THE UNITED REPUBLIC OF TANZANIA

Ministry Of Health, Community Development, Gender ,Elderly And Children

STANDARD MEDICAL RADIOLOGY AND IMAGING EQUIPMENT GUIDELINES (SMRIEG)

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TABLE OF CONTENTS

FOREWORD

Radiology services in Tanzania being complex as the technology behind them, is provided within a split framework of availability of the equipment, accessories and consumables. Not only that this split framework affects the smooth provision of the services but also increases the cost of these services to the end user. Principally, it is in the light of these complexities and unorganized plethora of manufacturers, vendors or suppliers directly dealing with the entire supply chain of radiology equipment that finally translates the high total cost of ownership of the same to the country.

Literally, existence of these multiple tiers of manufacturers, vendors or suppliers of both equipment, accessories and consumables coupled with rampant technology change further complicates the smooth operation of the designed supply chain leaving aside matters related to increased likelihood of manufacturers, suppliers or vendors curtailing in an attempt to maximize profit hence affecting the provision of quality and affordable radiology services.

In this regard, it is evident that the need for harmonization, standardization and streamlining procedures for selection of the technology, acquisition and redesign of the radiology services supply chain in Tanzania remain to be a priority intervention

This document is intended to guide users, suppliers and importers of radiology equipment in Tanzania on the best minimum utilization of the radiology facilities. It has been developed to be used as a guide in congruent with the already developed Basic Standards for Health Facilities in which human resources requirements are established in the document. For instance at a dispensary level a basic ultrasound equipment is recommended, this also requires that the staff at that dispensary have a person trained to operate the unit, be it a midwife or clinician for the purpose of monitoring pregnant women attending at the facility. In the Standards for facilities Ultrasound at the dispensary is optional. Thus, when this option is realized, there should be some guidance to requirements like human resource and the type of equipment needed.

The objectives of these guidelines are, therefore, to guide all stakeholders on Standard Medical Radiology equipment requirements, for a particular health facility level for both public and private.

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ABBREVIATIONS AND ACRONYMS

ADDS	Assistant Director Diagnostic Services
AMO	Assistant Medical Officer
APHFTA	Association of Private Health Facilities Tanzania
BAKWATA	Baraza Kuu la Waislamu Tanzania
BMC	Bugando Medical Centre
CAT	Computerized Axial Tomography
CD	Communicable Diseases
CM	Corrective Maintenance
CR	Computed Radiography
CSSC	Christian Social Services Commission
CT	Computed Tomography
DCS	Director of Curative Services
DEXA	Dual Energy X-Ray Absorptiometry
DR	Digital Radiography
HCT	Health Care Technology
HCTS	Health Care Technical Services
HRIS	Head Radiology and Imaging Services
IEC	International Electrotechnical Commission
KCMC	Kilimanjaro Christian Medical Centre
KCMUCO	Kilimanjaro Christian Medical University College
LINAC	Linear Accelerator
MAMC	MUHAS Academic Medical Centre
MD	Medical Doctor (Doctor of Medicine)
MNH	Muhimbili National Hospital
MoHCDGEC	Ministry of Health, Community Development Gender, Elderly and Children
MRI	Magnetic Resonance Imaging
MRIPC	Medical Radiology and Imaging Professionals Council
MSD	Medical Stores Department
MUHAS	Muhimbili University of Health and Allied Sciences
MZRH	Mbeya Zonal Referral Hospital
NCD	Non-Communicable Diseases
NM	Nuclear Medicine
NMI	Nuclear Medicine Imaging
NTD	Neglected Tropical Diseases
OPG	Orthopantomography
OR	Operating Rooms (theatres)
PET	Positron Emission Tomography

PPM	Planned Preventive Maintenance
SOP	Standard Operating Procedures
SPECT	Single Photon Emission Computed Tomography
SWOC	Strength, Weakness, Opportunities and Challenges (analysis)
SWOT	Strength, Weakness, Opportunities and Threats (analysis)
TAEC	Tanzania Atomic Energy Commission
TARA	Tanzania Association of Radiographers
TFDA	Tanzania Food and Drug Authority
USS	Ultrasound

TERMS AND DEFINITIONS

Accessory	Anything which can be added to something else in order to make it more useful, versatile, or attractive.
Biomedical Engineer	Professional using engineering principles to the fields of biology and health care
Brachytherapy	A form of radiotherapy where a sealed radiation source is placed inside or next to the area requiring treatment also known as internal irradiation therapy
C-ARM	Medical imaging device that is based on X-ray technology and can be used flexibly in various Operation Rooms (ORs) within a facility. The name is derived from the **C**-shaped arm used to connect the X-ray source and X-ray detector to one another
Consumable	Any item which is regularly used with the equipment and is either replaced often or disposed off.
CT Simulator	A process used by the radiation therapy team to determine the exact location, shape, and size of the tumour to be treated by use of CT Scanner.
Gamma Camera	Also called a scintillation *camera* or Anger *camera*, is a device used to image *gamma* radiation emitting radioisotopes, a technique known as scintigraphy.
Ionizing radiation	Radiation consisting of particles, X-rays, or gamma rays with sufficient energy to cause ionization in the medium through which it passes
Linear Accelerator	The device most commonly used for external beam radiation treatments for patients with cancer. The linear accelerator is used to treat all parts/organs of the body. It delivers high-energy x-rays or electrons to the region of the patient's tumour
Medical Physicist	A professional using a variety of analytical, computer-aided and bioengineering techniques in their work such as radiotherapy, x-ray imaging, ultrasound, tomography, radiology, nuclear magnetic resonance imaging and lasers.
Non Ionizing radiation	Any type of electromagnetic radiation that does not carry enough energy per quantum (photon energy) to ionize atoms or molecule, that is, to completely remove an electron from an atom or molecule

Nuclear Medicine Physician	Medical specialists that use tracers, usually radiopharmaceuticals, for diagnosis and therapy
Nuclear Medicine Technologist	Professional responsible for preparing radioactive drugs and administering them to patients for imaging or therapeutic purposes
ORET	OntwikkelingsRelevante Export Transacties (Development-Related Export Transactions Program)
ORIO	Internationaal Rijksdienst voor Ondernemend Nederland (Netherlands International Enterprise Agency for Grant facility in the development of infrastructure in developing countries)
Quality Assurance	An organized effort by the staff operating a facility to ensure that the diagnostic/therapeutic services are of a sufficiently high quality so that they consistently provide adequate diagnostic/therapeutic information at the lowest possible cost and with the least possible exposure of the patient to radiation
Quality Control	An integral part of quality assurance that involves specific actions designed to keep measurable aspects of the equipment within specified limits.
Radiation Oncologist	A radiation oncologist is a specialist physician who uses ionizing radiation (such as megavoltage X-rays or radionuclides) in the treatment of cancer. Radiation oncology is one of the three primary specialties, the other two being surgical and medical oncology, involved in the treatment of cancer
Radiation Oncology	Using ionizing radiation (such as megavoltage X-rays or radionuclides) in the treatment of cancer.
Radiographer	Also known as radiological technologists, diagnostic radiographers and medical radiation technologists are healthcare professionals who specialise in the imaging of human anatomy for the diagnosis and treatment of pathology
Radiologist	A physician specialized in radiology, the branch of medicine that uses ionizing and nonionizing radiation for the diagnosis and treatment of disease
Radionuclide Imaging	Imaging of parts of the body by using a small dose of a radioactive material

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Radiotherapist	Also known as a Radiation Therapist or Therapeutic Radiographer is an allied health professional (technologist) who works in the field of radiation oncology
Radiotherapy	Also known as Radiation therapy, often abbreviated RT, RTx, or XRT, is therapy using ionizing radiation, generally as part of cancer treatment to control or kill malignant cells.
Simulator	Process where a radiation therapy team carefully plans treatment in a process called radiation simulation before beginning radiation treatment.
SPECT	A nuclear medicine tomographic imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera
Teleradiology	Transmission of radiological patient images, such as x-rays, CTs, and MRIs, from one location to another for the purposes of sharing studies with other radiologists and physicians
Teletherapy	External beam radiotherapy is the most common form of radiotherapy. The patient sits or lies on a couch and an external source of ionizing radiation is pointed at a particular part of the body
Tesla	The unit of measurement quantifying the strength of a magnetic field

CHAPTER ONE: OVERVIEW OF MEDICAL RADIOLOGY SERVICES

Radiology and imaging services use medical imaging to diagnose diseases (radio-diagnosis); and or to treat diseases within the body. Currently radiology and imaging services include modalities such as conventional radiography (x-ray), ultrasound, mammography, computed tomography (CT), nuclear medicine including positron emission tomography (PET), and magnetic resonance imaging (MRI) which are used to diagnose and/or treat diseases. Interventional radiology is a medical procedure (usually minimally invasive) performed with the guidance of imaging technologies.

Radiography: is the creation of images of internal structures using electromagnetic waves and other physical waves. It is used for diagnostic, preventive, and therapeutic purposes. Its different modalities include X-rays, sonography, mammography, computed tomography, and magnetic resonance, among others.

Professionals who are mostly involved in radiology and imaging services as per MRIPC registered professionals include but not limited to: Radiographers, Radiologists, Radiation Oncologists, Radiotherapists, Medical Physicists, Biomedical Engineers, Radiopharmacists, Nuclear Medicine Physicians and Nuclear Medicine Technologists.

Organizational structures

Radiology and imaging services are organized under the Diagnostic Services Section of the Department of Curative Services (DCS), in the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC). These services are managed under the Head of Radiology and Imaging Services (HRIS) who reports to the Assistant Director, Diagnostic Services (ADDS); and who in turn reports to the Director of Curative Services (DCS).

Currently, there are six tiered levels of radiology and imaging services, from dispensary level, health centre, district, regional, zonal to national level. In between national and Zonal level lies the specialized health facilities. However, for the purpose of these Guidelines, they will be referred to as Zonal Level.

Roles and responsibilities of HRIS

1) To develop policy guidelines for the provision of radiology and imaging services
2) To develop standard operating procedures for medical radiology and imaging services
3) To facilitate availability of radiology and imaging supplies, equipment, instruments, apparatus and spare parts to health facilities
4) To monitor the quality of chemicals, films, equipment, instruments & apparatus for the provision of radiology and imaging services
5) To facilitate and monitor quality of radiology and imaging services to support

the provision of essential package of health services

6) To provide technical and management support for radiology and imaging services at all levels of health care
7) To liaise with Health Care Technical Service, Sub Section, in developing systems for conducting planned preventive maintenance of radiology and imaging equipment
8) To liaise with other departments, institutions, professional associations and regulatory authorities on issues relating to radiology and imaging services
9) To supervise, monitor and evaluate radiology and imaging services
10) To facilitate annual meeting of radiology and imaging personnel
11) To facilitate the determination of requirements for radiology and imaging supplies
12) To co-ordinate the development and strengthening of specialised radiology and imaging services

Purpose

The purpose, of this Standard Medical Radiology Equipment Guidelines (SMREG), is to enable medical radiology and imaging services to effectively and efficiently carry out its core functions as stipulated by its mandate, strategically coordinate and allocate the available limited resources by prioritising functions with effective impact to the health sector.

The Guidelines serve as guiding principles to the users, stakeholders and development partners in the selection and acquisition of medical equipment, consumables and supplies related to radiology and imaging services according the level of the health services provision and service demands. Most importantly, the Guidelines serve as key tool for supply chain management system, in particular for forecasting and quantification of medical radiology and imaging equipment, consumables and supplies.

Rationale

Currently Tanzania has registered a significant improvement in medical and imaging diagnostic services such as changing from grey scale to colour Doppler ultrasound machines, and from analogue to digital x-rays; improvement from single slice to multi-detector CT Scanners (such as 128 slice), introduction of MRI services as well as the use of networking in diagnostic radiology and imaging (Teleradiology). However, there is a wider range of variation in technologies and capacities at different health care levels that calls for harmonization and standardization of medical radiology and imaging equipment.

Further to that, these improvements are associated with other prerequisite conditions such as high cost, quality assurance measures, planned preventive

maintenance, reliable and continuous supply of consumables and supplies including spare parts, thorough training, stable electricity, ventilation system; and reliable infrastructure, such as appropriate premises with standard designs, internet connection, spacious working area and appropriate pattern of workflow.

Thus, for efficient and cost effective provision of quality assured radiology and imaging services, there is a need to harmonize and standardize radiology and imaging equipment and consumables. Standardization of the equipment is also useful in forecasting and quantification of radiology and imaging consumables and supplies and therefore ensuring continuous uninterrupted services, which is a cornerstone for quality management system

Scope

These Guidelines embrace requirements for medical radiology and imaging equipment in the health sector. In addition, it covers all levels of health care delivery ranging from community health care, dispensary, health centre, district, regional, zonal to national healthcare level in Tanzania Mainland.

The Guidelines will be useful for health care providers, policy makers, procuring entities, stakeholders and implementing partners wishing to support the Government in radiology and imaging equipment, consumables and related supplies. It covers standard list of radiology and imaging equipment, consumables, and supplies at each level, equipment specifications; equipment acquisition methods; equipment maintenance and service contracts.

Normative documents

In developing these Guidelines, the following documents were used including a variety of guidelines, strategic plans, standard lists, reports and relevant data as listed in table below:

Table 1: List of normative documents

1	Health Care Technology Guideline, (2002)
2	Guidelines for Medicines and Medical Supplies Donations, Tanzania Mainland, February, 2015
3	MOHCDGEC Medium Terms Strategic Plan (2017)
4	Draft National Health Policy, (2017)
5	Standard Treatment Guidelines and National Essential Medicine List, 5th Ed (Dec, 2017)
6	National Standard Guidelines for Medical Radiology and Imaging Services June 2004
7	WHO Technical Specifications for Medical Devices, 2014
8	Market Price of listed Radiology and Imaging Equipment (CFR, 2015-2018)
9	List of Manufacturers and Suppliers of Radiology and Imaging Equipment who submitted tenders to MSD (Aug, 2012-Jan, 2018)
10	List of Registered Manufacturers and Suppliers of Radiology and Imaging Equipment, TFDA (2017/2018)
11	Basic Standards for Health Facilities, Volume 2-5, (November 2017)
12	Proceedings of the 1st Workshop for standardization of Radiology and imaging equipment held on 23rd -24th Jan, 2018, MOHCDGEC, DSM
13	Guidelines for the design of x-ray rooms in medical diagnostic establishments, TAEC www.taec.or.tz .
14	The Protection from Radiation (Code of Practices) Regulations, TAEC, 1990.

CHAPTER TWO: CURRENT STATUS OF RADIOLOGY AND IMAGING SERVICES

Human resource

In medical radiology and imaging services there are different professionals according to their training acquired which may be in the field of diagnosis or therapy. Professionals under diagnosis are Radiologists, Radiographers, AMO radiology and Radiographic Assistants. According to manning levels, one radiologist is supposed to be at the regional referral hospital, and the number increases in zonal and national hospitals. Radiographers' placement start from district level, the minimum number is one and maximum is four. At regional referral hospital radiographers are supposed not to exceed seven in number. AMO Radiology is supposed to be one in the district hospital.

In radiation therapy, we have Radiotherapists, Nuclear medicine technologists, Medical Physicists, medical oncologists, Nuclear medicine physicians. Radiation therapy professionals are located, mostly at cancer centres/institute, Ocean Road Cancer Institute, Besta Diagnostic Centre, Aga Khan Hospital Dar es Salaam and Bugando Medical Centre.

Table 2 below shows approximate total number of registered medical radiology and imaging professionals in the country

Table 2: Number of Medical Radiology and Imaging Professionals in the Register of the MRIPC Registrar as of December, 2017.

	Professional	**Present**
1.	Radiographers	620
2.	Radiologists	75
3.	AMO Radiology	45
4.	Radiographic Assistant	45
5.	Radiotherapists	50
6.	Medical Physicists	5
7.	Medical oncologists	28
8.	Nuclear Medicine Physicians	4
9.	Nuclear Medicine Technologists	6
	Grand total	**878**

Equipment

There are variety of medical radiology imaging equipment installed in the country. Services are offered by both public and private institutions. According to information available from TAEC, number of facilities that have medical radiology and imaging equipment are as shown in table 3:

Table 3: Number of facilities with medical radiology and imaging equipment (March 2018).

