भारत सरकार
परमाणु ऊर्जा नियामक परिषद्
विकिरण संरक्षा प्रभाग

सत्यमेव जयते

GOVERNMENT OF INDIA
ATOMIC ENERGY REGULATORY BOARD
RADIOLOGICAL SAFETY DIVISION

Case File Number: TN-20126-SA-XRE-001 **Issuance Date:** 20/01/2021

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APPROVAL OF SERVICE AGENCIES FOR 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, the Atomic Energy Regulatory Board (AERB) hereby grants the **Approval** in favor of **MR. BABY GEORGE, AVANTTECMEDICAL SYSTEMS PVT LTD, Chennai** hereinafter referred to as the Licensee, for providing the services as given in Table 1 of Annexure-1. This Approval is applicable for Type of x-ray equipment as specified in Table 2 of Annexure-1.

DIRECTOR, AVANTTECMEDICAL SYSTEMS PVT LTD Chennai and **MR. BABY GEORGE** 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,

1. 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.
2. Ensuring compliance with terms and conditions stated overleaf.

Note:

This Approval 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 Approval shall be displayed in a prominent location in the Company premises.

Dr. P. K. Dash Sharma
Head, RSD

MR. BABY GEORGE
AVANTTECMEDICAL SYSTEMS PVT LTD
NO76, 7TH STREET PORUR GARDENS PHASE1 CHENNAI, TAMIL NADU-600095

Copy to: DIRECTOR, AVANTTECMEDICAL SYSTEMS PVT LTD, CHENNAI

TERMS AND CONDITIONS

1. No activity shall be carried out by your institute for purposes other than those specified in this Approval.
2. 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.
3. The spare parts used shall be those of OEM or equivalent.
4. All models of x-ray tube and x-ray tube inserts to be imported shall be registered with AERB through eLORA
5. For procurement/import of x-ray tube(s), the service agency shall obtain procurement permission from the competent authority
6. Availability of qualified and trained personnel and Personnel Monitoring Services to Radiation Workers shall be ensured all the time.
7. The Annexure-I will require amendment whenever there is any change in the details provided.
8. In case there is change in information specified in this Approval 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 Approval is obtained from the Competent Authority.
9. The inventory report in the prescribed format and frequency shall be submitted to AERB.
10. The Approval shall be renewed before expiry.
11. Full facilities shall be accorded to any authorised inspector of the competent authority to inspect the facility at any time. Records on supply/installation/servicing/QA shall be made available
12. Any incident involving radiation exposure to person shall be intimated to AERB immediately.
13. Service agency shall have Approval from OEM for providing the services to x-ray equipment manufactured by them.
14. This Approval 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 Approval. Where deemed appropriate, AERB may also initiate penal action against the Employer/licensee in such an event.
15. X-ray equipment shall be supplied only to authorized end-user(s) possessing the requisite procurement permission from AERB and shall be installed at the approved premises.

Additional Terms and Conditions for suppliers of pre-owned medical diagnostic x-ray equipment

1. The supplier shall re-sell to the customer only AERB Type approved models and

a) Every equipment re-sold, shall be labeled as PRE-OWNED before installation.

b) on installation of the equipment, shall carry out acceptance testing/quality assurance as part of commissioning of x-ray equipment;

c) shall ensure that the customer has the requisite radiation protection devices as applicable. In case of computed tomography equipment, the supplier shall provide the required phantoms for image quality checks

d) shall check for layout and shielding adequacy at the utility site before installation of x-ray equipment.

e) shall submit after every installation, an installation report to the regulatory body in the specified format.

f) shall submit confirmation of decommissioning to regulatory body, in case of decommissioning of the x-ray equipment.

g) In case of imported pre-owned equipment, the Service Agency should provide the relevant certificate from country of origin to utilities.

h) provide Technical catalogues, service, QA and Design manuals of the equipment.

i) undertaking that the equipment will be under warranty

j) provide exposure protocols for patient examinations

k) provide operational training to operator(s)

2. In case equipment does not perform in compliance with specifications, equipment will be taken back by the supplier.
3. AERB Approval will be valid for that duration for which OEM authorisation exists.

Quality Assurance Service Provider, shall

1. Present the copy of the AERB certificate to utility on demand
2. Ensure availability of QA equipment with valid calibration certificate while providing the services.
3. Maintain all records of utilities to which the services were provided, in the format as specified by regulatory body for specified period.