical Engineering Department should ideally schedule a pre-warranty completion inspection at six months to warranty completion for major devices, and 3 months for smaller devices to ensure that systems are optimally working at the end of the warranty.

5.14 Disaster/Contingency Planning

Disaster can strike anytime in the healthcare facility – critical device failures, power failures, infections etc. HTM/Clinical Engineering needs to have a proactive plan to ensure that the clinical services in the healthcare facility are not affected or are only minimally affected in case of disasters related to medical devices. Disasters related to loss of utilities (power, water, medical gases, IT, etc.) should be included in the plan.

A systematic program of identifying critical and high risk devices, and taking systematic steps to mitigate their risks, is required. HTM/Clinical Engineering must provide mechanisms to avoid failures or breakdowns of device during patient treatment, diagnosis or therapy.

- HTM/Clinical Engineering must be proactive in identification of possible points of failure of device related services and develop contingency plans before the catastrophic event or possible incident.

- Risk management and scoring of medical devices: One method for assessing and classifying medical device risk is by assessing a device’s basic function (Function Description), clinical use risk (Physical Risk to patient), and maintenance requirements (see 3 charts below).
Risk Scoring:

Total risk can be assessed by adding the three categories. Then a determination can be made as to the disaster plan threshold above which resources should focus (above 12 in the example below).

- Total Risk EM = Function + Risk + Required Maintenance.
- Device EM > 12 are included in the disaster plan.
- Device EM < 12 are not included in the disaster plan.

**Ref:** Page 27-28: WHO publication: Medical device Inventory Management by Tania O’ Connor: WHO Medical Device Technical Series 9789241501392.

---

### Table 5.2: Maintenance Risk Score.

<table>
<thead>
<tr>
<th>Maintenance requirement</th>
<th>Point score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extensive: routine calibration and part replacement required</td>
<td>5</td>
</tr>
<tr>
<td>Above average</td>
<td>4</td>
</tr>
<tr>
<td>Average: performance verification and safety testing</td>
<td>3</td>
</tr>
<tr>
<td>Below average</td>
<td>2</td>
</tr>
<tr>
<td>Minimal: visual inspection</td>
<td>1</td>
</tr>
</tbody>
</table>

---

### Table 5.3: Functional Risk Score.

<table>
<thead>
<tr>
<th>Category</th>
<th>Function Description</th>
<th>Point Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic</td>
<td>Life Support</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Surgical and Intensive Care</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Physical Therapy and treatment</td>
<td>8</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>Surgical and Intensive care</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Additional Physiological monitoring and diagnostic</td>
<td>6</td>
</tr>
<tr>
<td>Analytical</td>
<td>Analytical Laboratory</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Laboratory Accessories</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Computer and related</td>
<td>3</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>Patient related and other</td>
<td>2</td>
</tr>
</tbody>
</table>

---
Table 5.4: Physical Risk Associated with Clinical Applications.

<table>
<thead>
<tr>
<th>Description of use</th>
<th>Risk</th>
<th>Point score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential patient death</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Potential patient or operator injury</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Inappropriate therapy or misdiagnosis</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Device damage</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>No significant risk</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

25.15 User Training

Safe and effective use of medical device requires that users shall receive appropriate training as per manufacturer requirements. The training should focus on clinical use and the need to ensure that all features of the technology are used for best possible patient diagnosis and therapy.

- The key focus of user training programs would be to enable users to operate the device in a safe and effective manner. An additional objective will be to ensure that users cooperate in increasing the useful life of the device, while operating the device safely.
- Training will be mandatory when a new device is installed.
- Training may also be required based on failure data or wrongful use of the medical device.
- If any special training is required – either in-house or from manufacturers or specialized agencies- it shall be provided as requested and agreed upon in the initial purchase or subsequent support agreements for the life of the equipment.
- HTM/Clinical Engineering will keep records of the training; content and attendees.

5.16 HTM/Clinical Engineering Training programs

The staff in the HTM department shall be trained as follows:

- The required education for his job.
• The required training from the manufacturer.

5.17 Spare Parts procurement and management

• HTM/Clinical Engineering staff, based on their engineering assessment, shall source appropriate and genuine spare parts for maintenance based on manufacturer service manuals and technical bulletins.

• HTM/Clinical Engineering with the assistance of the device supplier should plan for appropriate inventories of spare parts to minimize downtime.

**Note:** Spare parts should cover periodic preventive maintenance spares, as well as spares for breakdowns.

5.18 On Site Libraries

To maintain devices, and to use devices appropriately, users and clinical engineers need access to operation and service manuals. A systematic method of maintaining service and user manuals should be developed to ensure that hard or soft copies of these documents are available on demand.

• HTM/Clinical Engineering must provide technical staff with appropriate manuals and documented instructions on maintenance and support of all medical devices.

• On site libraries should include manufacturer authorized and authenticated:
  - Service and repair manuals.
  - Operation manuals.
  - Other manuals including software manuals etc.
  - These may be provided in hard or soft copies.
  - Surveys of all medical device documentation can identify documentation gaps and requirements.
  - All HTM programs should include a plan for a documentation system with safe storage and easy access for all information.
  - This system should be catalogued based on manufacturer and model number for easy identification and retrieval.
- When a new device is commissioned, a copy of the manuals should be provided to HTM Department.
- It is suggested that all new devices must come with at least two copies of the manuals.
  – One for HTM and the other is for the end-users.

5.19 Workshop Space and Test Devices

A well-equipped workshop space is a mandatory requirement for a HTM/Clinical Engineering Department. The workshop must be equipped with work benches, test equipment, service toolkits, personal protective equipment, jigs and fixtures necessary to provide competent technical services.

**Workshop requirements:**

- The workshops should be of adequate size to accommodate the service teams, manuals and documentation.
- Test equipment: Appropriate test equipment for analyzing, performance and safety of medical devices shall be available.
- Ensure that all test equipment are procured and calibrated as per manufacturer requirements.
- Ensure that the workshop is appropriately equipped with all safety equipment (fire extinguishers, PPE, etc.).
- Workshop plans, and drawings must be available.

5.20 Inter Service Coordination

Medical devices are dependent for their optimal performance on many support systems such as air conditioning, medical gases, electrical power, emergency power (e.g. (UPS), IT, and other utilities. Failure of these services could result in medical device failure resulting in catastrophes. To prevent this, regular coordination between these facility services and HTM will help ensure higher uptime for the medical devices.
The HTM/Clinical Engineering Department must coordinate with many other departments of the healthcare facility, to ensure that quality services are provided to the healthcare facility. Typically, these include Facilities Management, IT, Quality, Infection Control, etc. This process addresses the framework of such coordination.

- Close coordination with many support services in the healthcare facility may require a formal framework.
- Healthcare Administration should facilitate this formal framework.
- A periodic (e.g. monthly) meeting with representatives of all services is suggested.

5.21 Checklist

<table>
<thead>
<tr>
<th>No.</th>
<th>Check list item</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Availability of a dedicated HTM/Clinical Engineering Department with appropriate budgets and management.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Medical device management plan.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Availability of CMMS system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Availability of PPM, CM, Safety testing and performance testing policy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>The Storage area is in compliance with Medical Devices manufacturer and any regulatory requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>All medical Devices are calibrated if applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Availability of Electrical Safety analyser</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Availability of Quality assurance test equipment as needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Availability of biomedical test equipment as needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>All test Equipment are calibrated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Availability of SFDA-Officer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Availability and applying of written procedure to manage recalls published by SFDA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Availability applying of written procedure to report adverse events to SFDA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Availability of Medical Devices Clinical Educator</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chapter 6: Disposal & Donation

6.1 Introduction

6.1.1 Objective
Ensuring safe and cost effective disposal or donation of medical devices.

6.1.2 Scope
This process applies to the healthcare organization and their staff who will dispose or donate surplus medical devices.

6.1.3 Ownership
- HTM/Clinical Engineering Department.
- End-user Medical Departments.
- Assets management.
- Legal.
- Finance.
- Quality Department.
- CSSD.
- Related Healthcare admin.

6.1.4 Background
Decommission and Disposal

Device may be recommended for disposal because of:
- Beyond economic repairs
- New safety requirements render the device unsafe
- Recent technology renders the device redundant
- Hazardous for use
- Recall advice from regulatory agencies

HTM/ Clinical Engineering and Facilities Engineering shall arrange for the device to be moved into long term storage facilities pending safe disposal.

Planning → Procurement → Installation → Operation → Decommission and Disposal

In the case of radiation device, laser systems etc., governed by statutory laws and regulations, appropriate authorities must be informed.

Update the device’s status record. The device’s history shall be kept for at least 5 years.

Figure 6.1: Decommission and Disposal Process.

6.1.4.1 Donating of Used Medical Devices (Decommissioning and Disposal)

Medical devices may be donated or sold to other healthcare organizations within the Kingdom of Saudi Arabia or to foreign countries. However, to improve the quality of donations of used medical devices process, it is suggested to follow the following guidelines:

- Healthcare organizations shall properly plan for the devices that can be donated and communicate with the anticipated recipients before removal of the devices from service.
- The used medical devices that are proposed to be donated or sold shall be removed from service after conducting the appropriate testing and removal all patients’ data. The devices shall be cleaned, disinfected from contamination and transported to a warehouse of suitable environment before delivering them to the recipient.
- The donating organization shall provide maintenance manuals, documents and available related spare parts to the receiving organization together with any information about missing parts, if any.
- The recipient shall assure the availability of the necessary consumables or in-vitro diagnostic devices (IVD), as well as the availability of a suitable location that contains the basic space, physical installation (alignment, shielding, etc.) and utility-related services (e.g. such as electricity, drainage, water supply, nitrogen outlets) as appropriate.
- The recipient of the used medical devices shall review their requirements, healthcare level, patient workload, number of users, their abilities, and their available technical experience level prior to acceptance of any used medical devices.
• Do not sell or donate medical devices to a third party as follows:
  - Any used medical devices that have at least 2 years left of their operational life.
  - Devices destroyed as junk, dismantled or having parts removed for spares.

