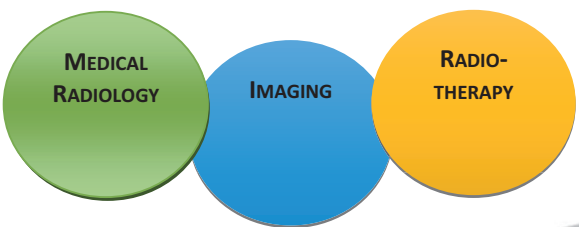
THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER. ELDERLY AND CHILDREN

# NATIONAL STANDARDS FOR MEDICAL RADIOLOGY AND IMAGING SERVICES

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National Standards for Medical Radiology and Imaging Services

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## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **ADDS** | Assistant Director Diagnostic Services |
| **Ag. ADDS** | Acting Assistant Director Diagnostic Services |
| **ALARA** | As Low As Reasonably Achievable |
| **AMO** | Assistant Medical Officer |
| **APHFTA** | Association of Private Health Facilities in Tanzania |
| **BMC** | Bugando Medical Centre |
| **CD** | Communicable Diseases |
| **CDR** | Control of Documents and Record |
| **CEM** | Control of Equipment |
| **CFE** | Control of Facility and Environment |
| **CM** | Corrective Maintenance |
| **CP** | Control of Personnel |
| **CPP** | Control of Processes and Procedures |
| **CPR** | Cardiopulmonary Resuscitation |
| **CQI** | Continuous quality improvement |
| **CR** | Computed Radiography |
| **CRBSOR** | Control of radiation and bio-safety and other risks |
| **CS** | Control of Services |
| **CSSC** | Christian Social Services Commission |
| **CT** | Computed Tomography |
| **CUHAS** | Catholic University of Health and Allied Sciences |
| **DAP** | Dose Area Product |
| **DCS** | Director of Curative Services |
| **DEXA** | Dual Energy X Ray Absorptiometry |
| **DR** | Digital Radiography |
| **HCT** | Health Care Technology |
| **HCTS** | Health Care Technical Services |
| **HLV** | Half layer value |
| **HRIS** | Head Radiology and Imaging Services |
| **IEC** | International Electrotechnical Commission |
| **KCMC** | Kilimanjaro Christian Medical Centre |
| **KCMUCO** | Kilimanjaro Christian Medical University College |
| **kV** | kilo voltage |
| **LBD** | Light Beam Diaphragm |
| **LINAC** | Linear Accelerator |
| **LSC** | least significant changes |
| **mA** | milliamperes |
| **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 Professional Council |
| **MRIS** | Medical Radiology and Imaging Services |
| **MSD** | Medical Store 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) |
| **ORCI** | Ocean Road Cancer Institute |
| **PACS** | Picture archiving and communication system |
| **Pb** | Lead |
| **PET** | Positron Emission Tomography |
| **PET-CT** | Positron Emission Tomography- Computed Tomography |
| **PPE** | Personal Protective Equipment |
| **QCT** | Quantitative Computed Tomography |
| **QUS** | Quantitative Ultrasound |
| **RFA** | Radio Frequency Ablation |
| **ROMPs** | Radiation Oncology Medical Physicists |
| **ROs** | Radiation Oncologists |
| **RTs** | Radiation Therapists |
| **SMREG** | Standard Medical Radiology Equipment Guideline |
| **TAEC** | Tanzania Atomic Energy Commission |
| **TBS** | Tanzania Bureau of Standards |
| **TMDA** | Tanzania Medicines and Medical Devices Authority |

## FOREWORD

Medical Radiology and Imaging covers the medical imaging investigation of a client to provide information for the diagnosis, prevention and treatment of disease and conditions. In recent decades, medical radiography has experienced new technological revolution and advances, and, therefore, Tanzania as a country must embrace these new technologies to improve the quality of health care delivery. Clinical advantages of these services are enormous and affect critical decision making at every stage of client management. However, they could cause harm to clients, operators and environment; and may represent unnecessary cost to health care systems in the country if the quality provided is less than optimal and/or not regulated. Hence, to assess the quality and safety of medical radiology and imaging services and to represent a method for monitoring of quality standards, basic accreditation programme needs to be implemented in the country for medical radiology and imaging services. These Standards reflect the expectations of good radiology and imaging services from the point of view of providers as well as that of *primary* (client), *secondary client* (referrer), *tertiary* (operator) and *quaternary* (environment).

National accreditation committee for medical radiology and imaging services establishes and maintain accreditation Standards for diagnostic radiology and imaging services with main goal to improve diagnostic accuracy and safety. These Standards along with Standards for calibration of testing laboratories by TBS are applicable to all diagnostic centres in the country.

The current National Standard Guidelines for Radiology and Imaging Services (2004) reflected the professional judgement of the expert panels of registered medical radiology and imaging professionals and TAEC, who have seen the need for revision of this document to embrace these new technological changes, which are appropriate for the country.

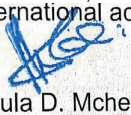
There are twenty-five (25) Standards that will govern the operations of MRIS in the country; which are contained in the following sections: Control of Services with two (2) Standards; Control of Processes and Procedures with three (3) Standards; Control of Facility and Environment with two (2) Standards; Control of Personnel with three (3) Standards; Control of Equipment with four (4) Standards; Control of Documents and Records with five (5) Standards and Control of Radiation, Bio-Safety and Other Risks with six (6) Standards.

The Standards have been categorised into: **Management requirements** section, which comprises the ***Standard*** statement and objective elements, where each ***Standard*** statement addresses one aspect necessary for the provision of the service; and **Technical requirements,** which comprises brief details why that ***Standard*** statement is considered to be important and guidelines to explain the objective element is provided.

These Standards have been developed, adapted and customized by the panel of radiology and imaging professionals and related cadres. The standards have also been subjected to a full public consultation exercise prior to their finalisation. The

process of formulating the Standards is evolutionary and dynamic, and shall be kept updated as and when required.

On behalf of the MoHCDGEC, I would like to take this opportunity to thank all panel of experts, consumers of MRIS, government agencies, public and private institutions, who in one way or the other contributed time and resources to develop this very important document, that will guide MRIS offering in health facilities towards national and/or international accreditation.



Prof. Mabula D. Mchembe
**PERMANENT SECRETARY (HEALTH)**

## ACKNOWLEDGMENT

This National Standards for Medical Radiology and Imaging Services (NSMRIS) is a product of dedicated efforts and contributions of Government, Implementing Partners, Non-Government Organisations, Institutions, Programmes and Individuals towards strengthening and improving the quality of medical radiology services in Tanzania. The MoHCDGEC through the Directorate for Curative Services (DCS) - the Diagnostic Services Section (DSS) would like to acknowledge all stakeholders who in one way or another contributed to not only revise the overdue National Standards Guidelines for Medical Radiology and Imaging Services (2004) but to develop NSMRIS. In particular, the MoHCDGEC would like to thank the Head of MRIS; and all technical experts and individuals for their active participation and constructive input and comments provided in developing this Standard.

In particular, the MoHCDGEC would like to acknowledge the MIS_draft_standard (1) www.qcin.org/nabh/pop/Medical_Imaging_Services/downloadpdf.php?...MIS...(India, and the Australia and New Zealand Radiology Standards: Standards of Practice for Diagnostic and Interventional Radiology Version10.2-2017, which were adapted and/or customized in parts to suit the Tanzania context towards standardizing its MRIS.

Our appreciations go to Director of Curative Services Dr Grace Elias Magembe for steering up the whole process, Mr Gerald Mrema for field coordination; and to all individuals who participated in developing the NSMRIS as per list of participants (**Table 1**); and to David Ocheng, the TWG Facilitator for successfully leading in guiding the development, editing, formatting and finalising the developed Standards. Further appreciations go to the support personnel and the management of VETA Morogoro for offering meeting facility.

Finally, I wish to recognize MoHCDGEC for providing financial and technical support for the meetings for development and finalisation of the Standards.

Prof. Abel N. Makubi
CHIEF MEDICAL OFFICER

**SCOPE OF SERVICE**

| Type of MRIS | Applications |
|---|---|
| **Radiography** | • General Radiography<br>• Dental Radiography<br>• Computerised Radiography<br>• Digital Radiography<br>• Fluoroscopy Guided investigative procedures<br>• Guided Interventional Procedures<br>• Angiocardiography (Cath-Labs) setups for vascular radiographic/radiological/ interventional procedures |
| **Mammography** | • Diagnostic and Mammography Screening<br>• Mammography Interventional Procedure |
| **Ultrasound** | • General Ultrasound<br>• Vascular Doppler flow imaging<br>• Cardiac ultrasound (Echocardiography)<br>• Musculoskeletal ultrasound<br>• Small parts ultrasound<br>• Interventional ultrasound procedures<br>• Radiotherapy planning |
| **Bone Mineral Densitometry** | • Dual Energy X Ray Absorptiometry (DEXA) |
| **Magnetic Resonance Imaging (MRI)** | • Diagnosis<br>• Intervention<br>• Functional MRI<br>• Radiotherapy planning |
| **Computed Tomography (CT) Scan/Simulator** | • Diagnosis<br>• Intervention<br>• Radiotherapy planning |
| **Nuclear Medicine** | • General Nuclear Medicine<br>• Positron Emission Tomography (PET)/PET-CT<br>• SPECT<br>• Functional Nuclear medicine |
| **Miscellaneous** | • Radio Frequency Ablation (RFA)<br>• Picture archiving and communication system (PACS)<br>• Tele radiology |

**REFERENCE DOCUMENTS**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3. https://iahs.muhas.ac.tz/index.php/features/school-of-radiography;
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13. Basic Standards for Health Facilities, Vol. I-IV, 2017;
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15. Miundo ya Utumishi ya Kada chini ya Wizara ya Afya na Ustawi wa Jamii 2009
16. TMDA act of 2003 (amended 2019);
17. MRIPC Act of 2007;

**TERMS AND DEFINITIONS AS APPLIED TO THIS DOCUMENT**

| Terms | Applicable Definition |
|---|---|
| Accessory | Refers to anything, which can be added to something else in order to make it more useful, versatile, or attractive. |
| Authorised personnel | Refers to a registered professional by MRIPC who has the necessary training and mandate to perform MRIS and/or report findings |
| Biomedical Engineer | Refers to a professional using engineering principles to the fields of biology and health care |
| Brachytherapy | Refers to 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 | Refers to a medical imaging equipment 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 | Refers to any item, which is regularly used with the equipment and is either replaced often or disposed off. |
| CT Simulator | Refers to 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 | Refers to a scintillation *camera* or Anger *camera*, is a device used to image *gamma* radiation emitting radioisotopes, a technique known as scintigraphy. |
| Ionizing radiation | Refers to radiation consisting of particles, X-rays, or gamma rays with sufficient energy to cause ionization in the medium through, which it passes |
| Linear Accelerator | Refers to a device most commonly used for external beam radiation treatments for clients 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 client's tumour |
| Medical Physicist | Refers to a professional using a variety of analytical, computer-aided and bioengineering techniques in their work such as radiotherapy, X-ray imaging, ultrasound, tomography, radiography, nuclear magnetic resonance imaging and lasers. |
| Non-Ionizing radiation | Refers to 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 |

## THE STANDARDS

National Standards for Medical Radiology and Imaging Services document, herein referred to as the ***Standards*** is grouped into ***seven*** operational areas as follows:

1) CONTROL OF SERVICES (CS);
2) CONTROL OF PROCESSES AND PROCEDURES (CPP);
3) CONTROL OF FACILITY AND ENVIRONMENT (CFE);
4) CONTROL OF PERSONNEL (CP);
5) CONTROL OF EQUIPMENT (CE);
6) CONTROL OF DOCUMENTS AND RECORDS (CDR);
7) CONTROL OF RADIATION, BIO-SAFETY AND OTHER RISKS (CRBOR).

**Management requirements** comprise of the ***Standard*** statement and ***Objective*** elements.

Each ***Standard*** statement addresses one aspect necessary for the provision of the intended service.

A list of objective elements under each **Standard** indicate the structures and processes necessary to deliver the Standard statement, whereas the term 'MRIS' refers to 'Medical Radiology and Imaging Services' in Tanzania.

**Technical requirements** comprise brief details why that ***Standard*** statement is considered to be important and guidelines to explain the objective element is provided thereafter.

**Medical Radiology and Imaging Services (MRIS)** participating in accreditation will be expected to provide three types of evidence:

a) Approved documents that identify relevant service policy, protocols and/or strategies and set out how the service plans to deliver each standard statement and objective element therein;
b) that the Medical Imaging service is implementing these policies, protocols and/or strategies;
c) that the service is monitoring its performance regularly (frequency of monitoring and any targets are set by the service) in the implementation of its policies, protocols and strategies.

# NATIONAL STANDARDS FOR MEDICAL RADIOLOGY AND IMAGING SERVICES IN TANZANIA

## 1. INTRODUCTION AND BACKGROUND

Vision 2025 and the Health Sector Strategic Plan IV (2015-2020) of the United Republic of Tanzania aims to achieve a high quality of livelihood for its citizens, peace, stability and unity, good governance, a well-educated society, and a competitive economy capable of producing sustainable growth and shared benefits. The Government aims to improve the health of all Tanzanians, especially those at risk, and to increase the life expectancy, by providing quality health services that meet the needs of the population. The government with stakeholders will strengthen and supervise diagnostic services, increase availability of diagnostic equipment and strengthen corrective and preventive maintenance system for diagnostic equipment.

Medical Radiology and Imaging Services (MRIS) cover investigations of clients that provide imaging information for diagnosis, prevention, and treatment of disease; through assessment of health at National, Zonal, Specialized, Regional Referral, District, health centre, dispensary or diagnostic centre. It includes conventional radiation based on diagnostic radiography as well as a wide variety of specialised techniques including ultrasound, Doppler, Bone densitometry, CT scan, MRI, PET-CT, LINAC, radiotherapy, nuclear medicine among others.

These services are essential for client care and therefore must meet the needs of all client and the clinical personnel responsible for the care of those clients. These services include arrangement for requisition, choice of correct (most informative and cost effective) imaging techniques, client information, client consent, client preparation, client identification, performance of imaging procedures, interpretation, reporting and advice regarding the result, in addition to the consideration of safety and ethics in diagnostic imaging services.

A medical radiology and imaging centre and/or provider must maintain certified standard of services (statutory or otherwise); as well as, strive for continuous quality improvement (CQI) in the quality of services they provide.

