

LEGAL NOTICE NO.

THE CANCER PREVENTION AND CONTROL ACT
(No. 15 of 2012)

IN EXERCISE of the powers conferred by section 36 of the Cancer Prevention and Control Act, 2012, the Cabinet Secretary for Health, on the recommendation of the National Cancer Institute, makes the following Rules—

**THE CANCER PREVENTION AND CONTROL (INSPECTION AND
CERTIFICATION) RULES, 2023**

Citation. **1.** This Rules maybe cited as the Cancer Prevention and Control (Inspection and Licensing) Rules, 2023

Interpretation. **2.** In this Order, unless the context otherwise requires—

No. 15 of 2012. “Act” means the Cancer Prevention and Control Act, 2012;

 “Board” means the Board of Management established by section 6 of the Act;

 “Cabinet Secretary” means the Cabinet Secretary for the time being responsible for health;

 “cancer centre” includes a medical institution and any other institution designated by the Institute as a centre providing cancer care services;

 “Committee” means the Inspections and Certification Committee established under rule 4;

 “Institute” means the National Cancer Institute of Kenya established by section 4 of the Act;

 “multi-disciplinary tumor board” means the

multidisciplinary expert team that manages cancer patients in a consultative approach consisting of different cancer experts;

Cap 253. “pathologist” has the meaning assigned to it under the Medical Practitioners and Dentists Act;

“radiologist” means a specialist in diagnostic medical imaging;

“radiotherapy” means the use of x-rays or other energies in the electromagnetic spectrum to cause cell death by DNA damage;

Cap 253. “specialist” has the meaning assigned to it under the Medical Practitioners and Dentists Act;

Purpose of these Rules. 3. The purpose of these Rules shall be to provide for the—
(a) the inspection of cancer centre premises; and
(b) the certification of the cancer centres.

PART II - ESTABLISHMENT OF THE INSPECTIONS AND CERTIFICATION COMMITTEE

Establishment of the inspections and certification committee. 4. (1) There is established a Committee to be known as the Inspections and Certification Committee.

(2) The functions of the Committee shall be to—
(a) receive and process all applications for designation and certification of cancer centres;
(b) inspect, approve and certify the premises infrastructure and level of cancer services and give such orders as appropriate;
(c) recommend the issuance of Certificates to eligible cancer

centres;

- (d) review, whenever it is in its opinion necessary, all applications for certification to engage in cancer treatment;
- (e) maintain a register of all cancer centres certified under these Rules;
- (f) review the fees charged in private practice by medical and dental practitioners, from time to time in consultation with other relevant regulatory bodies; and
- (g) perform any other functions as the Board may determine from time to time.

(3) The Committee shall comprise of —

- (a) one member from the Board;
- (b) the chief executive officer who shall be the chair;
- (c) the head of regulations and compliance directorate who shall be the secretary;
- (d) a representative from each of the following offices—
 - (i) cancer registry;
 - (ii) standards and quality assurance;
 - (iii) registration and accreditation;
 - (iv) inspection and compliance;
 - (v) cancer prevention and control; and
 - (vi) cancer research and clinical trials.

(4) The Committee may co-opt persons who shall not be members of the Institute, for the better carrying out of the business of the Committee.

(5) The persons co-opted under subrule 4 shall not be eligible to vote in any matter before the Committee.

(6) The Committee shall submit its recommendations to the Board of the Institute.

(7) The Committee shall regulate its own procedure

Eligibility of
practice.

5. An entity that intends to operate a cancer centre shall ensure that the premises where the cancer centre is located—

(a) is licensed by the relevant regulatory bodies under the Health Act and the certificate is displayed at a prominent place; and

(b) is inspected, approved and certified by the Institute.

Responsibilities
of
management
of cancer
centres.

6. The management of the cancer centre shall —

(a) ensure that the cancer specialists working in the cancer centres are qualified;

(b) be responsible for the discipline of its staff; and

(c) ensure that the staff members do not engage in practice outside the area of specialization except in cases of—

(i) emergencies; and

(ii) where specialist with the requisite specializations are not reasonably available prescribed supportive staff can be used under supervision in accordance with the Third Schedule.