• Used medical devices that will be donated or sold to a third party shall:
  - Pass mechanical safety tests, calibration and electrical safety tests, including but not limited to electrical leakage current testing.
  - Be accompanied by maintenance and user manuals whenever possible.
  - Be accompanied by usage starting date, periodic maintenance record, periodic test schedules and all reports describing the status of the device during service, if available.
  - Be free from medical any contamination or biological remains, radiological waste, splashes or any hazardous medical remains.

• All used medical devices that shall be sold or submitted for public tender shall be kept in a safe storage area (a warehouse with good temperature and humidity control) within or out of the healthcare organization. Such devices shall not be left in the open air. It is preferable to wrap these devices for their safety during storage and transport.

• The healthcare organization shall keep a separate record for all disposed of used medical devices by device. A separate record shall be maintained for identification of the sold items in addition to the identity of the purchaser.

6.1.4.2 Decommissioning and Disposal of Medical Device

Decommissioning of Medical device is required when a device needs to be removed from service. In some cases, there are specific protocols for removal of devices (e.g. devices with radiation sources) or other statutory laws and regulations (e.g. hazardous waste, patient data). This is a sensitive and hazardous activity, and in specifically identified cases, must only be done by experienced staff. When decommissioning a device, consider the following points:

• The organization is expected to have a well-defined and written procedure to coordinate removal and disposal of medical devices that have been decommissioned.

• The reasons for decommissioning must be clearly identified and may include:
  - Beyond economic repair.
- New safety requirements render the device unsafe.
- Recent technology renders the device redundant.
- Hazardous for use.
- Recall advice from regulatory agencies.
- Re-sale/public auction.

- Disposal of used medical devices shall follow the standards of disposal of medical waste, including disposal of nuclear and contaminated wastes.
- Disposal of used medical devices shall be carried out within the same healthcare organization and under the supervision of qualified professionals or licensed subcontractors who shall destroy the medical devices on behalf of the healthcare organization.
- The healthcare organization shall keep all the documents pertaining to the destroyed used medical devices.
- Spare parts may be Dismantled from used medical devices that are not destroyed due to contamination or fire or non-conformance or recall by the supplier.
- Spare part(s) to be dismantled from the disposed used medical devices shall conform with the following guidelines:
  - Shall not require disinfection before fixing it on another similar medical device.
  - Printed circuit boards or any other electronic part shall not be totally or partially damaged (e.g. due to heat from solder removal process).
  - Shall not be contaminated or cracked or damaged.
  - Shall not be expired (e.g. a consumable part passed its operational life as calculated by the number of hours of use).
  - An exposed radioactive part.
  - A part that directly or indirectly contributes to the clinical measurements and cannot be calibrated before using it again in another medical device.
  - A part in that has been in contact with the patient or touching the patient’s body directly or through an interface.
- Dismantling shall be conducted only by a trained and licensed biomedical engineering.
- A record of all dismantled used medical devices shall be kept within the respective healthcare organization.
- HTM/Clinical Engineering and Facilities Engineering shall arrange for the device to be moved into long term storage facilities pending safe disposal.
The CMMS data for the decommissioned medical device shall be updated and records shall kept for 5 years or longer.

In the case of radiation devices, laser systems or other devices governed by statutory laws and regulations, appropriate authorities must be informed.

6.2 Checklist:

<table>
<thead>
<tr>
<th>No.</th>
<th>Check list item</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Are reasons for decommissioning are identified and documented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Availability and applying of a medical device written procedure for disposal and donation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Availability of Group/ Committee for Medical Devices/Health Technology disposal and donation with involvement of all related parties in the ownership.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>The availability and applying written procedures of dismantled spare part</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Availability of record of all disposed medical devices for at least 5 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Devices to be disposed are isolated in storage area</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chapter 7: Special Topics

7.1 Introduction

7.1.1 Objective:
Define & demonstrate the special requirements for Medical Device Consumables, Single Use Medical Devices (SUMD), Implants, and Medical Devices Clinical Trials (Clinical Investigation).

7.1.2 Scope:
This chapter applies to the following products:
- Medical device consumables (reusable).
- Single use medical devices (SUMD).
- Single patient medical devices.
- Implants.
- Medical devices clinical trials (Clinical Investigation).

7.1.3 Background
Consumables and Accessories in medical devices for this chapter are defined as follows:
1. Accessories are those items which:
   - Connect the medical device to the patient (e.g. breathing circuits, ECG leads, probes/transducers).
   - Assist with the use of the medical device (e.g. internal trays, foot-switches, computer mouse).
   - Adapt its performance (e.g. different sized adaptors, objectives, lenses).

Note: The accessories are often the main link to the patient, the part most handled by staff flexed, bent, twisted and, sometimes misused. They are subject to a great deal of
wear and tear and often are the most vulnerable problem part of a medical device. Even
for medical device last for many years, accessories may need to be replaced regularly,
therefore accessories must be available for the lifetime of the medical device.

2. Consumables are those items which:

- Are used up and need to be replaced frequently (e.g. each case, daily, weekly) during
  the operation of the medical device (e.g. X-ray film, disposable electrodes, laboratory
  reagents, ultrasound gel, washing powder, copier toner).
- Consumables are needed throughout the lifetime of the medical device.
  - Consumables used in conjunction with a primary medical device are in fact
devices in their own right, albeit they may have a secondary function to the
primary device and may have gone through an independent regulatory review
process.
  - The availability of a medical device consumable item is significant. It is often
the case that when a device consumable is no longer available for supply and is
specific to the function of a primary medical device, it renders the primary device
unsusable.

Medical device consumables may be single use or reusable. There are some advantages
and disadvantages to both types and some of the re-use management aspects are discussed
later in this chapter.

A Primary electro-medical device (e.g. an infusion pump) that uses or relies on the use of
consumables often may use different brands of accessories or consumables which are not
easily interchangeable. There are, however, a number of key principles that apply to the
safe use and application of these components including:

- Functional compatibility with the primary medical device.
- Purchase from an establishment registered and licensed by SFDA.
• The product shall be authorized for marketing (e.g. MDMA & MDNR).
• Standardization and rationalization of as much of the consumable stock items as possible in order to reduce cost and minimize user training requirements.
• Effective stock control – many consumable items will have a specific shelf life and this requires an effective monitoring and management process to be in place.
• Ability for clinical users to access e-catalogues to inform staff about the range of consumable products available in stock or to purchase from approved suppliers.
• Appropriate environmental storage facilities.
• The volume of consumables used and the utilization of the primary device will have a significant impact on a health technology expenditure.
• An effective dissemination of guidelines for the use of medical devices and consumables.
• Availability of the consumable (when used in conjunction with a primary health technology) throughout the entire expected lifetime of the primary device.

The availability and usage of medical device consumables and accessories should be of significant interest to the healthcare facility. A failure of a device consumable will have a significant impact on the performance of a primary medical device with potential negative impacts on clinical service delivery and safety. In addition, the expense profile of a primary device can be significantly altered based on poor management of device consumables. Methods to consider managing consumable and accessory cost and performing the following:
• Direct purchase of consumables.
• Guaranteed price per reportable result (GPPRR) (e.g. Suppliers may offer to provide their devices free of charge against a fixed price for the supply of consumables.)
• Leased medical devices with or without consumables and accessories included in the lease cost.
Note: HTM/Clinical engineers have a significant role to play ensuring that the following two aspects (single use and re-use) are effectively addressed should a decision to move towards a different consumable plan be under consideration.

7.2 Medical device Consumables, Single Use.

- Medical device consumable expenditure can be a very significant component of the whole life cycle cost of a primary medical device.
- There are also consumables that are not always part of the functionality of a primary electro-medical device such as syringes, needles, etc.
- There is a wide range of consumables in use within healthcare and it would be impractical to list them all within this document.
- Manufacturers of single use devices indicate which devices are for single use only.

Figure 7.1: Example of manufacturer labelling for Single Use Device

Examples of SUMD include, but are not restricted to, the following:

- Endodontic reamers and files.
- Saliva ejectors.
- Aspirator tips and three-in-one tips.
- Dental burs.
- Matrix bands.
- Single use patient face masks.
7.3 SFDA requirements with regards to reprocessing of single use devices

1. Medical devices designed for single use only in surgical procedures performed in the tissues and internal organs of the human body shall not be reused for any medical application.

2. Medical devices that are for single use only utilized for the external organs of the human body can be reprocessed according to the requirements determined by the SFDA.

3. Sites that reprocess single use medical devices for themselves or any other party will be treated in accordance with No.7.3.2 above as a new manufacturer of the medical device and shall be responsible for the safety and efficiency of the product according to the requirements specified in the SFDA regulations.

4. Healthcare facilities shall comply with the provisions of above requirements when reprocessing medical devices.

5. The establishment that reprocesses the single use devices will be treated as a new manufacturer for that reprocessed single use device.

7.4 Reuse of Reusable, Limited Use & Single Patient Use Medical Devices

The reuse of reusable medical devices and single patient use medical devices shall be in accordance with manufacturer’s guidance.

7.5 Reuse of Single Use Medical devices

Healthcare facilities that use single use devices for patient care have several options:

- Dispose of all single use devices after a single use and purchase a new device.
- Contract with a regulated reprocessing organization and purchase devices from them.
• Become a reprocessing organization and comply with standards for reprocessing single use devices.
• Use only reusable medical devices as labelled by the manufacturer.

