GHANA HEALTH SERVICE

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# MEDICAL EQUIPMENT POLICY AND GUIDELINES

JUNE 2018

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## FOREWORD

Medical Devices are a very essential component of healthcare delivery in Ghana Health Service. They are used for safe and effective prevention, diagnosis, treatment and rehabilitation of illnesses and diseases. Currently, there is no policy document for the management of medical devices in Ghana Health Service. This policy seeks to ensure that medical devices are managed effectively and efficiently in compliance with existing laws and regulations.

The management of medical devices involves various stages such as medical device planning and assessment, budget and financing, technology assessment and selection, procurement and logistics, installation and commissioning, training and skill development, operation and safety, maintenance and repairs and decommissioning and disposal. These stages have been detailed out in this policy document.

This policy document also presents in detail, guidelines for the effective and efficient management of medical devices or equipment at all levels of health care delivery. It is my hope that this operational policy will enable health practitioners to rationalize and maximize the use of medical devices in the Ghana Health Service.

All staff of Ghana Health Service and other stakeholders are required to abide by the content of this policy document where medical devices are concerned.

Dr. Anthony Nsiah-Asare

Director General, Ghana Health Service

June 2018

## ACKNOWLEDGEMENT

The development of this medical equipment policy and guidelines for the management of medical equipment in Ghana Health Service was a collaborative effort between Clinical Engineering Department and National AIDS/STI Control Programme under the leadership of the Director General, Ghana Health Service and the Director, Health Administration and Support Services Division.

The document has been developed through extensive consultation and contribution of participants of the drafting group, stakeholders' consultation meeting, executive review group, Directors and Senior Managers of the Ghana Health Service, staff of the Clinical Engineering Department, representative of Food and Drugs Authority and Ghana Society of Biomedical Engineers. Without their input, it could not have been possible to have this operational policy document.

The Ghana Health Service would like to express its appreciation to the following individuals who worked tirelessly throughout the development of this policy document.

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- Dery ……. Deputy Director, HASS Department, Central Region

**Refer to appendices for full list**

## ABBREVIATIONS AND ACRONYMS

BMC - Budget Management Centre
CE - European Conformity
CED - Clinical Engineering Department
CEU - Clinical Engineering Unit
CHPS - Community-based Health and Planning Services
CT – Computed Tomography
DHD – District Health Directorate
DH – District Hospital
DHMT – District Health Management Team
ECG - Electrocardiograph
EPA – Environmental Protection Agency
EPI – Expanded Program on Immunization
FDA – Food and Drugs Authority, Ghana
GHS – Ghana Health Service
GMP – Good Manufacturing Practices
GSA – Ghana Standards Authority
HASS – Health Administration and Support Services
HTM – Health Technology Management
ICD – Institutional Care Division
ICU – Intensive Care Unit
IEC – International Electrotechnical Committee
ISO – International Organization for Standardization
MOH – Ministry of Health
MRI – Magnetic Resonance Imaging
NACP – National AIDS/STI Control Programme
NRA – Nuclear Regulatory Authority
OT – Operating Theatre
PPA – Public Procurement Authority
PPME – Policy, Planning, Monitoring and Evaluation
RHD – Regional Health Directorate
RH – Regional Hospital
SSDM – Supplies, Stores and Drugs Management
USFDA – United States Food and Drugs Authority Administration
WHO – World Health Organization

## GLOSSARY (TERMINOLOGIES)

For the purposes of this document, the following terms and definitions apply.

**Acceptance testing**: *A process that involves inspection, testing, verification and validation of a device and associated relevant documents upon the completion of installation, commissioning, calibration and training (where applicable) of medical device.*

***Accuracy:*** The skill of the engineers to perform work on each system within agreed times and to exact standards.

**Calibration**: *A procedure used to determine device's accuracy using test equipment whose own accuracy is appropriate and has been verified; and then, as needed, adjusting that device to meet the manufacturer's specification.*

**Clinical Engineering Department:** *refers to the Clinical Engineering Department under the Health Administration and Support Services Division at the Ghana Health Service Headquarters.*

**Clinical Engineering Unit:** *refers to the clinical engineering outfit within other institutions other than the GHS headquarters.*

**Commissioning:** *The process by which an equipment is tested to verify if it functions according to its design objectives or specifications.*

***Communication:*** This is an indication of how well information was passed to and received

***Courtesy:*** This is a measure of the politeness and respectfulness of a personnel.

**Decommissioning**: *A process that includes taking equipment permanently out of service, updating medical equipment management database, removal from maintenance contract, arranging for patient specific data to be securely erased, advising other departments of the availability of unused consumables that may be suitable for use in other equipment, and preparation for final disposal.*

**Disposal**: *Process where medical equipment is effectively managed when it reaches end of life to reduce the level of risk it poses at that stage in compliance with necessary regulations.*

**Down time**: *Time during which a medical equipment is out of service or unavailable for use*

***Ease of Operation:*** This is a measure of how easy it is for users to operate equipment.

**Health facility**: *Any premises in which one or more members of the public receive healthcare services, which includes*;

a) *Medical, dental, nursing, midwifery, allied health, pharmacy, and ambulance services and any other services provided by healthcare professional;*
b) *Accommodation for the purpose of a service provided;*
c) *Any service for the screening, diagnosis, or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind and body;*
d) *Any service for preventive and promotion of health purpose;*
e) *Any services provided by any healthcare para-professional;*
f) *Any service for curing or alleviating abnormal condition of the human body by the application of any apparatus, equipment, instrument or device or any other medical technology; or*
g) *Any health-related services.*

**Health Technology Management:** *the systematic process in which qualified healthcare professionals, typically clinical/biomedical engineers (with their unique ability to visualize a wide range of systems and issues and to determine the important linkages and solutions), in partnership with other health leaders, plan for and manage health technology assets to achieve the highest quality care at the best cost.*

**Health Technology**: *"The devices, drugs, medical and surgical procedures - and the knowledge associated with these – used in the prevention, diagnosis and treatment of disease as well as in rehabilitation and the organizational and supportive systems within which care is provided".*

**Manufacturer**: *entity that research, develop, design, produce or manufacture goods including medical equipment through processes involving raw materials, components or assemblies for approved usage.*

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

**Medical Equipment**: *Medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable*

*or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.*

***Output Quality:*** The ability of the equipment to produce results or images to satisfactory standards.

***Product Quality:*** This is a measure of the suitability of equipment for its intended use

***Professionalism:*** This is a measure of the skill, competency and knowledge of a staff

**Professional User**: *A person who has been trained on the usage of a particular Medical Equipment.*

***Reliability:*** The availability of the equipment for its intended use when required

***Repair Time:*** The total time taken to restore or put faulty equipment back its intended use.

***Response Time:*** The time taken for an engineer to attempt a solution to a reported fault.

**Reusable Medical device:** *Reusable medical devices are devices that can be reprocessed for subsequent patient use.*

**Single Use Device:** *single-use devices are not intended to be reused. It shall only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient*.

***Spare Parts Delivery:*** The time taken to deliver identified parts to repair defective equipment.

**Technical staff**: *A person who possesses a combination of knowledge, skills and behavior utilized to improve performance.*

**Troubleshooting**: *Tracing and correcting faults in a mechanical or electronic system. It is also referred to as "fault finding"*

**Vendor**: *an individual or company or firm that sells goods including equipment and services to another person, company or firm in the economic production chain. Vendor is also known as Supplier.*

## MEDICAL EQUIPMENT POLICY AND GUIDELINES DEVELOPMENT PROCESS

This Policy was developed through an intensive and extensive teamwork and consensus building. Its development was phased into three (3) stages.

### First Phase

A team from Health Administration and Support Services Division and the National AIDS/STI Control Programme both of Ghana Health Service met and developed a first draft.

### Second Phase

Key stakeholders were invited to review and fine-tune the basic draft to be in consonance with the strategic objectives of the Ghana Health Service. The output of this Group was the Second Draft.

### Third Phase (Executive Group)

A team consisting of the Acting Director, HASS, all the GHS-Headquarters Deputy Directors of HASS, representatives of the Regional Deputy Directors of HASS, representatives of Regional Equipment Managers all of Ghana Health Service, representatives from Capital Investment Management Unit of Ministry of Health and Food and Drugs Authority met to finalize the draft operational policy document. The output of this Group was the Third Draft.

### Approval by The Director General, Ghana Health Service

The Final Draft (Third Draft) was presented to the Divisional Directors of the Ghana Health Service and was finally approved (accented) by the Director General after endorsement by the Ghana Health Service Council on the 29th June 2018 for adoption and implementation.

# 1.0 INTRODUCTION

## 1.1 BACKGROUND

Health Technology Management plays a significant role in the process of achieving national and global health targets. This concept has come a long way since the 1920's in Ghana when the health system depended little on engineering systems and technologies. Technologies deplored for the health service delivery were simple and required little or no maintenance.

However, advances in engineering have resulted in a health system that depends on technologies which are not only difficult to apply and maintain but also require huge financial outlay. This has changed the way these technologies are acquired, applied, managed, maintained and finally disposed.

## 1.2 SITUATION ANALYSIS

The availability of safe and effective health care technologies is an important condition for a well-functioning promotive, preventive, curative and rehabilitative health service. Making safe and effective health care technologies available for health care delivery is more than just buying a piece of hardware component of a health care technology. It requires a number of specific managerial, technical and administrative inputs and support.

The poor state and availability of health care technologies is not only a problem in Ghana but other developing countries especially in the Sub-Sahara Africa. This necessitated the adoption of the WHO Resolutions on Health Care Technologies to urge member states to develop policies and strategies which shall improve the availability of safe and effective health care technologies for health delivery. With the support of its development partners, the Government of Ghana has over the years established systems and developed the capacity for the management and maintenance of health care technologies. However, lack of policy guidelines with effective implementation plan has not facilitated the realization of this goal.

Currently, there is a Clinical Engineering Department established within the Ghana Health Service to provide management and maintenance support for healthcare technologies (including medical devices) at all levels. Some of the training institutions (including Universities and Polytechnics) in Ghana have established programmes in Biomedical Engineering to support the capacity building required for healthcare technologies. In the absence of policy guidelines, the knowledge and

expertise acquired through these training programs have not been effectively deployed, managed and sustained for the required health technologies in the Ghana Health Service.

Unfortunately, there is no comprehensive data available to analyze the state of medical devices in the country. However, a visit to some of the health facilities revealed:

i. Inadequate number of competent engineers required for effective management of medical devices at all levels of healthcare delivery.
ii. Inadequate number of competent engineers trained by manufacturers to maintain certain complex medical devices.
iii. Information systems for the management of healthcare technology are not established, hence there is no basis for realistic and appropriate planning, budgeting, procurement as well as management of physical assets and the related development of human resources.
iv. Financing the procurement and maintenance of medical equipment in the Ghana Health Service is usually a challenge due to competing demands for limited resources in the Service.
v. Non-availability of reliable inventory and adequate records on medical devices.
vi. The non-availability of spare parts and limited technical capability has rendered some medical devices inoperable.
vii. The methods adopted for the maintenance and repairs of medical equipment in most health facilities were based on trial and error and this is not effective and render some equipment useless.
viii. Cannibalization, which could have salvaged some medical equipment was not always possible because of lack of standardization.
ix. End users are not adequately trained on a sustained bases.
x. Non-involvement of end users at the planning stage of procurement results in procurement of inappropriate and/or substandard equipment.
xi. Some of the suppliers of medical equipment do not provide after-sales support services.
xii. Personnel involved in the use and maintenance of healthcare technologies often resort to improvisations, which may affect the accuracy and reliability of results produced by the equipment to support clinical decision and treatment.

xiii. Poor storage conditions in some health facilities contribute to breakdown of equipment after commissioning.

xiv. The lifespan of certain equipment is greatly reduced as a result of inadequate maintenance particularly **preventive** maintenance.

xv. Planned Preventive Maintenance is not in practice in most of the health facilities. Maintenance activities are therefore reduced to unplanned and/or emergency repairs

xvi. Operational budgets for maintenance activities are very low or non-existence. Where approved budgets for maintenance are available, actual expenditures tend to be far lower than planned. Where financial resources are scarce in the midst of competing demands for financial allocation, maintenance of equipment is the first victim of expenditure cuts.

xvii. There are no financial resources ring-fenced for replacement of obsolete equipment and procurement of spare parts for maintenance.

xviii. Engagement of external technical service providers to maintain specialized and complex equipment has not been streamlined and where it has, they are poorly monitored and payment is irregular.

xix. Lack of competent technical personnel to support medical equipment at various levels of the health service delivery results in delay in responding to reported malfunction of equipment.

xx. Lack of maintenance management **standards** and guidelines for technical personnel to follow.

xxi. Poor maintenance **culture** among the general population at all levels contributes to neglect which results in premature deterioration of equipment and other health infrastructure and utilities.

xxii. Most medical devices are acquired without carrying out proper needs assessment and sufficient consideration of capabilities at the beneficiary health facility. This results in acquiring equipment that do not meet the needs of the health facility.

xxiii. The training of users and maintenance personnel during acquisition of new equipment is commonly neglected.

xxiv. Instances where engineering personnel are not involved in procurement results in selection and delivery of equipment which is not fit for purpose, without spare parts to maintain and accessories and consumables to operate them.

xxv. Some of the donations of used medical devices do not follow approved guidelines for donations resulting in donations of obsolete equipment which are neither accompanied by spare parts nor manuals.

This operational policy has been developed to address the aforementioned challenges to ensure that investment in medical devices yield the expected results. The policy is expected to provide guidance to facilitate the achievement of universal health coverage as enshrined in the Sustainable Development Goal (SDG 3).

### 1.3 PURPOSE AND SCOPE OF THE POLICY

This document sets out the broad guidelines and operational management framework for Clinical Engineering in the Ghana Health Service. It is part of the processes for strengthening the Service's operational system to ensure effectiveness and efficiency in its activities.

It sets out the focus and objectives of the Clinical Engineering Department in the Service and defines the roles and responsibilities of the managers, operators/users and technical staff responsible for health care technologies at various levels of the organization.

This policy is intended to cover all medical equipment used for diagnosis, prevention, monitoring, treatment, rehabilitation and alleviation of human disease or injury in whole. It shall also apply to some extent to equipment including but not limited to;

i. Waste handling and waste treatment plant and equipment
ii. Generators
iii. Laundry equipment
iv. Hygienic air conditioners
v. Sterilisation equipment
vi. Mortuary equipment
vii. Medical refrigeration
viii. Medical gas systems

However, this policy shall not be applicable to vehicles

## 1.4 OBJECTIVES OF THE POLICY

The following are the main objectives of the policy

i. To provide general framework for the management of all Clinical Engineering resources in the Service.
ii. To guide and serve as a reference document for effective and efficient management of healthcare technologies.
iii. To rationalize the use and management of all healthcare technologies.
iv. To contribute towards the achievement of organizational objectives.
v. To support:
    a. effective and efficient selection, acquisition, utilization and management of health technology.
    b. defining national objectives for improved impact of health technology on service delivery.
    c. formalizing strategies for the rational introduction and utilization of health technologies
    d. promoting Health Technology Management standards and norms as well as Health Technology Management code of practice
    e. promotion of maintenance systems
    f. strengthening Human Resource issues related to health technology management

## 1.5 STRUCTURE OF THE DOCUMENT

The document is made up of nine (9) main sections namely introduction, institutional framework for policy implementation, policy guidelines, organisational systems and responsibilities, financing, implementation plan, monitoring and evaluation, legislations & regulations and conclusion.

The document starts with an introduction which outlines the issues pertaining to health technology management in Ghana. It continues to spell out in the next section, the institutional framework with clearly defined roles and responsibilities that are involved in healthcare technology management.

Section 3 covers Policy Guidelines, which outlines the guiding principles to ensure that all issues pertaining to the life cycle of equipment are properly addressed from the time of planning acquisition to the time of disposal.

Organizational systems and responsibilities is covered in section 4. This section explains the structures and responsibilities at various levels of the service. It goes further to explain the human resources and training required for the management of healthcare technologies.

Section 5 entails funding/financing acquisition of equipment, maintenance and related matters to ensure availability of adequate budgets and financing supports for the implementation of the policy.

Implementation Plan is embodied in section 6 whilst section 7 covers Monitoring and Evaluation.

Section 8 spells out all the legislations and regulations that govern the use and management of healthcare technologies.

The last section, which is section 9, provides the conclusion.

