



Sri Lanka Atomic Energy Act No. 40 of 2014
SRI LANKA ATOMIC ENERGY REGULATORY COUNCIL



Application for licencing for a Radiotherapy Facility Using Ionizing Radiation
(This form can be used for new facility which requires licence for the first time)

Sources covered by this application: Tele-Gamma Facility/Gamma Knife Facility/Brachytherapy Facility

Maximum validity period of the licence- One year

1. General information: (Provision of all formation requested below is compulsory)

Details of the applicant		
Name with initials of the Applicant* (Licencee)		
Designation of the Applicant (If applicant is a person)		
Name and Address of the Institute		
Telephone No./ Fax No.		
E-mail address		
Business registration No. (only for private entities). Please attach a copy of registration		
Address where the sources/equipment are used (if different from the above address)		
Telephone No./ Fax No.		
E-mail address		
Details of the Head of Institute (If not the licensee)		
Name with initials		
Designation		
Telephone No./Fax No.		
E-mail address		

*Head of the institute or his representative, applicant may be either institute or a person

2. Information of personnel to be authorized:

2.1 Details of personnel to be authorized to operator and use of therapy machines (Medical Specialists, Physicists, Radiographers etc.) (if space is not adequate, use additional papers with same format to provide all information)

Name with initials	Date of Birth	National ID Number (Compulsory)	SLMC registration No. (Compulsory)	Designation	Qualification & experiences in the relevant field *	Details of radiation protection trainings received (title of training, organizer, year, training code etc.)*

** Certificates should be attached*

2.2 Details of personnel to be authorized to work in control areas (if space is not adequate, use additional papers with same format to provide all information)

Name with initials	Date of Birth	National ID Number (Compulsory)	Designation	SLMC registration No. (if applicable)	Qualifications & experience in the relevant field	Details of radiation protection trainings received

3. Sources & equipment:

3.1 For Tele-gamma facility/ Gamma knife facility:

Specifications	Unit 1	Unit 2	Unit 3	Unit 4
Information of the Machine:				
i. Type	-----	-----	-----	-----
ii. Manufacturer	-----	-----	-----	-----
iii. Model No.	-----	-----	-----	-----
iv. Serial No.	-----	-----	-----	-----
v. Type of gantry (stationary or rotary)	-----	-----	-----	-----
vi. Out- put in Gy/min at isocenter	-----	-----	-----	-----
v. Max design Activity in GBq	-----	-----	-----	-----
vi. Type of source carrier or shutter (exposures mechanism)	-----	-----	-----	-----
Information of the sources:				
i. Radionuclide	-----	-----	-----	-----
ii. Serial No.	-----	-----	-----	-----
iii. Initial activity of the source in GBq & date	-----	-----	-----	-----
iv. No. of sources installed	-----	-----	-----	-----
v. Present activity in GBq & date	-----	-----	-----	-----
Information of the facility:				
i. Approved room plan number	-----	-----	-----	-----
ii. AERC import authorization no. for the source	-----	-----	-----	-----

3.2 Details of brachytherapy machines:

3.2.1 Remote after loading systems:

Manufacturer	Model No. of the machine	Serial No. of the machine	Radio nuclide	Physical dimensions & shape of the source	Dose rate: (High, Medium Low) select & write	Number of sources		Current total activity (GBq) with date	Approved room plan number	SLAERC import authorization No.
						Source serial No.	Activity			

3.2.2 Manual after loading systems:

Radionuclide	Manufacturer of the source	Physical type (Ribbon, Wire, Individual)	Total activity (per cm for wires and ribbons)	Number of sources of radionuclide	Current total activity with date of each radionuclide (GBq)	Approved room plan number (if relevant)	SLAERC import authorization no. given for source

3.3 Details of the other sealed sources used /stored for radiotherapy related activities :(calibration sources etc.) *(if space is not adequate, use additional papers with same format to provide all information)*

Name of associated equipment	Model No.	Serial No.	Radionuclide	Source serial No.	Activity/ date	SLAERC import authorization no. of the source

4. Radiation protection & security programme:

4.1 Details of Radiation Protection Officer;

Name with initials:		
Mobile No.		
Telephone and Fax Nos.		
Qualifications: *		
Radiation Protection training received: (Title of the training course, training institute, year, training code, etc.) *		
Experience:		

*** Attach certificates**

4.2 Radiation monitoring equipment:

Description of radiation monitoring equipment available (survey meters, area monitors etc.)

