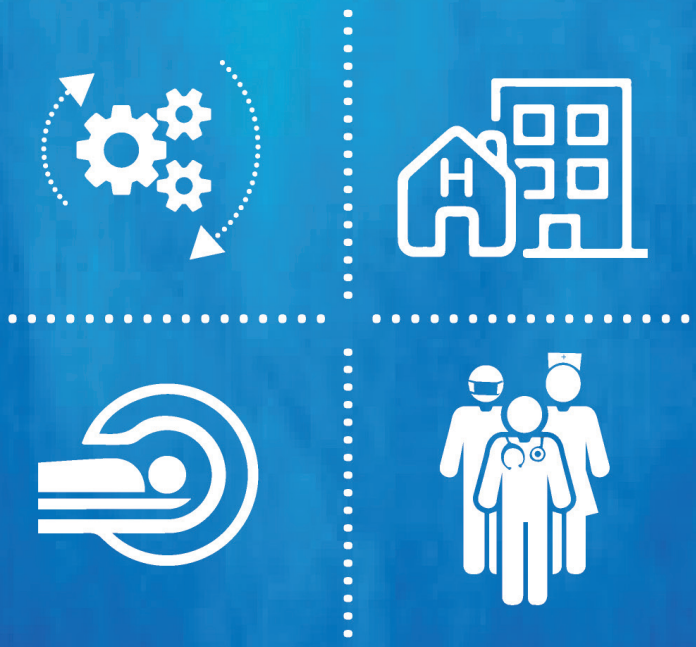
MINISTRY OF HEALTH

NATIONAL GUIDELINES FOR ESTABLISHMENT OF CANCER MANAGEMENT CENTRES IN KENYA



MINISTRY OF HEALTH

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Operational Definition of Terms

Chemotherapy	Systemic therapy using chemical substances that cause cell death through interruption of cell division
Radiotherapy	The use of x-rays or other energies in the electromagnetic spectrum to cause cell death by DNA damage
Basic cancer treatment centre	A facility at level 4 or above as per the Kenya Essential Package of Health (KEPH) that is able to provide at least one cancer treatment modality either as a stand-alone facility (chemotherapy, radiotherapy or surgical oncology unit) or within the precincts of a hospital. In addition, it should also be able to offer prevention, screening, early detection, diagnosis, registration, treatment, palliative care and survivorship services.
Comprehensive cancer treatment centre	An institution at level 6 as per the Kenya Essential Package of Health (KEPH) that is able to provide highly specialized cancer services in addition to those provided by the basic cancer treatment centre, including but not limited to comprehensive pathology services, comprehensive radiology services, comprehensive medical laboratory services, specialized surgical oncology including reconstructive surgery, comprehensive Radiation oncology, nuclear medicine, bone marrow transplants, oncology training programs and cancer research agenda
Comprehensive pathology services	The whole spectrum of services and tests done to determine both definitive tissue diagnosis of cancer as well as hematology, microbiology, chemistry and immunology to enable the initiation, continuation and monitoring of cancer treatment. This definition applies to comprehensive cancer centres/centres of excellence which are expected to do both diagnosis and treatment
Laboratory medicine services	Services and tests in hematology, microbiology, clinical chemistry, histopathology, molecular PCR and immunology to enable the initiation, continuation and monitoring of cancer treatment. This definition applies to cancer management centres which may receive results of the tissue diagnosis of cancer from another facility and only have capacity to treat.
Comprehensive radiology services	Includes the whole spectrum of radiological tests – X-rays, Fluoroscopy, Ultrasound, Mammograms, CT Scan, MRI, Endoscopy, Radiological guided biopsy
Multidisciplinary Team (MDT)	The multidisciplinary expert team that should manage cancer patients in a consultative approach. It consists of different experts including – medical oncologist, radiation/clinical oncologist, surgeon, pathologist, palliative physician and specialists, oncology pharmacist, oncology nurse, radiologist, interventional radiologist, haematologist, medical physicist, radiation therapist/therapy radiographer, medical laboratory technologists specialized in different laboratory disciplines among others.

Abbreviations

BLS/ACLS	Basic Life Support/Advanced Cardiovascular Life Support
BSC	Biosafety Cabinets
CT	Computed Tomography
DHIS	District Health Information System
EIA	Environmental Impact Assessment
GMP	Good Manufacturing Practices
HD	Hazardous Drugs
HEPA	High Efficiency Particulate Air Filters
HPLC	High Pressure Liquid Chromatography
HPV	Human Papilloma Virus
HVAC	Heating, Ventilation and Air Conditioning
IAEA	International Atomic Energy Agency
ICU	Intensive Care Unit
IEC	Information, Education & Communication
IVD	In-vitro Diagnostics
IV	Intravenous
KEPH	Kenya Essential Package of Health
KMLTTB	Kenya Medical Laboratory Technicians & Technologists Board
KMPDB	Kenya Medical Practitioners & Dentists Board
LEEP	Loop Electrosurgical Excision Procedure
LINAC	Linear Accelerator
MDT	Multi-disciplinary Team
MCF	Medical Cyclotron Facility
MRI	Magnetic Resonance Imaging
NCCP	National Cancer Control Program
NCI-K	National Cancer Institute of Kenya
PCR	Polymerase Chain Reaction
PET	Positron Emission Tomography
PPB	Pharmacy and Poisons Board
PPE	Personal Protective Equipment
PSAR	Preliminary Safety Assessment Report
QA	Quality Assurance
QAP	Quality Assurance Program
RPB	Radiation Protection Board
RPP	Radiation Protection Program
RSO	Radiation Safety Officer
SOP	Standard Operation Procedures

SPECT	Single Photon Emission Computed Tomography
TLC	Thin Layer Chromatography
TLD	Thermo-luminescent Dosimeter
TPS	Treatment Planning System
TSP	Technical Service Provider
UHC	Universal Health Coverage
VIA/VILI	Visual Inspection with Acetic Acid/Visual Inspection with Lugol's Iodine
WHO	World Health Organization

Foreword

TThe global burden of cancer has been on the rise with approximately 18 million new cancer cases diagnosed in 2018 as compared to 14 million in 2012 (GLOBOCAN). In Kenya, the GLOBOCAN report estimates about 45% increase in incidence in 2018 with 47,887 new cases as compared to 37,000 in 2012. The burden of disease is further compounded by a severely limited capacity of the health system to provide the necessary health services across the cancer continuum of care.

Article 43 of the Constitution of Kenya guarantees to every Kenyan the right to the highest attainable standard of health including emergency treatment. This has further been operationalized through the Health Act No. 21 of 2017 and the Cancer Prevention and Control Act No. 15 of 2012, both of which provide for a rights-based approach to the provision of health care services related to cancer management in Kenya. Towards achieving these commitments, the Ministry of Health has developed an elaborate policy framework outlined in the Kenya Health Policy 2014-2030, Kenya National Strategy for the Prevention and Control of Non-Communicable Diseases 2015-2020 and the National Cancer Control Strategy 2017-2022.

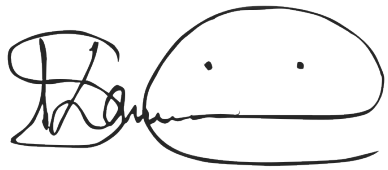
In line with the country's Big Four Agenda for economic development, the Ministry of Health has prioritized Universal Health Coverage with a particular focus on access to quality essential health services for all. Towards this end the Ministry has identified decentralization of specialized cancer care as critical to attaining universal access for cancer management through expansion of cancer management infrastructure across the country. Kenya's Vision 2030 envisages a globally competitive and prosperous nation with a high quality of life by the year 2030. In order to improve the overall livelihoods of Kenyans, the country aims to provide an efficient and high quality healthcare system with the best standards. As Kenya seeks to become a regional provider of highly specialized healthcare, provision of high quality cancer care in-country will reverse the cumulative economic losses as a result of medical tourism.

This National Guideline for Establishment of Cancer Management Centres thus provides the requisite policy guidance to all stakeholders towards the attainment of accessible, efficient, timely and high quality cancer management services for all. Health systems strengthening require interventions that cut across the six building blocks leadership and governance; health information; health products and technologies including infrastructure and equipment; service delivery, healthcare financing and human resources for health.

The purpose of these guidelines is to outline the minimum requirements in terms of operational management, physical infrastructure, equipment, and human resources for the establishment of a comprehensive cancer centre, a basic cancer management centre, a chemotherapy unit, and a radiation oncology unit among others. The guidelines shall thus apply to any public or private entity that has established or intends to establish any cancer centres or services.

This guideline is the first comprehensive document to outline what is required to establish a cancer management centre in Kenya. It provides a detailed account of what critical components would need to be considered to establish a cancer centre. These include operational considerations of the various units such as waste management, occupational health and safety, quality assurance, referral mechanisms among others; physical infrastructural considerations and generic layouts,; equipment and human resource requirements across the entire cancer continuum.

We look forward to working together with all stakeholders to operationalize these guidelines thus ensuring a standardized approach to the establishment of cancer management infrastructure in our country.



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Sicily K. Kariuki (Mrs), EGH
Cabinet Secretary
Ministry of Health

Acknowledgements

The Ministry of Health wishes to thank all those who contributed to the successful development and completion of these guidelines. This document was a result of several multi-stakeholder consultative forums with many meetings over a considerable length of time.

We appreciate the support from the leadership at the Ministry of Health which made this process a success. The Office of the Cabinet Secretary, Principal Secretary, Director of Medical Services, Department of Preventive and Promotive Health and the Division of Non-Communicable diseases were particularly helpful and provided guidance through- out the process. The development of this document was a result of several consultative meetings with various stakeholders keen to ensure cancer patients get quality services at the designated cancer management centres.

The National Cancer Institute of Kenya is particularly grateful to Radiation Protection Board, Pharmacy and Poisons Board, Kenya Medical Practitioners & Dentists Board, Ken- ya Medical Laboratory Technicians & Technologists Board, Nursing Council of Kenya, Kenyatta National Hospital, Moi Teaching and Referral Hospital, Ministry of Labour (Directorate of Occupational Safety & Health), Clinton Health Access Initiative and many other stakeholders for their financial and technical support during the development of this document.

This guideline will be very useful for establishment of cancer management centres in Kenya and guide counties and potential partners on investments that would be required to establish these centres. This guideline will also provide the framework to ensure that a high quality of cancer care services is provided by all facilities.

We look forward to collaborating with all stakeholders in implementing these guidelines and towards reducing the cancer incidence, morbidity, mortality and improved survival rates in Kenya.

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Peter K. Tum, OGW
Principal Secretary
Ministry of Health

Executive Summary

The National Cancer Control Strategy 2017-2022 has provided strategic direction by prioritizing decentralization of cancer services as per the Kenya Essential Package for Health to improve access to cancer care and services.

This guideline is the first comprehensive document to outline what is required to es- tablish a cancer management centre in Kenya. It provides a detailed account of what critical components would need to be considered to establish a cancer centre. These include operational considerations of the various units as well as physical infrastructural considerations and generic layouts, equipment and human resource requirements across the entire cancer continuum.

This guideline was developed in response to the need for a model reference guideline of minimum priority medical equipment, infrastructure and human resources required for cancer management, with the goal of increasing access to these services in Kenya. The purpose of this guideline is to provide guidance to stakeholders on the setting up as well as the successful operationalization of cancer centres.

The first section of this guideline defines the current cancer situation in Kenya, the country goals and priority activities in cancer control. The operational definition for various types of cancer centres as well as procedure for designation as a cancer centre is also outlined.

The second section describes the general operational considerations for a cancer centre that including service delivery and clinical considerations across the cancer continuum of care.

The third section lists the minimum requirements regarding physical infrastructure and equipment for all departments and units in a designated cancer centre.

The last section proposes the administrative and clinical human resource capacity requirements, the minimum qualifications for each and their roles and responsibilities within the various units of the cancer centre.

The annexes present the application form and inspection checklist for National Cancer Institute certification as a cancer centre, generic designs and layouts, cancer abstraction forms as well as various tools for service delivery. The various annexes provide guidance on key considerations on setting up and the day-to-day running of a cancer centre.

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Background

The global cancer burden is estimated at 18.1 million new cases and 9.6 million cancer deaths in 2018. In Kenya, cancer is the 3rd leading cause of death after infectious and cardiovascular diseases. The annual incidence of cancer was estimated at 47,887 new cancer cases, with an annual mortality 32,987 in 2018. Among men – prostate, oesophageal and colorectal are the leading cancers, while among women – breast, cervical and oesophageal cancers are most common. The leading cause of cancer death in Kenya is oesophageal cancer contributing 13.2% (4,351 deaths) of cancer mortality. Cervical cancer is the second leading cause of cancer death contributing 10% (3,266 deaths) while breast cancer comes in third at 7.7% (2,553 deaths). Late-stage presentation when cure is difficult to achieve is a common problem here, as is the case in many LMICs where diagnostic and treatment services are inadequate or non-existent. 70-80% of patients are diagnosed for treatment at an advanced stage of the disease when it is not amenable to cure.

Access to oncology services is a priority in the National Cancer Control Strategy 2017-2022. Currently in Kenya, there are limited oncology services within the public sector such as only 3 functional radiotherapy units in the public sector. These units are at Kenyatta National Hospital in Nairobi, highlighting the need for an urgent scale up of radiation oncology capacity in Kenya. There are ongoing efforts to decentralize chemotherapy services to County Referral Hospitals hence the need for guidance in establishing these services.

These guidelines have been developed as a result of the growing interest and need by various counties to manage their cancer patients locally rather than refer them to the National Referral Hospitals. This document outlines the requirements for a health facility wishing to offer cancer management services and will serve as a guide in the establishment of cancer management centres. Facilities can offer one or more of the services outlined in the document, so it is imperative for centres to develop collaborative arrangements with facilities that offer other services the patient may require.

Purpose of the Guideline

The purpose of these guidelines is to outline the minimum requirements in terms of operational management, physical infrastructure, equipment, and human resources for the establishment of a facility offering cancer services. Establishment of these centres and the services offered therein will be done in collaboration with various regulatory bodies in Kenya. The guidelines shall apply to any public or private entity that has established or intends to establish one of the above-mentioned centres.

Operational Definition of Cancer Treatment Infrastructure

The National Cancer Institute of Kenya (NCI Kenya) is a statutory body created under the Cancer Prevention and Control Act (No. 15 of 2012). This was in recognition of the need for a more coordinated health sector response among all the relevant stakeholders to the growing cancer burden in Kenya. The overall mandate of NCI Kenya is to provide general oversight and regulation for cancer prevention and control activities in Kenya. The specific functions under Section 5 of the Act include but not limited to policy advisory to the Cabinet Secretary on all matters relating to care for persons living with cancer, establishment of cancer care infrastructure, awareness creation, maintenance of the National Cancer Registry and coordination of cancer-related research.

Within the National Cancer Control Strategy 2017-2022, decentralization of oncology services have been prioritized as key towards enhancing access to cancer prevention and control. The definition of a centre offering oncology services can be broadly defined as follows:-

A. **Basic cancer treatment centre** is able to provide at least one cancer treatment modality either as a stand-alone facility (chemotherapy, radiotherapy or surgical oncology unit) or within the precincts of a hospital. In addition, it should also be able to offer prevention, screening, early detection, diagnosis, registration, treatment, palliative care and survivorship services. It is expected that this centre will be a facility at level 4 or above as per the Kenya Essential Package of Health (KEPH).