### 1.6 POLICY AND LEGAL CONTEXT

There is no single law that regulates the management of medical devices in Ghana. However, there are number of laws, policies and regulations governing various aspects of the management of medical devices. These laws, regulations and policies, which mandate certain institutions to regulate aspects of medical devices in the country include the following:

i. Ghana Health Service and Teaching Hospital Act, 1996 (Act 525) establishes the Health Service and mandates it to prudently manage its resources including medical devices.
ii. The Public Health Act, 2012 (Act 851) empowers the Food and Drugs Authority to regulate medical devices in the country. The law mandates FDA to regulate the manufacturing, importation, distribution, sales and use of medical devices in Ghana.
iii. The Public Procurement Act, 2003 (Act 663) and Public Procurement Amendment Act, 2016 (Act 914) provide guidance on public procurement for works, goods and services which includes medical devices.
iv. Nuclear Regulatory Authority Act, 2015 (Act 895) mandates the Nuclear Regulatory Authority to regulate peaceful use of nuclear material or energy, radioactive material or radiation

including X-Ray emitting equipment. For medical equipment with ionizing radiation, NRA ensures that the radiation is safe for use, only qualified users operate the equipment and the environment within which the equipment is used is safe.

v. Store Regulation 1984, Ministry of Finance and Economic Planning: this regulation provides a guide for efficient and effective management of stores to ensure continuous availability of resources for public services including unserviceable stores.

vi. Health Professions Regulatory Bodies Act, 2013 (Act 857) mandates the regulatory bodies to regulate all health professionals practicing in the country to be in good standing.

vii. Internal Audit Agency Act, 2003, (Act 658) mandates the Internal Audit Agency to ensure that public organizations establish internal audit systems to provide internal quality assurance for activities within public institutions

viii. Hazardous and Electronic Waste Control and Management Act, 2016, (Act 917) seeks to provide for the control, management and disposal of hazardous waste, electrical and electronic waste.

ix. Public Financial Management Act, 2016 (Act 921) establishes processes to regulate financial management of the public sector within a macroeconomic and fiscal framework.

x. Finance Lease Act, 1993, (PNDC Law 331) provides for acquisition of assets through finance lease between lessor and a lease.

xi. Other relevant policies, acts and regulations not stated.

## 1.7 UPDATE AND REVISION

This policy shall be reviewed and/or updated as and when necessary especially when there are major administrative or legal changes. However, such revisions and updates shall not be less than 5 years unless an earlier review is required.

Publication date: ……, 2018

## 2.0 INSTITUTIONAL FRAMEWORK FOR POLICY IMPLEMENTATION

The Alma-Ata Declaration (WHO, 1978) promotes the use of appropriate technologies, i.e. those technologies which are scientifically valid, socially acceptable and universally available to all individuals and families of the community at a cost that the community and the country can afford at all stages of the country's development in the implementation of primary health care. However, for varying reasons, certain countries are often unable to utilise and apply health technologies to their fullest extent to improve the health of their people.

In an effort to address this issue, WHO has adopted a number of resolutions (WHO/EMRO, 1997, WHO/AFRO, 1994, WHA60.29 and WHO/AFRO Harare Declaration 1998) related to health care technologies. These resolutions call upon Member States to:

i. *To collect, verify, update and exchange information on healthcare technologies as an aid to their prioritization of needs and allocation of resources.*

ii. *Develop appropriate national strategies and plans for the establishment of systems for assessment, planning, procurement and management of technologies especially medical devices in collaboration with personnel involved in health technology assessment and biomedical engineering.*

iii. *Draw national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other systems and other measures to ensure quality, safety and efficacy of medical devices and where appropriate, participate in international harmonization.*

iv. *To collect information that interrelates medical devices which deal with priority public health conditions at different levels of care and various settings and environment, with required infrastructure, procedures and reference tools.*

v. *Develop suitable mechanisms for the assessment and acquisition of health technologies.*

vi. *Develop means of obtaining access to health care technology information systems and databases.*

vii. *Take necessary measures to ensure that donor support in the area of health care technology is given where it is most needed and likely to be most cost–effective.*

viii. *Raise awareness of health care technology related issues amongst decision-makers and health workers in general.*

The Ministry of Health and Ghana Health Service shall develop and maintain appropriate structures and expertise, required for all aspects of healthcare technology management. Members of staff involved in the management of healthcare technology shall have clearly defined roles, responsibilities and relationships to each other.

Key stakeholders for healthcare technology management include the Clinical Engineering Department at the national level, Clinical Engineering Units at the regional, district and health facility levels and the national network of Clinical Engineering Workshops. Other stakeholders responsible for healthcare technology management shall liaise with all other health service providers and maintenance organizations, so that all aspects of healthcare technology management are properly coordinated.

All staff within the Service shall comply with this policy in pursuance of the risk-free use of healthcare technology to the benefit of clients and health workers. This policy guideline covers all levels of the Service and forms an integral part of the overall health policy. It is consistent with the country's needs, priorities, resources, public health conditions and capabilities.

It is therefore;

i. to provide an orientation for Health Technology Management and to guide its users in the decision making processes.
ii. to facilitate rational planning, acquisition, distribution, use of technological and infrastructural resources.
iii. to promote equity in the Ghana health system.
iv. to provide vision and guidance for all health workers.

## 2.3 MISSION OF THE HEALTH SECTOR

The mission of the health sector is to contribute to socio-economic development and the development of the local health industry by promoting health and vitality through access to quality health for all people living in Ghana using motivated personnel.

## 2.4 MANDATE OF THE GHANA HEALTH SERVICE

To provide and prudently manage comprehensive and accessible health service with special emphasis on primary health care at regional, district and sub-district levels in accordance with approved national policies.

## 2.5 VISION OF THE GHANA HEALTH SERVICE

A healthy population with universal access to quality health services.

## 2.6 STRATEGIC OBJECTIVES OF THE GHANA HEALTH SERVICE

The GHS has the following corporate strategic objectives:

i. Bridge equity gaps in access to health care and nutrition services and ensure suitable financing arrangement that protect the poor.
ii. Strengthening governance and improve the efficiency and effectiveness of the health systems.
iii. Improved access to quality maternal, neonatal, child and adolescent health services.
iv. Intensify prevention and control of communicable and non-communicable diseases and promote healthy lifestyles.
v. Improve institutional care, including mental health services delivery.

## 2.7 VISION OF CLINICAL ENGINEERING DEPARTMENT IN THE SERVICE

The vision is to enhance health service delivery by ensuring that all risks associated with acquisition and use of healthcare technologies are minimised.

## 2.8 MISSION OF CLINICAL ENGINEERING DEPARTMENT IN THE SERVICE

The mission of the Clinical Engineering Department is to advice on acquisition and the availability of the health care technologies, ensure effective and efficient managerial and technical support for the health care technologies and support the maximum utilization of all these health care technologies at all levels of health care delivery within the Service.

## 2.9 OBJECTIVES OF CLINICAL ENGINEERING DEPARTMENT

The strategic objectives are to ensure that each healthcare technology is:

i. Suitable for its intended purpose – "buy it right";
ii. Properly understood by the professional and other users – "use it right";
iii. Maintained in a safe and reliable condition – "keep it right".

## 2.10 FUNCTIONS OF CLINICAL ENGINEERING DEPARTMENT IN HEALTH CARE DELIVERY

The Clinical Engineering Department shall apply engineering and managerial skills to healthcare technology and environment in supporting and advancing patient or client care and where necessary promoting health in Ghana through the Ghana Health Service.

The department shall work with stakeholders to ensure that

i. healthcare technologies are prudently managed to minimize wastage.
ii. healthcare technologies are acquired to address specific needs of the Service.
iii. healthcare technologies are available and maximally utilized in all institutions within the Service.
iv. there is effective and efficient technical support for all available healthcare technologies.
v. breakdown of health care technologies, especially certain critical types are minimised.
vi. there is an effective and efficient replacement program for health care technologies.
vii. preventive maintenance of healthcare technologies are carried out to ensure safety.
viii. there is efficient mechanism for decommissioning and disposal of healthcare technologies that are:
    a. non-functional
    b. unserviceable
    c. obsolete
ix. there is availability of management information systems i.e. inventory management information system, maintenance management system for healthcare technologies at various decision-making levels.

## 2.11 CLINICAL ENGINEERING SYSTEMS OF THE GHANA HEALTH SERVICE

The policy covers all the major components of health care technology management. These include:

i. Management systems
ii. Planning healthcare technology service
iii. Selection of healthcare technology
iv. Acquisition and procurement of healthcare technology
v. Donation of healthcare technology
vi. Allocation of healthcare technology
vii. Installation and operation of healthcare technology
viii. Acceptance testing of healthcare technology
ix. Maintenance and repair
x. Spare-parts management
xi. Training
xii. Adverse Incident or Accident reporting
xiii. Decontamination
xiv. Decommissioning of medical equipment
xv. Disposal of medical equipment
xvi. Technology assessment, research and development
xvii. Local production
xviii. Healthcare technology safety

### 2.11.1 Director-General

The Director-General of the Service has overall responsibility and accountability for this policy.

### 2.11.2 Director, Health Administration and Support Services (HASS) Division

The Director of Health Administration and Support Services Division shall have the responsibility for healthcare technologies. He/she shall be assisted with the day to day management of this task through the Clinical Engineering Department in collaboration with other relevant stakeholders to ensure that:

i. all user staff are trained and have access to technical support in accordance with the healthcare technology policy.
ii. equipment needs for health facilities are identified, new equipment acquired to address the needs, new equipment acquired are properly installed, commissioned and tested.
iii. regular maintenance, testing, repair, calibration and decommissioning of healthcare equipment is carried out.
iv. new equipment are acquired and old ones disposed off in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914).
v. a library of evaluation reports and other guidance materials relating to the performance, safety and cost of equipment is maintained.
vi. action is taken on all complaints, publications on hazard, equipment safety and other relevant guidance.
vii. all technical aspects of procurement and maintenance contracts are cleared before the service is committed.
viii. a technical assessment of equipment is undertaken from time to time in conjunction with other relevant bodies.
ix. an inventory database is maintained for all equipment, together with records of performance reliability and cost. The database must comply with the GHS policy on records and form part of the Asset Register.
x. equipment replacement programme is prepared and maintained in liaison with the relevant stakeholders.
xi. equipment plans and budget are prepared in the prescribed format and submitted as required. This shall include both the capital investment budget and the regular budget.

### 2.11.3 Director, Supplies, Stores And Drug Management (SSDM) Division

The Director of Supplies, Stores and Drug Management Division together with the Clinical Engineering Department and with the support of relevant stakeholders shall:

i. collate and prepare national equipment procurement plans and identify sources of funding for procurement.

ii. prepare, advertise, receive, evaluate tenders and award contracts.
iii. ensure that all acquisitions are in accordance with the procurement and financial management laws of Ghana and the procurement guidelines of the Service.
iv. ensure that robust and effective procurement procedures are in place to support need-based and value-for-money acquisition of equipment.

### 2.11.4 Deputy Director, Clinical Engineering Department

The Deputy Director of Clinical Engineering Department shall support and advice in the effective and efficient management of healthcare technology in Ghana Health Service. He/she shall assist and advice in:

i. conducting national equipment needs assessment for Ghana Health Service.
ii. preparing national equipment plans and budget.
iii. preparing equipment procurement plan.
iv. developing technical specifications for equipment to be procured.
v. national equipment distribution, installation, technical training and acceptance testing

He/she shall also ensure:

i. all user staff are trained and have access to technical support in accordance with the healthcare technology Policy at all levels.
ii. regular maintenance, testing, repair, calibration and decommissioning of healthcare technology.
iii. availability of effective and efficient technical support at all levels.
iv. new equipment are acquired and old ones disposed off in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914).
v. a library of evaluation reports and other guidance materials relating to the performance, safety and cost of equipment is maintained.
vi. action is taken on all complaints, publications on hazard, equipment safety and other relevant guidance.
vii. all technical aspects of procurement and maintenance contracts are cleared before the Service is committed.

viii. a technical assessment of equipment is undertaken from time to time in conjunction with other relevant bodies.

ix. develop strategy for the procurement, replacement and disposal of Equipment for the Service

x. an inventory database is maintained for all equipment, together with records of performance reliability and cost. The database must comply with the GHS policy on records and form part of the Asset Register.

xi. equipment replacement programme is prepared and maintained in liaison with the PPME, Finance, SSDM and ICD Directorates.

xii. equipment plans and budget are prepared in the prescribed format and submitted as required. This shall include both the capital investment budget and the regular budget.

xiii. verify and confirm requests for new equipment submitted by regions and facilities.

xiv. the coordination of all equipment projects to ensure all requirements in the contract are fulfilled and apply all quality assurance procedures to ensure value for money is achieved.

xv. ensure supportive supervision on healthcare technologies at all levels in the health service.

xvi. to liaise with Human Resource Directorate to undertake employment of staff for clinical engineering and also ensure periodic training of such staff.

xvii. undertake annual performance appraisal of staff clinical engineering at the headquarters level.

### 2.11.5 Regional Director of Health Service (Regional Health Directorate)

The Regional Director of Health Service shall be responsible for the optimum availability and management of healthcare technologies within the region. The Regional Director shall be assisted by the Deputy Director, Health Administration and Support Services and the Regional Clinical Engineering Manager to undertake the management tasks at the regional level.

Responsibilities shall include but not limited to:

i. facilitate efficient and effective Clinical Engineering services in the Region

ii. ensuring all equipment needs in the region are captured in the National Procurement Plan and the Capital Investment Plan.

iii. facilitate availability of logistics to support the maintenance and management of equipment in the region.
iv. approve acquisition of new equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914) where necessary.
v. approve disposal of obsolete medical equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914).
vi. Monitor and oversee maintenance of an asset register for all equipment in the facilities within the region in accordance with the Public Financial Management Act 2016 (Act 921).
vii. ensure availability of effective and efficient technical support for healthcare technology at the regional level.

### 2.11.6 Regional Deputy Director of Health Administration & Support Service (Regional Health Directorate)

The Regional Deputy Director of Health Administration & Support Service with support of the Regional Director of Health Services shall be responsible for the optimum availability and management of healthcare technologies within the region and shall supervise the activities of the Regional Equipment Manager to undertake the management tasks at the regional level. Responsibilities shall include but not limited to:

i. ensuring availability of efficient and effective Clinical Engineering Unit in the region.
ii. ensure that all equipment needs in the region are collated and forwarded to the national level for inclusion in the National Procurement Plan and the Capital Investment Plan.
iii. ensuring availability of logistics to support the maintenance and management of equipment in the region.
iv. acquisition of new equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914) where necessary.
v. facilitating disposal of obsolete medical equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914).
vi. ensure that an asset register is maintained for all equipment in the facilities in the region in accordance with the Public Financial Management Act 2016 (Act 921).
vii. ensure availability of effective and efficient technical support for healthcare technology at the regional level.

### 2.11.7 Regional Equipment Manager, Clinical Engineering Unit

The Regional Equipment Manager for Clinical Engineering Unit shall provide technical advice in the efficient management of healthcare technology in the region. He/she shall:

i. conduct regional equipment needs assessment for Ghana Health Service.
ii. collate regional equipment capital plans and budget.
iii. collate and submit regional equipment procurement plan as required.
iv. develop technical specifications for equipment to be procured.
v. conduct and monitor equipment distribution, installation, commissioning, acceptance testing and technical training
vi. provide advice and guidance to all user staff on the application and operation of all equipment
vii. conduct servicing/maintenance and repairs of equipment
viii. assist BMCs to prepare their Equipment procurement plan especially for the Replacement Programme.
ix. develop strategy for the procurement, replacement and disposal of equipment for the Service.
x. facilitate the decommissioning and disposal of unserviceable/obsolete/condemned equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914).
xi. ensure availability of effective and efficient technical support at the regional level
xii. assist with tender evaluation for the procurement of equipment.
xiii. collate and maintain an updated equipment inventory database for the region.
xiv. verify and confirm requests for new equipment submitted by facilities.
xv. ensure safety standards are adhered to by all users.

### 2.11.8 Medical Directors and Medical Superintendents

The Medical Directors of the Regional Hospitals, the Medical Superintendent of District Hospitals and Polyclinics shall be responsible for the optimum availability and management of healthcare technology within their facility and shall be assisted by the Head of Administration and the Clinical Engineering Officer to undertake day to day management tasks at the facility level. The facility

team shall work closely with the Regional Equipment Manager and the Deputy Director of the CED for technical support. Responsibilities shall include but not limited to:

i. ensure effective and efficient management of all equipment in the facility.
ii. ensure effective and efficient maintenance and calibration of all equipment in the facility.
iii. ensure operationalisation of efficient clinical engineering unit in the facility.
iv. ensure funding and other logistics are made available for maintenance and management of equipment in their hospitals.
v. ensure that all equipment needs in the facility are collated and submitted to appropriate office for action.
vi. ensure that the equipment needs of the hospital is captured in the Regional Equipment Procurement Plan
vii. ensure that an asset register is maintained for all equipment in the facilities in the region in accordance with the Public Financial Management Act 2016 (Act 921).
viii. ensure development and implementation of equipment acquisition and maintenance plans and budget.
ix. ensure development of procurement plans for equipment.
x. ensure availability of spare parts, accessories and consumables for the operation and maintenance of equipment.
xi. ensure that proper procedures are followed for the disposal of equipment
xii. ensure overall safety of the health institution including health technology safety.

