



ATOMIC ENERGY AUTHORITY ACT NO. 19 OF 1969



Form M

Revision 01

**APPLICATION FOR LICENCING OF MEDICAL X-RAY MACHINES USE FOR
GENERAL RADIOGRAPHY, MAMMOGRAPHY AND DENTAL PROCEDURES**

*(This application should be used only for licencing of General Radiography, Mammography and
Dental Radiography Machines)*

Frequency of Licence : Biennially till 31st December of the following year

TYPE OF LICENCE

New Application

☐

Renewal of existing Licence

☐

If renewal,

Existing Licence No

Date of Expiry.....

PURPOSE OF APPLICATION

Possession / Use

(Please read the instructions and definitions given in page 08 and page 09 before filling the application form)

I - GENERAL INFORMATION

I-1 Name of the Applicant¹ :

I-2(a) Name of the organization :

(b) Address:

Mailing address	Address of the place where X-ray machines are installed (if different from mailing address)
.....
.....
.....
Tel:..... Fax:.....	Tel:..... Fax:.....

I-3 Responsible representative of the Applicant² :

Name:

Telephone :

Designation:

Facsimile :

**1-4 If applicant is not the owner of the premises in which the X-ray facility is installed (only for
private hospitals/ medical centres) provide :**

(a) Name and Address of the owner :

.....
.....

(b) Telephone..... Fax.....

1-5 Date from which the licence is required :

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I-4. Information of responsible persons and authorized users. *(Name of all persons who are involved in use of General Radiography, Mammography and Dental X-ray machines should be mentioned.)*

1-4 (a) Radiologists / Dental Surgeons and Medical Physicists

	Name	Designation	Qualifications & Experience (Attach copies of certificates)	SLMC Registration No.	Details of Radiation Protection training received (title of training, organizer, year , training code etc.)
1					
2					
3					
4					
5					

Use additional papers if necessary.

1-4 (b) Radiographers

	Name	Designation	Qualifications & Experience (Attach copies of certificates)	SLMC Registration No.	Details of Radiation Protection training received (title of training, organizer, year, training code etc.)
1					
2					
3					
4					
5					

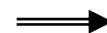
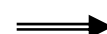
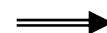
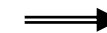
Use additional papers if necessary.

II – SOURCES

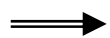
II Details of all General Radiography, Mammography and Dental Machines available at the facility :

(All above category X-ray machines available should be listed)

Type ³	Organization responsible for maintenance	Make ⁴	Purpose ⁵	Location ⁶	X-ray Tube	
					Model No	Serial No
Eg. : Static	Bio Medical Engineering Service	Dong-A	Angiography	Dept. of X-ray	R – 20	01211 – P



Note :



Continue on next page

For definitions of 3,4,5,6,7, please refer to page 9

	Max. tube voltage (kVp)	Max. tube current (mA)	Average exposure time for a patient	No. of Radiographs/ patients / week	Status ⁷	Quality control provisions of standards**
⇒⇒	125	500	20 minutes	105	Functioning	ISO
⇒⇒						
⇒⇒						
⇒⇒						
⇒⇒						
⇒⇒						

Use additional papers if necessary

** Please list and identify the standards and any applicable classification numbers under which the apparatus are manufactured, proto-type tested and subjected to quality control provisions of standards recognized by national or international standard setting organizations.
(Eg. IEC , ISO) , (Certificates issued for each machine to effect the above requirements should be attached)

III - FACILITIES AND EQUIPMENT

III-1 Lay out of X-ray room :

Attach a detailed lay out plan of the X-ray facility indicating the sizes of all X-ray rooms and dark rooms, and the location of control panels, protective barriers (lead cubicles) viewing glasses, cassette pass boxes, doors, windows / ventilators, changing rooms, waiting areas/ passages, warning symbols, safety lights, occupancy around the installation and the material & thickness of the walls.

III-2 Provide estimate of expected dose to the workers & general public during normal operations for the expected workload.

IV - RADIATION PROTECTION AND SAFETY PROGRAMME

IV-1 Details of Radiation Protection Officer : Level - 3

Name :

Qualifications :

.....

Experience :

.....

Radiation Protection training attended (title of the training, organizer, year, training code, etc.)

.....

.....

.....

Tel : Fax : E-mail :

IV-2 Individual Monitoring and Classification and Monitoring of areas :

- a.) Describe your programme for monitoring the work areas including the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.
- b.) Describe your policies and procedures for classification of controlled and supervised areas.
- c.) Describe personal dosimeters provided to workers and your policies for assigning dosimeters to individual workers. Describe your policy for reviewing individual doses, including levels and actions to be taken if exceeded.

