

दूरभाष / TELEPHONE : 91-22-2599 0100 / 0101  
फैक्स / FAX : 91-22-2599 0650, 2558 3230  
वेबसाइट / WEBSITE : www.aerb.gov.in



नियामक भवन / NIYAMAK BHAVAN,  
अणुशक्तिनगर / ANUSHAKTINAGAR,  
मुंबई / MUMBAI-400 094.



ISO 9001:2008

भारत सरकार  
GOVERNMENT OF INDIA  
परमाणु ऊर्जा नियामक परिषद  
ATOMIC ENERGY REGULATORY BOARD

Radiological Safety Division

Dr. A.U. Sonawane  
Head, RSD

Tel: 022-25990656  
Fax: 022-25990650

Ref: AERB/RSD/DRG/Adv-Letter/2016/2700

01/08/2016



Dear Sir/Madam

**Sub: Compliance of Dental X-ray Facilities with Regulatory Requirements Stipulated in the Atomic Energy (Radiation Protection) Rules 2004**

This is regarding compliance to the regulatory requirements for ensuring radiation safety in hospitals and clinics possessing dental x-ray units in the country. Atomic Energy Regulatory Board (AERB) is taking several efforts to enforce compliance of regulatory requirements as stated below, by such facilities for which, active support and proactive involvement is essential from the Dental Council of India and Professional Associations

AERB is a regulatory body constituted under the Atomic Energy Act 1962 with the mission to ensure the use of ionising radiation and nuclear energy in India does not cause undue risk to the health of people and the environment. AERB enforces the Atomic Energy (Radiation Protection) Rules, 2004 (AE (RP) R, 2004) promulgated under the aforesaid Act in all radiation facilities. These include facilities/institutions using radiation for diagnosis and therapy such as Medical Diagnostic X-rays, radiation therapy for cancer treatment and diagnostic & therapeutic in Nuclear medicine. Medical Diagnostic X-rays is the most widely used application of radiation in medicine, both in terms of the number of existing institutes/facilities and also number of persons who are exposed for investigations, and hence needs special mention.

Diagnostic X-ray equipment like radiography, Fluoroscopy, CT Scanner, Cath Labs, Interventional radiology units, C-arm and dental X-ray units etc are being widely used as primary tools for diagnostic purposes and have proven immensely beneficial to the society at



large. However, improper and unsafe use of such radiation generating equipment is associated with health hazards and hence it is imperative to ensure that due care is exercised in handling of these equipment. As per Rule 3 of AE (RP) R-2004 it is mandatory for all end users of medical diagnostic x-ray equipment (including dental x-ray equipment) to obtain Licence/Registration from AERB for operating such equipment and contravention of these Rules is liable for legal action as per the provisions of the Act.

However, during regulatory inspections carried out by AERB, it is observed that a majority of the dentists, hospitals and facilities operating dental x-ray units (dental intra oral (portable/hand held), extra-oral (OPG/CBCT units) claim to be unaware of the above regulatory requirements and are found to operate the equipment without the requisite regulatory clearances from AERB. Therefore, such situation has led to sealing of the equipment on the spot by AERB due to unsatisfactory safety status.

We are constantly striving to create awareness regarding these regulatory requirements through media advertisements, conducting awareness programs, carrying out regulatory inspections and publication of warning/notice in leading newspapers (enclosed as annexure 1). Special inspections are also being conducted all over the country and X-ray facilities operating without fulfilling the requirements were sealed or issue with warning for seal. For improving safety awareness, updated operational safety guidelines are sent periodically to all registered users by AERB.

However, it is felt that there is a pressing need for the statutory bodies like Dental Council of India and the associated professional bodies like the Indian Dental Association to pay close attention in this regard to ensure safe use of dental X-ray equipments for patient, operators and medical practitioners.

In view of this, we request the Dental Council of India to disseminate these requirements through appropriate forums and professional bodies, for operating dental x-ray equipment in compliance with the regulatory requirements and possess valid AERB license/registration. It is worth mentioning here that AERB has launched a user friendly web based e-licensing system (e-LORA) through which the users can obtain license/registration online. At present there is no fee involved in this process. A brief guideline on the procedure for obtaining the license from AERB is also enclosed herewith. Your support in this endeavor will go a long way in effective regulation of dental X-ray facilities and ensure safe practice of dental radiology in the country.

