NIGERIAN NUCLEAR REGULATORY AUTHORITY
CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF RADIOTHERAPY FACILITIES

Guidance Notes for Inspector(s):
Prepare a visit agenda to review the operating programme with details contained in the application for authorisation, the authorisation certificate, prior programme reviews, inspection reports and their implementation, relevant correspondence and other relevant documentation such as dosimetry reports.

Check the following for compliance with the authorisation and with the NNRA requirements.

Monitoring equipment and accessories required should be available for use as and when required.

Give entry briefing to the most senior management personnel.

I **IDENTIFYING INFORMATION**

I-1 **Name of the Institution**: ……..

I-2 **Address of Facility**: ……..
……..……..

I-3 **Telephone/facsimile/email**: Tel. #: …… Fax: ……..
Email: ……..

I-4 **Authorisation Number**: ……..

I-5 **Name and Qualification of the Radiation Safety Officer**
Name: ……..
Degree: ……...
Certification:…….
Experience: ……
……..
……..
……..

I-6 **Name and Qualifications of any Qualified Experts retained**
Physician:
Name: ……..
Degree: ……...
Certification:…….
Experience: …….

Radiotherapy Physicist:
Name: ……..
Degree: …….
Certification: ……
Experience: …….

Name: ……..
Degree: ……..……..
Certification: ……..……..
Experience: ……..

I-7 **The name and title of the Responsible representative of the legal person**: ……..
……..

II VERIFICATION OF SAFETY

II-1 For Brachytherapy, Devices:

Manufacturer	Model No.:	Radionuclide:	Type of loading: Manual (M) Remote R)	Dose Rate: High (H) Low (L)	Number of Channels: (Remote)	Maximum Activity
			M R	H L		/
			M R	H L		/
			M R	H L		/
			M R	H L		/

II-2 **Sealed Sources**:

Manufacturer	Model No.:	Radionuclide	Physical type: Ribbon R) Wire (W) Individual (I)	Physical dimensions and shape	Total Activity (per cm for wires and ribbons)	Number of sources: (total activity for wire)
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			
			R W I			

Do the devices and sources listed above conform to the standards in the application? If not, note the standards to which the devices and sources were manufactured.

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II-3 **External Beam Therapy unit Design**

Compare the External Beam Therapy unit with application descriptions and design specifications.

a) Is the unit as described in the application approved by the Regulatory Authority?		Yes	No
b) Type:	Accelerator? Gamma?	Yes Yes	No No
c) Name of manufacturer: …….. d) Model No. and Name: …….			
e) Country of manufacturer: …… f) Year of manufacturer: …….			
g) Type of gantry:	Stationary? Rotary?	Yes Yes	No No
h) Output Gy/min at isocenter:			

i) Describe the movement of the treatment table: …….. …….. ……..
j) for Gamma Units: i) Radionuclide: …… ii) Model No. of the source: …….. iii) Initial activity of sources: ……. iv) Number of sources installed: …… v) Maximum design activity: …… vi) Total activity installed: ……. k) For Accelerators: i) Maximum energy: …… ii) Maximum current (mA): ……...
l) Describe any accelerator differences or modifications: …….. …….. ……..

II-4 Facility Design

a) Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b) Is protection of the devices and sources from adverse environmental conditions (heat, moisture, etc.)	Provided? Working?	Yes Yes	No No
c) Is fire detection and protection in the radiation and source storage areas:	Provided? Working?	Yes Yes	No No
d) Is adequate ventilation and source storage areas:	Provided? Working?	Yes Yes	No No
e) Fixed area radiation monitor(s):	Provided? Working?	Yes Yes	No No
f) Mechanical door interlocks:	Provided? Working?	Yes Yes	No No
g) Prevention of unauthorised personnel entering treatment area:	Provided? Working?	Yes Yes	No No
h) Means of escape or communication from within treatment enclosure:	Provided? Working?	Yes Yes	No No
Describe any facility differences or modifications from those approved by the NNRA and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls, etc.): ……. ……. …….			

