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RADIATION PROTECTION AUTHORITY OF ZIMBABWE

RADIATION PROTECTION ACT (CHAPTER 15:15)

CHECKLIST FOR INSPECTION OF RADIOTHERAPY FACILITIES

A. GENERAL INFORMATION

(i) Name of Institution……..….

(ii) Address of facility ……

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(iii)Telephone: ……..

(iv)Fax: ……

(v) E-mail: ……..

(vi)Licence number: ……..

(vii) Name and qualifications of any qualified experts retained:

(a) Expertise: Radiation Safety Officer

Name: ……..
Qualification: ……..
Certification: ……...
Experience: ……..

(b) Expertise: Radiologist/Radiotherapy Physicist

Name: ……..
Qualification: ……..

Certification: ……...
Experience: ……..

(c) Expertise: Physician

Name: ……..
Qualification: ……..
Certification: ……...
Experience: ……..

(viii) Name and title of the responsible representative of the legal person:

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B. VERIFICATION OF RADIATION SAFETY

(i) For Brachytherapy Devices:

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

(ii) Sealed Sources:

Manufacturer	Model No.	Radio nuclide	Physical type: Ribbon(R) Wire(W) Individual(I)			Physical dimensions and shape	Total activity (per cm for wires and ribbons)	No. of sources(total activity for wire)
			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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(iii) External Beam Therapy unit Design

Compare the External Beam Therapy unit with the application description and design specifications

	Yes	**No**
(a) Is the unit as described in the application approved by the Regulatory Authority?		
(b)Type: Accelerator? Gamma?		
(c)Name of manufacturer: ……		
(d)Model No. and Name: ……..		
(e)Country of Manufacturer: …….		
(f)Year of Manufacture: …….		
(g)Type of gantry: Stationary? Rotary?		
(h)Output Gy/m in at isocentre:		
(i)Describe the movement of the treatment table: …… ……		
(j)For Gamma units: 1) Radionuclide: …….. 2) Model No. of the source: …… 3) Initial activity of sources: …… 4) Number of sources installed: …… 5) Maximum design activity: …… 6) Total activity installed: …….		
(k)For accelerators: 1) Maximum energy: …… 2) Total activity installed: …….		

(l) Describe any accelerator differences or modifications:

……

……

(iv) Facility Design

		Yes	No
(a) Was a safety assessment by a qualified expert performed prior to any modifications			
(b) Is the reactor hall protected from adverse environmental conditions (heat, moisture, etc)	Provided? Working?		
(c) Is fire detection and protection in the radiation areas (tested periodically)	Provided? Working?		
(d) Is there adequate ventilation and source storage areas	Provided? Working?		
(e) Fixed area radiation monitor(s)	Provided? Working?		
(f) Mechanical door interlocks	Provided? Working?		
(g) Prevention of unauthorized personnel entering treatment area	Provided? Working?		
(h) Means of escape or communication from within treatment enclosure	Provided? Working?		

Describe any facility modifications/differences made from those approved by RPAZ and considered in the safety assessment (e.g. shielding design, construction material, controls etc)…….

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(v) Safety Control Systems

		Yes	No
(a)External Beam Therapy Electrical Indicators/ Interlocks			
1) Treatment room door	Provided? Working?		
2) Head lock	Provided? Working?		
3) Off shield	Provided? Working?		
4) Hand control	Provided? Working?		
5) Treatment mode-fixed/Arc/Skip/Rotation	Provided? Working?		
6) Treatment angle	Provided? Working?		
7) Source drawer or shutter	Provided? Working?		
8) Emergency stop buttons to interrupt the irradiation	Provided?		

	Working?		
9) Head collision switch	Provided? Working?		
(b)External Beam Therapy Source Head Displays			
1) Beam “OFF” indicator	Provided? Working?		
2) Beam ÖN” indicator	Provided? Working?		
3) Head lock indicator	Provided? Working?		
4) Collimator rotation indicator	Provided? Working?		
5) Light field displays	Provided? Working?		
6) Off shield indicator	Provided? Working?		
(c)External Beam Therapy Control Console Displays			
1) Power switch	Provided? Working?		
2) Reset switch	Provided? Working?		
3) Beam “ON” switch	Provided? Working?		
4) Beam “OFF” switch	Provided? Working?		
5) Emergency switch	Provided? Working?		
6) Timer switch with treatment& elapsed time displays	Provided? Working?		
7) Treatment mode selection-Fixed/Arc/Skip/Rotation	Provided? Working?		
8) Selection switch for clockwise& anti clockwise rotation	Provided? Working?		

