

## **GUIDELINES TO START MEDICAL CYCLOTRON FACILITY**

A new era of Nuclear Medicine diagnosis has started with Medical Cyclotron technology. Medical Cyclotron produces mainly positron emitters, which can be used in molecular imaging of the organs. In Medical Cyclotron, particles such as protons, deuterons are accelerated and made to bombard to a suitable target material to produce positron-emitting radioisotopes. The positron emitters are produced by the (p, $\alpha$ ), (p, n) or (d, n) reaction. The neutron activation of the surrounding medium draws the major attention in radiation safety. The medical cyclotrons are mainly classified as self-shielded or non self-shielded one. The self-shielded medical cyclotrons are incorporated with heavy shielding around the cyclotron. Additional structural shielding needs to be provided for non self-shielded medical cyclotron to reduce the radiation levels to within safe limits.

A chemical synthesis module is necessary to prepare radiopharmaceutical from the positron emitting radioisotopes produced in medical cyclotron. The accelerated particles may lead to activation of materials around the target and leave residual radioactivity. Although, the radioactive isotopes produced due to neutron activation are generally of short half-lives, their accumulated activity should be considered while handling the shielding materials, particularly the components near to the target that are likely to get activated to significant levels.

The supplier has to apply separately to regulatory body for No Objection Certificate / Type Approval for the medical cyclotron. Based on the technical information and the test report and certification from the country of its origin, the regulatory body grants the NOC / Type Approval for the medical cyclotron. The copy of it should be included in the Preliminary Safety Analysis Report (PSAR).

The various stages of clearances needed from Atomic Energy Regulatory Board (AERB) are as follows

- 1. Site Assessment and Approval**
- 2. Design and Construction Approval**
- 3. Commissioning**
- 4. Decommissioning**

### **1. Site Assessment and Approval**

The medical cyclotrons are located either in the hospital premises or in the industrial area. The first stage of process is assessing the suitability of the site is in accordance with the seismic condition, history of earthquakes in the region, proximity to a capable fault, flooding potential, ground water level, and soil composition height from the sea level, geo-hydrology, approach road, and on the type of occupancy. It should be ensured that there should be no residential or public premises within a radius of 30 m from the site. The geological and soil characteristics are important from the point of view of induced soil activity and supporting heavy structures. Further, presence of any

ammunition dumps, and storage of inflammable and toxic substances in the vicinity are also considered. The regulatory body ensures the above-mentioned detail by conducting the site visit.

Basement of the premises maybe an ideal site for installation of cyclotron as the earth provides natural and effective shielding. Alternatively, medical cyclotron may be installed in ground level as well. The application for consent for site approval for location of Medical cyclotron facility is given in ([AERB/RSD/MCY/SA](#)).

## **2. Design and Construction Approval**

The medical cyclotron shall be housed in a room with adequate shielding. Radiation areas and electrical high voltage areas need adequate isolation and access control. The design should incorporate safe cable routing, segregation of power and signal cables and provision of barriers to prevent fire. Fire-propagating material should not be in the vicinity of electrical joints. The design of the medical cyclotron and its associated facilities has to be approved by the Regulatory Body prior to its Preliminary Safety Analysis Report (PSAR) submission. The application for consent for layout and construction approval for medical cyclotron facility is given in ([AERB/RSD/MCY/LCA](#)). The safety analysis report PSAR for a medical cyclotron facility should contain the details as given in [AERB/RSD/MCY/PSAR](#).

The authorisation for construction is granted after reviewing of the PSAR of the installation. The Regulatory Body may inspect the facility while under construction to verify whether the construction is as per approved design or not. The licensee is required to submit reports on Quality Assurance (QA) during construction and installation to the Regulatory Body. Installation of equipment and preliminary tests on various systems are to be carried out in a phased manner as per the checkpoints.

## **3. Commissioning**

For granting license for commissioning, the regulatory body evaluates the system performance and the shielding adequacy of the installation. Prior to seeking permission, the applicant should have

- (i) Qualified and trained manpower – operator(s), radio pharmacist(s) and RSO Level-III,
- (ii) Personnel monitoring services for all radiation workers;
- (iii) Radiation Protection Survey Meters (gamma, survey meters, neutron monitors, contamination monitors, zone monitor, teletector etc.)
- (iv) Safe handling tools and devices.

**3 a.** Trial operations are authorised / permitted to evaluate the system performance and radiation level measurement during pre-commissioning inspection by the AERB.

**3 b.** The final safety analysis report (FSAR) incorporating the results of commissioning, and QA reports are prepared by the applicant and submitted to the AERB

for obtaining the permission for routine operation as per the application for licence for commissioning and operation of medical cyclotron facility format given in ([AERB/RSD/MCY/LCO](#)). The safety analysis report FSAR for a medical cyclotron facility should contain the details as given in [AERB/RSD/MCY/FSAR](#).

The Licence is granted to the applicant to possess and safely operate the unit with a validity period after review and approval of FSAR. Renewal of licence would be done only after submitting the application given in ([AERB/RSD/MCY/LCO](#)).

The Licencee is required to submit periodic reports on safety status of installation. Unusual incidences should be promptly reported within 24 hours followed by a detailed report to the AERB.

The Licencee shall arrange to constitute a Local Safety Committee (LSC) with the Head of the Institution as Chairman and the RSO as one of the Member of the committee to review the safety status of the facility. This committee may also include service engineer as a member. The minutes of the meetings and action taken reports shall be available during inspection by the AERB.

#### **4. Decommissioning**

When the medical cyclotron is no longer to be used, the permission for decommissioning should be obtained from AERB. The induced radioactivity in the cyclotron components and the structures have to be considered for disposal as a radioactive waste or if the component of medical cyclotron are found to be free from induced radioactivity, the same components may be permitted to be dismantle and can be treated as general waste. The licensee is required to submit a report on completion of decommissioning, safe disposal of sources and personnel doses received during decommissioning operations to the regulatory body (AERB).