B. **Comprehensive Cancer Centre/Centre of Excellence** is any institution or facility able to provide highly specialized cancer services in addition to those provided by the basic cancer treatment centre, including but not limited to.

a. Comprehensive pathology services
b. Comprehensive radiology services
c. Comprehensive medical laboratory services
d. Specialized surgical oncology including reconstructive surgery
e. Comprehensive Radiation oncology
f. Nuclear medicine
g. Bone marrow transplants
h. Oncology training programs
i. Cancer research agenda

It is expected that this centre will be a facility at level 6 as per the Kenya Essential Package of Health (KEPH).

CHAPTER ONE

Operational Considerations

Chapter 1: Operational Considerations

This section outlines the general operational considerations for all cancer centres.

1.1 Procedure for designation as a Cancer Centre

A facility that plans to offer any cancer service must apply for designation to NCI Kenya and should adhere to the following:

a. The proposal for the Cancer Centre designation shall specify the objectives of the cancer management programme, the range of services to be provided, the approximate number of patients to be treated, and the physical infrastructure, equipment, human resources and operational management resources, as laid out in this document.

b. The facility will be issued with a comprehensive checklist of the components required for a Cancer Centre before it submits the application for designation.

c. Proposals for a Cancer Centre designation shall be submitted to the Ministry of Health together with the application form for approval not less than 90 days before the intended commencement of operations of the cancer centre.

d. The proposal and application form (see annex) shall be submitted to the Director of Medical Services, Ministry of Health, who will consult with the National Cancer Institute Kenya (NCI-K) for their recommendations before final approval.

e. Only upon final approval by the NCI-K will a facility be designated as a Cancer Centre. NCI-K will ensure that the Centre maintains the services and standards outlined in these Guidelines in order to retain this designation. The certificate of Cancer Management Centre designation (based on the service (s) to be offered) will be issued by NCI-K and shall be displayed at the facility.

f. NCI-K will conduct annual inspections and accredit the Centre to ensure compliance to the guideline.

g. All facilities should apply to be recognized as an NCI-K approved cancer management centre and renew their operational license annually.

1.2 Service Norms for Cancer Centres

a. The National Guidelines for Cancer Management shall form the basis for clinical management at the facility.

b. The centre or unit must have NCI-K approved protocols for diagnosis and treatment of all malignancies they manage founded on sound scientific principles and evidence-based medicine which must be accessible to the prescribers, pharmacists and nurses at the centre at all times.

c. The protocols must be updated as appropriate and be readily available for inspection when needed.
d. The centre or unit shall also commit to quality improvement, supporting cancer research and improving the training and mentoring of health care
e. The centre or unit shall have infrastructure in place to be able to carry out cancer registration and reporting to the National Cancer Registry and DHIS.

1.3 Service Delivery Considerations

Every cancer centre shall:

a. Formulate and prominently display a service charter that details the roles and responsibilities of both the patient and the centre.
b. Provide integrated and multidisciplinary care
c. Prioritize coordination and planning for professionals to help facilitate access to care at other levels of care, including awareness creation, screening/early detection, case management and appropriate downward referrals.
d. Have a reasonable time frame – definitive/tissue diagnosis should be done preferably within 2 weeks and the initiation of appropriate treatment within a month of diagnosis.
e. Follow evidence-based protocols and guidelines.
f. Have informed consent obtained prior to all procedures including treatments. In case of a minor, a parent/guardian shall give consent. The information prior to consenting shall be provided in a manner easily understandable by the patient. The rights of the child should be prioritized.
g. Establish clear navigation systems to enable patients' access to services.
h. Design patient-tracking systems for patient follow-up throughout the continuum of care.
i. Develop standard operating procedures for every service being provided.

1.4 Clinical Management Considerations

The cancer centre shall:

a. Provide cancer management that is holistic and patient-centred for best care outcomes
b. Before initiation of treatment, clearly define and communicate the goals of care to the patient in accordance with a patient care plan
c. Provide the patient the right to detailed information on his/her condition, treatment options including clinical trials, side effects, expected outcome and prognosis.
d. Allow the patient the right to seek a second or additional opinion before consenting to initiation of treatment.
e. Have all aspects of carefully documented, stored and easily retrievable.

f. Allow access of patients to their records as well as laboratory samples when needed
g. Comprehensively document patient history

1.5 Multi-disciplinary Tumor Boards

The cancer centre shall:

a. Establish multidisciplinary teams (MDTs)/tumour boards which shall guide and direct cancer management
b. Have MDTs meet regularly and have participation from all relevant disciplines depending on the cancer case and the level of care
c. Have all complex cases discussed by a multidisciplinary team
d. Have an MDT coordinator who will organize for meetings, keep records of discussions and provide reports on cancer patient management
e. Utilize technology to convene virtual MDT discussions with proper documentation of the same

1.6 Diagnostic Capacity Considerations

a. Diagnostic imaging

The cancer centre shall:

(i) Incorporate clinical findings in conducting diagnostic imaging modalities
(ii) Consider image-guided diagnostics where applicable
(iii) Use a standard protocol for conducting imaging procedures
(iv) Use internationally and locally recognized standards and guidelines for the safe installation, operation and use of imaging equipment.
(v) Use a standard imaging diagnostic reporting protocol
(vi) Outsource/provide access to an accredited imaging diagnostic facility where applicable

b. Pathology and Laboratory diagnosis

The cancer centre shall:

(i) Have access to a medical laboratory that is registered and licensed by KMLTTB and accredited by a relevant body. It should have comprehensive pathology and laboratory diagnostic facilities including a functional specimen referral and consultation mechanism.
(ii) Use a recognized cancer reporting protocol.
(iii) Subject any case to a second opinion if requested by the attending clinician or the patient.
(iv) Be obligated to avail tissue blocks to the patient upon request for a second pathology opinion.
(v) Provide the most precise diagnostic data as per best practice and using novel and advanced techniques which are regulated, validated and approved by relevant regulatory bodies for use in Kenya.

1.7 Nuclear Medicine and Radiation Oncology Considerations

The cancer centre shall:

a. Provide nuclear medicine and radiation oncology services in adherence to IAEA and local regulatory body guidelines including radiation safety protection.

b. Fully document all ionizing radiation therapeutic applications and maintain proper records for treatment planning simulation, isodose distribution plan, dosimetry, brachytherapy and physics documentation.

c. Deliver the most novel and advanced technologies available for nuclear medicine and radiation oncology. These technologies should be cost-effective, efficient, upgradable and practical.

d. Provide adequate information to patients receiving radioactive therapy regarding the procedure to be done.

e. Have access to radiopharmaceuticals used for diagnosis and treatment from an IAEA accredited source.

f. A reliable and uninterrupted source of positron emitting radiotracers is a basic prerequisite for a successful establishment of the clinical PET facility.

g. For information on setting up a medical cyclotron facility, please refer to relevant international and local policy documents on the same. The specific considerations include – site assessment & approvals, environmental assessments, design & construction requirements, administrative requirements,HR requirements, importation requirements, commissioning & decommissioning requirements, radionuclide distribution licensure & appointment of a radiation safety officer in charge.

h. Notify the RPB and shall apply for the commercial radionuclide distribution license along with documents or information to justify the practice e.g. demand from an authorized client, radionuclide transport and handling logistics, radiation safety program designed for the practice.

i. Ensure radiopharmaceuticals are manufactured according to the basic principles of good manufacturing practice. Because of their short half-lives, quality control may sometimes be retrospective.

1.8 Surgical Considerations

The cancer centre shall:-

a. Facilitate patients to access surgical diagnosis and treatment for solid malignancies through a multidisciplinary team approach.

b. Where tissue is obtained for histological examination, have the surgeon observe the SOP for histology specimen handling, storage and transport.

c. Have surgical treatment offered conforming to internationally recognized, evidence-based surgical-oncological practices.

1.9 Nursing Considerations

The cancer centre shall:-

a. Provide oncology and palliative nursing care for the entire continuum of care.
b. Support the coordinating role of oncology and palliative care nurses in the care team and community linkage for cancer patients

1.10 Chemotherapy Considerations

Chemotherapy infusions administered in an outpatient facility may take from 15 minutes to 12 hours. Intensive and complex chemotherapy infusions that may take 1-5 days, often involving sequential infusion of a variety of drugs will require a short stay in an inpatient facility.

The cancer centre shall:

a. Have only appropriately qualified oncologists initiate cancer patients on chemotherapy and biotherapies.
b. Have chemotherapy medications prepared by a pharmacist or pharmaceutical technologist preferably in a bio-safety cabinet vented to the outside.
c. Provide personal protective equipment to all members of the health care team who prepare, mix, administer and transport hazardous chemotherapy drugs.
d. Have a program that monitors exposure to hazardous chemotherapy drugs for all health workers.
e. Have a policy for pregnant and lactating health workers who are assigned to an area where chemotherapy drugs are present
f. Provide education and training for safe handling of these drugs to health workers exposed to hazardous chemotherapy drugs prior to their being assigned to an area where chemotherapy agents are present. These include pharmacy staff, medical and nursing staff as well as support staff such as cleaners and porters. The trainings shall be repeated annually, with the educational content being specific to the activities for which the health worker is responsible.
g. Prior to administration of chemotherapy ensure there is a system in place to confirm that the correct medication and dosage is administered to the correct patient.
h. Chemotherapy medicines especially vesicants like vinca alkaloids shall be whenever possible be administered via a central line e.g. using chemoports. Chemotherapy shall be administered through infusion pumps for accuracy and safety.
i. Have the facility ensure provision for management of extravasations and spills.

j. Provide patients and caregivers involved in the delivery of chemotherapy at home receive some basic education and training on the principles of safe handling, dealing with spills, waste disposal and patients' excreta. Written instructions shall be given to the patient and/or caregiver, including information on the use of oral chemotherapeutic agents.

k. Document the process for handling hazardous drugs waste generated during compounding and administration or during spills, as well as waste (bulk) products for chemotherapy.

l. Store chemotherapy medicines separately from other medicines – both storage area and refrigerator

m. Transport of chemotherapy medicines should maintain the integrity of the drug to avoid breakage or leakage that leads to spillages, contamination and exposure to the hazardous drug

n. Ensure labelling of chemotherapeutic agents includes storage, handling and disposal instructions

o. Develop facility SOPs for – designation of HD areas; receipt of HDs; storage of HDs; compounding of HDs; use and maintenance of proper engineering controls; hand hygiene and use of PPEs; deactivation, decontamination, cleaning & disinfection; dispensing of HDs; transport of HDs; administering HDs, environmental monitoring; disposal of HDs; spill control and medical surveillance.

1.11 Health Information and Records & Cancer Registry Office Considerations

The cancer centre shall:

a. Establish a health records department that will maintain all patient records in a system that is secure, confidential and easy to retrieve.

b. Capture data for all cancer cases comprehensively.

c. Notify the National Cancer Registry all new cancer cases using the cancer abstract form (see annex) as provided for by the Cancer Control Act 2012.

d. Ensure that the health records department sends reports to the National Cancer Registry and MoH-DHIS monthly.

e. Permanently archive cancer patient records.

f. Respect patients' rights to access their records at any point in their lifetime.

1.12 Palliative Care and Survivorship Considerations

The cancer centre shall:

a. Provide palliative care from the point of cancer diagnosis and at all times throughout the course of illness.

b. Integrate palliative care with other health services.

c. Prioritize and provide effective relief of pain and other distressing symptoms.
d. Provide timely rehabilitative and supportive services.
e. Facilitate formation of patient support groups.
f. Establish survivorship programs.
g. Adhere to the National Palliative Care Policy and the National Palliative Care Guideline.

1.13 Equipment Considerations

The cancer centre shall:

a. Have all the facilities and equipment registered and licensed for safe and effective conduct of its services.
b. For radiotherapy and nuclear medicine services, have access to qualified medical physicists who are responsible for establishment, implementation and supervision of radiation protection and safety program as well as quality assurance programs for medical devices.
c. Have access to a qualified biomedical engineer, who is ultimately responsible for ensuring that all equipment are in proper working condition and that the necessary safety devices are fitted and in working order.
d. Maintain service contracts and schedules of service with the contracted service providers to ensure regular servicing as per the manufacturer's instructions.
e. Ensure equipment compliance with relevant regulations according to the ap propriate governing regulatory body. Equipment more than 7 years old should not be acquired for cancer treatment.
f. Ensure safe disposal of obsolete or unserviceable equipment as guided by the relevant regulatory body.

1.14 Referral Considerations

The cancer centre shall:

a. Develop patient referral SOPs which conform to the national referral guidelines.
b. Properly document referrals to and away from the facility.
c. Promote upward, downward and horizontal referral where appropriate.
d. Facilitate referrals for specialized services that are unavailable at the centre to facilities that are accessible and are accredited by the relevant regulatory body.
e. Assess patients for fitness to travel and provide necessary supportive mechanisms (ambulance, nurse, oxygen supply) before referral.
f. Provide proper patient counseling on cancer, tests to be done, costs implications and expected treatment before referral.
g. Refer a patient to the right specialist for further management if a service outside oncology services is required

1.15 Quality Assurance

The aim of the QA program is to ensure that all procedures are appropriately defined, documented, understood, implemented and regularly reviewed in order to ensure consistent and accurate delivery of treatment.

The cancer centre shall:

a. Establish a Quality Assurance Programme (QAP) that is adequately supervised and provides reports to NCI Kenya as required.
b. For radiotherapy and nuclear medicine services, have a qualified physicist regularly calibrate radiation emitted or detected as per IAEA regulation for optimization of physical aspects of diagnostic and therapeutic procedures.
c. For ionizing radiation therapeutic applications, maintain accurate QA documents including annual onsite calibration report for primary standard ion chamber, TLD comparison reports for each energy level for all LIN ACs and cobalt machines, onsite dosimetry review reports or any additional documents as may be required.
d. Have risk assessment measures in place with objectives and systematic monitoring and evaluation so as to identify problems and system failures and guide the necessary action.
e. Have regular morbidity and mortality meetings to identify specific clinical performance indicators. Radiation safety committee needs to be constituted for reporting and review of radiation errors.
f. Meet international standards of care through accreditation by relevant bodies.

1.16 Infection Prevention and Control

Oncology patients are at increased infection risk due to immunosuppression and frequent exposure to healthcare settings.

The cancer centre shall:

a. Have a hospital's infection prevention and control program must be in accordance with the WHO Practical Guidelines for Infection Control.
b. Have hand-washing facilities for staff readily available. Hand sanitizers should be provided at every work station.
c. Have isolation rooms and practice barrier nursing by ensuring PPEs are available and easily accessible.