PART III- CERTIFICATION

Application
for certificate
of
compliance.

7. (1) A person who intends to operate a cancer centre shall apply to the Institute in the Form set out in the First Schedule accompanied by the fee prescribed in the Fourth Schedule.

(2) The Institute may—

(a) after consideration of the application in subrule 1; and

(b) an inspection conducted in accordance with the Fifth Schedule;

issue a certificate of compliance to operate a cancer centre which shall operate as a certificate for designation in the Form set out in the S chedu le .

(3) A certificate of compliance shall be issued subject to the premises—

(a) being kept in good order and in state of repair;

(b) being kept reasonably secure from unauthorized entry;

(c) conforming to the minimum requirements set out in Part A or Part B of the Second Schedule, as the case may be and any other written law and in particular the Public Health Act;

(d) not being in a residential building except with the permission from the Institute;

(4) Each cancer centre shall be inspected, approved and certified separately.

(5) A certificate of compliance issued shall be valid for one year.

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Re-inspection.	8. Upon the expiry of the certificate issued in rule 6(2) the cancer centre shall apply to the Institute for re-inspection.
Re-designation.	9. Where a cancer centre intends to re-designate the cancer centre, the cancer centre shall apply to the Institute for re-designation.
Renewal of certificate.	10. (1) Application for renewal of the certificate issued under rule 6(2) shall be made two months before the expiry of the certificate. (2) The Institute may request such further information from an applicant where necessary.
Change of premises.	11. An application for permission to change the premises to which the certificate relates may be made at any time
False information.	12. A person who includes or causes to be included in the application, or in response to a request for information from the Institute, information which he knows or has cause to believe is incorrect, shall be guilty of an offence and shall be liable to a fine not exceeding two hundred thousand shillings or to imprisonment for a term, not exceeding two years or to both.
Conditions for certificate of compliance.	13. (1) The Institute may impose conditions on the certificate issued. (2) A certificate of compliance shall be issued only in respect of the premises named therein and may not apply to any other premises. (3) A certificate holder shall display the certificate of compliance in a conspicuous place at the premises to which it relates and a certificate holder who contravenes this rule shall be guilty of an offence. (4) The Institute may cancel a certificate of compliance if any of the conditions imposed in the certificate of compliance are

contravened.

(5) The Institute shall, when considering application under rules 7, 10 and 11, give notice to the applicant before—

- (a) refusing to grant or renew a certificate of compliance;
- (b) refusing to allow a change of premises to which the certificate of compliance relates; or
- (c) canceling the certificate of compliance;

(6) The applicant shall, within twenty one days respond to the notice issued under subrule 13 (5) .

(7) Where the Institute refuses to grant or renew a certificate, or cancels a certificate, it shall inform the applicant of its decision within fourteen days of receipt of the response in subrule 13 (6).

(8) An applicant may appeal the decision of the Institute to the Court within thirty days of receipt of the decision.

PART IV-INSPECTIONS

Inspection of
cancer
centres.

14. (1) All cancer centres shall be inspected by the Institute.

(2) The operator of a cancer centre shall submit to the Institute in every three months a list of—

- (a) cancer specialists in their employment; and
- (b) cancer specialists who are authorized to use their premises, indicating in each case the authorized place for use as a private clinic.

(3) The Institute shall, upon inspection, designate such a facility in accordance with the levels set out in the Sixth

Schedule.

Composition
of inspection
teams.

15. The team of inspectors shall be composed of professionals with expertise in key service areas in lieu of the specialized nature of cancer management.

Inspection
procedures for
Cancer
Centres

16. The inspection procedures of the cancer centres shall be as set out in the Fifth Schedule.

PART V-MISCELLANEOUS

Fees.

17. (1) The Institute shall charge the fees prescribed in the Fourth Schedule.

(2) The Institute shall have powers to arbitrate in all complaints regarding fees charged in cancer centres

Offences.

