GOVERNMENT OF INDIA ATOMIC ENERGY REGULATORY BOARD RADIOLOGICAL SAFETY DIVISION (RSD)

Diagnostic Radiology Group Niyamak Bhavan, Anushaktinagar, Mumbai-94



Guidelines for obtaining regulatory consents from AERB for medical diagnostic X-ray equipment

1) Applications for Registration (Radiography/R&F/Mammography/OPG/BMD/Dental/Mobile Radiography/C-Arm):

- Completely filled duly signed and stamped application form (AERB/RSD/MDX/REG & RSO). Detailed requirements for Registration are given in Table-A
- DD for Rs. 3300/- (for Government hospitals Rs. 1650.00/-) in favor of "Pay and Accounts Officer, AERB" on SBI service branch, Mumbai as layout approval charges per institution/application.
- Layout requirements for room housing X-ray equipment (as per TABLE-A)

2) Application for License (CT/ Interventional Radiology (IR) installations) (Guidelines as per TABLE-B)

a) Layout Approval:

- Completely filled, duly signed and stamped application form (<u>AERB/RSD/MDX-CT-CATH /SLA & PROC)</u>
- 2 duly signed and stamped copies of layout to the scale 1:50 indicating positions of gantry, couch, control room, doors (with lead lining), wall thickness, internal dimensions of the room etc (sample layouts as per website)
- 1 duly signed and stamped copy of floor layout to the scale 1:100 indicating location of CT-Scan/ IR installation and occupancy in the surrounding areas
- Copy of Valid NOC/ Type Approval Certificate
- DD for Rs. 3300/- (for Government hospitals Rs. 1650.00/-) in favor of "Pay and Accounts Officer, AERB" on SBI service branch, Mumbai as layout approval charges per institution/application.

b) Licence:

- Completely filled, duly signed and stamped application form (<u>AERB/RSD/MDX-CT-CATH/LCO</u>) with authenticated staff list including names of radiologists, X-Ray technologists, RSO and their PMS numbers.
- Completely filled, duly signed and stamped QA report of X-ray equipment. (by hospital authority and counter signed by supplier of the equipment)

c) RSO Approval:

- Copy of certificates of educational qualifications and radiation protection training, if any.
- Copy of employment certificate from the hospital/institution.
- Radiologist / X-ray technologist with qualifications as below:
 - o Radiologist
 - An MBBS degree from a recognized university or an equivalent qualification
 - A post-graduate degree/ diploma in radio-diagnosis from a recognized university
 - X-ray technologist
 - 10+2 or equivalent examination passed with science subject from recognized board and
 - Radiographer's/X-ray technologist's course of minimum 1yr duration (including in-field training in diagnostic radiology) passed from a recognized institution
 - Availability of Personnel monitoring badge (TLD) for which he/she is nominated to become RSO.

3) Personnel Monitoring Service providers

Sr. No.	Name of Accredited Laboratory	States Covered	Telephone
1	M/s. Avanttec Lab. Private Limited,# 76, 7 th street, ground	Andhra Pradesh, Tamil Nadu, karnataka,	044-26345288,044-
	floor,Porur Garden,Phase-1, Chennai, Tamil Nadu, Pin-600095	Kerala, Puducherry (Southern Region)	26630553/54/56
			email:tldlab@avanttec.net
2	M/s. Renentech Lab. Private Limited, C-106, Synthofine	Maharashtra, Gujarat, Rajasthan, Goa	022-40037476
	Industrial Estate, Off Aarey Road, Goregaon(E), Mumbai, Pin-	(Western Region)	
	490063,		
3	M/s. Ultratech Lab. Private limited, Cloth Market, G.E. Road,	All other states in the Central, Northern and	788-3295166,
	kumhari, Bhilai, Durg, Chhattisgarh, Pin- 490042	North Eastern parts of the country	09981212431
4	Defence Laboratory, Jodhpur	All Defence institutions of the country	

4) Points to be noted

- a) No two X-ray equipment should be installed in the same room.
- b) X-ray installations should be located as far as feasible from areas of high occupancy such as Maternity, Pediatric and Sonography rooms and other departments not directly related to radiation applications in medicine.
- c) Periodic Safety status reports as per prescribed formats of AERB website should be maintained by registrant/licensee.
- d) Other requirements relevant to medical diagnostic installations are prescribed in AERB safety Code (AERB/SC/Med-2),2001.
- <u>5) Renewal of Registration/ License/RSO Approvals</u>: Application for renewal of Registration/ Licence/RSO Approvals shall be submitted to Head, RSD, AERB at least 3 months prior to their validity date.