1.17 Occupational health and safety

The cancer centre shall:

a. Implement the Occupational, Health & Safety (OSH) Act in the workplace.
b. Provide safety and health training at least once every 3 years.

c. Be subject to annual inspection by the local regulatory body and adhere to the basic safety standards as set by the regulatory body.
d. Disclose labeling laws for identification and classification of chemicals by types of hazards, including medication labels and safety data sheets.
e. Establish a system for identification and surveillance of exposure: estimating the number of workers who come into contact with substances and are employed in occupations with increased carcinogenic risk, and reducing to minimum the number of workers exposed, the duration of exposure and the degree of exposure, and establishing an appropriate system of records.
f. Ensure medical surveillance applies to all healthcare workers handling hazardous drugs and includes assessment and documentation of symptom complaints, physical findings & laboratory values
g. Provide personal protective equipment for workers and decontamination facilities in the workplace.
h. Establish/develop guidelines and recommendations for proper use and handling of carcinogenic chemicals and training packages for healthcare workers.
i. Have a system of monitoring services at the workplace and assess occupational exposures.
j. Empower workers by providing them with access to information about their exposures and risks.
k. Have programs to monitor employee performance, mental health, work-life balance and put in place debriefing programs.

1.18 Waste Management

The cancer centre shall:

a. Dispose radioactive, cytotoxic and radiopharmaceutical waste produced in the process of the diagnosis and treatment of cancer in accordance to international and relevant local guidelines.
b. Have written policies and SOPs for hazardous waste describing requirements for the segregation, packaging, labeling, collection, transportation storage and on site treatment of waste within the facility.
c. Provide waste disposal amenities and commodities.
d. Conduct regular capacity building on waste disposal for all healthcare providers including support staff.
e. Provide appropriate PPEs for handling hazardous waste.
f. Incinerate hazardous waste using special incinerators and maintain documentation on the same.
g. Minimize the risk of contaminating the local water supply and/or soil with hazardous drugs. Hazardous drug waste shall never be discarded into waste water (sink or toilet) or into a landfill.

h. Specific disposal systems should be mandatory for radioactive effluents. This system should be effectively and carefully maintained to prevent contamination and exposure of personnel to the radioactive waste both within and outside the facility.

1.19 Emergency Medical Care

The cancer centre shall:

a. Have facilities and human resources to handle oncologic and palliative care emergencies.
b. Ensure medical staffs are trained in BLS/ACLS.
c. Stabilize the patient and expeditiously refer for emergency management where applicable.
d. Be well equipped with resuscitation commodities and equipment.

1.20 Adverse Events

Any adverse event that occurs as a result of cancer diagnosis or treatment must be documented, discussed internally and reported to the relevant regulatory bodies such as the Pharmacy and Poisons Board, relevant regulatory body for radiation protection and the NCI-K.

1.21 Death of a Patient

The cancer centre shall:

a. Document all deaths occurring whilst patients are undergoing treatment appropriately.
b. Offer bereavement support to the family.
c. Have periodic mortality meetings where cancer deaths are discussed by a multidisciplinary team.

CHAPTER TWO

Physical Infrastructure

Chapter 2: Physical Infrastructure

The layout of the cancer centre should be planned taking into consideration equipment requirements, water and electrical utilities needed, room shielding required and climate control. It's important to consider the flow of patients in the facility. The layout should be planned in accordance with internationally accepted safety standards for the services to be provided.

The following section outlines the infrastructural considerations for different units. The cancer centre shall ensure the physical infrastructure meets the following requirements:

- Capacity for electricity, water, power backup, space
- Safety considerations – fire
- Separation of adult from pediatric management areas
- Disability infrastructure in all areas
- Maintenance considerations

2.1 All departments and units

For centres operating within the precincts of a hospital, it can utilize similar facilities within the hospital. For stand-alone centres, these services must be provided for:

a. Appropriate space for the following administrative services:
   i. Administration
   ii. Finance
   iii. Transport
   iv. Supply chain management
   v. Laundry
   vi. Healthcare waste management, including hazardous drug waste
   vii. Conference room
   viii. Resource centre
   ix. Reception area

b. Utilities
   i. Separate patient and staff changing rooms
   ii. Separate staff and patients rest rooms
   iii. Staff room

c. Health records and information – registration area
   i. Office space
   ii. Filing room
   iii. Use of electronic medical records system is strongly recommended

d. Other supportive services
    i. Provision for day care services where applicable
e. Cancer registry office
    i. Office space
    ii. Filing room

2.2 Ambulatory/Outpatient Oncology Clinic

Ambulatory care is medical care provided on an outpatient basis and includes screening diagnosis, observation, consultation, treatment and rehabilitation services.

a. Patient registration and reception area
b. Waiting area for patients/caregivers
c. Consultation and vaccination rooms
d. Procedure rooms including for screening services
e. Counseling rooms/rooms for chaplaincy and spiritual care
f. A medical laboratory registered and licensed by KMLTTB
g. Pharmacy which should meet the standards of PPB CAP 244 and the Narcotics and Psychotropic Act, 1994
h. If the ambulatory clinic offers chemotherapy treatment, it must meet the requirements of a chemotherapy unit

2.3 Chemotherapy Unit

a. Patient registration and reception area
b. Triage room/observation room
c. Procedure rooms
d. Counseling room
e. Waiting area for patients/caregivers
f. Consultation room
g. Chemotherapy administration area
h. At least one isolation room
i. Storage area for hazardous chemotherapy drugs with appropriate ventilation. Ideally, storage areas should have negative air pressure in relation to surrounding areas and have 12 air changes per hour
j. Chemotherapy reconstitution area should be large enough to contain a bio-safety cabinet
k. Staff changing area
l. Staff room/conference room
m. Pantry room
n. Separate staff and patients rest rooms
o. Sluice room
p. Have access to an accerited medical laboratory
q. Pharmacy should meet the standards of PPB

r. Storage facility for cytotoxic waste and other wastes
s. Disposal facilities for cytotoxic and other wastes
t. Eye wash station/shower

NB: if offering paediatric services, there should be dedicated child-friendly rooms

2.4 Radiation Therapy Unit

a. Patient registration and reception area
b. Observation room/triage
c. Waiting area for patients/caregivers
d. Control room area
e. Megavoltage bunker
f. CT /Ortho-voltage Simulator room
g. Treatment planning room
h. Medical physicists room (and for equipment storage)
i. Mould room where applicable
j. Patient changing room and washrooms
k. Brachytherapy suite includes mini theatre, brachytherapy bunker, brachytherapy imaging room, waste management and disposal facility

2.5 Nuclear Medicine Unit

a. Patient registration and reception area
b. Designated waiting area for patients and caregivers (clearly demarcated as cold area)
c. Treatment areas
d. Specialized scanning imaging rooms e.g. gamma cameras, SPECT, PET, PET/CT, bone densitometry
e. Patient holding, observation and recovery areas (clearly demarcated as hot area)
f. Radioactive waste store
g. Specially designated room with toilet and bathroom facilities for patients' exclusive use to minimize contamination
h. Waste management facilities as specified by IAEA for example a septic tank
i. Hot lab for preparation of radiopharmaceuticals
j. Imaging, viewing & scan reporting area (with requisite infrastructure)
k. Iodine wards for inpatients
l. Uptake rooms with calibration probes
m. Ventilation of the radiopharmaceutical production facility should meet

the requirements as per IAEA guidelines to prevent contamination of products and exposure of personnel to radioactivity. The production of sterile radioactive products should be carried out under negative pressure surrounded by a positive pressure zone ensuring that appropriate air quality requirements are met.

2.6 Surgical Oncology Unit

a. Patient registration and reception area
b. Waiting area for patients and caregivers
c. Consultation room
d. Triage/observation room
e. Counseling room
f. Procedure room
g. Support from:
    i. Operating theatre capable of handling minor and major surgical procedures
    ii. Diagnostic radiology unit
    iii. Pharmacy
    iv. Pathology unit
    v. Blood banking
    vi. Critical care unit
    vii. Rehabilitation centres
    viii. Endoscopy services
    ix. Morgue services

2.7 Inpatient oncology wards

a. Separate female, male, adolescents, geriatric and pediatric wards
    i. Side room facilities for ward reviews of post-operative wounds, minor procedures, and emergency resuscitation
b. Requirement for Comprehensive Cancer Centre:
    i. Isolation rooms for neutropenic patients and patients with infectious conditions.
c. Waste management facilities
d. Supportive services
    i. Pharmacy
    ii. Diagnostic radiology unit
    iii. Radiotherapy
    iv. Chemotherapy unit
    v. Medical laboratory unit
    vi. Blood banking

vii. Critical care unit
viii. Rehabilitation centre
ix. Hemodialysis unit
x. Nutrition
xi. Counseling
xii. Palliative care
xiii. Chaplaincy

e. Morgue services – cold room or alternative body preservation techniques e.g. embalming

2.8 Diagnostic Radiology Unit

a. Patient registration and reception area
b. Waiting area for patients/caregivers
c. Separate patients and staff rest rooms
d. Separate patients and staff changing rooms
e. Image reporting room
f. Imaging room specifications dependent on imaging modality and IAEA/local regulations
g. Procedure room
h. Recovery room
i. Conference room/staff room
j. Diagnostic & interventional radiology room

2.9 Pathology & Medical laboratory unit

a. Specimen collection and registration room
b. Reception area
c. Waiting area for patients/caregivers
d. Specimen preparation area/pre-analytic area
e. Reporting room
f. Availability of a conference room
g. Specimen storage room
h. Phlebotomy room
i. Access to a blood bank
j. Waste storage and disposal facility
k. Appropriate working space for
    i. Histopathology
    ii. Hematology
    iii. Clinical chemistry & immunoassays
    iv. Microbiology
    v. Cytology
    vi. Molecular diagnostics

2.10 Palliative Care and Survivorship Unit

a. Patient registration and reception area
b. Waiting area for patients/caregivers
a. Counseling room
b. Procedure room
c. Consultation room
d. Community room large enough to accommodate support groups
e. Support services
    i. Pharmacy
    ii. Nutrition
    iii. Chaplaincy
    iv. Counseling
    v. Rehabilitative unit
f. Pediatrics play area
g. Nutrition counseling rooms

2.11 Rehabilitation Unit

a. Patient registration and reception area
b. Waiting area for patients/caregivers
c. Consultation room
d. Counseling rooms
e. Procedure room
f. Storage for rehabilitation commodities

2.12 Medical Cyclotron Facility

The various stages of clearance needed for a medical cyclotron facility from RPB are as follows:

a. Site assessment and approvals

The Medical Cyclotron Facility (MCF) should be located and installed either in a hospital or in an industrial premise. The considerations for location are:

i. Maximum level of ground water and maximum flood level for the past ten years as per the county government, together with documentary evidence.
ii. Distance of site of installation of the MCF from the public or nearby residential facilities.
iii. Documentary evidence from an accredited agency that the soil and

ground characteristics will not cause deterioration in the strength and integrity of structure of irradiation cell and proof that no radioactive material was dumped there previously.

iv. Provision of suitable roads to approach the proposed site.

v. Details of any existing or planned auxiliary facilities such as ammunition dumps, and storage of inflammable and toxic substances within a radius of about 30 m from the proposed cyclotron vault of the MCF.

vi. There should be no residential or public premises within a radius of 30 m from the site.

b. Environmental Impact Assessment (EIA)

i. The applicant should not proceed with EIA until the board has approved the site.

ii. The board should be fully involved as a lead agency in radiation matters being the competent authority and as stipulated in section 104 of the Environmental Management and Coordination (amendment) Act 2015.

iii. The licensee shall acquire services of a competent party who is knowledgeable in radiological impact assessment and certified by the Radiation Protection Board to conduct an EIA.

c. Design and construction requirements

i. Consult the Services of a registered Architectural and structural Engineering firms, for the facility design and construction.

ii. Engage the services of a certified Technical Service Provider (TSP) to undertake baseline radiation studies, shielding calculations for the design, radiation protection provisions, emergency response, and radioactive waste management and decommissioning. This report should detail the layout plan of the facility and include the Preliminary Safety Assessment Report (PSAR). The suggested format is as follows:

   a. Organizational setup.
   b. Detailed system parameters of cyclotron, synthesis and dispensing units.
   c. Design safety features of cyclotron, synthesis and dispensing units.
   d. Zoning and Ventilation.
   e. Auxiliary facilities.
   f. Identification of hazards and its evaluation.

g. Emergency response planning and procedures.
h. Quality Assurance (QA)
i. Manual for construction.
j. Physical security measures.
k. Decommissioning manual.
l. Shielding evaluation calculations.

c. The Architectural Drawing, along with the shielding requirements shall be submitted to the equipment manufacturer for recommendations. The final Manufacturer endorsed drawings, shielding reports and any other related documents shall be forwarded to the Authority.
d. The structural Engineer should consider the floor loading of the cyclotron vault during construction putting in mind the gross weight of the cyclotron to be installed.
e. For any modification of the approved design, approval has to be obtained from RPB.

iv. Administrative requirements
a. Submit a copy of Certificate of Premises Registration.
b. Provision of certified copies of proof of registration of the company.
c. Name of company or organization, telephone, fax, email. Postal address of company or organization; Location and description of site.
d. Practice to be carried out and justification thereof.
e. Persons with legal and technical responsibility: name, field of specialization and qualifications of the applicant (legal and the technical person).
f. Designation of an officer (RSO) who shall develop skills in basic radiation safety and understand the regulatory requirements for practices involving radioactive materials and ionizing radiation.
g. Contractual agreement with a Technical Service Provider (TSP) for personnel monitoring.

2.13 Clinical PET Facilities

A PET/CT scanner can be installed in a room measuring approximately 8m x 5m, or even less, that meets requirements from the manufacturer such as weight bearing capacity, temperature stability, adequate power supply and radiation safety e.g. shielding. Access to a PET/CT scanner will strongly influence performance of diagnostic services. Models for setting up PET facilities depends on the organizational structures of different health-care systems and can be:-

a) **Located inside a hospital** – locating a PET facility within a large

hospital has the advantage of convenience to patients in accessing PET/CT investigations. The logistic services of hospital supports operation of the PET facility in terms of referrals, availability of resuscitation services, ease of scheduling patients etc

b) **Stand-alone PET facility** – these facilities are located outside a hospital since majority of patients can undergo a PET/CT on an outpatient basis. A necessary requirement for such a facility is access to good transportation for patients. There is also a need for good communication between such a PET centre and referring healthcare providers. Connection through picture archiving computerized systems (PACS) for rapid access to reports and images, and the possibility of teleconferencing, are desirable.

Regardless of the type of setup, access to medical emergency facilities is important to prevent potentially fatal allergic reactions to radiological contrast media used for the CT component of the procedures.

Layout of a PET/CT Facility

The facility can be divided into two parts – the PET/CT imaging facility and the cyclotron-radiopharmacy section. The location of the facility should ensure easy access for patients, radiation safety, cleanliness and sterility. Setting up the PET/CT facility in a pre-existing PET only facility may require significant renovation work. Consideration must be given to the size of the scanning room, number of preparation rooms (depending on patient workload) and the need to meet additional radiation protection requirements.