(vi) Warning Systems

		Yes	**No**
(a) Exposure signals and posted explanation (e.g. audible or visible alarms, illuminated signs)	Provided? Legible? In local language?		
(b) Warning notices	Provided? Local language?		
(c) Security monitoring systems and the reactor associated alarms	Provided? Up to date?		

(vii) Safety Operations Management

	Yes	No
(a) Is management knowledgeable about the certificate of authorization and its restrictions and requirements?		
(b) Does management provide adequate staffing levels?		
(c) Has management provided adequate powers to the radiation safety officer to stop unsafe operations?		
(d) Has management provided adequate monitoring equipment?		
(e) Does management provide adequate resources for personnel training (time, money)?		
(f) Does management provide for periodic programme reviews and recommendations? Scheduled? Performed?		
(i)Date of the last program review: …… (ii)Status of recommendations: …… …… …… .		

(viii) Safety Operations- Technical

	Yes	No
(a) Does the Radiation Safety Officer (RSO) have adequate knowledge and expertise?		
(b) Does the RSO have qualified experts available?		
(c) Is the RSO knowledgeable about the requirements of the RPAZ and the provisions of the certificate of authorization?		
(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?		
(e) Does RSO maintain knowledge of activities of workers using radiation sources?		
(f) Does RSO conduct initial and periodic training of workers?		
(g) Does RSO maintain adequate records to demonstrate worker and public protection?		
(h) Are there provisions for inventory of sources and accountability a. Procedures? b. Performed?		

(ix) Investigation and Quality Assurance

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

C. VERIFICATION OF WORKER PROTECTION

(i) Classification of areas

		Yes	No
a) Are controlled areas demarcated?			
b) Are approved signs at access points	Provided? Legible? Local language?		
c) Is the radioactive material storage at a physically defined location (e.g. cabinet, safe? Room?)			
(1) Locked/secured location with key control			
(2) Proper shielding (e.g. individual containers, room)?			
(3) Reserved for radiation sources?			
d) Are supervised areas demarcated?			
e) Are approved signs at access points	Needed? Provided? Legible? Local language?		

(ii) Local rules and supervision

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

(iii) Monitoring

	Yes	No
(a) Does the authorized organization provide personnel dosimeter?		
(b) Are the dosimeters: i) Worn properly? ii) Calibrated? iii) Exchanged at required frequency?		
(c) Are personnel exposures within limits?		
(d) Area and portable survey instruments:		
i) Appropriate? ii) Calibrated? iii) Operational? iv) Operational check performed before use?		
(e) Does the authorized organization's survey indicate that the radiation room shielding is adequate and the dose rates around the room meet authorized radiation levels?		
(f) Does the authorized organization make periodic tests for leakage of radioactive materials from sealed sources?		
(g) Is the instrumentation:		
a. Appropriate? b. Calibrated? c. Operational?		
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……		

D. VERIFICATION OF PUBLIC PROTECTION

(i) Control of visitors

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

(ii) Sources of Exposure

	Yes	No
(a) Are the shielding and other protective measures optimized for restricted public exposure to x-ray operation?		
(b) Are the floor plans and arrangement of equipment appropriate considering public and adjacent to the installation?		

(iii) Radioactive waste and discharges

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

(iv) Monitoring of public exposure

	Yes	No
(a) Are routine measurements made of dose rate at places occupied by the members of the public by the RSO or qualified expert?		
(b) Are the inspector-independent measurement in agreement with those made by RSO or qualified expert?		
(c) Do the survey measurements indicate that adequate shielding is provided so that dose rates outside controlled and supervised areas meet authorized radiation levels?		
Type/Model/No of survey meter used:		
Date of last calibration		
Record independent measurements made during the inspection: …… …….....		

E. EMERGENCY PREPAREDNESS

(i) Emergency Plan

	Yes	No
(a) Is there a written plan?		
(b) Is the plan periodically reviewing and updated?		
(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?		
(d) Does the plan take account of lessons learnt from operating experience and accidents at similar facilities?		
(e) Have workers involved in implementing the plan received?		
(f) Adequate training?		
(g) Have provisions been made for the plan to be rehearsed at suitable intervals (e.g. fire accident, exposure does not terminate at a present time)?		