18. Where a person is guilty of an offence under these rules for which no penalty is expressly provided, the person shall be liable to a fine not exceeding two hundred thousand shillings or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(r. 7(1))

FIRST SCHEDULE

Application Form

Applicant details		
Please type or print in capital letters		
Cancer Management Center name		
Physical address		
Mailing address		
Service Center type (Tick as appropriate)	Chemotherapy	
	Radiotherapy	
	Surgical Oncology	
	Cancer Management Centre	
	Comprehensive Cancer Care	
Hospital/Institute head		

Mailing address		
Contacts	Tel.	E-mail
Department head/Cancer Center Manager		
Mailing address		
Contacts	Tel.	E-mail

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

Please indicate compliance with each of the 13 items

	Item	Yes	No	N/A
1	Does your cancer center 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 center provide routine patient assessment of - Physical - Psychological symptoms - Social support			
4.	Does the center incorporate support of family members/caregivers?			
5.	Does the center provide emergency care of inadequately relieved physical and psychological symptoms?			
6.	Does the center have mechanisms for linkage to home based care, hospices and coordination of cancer care with primary care providers?			
7.	Is the center 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			

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 _____

SECOND SCHEDULE**Inspection Tool**

Mandatory	Name of Facility				
	County				
	Sub County				
	Ward				
	Street/ Market				
	MFL Code				
	Ownership				
	Designation	Basic, Middle Level or Comprehensive			
	Treatment Modalities	Chemotherapy	Radiotherapy	Surgical Oncology	Nuclear Medicine
	Status	Operating/ Being Established			
	Unit	Yes	No	Comments	
Mandatory	Registration and Licensing				
	Does the facility have relevant professional regulatory bodies	Y	N		
	· Medical	Y	N		

	Council			
	· KMLTTB	Y	N	
	· PPB	Y	N	
	· KNRA	Y	N	
	Cancer services			
	· Does the facility have service charter prominently displayed	Y	N	
	· Does the facility have a Functional MDT/tumor board	Y	N	
	Is Yes provide List of members	Y	N	
	Minutes	Y	N	
	Link with other MDT	Y	N	
	Quality assurance system	Y	N	
	· Does this cancer centre have a Focal person for QA	Y	N	
	· Are the necessary QA Documents available? (Minutes, SOPs,	Y	N	

	Policy)			
	Does the facility have a waste management system – check for program on waste management, SOPs	Y	N	
	Occupational health & safety facility policy	Y	N	
	· Do the HCWs undergo Safety and health training at least once every 3 years - specify	Y	N	
	· Does the facility have an established a system for identification and surveillance of exposure	Y	N	
	· Does the facility have Personal protective equipment (PPEs)	Y	N	
	· Does the facility have guidelines and recommendations for proper use and handling of	Y	N	

	carcinogenic chemicals			
	Patient documentation	Y	N	
	Does the facility have Structured patient file	Y	N	
	Does the file have Biopsy report	Y	N	
	Does the file have consent Form	Y	N	
	Does the file have Treatment Plan	Y	N	
	Does the facility have a Cancer registry office (lockable)	Y	N	
	Does the facility have cancer management/treatment protocols	Y	N	
		Yes	No	Comments
	General Operational Considerations	Y	N	
	Does the facility have Infection prevention and control in cancer	Y	N	

	Does the facility have patient referral system	Y	N	
	If YES is there clear referral for the following			
	· Blood services	Y	N	
	· Critical Care	Y	N	
	· Palliative care	Y	N	
	Does the facility have SOPs that are displayed and visible	Y	N	
	Does the facility have health education materials on cancer	Y	N	
	Does the facility have legible and appropriate signages	Y	N	
	Does the facility have patient navigation system	Y	N	
	Does the facility have staff capacity building program	Y	N	
	Does the facility have Equipment service contracts & preventive	Y	N	

	maintenance plans				
	Average number of patients per day				
		Yes	No	Resident / Nonresident (R/NR)	Number of Staff
Mandatory	Human Resource Capacity				
	Medical Director (Standalone cancer centre)/ Physician in-charge for oncology services	Y	N		
	Radiation oncologists/clinical oncologist	Y	N		
	Clinical pharmacist	Y	N		
	Medical Officers (Mentored/ trained in Oncology)	Y	N		
	Nurse Specialized oncology (Adult and paediatric care)	Y	N		
	Nurses - Palliative care	Y	N		
	Nurse - Advanced Oncology (Adult and pediatric care)	Y	N		