CHAPTER THREE

Equipment

Chapter 3: Equipment

Equipment may be acquired through direct purchase, donation, placement or lease. Technical specifications for the equipment to be acquired should be developed with the advice of the users in collaboration with experts including qualified clinical medical physicits for radiotherapy equipment and should not be more than 7 years old. Equipment must have service contracts and appropriate measures for plans for preventive maintenance purposes. There is need for equipment insurance. It's important to ensure standardization of equipment within the facility. In-vitro diagnostics (IVD) need validation and approval by the relevant regulatory bodies for in-country use.

Elements that are important for the life of the equipment and for safety shall be addressed early in the planning stage and should be included in contractual forms, such as:

1. Compliance with quality and safety standards
2. Acceptance tests and conditions to correct deficiencies revealed during acceptance
3. Warranty conditions
4. Enforceable assurances on availability of maintenance support (technical and financial), manufacturer support, manuals and spare parts
5. Training of all users

Acceptance testing and commissioning

Radiation sources need to be safely received, registered and stored; radiation measurement equipment tested and calibrated; shielding properties of special rooms measured; and the radiation sources tested and calibrated. All major equipment will require commissioning including teletherapy machines, imaging machines (simulators), brachytherapy units and TPSs. A record keeping system should also be in place. After commissioning has been completed, the specific tests needed for ongoing quality control and safety assurance will need to be carried out.

Equipment Donations

To ensure that the country does not become a dumping site for obsolete medical equipment and devices, the donations should be guided by the prin- ciples developed by the WHO. There should be effective communication between the donor, the recipient authority and, whenever possible, the end-user, before, during and after the donation. Donated second hand equipment should have a guarantee for refur- bishment guided by IAEA.

Timely replacement of equipment including radiotherapy machines is required to ensure cost-effective service delivery. A programmed schedule of asset management is required for replacement of equipment in compliance with international guidelines. For example, linear accelerators have a notional useful life of 10 years (or 82,500 treatments).

3.1 All Departments and Units

a. Appropriate equipment for the following services
   - i. Administration
   - ii. Finance
   - iii. Transport for emergency referral
   - iv. Supply chain management
     - Office equipment
     - Bar coding equipment
   - v. Laundry
   - vi. Healthcare waste management
   - vii. Grounds maintenance
   - viii. Security - Controlled access entries
   - ix. ICT
     - Computers
     - Telephones
     - Internet access
   - x. Reliable electricity – backup generator
   - xi. Reliable water supply
   - xii. Sterile services
     - Autoclave machine
   - xiii. Healthcare waste management infrastructure
     - Autoclave
     - Incinerator
     - Personal protective equipment

b. Health records and information
   - i. Computers
   - ii. ICD sets
   - iii. Software
   - iv. Printer/Copiers

c. Cancer registry office
   - i. Computers
   - ii. Software
   - iii. Printer/Copiers

d. Equipment for dissemination of health education materials in all waiting rooms.

3.2 Ambulatory/Out-patient department

a. Screening
   i. HPV test machines and kits
   ii. PAP smear kits
   iii. VIA/VILI reagents and commodities,
   iv. Cryotherapy and LEEP equipment & accessories
   v. Ultrasound and access to mammography equipment.
   vi. Biopsy guns
   vii. Endoscopy equipment

b. Consultation
   i. Equipment to take vital signs
   ii. Examination table
   iii. Furniture:
      - Desk
      - Chair
      - Shelves
   iv. Availability of
      - Computer
      - Printer
      - Scanner
      - Health Management Information Service
   v. Chaplaincy and Counseling
      - IEC materials
      - Information on nutrition, sexual dysfunction and healthy lifestyle

3.3 Chemotherapy Unit

a. Medical furniture
   i. Chemotherapy chairs
   ii. Assorted hospital beds
   iii. Bedside cabinets
   iv. Wheelchairs
   v. A biosafety cabinet
b. Hazardous drug spill kit
c. Infusion pumps
d. 4-hooked mobile drip stands
e. Lockable cabinets

f. Refrigerator
g. Crash cart for emergency/resuscitation including ambu-bags and masks for appropriate ages
h. Suction machine
i. Oxygen & oxygen masks
j. Weighing scale
k. Heightometer
l. Vital signs monitor including sphygmomanometer, thermometer, pulse oximeter
m. Measuring Cylinders
n. Stretchers
o. Procedure trolleys
p. Portable examination lamps
q. Audio-visual equipment –Television
r. Clock
s. ICT equipment

3.4 Radiation Therapy Unit

a. External Beam Radiation Therapy/Teletherapy machine

b. Electronic Portal Imaging Device (EPID) photo imaging device for verification
c. High dose Rate (HDR) brachytherapy machine (afterloader)
d. CT/Conventional treatment planning simulator complete with accessories
e. Dosimetry quality assurance equipment
f. Radiation Safety monitoring devices and radiation safety checklists and reporting.
g. ICT infrastructure and support
h. Treatment planning system
i. Standardized rulers
j. Two-way video cameras, with audio capability
k. Appropriate shielding requirements of radiation sources
l. 3-D water scan phantom
m. Range of radiation dosimeters for measuring radiation doses
n. Immobilization devices
o. Mould room equipment
p. Provision for anaesthesia space and recovery if facility is to offer pediatric radiation therapy

3.5 Nuclear Medicine Unit

a. Computer systems
b. Gamma cameras
c. Mixing/Reconstitution chamber
d. Radiation measuring equipment (dosimeters, isotope dose calibrators, scintillation counter, Portable contamination monitor/survey meter)
e. Hospital beds
f. Patient trolleys
g. Probes system including collimators
h. SPECT/PET/CT/Cyclotron imaging equipment as guided by RPB and NCI Kenya

3.6 Surgical Oncology Unit

i. Fully equipped major and minor theatres with standard anaesthetic, surgical and interventional equipment
ii. Fully equipped endoscopy suite

3.7 In-patient Oncology Wards

a. Wards
    i. Beds
    ii. Wheelchairs
    iii. Trolleys
    iv. Consumable and reusable equipment for IV and medication equipment
    v. Consumable equipment for phlebotomy
b. Requirement for a Comprehensive Cancer Centre
    i. High dependency unit for patients with complications awaiting referral to a facility with an ICU:-
        1. Cardiac monitoring device with defibrillator
        2. Emergency medications (crash cart and ambu bags and masks)
        3. Intubation equipment
        4. Oxygen supply
        5. Ventilation system
    ii. Hemodialysis unit
        1. Hemodialysis machine
        2. Water treatment
        3. Dialyzer reprocessing machine
        4. Consumables
c. Pharmacy
    i. Refrigerator for oncology medicines

ii. Weighing balance
iii. Measuring Cylinders
iv. Secure storage
v. Reference books (e.g. Martindale, other Pharmacopoeias)

d. Rehabilitation
   i. Prosthetics e.g. breast prostheses and orthotics for upper and lower limbs
   ii. Equipment to aid in lymphedema (upper and lower limbs)
   iii. Bowel/bladder dysfunction e.g. colostomy bags, gastrostomy tubes and other enterostomal products, nephrostomy tubes
   iv. Stents e.g. oesophageal, ureteral stents
   v. Chemoports and needles for both adults and pediatrics
   vi. Pediatric programs
   vii. Audiometry equipment

e. Chaplaincy and Counseling
   i. IEC materials
   ii. Information on nutrition, sexual dysfunction and healthy lifestyle

f. Morgue services
   i. Refrigeration system
   ii. Dissecting accessories
   iii. Microscope slides and accessories
   iv. Pathology instruments

3.8 Diagnostic Radiology Unit

a. X-ray unit
b. Ultrasound machine
c. Mammogram
d. Comprehensive cancer centre – in addition to the above, have a
   i. CT canner
   ii. MRI scanner

3.9 Pathology and Medical Laboratory Unit

The laboratory will be comprehensively equipped according to the scope of analyses to be performed in regard to cancer management.
The minimum equipment requirements are as shown in respect sections below:

a. Histopathology and cytology
   i Automated tissue processor
   ii Automated stainer

iii Microtome
iv Immunohistochemistry analyzer
v Cytospincentrifuge
vi Refrigerator
vii Freezer
viii Water bath
ix Hot air oven
x Binocular microscope
xi Multi head microscope
xii Reagents, accessories and consumables.

b. Biochemistry, immunology and virology
- Automated biochemistry analyzer
- Auto immunoassay analyzers
  - Centrifuge
  - Flow cytometry
  - Molecular PCR
- Reagents, accessories and consumables.

iii. Hematology and blood transfusion
- Hematology auto analyzer
- Binocular microscope
- Flow cytometer
- Water bath
- Apheresis equipment
- Centrifuge
- Freezer
- Refrigerator
- Reagents, consumables, and accessories

iv. Microbiology
- Binocular microscope
- Incubator
- Autoclave
- Hot air oven
- Freezer
- Refrigerator
- Culture plates and media
- Drug sensitivity discs
- Reagents, consumables, and accessories

v. Molecular
- Real time polymerase chain reaction machine
- Reagents, consumables, and accessories

3.10 Palliative Care & survivorship Unit

a. Furniture
   i. Examination couch
   ii. Storage cabinets and desks
   iii. Chairs
b. Equipment
   i. Dressing trolleys
   ii. Drip stands
   iii. BP machine
   iv. Thermometers
   v. Weighing scales
   vi. Infusion/syringe pumps
c. Electronics
   i. Computer
   ii. Printer
d. Pharmacy
   i. Refrigerator
   ii. Weighing balance
   iii. Measuring Cylinders
   iv. Spatulas
   v. Secure storage
   vi. Reference books (e.g. Martindale, other Pharmacopoeias)
e. Morgue services

3.11 Rehabilitation unit

a. Appropriate rehabilitation equipment and commodities e.g. lymphedema stockings, stoma bags, prostheses etc

3.12 Cyclotron facility

Importation Requirements

a. Model Number, Serial Number, Year of Manufacture, Country of Manufacture, Name of Manufacturer.
b. Equipment Specifications: Design and working principle, beam injection, Beam energy and current, type of cyclotron shielding, beam particles, magnetic properties, Radio frequency system, Vacuum system etc.
c. Standards to which the Medical Cyclotron comply.
d. Drawing and functional description of the accelerating chamber and target systems along with the radiation shielding.

e. Drawings along with the functional description of safety related control systems and devices.
f. Cyclotron Test Report Certificate from the country of manufacture.
g. Certificate from the competent Authority of country of design/ manufacture to verify that the equipment is approved for isotope production.
h. Information about the Radiochemistry synthesizer and dispensing system, HVAC system, Hot lab equipment, Radiation safety equipment, Quality Control equipment, etc., should be forwarded to the Authority.

Commissioning requirements

The process of Commissioning involves Pre-Commissioning and Trial run permission.

- After completion of construction and installation, the applicant should approach the regulatory body for permission to carry out a trial run for commissioning.
- For this purpose, the applicant should submit the following to the regulatory body:

a. Acceptance Tests conducted on the following equipment;
   i. Cyclotron
   ii. Radiochemistry Synthesizer System
   iii. Any other major equipment installed within the facility
b. Radiation Protection Program (RPP).
c. Details regarding availability of qualified and trained manpower – operator(s), radio pharmacist(s)/radio-chemist(s) and a Board approved Radiological Safety Officer (RSO).
d. Personnel monitoring services for all radiation workers
e. Appropriate radiation measuring and monitoring Instruments
f. Operational procedure manual
g. Safe handling tools and devices required for operation and maintenance of the medical cyclotron and auxiliary equipment
h. Security Plan
i. Submit the Commissioning Test Report for the medical Cyclotron to the Authority

After successful trial runs, the applicant becomes eligible for obtaining consent for trial operations.

Decommissioning requirements

When the medical cyclotron is no longer to be used, the permission for decommissioning shall be obtained from the Radiation Protection Board. The licensee should apply for the decommissioning license and supply the Authority with the following;

a. Safety assessment survey report of the radiological and non-radiological hazards involved during decommissioning exercise.
b. Decommissioning Plan.
c. Radiation Protection considerations for the decommissioning workers.
d. Public radiation protection consideration at vicinity.
e. Qualified Radiation safety supervisor designated for the exercise.
f. Radiation safety equipment to be used for decommissioning.
g. Radioactive waste management, transport and disposal plan for the decommissioning.
h. Site radiation decontamination and final radiation survey.

The licensee shall submit a report on the completion of decommissioning, which includes among others; safe disposal of sources and personnel exposures received during decommissioning.

3.13 PET Equipment

PET/CT Scanners

The basic components of a PET system include the scintillator, detector, photomultiplier tubes (PMT), electronics and reconstruction software. Each of these components contribute to the overall performance of the PET system.

Radionuclide Activity Calibrator

A radionuclide activity calibrator is a fundamental requirement for the operation of a PET centre. It allows accurately measured radiopharmaceutical doses to be administered to patients, and is also used for other laboratory tasks like measuring time-activity curves. A PET centre will thus be equipped with one or more radionuclide activity calibrators, depending on the type of installation.

Radioanalytical equipment

Appropriate quality management systems for validation and the appropriate radioanalytical equipment for radioanalytical testing should be duly considered to ensure safety of drugs administered. HPLC, TLC and gamma spectroscopy are used for this purpose.

CHAPTER FOUR

Human Resource

Chapter 4: Human Resource

4.1 Minimum Human Resource for a Cancer Centre

In this section, the minimum cadres of staff required for a cancer centre is stated as well as the minimum recommended qualifications for each. Ideally patient navigators should be incorporated in patient care to ensure quality service.

