



DRS / 740 / 09

Dated: 30-10-2009

CIRCULAR TO INSTITUTIONS USING X-RAYS

Dear Sir,

Sub: Site Approval and Registration of X-Ray Equipments

Ref: GO (MS) No.36 / 2008 / H&FWD / Dt. TVM 07.02.2008

Operation of an X-Ray Equipment without Registration Certificate from Atomic Energy Regulatory Board (AERB) is violation of the Atomic Energy Act 1962 and is liable for penalty and legal proceedings. Directorate of Radiation Safety (DRS) is set up by the Government of Kerala to enforce AERB's Safety Codes and Guidelines on medical x-ray installations. All x-ray units (*X-ray, CT Scan, C-Arm, Cath Lab, Mammography, OPG, Dental, Portable, Mobile, BMD, etc.*) are strictly liable to register with the AERB through Directorate of Radiation Safety and obtain Registration Certificate.

Registration of a x-ray unit involve two steps, (1) Site Approval by DRS (2) Registration by AERB. For Site Approval, the institution shall apply to DRS in the prescribed format, along with 3 copies of endorsed Layout Plan (one original) and Fees by Demand Draft. As per the Government Order cited, the fees are as follows.

1	Site inspection, approval of plan and acceptance and quality control tests for major X-ray installations with bucky table and installed in a planned room	Rs.5,000/-
2	Site inspection, approval of plan and acceptance and quality control tests for major X-ray installations and used as portable units without bucky table	Rs.3,000/-
3	Site inspection, approval of plan and acceptance and quality control tests for major specialized X-ray installations (CT Scanner, Imaging equipments like fluoroscopy, Image intensifier, CATH Lab, DSA and C-ARM) installed in a planned room	Rs.10,000/-
4	Renewal of procedure after three years for category 1	Rs.3,000/-
5	Renewal procedure for category 2 after 3 years	Rs.2,000/-
6	Renewal procedure for category 3 after 3 years	Rs.5,000/-
7	Fine for renewal after the prescribed time limit	Rs.1,500/-
8	Inspection fee for shifting units within three years	Rs.2,000/-
9	Penalty for violation of AERB norms	Rs.1,500/-

(Government hospitals and Government units are exempted from the payment of the charges / fees)

Observance of Radiation Safety and Regulatory Control has become inevitable with the liberal use of ionizing radiation for medical diagnostic purpose. If you have not obtained / renewed AERB Registration Certificate, please do so immediately. Application for Layout Approval / Registration and Basic Safety Requirements in brief may be obtained from DRS on request. The Directorate is ever willing to assist you in achieving safety standards. Non-compliance may invite penalty, disconnection of electrical power and/or legal proceedings.

New owners shall install unit only after obtaining 'Site Approval' and buy only AERB Type Approved Unit. Soon after installation they must apply for 'AERB Registration Certificate' too. Please pay fees by Demand Draft favouring the 'Director of Radiation Safety'

