

Regulatory Requirements and Guidelines for Research Accelerator Facility

1. Introduction

To establish a Research Accelerator Facility, the user institute must go through the Regulatory requirements as mentioned in the Atomic Energy (Radiation Protection) Rules, 2004 and AERB Safety Codes 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 Research Accelerator 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 research accelerator, 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'.

The screenshot displays the eLORA system interface. At the top, it features the Government of India Atomic Energy Regulatory Board logo and the text 'e-Licensing of Radiation Applications (eLORA) System'. The main content area is divided into several sections:

- Guidelines for Institute Registration**: Includes links for 'Guidelines for Radiation Professional Registration', 'Licensed Diagnostic Radiology facilities in India and Type approved Medical Diagnostic X-ray equipment', and 'Verification of Consent/Document issued through eLORA'.
- Submission of Over Exposure Investigation Report**: A button to 'Click here to submit Over Exposure Investigation Report-Applicable for Institutes not registered in eLORA'.
- Guidelines for Over Exposure Management for Unregistered Institutes and Standard Format for Attachments**: A link to 'Click here to download Guidelines for Over Exposure Management for Unregistered Institutes and Standard Format for Attachments'.
- Help to operate eLORA System**: A link to 'Click here to download Help desk email ids and Phone nos.'.
- eLORA System**: A central banner with the text: 'An e-Governance system for obtaining Regulatory Consents from AERB for following Radiation Facilities/Stakeholders: Diagnostic Radiology | Radiotherapy | Nuclear Medicine | RIA (Radio Immuno Assay) | Gamma Irradiation Chamber | Industrial Radiography | Nucleonic Gauge | Well Logging | Gamma Radiation Processing Facility | IARPF (Industrial Accelerator and Radiation Processing Facility) | Calibration Facility | Consumer Product Medical Cyclotron | Research and Sealed Source | Research Directorate of Radiation Safety/Radiation Safety Agency | Transport Package Manufacturers DAE (Department of Atomic Energy) Facilities-For Transport Approvals'.
- Login**: A form with fields for 'Username' and 'Password', a 'Login' button, and links for 'Forgot Password?' and 'Forgot Username?'.
- Registration Form**: A form with fields for 'Register Institute', 'Register Radiation Professional (RP)', and 'Register Incoming Employer - after Initiation of Employer Change Process'.
- Know Status of Registration Application**: A form with fields for 'Status of Institute Registration Application form' and 'Status of Radiation Professional Registration Application form', and a 'Show More' link.
- Disclaimer**: A button at the bottom right.

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 Research Accelerator 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 Commissioning/License for operation
- 3.6 Renewal of license
- 3.7 Decommissioning

3.1. Site Assessment and Approval

The Research Accelerator Facility (RAF) should be installed within the premises of a research institute 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 RAF 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 RAF.

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

Basement/Ground floor of the building maybe an ideal site for installation of Research Accelerator, as the earth offers higher load bearing capacity and provides natural and effective shielding.

The application form for consent for site approval for location of Research Accelerator Facility is given in eLORA.

3.2. Design and Construction Approval

The Research Accelerator 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.

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 RAF. 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 Research Accelerator 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 for procurement of the Research Accelerator device. 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 Research Accelerator.

Equipment Receipt Intimation

Provide intimation of receipt of the equipment within 15 days of its receipt. Install the Research Accelerator 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 RAF should be operated with adequate number of Operator(s), and an RSO. All personnel should undergo a specialized on-the-job supervised training to be certified by the manufacturer/supplier of the accelerator.

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 etc.).

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.

3.5. Pre-Commissioning and Trial run permission

The process of Commissioning involves, a) making the RAF functional, b) Ensuring functioning of the RAF 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), 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 Research Accelerator and auxiliary equipment.

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 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 licensee is required to submit quarterly periodic reports on safety status of installation as per the format given in eLORA. Unusual incidences should be promptly reported within 24 hours followed by a detailed report to the AERB. The licensee 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 Research Accelerator Facility format given in eLORA. The safety analysis report FSAR for a research accelerator 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 Research Accelerator Facility 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 accelerator 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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