II-5 Safety Control Systems

a) External Beam Therapy Electrical Indicators/Interlocks			
i) Treatment room door	Provided? Working?	Yes Yes	No No
ii) Head lock	Provided? Working?	Yes Yes	No No
iii) Off shield	Provided? Working?	Yes Yes	No No
iv) Hand control	Provided? Working?	Yes Yes	No No
v) Treatment mode-fixed/Arc/Skip/Rotation	Provided? Working?	Yes Yes	No No
vi) Treatment angle	Provided? Working?	Yes Yes	No No

vii) Source drawer or shutter	Provided? Working?	Yes Yes	No No
viii) Emergency stop buttons to interrupt the irradiation	Provided? Working?	Yes Yes	No No
ix) Head collision switch	Provided? Working?	Yes Yes	No No
b) External Beam Therapy Source Head Displays			
i) Beam "OFF" indicator	Provided? Working?	Yes Yes	No No
ii) Beam "ON" indicator	Provided? Working?	Yes Yes	No No
iii) Head lock indicator	Provided? Working?	Yes Yes	No No
iv) Collimator rotation indicator	Provided? Working?	Yes Yes	No No
v) Light field displays	Provided? Working?	Yes Yes	No No
vi) Off shield indicator	Provided? Working?	Yes Yes	No No
c) External Beam Therapy Control Console Displays			
i) Power switch	Provided? Working?	Yes Yes	No No
ii) Reset switch	Provided? Working?	Yes Yes	No No
iii) Beam "ON" switch	Provided? Working?	Yes Yes	No No
iv) Beam "OFF" switch	Provided? Working?	Yes Yes	No No
v) Emergency switch	Provided? Working?	Yes Yes	No No
vi) Timer switch with treatment & elapsed time displays	Provided? Working?	Yes Yes	No No
vii) Treatment mode selection switch – Fixed/Arc/Skip/Rotation	Provided? Working?	Yes Yes	No No
viii) Selection switch for clockwise & anti-clockwise rotation	Provided? Working?	Yes Yes	No No

II-6 Warning Systems

a) Exposure signals and posted explanation (e.g. audible or visible alarms, illuminated signs)	Provided? Legible In Local language?	Yes Yes Yes	No No No
b) Warning notices	Provided? Local language?	Yes Yes	No No

II-7 Safety Operations Management

a) Is management knowledgeable of the certificate of authorisation and its restrictions and requirements?		Yes	No
b) Does management provide adequate staffing levels?		Yes	No
c) Has management provided the Radiation safety officer authority to stop unsafe operations?		Yes	No
d) Does management provide adequate resources for personnel training (time and money)?		Yes	No
e) Does management provide adequate equipment?		Yes	No
f) Does management provide for periodic programme reviews and recommendations?	Scheduled? Performed?	Yes Yes	No No

v) Date of the last programme review: ……..
vi) Status of recommendations: ……
……...
……...
……...

II-8 Safety Operations - Technical

a) Does the Radiation Safety Officer (RSO) have adequate knowledge and expertise?		Yes	No
b) Does the RSO have qualified experts available?		Yes	No
c) Is the RSO knowledgeable about the requirements of the NNRA and the provisions of the certificate of authorisation?		Yes	No
d) Is the RSO given sufficient time and resources to do the job (e.g., not kept too busy with other assignments or given insufficient technical and secretarial help?)		Yes	No
e) Does RSO maintains knowledge of activities of workers using radiation sources?		Yes	No
f) Does RSO conduct initial and periodic training of workers?		Yes	No
g) Does RSO maintain adequate records to demonstrate worker and public protection?		Yes	No
h) Are there provisions for inventory of sources and accountability?	Procedures? Performed?	Yes Yes	No No