The healthcare facility shall follow the SFDA requirements regarding the reuse of reprocessed single use medical devices. The reprocessed single use medical device will be treated as a new medical device.

Key good practice actions⁴ that should be considered by healthcare providers:
a) Be informed about current laws, regulations and guidance that may affect the healthcare providers’ decisions regarding use of reprocessed single use devices.
b) Establish an interdisciplinary "reuse committee" to consider the issues that should inform policies, procedures, and protocols.
c) Educate clinical staff about the facility’s policy for use of reprocessed single use devices and provide a supporting rationale.
d) Develop and implement criteria for selecting the reprocessed single use devices the healthcare provider will use and for evaluating third-party reprocessing organizations.
e) Review provisions in contracts with original equipment manufacturers (of single use devices) that would prohibit or inhibit third-party reprocessing of their single use devices.
f) Ensure that the facility's event reporting system captures adverse events related to reprocessed single use devices and that a procedure is in place for mandatory reporting of medical-device-related deaths and voluntary reporting of serious adverse events related to medical devices to the SFDA.

All reprocessing organizations (e.g. hospitals, manufacturers, third-party vendors) are required to follow the SFDA licensing requirements.

Through a process of clinical and technical testing and evidence the reprocessing organization will need to identify the maximum number of reprocessing cycles to which a device can be subjected while maintaining safe device functionality and performance.
Once the maximum number of reuse cycles has been reached the product should be discarded and safely disposed of.

Reprocessing of single use devices generally consists of the following processes:

a) Cleaning.
b) Disinfection (reduces the number of viable microorganisms).
c) Sterilization (kills all microorganisms and is required for devices that likely will become contaminated with pathogens during use).
d) Functional testing.
e) Relabeling.
f) Repackaging.

Reprocessing may require disassembly and reassembly to facilitate cleaning. Each reprocessed item must be inspected before reuse and also function-tested and repackaged for reuse. After every single use of a reprocessed single use device, the device must again go through the entire reprocessing system. (Vocalic)^2.

7.6 Medical Device Implants

Medical device implants range from simple devices, such as intraocular lenses, cosmetic implants, orthopedic hardware, stents, and joint replacements, to highly complex devices, such as retinal implants, artificial hearts, implantable cardioverter-defibrillators (ICDs), and cochlear implants.

Examples of ‘active’ implants can include the following:

- Implantable nerve stimulators.
- Implantable cardiac rhythm management devices (pacemakers, defibrillators, etc.).
- Leads, electrodes, adaptors for the above.
- Cochlear implants.
- Catheters, sensors for active drug administration technologies.
A key feature of the management procedures for medical implants concerns the management of stock and product requirements. There are a number of options to consider which will help manage the cost of these often expensive devices. Good practice considerations include the following actions:

- Establish the full range of device implant suppliers and products used by the healthcare provider.
- Identify the product volumes consumed.
- Consider any unused stock held on the premises and identify reasons, and follow-up actions, to more efficiently manage implant logistics.

### 7.6.1 Tracking Medical Device Implants

The healthcare provider has a responsibility to be able to notify its patient population should a product recall occur. An inability to notify the recipient of an implanted device that is the subject of a recall is to be avoided. The following is an example of data that should be collected by healthcare providers to enable effective implant tracking to take place:

- Any unique identification number, lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device.
- The name, address, telephone number of the patient in receipt of the device.
- The date the device was provided for use by the patient.
- The name, address, and telephone number of the prescribing clinician.
- The name, address, and telephone number of the clinician regularly following up care with the patient, if different from the prescribing clinician.
- The date of the patient's death, if applicable.
- At the device explant point: the name, mailing address, and telephone number of the explanting clinician.
- When applicable, the date the device was permanently retired from use, explanted or otherwise permanently disposed of.
Device tracking good practice areas for consideration for healthcare providers are provided below:

1. Ensure that the healthcare provider has implemented a device tracking program that meets current legal and regulatory requirements.

2. Designate a medical device "tracking manager" to oversee the device tracking process, to act as a liaison with device manufacturers and the SFDA for tracking purposes, and to ensure that pertinent staff are educated about the facility's tracking program.

3. Establish a system for collecting and submitting tracking information to manufacturers and SFDA. Address whether and how patient consent to the release of his or her identity will be obtained and documented.

4. If a consent process is established, ensure that it includes a mechanism for documenting refusals.

5. Verify that a patients’ rights to refuse to release identifying information to the manufacturer for purposes of tracking are being upheld.

6. Address the need to retain device tracking records and determine the length of retention.

7. Establish a method by which the healthcare provider can monitor changes to any list of tracked devices and future SFDA regulations and recommendations regarding tracking and cooperate with tracking procedures implemented by manufacturers in response to new or revised regulations.

7.6.2 Implanted Medical Devices Registries in Saudi Arabia

In order to monitor the performance of medical device implants, tracking any associated side effects or complications that may arise in health facilities in Saudi Arabia, the SFDA has established the (Comprehensive Implanted Medical Device Registry - CIMDR) that will help facilitate tracing and tracking of these devices and their users, where potential risks may or could threaten their safety and health. Additionally, this process supports and encourages medical research conducted by healthcare providers, researchers, innovators,
and manufacturers on medical device implants for verification of their effectiveness and intended use leading to the best healthcare services. It also provides SFDA with a post market surveillance tool by analyzing the registry data about the safety, effectiveness, and quality of medical devices implants.

Currently, there are four established registries: Hip joints, knee joints, stents, and ICDs. SFDA is planning also to include cochlear implants and breast implants registries in 2019. The registry captured data includes: demographics, diagnosis, patient history, comorbidities, previous procedures, complaints/symptoms, surgery information, outcomes, device information, and follow up information.

More information about this national initiative and how health facilities can participate in the registry, can be found at: http://cimdr.sfda.gov.sa

7.6.3 Reporting Processes - Medical Device Implants

Good practice recommendations for an effective implant reporting process includes the following:

1. A closed-loop process that, in addition to the distribution of recalls, includes confirmation that the recall has been received by a responsible party and documentation of the remediation efforts taken.

2. A written policy is available specifying, for example, to whom incoming recalls should be sent, how recalls should be processed, and how the response to those recalls should be documented.

3. A manufacturer or other organization that issues a recall might direct the recall to a specific department, to an individual physician, or to others. This data needs to be captured within a centralized recalls management process.

4. All parties will need to be educated about the process for forwarding recalls to the correct individual or department.
Recalled implanted devices require careful clinical management and follow-up. The primary responsibility for the clinical management of recalled implants usually rests with the patient’s clinician and/or referring clinician. When a recall affects an implanted device, the healthcare provider should notify both clinicians so that they may provide appropriate follow-up care to patients.

Clinicians whose names are included on the device registration may be notified of the product recalls directly by the manufacturer. The clinician concerned should report the receipt of this recall so that this information can be captured in the healthcare providers’ central medical device recall/patient safety reporting system.

### 7.6.4 Explanted Medical Devices

Implanted medical devices may be removed for numerous reasons:

- Device may have reached the end of its useful life; or
- Product defect or malfunction may necessitate the explant.

In the case of a recall involving an implant, when the manufacturer notifies the implant clinician or hospital, an incident report should be filed within the healthcare providers own health technology recalls or patient safety incident reporting management system. Such recalls should also be reported to the SFDA for regulatory purposes. Where an implant is deemed to be a patient safety risk by the implant clinician this matter should be reported to the SFDA and the original device manufacturer (not the distributor).

It is also recommended that prior patient consent for post-mortem device evaluation and explantation be documented and, in the absence of such consent, seek approval be obtained for explantation from family members. Some medical device companies post contact information and information about where and how to return the devices on their web sites.
7.6.5 Medical Devices Clinical Trials (Clinical Investigation)

7.6.5.1 Objectives
To ensure the compliance of medical devices clinical trials to the Saudi Food and Drug Authority (SFDA) requirements.

7.6.5.2 Scope
Any party who wishes to conduct medical devices clinical trials in KSA.

7.6.5.3 Background
A clinical investigation is defined as a “systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device”.

Note: “Clinical trial” and “clinical study” are synonyms for “clinical investigation”. The objective of a clinical investigation is to assess the safety and performance/efficacy of the device in question and evaluate whether the device is suitable for the purpose(s) and the population(s) for which it is intended (ISO 14155:2011). Clinical investigations must take into account scientific principles underlying the collection of clinical data along with accepted ethical standards surrounding the use of human subjects. The clinical investigation objectives and design should be documented in the clinical investigation plan.

7.6.5.4 Ownership
- Institutional Review Board (IRB).
- Principal investigator.
7.6.5.5 Requirements

- Shall comply with the Law of Ethics of Research on Living Creatures by National Committee of Bioethics (NCBE).
- Shall request “No Objection Letter” issued by SFDA before starting the study recruitments.
- Should be in accordance with:
  - Declaration of Helsinki.
  - ISO 14155 (or any equivalent standard GCP).
### 7.7 Checklist

The table below represents a best practice checklist. Its purpose is to serve as a tool for evaluating medical device consumables, single use devices and implant activities and assist in the development of process improvements.

<table>
<thead>
<tr>
<th>No</th>
<th>Checklist item</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identify the stock of medical device consumables and implants needed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Provision of an effective stock control system for medical consumables and implants.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Implement a medical device implant tracking process.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Availability of Registration Documents by SFDA for any Medical Device intended to be used for Clinical Investigation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8. References
9. Appendices

9.1 Planning:

- Appendix 9.1.2 Includes facility planning examples for Operating rooms, intensive care units and Imaging.
- Appendix 9.1.3 Includes sample emerging technology descriptions for multiple modality systems, 3-D printing in healthcare; integrating the Healthcare Enterprise (IHE) profiles for device integration; medical device surveillance monitoring; genomics; and a few examples of the use of artificial intelligence (AI) and big data in healthcare and HTM.