S/N	EQUIPMENT	PUBLIC	PRIVATE	TOTAL
1	MRI (Magnetic Resonance Imaging)	4	8	12
2	CT (Computed Tomography) Scanner	5	34	39
3	CATH LAB (Cardiac Catheterization Lab)	2	1	3
4	Gamma Camera (Nuclear Medicine)	2	1	3
5	Mammography	4	6	10
6	LINAC (Linear Accelerator)	0	1	1
7	DEXA (Double Energy X-Ray Absorptiometry	1*	1**	2
8	C-ARM	4	6	10
9	Cobalt 60	2	0	2
10	Simulator	1	0	1
11	Dental	6	24	30
12	X-Ray (Both Plain and Fluoroscopy)	131	260	391
	Available facilities with such equipment	**161**	**341**	**502**

Source: TAEC

*** Procured but not yet installed expected to be installed by June 2018*

** Procured but not yet installed*

Note: *A list of Ultrasound equipment is difficult to obtain as this information is not available. Moreover, some of these are very handy and can be easily acquired.*

Infrastructure and Premises

The infrastructure in most of medical radiology and imaging facilities is challenging due to unstable power supply, unreliable water supply and unsuitable room condition just to mention a few. On the other hand, few health facilities such as Benjamin Mkapa Hospital in Dodoma, MAMC – Mloganzila, Ilala Afya Center, TMJ and Aga Khan in Dar es Salaam, have state of the art infrastructure for medical radiology and imaging departments.

The premises for medical radiology equipment should comply with safety requirements in order to ensure safety of the patient, radiation worker, community

and environment. Generally, most of x-ray rooms are of acceptable size. However, most challenges are observed with regard to radiation leakage, lack of patients changing cubicles and toilets, lack of staff offices and inadequate personnel protective equipment. Also a significant number of radiology facilities do not have radiation warning lights, radiation symbols and warning notices displayed at the entrances. Table 4 below shows the status of radiology premises in 175 health facilities in Arusha, Dar es Salaam, Dodoma, Manyara, and Singida regions as of the year 2017.

Table 4: Status of radiology premises in Arusha, Dar es Salaam, Dodoma, Manyara, and Singida regions (2017)

Requirement	**Compliant facilities**	**Non-compliant facilities**
Appropriate room size	157 (90%)	18 (10%)
Toilet	93 (53%)	82 (47%)
Warning sign, warning notice, Radiation symbol	109 (62%)	66 (38%)
Appropriate radiation shielding (walls, lead glass window and doors)	119 (68%)	56 (32%)
Personnel protective equipment	103(59%)	72 (41%)
Staff office	103 (59%)	72 (41%)

Source: TAEC

Training programs

There are two radiography schools which provide diploma in diagnostic radiography. One is located at Catholic University of Health and Allied Sciences (CUHAS) in Mwanza. The other one is at Muhimbili University of Health and Allied Health Sciences (MUHAS) in Dar es Salaam. They enrol students who complete secondary education in a three years training programme; the graduates are called Radiographers, with an output of approximately 80 graduates annually.

There are two Master of Medicine in Radiology training programmes at MUHAS and KCMUCO with three and four years programmes respectively. Enrolment is for graduates holding a degree of Medicine (MD) or equivalent and graduates are called Radiologists; the output is approximately 15 graduates annually.

Two more training programmes are found at KCMC, which are two years AMO Radiology course and a three months certificate in Ultrasound. The former enrols in-service Assistant Medical Officers and the latter enrols medical doctors, nurses, clinical officers, AMOs and radiographers, with an output of an average 8 and 40 graduates per annum respectively.

Corrective and preventive maintenance

(i) Maintenance contracts

All 105 public hospitals equipped with Philips equipment were serviced by Philips Medical Systems until the maintenance contract between the MoHCDGEC and Philips came to an end on 31st December, 2016. The current practice in both public and private facilities is to ensure that maintenance contracts, especially on high end radiology equipment (such as CT, MRI, Cath Lab etc.) are maintained by the supplying company or manufacturer. However, conventional X-Ray equipment and basic ultrasound units are either serviced by suppliers or servicing firms as per their respective agreements. Some of the facilities which do not have service contracts, depend on some firms to do corrective maintenance, which at the end is an expensive undertaking. Lack of planned preventive maintenance is the main cause of frequent breakdown of radiology equipment.

Regulatory framework

(i) Medical Radiology and Imaging Professional Council

Medical Radiology and Imaging Professionals Council (MRIPC) is a professional regulatory body, with authority to register, enrol and enlist medical radiology and imaging professionals. It regulates and sets standards of conduct and practice of Medical Radiology and Imaging Professionals; promotes interest in, and the advancement of, professionals in Medical Radiology and Imaging Professionals; evaluates academic and practical qualification of Medical Radiology and Imaging Professionals for the purpose of registration, enrolment or enlisting; approves institutions and curricula for training of Medical Radiology and Imaging Professionals; considers any matter affecting the profession in Medical Radiology and Imaging Professional and takes such actions in connection therewith as the Council considers necessary.

(ii) Tanzania Atomic Energy Commission – TAEC

Tanzania Atomic Energy Commission is the Official Government Body responsible for regulating the peaceful use of Atomic Energy Matters in the country. Regulatory activities are conducted in conformity with the power conferred on the Commission by Atomic Energy Act No. 7 of 2003 of United Republic of Tanzania. As such the Commission has mandate to regulate practices involving the use of radiation sources in order to ensure that there is adequate protection of the patients, occupationally exposed workers and general members of the public.

The Atomic Energy Act No. 7 of 2003 requires that importation, transport, transfer/hiring, possession and use, and disposal of sources of ionizing radiation

is authorized by the Commission. Furthermore, the Commission has mandate to regulate the premises where radiation sources are installed. This includes approval of safety plan (site, layout, and shielding plan) of the premises.

(iii) Tanzania Food and Drugs Authority – TFDA

Tanzania Food and Drugs Authority (TFDA) is a Government Agency under the MoHCDGEC. Medical radiology and imaging equipment are regulated by the TFDA Act Cap 219 as medical devices. The Section 5(1) of the Act mandates TFDA to regulate all matters relating to performance of medical devices.

TFDA is responsible for assuring the safety and effectiveness of the medical devices. Medical imaging equipment that are imported to the country should conform to the international standards such as International Electrotechnical Commission (IEC) standards. TFDA believes conformity to certain IEC standards would improve the same level of or safeguard protection of the public health and safety from radiation. If manufacturers and importers conform to a recognized and applicable IEC standards to meet the requirements of the premarket approval (registration) they must submit a declaration of conformity that certifies that device is in conformity with the standard.

For further details on safety and effectiveness of medical devices refer to “TFDA’s Safety and Effectiveness Issue of Medical Devices”

CHAPTER THREE: SITUATION ANALYSIS

Background

Environmental scan for these Guidelines cover the situation for the period of January 2008 to January 2018. It takes into account the mandates, roles and functions of radiology and imaging services sub-section under the Diagnostic Services Section of the Directorate of Curative Services. The scan also analyses the achievements, constraints and way forward based on Strengths Weaknesses Opportunities and Challenges (SWOC) analysis. Areas for improvement which were identified as critical issues and recent initiatives are addressed in these Guidelines.

SWOC analysis

Strengths

i) Organization of radiology and imaging services at the national level
ii) An Office for radiology and imaging services at national level
iii) Existence of a legal framework to govern the provision of medical radiology and imaging services
iv) Existence of a clustered system to structure the provision of medical radiology and imaging services per levels of care.
v) Active networking among radiology and imaging professionals at all levels
vi) Existing good relations with training institutions
vii) Six tiered levels of medical radiology and imaging services
viii) Presence of infrastructure for Teleradiology services

Weaknesses

i) Insufficient reliable data for radiology and imaging services
ii) Weak coordination of radiology and imaging services
iii) Insufficient knowledge and skills in quality management system
iv) Insufficient standardization system for radiology and imaging equipment
v) Inadequate quantification data for medical radiology and imaging consumables and supplies at all levels
vi) Inadequate and unreliable supply of consumables and supplies
vii) Inadequate planned preventive maintenance for radiology and imaging equipment program
viii) Inconsistence in utilisation of National SOPs
ix) Lack of robust inventory management system

Opportunities

i) Strong political will and commitment to support technology acquisition and transfer in the provision of medical radiology and imaging services
ii) Political stability providing conducive environment to investors and for development

iii) High demand for medical radiology and imaging services
iv) Increased awareness on radiology and imaging services
v) The existence of Medical Radiology and Imaging Practitioners Council (MRIPC) to regulate the conduct of medical radiology and imaging practitioners.
vi) The existence of Medical Stores Department (MSD) to procure, store and distribute medical radiology and imaging equipment, accessories and consumables
vii) The existence of Tanzania Atomic Energy Commission (TAEC) to regulate the provision of medical radiology and imaging services
viii) Existence of Public and Private Partnership (PPP)
ix) The existence of Training Institutions to support productions of human resources in medical radiology and imaging
x) The existence of projects to support equipment maintenance and placement such as ORIO.
xi) Presence of Radiology and Imaging Professional Associations
xii) The existence of Tanzania Food and Drug Authority (TFDA) to regulate the quality of medical radiology and imaging equipment, accessories and consumables.
xiii) The existence of Health Insurance Providers to support complementary health financing schemes to its beneficiaries.

Challenges

i) Inadequate financing of radiology and imaging services from central government
ii) Inadequate qualified radiology and imaging personnel in numbers and skills mix (including biomedical engineers)
iii) Conflicting regulation of radiology and imaging equipment
iv) Inadequate infrastructural support systems
v) Overwhelming disease burden (CDs, NCDs and NTDs)
vi) Donors dependency
vii) Rapid and dynamic change in medical radiology and imaging technology
viii) Higher acquisition cost of medical radiology and imaging equipment
ix) Environmental pollution due to use of outdated technology
x) Increased risk of safety due to use of obsolete technology
xi) Absence of a common forum to discuss issues related to medical equipment
xii) Lack of disposal and replacement policy for radiology and imaging equipment

CHAPTER FOUR: RADIOLOGY AND IMAGING STANDARD LIST

Standard list of equipment at each level

The following is the list of standard medical radiology and imaging equipment recommended for use in Tanzania mainland, according to the levels of radiology and imaging services. The list is based on the existing technology in the country, the quality of equipment, users' qualification and experience. See table 5 below

***Table 5**: List of standard medical radiology and imaging equipment at each level*

S/N	Equipment	Facility Level							
		Dispensary	Health Centre	Hospitals					
				District (Level I)	Regional (Level II)	Zonal (Level III)	Specialized Hospital	National Hospital	Stand Alone /Polyclinics
1	Basic Ultra Sound	√	√						√
2	Standard Ultrasound		√	√					√
3	Advanced Ultrasound				√	√	√	√	√
4	Dental periapical x-ray		√	√	√	√	√	√	√
5	Dental OPG			√	√	√	√	√	√
6	Dental CT					√	√	√	√
7	Basic X-ray Machine		√	√					√
8	CR-System		√	√	√	√	√	√	√
9	Digital X-ray - DR			√	√	√	√	√	√
10	Digital Fluoroscopy			√	√	√	√	√	√
11	Digital Mammography				√	√	√	√	√
12	Cath Lab						√	√	
13	Digital C-arm				√	√	√	√	
14	CT Scan (64 slice)				√	√	√	√	√
15	CT Scan (128 slice)					√	√	√	√
16	MRI 1.5 Tesla					√	√	√	√
17	MRI 3.0 Tesla							√	√
18	Gamma camera					√	√	√	√
19	Dual Energy X-Ray Absorbtion (DEXA)				√	√	√	√	√
20	Extramural (Mobile and Portable)		√	√	√	√	√	√	
21	Simulator	Any Zonal or Specialized health facility providing oncology services							
22	CT Simulator								
23	Linear accelerator								
24	Radiotherapy Machine (Cobalt 60)								
25	Brachytherapy System.								

Note: *To determine the number of medical radiology and imaging equipment required per health facility level; refer to Basic Standards for Health Facilities, Volume 2-5, (November 2017) and National Standard Guidelines for Medical Radiology and Imaging Services June 2004*

List of common consumables, spare parts and accessories

The list of consumables, spare parts and accessories is based on items that are commonly required at the medical radiology and imaging facilities. See table 6 in Annex I.

List of manufacturers of existing radiology and imaging equipment in Tanzania

The Medical Stores Department (MSD) will be responsible for providing the list of Pre-Qualified Manufacturers and Suppliers.

CHAPTER FIVE: TECHNICAL SPECIFICATIONS

In order to set standards, technical specifications for each equipment must be specified and narrated. However, for the purpose of these Guidelines, basic technical specifications for medical radiology and imaging equipment are provided.

Specific technical specifications will depend on the level of the facility, capacity and type of technology required according to the needs and priorities.

NOTE:

1. *Procuring entities/units planning to procure radiology and imaging equipment are strongly advised to consult radiology and imaging practitioners/users and biomedical engineers; and*
2. *The list of medical radiology and imaging equipment with technical specifications, provided in these Guidelines, is not exhaustive.*

Specifications of Medical Radiology and Imaging Equipment at Each Level

The WHO Guide for technical specifications for medical devices was incorporated during the preparation of these technical specifications. The specifications have the following main parts which are: general information, name category coding, purpose of use, technical characteristics, physical/ chemical characteristics and utility requirements, packaging, training, installation, environmental requirements, documentation, warranty, maintenance, safety and standards. Detailed specifications for the equipment recommended for use in Tanzania are provided in ***Annex II*****.**

Infrastructure Suitable for Medical Radiology and Imaging Equipment

Facility design for medical radiology and imaging equipment shall have appropriate specifications to meet requirement of the Tanzania Atomic Energy Commission. Therefore, facilities are advised to consult regulatory bodies where applicable.

Depending on the type of technology to be used, the important infrastructure criteria to be considered before installation of the equipment are summarised in table 6.

Table 6: Important infrastructure criteria

S/N	Equipment	Fan	Air Condition	Appropriate Wall thickness	Warning lamp	Warning Signs	Lead Glass	Lead door
1	Basic Ultra Sound	√						
2	Standard Ultrasound	√	√					
3	Advanced Ultrasound	√	√					
4	Dental periapical x-ray	√		√	√	√		
5	Dental OPG	√	√	√	√			
6	Dental CT	√	√	√	√	√	√	√
7	Analogue X-ray Machine	√	√	√	√	√	√	√
8	CR-System	√	√	√	√	√	√	√
9	Digital X-ray - DR	√	√	√	√	√	√	√
10	Digital Fluoroscopy	√	√	√	√	√	√	√
11	Digital mammography	√	√	√	√	√	√	√
12	Cath Lab		√	√	√	√	√	√
13	Digital C-arm		√	√	√	√	√	√
14	CT Scan (64 slice)		√	√	√	√	√	√
15	CT Scan (128 slice)		√	√	√	√	√	√
16	MRI 1.5 Tesla		√	√		√		
17	MRI 3.0 Tesla		√	√		√		
18	Simulator		√	√	√	√	√	√
19	CT Simulator		√	√	√	√	√	√
20	Nuclear Medicine Equipment (Gamma camera)		√	√	√	√	√	√
21	Linear accelerator		√	√	√	√		√*
22	Radiotherapy Machine (Cobalt 60)		√	√	√	√		√
23	Brachytherapy System.		√	√	√	√		√
* In addition to lead, the door must also be made up of steel and boroted.								