	Clinical Officers in oncology	Y	N		
	Cancer registrars	Y	N		
	Clinical counsellors	Y	N		
	Nutritionists trained on Oncology	Y	N		
	Nutritionists	Y	N		
	Medical Officers not trained/ mentored in Oncology	Y	N		
	Pharmacist not trained/ mentored in Oncology	Y	N		
	Nurse - General (adult care and pediatric care)	Y	N		
	Pharmaceutical technologists	Y	N		
	Quality Assurance Officer/ Safety health officer	Y	N		
	Radiotherapy Services Manager	Y	N		
	Clinically qualified radiotherapy physicists/Medical Physicists	Y	N		
	Radiation Therapists (RTT)	Y	N		

	/Therapy radiographers				
	Onco - surgeons	Y	N		
	Surgeons	Y	N		
	Medical Social Worker	Y	N		
		Yes	No	Comments	
Optional depending on services available	Chemotherapy Area	Y	N		
	Patient registration and reception area	Y	N		
	Triage room/observation room	Y	N		
	Procedure rooms	Y	N		
	Counselling room	Y	N		
	Waiting area for patients/caregivers	Y	N		
	Consultation room	Y	N		
	NCD/ Cancer Screening room	Y	N		
	Does the facility have a chemotherapy administration area	Y	N		
	Are the SOPs for chemotherapy administration area	Y	N		

	displayed and visible			
	Is the chemotherapy administration well ventilated	Y	N	
	Does the chemotherapy administration have a non-slippery floor	Y	N	
	Does the chemotherapy administration have entertainment	Y	N	
	Does the facility have at least one isolation room	Y	N	
	Does the facility have an emergency Room	Y	N	
	Does the facility have a storage area for hazardous chemotherapy drugs?	Y	N	
	Is the storage area for hazardous chemotherapy drugs well ventilated? Ideally, storage areas should have negative air pressure in relation	Y	N	

	to surrounding areas and have 12 air changes per hour			
	Is the chemotherapy reconstitution area large enough to contain a bio-safety cabinet	Y	N	
	Does the facility have a bio safety cabinet Class 2B and above	Y	N	
	Are the SOPs for chemotherapy reconstitution area displayed and visible	Y	N	
	Is the chemotherapy administration area next to the chemotherapy reconstitution	Y	N	
	If NO is there a safe procedure of transporting reconstituted chemotherapy drugs	Y	N	
	Does the facility have staff changing area	Y	N	
	Does the facility have a staff	Y	N	

	room/conference room			
	Does the facility have pantry room	Y	N	
	Does the facility have separate staff and patients toilets	Y	N	
	Does the facility have a sluice room	Y	N	
	Does the facility have have access to an accredited medical laboratory	Y	N	
	Does the facility have pharmacy with adequate space	Y	N	
	Is there a designated lockable cabinet for chemotherapy drugs	Y	N	
	Does the pharmacy have a refrigerator for oncology medicines	Y	N	
	Does the facility have a storage facility for cytotoxic waste and other wastes	Y	N	

	Does the facility have a disposal facilities for cytotoxic and other wastes – check for service contracts	Y	N	
	Emergency Tray	Y	N	
	Eye wash station and hand washing for staff	Y	N	
	Equipment for Chemotherapy	Yes	No	Comments
	Does the chemotherapy unit have the following equipment			
	· Chemotherapy chairs	Y	N	
	· Assorted hospital beds	Y	N	
	· Bedside cabinets	Y	N	
	· Hazardous drug spill kit	Y	N	
	· Infusion pumps	Y	N	
	· 4-hooked mobile drip stands	Y	N	
	· Refrigerator	Y	N	