<table>
<thead>
<tr>
<th>Table 9.1: Typical healthcare facility Utilities for Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical power - Emergency electrical power</td>
</tr>
<tr>
<td>Fire detection and prevention</td>
</tr>
<tr>
<td>Elevators (move planning relevant)</td>
</tr>
<tr>
<td>Domestic water - Water for dialysis and other special water treatment systems</td>
</tr>
<tr>
<td>Heating, ventilation and air conditioning (HVAC)</td>
</tr>
<tr>
<td>Hot water</td>
</tr>
<tr>
<td>Building temperature control</td>
</tr>
<tr>
<td>Cooling &amp; Heating</td>
</tr>
<tr>
<td>Humidification</td>
</tr>
<tr>
<td>Sanitary sewer</td>
</tr>
<tr>
<td>Storm sewer</td>
</tr>
<tr>
<td>Medical gases and vacuum</td>
</tr>
<tr>
<td>Compressed medical air</td>
</tr>
<tr>
<td>Oxygen</td>
</tr>
<tr>
<td>Vacuum</td>
</tr>
<tr>
<td>Other piped specialty gases (CO2, NO, N2)</td>
</tr>
<tr>
<td>Steam</td>
</tr>
<tr>
<td>For heating and air conditioning</td>
</tr>
<tr>
<td>For sterilizers</td>
</tr>
<tr>
<td>Natural gas</td>
</tr>
<tr>
<td>For steam</td>
</tr>
<tr>
<td>For electricity if co-generation plant</td>
</tr>
<tr>
<td>IT *</td>
</tr>
<tr>
<td>Wiring infrastructure</td>
</tr>
<tr>
<td>Wireless infrastructure</td>
</tr>
<tr>
<td>Data closets (MDF, IDFs)</td>
</tr>
<tr>
<td>Data centers</td>
</tr>
<tr>
<td>Other, non-IT-based communication technologies requiring separate wiring</td>
</tr>
</tbody>
</table>
9.1.1 Appendix A: Certificate of Need Process

A certificate of need is a review and approval process, typically from a government agency, to proceed with a major project (e.g. building, large cost equipment purchase) taking into account the overall needs of the community being served. Many countries do not have this process in place but it may be something decision makers may want to consider. For those countries who have or will implement this process, it is important to take into consideration the following when applying for a certificate of need.

- General Data
  - Place.
  - Catchment area.
  - Epidemiology information.
  - Mortality/morbidity.
  - Applicant’s data.

- Description of need
  - Service characteristics.
  - Clinical procedures required.
  - Number of referred patients to another site.
  - Other available equipment in the area.

- Proposal
  - Medical equipment.
  - Staff.
  - Infrastructure.

- Resources needed
- Investment.
- Operational costs.
- Sources of financing.

9.1.2 Planning Examples:

9.1.2.1 Operating Rooms:
Operating Rooms (ORs) provide a safe and fully controlled environment for patients undergoing diagnostic and surgical procedures under anesthesia and pre-operative care including post procedure recovery. Medical devices are the backbone of all types of ORs, ranging from the “same day”, short stay OR up to the most advanced open heart and neurosurgery ORs. Effective lifecycle management of medical devices ranging from the basic single use devices and surgical tools, up to the most advanced robotic surgery and imaging equipment plays a key role in clinical effectiveness and patient’s surgical outcomes.

9.1.2.2 Medical Devices Storage and Special Areas:
From a planning perspective, it is an essential and major requirement to include sufficient OR storeroom space for medical devices and equipment. Depending on the type of OR, storage requirements of at least 10 m2 per OR should be provided. It is important to ensure the following when designing the OR storage and medical equipment special areas:

a) Storerooms are best designed in an elongated rectangular to allow easy access to all items.

b) The design of the Operating Unit should allow for ease of access to the storage areas for delivery of operating room consumables. Controlled access from an external corridor is highly desirable.

c) Mobile equipment bays need to be provided for equipment such as portable X-ray equipment, stretchers, trolleys, warming devices and mobile equipment.

d) Equipment bays are best designed as elongated rectangular shapes and may be combined for space efficiency with an area for testing operating room
equipment. This room may be co-located with a general storeroom, or a dedicated room for testing equipment may be necessary. Direct corridor access to this room is recommended, with controlled access to the remainder of the ORs.

9.1.2.3 Planning and Design Considerations:
Several factors must be considered when designing operating rooms including expected utilization, specialties cases expected, and layout of the operating rooms. The following must be considered:

a) The number of operating rooms and recovery beds and sizes of the support areas shall be based on the expected surgical workload

b) The surgical suites corridor layout shall be located and arranged to prevent non-surgery-related traffic through the suite. This is important for infection control purposes.

c) The operating room suite shall be designed with a sterile core to have no cross traffic of clean supplies and soiled/decontaminated supplies and areas. Flow of clean and soiled/decontaminated supplies and equipment to the OR suites themselves shall be designed to not compromise universal precautions and aseptic techniques.

d) The surgical suite shall be divided into three distinct areas; unrestricted, semi-restricted, and restricted.

e) Consideration should be given to the effects of building vibration, as building vibration could interfere with the accuracy of patient position, testing and delicate surgeries (e.g. ophthalmic procedures).

f) Patient corridors should be a minimum of 8’-0” wide, to accommodate wheelchairs, equipment, and gurneys.

g) Operating rooms shall have the following:

1. Provision shall be made for a closed-circuit television (CCTV) system.

2. Communication needs are as follows: patient data computer outlets, nurse call/intercom system, telephone with speakerphone capability.
3. All floors of the ORs to be homogeneous with a coved floor base extending no less than 6” above the finish floor for floor cleaning purposes. No floor drains are permitted.

9.1.2.4 OR Space Requirements:

OR space requirements vary depending on the standards implemented and the operating rooms’ layout implemented (e.g. single or double corridor). It is always the role of hospital planners to consider local needs and national standards for recommended spaces.

It is important to understand the medical equipment quantities and requirements in the operating rooms in order to plan for the utility and space requirements. Radiology equipment is also used in the OR such as the RF C-arms and mobile x-ray units and radiation protection precautions and shielding must be considered.

<table>
<thead>
<tr>
<th>No.</th>
<th>OR space</th>
<th>Recommended space (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Operating Room, General</td>
<td>41</td>
</tr>
<tr>
<td>2</td>
<td>Operating Room, Special Purpose</td>
<td>65</td>
</tr>
<tr>
<td>3</td>
<td>Operating Room, Neurosurgery</td>
<td>42</td>
</tr>
<tr>
<td>4</td>
<td>Equipment Room, Neurosurgery</td>
<td>17</td>
</tr>
<tr>
<td>5</td>
<td>Operating Room, Cardiac</td>
<td>65</td>
</tr>
<tr>
<td>6</td>
<td>Pump Room, Cardiac</td>
<td>17</td>
</tr>
<tr>
<td>7</td>
<td>Cystoscopy Room</td>
<td>42</td>
</tr>
<tr>
<td>8</td>
<td>Cystoscopy Instrument Prep / Storage Room</td>
<td>19</td>
</tr>
</tbody>
</table>

Table 9.2: Recommended Sizes for OR Spaces (Sample)

Following is a sample list of medical equipment and devices typically found in operating rooms:

1. Operating table.
2. Operating lights (ceiling mounted and mobile).
3. Surgical and Neurosurgical microscopes.
4. Robotics surgery (Orthopedic, neurosurgery, etc.).
5. Patient monitoring systems.
6. Anesthesia and patient ventilation equipment.
7. Electrosurgical units.
8. Surgical sets.

Modern ORs are complex. Surgical robotics, other minimally invasive surgical instrumentation, new and larger imaging devices, and more and more other equipment are being added to ORs all the time. Therefore, new ORs are being planned larger and larger. In addition, in busy ORs, efficiency and throughput are critical. All of these factors need to be taken into consideration in all facets and phasing of the planning processes for new and remodeled operating rooms.

9.1.2.5 Cardiac Operating Rooms:
The cardiac OR requires some special nonstandard spaces such as a perfusion room. The perfusion room is for the preparation of perfusion equipment, and for set-up for cardiac procedures. The perfusion room must be near the cardiac OR and adjacent to a perfusion storage area with the following main requirements:

a) Heavy duty shelving for storage of perfusion fluids and equipment.
b) Computer workstation for a perfusion technician including power and data outlets.
c) Bench, sink and cupboard unit for servicing of the perfusion machine.

