ATOMIC ENERGY COUNCIL
P.O BOX 7044
KAMPALA

Regulations 15, 20
ATOMIC ENERGY
FORM 2B (AEC 2B)

THE REPUBLIC OF UGANDA

THE ATOMIC ENERGY ACT, 2008, ACT NO.24 OF 2008

FORM 2B

APPLICATION FOR AUTHORISATION TO POSSESS AND USE A SOURCE(S) FOR MEDICAL APPLICATION

TYPE OF AUTHORIZATION (please tick)

☐ New application

☐ Renewal of authorization number: _____

GENERAL INFORMATION

1. **Name and address of applicant:**

Mail	Mailing address (if different)	Address of use (if different)

2. **Name and information about qualified experts:**

A. Expertise Radiation Safety Officer **B. Expertise:**_____

Name: _____ Name:_____

Qualification:_____Qualification:_____

Experience: _____ Experience: _____

Telephone _____Telephone_____

3. **The representative of the applicant:**

Name: _____ Telephone :_____

Title : _____ e-mail address:_____

4. Proposed date of installation and /or commissioning of facilities and equipment

_____

PART I – MEDICAL DIAGNOSTIC X-RAY EQUIPMENT

5. Details of X-ray generator

Manufacturer address/Workload	Number of tubes	Model number	Serial number	Max. Voltage (kV)	Max. Current (mA)
Name:_____ Address:_____ Max Output:_____ Exposure time per week:_____ Weekly Work Load:_____					
Name:_____ Address:_____ Max Output:_____ Exposure time per week:_____ Weekly Work Load:_____					

6. Device Standards

a) Is each device manufactured, prototype tested and subject to quality control provisions of an international standard setting organization (e.g IEC, ISO)? *Tick where appropriate*

Yes ☐

No ☐

b) If the answer above is Yes, identify the standards abs any applicable classification numbers.

_____

_____

7. Is the type of installation of the X-ray machine fixed or mobile?_____

a) Identify who is (or will be) authorized to perform the service and maintenance of the device(organization and address)

_____

_____

b) Location of the device

Provide the details of a location in which the device will be used

i) Name of unit/department_____ Building No._____ Room No. _____

ii) Plot No. _____ Town/street/ward_____ Vehicle No. _____

iii) District _____

PART II-RADIOTHERAPY

8. Type sources or Equipment

☐ Accelerator

☐ Gamma

(a) For external beam therapy

Name and address of manufacturer	Model No. And Name	Country of manufacture	Year of manufacture	Type of gantry
				Stationery rotary

Describe the movement of treatment table

_____

_____

(i) For gamma unit, fill the table below

Name and address of supplier of the source(s)	Model No of source	Radionuclide	Initial activity	Maximum design activity	Total activity

(ii) For accelerator

Type of radiation	Maximum energy (MeV)	Maximum current (mA)

(b) Brachytherapy

(i) Equipment

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		
			M R	H L		

(ii) Sources

Manufacturer	Model No.	Radionuclide	Physical type: Ribbon (R) Wire (W) Individual (I)	Physical dimensions and shape	Total activity per cm for wire and ribbon	Maximum activity

9. Standards:

Indicate to which IEC and ISO standards the equipment does and sources used for medical exposure conform:

Equipment; _____

Are prototype test certificates available:

☐ Yes

☐ No: if yes attach copies

Sources: _____

Are sources certificates available?

☐ Yes

☐ No: if yes attach original copies

10. Services and maintenance

Identify who will be authorized to perform the service and maintenance of the equipment;

Name: _____ authorized reference No _____

Organization: _____ address: _____

Telephone Number: _____

11, location of equipment/sources

Provide the details of the location of equipment/sources

(a) External beam therapy
   (i) Name of the unit/department _____ building No _____ room No _____
   Floor _____ (if applicable)
   (ii) Plot No: _____ town/street/ward _____ vehicle No _____
   (iii) District: _____
(b) Brachytherapy
   (i) Name of the unit/department _____ building No _____ room No _____
   Floor _____ (if applicable)
   (ii) Plot No: _____ town/street/ward _____ vehicle No _____
   (iii) District: _____

PART III – NUCLEAR MEDICINE, ANALYTICAL AND RESEARCH LABORATORY

12. Give details of radioactive materials available

	Radionuclide (s)	Maximum activity (Bq)	Physical/chemical form	Use/application
e.g	$Tc99^{m}$ generator	37GBq	Sodium pertechnetale	Diagnostic imaging
(a)				
(b)				
(c)				
(D)				

13. Attach a sketch of the laboratory layout and describe the laboratory facilities and factors such as.

(a). Physical separation of the laboratory from personal offices, meeting space and eating areas

.....

(b). Laboratory ventilation in order to allow air circulation

.....

(a). Fume hood available in case of experiments involving the use of volatile radioactive sources (e.g radioiodine, and sulphur-35 labelled amino acid compounds to avoid airborne radioactivity.

(b). Working area for wet chemistry experiments or admission of radioisotopes to patients (in case of nuclear medicine).....

(c)Laboratory emergency exit door or windows with shutters, which open outwards

.....

14. Describe any arrangement or facilities made for working with radioactive sources in field (if applicable)

.....

15. Describe procedures for monitoring and managing the generated wastes from patients who have been administered with radioactive materials in case of urination, vomiting etc.

.....