	· Crash cart for emergency/resuscitation including ambu-bags and masks for appropriate ages	Y	N	
	· Suction machine	Y	N	
	· Oxygen & oxygen masks	Y	N	
	· Weighing scale	Y	N	
	· Heightometer	Y	N	
	· Vital signs monitor including sphygmomanometer, thermometer, pulse oximeter	Y	N	
	· Measuring Cylinders	Y	N	
	· Stretchers	Y	N	
	· Procedure trolleys	Y	N	
	· Portable examination lamps	Y	N	
	· Audio-visual equipment – Television	Y	N	
		Yes	No	Comments

Optional depending on services available	Radiation Therapy Unit			<i>All have to be available</i>
	Does the unit have a patient registration and reception area	Y	N	
	Does the unit have an observation room /triage	Y	N	
	Does the unit have a waiting area for patients/caregivers	Y	N	
	Does the unit have a control room area	Y	N	
	Does the unit have a megavoltage bunker	Y	N	
	Does the unit have a CT /Ortho-voltage Simulator room Treatment planning room	Y	N	
	Does the unit have a medical physicists room (and for equipment storage)	Y	N	
	Does the unit have a mould room where applicable	Y	N	
	Does the unit have a patient changing	Y	N	

	room and washrooms			
	Does the unit have a Brachytherapy suite?	Y	N	
	If YES does it have the following	Y	N	
	· Is there a mini theatre	Y	N	
	· Is there a brachytherapy bunker	Y	N	
	· Is there a brachytherapy imaging room	Y	N	
	· Is there a waste management system	Y	N	
	· Is there a disposal facility available	Y	N	
	Does the unit have Radiotherapy Treatment Protocols	Y	N	
	Does the unit have Radiotherapy SOPs	Y	N	
	Are the SOPs for radiotherapy administration area displayed and	Y	N	

	visible			
		Yes	No	Comments
Optional depending on services available	Nuclear Medicine Unit			<i>All have to be available</i>
	Does the unit have SOPs available	Y	N	
	Are the SOPs for nuclear medicine unit area displayed and visible	Y	N	
	Does the unit have a patient registration and reception area	Y	N	
	Does the unit have a designated waiting area for patients and caregivers (clearly demarcated as cold area)	Y	N	
	Does the unit have treatment areas	Y	N	
	Does the unit have a specialized scanning imaging rooms e.g. gamma cameras, SPECT, PET, PET/CT, bone densitometry	Y	N	

	Does the unit have a patient holding, observation and recovery areas (clearly demarcated as hot area)	Y	N	
	Does the unit have a radioactive waste store	Y	N	
	Does the unit have a specially designated room with toilet and bathroom facilities for patients' exclusive use to minimize contamination	Y	N	
	Does the unit have a waste management facilities as specified by KNRA/ IAEA for example a septic tank	Y	N	
	Does the unit have a hot lab for preparation of radiopharmaceuticals	Y	N	
	Does the unit have an imaging, viewing & scan	Y	N	

	reporting area (with requisite infrastructure)			
	Does the unit have a iodine wards for inpatients	Y	N	
	Does the unit have an uptake rooms with calibration probes	Y	N	
	Does the unit have a radiopharmaceutical production facility that is well ventilated and does it meet the requirements as per KNRA/IAEA guidelines to prevent contamination	Y	N	
		Yes	No	Comments
Mandatory	Support Services (assess availability of service/ the availability of up to date MOUs or service contracts)			<i>All have to be available</i>
	Does the facility have access to diagnostic	Y	N	

	radiology unit			
	Does the facility have access to pharmacy	Y	N	
	Does the facility have access to laboratory and pathology unit	Y	N	
	Does the facility have access to blood banking	Y	N	
	Does the facility have access to critical care unit	Y	N	
	Does the facility have access to rehabilitation centres	Y	N	
	Does the facility have access to endoscopy services	Y	N	
	Does the facility have access to morgue services	Y	N	
	Does the facility have access to nutrition Support	Y	N	
		Yes	No	Comments
Mandat	Pathology & Medical			