9.1.2.6 Imaging and Radiology Rooms:
Imaging departments are one of the most strategic departments in any hospital because of both the diagnostic imaging role in clinical outcomes and the high cost of imaging equipment. The major imaging rooms in a typical diagnostic imaging department may include the following:
a) Chest x-ray rooms: A specific or specialized radiography room used for routine chest X-rays and those radiographic procedures that can or should be performed in an upright position.

b) Computed Radiography (CR): CR uses a special plate technology, scanning and computer processing, to produce a digital image of a patient’s organ or body part. This digital image can then be output to a digital reading station, sent to PACS, and/or printed to a dry processor.

c) Computed Tomography (CT): CT employs ionizing radiation to produce axial (cross sectional) body section images. Data obtained by X-ray transmission through the patient is computer analyzed to produce these images. This series of sectional, planar images can be manipulated to produce different planar views of the areas of interest and eliminate overlying structures such as bone. Manipulations of data allow for the selective view of either dense tissues such as bones or diffuse tissues such as the heart, brain, or lung. CT is used for both head and body imaging and is applicable to diagnosis, biopsy, and therapy planning.

d) General radiology rooms: Images of the skull, chest, abdomen, spine, and extremities are produced by the basic radiographic process.

e) Magnetic Resonance Imaging (MRI): This technique utilizes magnetic and radio frequency fields to produce computer calculated images of human anatomy (body tissue) and can also provide body chemistry analysis. While immersed in a magnetic field, the portion of the body to be scanned is exposed to energy in the radio frequency range. The effects of this exposure on atomic nuclei position are read by the computerized system and converted into images. MRI reflects tissue density and body chemistry.

f) Interventional Radiology (IR): This clinical subspecialty uses fluoroscopy, CT and ultrasound to guide percutaneous (through the skin) procedures such as performing biopsies, draining fluids, inserting catheters, or dilating or stenting narrowed ducts or vessels. IR procedures are complex, requiring a team of doctors and technicians. As such, they are often performed in the surgical suite, and scheduled in advance as they require special preparation. IR / Special
Procedure rooms can be categorized as angiography rooms and/or vascular/neuro-vascular rooms.

g) Ultrasound: High frequency sound waves are utilized to determine the location, size and shape of internal organs based on the differential rates of reflection of different density tissues. In addition, images can be observed in real time to reveal motion, and ultrasound systems add coloration to indicate arterial and venous blood flow. Cyst aspiration and fluid removal are also procedures done with ultrasound imaging assistance.

One important factor to be considered by hospital planners during the planning of a radiology department is the radiation protection for patients, radiologists, radiographers and other hospital staff. This is can be done by providing the required shielding on the walls, doors and even windows to make sure that leaked radiation is within allowed limits according to the local national standards. Space requirements for imaging equipment vary between different international standards. The location of the imaging equipment within the radiology department is essential. The following diagram illustrates an example radiology department.
9.1.2.7 Planning and Design Considerations:
Radiology imaging services should be strategically located in order to:

1) Maximize efficiency (i.e., maximizing the use of high cost equipment).
2) Plan to accommodate the high probability that the area may require expansion in the future.
3) Avoid the substantially higher cost of enlarging a Radiology Suite through relocation rather than expansion.
4) Locate soft spaces such as administrative and conference areas adjacent to the high technology/diagnostic equipment areas that have a higher probability to expand.
5) Hospital planners should give special attention to the following when designing new hospital imaging departments.

6) Structural support, especially for heavy imaging equipment like MRIs and CTs.

7) Level floors for the radiology department. In addition, placing radiology departments in upper floors will face challenges in transferring and installing heavy equipment (e.g. MRI magnet). Easy access floors are always preferred.

8) Temperature and ventilation for the control and patient rooms.

9) Provision of cable trays, ducts and conduits.

10) Location of other required medical equipment and flow of patients and staff.

11) Other local factors such as male and female waiting areas and changing rooms.

9.1.2.8 Imaging modalities Space Requirements:
Recommended space for imaging modalities varies between different international standards. Following is a summary example list of patient space requirements for some imaging modalities (excluding reception & support areas).

<table>
<thead>
<tr>
<th>No.</th>
<th>Imaging modality</th>
<th>Recommended space (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>General Purpose Radiology Room</td>
<td>28</td>
</tr>
<tr>
<td>2</td>
<td>Chest Room</td>
<td>23</td>
</tr>
<tr>
<td>3</td>
<td>Radiographic / Fluoroscopic (R/F) Room</td>
<td>30</td>
</tr>
<tr>
<td>4</td>
<td>Ultrasound Room – 1 unit</td>
<td>17</td>
</tr>
<tr>
<td>5</td>
<td>Interventional Radiology Procedure Room (including control room)</td>
<td>56</td>
</tr>
<tr>
<td>6</td>
<td>CT Scanning Room</td>
<td>37</td>
</tr>
<tr>
<td>7</td>
<td>MRI scanning room</td>
<td>47</td>
</tr>
<tr>
<td>8</td>
<td>Stereotactic Mammography Room</td>
<td>20</td>
</tr>
</tbody>
</table>

Table 9.4: Sample Recommended Space Requirements for Imaging Modalities
9.1.2.9 Imaging Room Layout:
Clinical engineers must always refer to the latest manufacturer’s recommendation for an imaging modality’s layout to make sure the layout accommodates all possible configurations. The following figure demonstrates a sample MRI scanning room layout.

Figure 9.2: MRI Scanning Room Layout.
In summary, new imaging systems and departments are high cost, complex and strategic investments where good, prior planning is paramount to a successful long-term efficient operation. HTM involvement in imaging equipment planning and support is required in order to optimize this important healthcare diagnostic and treatment tool.

### 9.1.2.10 Intensive Care Units:
There are several types of intensive care units depending on patient type and age such as Neonatal ICU, Pediatric ICU, Adult ICU and Coronary Care Units (CCU) in cardiac centers. In this section, discussion will be kept generic to critical care. The intensive care unit provides a concentration of clinical expertise, technology and therapeutic resources, which are coordinating care for the critically ill patient.

Typical list of medical equipment needed for all types of ICU units include:
- Patient monitoring system.
- Patient ventilator.
- Infusion pump.
- Bedhead unit.
- ICU electrical bed.
- Suction unit.

### 9.1.2.11 Planning and Design Considerations:
The level of intensive care available should support the role of the hospital. The role of an ICU will vary, depending on staffing, facilities and support services as well as the type and number of patients it needs to manage.

### 9.1.2.12 Main Functional Areas:
a) Intensive Care Units normally consist of the following main functional areas:
b) Family/visitor waiting areas.
c) Patient treatment areas including patient beds and treatment rooms.
d) Support areas including clean and dirty utility rooms, storeroom, linen room, housekeeping/cleaner's room.

e) Administrative / office areas.

f) Staff amenities areas.

The following figure illustrates an example of the ICU functional relation and layout diagrams:

![Figure 9.3: Intensive Care Unit Functional Relationship Diagram](image-url)
9.1.2.13 Medical Equipment Support:
Depending on the location of the main HTM unit (or biomedical department) and its distance from the ICU, it must be noted that fastest response is required to support medical devices in the ICU units. A 24 hours on-call emergency biomedical support service is recommended. It is common practice to have a full-time biomedical engineer or technician covering OR and ICU during working hours and on-call emergency service after working hours. The competency list of biomedical staff covering ICU and OR must include several technical and clinical skills that must be continuously updated according to an effective outcome-based competency development program. The training of such biomedical support staff must be part of the technical specification and tender requirements for OR and ICU medical devices.

9.1.2.14 Laboratory Support:
All ICU units must have available 24-hr clinical laboratory services. When this service cannot be provided by the central hospital laboratory, a satellite laboratory within or immediately adjacent to the ICU must serve this function. Satellite facilities must be able to provide minimum chemistry and hematology testing, including arterial blood gas analysis. It is common practice to have a hematology analyzer within the ICU unit operated by the ICU nursing staff that are trained by laboratory staff.

9.1.2.15 Storage Areas:
A dedicated storage area, that is out of traffic paths but conveniently located for easy access by staff, is required to store mobile equipment such as cardiopulmonary resuscitation trolleys and mobile x-ray machines. Storage space considerations should be given to the increasing amount of equipment used in these units.
9.1.2.16 Design and Space Planning:
The recommended space requirements for intensive care units varies between different international standards, yet it is very common to recommend enough spaces to allow patient treatment and staff access.

9.1.2.17 Patient Treatment Areas:
Patient bed layout is very important in the ICU. It must provide continuous direct or indirect visualization for clinical staff. The preferred design is to allow a direct line of vision between the patient and the central staff station. In ICUs with a modular design, patients should be visible from their respective nursing substations. Sliding glass doors and glass partitions facilitate this arrangement and increase access to the room in emergency situations.

9.1.2.18 Bedside Monitoring:
Bedside patient monitoring systems should be located to permit easy access and viewing, and should not interfere with the visualization of, or access to, the patient. The bedside nurse, and/or monitor technician, must be able to observe the monitored status of each patient at a glance. This goal can be achieved either by a central monitoring station, or by bedside monitors that permit the observation of more than one patient simultaneously. Neither of these methods is intended to replace bedside observation. Weight-bearing surfaces that support the monitoring equipment should be sturdy enough to withstand high levels of strain over time. It should be assumed that monitoring equipment will increase in volume and connectivity over time. Therefore, space, electrical and IT facilities should be designed accordingly³.

9.1.2.19 Environmental Conditions (Acoustics):
Signals from patient call systems, alarms from monitoring equipment, and telephones add to auditory sensory overload in critical care units for both patients and staff. Without reducing their importance or sense of urgency, such signals should be modulated to a level that will alert staff members yet be rendered less
intrusive. For these reasons, floor coverings that absorb sound should be used while keeping infection control, maintenance, and equipment movement needs under consideration. Walls and ceilings should be constructed of materials with high sound absorption capabilities. Ceiling soffits and baffles help reduce echoed sounds. Doorways should be offset, rather than being placed in symmetrically opposed positions, to reduce sound transmission. Counters, partitions, and glass doors are also effective in reducing noise levels. 

9.1.2.20 ICU Space Requirements: 
Spaces recommended for the whole ICU and the different sections within the ICU vary widely between different international standards. Where an open plan arrangement is provided, bed spaces shall be arranged so that there is a clearance of at least 1200 mm from the side of the bed to the nearest fixed obstruction (including bed screens) or wall. At the head of the bed, at least 900 mm clearance shall be allowed between the bed and any fixed obstruction or wall.