### 2.11.9 Head, Hospital Clinical Engineering Unit

The Clinical Engineering Officers for the various health facilities shall provide direction and advice in the efficient management of healthcare technology in the facility. He/she shall:

i. conduct facility equipment needs assessment.
ii. develop facility equipment plans and budget.
iii. develop and submit equipment procurement plan in collaboration with unit heads as required.
iv. when necessary shall ensure that all equipment acquired are distributed, installed, commissioned, tested and users are properly trained.

v. carry out acceptance testing on every new equipment acquired by the health facility and properly documented in the inventory database.
vi. provide advice and guidance to all user staff on the application and operation of all equipment.
vii. develop and execute equipment maintenance plan and maintain proper documentation on them.
viii. conduct regular inspection, servicing, maintenance and repairs of equipment.
ix. develop strategy for the procurement, replacement and disposal of equipment for the facility.
x. assist with tender evaluation for the procurement of equipment at the facility level.
xi. develop and maintain an updated equipment inventory database for the facility.
xii. assist in taking delivery of equipment.
xiii. identify equipment needs and notify the relevant Directorates and department of all proposed equipment purchases.
xiv. develop strategy for the procurement, replacement and disposal of equipment for the Service. facilitate the decommissioning and disposal of unserviceable/obsolete/condemned equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914).
xv. advise on appropriate training programmes for members of staff on usage/application/operation and maintenance of healthcare equipment.
xvi. compile information on spare parts, accessories and consumables for medical equipment.
xvii. liaise with the relevant departments to ensure that the requirements for maintenance are complied with.
xviii. liaise with Estate Management Unit in labelling of all equipment.
xix. ensure that all safety standards are maintained in the use of healthcare technology.

### 2.11.10 Hospital Staff

It is important that the users of equipment are trained on the safety, proper use and maintenance of equipment given to them. The Medical Directors of Regional Hospitals and Medical Superintendent of District Hospitals and Polyclinics shall ensure that each staff is well trained on the equipment they use within the hospital before they are allowed to use them. Responsibilities shall include but not limited to:

i. use equipment only for its intended purpose
ii. operation of devices/equipment in accordance with approved standards and practices
iii. undertake day-to-day care and user maintenance of equipment.
iv. identify replacement needs and submit these for inclusion in the Equipment Replacement Programme and the annual procurement plan.
v. co-operate with the authorized persons or teams in the servicing, repairs, evaluation and testing of equipment.
vi. report equipment faults, damage or unsatisfactory performance to the clinical engineering officer.
vii. maintain equipment inventory of all equipment within their jurisdiction.
viii. do not operate or use equipment they have not been trained on.
ix. do not use equipment suspected or confirmed to be malfunctioning until repairs or corrective action taken.
x. report overdue servicing dates, inspection dates and expired licenses to head of administration for action.
xi. proper handing over of equipment in their care when moving out of the duty post and training the incoming staff on the proper handling and operation of the equipment.
xii. have consumables and accessories required for the operation of equipment and report all stockouts to the head of administration and the equipment officer through their unit head for proper stock management.
xiii. and unit heads shall display all relevant maintenance and operation protocols in their area of work for staff compliance.
xiv. ensure that all safety standards are maintained in the use of healthcare technology.

### 2.11.11 District Director, District Health Directorate

The District Director of Health Service shall be responsible for the optimum availability and management of healthcare technologies within the district and shall be assisted by the Head of Administration and the Clinical Engineering Officer to undertake the management tasks at the district level.

Responsibilities shall include but not limited to:

i. ensuring availability of efficient and effective Clinical Engineering Unit in the district
ii. ensure availability of effective and efficient technical support for healthcare technologies at the district level.
iii. ensure all equipment needs in the district are collated and forwarded to the regional level.
iv. ensure all equipment needs are captured in the District Procurement Plan and the Capital Investment Plan.
v. ensuring availability of logistics to support the maintenance and management of equipment in the district.
vi. acquisition of new equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914) where necessary.
vii. facilitating disposal of obsolete medical equipment in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914).
viii. ensure that an asset register is maintained for all equipment in the facilities in the district in accordance with the Public Financial Management Act 2016 (Act 921).

### 2.11.12 District Equipment Officer, District Clinical Engineering Unit

The District Equipment Officer for the District Clinical Engineering Unit shall provide technical advice in the efficient management of healthcare technology in the region. He/she shall:

i. conduct district equipment needs assessment for Ghana Health Service.
ii. collate district equipment capital plans and budget.
iii. collate and submit district equipment procurement plan as required.
iv. develop technical specifications for equipment to be procured.
v. conduct and monitor equipment distribution, installation, commissioning, acceptance testing and technical training.
vi. provide advice and guidance to all user staff on the application and operation of all equipment.
vii. conduct servicing/maintenance and repairs of equipment
viii. assist BMCs to prepare their Equipment procurement plan especially for the Replacement Programme.
ix. develop strategy for the procurement, replacement and disposal of equipment for the Service in the district

x. facilitate the decommissioning and disposal of unserviceable/obsolete/condemned equipment in accordance with Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914) for the district.
xi. ensure availability of effective and efficient technical support at the district level
xii. assist with tender evaluation for the procurement of equipment.
xiii. collate and maintain an updated equipment inventory database for the district.
xiv. verify and confirm requests for new equipment submitted by facilities in the district.

### 2.11.13 Head of Sub District

The sub district head shall be responsible for the optimum availability and management of healthcare technology within their facility and shall work closely with the District Equipment Officer and the District Director of Health Service for technical support. Responsibilities shall include but not limited to:

i. ensure effective and efficient management of all equipment in the sub district.
ii. ensure effective and efficient maintenance and calibration of all equipment in the sub district facilities.
iii. ensure funding and other logistics are made available for maintenance and management of equipment in their sub district facilities.
iv. ensure that all equipment needs in the sub district facilities are collated and submitted to district health administration for action.
v. ensure that the equipment needs of the sub district facilities are captured in the District Health Directorate (DHD) Equipment Procurement Plan.
vi. ensure that an asset register is maintained for all equipment in the sub district facilities in accordance with the Public Financial Management Act 2016 (Act 921).
vii. ensure development and implementation of equipment acquisition and maintenance plans and budget.
viii. ensure availability of spare parts, accessories and consumables for the operation and maintenance of equipment.
ix. ensure that proper procedures are followed for the disposal of equipment
x. liaise with District Health Directorate (DHD) to ensure that district equipment officer(s) visit the sub district facilities to undertake technical repairs of equipment.

### 2.11.14 Head of Health Centre

The head of the health centre shall be responsible for the optimum availability and management of healthcare technology within their facility and shall work closely with the District Equipment Officer and the head of the sub-district for technical and administrative support. Responsibilities shall include but not limited to:

i. ensure effective and efficient management of all equipment in the health centre.
ii. ensure effective and efficient maintenance and calibration of all equipment in the health centre.
iii. ensure funding and other logistics are made available for maintenance and management of equipment in the health centre.
iv. ensure that all equipment needs in the health centre are collated and submitted to the head of the sub-district for action.
v. ensure that the equipment needs of the health centre are captured in the sub-district Equipment Procurement Plan.
vi. ensure that an asset register is maintained for all equipment in the health centre in accordance with the Public Financial Management Act 2016 (Act 921).
vii. ensure development and implementation of equipment acquisition and maintenance plans and budget.
viii. ensure availability of spare parts, accessories and consumables for the operation and maintenance of equipment.
ix. ensure that proper procedures are followed for the disposal of equipment
x. liaise with the sub-district to ensure that district equipment officer(s) visit the health centre to maintain the equipment.

### 2.11.15 Head of CHPS

The head of the CHPS shall be responsible for the optimum availability and management of healthcare technology within their facility and shall work closely with the District Equipment Officer and the head of the sub-district for technical and administrative support. Responsibilities shall include but not limited to:

i. ensure effective and efficient management of all equipment in the CHPS.
ii. ensure effective and efficient maintenance and calibration of all equipment in the CHPS.

iii. ensure funding and other logistics are made available for maintenance and management of equipment in the CHPS.
iv. ensure that all equipment needs in the CHPS are collated and submitted to the head of the sub-district for action.
v. ensure that the equipment needs of the CHPS are captured in the sub-district Equipment Procurement Plan.
vi. ensure that an asset register is maintained for all equipment in the CHPS in accordance with the Public Financial Management Act 2016 (Act 921).
vii. ensure development and implementation of equipment acquisition and maintenance plans and budget.
viii. ensure availability of spare parts, accessories and consumables for the operation and maintenance of equipment.
ix. ensure that proper procedures are followed for the disposal of equipment
x. liaise with the head of the sub-district to ensure that district equipment officer(s) visit the CHPS to maintain the equipment.

### 2.11.16 Clinical Engineering Unit at the Sub-district level

There shall be ***no sub-district Clinical Engineering Unit***. Requirement for Clinical Engineering services at the sub-district level shall be performed by the District Clinical Engineering Unit. Where required, there shall be a designated focal person for equipment at the sub-district health facility to coordinate equipment issues with the District Equipment Officer through the Head of the sub district.

This shall be reviewed when the level of technology at the sub-district level increases to the level where local clinical engineering services shall be required.

### 2.11.17 Staff at the Sub-district level

It is important that the users of equipment are trained on the safety, proper use and maintenance of equipment before they are used to provide healthcare. The District Director through the head of the sub district facility shall ensure that all staff within the district are trained adequately to use the equipment provided for the intended purpose. The responsibility of the staff at the subdistrict level shall include but not limited to the following:

i. operate devices/equipment in accordance with approved standards and practices
ii. undertake day-to-day care and user maintenance of equipment.
iii. identify replacement needs and submit these for inclusion in the Equipment Replacement Programme and the annual procurement plan.
iv. co-operate with the authorized persons or teams in the servicing, repairs, evaluation and testing of equipment.
v. report equipment faults, damage or unsatisfactory performance to the district equipment officer.
vi. maintain equipment inventory of all equipment within their jurisdiction.
vii. who have not been trained on particular equipment are not allowed to apply that equipment on patients or clients.
viii. do not use equipment suspected or confirmed to be malfunctioning
ix. report overdue servicing dates, inspection dates and expired licenses to sub district head for action.
x. properly handing over of equipment in their care when moving out of the duty post and train the incoming staff on the proper handling and operation of the equipment
xi. ensure that consumables and accessories required for the operation of equipment are available and/or requirements communicated to the sub district head for proper stock management.
xii. ensure that the relevant maintenance and operational protocols are clearly displayed in their area of work for staff compliance.
xiii. ensure all safety standards are maintained in the use of healthcare technology.

# 3.0 POLICY GUIDELINES

## 3.1 GUIDING PRINCIPLES

These are the guiding principles to ensure that all issues pertaining to the life cycle of equipment are properly addressed from the time of acquisition to the time of disposal.

## 3.2 ACQUISITION OF EQUIPMENT

Correct procedure for acquisition of equipment is a basic requirement to ensure safe, efficient and good quality equipment to achieve value-for-money. It is therefore important to follow defined procedures based on standard guidelines to ensure acquisition of trouble-free equipment. It is important to note that if poor quality equipment is obtained, the long-term cost may be higher than if good quality equipment is acquired. Poor quality equipment is not safe and also not reliable.

Under this policy, the processes to ensure acquisition of safe and quality equipment especially those intended for use on patients or clients are recommended. The acquisition process shall ensure that issues related to planning, inspection, installation, commissioning, calibration, utilisation, maintenance and decommissioning, proper instructions for use, training for users, accessories, consumables, spare parts as well as technical documentation are properly addressed.

The management of each health facility is responsible for defining the equipment needs and ensuring that all aspects of use and viewpoints of all staff concerned are considered.

All medical devices adopted for use must be registered by Ghana Food and Drug Authority. Similarly, all vendors of medical devices to supply medical devices must be licensed by the Ghana Food and Drug Authority. Where specific statutory requirements exist for particular equipment, those requirements shall be complied with. All equipment must pass an acceptance test before they are used on patients or clients.

The acquisition of equipment must include spare parts, accessories, consumables, appropriate training for the users and technical staff such that their competence is adequate to ensure safe use of the equipment on patients as well as their maintenance.

### 3.2.1 Planning and Assessment

The acquisition of new equipment must start with identification and description of needs and end with acceptance test. All equipment must be planned and budgeted for before acquiring them. The budget shall include the capital investment cost of the equipment, shipping cost, handling cost, transportation cost, cost of consumables, cost of installation, cost of calibration, cost of testing for acceptance, training cost, maintenance cost and cost of spare parts for at least five years where applicable.

The acquisition shall be planned in consultation with relevant stakeholders (technical staff, clinical staff, other users, Estates, the Clinical Engineering Department and the Regional Clinical Engineering Units). The planning shall take into consideration the needs and preferences of professionals and end users, whilst remaining consistent with the Public Procurement Act 2003 (Act 663) and Procurement Amendment Act 2016 (Act 914). The plan shall distinguish between equipment for replacement and equipment for service upgrade or expansion or new construction.

The planning shall take into consideration the following:

i. Demonstrated needs formulated by user and decision by health facility management.
ii. Needs and technology assessment, taking into consideration available qualified users or arrangements to train users if the capacity is lacking, safety and space requirements for the installation of the new equipment as well as requirements for (environmental and safety) the assessment of disposal needs and its environmental impact where applicable
iii. Approved budget, available funds and reassured source of recurrent budget for the operation of equipment
iv. Confirmed maintenance services and support
v. Specification of product requirements
vi. Procurement method and processes
vii. Acceptance of tender and decision by management
viii. Contracting the selected supplier
ix. Delivery and installation
x. Acceptance testing and technical controls
xi. Training of users and maintenance staff
xii. Warranty conditions

New equipment can be acquired to replace obsolete or damaged equipment or to introduce a new service or expand existing service.

### 3.2.2 Procurement

The procurement of health care equipment shall be done in accordance with the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914). (Act 914) and must meet all relevant standards and regulations.

Equipment to be procured must be registered by the Ghana Food and Drug Authority. Also, vendors and suppliers must be licensed by the Food and Drug Authority. Each equipment to be procured shall be need-based and captured in the approved budget and the Procurement Plan for that procurement year.

Each BMC with the support of their Equipment Manager or Officer shall prepare equipment procurement plan annually and submit the plan to the Regional Health Directorate for onward submission to the office of the Director General, GHS.

Clinical Engineering Department shall finalise the list for procurement taking into consideration the available funds, priority programmes etc. and generate the specifications for the listed equipment.

To ensure prudent management of resources, BMCs must provide regular feedback to the Clinical Engineering Department on their confirmed plans to acquire the equipment and immediately after it has been acquired.

The Ghana Health Service shall not procure and stock equipment that have not been planned for in warehouses or stores except equipment that are:

i. not bulky for storage or
ii. considered to have serious consequences on service when they are absent from service

The budget for the procurement must be confirmed before the procurement process is initiated.

The whole procurement package - e.g. selection, shipment, clearing, warehousing, delivery, installation, commissioning, testing, spare-parts, special tools (for calibration, servicing and repairs) and equipment for maintenance, warranty, training, servicing and maintenance requirements must be considered and included in the budget for the equipment procurement.

Before tender document or client requirements document is finalized, the clinical needs and requirements for the equipment must be defined by the users based on the intended use. The Clinical Engineering Department/Unit together with the users shall determine the specifications requirements for the equipment. When the specification is accepted by all stakeholders, the tender process can be initiated. The specifications shall include:

i. all the clinical features, functional and technical requirements
ii. applicable standards
iii. utility supply (electrical and water) and gases requirements
iv. environmental conditions and requirements
v. accessories, consumables and spare parts
vi. training and services to be provided by the vendor
vii. weight and dimensional limitations
viii. documentation

The following shall be considered during selection of equipment:

i. Safety, ease of use, appropriateness to priority health needs, geographic and climatic conditions, cost implications including lifecycle cost and the purpose for which the equipment is required.
ii. Personnel requirements, services to be provided, availability of the skilled professionals required to apply the equipment must be identified, environmental conditions, local capacity to carry out maintenance, safety factors, technical suitability, and building and utility service supply requirements.
iii. The technology or equipment selected for various levels of healthcare delivery shall be in accordance with the approved equipment standard list ***(refer to medical equipment policy and guidelines addendum)***.
iv. The selected equipment must meet the specification for that procurement process.
v. Existence of manufacturer's representative and technical capacity of the local agent.

vi. Availability of spare-parts, accessories, technical consumables and user consumables locally.

vii. Previous experience with respect to performance and technical support.

viii. The life cycle cost (the investment cost, operational and maintenance cost) of equipment shall be considered rather than just focusing on the cost of the hardware.

All contract agreements shall include mandatory clauses for the supplier to provide operating and service manuals, clinical application training for clinical users, operation training for end users, maintenance training for maintenance staff and guarantees for availability of essential spare parts, consumables and accessories for at least five (5) years.

The contract must ensure provision of spare parts, accessories, consumables, appropriate training for the users and technical staff such that their competence is adequate to ensure safe use of the equipment on patients as well as their maintenance.