Human resource category	Minimum Qualifications	Roles and Responsibilities (in addition to relevant job description and scope of professional practice)
Anesthesiologists	- MMed in Anesthesia - Licensed to practice by KMPDB	Review patients for surgery; pain management; in charge of ICU/HDU
Biomedical engineering officers (medical engineers or technologist)	- Diploma or bachelors in medical engineering and trained on maintenance of cancer equipment. - Registered by the Association of Medical Engineers of Kenya (AMEK) or relevant international body	Installation, maintaining service contracts and equipment documentation and regular maintenance of cancer equipment at the facility
Biosafety/biosecurity officer	- Degree in Medical Laboratory or related discipline - Registered and licensed by KMLTTB	Research; biosafety services in lab

Cancer registrars	- Degree/diploma holder in Health Records & information. - Trained in cancer registration from African Cancer Registry Network (AFCRN) approved provider	Cancer data abstraction, maintenance of cancer patients records and participation in cancer research
Clinical counselors	- Diploma/degree in psychological counseling. - License to practice from relevant body	Counseling of patients and their caregivers/ families on cancer; patient navigation; research; member of MDT
Clinical Officer anesthetist	- Higher Diploma in Anesthesia - Licensed to practice by the Clinical Officers Council	Review patients for surgery; pain management in consultation with the anesthesiologist
Clinical Officers in oncology	- Higher National Diploma in Clinical Medicine Oncology. - Trained in BLS/ACLS - Licensed to practice by the Clinical Officers Council	Health education; screening activities; assess, prescribe and administer subsequent cancer treatment under supervision of an oncologist; participate in research and MDT activities
Clinical pharmacist	- Masters in clinical pharmacy or equivalent - Licensed to Practice by PPB. - Training and certification in chemotherapy handling and administration	Head of pharmaceutical oncology services; allocation of duties; supervision; member of MDT; research; in charge of supply chain of oncology commodities; in-charge of preparation of chemotherapy medications

Clinically qualified radiotherapy physicists/Medical Physicists	Bsc in physics with postgraduate training in medical physics or Msc Medical Physics with clinical training in radiotherapy physics	Responsible for equipment selection, specifications, acceptance, delivery, , design of installations and shielding requirements, commissioning and management for radiotherapy, diagnostics and nuclear medicine; Treatment planning in collaboration with the radiation oncologist; safety assessment, establishment, measurement and supervision of QA for radiotherapy and nuclear medicine devices,; radiation protection and safety; dose calibration and instrumentation; technical supervision of maintenance; research and innovation of new medical devices; teaching – radiation protection & users of equipment
Gynaecology Oncologist	- MMED Obs/Gyne with a fellowship in Gynae Oncology. - Licensed to practice as a Gynae oncologist by KMPDB	May be the designated head of the cancer centre/facility; assessment, initiation, surgical management and review of gynaecological cancer patients; participate in MDTs meetings; participate in clinical research in oncology; screening for gynae cancers
Haemato-oncologist	- MMED/Fellowship with specialization in hemato-oncology - Licensed to practice by KMPDB	May be the designated head of the cancer centre/facility; cancer diagnosis; assessment, initiation, review of patients cancer treatment; chair MDTs meetings; participate in clinical research in oncology
Health education and outreach coordinators	Training in Health Education/Health promotion	Design health education programs, outreaches & materials for patients and caregivers
Health records and information officer	- Degree/diploma holder in Health Records & information - Registered with Association of Medical Records of Kenya. - Preferably trained in customer care	Registration and maintenance of patient records/files
Housekeeping staff	- KCSE Certificate - Relevant training in housekeeping - Training in safe handling of hazardous products	Handling of waste and cleaning

Interventional radiologists	- MMED in radiology - Fellowship in interventional Radiology - Licensed to practice by KMDPB	In-charge of interventional diagnostic radiology activities including biopsy collection; research; member of MDT
Laboratory manager	- Degree in Medical Laboratory or related discipline and management training - Registered & licensed by KMLTTB	In-charge of lab services; allocation of duties; research; member of MDT
Lab quality assurance officer	- Degree in Medical Laboratory or related discipline - Registered and licensed by KMLTTB	Research; QA in lab
Medical Laboratory technologist	- Diploma or degree in Medical Laboratory (Bsc) or related discipline - Registered and licensed by KMLTTB - Each section of the laboratory to be headed by a medical laboratory technologist with a diploma in Medical Laboratory Sciences in the disciplines - Clinical Cytology/ Histopathology, Biochemistry, Microbiology, Immunology, Molecular Sciences, Blood Transfusion/ Haematology Sciences, Epidemiology, public health or virology	Provide lab services, research; sample collection; safe waste disposal; relay of results

Medical Officers	- MBCHB - Licensed to practice by KMPDB - Training and certification in chemotherapy handling and administration - Trained in BLS/ACLS	Health education; screening activities; assess, prescribe, administer subsequent cancer treatment under supervision of an oncologist; participate in research and MDT activities
Medical oncologists	- MMED and a fellowship in medical oncology - Licensed to practice as an oncologist by KMPDB	May be the designated head of the cancer centre/facility; assessment, initiation, review of patients cancer treatment; chair MDTs meetings; participate in clinical research in oncology
Medical social worker	Diploma or bachelors in social Sciences	Assessment of socio-economic background of patients; Contact tracing; patient navigation; research; member of MDT
Nuclear medicine physician	- MMed or equivalent in Nuclear medicine. - Licensed to practice by KMPDB	In-charge of nuclear medicine department; supervision; allocation of duties; assess, prescribe, prepare & administer radioisotopes ; diagnosis; interpretation & reporting of tests; enforce radiation protection standards for patients & staff; quality control of nuclear medicine services; training; research; waste management; equipment selection; MDT member
Nuclear medicine technologist	- Degree/diploma in nuclear medicine - Trained in BLS	Obtains patient history & describe procedure to patient; administer nuclear medicine treatment; prepare & administer radiopharmaceuticals; monitors patient's condition during procedure; perform imaging procedures for diagnosis; analyze biological specimens in the lab; nuclear waste disposal; equipment calibration
Nurse anesthetist	- Higher diploma in anesthesia - Licensed by NCK	Review patients for surgery; pain management in consultation with the anesthesiologist

Nurse - Advanced Oncology (Adult and pediatric care)	- MSc Nursing or equivalent focused in oncology Nursing - Trained in BLS/ACLS - Registered with Nursing Council of Kenya (NCK)	May be the designated head of the cancer centre/facility; providing nursing care to cancer patients; health education; screening activities; part of the MDT; comprehensive patient assessments; symptom management; treatment side effects management; patient navigation activities; clinical research in oncology; advocacy; mentorship and teaching; policy formulation and implementation; screening activities
Nurse - General (adult care and pediatric care)	- Diploma or Degree in Nursing -Certification in chemotherapy handling and administration (those working in chemotherapy units) -Undergone an appropriate induction program in cancer management - Trained in BLS/ACLS - Registered with Nursing Council of Kenya	Providing nursing care to cancer patients in collaboration with other members of the MDT, in all areas of cancer treatment; health education; screening activities; participate in clinical research in oncology; screening activities
Nurse Manager	- BSc Nursing with Specialized oncology nursing training, - Registered with Nursing Council of Kenya. - Additional qualification in admin and MSc is an added advantage	Head of Nursing oncology services; Coordination, Directing and organization of patient care activities in the unit; Resource management and Budgeting; Staffing activities; Quality management; Reporting participate in MDTs meetings; Participate in clinical research; policy formulation, implementation and monitoring

Nurses - Palliative care	- Diploma or Degree in Nursing - Specialized Palliative care nursing - Higher Diploma, MSc Nursing or an accredited Palliative program - Registered with Nursing Council of Kenya	May be the designated head of the palliative care services in the facility; nursing care to cancer patients in the MDT; comprehensive patient assessments; Pain and Symptom management; Management of treatment side effects; Patient navigation activities; initiating , organizing and facilitating family conferences and advance care planning; end of life and bereavement care; clinical research in palliative care; advocacy; mentorship and teaching; policy formulation and implementation
Nurses - Peri-operative	- Diploma in Nursing. - Peri operative nursing training is an added advantage - Registered with the Nursing Council of Kenya	Providing post-surgical nursing care to cancer patients in collaboration with other members of the MDT; clinical research in oncology
Nurse - Specialized oncology (Adult and paediatric care)	- Diploma or BSc Nursing - Specialized oncology nursing training at Higher Diploma, MSc Nursing or an accredited oncology program - Trained in BLS/ACLS - Registered with Nursing Council of Kenya	Provide nursing care to cancer patients in collaboration with other members of the MDT; health education; screening activities; comprehensive patient assessments; symptom management; management of treatment side effects; patient navigation activities; clinical research in oncology; advocacy; mentorship and teaching; policy formulation and implementation; screening activities
Nutritionists	- Diploma or degree in Nutrition - License to practice from Nutritionists & Dieticians Council	Provision of nutritional counseling and support to patients and their families/caregivers; research; member of MDT
Orthopedic technologists	Diploma, higher diploma or bachelors in orthopedics	Provision of rehabilitative services to patients; research; member of MDT

Occupational therapists	Diploma, higher diploma or bachelors in occupational therapy	Provision of rehabilitative services to patients; research; member of MDT
Paediatric Oncologist	- MMED Paediatrics with fellowship in paediatric oncology - Licensed to practice by KMPDB	May be the designated head of the cancer centre/facility; cancer diagnosis; assessment, initiation, review of paediatric patients cancer treatment; chair MDTs meetings; participate in clinical research in oncology
Paediatric palliative care specialist Palliative care social workers Palliative Counselors Palliative care doctor	Minimum is a diploma in palliative care in addition to the basic and postgraduate cadre qualification and licensed to practice by the relevant regulatory body	Provision of palliative and supportive care to patients; research; member of MDT; assist in developing a patient care plan in collaboration with the oncologist; rehabilitation; survivorship; referrals to hospices
Pathologists	- MMED/fellowship in anatomic /clinical Pathology - Licensed by KMPDB	Head pathology services; collection of samples for diagnosis; reporting of pathology specimens; member of MDT; research
Pharmacists	- Degree in pharmacy - Licensed to Practice by PPB - Training and certification in chemotherapy handling and administration	Preparation of chemotherapy medications under supervision of a clinical pharmacist; member of MDT; research; supply chain management of oncology commodities
Pharmaceutical technologists	- Diploma/Higher National diploma in Pharmacy - Enrolled to Practice by PPB - Training and certification in chemotherapy handling and administration	Preparation of chemotherapy medications under supervision of a clinical pharmacist; research; supply chain management of oncology commodities
Physiotherapists	Diploma, higher diploma or bachelors in physiotherapy	Provision of rehabilitative services to patients; research; member of MDT

Porters	- KCSE Certificate - Training in customer service - Training in basic life support for non-medical providers	Ferrying of patients between service points within the facility
Psychologists (both adult and paediatric)	- Degree in psychology. - License to practice from relevant body	Counseling of patients and their caregivers/ families on cancer; patient navigation; research; member of MDT
Quality Assurance Officer/ Safety health officer - Quality assurance officers - Radiation Safety Officers - Patient Safety officer - Occupational safety & health officer	A designated Quality Assurance Officer/ Safety health officer	Liaise with all departments to ensure safety & quality assurance is embedded in their processes
Radiation oncologists/clinical oncologist	- MMED/Fellowship in radiation oncology/ Clinical oncology - Licensed to practice as an oncologist by KMPDB	May be the designated head of the cancer centre/facility; in charge of radiotherapy treatment; assessment, initiation, review of patients cancer treatment and patient follow up; treatment planning; chair MDTs meetings; participate in clinical research in oncology; participates in equipment procurement
Radiation Therapists (RTT) /Therapy radiographers	-Diploma or higher diploma in radiation therapy - Trained in BLS	Participate in treatment planning; administer radiotherapy treatment under supervision of the radio-oncologist; participate in research and MDT activities

Radiographers	- Diploma in Radiography - Trained in BLS - Licensed to practice by the Radiation Protection Board	Diagnostic imaging services; research
Radiologists	- MMED diagnostic imaging & radiation medicine or equivalent - Licensed to practice by KMDPB	In-charge of diagnostic radiology activities; allocation of duties; research; member of MDT
Radiotherapy Services Manager	The officer in charge to hold at least a bachelor's degree in therapy radiography	To head and coordinate radiotherapy services in the centre
Sonographer	-Minimum qualification of higher diploma in ultrasound imaging - Trained in BLS	Ultrasound services; research
Surgeons	- MMED Surgery or equivalent and/or specialization in Oncology. - Licensed to practice by KMPDB	May be the designated head of a surgical cancer facility; assessment, conduct surgery and review of cancer patients after surgery; participate in research and MDT activities; patient referrals

4.2 Human Resources for Operation of a Medical Cyclotron & PET Facility

Human Resource Category	Minimum Education	Specialized Training & Role
Cyclotron Operator(s)	Technical degree or equivalent e.g. BSc in Electrical/Mechanical/Instrumentation/ Bio-medical/Physics	• Supervised training for 6 months • On the job training • Radiation Protection and Safety • Electrical and mechanical repairs
Electronics Engineer	Diploma or degree in electronics, electro-mechanical engineering or equivalent	• On the job training • Supervised training for 6 months • Radiation Protection and Safety
Mechanical Engineer	Diploma or degree in mechanical, electro-mechanical engineering or equivalent	• On the job training • Supervised training for 6 months • Radiation Protection and Safety
Production Chemist (s)	Diploma or BSc in Chemistry or equivalent	• On the job training • Supervised training for 6 months • Radiation Protection and Safety
Quality Control Chemist (s)	Diploma or BSc in Chemistry, biochemistry, pharmacy or equivalent	• On the job training • Supervised training for 6 months • Radiation Protection and Safety • Experience in GMP • Experience in target preparation • Synthesis of radiotracers • Training in laboratory operations
Radiation Safety Officer (RSO)	Advanced degree in Medical Physics, Health Physics, radiation physics or equivalent	• Supervised training for 6 months • Radiation Protection and Safety
Radiopharmacist	Degree in pharmacy with post graduate training in radiation physics/radiopharmaceutical sciences	• Preparation & dispensing of radiopharmaceuticals • Skills in aseptic manipulation & safe handling of radioactive products • Knowledge on analytical techniques for quality control • Trained in GMP

As a good practice, countries involved in radioisotope production technology require staff of such facilities to be certified by the manufacturer of the cyclotron facility.

ANNEXES

ANNEX 1: APPLICATION FORM TO NCI-K

THE NATIONAL CANCER INSTITUTE OF KENYA
CANCER MANAGEMENT CENTRE CERTIFICATION APPLICATION FORM

Applicant details		
Please type or print in capital letters		
Cancer Management Centre name		
Physical address		
Mailing address		
Service Centre type (Tick as appropriate)	Basic Cancer Treatment Centre	
	Comprehensive Cancer Centre	
Hospital/Institute head Name		
Mailing address		
Contacts	Tel.	E-mail
Department head/Cancer Centre Manager Name		
Mailing address		
Contacts	Tel.	E-mail

Please indicate compliance with each of the 13 items

	Item	Yes	No	N/A
1	Does your cancer centre or oncology department provide the following services:			
	a. Cancer prevention e.g. HPV, Hep B vaccination			
	b. Cancer screening, early detection and treatment of pre-cancerous lesions			
	c. Inpatient wards			
	d. Ambulatory/outpatient			
	e. Basic diagnostic laboratory & pathology			
	f. Basic diagnostic radiology			
	g. Surgical capacity for diagnosis and treatment			
	h. Radiotherapy			
	i. Medical oncology services			
	- Chemotherapy			
	- Targeted therapy			
	- Hormonal therapy			
	- Immunotherapy			
	- Bone marrow transplants			
	j. Palliative care			
	- Pain assessment & management			
	- Psychosocial management			
	- Rehabilitation			
	- Survivorship			
	- End of life care			
	k. Cancer registration			
	l. Comprehensive laboratory & pathology services			
	m. Comprehensive radiology services			

	n. Radiation oncology			
	o. Nuclear medicine			
	p. Oncology training programs			
	q. Cancer research			
	r. Other (specify)			
2.	Does the centre have a mechanism to ensure continuity of care, follow up and survivorship?			
3.	Does the centre provide routine patient assessment of - Physical			
	- Psychological symptoms			
	- Social support			
4.	Does the centre incorporate support of family members/caregivers?			
5.	Does the centre provide emergency care of inadequately relieved physical and psychological symptoms?			
6.	Does the centre have mechanisms for linkage to home based care, hospices and coordination of cancer care with primary care providers?			
7.	Is the centre involved in oncology-related capacity building of healthcare providers?			
	NB: Attach relevant documents with the application form			
	▪ Clinical service license facility form from KMPDB			
	▪ Certified academic qualifications of staff at the centre			
	▪ Professional practice registration forms			
	▪ Retention certificates			
	▪ Design plans for the centre			
	▪ Waste disposal plan			
	▪ Evidence of compliance with relevant regulatory bodies			

Name of Applicant: _____

Designation : _____

Signature: _____

Date : _____

Send to	Send via E-mail to
National Cancer Institute-Kenya **Ministry of Health, Cathedral Road, Upper Hill,** **P.O. Box 30016-00100, Nairobi**	**ncikenya@gmail.com**

FOR OFFICIAL USE ONLY

Received by: Name: _____

Signature : _____

Date: _____

ANNEX 2: CANCER ABSTRACT FORM

M.O.H. HOSPITAL BASED CANCER ABSTRACT FORM MOH NO.

