

Regulatory Requirements and Guidelines for Medical Cyclotron Facility

1. Introduction

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,α) , (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.

To establish a Medical Cyclotron facility, the user institute must go through the Regulatory requirements as mentioned in the Atomic Energy (Radiation Protection) Rules, 2004 and AERB Safety Guide on Medical Cyclotron facilities and shall obtain requisite regulatory consent from AERB as per AERB Safety Guide for Consenting process for Radiation Facilities (AERB/SG/G-3). No regulatory clearance is issued for establishing the medical cyclotron facility by AERB, unless the user complies with the regulatory requirements, specified in these documents.

The requirements and guidelines listed below includes procedures for obtaining Licence for operation, device procurement, decommissioning of medical cyclotron unit, disposal of radioactive waste and submission of safety status report etc.

For obtaining requisite regulatory clearance, user need to submit relevant application through AERB's e-Governance application - eLORA (e-Licensing of Radiation Applications) System. To access eLORA system, visit AERB website www.aerb.gov.in and click on 'eLORA'.

Please refer 'User Manual for Medical Cyclotron Facilities' available in 'Help' menu of eLORA for detailed information on forms to be used for obtaining requisite regulatory clearance from AERB through eLORA system.

2. Registration of Institute in eLORA

In order to submit application form for obtaining requisites regulatory clearances from AERB, the Employer of institute shall register his/ her institute in eLORA. The application form for Institute Registration is available on eLORA home page. After institute registration, user account of the Employer is created in eLORA. The guidelines to submit application form for 'Institute Registration' are available on eLORA home page.

3. Various stages of clearances needed for medical cyclotron facility from Atomic Energy Regulatory Board (AERB) are as follows:

- 3.1 Site Assessment and Approval
- 3.2 Design and Construction Approval
- 3.3 Equipment procurement and equipment receipt intimation

3.4 Appointment of RSO and staff, procurement of Personnel Monitoring Badges, monitoring instruments.

3.5 Pre-Commissioning & Trial run permission

3.6 Licence and Renewal of licence

3.7 Decommissioning

All relevant application forms for various clearances for Medical Cyclotron Facility are available for download in eLORA. Refer “Guidelines for Medical Cyclotron Facility” available in ‘Help’ menu of eLORA for step-by-step instructions for submission of various application forms.

Application Details	
Application for Site Approval	Download
Application for Layout Approval	Download
Application for Design and Construction Approval	Download
Application for Equipment Procurement	Download
Permission for Trial Run Operation	Download
Modification in Design of Radiation Facility	Download
Resumption of Routine Operation	Download
Procurement of Check Source	Download

3.1. Site Assessment and Approval

The Medical Cyclotron Facility (MCF) should be located and installed either in a hospital or in industrial premises. It should be ensured that there should be no residential or public premises within a radius of 30 m from the site. The applicant is required to provide to the regulatory body the following site specific information:

- a. Seismic zone as per IS-1893-1 (current version), ‘Criteria for Earthquake Resistant Design of Structures’ (Documentary evidence from relevant state/central govt. authority)
- b. Maximum level of ground water and maximum flood level for past ten years as per the concerned central/state govt. records, along with documentary evidence.
- c. Distance of site of installation of MCF from public and nearby residential localities, if any.
- d. Documentary evidence from accredited geotechnical investigation agency that the soil and ground characteristics (e.g. soil profile, stratum, foundation type, soil and rock, elemental analysis of sub soil and ground water) will not cause deterioration in the strength and integrity of structure of irradiation cell.
- e. Provision of suitable roads to approach the proposed site.
- f. Details of any existing or planned auxiliary facilities such as ammunition dumps, and storage of inflammable and toxic substances within a radius of about 30 m from the proposed cyclotron vault of the MCF.

The applicant should take into account all above site-specific parameters and ensure that the design of the MCF adequately addresses safety of the systems, structures and components. The regulatory body will inspect the site for necessary approval.

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 form for consent for site approval for location of Medical cyclotron facility is given in eLORA.

3.2. 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 or any hazardous material should not be in the vicinity of electrical joints.

For obtaining Layout, design and construction approval, the applicant is required to submit application along with layout plan of the facility and Preliminary Safety Assessment Report (PSAR) in the specified format.