Note: *For Ionizing radiation equipment refer to "Guidelines for the design of x-ray rooms in medical diagnostic establishments", TAEC (attached as Annex III) and "The Protection from Radiation (Code of Practices) Regulations, TAEC, 1990".*

CHAPTER SIX: CRITERIA FOR SELECTION AND ACQUISITION

Equipment Selection

Selection of medical radiology and imaging equipment should be as per the following criteria:

(i) The equipment should be in the National Equipment Standard List; and be registered with the Country regulatory authorities including the TFDA and TAEC.
(ii) Track equipment record in health sector if any (such records as Mean Time Between Failures (MTBF), Failure rate, average repair cost);
(iii) Should meet international standards on safety requirements (such as IEC601, ISO); and National standards as provided by Tanzania Bureau of Standards (TBS)
(iv) Ease of use and maintenance;
(v) Appropriateness to priority health needs;
(vi) Geographical and climatic conditions;
(vii) Compatibility to conditions of infrastructure (such as electricity and water supply);
(viii) Quality of materials and the manufacturing process;
(ix) Appropriate level of technical and technological complexity;
(x) Purchasing price and life-time cost;
(xi) Availability of reliable local maintenance and repair support; including defined and agreed equipment down time in case of emergency/breakdown
(xii) Availability of genuine spare parts, accessories, and consumables;
(xiii) Availability of service and user information in English or Swahili (such as service and user manuals);
(xiv) Commitment from the manufacturer/supplier on availability of spare parts, accessories, and consumables stock throughout the equipment life time;
(xv) Assurance of availability of maintenance and repair support after the end of the technology's production;
(xvi) Accessibility of manufacturer (such as manufacturer's Web site written in English);
(xvii) Requirements of international standards on manufacturing practices (such as ISO 9000);
(xviii) Warranty and after sale service contract;
(xix) Assurance of being vendor neutral for archiving and communicating purpose;
(xx) Life span of the equipment should be stated

Note: *In order to encourage standardisation practices, criteria (i), (ii) and (iii) have higher priority than others.*

Personnel Involved

In order to facilitate standardisation practice and ensure appropriate selection of technology, HCTS personnel, User (Radiologist, Radiographer and Medical Physicist) and Health Administrator should be involved in the process of technology selection. HCTS section at the Ministerial level (on demand) should provide any related information available to HCTS at health facility level when they are in the

process of technology selection.

The role of each personnel is as follows.

(i) Health administrator confirms budgetary appropriateness;
(ii) User (Radiologist, Medical Physicist, Radiographer and Oncologist) Confirms clinical appropriateness of technology or its application;
(iii) HCTS personnel confirms technical specifications and design appropriateness of technology and infrastructure;
(iv) Procurement management unit recommends appropriate acquisition method

Equipment acquisition

Acquisition of medical radiology equipment will be based on:

i) The National Essential Health Intervention Package
ii) The Public Procurement Act (Act No 7 of 2011 and its regulations of 2013, and amendments of 2016).
iii) Rational, planned, and based on four areas of expenditure in the following order of priority:
    a) Replacement of technology (on-going as it reaches the end of its life) in order to ensure the continued provision of existing health services;
    b) Acquisition due to shortfall of technology
    c) Project linked to operational research for technology assessment;
    d) Requirements for any future expansion of the health services to be delivered.

Types of equipment acquisition:

Equipment acquisition can be achieved in three main ways:

(i) Equipment purchase
(ii) Equipment Placement (Lease)
(iii) Equipment donation

Equipment purchase

Equipment purchase is the method of equipment acquisition by buying directly from the supplier or manufacturer

(a) Advantage of equipment purchase:

(i) The purchaser owns and have control of the equipment
(ii) The purchaser is free to choose a firm for servicing and maintaining the equipment
(iii) Purchaser is free to do any modification on equipment
(iv) Buying is easier as the purchaser don't have to deal with agreement or contracts

(b) Disadvantages of equipment Purchase:

(i) Purchaser need to have capital investment
(ii) Technology may change shortly after equipment purchase (e.g. Software upgrading)

(iii) Frequent change of technology may necessitate frequent equipment purchase
(iv) There is no guarantee on service contract
(v) Additional cost on disposal of equipment
(vi) No assurance on continuous and uninterrupted supply of consumables and accessories

(c) Conditions for equipment purchase:

Equipment purchase is recommended in the following conditions:

i) Ability to pay for both equipment and its sustainable maintenance
ii) Availability of competent and authorized biomedical engineering professional
iii) Equipment which is less sophisticated and can be maintained by the available resident biomedical engineering professional

(d) Purchase agreements for medical radiology and imaging equipment.

Health sector shall procure equipment together with at least the following items, depending on the type of equipment, and they must be detailed in terms of specification, purchase agreement, or tender document for the suppliers to cost:

(i) The necessary accessories (sufficient number to cover those in use, those being sterilised, and back-up spares);
(ii) a stock of consumables (for example, to last for 1 to 2 years);
(iii) a stock of recommended spare parts (for example, to last for 1 to 2 years) to cover PPM needs and typical repair requirements;
(iv) operation manuals in English or Kiswahili and service manuals in English;
(v) a performance guarantee/warranty for a suitable period after the commissioning date;
(vi) information on site preparation details and service supply requirements;
(vii) freighting to a given destination (including insurance);
(viii) a required delivery data;
(ix) installation and/or assembly;
(x) Initial calibration and phantoms availability (if necessary);
(xi) Commissioning and user acceptance testing;
(xii) Training of users and maintainers in operation, care and cleaning, safety, PPM and repair.

Equipment Placement (Lease)

Equipment placement is the method of equipment acquisition by getting an equipment from the supplier or manufacturer through a contractual arrangement under which the owner of the equipment allows the user to operate or otherwise make use of equipment in exchange for periodic lease (rental) payments.

(a) Advantages of equipment placement:

(i) The equipment is acquired without prior payment (rented equipment)
(ii) There is no payment for equipment service and maintenance
(iii) Allows the user to cope with frequent equipment technology changes

(iv) Equipment disposal is supplier's responsibility
(v) Ensures minimal equipment down-time
(vi) Ensures continuous and uninterrupted supply of consumables and accessories

(b) Disadvantages

(i) High cost of consumables or services
(ii) The user does not own the equipment
(iii) Requires contractual arrangement
(iv) No freedom to modify or change the equipment before the contracts ends

Rationale for equipment placement/lease:

Smooth provision of health services using high end capital investment technologies consume higher budget and management time due to high investment cost, high running and maintenance cost, long downtime and high rate of consumable expiry during downtimes. In order to mitigate this, health sector should rather embark on technology placement/lease contracts rather than purchasing them.

Conditions recommended for equipment placement/lease

Equipment placement/lease is highly recommended for the following conditions:

i) High cost of the equipment which the Health facility may not be in position to pay at once
ii) Where equipment maintenance is mandatory but costly
iii) Where the facility does not have biomedical engineering professionals, and due to sophistication of the equipment planned preventive maintenance is compulsory
iv) Medical Radiology imaging equipment with closed system

Equipment donation

Equipment donation is the method of equipment acquisition in which the equipment is transferred from the donor (giver) to the user (recipient) in a form of gifts in kind or charitable purposes such as development aid support, emergency, relief or humanitarian medical care needs.

NOTE: *Donation of medical radiology equipment should not be done for the purpose of disposal of old or obsolete technology*

(a) Advantages of equipment donation

Acquisition of equipment:

(i) Can be free or at low cost
(ii) Process takes shorter duration
(iii) Is easier as the purchaser doesn't have to deal with agreements or contracts

(b) Disadvantages of equipment donation

(i) Most of the time, there is no warranty and/or service contracts

(ii) Unreliable supply of spare parts, consumables and supplies
(iii) Minimal specific choice on technology
(iv) Difficulty and higher cost in disposal of equipment

(c) Categories of equipment donation

Medical equipment donation may be divided into two categories:
(i) Donation of new health care technology
(ii) Donation of used health care technology

i) Donation of new health care technology

Donation of new health care technology will be based on the National Donation Guideline and the following principles:

a) End user health facility will always negotiate with external support agencies regarding Medical Radiology and Imaging Equipment technology to be supplied;
b) External agencies will be required to comply with the following MoHCDGEC guidelines:
   (i) The equipment should be in the National Equipment Standard List;
   (ii) National standards and specifications;
   (iii) Details of the 'package' of input to be included in purchase agreements;
   (iv) National standards on safety;
   (v) Criteria defining the suitability/appropriateness of products.

End user at all levels are mandated to reject the technology from use if found to be unsafe or unsuitable. Such events should be documented and reported to respective authority for necessary action (i.e. HCTS MOH, TAEC, TFDA, etc.)

ii) Donation of used health care technology

Donation of used medical radiology and imaging equipment should consider the following:

a) Recognising the issues anticipated with used health care technology, such as reduced life-time, more intensive maintenance needs, difficulties in obtaining spare-parts, manuals and after sale support, the government in principal, **DOES NOT** approve used donation.
b) However, exception could be made at the discretion of the MoHCDGEC if the items have been refurbished (restored to their original working condition for the purpose for re-sale) by a reputable company following the Good Manufacturing Practices established by their national authorities for the manufacture of medical radiology and imaging technology; and the items should be supplied together with the necessary manuals, accessories, stocks of consumables, stocks of spare parts, and after-sales support for at least five years.
c) When soliciting donation of used medical radiology and imaging technology, administration of recipient health sector should observe the following principles:

(i) The recipient health facility shall be provided with details of technology to be donated including type, age of technology, availability of spare parts and consumables prior equipment shipment for review and advice by the HCTS professional;
(ii) The HCTS professional at the health facility shall advise and recommend to the facility in-charge.
(iii) The recipient facility shall seek for approval from the MoHCDGEC and other regulatory authorities for importing used technology prior shipping the equipment;
(iv) Donor shall not dispatch the used donation prior to end user receiving approval from the MoHCDGEC for importing used equipment;

Manufacturers/Suppliers

The health sector will select manufacturers/suppliers who will conform to the following criteria as stated in the Purchase Agreement;

a) The product to be supplied should be registered by TFDA
b) The manufacturer should have a registered local representative
c) All suppliers must guarantee user training, local service, after-sales support and maintenance
d) Relevant companies must guarantee lifetime supply of factory-tested original goods
e) All suppliers must guarantee delivery according to a given delivery dates
f) The manufacturer should meet all import regulations and requirements
g) A manufacturer/supplier should be chosen in tender process based on existing national procurement legislations
h) Technical quality by evaluation of the firms' competence, the staff seconded to the assignment and the technical value or quality of the proposal;
i) Technical quality with price consideration;
j) Lowest price after establishing compatibility of technical proposals and the service to be provided.
k) Manufacturer should be able to provide historical evidence on product performance

CHAPTER SEVEN: INSTALLATION, MAINTENANCE, DISPOSAL AND REPLACEMENT OF RADIOLOGY EQUIPMENT

7.1 Equipment Installation

Unsophisticated technology which does not need commissioning process can be installed by the user and facility biomedical professional, but other technology must be installed by a qualified biomedical engineer from supplier or its recommended agent. Facility biomedical engineer should monitor the installation process. The following are critical steps to be observed during installation:

(i) Site Preparation

Site preparation should be planned by facility administration through close consultation with supplier, medical radiology professional and biomedical engineering unit at the facility for small scale or simple preparation and by external contractor for large scale or complicated preparation. Facility administration should monitor and supervise the preparation process. Site preparation should take into consideration all safety measures.

(ii) Initial Calibration

Supplier of technology should be responsible to arrange performing initial calibration, and has to report to facility administration and biomedical engineer about the result of calibration.

(iii) Application Training

User of the technology and biomedical engineer should be trained initially by experienced instructors arranged by the manufacturer or supplier before the technology is accepted into service.

(iv) Commissioning

After installation is completed a series of tests should be done to confirm technology is functioning correctly in the presence of facility administrator, biomedical engineer, users and supplier. Commissioning should be done very carefully. Even a small defect or malfunctioning which might not cause any difficulties in real application of the technology should be rectified at supplier's responsibility before commissioning. Relevant regulatory bodies should verify the compliance status of the equipment before it is used for clinical purposes

(v) Accepting Technology into Service

Only after completion of commissioning and initial operational training, facility administration approves to put the technology into Service. Whenever technology is accepted into service, facility administration, store keeper and biomedical engineer should include the technology into maintenance management inventory.

7.2 Equipment Maintenance

7.2.1 Concept of Maintenance

Health facility administration should ensure availability of maintenance services by providing proper tools and test equipment to biomedical engineering department/unit, and also should provide spare parts and maintenance material for corrective maintenance on demand basis. As for spare parts and maintenance material for Planned Preventive Maintenance, health sector administration should procure them according to annual plan and budget.

Types of maintenance recommended to medical radiology and imaging equipment are as follows:

(i) Preventive maintenance: All actions carried out on a planned, periodic, and specific schedule to keep an equipment in state of working condition through the process of checking and reconditioning.

(ii) Corrective maintenance: The unscheduled maintenance or repair to return equipment to a defined state and carried out because maintenance persons or users perceived equipment deficiencies or failures.

(iii) Predictive maintenance: The use of modern measurement and signal processing methods to accurately diagnose an equipment condition during operation.

7.2.1 Maintenance Service Contract

Service contracts are aimed at strengthening the close, longstanding relationship between the supplier and the user. The service contract is always tailored to the user's needs based on the operating requirements of the particular equipment technology.

Service contracts focus on preventive maintenance, small and larger repairs, supplying spare parts, monitoring and regularly assessing the equipment condition including remote on-line monitoring. Service contracts define inspection and on-line monitoring report intervals, the response time for the arrival of specialized staff who set the priority for handling urgent matters.

7.2.1.1 Criteria for entering into service contract:

i) The complexity of the technology for example digitalization, automation and closed systems
ii) Where there is no HCTS personnel capable of maintaining that technology
iii) Maintenance cost benefit to the health facility. For example compare costs and benefits of utilizing in-house HCTS personnel vs entering service contract.
iv) Acquisition of equipment through equipment placement/lease.

7.2.1.2 Conditions to consider:

i) Cost of the contract
ii) Frequency of PPM
iii) Availability of Service provider
iv) Capacity of the provider to meet demands related to contract, so that

equipment downtime is minimum as per agreement

v) Manufacturer's instructions

7.2.1.3 User's benefits:

i) Continuous uninterrupted service

ii) Resources for equipment maintenance will be used for other operational activities.

iii) Longer equipment lifetime

iv) Reduced repair costs and eliminated losses from outages

v) Improved operating conditions

vi) Transparent costs

7.3 Disposal and Replacement

(i) Disposal

Both user and Biomedical engineering personnel should advise health sector administration to dispose technology when it is found to be at or beyond end of its life-time. PMU should be informed accordingly for the disposal process. Contaminated technology must be incinerated. However radioactive technology must be disposed according to international regulations under the authorization of TAEC. Other technology should be disposed after reusable general parts being disassembled from the technology for stock parts. Biomedical engineering personnel should also update maintenance inventory excluding the disposed technology from the inventory.

(ii) Replacement

In order to prevent interruption of health services, whenever technology is scheduled to be disposed, administration of health facilities should prepare its replacement plan in advance. Replacement should be rational and planned, and it is required that health care technology be replaced only when one or more of the following valid reasons have been fulfilled.

i) Technology has reached the end of its life-time;
ii) It is damaged beyond repair;
iii) Consumables and/or spare parts are no longer available;
iv) It is no longer economical to run the equipment;
v) It is technically or clinically obsolete;
vi) It is no longer safe;
vii) Utilisation statistics are available to show that it is not required.