Close collaboration with clinical teams, verification of result and correct maintenance and calibration of the equipment are also a part of quality management system in the department of medical imaging.

Standards for Accreditation for MRIS at national and international levels are thus developed and formulated, they are divided into seven (7) sections containing twenty-five (25) Standards. These Standards provide general assurances pertaining to all diagnostic MRIS. Specific assurances for X-ray, Fluoroscopy, Ultrasound, CT scan, MRI and Nuclear Imaging, Oncology and radiotherapy are then provided in the document.

## 2. 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 DCS.


**FIGURE 1: MRIS Hierarchy**

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

## 3. History of MRIS in Tanzania

In 1940, missionary hospitals and Ocean Road Hospital started providing X-ray services for diagnostic purposes in Tanzania. After the second World War (1946) many hospitals were built and/or upgraded and were given X-ray facilities. In the periods before and shortly after independence X-ray units were operated by Europeans and Asians who left the country thereafter. At the beginning of our independence (1961) a few Tanzanians (by then Tanganyika) were sent to London to train as Radiographers. A few years later other Tanzanians were trained in Germany, England and Kenya. They graduated as Radiologists and Radiographers. Radiotherapy services started in the late 1960s. The services of medical physicists and radiation oncology started in 1970s at Muhimbili Hospital (now Muhimbili

National Hospital). Training programs for local radiographic/imaging personnel were established in the country to fill vacancies as follows:

a) Radiographic auxiliaries school at Princess Margaret Hospital now Muhimbili National Hospital in Dar es Salaam from 1964 to 1971;
b) Courses were between three and six months;
c) Radiographic Auxiliaries School was transferred to KCMC in 1972. The course was of one year full time training up to 1979;
d) Radiographic Auxiliaries School was upgraded to two years training and transferred from KCMC to Bugando Medical Centre in 1980;
e) Entry qualification for the above training was Primary School Leavers;
f) School of Radiography started in 1972 at Muhimbili National Hospital to date - Its entry qualifications are form four school leavers and Radiographic Assistants;
g) Tanzania Association of Radiographers (TARA) was formed in 1976 -Through TARA, the National Radiation Commission was established in 1983;
h) Second School of Radiography started in October 2003 at Bugando Medical Centre by phasing out the previous School of Radiographic Assistants;
i) Also, the Government has been trying to improve the quality of the services from time to time by equipping the hospitals with required equipment. Thus, now all the hospitals (District, Regional, Referral and the National Hospitals) are now equipped with new and modern Imaging and Ultrasound equipment;
j) Radiotherapy services started in the late 1960s. The services of medical physicists and radiation oncology started in 1970s;
k) Tanzania Radiology Society was formed in 1990s.

These services are essential for client care and therefore must meet the needs of all client and the clinical personnel responsible for the care of those clients. These services include arrangement for requisition, choice of correct (most informative and cost effective) imaging techniques, client information, client consent, client preparation, client identification, performance of imaging procedures, interpretation, reporting and advice regarding the result, in addition to the consideration of safety and ethics in diagnostic imaging services.

## 4. RATIONALE

National Standard Guidelines for Medical Radiology and Imaging Services (2004) is now overdue for revision. Basic standards for health facilities of Nov. 2017. Radiography services start from Dispensary level to national hospital. Radiology stand-alone facility are registered under registered medical radiology and imaging professionals. Number of radiography personnel per each health facilities. Current Standard medical radiology and imaging equipment guidelines. Rapid technological changes in radiography industry. Lack of supervision tool guide. To improve and sustain quality of medical imaging services in Tanzania.

## 5. CURRENT STATUS OF MRIS PRACTITIONERS

| *Professional Types* | *No.* | *%* |
|---|---|---|
| *Radiographers* | 1006 | 75.01% |
| *Radiologists* | 111 | 8.27% |
| *Radiotherapists* | 75 | 5.59% |
| *AMO Radiology* | 57 | 4.25% |
| *Radiographic Assistant* | 53 | 9.95% |
| *Medical Oncologists* | 20 | 1.49% |
| | | |
| *Nuclear Medicine Technologists* | 2 | 0.14% |
| *Medical Physicists* | 5 | 0.37% |
| *Nuclear Medicine Physicians* | 2 | 0.14% |
| *Sonographers* | 10 | 0.74 |
| ***Total*** | **1,341** | **100%** |

**Source:** MRIPC 2020

## *Management requirements*

**This section, comprises the Standard statements and their objective elements for quality and competence of MRIS in the United Republic of Tanzania**

# 6 MANAGEMENT REQUIREMENTS

## 6.1 CONTROL OF SERVICES

Control of Services (CS) has two (2) Standards as follows:

### 6.1.1 CS 1 STANDARD

### MRIS SHALL DELIVER THE SERVICE FROM POINT OF REFERRAL TO DISCHARGE

#### *6.1.1.1 Objective elements*

MRIS ensures:

a) roles and responsibilities of each section of service delivery are defined;

b) that protocols for radiographic modalities and processes are specified, implemented and monitored;

c) turnaround time to manage radiography pathways from referral to discharge from the MRIS is defined, displayed/disseminated, implemented and monitored;

d) justification, scheduling and prioritisation of referrals according to client conditions and urgency of diagnosis;

e) that alternative radiographic modalities are offered if considered in accordance with radiation risk or emerging newer clinical practices in collaboration with the referrer.

### 6.1.2 CS 2 STANDARD

### MRIS SHALL DELIVER SERVICES THAT ARE CLIENT FOCUSED

#### *6.1.2.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for personnel managing each section of service to the client (information, delivering of service and care, safety, privacy) are defined;

b) that the information about specific examination/procedure/treatment is available to clients and attendant/care giver/guardian in relevant format and language;

c) that informed consent is obtained from the client/care giver/guardian by designated personnel in relevant format and language;

d) safety of clients, care giver and public and their belongings while in the facility;

e) safe movement of the client within, to and from the facility is available whenever required;

f) privacy and dignity of the client without any discrimination;

g) continuity of care of client in collaboration with the referrer;

*(…….. that radiographical and treatment information shall be correlated with relevant clinical, laboratory and previous radiographical details to provide complete and comprehensive information about the client condition)*

h) that client feedback is obtained, collated, analysed and used as guide to future improvement in service delivery system.

### 6.2 Control of Processes and Procedures

Control of Processes and Procedures (CPP) has three (3) Standards as follows:

#### 6.2.1 CPP 1 STANDARD

## MRIS SHALL PROVIDE OPTIMAL QUALITY DIAGNOSTIC AND THERAPEUTIC PROCEDURES

#### *6.2.1.1 Objective elements*

MRIS ensures:

a) clear definitions of roles and responsibilities of personnel for management of each area of image acquisition, image quality and therapeutic procedures are defined in accordance with their training and experience;

b) that diagnostic and therapeutic protocols for all procedures are developed, communicated, implemented and monitored.

#### 6.2.2 CPP 2 STANDARD

## MRIS SHALL PROVIDE QUALITY CLINICAL AND TECHNICAL REPORTS

#### *6.2.2.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for personnel who report images/radiotherapy planning are defined in accordance with their training and experience;

b) that the structure, content and format of reports are consistent as developed and communicated to the relevant personnel;

c) the quality, accuracy and verification of reports and amendments within specified TAT;

d) communication of reports to primary and secondary clients within specified TAT.

#### 6.2.3 CPP 3 STANDARD

### MRIS SHALL PROVIDE PROPER MANAGEMENT OF MEDICINES AND CONTRAST MEDIA

#### *6.2.3.1 Objective elements*

MRIS ensures:

a) roles and responsibility for the personnel in the area of medicines and contrast media are defined in accordance with their training and experience;

b) that protocols for prescription, purchase, storage, supply, handling, labelling and administration of medicines and contrast media are defined, communicated, implemented and monitored;

c) coordination between relevant teams/departments/organizations regarding the administration of medicines and contrast media to the clients and corrective action taken in case of adverse drug/contrast reaction;

d) that clients at higher risk of adverse reactions to specific medicines and contrast media are defined and accordingly managed.

## 6.3 CONTROL OF FACILITY AND ENVIRONMENT

Control of Facility and Environment (CEF) has two (2) Standards as follows:

#### 6.3.1 CFE 1 STANDARD

### MRIS SHALL PROVIDE PROPER MANAGEMENT OF THE FACILITY

#### *6.3.1.1 Objective elements*

MRIS ensures:

a) roles and responsibilities of management of each section of facility are defined,

b) proper and adequate signage to guide the client, personnel and relatives to and within the facility;

c) that design and construction of the facility shall be in accordance with the legal requirements pertaining to the equipment and the services offered;

d) that design and construction of the facility supports specific needs of the client population (including children and those with particular needs) and personnel;

e) the management of space to facilitate efficient working, comfort, safety and hygiene;

f) that all the areas used by service are well-maintained in respect to hygiene, cleanliness, ventilation, water and electricity supply, sewage and waste disposal;

g) that the access to particular areas is restricted according to specific needs and risks with proper barrier and signage's;

h) ensure effective separation between neighbourhoods in, which there are incompatible activities.

### 6.3.2 CFE 2 STANDARD

## MRIS SHALL PROVIDE PROPER MANAGEMENT OF FACILITY ENVIRONMENT

#### *6.3.2.1 Objective elements*

MRIS ensures:

a) that the protocols to assess and manage specific risks related to internal and external incident are defined, communicated, implemented and monitored;

b) that the facility is designed to minimise the risk of injury and occupational disease;

c) that the facility has process to monitor, control and record environmental conditions as required by relevant specification;

d) strategic planning process addresses the operational and physical organisation of the facility and takes account of changing needs;

e) a documented strategic plan with a facility-agreed timeframe (not greater than five (5) years) that identifies the ongoing development needs of the facility in order to maintain or improve the service provided.

## 6.4 CONTROL OF PERSONNEL

Control of Personnel (CP) has three (3) Standards as follows:

### 6.4.1 CP 1 STANDARD

## MRIS SHALL MANAGE AND SUPPORT PERSONNEL TO DELIVER SERVICES

#### *6.4.1.1 Objective elements*

MRIS ensures:

a) roles and responsibilities of personnel to deliver the service are defined, communicated and consistently applied;

b) that the appropriate skill mix and personnel complement exist for specific areas of task;

c) that agreed contracts of employment, job descriptions, appraisals or personnel development reviews are conducted for all personnel;

d) that employment policies and procedures and any changes to the service are communicated and consistently applied within defined time frame;

e) that management of the personnel service provision and working hours are defined;

f) to support personnel in managing stress, conflicts and grievance in a fair and judicious manner;

g) that personnel are able to comment/feedback in confidence regarding service and considered while planning future changes in improving quality of services.

### 6.4.2 CP 2 STANDARD

## MRIS SHALL BE DELIVERED BY COMPETENT PERSONNEL

#### *6.4.2.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for the management of personnel competence is defined;

b) that policies and procedures for selection and recruitment of personnel are implemented and monitored;

c) that there are registers of current registration/license to practice for all applicable personnel;

d) that record and check of qualification, training, experiences and registration status of personnel are maintained and verified by relevant authority;

e) that all the personnel are supported to maintain necessary skills knowledge and levels of competence and are encouraged to develop new skills.

#### 6.4.3 CP 3 STANDARD

### MRIS SHALL PLAN AND DEVELOP SERVICE AND WORKFORCE REVIEW

#### *6.4.3.1 Objective elements*

MRIS ensures:

a) that roles and responsibilities for each area of review, planning, improvement, workforce planning and development are defined;

b) involvement of feedback and comments from clients, personnel, users and others are encouraged by the management while reviewing and planning service and development;

c) that workforce development initiatives are defined, communicated and evaluated;

d) the timing frequency of content and delivery of relevant education and personnel training are defined;

e) that policies pertaining to the service review to support and monitor personnel retention and succession planning are defined;

f) effective and fair management of grievance and complaints from clients by competent and authorised personnel.

## 6.5 CONTROL OF EQUIPMENT

Control of Equipment (CE) has four (4) Standards as follows:

#### 6.5.1 CE 1 STANDARD

### MRIS SHALL PROCURE AND INSTALL APPROPRIATE EQUIPMENT

#### *6.5.1.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for each area of the procurement and management of all equipment are defined;

b) that the policies and protocols for the procurement of all equipment and consumables are defined, implemented and monitored;

c) new diagnostic and therapy equipment, and any significant or major modification to same, is installed, acceptance tested and commissioned for clinical use by qualified personnel. To ensure accurate and safe clinical usage, any newly commissioned equipment requires TAEC and IAEA accredited or equivalent recognised by the regulator dosimetric inter-comparison, where applicable.

### 6.5.2 CE 2 STANDARD

## MRIS SHALL MAINTAIN APPROPRIATE OPERATION AND WORKING OF THE EQUIPMENT

#### *6.5.2.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for each area of the operation and working of all equipment and machines are defined;

b) that calibration, validation and performance of equipment and machines are defined, implemented and monitored

c) that proper documentation and record of calibration of the equipment are maintained;

d) that operation of equipment and machines are defined, implemented and monitored.

### 6.5.3 CE 3 STANDARD

## MRIS SHALL MAINTAIN APPROPRIATE PLANNED PREVENTIVE MAINTENANCE AND REPAIR OF THE EQUIPMENT TO DELIVER INTENDED SERVICE

#### *6.5.3.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for PPM and repair of the equipment are defined;

b) that maintenance and service contracts of all equipment are drawn and kept updated;

c) that equipment downtime, breakdown and faults are monitored and managed and that safety warnings, alerts and recalls are circulated and acted upon within specified time;

d) that records pertaining to maintenance and repair of equipment are maintained according to pre-set guidelines/protocols.

#### 6.5.4 CE 4 STANDARD

### MRIS SHALL MAINTAIN APPROPRIATE PLAN FOR REPLACEMENT OF EQUIPMENT FOR CONTINUATION AND EXPANSION OF SERVICES

#### *6.5.4.1 Objective elements*

MRIS ensures:

a) that roles and responsibilities for replacement of existing equipment; and planning for new equipment for expansion of service are defined;

b) that equipment replacement and/or up grading is planned and implemented in accordance with relevant authority.

## 6.6 Control of Documents and Records

Control of Documents and Records (CDR) has five (5) as Standards as follows:

#### 6.6.1 CDR 1 STANDARD

### MRIS SHALL MANAGE INFORMATION FOR PERSONNEL, CLIENTS, EQUIPMENT, FACILITY AND OTHERS

#### *6.6.1.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for preparation, production, dissemination, supervision, retention, and evaluation/monitoring of client and personnel information data created in acceptable format and language;

b) that the mechanisms for obtaining feedback from personnel, client and others for revision and updating of information data are maintained and implemented;

c) that document related to all the legislative and statutory requirements related to personnel, facility, equipment and risk monitoring are maintained;

d) that data base for personnel are maintained, reviewed, and updated in a prescribed time.