When an open plan arrangement is provided, a circulation space of 2200 mm minimum clear width shall be provided beyond the dedicated cubicle space4. Separate cubicles and single patient bedrooms including isolation rooms, shall have minimum dimensions of 3900 mm x 3900 mm. Following are the main types of isolation rooms:
Neutral or standard room air pressure, for example standard air conditioning, also known as Class S.
Positive room air pressure where an immune-compromised patient is protected from airborne transmission of any infection, Class P.
Negative room air pressure, where others are protected from any airborne transmission from a patient who may be an infection risk, Class N.
Negative room air pressure with additional barriers, including an Anteroom, also known as Class Q for quarantine isolation.
<table>
<thead>
<tr>
<th>No.</th>
<th>ICU</th>
<th>Recommended space (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient Room, Intensive Care</td>
<td>28</td>
</tr>
<tr>
<td>2</td>
<td>Patient Room, Airborne Infection Isolation</td>
<td>28</td>
</tr>
<tr>
<td>3</td>
<td>Nursing station</td>
<td>17</td>
</tr>
<tr>
<td>4</td>
<td>Medication Room</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Storage, ICU Equipment</td>
<td>17</td>
</tr>
<tr>
<td>6</td>
<td>Workroom, Nurse</td>
<td>11</td>
</tr>
<tr>
<td>7</td>
<td>Utility Room, Clean / soiled</td>
<td>11</td>
</tr>
</tbody>
</table>

*Table 9.5: Sample recommended spaces for ICU.*

### 9.1.3 Appendix: Emerging Technology Examples:

#### 9.1.3.1 Emerging Technologies Introduction

For new and emerging technologies, it is difficult to predict what will become a clinical success in the near-future and nearly impossible to predict what will be commercially successful five to ten years from now. It is also impossible to include a comprehensive list of emerging technologies in a few pages. Therefore, this section reviews a few, new and emerging technologies chosen for their potential impact on healthcare providers and HTM. Included are the following: Multiple modality systems; 3D printing in healthcare; integrating the Healthcare Enterprise (IHE) profiles for device integration; medical device surveillance monitoring; genomics; and a few examples of the use of artificial intelligence (AI) and big data in healthcare and HTM.

#### 9.1.3.2 Multiple Modality Imaging Systems

Multi-modality imaging such as combinations of CT, MRI, fMRI (functional MRI), ultrasound, PET, and SPECT imaging combine two of these modalities into one system with a common gantry. These systems typically use one modality focused on structure (anatomy) and one focused on function (physiology). Since the patient
is placed on a common gantry, problems with patient registration to the correct reproducible imaging system position are minimized compared to using two different physical systems and localizing the patient to anatomic landmarks.

**Example:** in PET/CT, a widely-used technology, the CT scanner is used to image the brain or other structures, while the PET subsystem provides information about the function (physiology) of the area in the image. Positron emission tomography (PET) uses small amounts of radioactive pharmaceuticals called radiotracers, a special camera detector that detects the radiotracers, and a computer to develop human-readable images used to evaluate organ and tissue functions. PET scans measure important body functions, such as blood flow, oxygen use, and glucose metabolism to help doctors evaluate how well organs and tissues are functioning. PET is used for brain imaging of patients with seizure disorders, cancer diagnosis and tumor metastasis determination, heart muscle evaluation and other functions. Currently, almost all PET scans are performed on instruments that are combined PET and CT scanners. The combined PET/CT scans provide images that pinpoint the anatomic location of abnormal physiologic activity. The combined scans have been shown to provide more accurate diagnoses than the two scans performed separately. (Griffeth, 2005).

Similar types of multi-modality systems are under development and early implementation for MR/PET and CT/MR. MR/PET systems have been developed to stage cancer progression and for the diagnosis and treatment planning for other diseases. MR imaging has major strengths compared with CT, including superior soft-tissue contrast resolution, and functional imaging capability through specialized techniques such as MR spectroscopy. Furthermore, the lack of ionizing radiation from MR scanners, compared to CT, is highly appealing, particularly for pediatric and pregnant patients. (Savage, 2013).

In the research stage are systems that combine CT and MR. MR provides high contrast images and allows doctors to measure functional and even molecular
changes. CT provides greater structural detail. Together, they allow doctors to get a superior picture of processes in action, such as imaging certain types of plaques on artery walls that are particularly unstable and prone to causing heart attacks or strokes. A combination of structural, functional, and molecular information is needed to tell just how dangerous the plaque may be. There are many challenges in building combined MR/CT systems, including the moving metal of rotating CT gantries causing interference with MR’s magnetic fields.

Also available are combined CT/radiation therapy linear accelerators and several combinations of ultrasound scanners with the various other imaging modalities. These multi-modality systems are all very expensive and complex. Repair and maintenance of them are primarily the responsibility of the OEM. However, where HTM staff is appropriately trained, and already supporting the base modality (e.g. CT scanners), they can be trained to provide some service support for the additional modality (e.g. PET/CT). In some locations, shared agreements are offered where HTM shares responsibilities with the OEM and the Healthcare Provider, receives a discounted service contract.

9.1.3.3 3-D Printing in Healthcare

3-D printers have been used for several years for rapid prototyping of simple and complex parts in the research and development environment. Parts are made from various thermoplastic and sintered metal materials. This additive manufacturing technology has slowly made its way into healthcare and is emerging as a tool for manufacturing implant parts and custom one-time-use designs, sometimes originating from patient CT or MRI scans. Applications include custom prosthetics (e.g. artificial hands); custom assistive devices (e.g. canes, crutches); parts for, and complete, artificial ankles, knees and other orthopedic implants; casts for fracture immobilization; and crowns, bridges and other dental products. Another application is 3-D modeling of anatomy and disease (e.g. tumors) to assist surgeons in complex surgical planning or construction of complex models of body parts (e.g. heart) for teaching purposes in lieu of using processed cadavers. (Crawford, 2017).
For HTM, 3-D printers have been used to make simple custom parts, such as covers for protruding connectors prone to damage (Clark, 2017). 3-D printed parts can also be used for making simple replacement parts for obsolete equipment where the parts are no longer sold stretching the operational lifespan of these devices. Regulatory guidance on 3-D printed repair parts is still in its infancy, however, manufacturer approval should be obtained whenever possible (FDA, 2017).

9.1.3.4 Integrating the Healthcare Enterprise and Emerging Connectivity Standards

Integrating the Healthcare Enterprise (IHE) is an initiative by healthcare professionals and the medical device and healthcare IT companies and communities to improve the way medical devices and computer systems in healthcare share information. IHE promotes the coordinated use of established standards to address specific clinical needs in support of patient care. IHE’s Patient Care Devices group (IHE-PCD) develops medical device integration profiles for a variety of connectivity “use cases” based on existing standards such as HL-7, DICOM and IEEE 11073. As more medical device manufacturers develop products that meet these IHE profiles, and more Healthcare Providers implement them, it will become much easier to implement the integration of medical devices into the electronic medical record and other healthcare IT systems. The intent of these IHE PCD profiles is to give a uniform methodology for representing common data to facilitate interoperability of systems between different vendors. IHE PCD currently includes 14 different profiles in use or under development ranging from alarm management to waveform communication (IHE PCD Wiki, 2017).

The following example describes how the implementation of the IHE PCD DEC profile may help Healthcare Providers and HTM in their device integration projects now and in the near future.

The Device Enterprise Communication (DEC) profile provides vendor independent, consistent communication of PCD data to the Electronic Medical
Record (EMR) and other clinical repositories. Examples of patient care devices in this profile include: ICU physiological monitors, vital signs monitors, point of care blood analyzers, infusion pumps, point of care glucometers, anesthesia systems, ventilators, and dialysis systems. For example, DEC allows patient monitors to automatically send vital signs data to the electronic medical record reducing staff time spent manually entering data and significantly reducing transcription errors. The data is time stamped with consistent enterprise time. This profile also provides an option to address the binding of patient identification information (e.g. patient name, medical record number) with the data from the device (IHE PCD Wiki, 2017).

Another emerging connectivity standards-related technology is FHIR. In order to improve device integration processes, researchers and the HL-7 organization have developed a new connectivity standard called Fast Healthcare Interoperability Resources (FHIR, 2017). Currently (2017) FHIR is published as a “Standard for Trial Use”. FHIR is a more granular way to exchange data without the rigid workflow of traditional HL-7. FHIR has a higher emphasis on conformance and reference implementations than prior versions of HL-7. It has drivers for mobile healthcare applications and the cloud, medical device integration, and incorporates more flexible, yet well organized, custom workflow than the HL-7 version 2.x, currently in widespread use. As FHIR matures beyond the trial use, it is likely that new applications, and new IHE PCD profiles, will make use of FHIR.

For HTM, IHE and/or FHIR will simplify the integration of medical devices making support easier. As more and more devices are connected, standards-based connectivity makes implementing, monitoring and troubleshooting problems easier. HL-7 private tags and other proprietary constructs are significantly reduced. New project development time is shortened, problems are decreased, and problem resolution is quicker.
9.1.3.5 Device Surveillance Monitoring

Medical device surveillance monitoring provides self-test data and other device status information such as battery status to the HTM department automatically from networked devices. As more and more medical equipment is networked, devices don't only have the capability to send out clinical data to the EMR, but to also send device self-test results and other device-status-related information. On some products, service-related surveillance monitoring is currently available using proprietary applications. (Zoll, 2017).