### 3.2.3 Procurement of Used Equipment

Ghana Health Service shall not procure any used equipment except under special consideration with waiver from the Director General or his/her authorised representative. If decision is made to procure used equipment, there shall be a demonstrated advantage for procuring the used equipment over procuring new equipment.

### 3.2.4 Procurement of Refurbished Equipment

Ghana Health Service shall not procure refurbished equipment except when it is authorised by the Director General of the Service or his/her authorised representative. The procurement of a refurbished equipment must meet all the requirements applied to the procurement of a new equipment.

### 3.2.5 Procurement of Consumables and Accessories

Consumables and accessories are part of equipment and they are used in combination with them. They shall be purchased or procured according to the recommendations of the manufacturer of the equipment to guarantee the safety and performance. The purchase of accessories other than those recommended by the manufacturer shall therefore be avoided.

When procuring new equipment, the list of associated accessories and consumables shall be requested from the vendor or the manufacturer. All consumables, single-use items and accessories shall be accompanied by instructions for use, either stated on the device or on the package or in a separate instruction leaflet in English language.

Consumables and accessories shall meet the standards required for the equipment and must be registered together with the equipment by FDA. Consumables must be labelled or marked with lot/batch number, expiry date, storage conditions and sterile conditions where applicable.

Consumables shall not be procured in large quantities than needed to avoid wastage pertaining to expiration. The remaining shelf life of consumables with expiry date on delivery shall not be less than 75% of its shelf life or as required by Ghana FDA regulations.

Single use items or consumables are not designed for reuse. To avoid compromising the safety of patients and staff, re-use of single-use items or consumables must be avoided.

Where the accessories and consumables are proprietary, they can only be sourced from the manufacturer of the equipment. Under such circumstances, procurement process applicable to proprietary products shall apply.

### 3.2.5 Spare Parts

Spare parts are essential for maintenance of equipment. When procuring new equipment, the quotation for spare parts submitted by the vendor shall be used to estimate the budget required for future maintenance.

When there is a need for spare parts, the procurement must be done in consultation with the Clinical Engineering Department/Unit undertaking the maintenance after sufficient troubleshooting (fault finding) has been carried out on the defective equipment. The spare part to be procured must be genuine (not counterfeit or fake) as recommended by the manufacturer.

Refurbished spare parts shall be avoided unless they can be guaranteed to work safely and satisfactorily by the manufacturer. The use of a refurbished or an alternative spare part must be demonstrated to be equivalent to the manufacturers' recommended spare part and must take into account all risks to patients and users and be fully documented.

Procurement of counterfeit spare parts shall be avoided since it is dangerous and compromises the safety for both the patient and the user.

Procurement of technical consumables and spare parts for servicing or planned preventive maintenance shall be planned, budgeted for and included in the annual budget and procurement plan. However, procurement of spare parts for repairs shall be done on basis of need, since it is not possible to determine what is going to break down in advance.

Where equipment in health facility is not standardised, there may be wide variety of different types of equipment. It is therefore not efficient or even possible to build up a standard spare part stock. Vendors shall therefore be required to provide such spare parts when needed. Only spare parts and technical consumables that are required for preventive maintenance and critical for corrective maintenance shall be stocked.

When procuring equipment, the proposal from the vendor shall include information on delivery time, prices of technical consumables and prices for spare parts. Where equipment is considered essential for service delivery and are critical for lifesaving and down-time cannot be accepted, the clinical engineering department/unit shall stock spare parts for emergency repair works. Such spare parts shall be identified by the vendor during procurement.

The procurement for spare parts shall be streamlined and given special consideration to ensure that whenever it is needed it is easier to order and delivered within the shortest possible time to avoid long waiting time to repair defective equipment. Long waiting time for repair of defective equipment or downtime shall be considered as an inefficient equipment management practice in the health facility.

### 3.2.6 Loan Equipment

Health facilities can loan equipment to another health facility to resolve or fulfil a temporary need. Vendors can also loan FDA registered equipment, where applicable, to health facility for trial before purchase or for evaluation purposes. Where equipment is loaned to a health facility, there shall be a written mutual agreement between the two parties and the Clinical Engineering Department/Unit shall be informed. Such equipment shall be captured in the equipment database of the lender and borrower to prevent ownership conflict. The beneficial institution shall ensure proper maintenance to guarantee patient safety.

Where the equipment belongs to Ghana Health Service, the lender shall maintain the ownership and shall call it back when needed. This notwithstanding if the loan equipment exceeds the timeframe agreed by the two parties involved, arrangements for permanent acquisition shall be made. Loaned equipment shall be captured in the stores receiving/issuing documentation.

All loaned equipment shall be subject to testing before acceptance. All users must be trained and given instructions in the safe use of the equipment before the equipment is used on patients. All policies relating to new equipment shall apply.

### 3.2.7 Use of Personal Equipment/Instruments for Official Duties

Personal equipment is equipment owned by individual professionals that are used to deliver services in the health facility. Ghana Health Service shall not encourage the use of personal equipment for clinical work, except where there is enough evidence that the said equipment/instrument cannot be officially provided.

Where an officer concerned proposes to use his/her personal equipment for official service delivery, it shall be formally communicated to the management of the health facility for acceptance. There shall be a written mutual agreement between the two parties and the Clinical Engineering Department/Unit shall be informed and the equipment captured in the equipment database. The agreement shall include clauses on compensation and maintenance.

The equipment shall meet the required safety and performance standards and shall be subject to testing before acceptance. All users must be trained and given instructions on the safe use of the equipment before the equipment is used on patients. The equipment shall be subject to the same conditions as equipment owned by the health facility.

Withdrawal of such equipment/instrument shall follow the agreement on the use of the equipment.

Non-Governmental Organizations and other Medical Outreach Organizations shall submit a list of equipment with their respective acceptance testing certification which must be duly certified by an appropriate agency before they use the equipment on patients.

### 3.2.8 Acquisition of Equipment through Leasing or Placement

Health facilities can acquire new equipment through leasing or placement in accordance with the Finance Lease Act – 1993 (PNDCL 331) and the Public Procurement Act 2003 (Act 663) and the Public Procurement Amendment Act 2016 (Act 914) and relevant prevailing laws. Under lease arrangement, there shall be a legally binding contract between the two parties (the health facility and the vendor that is leasing the equipment). Under this arrangement the health facility shall pay an agreed periodic fee whilst the vendor owns the equipment and ensure that the equipment is well maintained to keep it functional throughout the lease period for service delivery. The lease terms shall be based on the capital cost of equipment, the useful operational life and associated accessories and consumables. The lease term shall not exceed the useful operational life of the equipment.

Generally, lease arrangement may require the health facility to have a fiduciary responsibility to safeguard the lease equipment in their care and provide security to prevent it from being stolen and/or damaged. Where the equipment under the care of the health facility is stolen or damaged that health facility may be required to replace the equipment. Where the health facility decides to cancel the lease before the expiration of the contract, they may incur some financial repercussions. Health facility management that decide to lease equipment shall seek legal advice and ensure due diligence on the transaction before committing the health facility contractually.

#### *3.2.8.1 Placement or Operating or Fair Market Value Lease*

This is a long-term rental of equipment and payment for the use of equipment over a specified period. At the end of the lease period, the equipment shall be returned to the vendor or purchased at the current fair market value. For laboratory analysers, this type of lease can be applied for "reagent rental agreement" where the health facility shall purchase only reagents for use on the equipment placed in the health facility by the vendor.

#### *3.2.8.2 Finance or Capital Lease*

Under this type of lease, payments are structured like a regular loan (with interest) for the equipment leased. Under this arrangement, the health facility shall own the lease equipment at the end of the lease term for a normal cost of the equipment.

The decision to lease equipment shall be guided by the following criteria:

i. Technical and operational useful life of the equipment
ii. Likelihood of continued use beyond the lease term
iii. Budgeting and availability of funds to meet the financial obligations
iv. Financing terms (cost of borrowing)

Leasing shall be applied only to equipment that has been demonstrated to generate high financial returns on investments to service the agreed payment terms.

It shall not be applicable where such investment is not financially viable. In this regard, the health facility shall confirm the source of funding to service the agreed payment terms before the leasing arrangement is considered.

All factors or conditions to consider when acquiring new equipment shall apply in the leasing arrangement. The leased equipment shall meet the required safety and performance standards and shall be subject to testing before acceptance. All users must be trained and given instructions in the safe use of the equipment before the equipment is used on patients. The equipment shall be subject to the same conditions as equipment owned by the health facility.

### 3.2.9 Management of Equipment under Turnkey Projects

This covers equipment supplied through turnkey projects involving civil works and equipment. It is also applicable for turnkey projects without civil works. The contractor team for the execution of the project shall include a medical equipment planner and biomedical/clinical engineer in good standing with the relevant professional body. The client team for the project shall also include Biomedical/Clinical engineer to monitor and supervise the implementation of the project. The conditions or factors to consider when acquiring equipment shall apply.

i. The planner shall produce the relevant drawings indicating the layout and positioning of equipment and related services.
ii. The selection and specification of the makes and models of equipment shall be done in consultation with the potential users from the project site or beneficiary health facilities and the Clinical Engineering Department/Unit. Where the project involves multiple sites, the potential users shall be selected from some of the sites.

iii. The selected equipment (makes and models), accessories and consumables, spare parts and scope of training, including manufacturers' training, shall be submitted for approval by the client's appointed biomedical/clinical engineer for the project. Such projects shall include at least six months transition period to allow users to acquaint themselves with the new equipment provided before the start of warranty period during the handing over period.

### 3.3 STANDARDISATION

The risks associated with costly and sophisticated equipment like classes III and IV medical equipment are very high. As much as possible, this equipment shall be standardized and the required training to support the operation and maintenance readily available. This requires high level of standardization to achieve greater managerial and economic benefits through planning and bulk procurement of significant quantities of the same make and model of equipment. Where this is not possible, the Director General of Ghana Health Service with the approval of the Public Procurement Authority shall compile and publish the trusted makes and models of selected equipment in the standardisation list every five (5) years. This shall be done in fair and transparent manner to prevent undue disadvantage to vendors of medical devices. The aim is to reduce cost and burden of maintenance, input for maintenance, spare-parts, consumables and accessories management.

### 3.4 INSPECTION AND ACCEPTANCE OF INCOMING EQUIPMENT

All newly acquired equipment must be tested before they are used on patients. Each health facility shall organize a procedure to ensure that this is complied with and must be done by a trained and competent technical person. Where there is no in-house capacity to undertake the acceptance test, a third party can be arranged to undertake the test in the presence of the in-house team. Acceptance test shall be carried out after major maintenance work on the equipment. Only the equipment that passes the acceptance test shall be accepted for clinical services. The following shall be checked during the acceptance test:

i. Equipment delivered complete and in good condition without visible defect.
ii. In good working order and perform as expected in accordance with the intended use.
iii. Passes the safety controls and test.
iv. Delivered with full set of documentation including operational and maintenance manual.

v. The required training provided.

Equipment that passes the acceptance test shall be tagged with the inventory or asset number and the relevant information registered in the equipment database and other records.

## 3.5 INSTALLATION AND COMMISSIONING

All medical equipment shall be installed in accordance with the manufacturers' specifications. Installation of equipment shall be undertaken by a qualified engineer trained and authorized by the manufacturer of the equipment to undertake such technical work. No unqualified or untrained personnel shall be allowed to carry out installation, commissioning or training on equipment.

All newly installed equipment shall be tested and commissioned before authorized to be used for service delivery. This condition shall also apply after major maintenance, repairs and modification work on the equipment.

All newly commissioned equipment shall be handed over to the health facility administration with duly signed commissioning certificates detailing the equipment name, make, brand/model, serial numbers, and details of the operational and functional tests carried out. The commissioning certificate shall form part of the final Contract Completion Report.

Upon receipt, the responsible Clinical Engineering Unit shall tag the equipment with the proper inventory code. Once the equipment has been accepted, the commencement of the warranty period shall be logged.

The acceptance testing shall consist of testing by the users, the clinical engineering staff together with the vendor or its representative.

The following specific installation and commissioning procedures shall apply for specialized Medical Equipment:

***Medical Devices with Ionizing Radiation sources****:*

All diagnostic and therapeutic X-Ray systems shall be installed in accordance with the relevant regulatory requirements on ionizing radiation sources (the Nuclear Regulatory Authority Act, 2015, Act 895). Radiation protection tests shall be carried out for new X-Ray installations before they are authorized for clinical use. The beneficiary hospital shall apply for inspection and licensing by the Nuclear Regulatory Authority.

***Electrically operated medical devices which are connected directly to patients:***

Medical devices which are electrically operated and connected directly to patients have the potential of causing electric shock if faulty. These equipment include ECGs, Defibrillators, Electrosurgical Unit, Patient monitors, etc. Such equipment shall include a grounding system to provide protection against shock. Electrical safety test must be carried out before authorized for clinical use after installation as well as after maintenance.

***Medical gases and equipment operated on medical gases:***

The installation of gas systems requires the services of experts. No unqualified or untrained personnel shall be allowed to carry out installation, commissioning or training on medical gas system. Similarly, no untrained person shall be allowed to install, commission or train users or operate anesthesia gases and related equipment. All anesthesia machines shall be connected to anesthesia scavenging system.

***Sterilization Equipment:***

Upon completion of installation, complete orientation and demonstration, including calibration and testing of the processes of the sterilizers shall be carried out.

## 3.6 DONATION OF MEDICAL DEVICES

Donation of medical devices contributes significantly to medical devices acquired by the health facilities in Ghana. Majority of such donated devices never function or if at all for a short period of time. The reasons are numerous but they can be addressed. To pursue safe and cost-effective management of medical devices, all equipment donations shall comply with the Public Health Act, 2012 (Act 851) and the Ministry of Health policy on donation and any other regulatory requirement including the following guidelines:

i. Donation of pre-owned medical devices shall comply with the Food and Drugs Authority Guidelines for Donation of Medical Devices (FDA/MDD/GL-02) and Ministry of Health Guidelines for Donation and Voluntary Medical Outreach Programme in the Health Sector of Ghana.

ii. Where ionizing radiation equipment (e.g. X-Ray machine, CT scan, Fluoroscopy, Mammography) are concerned, the Nuclear Regulatory Authority shall be contacted for import clearance.

iii. All medical devices to be donated shall be based on stated needs of the Service as well as the health facility and the intervention it is intended for. In this regard, the donors shall consult with the Ghana Health Service / Ministry of Health or the intended recipient(s) in the country.

iv. Donations of medical devices or other related devices intended for use in the Service shall be shipped with the prior consent of the Ghana Health Service and Ministry of Health and the intended recipient(s).

v. All donated medical devices shall be obtained from reliable sources and shall comply with quality standards of both the donor country and that of Ghana including the recommended medical device list and specifications.

vi. For electrically operated medical devices, the electrical needs shall be determined prior to shipping. Donors shall verify with recipients that the electrical needs can be met. Only equipment with input using 220V-240V/50Hz shall be accepted.

vii. the donor organization and the recipient shall ensure that the equipment to be donated can be utilized.

viii. All donated medical devices shall have labels in English and shall be easily understood by health professionals and other users. In addition, packaging, box(es) or container(s) shall be labeled. The label shall include the name of the item, make, model, serial number, the name of manufacturer and the vendor/supplier.

ix. The donated medical device shall be packed in accordance with international shipping regulations and shall be accompanied by a detailed packing list which specifies the contents of each numbered carton by quantity, serial number, weight and any special storage conditions.

x. The value of the donated equipment shall be provided. In order to estimate the value of the donation, the cost of the donated medical devices shall be provided in international convertible currency or equivalent in Ghana Cedis.

xi. Cost of international and local transport, warehousing, port clearance and appropriate storage and handling shall be paid for by the donor, unless otherwise specifically agreed with the Ghana Health Service or the Ministry of Health or the recipient in advance.

xii. Where electrically operated equipment is involved, records on the maintenance, safety and decommissioning report must be presented to the Clinical Engineering Department for advice.

xiii. All relevant documentation concerning the donation ie. Manuals, certifications etc shall be made available by the donor. Equipment donated shall comply with international and national standards such as IEC, ISO, CE, FDA.

### 3.7 ALLOCATION

Equipment procured shall be delivered to where it is needed through the approved distribution channel and Store management system of Ghana Health Service.

Where equipment acquired is not earmarked, the allocation shall be based on the following through the approved administrative reporting system;

i. Health facility with good equipment management system in place
ii. Health facility without the type of equipment under consideration
iii. New or priority health facilities
iv. Specialist health facility
v. Equipment required to upgrade approved services in a health facility
vi. Health facilities with similar equipment obsolete
vii. Any other overwhelming national priorities
viii. Strategic location of a health facility
ix. Pending approved requests from the health facility

The Director General of Ghana Health Service or his/her representative shall approve allocation of equipment.