### 6.6.2 CDR 2 STANDARD

## MRIS SHALL MAINTAIN AND UPDATE MAINTENANCE REPORTS OF ALL EQUIPMENT

#### *6.6.2.1 Objective elements*

MRIS ensures:

that all the records pertaining to purchase, verification, license, operation, maintenance and disposal of equipment are maintained.

### 6.6.3 CDR 3 STANDARD

## MRIS SHALL MAINTAIN RADIOGRAPHIC / RADIOLOGICAL IMAGES AND REPORTS

#### *6.6.3.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for safeguarding of radiographic / radiological images, records and reports of clients are clearly stipulated and maintained;

b) that the protocols and procedures to define duration, format, content and confidentiality of client's records are maintained and implemented.

### 6.6.4 CDR 4 STANDARD

## MRIS SHALL MAINTAIN AND UPDATE ALL RECORDS AND DOCUMENTS PERTAINING TO PERIODICAL AUDIT, QUALITY CONTROL AND QUALITY IMPROVEMENT OF ALL PROCESSES AND SERVICES

#### *6.6.4.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for maintenance and updating of all records and documents pertaining to periodical audit, quality control and quality improvement of all processes and services are defined;

b) that the protocols and procedures for periodical audit, quality test, verification and validation are maintained and implemented;

c) that the protocols and procedures for quality indicators, quality assurance and quality improvements are defined.

### 6.6.5 CDR 5 STANDARD

## MRIS SHALL MAINTAIN, INTEGRATE AND PROVIDE SAFETY, CONFIDENTIALITY AND RETRIEVABILITY OF ALL THE RECORDS

#### *6.6.5.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for maintenance, integration, safety, confidentiality and retrievability of all the records are defined;

b) that the protocols and procedures for identification, verification and classification of records and documents are clearly stipulated in computerized format;

c) that the protocols and procedures for confidentiality and retrievability of records are implemented and monitored.

## 6.7 Control of Radiation, Bio-Safety and Other Risks

Control of Radiation, Bio-Safety and Other Risks (CRBS) has six (6) Standards as follows:

### 6.7.1 CRBOR 1 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE RISKS ASSOCIATED WITH RADIOGRAPHICAL PROCEDURES

#### *6.7.1.1 Objective elements*

MRIS ensures:

a) roles and responsibilities for all level of risk management in all areas of radiography are defined;

b) that the radiation doses are as low as reasonably achievable for all clients (ALARA principle) especially for children, women of child bearing age, pregnant women, children and clients undergoing repeated exposures;

c) that system in place to define, assess and manage risks of occupational exposure to ionising radiation and record for the same is maintained;

d) that facility, environment and equipment design and performance will be kept in accordance with reduction of radiation risk to the minimum;

e) that risks of acoustic output and exposure times are defined, assessed and managed,

f) minimum exposure to different types of electromagnetic fields, radiofrequencies and any noise;

g) pre-entry safety checks for all clients, personnel and others to minimise risk associated with MRI;

h) that all the ancillary equipment and machines used in MR examination area are approved for MR environment;

i) that the risk associated with use of ablative and therapeutic devices during interventional procedures are defined, assessed and managed;

j) that the incidents and errors pertaining to risks associated with radiographical procedures are reported, investigated, recorded, analysed, acted upon and used to guide and plan the future action.

### 6.7.2 CRBOR 2 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK OF INFECTION TO PERSONNEL, CLIENT AND PUBLIC

#### *6.7.2.1 Objective elements*

MRIS ensures:

a) roles, responsibilities and accountabilities regarding infection control are defined;

b) that protocols and procedures to identify, assess, manage and minimise the risk of infection to personnel, client and public are defined, implemented and monitored;

c) that protocols and procedures to identify, assess, manage and minimise the risk of infection to the client with contagious and communicable disease are defined, implemented and monitored;

d) that the protocols and procedures for decontamination of equipment, machines and environment are defined, implemented and monitored;

e) that the incidents and errors pertaining to risks of infection are reported, investigated, recorded, analysed, acted upon and used to guide and plan the future action.

### 6.7.3 CRBOR 3 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK ASSOCIATED WITH HAZARDOUS SUBSTANCES AND MATERIALS TO PERSONNEL, CLIENT AND PUBLIC

#### *6.7.3.1 Objective elements*

MRIS ensures:

a) roles, responsibilities and accountabilities for the control of hazardous substances and materials are defined;

b) that protocols and procedures to identify, assess, manage and minimise the risk associated with hazardous substances and materials to personnel, client and public are defined, implemented and monitored;

c) that the protocols and procedures to manage and dispose of waste are defined, implemented and monitored;

d) that appropriate PPE and equipment and machines required to decontaminate and manage exposure to hazardous substances are available and maintained;

e) that the incidents and errors pertaining to risks associated with hazardous substances and materials are reported, investigated, recorded, analysed, acted upon and used to guide and plan the future action.

### 6.7.4 CRBOR 4 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK OF VIOLENCE AND AGGRESSION TO PERSONNEL, CLIENT AND PUBLIC

#### *6.7.4.1 Objective elements*

MRIS ensures:

a) roles and responsibilities regarding risk of violence and aggression are defined;

b) that protocols and procedures to identify, assess, manage and minimise the risk of violence and aggression to personnel, client and public are defined, implemented and monitored;

c) that the protocols and procedures for support and counselling of clients, personnel and others who have been involved in an incident of violence and aggression are defined, implemented and monitored;

d) that the incidents and errors pertaining to risks of violence and aggression are reported, investigated, recorded, analysed, acted upon and used to guide and plan the future action.

### 6.7.5 CRBOR 5 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK ASSOCIATED WITH FIRE, ELECTROCUTION AND OTHER DISASTER TO PERSONNEL, CLIENT, VISITORS; AND TO FACILITY AND ENVIRONMENT

#### *6.7.5.1 Objective elements*

MRIS ensures:

a) roles and responsibilities regarding risk associated with fire, electrocution and other disaster are defined;

b) that protocols and procedures to identify, assess, manage and minimise risks associated with fire, electrocution and other disaster to personnel, client and public are defined, implemented and monitored;

c) that the protocols and procedures to define, access and manage general health and safety risks are defined, implemented and monitored;

d) that there are adequate safety equipment and machines available and personnel are aware and trained in handling emergency/disaster;

e) that the incidents and errors pertaining to risk associated with fire, electrocution and other disaster are reported, investigated, recorded, analysed, acted upon and used to guide and plan the future action.

### 6.7.6 CRBOR 6 STANDARD

## MRIS SHALL MAINTAIN A DOSIMETRY SYSTEM CONSISTENT WITH NATIONAL AND INTERNATIONAL STANDARDS

#### *6.7.6.1 Objective elements*

MRIS ensures that:

a) dose measurement ensures compliance of the dose delivery with the treatment Prescription;

b) radiation dose delivered by all clinical treatment units is consistent with dosimetry codes of practice recommended by regulatory authority;

c) facility governance acknowledges and supports safe practice, quality improvement, innovation and the safe and considered introduction of new technologies;

d) risk to clients, personnel and the public is managed in accordance with the relevant TAEC requirements and legislation for the respective jurisdiction, national standards and the principles of safe practice;

e) management plan for radiation safety defines responsibilities and delegations of all persons involved with radiation exposures and management of radiation safety;

f) radiation oncology facility maintains a register of equipment, personnel and safety notifications relating to radiation safety and ensures notification and communication as required by the regulatory authority;

g) appropriate equipment and resources are available for radiation survey measurement in both routine checks and emergency situations;

h) there is regular review of all radiation safety procedures and physical verification to confirm;

i) radiation therapy facility participates in an incident monitoring program, continuing radiation safety.

## *Technical Requirements*

**This section, comprise brief details why that Standard statement is considered to be important and guidelines to explain the objective element is provided thereafter**

# 7 TECHNICAL REQUIREMENTS

## 7.1 CONTROL OF SERVICES

### 7.1.1 CS 1 STANDARD

## MRIS SHALL DELIVER THE SERVICE FROM POINT OF REFERRAL TO DISCHARGE

MRIS shall ensure following services for delivering of service from point of referral to discharge:

#### *7.1.1.1 Receiving the Requisition and Referral*

a) There shall be written request from the referring physician or other appropriately licensed health care providers, which shall provide appropriate information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation;

b) The documentation of referring physician shall include:

   b.1. Completed request for a specific procedure to be performed on a client to aid diagnosis, therapeutic planning and treatment;

   b.2. Relevant clinical information and history (including provisional diagnosis and history of allergies/reactions to contrast);

   b.3. Details of any previous images performed for the same illness;

   b.4. Female clients of child bearing age shall be referred with the LMP history.

#### *7.1.1.2 Scheduling the Examination*

a) Radiographical procedures used shall normally be those previously developed and accepted as standard practice. Selection of the procedure to be performed shall be those requested by the referring physician;

b) If the referring clinician does not specify the procedure, the examination will be postponed and the referrer will be required to provide the information;

c) There shall be a documented TAT for radiographical processes from point of registration to discharge and to be made available in a clinically appropriate, manner to personnel, client and others;

d) Reasons for failure to meet the TAT shall be communicated to the clients and referrers;

e) There shall be documented procedure for urgent and significant unexpected emergency clients.

#### *7.1.1.3 Reception, Registration and movement of client*

The service shall ensure that there are written policies and protocols for reception, registration and client flow within the facility and within documented TAT.

#### *7.1.1.4 Client Information and Consent Regarding Procedure, Payment and Report*

a) MRIS shall ensure that the practices allow referrers and clients the opportunity to communicate with the personnel, access the facility to clarify request or clarification on results and register complaints on standard of service, while keeping confidential information related to referrer and clients;

b) Fee information shall be documented, displayed and provided to the client /care giver on request, prior to the examination;

c) Client informed written or verbal consent shall always be obtained prior to the examination/procedure. For invasive procedures or procedures that employ use of contrast media written consent shall be obtained;

d) All the clients shall have access to appropriate information on radiographical procedures to make an informed decision;

e) In general, MRIS shall provide following information specific to radiographical services provided:

   e.1. Provision of useful information to the client in relation to the examination procedure;

   e.2. Advising the client of the risks associated with the examination procedure;

   e.3. Obtaining of client's consent;

   e.4. Obtaining information from the client in relation to any medication or medical condition which may complicate examination;

   e.5. Questioning of client in relation to claustrophobia and advising the client of available options to reduce complications;

   e.6. Provision for post examination care of the client, where necessary;

   e.7. Seeking feedback from the client in relation to the quality of services provided.

#### *7.1.1.5 Client Identification*

a) There shall be procedure to ensure that every report is correctly identified to the client. If required, client identification and detail must be verified;

b) Records relating to any given client shall be uniquely identified through all stages of procedure;

c) Such records include worksheets, report, films etc. Identification may be achieved by use of:

c.1. Unique MRIS number/ Clients Medical record number or;

c.2. Client's full name (three names shall be provided – **Given Name, Middle Name and Surname**) or;

c.3. Date of birth.

**NOTE: Discrepancies on the request/referral forms shall be documented and remedial action implemented.**

#### *7.1.1.6 Client Preparation*

There shall be documented protocols and procedures for client's preparation before the examination procedure.

#### *1.1.1.7 Client Sedation*

**If Required**

There shall be documented protocols and procedures for identification of clients who require sedation including those for conscious sedation in the absence of anaesthetist.

#### *1.1.1.8 Performance of Examination*

**Protocols for Radiographic / Radiological Pathways and Processes**

a) There shall be documented Protocols describing the performance of all the procedures/examinations performed by the practice personnel in that particular medical radiographic / radiological service;

b) In general, these protocols shall include all necessary information including that for:

b.1. Client management;

b.2. Radiographic procedures appropriate to specific clinical indications;

b.3. Deviation from standard radiographic protocols;

b.4. Operation of the equipment;

b.5. Quality control procedures;

b.6. Necessary remedial action e.g. adverse event management;

b.7. Records to be kept (such as amount of contrast given, films, exposure factors/dose used);

b.8. Emergency evacuation of the facility;

b.9. Safety issue;

b.10. Issuing of results.

#### *7.1.1.9 Client Care During and After Procedure*

a) MRIS shall allow referrers and clients the opportunity to communicate with personnel, access the premises to clarify requests or clarification on results and register complaints on standard of service, while keeping confidential information relating to other referrers and clients;

b) There shall be provision for communication 'to and from the client during the process of performing a radiographic / radiological procedure on a conscious client. The verbal communication could be direct or through a system of microphones, speakers, receiver systems or bell or light methods. The client must be explained the use of such equipment before the procedure, and encouraged to use the same when required;

c) An unconscious or sedated or anaesthetised client shall be continuously monitored as per protocols by skilled personnel during the procedure for parameters such as pulse, respiration, oxygen saturation, level of consciousness etc.;

d) Post procedure monitoring of clients for effect of sedation/anaesthesia; and for development or resolution of effects of contrast/medication reaction shall also be performed as per set protocols in specified aftercare area by skilled, authorised personnel;

e) Availability of resuscitation and monitoring equipment and medication in emergency trolley shall be compulsory for all MRIS in areas where such procedures are routinely performed;

f) Availability of protocols for management of contrast media reactions and extravasation in all examination rooms;

g) Quality improvement programme must be established under supervision of a registered radiographic / radiological personnel with added training in Quality Assurance to monitor relevant issues in client care during and after procedure. This shall include recording of adverse events during client examination and system malfunction.

#### *7.1.1.10 Interpretation and Reporting*

**See 7.6 Control of Documents and Records**

#### *7.1.1.11 Dispatch of Report and Advice Regarding the Result*

a) MRIS shall ensure that the interpretation of images and reporting is done by authorised personnel within the specified timeframe in a specified format and language;

b) The report along with image records shall be signed and dispatched to the referrer; or handed over to the client/authorised person within a specified period;

c) Unexpected findings requiring urgent attention shall be addressed as per set protocols and procedures of urgent reporting and record for the same shall be appropriately maintained;

d) Regular review or audits shall be performed on the time between the performance of the procedure and issuing of written report.

#### *7.1.1.12 Discharge of Client*

a) MRIS shall have documented policies and procedure regarding discharge of the client after the procedure;

b) The client shall be given complete information about the procedure, its outcome and instructions regarding time and procedure for procurement of written report / radiographic / radiological record at the time of discharge from radiology.