***Note**: HCT will not be replaced simply because:*

i) It is old; or Staff do not like it;
ii) A newer model has arrived on the market.
iii) Utilisation statistics are available to show that it is still required

Annex I: List of common consumables, spare parts and accessories

MSD Part No.	Description	UOM
30010001SP	FILM X-RAY 24 CM X 18(GREEN SENSITIVE)	100PC
30010002AG	FILM X-RAY 35 CM X 35(GREEN SENSITIVE)	100PC
30010003SP	LASER FILM DT C 14X17 (35cmX43cm) CT SCAN GREEN SENSITIVE	100PC
30010005MD	FILM X-RAY 43CM X18CM (GREEN SENSITIVE)	100PC
30010006AA	A Plane Collimator Assembly	EACH
30010007AA	Brush, PWR Block PCB Assembly	EACH
30010008AA	Brush, Signal Block Assembly	EACH
30010031SP	Acropars 200 Special Tray Powder & liquid 500g bottle	1BT
30020001AA	AUTOMATIC DEVELOPER	40L
30020003MD	FIXER LIQUID	20L
30020004MD	IOPAMIDOL(GASTROMIRO,IOPAMIRO)	1VL
30020005MD	IOHEXOL (OMNIPAQUE)	20ml
30020007AG	BARIUM SULPHATE 95% W/W FOR DOUBLE CONTRAST RADIOGRAPHY	300g
30020008AA	BARIUM SULPHATE 92% W/W FOR ENEMA DISPOSABLE KIT 4000GM TOGETHER WITH AIR INSUFLATOR AND ONE SHOT INFLATOR	24DS
30020009AA	MICROBAR -RT-BARIUM SULPHATE I.P 90% W/W	125g
30020010MD	MEGLUMINE DIATRIOZATE INJECTION 76% (UROGRAFFIN 76%)	10AMP
30020011AA	CURIX 60 AUTOMATIC FILM PROCESSOR PARTS	1KT
30020012AA	FILM X-RAY 30CM X 24CM (GREEN SENSITIVE)	100PC
30020013AA	FILM E-RAY 40CM X 30CM (GREEN SENSITIVE)	100PC
30020014AA	FILM X-RAY 43CM X18CM (GREEN SENSITIVE)	100PC
30020015AA	FILM X-RAY 43CM X 35CM (GREEN SENSITIVE)	100PC
30020016AA	ULTRA SOUND JELLY(WITH DISPENSER)	5L
30020018MD	BARIUM SULPHATE 100 W/W FOR ESOPHAGUS 200GM	1.2KG
30020019SP	GADOLINIUM CONTRAST 20ML	1VL
30020020SP	ULTRASOUND GELLY 5 LITRES	P/4
30020021SP	Metaiodobenzyl guanidine (1-131 MIBG) DOSES	EACH
30020022SP	MEDRONATE INJECTION MDP KITS	EACH
30020023SP	DIETHYLENETRIAMINE PENTAACETIC ACID (DTPA) KITS	EACH
30020024SP	DISIDA/HEPATOLITE/MEBROFENIN (HIDA) KITS	EACH
30020025SP	IODINE 131 5mCi Capsule	EACH
30020026SP	IODINE 131 10mCi Capsule	EACH

MSD Part No.	Description	UOM
30020027SP	IODINE 131 15mCi Capsule	EACH
30020028SP	IODINE 131 100mCi Capsule	EACH
30020029SP	IODINE 131 150mCi Capsule	EACH
30020030SP	IODINE 131 200mCi Capsule	EACH
30020031SP	GALLIUM 67 CITRATE (GA-67)3M Ci VIAL	EACH
30020032SP	GALLIUM 67 CITRATE (GA-67) 5M Ci VIAL	EACH
30020033SP	GALLIUM 67 CITRATE (GA-67) 10M Ci VIAL	EACH
30020034SP	10GBq Tc99m GENERATOR	EACH
30020035SP	ULTRASOUND JELLY WITH DISPENSER	500ml
30030001MD	X-RAY INTENSIFYING SCREENS 24CM X18CM(GREEN SENSITIVE)	EACH
30030002MD	X-RAY INTENSIFYING SCREENS 30CM X 24CM(GREEN SENSITIVE)	EACH
30030003MD	X-RAY INTENSIFYING SCREENS 40CM X30CM(GREEN SENSITIVE)	EACH
30030004MD	CASETTES FOR X-RAY FILMS 24CM X 18CM,MOUNTED WITH INTENSIFYING SCREEN GREEN SENSITIVE	EACH
30030005MD	CASSETTES FOR X-RAY FILMS 30CM X 24CM,MOUNTED WITH INTENSIFYING SCREEN GREEN SENSITIVE	EACH
30030006MD	CASSETTES FOR X-RAY FILMS 35CM X35CM,MOUNTED WITH INTENSIFYING SCREEN GREEN SENSITIVE	EACH
30030007MD	CASSETTES FOR X-RAY FILMS 40CM X30CM,MOUNTED WITH INTENSIFYING SCREEN GREEN SENSITIVE	EACH
30030008MD	CASSETTES FOR X-RAY FILMS 43CM X 18CM,MOUNTED WITH INTENSIFYING SCREEN GREEN SENSITIVE	EACH
30030009MD	CASSETTES X-RAY FILMS 43CM X35CM ,MOUNTED WITH INTENSIFYING SCREEN GREEN SENSITIVE	EACH
30030011MD	X-RAY - INTENSIFYING SCREEN FOR FILM 25.4 CM X 20.4 CM (10""X 8"") "	EACH
30030012MD	X-RAYINTENSIFYING SCREEN FOR FILM 30.5 CM X 25.4 CM (12""X10"") "	EACH
30030013MD	X-RAY INTENSIFYING SCREEN FOR FILM 35.6 CM X 35.6 CM (14""X14"") "	EACH
30030014MD	X-RAY INTENSIFYING SCREEN FOR FILM 38.1 CM X 30.5 CM (15""X12"") "	EACH
30050002AH	X-RAYS VIEWER	EACH

MSD Part No.	Description	UOM
30050003AH	CASSETTE FOR X-RAY FILM 25.4 CM X 20.4 CM (10""X 8"") "	EACH
30050004MD	CASSETTE FOR X-RAY FILM 30.5 CM X 25.4 CM (12""X10"") "	EACH
30050005MD	CASSETTE FOR X-RAY FILM 35.6 CM X 35.6 CM (14""X14"") "	EACH
30050006MD	LEAD APRON	EACH
30050009MD	ILLUMINATOR X-RAY DOUBLE	EACH
30050016SP	SONOGRAPHIC PRINTING PAPERS - V(High glossy), MODEL-110HG, SIZE- 110*18M	EACH
30050018SP	GANTRY MOTOR	EACH
30050019SP	SWITCH FOR EQUINOX	EACH
30050020SP	SENSOR CABLE	1SET
30050021SP	DUAL GANG POT 10 TURN	1SET
30050022SP	CUMPUTER CABINET ASSEMBLY	SET
30050024SP	COLLIMATOR C/W MOTORIZED WEDGE	EACH
30050025SP	MEDICAL X-RAY PROCESSOR, TABLETOP	EACH
30050027SP	PCB, CABLE ASSY	EACH
30050028SP	EQUINOX AMPLIFER PCB	EACH
30050029SP	SOURCE CHANGE ASSY 1	EACH
30050030SP	CABALT 60 THERAPY SOURCE	EACH
30050037SP	UPS 160KVA FOR MRI MACHINE	EACH
30050041SP	UPS 160KVA FOR CATHLAB MACHINE	EACH
30050042AA	Set of Springs Cassette for CT Scan	EACH
30050043AA	Microswitch for CT Scan	EACH
30050044AA	Locking Device Complete for CT Scan	EACH
30050045AA	Ball Holder for CT Scan	EACH
30050046AA	Flat Belt Complete for CT Scan	EACH
30050047AA	Tension Spring for CT Scan	EACH
30050048AA	Set of Cassete Positioner for CT Scan	EACH
30050049AA	Set of Sliding Carriage for CT Scan	EACH
30050050AA	PCB Battery Charger for CT Scan	EACH
30050051AA	Set of Screws of Cassettes for CT Scan	EACH
30050052AA	PCB HT Control INT.IGBT for CT Scan	EACH
30050053AA	MRS Table Top for CT Scan	EACH
30050054AA	Knob Set F. Manuel Movement for CT Scan	EACH
30050055AA	Kit Battery Charger for CT Scan	EACH
30050056AA	MRS C-Arm and PSU (FC070400047) for CT Scan	EACH
30050057AA	Interface Control PCB for CT Scan	EACH
30050058AA	Replacement Kit of MRS Ropes for CT Scan	EACH

MSD Part No.	Description	UOM
30050059AA	PCB IPM Driver for CT Scan	EACH
30050060AA	APT Console for CT Scan	EACH
30050061AA	Headrest Strap Assay for CT Scan	EACH
30050062AA	Head Cushion for CT Scan	EACH
30050063AA	L-14" Patient Resistant Strap/ 42" for CT Scan	EACH
30050064AA	Cushion Patient for CT Scan	EACH
30050065AA	Velcro-30' Package for CT-Scan	EACH
30050068AA	SET OF JOYSTICK KNOBS	EACH
30050070AA	MAIN PCB	EACH
30050079AA	REPLACEMENT KIT PCB	EACH
30050081AA	POTENTIOMETER	EACH
30050083AA	Monitor Video, Assay Chameleon	EACH
30050086AA	Motor with gear and Encoder in-Out	EACH
30050087AA	Motor Control Titting	EACH
30050088AA	Flat Cable	EACH
30050089AA	TC-Generator 10GBq	EACH
30050090AA	MDP Kit	1KT
30050091AA	Therapy Cups 200mci (7400MBq0- T-131	EACH
30050092AA	PACKED HT CONV. TANK BV300 SPARE PARTS FOR CT SCAN	EACH
30050094AA	X-RAY TUBE	EACH
30050096AA	HV Transformer	EACH
30050097AA	Monitor, Video, Assy, OEMSVC	EACH
30050098AA	RENATEK DTPA KIT	1KT
30050100AA	RENOCIS (DMSA)	EACH
30050101AA	ADAPTER, AC PWR	EACH
30050102AA	MOTOR WITH GEAR AND ENCODER	EACH
30050103AA	PCB HALL SENSOR	EACH
30050104SP	COBALT SOURCE FOR INTRACAVITY GYNESOURCE MACHINE.	EACH
50020089SP	X-RAY FILMS INSTANT	50PC
50020149SP	X-RAY DEVELOPING UNIT (AUTOMATIC)	EACH
50020226SP	X-Ray Films- Bitewing Size 3 (Df42)	100PC
50020312SP	X-Ray Films- Intraoral Film Speed E - Periapical Adult-P/150	PK
50020313SP	X-Ray Films- Intraoral Film Speed E - Periapical Child P/150	PK
50020314SP	X-Ray Film - Occlusal, Instant Processing Film,Df50 P/25	PK

MSD Part No.	Description	UOM
50020315MD	X-Ray Films- -Super Phil X-30,Sachet Contain Both Fixer And Developer -P/50	PK
50020315SP	X-Ray Films- -Super Phil X-30,Sachet Contain Both Fixer And Developer -P/50	PK
50020316SP	X-Ray Films – Extra oral Film. Ortho Pantomography 12x30 Cm In Pack Of 100	PK
50020377SP	X-RAY VIEWER PORTABLE TABLE TOP, MARK II	EACH
50020380SP	X-RAY FILM FUJI MEDICAL DRY IMAGING FILM DI-HL (20X25cm) PACK OF 150NIF	150NIF
	MRI Coil	Each
	MRI Injector pump	Each
	CT Scan Injector Pump	Each
	Disposable syringe (200cc) for CT Injector pump	Each
	Disposable syringe (200cc) for MRI Injector pump	Each
	Dripping Chambers (Y-Tube)	Each
	Patient Line	Each
	ECG Lead for CT Scan	Each
	ECG Lead MRI Compatible	Each
	MRI Compatible patient monitor	Each
	Collimator lamp	Each
	Ultrasound Transducer	Each

Annex II Equipment Specifications

Specifications for the Basic Ultrasound Machine

SPECIFICATIONS OF BASIC ULTRA SOUND MACHINE		
i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Basic Ultrasound Machine
2	GMDN name	General ultrasound imaging system, line-powered /General ultrasound imaging system, battery-powered
3	GMDN code	40761, 40762,60924
4	GMDN category	
5	Alternative name/s (optional)	Grey Scale (B/W) Ultrasound Machine
PURPOSE OF USE		
6	Clinical or other purpose	To perform general abdominal and obstetric ultrasound examinations
7	Level of use	Dispensary, Hearth Centre, District, Region, Zonal, or National Hospital
8	Clinical department/ward	Radiology/Labour ward
9	Overview of functional requirements	This machine should be able to perform basic abdominal examinations including examination of the liver, spleen, kidneys, reproductive organs and basic obstetric examinations to determine number of foetuses, viability, presentation, placenta location, amount of liquid and others.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	Should have a minimum of one transducer (convex 2-5MHZ) should be able to perform all measurements of basic parameters to enable functional requirements. It should have USB port for data transfer. Apart from that the Machine should be DICOM Compatible. Should have inbuilt battery which can last for One Hour and above.
11	Displayed parameters	Should display Patient ID, demographic data, focus, frequency, depth and any other important parameter.

12	User adjustable settings	Should provide a room for doing adjustment of language to be used (multi-Language- English is a must), time and date settings, frequency, brightness, contrast, gain, focus, depth, resolution, thermal index (MI) and Mechanical Index (MI).
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	Monitor should have the size of 7 inches (17.7cm) LCD Colour Display and above.
14	Mobility, portability	Should be portable or non-portable but mobile.
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	Should have thermal printer (in build or out build), Must come with UPS which can supply back up power for a minimum of 60 Minutes.
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	Should come with one set of consumables (Jelly 500mls, thermal paper) all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
19	Shelf life	N/A
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90% Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.

TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	Should be available for lifetime period after installation of machine.
31	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
32	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
33	Life Span	Life span of the machine should be not less than 8 Years
SAFETY AND STANDARDS		
34	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
35	Regulatory Approval / Certification	TAEC, TBS and TFDA

36	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
37	Regional/Local Standards	TAEC, TBS and TFDA
38	Regulations	TAEC, TBS and TFDA

Specifications for the Advanced Ultrasound Machine

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Advanced Ultrasound Machine
2	GMDN name	
4	GMDN code	61236, 40771, 40772
5	GMDN category	
6	Alternative name(s) (optional)	
PURPOSE OF USE		
6	Clinical or other purpose	To perform small parts, musculo-skeletal, general abdominal, gynaecological, obstetric ultrasound examinations and vascular studies. It should also be able to perform advanced studies such as 3D examinations and tissue elasticity.
7	Level of use	Regional, Zonal and National
8	Clinical department/ward	Radiology
9	Overview of functional requirements	Delivers real-time, non-invasive imaging of internal organ structures and functionality Displays images on integral screen and also enables DICOM compliant image transfer Supplied with all necessary probes for abdominal, cardiac, vascular, obstetrics and gynaecology, prostate and breast imaging, with colour Doppler imaging, for patients of all ages.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	1) Minimum of three transducers (convex, linear and endo-cavity). Colour monitor, TFT or LCD from 15" up. 2) Dynamic range at least 180 dB. 3) Frequency range of at least 1-15 MHz 4) Modes: M (Bi-dimensional, simultaneous); Colour Doppler; Pulsed Doppler; Colour perfusion; Harmonic images. Should have a minimum of 3D capability.

		5) Digital and calliper measurement functions required for both distance, area and volume. 6) Trackball and/or touchpad in user panel. 7) Frame by frame image memory or cine-loop. 8) Doppler display to indicate blood flow both numerically and in colour. 9) Connection port for image printing to be included (printer specified separately). 10) HD/CD/DVD/USB storage unit **11)** Hard disk of at least 1 TB
11	Displayed parameters	Unit display of at least 512 x 512 pixels. Should display patient ID, demographic data, focus, frequency, depth, Doppler angle, area, and other relevant parameters.
12	User adjustable settings	1) Adjustable depth gain, freeze frame and image zoom facilities required. 2) Protocols. 3) Cine record and playback feature required, with frame rate at least 500 fps. 4) Measurement accuracy to be better than 2% over 10cm distance. 5) Alphanumeric annotation to be possible"
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	Where relevant (in case of a portable system),the Unit to be supplied on stable, mobile trolley fitted with 4 wheels that can be braked Display to have tilt/swivel facility for easy viewing Probe leads to be at least 1.5m in length Included a minimum of 3 probes a) Convex with at least triple frequency, bandwidth of at least 2Mhz, including 3.5Mhz frequency; b) Linear with at least triple frequency, bandwidth of at least 2Mhz, including 6.5Mhz frequency; c) Endo-cavity probe with at least triple frequency, and Field Of View of at least 185° for one equipment. Trolley to include shelf space for image printer and documentation
14	Mobility, portability	Should be portable or non-portable and mobile.
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		

16	Accessories	1) UPS with minimum backup power supply of 30 minutes .Linear probe, 5 to 12 MHz 2) Convex probe, 2 to 5 MHz 3) Endo-cavity probe, 4 to 8 MHz 4) Colour or B/W printer 5) Licenses DICOM Send o Print, DICOM Storage and DICOM Worklist.
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	Should come with one set of consumables (Jelly 500mls, thermal paper) all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
19	Shelf life	Life span of the machine should be indicated in specific document
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also be specified and provided.