### 3.8 RELOCATION OF EQUIPMENT

Equipment shall be considered for relocation where one or more of the following factors prevail:

i. Where equipment remains unused as a result of excess supply (after back-up) or lack of user, such equipment shall be relocated to the facility that has the need for it.
ii. Where functional equipment is supplied but the infrastructure and utility (water, electricity, gas etc.) required is/are not available for installation, such equipment shall be relocated to another facility where it can be installed and used.
iii. Where the equipment is not used or applied for its intended purpose
iv. When the health facility is relocating to another site where there is no need for the old equipment

Before the equipment is moved from the current location to the intended location, the Director-General or his/her representative must approve of it.

With the endorsement by the Director-General or his/her representative, the host health facility shall forfeit the right of ownership but may be compensated with other equipment based on the need of the health facility.

### 3.9 REPLACEMENT OF EQUIPMENT

To ensure the continuation of the services, equipment that have reached the end of their useful lifespan must be replaced. The factors to be considered when deciding on replacement of existing equipment shall include:

i. the condition of the equipment
ii. its age and reliability
iii. estimated life
iv. clinical obsolescence
v. maintenance cost
vi. replacement costs
vii. availability of spare parts
viii. equipment functional status
ix. safety implications
x. infrastructure, technical, professional and other user requirements.

xi. adherence to maintenance schedule

Replacement of equipment shall be considered only when technical evaluation has confirmed the need for the replacement (***refer to appendix for evaluation tool for replacement***).

The intended equipment to be replaced shall be included in the plans and budget as well as the annual procurement plan of the health facility. The need for replacement of high cost equipment such as X-Ray machine, CT scan, MRI, Anesthetic machine, Steam Sterilizers, laundry equipment etc., shall be communicated to the Director General of Ghana Health Service for inclusion in the capital investment plan as well as the annual procurement plan at the national level (***refer to medical equipment policy and guidelines addendum***).

Procurement of medical devices for replacement shall be in accordance with the Public Procurement Act 2003 (Act 663) and Public Procurement Amendment Act 2016 (Act 914).

With the rapid changes in technology, the new equipment to replace the existing equipment shall be a recently designed model that has the advantage over the older model with regards to safety, performance and value for money. Such advantages must outweigh the disadvantages related to refurbishment and upgrade of the existing equipment.

The Clinical Engineering Department shall carry out assessment on such equipment and report on the condition of the existing equipment, age, reliability, estimated life, replacement costs, suitability of the equipment, maintenance requirements, durability etc, and shall advise based upon their findings.

The Clinical Engineering Department shall advise health facility managers on the need for the annual procurement plan and equipment replacement programme for all the health institutions, based on the needs and the condition of the stock of equipment. No action shall be taken on request for equipment replacement if it is made to avoid maintenance responsibilities.

This notwithstanding, the estimated life span of the equipment shall be a major determinant in decision to replace an old equipment ***(Refer to medical equipment policy and guidelines addendum).***

### *3.9.1 RESPONSIBILITY FOR REPLACEMENT OF EQUIPMENT*

Basic equipment shall be replaced by the health facility. For expensive equipment that the health facility cannot replace, a request shall be made to the Director General, Ghana Health Service for support ***(refer to the list of basic and expensive equipment at the different levels of healthcare delivery in the medical equipment policy and guidelines addendum).***

***Equipment replaced shall not remain in service and shall be disposed off in accordance with the Public Procurement Act 2003 (Act 663), Public Procurement Amendment Act 2016 (Act 914) and other relevant laws.***

## 3.10 THEFT/MISPLACEMENT OF EQUIPMENT

The Head of Facility shall be responsible for all equipment in the facility and shall ensure that a control system exist for proper security and custody of the equipment. If any incident of theft/misplacement of equipment occurs, the user of the equipment concerned shall inform the head of the health facility in writing explaining the circumstance that led to such incident through the regular channel of communication.

The head of the health facility shall investigate the incident and report on it to the Regional Director through the regular channel of communication for further action. In the event that theft/misplacement of equipment occurs at the national level, the incident must be reported to the Director, Health Administration and Support Services.

Since theft is a criminal issue it must be reported to the Police for further investigation.

## 3.11 MISUSE OF EQUIPMENT

All Equipment shall be used for their intended purpose only. Misuse of equipment shall include the following:

i. Storing items in a piece of equipment that is not a storage facility
ii. Using a patient transport system to transport other load other than patients
iii. Using health care equipment to perform domestic functions (i.e. baking bread in hot air oven, using blood-bank refrigerator to store food and drinks, wheelchair to transport food items, autoclave to boil yam or meat)

Where such incident occurs, the need for the equipment shall be assessed and if the equipment is no longer needed the following shall apply:

a. The equipment shall be relocated to another department or institution where it shall be used for its intended purpose only.
b. The equipment shall be taken out of service and stored for safety reasons or prevent damage.

Where the equipment is found to be damaged due to misuse or misapplication, the person(s) involved shall be dealt with in accordance with the GHS Code of Conduct and Disciplinary Procedures.

## 3.12 REGULATION, OPERATION AND QUALITY

### 3.12.1 Medical Devices Regulation

GHS shall collaborate with regulatory bodies or agencies (FDA, NRA, GSA, etc.) responsible for the protection of the population against unsafe and inappropriate medical devices to monitor and ensure the quality and safety of all medical devices used in GHS facilities.

### 3.12.2 Operation of Medical Equipment

All health workers are responsible for ensuring that medical devices are used well for their intended purposes, safe and well maintained. Only competent users shall be allowed to apply or operate the equipment. Equipment shall be used only after it has been declared safe through completion of acceptance procedure. All operational procedures/steps must be followed, understood and adhered to for the safety of both the users and their clients.

Problems related to malfunctioning shall be reported promptly for correction. Clinical Engineering Departments/ Units shall be empowered to implement the policy and adequately resourced with funds to carry out maintenance activities for equipment.

#### *3.12.2.1 Equipment User Training*

Continuous training on the safe and effective use of medical devices shall be conducted regularly.

i. Every user shall be trained on the safe and effective use of medical devices before being allowed to operate or apply them. They shall also have access to manufacturer's instructions on the safe use of the equipment concerned. The training shall be carried out during/after

installation and servicing of the equipment. It shall be done even if the type of newly installed equipment is well known to the staff in the health facility. The users shall sign statements to indicate that they have received such training. Where manufacturers automatically send copies of revised instructions to a named recipient, they shall be distributed accordingly.

ii. It is the responsibility of the manager in charge to identify suitable staff to receive training to become an authorized user. The managers in charge shall facilitate access to application or user training and up to date information on the use of that equipment. Managers in charge shall keep records of staff training and proof of individuals' updated competency relevant to the use of the equipment.

iii. Anyone using or working on medical devices/equipment without proper training or authorization, as well as the manager who authorizes or allow a person who has not been trained to do so shall be held liable in the event of an accident or damage to a device and shall be dealt with in accordance with the GHS Code of Conduct and Disciplinary Procedures.

#### *3.12.2.2 Application Training*

This is a specialized training to enable the professional user to operate, apply device clinically, interpret results etc. The training shall be provided by an application specialist for that device. For all new specialized and/or complex medical devices e.g. Ultrasound Machine, X-Ray Unit, MRI, CT Scanners, automated laboratory analyzers, automated steam sterilizers (autoclave) etc, significant application training shall be conducted. This training shall be incorporated in contracts for all specialized devices. The beneficiary health facilities shall be responsible for selection of trainees.

Professional users need to be able to demonstrate the necessary skills, competency and understanding of the normal operation of the device including:

i. The identification of potential risks to themselves, colleagues, patients or clients when using the device.
ii. Any differences between models of a given device where these affect safety or device function.
iii. The ability to link the device to a patient effectively with a minimum discomfort.
iv. To be able to show the patient/client how to use the device where applicable.
v. Recognition of device malfunctions.

vi. The ability to correct malfunctions or to withdraw the device from service.
vii. Know how to contact the appropriate personnel for support.
viii. The correct cleaning and decontamination procedure.

#### *3.12.2.3 Non-Professional User Training and Instruction*

Training for other users must enable them to use a device safely and effectively, and if necessary to perform user servicing or maintenance.

It is essential that these users be provided with clear concise information contained within the manufacturer's instructions including common sense advice. These instructions shall be explained and where necessary expanded upon.

A variety of written information and forms of instructions must be available for the user (e.g. large print or access to telephone help/advice). Technical or difficult language shall be avoided as much as possible.

#### *3.12.2.4 Technical Training/Orientation*

All technical staff employed by the Ghana Health Service to service, repair or maintain equipment, must undergo a prescribed technical training/orientation course before they will be permitted to work on any equipment**.**

#### *3.12.2.5 Training of Trainers*

For health facilities in the sub districts designated user trainers shall be trained to support further training to improve equipment care, handling and maintenance. Equipment Officers or Technicians at the DHDs and health facilities shall be designated as the user trainers. These user trainers shall be trained and equipped to train others in the following:

i. Operation, care and handling of basic medical devices
ii. simple maintenance activities especially for basic medical devices.
iii. management of inventory for medical devices
iv. basic health technology management and preparation of reports
v. monitoring and evaluation of the performance of medical devices

District User Trainers shall also carry out support supervision for medical devices and report to the respective Regional Clinical Engineering Unit.

### 3.12.3 Medical Equipment Safety

Medical devices in use shall be tested and cleared for safety by qualified technical staff or authorized institution. The suppliers shall be responsible for carrying out the recommended safety and quality assurance tests after installation. Safety test shall also be carried out after maintenance activities before users are authorized to use them clinically. The specific areas of safety are highlighted below and these guidelines shall be implemented through the entire life cycle of medical devices.

#### *3.12.3.1 Electrical Safety*

Medical equipment and working environment shall be electrically safe. Scheduled inspections and safety tests shall be carried out on all electrically operated devices at specified intervals and the corresponding limits shall comply with the International Electro-technical Commission standard IEC60601-1 or equivalent.

Grounding performance tests, measured from equipment chassis to ground, for electrically operated medical devices shall be conducted to ensure that any leakage current in the case of insulation failure is within internationally acceptable limits.

#### *3.12.3.2 Radiation Safety*

Radiology Departments/Units shall be designed to provide a safe environment for the health workers and patients. New x-ray machines shall be tested and commissioned in accordance with the manufacturers' procedures to meet national (NRA) and international safety standards.

i. Lead aprons shall be worn by all radiology staff and a dosimeter shall be worn outside of the apron at the collar/neck region so that exposure to the head, neck, eyes and thyroid can be measured. A second dosimeter shall be worn under the apron to record possible inner exposure. The dosimeter shall be sent for reading every month.

ii. Regular quality and safety checks shall be carried out before use of X-Ray equipment or equipment with ionizing radiation source

iii. Regular testing and calibration of radiation safety equipment shall be carried out to ensure safety of the health workers and clients.

iv. Safety warning light shall be displayed at all entrance(s) to X-Ray, CT Scan, Mammography or ionizing radiation rooms.

v. There shall be inspections by the NRA and other relevant regulatory bodies to ensure compliance to radiation safety standards.

#### *3.12.3.3 Environmental and Occupational Health and Safety*

Medical Devices and their related consumables used in health delivery service shall not contaminate the environment. They must be disposed in accordance with the related guidelines and policies on medical waste management or environmental protection and safety (MOH/GHS policy and guidelines on occupational health and safety, MOH/GHS policy and guidelines on waste management, sanitation and Environmental hygiene, Public Health Act, 2012 (Act 851), Nuclear Regulatory Authority Act, 2015).

Health facilities shall restrict the use of devices, such as cell phone, that emit electromagnetic waves that interfere with proper operation of medical devices in relevant areas such as operating rooms, emergency rooms and Intensive Care Unit etc. The head of the health facility shall be responsible for the application and implementation of this guideline.

#### *3.12.3.4 Infection Control and Safety of Staff, Patients and the Public*

Health workers have the responsibility to protect the public, patients and themselves against safety hazards that could potentially be caused by the use of medical devices. Prevention of cross infection mediated by medical devices is critical in all health facilities. Where applicable, proper cleaning and disinfection shall be carried out before and after use of all medical devices.

Health workers have the responsibility to ensure that the workplace is free of safety hazards. The health facility managers shall:

i. provide staff with protective clothing e.g. X-Ray protective apron, face mask, etc. and promote awareness of biohazards.

ii. provide warning signs for mechanical and electrical hazards e.g. high voltage power supplies, high pressure gas tanks, etc.

iii. take appropriate steps to ensure that the health facility complies with all applicable safety standards/procedures/guidelines.

iv. make every effort to ensure that every activity within the health facility is safe for workers and patients.

All personnel assigned to the health facility shall be familiar and comply with the MOH/GHS policy and guidelines on infection prevention and control. This shall include the engineering staff since they may come in contact with potentially infectious materials in performing their duties.

#### *3.12.3.5 Decontamination*

Reusable equipment which have been contaminated by blood, other body fluids, pathological specimens or exposure to patients in isolation must be properly decontaminated prior to each use, examination, servicing or repair.

Decontamination shall be carried out by the clinical staff or user in accordance with the Infection Prevention and Control Policy (procedures and guidelines) of the Ghana Health Service.

It is the responsibility of the head of the unit to ensure that their equipment are properly decontaminated between patient use as well as for maintenance.

Where maintenance work is required on the equipment, evidence of decontamination shall be produced before maintenance is carried out ***(see medical equipment policy and guidelines addendum for sample certificate).*** Technical staff shall not accept any contaminated equipment or equipment suspected to be contaminated for maintenance. The user unit shall be requested to take such equipment back for proper decontamination if there is evidence that the equipment has not been properly decontaminated.

#### *3.12.3.6 Medical Gases Safety*

In general, using medical gases is safe. There is however the potential for a serious accident if the gas cylinder, pipe system or the attachments are not handled properly. To ensure safe use of gas cylinders and systems, the following procedures shall be adhered to:

i. Only trained persons shall be allowed to handle medical gas cylinders and systems
ii. Use only medical grade gas (oxygen) of purity 93% and above for medical purposes
iii. Use only the appropriate labeled regulator
iv. Do not attempt to lift cylinder by its valve or cap

v. Carry out leak test before and after filling the cylinder by brushing a leak detector solution and look out for bubbles.

vi. No oil or grease shall be allowed to be used or mixed together with medical gases especially oxygen.

vii. Cylinders shall be stored in a secured well-ventilated enclosure.

viii. Gas cylinders must always be firmly secured and never left unsupported

ix. Cylinder stock shall be rotated so that older cylinders are used first.

x. Full cylinders shall be kept separate from empty ones and "FULL" and "EMPTY" signs posted on each cylinder.

xi. Flammable gas cylinders shall be stored separately within the storage area and shall not be stored with oxidizing agents.

xii. Cylinders shall not be operated or stored close to medical air compressors, vacuum pumps, direct sunlight or heat sources.

xiii. Color coding for medical gas fittings and connections shall follow the ISO standards (all white for Oxygen, Black and white for medical air, all blue for Nitrous Oxide, all grey for Carbon dioxide, all yellow for Vacuum systems).

xiv. Flammable compressed gases storage areas shall be separated from the buildings.

xv. All gas cylinders (Oxygen) shall be emptied to zero to avoid condensation of residual gas at the bottom of the cylinder which could lead to corrosion and hazardous to patients.

#### 3.12.3.7 Mercury Containing Medical Devices

With Ghana signing and ratifying Minamata Convention on Mercury on 24th September 2014 and 23rd March 2017 respectively, the use of mercury containing medical devices is being phased out. The acquisition and use of mercury containing medical devices shall not be encouraged except where alternative technology does not exist. Common devices containing mercury include thermometers and sphygmomanometers. Damaged or decommissioned mercury containing devices shall be submitted to the nearest EPA office for safe disposal.

### 3.12.4 Quality Assurance

Quality is defined as the characteristic that a product or service must have. Quality Assurance is a set of activities whose purpose is to demonstrate that an entity meets all quality requirements.

Based on the above definition, the following systems and principles shall be observed to prevent any adverse incident and ensure staff and client safety.

i. All equipment shall be tested before allowed to use.
ii. Only authorized or trained staff or persons shall be allowed to operate equipment.
iii. All equipment shall be applied for their intended use only.
iv. All safety notices displayed on the equipment must not be:
    a. Removed from the equipment whether intentional or unintentional
    b. Disregarded
    c. Modified without informing the appropriate authority
    d. Abused -e.g., staining or discolouring, tearing or mutilating such notice could lead to disastrous consequences.
v. All caution symbols displayed on specific parts of equipment instructions must be:
    a. Read and understood and if necessary seek interpretation or explanation of symbols, e.g. (caution on high voltage)
    b. Inspected routinely
vi. All equipment scheduled for maintenance work or repairs shall be:
    a. Cleaned and devoid of biological and pathological fluids.
    b. Accompanied by all the necessary user/operational manuals
    c. Well packed with the necessary accessories to facilitate repairs and calibrations.
vii. Only authorized or trained technical staff shall be allowed to service, maintain or repair equipment.
viii. All equipment that are in use if suspected of being faulty shall immediately be arranged for repairs and safety checks performed, calibrated and tested before the equipment is taken back for use.
ix. All faulty equipment shall be labelled with the appropriate caution notices.
x. All accessories, consumables, tools and other attachments must always accompany the equipment for maintenance.
xi. Old and unserviceable equipment shall be disposed off and removed from the institution.
xii. Clinical Engineering Department shall be notified of the presence of any equipment being brought into the institution for technical advice or acceptance checks before they are put to use.

xiii. Equipment decommissioned and disposed off shall not be re-commissioned for service except when they are refurbished by the manufacturer's authorised person(s) in line with FDA requirements. This is because, the refurbishment may not conform to safety standards and may be harmful to staff and clients.