ory	laboratory unit			
	Does the unit have histopathology	Y	N	
	Does the unit have hematology	Y	N	
	Does the unit have clinical chemistry & immunoassays	Y	N	
	Does the unit have microbiology	Y	N	
	Does the unit have cytology	Y	N	
	Does the unit have molecular diagnostics	Y	N	
		Yes	No	Comments
Mandat ory	Cancer registry			
	Does the facility have paper based system	Y	N	
	Does the facility have an Electronic Medical Record System (EMR)	Y	N	
	Does the facility have lockable Room	Y	N	
	Does the facility have a designated Functional	Y	N	

	Computer with Internet access for cancer registry			
	Does the facility have NCI-Kenya Notification Tools	Y	N	
	Does the facility have a designated filing system for the cancer registry	Y	N	
	Does the facility report to the NACARE system	Y	N	
	Does the facility have an officer (HRIO) trained in cancer registry	Y	N	
		Yes	No	Comments
Optional depending on services available	Surgical Unit			
	Patient registration and reception area	Y	N	
	Waiting area for patients and caregivers	Y	N	
	Consultation room	Y	N	
	Triage/observation room	Y	N	
	Counseling room	Y	N	
	Does the facility			

	have a			
	Fully equipped major and minor theatres	Y	N	
	Available standard anaesthetic	Y	N	
	Surgical equipment	Y	N	
	Interventional equipment	Y	N	
	Fully equipped endoscopy suite	Y	N	
	Key Findings			
	Key Recommendations			
	Agreed Decision			
	Compliance Score			
	Compliance	Fully Compliant, Partially Compliant and Non-Compliant		

	Recommended Timeline	
	Inspection Team Lead name & signature	
	Hospital Team Lead name & signature	

THIRD SCHEDULE**Minimum Requirements for Cancer Centres**

The Institute recommends the following to ensure that cancer centres meet the necessary minimum requirements to deliver quality oncology services—

Human Resource

The human resource requirements for cancer centres are as follows depending on the level of cancer centres

Core Human Resource	Supportive Human Resource
Oncologist (Medical, Clinical, Radiation) Oncology Nurse Clinical Pharmacist Medical Physicist Radiation therapist Oncology Surgeon Cancer Registrar Clinical Counsellor Nutritionist Medical social worker Infection Prevention and Control Expert Quality Assurance Expert Patient navigators	Medical Officers Clinical Officers in Oncology Nurses - Palliative care Pharmaceutical Technologists Pharmacists Please note: Supportive staff are NOT supposed to replace the core staff, there supposed to work under supervision of the core staff

Equipment

Equipment must have service contracts and appropriate measures for plans for preventive maintenance purposes and provide service stickers showing dates for last service and next service due dates. 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 and keep documentation of the same

Acceptance testing and commissioning

Commissioning is done by the manufacturer or his representative, Biomedical Engineer and the Clinical Pharmacist. 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.

Expected Equipment's needed in cancer centres are referenced in the Guidelines for Establishment of Cancer Centres

Operational Considerations

The following operational considerations are required to facilitate the delivery of cancer treatment to ensure health care worker and patient safety

- ✓ Multidisciplinary Tumour Board
- ✓ Service charter for oncology
- ✓ SOPs and job aids in all service areas

- ✓ Clinical management protocols
- ✓ Standard patient files with biopsy report, registration forms, consent forms and treatment plan
- ✓ Waste management
- ✓ Signages
- ✓ Infection Prevention and Control protocols
- ✓ File tracing system
- ✓ Capacity building
- ✓ Medical surveillance

Physical Infrastructure

The cancer centre shall ensure the physical infrastructure meets the following requirements:

