



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



Application for Licencing of Sterilization, Food Preservation and Blood Irradiation Using Ionizing Radiation

(This form can be used for new facility which requires licence for the first time)

Sources Covered by this application: Gamma Irradiation Chambers/Electron Beam Accelerators/ X-ray machines

Maximum Validity Period of the Licence–Two years

1. General Information: (provision of the all information 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 source/ equipment are used (if different from the above address)		
Telephone No./ Fax No.		
E-mail address		
Purpose of Use		
<i>Important Requirement: Application for licence of food preservation shall accompany with a letter from Health Ministry giving approval for foods to be irradiated.</i>		
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 operate the Gamma irradiation chambers/Electron beam accelerators/ X-ray machines:
(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	Qualifications & experience *	Details of radiation protection training received (title of training, organizer, year, training code etc.) *

* Attach certificate

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	Qualifications & experience	Details of radiation protection training received (title of training, organizer, year, training code etc.)

(3) Details of machines & sources:**3.1 Details of the electron beam accelerator/X-ray irradiators:(except for blood irradiator)**

Type/Make of the Electron beam accelerator	Max energy MeV	Serial number	Beam Current mA	Purpose of use and status of the device	Import authorization letter number	Room plan approved letter No. and date
Eg: Toshiba	2.5	65267	65	Sterilization	AERC/IMP/A1/01	AERC/CS/A1/01

3.2 Details of the Gamma chambers:

Irradiator facility details		
	Irradiator 1	Irradiator 2
Model/Type, identification number of the irradiator		
Name and address of the manufacturer/s of the irradiator		
Approved room plan number and date		
Source details	Details of sources in irradiator 1	Details of sources in irradiator 2
Radionuclide		
No. of sources installed		
Model No. of the source		
Current activity with date (MBq/Ci)		
Import authorization number and date		
Purpose of use		

3.3 Details of the X-ray machines used for blood irradiation:

Model/Type and identification number of the irradiator	Serial number	Max kV/mA	Purpose of use	AERC Import authorization letter number	Room plan approved letter No./Authorization letter No. and date
Eg:MDS Nordian/Raycell CE	65267	160/20	Blood Irradiation	AERC/IMP/A1/02	AERC/CS/A1/02

3.4 Details of other sources used or stored in the premises (eg: calibration sources etc.)

Radio nuclide	Activity with date	Source serial No.	Purpose of use and status of the source	Import authorization letter number and date
Eg. Cs-137	185 MBq (5mCi)	65267	Test source / use	AERC/IMP/A1/03

4. Radiation protection & monitoring 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 & contamination monitors)

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 and accessories accessible in the plant: List personnel protective equipment/emergency equipment available

Name of equipment / Tool	Type / Model	No. of units available	Purpose of use

if space is not adequate, use additional papers with same format to provide all information

4.4. Attach prepared emergency preparedness & response plan including procedures for the following emergencies;

4.4.1. For Electron Beam Accelerator/X-ray Irradiator

- a. Malfunction or deliberate defeat of the safety interlock system and access control systems
- b. Fire or explosion inside the radiation room
- c. Jamming of automatic conveyor systems
- d. Natural Phenomena, including earthquakes, tornadoes floods or other phenomena as appropriate at the location of the facility
- e. Over exposure of a person or persons

4.4.2. Gamma Irradiation Chambers

- a. Stuck Source in an unshielded position
- b. A Source damage and leakage source
- c. An attempted stealing of a source
- d. Fire involving a source
- e. Over exposure of a person or persons

4.5. Emergency contact numbers: Persons to be contacted and their contact numbers

4.5.1. Head of the Institute

4.5.2. Radiation Protection Officer and an alternative person

4.5.3. The supplier and service agent

4.6. Implementation of administrative rules and QA programme:

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

4.6.1. Quality Assurance (QA) programme: Attach copy of the established written QA Programme, which should include;

- i. Arrangements for periodic testing and maintenance of equipment,
- ii. Name/s of personnel responsible for the QA Programme and details of their training and experience in QA.

4.6.2. Local Rules (Protection of workers and the public): Attach 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. Management procedures for the followings
 - In case of over exposure of a person
 - Contamination of persons & areas

4.6.3. Educational and training programmes:

Details of educational and training programmes established for new workers and periodic refresher training for existing workers on Radiation Protection and Quality Assurance.

4.6.4. 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 for actions to be taken if doses are exceeded levels established by the regulatory authority.

4.6.5. Security of the radiation sources:

Attach site security plan and provide details of 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) Any malicious act involving a radioactive sources.
- iii) Lost or theft of the source during a transport of the sources.

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

4.6.7. Design features for preventing contamination: What are the special features provided to the facility to limit the spread of surface and airborne contamination by radioactive material?

5. Management of radioactive waste:

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

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 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