### 7.1.2 CS 2 STANDARD

## MRIS SHALL DELIVER SERVICES THAT ARE CLIENT FOCUSED

MRIS shall ensure that service delivery is client focused and respectful of the individual client and their specific requirements. This is achieved through provision of appropriate information and support for clients and carers with due regards to differences in culture, religion, age and other factors;

a) Roles and responsibilities of each person coming in contact with the client shall be defined by the management. All measures to actively promote client privacy, dignity and security shall be in place. MRIS shall ensure that clients are involved in decision about their examination and procedures through the process of obtaining of valid and informed consent;

b) The language and format of written and verbal communication with the client and their carers shall be such that they can understand;

c) Client safety during client handling, transport, stay and performance of procedures shall be given uppermost priority.

#### *7.1.2.1 Practice Developed Procedures*

a) There may be instances where standard protocols/procedures will need to be amended to accommodate the particular diagnostic needs of the client according to presenting features and/or clinical details e.g. Instead of abdominal, trans-vaginal ultrasound in obstetric radiography, opposite hip scanned for DEXA due to past surgery. In such cases, MRIS shall have record and/or request form of the reason(s) duly signed by radiographer/ radiologist;

b) Any adoptions of procedure/examination shall have benefit to the client over those currently in use.

#### *7.1.2.2 Clients Complaints and Grievances*

a) Client shall be given opportunity to express any grievance they may have towards the service/service personnel. Their complaints shall be recorded by the authorised person. Immediate cognisance and remedial action must be initiated, if such is warranted. The same shall also be recorded and reported;

b) Follow-up action taken to improve services so as to prevent recurrence of similar instances in future shall also be recorded and reported to management, and the complainant;

c) Confidentiality and respect shall be evident in all instances of client complaint/grievance handling by the MRIS personnel.

### 7.2 CONTROL OF PROCESSES AND PROCEDURES

#### 7.2.1 CPP 1 STANDARD

## MRIS SHALL PROVIDE OPTIMAL QUALITY DIAGNOSTIC AND THERAPEUTIC PROCEDURES

MRIS shall guarantee that all images are attained in accordance with agreed protocols, by competent personnel, working within their defined scope of practice and provide essential image characteristics;

a) The radiographic / radiological protocols shall address general population as well as provide for specific modifications in case of children or adult with special requirements;

b) The SOP shall be developed in collaboration with radiography personnel and any relevant professionals who work closely with radiography such as physicists and biomedical engineers. They shall be endorsed by hospital management and communicated to those performing the examinations. MRIS personnel in charge

shall ensure uniform implementation of the protocols and monitor any deviations. The SOP shall be reviewed, modified and updated at predefined regular intervals;

c) The quality of images shall be verified by trained and registered Radiology and Imaging personnel, in terms of its technical nature and also for the therapeutic and diagnostic content relevant to the client condition;

d) A non-compliance if any, occurs shall be documented and recorded. It includes variation from documented management requirements (e.g. Use of uncontrolled Documents, unacceptable quality control results, unacceptable equipment calibration) and procedural management (wrong client identification on the image or issued report). The event can occur at any stage of medical radiographic / radiological service, from the time that the client presents at the practice through to the issue of the final report;

e) These non-compliances shall be identified by complaints from practicing personnel or external referrer, internal audits, management review among others. And there shall be an appropriate record of action taken to rectify the problem;

f) There shall be a record of documented procedures that the personnel are aware of the action to be taken. These documents shall also need to define who is responsible for overseeing the remedial action required and ensuring that it has been successful in resolving the problem;

g) A record of remedial action taken shall be maintained, for example steps taken in response to unacceptable equipment calibration results, re-imaging of a client due to unacceptable image quality and re-issuing of report due to incorrect client details;

h) The corrective action taken shall be monitored to ensure effectiveness and record for the same shall be retained for future references and audit.

### 7.2.2 CPP 2 STANDARD

## MRIS SHALL PROVIDE QUALITY CLINICAL AND TECHNICAL REPORTS

#### *7.2.2.1 Reporting TAT*

a) There shall be a documented timeline for written report to be made available in a clinically appropriate, manner;

b) Urgent and unexpected findings shall be communicated by the radiographer/radiologist directly to the referrer or an appropriate representative as per established standard using rational means.

#### *7.2.2.2 Image Reports*

a) All studies shall be interpreted and reported by a trained and registered personnel. The written and confirmed report duly signed by the aforementioned personnel shall be sent to the referrer or other health care provider providing the clinical follow-up;

b) The reports shall be interpreted in presence of adequate clinical and laboratory findings to guide appropriate diagnosis;

c) These reports shall be sealed handed over to the client/person authorised by the client/guardian in case of minor for delivery to the referrer. In centres with digital hospital management system, reports shall be uploaded into the system by trained and registered personnel for use by the referrer and/or other physicians in the management of the client;

d) A record shall be kept of the time and date of report, recipient of report and the reporting personnel as well as the person who releases the reports to the client/guardian in case of minor;

e) There shall be documented protocol and procedures for the following:

   e.1. Mechanism and authority for the release of urgent results;

   e.2. Provision of advice in relation to follow-up studies or additional examination;

   e.3. Release of result by telephone, fax or other electronic means;

   e.4. Release of result to the client;

   e.5. Confidentiality of results and other client records;

   e.6. Retention, storage and retrieval of records and reports.

f) Radiographic reports shall in general include the following:

   f.1. A title e.g. radiographic / radiological report;

   f.2. Name and address of the medical radiological centre, and location/site where the procedure(s) was performed if different to the practice address on the report;

   f.3. Referrer name;

   f.4. Date of issue of report;

   f.5. Unique identification of client i.e. Full name (Given Name, Middle Name and Surname) and date of birth or medical record number;

   f.6. Date of radiographic procedure;

   f.7. Identification of the modality used;

   f.8. Radiographic procedure(s) result, and where appropriate, the unit of measurement.

f.9. Where necessary, an explanation of any modifications to the procedure as identified in the practice's procedure manual;

f.10. Adverse reaction to the radiopharmaceuticals administered;

f.11. Incidental observations or findings not specifically related to the examination requested;

f.12. Opinion and interpretation where relevant;

f.13. Correlation with previous radiographic details/other relevant clinical details if available;

f.14. Advice in relation to follow up studies or additional examinations;

f.15. Name and signature of reporting trained and registered Radiology and Imaging personnel;

g) Notification of preliminary results by telephone to the referrer, prior to issue of the final diagnostic report;

h) Seeking second opinions for difficult to interpret or ambiguous images or for images arising from highly specialised examination/procedures;

#### *7.2.2.3 Amendment to Report*

When a report is found to be invalid after issuing, the original report shall be withdrawn and replaced by a report which is clearly identified as a replacement report.

### 7.2.3 CPP 3 STANDARD

## MRIS SHALL PROVIDE PROPER MANAGEMENT OF MEDICINES AND CONTRAST MEDIA

MRIS shall ensure that medicines including controlled medicines and contrast media are prescribed, prepared and administered safely to reflect legal requirements. It shall also reflect differences between adults and children:

a) All medicines and contrast media shall be stored as per manufacturer's instructions'

b) There shall be checklists to identify client at higher risk to develop adverse reaction to administered drug and contrast media;

c) Client receiving drug and contrast media shall be informed of possible adverse reactions, receive continuous care and monitoring during and after the administration;

d) All adverse reaction shall be dealt with, efficiently and effectively, as per set guidelines by trained personnel/teams;

e) Information about adverse reaction shall be recorded and included in clients' report.

## 7.3 Control of Facility and Environment

### 7.3.1 CFE 1 STANDARD

## MRIS SHALL PROVIDE PROPER MANAGEMENT OF THE FACILITY

#### *7.3.1.1 Roles and Responsibility*

The medical radiography facility shall have a process to provide radiographic services, which shall be maintained free of hazards for clients, personnel and public, and at the same time providing quality services for effective diagnosis.

#### *7.3.1.2 Location and Surroundings*

a) The roles and responsibilities for each area of the facility and environment management shall be defined according to area service or service managed;

b) Proper signage in language(s) and format in accordance with the served population shall ensure guidance to and within the facility of the medical radiology services;

c) The medical radiology service shall be located in such a way that it is easily accessible to clients, service providers and ambulances. The ground floor is the most suitable to accommodate and it shall have adequate space for future expansion away from traffic, which is also away from open sewerage, drain, public toilet or similar unhygienic surroundings;

d) The medical radiology building shall be constructed in such a way that it permits operation of various medical radiographic / radiological services under strict sterile conditions; with comfort and efficiency of operation and easiness of movements;

e) MRIS building shall adhere to legal standards as per design recommendations, and there shall be no deviation of the design of the building from that authorised as per plan;

f) Building shall be designed for dimensions as per guidelines laid down as per approved designs;

g) Rooms shall be well lit, ventilated and screened (mesh), whenever necessary;

h) The walls and floor of the rooms, where radiographic equipment is placed shall be smooth, washable and capable of being kept clean. Drains shall be of adequate size and directly connected to sewer;

i) There shall be adequate method of biomedical waste management and excreted radioactive substances to prevent any hazards therein;

j) Temperature and humidity control for client comfort as well as for the machine to perform as per specifications;

k) MRIS shall be designed to minimise the risk of injury and occupational disease;

l) The MRIS shall be designed to protect from psychological, biological, chemical, radiation or any other recognised hazards;

m) Provision for the safe emergency exit from the site shall be maintained and signage to indicate them shall be in place.

#### *7.3.1.3 Accommodation of facility*

Medical radiology and imaging centres shall be expected to adequately provide for at least the following items relevant to accommodation:

a) Clients waiting area with washrooms;

b) Client interview and preparation area;

c) Client change cubicles. These shall be Lead (Pb) lines with 3mm commercially available Pb, if the cubicles are within the X-ray examination room;

d) Facility for the secure storage of clients' belongings;

e) Radiation Protection Signage in relation to restricted areas;

f) Equipment console and operating areas;

g) Separate area for stabilizers/transformers/UPS system for back-up;

h) Area for resuscitation equipment and medication in emergency trolleys;

i) Film viewing and reporting areas/ workstations;

j) Facilities for performance of administrative duties;

k) Sluice and washing room;

l) Store and record room;

m) Areas for storage of equipment accessories and consumables;

n) Provision for storage of equipment related to fire safety and other safety measures. In addition to the above general accommodation requirements, the concerned facility is expected to provide for at least the following specialist items relevant to the accommodation of particular equipment in that facility:

#### *7.3.1.4 General Radiography*

a) Building plan as per the guidelines of TAEC;

b) Area of the room shall be adequate depending on the size/type of equipment installed; Construction shall be designed as per TAEC guidelines;

c) Mandatory MOHCDGEC/TAEC certification for facility and installation;

d) Doors for X-ray room shall be shielded as per TAEC guidelines for radiation safety;

e) Signage and red warning light indicator identifying restricted area for radiation safety;

f) Facility for loading, uploading, developing and processing of X-ray film; the darkroom shall be fitted with an exhaust fan and be coloured as per TAEC guidelines;

g) Area for special radiation procedures, fluoroscopy with TV;

h) Area for barium preparation;

i) Attached bathroom and toilet facility for clients;

j) Availability of emergency trolley (crush cart); with emergency medicine tray and oxygen cylinder.

#### *7.3.1.5 Ultrasound*

a) Signage in accordance with MoHCDGEC/TAEC Standards;

b) Size of the facility shall be adequate with adequate ventilation, temperature and humidity control;

c) Private examination rooms and provision of screens/shields/covers providing proper privacy for clients undergoing 'sensitive' examination;

d) Facility shall provide presence of at least one chaperone during procedures on a client with different gender during 'sensitive' examination;

e) Emergency recovery facility for interventional procedures like FNAC, drainage of abscess and collection;

f) Facility for obtaining printouts and hard copies of the image;

g) Separate toilet facility.

#### *7.3.1.6 Mammography*

a) Facilities for changing for clients;

b) Size of the facility shall be adequate with adequate ventilation, temperature and humidity control;

c) Facilities for examination and reporting areas;

d) Facility shall provide presence of at least one chaperone during procedures on a client with different gender.

#### *7.3.1.7 Bone Mineral Densitometry*

a) Size of the facility shall be adequate with adequate ventilation, temperature and humidity control;

b) Equipment area for conducting examination;

c) Image processing and reporting area.

#### *7.3.1.8 Nuclear Medicine*

a) Radioisotope preparation and storage facilities Hot Lab;

b) Radiopharmaceutical administration area;

c) Radioactive Scanning facilities with dimensions approved by TAEC;

d) Delay Tanks and separate Ward if I-131 therapy for thyroid ablation dose are given;

e) Safe waiting area for the attendants and visitors to the department with toilet/washroom;

f) Client recovery area;

g) Personal decontamination facilities;

h) Controlled access to radiographic room and appropriate signage;

i) Device for communication with the client being examined and treated;

j) Sedation and general anaesthesia facilities;

k) Client toilet facilities specific to nuclear medicine with drain straight to the municipal drain without mixing with the hospital drain;

l) Availability of emergency trolley (crush cart) with medicine and oxygen cylinder.

#### *7.3.1.9 MRI*

a) Construction and design to minimise effects of magnetic and RF Fields on the surroundings;

b) The wooden doors to MRI scan shall possibly be painted with fire retardant paint. (Check paint for magnetic properties before use);

c) Definition of 5 gaussline;

d) Controlled access to the radiographic / radiological room and appropriate signage informing for client and personnel about magnet sensitive objects/devices;

e) Temperature and humidity control for computing equipment with monitoring on daily basis;

f) Indications for detection of helium boil-off and/or oxygen depletion;

g) Apparatus for communication with the client during examination e.g. speaker-receivers, bell, light system, cameras for client observation;

h) Sedation, GA facility and MR compatible equipment for client monitoring during sedation;

i) Pipelined gases and suction facilities;

j) MR compatible anaesthetic equipment for resuscitation and emergency trolley;

k) The MRI room shall have a fire alarm system, checked weekly;

l) Availability of emergency trolley (crush cart) with medicine and oxygen cylinder.