All medical devices procured by GHS shall conform to international standards and must be registered by FDA.

#### *3.12.4.1 Quality Control Recalls, Warnings*

The Clinical Engineering Department/Unit shall be responsible for processing recall/ warning/ alert messages related to medical devices. They shall also be responsible for coordinating actions, disseminating information and ensure implementation of corrective action.

Should potentially hazardous situations arise in any health facility, the users shall report to FDA and also to their respective Clinical Engineering Units or where necessary, to the manufacturer or their local agent. The information contained in the report shall include the name of the device (including the inventory number, make, model, serial number, manufacturer etc.), the nature of the problem and the action taken to correct the problem.

#### *3.12.4.2 Adverse Incidence*

Adverse Incidence is an event involving an equipment, which has produced, or has the potential to produce unexpected or unwanted effects involving the safety of patients, users or other persons.

Any incident involving equipment shall be reported using the FDA Incident Reporting Format (see appendix for sample of the form).

The Deputy Director of the Clinical Engineering Department or the Regional Equipment Manager shall be notified immediately if an injury occurs since urgent investigations may be necessary.

In the event of adverse incident:

i. Switch off any electrical/gas supplies to the equipment to ensure patient and staff safety.
ii. The equipment shall not be interfered with in any way, especially its controls, except for safety reasons or to prevent loss of evidence.
iii. Label the equipment as FAULTY and keep separated from all other equipment.

iv. Notify the Clinical Engineering Department or Unit as soon as possible for urgent investigation.

Where investigation is required, the Clinical Engineering Department or Unit shall issue report on the incidence and institute measures to prevent future occurrence.

***The faulty equipment must not be used until it has been repaired.***

#### *3.12.4.3 Calibration*

Calibration is the process of ensuring that a piece of equipment is producing reliable and accurate results as per defined standards. It is essential that all equipment for diagnosis, treatment and measuring purposes are safe to use on patients. They must therefore produce consistent and accurate results.

Calibration shall be carried out on all diagnostic, treatment and measuring equipment to ensure the parameters are within the required specifications and meet the required standards. Equipment shall be calibrated in accordance with the manufacturer's recommendation to ensure readings or results are within acceptable range.

Calibration shall be carried out by trained and competent professionals. Calibration shall be part of the routine maintenance activities. All equipment requiring calibration shall be accompanied by manufacturers' calibration reports/certificate and equipment shall be checked to confirm accuracy of their results before acceptance for use.

All clinical engineering professionals shall acquire competency in calibration, make sure they understand the procedures and follow manufacturers' instructions for calibration.

All calibration materials (standard weights, timer, tachometer, thermocouple, calibrators, controls, lung analyzer, ECG simulator, defibrillator analyzer, patient simulator, testing software, pipette calibrator, analytical balance etc.) must be calibrated to a traceable standard.

Calibration certificates shall be issued and displayed annually by the calibration body to the health facilities whose equipment have been calibrated for the year after every calibration is done.

### 3.12.5 Power Supply

Most equipment operates on electricity supply. They can only be supplied and installed in health facilities where there is electricity. It is therefore essential for health facilities to have adequate

and quality electricity supply. All health facilities shall be connected to the national electricity grid. The following shall be considered for health facilities to ensure safe power for the operation of equipment:

i. In addition to the national grid, all hospitals and polyclinics shall have standby generator with adequate capacity to operate equipment for essential clinical service delivery. Selected areas within hospitals shall be provided with renewable energy including solar systems.
ii. To protect individual equipment, the incoming power supply from the national grid shall be cleaned or regulated by installing stabilizers, voltage regulators, line conditioners, surge arrestors, etc.
iii. For equipment that require continuous supply of power when in operation they shall be protected by installing uninterruptible power supply with capacity to sustain power when the main power supply is disrupted for a duration of the time lag before the standby generator power is restored.
iv. All health centers shall in addition to the electricity supply from the national grid, be supported with installation of renewable energy sources including solar systems.
v. All CHPS should in addition to the national grid be connected with renewable energy sources including solar energy.

To reduce cost of energy used in health facilities all managers of health facilities should as much as possible ensure installation of only energy efficient equipment e.g. lighting bulbs. In addition, motion sensors or alternative devices to switch off power supply when not in use should also be installed.

Appropriate and stable power supply system is essential for proper functioning and long-term operation of the equipment. All electricity dependent equipment acquired for health facilities in Ghana shall operate on electric voltage of 230V ±10% and frequency of 50 Hz, and electric plugs shall be 3-pin (BS 1363/A) or appropriate connector with grounding to avoid electrical hazard or shock. All major electrically operated medical devices shall be supplied with Uninterrupted Power Supply (UPS) system with surge protector and/or voltage regulator/stabilizer to ensure continuous operation of the medical device in case of power cut, outages or fluctuation.

## 3.13 MAINTENANCE

Proper maintenance of equipment is essential to obtain sustained benefits and to preserve capital investment. Equipment must be maintained in good working condition and periodically calibrated for effective performance and accurate results.

The Clinical Engineering Department/Unit shall track and maintain information on maintenance activities for each equipment. The information shall cover the following; (***see medical equipment policy and guidelines addendum for details***)

This policy classifies maintenance into three categories; daily user maintenance, periodic preventive maintenance and corrective maintenance.

### 3.13.1 Daily User Maintenance

Users of medical devices shall carry out daily maintenance as part of the operation of the equipment. This shall include daily visual inspection, daily cleaning, operation checks, proper storage etc. to ensure that the equipment does not deteriorate and to prolong its life span. The Daily User Maintenance activity shall be part of daily operation of the device and shall be performed by the staff who use the equipment.

The daily user maintenance shall be included in the user or operation training for the equipment. The Clinical Engineering Department/Unit shall prepare the detailed checklist for daily user maintenance.

### 3.13.2 Preventive Maintenance

Preventive Maintenance involves maintenance performed to extend the life of the equipment and prevent its failure. Preventive Maintenance is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, calibration, 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 special cases the user may change the frequency to accommodate local environmental conditions.

Preventive maintenance is a mandatory requirement for all medical equipment to enhance the efficiency, effectiveness and reliability and must be carried out at appropriate intervals as recommended by the manufacturer/service provider.

The health facility managers shall be responsible for the implementation of scheduled preventive maintenance program for medical devices within their facility. The Clinical Engineering Department/Unit shall provide technical support or facilitate the implementation of the scheduled preventive maintenance programme in the health facility.

Where there is no in-house technical expertise available, the implementation of the scheduled preventive maintenance programme shall be done in collaboration with either the Regional CEU or the national CED.

The conditions for preventive maintenance required for equipment vary due to factors such as type of equipment, age of equipment, frequency of use of equipment, etc. The Clinical Engineering Department/unit shall prepare the preventive maintenance schedule as per manufacturer's recommendations ***(refer to maintenance intervals for specific equipment in medical equipment policy and guidelines addendum).***

Preventive Maintenance shall be carried out on all the equipment whether in use or not and shall be done periodically as recommended by manufacturer. Periodic testing and safety checks shall also be carried out on all equipment in accordance with manufacturer's recommendation.

In critical care areas like Casualty, ICU, OT, Dialysis etc., preventive maintenance shall be carried out in a manner that shall not interfere with the care of the patient. Where necessary, backup equipment shall be made available for use when equipment is undergoing maintenance.

To prolong the life span of the equipment, only quality and original technical consumables shall be used for preventive maintenance.

Service report shall be provided after preventive maintenance activity. A report on the preventive maintenance activity provided shall be submitted to the user department of the health facility and the Clinical Engineering Unit. Where the maintenance activity is carried out from the national level, a copy of the report shall be submitted to the Clinical Engineering Department. In addition to the report, a sticker indicating the last service date as well as next service due date shall be fixed on all equipment that undergo preventive maintenance.

### 3.13.3 Corrective Maintenance

The corrective maintenance, or repair refers to activities or any work carried out to restore defective equipment to its normal working condition. The maintenance activities carried out include identification, isolation and rectification of a fault.

All medical equipment in use shall be free from any fault or defect and all repair work shall be carried out to acceptable standards by competent person(s) only.

Faulty or defective equipment shall not be used regardless of how minor the problem is and must be reported to the responsible Clinical Engineering Department/unit for action to be taken.

In the event of any malfunction or breakdown of equipment, the designated staff involved shall first contact the responsible Clinical Engineering Department/Unit, whether the said equipment is under warranty, service contract or not. The relevant fault reporting form or service request form shall be completed for action to be taken.

Cannibalisation (used parts taken from one piece of equipment and used in another) shall be considered where necessary. This is possible in health facilities where the equipment are standardised. Where cannibalisation is considered, it shall be done in accordance with the Stores Regulations, Ministry of Finance and Economic Planning 1984 chapter 15 clauses 1523 to 1533.

#### *3.13.3.1 Procedure for Reporting Equipment Breakdown*

In an event of equipment breakdown, the following procedure shall be followed:

i. The Head of the Unit/Department shall complete the Fault Reporting Form.
ii. The completed form shall be submitted to the in-house Clinical Engineering Unit for urgent attention.
iii. Where necessary the fault shall be reported by telephone or in person.
iv. The Clinical Engineering Unit shall initiate the process for repair.
v. The faulty equipment shall be withdrawn from service until it is restored.
vi. Where the spare-parts are not available but required for repairs, the hospital shall be informed and the necessary arrangement made for it.
vii. Where the work cannot be done in-house, technical assistance shall be sought from the next higher level of Clinical Engineering Unit/Department.

viii. Equipment under maintenance contract (e.g. Diagnostic Imaging Equipment and Anaesthetic machines) shall be reported directly to the Contractor. The outcome shall be communicated to the Clinical Engineering Department at the national level.

### 3.13.4 Maintenance Contracts

It is essential and economic to have maintenance contract for certain complex medical devices (e.g. X-Ray machines, CT Scanners, MRI, Ultrasound Scanners, Anaesthetic machines, Dialysis machines, Automated Laboratory analyzers, etc.). For such equipment, manufacturers normally guarantee the safety and performance of the equipment only when manufacturers'-trained and authorized service engineers or technicians carry out the periodic and corrective maintenance. The most convenient way to guarantee this is to have maintenance contracts when the equipment is being procured. Procurements of such equipment shall therefore include maintenance contracts ***(refer to medical equipment policy and guidelines addendum).***

Where funding is limited to only the cost of the equipment, alternative funding arrangement shall be secured for the maintenance contracts.

The Clinical Engineering Unit shall facilitate, monitor and evaluate the performance of the contract agreement. The role of the Clinical Engineering Unit shall be clearly stated in the contract. The head of the Clinical Engineering Unit shall report the outcome of monitoring and evaluation to the Head of facility.

Where the maintenance contract is managed at the national level, the Clinical Engineering Unit shall facilitate, monitor and evaluate the performance of the contracted service and report to the Clinical Engineering Department through the normal/ prescribed channel of communication.

### 3.13.5 Refurbishment and Modification of Equipment

Ghana Health Service shall not procure refurbished equipment with public funds, however if refurbished equipment is donated in accordance with the donation policy and guidelines it shall be accepted.

Under certain circumstances, equipment refurbishment and/or modification shall be necessary to restore defective equipment to its normal working condition or upgrade it. Refurbishing or modifying existing equipment may have safety implications. The person/institution undertaking

the refurbishment or modification shall be considered a manufacturer and shall comply with the required regulations. The original manufacturer's liability shall be transferred partially or wholly to the person/institution undertaking the modification.

No modification to any item or equipment shall be permitted unless it has been approved by either the manufacturer or the Regional Equipment Manager or the Deputy Director, Clinical Engineering Department as may be applicable. The records on the modification shall be kept together with the records of that equipment.

### 3.13.6 Documentation of Maintenance Job

Proper records shall be maintained for all pieces of equipment throughout the operating life. This record shall contain details of all repairs, modifications, calibrations and safety test results for the purposes of audit and potential litigation.

It is also a valuable source of information in assessing equipment reliability, safety and performance. It also ensures that the most economical use is made of the equipment and where there is any deterioration in safety readings, it is highlighted and acted upon. Where applicable, service records shall be forwarded to Clinical Engineering Unit or Department, as appropriate, to enable a complete device history to be kept.

### 3.13.7 Handover of Equipment After Servicing

Before handing over serviced equipment, the technical staff shall:

i. ensure that functional and safety checks are performed.
ii. attach stickers on all equipment that has been repaired or serviced, indicating the date a service has taken place and next date of service.

The first user of equipment after service or repair shall be made aware of its status so that user functional checks are made before use.

## 3.14 LOCAL PRODUCTION OF EQUIPMENT

Local innovation (research and development) and manufacturing of medical equipment that meet acceptable quality standards and good manufacturing practices shall be encouraged. The

manufacturer of such equipment shall comply with the medical devices regulation of the Food and Drugs Authority.

Facilities of Ghana Health Service shall be encouraged to patronize equipment manufactured locally that meets acceptable standards. This shall be done in compliance with the Public Procurement Act, 2003 (Act 663) and the Public Procurement Amendment Act, 2016 (Act 914).

Where a Clinical Engineering Department/Unit produces a device for use in a particular health facility, the device must be authorized by the Deputy Director, Clinical Engineering Department. Such equipment shall not be transferred to another health facility without authorization from the head of the health facility in consultation with the Regional Equipment Manager. Such equipment shall not be sold unless it has been registered by Food and Drugs Authority. The manufacturer of such equipment shall be liable for its safety.

Where a piece of medical equipment is manufactured in-house for a patient on a named basis, the user who specified it carries responsibility for the safety and performance of the device.

### 3.15 DECOMMISSIONING AND DISPOSAL OF EQUIPMENT

Equipment at the end of their useful lifecycle or when declared obsolete may pose risk to users, patients and the public. They must therefore be decommissioned and disposed off safely in accordance with the Public Procurement Act, 2003 (Act 663) , the Public Procurement Amendment Act, 2016 (Act 914) and the Public Health Act, 2012 (Act 851) part 7. The reasons for decommissioning and disposal of equipment shall follow the criteria for replacement of equipment ***(refer to section 3.9 on replacement).***

The head of the Clinical Engineering Unit shall advise the head of the health facility on the device(s) which are due for decommissioning, disposal and replacement. The advice shall include the risk that could arise from continuous use of the device. The head of the health facility shall initiate the disposal process accordingly.

The equipment approved for disposal shall be discarded in accordance with the environmental regulation on disposal of medical waste or electronic waste.

Where the equipment approved for disposal is considered special or hazardous waste (e.g. Radiotherapy equipment, Mercury-containing devices such as Sphygmomanometers,

Thermometers, etc.), it shall be discarded in accordance with applicable national and international regulations including the Hazardous and Electronic Waste Control and Management Act, 2016 (Act 917). These devices may contain materials that can pose risk to the environment and the public. Such equipment must therefore be rendered harmless before final disposal.

Where nuclear materials are concerned, the head of facility shall collaborate with the Ghana Atomic Energy Commission and the Nuclear Regulatory Authority to ensure safe disposal. Where microbiological or chemical hazards exist, the equipment must be safeguarded and decontaminated before disposal.

When the equipment approved for disposal is taken by another facility, the donor bears no responsibility for any harm caused from the usage of the equipment.

Electrically operated equipment approved for disposal, must be rendered unusable before final disposal.

Equipment containing batteries that have been approved for disposal must have their batteries removed and disposed off in accordance with the Environmental Protection Agency regulations.

A certificate of disposal shall be issued after the final disposal of equipment and forwarded to the head of facility and the Clinical Engineering Unit to update the equipment inventory.

## 3.16 MANAGEMENT INFORMATION SYSTEM FOR EQUIPMENT

All health facilities shall have a system to organize, plan and monitor equipment that are in clinical use. The equipment shall preferably be registered in a centralized computerized equipment information system, or if not possible in a local manual inventory system or register. Records on all equipment shall be kept at all management levels and even when the equipment is disposed off in accordance with the Public Financial Management Act, 2016 (Act 921) and the Public Records and Archives Administration Act, 1997(Act 535). Information regarding equipment shall be developed, monitored and updated in a systematic manner.

The information management system shall include features that allow monitoring of equipment from the health facility with regard to issues such as cost, safety, efficient use and needs of replacement.

Each health facility shall keep track of their equipment and shall have procedures for registration of equipment in the information system. All equipment in the health facility shall be registered in the information system. All health facilities shall be required to update their database quarterly. Single use medical devices accessories and disposables shall be excluded.

