

Government of India
Atomic Energy Regulatory Board
Directorate of Regulatory Affairs and Communication

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**OFFICIAL STATEMENT OF AERB ON REGULATORY CONTROL FOR
RADIATION SAFETY IN USE OF
MEDICAL DIAGNOSTIC X-RAY EQUIPMENT IN THE COUNTRY**

This statement is issued by the Atomic Energy Regulatory Board (AERB) to clarify its position on regulation of medical diagnostic X-ray facilities, towards radiation safety in the country and is issued in the public interest. AERB herewith explains the persistent regulatory efforts towards streamlining the regulatory control over medical diagnostic X-ray facilities and bringing them under the regulatory ambit.

AERB discredits any adverse hearsay statements in this regard made through any print, electronic & social media, or any other source or needless litigation and casting aspersions on AERB without substantiating them.

AERB issues Licenses/ Registration, from radiation safety view point, to nuclear and radiation facilities in the country. Radiation facilities include, inter-alia, medical X-ray facilities. The X-ray equipment consists of Cath lab (interventional radiology), CT scanners, Radiography / Fluoroscopy units, Mammography units, Dental units, X-ray C-arm units, X-ray Bone Scanners etc.

The Licenses/ Registration for operation of medical X-ray equipment are issued under Atomic Energy (Radiation Protection) Rules 2004 (AE (RP) R, 2004) promulgated under Atomic Energy Act, 1962. Rules under AE (RP) R, 2004, addresses radiation safety of occupational staff and general public. With respect to medical diagnostic X-ray equipment, the occupational staff imply those operating the X-ray equipment i.e. X-ray technologists, medical professionals (*such as Radiologists, Cardiologists, Interventionists, Orthopedicians, Dentists*) and those staff routinely present in the vicinity of the operating X-ray equipment (i.e. *nursing and support staff*). The general public are those near the vicinity of the X-ray room (*such as relatives of patients, receptionists and other members of hospital staff*).

1) Correct perspective about radiation hazards of medical X-ray equipment

X-rays are generated only when the X-ray equipment is energized and lasts just for a millisecond for radiography and a few minutes for fluoroscopy. The information as Image or Video respectively is aimed at improving patient's health by proper diagnosis/ radiological procedures. In the process, though the patient receives a direct radiation (primary) on the specific part of the body and likelihood of a small risk of radiation exposure for that occasion, he/she has benefitted from the radiology procedures in terms of improved health status.

The occupational staff are exposed to radiation that is scattering from patients and other nearby objects, which however, is considerably less (~0.1 % of the primary radiation/patient). The protective accessories such as lead (equivalent) apron, lead goggles, thyroid shield, mobile protective barriers, prescribed by AERB, offers near-complete shielding to the occupational staff. The exposures to the public, which are a moving population in general, is minimal. Certain basic layout requirements for X-ray facilities specified by AERB, ensures that there are no unnecessary radiation exposures to public. Thus, it is highly unlikely that there are any major hazardous situations from X-rays encountered during proper medical X-ray procedures.

Having said this, there is a requirement to regulate the use of medical X-ray facilities to the extent that it does not pose undue radiation hazard to patient and occupational staff. This can be achieved with compliance to certain minimum and effective regulations. Through the

Licensing/ Registration process of X-ray equipment, AERB intends to ensure such acceptable radiation safety.

2) **Background and strategy to regulate medical X-ray facilities**

Regulation of Medical diagnostic X-rays in the country is challenging owing to its sudden growth in the healthcare sector, wide-spread use and the lack of awareness of regulatory requirements for radiation safety. Prior to 2013, AERB was issuing manual licences to the users of X-ray equipment. At that time, it was difficult to cover the entire country with this manual mechanism. Therefore, AERB had sought the help of State Health Department towards formation of the Directorate of Radiation Safety (DRS). However, only few States came forward for establishing the State level DRS. Even with these States, the inter-organization communication was not effective. Also, States had their own policy in functioning the DRS.

There was also a writ petition No. 501 of 2001 in the matter of J.P. Sharma Vs Union of India & Ors, dealing with regulation of Medical diagnostic X-ray equipment, under consideration of Honorable Supreme Court. The Honorable Supreme court has pronounced its final decision on September 17, 2013, where-in the case has been disposed of without any further directions to AERB regarding the formation of DRS in States.