#### *7.3.1.10 CT Scan*

a) Controlled access to the imaging room and appropriate signage, symbols and red warning light indicators for restricting access;

b) Doors of CT scan shall be shielded as per TAEC guidelines for radiation safety;

c) Temperature and humidity control for computing equipment;

d) Devices for communication with the client during examination e.g. speaker-receivers, bell, light system, cameras for client observation;

e) Rooms must have adequate number of PPE for radiation protection;

f) Client monitoring equipment during sedation;

g) Pipelined gases and suction facilities;

h) Availability of emergency trolley (crush cart) with medicine and oxygen cylinder;

i) CT room shall have a fire alarm system, checked weekly

j) Availability of emergency trolley (crush cart) with medicine and oxygen cylinder.

#### *7.3.1.11 MRIS Interventional Procedures*

a) The angiography suit/image guiding suite of sufficient size;

b) Availability of sterile/autoclaved clothing, equipment and material;

c) Facility for hand wash and change of clothing for personnel and client;

d) Emergency switches on the machine in the examination room;

e) Rooms shall have sufficient number of PPE for radiation protection;

f) Equipment and medical record storage space, consultation space, and rest room;

g) Equipment and facility for decontamination/sterilization/storage/supply of equipment and material;

h) Room with client support system;

i) Adequate space for operating team and support personnel;

j) Admitting privileges for critical or elective clients;

k) Pipelined gases and suction facilities;

l) Relevant statutory requirements (**Section 3** refers);

m) It shall be responsibility of each practice to ensure compliance with legislative requirements

n) Availability of emergency trolley (crush cart) with medicine and oxygen cylinder.

#### 7.3.2 CFE 2 STANDARD

### MRIS SHALL PROVIDE PROPER MANAGEMENT OF FACILITY ENVIRONMENT

MRIS shall ensure that the management is able to respond appropriately to any major external or internal incidents that risk the safety of the personnel, client, relative, facility or the equipment. The continuity of care and service to client during the time of incident management shall be ensured;

a) The occurrence of such incidents and the response shall be analysed and findings disseminated to those concerned. The information thus gathered shall be used for implementation, improvement and modification in procedures/plan to augment future safety;

b) MRIS shall have process to minimize and respond to environmentally related risk to the health and safety of employees. This includes immunization.

## 7.4 Control of Personnel

#### 7.4.1 CP 1 STANDARD

### MRIS SHALL MANAGE AND SUPPORT PERSONNEL TO DELIVER SERVICES

MRIS shall be responsible to ensure personnel are competent, skilled and supported to maintain improve and widen the scope or their competencies through suitable opportunities for training and education provided to them.

### *7.4.1.1 RADIOLOGIST/NUCLEAR MEDICINE PHYSICIAN/CLINICAL ONCOLOGIST*

#### 7.4.1.1.1 Roles and responsibilities

a) The radiologist has knowledge of the basic technology of image acquisition, transmission, manipulation, processing, archival, retrieval, and display including the strength weakness and limitations;

b) The incumbent shall be knowledgeable in how to optimally utilise the image viewing equipment;

c) The interpreting radiologist must be familiar with the principles of radiation hazards and radiation protection to both the client and the radiological personnel;

d) The interpreting radiologist shall be responsible for the quality of images being reviewed and understands the elements of quality control;

e) Ensuring appropriate quality assurance procedure are performed including quality control of instruments, procedure, radiopharmaceuticals and blood and blood products;

f) Preparation and maintenance of the procedure manuals

#### 7.4.1.1.2 Nuclear Medicine

a) Trained and registered personnel shall be responsible for the quality and safety of all procedure performed by the personnel performing at the unit;

b) Ensure personnel are properly trained and competent;

c) Ensure appropriate quality assurance procedure are performed including quality control of instruments, procedure and radiopharmaceuticals;

d) Ensure preparation and maintenance of the procedure manuals;

e) The personnel shall make a formal assessment of the client prior to the administration of unsealed sources taking into account clients overall medical history and treatment given;

f) Select the radionuclide and dose for each individual client based on that formal assessment.

### *7.4.1.2 RADIOGRAPHER*

In general, radiographer is a trained medical personnel who uses radiation (ionizing and non-ionizing) in the imaging of internal human body for diagnosis and treatment of diseases and disease processes.

a) client preparation;

b) client positioning;

c) operating the equipment;

d) image evaluation and pattern recognition;

e) follow safety measures to prevent unnecessary exposure to radiation, to themselves, their client, and their co-workers;

f) Adjustment and maintenance of medical radiographic equipment;

g) Monitoring of inventory levels, ordering for materials and supplies in accordance with established policies and procedures;

h) Knowledge of the policies, procedures and practices necessary to conduct the normal function of a specific section, unit, or work area;

i) Quality Assurance procedures;

j) Client record keeping;

k) Provide assistance to the radiologist/physician performing special procedures including and ensuring completeness of the consent form before the start of procedures.

### 7.4.2 CP 2 STANDARD

## MRIS SHALL BE DELIVERED BY COMPETENT PERSONNEL

a) MRIS shall ensure that the management of personnel is effective, fair, consistent, supportive and in full compliance with current best practice;

b) There shall be defined policies and procedures for employment and applied consistently.

#### *7.4.2.1 Radiologist*

Radiologist or nuclear medicine physician shall be a trained and registered personnel.

#### *7.4.2.2 Technical Personnel*

a) Radiographer shall be a trained, registered and with practicing license;

b) Along with general qualification the technical personnel shall also have following specific requirements:

   b.1. Image acquisition technology;

   b.2. Image processing protocols;

   b.3. Proper selection of examination specific option;

   b.4. Image evaluation and pattern recognition;

b.5. Radiation dose indicators;

b.6. Client safety procedures.

*All technical personnel working in medical radiographic / radiological services shall undergo continuous professional development (CPD) training.

### *7.4.2.3 Nurses*

#### 7.4.2.3.1 General

a) Each nurse shall be a trained and registered personnel with practicing license;

b) Nurses involved in MRIS shall have adequate awareness and experience in such practices;

c) Training experience in resuscitation;

d) MRIS shall ensure that there is adequate training in cardiopulmonary resuscitation (CPR), appropriate management of contrast reaction and the use of resuscitation equipment;

e) There shall be designated personnel member at each site to ensure resuscitation equipment, accessories and medicines, are present in state of readiness.

### *7.4.2.4 Anaesthetist, Biomedical Engineer/Technician and Medical Physicist*

MRIS shall ensure that the services of the above named trained and registered professionals are available when and where necessary.

### *7.4.2.5 Ancillary Personnel*

a) There shall be appropriate personnel at the reception, store, quality management, security, ambulance etc.;

b) Along with general qualification radiologist shall also have following specific requirements:

7.4.2.5.1 General Radiography

Radiologist shall have working knowledge of digital imaging services including all from acquisition to display that affect the image quality and that have the potential for producing artefacts.

7.4.2.5.2 Mammography

Each radiologist shall interpret mammograms on a regular basis during their training.

7.4.2.5.3 Ultrasound

Each trained and registered personnel must have experience and knowledge in performing and interpreting diagnostic ultrasound images.

7.4.2.5.4 Bone Mineral Densitometry

The Radiologist shall have knowledge and understanding of:

a) Bone structure, metabolism, and osteoporosis;
b) Process of QCT data and image acquisition;
c) Reporting parameters and criteria for accurate and precise comparison of serial changes;
d) Alternative bone density techniques, such as central and peripheral DXA, RA and QUS etc.;
e) Reporting and making clinical recommendation about incidental findings on QCT images such as mass lesions, adenopathy etc.

7.4.2.5.5 Nuclear Medicine

a) Trained and registered personnel working in the field of nuclear medicine must hold the required credentials, recognized by MRIPC;
b) Radiologist shall also comply with:
   b.1. Nuclear medicine practices with use of radioactive substances;
   b.2. Include professional, scientific, consultative or advisory organisational, administrative and educational matters. These shall be relevant to the services offered by the centre;
   b.3. Training for radiation safety measures (level II);
   b.4. The trained and registered personnel shall have experience in nuclear medicine therapy procedures and have adequate training and practical experience. Incumbent must be located on site through-out the procedure and responsible for all component of each nuclear medicine service including:
      b.4.1. Personal attendance;
      b.4.2. Determining the appropriateness of and monitoring the quality procedure;

b.4.3. Assessing and influencing outcome of procedure;

b.4.4. Providing a final consultation report.

7.4.2.5.6 MRI

a) The supervising radiologist must have evidence of competence in the techniques and application of MRI of the brain, spine, musculoskeletal system and other relevant anatomic regions;
b) Each MRI unit must have one or more supervising radiologists with overall responsibility for running the section.

7.4.2.5.7 CT Scan

The supervising radiologist shall have a thorough understanding of CT technology and instrumentation as well as radiation safety.

7.4.2.5.8 Interventional Radiology

a) Each trained and registered personnel shall meet the training requirements and shall have evidenced experience of performance of interventional procedures that staff is performing at the MRIS;
b) Trained and registered personnel shall have special training in Radiation safety measures (RSO level I);
c) Trained and registered personnel shall have special training in resuscitation measures.

### 7.4.3 CP3 STANDARD

## MRIS SHALL PLAN AND DEVELOP SERVICE AND WORKFORCE REVIEW

a) The service shall periodically review clinical and nonclinical practice and workforce deployment;
b) Regular periodic review of performance and knowledge of the personnel shall be performed and the record for the same shall be maintained;
c) There shall be defined protocols and policies for employment, re-employment, deployment, promotion or transfer of a person in the MRIS;

d) There shall be defined protocols and policies for the team of radiologist, radiographer, nurses and ancillary personnel working at each section of radiological;

e) Quality indicators to monitor various service parameters shall be identified, recorded and reassessed after implementation of improvement/corrective management.

## 7.5 CONTROL OF EQUIPMENT

### 7.5.1 CE 1 STANDARD

### MRIS SHALL PROCURE AND INSTALL APPROPRIATE EQUIPMENT

a) The medical radiology and imaging service shall be furnished with all the equipment that is required for the provision of services (including X ray, ultrasound, mammography equipment, CT Scan, MRI, gamma camera and associated nuclear medicine equipment, and others according to the level of health service provision in Tanzania;

b) The medical radiology and imaging services shall ensure that procurement and installation of the equipment are as per established policies and procedure to conform with specified performance criteria requirement and are obtained only from approved supplier;

c) Supplier must be selected on the basis of their ability to meet specified requirement. There shall be a policy based on specified requirements for selection of supplier. A list of all suppliers, contractors and consultants must be maintained from relative authority;

d) There shall be procedure for maintenance of record of purchase. Purchasing document shall describe the product being ordered, specification requirements and relevant information to that order;

e) There shall be procedure and recording of verification and inspection of the purchased products and services at appropriate intervals;

f) Purchased materials and products shall be stored in designated storage areas within the facility. There shall be policy for storage methods to prevent damage and deterioration of product prior to use;

g) Procuring of medical radiography equipment shall be based on The Public Procurement Act (Act No. 7 of 2011 and its regulations of 2013, and amendments of 2016). The process of acquisition all equipment to be procured shall meet the specifications indicated in the Standard for Medical Radiology and Imaging Equipment Guideline (SMRIEG 2018);

h) There shall be Installation of “Type Approved” machines only for medical diagnostic purpose. (Obtain from the vendor/seller of the X-ray machines a copy of the TAEC “Type Approval” certificate prior to purchasing the unit).

### 7.5.2 CE 2 STANDARD

## MRIS SHALL MAINTAIN APPROPRIATE OPERATION AND WORKING OF THE EQUIPMENT

a) MRIS ensure that only authorised personnel shall operate the equipment. There shall be up-to-date instruction on the use and maintenance of the equipment (User manual and service manual) and readily available to personnel;

b) Personnel operating equipment shall be responsible for checking the performance and performing basic calibration of all the equipment;

c) They shall also maintain logs of performance and calibration as well as consumption of consumable material;

d) Records shall be maintained for each equipment and shall be available for inspection, at all reasonable time, to the competent authority or its representative;

e) These records shall include at least the following:

   e.1. Identification of equipment;

   e.2. Manufacturer’s name, type, identification and serial number or other unique identification;

   e.3. Manufacturer’s contact persons and telephone numbers;

   e.4. Date of receiving and date of putting into service;

   e.5. Current location, where appropriate;

   e.6. Condition when received (new, used or reconditioned);

   e.7. Manufacturer’s instructions, if available, or reference of their retention;

   e.8. Equipment verification and validation of performance records that confirm the equipment suitability for use;

   e.9. Maintenance carried out and planned for the future;

   e.10. Damage to or malfunction, modification or repair of the equipment;

   e.11. Certificate of Quality and name of local vendor/representative.

### 7.5.3 CE 3 STANDARD

## MRIS SHALL MAINTAIN APPROPRIATE PLANNED PREVENTIVE MAINTENANCE AND REPAIR OF THE EQUIPMENT TO DELIVER INTENDED SERVICE

a) The MRIS shall ensure that maintenance of all equipment and corresponding records are performed as per PPM schedule and SOPs by authorised personnel;

b) The MRIS shall also ensure that maintenance of contract with authorised as well as external authority are kept updated. Regular preventive maintenance and calibration of all equipment shall be carried out and recorded as per PPM schedule;

c) The MRIS shall also ensure equipment failure and faults are monitored and managed and that safety warnings, alerts and recalls are circulated and acted upon within specified time scale.

#### *7.5.3.1 Equipment Checks and Calibration*

a) There shall be record of compliance test of all equipment at the time of installation, prior to regular client radiographic / radiological. These records shall be available for inspection, at all reasonable time. All medical radiographic equipment at each level shall be maintained in accordance with the requirements detailed in manufacturer's documents;

b) Under no circumstances shall the completion of necessary equipment servicing or calibration be delayed or cancelled in order to accommodate further client examinations;

c) In general, calibrations shall be carried out by external calibrating authority or trained in-house personnel and an endorsed test report is obtained for this work;

d) All the equipment shall be checked and calibrated for at least the following:

   d.1. Calibration of signal to noise ratio;

   d.2. Check of signal uniformity;

   d.3. Check of geometric distortion;

   d.4. Check of positioning accuracy;

   d.5. Check of phantom image quality;

   d.6. Check of light output of film viewing objects;

   d.7. Check of ambient light level in the film viewing box;

   d.8. Check of functioning of film processing units.

In addition to above all the equipment shall be checked and calibrated specifically as following:

**7.5.3.1.1 General Radiography**

a) All X-ray machine available shall be calibrated as per manufacturer instructions;

b) Calibration of mA;

c) Calibration of kV;

d) Calibration of timer;

e) Calibration of dose index;

f) Check of collimeter/diaphragm;

g) Check of positioning accuracy;

h) Check of table movement and tilt;

i) Check phantom image quality;

j) Check of film processing unit.