II-9 Investigation and Quality Assurance

a) Were there any incidents or accidents?		Yes	No
b) If so, were incident and accident investigation reports prepared?		Yes	No
c) Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d) Is there a written Quality Assurance programme?	Procedures? Performed?	Yes Yes	No No
e) Is maintenance and repair work in accordance with manufacturer's recommendations?	Scheduled? Performed?	Yes Yes	No No
f) Are repair/maintenance procedures?	Developed? Followed?	Yes Yes	No No

III <u>VERIFICATION OF WORKER PROTECTION</u>

III-1 <u>Classification of Areas</u>

a) Are controlled areas demarcated?		Yes	No
b) Are approved signs at access points?	Provided? Legible? Local language?	Yes Yes Yes	No No No
c) Is radioactive material storage at a physically defined location (e.g. cabinet, safe, room)? i) locked/secured location with key control? iii) proper shielding (e.g., individual containers, room)? iv) reserved only for radiation sources?		 Yes Yes Yes Yes	 No No No No
d) Are supervised areas demarcated?		Yes	No
e) Are approved signs at access points?	Needed Provided? Legible? Local language?	Yes Yes Yes Yes	No No No No

III-2 <u>Local Rules and Supervision</u>

a) Are rules established in writing?	Yes	No

b) Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?	Yes	No
c) Are workers (including nurses attending brachytherapy patients) instructed in the implementing procedures?	Yes	No
d) Are work activities involved with treatment done in accordance with prescribed operating procedures and conditions?	Yes	No
e) Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?	Yes	No

III-3 Monitoring

a) Does the authorised organisation provide personal dosimeter?	Yes	No
i) Worn properly?	Yes	No
ii) Calibrated	Yes	No
iii) Exchanged at required frequency?	Yes	No
b) Are personnel exposures within limits?	Yes	No
c) Area and portable survey instruments		
i) Appropriate?	Yes	No
ii) Calibrated?	Yes	No
iii) Operational?	Yes	No
iv) Operational check performed before use?	Yes	No
d) Do the authorized organization's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorized radiation levels?	Yes	No
f) Does the authorized organization make periodic tests for leakage of radioactive materials from sealed sources	Yes	No
g) Is the instrumentation: Appropriate? Calibrated? Operational?	Yes	No
Record independent measurements made during the inspection: …….. ……. …… ……		
Type/Model No. of Survey Meter:		
Date last calibrated:		
Do the inspector's independent surveys agree with the survey results of the authorized organization?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: ……. …… ……. …….		

IV VERIFICATION OF PUBLIC PROTECTION

IV-1 Control of Visitors

a) Are visitors accompanied in controlled area?	Yes	No
b) Is adequate information provided to visitors entering controlled areas?	Yes	No
c) Are there adequate control over entries into supervised areas and appropriate postings?	Yes	No

IV-2 Sources of Exposure

a) Are the shielding (including rooms of patients implanted with brachytherapy source) and other protective measures optimized for restricting public exposure to external sources of radiation?	Yes	No
b) Are the floor plans and arrangement of equipment appropriate considering public areas adjacent to the installation?	Yes	No

IV-3 Radioactive Waste and Discharges

a) Have provisions been made to transfer sources to an appropriate registrant or licensee or to an authorised waste disposal facility at the end of use?	Yes	No
b) If sources are no longer in use and being stored, does the authorised organization have a plan for timely transfer or disposal of the sources?	Yes	No

IV-4 Monitoring of Public Exposure

Are routine periodic measurements of exposure rates in areas adjacent to treatment and storage made by the staff or qualified expert?	Yes	No
Record independent measurements made during the inspection. …….. ……. ……. ……. …….		
Type/Model No. of Survey Meter: ..…… …….		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organisations routine measurements	Yes	No
Do surveys shows that the shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No