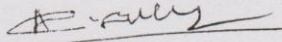
We also propose certain actions for ensuring the above objectives such as i) selective news item/article/advertisements by AERB in your periodic publications ii) participation in your

परमाणु ऊर्जा नियामक परिषद  
ATOMIC ENERGY REGULATORY BOARD

CME /Conferences to emphasize on requirements about safety aspects of dental X ray equipment and iii) providing eLORA portal in your official website.

For further information you may contact Smt. S. Mahalakshmi, Officer-in-Charge, Diagnostic Radiology, AERB at 022-25990662 email: [lakshmi@aerb.gov.in](mailto:lakshmi@aerb.gov.in)

With warm regards,

  
(A.U. Sonawane)

Dr. Dibyendu Mazumder  
President, Dental Council of India  
Aiwan-E-Galib Marg,  
Kotla Road, Temple Lane  
New Delhi – 110002  
INDIA

Cc: ✓ Executive Committee Members, DCI  
Council Members, DCI  
Secretary, IDA



## Brief Guidelines for Obtaining Licence/Registration for operation of Medical Diagnostic X-ray Equipment through e-LORA

It is mandatory for all users/owners of medical diagnostic x-ray equipments to obtain Licence/Registration from AERB for Operation of the equipment as per Atomic Energy (Radiation Protection) Rules 2004. Here are the simple steps to help you in obtaining the requisite licence/registration through e-LORA

### Step-1 : Register Your Institute

Visit our website [www.aerb.gov.in](http://www.aerb.gov.in) and click on the button eLORA. It will redirect you to the eLORA home page. Use the "Register Institute" option to submit the application for Institute Registration. (USERNAME and PASSWORD will be sent to your email address after processing of application). Detailed [Guidelines for Institute Registration](#) are available in e-LORA home page.

### Step-2A: Obtain Licence for operation of existing medical diagnostic x-ray equipment (for equipment existing/ installed prior to January, 2015)

To obtain the Licence/Registration for existing medical diagnostic x-ray equipment (*existing/ installed prior to January, 2015*) follow the sequence;

1. *Declare the existing equipment(s):* Click on "Declare Existing X-ray Equipment" and declare all existing X-ray equipments one by one.
2. *Record of Licence/Registration:* If you have valid AERB Licence/Registration against any of the declared equipment, click on "Record Licence for operation of X-ray Equipment" and record the same by uploading a scanned copy of Licence/Registration.
3. *Apply for Licence/Registration:* If you have not obtained Licence/ Registration from AERB for any equipment, apply for the same by clicking "Licence for Operation of Existing Equipment".

### Step-2B: Licence for operation of new medical diagnostic x-ray equipment

To obtain the Licence/Registration for new medical diagnostic x-ray equipment follow the sequence

1. *Obtain Procurement Permission:* Obtain permission from AERB for procurement of new x-ray equipment
2. *Apply for Licence/Registration for operation:* Apply and obtain license/registration for operation of your new x-ray equipment. You will be able to apply for the licence/registration, as soon as the supplier submits the installation report to AERB through eLORA.

**NOTE:** Detailed guidelines for obtaining regulatory consents through e-LORA is available in the 'Help' menu which can be accessed when you log in to your e-LORA account. Prior to applying for Licence/ registration please ensure the following:

(i) Add safety tools through Add Instrument in Instrument Management. (ii) add radiation worker and their role (operator/medical practitioner) through Add Employee in User Management.

Prepare a sketch of room layout (1:50 scale) of each x-ray room (not applicable for Radiography (mobile), C-Arm, O-Arm, Dental (Intra-oral) and Dental (Hand-held) X-ray equipment).

Additional requirements for Computed Tomography and Interventional Radiology Facilities. Ensure that approved RSO (Radiological Safety Officer) is available in your institution.