Thanking you,



Yours Sincerely,

Director

DIRECTORATE OF RADIATION SAFETY

District Hospital Compound
Thrissur- 680 001

Tel / Fax : 0487 - 2440001

Basic requirements of a single X-ray imaging system

1. No X-ray unit shall be commissioned unless the layout of the proposed installation is approved and the unit is registered with the Competent Authority. Commissioning / operation of any x-ray installation without layout approval and registration with competent Authority is punishable offence under the Atomic Energy Act, 1962.
2. All diagnostic X-ray installations may be under the direct control of a Radiologist and shall be operated by a qualified Radiographer. A Radiologist is compulsory for fluoroscopy and where more than 2 machines are in use.
3. **The X-ray machines:**
 - a) The unit must be 'type approved' by AERB (This is to be ensured from the supplier before purchase)
 - b) Must be installed in an **approved room** (Get layout approved by DRS prior to installation)
 - c) Must have light beam and X-ray collimation
 - d) Filtration : Total 2.5mm of Al above 100kV (1.5mm permanent filtration)
: Total 2.0mm of Al up to 100kV (1.5mm permanent filtration)
 - e) Cable length > 2m to enable operation from a minimum distance of 3 meters from the x-ray tube.
 - f) Fluoroscopy: Total filtration 2mm of Al, general.
Protective glass : 2mm Pb up to 100kVp, or increased at the rate of 0.01mm per kVp.
Diaphragm to be limited to leave 1cm margin on the screen all around.
Focus to table top distance shall be not less than 30cm for general fluoroscopy.
Fluoro-timer, foot switch etc must be provided.
4. **Operating Staff:** Radiographer with Diploma in Radiological Technology (DRT/CRA) conducted by Government of Kerala or equivalent (Course conducted by a Medical College or University of duration not be less than 1 year). Courses conducted by different institutions in Kerala other than this are not approved.
5. **Protective devices:**
 - a) Barrier near control panel: Tri-sectional to cover whole body with minimum Pb equivalence of 1.5mm, including viewing window.
 - b) Aprons : Minimum 0.25mm Pb equivalent
 - c) Gloves : Minimum 0.25mm Pb equivalent
 - d) Gonad shields : Minimum 0.50mm Pb equivalent
 - e) Cassette pass box : 2.0mm Pb equivalent
6. **Periodic Inspection:** Contact Directorate of Radiation Safety for Quality Assurance check at least once in a year.
7. **Personnel Monitoring Badges :** Personnel Monitoring Badge is mandatory : **Please contact** "Avantec Laboratories Private Limited, #31, Kamaraj Street, Srinivasa Nagar, Padi, Chennai - 600050"
8. **Warning sign:** X-ray warning sign & red light indication must be placed outside the x-ray room.
9. **X-ray room :** Must be situated away from areas of high occupancy
Area : **CT Scanner 25.00 sqm (5mx5m) No dimensions less than 4.00 meters**
X-ray 18.00 sqm (4mx4.5m) No dimensions less than 4.00 meters.
Wall thickness: Walls of the X-ray room must offer adequate protection all around. About 23cms thick brick or stone wall with Cement plastering is alright. Hollow bricks, wood, asbestos etc., are not suitable. Wall behind the chest stand should be 35cms thick if there is any likely hood of occupancy on the other side of the wall or alternatively give lead backing of 1.0mm lead sheet on 23cms thick wall.
Dark Room : Preferably (3mx4m)
Waiting Room : Patient waiting shall be outside the X-ray room.
Entrance to the X-ray room: Number of doors for entry to the x-ray room shall be kept minimum. Doors shall be Lead lined with 1.70mm Pb equivalent, including door frame.
Windows/exhausts/AC : At a height of 2m from the ground level outside.
10. **The installation / lay out :** Should ensure adequate safety of the operator, patient and those waiting outside. The direct beam shall not be directed to an occupied area, control panel, waiting area etc. Get the layout approved before installation and unit registered before commissioning by DRS. Apply in the prescribed format with a layout plan and prescribed fees.
11. All special installations like Dental X-ray, Mammography, CT Scan, Cath Lab, DSA, C-Arm and other special systems require customized planning of all radiation safety aspects. DRS is available for consultation.
12. **Contravention of the rules:** Punishable under relevant sections of Atomic Energy Act - 1962.
13. The requirements listed above are only brief for details please refer : **AERB Safety Code No.SC/MED-2(Rev.1)**



Government of Kerala
Department of Health & Family Welfare
DIRECTORATE OF RADIATION SAFETY
District Hospital Compound
Thrissur- 680 001

Tel / Fax : 0487 - 2440001



ESTD: 1998

APPLICATION FOR SITE APPROVAL OF X-RAY INSTALLATION LAYOUT (for X-ray, CT Scan, C-Arm, Cath Lab, Mammography, OPEG, Dental)*

1. Name of owner and address of the institution:

[illegible]

2. Address of the proposed X-ray installation:

								PIN										
Ward No. & Building No.																		
Name of the Panch/Mun/Corp																		

- ### 3. Mode of communication

[illegible]

4. Name and address of the supplier

							PIN							

5. Personnel Monitoring Badges Yes / No / Applied - it is compulsory

Institution Number for Personnel Monitoring

6. Details of the X-ray unit (write type of unit*) :

- (i) Model number :
- (ii) Make :
- (iii) Type approval certificate No. :
- (iv) Maximum operating voltage (kVp) :
- (v) Maximum operating current (mA) :

7. Name and address of the manufacturer:

							PIN							
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8. Expected work load

S. No.	Type of examination	Number of examination	kV	mAs	mA mt
1.					
2.					
3.					
4.					

9. The layout plan (scale 1:50) showing the location of X-Ray unit, chest stand, doors, control panel, mobile protective barrier, windows, ventilation, waiting area and type of occupancy around including above ceiling and below floor should be enclosed. Thickness of walls, dimensions of room and distances of doors & control panel from the x-ray machine/chest stand also should be indicated.

Area of the Room: _____ Sq.meter Length: _____ cm Width: _____ cm

DD for Rs. _____ DD No. _____ Bank: _____

DECLARATION

I here by certify that all statements made above are correct to the best of my knowledge.

Place:

Signature :

Date:

Name :

Designation :

(Seal of the institution)

(Do not install the unit prior to getting layout approval from the Directorate of Radiation Safety)