Regulatory Requirements for Local Supplier in Radiotherapy

1. Introduction
No supplier is allowed to supply any radiotherapy equipment/source in the country without having valid authorization from Atomic Energy Regulatory Board (AERB). Foreign supplier of the radiotherapy equipment needs to identify local supplier in India in order to supply their products. In order to supply the radiotherapy equipment/source, following process needs to be followed:

2. Register institute in eLORA
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.

3. 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 authorized to supply and provide maintenance services to OEM’s equipment in India.
   ii. Provision for availability of trained service engineer(s) in radiation safety conducted by AERB recognized agency and 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 & Safety tools which must be declared in eLORA.
   iv. Provision for personnel monitoring services for the service engineer(s) who will be involved in installation/servicing/maintenance/decommissioning of the equipment.

4. NOC for import/supply of radiotherapy equipment
No radiotherapy equipment is allowed to be supplied in the country without a valid ‘No Objection Certificate (NOC)/Type Approval’ from AERB. When a new model is intended to be supplied by the local supplier in the country for the first time, AERB issues NOC to the local supplier for its supply based on the radiation safety review with respect to evaluation of technical specifications of the equipment, the documents related to the design standards and approval from the competent authorities of country of origin (if available).

5. 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 equipment and evaluate whether the unit meets the required standards and other requirements as stipulated by AERB. Based on
the physical evaluation of the equipment, the Type Approval certificate is issued to the local supplier for its supply with certain terms and conditions.

6. Supply Status Report
Local supplier is required to submit periodic report on supply status to AERB through eLORA system.