Form I-1 / Revision 0

# SRI LANKA ATOMIC ENERGY ACT NO.40 OF 2014

**[Requirement Under Section 48(1)]**

## Sri Lanka Atomic Energy Regulatory Council

**Application for Registration of Importers of Radioactive Material / Source or Equipment containing Radioactive Material / Source**

**** This application should be submitted along with the information requested in page-4***

**(1) Details of the importer:**

| | |
|---|---|
| Name of the Importer | |
| • Office | Mailing Address: |
| | Telephone: |
| | Fax: |
| | Email: |
| • Private | Mailing Address: |
| | Telephone: |
| | Fax: |
| | Email: |
| National Identity Card No. | |
| Business Registration No. | |

**(2) Details of the radioactive material / source to be imported:**

| No | Chemical Name | Physical form (sealed source /unsealed source) | Total activity (Ci/GBq) per week/month/ year | Serial No. of source (if applicable) | Category of the source as per IAEA categorization (if applicable) | If source is incorporated with the equipment indicate Name, Model No. & Serial No. of the equipment |
|---|---|---|---|---|---|---|
| i | | | | | | Name: |
| | | | | | | Model No. |
| | | | | | | Serial No. |
| ii | | | | | | Name: |
| | | | | | | Model No. |
| | | | | | | Serial No. |

**(3) Details of the user/s of radioactive material / source or equipment containing radioactive material / source:**

| Details | If importer is the user | If importer is not the user | |
|---|---|---|---|
| | | user 1 | user 2 |
| Name of the user | | | |
| Address | | | |
| Telephone No. | | | |
| Fax No. | | | |
| E mail | | | |
| Licence No. issued by the Council & Date of expiry | | | |
| Purpose of use | | | |
| Name of radioactive material / source | | | |
| Quantity & Activity (GBq/Ci) | | | |
| Serial no. of source (if applicable) | | | |
| Duration of Use | | | |

*(Use separate sheets if necessary for the above tables)*

**(4) Details of the Manufacturer / Foreign Supplier of radioactive material / source:**

| | |
|---|---|
| Name of the Manufacturer / Supplier | |
| Name of the contact person | |
| County | |
| Address | |
| Telephone / Fax | |
| E-mail | |

**(5) Details of Accredited Local Agent :(if applicable)**

| | |
|---|---|
| Name of the Institute | |
| Name of the contact person | |
| Address | |
| Telephone / Fax | |
| E-mail | |

**(6) Details of personnel responsible for transport of radioactive material / source within the country and the other regulatory requirements:**

| | |
|---|---|
| Name and address of the institution responsible for transport of packages | |
| Licence no. issued by the Council for transport | |
| Name of the authorized persons accompanying the shipment | |
| Whether the transport personnel are covered by a radiation surveillance programme, if yes provide details | |
| Provide details of training & experience in preparation of documents of transport with regard to radioactive materials / sources | |
| Type of vehicle used for transportation | |
| Telephone numbers (of transport personnel) to be contacted in case of emergency | |
| Describe arrangements made to mitigate consequences of any emergency with radioactive materials / sources | |

**I hereby certify that the information furnished above is correct to the best of my knowledge and make arrangements to follow the radiological safety precautions to be observed during the handling & transport of the package to ensure safety of transport personnel & general public.**

Signature of the importer : ……

Name : ……

Designation : ……..

Date : ……..

Signature of Head of the importer's Institute : ……..

Name : ……..

Designation : ……

Date : ……

Seal of the Institute : ……..

**Documents to be enclosed with the application**

1) Licence or approval given by the competent authority of country of manufacturer of radioactive material for production of radioactive materials (This is required only for radioactive material used for in vivo use of patients)
2) Certificate issued by the competent authority / responsible organization of the country of origin of quality of the radioactive material / radiation source imported. (This is required for the material imported for diagnosis & therapy)
3) Approval issued by the competent authority that the products / radioactive materials are suitable for diagnostic / therapeutic procedures (This is required for the material imported for diagnosis & therapy)
4) Approval issued from relevant authority for exportation of the products/radioactive materials
5) List of other institutes (local or foreign) that already used the above product/radioactive material
6) Copies of licence to import medicine and certificate of registration medicine issued by the National Medicines Regulatory Authority (NMRA), Sri Lanka (This is required only for radioactive material used for in vivo use of patients)
7) Copy / ies of licence/s issued to the user / s
8) A letter from each user. (If radioactive material / radiation sources are imported for use under Department of Health, a letter from Director General of Health Services should be attached)
9) If a sealed source is imported, letters from the user, supplier / manufacturer and the agent stating that they undertake to return back the source to manufacturer for disposal should be attached. Name of the party which is responsible to bare the expenses in connection with sending the source back to supplier should also be mentioned.
10) A copy of the plan approved by the Council along with a letter from the Head of the Institute stating that the construction of the room is completed as per the approved plan and the source to be imported, will be installed in the approved plan.
11) If the sources to be imported are already available, explain why the sources already available cannot be used for the intended purpose. (Applicable for long lived sealed & unsealed sources: ie. half-lives> 5 years)
12) If a sealed source is imported, the sealed source certificate, package design certificate/package details & special form certificate (if applicable) issued by the country of origin, should be submitted.
13) Copy of the Business Registration Certificate of importer (This will not applicable to Government Institutes)

***If the radioactive material / source to be imported associated with an equipment / machine,***

14) Type approval certificate or similar document acceptable to the Council of the equipment containing radioactive material / source issued by the competent authority of the country of manufacture
15) Operation & technical manual of the machine / equipment issued by the competent authority / manufacturer / responsible organization of the country of origin.
16) Details on safety features provided to the equipment / machine to optimize radiation safety of personnel. (Both patients & workers for if equipment / machine is for medical use)

**Instructions for Applicants**

1) The duly filled application should be submitted to the following address enclosing the relevant documents **Director General, Sri Lanka Atomic Energy Regulatory Council, No.977/18, Kandy Road, Bulugaha Junction, Kelaniya.**
2) For any inquiries contact Tel:**011 2987860** Fax:**011 2987857** E-mail:officialmail@aerc.gov.lk
3) For details of information and download application, visit: www.aerc.gov.lk
4) After registration is obtained, the registered institutes / persons are required only to submit the duly filled application Form I-3 for approval for import of radioactive materials/sources

**Important:**

1) Incomplete applications and / or applications with insufficient information/documents are liable to be returned to the applicant or rejected.
2) Decision taken by the Council on the application is conveyed to the applicant within 15 working days on receipt of all requested information to assess the application.