भारत सरकार परमाणु ऊर्जा नियामक परिषद् विकिरण संरक्षा प्रभाग



GOVERNMENT OF INDIA ATOMIC ENERGY REGULATORY BOARD RADIOLOGICAL SAFETY DIVISION

Case File Number: MH-21482-INST

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AUTHORISATION FOR SUPPLY OF RADIATION EQUIPMENT/SOURCE

This has reference to your application no. 23-1047051 dated 23/01/2023 . In exercise of the powers conferred under Section 16 and 17 as applicable of 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 **consent** in favour of **MR. ADVAIT MAHAJAN, MAHA XRAY EQUIPMENTS PVT. LTD., PUNE** hereinafter referred to as the Licensee, for supply of radiation equipment/source.

The **DIRECTOR, MAHA XRAY EQUIPMENTS PVT. LTD. and MR. ADVAIT MAHAJAN** 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. All applicable Safety Codes, Guides and Regulatory documents issued by AERB from time to time.
 - iv. Directives issued by Competent Authority from time to time.
- 2. Ensuring compliance with terms and conditions stated in Annexure-I and/or Annexure-II as applicable.

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.

This approval may be suspended, modified or withdrawn as specified in the Atomic Energy (Radiation Protection) Rules, 2004, in the event of contravention of the provisions of the above Act / Rules / Codes or terms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. A copy of this approval shall be displayed in a prominent location in the Company premises.

Issuing Authority

Shri R. K. Singh Head, IAS

MR. ADVAIT MAHAJAN MAHA XRAY EQUIPMENTS PVT. LTD. SHED NO. A-43, ANANT INDUSTRIAL ESTATE, PHASE - I, NARHE DHAYARI ROAD NEAR ASIAN JUNIOUR COLLEGE PUNE-411041, MAHARASHTRA

Note: This document is also available at <u>www.aerb.gov.in/elora</u>



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

दूरभाष/Tel: 91-22-2599 0656

ANNEXURE-I

- 1. AERB approval will be valid for that duration and those models for which OEM authorisation exists.
- 2. Availability of qualified and trained personnel and as per the requirements personnel monitoring service to radiation workers shall be ensured all the time.
- 3. The supplier shall supply to the customer only AERB Type approved models.
- 4. On installation of the equipment, supplier shall carry out acceptance testing/quality assurance as part of commissioning.
- 5. Supplier shall submit after every installation, an installation report to the regulatory body in the specified format.
- 6. The supplier shall obtain a NOC/Type Approval Certificate from the competent authority prior to marketing the equipment/source.
- 7. In case there is change in information specified in this Authorisation 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 Authorization is obtained from the Competent Authority.
- 8. The inventory report in the prescribed format and frequency shall be submitted to AERB.
- 9. The Authorization shall be renewed well in advance before its expiry.
- 10. Full facilities shall be accorded to any authorised inspector of the competent authority to inspect the facility at any time. Records on supply/installation /Type Approvals shall be made available.
- 11. The employer shall inform the Competent Authority within twenty four hours, if any accident involving sources or loss of source of which he is the custodian. In case of supplier of industrial radiography sources,
 - a) The supplier shall, ensure the availability of certified personnel such as radiological safety officer (RSO) and operators for the source replacement operation.
 - b) The sources shall be supplied to only authorized radiography agencies who have procured AERB type approved radiography devices.
 - c) The supplier shall be solely responsible for arranging return of decayed radiography sources for disposal to the original source supplier with prior permission of AERB. Further, in case original supplier does not accept the sources for disposal, supplier shall be responsible for an alternate proposal for disposal of decayed sources with prior approval of AERB.
 - d) The supplier shall maintain the detailed inventory of radiography sources supplied to radiography agencies, unloaded decayed sources for disposal and disposed radiography sources.
 - e) The supplier shall provide measures for ensuring safety & security of fresh and decayed radiography sources available at their own site at all the time.

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ANNEXURE-II

(Applicable for Nuclear Medicine Source Supplier)

- 1. Your institution is hereby permitted to receive imported radioactive material/radiopharmaceuticals and forward the same only in the original packing condition to the institutions licensed by AERB to import and use radiopharmaceuticals.
- 2. The users of radiopharmaceuticals licensed by AERB may authorize your institution to receive the radiopharmaceuticals on their behalf and forward the same to their destination of use.
- 3. All the relevant rules and national/international regulations applicable to the transport of the radioactive materials in India shall be duly fulfilled by your institution.
- 4. The import of radioactive materials /radiopharmaceuticals shall be done only against the valid NOCs issued by AERB to end users.
- 5. The individual consignments shall be transported in a separate vehicle under exclusive use, as stipulated in the AERB Safety Code on Safe Transport of Radioactive Material and directly delivered to the respective users without opening the package and without any delay.
- 6. If the user is located in another city, then without any transit storage of the radioactive material/radiopharmaceuticals, the consignment shall be forwarded as radioactive cargo by the next available domestic flight to the respective destination.
- 7. The total time taken from the date of dispatch by the overseas supplier to the date of delivery to the end user shall not exceed three days.
- 8. Personnel of your institute involved in handling the packages containing radioactive material/radiopharmaceuticals should have an appropriate awareness in radiation safety.
- 9. Any untoward incident such as damage of package and spillage of radioactive material while handling the radioactive consignments shall be immediately reported to this Division.
- 10. Your institute shall forward a quarterly report to AERB on the radioactive materials imported and the names and full addresses of the persons to whom they are delivered, with full details of the institution number, radioactive materials, activity, and date of supply and reference no. of NOC issued by AERB.

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