TABLE -A Requirements for Registration to use/ operate X-ray equipment.					
Type of X-ray unit	Requirements for layout of the room to install X-ray equipment			Requirements for Registration (Ref.: Application form No. AERB/RSD/MDX/REG &	
	Min. dimension requirement	Min. area requirement	Layout requirements	RSO)	
Radiography/ Fluoroscopy	Any single dimension should not be less than 4m	18 m ²	 AERB Type approved X-ray equipment 23cm thick brick walls/35cm in case of residency premises 1.7 mm Lead lined doors Mobile protective barrier with lead glass viewing window of 1.7 mm Pb equivalent Separate control room (for X-ray equipment > 125kVp 	 Copy of proposed / already approved layout of X-ray equipment room for installing the X-ray equipment Copy of valid NOC/ Type Approval certificate of X-ray equipment Copy of RSO approval, if obtained Availability of protective accessories (Mobile protective barrier, Lead apron of 0.25mm) List of qualified/ trained personnel with TLD badges numbers QA report 	
Bone densitometry	Any single dimension should not be less than 3.5m	15 m ²	 AERB Type approved X-ray equipment 23cm thick brick walls 1.7 mm Lead lined doors 	 Copy of proposed / already approved layout of X-ray equipment room for installing the X-ray equipment Copy of valid NOC/ Type Approval certificate of X-ray equipment Copy of RSO approval Availability of PMS Copy of QA report 	
OPG	Any single dimension should not be less than 3 m	13 m ²	 AERB Type approved X-ray equipment 23cm thick brick walls/35cm in case of residency premises 1.7 mm Lead lined doors Mobile protective barrier with lead glass viewing window of 1.7 mm Pb equivalent 	 Copy of proposed / already approved layout of X-ray equipment room for installing the X-ray equipment Copy of valid NOC/ Type Approval certificate of X-ray equipment Copy of RSO approval Availability of PMS Copy of QA report 	
Mammography	Any single dimension should not be less than 3 m	10 m ²	 AERB Type approved X-ray equipment 23cm thick brick walls/35cm in case of residency premises 	 Copy of proposed / already approved layout of X-ray equipment room for installing the X-ray equipment Copy of valid NOC/ Type Approval certificate of X-ray equipment Copy of RSO approval 	

			 1.7 mm Lead lined doors Mobile protective barrier with lead glass viewing window of 1.7 mm Pb equivalent 	Availability of PMSCopy of QA report
C-arm/Mobile radiography/ Intra oral dental equipment	Not Applicable	Not applicable	Not Applicable	 Copy of proposed / already approved layout of X-ray equipment room for installing the X-ray equipment Copy of valid NOC/ Type Approval certificate of X-ray equipment Copy of RSO approval Availability of PMS Copy of QA report

TABLE -B Requirements for License to use/ operate CT/ IR equipment					
Type of X-ray unit	Minimum dimensions of X-ray Room	Min. area requirement	Requirements for Layout Approval of CT/IR room (Ref. Application form No.: AERB/RSD/MDX-CT-CATH/SLA & PROC)	Requirements for Licence (Ref. Application form No. : AERB/RSD/MDX-CT-CATH/LCO)	
Computed Tomography	Any single dimension should not be less than 4m	25 m ²	 AERB Type approved X-ray equipment 23cm thick brick walls/2mm lead lined doors lead glass viewing window of 2 mm Pb equivalent Separate control room 	 Copy of AERB Layout Approval Copy of valid NOC/ Type Approval certificate X-ray equipment Copy of RSO approval Availability of PMS QA report 	
Interventional Radiology (Cath- Lab)	Any single dimension should not be less than 4m	25 m ²	 AERB Type approved X-ray equipment 23cm thick brick walls 2mmLead lined doors lead glass viewing window of 2 mm Pb equivalent Separate control room 	 Copy of AERB Layout Approval Copy of valid NOC/ Type Approval certificate X-ray equipment Copy of RSO approval Availability of PMS QA report 	