26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	Should be available for lifetime period after installation of machine.
31	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
32	Documentation requirements	Two sets (hard copy and soft copy) of Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
33	Life Span	Life span of the machine should be not less than 8 Years
SAFETY AND STANDARDS		
34	Risk Classification	Class B (GHTF Rule 10); Class II (USA); Class II (EU, Japan, Canada and Australia)
35	Regulatory Approval / Certification	TAEC, TBS and TFDA
36	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
37	Regional / Local Standards	TAEC, TBS and TFDA
38	Regulations	TAEC, TBS and TFDA

Specifications for a Standard Ultrasound Machine

i)	Version No.	One
ii)	Date of initial version	January, 2018
iii)	Date of last modification	February, 2018
iv)	Date of publication	TBD
v)	Completed/submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Standard Ultrasound Machine
2	GMDN name	
3	GMDN code	61,236
4	GMDN category	
5	Alternative name/s (optional)	Ultrasound Machine with Doppler Capability
PURPOSE OF USE		
6	Clinical or other purpose	To perform small parts, general abdominal, obstetric ultrasound examinations and vascular studies
7	Level of use	Health Centre and District Hospital
8	Clinical department/ward	Radiology
9	Overview of functional requirements	Delivers real-time, non-invasive imaging of internal organ structures and functionality Displays images on integral screen and also enables DICOM compliant image transfer Supplied with all necessary probes for abdominal, cardiac, vascular, obstetrics and gynaecology, prostate and breast imaging, with colour Doppler imaging, for patients of all ages.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	1) Minimum of three transducers (convex, linear and endo-cavity). Colour monitor, TFT or LCD from 15" up. 2) Dynamic range at least 180 dB. 3) Frequency range of at least 1-15 MHz 4) Modes: M (Bi-dimensional, simultaneous); Colour Doppler; Pulsed Doppler; Colour perfusion; Harmonic images 5) Digital and calliper measurement functions required for both distance, area and volume. 6) Trackball and/or touchpad in user panel. 7) Frame by frame image memory or cine-loop.

		8) Doppler display to indicate blood flow both numerically and in colour. 9) Connection port for image printing to be included (printer specified separately). 10) HD/CD/DVD/USB storage unit 11) Hard disk of at least 1 TB
11	Displayed parameters	Unit display at least 512 x 512 pixels. Should display patient ID, demographic data, focus, frequency, depth, Doppler angle, area, and other relevant parameters.
12	User adjustable settings	1) Adjustable depth gain, freeze frame and image zoom facilities required. 2) Protocols. 3) Cine record and playback feature required, with frame rate at least 500 fps. 4) Measurement accuracy to be better than 2% over 10cm distance. 5) Alphanumeric annotation to be possible"
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	Where relevant (in case of a portable system),the Unit to be supplied on stable, mobile trolley fitted with 4 wheels that can be braked Display to have tilt/swivel facility for easy viewing Probe leads to be at least 1.5m in length Included a minimum of 3 probes : a) Convex with at least triple frequency, bandwidth of at least 2Mhz, including 3.5Mhz frequency; b) Linear with at least triple frequency, bandwidth of at least 2Mhz, including 6.5Mhz frequency; c) Endo-cavity probe with at least triple frequency, and Field Of View of at least 185° for one equipment. d) Trolley to include shelf space for image printer and documentation
14	Mobility, portability	Should be portable or non-portable and mobile.
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	1) UPS with minimum backup power supply of 30 minutes .Linear probe, 5 to 12 MHz 2) Convex probe, 2 to 5 MHz 3) Endo-cavity probe, 4 to 8 MHz

		4) Colour or B/W printer 5) Licenses DICOM Send o Print, DICOM Storage and DICOM Worklist.
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	Should come with one set of consumables (Jelly 500mls, thermal paper) all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
19	Shelf life	Life span of the machine should be indicated in specific document
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).

WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	Should be available for lifetime period after installation of machine.
31	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
32	Documentation requirements	Two sets (hard copy and soft copy) of Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
33	Life Span	Life span of the machine should be not less than 8 Years
SAFETY AND STANDARDS		
34	Risk Classification	Class B (GHTF Rule 10); Class II (USA); Class II (EU, Japan, Canada and Australia)
35	Regulatory Approval / Certification	TAEC, TBS and TFDA
36	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
37	Regional / Local Standards	TAEC, TBS and TFDA
38	Regulations	TAEC, TBS and TFDA

Specifications for the MRI Machine

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	3Tesla MRI machine
2	GMDN name	
3	GMDN code	37654
4	GMDN category	
5	Alternative name/s (optional)	
PURPOSE OF USE		
6	Clinical or other purpose	High performance MRI to cover emerging clinical indications in neurology, oncology and cardiology.
7	Level of use	ZONAL, SPECIALIZED , NATIONAL
8	Clinical department/ward	Radiology
9	Overview of functional requirements	A diagnostic general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body (full-body imaging). This system includes a superconducting magnet assembly and can be fixed-location, mobile, or transportable. Some systems can perform MR spectroscopy or various real-time imaging procedures for MRI guided interventional, therapeutic, or surgical applications.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	The machine should be with a fixed 3T magnet and should be provided with respective coils for scanning-brain, head, neck, spine, shoulder, Body/torso, Knee, Wrist, Cardiac imaging, Breast. It should be able to perform non contrast angiography, spectroscopy, plague imaging and colour analysis, motion compensating radial techniques, brain volume imaging. USB port for data transfer. At last gradient amplitude of 30mT/m, slew rate 125T/m/s. Apart from that the Machine's work station be of latest technology and DICOM Compatible. Should have zero boil off

		technology for saving helium. The examination table minimum patient load should be 200 kg.at least two emergency buttons should be provided, one in the console room and the other in the magnet room.
11	Displayed parameters	Should display patient ID and other important parameters.
12	User adjustable settings	Should allow for user adjustment of relevant settings/variables.
13	Components	Magnet, gradient coils, Radiofrequency transmitter and receiver, patient table and computer.
14	Mobility, portability	Stationary/Fixed
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	MRI compatible stretcher, MRI compatible wheelchair, MRI compatible pump for dynamic studies, MRI compatible patient monitoring system, MRI compatible ventilator, cardiac imaging accessories. DICOM printer
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables/reagents	Should come with one set of consumables (contrast, syringes, patients line for injector pump) all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
19	Shelf life	Life span of the machine should be indicated in specific document
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		

22	Context-dependent requirements	Storage and operating temperatures, resistance to high humidity and/or dust levels should be stated by manufacturer /vendor in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor.
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 3 Years: should be comprehensive including service, spare parts and labour starting from the day of the acceptance testing of the machine.
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	Lifetime support; spare parts, consumables should be available throughout the lifetime period of the machine.
31	Uptake time	Uptake time of a minimum of 90%, compensation should be included in case of default.
32	Technical support Personnel	Evidence of locally based technical support personnel, including CVs and relevant qualifications. Should include work permits for foreign personnel.
33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format

DOCUMENTATION		
34	Documentation requirements	Two sets (hard and soft copy) of Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of CT Scan Machine

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	128 slice CT scanner
2	GMDN name	
3	GMDN code	
4	GMDN category	
5	Alternative name/s (optional)	
PURPOSE OF USE		
6	Clinical or other purposes	High performance CT to cover emerging clinical indications in neurology, oncology and cardiology.
7	Level of use	National
8	Clinical department/ward	Radiology
9	Overview of functional requirements	A high performance 128 slice CT scanner featuring the latest hardware technology as well as extensive clinical software functionality to support a wide range of clinical applications which include Cardiac imaging, CT angiography, CT colonoscopy, CT fluoroscopy, Brain perfusion studies, body perfusion studies, Computer assisted reading(lung, Colon),bone mineral densitometry, image perfusion and dental software. Should have single energy scanning capability or more.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	CT scanner with 128 slices ,with a minimum wide bore /aperture of 72 cm, high frequency generator, water chiller for cooling, x-ray tube with moving dynamic spot, detector system with a maximum number of 128 simultaneously acquired data states, Multipurpose table option, image reconstruction matrix of 512 x 512,simultaneous scanning and archiving /transfer to second console or workstation.

		Operator console with minimum of two monitors, casual breath hold indicator, and display type LCD or latest technology, reconstruction operating system should be windows. Image archive with external media options (DVD, CD-R), Disc burning facility, interoperability between scanner and workstation with PACS, Radiology Information system (RIS).
11	Displayed parameters	Should display patient ID, date of examination, application(s), transfer, edit, view, Tools, KV, mAs, TI, GT, SL, and any other important parameter.
12	User adjustable settings	Should be Extensive.
UTILITY REQUIREMENTS		
13	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
14	Accessories	Contrast injector pump, insufflators (C02/optional),Head Rest, Stereo-static head restraint, restraining strips, slicker mattress cover, CT fluoroscopy hardware, Hardcopy imaging device with one/multiple trays, Gantry monitored ECG.
15	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
16	Consumables	Should come with one set of consumables (gadolinium contrast syringes, patients lines for injector pump, DVD/CDs, ECG gadgets) all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
17	Shelf life	Life span of the machine should be indicated in specific document
18	Transportation and storage	Specific considerations for transportation and storage must be indicated
19	Labelling	Specific labelling requirements should be indicated

ENVIRONMENTAL REQUIREMENTS		
20	Context-dependent requirements	Storage and operating temperatures, resistance to high humidity and/or dust levels should be stated by manufacturer /vendor in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
21	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
22	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
23	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
24	User care S	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
25	Warranty	Minimum of 2 Years: should be comprehensive including service, spare parts and labour starting from the day of the acceptance testing of the machine.
26	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
27	Type of service contract	Comprehensive Contract
28	Spare parts availability post-warranty	Lifetime support; spare parts, consumables should be available throughout the lifetime period of the machine.
29	Uptake Time	Uptake time should be a minimum of 90%. Compensation is the minimum is exceeded.
30	Technical support personnel	Proof of locally available technical support personnel, including CVs and work permit for foreign personnel.
31	Elements of scanner/plant not covered in standard support	This should be specified in detail.
32	Technical support Personnel	Availability of technical personnel within the country should be stated; this should include CVs, work permits for foreign personnel.

33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
34	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of Basic X-Ray Machine

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Analogue X-ray machine
2	GMDN name	Stationary Basic Diagnostic X-ray system.
3	GMDN code	37644
4	GMDN category	12 Diagnostic and Therapeutic radiation devices.
5	Alternative name/s (optional)	Basic radiologic system (BRS); General radiographic x-ray equipment; Radiographic unit, general-purpose; Paediatric radiographic unit; Radiographic unit, skeletal
PURPOSE OF USE		
6	Clinical or other purpose	An assembly of devices that comprise a general-purpose stationary diagnostic x-ray system used in a variety of routine planar x-ray imaging applications.
7	Level of use	Health centres
8	Clinical department/ward	Radiology
9	Overview of functional requirements	1) Provides X-ray film images of all body parts except for brain. 2) X ray generator and cassette holder can be moved to image body part of interest. 3) X-ray generator, Bucky and patient table movable to enable comfortable and precise imaging. 4) Separate control console (behind protective screens). 5) Fluoroscopic capacity is not required."
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	1) Must have a digital display of mAs and kV, and an electronic timer. 2) kV range at least 50 kV to 150 kV, digitally displayed. 3) mA range at least 0 to 600 mA. 4) Exposure time range at least 1 ms to 5 s. 5) Automatic exposure control facility required. 6) Tube power rating at least 60 kW.

		7) Resolution to be better than 5 line pairs/mm. 8) Must have a rotating anode with focal spot size less than 1mm. 9) Heat storage capacity of the anode at least 350,000 HU. 10) Adjustable multi-leaf collimator, rotatable ±90^0 with patient centring light beam.
11	Displayed parameters	Console should display KV and MAS and any other relevant parameter.
12	User adjustable settings	Exposure factors, Examination type, post-processing settings,
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	1) Patient table to have motorized tilt from at least +90^0 to -15^0 C. 2) All cables on the patient table unit should be concealed. 3) Patient table longitudinal and lateral movements to be at least 160 cm and 20 cm respectively. 4) Patient table vertical movement to include the range 60 cm to 120 cm from ground. 5) X-ray head longitudinal, vertical and lateral patient movement to be at least 100 cm, 30 cm and 20 cm respectively. 6) Source to image distance should at least include the range 90 cm to 125 cm. 7) The tube head must be fully counterbalanced for safe and easy movement. 8) Maximum possible patient weight to be at least 150 kg. 9) Dust cover for control unit to be supplied. 10) Protection against insect and rodent ingress to be incorporated. 11) Chest stand / bucky
14	Mobility, portability	Should be non-mobile/fixed
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	Cassettes for different

		Medium and 1 Large),Gonad shield (minimum 2 small ,2 medium, 2 large),neck collar shield(minimum of 1 small, 1 medium ,1 large), Gloves (2 small,2 medium, 2 large). Radiation hard warning signs to be supplied with unit. Supplier to specify full range of grids available)
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
PACKAGING		
18	Shelf life	Life span of the machine should be indicated in specific document
19	Transportation and storage	Specific considerations for transportation and storage must be indicated
20	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
21	Context-dependent requirements	1) Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90%. 2) Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
22	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
23	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
24	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
25	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
26	Warranty	Minimum of 1 Year
27	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine

28	Type of service contract	Comprehensive Contract
29	Spare parts availability post-warranty	Guarantee of variability of spare parts for lifetime period should be provided.
30	Up time	Uptake time of a minimum of 90%, compensation should be included in case of default.
31	Technical Support personnel	Evidence of locally based technical support personnel, including CVs and relevant qualifications. Should include work permits for foreign personnel.
32	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
33	Documentation requirements	Two sets (hard copy and soft copy) of Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
34	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
35	Risk Classification	Class C (GHTF Rule 10 (ii)); Class II (USA); Class II b (EU and Australia); Class II (Japan and Canada)
36	Regulatory Approval / Certification	TAEC, TBS and TFDA
37	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
38	Regional / Local Standards	TAEC, TBS and TFDA
39	Regulations	TAEC, TBS and TFDA

Specifications of CR System

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Computed Radiography (CR)system
2	GMDN name	
3	GMDN code	
4	GMDN category	
5	Alternative name/s (optional)	
PURPOSE OF USE		
6	Clinical or other purpose	Digitizer/Image reader used with analogue x-ray machines giving an advantage of image processing and increased speed.
7	Level of use	Health Centre and District
8	Clinical department/ward	Radiology
9	Overview of functional requirements	This machine should be able to digitize x-ray images generated from analogue x-ray machines which include conventional x-ray machines, mammography.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	Should have rigid plate scanning with processing capability of minimum of 80 plates/films per hour for 14 x 14 or 70 plates /films per hour for 14 x 17. Imaging preview time of less than 60 secs. Should have a standard work station(console) coupled with CR image storage of at least 2000 images with 17 inch grade monitor, which is capable of processing raw image data of the CR reader and should have post processing facilities such as window level adjustments, Image flipping, cropping ,image zooming, edge enhancement, noise reduction, magnification and others. Should be DICOM compatible. It should be able to process cassettes of size 8 x 10, 10 x 12, 14 x 14, 14 x 17, 12 x 30.
11	Displayed parameters	Should display patient ID, demographic data, focus, frequency, depth and any other important parameter.

