

Regulatory Requirements for Local Supplier in Radiotherapy

1. Register institute in eLORA

New local supplier is required to register its institute in AERB's web-based application eLORA system (Please visit AERB website www.aerb.gov.in to access eLORA system). The guidelines for institute registration are available on eLORA home page.

2. Supplier Authorisation

New local supplier is required to obtain 'Supplier Authorisation' from AERB. For obtaining supplier authorisation, supplier is required to:

- i. Provide OEM (Original Equipment Manufacturer) authorisation letter stating that supplier is authorised for sell and provide maintenance services to OEM's equipment in India.
- ii. Provide details of trained service engineer (also trained from OEM of the equipment). The trained service engineer must be registered in eLORA as Radiation Professional (RP) and declared as staff of the institute. For RP registration eligibility, please see RP registration guidelines available on eLORA home page.
- iii. Provide details of radiation measuring, monitoring and QA tools. Radiation measuring, monitoring and QA tools must be declared in eLORA.

3. NOC for import/supply of radiotherapy equipment

No radiotherapy unit is allowed to be sold in the country without a valid certificate from AERB. When a new model is to be imported to the country or supplied (for locally manufactured) for the first time, AERB issues NOC to the local supplier to import/supply unit based on the evaluation of specifications of the unit, the documents related to the design standards the unit meet and approval from the competent authorities of other countries.

4. Type Approval

Once the first unit is imported/supplied and installed, local supplier needs to submit application to AERB for Type Approval. AERB representatives witness the performance of the unit and check whether the unit meets the required standards. Based on the physical evaluation of the unit, the Type Approval certificate is issued to the local supplier to sell the same type of unit with certain terms and conditions.

It may be noted that, Licence to operate NOC equipment is not issued till local supplier obtains Type Approval for the equipment.

5. Supply Status Report

Local supplier is required to submit periodic supply status report to AERB through eLORA system.

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