16. Give details of the preparation made for which the radioactive material stock solution(s) will be kept secure both during the use and storage including;

(a)Materials used to construct shelving/cabinets for chemical storage (e.g hardwood or metal etc)

.....

(b)Physical barriers provided in store for safe storage of radioactive materials (e.g locked doors/refrigerator/drawers/boxes).

.....

(c)Logbooks for recording receipts, usage, discharge or disposal of radioactive materials

.....

(d)Name of person responsible for constant surveillance of all radioactive stock materials in store and control access to radioactive materials with unauthorised individuals

.....

17. Descibe how arrangement is made to separate corrosive and flammable materials from radioactive stock solutions in store.

.....

18. Explain the availability of chemical resistant and readily cleaned bench surface used on bench tops (eg.chemical grade Formica).....

19. Explain the availability of laboratory of washing sinks installed and labelled for radioactive materials;

20. Describe the laboratory absorbent materials available to cover laboratory bench tops which can be changed periodically when contaminated

21. Describe the type of spill trays available to contain materials in the event of spill

22. Mention the protective gears available for working with unsealed radioactive materials (e.g laboratory coats, disposable gloves, shoe cover, safety glasses, pipettes (automatic/manual)

23. Describe the type and model f the survey meters or contamination monitors available

24. In the table below indicate the types of possible waste (s) that will be generated after the intended application of radioisotope;

Radionuclide (s)	Waste type	Maximum activity	Proposed disposal route

25. Give details on how foot operated dustbins with plastic liners inside are used to store the types of wastes indicated in the above

26. Mention how radioactive wastes with activity below clearance levels (e.g boxes, gloves, liquid etc) will be disposed (e.g dumpsite, incinerator)

PART IV – LAYOUT OF THE INSTALLATION

(Fill in where applicable)

27. Describe factors such as the layout of the facility and its safety systems including

(i). Building materials. (ii). Alarm (iii) shielding (IV) Engineering controls (e.g interlock. Warning safety devices Emergency stop button, prevention of unauthorised personnel entering area means of escape or communication from within enclosure etc) (v) darkroom facilities

(attach a layout drawing of the installation showing adjacent surroundings with controlled and supervised areas clearly identified)

28. Safety assessments:

(a) Taking into account of shielding, provide calculation of maximum dose rates in all adjacent areas outside the installation:

(c) Provide estimates of the magnitude of the expected doses to persons during normal operations:

(d) Identify the probability and magnitude of potential exposures arising from accidents or incidents:

Attach a layout drawing of the installation showing *adjacent surrounding. Controlled and supervised areas should be clearly identified in the drawing.*

PARTY-RADIATION AND SAFETY PROGRAMME

29. Organisational structure

(a)Describe your organisational and management systems, including assignment of responsibilities and clear lines of authority related to radiation safety.

(I)Staffing levels……

(i) equipment selection……

(i) Other assignments of the radiation safety

……

……

(iv) Authority of the radiation safety office to stop unsafe operations.

……

(v) Personnel training

……

……

(vi) Maintenance records

……

……

(vii) how problems affecting safety are identified and correctd.

……

(viii) Other useful important information

……

(b)Identify the authorised users, qualified experts and radiation safety officer by name and include their training, education, experience and qualifications (Note, the user and/or radiation safety officer may be the same individual).

Name	Qualification	Experience
1		
2		

30. Security and safety of radiation sources

Describe measures to be undertaken to ensure the security and safety of radiation sources during;

Use.

……

Transport

.....

Storage

.....

31. Individual monitoring

(a)Name and address of dosmetry service provide

.....

.....

What the personal dosimeters provided to workers? Tick where appropriate

- o Thermo luminescent dosimeter (TLD)
- o Direct reading dosimeter (DRT)
- o Optically stimulated luminescence (OSL)
- o Others

32. Local rules and supervision

(a)Describe your training program to ensure that all appropriate personal are trained in the correct operating procedures and how their actions may affect safety.

.....

.....

.....

(b)Describe how you provide workers the information regarding health risks due to occupational exposure

.....

.....

(C)Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus/embryo) and the instructions you will provide to them.

.....

.....

.....

33. Quality Assurance.

(a)Describe your quality Assurance program for your equipment in particular performance of the equipment, safety interlocks, radiation meters etc,

(c)Describe your program for optimising occupational and public exposure as low as reasonably achievable

.....

34. Emergency procedures

Provide your emergency procedures to address emergencies such as substantial accidental exposure of an individual. If other emergencies are envisaged

.....

.....

Attach more sheets if necessary.

35. Radioactive waste management.

How will the generated radioactive wastes be managed?

(a)Source(s) return to the supplier

- o Yes
- o No, if yes attach a copy of the agreement if no

(c) how will be managed in the country?

36. Other radiation protection and safety requirements. (If applicable)

(a)Occupational and public exposures control. Describe your program for monitoring your work place (eg.dose rate measurements, leak tests etc) including any dose constraints that will be applied.

……
……
……
(b)Medical exposure control. Describe your program for ensuring the radiation protection of patients and/or comforters during treatment with reference to the patient flow in your department (e.g diagnosis,prescription,simulation,physical dosimetry and treatment planning, patient set up records keeping, patients follow up etc)

……
……

PART VI DECLARATION

1…… (name of legal person) Certify that all the information given herein is true and correct to the best of my knowledge.

Date:……Signature of applicant:……

For official use only			
Registration No.			
	BY	Date	Signature
Received			
Evaluated			
General Remarks and/or comments			