The major components of the PSAR are:

- a. Organizational setup
- b. Detailed system parameters of cyclotron, synthesis and dispensing units.
- c. Design safety features of cyclotron, synthesis and dispensing units
- d. Zoning and Ventilation
- e. Auxiliary facilities
- f. Identification of hazards and its evaluation
- g. Emergency response planning and procedures
- h. Quality Assurance (QA) Manual for construction
- i. Physical security measures
- j. Decommissioning manual
- k. Shielding evaluation calculations

The approval for layout, design and construction may be granted after multi-tier review of the PSAR submitted for the installation of the MCF. The regulatory body may inspect the facility while under construction to ensure that the construction is as per the approved design and in accordance with QA Manual.

The application for consent for Design and construction approval for medical cyclotron facility is given in eLORA.

For any modification to the approved design, approval has to be obtained from AERB by submitting relevant application form along with justification.

3.3. Equipment procurement and equipment receipt intimation

Equipment procurement

The user has to apply separately to regulatory body for 'No Objection Certificate' (NOC) for procurement of the medical cyclotron equipment. Based on the technical information and the test report and certification from the country of its origin, the regulatory body grants the NOC to the applicant for procurement of the medical cyclotron.

Equipment Receipt Intimation

Provide intimation of receipt of the equipment within 15 days of its receipt. Install the medical cyclotron equipment as per the approved plan and carryout the mechanical and electrical tests thoroughly prior to switching on the Radiation beam.

3.4 Appointment of RSO and staff, procurement of Personnel Monitoring Badges, monitoring instruments.

Appointment of Staff

Personnel requirements and their qualification:

A MCF should be operated with adequate number of Cyclotron Operator(s), Radio chemist(s) and an RSO. Table below gives the minimum qualification for the required personnel. All personnel should undergo a specialized on-the-job supervised training to be certified by the manufacturer/supplier of the cyclotron or by an AERB recognized facility for the operation of the facility.

Table : Educational Qualification of Personnel working in a MCF

Staff	Minimum Educational Qualification
Cyclotron Operator	DMRIT/M. Sc. (Nuclear Medicine)/DNMT/BNMT/ Diploma in Engineering (Electrical /Mechanical/Instrumentation/Bio-medical) / B.Sc. (Physics)
Radio chemist	B. Sc. (Chemistry)/B. Pharm.
Radiological Safety Officer	Dip. R.P/M.Sc. (Medical Physics) or Equivalent

Nomination and Approval of Radiological Safety Officer

The person to be nominated as RSO should be registered as 'Radiation Professional' (RP) in eLORA. Obtain RP registration id and date of birth of appointed staff for declaring them in your institute's eLORA account.

Nominate the eligible "Radiation professional" to work as Radiological Safety Officer (RSO) in your institution by submitting application form in eLORA. It is essential to obtain RSO approval for obtaining licence.

Procurement of Personnel Monitors Badges

Procure Personnel Monitoring Badges (i.e.TLD badges) from the agency accredited by AERB for all the radiation workers. Pocket dosimeters for the radiation workers may also be procured, which are meant for measuring radiation dose received by the radiation worker on the spot.

The following Accredited Laboratories provide TLD services in the respective states as mentioned below:

Sr. No.	State	Name of Accredited Laboratory
1.	Andhra Pradesh, Telangana, Tamil Nadu, Karnataka, Kerala, Puducherry, Andaman and Nicobar and Lakshdeep (Southern Region)	Avanttec Lab. Private Limited Plot No.17, Arignar Anna Industrial Estate, Mettukuppam, Vanagaram, Chennai Pin- 600095
2.	Maharashtra, Gujarat, Rajasthan, Goa, Dadra and Nagar Haveli and Diu (Western Region)	Renentech Lab. Private Limited C-106, Synthofine Industrial Estate, Off Aarey Road, Goregaon (E), Mumbai, Maharashtra Pin- 490063
3.	All other states in the Central, Northern and North Eastern parts of the country	Ultratech Lab. Private limited Cloth Market, G.E. Road, kumhari, Bhilai, Durg, Chhattisgarh Pin- 490042
4.	All Defense institutions of country	Defense Laboratory, Jodhpur

Monitoring Instruments

Procure appropriate monitoring instruments for area monitoring (Survey Meters, Contamination Monitors, Gamma Zone Monitors, Tele-tectors etc.) and QA instruments.