Health facility Name_____	Sub county_____	County _____
Year:	Month_____	Year _____

REGISTRATION NUMBER								

A. PATIENT:

1. NAME

SURNAME	MIDDLE NAME	LAST NAME

2. Identification No._____ 3. Marital Status ☐ 1=Single 2=Married 3=Widowed 4=Separated

4. Tel No: [Patient]_____5.Tel. No: [NoK]_____

6. Age ☐☐ 7.Date of Birth d d / m m / y y y y 8. Sex___ [1=Male 2=Female 9=Unk]

9. Place of Residence

A. COUNTY	B. CONSITUENCY	C. WARD / ESTATE

10. Place of Birth_____ 11. Tribe _____

12. Religion ☐
- 1 – Christian
- 2 – Muslim
- 3 – Hindu
- 4 – Other

13. Education level _____

14. Occupation _____

15. Smoking Status ☐ [1.Never 2.Smoker 3.Ex-Smoker 9.Unknown]

16. Drinking status ☐ [1.Never 2.Alcoholic 3.Ex-alcoholic 9.Unknown]

B. TUMOUR:

17. Incidence date d d m m y y y y

18.Basis of Diagnosis ☐
- 0 – Death cert only
- 1 – Clinical only
- 2 – Clinic. Invest/ radio-imaging
- 4 – Biochem. Immuno test
- 5 – Cytology/Haematology
- 6 – Histology of metastasis
- 7 – Histology of primary
- 9 – Unknown

19. Primary Site _____ Code No._____

20. Laterality 1.Unilat. ☐ 2. Bil. ☐ 3. Rt ☐ 4.Lt ☐ 5.Unk. ☐

_____

_____Morphology code ☐☐☐☐

22. Behaviour ☐
- 0 – Benign
- 1 – Uncertain
- 2 – In situ
- 3 – Malignant
- 6 Malignant metastatic
- 9 Malignant unknown

23. Grade ☐
- 1 – Well diff
- 2 – Moderately diff
- 3 – Poorly diff.
- 4 – Undifferentiated/Anaplastic
- 5 – T-cell
- 6 – B-Cell
- 7 – Null Cell
- 8 – Killer cell
- 9 – Unknown

24. Stage ☐
- 0 – In Situ
- 1 – Stage I
- 2 – Stage II
- 3 – Stage III
- 4 – Stage IV
- 9- Unknown

T _____

N _____

M _____

C.TREATMENT

25.FIRST COURSE OF TREATMENT: [1=N0; 2=YES; 9=UNKNOWN]

Surgery ☐	Date / / Date / /	Radiotherapy ☐	Date / / Date / /
Chemotherapy ☐	Date / / Date / /	Hormone therapy ☐	Date / / Date / /
Immunotherapy ☐	Date / / Date / /	Other	Date / / Date / /

D. CONCURRENT ILLNESS:

26. DOCUMENTATION OF HIV STATUS.

Lab Report Available in Pt. file. Yes ☐ ☐ Lab No. _____

CD4 Count _____

Status Indicated in the Clinical Notes ☐ Yes ☐ No

27. Specifically (-ve) ☐

28. Specifically (+ve) ☐

29. Other Concurrent illness_____

E. SOURCES:

30. Source 1. Hosp._____Hosp. No. _____ SRC date 1_____

31. Source 2. Lab._____ Lab. No. _____ SRC date 2_____

32. Referred from_____ IP NO._____

33. Referred to_____ IP NO._____

F. FOLLOW UP:

34. Present Status ☐ 1-Alive 2-Dead

37. Date of Last Contact/Date of death: _____ / _____/ _____

35. Hospice No._____

39.If dead, cause of death_____

Remarks if any _____

Form filled by_____ Date_____ Checked By_____

ANNEX 3: CANCER SCREENING FORM

SERIAL NUMBER_____

CANCER SCREENING AND EARLY DIAGNOSIS FORM

FACILITY NAME_____ DATE_____

SECTION A: SOCIO-DEMOGRAPHIC DATA

Inpatient/Outpatient number_____ National ID no _____

Name_____ Sex_____ Age (years) _____

Marital status_____ No. of children _____

Patient phone no_____Address_____

Next of kin (nok) name_____ relationship to n.o.k_____ N.O.K. phone No_____

Current residence: county_____Sub-county_____Ward/Estate_____

Length of time lived in current residence (years) _____

Highest educational level_____ Occupation_____

Ethnicity/Race_____

Where did you learn about this screening program?

Word of mouth ☐ From media ☐

Healthcare worker ☐ other ☐ (specify) _____

Screening service point: MCH/FP ☐ CCC ☐ GOPC ☐ OUTREACH ☐

other ☐ (specify) _____

Referred to this facility? Yes ☐ No ☐ if yes, from_____

REASON FOR REFERRAL_____

VITAL SIGNS: BP_____ PULSE RATE_____

WEIGHT_____ HEIGHT_____BMI_____

BLOOD SUGAR LEVEL_____

CSF 1

SECTION B: FAMILY HISTORY

Any history of cancer in the family?

If yes, which cancer? _____

Who was affected? Parent ☐ Sibling ☐ 1st or 2nd degree relative ☐

Other ☐ (Specify) _____

What was the age at diagnosis? (Years)_____

What was the sex of the person affected? Male ☐ Female ☐

SECTION C: CLINICAL/RISK FACTOR HISTORY

Tick as appropriate

RISK FACTORS

Risk factors history	Tick
Smoking	
Alcohol intake	
Previous chemotherapy or radiation treatment	
Any other (specify)	

COMMON SYMPTOMS

Symptom history	Tick
Recurrent indigestion (dyspepsia)	
Blood in stool	
Yellow eyes	
Blood in urine	
Epistaxis (nose bleeding)	
Difficulty in swallowing	
General weight loss	
Easy fatigability, palpitations	
Abnormal vaginal bleeding	
Enlarging/changing skin moles	
Chronic skin ulcers	
Any lumps or swellings	
Chronic cough	
Persistent headaches	
Changing bowel habits	
Others (specify)	

CSF 2

SECTION D: TYPE OF CANCER SCREENING

Cancer	Visit type	Screening modality	Last screening modality done	Date of last screening
Cervical	Initial screening ☐ Repeat screening ☐ Post-treatment screening ☐	HPV testing ☐ Pap smear ☐ VIA/VILI ☐		
Breast	Initial screening ☐ Repeat screening ☐ Post-treatment screening ☐	Clinical breast examination ☐ Ultrasound ☐ Mammogram ☐		
Prostate	Initial screening ☐ Repeat screening ☐ Post-treatment screening ☐	DRE in combination with PSA testing ☐		
Colorectal	Initial screening ☐ Repeat screening ☐ Post-treatment screening ☐	Fecal occult blood test ☐ Colonoscopy ☐		
Retinoblastoma (known Retinoblastoma 1 mutation or positive family history)	At birth ☐ Vaccination clinic ☐	Eye exam under anaesthesia ☐		

Retinoblastoma screening frequency

1. Known RB 1 mutation on genetic testing:
    - Every 6 weeks until 1 year, then every 3 months until 3 years, then every 6 months until 6 years
2. No genetic testing available
    - Option 1 – positive family history for parent
        - At birth, then every month for 3 months, then every 3 months for 3 years
    - Option 2 – positive family history for sibling
        - At birth, then every month for 3 months, then every 3 months for 1 year

CSF 3

SECTION E: SCREENING RESULTS

Cancer	Screening modality	Results/findings	Recommended action
Cervical	▪ HPV ▪ Pap smear ▪ VIA/VILI		
Breast	▪ Clinical breast examination ▪ Ultrasound (<40 years) ▪ Mammogram ≥ 40 years		
Prostate	▪ DRE in combination with PSA testing		
Colorectal	▪ Fecal occult blood test ▪ Colonoscopy		
Retinoblastoma	▪ Eye exam		

SECTION F: FOLLOW UP

Return date_____

Referred to_____

Referred for further screening (give reasons)

_____

_____

Health service provider:

Name_____**Cadre**_____**Signature**_____

CSF 4

ANNEX 4: CANCER TREATMENT INFORMED CONSENT/ASSENT FORM

MINISTRY OF HEALTH

Informed Consent/Assent to Cancer Treatment

Name of Cancer Management Centre_____

Date: _____

Patient Details:

Name _____

Age (Years) _____

Gender _____

Name of translator (if applicable)_____

Name of parent/guardian (for children) _____

Place of consent_____

I understand that I (or my child) have been diagnosed with

_____

I understand that the treatment suggested by my healthcare team led by Dr. (Name of oncologist) _____, will involve (tick all that apply)

- ☐ Chemotherapy
- ☐ Radiotherapy
- ☐ Radio-ablative therapy
- ☐ Surgery
- ☐ Others (Specify) _____

The aim of my/my child's treatment is

- ☐ Cure
- ☐ Relief of symptoms
- ☐ Reduction of tumour size
- ☐ Maintenance therapy
- ☐ Others (Specify) _____

Further, I understand that:

1. I am an adult of sound mind capable of making decisions on my behalf (or my child)
2. Other health care providers may be needed for my care
3. There are benefits of this treatment if it is successful
4. My healthcare team cannot guarantee that the treatment aim will be achieved.
5. The treatment recommended by my healthcare team can have short-term and long-term adverse effects. I have been informed about the side effects that I might experience because of my treatment
6. The reasonable alternatives to this treatment have been explained to me

7. Upon review, my healthcare team may recommend a change or termination of my treatment

8. I can voluntarily opt out of the suggested treatment option at any time without any prejudice.

9. I have had the chance to ask questions about this treatment, and all my questions have been answered to my satisfaction

10. I can contact my health care team at any time if I have questions, by calling this phone number_____
11. I am signing this consent without any coercion or under duress.

12. I will receive a copy of this consent form and by signing this document I am consenting to receive the treatment proposed by my health care provider.

Patient/Guardian Name_____

Patient/Guardian Signature _____

Date_____

Healthcare Provider Signature_____ Date_____

Witnesses

1. Patient's Witness: Name _____Signature _____

   Date_____

2. Healthcare worker: Witness Name _____Signature _____

   Date_____

3. Child Assent (for children >7 years): Name _____

   Signature/Thumb print _____ Date _____

ANNEX 5: CHEMOTHERAPY ADMINISTRATION FORM

CHEMOTHERAPY ADMINISTRATION FORM

Date of treatment_____ Cycle No___/___
Patient Name_____ Age_____ Gender_____
Hosp. No._____ Diagnosis_____
Weight_____ Height_____ BSA_____
Drug Allergies_____
Doctor's Name & Signature _____

PREVIOUS CHEMOTHERAPY ADMINISTERED

Previously received chemotherapy? Yes [ ] No [ ]

If yes, list as shown below:-

Drugs administered	**Dosages**	**No. of cycles given**	**Last date given**

PARAMETERS

Date	TBCs					U/E/Cs				LFTs		
	HB g/dl	**WBC** X10/L	**NEUT** X10/L	**ABS NEUT** %	**PLTS** X10/L	**Creatinine**	**CrCl** ml/min	**UREA**	**K**	**AST/ ALT**	**T/BILI**	**ALP**

PRE- HYDRATION

Date	Type of fluid	Amount	Administered by	Duration

PRE- CHEMOTHERAPY ORDERS

							Pharmacy			Nursing	
Date	**Drug**	**Dose**	**Route**	**Freq**	**Diluent and volume**	**Duration**	**Dispensed by**	**QTY**	**Reconstituted by**	**Time given**	**Given by**

CHEMOTHERAPY ORDERS (INJECTABLES

							Pharmacy		Nursing	
Date	**Drug**	**Dose**	**Route**	**Diluent and volume**	**Duration /rateof administration**	**Ordered by**	**Dose**	**Dispensed by**	**Time given**	**Given by**

CHEMOTHERAPY ORDERS (ORAL)

						Pharmacy		Nursing	
Date	**Drug**	**Dose**	**Freq**	**Duration**	**Ordered by**	**Qty**	**Dispensed by**	**Time given to patient**	**Given by**

POST HYDRATION ORDERS

Date	Type of fluid	Quantity	Ordered by	Duration

POST-CHEMOTHERAPY ORDERS/DISCHARGE DRUGS

							Pharmacy		Nursing	
Date	**Drug**	**Dose**	**Route**	**Frequency**	**Duration**	**Ordered by**	**Quantity**	**Disp by**	**Time given**	**Given by**

ANNEX 6: GENERIC LAYOUT DESIGNS

a) Chemotherapy Unit

Part B: Health Facility Briefing & Design Oncology Unit - Medical (Chemotherapy)

Functional Relationship Diagram - Oncology Unit - Medical (Chemotherapy)