**7.5.3.1.2 Mammography**

a) Collimation alignment check;

b) Focal spot size measurement;

c) kVp accuracy and reproducibility measurement;

d) Beam quality half layer value (HLV) assessment;

e) Automatic exposure control;

f) Screen speed uniformity check;

g) Breast entrance exposure management;

h) Average glandular dose measurement;

i) Artefact evaluation;

j) Darkroom cleanliness check;

k) Processor quality control check;

l) Screen cleanliness check;

m) Darkroom fog check;

n) Screen film contact test;

o) Compression force measurement.

**7.5.3.1.3 Ultrasound**

a) Calibration of power output;

b) Calibration of callipers;

c) Calibration of signal to noise ratio;

**7.5.3.1.4 Bone Mineral Densitometry**

a) Precision error of measurements of the phantom or standard that do not exceed the specifications or recommendations of the manufacturer and are less than 1%;

b) Maintenance of CT system used;

c) Maintenance of the QCT software, phantom and associated accessories;

d) Recalculation of LSC (least significant changes) in case of replacement of a CT scanner, replacement of CT X Ray tube, recalibration of CT scanner or modification to the QCT accessory components.

**7.5.3.1.5 Nuclear Medicine**

a) Dose calibration and constancy check;

b) Reproducibility and linearity checks of the dose calibrator;

c) Geometric correction factor check;

d) Calibration of energy window setting;

e) Check of signal uniformity, linearity, sensitivity and resolution;

f) Check of geometric distortion and spatial resolution;

g) Check of collimator absolute and relative sensitivity;

h) Centre of rotation check;

i) Pixel calibration;

j) SPECT phantom reconstruction check;

k) Crystal energy resolution check;

l) Molybdenum breakthrough check;

m) Ambient radiation dose management;

n) Radiopharmaceuticals sterility checks;

o) Film processor checks.

**7.5.3.1.6 CT Scan**

a) Calibration of signal to noise ratio;

b) Check of signal uniformity;

c) Check of geometric distortion;

d) Check of slice thickness and positioning accuracy;

e) Check of phantom image quality;

f) Check of signal optimisation using SMPTE;

g) Check of light output of film viewing objects;

h) Check of ambient light level in the film viewing box;

i) Check of functioning of film processing units;

j) Calibration of Ma;

k) Calibration of Kv;

l) Calibration of dose index.

#### 7.5.3.1.7 MRI

a) Calibration of field strength;

b) Calibration of rate of change of field strength;

c) Calibration of RF power deposition (specific absorption rate);

d) Check of auditory noise level;

e) Check of magnetic field strength homogeneity;

f) Check of RF shield integrity;

g) Check of ghost intensity.

### 7.5.4 CE 4 STANDARD

## MRIS SHALL MAINTAIN APPROPRIATE PLAN FOR REPLACEMENT OF EQUIPMENT FOR CONTINUATION AND EXPANSION OF SERVICES

MRIS shall ensure equipment condemnation; replacement and up-grading are performed as per pre-set guideline so as to ensure continuity of care:

a) MRIS shall ensure that the replacement of equipment or facilities or transfer of services to a referral centre is available during downtime of any equipment. Prior information shall be given and displayed of such downtime is planned;

b) MRIS ensures that equipment and machines when found to be at or beyond end of its life-time shall be disposed according to international regulations under the authorization of relevant authority.

## 7.6 Control of Documents and Records

### 7.6.1 CDR 1 STANDARD

## MRIS SHALL MANAGE INFORMATION FOR PERSONNEL, CLIENTS, EQUIPMENT, FACILITY AND OTHERS

MRIS shall define documents and maintain procedures to control all documents and information that sustain its quality documentation.

a) Document control is a mean to ensure that only the latest version of approved documents is being used by practice personnel. There shall be assign personnel responsible for of overseeing the document control system;

b) Procedures shall be adopted to ensure that all documents issued to radiographic / radiological personnel as part of the quality management system are reviewed and approved by authorized personnel prior to issue;

c) Document control shall include:

c.1. Document identification (numbering/coding);

c.2. Version identification;

c.3. Change control;

c.4. Maintenance of master list document distribution;

c.5. Archiving.

d) Practice shall be developed as an identification system that includes all documents. A formal means of change control must be established to ensure:

d.1. That, only authorized changes are made to approved documents;

d.2. That all the changes are reviewed and approved prior to the amended document being placed in use;

d.3. That all copies of the document in use reflect the change;

d.4. Documents are periodically reviewed, revised when necessary, and approved by authorized personnel.

e) There shall be a master list, listing all the documents currently in use. Whenever new version is created or a document is changed and updated to a new version, the master list must also be updated. The master list shall include:

e.1. Document name;

e.2. Document number;

e.3. Version designation;

e.4. Document location(s).

f) Procedures shall be established to describe how changes to documents maintained in computerised systems are to be made and controlled;

g) Whenever a document is changed or withdrawn, a copy must be held in an archive with date of issue/withdrawal;

h) Archive documents shall be secured to prevent loss, fire or damage and easy accessed for retrieval. There are shall be a prescribed retention time for archived documents.

### 7.6.2 CDR 2 STANDARD

## MRIS SHALL MAINTAIN AND UPDATE MAINTENANCE REPORTS OF ALL EQUIPMENT

MRIS shall ensure that all documents related to legislative and statutory requirements as per (e.g. TAEC, TBS, TFDA, MRIPC Annexure refers) are maintained and updated regularly by authorised personnel.

### 7.6.3 CDR 3 STANDARD

## MRIS SHALL MAINTAIN AND UPDATE PERSONNEL DATA RECORDS OF ALL STAFF

a) MRIS shall maintain records of the personal information, relevant educational and professional qualification, training and experience, and competence of all personnel.

b) This information shall be readily available for reference to relevant personnel and may include:

b.1. Qualification, competence and registration/retention record;

b.2. Employment contract and record;

b.3. Training record;

b.4. Health and medical record (check-up and benefits);

b.5. Annual performance review records;

b.6. Complaints and merits record;

b.7. Retention/renewal or breach of contract/promotion record;

b.8. Certification or license, if required;

b.9. Reference from previous employment, if required;

b.10. Job description;

b.11. Record of continuing education and achievement;

b.12. Record of identification of signature and initials;

b.13. Record of training attended;

b.14. Competency evaluation.

### 7.6.4 CDR 4 STANDARD

## MRIS SHALL MAINTAIN AND UPDATE ALL RECORDS AND DOCUMENTS PERTAINING TO PERIODICAL AUDIT, QUALITY CONTROL AND QUALITY IMPROVEMENT OF ALL PROCESSES AND SERVICES

Refer to: **7.5 Control of Equipment Standard**

### 7.6.5 CDR 5 STANDARD

## MRIS SHALL MAINTAIN, INTEGRATE AND PROVIDE SAFETY, CONFIDENTIALITY AND RETRIEVABILITY OF ALL THE RECORDS

a) The medical radiographic / radiological section shall have policies, processes and procedure to ensure that records are identified, reviewed, retained and that personnel, medical radiography and reports records are created, stored, and archived in accordance with record retention guidelines/policies;

b) A client record shall be maintained for each client receiving services provided by the medical radiographic / radiological sections and it includes:

   b.1. Client identification;

   b.2. Name of nearest relative or next of kin;

   b.3. Identification of primary source of medical care/ referring clinician;

   b.4. Dates and time of visit;

   b.5. Signed informed consent, where applicable;

   b.6. Operative reports;

   b.7. Exposure parameters including client radiation dose where possible;

   b.8. Reports of diagnostic radiographic procedures along with examination(s) performed and the results authenticated by the appropriate personnel.

c) Client records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorised representative of the client or relevant authority.

#### *7.6.5.1 Radiography*

There shall be general radiographic / radiological reporting format prepared and duly signed by Trained and Registered Medical Radiology and Imaging Personnel. In addition to the results of each examination the following information shall also be reported:

a) Client identification;

b) Name of nearest relative or another responsible care giver;

c) Identification of primary source of medical care/ referring clinician;

d) Dates and time of examination;

e) Signed informed consent where applicable;

f) The name of examination's and interpreting personnel;

g) Radiological diagnosis.

#### *7.6.5.2 Mammography*

There shall be Breast radiographic / radiological reporting format prepared and duly signed by Radiologist/Radiographer. In addition to the results of each examination following information shall also be reported:

a) The name of the client and an additional client identifier (Whether examination was for screening or diagnosis);

b) The date of examination;

c) The name of examination's and interpreting personnel;

d) Radiographic diagnosis.

Current mammograms and records must be kept by the facility:

a) For at least 7 years, or;

b) At least 10 years if no additional mammogram of the client are performed at the facility;

c) And 5 years after death.

#### *7.6.5.3 Ultrasound*

There shall be ultrasound radiological reporting format prepared and duly signed by trained and registered Radiology and Imaging personnel. In addition to the results of each examination the following information shall also be reported:

a) Record of client identification and referring clinician;

b) Record of client's details as government requisition forms;

c) Record of date and time of scan;

d) Record of name and signature of performing trained and registered medical radiology and imaging personnel;

e) Record of sedation/any other medication if given;

f) Record of report, image and further advice and shall be retained for a minimum of 7 years following initial examination, 10 years if no additional scan done and 5 years after death.

#### *7.6.5.4 Bone Mineral Densitometry*

There shall be Bone mineral densitometry reporting format prepared and duly signed by trained and registered Medical Radiology and Imaging personnel. In addition to the results of each examination the following information shall also be reported.

A permanent record shall be maintained, including:

a) Client identification, facility identification, examination date, image orientation, and unit manufacturer and model;

b) Clinical notes or client questionnaire containing any pertinent history;

c) Positioning, anatomical information and/or technique settings needed for performing serial measurements;

d) Printouts of the images and regions of interest, if provided by the unit and BMD values obtained;

e) For premenopausal women, men younger than age 50, and children, the BMD and Z score shall be reported for each site examination;

f) For postmenopausal women, men age 50 and older, report shall include the BMD for area density, T-score, and WHO classification at the hip; and for trabecular volume density at the spine;

g) The report shall include whether the artefacts or other technical issue may have influenced the reported BMD measurements.

#### *7.6.5.5 Nuclear Medicine*

a) There shall be nuclear medicine reporting format prepared and duly signed by trained and registered Nuclear Medicine Technologist/Physician. In addition to the results of each examination the following information shall also be reported;

b) Records of client upon whom studies have been performed shall be retained for a minimum of 7 years following initial examination, 10 years if no additional scan done and 5 years after death;

c) There shall be record of receipt, usage, administration, and disposal of all radio nuclides in compliance with the licensee conditions and applicable medical records and radiation control regulations;

d) There shall be record of storage, preparation and disposal of radioactive and radiopharmaceutical materials as per requirements of appropriate regulatory agency;

e) Client record shall include following details:

   e.1. Client name and identification number;

   e.2. Requesting practitioners name;

   e.3. Type of nuclear medicine procedure performed (and explanation if some modification to the procedure);

   e.4. Type, activity, route, and injection site of any radioactive or non-radioactive substance administered to the client;

e.5. Name of nuclear medicine technologist performing the procedure;

e.6. Date procedure performed;

e.7. Description of findings;

e.8. Interpretative information;

e.9. Identification of responsible nuclear medicine specialist;

e.10. Description of any adverse effect or unusual features prior to, during, or following the study;

e.11. Supplementary information e.g. Evidence of previous surgery.

#### *7.6.5.6 Admission, isolation and discharge documentations maintained*

Medical facilities offering MRIS shall ensure that client's admission, isolation and discharge documentations are maintained and updated on regularly basis.

#### *7.6.5.7 Records of Client Sedation*

Drug used for sedation and further management shall be recorded in the clients record details, along with time of administration and details of any adverse reaction.

##### *7.6.5.7.1 MRI*

There shall be MRI reporting format prepared and duly signed by trained and registered medical radiology and imaging personnel. In addition to the results of each examination the following information shall also be reported:

a) Record of client identification and referring clinician;

b) Record of date and time of scan;

c) Record of name and signature of performing radiographer/Radiological Technologist/Radiologist;

d) Record of sedation/contrast/medication if given (type, amount and route);

e) Record of adverse reaction and remedial action taken;

f) Record of report, image and further advice and shall be retained for a minimum of 7 years following initial examination, 10 years if no additional scan done and 5 years after death.

##### *7.6.5.7.2 CT Scan*

There shall be Computerized Tomography reporting format prepared and duly signed by trained and registered medical radiology and imaging personnel. In

addition to the results of each examination the following information shall also be reported:

a) There shall be permanent record of the CT examination and its interpretation;

b) Images of all appropriate areas both normal and abnormal shall be recorded in suitable archival format;

c) An official interpretation of the CT findings duly signed by concerned radiologist shall be included in the client's medical record;

d) Retention of the CT examination shall be consistent both with clinical need and with relevant legal and local health care facility requirements for a minimum of 7 years following initial examination, 10 years if no additional scan done and 5 years after death.

#### *7.6.5.7.3 Interventional Radiology*

There shall be Interventional Radiography reporting format prepared and duly signed by trained and registered Medical Radiology and Imaging personnel. In addition to the results of each examination the following information shall also be reported:

a) Record of client identification and referring clinician;

b) Record of date and time of scan and intervention procedure;

c) Record of name and signature of performing Radiographer/Technologist/Radiologist and/or Pathologist;

d) Procedure or operative record;

e) Record of sedation/contrast/medication if given;

f) Record of adverse reaction/complications and remedial action taken;

g) Record of report, image and further advice and shall be retained for a minimum of 7 years following initial examination, 10 years if no additional scan done and 5 years after death

### 7.6.5.8 Compliance Records and Corrective Action Record

a) A noncompliance if any, occurs shall be documented and recorded. It includes variation from documented management requirements (e.g. Use of uncontrolled Documents, unacceptable quality control results, unacceptable equipment calibration,), procedural management (wrong client identification on the image or issued report) and client refusal of investigation. The event can occur at any stage of medical radiographic service, from the time that the client presents at the practice through to the issue of the final report.

b) These non-compliances shall be identified by complaints from practice personnel or external referrer, internal audits, management review etc. And there shall be an appropriate record of action taken to rectify the problem.

c) There shall be a record of documented procedure so that the personnel are aware of the action to be taken. These documents shall also need to define who is responsible for overseeing the remedial action required and ensuring that it has been successful in resolving the problem.

d) A record of remedial action taken must be maintained, for example:

d.1. Steps taken in response to unacceptable equipment calibration results;

d.2. Re-radiological of a client due to unacceptable image quality;

d.3. Reissuing of report due to incorrect client details.

d.4. The corrective action taken must be monitored to ensure effectiveness and record for the same shall be retained for future references and audit.