In order for medical devices to provide the above described self-reporting, surveillance features in a standards-based methodology, the IHE PCD group has drafted a surveillance monitoring profile using HL7-based messaging called the Medical Equipment Management Device Management Communication (MEMDMC) (IHE PCD, 2017). MEMDMC covers device identification, configuration and condition messages (e.g., self-test passed/failed, battery low) and status (e.g., on/off/standby, battery power/line power). Once a device is already connected to the network, and delivering clinical data to the EMR, with MEMDMC that device can also connect to the CMMS or some other HTM-focused application to send device management and maintenance-related information allowing problems to be seen prior to any downtime or other clinical impact. IHE PCD’s MEMDMC profiles has been developed to encode in a standardized manner some of these maintenance management data. Devices that use this profile will be able to send to HTM automatically self-tests, battery levels, utilization information (e.g. hours meter), network parameters, date-sensitive connected consumable (e.g., defibrillator pads) information that they are nearing their expiration date, and many other parameters.

9.1.3.6 Artificial Intelligence and Big Data

Clinical decision support systems have been available for several years. For example, these systems use pattern recognition and other image analysis techniques to identify potential tumors and other abnormal structures within normal structures,
and then display them to a radiologist or pathologist for confirmation and final diagnosis. These systems also help radiologists and pathologists screen large numbers of routine scans quicker (e.g. screening mammography). Artificial intelligence (AI)-based decision making is the next step after computer-aided decision support. AI can help detect abnormalities on medical images and supervise diagnostic processes (e.g. what test to do next?).

Technology giants, such as IBM, Google, and Microsoft are building artificial intelligence solutions to design personalized treatments for some cancers. For example, instead of spending the time to read through large amounts of research material themselves, physicians can use IBM’s Watson, the company’s advanced artificial intelligence platform, to read through dozens of research papers to find information relevant to a specific patient’s case. Watson has been used in oncology, radiology and genomics (IBM-Medical Sieve, 2017, IBM-Watson, 2016).

9.1.3.7 Big Data:
Using data analytics electronic health records (EHRs) and other large healthcare data sets, can be analyzed to help improve the quality and coordination of care, reduce costs and avoid unnecessary use of resources. Clinical registries, typically medical specialty or disease focused, provide repositories for large amounts of data for a specific disease or medical specialty. For example, in 2016, the American Academy of Dermatology introduced a clinical registry called DataDerm (DataDerm, 2016). This database contains data on millions of patients from thousands of dermatologists throughout the US. As more data is collected these can be used for data analyses, patterns and clinically-relevant trends in diagnosis and treatment (e.g. which medications work best for a specific skin problem).

Big data can be used in real-time to alert clinicians that a patient’s condition is trending downward, prior to any obvious symptoms. Within EMRs, and as separate products, applications are emerging for “early warning” clinical alerts based on algorithms developed from big data. These applications use multiple parameters,
typically vital signs trends plus lab values, and in some cases real-time analysis of respiratory and cardiac waveforms, with complex computer algorithms and statistics to predict the risk that an already ill patient will become significantly more ill very soon. These systems can currently identify that there is a high-risk that the patient is currently developing serious clinical problems, including early signs of sepsis, potential for significant bleeding problems, likely respiratory failure leading to the need for intubation, and some cardiac problems (Moorman, 2017).

For example, if the early warning system shows signs that there is a high risk that sepsis may be occurring a blood culture can be obtained earlier than typical, and if positive, early treatment with special antibiotics to help prevent further morbidity or mortality. Early treatment of sepsis is one key to survival from sepsis. From the HTM department standpoint, the interface of physiological monitors to the EMR for vital signs data collection, and waveform analysis in the future, becomes critical for the proper function of these early warning systems.

9.1.3.8 HTM and Big Data:
Reliability centered maintenance (RCM) and related maintenance strategies have been used in the airline industry for many years. In the past few years there have been attempts to use similar data-driven methodologies in HTM to help optimize planned maintenance. Related efforts are currently underway, from groups under the auspices of AAMI, to develop standardized data definitions for a variety of maintenance–related data, and collect data using these standard definitions, with the ultimate goal to be able to share that data amongst HTM, HTM regulators and accrediting bodies, and the medical device industry. (Ridgway, 2017). Whether the HTM field will ever have a widely-shared maintenance data repository remains to be seen. If this effort ever comes to fruition, there will be an opportunity to use data analytics to analyze the data and further optimize HTM’s scheduled maintenance programs.
Genomic Testing:
The Human Genome Project (HGP) was an international, collaborative research program whose goal was the complete mapping and understanding of all the genes of the human being. It was completed in 2003 revealing that there are about 20,500 human genes. Researchers deciphered the human genome in three major ways: The order or sequence of the bases in our genome’s DNA. The development of maps which show the locations of genes for major sections of the human chromosomes. And the production of linkage maps which show how inherited traits, such as those of genetic diseases, are tracked over generations (Human Genome Project, 2016). DNA sequence information is important to scientists investigating the functions of genes. DNA sequencing is a laboratory technique used to determine the exact sequence of the DNA bases, adenine (A), cytosine (C), guanine (G), and thymine (T) in a DNA molecule. The DNA base sequence carries the information a cell needs to assemble protein and RNA molecules. Increasing the speed and reducing the cost of DNA sequencing technology continues and is resulting in the increased availability of such testing.

In the clinical arena, genetic screening tests are used for the possible presence of genetic diseases, or mutant forms of genes associated with increased risk of developing genetic disorders. Types of mutations include base substitutions (one base substituted for another); base deletions (one or more bases missing in a DNA strand), and base additions (one or more bases added to the DNA strand).

From a technology perspective, in order for a potential DNA sample to be analyzed, it needs to be amplified (copied), fragmented and then analyzed. One common methodology for amplification is PCR (polymerase chain reaction). This method involves using short DNA sequences called primers to select the portion of the genome to be copied. The temperature of the sample is repeatedly raised and lowered to help a DNA replication enzyme copy the target DNA sequence. The technique can produce a billion copies of the target sequence in just a few hours.
Various other techniques using bacteria and yeast are used to first fragment and then grow specific segments of the DNA strands for further analysis using electrophoresis and other analysis techniques. Different sequencers use different analytic techniques and offer varying speed and accuracy. Choosing a DNA sequencer and method will typically depend on the clinical and research objectives and available budget.

Clinical examples of DNA analysis include: Screening for well-known genetic diseases such as cystic fibrosis, finding mutations that cause intellectual disabilities; locating certain mutations that cause one form of colorectal cancer that is treatable with aspirin; tracking donor tissue DNA to track transplant rejection sooner than when symptoms appear; and tracking tumor DNA to discover cancer spread sooner. Medications for various cancer and cardiovascular diseases have been developed that are specific for diseases confirmed by DNA testing.

The increasing use of comprehensive genomic profiling in clinical practice for the genomic characterization of tumors is having an increasingly important impact on patients with cancer, empowering the rational use of targeted therapies and driving smarter, faster drug development. New sequencers and analyzers, and large databases of DNA test results, are bringing personalized cancer treatment to the marketplace (Mesko, 2017).

One challenge for the widespread use of genetic testing in clinical practice is that current electronic medical records (EMRs) store genetic test results only in free text reports. As the amount of genetic data continues to rapidly grow, EMRs will need to become capable of allowing physicians to effectively process this new type of information. Genetic results differ from traditional laboratory tests because of their persistent nature, broad scope, and complex interpretation. While current EMRs present laboratory results in a structured and predictable format, genetic data are often stored as free text and presented as cumbersome, highly detailed reports. Building EMRs that can adapt to the genetic information needs of the clinician is a challenge that is yet to be solved.
Technology support for sequencers, and the other complex equipment used for genetic testing, is typically provided by the OEM. Biomedical engineering support has made some progress with a few third-party and in-house providers supporting clinical and research systems. As more and more systems and companies develop products, and the products become less expensive, increased technical training and support opportunities should become available.

9.1.3.10 Emerging Technology Final Comments:

Of course, there are many more emerging technologies. Medical devices are getting smaller and smaller, with some integrated into cell phones (e.g. cell phone-based ultrasound machines). Whether in a patient room, in an MRI gantry, or in surgery, more and more companies and hospitals are providing entertainment and relaxation audio and video experiences for the patient. For example, MRI exams are very noisy and claustrophobic, and can take one hour or longer. The patient needs to remain very still during the MRI exam. Providing, soothing, relaxing, or distracting audio and video entertainment, preferably as chosen by the patient, can improve the patient experience, and reduce exam re-takes. Similar systems are being offered for operating rooms, and procedure areas. (GE Healthcare, 2017).

There are many other new technologies on the horizon including: Vocal analytics that use voice patterns to detect various diseases and robotic devices that not only scan for, and automatically identify suspect skin lesions, but can treat them using robot-guided laser irradiation (Mesko, 2017).

The above discussion is just a small sample of emerging technologies. Modern technology is rapidly changing and improving. It remains to be seen which technologies will have widespread positive impact on population health, healthcare providers, the practice of medicine, and HTM.
### 9.2 Procurement

*Table (9.6): SFDA Storage requirements for medical devices.*

| Storage Area | 1 | • Storage areas should:  
| | | • Be designed or adapted for the storage of medical devices.  
| | | • Be *clean.*  
| | | • Be equipped with *thermometers/hygrometers.* The thermometers/hygrometers should be placed to allow effective monitoring where temperatures/humidity are most likely to fluctuate or rise.  
| | | • Have *surfaces and shelves,* if applicable, made of or covered by an impermeable material to enable proper and safe cleaning.  
| | | • Be suitably *spaced* to allow cleaning and inspection.  
| | | • Include a *physically separate area* for keeping *damaged, defective, expired, counterfeit or recalled medical devices.* This area should be clearly *labeled and controlled* to prevent the use of these devices until a final decision is taken on their fate.  
| | | • Be adequately *lit.*  
| | | • Be adequately *ventilated.*  
| | | • Have an emergency plan set up and used in case of an electricity shutdown (*power outage*), if applicable.  
| Traceability in the Storage Area | 2 | In the case of a *recall/field safety notice* by the SFDA or the manufacturer, the healthcare providers should be able to *trace* a product in the storage area by its lot/batch/serial number.  
| Transportation | 3 | The *expiration dates* of medical devices in the storage area should be monitored through periodic inventories to avoid unintended dispatch of expired medical devices.  
| | 4 | Vehicles used to transport medical devices should be properly *designed and equipped to ensure protection* from different environmental and weather conditions in which it operates.  