(ii) Training and Exercises

	Yes	No
(a) Have workers involved in implementing the plan received training?		
(b) Have provisions been made of the plan to be rehearsed at suitable intervals (e.g. fire accident, exposure does not terminate at a present time)?		

F. MEDICAL EXPOSURE

(i) Responsibilities

		Yes	No
(a) Are there procedures or arrangements to ensure that no patient treated unless the exposure is prescribed by a medical practitioner?	Procedures? Followed?		
(b) Are there adequately trained medical and paramedical staffs available to discharge assigned duties?			
(c) Are diagnostic imaging and QA requirements fulfilled with the advice of a qualified expert in radiodiagnostic physics?			

(ii) Justification

	Yes	No
(a) Are new therapy procedures justified by taking into account the benefits and risks of alternative techniques that do not involve medical exposure?		
(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 Organization?		

(c) Is each exposure of humans for medical research subject to the advice of an Ethical Review Committee or other similar institutional body?		

(iii) Optimization

		Yes	No
Design considerations			
(a) Is there documentary evidence that equipment and sources comply with IEC and ISO standards?			
(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?			
(c) Are performance specifications, 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"			
(d) Where applicable, are the operating terminology (or its abbreviations) and operating values displayed on operating consoles in a major world language acceptable to the user?			
(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 minimized?			
(f) Use backup system for terminating irradiation:	Provided? Working?		
(g) Do radioactive sources conform to the definition of a sealed source?			
(h) Are the appropriate contingency plans for responding to the events that may occur, while the patient is being treated?	Provided? Working?		
(i) Are there plans for patient protection displayed prominently and practiced periodically?			
(j) Are the provisions for selection, reliable indication and conformation (when appropriate 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?		
(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?		
(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?		

(iv) Operational Considerations

		Yes	No
(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?		
(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?		
(c) Are any therapeutic procedures for pregnant women planned to	Provided?		

deliver the minimum dose to any embryo or foetus?	Followed?		
(d) Are patients informed of possible risks?			

(v) Calibration

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

(vi) Clinical Dosimetry

	Yes	No
(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?		
(b) For brachytherapy, is the absorbed dose determined and documented for selected relevant points in each patient?		
(c) For all radiotherapy, is the absorbed dose to relevant organs determined and documented?		

(vii) Quality Assurance

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

(vii) Dose Constraints

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

(ix) Discharge of Patients

		Yes	No
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?		

(x) Investigation of Accidental Medical Exposures

	Yes	No
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 fraction differing substantially from the values prescribed by the medical practitioner?		
(b) An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended?		
(c) With respect to any incidents investigated, did the registrant or licensee:		
(1) Calculate or estimate the doses received and their distribution within the patient?		
(2) Indicate the corrective measures required to prevent recurrence of such an incident?		
(3) Implement all corrective measures that were under their control?		
(4) Submit to the RPAZ, as soon as possible after the investigation or as otherwise specified by the RPAZ, a written report which stated the cause of the accident and included the information specified in (1) and (3) as relevant?		
(5) Inform the patient and his or her doctor about the incident?		

G. VERIFICATION OF RECORDS

	Yes	No
(a) Is a copy of authorization certificate available for inspection?		
(b) Are personal dosimetry records being kept		
(c) In Dosimetry, are :		
(1) Current dose and analyzed?		
(2) Collect dose and analyzed?		
(d) Are clinical dosimetry records being kept?		
(e) Are area Surveys records being kept?		
(f) Are tests for leakage of radioactive material from sources records kept?		
(g) Are inventory of sources and accountability records kept?		
(h) Are instruments tests and calibration records being kept?		

(i) Are incident /accident records and reports being kept?		
(j) Are audits and reviews of radiation safety programmes records kept?		
(k) Are maintenance and repair work records kept?		
(l) Are facility modifications records kept?		
(m) Are training provided		
(1) Initial?		
(2) Fresher?		
(n) Is evidence of health surveillance records kept?		
(o) Are waste disposals programme and records kept?		
(p) Are transportation of radioactive material records kept?		
(1) Package documentation?		
(2) Package survey?		
(3) Transfer/receipt documents?		
(4) Details of shipments dispatched?		
(q) Patient discharge surveys?		
(r) Clinical dosimetry records?		

H. INSPECTION FINDINGS

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RECOMMENDATIONS

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Name of Inspector: ……

Signature: ……

Date: ……