## 7.7 Control of Radiation, Bio-Safety and Other Risks

### 7.7.1 CRBOR 1 STANDARD

### MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE RISKS ASSOCIATED WITH RADIOGRAPHIC / RADIOLOGICAL PROCEDURES

#### *7.7.1.1 Radiation Safety Manual*

MRIS shall ensure that organization has arrangements and general radiation protective measures for personnel, client and public to restrict exposure to radiation. There shall be documentation of Radiation safety manual containing radiation safety policies and procedures, which aim to minimize radiation exposure in accordance with the 'ALARA' principal. Example:

a) Procedure for handling and maintenance of X-ray machines and other radiographic equipment using radiation for radiographic / radiological;

b) Procedure for handling and maintenance of radioactive, chemical and biological spills;

c) Procedure for dealing with needle prick injuries;

d) Policies on the use of protective clothing and personal devices;

e) Policy on eating, drinking etc.;

f) Waste disposal procedures;

g) Immunization policies.

#### *7.7.1.2 Radiation Safety Officer*

Each medical radiography and radiotherapy centre shall appoint Radiation Safety Officer whose responsibilities is to:

a) Ensure that practice is adhering to the relevant legislation of the state;

b) Monitor changes in the legislation;

c) Coordinate record keeping related to radiation safety;

d) Proper interpretation of monthly and quarterly reports of TLD badges in radiotherapy and radiography respectively, informing each radiation worker regarding their TLD report and in case of alarming results taking appropriate action;

e) Must ensure proper calibration of all the radiation equipment and conduct QC tests such as focal spot test, beam alignment test, etc.

#### *7.7.1.3 Signage and Restricted Access Areas*

a) The Medical Radiology and Imaging Services ensures that there are appropriate signage and hazardous warning notices;

b) There shall be proper display of radiation and safety signs and boards like:

   b.1. Signs of identification of safety equipment such as fire extinguishers, showers, eyewash facilities;

   b.2. Signs to identify hazards and hazardous activities;

   b.3. Signs and instructions to delineate public areas from area of restricted access;

   b.4. Evacuation routes used in case of emergency shall always be kept clear (shall not be used as general storage areas);

   b.5. Instruction for pregnant women;

   b.6. Signs to identify radioactive source and radiation device.

#### *7.7.1.4 Spill kits shall be available for acids and solvents;*

MRIS shall ensure availability of spill kits for acids and/or solvents in case of accidental spillage. Detailed log book of such spillage must be maintained.

#### *7.7.1.5 Client Safety*

MRIS shall ensure that risk associated with radiographic procedures are defined, assessed and minimized to the client.

#### 7.7.1.5.1 Radiography

a) The X-ray unit design shall be approved by TAEC;

b) The room layout design of the room for housing the X-ray unit shall be approved by TAEC;

c) The rooms housing diagnostic X-ray units, nuclear medicine and radiotherapy unit and related equipment shall be located as far away as feasible from areas of high occupancy and general traffic such as maternity and paediatric wards and other departments of the hospital that are not directly related to radiation and its use;

d) The layout of rooms in an X-ray department shall aim at providing integrated facilities so that handling of X-ray equipment and related operations can be conveniently performed with adequate protection;

e) Unnecessary doors and windows present in an existing room, where X-ray machine is installed shall be bricked off and if not possible shall be provided with adequate lead lining (2.0mm) and kept permanently closed;

f) The doors and passages leading to the X-ray installation shall permit safe and easy transport of equipment and non-ambulatory clients;

g) The dark room shall be so located that the primary X-ray beam cannot be directed on it;

h) The room housing the X-ray equipment must be spacious enough to permit installation and servicing of the equipment and operation of the equipment with safety and convenience for the servicing personnel and operators as well as the convenience for clients;

i) Appropriate structural shielding shall be provided for the walls, the ceiling and the floor of the X-ray room so that the doses received by workers occupationally exposed to radiation and the members of the public are kept to a minimum and shall not exceed the annual effective equivalent dose limits of 20mSv and 1.0mSv respectively;

j) The doors of an X-ray room shall provide the same shielding as that of adjacent walls.

k) Appropriate shielding must be provided for dark room to ensure that underdeveloped X-ray films stored in it will not be exposed to radiation;

l) Unshielded openings, if provided in an X-ray room for ventilation/exhaust or natural light, must be located at a height of not less than 2.0m from the finished floor level /ground outside the X-ray room;

m) For mobile diagnostic X-ray equipment, a mobile protective barrier/lead aprons shall be used. For fixed X-ay equipment the control panel must be installed in a separate control room located outside but contiguous to the X-ray room and provided with direct viewing window (2.7mm lead equivalence) and oral

communication facilities between the operator and the client shall be provided. The protective barrier shall have sufficient radiation shielding to the acceptable dose rate limits;

n) In order to avoid the crowding of clients and relatives near the entrance door, a waiting area must be provided outside and adjacent to the X-ray room;

o) A suitable warning signal such as a red light must be provided at a conspicuous place outside the X-ray room and kept 'ON' when the X-ray equipment is energized in order to prevent inadvertent entry of persons not connected with the examination into the diagnostic room. An appropriate warning poster also shall be displayed outside the diagnostic room;

p) There shall be qualified and trained personnel in radiation safety deployed for the work.

q) Light Beam Diaphragm (LBD) must be functional;

r) Pregnant clients shall be well shielded and are subjected to radiation only if it is most important;

s) Evacuation procedures, including a plan of the site showing the location of safety equipment and fire extinguishers;

t) Provision for personnel radiation monitoring service through TAEC.

**7.7.1.5.2 Fluoroscopy**

a) The room layout design of the room for housing the X-ray unit shall be approved by TAEC;

b) Fluoroscopy examinations shall be done under image intensifier system;

c) A log book of screening times for all fluoroscopic examinations must be kept;

d) Fluoroscope X-ray machine shall be installed with Dose Area Product (DAP) meter;

e) Adequate protection of practitioners, radiation workers and other personnel in the fluoroscope room shall be ensured;

f) Acquire adequate protective gears such as thyroid protective gears, lead apron, eye goggles.

**7.7.1.5.3 C-ARM**

a) Ensure that personnel working with X-ray machines in the theatre always wear protective gears when operating the equipment;

b) Ensure that the personnel conducting radiographic examination/procedures optimize distance and time used around the machine during exposure;

c) Ensure that the rest of the personnel in the theatre room shall stay at least 2 meters away from the X-ray machine;

d) Acquire adequate protective gears such as thyroid protective gears, lead apron, eye goggles;

e) C-arm X-ray equipment shall be installed with DAP meter;

f) Define protective gears and thickness.

**7.7.1.5.4 Ultrasound**

a) Registration of clinic is mandatory along with details of machine and medical radiology and imaging personnel;

b) All ultrasound results report shall be documented along with the copy of referral letter from referring Physician;

c) Minimum acoustic output and exposure time;

d) Proper client privacy;

e) Chaperone to be available in special/sensitive examination (Define; special, sensitive, chaperone);

f) Clean hygienic disposable towel or tissue papers shall be available;

g) The ultrasound room shall have a toilet.

**7.7.1.5.5 Mammography**

a) The room layout design of the room housing the X-ray unit shall be approved by TAEC;

b) There shall be registration/license of unit with TAEC;

c) There shall be warning placard/instructions, red light and radiation symbol displayed outside the room;

d) Dose rate at the entrance door, control cubicle and walls shall be within acceptable limits;

e) There shall be use of control cubicle/protective barrier;

f) Average glandular dose as determined by the dosimeter must not exceed 2mGys (200mrads) per view, using the RMI-156 phantom or another of equivalent constitution.

**7.7.1.5.6 CT Scan**

a) The room layout design for the room housing CT scan shall be approved by TAEC;

b) There shall be registration/license of unit with TAEC;

c) MRIS shall ensure employment of only qualified personnel;

d) MRIS shall ensure that personnel monitoring badges to radiation workers is provided through TAEC;

e) They shall carry out periodic quality assurance tests of CT machine;

f) Radiation dosages shall be measured, managed, and then prescribed so that exposure from radiation sources is as low as reasonably achieved (ALARA);

g) There shall be warning placard/instructions, red light and radiation symbol displayed outside the CT room;

h) Dose rate at the entrance door, control cubicle and walls shall be within acceptable limits;

i) Evacuation procedures, including a plan of the site showing the location of safety equipment and fire extinguishers;

j) A CT scan is not recommended for a pregnant woman and paediatric age group except where very necessary.

**7.7.1.5.7 MRI**

a) Pre-entry safety check of all clients;

b) Minimum exposure to different types of electromagnetic fields, radiofrequencies and any noise;

c) An appropriately equipped emergency kit must be immediately available to treat serious adverse reactions and for resuscitation in case of respiratory and cardiac arrest.

**7.7.1.5.8 Bone Mineral Densitometry**

a) Client shall wear loose, comfortable clothing, avoiding garments that have zippers, belts or buttons made of metal. Objects such as keys or wallets that would be in the area being scanned shall be removed;

b) Jewellery, eye glasses and any metal objects or clothing that might interfere with the X-ray images shall be removed;

c) History of barium examination or injectable contrast material for a computed tomography (CT) scan or radioisotope scan shall be obtained, and client shall be advised to wait for 10 to 14 days before undergoing a DXA test;

d) History of pregnancy is taken and If an X-ray is necessary, precautions will be taken to minimize radiation exposure to the baby;

e) Facilities, in consultation with the radiologist shall have in place and shall adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account client body habitus, such as height and/or weight, body mass index, or lateral width;

f) The dose reduction devices that are available on radiographic equipment shall be active; if not, manual techniques shall be used to moderate the exposure while maintaining the necessary diagnostic image quality;

g) Client radiation doses shall be periodically measured;

h) There shall be warning placard/instructions, red light and radiation symbol displayed outside the DXA room.

**7.7.1.5.9 Nuclear Medicine**

a) The room layout design shall be approved by TAEC;

b) Client waiting areas shall be located and if necessary shielded, so that exposure from radiation sources is as low as reasonably achieved (ALARA);

c) Person who may be exposed to radiation as a result of nuclear medicine procedure must be advised of precaution they can take to minimise their radiation dose;

d) The quantity of radioactivity to be administered must be prescribed (either individually by prescription or by protocol), assayed, and recorded;

e) The identity of the radiopharmaceutical and the client, route of administration, and the pregnancy and breast-feeding status of the client shall be verified prior to administration;

f) There shall be registration/license of unit with TAEC;

g) MRIS shall ensure employment of only qualified personnel;

h) MRIS shall provide personnel monitoring badges to radiation workers;

i) Sufficient numbers of syringe shields and shielded containers must be available in good condition and shall be used unless contraindicated for a specific client;

j) Written instruction must be available, in particular for therapeutic procedures involving potentially larger exposures;

k) Appropriate precautions regarding pregnant and breast feeding client must be observed. Including warning signs, verbal enquiry and the issue of special instructions to the client where required;

l) Written instructions must be available for clients undergoing nuclear medicine therapy;

m) There shall be appropriate procedures and resources for handling accidents involving radioactive materials and for subsequent decontamination must be available;

n) Radiation monitoring equipment for the detection of contamination and radiation exposure level must be available;

o) Materials presenting a hazard of airborne transport shall be handled in fume hood.

p) There shall be provision of emergency eyewash clearly defined and appropriately labelled;

q) There shall be provision of appropriate labelling of all toxic, irritant, caustic and otherwise hazardous substances;

r) There shall be appropriate personnel protective equipment such as eye protection devices, impervious aprons etc.;

s) There shall be provision of flushing materials from the skin rapidly in the event of accidental splashing;

t) There shall be developed guidelines for identification of clients not suitable for intravenous sedation in absence of anaesthetist;

u) There shall be a documented procedure for management of likely mishaps (resuscitation).

v) Evacuation procedures, including a plan of the site showing the location of safety equipment and fire extinguishers;

w) There shall be warning placard/instructions, red light and radiation symbol displayed outside the CT room.

**7.7.1.5.10 Interventional Radiology**

a) The room layout design for Cathlab X-ray units shall be approved by TAEC;

b) There shall be appropriate personnel protective equipment such as eye protection devices, lead aprons, thyroid protection etc.;

c) Ensure that personnel monitoring badges is provided to radiation workers;

d) There shall be warning placard/instructions, red light and radiation symbol displayed outside the CT room;

e) Surgical support shall be available, with its prerequisite ancillary services such as available in an acute care hospital If this support is not available, there shall be provision of along with formal detailed protocols for rapid transport to an appropriate acute care facility;

f) Ensure that only qualified personnel (radiographers) shall operate the X-ray equipment in the Cathlab;

g) To maintain registration, sites must annually confirm or update equipment information to the relevant authority.

***7.7.1.6 Personnel Safety***

a) All the medical radiology and imaging personnel shall be informed of hazards including radiation hazards. There shall be appropriate hand washing and hand drying facilities available:

   a.1. Hand basins shall not be fitted with domestic taps but with a suitable alternative (e.g. elbow or foot activated devices);

   a.2. There shall be single use towels or automatic hand drying facilities;

   a.3. A suitable hand cleansing agent shall be available;

a.4. Dustbins are labelled as per recommended colour coding for health care waste management or segregation (**Black**/**Blue** for non-infectious, **Yellow** for infectious and **Red** for highly infectious);

a.5. Sluice rooms are available.

b) Where warranted, a safety shower shall be available in close proximity to all personnel and its operation shall be checked regularly;

c) Where warranted, eyewash solutions or eye wash stations shall be available in close proximity to personnel work stations. If commercial eyewash preparations are used make sure that the solutions are within expiry date;

d) Other than general safety measures following specific safety measures shall be taken by personnel.

**7.7.1.6.1 Radiography and Fluoroscopy**

a) Registrants and licensees shall ensure that workers are provided with suitable and adequate personal protective equipment;

b) Protective equipment includes lead aprons, gonad shields, thyroid shields, protective eye-googles and lead gloves;

c) The need for these protective devices shall be established by the RSO;

d) Use of suspended screen and other personal shielding tools available;

e) Collimate the X-ray beam to the area of interest;

f) The room housing the X-ray equipment must be spacious enough to permit installation and servicing of the equipment and operation of the equipment with safety and convenience for the servicing personnel, operators and clients;

g) Personnel monitoring badges shall be used;

h) Personnel monitoring badges shall be stored in a radiation free area;

i) Additional filter provided in the X-ray tube shall be in place;

j) There shall be sufficient area for X-ray installation;

k) There shall be use protective equipment such as mobile protective barrier, lead rubber aprons, gloves, thyroid shields etc.