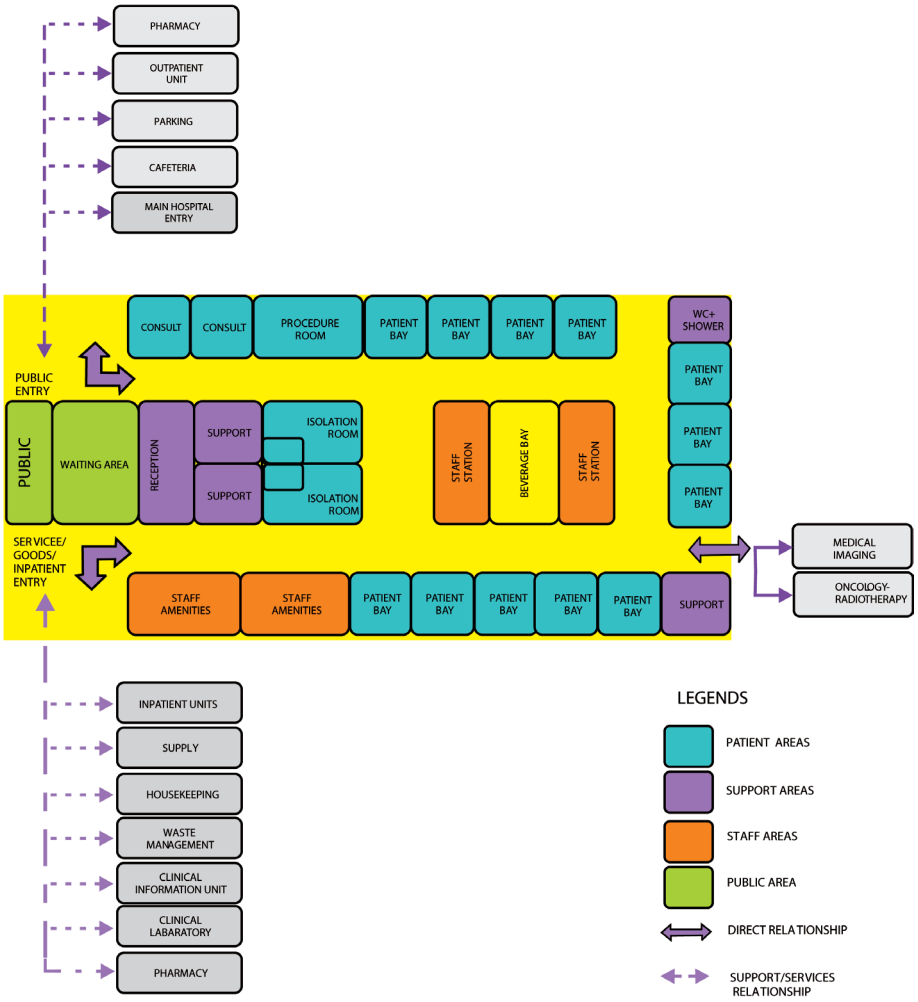


Figure 1- Functional Relationship Diagram

b) Radiation Unit

Functional Relationship Diagram

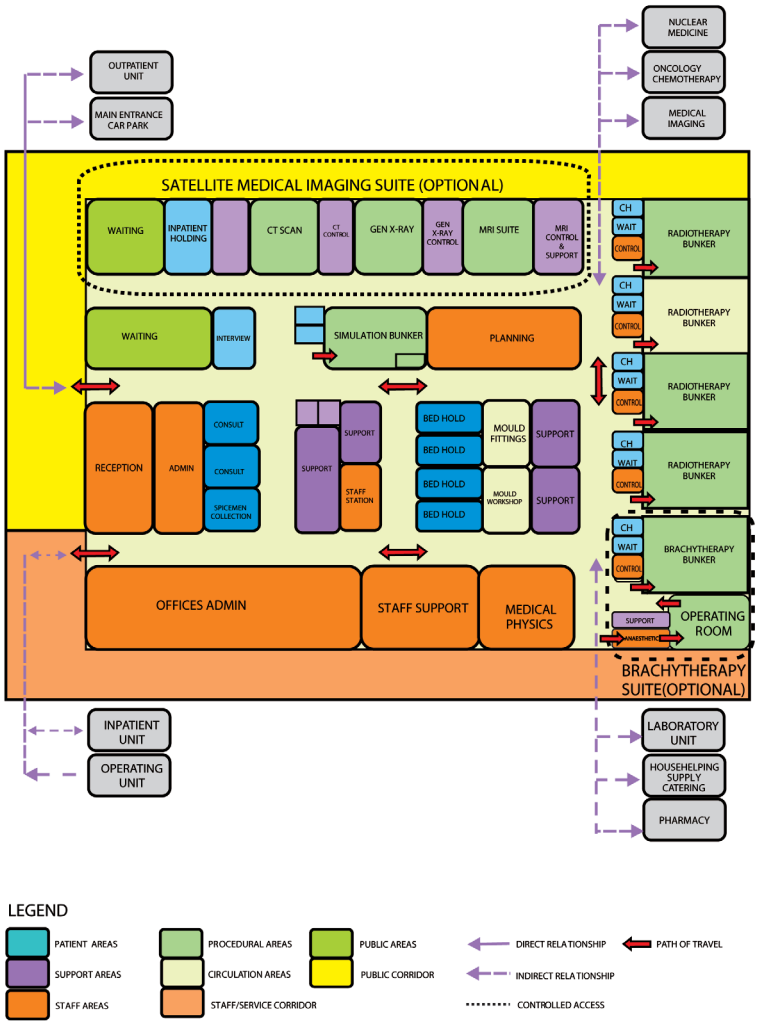
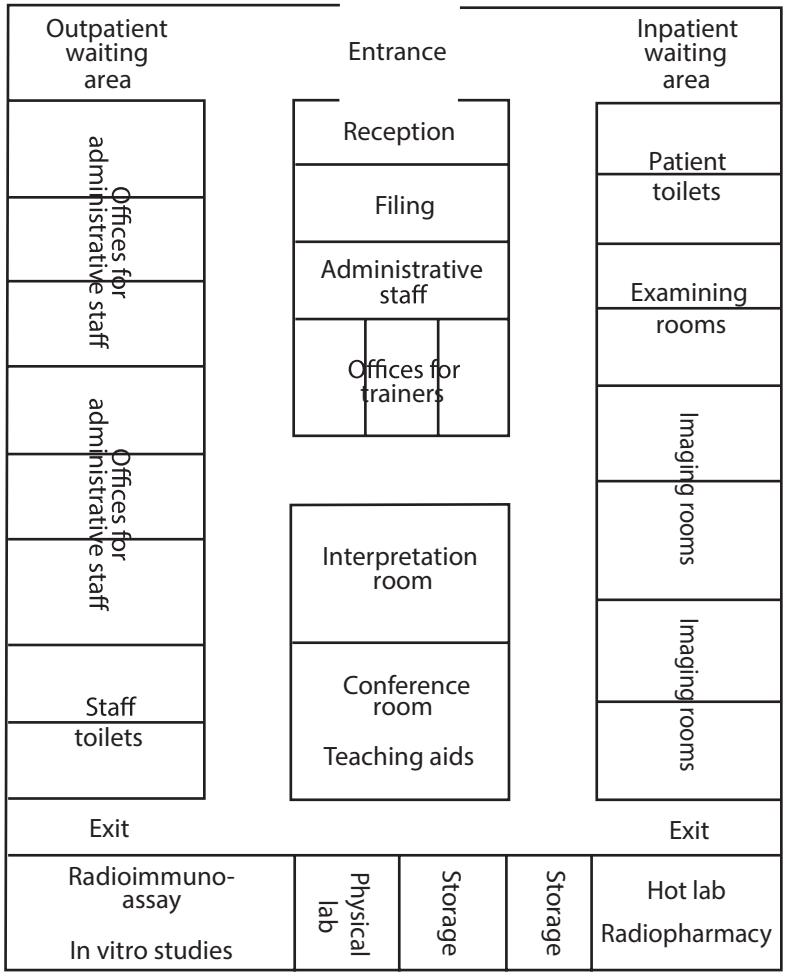


Figure 1- Functional Relationship Diagram:

Source - International Health Facility Design Guidelines 2016

c) Nuclear Medicine Unit



Source: IAEA Nuclear Medicine Handbook

ANNEX 7: MEDICATION LABEL

SAMPLE MEDICATION LABEL FOR CYTOTOXIC MEDICATIONS ADMINISTERED IN THE FACILITY/HOSPITAL

CYTOTOXIC GENERIC DRUG NAME _____

DRUG DOSE _____

DRUG ADMINISTRATION ROUTE _____

DRUG ADDITIVE	AMOUNT

Date prepared _____ Time _____am _____ pm

Use by date _____ Time _____ am _____ pm

Prepared by _____

Patient name (3 names) _____

Hospital no (inpatient/outpatient no) _____

SPECIAL INSTRUCTIONS (e.g. administration, storage conditions)

_____

_____

NB: Consider having a label with a different colour (preferably a bright colour) from the labels normally used in the facility

LABEL FOR CYTOTOXIC MEDICATIONS DISPENSED FROM A HEALTH FACILITY TO BE TAKEN HOME

Patient name (3 names) _____

Hospital no (inpatient/outpatient no) _____

Date prepared _____ Time _____am/pm

Use by date _____ Time _____ am/pm

Generic drug name _____

Dosage form and strength _____

Dosage _____

Quantity dispensed _____

SPECIAL INSTRUCTIONS (e.g. administration, storage conditions)

_____

_____

Caution statement label attached to the prepared product, for example: 'CAUTION: CHEMOTHERAPY' or 'HAZARDOUS DRUG'

SPECIAL LABELS – ROUTES OF ADMINISTRATION

- For drugs such as vincristine, which if given via intrathecal route, are fatal, the label should read as follows:

'FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES'

- All medications intended for intrathecal administration should be packaged separately from other types of medication, and should be supplied by the pharmacy in a distinctive container to prevent confusion with intravenous drugs. They should display a prominent warning stating:

  'FOR INTRATHECAL INJECTION ONLY'

ANNEX 8: NCI-K INSPECTION CHECKLIST

Unit	Section/Item	Complete	Partial	Absent	Comments/Remarks
Minimum requirements	Licensed by the relevant professional regulatory body				Specify the regulatory body -
	Functional MDT/tumour board				
	Service charter prominently displayed				
	Quality assurance system				
	Waste management system				
	Occupational health & safety facility policy				
	Patient documentation				
	Management/Treatment protocols				
	Infection prevention and control				

General Operational Considerations	Patient referral system				
	Facility SOPs				
	Health education materials				
	Patient navigation system				
	Staff capacity building program				
	Equipment service contracts & maintenance plans				
	Linkage with support services e.g. blood banks, ICU				
Units					
Administration	Physical Infrastructure				
	Equipment				
	Human Resource				
Ambulatory/outpatient	Physical Infrastructure				
	Equipment				
	Human Resource				
Chemotherapy	Physical Infrastructure				
	Equipment				
	Human Resource				

Laboratory/Pathology	Physical Infrastructure				
	Equipment				
	Human Resource				
Radiology	Physical Infrastructure				
	Equipment				
	Human Resource				
Surgery	Physical Infrastructure				
	Equipment				
	Human Resource				
Chemotherapy	Physical Infrastructure				
	Equipment				
	Human Resource				
Health Records/Registry	Physical Infrastructure				
	Equipment				
	Human Resource				
	Inspected and approved by Radiation Protection Board				

Radiotherapy	Physical Infrastructure				
	Equipment				
	Human Resource				
	Inspected and approved by Radiation Protection Board				
Nuclear Medicine	Physical Infrastructure				
	Equipment				
	Human Resource				
Palliative Care and survivorship	Physical Infrastructure				
	Equipment				
	Human Resource				
Nursing	Physical Infrastructure				
	Equipment				
	Human Resource				
Inpatient	Physical Infrastructure				
	Equipment				
	Human Resource				
Rehabilitation	Physical Infrastructure				
	Equipment				
	Human Resource				

ANNEX 9: NEW PATIENT ONCOLOGY ASSESSMENT FORM

MINISTRY OF HEALTH

NEW PATIENT ONCOLOGY ASSESSMENT FORM

Facility Name_____

Patient Bio-data Date: _____

Patient Name (3 names): _____ ID No: _____

Date of Birth: _____ Age in years: _____Sex_____

Mobile Phone: _____

Address: _____ City:

_____

Place of Birth: _____ Next of Kin name _____

Next of Kin relationship_____ Next of Kin phone_____

Marital Status: _____ Number of Children: _____

Highest level of Education (tick): Primary ☐

Secondary ☐

Tertiary ☐

Mode of payment: Cash ☐

NHIF ☐

Other Insurance ☐ (Specify) _____

Referring Physician and Facility

Name: _____ Phone No:_____

Facility: _____

Vital Data

Blood Pressure…….. Pulse rate……

Weight (kg)……Height (cm)……BSA (m^2)…….....

Current clinical history and findings

1. Presenting complaints

   _____

   _____

   _____

2. Do you currently use tobacco? [ ] Yes [ ] No
   If yes, for how long (years)? _____
   If No, have you ever used tobacco in the past? [ ] Yes [ ] No
3. Do you currently drink alcohol? [ ] Yes [ ] No
   If yes, for how long (years)? _____
4. What other medications are you on?

   _____
5. Do you have other disease conditions?

   _____
6. HIV status _____
7. Do you have any food or drug allergies? List those known

   _____
8. Are you using alternative/complimentary therapy to assist you to control your cancer?
   [ ] Yes [ ] No
   If yes, which ones?

   _____
9. Do you have any family history of cancer? [ ] Yes [ ] No
   If yes, list as shown below.

Cancer diagnosed (if known)	**Relative affected**

Female patients: LMP _____ Gravid? [ ] Yes [ ] No

History of contraception: [ ] Yes [ ] No

Current method of contraception _____

Fertility counseling done? [ ] Yes [ ] No

Past Medical History

Please list all major illnesses and surgeries for which you have had or been treated (starting with the most recent):

1._____
2._____
3._____
4._____
5._____

Previous cancer treatment given

Treatment Modality	Treatment details	Date given
Chemotherapy		
Hormonal therapy		
Radiotherapy		
Surgery		
Targeted therapy		
Others (specify)		

Physical Examination findings

_____
_____
_____
_____

Diagnostic and Staging Information

Histopathological Diagnosis (attach copy of the histology report)

_____

Stage _____

Pathology Number _____ Date reported _____

Other Diagnostic Information: Tumour markers, imaging, immunohistochemistry

_____

_____

_____

Radiological findings

_____

_____

Psychosocial assessment

_____

_____

Pain assessment (refer to pain assessment form)

_____

_____

Any other examinations (specify)

_____

_____

Treatment plan (as agreed upon by the multidisciplinary team)

_____

Indicate treatment goal: [ ] Curative [ ] Palliative

If curative: [ ] Neoadjuvant then surgery

[ ] Surgery then adjuvant

Radiotherapy regimen prescribed: _____

Chemotherapy regimen prescribed

_____

_____

Hormonal therapy regimen
prescribed:_____

Other (specify) _____

Follow-up plan _____

Doctor's name _____

Sign _____ **Date** _____

ANNEX10: PAIN ASSESSMENT TOOLS

PAIN ASSESSMENT TOOLS

1. **Wong-Baker Faces Pain Rating Scale**

The scale shows a series of faces ranging from a happy face at 0 which represents 'no hurt' to a crying face at 10 which represents 'hurts worst'. Based on the faces and descriptions, the patient chooses the face that best describes their level of pain. Is used for children older than 3 years old.

2. **Face, Legs, Activity, Cry, Consolability (FLACC) Scale**

Is a measurement that assesses pain in children below 3 years or in individuals who are unable to communicate theirp ain. The scale is scored in a range of 0-10 with 0 representing no pain. The scale has 5 criteria, which are each assigned a score of 0, 1 or 2. The scale is also accurate for use with adults in intensive care units (ICU) who are unable to speak due to intubation.

Criteria	Date/Time					
Face 0 – No particular expression or smile 1 – Occasional grimace or frown, withdrawn, disinterested 2 – Frequent to constant quivering chin, clenched jaw						
Legs 0 – Normal position or relaxed 1 – Uneasy, restless, tense 2 – Kicking or legs drawn up						
Activity 0 – Lying quietly, normal position, moves easily 1 – Squirming, shifting back and forth, tense 2 – Arched, rigid or jerking						
Cry 0 – No cry (awake or asleep) 1 – Moans or whimpers; occasional complaint 2 – Crying steadily, screams or sobs, frequent complaints						
Consolability 0 – Content, relaxed 1 – Reassured by occasional touching, hugging or being talked to, distractible 2 – Difficult to console or comfort						
Total Score						

3. Numeric Pain Rating Scale

Is a uni-dimensional measure of pain intensity in adults whereby, a respondent selects a number between 1 and 10 that best reflects the intensity of their pain.