AERB has been concerned about regulating the safety of large number of medical X-ray facilities and has been taking related actions in right earnest, as below:

i) **Simplification in procedures**

a) ***Simplification of AERB Safety Code of Medical Diagnostic X-ray equipment***

- AERB has prescribed detailed radiological safety requirements for medical X-ray equipment and installations in the Safety Code, “Radiation Safety in Manufacture, Supply and Use of Medical Diagnostic X-Ray Equipment”, 2016 (AERB/SC/MED-3). This Safety Code has been revised from the earlier versions in 1986 and 2001 based on the operational feedback, improvements in design and international developments and stakeholder feedback. (www.aerb.gov.in/publications)
- ***AERB has recently simplified the regulatory requirements, without compromising radiation safety, for dental equipment owing to their low hazard potential and in-built design safety.***

b) ***Efficient online web-based Licensing system, e-LORA***

AERB has made the on-line e-Governance system operational, towards issuance of Licence i.e. e-Licensing for Radiation Applications (e-LORA) since 2013. With the advent of e-LORA, AERB is able to make licensing faster, transparent and easier for obtaining license/ registration of X-ray equipment under a uniform policy throughout the country. The e-LORA system with its user-friendly mechanisms facilitate faster and correct submission of applications. AERB reviews the mandatory on-line submissions by the applicant before issuance of License / Registration for operation. The e-LORA system ensures “Minimum Government and Maximum Governance”.

NO FEES IS LEVIED at present for obtaining License /Registration from AERB.

c) ***Graded approach of Licensing***

In line with the spirit of graded approach under the provisions of Atomic Energy (Radiation Protection) Rules, 2004, AERB’s rigor in review is as per the hazard potential of X-ray equipment. (*i.e. Cath lab, CT equipment, fluoroscopy/radiography, mammography and dental in decreasing order of their hazard potential*). Physical

verification of the X-ray installation(s)/ X-ray equipment is on sample basis, during AERB regulatory inspections.

d) Regional Regulatory Centers (RRC)

AERB has established Regional Regulatory Centers (RRC) at Chennai, Kolkata and Delhi besides the Headquarters in Mumbai. The RRCs enhance regional presence for improved outreach/ radiological surveillance.

ii) Spreading awareness

- a) Continuous interactions of AERB officers with professional associations like IRIA (Indian Radiological & Imaging Association), IOA (Indian Orthopedic Association), ISVIR (Indian Society for Vascular and Interventional Radiology), ISRT (Indian Society for Radiographers & Technologist), CSI (Cardiology Society of India), Society for Indian Radiographers (SIR), Radiographer Association of Maharashtra (RAM), etc;
- b) On-going actions for improving stakeholder and public awareness about AERB requirements through print, electronic media and radio-jingle, as well as by means of (i) development of Video films on safety awareness through Bureau of Outreach and Communication (BOC) (ii) leaflets and brochures. (iii). use of social media tools for public awareness (iv) periodic updates on AERB website. (For more information, visit to : <https://www.aerb.gov.in/english/aerb-advertisement>)

iii) Inter-ministerial co-ordination

AERB co-ordinates with other Governmental agencies to facilitate the implementation of safety regulations for medical devices emitting ionizing radiation.

- a) Communication with Chief Secretaries of the States/Union Territories sensitizing all the medical X-ray facilities through the District Law Enforcement Authorities and District Health Authorities under their jurisdiction to obtain requisite Licence /Registration from AERB.
- b) Co-ordinated with Directorate General of Foreign Trade (DGFT), which resulted in DGFT notifying the amendment in the import policy conditions under EXIM code of ITC (HS) 2017, Schedule I, where the import of diagnostic medical equipment and X-ray tubes are permitted subject to Atomic Energy Act, 1962 and the Rules thereunder including prior regulatory clearance from AERB.
- c) Co-ordination with National Accreditation Board for Calibration and Testing Laboratories (NABL) with regards to Accreditation of Testing and Quality Assurance Agencies of medical X-ray equipment.
- d) Exploring possibilities of establishing a cohesive administrative mechanism with the DGHS, Ministry of Health & Family welfare, under the Clinical Establishment Act, 2010.

Owing to these on-going efforts, most of the medical X-ray equipment are in compliance with the AERB safety regulatory requirements. In line with its mission, AERB will continue to play a pivotal role in bringing out / establishing effective regulations to ensure the radiation safety of people and environment from ionizing radiation.



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Note: AERB do not regulate medical imaging equipment such as MRI, Ultrasound since these are based on Non-ionizing radiation.