12	User adjustable settings	Should provide a room for doing adjustment of language to be used (multi Language- English is a must), time and date settings, frequency, brightness, contrast, gain, focus, depth, resolution, thermal index (MI) and Mechanical Index (MI).
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	Image reader/digitizer, cassettes, computer console, monitors and printer.
14	Mobility, portability	Should be movable.
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	Should have thermal printer (in build or out build), Must come with UPS which can supply back up power for a minimum of 60 Minutes.
17	Users care ,Cleaning, Disinfection and Sterility issues	Sterilization not required. Disinfection: parts of the device that are designed to come into contact with the patient or operator should be either capable of easy disinfection or be protected by a single use cover.
18	Consumables / reagents	Should come with one set of consumables (Jelly 500mls, thermal paper) all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
19	Shelf life	Life span of the machine should be indicated in specific document
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of operating continuously in ambient temperatures of 5-50^0 C and relative humidity of 15-80%.
TRAINING, INSTALLATION AND UTILISATION		

23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	At least 5 years after device acquisition.
31	Breakdown call response and down time	
32	Technical support personnel	Evidence of locally available technical support, this should include CVs, Work permits for foreign personnel.
33	Uptake Time	Minimum of 90% uptake time, exceeding this should be compensation.
34	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
35	Documentation requirements	2 sets of (hard copy and soft copy) Operating and service manuals (In English) including lists of important spares and accessories and their cost - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available

DECOMMISSIONING		
36	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
37	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
38	Regulatory Approval / Certification	TAEC, TBS and TFDA
39	International standards	ISO 13485
40	Regional / Local Standards	TAEC, TBS and TFDA
41	Regulations	TAEC, TBS and TFDA

Specifications of Digital Mammography Machine

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Digital Mammography Machine
2	GMDN name	Stationary Mammographic X-ray system
3	GMDN code	37672
4	GMDN category	
5	Alternative name/s (optional)	
PURPOSE OF USE		
6	Clinical or other purpose	A stationary assembly of devices designed to generate x-ray images of the breast using digital techniques for image capture and display. It is designed specifically to compress the breast during imaging and is intended to visually evaluate the anatomy and function of blood and lymphatic vessels within the breast. Often referred to as a digital mammography system (DMS) it is typically used for breast cancer screening or during biopsy procedures (e.g., placement of biopsy markers, stereotactic biopsy). It is designed to capture two-dimensional (2-D) x-ray images, however may include software intended to process multiple images to create a three-dimensional (3-D) image/model (tomosynthesis)
7	Level of use	Regional, Zonal
8	Clinical department/ward	Radiology
9	Overview of functional requirements	This machine should be able to provide general screening, diagnostic and interventional applications.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	Should have a large field panel flat panel detector, high frequency generator, exposure control system and selectable dose modes, Radiation shield, should be Upgradable to advanced applications, should have a magnification device. Should be DICOM compatible (storage, Transfer and printing).Should have a

		diagnostic workstation with multi-modality viewer to display U/S,DX,MR,NM,PET & CT, dedicated mammography pad, patient list management tool.
11	Displayed parameters	Should display patient ID, demographic data, focus, frequency, depth and any other important parameter.
12	User adjustable settings	Should provide a room for doing adjustment of language to be used (multi Language- English is a must), time and date settings, and other
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	Compression device
14	Mobility, portability	Stationary/Fixed
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	Must come with UPS which can supply back up power for a minimum of 60 Minutes. Should be supplied with a basic grey scale printer.
17	Sterilization process for accessories	Procedures for sterilization and or cleaning must be well elaborated if it is present.
18	Consumables / reagents	N/A
PACKAGING		
19	Shelf lif	N/A
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		

23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	There should be a guarantee for availability of spare parts for lifetime period after successful commissioning of the machine.
31	Uptime	Uptake time of a minimum of 90%, compensation should be included in case of default.
32	Technical Support personnel	Evidence of locally based technical support personnel, including CVs and relevant qualifications. Should include work permits for foreign personnel.
33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
34	Documentation requirements	Two sets (hard and soft Copy) of Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		

35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of MRI 1.5t

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	1.5 Tesla MRI machine
2	GMDN name	
3	GMDN code	37654
4	GMDN category	
5	Alternative name/s (optional)	
PURPOSE OF USE		
6	Clinical or other purpose	A diagnostic general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body (full-body imaging). This system can perform MR spectroscopy or various real-time imaging procedures for MRI guided interventional, therapeutic, or surgical open-sided or other kinds of patient accessible designs.
7	Level of use	Zonal, National
8	Clinical department/ward	Radiology
9	Overview of functional requirements	This machine should be able to perform basic MRI examinations such as musculoskeletal, brain, spine, and abdomen as well as perform advanced imaging such as MR spectroscopy, diffusion imaging and functional MRI.
TECHNICAL CHARACTERISTICS		
10	Detailed Requirements	The machine should be with a fixed 1.5T magnet and should be provided with respective coils for scanning-brain, head, neck, spine, shoulder, Body/torso, Knee, Wrist, Cardiac imaging Breast. It should be able to perform non contrast angiography, spectroscopy, plague imaging and colour analysis, motion compensating radial techniques, brain volume imaging. USB port for data transfer. Apart from that the Machines work station be of latest technology and DICOM Compatible. Should have zero boil of

		technology for saving helium. The examination table minimum patient load should be 200 kg. At least two emergency buttons should be provided, one in the console room and the other in the magnet room.
11	Displayed parameters	Should display all relevant parameters.
12	User adjustable settings	Should provide a room for doing adjustment of language to be used (multi-Language- English is a must), time and date settings, and relevant parameters.
13	Components	Magnet, gradient coils, Radiofrequency transmitter and receiver, patient table and computer.
14	Mobility, portability	Should be non-mobile
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	MRI compatible stretcher, MRI compatible wheelchair, MRI compatible pump for dynamic studies, MRI compatible patient monitoring system, MRI compatible ventilator, cardiac imaging accessories.
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	Should come with one set of consumables (such as contrast, syringes, and patient lines for injector pump).
PACKAGING		
19	Shelf life	N/A
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Storage and operating temperatures, resistance to high humidity and/or dust levels should be stated by manufacturer /vendor in accordance with local/anticipated conditions.

TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 3 Years: should be comprehensive including service, spare parts and labour starting from the day of the acceptance testing of the machine.
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	Lifetime support; spare parts, consumables should be available throughout the lifetime period of the machine.
31	Uptime	Uptake time of a minimum of 90%, compensation should be included in case of default.
32	Technical support Personnel	Evidence of locally based technical support personnel, including CVs and relevant qualifications. Should include work permits for foreign personnel.
33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
34	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available

DECOMMISSIONING		
35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of Digital X-Ray Machine

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iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Digital X-ray machine
2	GMDN name	Stationary basic diagnostic system, digital
3	GMDN code	37645
4	GMDN category	12 Diagnostic and therapeutic Radiation devices.
5	Alternative name/s (optional)	Basic radiologic system (BRS); Digital radiography; Electronically recorded digital radiography; General radiographic x-ray equipment; Radiographic unit, chest; Radiographic unit, general-purpose;
PURPOSE OF USE		
6	Clinical or other purpose	A digital X-ray machine with robust design that can offer high quality and standard digital x-ray imaging.
7	Level of use	Dispensary, Hearth Centre, District, Region, Zonal, or National Hospital
8	Clinical department/ward	Radiology
9	Overview of functional requirements	Provides X-ray film images of all parts of the body including the skull, spine, pelvis, chest, abdomen and extremities. X ray generator and image intensifier can be moved to image required body part Control unit to be separate for operation from behind protective screens DICOM compatible image storage and transfer required Fluoroscopic capacity is not required
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	This machine should be able to produce a minimum of 300 images per day. Should have a high frequency generator of 50 - 150 KW, automatic exposure device, anatomical programming radiography, overloading protection feature, digital display of KV and mAs. X ray tube shouldbe stand mounted or ceiling suspended, high speed rotating anode and exposure should be 50 150KV and 0-600mA.Heat strength capacity of the

		anode at least 350,000 HU. The digital detector should be flat panel detectors of latest technology wireless or wired. The digital workstation should have a high speed processors, preview time of 5s or less.
11	Displayed parameters	The Console Monitor should display Patient ID, Exposure factors, warning sign and other important parameters.
12	User adjustable settings	Exposure factors, Examination type, post-processing settings and other relevant parameters.
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	1) Patient table to have motorized tilt from + 90^0 to - 15^0 at least 2) All cables on the patient table unit should be concealed in the system 3) Patient table longitudinal and lateral movements to be at least 160 cm and 20 cm respectively 4) Patient table vertical movement to include the range 60 cm to 120 cm from ground 5) X-ray generator longitudinal, vertical and lateral movement to be at least 100 cm, 30 cm and 20 cm respectively 6) Source to image distance should at least include the range 90 cm to 125 cm 7) The tube head must be fully counterbalanced for safe and easy movement 8) Maximum possible patient weight to be at least 150 kg Dust cover for control unit to be supplied 9) Protection against insect and rodent ingress to be incorporated 10) Chest stand / bucky
14	Mobility, portability	Stationary/Fixed
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	Multi-tray Printer for different X-ray film sizes (10 x 12, 14 x 14, 14 x 17, 10 x 8). Protective gear (lead apron minimum of 2 small, 2 medium and 2 Large),Googles (minimum 1 small, 1 Medium and 1 Large),Gonad shield (minimum 2 small ,2 medium, 2 large),neck collar shield(minimum of 1 small, 1 medium ,1 large),

		Gloves (minimum 2 small,2 medium and 2 large).Radiation hazard warning signs to be supplied with the machine.
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	Should come with one set of consumables if indicated, all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
19	Shelf life	Life span of the machine should be indicated in specific document
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).

WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	There should be a guarantee for availability of spare parts for lifetime period after successful commissioning of the machine.
31	Uptime	Uptake time of a minimum of 90%, compensation should be included in case of default.
32	Technical Support personnel	Evidence of locally based technical support personnel, including CVs and relevant qualifications. Should include work permits for foreign personnel.
33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
34	Documentation requirements	Two sets of (hard copy and soft copy) Operating and service manuals (In English) including lists of important spares and accessories with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for sisposal and any probable hazards to the environment and/or community. After- Sale Services Support Documentation to be available
DECOMMISSIONING		
35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of Digital Fluoroscopy Machine

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NAME, CATEGORY AND CODING		
1	Generic name	Digital Fluoroscopy Machine
2	GMDN name	
3	GMDN code	
4	GMDN category	
5	Alternative name/s (optional)	
PURPOSE OF USE		
6	Clinical or other purpose	To enable users to visually and quantitatively evaluate the anatomy and physiological function of various targeted body areas in real-time
7	Level of use	Regional, Zonal, Specialized and National
8	Clinical department/ward	Provides fluoroscopic images of all parts of the body X ray generator and image intensifier can be moved to image required body part
9	Overview of functional requirements	This machine should be able to perform basic abdominal examinations including examination of the liver, spleen, kidneys, reproductive organs and basic obstetric examinations which are determination of number of foetuses, viability, presentation, placental location and amount of liquor.
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	1) kV range at least 40kV to 110kV 2) mA range to include the range 0.5 to 6 mA 3) Focal spot size less than 0.8mm. 4) Adjustable multi-leaf collimator, rotatable ±900 5) Pulsed fluoroscopy option is required 6) Automatic dose control is required to maintain continuously image quality 7) Alphanumeric annotation of images required 8) DICOM compatible image and video storage and transfer required

		9) The system should be capable of storing at least 4000 image frames, with capacity for removable media storage
11	Displayed parameters	Image to be displayed immediately after exposure. Must have display of dose, mA and kV and other relevant parameter.
12	User adjustable settings	The exposure release switch should be detachable, with a cord of at least 5 metres long. Last image hold facility required, displayed on clear, movable screen. Display screen should be on a separate, mobile unit. Display screen to be movable and have adjustable brightness to allow easy viewing in all ambient light levels
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	The tube stand must be fully counterbalanced for rotation in all directions. All cables shall be concealed in the tube system. Display screen should be on a separate, mobile unit
14	Mobility, portability	Non Mobile unit/Fixed.
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	"Must be supplied with protective dust cover at least for control panel To be supplied with adult size protective lead apron"
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	N/A
PACKAGING		
19	Shelf life	N/A
20	Transportation and storage	Specific considerations for transportation and storage must be indicated

21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	There should be guarantee for availability of spare parts for lifetime period after successful commissioning of the machine.
31	Uptake time	Uptake time of a minimum of 90%, compensation should be included in case of default.
32	Technical Support personnel	Evidence of locally based technical support personnel, including CVs and relevant qualifications. Should include work permits for foreign personnel.
33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format

DOCUMENTATION		
34	Documentation requirements	Two sets (hard copy and soft copy) of Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices. IEC 60601-2-33.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of C-Arm Machine

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	
2	GMDN name	Mobile general-purpose fluoroscopic x-ray system, digital
3	GMDN code	37646
4	GMDN category	12 Diagnostic and therapeutic radiation devices
5	Alternative name/s (optional)	Camera, x-ray, fluorographic, cine or spot; C-arm, diagnostic x-ray unit, mobile; X-ray mobile image intensifier
PURPOSE OF USE		
6	Clinical or other purpose	To enable users to visually and quantitatively evaluate the anatomy and physiological function of various targeted body areas in real-time
7	Level of use	District, Regional, Zonal , National, Specialized
8	Clinical department/ward	Radiology/Operating Theatre
9	Overview of functional requirements	Provides fluoroscopic images of all parts of the body X ray generator and image intensifier can be moved to image required body part
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	1) kV range at least 40kV to 110kV 2) mA range to include the range 0.5 to 6 mA 3) Focal spot size less than 0.8mm. 4) Adjustable multi-leaf collimator, rotatable ±90^0 C 5) Pulsed fluoroscopy option is required 6) Automatic dose control is required to maintain continuously image quality 7) Alphanumeric annotation of images required 8) DICOM compatible image and video storage and transfer required 9) The system should be capable of storing at least 4000 image frames, with capacity for removable media storage

11	Displayed parameters	Image to be displayed immediately after exposure Must have display of dose, mA and kV. Warning sign should be displayed.
12	User adjustable settings	The exposure release switch should be detachable, with a cord of at least 5 metres long. Last image hold facility required, displayed on clear, movable screen. Display screen should be on a separate, mobile unit. Display screen to be movable and have adjustable brightness to allow easy viewing in all ambient light levels
PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	1) The tube stand must be fully counterbalanced for rotation in all directions. 2) It must have an articulated arm for imaging with any patient position. 3) All cables shall be concealed in the arm system. 4) Arm space to allow at least 70 cm width and 70 cm depth of target 5) Display screen should be on a separate, mobile unit 6) Cable connection between units to be removable, but locked when connected"
14	Mobility, portability	Mobile
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	Must be supplied with protective dust cover at least for control panel To be supplied with adult size protective lead apron
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	Should come with one set of consumables if indicated, all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.

PACKAGING		
19	Shelf life	N/A
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50^0 C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40^0 C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 2 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	There should be a guarantee for availability of spare parts for lifetime period after successful commissioning of the machine.
31	Uptime	Uptake time of a minimum of 90%, compensation should be included in case of default.
32	Technical Support personnel	Evidence of locally based technical support personnel, including CVs and relevant qualifications. Should include work permits for foreign personnel.

33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
34	Documentation requirements	Two sets of (hard copy and soft copy) Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of Cath Lab

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Cath Lab
2	GMDN name	
3	GMDN code	37807, 10980
4	GMDN category	
5	Alternative name/s (optional)	Cardiac catheterization Laboratory
PURPOSE OF USE		
6	Clinical or other purpose	A system with flat detector technology digital imaging system for diagnostic procedures and interventional vascular procedures, valvoplasty and vascular-angiography, online DSA and cardiovascular electrophysiology.
7	Level of use	Zonal, National ,Specialized
8	Clinical department/ward	Radiology
9	Overview of functional requirements	Diagnostic imaging equipment used to visualize the arteries
TECHNICAL CHARACTERISTICS		
10	Detailed requirements	Single or bi-plane C-arm, all movements of C-arm should have angulations of minimum RAO/LAO + 110^0/-110^0. It should have a floating or floor mounted with asy patient mobility. Should be DICOM compatible. FDA approved system for recording images on DVD/CD.
11	Displayed parameters	Image to be displayed immediately after exposure Must have display of dose, mA and kV. Warning sign should be displayed.
12	User adjustable settings	Should provide a room for doing adjustment of language to be used (multi-Language- English is a must).