Type of equipment	Brand name	Measuring energy range	Model No.	Serial No.	Date of last calibration	Calibration report No.	Status of the equipment

4.3 Emergency equipment: List personnel protective /emergency equipment available

(L-shields, lead bricks, fume hoods, syringe shields, vial shields, remote handling tools, forceps emergency container to store the source etc.) *(if space is not adequate, use additional papers with same format to provide all information)*

Equipment / Tool	Type / Model	No. of units available	Purpose of use

4.4 Servicing of equipment:

List persons and institutes responsible for servicing and maintenance of the equipment.

4.5 Implementation of administrative rules and QA programme:

In an attachment to the application, provide information for followings;

4.5.1 Quality Assurance (QA) programme: A copy of the established written QA Programme, which should include;

- i) Administrative arrangements (procedure for admitting patients and identification)
- ii) Arrangements for periodic testing and maintenance of equipment,
- iii) Name/s of personnel responsible for the QA Programme and details of their training and experience in QA.

4.5.2 Local Rules (Protection of workers and the public): Provide a copy of the written local rules related to;

- i) Medical surveillance of workers
- ii) Investigation of accidental exposures of workers
- iii) Ensuring protection of workers and general public, employing pregnant female workers, classifications of areas including instructions and warning provided
- iv) Periodic radiation surveys and maintenance of records and
- v) Emergency procedures for the followings
 - Source stuck in Tele gamma & Brachytherapy facilities
 - Removal of the source from guide tube in Brachytherapy facilities

4.5.3 Measurement of exposure of workers and dose reports:

Describe arrangements made for measurement of exposure of workers and maintenance of records and review of doses and procedure for actions to be taken if dose exceed the levels established by the Atomic Energy Regulatory Council.

4.5.4 Educational and training programmes:

Details of educational and training programmes established for new workers and periodic refresher training for existing workers on radiation safety & security.

4.5.5 Security of the radiation sources:

a. Describe physical security arrangements made to prevent the following scenarios;

- i) Unauthorized access or damage to and for loss, theft or unauthorized transfer of radioactive sources.
- ii) Radiological consequences of any malicious act involving a radioactive sources.
- iii) Lost or theft of the source during a transport of the sources

b. Attach details source security programme implemented by the institute such as Site Security Plan, Target Folder etc..(If not implemented, provide an action plan for implementation)

4.5.6 Safety and security review: Describe your program of periodically review procedures, assessment of the quality of main safety equipment and physical protection system.

5. Management of radioactive waste:

Describe procedure for management of radioactive sources when sources become unusable and arrangement made for repartition to the supplier/manufacture.

6. Declaration:

I hereby declare that the all the information submitted is correct to the best of my knowledge and belief. In case, it is found, at any stage, that the information provided by me is false and/or not authentic, then I hereby accept that appropriate regulatory actions may be initiated against me and my institution, in accordance with the provisions of the Sri Lanka Atomic Energy Act No. 40 of 2014 and rules and regulations made there under..

Signature of the applicant
(if not the Head)

Date:_____

Signature of Head of the institution and seal

Date:_____

Instructions for applicants

1. The duly filled application form should be submitted to the Council along with the application processing fee of Rs 2400.00.
2. Processing fees should be made by cheque /MO/PO in favor of the Sri Lanka Atomic Energy Regulatory Council or by cash.
3. Application/s should be submitted to the Council before 30th September of each year along with the **application processing fee of Rs. 2400/=**. If application is not be submitted for renewal before 30th September, the applicant/institute **liable to pay Rs.100.00 as a surcharge for each day** until the date of submission of the renewal application, as per the Rule No. 1924/27 gazetted on 21-07-2015 on this behalf.
4. For any inquiries: Contact : Director, (Authorization) of the Council
General line : **011 2987857,59,60** E-mail : officialmail@aerc.gov.lk
Direct line : **011 2984098** E-mail : prageeth@aerc.gov.lk
Fax No : **011 2984099**
5. For details of information and to down load the licence application, visit: www.aerc.gov.lk
6. Please forward your applications to:
Director General,
Sri Lanka Atomic Energy Regulatory Council,
No. 977/18,
Kandy Road,
Bulugaha Junction,
Kelaniya.
Fax: 011 2984099
7. The licence renewal fee shall be paid upon receipt of an invoice/ proforma invoice.

Important: Incomplete applications and/or applications with insufficient information are liable to be returned to the applicant or rejected