The health facilities within the district shall submit their equipment information records to their respective District Health Directorate for compilation of district equipment database. The District Health Directorate shall in turn submit summaries of their equipment database to their respective Regional Health Directorate. The Regional Health Directorate shall submit a summary of the equipment database of their respective regions to the Director, Health Administration and Support Services as part of their quarterly returns. Such information shall be updated semi-annually.

To facilitate identification and reporting processes, each equipment shall be marked or tagged with a unique registration number which is organised in a logical number sequence. The unique registration number shall be referred to as "inventory or asset number". The material of the inventory tag shall resist cleaning agents and tempering.

The information to be registered either on paper or computer format shall include:

i. the manufacturer
ii. the vendor
iii. equipment description
iv. serial number
v. the inventory or asset number
vi. the acquisition date
vii. the value of the equipment (real or estimated value)
viii. current location
ix. preventive maintenance and recommended intervals
x. repair and maintenance history
xi. date of disposal

***(refer to medical equipment policy and guidelines addendum for further details)***

Detailed Service and maintenance data shall be documented for performance monitoring of both in-house and vendors' activities. To track the performance of repairs and servicing for each equipment, the following information shall be registered:

i. Name of person who performed the repair/maintenance.
ii. Name of person who reported a problem with a medical device.
iii. General description of the problem or service need.
iv. Spare parts used during the repair/maintenance.
v. Name of company if the work has been carried out by such.
vi. Detail of the work performed.
vii. Information on service-contract.

Equipment that has been decommissioned and disposed off shall have its inventory tag removed and inventory information transferred to equipment disposal register or database.

The equipment information to be maintained by health facilities shall include:

i. Equipment inventory (inventory for both the database and the asset register)
ii. Equipment preventive and corrective maintenance records (for both database and asset register)
iii. Records on broken down equipment
iv. Training register
v. Decontamination records
vi. Standard Equipment list

The inventory or asset number of an equipment shall be referred to provide effective means of identification of equipment for scheduled servicing, repairs, replacement, evaluation and the like.

### 3.17 LOGISTICS MANAGEMENT FOR EQUIPMENT

All equipment procured irrespective of the source shall be delivered to the health facility where the equipment is intended. The processes including shipping, clearing, warehousing, local

transportation, documentation etc. shall be included in equipment transaction in line with applicable guidelines for all health products, equipment and consumables inclusive.

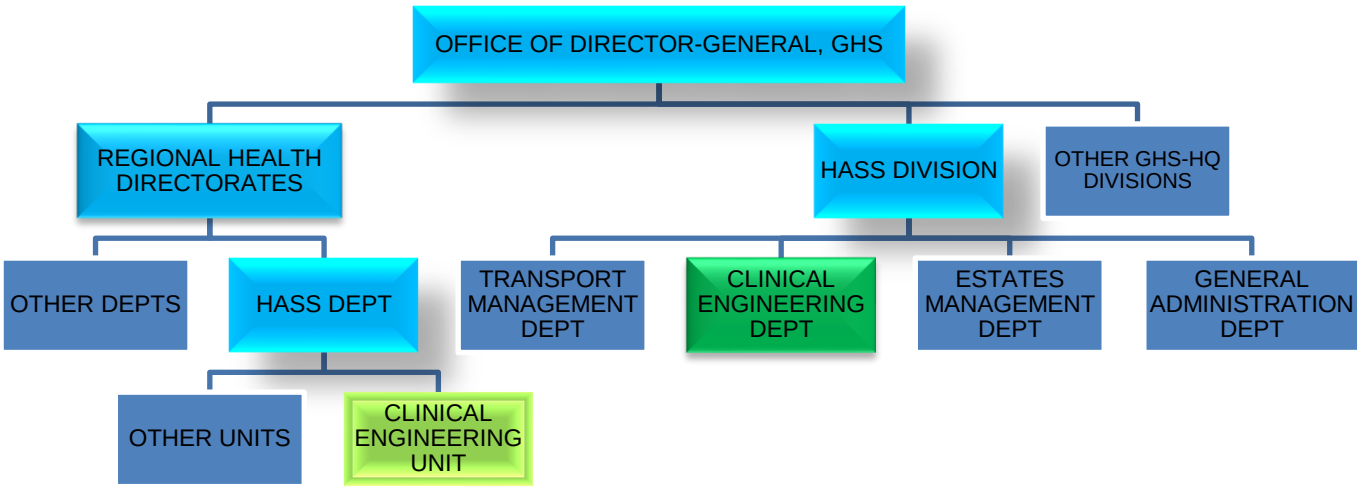
All equipment shall be shipped in accordance with shipping principles with the applicable incoterms, warehoused as per Logistics Management of Public Sector Standard Operating Procedures, inspected and transported to its final destination for installation.

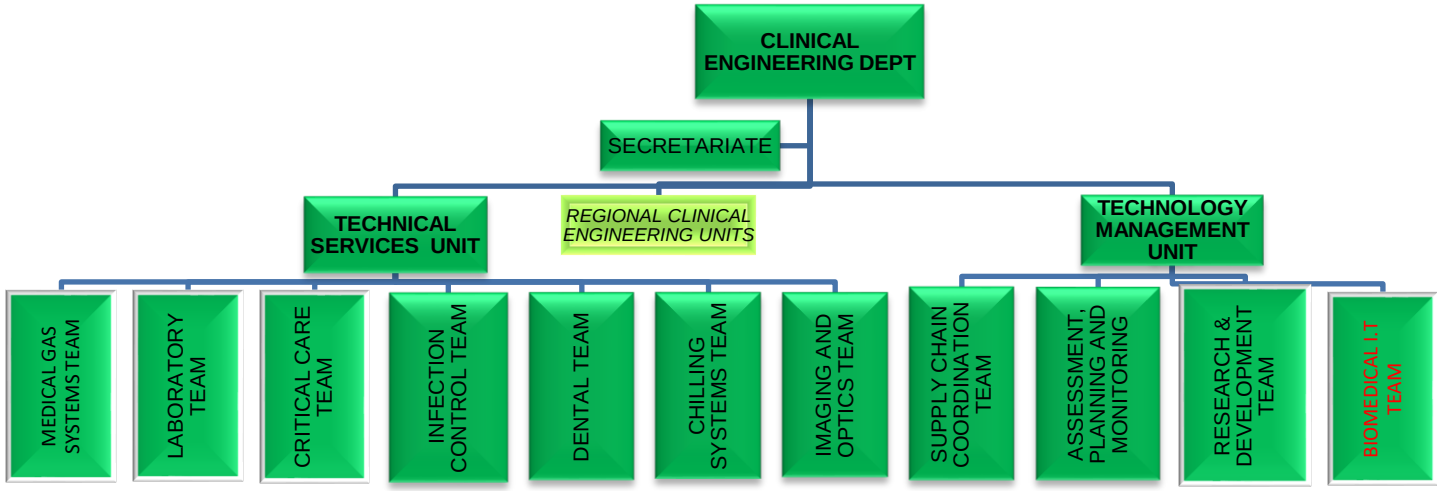
Where applicable, the national level, regional level and facility warehousing structures shall be used in warehouse management of the equipment as per the warehousing SOPs.

## 4.0 ORGANISATIONAL SYSTEMS AND REPONSIBILITIES

The Clinical Engineering Department is organized at both National, Regional and District levels as shown below.

### 4.1 NATIONAL LEVEL



Clinical Engineering Department at the national level has two (2) Units:

i. Technical Services Unit
ii. Technology Management Unit

Each unit is made up of Subunits or Teams. The functions of the units are as follows:

### 4.1.1 Technical Services Unit

This unit shall manage and maintain all the specialized equipment which neither shall be cost effective in establishing the skills required at the regional and district level nor contracting out the maintenance of such equipment.

The responsibilities shall include:

i. Installation and re-installation of equipment
ii. Commissioning and acceptance testing of new equipment acquired
iii. Carry out preventive maintenance on specialized equipment
iv. Carry out repairs or corrective maintenance on specialized equipment
v. Updating management information systems (equipment database)
vi. Monitor contracted maintenance
vii. Ensure all equipment within the service comply with safety standards
viii. Monitor equipment performance and advise on the selection of new equipment
ix. Manage the spare-parts, accessories and related technical and user consumables

The Sub-Units or teams under the Technical Services unit are:

i. Critical Care team
ii. Laboratory team
iii. Infection Control team
iv. Dental team
v. Medical refrigeration/Solar Systems team
vi. Diagnostic Imaging & Optics team

vii. Medical Gas/Plant Systems Team

#### *4.1.1.1 Laboratory team*

The team shall be responsible for all the laboratory analyzers and related laboratory equipment which are currently not covered by any maintenance contract.

#### *4.1.1.2 Critical Care team*

The team shall be responsible for intensive care equipment, renal dialysis equipment, theatre equipment, emergency room equipment, medical gas systems including anaesthesia machines.

The equipment for critical care services requires the presence of technical staff at all times. Where such situation exists, a well-trained technical staff shall be assigned the responsibility.

#### *4.1.1.3 Infection Control team*

The team shall be responsible for equipment used in the health institutions for infection control. These include laundry machines, autoclaves, bedpan washers, scrubbing units with electronic controls, incinerators and liquid waste treatment system.

#### *4.1.1.4 Dental team*

The team shall be responsible for the maintenance of dental chairs, dental hand-pieces and dental laboratory equipment.

#### *4.1.1.5 Medical Refrigeration/Solar Systems team*

This team shall be responsible for all the

**i.** Mortuary refrigeration unit
**ii.** Blood bank fridges and related equipment such as refrigerated centrifuge
**iii.** Laboratory fridges
**iv.** Hygienic air-conditioners
**v.** Vaccine fridges
**vi.** Solar systems
**vii.** Cold rooms for vaccines
**viii.** Cold rooms for kitchen

ix. Domestic air-conditioners, vehicle air-conditioners and refrigerators as may be agreed on with the EMU and TMU

#### *4.1.1.6 Diagnostic Imaging and Optics team*

The team shall be responsible for;

i. Magnetic Resonance Imaging (MRI) Scan
ii. CT Scan, Fluoroscopy, Fluoroscopy and another X-Rays equipment
iii. Ultrasound equipment
iv. Eye care equipment including lasers
v. Ear, nose and throat equipment
vi. Endoscopes

#### *4.1.1.7 Medical Gas/Plant Systems team*

The team shall be responsible for oxygen generators, piped medical gas systems, gas manifolds, vacuum systems, compressed air systems, cylinders, regulators and generator Plants.

### 4.1.2 Technology Management Unit

This unit shall plan and develop systems for the advancement of Clinical Engineering within the Ghana Health Service. The responsibilities include the following:

i. Maintenance of equipment inventory
ii. Keeping records on equipment maintenance
iii. Planning and acquisition of equipment for replacement programs
iv. Planning and acquisition of equipment for expansion/upgrading of services either within a hospital, district or region.
v. Ensure effective usage of all equipment acquired by the GHS
vi. Identify training needs for further action
vii. Update Hospital Managers on programs and projects, incident and accident warning, distribution of equipment and installation of new equipment in liaison with the Technical Services Manager
viii. Investigate incidents and accidents and manage the risk involved
ix. Keeping professionals within the Ghana Health Service abreast with advances in clinical engineering

x. Compliance with legal and regulatory framework on the use of technology, namely; Data Protection Act, Electronic Transmission Act and Ghana Cyber Security Strategy.

The sub-units and teams under the Technology Management Unit shall include

**(i)** Supply Chain Coordination Team
(ii) Assessment, Planning and Monitoring Team
(iii) Research & Development Team
(iv) Biomedical Information Technology Team

#### *4.1.2.1 Supply Chain Coordination team*

The supply chain team which is under the Technology Management Unit shall be responsible for

**i.** the compilation of data on equipment request, carry out need assessment where necessary and prepare the procurement plan,
**ii.** the preparation of equipment schedules
**iii.** the writing of specifications
**iv.** providing support to the Procurement Unit of the GHS in preparing bidding documents and the evaluation of bids
**v.** organizing installation, commissioning, acceptance testing where necessary and determine the inclusion of new equipment on the maintenance schedule
vi. monitoring the utilization of spare parts, accessories, technical and user consumables and arrange for procurement to replenish the stock level

#### *4.1.2.2 Assessment, Planning and Monitoring Team*

The responsibilities of the team are as follows:

**i.** Monitoring of equipment performance within the GHS
**ii.** Investigating incidence, accident, manufacturing defect and formulate policies, standards or regulations to prevent future re-occurrence of such incidence
**iii.** Carrying out quality assurance and control programs to ensure results or output of every equipment is accurate or within normal limit and also safe to apply on patients or clients.

**iv.** Monitoring medical electrical safety of each electrically operated equipment and the radiation safety of equipment with source of radiation to ensure their safety

**v.** Where sterilization is concerned, they shall collaborate with the unit responsible for infection prevention and control within the GHS.

**vi.** Final recommendation for decommissioning and writing off of major equipment from the inventory and asset register.

vii. Responsible for the information management of the unit.

#### *4.1.2.3 Research and Development team*

The responsibilities of the team are as follows:

i. Research into technology requirements for various services and determine the technology suitable for the service.

ii. Investigate incidence, accident, manufacturing defect and formulate policies, standards or regulations to prevent future re-occurrence of such incidence.

iii. Designing and redesigning of systems for production or refurbishment for teaching purposes or usage.

iv. Trial test of newly registered equipment introduced or proposed by any supplier.

#### *4.1.2.4 Biomedical Information Technology Team*

The team is responsible for defining the compliance details under the Data Protection Act, Electronic Transaction Act and Ghana Cyber Security Strategy. The responsibilities of the team are as follows:

i. Responsible for writing specifications of IT components

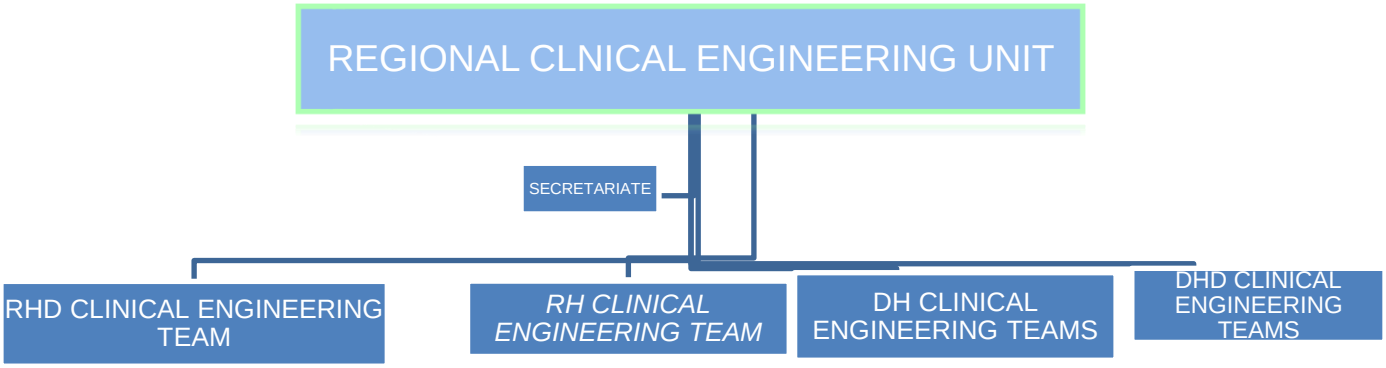
ii. Define the documentation for implementation, testing and service levels

iii. Define the security protocols for data types like audio, video, images and raw data.

iv. Define interoperability standards for data transfer, sharing and storage.

v. Responsible for defining data ownership and storage of the data types generated from the medical devices.

## 4.2. THE REGIONAL LEVEL




Every Regional Health Directorate shall have an effective and efficient Regional Clinical Engineering Unit. The responsibilities of the unit are as follows:

i. Management of all equipment in all facilities within the region
ii. Keep and update equipment inventory
iii. Carry out preventive and corrective/breakdown maintenance on all equipment in accordance with the available capacity
iv. Manage a contracted maintenance
v. Carry out installation and testing of incoming equipment for acceptance where necessary
vi. Arrange for technical support from the CED, where the capacity to maintain is not available
vii. Ensure all equipment are effectively and efficiently used for their intended purposes
viii. Identify the equipment needs, prepare equipment replacement plan and equipment procurement plan
ix. Advise on allocation and relocation of equipment
x. Advise on the Clinical Engineering needs for the region

The Unit shall be an integral part of the Health Administration and Support Services Department of the Regional Health Directorate. The unit shall report administratively to the Deputy Director, HASS at the Regional Health Directorate whiles technically report to the Deputy Director, Clinical Engineering Department. The Regional Health Directorate shall provide the Unit with all the necessary support to function whiles the Clinical Engineering Department provide technical support.

The Regional Clinical Engineering Unit shall also be made up of Sub-units or Teams of technical and other supporting staff. Each sub-unit or team shall be assigned responsibility as determined by the available skills or capacity.