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

Chemotherapy Unit	Radiation Therapy Unit
1) Patient registration and reception area	1) Patient registration and reception area
2) Triage room/observation room	2) Observation room/triage
3) Procedure rooms	3) Waiting area for patients/caregivers
4) Counselling room	4) Control room area
5) Waiting area for	

patients/caregivers 6) Designated Consultation room 7) Chemotherapy administration area 8) Oncology pharmacy 9) Chemo holding/receiving station in close proximity to the chemo administration area-with shelves, work tops, a hand washing area and hooks 10) At least one isolation room 11) 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 12) Chemotherapy reconstitution area should be large enough to contain a bio-safety cabinet 13) Staff changing area 14) Staff room/conference room 15) Pantry room 16) Separate staff and patients rest rooms 17) Sluice room 18) Storage facility for cytotoxic waste and other wastes	5) Megavoltage bunker 6) CT /Ortho-voltage Simulator room 7) Treatment planning room 8) Medical physicists room (and for equipment storage) 9) Mould room where applicable 10) Patient changing room and washrooms 11) Brachytherapy suite includes mini theatre, brachytherapy bunker, brachytherapy imaging room, waste management and disposal facility
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19) Disposal facilities for cytotoxic and other wastes – Incinerator (combusts at 1200C) 20) Eye wash station/shower	
Nuclear Medicine Unit	Surgical Oncology Unit
1) Patient registration and reception area 2) Designated waiting area for patients and caregivers (clearly demarcated as cold area) 3) Treatment areas 4) Specialized scanning imaging rooms e.g. gamma cameras, SPECT, PET, PET/CT, bone densitometry 5) Patient holding, observation and recovery areas (clearly demarcated as hot area) 6) Radioactive waste store 7) Specially designated room with toilet and bathroom facilities for patients' exclusive use to minimize contamination 8) Waste management facilities as specified by IAEA for example a septic tank 9) Hot lab for preparation of	1) Patient registration and reception area 2) Waiting area for patients and caregivers 3) Consultation room 4) Triage/observation room 5) Counseling room 6) Procedure room 7) Operating theatre capable of handling minor and major surgical procedures

radiopharmaceuticals 10) Imaging, viewing & scan reporting area (with requisite infrastructure) 11) Iodine wards for inpatients 12) Uptake rooms with calibration probes 13) 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.	
Inpatient oncology wards	Palliative Care and Survivorship Unit
1) Separate female, male, adolescents, geriatric and pediatric wards 2) Side room facilities for ward reviews of post-operative wounds, minor procedures, and emergency resuscitation	4) Patient registration and reception area 5) Waiting area for patients/caregivers 6) Counseling room 7) Procedure room

3) Requirement for Comprehensive Cancer Centre: Isolation rooms for neutropenic patients and patients with infectious conditions.	8) Consultation room 9) Community room large enough to accommodate support groups 10) Pediatrics play area 11) Nutrition counseling rooms 12) Support services · Pharmacy · Nutrition · Chaplaincy · Counseling · Rehabilitative unit
Key supportive services required	
1. Diagnostic radiology unit 2. Pharmacy 3. Pathology unit 4. Blood banking 5. Critical care unit 6. Rehabilitation centres 7. Endoscopy services 8. Morgue services	

FOURTH SCHEDULE

Fees

- 1) Application for Facility Licensure/ Re-designation fee - means any non-refundable fee, which is paid by a health facility or institution for the purpose of being considered as a cancer centre - KSH 5,000
- 2) Facility Inspection Fee - fee payable to the NCI Kenya for performing any inspection required for designation in an amount not exceeding as below per inspection.
 - a. Basic/ Essential Cancer Treatment Centres - KSH 20,000
 - b. Middle Level Cancer Centre – KSH 25,000
 - c. Comprehensive Cancer Centre - KSH 50,000
- 3) Designation Fee - fee payable to the NCI Kenya for designation of a cancer centre. The amount will not exceed as per level of facility per below. This amount is paid every 2 years.
 - a. Basic/ Essential Cancer Treatment Centres - KSH 25,000
 - b. Middle Level Cancer Centre – KSH 25,000
 - c. Comprehensive Cancer Centre - KSH 50,000
- 4) License Renewal Fee - means a fee payable annually in respect of a licence, in order to ensure the continued validity of the licence - KSH 5000