<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5</strong></td>
<td>Medical devices should be transported in such a manner that does <strong>NOT allow exceeding of appropriate temperature and relative humidity conditions</strong> which could negatively affect their integrity and quality.</td>
</tr>
<tr>
<td><strong>6</strong></td>
<td>Medical devices should be transported and <strong>carried carefully</strong> in a manner that corresponds to the special transport precautions and requirements.</td>
</tr>
<tr>
<td><strong>7</strong></td>
<td>Any case of spoilage or breakage should be <strong>reported</strong>.</td>
</tr>
<tr>
<td><strong>8</strong></td>
<td>The transporting vehicle or containers should be adequately <strong>suitable for the intended purpose and cleaned</strong>.</td>
</tr>
<tr>
<td><strong>Manufacturer’s Instructions/Requirements</strong></td>
<td><strong>9</strong> Medical devices should be stored, handled and transported under conditions specified by the manufacturer’s instructions/requirements to prevent deterioration. These conditions might be related to one or more of the following:</td>
</tr>
<tr>
<td></td>
<td>o Temperature (all the medical devices should be kept during storage and/or transportation at temperature ranges specified by the manufacturer),</td>
</tr>
<tr>
<td></td>
<td>o Moister and humidity,</td>
</tr>
<tr>
<td></td>
<td>o Exposure to light,</td>
</tr>
<tr>
<td></td>
<td>o The direction the package should face,</td>
</tr>
<tr>
<td></td>
<td>o The maximum number of packages stacked above each other,</td>
</tr>
<tr>
<td></td>
<td>o Other specific instructions/requirements,</td>
</tr>
<tr>
<td>Note 1:</td>
<td>If the packaging labelling do not include information about the required storage and transportation conditions of a medical device, <strong>healthcare providers should obtain such information from the manufacturer and/or its authorized representative located within the KSA</strong>.</td>
</tr>
<tr>
<td>Note 2:</td>
<td>If the manufacturer does not specify the temperature values or not define the storage conditions on the packaging labelling, see <strong>Annex 1</strong> to determine these values and the set of storage definitions.</td>
</tr>
<tr>
<td>Note 3:</td>
<td></td>
</tr>
</tbody>
</table>
If the manufacturer requires medical devices to be stored or transported under certain conditions (e.g. temperature and humidity), healthcare providers should monitor and periodically record these conditions.

| Sterile Medical Devices | 10 | In addition to manufacturer-specific instructions, medical devices that are dispatched in a sterile state, should be stored, handled and transported in a manner that protects their packaging from:
| o exposure to moisture,
| o direct sunlight,
| o Damage,
| o dirt and unclean environment.

Note:
Sterile medical devices should be considered unsterile if packaging loses its integrity.

| Staff | 11 | Staff involved in the storage, handling and/or transport of medical devices should:
| o have proper knowledge about these activities, and
| o be able to deal with those devices that have different storage and transportation requirements, if applicable.

| Written Procedures | 12 | Healthcare providers should have a written procedure that describes the practices taken to ensure medical devices are stored, handled and/or transported based on the manufacturer’s instructions/requirements. The written procedure ideally should be part of a quality management system. |
Table (9.7): Medical Devices Storage Temperature Values and Storage Condition Definitions.

<table>
<thead>
<tr>
<th>ON THE LABELLING</th>
<th>GUIDANCE VALUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezer</td>
<td>The temperatures are between -20 °C and -10 °C.</td>
</tr>
<tr>
<td>Refrigerator</td>
<td>The temperatures are between 2 °C and 8 °C.</td>
</tr>
<tr>
<td>Cold place</td>
<td>The temperatures do NOT exceed 8 °C.</td>
</tr>
<tr>
<td>Cool place</td>
<td>The temperatures are between 8 °C and 15 °C.</td>
</tr>
<tr>
<td>Room temperature</td>
<td>The temperatures are between 15 °C and 30 °C.</td>
</tr>
<tr>
<td>Warm place</td>
<td>The temperatures are between 30 °C and 40 °C.</td>
</tr>
<tr>
<td>Excessive heat</td>
<td>The temperature is above 40 °C.</td>
</tr>
<tr>
<td>Do not store over 30 °C</td>
<td>The temperatures are between +2 °C to +30 °C.</td>
</tr>
<tr>
<td>Do not store over 25 °C</td>
<td>The temperatures are between +2 °C to +25 °C.</td>
</tr>
<tr>
<td>Do not store over 15 °C</td>
<td>The temperatures are between +2 °C to +15 °C.</td>
</tr>
<tr>
<td>Do not store over 8 °C</td>
<td>The temperatures are between +2 °C to +8 °C.</td>
</tr>
<tr>
<td>Do not store below 8 °C</td>
<td>The temperatures are between +8 °C to +25 °C.</td>
</tr>
<tr>
<td>Protect from moisture</td>
<td>No more than 60% relative humidity in normal storage conditions; to be provided to the user in a moisture-resistant container.</td>
</tr>
<tr>
<td>Protect from light</td>
<td>To be made available to the user in a light-resistant container.</td>
</tr>
</tbody>
</table>
9.3 Device Inventory Auditing Example

Equipment inventories can be audited using sampling techniques of which there are many techniques. A random sample is taken based on the inventory size (population) and accuracy expected. If the results do not meet the accuracy expected, then a complete audit is required or depending on the method selected, a second random sample taken if those results are not met, then a complete inventory audit must be completed.

<table>
<thead>
<tr>
<th>Sampling Procedure</th>
<th>Product Population Range</th>
<th>Step 1 Sample Size</th>
<th>Step 1 Accept</th>
<th>Step 1 Reject</th>
<th>Move to step IF unacceptable is:</th>
<th>Step 2 Sample Size</th>
<th>Step 2 Accept</th>
<th>Step 2 Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td>151 to 280</td>
<td>32</td>
<td>3</td>
<td>4</td>
<td>2 to 3</td>
<td>20</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Double</td>
<td>151 to 280</td>
<td>20</td>
<td>1</td>
<td>4</td>
<td>3 to 4</td>
<td>32</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Single</td>
<td>280 to 500</td>
<td>50</td>
<td>5</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double</td>
<td>280 to 500</td>
<td>32</td>
<td>2</td>
<td>5</td>
<td>4 to 6</td>
<td>50</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Single</td>
<td>501 to 1,200</td>
<td>80</td>
<td>7</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double</td>
<td>501 to 1,200</td>
<td>50</td>
<td>3</td>
<td>7</td>
<td>4 to 6</td>
<td>50</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Single</td>
<td>1,201 to 3,200</td>
<td>125</td>
<td>10</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double</td>
<td>1,201 to 3,200</td>
<td>80</td>
<td>5</td>
<td>9</td>
<td>6 to 8</td>
<td>80</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Single</td>
<td>3,201 to 10,000</td>
<td>200</td>
<td>14</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double</td>
<td>3,201 to 10,000</td>
<td>125</td>
<td>7</td>
<td>11</td>
<td>8 to 10</td>
<td>125</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>Single</td>
<td>10,001 to 35,000</td>
<td>315</td>
<td>21</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double</td>
<td>10,001 to 35,000</td>
<td>200</td>
<td>11</td>
<td>16</td>
<td>12 to 15</td>
<td>200</td>
<td>26</td>
<td>27</td>
</tr>
</tbody>
</table>

Table 9.8: Attribute sampling for inventory audit. Reference: ANSI/ASQC Z1.4.

For example, in the chart above, (Table 9.8), if there is a population of 5,000 devices, based on a + 4% accuracy requirement, two options are provided for an inventory audit.

Option 1: Single sampling:

a) 5,000 devices in device population
b) 4% quality limit (see references for other quality limits)
c) From chart Figure 5.x:
c.1.1 200 device identification numbers randomly are selected from CMMS or other source. Note the sample has to be randomly selected or this process does not work!

c.1.2 If the identification numbers match (serial numbers, asset id numbers etc.) the device passed audit. Otherwise it is counted as unacceptable.

c.1.3 If 14 or fewer of the 200 devices audited are acceptable, the process is finished and the audit is complete.

c.1.4 If 15 or more are unacceptable the audit is unacceptable and all devices would have to be inventoried.

Option 2: Double sampling:

a) 5,000 devices in device population
b) 4% quality limit (see references for other quality limits)
c) From chart Figure 5.x:

c.1.1 125 device identification numbers are randomly selected from CMMS or other source. Note the sample has to be randomly selected or this process does not work!

c.1.2 If the identification numbers match (serial numbers, asset id numbers etc) the device passed audit. Otherwise it is counted as unacceptable.

c.1.3 If 7 or fewer of the 125 devices audited are acceptable, the process is finished and the audit is complete.

c.1.4 If 11 or more audited devices are unacceptable the audit is unacceptable and all devices would have to be inventoried.

c.1.5 If between 8 an 10 device id audits were unacceptable then randomly select a second sample of 125 devices and:

c.1.5.1.1 If a total of 18 or fewer of the 250 devices audited are acceptable, the process is finished and the audit is complete.
c.1.5.1.2 If 19 or more of the 250 audited devices are unacceptable the audit is unacceptable and all devices would have to be inventoried.