TELEPHONE : (O) 2550 0018 (Direct)/ 25990612

FAX : (022) 2550 0018 / 25562344

E-MAIL: harikumar@aerb.gov.in

वेबसाइट/WEBSITE: www.aerb.gov.in



ISO 9001 : 2008

सचिव, पञ्जीप

No. AERB/SEC/2016/2008



सत्यमेव जयते

भारत सरकार

GOVERNMENT OF INDIA

परमाणु ऊर्जा नियामक परिषद

ATOMIC ENERGY REGULATORY BOARD

नियामक भवन/NIYAMAK BHAVAN,

अणुशक्तिनगर/ANUSHAKTINAGAR,

मुंबई/MUMBAI-400 094

Secretary, AERB

July 5, 2016

### PRESS RELEASE

#### **AERB shuts down operation of some of the medical diagnostic X-Ray facilities at Jammu owing to non-compliances.**

The Atomic Energy Regulatory Board (AERB) has suspended the operation of some of the medical diagnostic facilities at Jammu which were not complying with the specified regulatory and radiation safety requirements. AERB has sealed 13 diagnostic X-ray equipment owned by the facilities, following surprise inspections carried out during June 29 – July 1, 2016. The sealed equipment included three Computed Tomography (CT) equipment. AERB has also issued warnings for few facilities to comply with the specified regulatory and safety requirements within thirty days.

The equipment sealed were found to be operating without complying with the mandatory requirement of obtaining the requisite license and registration from AERB, as per the provisions of the Atomic Energy (Radiation Protection) Rules, 2004. The Rules prohibit setting up and operating any CT equipment without obtaining the requisite License, whereas a Registration is mandatory for the diagnostic X-ray facilities. Though the X-ray equipment are of low radiation hazard potential, it is important that they are installed and operated in accordance with the radiological safety requirements specified by AERB. AERB issues the requisite Licence/Registration after ensuring that they conform to the specified safety requirements.

AERB's action at Jammu comes on the heels of the continuing drive initiated against the errant medical diagnostic facilities that are operating in violation of the regulatory and safety requirements. AERB had earlier initiated similar action against a number of medical X-ray diagnostic facilities in Mumbai, Jaipur, Raipur, Nagpur, Chennai, Hyderabad, Bengaluru, Pune, New Delhi, Kolkata, Goa, Gaya, Patna, Lucknow, Kanpur and others. AERB will be continuing similar action in other places in the country as well.

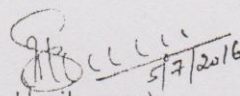
Though the country has a large number of medical diagnostic X-ray facilities many of them have not been registered with AERB. In the recent times AERB has initiated a number of steps to improve compliance by the X-ray facilities to the provisions of the Rules as well as the specified safety requirements. This is important to ensure radiation safety for the persons



operating these equipment as well as the patients who make use of them. In order to make the process of filing of applications and obtaining the AERB Registration/Licence easy, AERB has launched a web based e-licensing system (e-LORA). AERB has also undertaken a series of outreach programmes for the medical diagnostic X-ray facilities regarding the importance of obtaining the requisite registration and license, through advertisements in the print media and awareness programmes. The programme of surprise inspections and closure of the non-compliant facilities / equipment is coming on the back of such efforts from AERB.

AERB is therefore advising all those medical diagnostic X-ray facilities that are presently operating in the country, without the valid Licence / Registration from AERB to immediately obtain the Licence / Registration, by filing an application through AERB's internet based e-licensing system (e-LORA).

AERB also advises the public not to patronize the X-ray facilities which are not having valid Licence / Registration issued by AERB.

  
(S. Harikumar)



TELEPHONE : (O) 2550 0018 (Direct)/ 25990606  
FAX : (022) 2550 0018 / 25562344  
E-MAIL: harikumar@aerb.gov.in  
वेबसाइट/WEBSITE: www.aerb.gov.in



ISO 9001 : 2008

सचिव, पञ्जिप



भारत सरकार

GOVERNMENT OF INDIA

परमाणु ऊर्जा नियामक परिषद

ATOMIC ENERGY REGULATORY BOARD

नियामक भवन/NIYAMAK BHAVAN,  
अणुशक्तिनगर/ANUSHAKTINAGAR,  
मुंबई/MUMBAI-400 094

SECRETARY, AERB

No. AERB/SEC/PRESS/2015/11

September 24, 2015

## PRESS RELEASE

### **AERB's enforcement action against medical X-ray Facilities at Delhi and Kolkata owing to non-compliance to Regulatory requirements**

The Atomic Energy Regulatory Board (AERB) has suspended the operation of some of the medical diagnostic facilities at Delhi and Kolkata, which were not complying with the specified regulatory and radiation safety requirements. In a series of surprise inspections held at two cities simultaneously during September 22 & 23, 2015, AERB has sealed 9 diagnostic X-ray equipment located in five centers in Delhi and 4 equipment at three centers in Kolkata. AERB has also issued warnings in relation to 84 X-ray equipment at these facilities (9 in Kolkata and 75 in Delhi), with a direction to ensure compliance with the specified regulatory and safety requirements within thirty days.