FIFTH SCHEDULE

Inspection procedures for Cancer Centres

1. The inspection team meets the facility team.
2. The inspection team lead shall introduce the team and brief the facility staff on the inspection procedure and what is expected.
3. The facility shall provide the necessary documents required for assessment.
4. The inspection team shall move together through various service areas to assess the facility.
5. After moving through each service area, the inspection team shall converge together to discuss the assessment and provide the necessary recommendations. At this point the team shall determine whether the facility has meet the minimum requirements
6. After the completion of the inspection, the tablet shall produce the Institute result for the facility with key scores of the service areas and accompanying summary information on the inspection score and compliance category
7. The Institute score determines the compliance category and the type of follow-up needed.
8. There following are the compliance categories of an inspection—
 - (a) **Non-compliant facilities**, are those that score **40% and below** in the assessment. These facilities shall be recommended to re-evaluate the need for cancer centre or for immediate closure by the respective regulatory body
 - (b) **Partially compliant facilities**, are those that score between **41% and 70%** in the inspection. Facilities in this category

shall be re-inspected after one to twelve months' period. If after repeated inspections and at the 3rd inspection (after one year), the facility has not yet improved to a higher category, it is recommended for immediate closure.

(c) **Fully compliant facilities**, are those that score **over 70%** in the inspection. Facilities in this category are meet the minimum standards and will be re-inspected after two years.

9. The findings of the inspection will be conveyed to the facility team
10. The inspection team will later provide a comprehensive report of the inspection findings and key recommendations within 7 days
11. A facility that meets the minimum regulatory requirements will be issued with a compliance certificate
12. Non-compliant facilities/ unit will be closed and relevant regulatory agencies will be informed that is Kenya Health Professional Oversight Authority, Kenya Medical Practitioners' and Dentists' Council, National Health Insurance Fund and other regulatory agencies

Follow up Actions Based on Institute Result

Inspectors may also wish to report additional findings from the inspection, which may not be included in the inspection report, such as the recommendation for reclassification of the facility and reports on suspected malpractice at the facility. Reports such as these will be submitted and monitored following the reporting procedures.

The inspection report will be shared with the following institutions—

- ✓ Kenya Medical Practitioners and Dentists' Council
- ✓ Kenya Health Professional Oversight Authority
- ✓ National Health Insurance Fund
- ✓ Other regulatory agencies

The inspected, designated and accredited facilities will be publicized and shared to the general public on different platforms.

For facilities with malpractices the relevant regulatory agencies will be alerted and informed for further action through prescribed miscellaneous rules

(r. 14(3))

SIXTH SCHEDULE

CANCER CENTRES DESIGNATION

Basic Cancer Centre	Middle Level Cancer Centre	Comprehensive Cancer Centre
Radiation/Clinical/Medical Oncologist	Radiation/Clinical/Medical Oncologist	Radiation/Clinical/Medical Oncologist
Oncology Nurse	Oncology Nurse	Oncology Nurse
Clinical Pharmacist	Clinical Pharmacist	Clinical Pharmacist
Infection Prevention and Control (IPC Expert)	Infection Prevention and Control (IPC Expert)	Infection Prevention and Control (IPC Expert)
Quality Assurance Expert	Quality Assurance Expert	Quality Assurance Expert
Cancer Registry Expert	Cancer Registry Expert	Cancer Registry Expert

Additional experts as follows	Additional experts as follows	Additional experts as follows
Clinical officers with oncology specialization	· Surgeon	· Surgeon
Nutritionist	· Radiation Therapist	· Radiation Therapist
Pharmaceutical technologist	· Medical Physicists	· Medical Physicists
Pharmacists	· Onco - surgeons	· Onco – surgeons
Medical officers	· Clinical officers with oncology specialization	· Curriculum Specialist
		· Clinical Pathologist
		· Clinical officers with oncology specialization

Made on the, 2023.

**SUSAN NAKHUMICHA ,
Cabinet Secretary for Health**