



अध्यक्ष
Chairman

भारत सरकार
परमाणु ऊर्जा नियामक परिषद्



GOVERNMENT OF INDIA
ATOMIC ENERGY REGULATORY BOARD

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LICENSE FOR COMMERCIAL PRODUCTION OF MEDICAL DIAGNOSTIC X-RAY EQUIPMENT

In exercise of the powers conferred under section 16 of the Atomic Energy Act, 1962 read in conjunction with Rule-3 of the Atomic Energy (Radiation Protection) Rules, 2004; Atomic Energy Regulatory Board (AERB) hereby grants the licence in favour of **Mr. SANTASIL BAGCHI, X TECH MEDICAL SYSTEMS PRIVATE LIMITED, Kolkata** hereinafter referred to as the Licensee, for commercial production of medical diagnostic x-ray equipment.

The **DIRECTOR, X TECH MEDICAL SYSTEMS PRIVATE LIMITED** and **Mr. SANTASIL BAGCHI** are hereby identified as the employer and licensee respectively, for the purpose of assigning the responsibilities specified in the Atomic Energy (Radiation Protection) Rules, 2004.

The Employer and Licensee are responsible for,

- I. Ensuring compliance with the relevant provisions of the
 - i. Atomic Energy Act, 1962
 - ii. Atomic Energy (Radiation Protection) Rules, 2004;
 - iii. AERB Safety Code (AERB/SC/Med-2), 2001, Amendment 2012, and the revisions thereof
 - iv. All applicable Safety Codes, Guides issued by AERB for the above practice and regulatory documents issued by AERB from time to time.
 - v. Directives issued by Competent Authority from time to time.
- II. Ensuring compliance with terms and conditions stated overleaf.

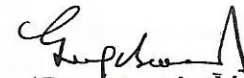
Note:

This Licence is issued ONLY from the RADIATION SAFETY VIEW POINT. All other clearances shall be obtained from concerned state/central/local authorities as applicable.

A copy of this Licence shall be displayed in a prominent location in the Company premises.

MR. SANTASIL BAGCHI
X TECH MEDICAL SYSTEMS PRIVATE LIMITED
P 434 PARNASREEPALLY, BEHALA
KOLKATA, WEST BENGAL-700060

Copy to: DIRECTOR, X TECH MEDICAL SYSTEMS PRIVATE LIMITED, KOLKATA


(Competent Authority)

गुंदूर नागेश्वर राव / G. NAGESWARA RAO
अध्यक्ष / Chairman
परमाणु ऊर्जा नियामक परिषद्
Atomic Energy Regulatory Board



परमाणु ऊर्जा नियामक परिषद्, नियामक भवन, अनुशक्तिनगर, मुंबई 400094 (महाराष्ट्र)
Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai 400094 (Maharashtra)

TERMS AND CONDITIONS

1. No activity shall be carried out by your institute for purposes other than those specified in this Licence.
2. The radiation testing of the x-ray equipment shall be carried out in the location as per approved layout.
3. The regulatory **responsibilities of the employer, licensee and RSO** as laid down in the Atomic Energy (Radiation Protection) Rules, 2004 or the latest revision of AERB Safety Code (AERB/SC/Med-2) shall be adhered to.
4. Availability of qualified and trained personnel and personnel monitoring service to radiation workers shall be ensured all the time.
5. All models of x-ray tube and x-ray tube insert to be imported/indigenously manufactured shall be registered with AERB through eLORA.
6. For import/procurement of x-ray tube(s)/x-ray tube inserts, the manufacturer shall obtain NOC for import/permission for procurement from the competent authority.
7. Prior to commercial production of every model of x-ray equipment the manufacturer shall obtain Type Approval from the competent authority, on demonstration of performance of the prototype of x-ray equipment.
8. Shall abide by the Quality Control procedure in manufacturing and ensure quality of the type approved model/s is maintained.
9. Manufacturer shall ensure that before supply, their supplier(s) (if any) obtain AERB Authorization.
10. The **periodic safety status report** in the prescribed format and frequency shall be submitted to AERB.
11. In case there is change in information specified in this licence after its issuance, such as change of Employer, Licensee, name of institution it shall be ensured by licensee that the necessary **amendment** to this effect to the licence is obtained from the Competent Authority.
12. The Licence shall be renewed before expiry.
13. Facilities shall be accorded to any authorized inspector of the competent authority to inspect the facility at any time. Records on manufacturing/supply/Quality Assurance Tests /Type Approvals shall be made available.
14. If part or complete activity of manufacturing is outsourced by the OEM, to any agency, it shall be the responsibility of the OEM to ensure that all the quality protocols in the manufacturing are duly complied with. The outsourced agency shall also be subjected to inspection by the regulatory body as applicable to OEM.
15. Any incident involving radiation exposure to person shall be intimated to AERB immediately.
16. For closure of manufacturing facility, the licensee shall obtain the requisite consent for decommissioning of the facility. All authorized suppliers shall be intimated in advance prior to actual decommissioning.
17. This license may be suspended, modified or withdrawn as specified in the Atomic Energy (Radiation Protection) Rules, 2004, in the event of contravention of the provisions of the above Act / Rules / Codes or terms and conditions of the Licence. Where deemed appropriate, AERB may also initiate penal action against the Employer/licensee in such an event.