The Inspections are still ongoing in these cities at the time of issuing this press release.

The equipment sealed were found to be operating without obtaining the requisite license or registration from AERB and not conforming to the safety requirements as per the provisions of the Atomic Energy (Radiation Protection) Rules, 2004. AERB issues the requisite Licence/Registration after ensuring that the equipment and installation conform to the specified safety requirements.

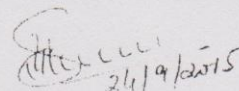
The action of AERB in these cities is in continuation with its on-going drive initiated against facilities operating diagnostic X-ray equipment in contravention to the provisions of the Atomic Energy (Radiation Protection) Rules, 2004. Similar inspections and enforcement actions were undertaken by AERB earlier at Hyderabad, Bengaluru, Chennai, Jaipur, Raipur, Pune, Nagpur, Mumbai and Navi Mumbai, where several errant facilities were sealed.



Though the country has a large number of medical diagnostic X-ray facilities, many of them have not been registered with AERB. AERB has initiated a number of steps to improve compliance by the X-ray facilities to the provisions of the Rules as well as the specified safety requirements in the recent times. This is important to ensure radiation safety for the persons operating these equipment as well as the patients who make use of them. In order to ease the procedures for filing of applications and obtaining the Registration/Licence, AERB has launched a state - of- art e-licensing system (e-LORA) on AERB website at [www.aerb.gov.in](http://www.aerb.gov.in). AERB has started a series of outreach programs for these facilities emphasizing the importance of obtaining the requisite registration and license. The program of surprise inspections and closure of the non-complaint facilities/equipment in the country is coming on the back of such efforts from AERB.

AERB is therefore advising all those operating medical diagnostic X-ray facilities to obtain Licence / Registration through e-LORA in order to avoid regulatory actions against their facilities.

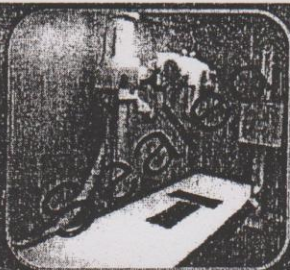
AERB also advises the public not to patronize the X-ray facilities which are not having valid Licence / Registration issued by AERB.

  
24/9/2015  
(S. Harikumar)



**Attention.... Owners of Medical Diagnostic X-ray Equipment**  
**Is your X-ray Equipment Licensed?**

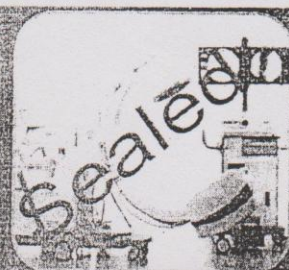
- ➔ For ensuring radiation safety of medical practitioners, operators and patients, it is necessary to obtain the Licence from **Atomic Energy Regulatory Board (AERB)** for operation of Medical Diagnostic X-ray equipment.
- ➔ Unauthorised use of Medical Diagnostic X-ray equipment without Licence of AERB is an offence under **Atomic Energy (Radiation Protection) Rules, 2004.**
- ➔ Several unauthorised Medical Diagnostic X-ray equipment have been sealed by AERB throughout the country for operating without AERB Licence.



Delhi  
Jaipur  
Raipur  
Nagpur  
Mumbai



Kolkata  
Pune  
Bengaluru  
Hyderabad  
Chennai  
etc.



