FLOW DIAGRAM OF REGULATORY PROCESS OF MEDICAL CYCLOTRON

AUTHORISATION AS A SUPPLIER FOR MEDICAL CYCLOTRON

(Prerequisite: Institute Registration in e-LORA under practice " Medical Cyclotron Facility" and Institute Role : Supplier- Medical Cyclotron, Trained and certified personnel in operation, servicing and maintenance of Medical Cyclotron equipment & radiation safety), Radiation Protection Instrument, Authorization /MoU/Declaration from the original equipment manufacturer(OEM) for Indian representative to import, supply, marketing, sale and servicing & maintenance.

Ref. documents AERB/RF-RS/SG-3 & AERB/RF/SG/G-3)

↓

NO OBJECTION CERTIFICATE (NOC) TO IMPORT MEDICAL CYCLOTRON IN INDIA

(Application Form), Design certification from Competent Authority of country of origin with respect to radiological safety, IEC certification, Undertaking for servicing and maintenance of the equipment till its useful life., Factory acceptance Test report, Design specification of **Medical Cyclotron** etc.

↓

TYPE APPROVAL OF MEDICAL CYCLOTRON

(Conversion of NOC to TA)

(Application Form), Installation Report, QA Report, Acceptance Test Report, customer operational feedback etc.

(Type approval testing may be carried out in presence of officers / representative from AERB)

REMARK:

For more detail please refer AERB Safety Guides No. AERB/SG/IS-5, AERB/RF-RS/SG-3 and AERB/RF/SG/G-3). Please apply through e-LORA for all the above stages.

REGULATORY REQUIREMENTS FOR LOCAL SUPPLIER IN MEDICAL CYCLOTRON

1. Register institute in e-LORA

New local supplier is required to register its institute in AERB's web -based application e-LORA system (Please visit AERB website www.aerb.gov.in to access e-LORA system). The guidelines for institute registration are available on e-LORA 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 man power (also trained from OEM of the equipment). The trained man power must be registered in e-LORA and declared as staff of the institute. For RP registration eligibility, please see RP registration guidelines available on e-LORA home page.

iii. Provide details of radiation measuring, monitoring and QA tools. Radiation measuring, monitoring and QA tools must be declared in e-LORA.

3. **NOC for import/supply of Medical Cyclotron.**

No Medical Cyclotron 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 for the first time, the local supplier needs to obtain NOC to import from AERB. The NOC is issued on the evaluation of specifications of the unit, the documents related to the design standards of the unit and approval from the competent authorities of other countries. The unit should be supplied to authorised user only. The user also has to obtain procurement permission for the same.

4. **Type Approval**

Once the first unit is imported/supplied and installed, local supplier needs to submit application to AERB for Type Approval (conversion of NOC to TA). For indigenously manufactured equipment supplier has to apply for type approval prior to its supply to end user. AERB representatives shall 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 supply the unit with terms and conditions. The user also has to obtain the procurement permission for the same.

5. **Supply Status Report**

Local supplier is required to submit periodic supply status report to AERB through e-LORA system.

=O=O=O=O=O=