PHYSICAL/CHEMICAL CHARACTERISTICS		
13	Components	Table, C-arm, laboratory computer, Cardiac Catheterization monitor system
14	Mobility, portability	Non Mobile.
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	State of art High pressure injector (minimum of one), ceiling suspended radiation protection, one laser network printer, integrated two way communication system between control room and examination room, For radiation protection Protective gear (20 lead aprons, 10 googles, 20 thyroid shields) and ceiling suspended, table mounted radiation protection, computer audio visual system .Integrated two way communication system between control room and examination room. One colour laser network printer of high resolution. Suitable online UPS with 30 min battery backup for complete Cath Lab including cine and fluoroscopy. Emergency lighting should be on UPS.
17	Sterilization process for accessories	Procedures for sterilization must be well elaborated if it is present.
18	Consumables / reagents	Should come with one set of consumables if indicated, all must be labelled with all important information including Manufacturer's name, country of original, Catalogue and Batch Number, Manufacturing and expiring date. Must indicate the storage temperature/Condition and all other required pre-quotations.
PACKAGING		
19	Shelf life	N/A
20	Transportation and storage	Specific considerations for transportation and storage must be indicated
21	Labelling	Specific labelling requirements should be indicated

ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Storage and operating temperatures, resistance to high humidity and/or dust levels should be stated by manufacturer /vendor in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Minimum of 5 Years
28	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	There should be guarantee for availability of spare parts for lifetime period after successful commissioning of the machine.
31	Up time	Should have a minimum of uptime of 90%.In case of failure to comply Compensation should be considered and agreed upon.
32	Technical support personnel	Evidence of locally based technical support, including CVs and related qualifications. Work permits should be provided in case of foreign personnel.
33	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
34	Documentation requirements	Two sets (hard and soft copy)Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for

		calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
35	Life Span	Life span of the machine should be not less than 10 Years
SAFETY AND STANDARDS		
36	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
37	Regulatory Approval / Certification	TAEC, TBS and TFDA
38	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
39	Regional / Local Standards	TAEC, TBS and TFDA
40	Regulations	TAEC, TBS and TFDA

Specifications of a Dental periapical x-ray

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Dental periapical x-ray machine
2	Specific type or variation (optional)	It can mobile unit or mounted on the wall
3	GMDN name	
4	GMDN code	
5	GMDN category	
6	Alternative name/s (optional)	Periapical x-ray machine
PURPOSE OF USE		
7	Clinical or other purpose	Used for diagnosis of dental cavities and check health of alveolar bone surrounding a tooth
8	Level of use	health centre, council hospital, regional referral hospital, zonal and National hospital
9	Clinical department/ward	Designated x-ray room within the dental clinic/department
10	Overview of functional requirements	For intraoral film to be taken, periapical xray film has to be inserted into the mouth and the collimator is directed towards a tooth to be exposed
TECHNICAL CHARACTERISTICS		
11	Detailed requirements	Minimum power of 0.75W, 70Kv 10mA with operation Pictographic control workable reach 72".
12	Displayed parameters	Has a pictographic control and timer that guides radiation exposure
13	User adjustable settings	Has a pictographic control and timer that is adjustable would guide the time of exposure depending on speed of periapical x-ray films

PHYSICAL/CHEMICAL CHARACTERISTICS		
14	Mobility, portability	It can mobile unit or mounted on the wall
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Sterilization process for accessories	Surface disinfectants are used and infection and prevention control are to be observed in course of taking intraoral films
17	Spare parts	Manufacturer must indicate important spare parts which are needed in first year of use.
18	Other components	To be supplied with Daylight developing tank with containers for fixer and developer and water wash. Observation panel with orange filter. Dimensions: Minimum 340x250x310mm. Also has to be supplied with protective gears: lead apron, thyroid collar and gonadal shield
PACKAGING		
19	Shelf life	Life span of the machine should be indicated in specific document
20	Transportation and storage	Machine should be packed in a strong shock absorbing case for safety during transportation. Reagents should all be packed in such a way they should not leak during transportation.
21	Labelling	Machine should be graved with name of manufacturer, serial number and CE-Mark. Item name/description must be printed on the Machine.
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Should be able to be operated at a temperature range of between 18°C to 30°C
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.

25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Two years after installation
28	Maintenance tasks	User manual should specify
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	five years after warranty expire
31	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
32	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
33	Estimated Life Span	Not Less than 10 Years
SAFETY AND STANDARDS		
34	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
35	Regulatory Approval / Certification	TAEC, TBS and TFDA
36	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
37	Regional / Local Standards	TAEC, TBS and TFDA
38	Regulations	TAEC, TBS and TFDA

Specifications of a DENTAL OPG

i	Version No.	One
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	OPG XRAY MACHINE
2	Specific type or variation (optional)	Is a panoramic dental x-ray machine which can be digital or analogue
3	GMDN name	
4	GMDN code	
5	GMDN category	
6	Alternative name/s (optional)	OPG Panoramic x-ray machine
PURPOSE OF USE		
7	Clinical or other purpose	Used for diagnosis of diseases/injuries affecting maxillofacial areas in the head and neck
8	Level of use	Regional referral hospitals, Zonal and Nation hospital
9	Clinical department/ward	X-ray department
10	Overview of functional requirements	The head that emits the x-ray circles behind the head of patient and film circles across the front. Has devices attached to the x-ray machine which holds the head of the patient in place
TECHNICAL CHARACTERISTICS		
11	Detailed requirements	Panoramic Dental X-Ray IMAX touch 2D complete with 2 fixed sensors (one for pan and one for cephalic) instead of standard single moveable sensor (to avoid damage/dropping), to provide high quality panoramic x-ray images, with cephalometric attachment and 2D imaging. Free standing, supplied with the following specifications: Examination Programmes: 1) Panoramic - Adult, Child, Child with deceleration ramp for spine compensation. 2) Sinus Studies

		Anatomic Programmes: 3) Patient size: 3 Choices: Small, medium, large 4) Patient type: 2 Choices: Adult, child 5) Arch shape: 3 Choices: Standard, protrusive, retrusive Generator: 6) Automatic line voltage compensation 7) High voltage: 60/85kVP step 5kV 8) Current 10mA 9) Exposure time: 17 sec panoramic adult, 14 sec panoramic child, 15 sec panoramic child with slow-down ramp for spine compensation. X-Ray Tube: 10) Soft tissue filter enhances profile of the soft tissues of the face on the lateral skull view. Motorized Positioning of the filter can be adjusted to match the contour of any patient. Standard Accessories: 11) Chin support for edentulous patients 12) Reduced height support for sinus 13) Specific support for TMJ analyses 14) 10 Bites 15) 2 Temple clamps & 1 front rest 16) X-Ray push button with extensible cable 17) 10 ear centring pins for cephalic 18) Disposable byte protective sleeves PAN CCD Sensor: 19) Technology: CCD sensor with Caesium Iodide (CsI) scintillator screen 20) Sensor size: 6x146mm 21) Pixel size: 48µm (96µm in 2x2 binning modality) 22) Image matrix: 1536 x 2805 pixels in 2x2 binning modality (Standard panoramic) 23) Sensor resolution: 10.4 lp/mm maximum theoretical 5.2 lp/mm with CTF 60% real (in 2x2binning modality) 24) Gray levels: 4096 (12 bits) in acquisition (A/D converter) 25) Max useful image size: equivalent to a 15x30cm film 26) Quick vision software supplied with software suitable for image acquisition, storage and processing. Mechanical Characteristics: 27) Source to image distance 500mm (19.7") 28) Vertical column movement 850mm (33.5")

		29) Weight 177Kg (Floor mount) 30) Total height max: 2450mm (96.4") 31) Type of installation: floor mount Electrical characteristics: 32) Power supply/voltage: 220-230/240Vac (+10%), 120Vac (+10%) Single phase 33) Frequency: 50Hz/60Hz 34) Current rating: 5A @ 230V/10A @ 108V 35) Power rating: 1.15kVA/1.15kVA
12	Displayed parameters	Pictographic control
13	User adjustable settings	Pictographic guide which enables to adjust various parameters
PHYSICAL/CHEMICAL CHARACTERISTICS		
14	Mobility, portability	Is a free standing x-ray machine
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	X-ray push button with extensible cable-less, chin support for edentulous patient, reduced height support for sinus, 2 temple clamps and 1 front rest, disposable byte protective sleeves
17	Sterilization process for accessories	Be done according manufacturer specifications
PACKAGING		
18	Sterility status on delivery	To be specified - applies to implantable or single-use devices that are delivered sterile
19	Transportation and storage	Be specified by manufacturer
20	Labelling	Specific labelling requirements, all important information must be labelled on the packaging materials and item itself
ENVIRONMENTAL REQUIREMENTS		
21	Context-dependent requirements	Be stated by manufacturer

TRAINING, INSTALLATION AND UTILISATION		
22	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
23	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
24	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
25	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
26	Warranty	Two years after installation
27	Maintenance tasks	User manual should specify
28	Type of service contract	Comprehensive Contract
29	Spare parts availability post-warranty	five years after warranty expire
30	Software/Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
31	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
32	Estimated Life Span	Not Less than 10 Years
SAFETY AND STANDARDS		
33	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
34	Regulatory Approval/ Certification	TAEC, TBS and TFDA

35	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
36	Regional/Local Standards	TAEC, TBS and TFDA
37	Regulations	TAEC, TBS and TFDA

Specifications of a Dental CT Scan		
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ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Dental CT Scan
2	Specific type or variation (optional)	Is a three dimensional dental cone beam CT scan which also offers 2D digital panoramic imaging and one shot cephalometric imaging. It offers greater flexibility to collimate the view to suit the patients
3	GMDN name	
4	GMDN code	
5	GMDN category	
6	Alternative name/s (optional)	Dental Cone Beam CT Scan
PURPOSE OF USE		
7	Clinical or other purpose	Used for diagnosis of TMJ diseases, accurate placement of dental implants, diagnosis of tumours in the maxillofacial region
8	Level of use	Zonal and National Hospital
9	Clinical department/ward	X-ray Department
10	Overview of functional requirements	With Cone beam CT, an x-ray beam in the shape of a cone is moved around the patient to produce a large number of images of the area exposed with x-rays radiations
TECHNICAL CHARACTERISTICS		
11	Detailed requirements	Anode voltage: 60-90kV; Anode current: 1-14mA; Focal spot 0.5mm fixed anode; Image detector- flat panel; Image acquisition-single 200 degree rotation; Typical reconstruction time; 2-25s. It should have client workstation and data base server (3D explorer, data base server, image database).
12	Displayed parameters	A desired field of view is achieved by selecting the program from a streamlined user interface with clear graphics

13	User adjustable settings	A dental cone beam CT Scan has a control panel which is adjustable by using laser beam
PHYSICAL/CHEMICAL CHARACTERISTICS		
14	Mobility, portability	Should be Mobile/Fixed
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories	3D Cross section module, 3D TMJ Module, 3D Implant planning module and DICOM Module
17	Sterilization process for accessories	To be specified by manufacturer
18	Spare parts	Any spare part needed must be specified by manufacturer and come with the manufacturer
PACKAGING		
19	Sterility status on delivery	To be specified - applies to implantable or single-use devices that are delivered sterile
20	Transportation and storage	Be specified by manufacturer
21	Labelling	Specific labelling requirements, all important information must be labelled on the packaging materials and item itself
ENVIRONMENTAL REQUIREMENTS		
22	Context-dependent requirements	Be stated by manufacturer
TRAINING, INSTALLATION AND UTILISATION		
23	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer/vendor
24	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
25	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.

26	User care	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
27	Warranty	Two years after installation
28	Maintenance tasks	User manual should specify
29	Type of service contract	Comprehensive Contract
30	Spare parts availability post-warranty	five years after warranty expire
31	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
32	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
33	Estimated Life Span	Not Less than 10 Years
SAFETY AND STANDARDS		
34	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices.
35	Regulatory Approval / Certification	TAEC, TBS and TFDA
36	International standards	ISO 13485 (Represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
37	Regional / Local Standards	TAEC, TBS and TFDA
38	Regulations	TAEC, TBS and TFDA

Specifications of Simulator

i	Version No.	Five
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Simulator
2	GMDN name	
3	GMDN code	
4	GMDN category	
PURPOSE OF USE		
5	Clinical or other purpose	For treatment planning of cancer patients
6	Level of use	Any Oncology Centre
7	Clinical department/ward	Radiotherapy
8	Overview of functional requirements	This X-ray machine should be able to perform both diagnostic and fluoroscopy and obtain treatment parameters of any cancer patient require external beam irradiation.
TECHNICAL CHARACTERISTICS		
9	Detailed requirements	High frequency generator control of at least 120 KV having both automatic and manually mode, Table made of carbon fibres pellets or wire mesh and able to move vertically, longitudinal and lateral, gantry and collimator able to rotate to at least +/-181 degree, image intensifier of diameter at least 23 cm, hand control, clutch pendent, field size should be at least 35 cm x 35 cm at 80 cm SSD described by wires and blades for shielding. The system should have user password and DICOM 3.0 interface, at least 2 LCD monitors for parameter display, emergency buttons, warning lights, and intercom and cassette holder. Printer with cartilage with option of A4 and A3. Auto set up for gantry, collimator, image intensifier and field size. Battery chargers and Long lasting batteries. Survey meter and UPS

10	Displayed parameters	Should display patient ID, demographic data, gantry angles, collimator angles, field sizes and couch angles.
11	User adjustable settings	kV and mAs
PHYSICAL/CHEMICAL CHARACTERISTICS		
12	Components	2 LCD monitors for display of treatment parameters, 1 LCD monitor to display X-ray image, High frequency Generator, long lasting battery, generator control, 2 computer control and LCD screen at the control console
13	Mobility, portability	FIXED
UTILITY REQUIREMENTS		
14	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
15	Accessories	Hand control, gantry cards, capacitors, resistors, image intensifier cards of all motions, 2 pairs of head rests, base plates and at least 100 thermoplastic masks for adult and paediatrics.
PACKAGING		
17	Shelf life	Life span of the machine should be indicated in specific document
18	Transportation and storage	Specific considerations for transportation and storage must be indicated
19	Labelling	Radiation signs
ENVIRONMENTAL REQUIREMENTS		
20	Context-dependent requirements	Storage and operating temperatures (specify ranges), resistance to high humidity and/or dust levels (specify requirements) - in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
21	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer
22	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance testing should be performed by both Manufacturer and Local Physicist and satisfied by all.

23	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
WARRANTY AND MAINTENANCE		
24	Warranty	Minimum of 2 Year
25	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
26	Type of service contract	Comprehensive Contract
27	Spare parts availability post-warranty	at least 5 years after acceptance testing
28	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
29	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
30	Life Span	Life span of the machine should be at least 15 Years
SAFETY AND STANDARDS		
31	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices., IAEA 2007,
32	Regulatory Approval / Certification	TBS , TAEC and TFDA
33	International standards	IEC 60601-1, IEC 60601-1-7, IAEA 2008, IAEA 2014, IEC 61217
34	Regional / Local Standards	TAEC, TBS and TFDA
35	Regulations	TAEC, TBS and TFDA

Specifications of Cobalt-60 Machine

i	Version No.	Six
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Cobalt-60 Teletherapy Machine
2	GMDN name	
3	GMDN code	
4	GMDN category	
PURPOSE OF USE		
5	Clinical or other purpose	For treatment planning of cancer patients
6	Level of use	Any Oncology Centre
7	Clinical department/ward	Radiotherapy
8	Overview of functional requirements	This machine should be able to deliver radiation dose to any cancer patients in normal and arc mode
TECHNICAL CHARACTERISTICS		
9	Detailed requirements	Table should be made of carbon fibres pellets or wire mesh and able to move vertically, longitudinal and lateral, gantry and collimator able to rotate to at least +/-181 degree hand control, maximum field size should be 35 cm x 35 cm at 80 cm SSD and 40 cm x 40 cm at 100 SSD , at least 2 LCD monitors for parameter display, emergency buttons, warning lights, intercom, at least one of the field size should be able to be operated asymmetrically, each user should have his own password, pause or terminate buttons at the control console. The machine should be able to do remote console control (auto setup) for field size, gantry and collimator. The source activity at initial strength should be not less than 12,000 Ci, upgradable to Multi-leaf collimator and should have motorized wedge.
10	Displayed parameters	Should display gantry angles, collimator angles, and field sizes and couch angles.
PHYSICAL/CHEMICAL CHARACTERISTICS		

11	Components	2 LCD monitors for display of treatment parameters, three lasers and tool box.
12	Mobility, portability	FIXED
UTILITY REQUIREMENTS		
13	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
14	Accessories	Hand control, control box, secondary and primary control board 2 sets of Head rests, base plates and at least 100 thermoplastic masks for adult and paediatrics.
PACKAGING		
15	Shelf life	The life span of the machine should be at least 18 years
16	Transportation and storage	Specific considerations for transportation and storage must be indicated
17	Labelling	Radiation signs
ENVIRONMENTAL REQUIREMENTS		
18	Context-dependent requirements	Storage and operating temperatures (specify ranges), resistance to high humidity and/or dust levels (specify requirements) - in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
19	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer
20	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance testing should be performed by both Manufacturer and Local Physicist and satisfied by all. Commissioning is the responsibility of a Local Physicists. Local physicist should allow the machine for clinical use until passed IAEA dosimetry audit.
21	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.