The following principles shall be adopted

i. The Regional Equipment Manager in consultation with the Deputy Director, Health Administration and Support Services shall establish teams of skilled technical staff and appoint a team leader in both the regional hospital and all the district hospitals within the region.
ii. Each Regional Equipment Manager shall be trained in a specialized area in line with National Teams and could be called upon for national duties.
iii. The Regional Equipment Manager in consultation with the Deputy Director, Health Administration and Support Services shall establish teams of skilled technical staff and appoint a team leader in all the District Health Directorates within the region.
iv. The establishment of a team to provide technical support within a hospital or sub district level at the District Health Directorate with a team leader shall not relieve the Regional Equipment Manager from his/her responsibilities to that hospital.

### 4.2.1 Regional Workshop Team

The team shall provide technical support to the other teams within the hospitals and the District Health Directorates and shall report to the Regional Equipment Manager.

### 4.2.2 Regional Hospital Team

The team shall be responsible for the maintenance of equipment within the hospital and work in close collaboration with the Regional Equipment Manager. The team leader shall be the Regional Hospital Equipment Manager and shall be part of the hospital administration responsible for

engineering issues. He/she shall report administratively to the head of administration of the hospital but technically to the Regional Equipment Manager.

The hospital management shall provide the necessary support to the team to function whilst the Regional Clinical Engineering Unit provides technical support.

### 4.2.3 District Hospital Team

The team shall be responsible for the maintenance of equipment within the hospital and work in close collaboration with the Regional Equipment Manager. The team leader shall be the District Hospital Equipment Manager and shall be part of the administration of the hospital responsible for equipment engineering issues. He/she shall report administratively to the head of administration of the hospital but technically to the Regional Equipment Manager.

The hospital management shall provide the necessary support to the team to function whiles the Regional Clinical Engineering Unit provides technical support.

### 4.2.4 DHD Teams

The team shall be responsible for the maintenance of all equipment in the sub-district health facilities within the district. The team leader shall be the District Equipment Manager and shall be part of the District Health Administration responsible for engineering issues. He/she shall report administratively to the District Director of Health Service but technically to the Regional Equipment Manager.

The District Health Directorate shall provide the necessary support for the team to function whilst the Regional Clinical Engineering Unit provide technical support.

### 4.2.5 Other teams to be established at the Regional level

Other teams to be established by the regional CEU shall include team for maintenance of surgical instruments and cold chain equipment. Other teams may be considered as and when required. The surgical team shall be required to maintain and repair all surgical instruments and educate users on the proper handling of surgical instruments. The workshops shall be equipped to provide this service to all the hospitals within the region.

Similarly, the cold chain team shall be responsible for the maintenance of all EPI cold chain equipment within the region.

## 4.3 ORGANISATIONAL REQUIREMENTS

### 4.3.1 HUMAN RESOURCE

To meet the objectives of this policy, a team of well trained, competent engineering and medical professionals shall be required. The competence required for management and maintenance of equipment shall include Biomedical/Clinical Engineering, Electronic/Electrical Engineering, Mechanical Engineering, Computer Engineering, Medical Equipment Management, ICT and Medical Physicist; whilst the application and operation of medical devices require the services of professionals such as Medical Doctors, Nurses, Radiographers, Biomedical Scientists, Physiotherapist etc. Similarly, for effective and efficient management, Supply Chain Management Professionals and Administrators are also required.

It is critical that persons involved in the servicing and repairs of clinical equipment understand both the principle of operation and technical aspects of these equipment.

All health facilities (excluding sub-districts facilities), District Health Directorates, Regional Health Directorates and the Clinical Engineering Department shall have established post for Clinical/Biomedical Engineering to properly manage and maintain equipment to ensure safe use on patients. They shall also be required to operate certain equipment such as ECG, EEG, spirometer etc. for clinical measurement.

The establishment of the various positions and recruitment to fill the positions shall be done in accordance with the GHS recruitment guidelines. The preservice qualification for appointment of engineering staff shall be in accordance with the prevailing HR policy and guidelines. Staff to be recruited for Clinical Engineering shall not be below HND or its equivalent.

### 4.3.2 Staff Requirements

Staffing for the Clinical Engineering Department/Units shall consist of mixture of personnel with varied background suitable for the functions assigned. Below are the staffing requirements for the Clinical Engineering Department/Units at the various service levels specified.

The Clinical Engineering Department (national level)

i. Deputy Director
ii. Unit Managers

iii. Team Leaders
iv. Team Members
v. Logistics Manager for spare parts and consumables
vi. Secretariat staff
vii. Security for workshop

The minimum number of technical staff required for the unit at the headquarters shall be forty (40).

The core technical staff required shall consist of engineers and technologists, and where necessary scientists (medical physicist, biomedical scientist, etc.) and users to support application of certain equipment. These core staff may serve in one or more teams as may be determined. Where possible some of the technical staff at the Regional Clinical Engineering Units may be assigned temporary duties at the National level and vice-versa. Some staff such as those to support application may be invited from time to time to provide specific support.

The other supporting staff required shall include: secretarial staff, store keepers, drivers, cleaners, labourers and security personnel where necessary.

Positions for the needed staff shall be established by the Human Resource Division to recruit and train the needed personnel for the various positions.

**Clinical Engineering Unit (regional level)**

i. Regional Clinical Engineering Manager
ii. Regional Team
iii. Regional hospital team leader
iv. District hospital team leader

A team shall be assigned to the Regional Hospital, District Hospital, Polyclinic and the District Health Directorate where technical support is required at all times and the general team for the rest of the health institutions in the region.

### 4.3.3 TRAINING

Staff practicing Clinical/Biomedical Engineering shall be required to register with the appropriate professional body. With the rapid development of technology, technical staff shall be up-to-date in knowledge to enhance performance and broaden their knowledge in the field of practice to

maintain their license. This shall be done by constantly upgrading their knowledge through continuous professional development program.

Vendors providing installations, maintenance, training, calibration services to health facilities shall register with the relevant entity and technically cleared by the Clinical Engineering Department or the Clinical Engineering Unit at the regional level to confirm the technical competence for the assignment or services to be provided.

The continuous professional development program shall include but not limited to:

i. Physiology and Anatomy
ii. Medical Equipment Management
iii. Electrical Safety
iv. Medical Electronics
v. Clinical Measurements
vi. Medical Physics
vii. Principles, operation, maintenance and repairs of various clinical equipment, clinical laboratory and other diagnostic equipment, cold storage equipment, dental technology, imaging equipment and other equipment used in hospital environment.
viii. Medical equipment safety
ix. Equipment management including the use of computer and other information technologies in medicine
x. Computerised Maintenance Management System
xi. Health and safety
xii. Quality assurance
xiii. Information Technology

No user shall be allowed to use equipment on patient when they have not been trained and authorised to do so. For high risk equipment (classes III and IV) users must be trained and certified to use these.

No engineering professional shall be allowed to carry out maintenance on equipment if they have not been trained and certified to do so.

### 4.3.4 Logistics

The Clinical Engineering Department and each Regional Clinical Engineering Unit shall require the following:

Transport for all the workshops as follows

| | | |
|---|---|---|
| i. | CED Headquarters | at least 7 purposeful built vehicles |
| ii. | Regional CEU | at least 1 purposeful built vehicle per region |
| iii. | District Health Directorates | at least 1 purposeful built vehicle per district |

Set of test equipment, calibration tools, workshop tools and equipment

- CED headquarters at least 3 each
- Regional CEU at least 1 each
- regional hospital workshops at least 1 each
- District hospital at least 1 each
- District health directorate at least 1 each

## 6.0 FUNDING/FINANCING

Financing for equipment is critical for successful implementation of management systems that ensure high level of operation (high uptime) and use whilst minimising breakdown and long downtime. It is therefore important to have adequate budget and financing support for implementation of this policy at all levels of healthcare delivery.

The financing shall cover procurement of equipment, installation, commissioning, spare parts, consumables, accessories, logistics for maintenance, maintenance contracts, recruitment of qualified staff, training, etc. Health facilities shall therefore make adequate provision in their annual budget to cover full implementation of this policy.

### 6.1 FINANCING FOR PROCUREMENT OF EQUIPMENT

Per the Public Procurement Act, 2003 (Act 663) and the Public Procurement Amendment Act 2016, (Act 914), all health facilities shall be required to include the equipment needs of their health facilities in the annual procurement plan. Similarly, capital equipment needs of the health facilities shall be compiled and forwarded to the Director, Health Administration and Support Services to include them in the capital investment plan for Ghana Health Service. Also, health facilities shall ensure that the equipment needs are properly captured in their programme of work.

### 6.2 FUNDING MAINTENANCE

Funding for maintenance work shall be in two parts;

- preventive maintenance and
- Breakdown or corrective maintenance.

Preventive maintenance is a predictable activity that can be scheduled. Health facilities are therefore required to budget for preventive maintenance undertaken by both in-house Clinical Engineering team and maintenance/service contractors.

Where the preventive maintenance is undertaken by the Clinical Engineering Unit at the regional level or the Clinical Engineering Department at the national level, the beneficiary health facility shall finance the cost of logistics (spare parts, calibrators, controls, replacement parts, technical consumables such as oil, grease, refrigerant etc.), transport, and per diem.

Unlike preventive maintenance, corrective maintenance is not predictable and therefore difficult to budget for. A provisional estimated amount shall therefore be included in the annual budget to cater for repairs or breakdown maintenance. Where repairs are undertaken by the CED or regional CEU, the budget shall cover transport, per diem, spare-parts and other materials used.

Where the equipment is contracted out for maintenance service, conditions in the contract shall be followed.

To sustain availability of spare parts, Ghana Health Service shall establish equipment revolving fund to enable it replenish the stock of spare parts, accessories, consumables and other requirements for the equipment. A similar revolving fund concept shall be implemented at the regional, district and health facility levels. Under this policy, spare parts used by the CED/CEU to repair equipment shall be reimbursed by the beneficiary health facilities. Procurement, storage and management of the spare parts shall be guided by the applicable public procurement and financial regulations. Heads of beneficiary institutions renewal of mandate shall be based also on equipment maintenance report.

### 6.3 FUNDING FOR HUMAN RESOURCE

New technologies and more medical equipment are constantly being introduced to meet the increasing disease burden. To meet these changing demands, technical staff with varying expertise would need to be recruited and trained to operate and maintain the equipment provided to support health care delivery. In view of this, the service shall make adequate budget provision for recruitment of technical staff including clinical engineers, radiographers, etc. Funding for training for medical staff and engineering staff required for operation and maintenance of equipment procured shall be allocated to provide application training and manufacturers maintenance training where necessary. The cost of such training shall be included in the budget for the procurement or project.

## 7.0 IMPLEMENTATION PLAN

To facilitate the effective and efficient implementation of this policy, the GHS shall prepare and periodically update relevant procedures and guidelines required. The GHS shall disseminate the policy through series of training workshops and seminars. In addition, training manuals shall be developed for managers, engineering staff and end-users of medical devices.

The following guidelines shall be used to assist institutions/practitioners to plan for their equipment needs:

i. Needs assessment, planning and budgeting for medical devices.
ii. Procurement, preparation of specification, preparation of tender documents, preparation of contract, evaluation of tenders and monitoring of contracts for medical devices
iii. Pre-installation, installation, commissioning, calibration, and relevance of various types of training for medical devices
iv. Management of medical devices
v. Replacement of medical devices
vi. Preventive Maintenance of medical devices
vii. Corrective maintenance and repairs of medical devices
viii. Maintenance systems and options to apply for medical devices
ix. Donations of medical devices
x. Decommissioning and disposal of medical devices
xi. Planning, Monitoring and evaluation tools
xii. Legislation and regulation

The Policy Implementation Plan shall prioritize the activities and provide budgets, schedules, responsible persons, expected outcomes and the relevant indicators.

# 8.0 MONITORING AND EVALUATION

The monitoring and evaluation of the equipment management and the implementation of this policy shall be an integral part of the Ghana Health Service Monitoring and Evaluation System. The monitoring shall include all reported incidences related to equipment use, competence, maintenance and repair, identifying any immediate action required.

Health facilities shall submit regular reports on equipment to their respective District Health Directorates who shall in turn submit the aggregated information to the Regional Health Directorate on monthly basis. A summary of the regional reports shall be included in the quarterly returns from the Regional Health Directorate to the Director General. The quarterly reports shall include information on inventory, records of preventive and corrective maintenance, medical equipment disposals, monitoring of maintenance contracts, user training and accountability.

The monitoring tools ***(refer to medical equipment policy and guidelines addendum)*** shall include a tool for medical devices inventory management. A computerized maintenance and management software shall be used at all levels and be linked to the DHIMS II.

## 8.1 KEY INDICATORS

The following shall be used to assess the performance of the equipment and the technical staff of the department.

8.1.1 Equipment Availability (A): the ideal number of equipment defined for each service provision (a) and the real number of equipment available for service provision (b)

$$\frac{b}{a} x100 = A\%$$

Sources of information: standard equipment list and asset register

8.1.2 Functionality Index (F): the number of functional equipment in the institution (c) as against the real number of equipment available for service provision (b)

$$\frac{c}{b} x100 = F\%$$

Sources of information: maintenance records and asset register/inventory

8.1.3 Planned Preventive Maintenance Performance (M): the number of equipment scheduled for preventive maintenance (d) and the actual number of equipment serviced (e)

$$\frac{e}{d} x100 = M\%$$

Sources of information: maintenance records and inventory

8.1.4 Staff Performance (P): the number of scheduled job planned (f) and the number of scheduled jobs executed (g)

$$\frac{g}{f} x100 = P\%$$

Sources of information: maintenance plan and maintenance records

8.1.5 Corrective maintenance Performance (N): % of corrective maintenance executed (x) against number of service calls received (y)

$$N\% = \frac{x}{y} \times 100$$

8.1.6 Number of functional workshops at National and Regional levels.

8.1.7 Percentage of institutions with updated asset register on equipment.

8.1.8 The Operational availability (O) of equipment expressed in % is defined as period when the equipment is available for its intended use.

The method of calculation shall be as follows:

Operational availability (O) of each equipment $= \{1 - (r + z)/w\}$ x 100%

Where,

Response Time (r) = Time when a fault is reported to a vendor to the time when vendor engineer attempts a solution

Repair Time (z) = total time spent to restored or put equipment back to normal working condition or into clinical use.

Working Time (w) = Total Available Working Time during the agreed period or the normal working hours within the agreed period

The sum of Response Time and Repair Time is the Total Downtime (T) for the equipment. It excludes downtime relating to planned or scheduled preventive maintenance

Total Operational Availability ($O_T$) of all the installed base of equipment in a health facility or under contract shall be the average of the individual equipment Operational Availability

The minimum average operational availability of an installed base of equipment measured over an agreed period shall not be less than 95%.

This indicator can be used to track performance of equipment under contract.

Source of data is maintenance records, service call records and fault reporting book(s).

***8.1.9 Professionalism:*** This is a measure of the skill, competency and knowledge of the staff

***8.1.10 Courtesy:*** This is a measure of the politeness and respectfulness

***8.1.11 Communication:*** This is an indication of how well information was passed to and received from our customers.

***8.1.12 Professional Accuracy:*** The skill of the engineers to perform work on equipment within agreed time to exact standards.

***8.1.13 Product Quality:*** This is a measure of the suitability of equipment for its intended purpose

***8.1.14 Output Quality:*** The ability of the equipment to produce the desired output to satisfactory standards.

***8.1.15 Reliability:*** The availability of the equipment for its intended use when required

***8.1.16 Ease of Operation:*** This is a measure of how easy it is for users to operate equipment.

***8.1.7 Spare Parts Delivery:*** The time taken to deliver identified parts to repair a defective equipment.

## 9.0 LEGISLATION AND REGULATIONS

The legislation and regulation for medical devices shall support, guide and regulate aspects associated with the provision, acquisition and utilization of medical devices.

The MOH and GHS shall ensure that the appropriate administrative and legal measures, organizational and support mechanisms and appropriate infrastructure are in place, within the framework of the national health policy. The safety of clients, health workers, the public and the environment as well as risk management shall be included in the framework.

Safety issues (including incidents, adverse events, accidents and hazards) shall be monitored and reported for effective management to minimize risk to the health workers, clients, the public and the environment.

There are regulatory bodies or agencies that are responsible for the protection of the general public against unsafe and inappropriate use of medical devices and their activities must be harmonized. Some of these regulatory bodies are; Food and Drugs Authority (Public Health Act, 2012), Allied Health Professions Council, Public Procurement Authority, Nuclear Regulatory Authority, Internal Audit Agency, Environmental Protection Agency, Auditor General, etc. All health institutions within the Ghana Health Service should therefore ensure compliance with these regulations.

## 10.0 CONCLUSION

This is the framework for the acquisition, management, operation, maintenance and disposal of equipment in the GHS. It is therefore important that all members of staff, other users, vendors and partners observe the policy components in this document. In case of non-compliance, appropriate sanctions shall be applied.

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## APPENDIX 1

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