

## **Regulatory requirements for suppliers of radioactive material to nuclear medicine centres in India**

1. Institute registration in eLORA as supplier of Nuclear Medicine (NM)

Please refer to the guidelines for Institute Registration available on eLORA portal.

2. Obtaining Authorisation as Supplier

Following details are to be furnished alongwith application being submitted through eLORA:

- a) Letter from the principles declaring the applicant as authorised supplier of their products used for nuclear medicine such as Mo-Tc generator and other radioisotopes in India.
- b) Certificate, from the country of origin, regarding the approval of transport package for the generator and other radioisotopes.
- c) Details of the generator including the shielding provided. (Please provide a copy of the information brochure)
- d) Range(s) of activity to be imported and whether the activity mentioned on the package corresponds to activity on date of dispatch or as on date of delivery to the customer.
- e) Provisions made to export the spent generators to the original supplier after their useful life.

3. Source Type Registration through eLORA: Addition of source(s) to be supplied

4. Supply of radiopharmaceutical to authorised NM facilities shall be done only on intimation received by the supplier from the NM facility through the Source Procurement Intimation (SPI) functionality available in eLORA and shall be within the authorised quantity.