**7.7.1.6.2 Mammography**

a) Proper client privacy;

b) Radiographer to carry out examinations;

c) Chaperone shall be available;

d) A film processing system only dedicated for mammography procedures;

e) There shall be use of control cubicle or protective barrier.

#### 7.7.1.6.3 Ultrasound

a) Trained and registered personnel to carry out examination and/or procedures;

b) Chaperone to be available in case client of opposite gender to the radiographer is being examined;

c) Clean hygienic disposable towel or tissue papers shall be available for wiping transducer and client skin.

#### 7.7.1.6.4 Bone Mineral Densitometry

a) The dose reduction devices available on radiographic equipment shall be active;

b) Client radiation doses shall be periodically measured in accordance with technical standards.

#### 7.7.1.6.5 Nuclear Medicine

a) The volume and radioactivity of the generator eluate must be measured and recorded. Care must be taken to minimize exposure to personnel at all steps in setting up, eluting, and assaying the elute;

b) Aseptic procedures must be followed whenever handling parenteral radiopharmaceutical preparations or their components;

c) Labelling efficiency of kit-prepared technetium-99m radiopharmaceuticals shall be evaluated periodically, such as the first vial of a new lot;

d) Specifically, testing for free Pertechnetate and hydrolysed-reduced radiochemical impurities shall be performed. Radiopharmaceuticals shall not be administered if the total level of radiochemical impurities exceeds 10%;

e) Under no circumstances may pipetting of any materials by mouth be permitted;

f) Personnel who routinely handle radionuclides must be monitored for radiation exposure.

g) Special nuclear medicine gowns for personnel working in nuclear medicine department

#### 7.7.1.6.6 MRI

a) Provide reading material to clients to reduce anxiety/fear;

b) Pre-entry safety check of all clients;

c) Client shall use ear muffs during scanning to reduce noise pollution and anxiety.

#### 7.7.1.6.7 CT Scan

a) Radiation monitoring of the facility through TAEC or authorized firm;

b) Personnel monitoring badges shall be used;

c) Personnel monitoring badges shall be stored in a radiation free area;

d) Acquire adequate protective gears.

#### 7.7.1.6.8 Interventional Radiology

a) MRIS shall ensure that for the CathLab X-ray installations procurement is of type approved X-ray unit and construction of the room as per the approved layout plan;

b) There shall be adequate qualified personnel, monitoring equipment including personnel monitoring facilities and availability of personal protective equipment such as lead apron, thyroid shield, lead protective barriers etc.

### 7.7.2 CRBOR 2 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK OF INFECTION TO PERSONNEL, CLIENT AND PUBLIC

MRIS shall ensure that the risk of infection is minimised by providing appropriate training and equipment and upholding rigorous standard of hygiene. Refer National Standard for Infection Prevention Control and Injection Safety (IPC-IS) 2004;

a) Policies and procedures for all infection control issue including sterilization/disinfection must be documented and comply with the state legislation;

b) The medical radiographic / radiological centre shall follow Universal precautions for infection Control and use of Personal Protective Equipment (PPE);

c) There shall be defined policies and protocols to manage the risk of infection with specific reference to immune suppressed clients or clients with communicable diseases;

d) There shall be defined policies and protocols for decontamination of equipment and environment following an incident;

e) Cleaning and disinfection including infection control procedures.

#### *7.7.2.1 Personnel Safety*

a) All the medical radiology and imaging personnel shall be informed of hazards to infection like needle stick injury, eye contamination etc.; and they shall immediately be reported, investigated, recorded and analysed with finding disseminated, communicated to all relevant authority and acted upon. Post exposure prophylaxis shall be used as per guidelines of regulatory authority;

b) Immunization status of each personnel shall be requested and records kept. Immunization against Hepatitis B infection shall be implemented after appropriate tests;

c) There shall be appropriate hand washing and hand drying facilities available:

c.1. Hand basins shall not be fitted with domestic taps but with a suitable alternative (e.g. elbow or foot activated devices);

c.2. There shall be Single use towels or automatic hand drying facilities;

c.3. A suitable hand cleansing agent shall be available;

c.4. Sluice room shall be available;

c.5. Dustbins are labelled as per recommended colour coding for health care waste management or segregation (Black/Blue for non-infectious, Yellow for infectious and Red for highly infectious).

d) Where warranted a safety shower shall be available in close proximity to all personnel and its operation shall be checked regularly;

e) Trained and registered personnel shall have knowledge of infection process and application of infection control principles.

Along with general requirements, centre shall follow the following methods:

**7.7.2.1.1 Radiography**

a) Multidose vials of contrast media;

b) Washed, clean linen shall be provided;

c) Sterilised instruments, syringes and catheter shall be used for procedures like HSG, IVU, etc.;

d) The use of multidose contrast media is acceptable if the following procedures are used:

e) Withdrawal of contrast under strict aseptic conditions;

f) Use of new needle and syringe for re-entering vials even for the same client's use;

g) Discarding of any unsealed contrast medium not used after 4 hours.

**7.7.2.1.2 Ultrasound**

a) Disinfection of endocavitatory ultrasound transducers;

b) Use of double protective shield before insertion of endocavitatory probe;

c) Practices shall comply with the equipment manuals and State guidelines for Disinfection of transvaginal transducers;

d) There shall be availability of clean linen, disposable consumables and sterilised instruments.

**7.7.2.1.3 Mammography**

There shall be provision of washed clean linens.

#### 7.7.2.1.4 CT Scan

a) There shall be provision for sterilised instrument, disposable syringes and needle and catheter;

b) There shall be provision of washed clean linens.

### 7.7.3 CRBOR 3 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK ASSOCIATED WITH HAZARDOUS SUBSTANCES AND MATERIALS TO PERSONNEL, CLIENT AND PUBLIC

The medical radiology and imaging services shall ensure to minimize the potential of harm from hazardous substances and materials by providing appropriate training and equipment;

a) There shall be procedure and policy for storage of hazardous chemicals and substances, where warranted, a flammable liquids storage cabinet is recommended for all but small volume;

b) There shall be procedures and policies for management of spill of hazardous materials by trained personnel;

c) There shall be documented policies and procedures for the safe disposal of contaminated/medical waste, which must be in accordance with relevant regulations. Waste disposal methods shall comply with Atomic Energy Act No. 7 of 2003;

d) All the radiographic / radiological and imaging centre personnel shall be informed of bio medical hazards and if incident occurs they shall immediately be reported, investigated, recorded and analysed with finding disseminated, communicated to all relevant authority and acted upon. Post exposure prophylaxis shall be used as per guidelines of regulatory authority. There shall be pre-set policies and procedures for decontamination of equipment and environment following an incident;

e) There shall be procedures for cleaning and disinfection of work areas depending on the microorganisms and other agents encountered. Most commonly used reagents for such purpose includes hypochlorite, alcohol and phenols.

#### *7.7.3.1 Personnel Safety*

a) All the radiographic / radiological and imaging centre personnel shall be informed of hazards including radiation hazards. There shall be appropriate hand washing and hand drying facilities available:

   a.1. Hand basins shall not be fitted with domestic taps but with a suitable alternative (e.g. elbow or foot activated devices);

a.2. There shall be Single use towels or automatic hand drying facilities;

a.3. A suitable hand cleansing agent shall be available.

b) Where warranted, a safety shower shall be available in close proximity to all personnel and its operation shall be checked regularly;

c) Where warranted, eyewash solutions or eye wash stations shall be available in close proximity to all personnel. If commercial eyewash preparations are used make sure that the solutions are within expiry date;

d) Other than general safety measures following specific safety measures shall be taken by personnel:

d.1. Radiography and Fluoroscopy;

d.2. Personnel monitoring badges shall be used;

d.3. Personnel monitoring badges shall be stored in a radiation free area;

d.4. Lead aprons shall be used by doctors/radiographers during fluoroscopic examinations;

d.5. Additional filter provided in the X-ray tube shall be in place;

d.6. There shall be sufficient area for X-ray installation;

d.7. There shall be use protective equipment such as mobile protective barrier, lead rubber aprons, gloves, thyroid shields etc.

**7.7.3.1.1 Mammography**

a) Proper client privacy;

b) Trained and registered personnel to carry out examinations;

c) A film processing system dedicated for mammography radiological only.

**7.7.3.1.2 Ultrasound**

a) Proper client privacy;

b) Clean hygienic disposable towel or tissue papers.

**7.7.3.1.3 Bone Mineral Densitometry**

a) The dose reduction devices available on radiographic equipment shall be active;

b) Client radiation doses shall be periodically measured in accordance with technical standards.

**7.7.3.1.4 MRI**

a) Provide reading material to clients to reduce anxiety/fears;

b) Pre-entry safety check of all clients.

**7.7.3.1.5 CT Scan**

a) Personnel monitoring badges shall be used;

b) Personnel monitoring badges shall be stored in a radiation free area;

c) Lead aprons shall be used by doctors/radiographers and any other person who need protection during fluoroscopic examinations.

### 7.7.4 CRBOR 4 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK OF VIOLENCE AND AGGRESSION TO PERSONNEL, CLIENT AND PUBLIC

a) MRIS shall ensure that enough security personnel shall be available for assistance, whenever act of violence or aggression is encountered;

b) MRIS shall ensure that incidents of violence and regression are reported; investigated, recorded and analysed with findings disseminated, communicated to all relevant parties and are acted upon.

### 7.7.5 CRBOR 5 STANDARD

## MRIS SHALL IDENTIFY, ASSESS, MANAGE AND MINIMISE THE RISK ASSOCIATED WITH FIRE, ELECTROCUTION AND OTHER DISASTER TO PERSONNEL, CLIENT, VISITORS; AND TO FACILITY AND ENVIRONMENT

MRIS shall ensure to promote good health and safety culture, manage adverse healthcare events and minimise risk and failure, including risk of fire.

a) Practices in medical radiographic and radiological centre shall ensure fire safety issues along with other relevant statutory requirements are in place:

   a.1. There shall be appropriate fire extinguishing devices;

   a.2. There shall be installation of fire alarm and smoke/fire detector;

   a.3. There shall be proper display of radiation and safety signs and boards like:

   a.4. Signs of identification of safety equipment such as fire extinguishers, showers, eyewash facilities;

   a.5. Signs to identify hazards and hazardous activities;

   a.6. Signs to delineate public areas from area of restricted access.

b) Evacuation procedures, including a plan of the site showing the location of safety equipment and fire extinguishers;

c) Corridors shall not be used as general storage areas and evacuation routes must always be kept clear.

### 7.7.6 CRBOR 6 STANDARD

## MRIS SHALL MAINTAIN A DOSIMETRY SYSTEM CONSISTENT WITH NATIONAL AND INTERNATIONAL STANDARDS

MRIS shall ensure a dosimetry system, consistent with national and/or international standards, ensures the safety and accuracy of the prescribed radiation dose for all clinical treatments. There shall be:

a) A management plans for radiation safety that complies with the requirements of the relevant regulatory authority and the legislation for the jurisdiction;

b) Annual audit of compliance with the management plan for radiation safety;

c) Equipment for monitoring radiation and for use in responding to emergency situations;

d) Documentation that the facility records all incidents (including near-misses) and analyses the data, follows up and acts as appropriate;

e) Evidence of feedback to personnel

#### *7.7.6.1 Incident monitoring programme*

Participation in incident monitoring programmes provides confidence that radiation is safely delivered in a radiation therapy facility with a safety-conscious culture focused on learning and prevention of error.

## *Section Three*

### ANNEX 1: THIS SECTION COMPRISES OF STATUTORY REGULATIONS

1. The Medical Radiology and Imaging Professionals Council Act. No. 21 of 2007
   1.1. The mandate of MRIPC is to:
      1.1.1. The regulatory body responsible for control of quality and safety of MRIS and practitioners;
      1.1.2. The Medical Radiology and Imaging Professionals Council (MRIPC) Code of Ethics and Professional Conduct for Medical Radiology and Imaging Professionals in Tanzania (GN September 2010).
2. The Tanzania Atomic Energy Commission (TAEC) was established by the Act of Parliament referred to as the Atomic Energy Act Number 7 of 2003.
   2.1. The mandate of TAEC is to:
      2.1.1. Provide Regulatory and Radiation Protection Services;
      2.1.2. Coordinate, monitor, and promote peaceful use of nuclear science and technology in the country.
   2.2. TAEC is the official government body responsible for all atomic energy matters in the United Republic of Tanzania.
3. Tanzania Bureau of Standards was established by the Act of Parliament referred to as the Tanzania Bureau of Standards Act No. 2 of 2009.
   3.1. The mandate of TBS is to:
      3.1.1. Undertake measures for quality of products of all descriptions and promote standardisation in industry and commerce.
4. The Tanzania Medicines and Medical Devices Authority (TMDA) was established by the Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003 (amended 2019)
   4.1. The mandate of TMDA is to;
      4.1.1. The regulatory body responsible for control of quality and safety of food, drugs (including herbal drugs), cosmetics and medical devices.

## NOTES

## NOTES

## TABLE 1: LIST OF PARTICIPANTS WHO REVIEWED AND FINALISED THE MRIS STANDARD

| S/N | Name | Title | Working Place | Email |
|---|---|---|---|---|
| 1. | Akida Mhoja | Senior Radiographer/D-MRIPC | MoHCDGEC | akidagiva3@gmail.com |
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| 5. | Dr. Dorothy Gwajima | Director of Curative Services (Formerly) | MoHCDGEC | dorothygwajima@gmail.com |
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| 9. | Dr. Lulu Fundikira | Radiologist | MUHAS | fundikira_lulu@hotmail.com |
| 10. | Dr. Ramadhani Kazema | Radiologist, Senior Lecturer | MUHAS | rkazema@hotmail.com |
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| 14. | Gerald Shuware | Radiographer | MAWENZI RRH | gshuware@gmail.com |
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| 20. | Sylvester J. Kadugu | Senior Radiographer | MNH | sylkadugu@yahoo.com |
| 21. | Wilson N. Ngoye | Radiation/Research Officer | TAEC | son871@yahoo.co.uk |
| 22. | Joel Kumbuka | Driver | MoHCDGEC | Box 743 Dodoma |
| 23. | Rudia Magoma | Support Personnel | M0HCDGEC | rmagoma2002@yahoo.com |

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