Rating	Pain Level
0	No pain
1 - 3	Mild pain
4 - 6	Moderate pain
7 - 10	Severe pain

ANNEX11: PPE LIST

LIST OF PERSONAL PROTECTIVE EQUIPMENT FOR SAFE CHEMOTHERAPY HANDLING

Item Description
Lint free disposable gowns (knitted cuff)
Nitrile gloves, non-powdered (assorted sizes)
Disposable shoe covers
Safety goggles/eye splash shields
N95 respirators/masks
Cytotoxic drug spill kits (can be assembled on-site or purchased as a kit) - absorbent sheets/spill pads; disposable scoop for picking up broken glass/fragments; puncture-resistant container for glass fragments; disposable gown; N95 respirators; disposable shoe covers; 2 pairs of chemotherapy gloves; safety goggles/eye splash shields; sign saying 'caution hazardous drug spill; detergent/bleach; hazardous waste disposable bags with a hazardous waste label
Needles, syringes and tubing with luer lock connectors
Disposable hair covers
Disposable beard cover
Hazardous waste disposal bags
Closed system transfer devices
Cold & hot packs

ANNEX12: CHECKLIST FOR REGULATORY INSPECTION OF MEDICAL CYCLOTRON FACILITY

RADIATION PROTECTION BOARD

INSPECTION CHECKLIST FOR A MEDICAL CYCLOTRON FACILITY

	Inspection number	
	Registration Number	
Name of the facility		
Address (include location of the facility)		
Telephone Number		
Radiation Safety Officer		
Licencee's representative for the inspection		
Date of last Inspection	____/____/_____	
Date of this Inspection	____/____/_____	
Starting time:	**Exit time:**	
Type of Inspection Pre-authorization	☐	
Planned	☐	
Investigation	☐	
Termination	☐	
Recommended Date of NEXT Inspection	____/____/_____	
Summary of Findings and Actions No items of non-compliance found	☐	
Items of non-compliance found	☐ (to be detailed in Comments)	
Follow-up on previous non-compliance	☐	
Inspector (1) Name & Signature Date		
Inspector (2) Name & Signature Date		
Inspector (3) Name & Signature Date		
Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No)**	
Supervisor's signature		
Comments (*to be signed and dated*)		

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not relevant*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any amendments submitted by the facility and approved by the Board since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR(S)	VIOLATIONS

3. IMPLEMENTATION OF THE PREVIOUS INSPECTION RECOMMENDATIONS

Prior to the inspection, check in the file for any correspondence from the facility on implementation

……
……
……
……
……

4. INCIDENT / EVENT HISTORY *Prior to the inspection, list for review any incidents or events reported by the facility to the Board since the last inspection*

5. ON-SITE VERIFICATION OF LICENCES/AUTHORIZATIONS ISSUED		
Is the licence for operation is valid?	☐Yes	☐No
Is layout approval available?	☐Yes	☐No
Is the RSO licence/certificate valid	☐Yes	☐No
Is RSO (licensee) the same as mentioned in the licence ?	☐Yes	☐No
Comments:		

6. OPERATING PERSONNEL

During inspection list all operating personnel employed by the facility, their qualification and experience. (a separate sheet can be used)

No.	Type of Personnel	Name	Qualifications
1			
2			
3			
4			
5			
6			
7			
8			

7. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; and emergency response

All personnel responsible for the operation/maintenance of the facility and production of F-18 have prescribed qualifications and/or training?	☐Yes	☐No
All occupationally exposed personnel have undertaken a radiation safety course?	☐Yes	☐No
Refresher radiation safety training is provided periodically?	☐Yes	☐No
Training records maintained for each worker?	☐Yes	☐No
Interviews with personnel demonstrate an adequate level of understanding regarding safe working procedures?	☐Yes	☐No
Discussion with the RSO demonstrates an appropriate knowledge of the Act and subsidiary legislations, the licence requirements, the licence conditions, safe working	☐Yes	☐No
Does the RSO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?	☐Yes	☐No
Comments:		

8. PERSONNEL RADIATION MONITORING *Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers*		
Operator provides personal dosimeters to all radiation workers?	☐Yes	☐No
Dosimetry Service Provideris an authorized provider?	☐Yes	☐No
Name of dosimetry service provider:		
Dosimeters provided are appropriate for the radiation type and energy?	☐Yes	☐No
Dosimeters are exchanged at the prescribed period?	☐Yes	☐No
Dosimetry reports are promptly reviewed by the RSO?	☐Yes	☐No
Is it evident that personal dosimeters are being worn by workers?	☐Yes	☐No
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?	☐Yes	☐No
Personnel monitoring records are maintained?	☐Yes	☐No
Are pocket dosimeters (active dosimeters) available? Are they used by radiation workers?	☐Yes	☐No
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period)*		

9. DETAILS OF CYCLOTRON			
Cyclotron Unit make:			
Cyclotron Unit Model:			
Cyclotron Unit Serial No.			
Type of shielding:	☐Unshielded	☐Self-shielded	
Beam Type:	☐Protons	☐Deuterons	☐Both
Nominal Beam Energy:	Protons: …….. MeV	Deuterons: …… MeV	
Maximum Beam Current	Protons: …….. µA	Deuterons: …… µA	
Number of target ports available for radioisotopes production: ……			
Number of target ports used at the time for radioisotopes production: ……			
Radioisotopes produced: ……			
Comments			

10. INTERLOCKS, ACCESS CONTROL AND OTHER SAFETY FEATURES			
Tally			
(i)	Control console access password/key is working and secured	☐Yes	☐No
		Provided	**Working**
(ii)	Cyclotron vault door interlock	☐Yes ☐ No	☐Yes ☐ No
(iii)	Emergency switch "off" on control console	☐Yes ☐ No	☐Yes ☐ No
(iv)	Cyclotron vault door interlock	☐Yes ☐ No	☐Yes ☐ No
(v)	Shelf Shielding interlock	☐Yes ☐ No	☐Yes ☐ No
(vi)	Uninterrupted power supply/standby power supply	☐Yes ☐ No	☐Yes ☐ No
(vii)	Provision for safe "STANDBY' mode for cyclotron in case of power failure	☐Yes ☐ No	☐Yes ☐ No
(viii)	Provision of emergency power for ventilation system, access control system and radiation monitoring system	☐Yes ☐ No	☐Yes ☐ No
(ix)	Interlock for access prevention into cyclotron vault, if residual radiation dose inside the vault is high	☐Yes ☐ No	☐Yes ☐ No
(x)	Beam 'ON' alarm/signal warning light at the entrance of vault	☐Yes ☐ No	☐Yes ☐ No
(xi)	Cooling System/vacuum system/compressed air system interlock	☐Yes ☐ No	☐Yes ☐ No
(xii)	Area monitors inside the vault with audible warning set to a threshold radiation level	☐Yes ☐ No	☐Yes ☐ No
(xiii)	Area monitors in console room, hot lab, chemistry module and other rooms set to a threshold radiation dose level	☐Yes ☐ No	☐Yes ☐ No
(xiv)	Portable contamination monitors/area survey meters (neutron and gamma)/pocket dosimeter are available	☐Yes ☐ No	☐Yes ☐ No
Comments			

11. INDICATION OF VARIOUS PARAMETER ON THE CONTROL CONSOLE DISPLAY			
Tally			
(i)	Various interlock position	☐Yes	☐No
(ii)	Beam parameter	☐Yes	☐No
(iii)	Beam current	☐Yes	☐No
(iv)	Target selection	☐Yes	☐No
(v)	Utility parameter (temperature, water level, cooling agents, compressed air pressure, nitrogen, helium, vacuum etc)	☐Yes	☐No
(vi)	Beam ON/OFF indication	☐Yes	☐No
(vii)	Ventilation/exhaust control system	☐Yes	☐No
(viii)	Transfer of radionuclide status	☐Yes	☐No
(ix) I	nterlock for access prevention into cyclotron vault, if residual radiation dose inside the vault is high	☐Yes	☐No
(x)	Beam 'ON' alarm/signal warning light at the entrance of vault	☐Yes	☐No
(xi)	Beam ON time display	☐Yes	☐No

12. CONTROL OF AIRBONE ACTIVITY				
Tally				
(i)	Cyclotron vault ventilation interlock	Provided	☐Yes	☐No
		Working	☐Yes	☐No
(ii)	Provision for negative pressure inside cyclotron vault and other room?		☐Yes	☐No
(iii)	Standby exhaust pump/fan at the end of ventilation duct?		☐Yes	☐No
(vi)	HEPA/charcoal filter/other high efficiency filter provided?		☐Yes	☐No
(vii)	Provision of decontamination and containment of used air filter?		☐Yes	☐No
(viii)	Ventilation/exhaust control system		☐Yes	☐No

13. EMERGENCY PREPAREDNESS AND RESPONSE			
(i)	Has the facility prepared it radiological emergency preparedness (REPR) and response plan?	☐Yes	☐No
(ii)	Has the facility submitted a copy of its REPR to the Board?	☐Yes	☐No
(iii)	Has the REPR been ever exercised?	☐Yes	☐No
(iv)	Has the facility documented the emergency procedures?	☐Yes	☐No
(v)	***Are the following response procedures displayed in controlled and supervised area:***		
	Target foils rupture	☐Yes	☐No
	Radioactive source stuck in transfer line	☐Yes	☐No
	Power failure	☐Yes	☐No
	Containment rapture in chemistry hot cell	☐Yes	☐No
	Vial break in the QC lab	☐Yes	☐No
	Fire breakout	☐Yes	☐No
	Failure of ventilation system	☐Yes	☐No
	Spillage in controlled/ supervised areas	☐Yes	☐No
(vi)	Is fire alarm system available?	☐Yes	☐No
Comments			

14. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; loss; incidents; overexposures; safety-related equipment failures; change in RSO, and radiation dose reports to workers.

Have any notifiable incidents or accidents occurred since the last inspection?	☐Yes	☐No
If yes, have they been reported to the Board? (*If no, list the incidents or accidents in Comments)*	☐Yes	☐No
Actions taken to prevent recurrence:		
Comments		

15. TRANSPORT OF F-18

Name of transport company:		
Is the transport company certified by the Board?	☐Yes	☐No
Maximum Activity per shipment by company:		
Shielding, packaging and transporting in accordance with Board's regulations and guidance, and IAEA SSR-6 (2012) regulations?	☐Yes	☐No
Company's declaration papers have correct details and used when shipping sources?	☐Yes	☐No
Any Radioactive material Shipments transported, by other than above Company? *(If the answer is yes, give details of the company in the comments section)*	☐Yes	☐No
Are vials checked for contamination prior to packing?	☐Yes	☐No
Comments		

16. DELIVERY OF F-18 AT CUSTOMERS' PREMISES		
Are there documented procedures for delivery/receipt?	☐Yes	☐No
Are there accurate records of shipments?	☐Yes	☐No
What are the security measures during delivery?		
What happens if no one is present to accept delivery?		
Comments		

17. WASTE MANAGEMENT		
Overview (types of solid/liquid/contaminated wastes, any disposal through sink to sewer):		
Location of waste:		
Is the waste labelled:	☐Yes	☐No
Records of storage/disposal:	☐Yes	☐No
Monitoring:	☐Yes	☐No
Comments		

18. RECORDS			
Is the following information recorded and maintained?			
(i)	Authorizations from the Radiation Protection Board	☐Yes	☐No
(ii)	Staff access and visits to the facility and irradiation room	☐Yes	☐No
(iii)	Discharges and evaluation of doses to the public	☐Yes	☐No
(iv)	Results of radiation monitoring of areas	☐Yes	☐No
(v)	Inventory of radiation protection equipment	☐Yes	☐No
(vi)	Results of tests and checks of safety systems (annual, biannual, monthly, daily and special)	☐Yes	☐No
(vii)	Calibration certificates for measuring instruments	☐Yes	☐No
(viii)	Schedules for and results of maintenance and repairs	☐Yes	☐No
(ix)	Reports on internal audits and inspections, etc	☐Yes	☐No
(x)	Information on waste management	☐Yes	☐No
(xi)	Reports on investigations of incidents and accidents	☐Yes	☐No
Comments			

19. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
Inspector made area and other measurements for comparison to operator's	☐Yes	☐No
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

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Dr. Anne Ng'ang'a - MoH	Dr. Alfred Karagu – MOH/NCI-K
Dr. Mary Nyangasi - MOH	Dr. Eunice Gathitu – MOH
Dr. Joan-Paula Bor - MOH	Lydia Kirika – MOH
Hannah Gitungo - MOH	Dr. Valerian Mwenda - MOH
Dr. Zipporah Ali - KEHPCA	Dr. Adamali N.E – HCG/CCK
Prof Abinya Othieno - UON	Dr. Eliud Njuguna - KNH
Dr. Naftali Busakhala - MTRH	Dr. Fred Chite - MTRH
Dr. Irene Weru - KNH	Dr. Vijay Kumar – MP Shah
Dr. Lillian Kocholla - MOH	Dr. Julius Ogato - MOH
Dr. Anthony Ndiritu - KNH	Dr. Catherine Nyongesa - KNH
Dr. Jesse Opakas - MTRH	Ndungu Ngigi - KNH
Robert Makori - KNH	Dr. Esther Munyoro - KNH
Roselyne Okumu - KNH	Immaculate Wambugu – Nairobi Hospital
Dr. Richard Njoroge - MOH	David Makumi - KENCO
Dr. Helena Musau – HCG CCK	Dr. Eric Hungu - KNH
David Musyoki - KEHPCA	Dr. Asaph Kinyanjui - KEHPCA
Charles Okello - MOH	Dr. Esther Muinga - KEHPCA
Fred Asige – Nairobi Hospital	Dr. David Wata - KNH
Ann Barsigo - MOH	Onesmus Kamau - MOH
Dr. Annah Wamae - MOH	Mishka Cira – US NCI
Nathan Brand - US NCI	George Kaiyare – Biozeq Kenya
Patricia Mbaabu - GE	Bob Omondi – KNH
Dr. Sarah Chuchu - MoH	Patricia Njiri – CHAI
Longino Mucheusi - KNH	Farrok Karsan – AKUH
Gladys Mukosi - KNH	Prof Githanga – UoN/KNH
Dr. Patrick Asaava – Kijabe Hospital	Binti Omar Tsala - KMLTTB
Judith Kudoyi – Nursing Council of Kenya	Dr. Joyce Nato – WHO
Dr. Daniel Ojuka – UoN/KNH	Gamaliel Omondi – MoH
Judith Otele - NHIF	Dr. Laban Thiga - MoH
Dr. Beatrice Mugi - KNH	Dr. Vera Manduku - KEMRI
Dr. Gladwell Kiarie – KMPDB	Dr. Catherine Murithi – Roche Diagnostics

Linda Ogol – MoH	Evans Obaga – MoH
Dr. Ahmed Kalebi – Lancet Laboratories	Dr. Paulyne Wairimu - PPB
Margaret Mbogo – AIC Kijabe Hospital	Jentrix Nyongesa – Texas Cancer Centre
Esther Sigilai - MoH	Dr. Linet Kugo – MTRH
Roselyne Yatich – MTRH	Dr. Lyndon Marani – HCG/CCK

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