V <u>EMERGENCY PREPAREDNESS</u>

V-1 Emergency Plan

a) Is there a written plan?	Yes	No
b) Is the plan periodically reviewed and updated?	Yes	No
c) Are there procedures for staff to safely handle gamma teletherapy and brachytherapy patients if the radiation source fails to return to the shielded position?	Yes	No
d) Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No

V-2 Training and Exercises

a) Have workers involved in implementing the plan received training?	Yes	No
b) Have provisions been made of the plan to be rehearsed at suitable intervals ?	Yes	No

VI MEDICAL EXPOSURE

VI-1 Responsibilities

a) Are there procedures or arrangements to ensure that no patient treated unless the exposure is prescribed by a medical practitioner?	Procedures? Followed	Yes Yes	No No
b) Are there an adequate number of trained medical and paramedical personnel to discharge assigned tasks?		Yes	No
a) Are calibration, dosimetry and quality assurance requirements conducted by or under the supervision of a qualified expert in radiotherapy physics?		Yes	No

VI-2 Justification

a) Are new therapy procedures justified by taking into account the benefits and risks of alternate techniques that do not involve medical exposure?	Yes	No
b) Are there procedures to ensure that exposure of humans for medical research is in accordance with the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organisation?	Yes	No

c) Is each exposure of humans for medical research subject to the advice of an Ethical Review Committee or other similar institutional body?	Yes	No

VI-3 Optimization

Design considerations			
a) Is there documentary evidence that equipment and sources comply with IEC and ISO standards?		Yes	No
b) Whether imported into or manufactured in the country, does the equipment conform to applicable standards of IEC and ISO or to equivalent national standards.		Yes	No
c) Are performance specifications and operating and maintenance instructions provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents"?		Yes	No
d) Where practicable, are the operating terminology (or its abbreviations) and operating values displayed on operating consoles in a major world language acceptable to the user?		Yes	No
e) Is the design of newly acquired equipment evaluated to ensure that failures of components are promptly detectable and the incidence of human error is minimised?		Yes	No
f) Is backup system for terminating irradiation:	Provided? Working?	Yes Yes	No No
g) Do radioactive sources conform to the definition of a sealed source?		Yes	No
h) Are there appropriate contingency plans for responding to events that may occur, while the patient is being treated?	Provided? Practised?	Yes Yes	No No
i) Are these plans for patient protection displayed prominently and practised periodically?		Yes	No
j) Are there provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operational parameters such as type of radiation, indication of energy, beam modifiers, treatment distance, field size, beam orientation and either treatment time or preset dose?	Provided? Working?	Yes Yes	No No
k) Will radioactive sources be automatically shielded in the event of an interruption of power and remain shielded until reactivated at the control panel?	Provided? Working?	Yes Yes	No No
l) Are monitors provided to give warning of an unusual situation such as high radiation levels when position indicators show the source has been returned to a shielded position?	Provided? Working?	Yes Yes	No No

VI-4 Operational Considerations

a) Do treatment plans include exposure of normal tissue is kept as low as is reasonably achievable consistent with delivering the planned dose to the target volume?	Provided? Followed?	Yes Yes	No No
b) Are radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant avoided except when there are strong clinical indications	Provided? Followed?	Yes Yes	No No
c) Are any therapeutic procedures for pregnant women planned to deliver the minimum dose to any embryo or foetus?	Provided? Followed?	Yes Yes	No No
d) Are patients informed of possible risks?		Yes	No

VI-5 Calibration

a) Is the calibration of sources used for medical exposure traceable to a standards dosimetry laboratory?	Yes	No
b) Is radiotherapy equipment calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions?	Yes	No
c) Are sealed sources calibrated for a specified reference date for activity or at a specific distance in terms of reference air kerma in air or absorbed dose rate in a specific medium?	Yes	No
d) Are calibrations carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals?	Yes	No