WARRANTY AND MAINTENANCE		
22	Warranty	Minimum of 2 Year
23	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
24	Type of service contract	Comprehensive Contract
25	Spare parts availability post-warranty	at least 5 years after passing the acceptance testing
26	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
27	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
28	Life Span	Manufacturer should be able to dispose the Cobalt-60 after has been decayed.
SAFETY AND STANDARDS		
29	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices., IAEA 2007,
30	Regulatory Approval / Certification	TBS , TAEC and TFDA
31	International standards	IEC 60601-1, IEC 60601-1-7, IAEA 2008, IAEA 2014, IEC 61217
32	Regional / Local Standards	TAEC, TBS and TFDA
33	Regulations	TAEC, TBS and TFDA.

Specifications of Linear Accelerator Machine

i	Version No.	Seven
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	Linear accelerator Machine
2	GMDN name	
3	GMDN code	
4	GMDN category	
PURPOSE OF USE		
5	Clinical or other purpose	For treatment cancer patients
6	Level of use	Any Oncology Centre
7	Clinical department/ward	Radiotherapy
8	Overview of functional requirements	This machine should be able to deliver radiation dose to any cancer patients at Flattening Filter Free (FFF) and Flattening Filter (FF)
TECHNICAL CHARACTERISTICS		
9	Detailed requirements	Table should be made of carbon fibres pellets and able to move vertically, longitudinal and lateral, collimator able to rotate to at least +/-181 degree hand control, maximum and 40 cm x 40 cm at 100 SSD, at least 2 LCD monitors for parameter display. Emergency buttons, warning lights, intercom, and lasers have to be provided. The machine should have any of the following photon energies 6 MV, 10 MV and 15 MV and electrons of 6 MeV, 9 MeV, 12 MeV and 15 MeV. The manufacture should provide excellent Record and Verify system able to connect with all other unit in the department. The Machine should have radiation leakages not exceeding 0.1%, anti-collision system, multi-leaf collimator of about 120 leaves, dynamic/virtual wedges, supplied with applicators for electrons, chiller, hair handling system, ceiling hooks have to be supplied by manufacturer. The gantry should be able to rotate +/-361 degree. Manufacturer should guarantee of 97% down time for 40

		hours week. Treatment planning system and contouring sections have to be included and connected to the Oncology information system of a manufacturer.
10	Displayed parameters	Should display gantry angles, collimator angles, and field sizes and couch angles.
PHYSICAL/CHEMICAL CHARACTERISTICS		
11	Components	2 LCD monitors for display of treatment parameters, three lasers and tool box.
12	Mobility, portability	FIXED
UTILITY REQUIREMENTS		
13	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
14	Accessories	2 sets of Head rests, base plates and at least 100 thermoplastic masks for adult and pediatrics,2 breast boards, vacuum cushion, tattoo ink, 100 pelvic masks and base plates
PACKAGING		
15	Shelf life	The life span of the machine should be 15 years
16	Transportation and storage	Specific considerations for transportation and storage must be indicated
17	Labelling	rain and glass signs
ENVIRONMENTAL REQUIREMENTS		
18	Context-dependent requirements	Storage and operating temperatures (specify ranges), resistance to high humidity and/or dust levels (specify requirements) - in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
19	Pre-installation requirements	pre-installation is necessary, information must be indicated by manufacturer and hospital
20	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance testing should be performed by both Manufacturer and Local Physicist and satisfied by all. Commissioning is the responsibility of a Local Physicists.

		Local physicist should allow the machine for clinical use until passed IAEA dosimetry audit.
21	Training of user/s	Training of users in operation have to be provided.
WARRANTY AND MAINTENANCE		
22	Warranty	Minimum of 2 Year
23	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
24	Type of service contract	Comprehensive Contract
25	Spare parts availability post-warranty	at least 5 years after passing the acceptance testing
26	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
27	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
28	Life Span	Manufacturer should be able to dispose some parts of the machine component.
SAFETY AND STANDARDS		
29	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices., IAEA 2007,
30	Regulatory Approval / Certification	TBS , TAEC and TFDA
31	International standards	IEC 60601-1, IEC 60601-1-7, IAEA 2008, IAEA 2014, IEC 61217
32	Regional / Local Standards	TAEC, TBS and TFDA
33	Regulations	TAEC, TBS and TFDA.

Specifications of CT-Simulator

i	Version No.	Nine
ii	Date of initial version	January, 2018
iii	Date of last modification	February, 2018
iv	Date of publication	TBD
v	Completed / submitted by	**National ''Standard Medical Radiology and Imaging Equipment Guidelines" Task Force**
NAME, CATEGORY AND CODING		
1	Generic name	CT-Simulator
2	GMDN name	
3	GMDN code	
4	GMDN category	
PURPOSE OF USE		
5	Clinical or other purpose	For diagnosis of different patients and treatment planning of cancer patients
6	Level of use	Any Oncology Centre
7	Clinical department/ward	Radiotherapy
8	Overview of functional requirements	This X-ray machine should be able to perform both diagnostic and fluoroscopy and obtain treatment parameters of any cancer patient require external beam irradiation.
TECHNICAL CHARACTERISTICS		
9	Detailed requirements	The machine should have maximum energy of at least 140 KV and 666 mA. Table made of carbon fibres pellets, with bore of at least 80 cm and supplied with laser. Both concave and flat table insert have to be produced. Emergency buttons, warning lights, intercom and printer with cartilage. Both hand control and auto set up operations should be possible, the manufactures should also provide chiller and UPS. The couch have the capacity of at least 150 Kg, with sag angle of less than 2 degree. It should have latest mode of image reconstruction. Lasers should be included with +-1 mm accuracy for scanning, Field Of View should be more than 60 cm, The CT scanner should provide images with CT number precision and accuracy of (<2%). 12. It should have 1 virtual simulator work station capable of reconstruction planes with sagittal and coronal reconstructions being minimum, It should

		provide at least 64 slice, Image analysis software should be capable of delineating regions of interest for CT numbers, statics, distance rulers, geometric zooms, image subtraction and multiple format viewing, Metal artefact reduction algorithms should be available, It should be DICOM-RT and able to be connected to any Record and Verify System and transfer data to Treatment planning system, Should be able to display good Beam Eye View (BEV) and DRR, X-ray and optical image coincidence within 0.5 mm, X-ray image shift with focal image change within 0.5 mm, X-ray image wander within 0.5 cm. Optical image wander within 0.5 cm
10	Displayed parameters	Should display patient ID, demographic data, and all measurements of patients required for treatment planning.
11	User adjustable settings	kV and mAs
PHYSICAL/CHEMICAL CHARACTERISTICS		
12	Components	2 LCD monitors for display of treatment parameters, 1 LCD monitor to display X-ray image, one simulation work station.
13	Mobility, portability	FIXED
UTILITY REQUIREMENTS		
14	Electrical, water and/or gas supply	Should meet Tanzania Electrical Standards (voltage of between 220-240 V and the standard frequency of 50-60 Hz) with type G adaptor System.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
15	Accessories	Hand control, different types of cards, 2 breast boards, 2 pairs of head rests, base plates and at least 100 thermoplastic masks for adult and paediatrics.
PACKAGING		
16	Shelf life	Life span of the machine should be indicated in specific document
17	Transportation and storage	Specific considerations for transportation and storage must be indicated
18	Labelling	Water, positioning and sensitivity.

ENVIRONMENTAL REQUIREMENTS		
19	Context-dependent requirements	Storage and operating temperatures (specify ranges), resistance to high humidity and/or dust levels (specify requirements) - in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
20	Pre-installation requirements	If there is a need of pre-installation requirements, information must be indicated by manufacturer
21	Requirements for commissioning	Manufacturer/supplier should perform installation, safety and operation checks before handover. Acceptance testing should be performed by both Manufacturer and Local Physicist and satisfied by all. Commissioning should be done by local physicist.
22	Training of user/s	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel should also to be specified and provided.
WARRANTY AND MAINTENANCE		
23	Warranty	Minimum of 2 Year
24	Maintenance tasks	User Manual must specify/ state the maintenance and calibration schedules of the Machine
25	Type of service contract	Comprehensive Contract
26	Spare parts availability post-warranty	at least 5 years after acceptance testing
27	Software / Hardware upgrade availability	Software should be flexible and provide the room for upgrade to add new parameters to be measured by the Machine and report format
DOCUMENTATION		
28	Documentation requirements	Operating and service manuals (In English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance should be provided. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. After - Sale Services Support Documentation to be available
DECOMMISSIONING		
29	Life Span	Life span of the machine should be at least 15 Years
SAFETY AND STANDARDS		
30	Risk Classification	As per ISO 14971:2007- Application of risk management to medical devices., IAEA 2007,

31	Regulatory Approval / Certification	TBS , TAEC and TFDA
32	International standards	IEC 60601-1, IEC 60601-1-7, IAEA 2008, IAEA 2014, IEC 61217
33	Regional / Local Standards	TAEC, TBS and TFDA
34	Regulations	TAEC, TBS and TFDA

Annex III: Guidelines for the Design of X-Ray Rooms in Medical Diagnostic Establishments

1 General/Fluoroscopy/CT scan Rooms

1.1 Room size

1.1.1 General radiographic rooms should be approximately 16m^2 **excluding control cubicle.** There should be sufficient space for a permanently built protective cubicle.

1.1.2 Fluoroscopic rooms should be approximately 25m2 excluding control cubicle

1.1.3 CT scan rooms should be approximately 30m2 excluding protective cubicle

1.1.4. Mammography and dental rooms should be approximately 9 m2 excluding **control cubicle**

1.1.5 Special procedure rooms should be considered individually.

1.2 Doors and Walls

1.2.1 Access doors should be of the sliding type giving better radiation protection.

1.2.2 A clearing of 1.5 m is recommended. The overlap should be 100mm each side.

1.2.3 The doors should be lined with lead sheet of 2 mm thickness.

1.2.4 The walls should be 250 mm (for general radiography) and 300 mm (for CT scan) concrete blocks or 230mm kiln baked solid clay brick or 2 mm lead sheet sandwiched between partitioning, or 115mm brick with 6 mm barium plaster.

1.2.5 Walls should be protected up to a height of 2.2 meter.

1.3 Lead equivalence

Material	Material Thickness (mm)	Lead Equivalent at Tube voltage (mm)	
		100kV	150kV
Brick	115	1.0	0.9
Brick	230	2.4	2.0
Barium Plaster	6	1.0	0.55
Barium Plaster	11		1.0

1.3.1 Barium plasters mix:

1 part coarse barium sulphate
1 part fine barium sulphate
1 part cement

1.3 Ceiling and floors

1.3.1X-ray rooms should preferably be sited on the ground floor of a building.

1.3.2 If the x-ray room is above ground level the thickness of floor slabs should

be of solid concrete slab of density 2.35g/cm3 and must be of 150mm thickness.

1.3.3 Thickness of ceiling slabs, if space above is occupied, should not be less than 100mm.

1.3.4 Single story buildings do not require a ceiling slab.

1.4 Windows and air conditioning units

1.4.1 Windows and air conditioning units should be sited at least 2m above the ground when measured from outside the room. Alternatively access near the window must be prevented effectively.

1.4.2 Windows of upper floor x-ray rooms can be of normal height.

1.5 Control/Protective cubicle

1.5.1 A protective cubicle allowing space for the control panel of the machine as well as personnel should be constructed in the x-ray room.

1.5.2 The cubicle should be located such that attenuated direct scatter radiation originating on the examination table or the erect Bucky do not reach the operator in the cubicle.

1.5.3 The x-ray control for the system should be fixed within the cubicle and should be at least 1.00 m from any open edge of the cubicle wall which is nearest to the examination table.

1.5.4 The cubicle should have at least one viewing window which will be so placed that the operator can view the patient during any exposure.

1.5.5 The size of the window should be at least 60cm x 40cm for general radiography and at least 100 cm x 80 cm for CT Scan.

1.5.6 The minimum height of the cubicle is 2.2m.

1.5.7 The lead equivalence of the wall or panel as well as the protective glass should be at least 2mm

1.5.8 The lead glass and protective wall/material must overlap each other by at least 25mm.

1.6 Change cubicles

1.6.1 Should the change cubicles lead into the x-ray room the doors must be lined with at least 1.5mm lead sheet.

1.6.2 Access doors into the x-ray room must be lockable from the x-ray room side to prevent entrance during radiation exposures.

1.7 Toilet room

1.7.1 For x-ray rooms where special examination procedures that require patient to go toilet during or soon after the examination procedures, there should be a toilet within the vicinity of the x-ray room.

1.7.2 Toilet should have access door into the x-ray room only to prevent entrance during radiation exposures.

1.8 Radiation warning notices/lights/symbol

1.8.1 Warning lights are required at the entrances to x-ray rooms. The light must

be connected to the generator in such a way that it will illuminate only during activation of the tube.

1.8.2 Radiation warning notice, Radiation symbol and instructions must be displayed at all entrances to x-ray rooms.

1.8.3 Instructions for female patients who are or might be pregnant should be displayed at all entrances to x-ray rooms as well as patients waiting area for radiology facility.

1.9 Offices

To avoid staff congestion in the examination room or control cubicle, office rooms such as radiographer's office, radiologist's office should be available.

2 Special procedure rooms

General guidelines for special procedure rooms:

2.1 Computed tomography

2.1.1 Doors - lined with 2mm lead sheet

2.1.2 Walls - The walls should be 300 mm concrete blocks or 230mm kiln baked solid clay brick or 2 mm lead sheet sandwiched between partitioning or 115 mm brick with 4 mm barium plaster.

2.1.3 Warning lights, Radiation symbol, warning notice and instructions are required outside all entrances to CT rooms. The light must be connected to the generator in such a way that it will illuminate only during activation of the tube.

2.2 Cath Lab

2.2.1 Doors - lined with 2mm lead sheet

2.2.2 Walls - The walls should be 230mm kiln baked solid clay brick or 250 mm concrete or 2mm lead sheet sandwiched between partitioning or 115mm brick with 6mm barium plaster

2.2.3 Protective glass - The lead equivalence of the viewing window must be at least 2 mm of lead

2.2.4 Warning lights, radiation symbol, warning notice and instructions are required outside all direct entrances to Cath labs. The light must be connected to the generator in such a way that it will illuminate only during activation of the tube

2.3 Panoramic & Cephalometric Dental Unit

2.3.1 Doors - lined with 1mm lead sheet

2.3.2 Walls - 115mm brick or 230 mm concrete blocks or 1mm lead sheet

2.4 Intra-Oral Dental X-ray Unit

Shielding requirements for the door depend on size of the room and position of the x-ray machine from entrances. In case where partition walls are used, lead plate with dimensions 1m x 1m and 1mm thick, should be attached to the wall. The height of the plate should be 0.5m above the floor in order to fully intercept

radiation from the primary beam. This is required only in cases where for example the waiting room is adjacent to the X-ray room with patients sitting at distances less than ±3m from the tube head of the X-ray unit.

2.5 Fixed C-arm (or mobile used as a fixed unit)

2.5.1 Doors - lined with 1 mm lead sheet
2.5.2 Walls - 115 mm brick or 1 mm lead sheet

2.6 Mammographic Unit

Shielding requirements for the door will depend on the position of the x-ray machine from entrance and the size of the x-ray room.

Annex IV: Members of the Task Force which Developed these Guidelines

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