The requisite instruments must be declared in eLORA system and its calibration details must be updated as and when instruments are being calibrated.

Area Monitoring:

- a. Installed gamma and neutron radiation area monitoring devices with audio-visual alarm should be provided in all areas that can have continuous occupancy and where radiation levels are likely to rise above the permissible levels.
- b. The output of all the fixed radiation monitors should be easily legible and measurement data from all locations should be displayed at a centralized control center in the facility preferably control room for the cyclotron.
- c. The area monitors should have appropriate preset alarm conditions depending on the location of installation of the same.
- d. Low and high range gamma radiation survey instruments, neutron survey meters should be available for measurement of ambient radiation fields.
- e. The radiation monitoring and measuring instruments should undergo periodic calibration and performance checks.
- f. A portable air sampler may also be made available at the facility to collect and measure air samples.

Contamination Monitoring:

- a. Hand and Foot monitors at appropriate location interfacing the R & R room to other areas of the MCF should be provided to detect the presence of any radioactivity contamination on the skin, body, personnel protective clothing, personal clothing and foot wear etc.
- b. In case of spillage of any radioactive material, the presence of loose/transferrable contamination on any work surface should be evaluated either by direct survey or taking a smear/swipe sample for counting.

- c. Periodic surveillance for possible contamination from activation products either in the cyclotron vault or radiochemistry laboratory or QC labs should be ensured.
- d. Provision of instruments and de-contamination facilities both for equipment and personnel should be made.
- e. Contamination, should be promptly addressed through proper decontamination procedures.

3.5. Pre-Commissioning and Trial run permission

The process of Commissioning involves, a) making the MCF functional, b) Ensuring functioning of the MCF in accordance with the approved design specifications, c) Verification of structures, systems and components including safety systems as per performance criteria.

After completion of construction and installation, the applicant should approach the regulatory body for permission to carry out trial run for commissioning.

For this purpose, the applicant should submit the following to the regulatory body:

- a) Radiation Protection Manual (RPM) as per the prescribed format
- b) Details regarding availability of qualified and trained manpower – operator(s), radio pharmacist(s)/radiochemist (s) and AERB approved Radiological Safety Officer (RSO).
- c) Personnel monitoring services for all radiation workers;
- d) Appropriate radiation measuring and monitoring Instruments
- e) Operational procedure manual
- f) Safe handling tools and devices required for operation and maintenance of the medical cyclotron and auxiliary equipments.
- g) Security Plan

Trial operations are authorised/ permitted to evaluate the system performance and radiation level measurement during pre-commissioning inspection by the AERB. After successful trial runs, the applicant becomes eligible for obtaining consent for trial operations.

3.6. Licence and Renewal of licence

Licence for regular operation

For obtaining licence for regular operation, the applicant shall submit the duly filled in application for licence along with Final Safety Analysis Report (FSAR) in the prescribed format incorporating the results of commissioning and trial run operations.

Based on the review of all safety aspects and inspection by regulatory body, licence may be granted to operate the unit subject to terms and conditions. The Licence is granted to the applicant to possess and safely operate the unit with a validity period.

The Licencee is required to submit quarterly periodic reports on safety status of installation as per the format given in AERB/RSD/MCY/QSR. Unusual incidences, if any, 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.

Application for licence for commissioning and operation of medical cyclotron facility format given in eLORA. The safety analysis report FSAR for a medical cyclotron facility should contain the details as given in eLORA.

Renewal of licence

Renewal of licence would be done only after submitting the application for renewal of licence given in eLORA.

Documents to be attached with the Application for renewal of licence:

1. Safety performance of the facility including radiological survey reports
2. Significant Event Reports
3. In- Service Inspections reports as applicable
4. Violations of technical specifications
5. Personnel exposures
6. Environmental releases etc.

3.7. Decommissioning

When the medical cyclotron is no longer to be used, the permission for decommissioning shall be obtained from the Competent Authority and decommissioning should be carried out in accordance with an approved procedure laid down by the Competent Authority. The induced radioactivity in the cyclotron components and the structures should be considered during decommissioning/disposal as a radioactive waste. The licensee shall submit a report on the completion of decommissioning, which includes, inter alia, safe disposal of sources and personnel exposures received during decommissioning.

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