**AERB Licence can be obtained online through AERB's web application eLORA (e-Licensing of Radiation Applications) System.**  
**Visit AERB website [www.aerb.gov.in](http://www.aerb.gov.in) for more information.**

**AERB advises Public to undergo prescribed medical X-ray examination on X-ray equipment duly Licensed by AERB.**



**Issued by: Atomic Energy Regulatory Board**  
Government of India  
Niyamak Bhavan, Anushaktinagar,  
Mumbai – 400094 (Maharashtra)



# WARNING !

**Atomic Energy Regulatory Board (AERB)** has taken serious note of unauthorized manufacture, supply, usage of medical diagnostic X-ray equipment by different persons/ agencies without possession of the statutory licence from AERB, under the **Atomic Energy (Radiation Protection) Rules, 2004.**

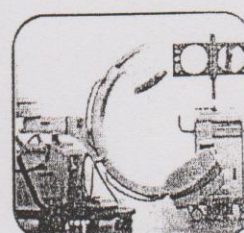
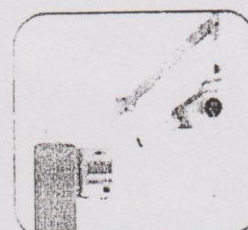
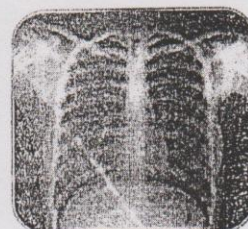
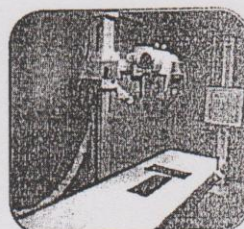
Thus

**1. Owners** of medical diagnostic X-ray equipment being operated in hospitals, nursing homes, clinics, stand-alone centers, etc

**2. Suppliers** of any model of medical diagnostic X-ray equipment to hospitals, nursing homes, clinics, stand-alone centers, etc

**3. Manufacturers** of any model of medical diagnostic X-ray equipment,

are hereby warned that not obtaining statutory AERB licence renders the violators of the above Rules liable for prosecution under the said Rules, which may include sealing of the radiation installation and imprisonment for a term extending up to 5 years or fine or both.



**AERB Licence can be obtained online through AERB's web application eLORA (e-Licensing of Radiation Applications) System.**

**Visit AERB website [www.aerb.gov.in](http://www.aerb.gov.in) and click on eLORA for more information.**



**Issued by: Atomic Energy Regulatory Board**  
(Government of India)  
Niyamak Bhavan, Anushaktinagar,  
Mumbai – 400094 (Maharashtra)



दूरभाष : 23238542, 23236740  
Telephone : 23238542, 23236740  
फैक्स : 0091-011-23231252  
E-mail ई-मेल : secretary@dcindia.org  
Website : http://www.dciindia.org



ऐवान-ए-गालिब-मार्ग  
कोटला रोड, नई दिल्ली - 110 002  
Aiwan-E-Galib Marg, Kotla  
Road, New Delhi - 110 002

# भारतीय दन्त परिषद DENTAL COUNCIL OF INDIA

(CONSTITUTED UNDER THE DENTISTS ACT 1948)  
Speed Post

No. DE-130- 2016 5976

Dated the 22 August, 2016

To

- ✓ The Secretary's of all State Governments
- The Directors (Medical Education) of all the State Governments
- The Registrar of all the State Dental Councils/Tribunals

**Sub : Regarding compliance of Dental X-ray facilities with regulatory requirements stipulated in the Atomic Energy (Radiation Protection) Rules 2004**

Sir,

In view of the decision of the Executive Committee of the DCI in its meeting held on 12.08.2016 at New Delhi, I am directed to forward herewith a copy of letter No.AERB/RSD/DRG/Adv-Letter/2016/2700 dated 01.08.2016 received from Dr. A.U. Sonawane, with a request to operate dental x-ray equipment in compliance with the regulatory requirements and possess valid AERB license/registration.

The above decision of the Executive Committee of the Dental Council of India is communicated to you for your information & necessary action.

Yours faithfully,

Encls: As above

(Dr. Sabyasachi Saha)  
Secretary  
Dental Council of India

Copy for information to:-

Dr. A.U. Sonawane, Atomic Energy Regulatory Board, Govt of India, Niyamak Bhavan, Anushaktinagar, Mumbai-400094.

Diary No. PDCI 3163  
Dated. 11/9/16.

CC:-

- The President, Dental Council of India, New Delhi
- DE-55-2016(EC-12/08/2016) 9(3)/Misc II.

(Dr. Sabyasachi Saha)  
Secretary  
Dental Council of India

1002-11/11/16