VI-6 Clinical Dosimetry

a) Are the maximum and minimum absorbed doses from external beam teletherapy determined and documented for the planning target volume together with the absorbed dose at selected relevant points?	Yes	No
b) For brachytherapy, is the absorbed dose determined and documented for selected relevant points in each patient?	Yes	No

c) For all radiotherapy, is the absorbed dose to relevant organs determined and documented?	Yes	No

VI-7 Quality Assurance

Does the medical quality assurance programme include:			
a) Verification of he appropriate physical and clinical factors used in treatment including measurements of physical parameters at the time of commissioning and periodically thereafter?	Procedures? Followed?	Yes Yes	No No
b) Written records of relevant procedures and results?	Procedures? Followed?	Yes Yes	No No
c) Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment?	Procedures? Followed?	Yes Yes	No No
d) Verification of patient identity?	Procedures? Followed?	Yes Yes	No No
e) Regular and independent quality audit reviews?	Procedures? Followed?	Yes Yes	No No

VI-8 Dose Constraints

a) Does an Ethical Review Committee or other institutional body specify dose constraints to be applied on a case by case basis in the optimisation of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual?	Yes	No
b) Have dose constraints been established for individuals knowingly exposed while voluntarily helping in the care or comfort of patients under going medical diagnosis?	Yes	No
b) Have dose constraints been established for individuals knowingly exposed while voluntarily visiting patients under going medical diagnosis?	Yes	No

VI-9 Discharge of Patients

Are patients monitored prior to discharge to determine that all temporary implants of radioactive sources have been removed and that the activity is below the level specified.	Procedure? Followed	Yes Yes	No No

VI-10 Investigations of Accidental Medical Exposures

Did the registrant or licensee promptly investigate any or all instances where:		
a) A therapeutic treatment was delivered to the wrong patient, the wrong treatment site, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner.?	Yes	No
b) An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended?	Yes	No
c) With respect to any incidents investigated, did the registrant or licensee:		
i) Calculate or estimate the doses received and their distribution within the patient?	Yes	No
ii) Indicate the corrective measures required to prevent recurrence of such an incident?	Yes	No
iii) Implement all corrective measures that were under their control?	Yes	No
iv) Submit to the NNRA, as soon as possible after the investigation or as otherwise specified by the NNRA, a written report which stated the cause of the accident and included the information specified in "i" to "iii" as relevant?	Yes	No
v) Inform the patient and his or her doctor about the incident?	Yes	No

VI1 Verification Of Records

i)	Is a copy of authorisation certificate available for inspection?	Yes	No
ii)	Are personal dosimetry records being kept?	Yes	No
iii)	Dosimetry		
	a) current dose and analyzed?	Yes	No
	b) collect dose and analysed?	Yes	No
iv)	Area surveys records being kept?	Yes	No
v)	Are instrument tests and calibrations records kept?	Yes	No

vi)	Are tests for leakage of radioactive material from sources records kept?	Yes	No
vii)	Are inventory of sources and accountability records kept?	Yes	No
viii)	Are audits and reviews of radiation safety programmes records kept?	Yes	No
ix)	Are incident and accident investigation reports kept?	Yes	No
x)	Are maintenance and repair work records kept?	Yes	No
xi)	Are facility modifications records kept?	Yes	No
xii)	Are training provided	Yes	No
	a) initial	Yes	No
	b) fresher	Yes	No
xiii)	Are evidence of health surveillance records kept?	Yes	No
xiv)	Are waste disposals programme and records kept?	Yes	No
xv)	Are transportation of radioactive material records kept?	Yes	No
	a) package documentation?	Yes	No
	b) package surveys?	Yes	No
	c) transfer/receipt documents?	Yes	No
	d) details of shipments dispatched?	Yes	No
xvi)	Patient discharge surveys	Yes	No
xvii)	Clinical dosimetry records	Yes	No

VII INSPECTION FINDINGS

IX RECOMMENDTIONS

Name of Inspector: ……..

Signature: …….. Date: …….