Type of dosimeter	No. of workers covered
Thermoluminescent Dosimeters (TLDs)	
Direct Reading Dosimeter (DRDs)	
Other (Specify)	

IV-3 Local Rules and Supervision :

- a.) Describe your local rules and procedures regarding investigation or authorized levels, for protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instructions.
- b.) Describe your training policy to ensure all appropriate personnel are adequately trained in the correct operating procedures.
- 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 (Regulation No. 33 (b) of Ionising Radiation Protection Regulations No. 1 of 1999)
- d.) Describe your programme of health surveillance based on general principles of occupational health designed to assess the initial and continuing fitness of workers for their intended tasks. (Regulation 42 of Ionizing Radiation Protection Regulations No. 1 of 1999)

IV-4 Quality Assurance :

Describe your Quality Assurance Programmes established for Quality Control of X-ray machines and Dark rooms, and the evaluation of safety status of the facilities.

IV-5 Radiation Protection Gears :

Provide details of radiation protection gears made available for each X-ray facility giving name of items & no. of items.

V Investigation of accidental medical exposures :

- a) Confirm that you will investigate any or all instances where:
 - (i) A diagnostic / therapeutic dose was substantially greater than intended or resulted in doses repeatedly and substantially exceeding the established guidance levels.
 - (ii) An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

- b) With respect to any incidents investigated, describe arrangements that were made to :
 - (i) Calculate or estimate the doses received and their distribution within the patient.
 - (ii) Take all corrective measures required to prevent recurrence of such an incident
 - (iii) Implement all corrective measures that were find from the investigation
 - (iv) Submit to the AEA as soon as possible after the investigation or as otherwise specified by the authority, a written report which stated the cause of the accident and included the information specified in “i” to “iii” , as relevant.
 - (v) Inform the patient and his or her doctor about the incident.

DECLARATION:

I hereby declare that the information provided on this form and in support of this application is to the best of my knowledge complete and true.

.....
Date

.....
Signature of the applicant or responsible representative of the applicant & seal

Instructions

1. Section I to V should be filled for all categories of applications of new and renewal.
2. If new X-ray machines are added during the validity period of the licence or location of the machine is changed, an amendment to the existing licence is required (Application form for amendment of Medical Diagnostic X-ray facilities should be filled. This form can be obtained from the AEA on request).
3. The application should be submitted 2 months prior to expiry of the existing licence, for renewal.
4. Licence Fee
Fee for both renewal and new facilities

Type of X-ray machine	Fee for one unit (Including 12 % VAT and 3 % NBT)
General Radiography Fixed / Portable / Mobile	5909.89
Dental Radiography	3143.56
Mammography	7418.80

5. Please note that the inspection charge will be levied in addition to the license fee as per rates determined by the authority.
6. Duly filled application forms (new, renewal) should be submitted to the AEA **without the licence fee**.
7. All payments should be made by cheque / MO / PO or by cash drawn in favor of the Chairman, Atomic Energy Authority, **after an invoice is received**.
8. Please forward your application to

**Head,
Division of Radiation Protection,
Atomic Energy Authority,
60/460, Baseline Road,
Orugodawatta,
Wellampitiya.**

Tel. : 0112 533427-8, 0112 534209

Fax : 0112 533448

E-mail : officialmail@aea.ac.lk

Web : <http://www.aea.ac.lk/>

Definitions

- 1 Applicant : Any legal person who applies to the Atomic Energy Authority for authorization to undertake any of the actions described in the Atomic Energy Safety Regulations No 1 of 1999.
- Any organization, corporation, partnership, firm, association, trust, state, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under the Atomic Energy Authority Safety Regulations No. 1 of 1999.
- 2 Responsible representative of the applicant : The applicant shall bear the responsibility for setting up of and implementing the technical and organizational measures that are needed for ensuring protection and safety for the X-ray machines for which they are seeking authorization. The applicant may appoint a representative to carry out actions and tasks related to the application, but retains the responsibility for the actions and tasks himself. In this case, the representative can make commitments on behalf of the applicant on all tasks and actions relating to the application.
3. Type of X-ray machine :
- Eg. : (i) Static (ii) Mobile (iii) Portable
4. Make of X-ray machine :
- Eg. : (i) Dong - A (ii) Philips (iii) Shimadzu etc.
5. Purpose of the use :
- Eg. (i) General Radiography
(ii) Mammography
(iii) Dental
6. Location :
- Eg. (i) Room No. 6, Dept. of Radiology
(ii) Paediatric Ward
(iii) Intensive Care Unit
(iv) OPD
(v) Theater
7. Status :
- Eg. (i) Functioning
(ii) Out of order / condemned
(iii) Storage / Unserviceable