

# Regulatory Requirements and Guidelines for new Radiotherapy Facility

## 1. Introduction

To establish a Radiotherapy facility, the user institute must go through the Regulatory requirements as mentioned in the Atomic Energy (Radiation Protection) Rules, 2004 and AERB Safety Codes [AERB/RF-SC/MED-1(Rev.1)] 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 radiotherapy 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, radioactive source procurement, decommissioning of radiotherapy unit, disposal of radioactive source and submission of safety status report.

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](http://www.aerb.gov.in) and click on 'eLORA'.

Government of India  
Atomic Energy Regulatory Board  
e-Licensing of Radiation Applications (eLORA) System

हिंदी संस्करण | AERB Website

संयोजित ज्ञान

Guidelines for Institute Registration  
Guidelines for Radiation Professional Registration  
Licensed Diagnostic Radiology facilities in India and Type approved Medical Diagnostic X-ray equipment  
Verification of Consent/Document issued through eLORA  
Feedback

**Submission of Over Exposure Investigation Report**  
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

**Help to operate eLORA System**  
Help desk email ids and Phone nos.

**eLORA**  
(e-Licensing of Radiation Applications) System

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

**eLORA System**  
eLORA (e-Licensing of Radiation Applications), an e-Governance initiative by AERB, is a web-based application for automation of regulatory processes for various Radiation Facilities in India. The objective of the project is to enhance efficiency and transparency in the regulatory processes of AERB. The system is aimed at achieving paperless licensing of Radiation Facilities. ... Show More

**Login**  
Username:   
Password:   
Login  
Forgot Password? | Forgot Username?

**Registration Form**  
Register Institute  
Register Radiation Professional (RP)  
Register Incoming Employer - after Initiation of Employer Change Process

**Know Status of Registration Application**  
Status of Institute Registration Application form  
Status of Radiation Professional Registration Application form

Disclaimer

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

Home | Switch Profile | View Profile | View All Messages | Help | Logout

Government of India  
Atomic Energy Regulatory Board  
e-Licensing of Radiation Applications (eLORA) System

संयोजित ज्ञान

Login:  
Institute:  
Role:  
Profile:

## 2. Clearance of the unit by AERB (Type Approved or NOC issued equipment)

Verify from the supplier that the unit (which is either radiation generating equipment such as Medical Accelerator / Simulator or houses sealed radioactive material such as Telecobalt /Gamma Knife / Brachytherapy unit) to be installed is either type approved by AERB or a NOC is issued by AERB to the local supplier of the unit. The copy of type approval certificate or NOC issued by AERB will be furnished by the local supplier on demand.

## 3. Type Approval/NOC

No radiotherapy 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, AERB issues NOC to the local supplier to import unit based on the evaluation of specifications of the unit, the documents related to the design standards the unit meet and approval from the competent authorities of other countries.

Once the first unit is imported and installed, local supplier needs to submit application to AERB for Type Approval. AERB representatives 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 sell the same type of unit with certain terms and conditions.

It may be noted that, Licence to operate NOC equipment is not issued till local supplier obtains Type Approval for the equipment.

## 4. Registration of Institute in eLORA

In order to submit application form for obtaining requisite 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.



## 5. Approval of Room Layout Plan of Radiotherapy Installation

Prepare room layout drawings and the site layout drawing in consultation with expert Medical Physicists, Radiation Oncologists, Architects and the Supplier of the unit. Once the planning is finalized from institute side, submit the application form for 'Site and Layout Approval' along with PDF files of the drawings as an attachment of the application form. The drawings are reviewed by AERB and approval is issued from radiation safety stand point. The application for 'Site and Layout Approval' is liable for rejection if (1) the plans not submitted in proper format, (2) insufficient information in the drawings and (3) plans not suitable from radiation safety stand point.

The guidelines to prepare site and layout plan drawing refer to "Guidelines for preparation radiotherapy site and layout drawing", available in 'Help' menu of eLORA.

It is recommended to commence the construction of the Radiotherapy facility only on receipt of the site and layout plan approval from AERB.

Construct radiotherapy facility as per the site and layout plan the approved by AERB. In case any modification is required to be carried out in the approved layout plan, concurrence must be obtained from AERB prior to modification. Please refer 'User Manual for Radiotherapy' available in 'Help' menu of eLORA for more detail.

## 6. Appointment of Radiotherapy Staff

Appoint adequate number (must also be considered for additional facility in existing setup) of full time Radiation Oncologists, Medical Physicists and Radiation Therapy Technologists as per the qualification and experience stipulated in AERB Safety Code SC/MED- 1. In case of appointment of Medical Physicists, it is to be ensured that at least one of them is eligible to work as Radiological Safety Officer (RSO).

It may be noted that, only 'Radiation Professional' (RP) registered Radiotherapy staff can only be declared for your institute in eLORA. Obtain RP registration id and date of birth of appointed radiotherapy staff for declaring them in your institute's eLORA account.

## 7. 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

## 8. Nomination and Approval of Radiological Safety Officer

Nominate the Medical Physicist (if eligible), 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 procurement permission for any Radiotherapy equipment in new Radiotherapy facility.

## 9. Measuring and Monitoring Instruments

Procure appropriate measuring instruments for measurement of output and other dosimetric parameters (Thimble Ionisation Chamber, Parallel Plate Ionisation Chamber, Well type Ionization Chamber, Electrometer, Dosimetric Phantom, Radiation Field Analyser, etc.), appropriate monitoring instruments for area monitoring (Survey Meters, Contamination Monitors, Gamma Zone Monitors etc.) and QA instruments. Detail on requisite instruments for each type of radiotherapy installation is provided in 'User Manual for Radiotherapy', available in 'Help' menu of eLORA

It may be noted that Gamma Zone Monitor for Telecobalt unit and Remote after loading Brachytherapy unit should be of auto-reset type, whereas, that for manual Brachytherapy must have manual-reset button. The requisite instruments must be declared in eLORA system and its calibration details must be updated as and when instruments are being calibrated.

## 10. Other Associated Equipment/Accessories

One of the major associated equipment for Radiotherapy includes Simulator / CT-Simulator for simulating the patient prior to Radiation Therapy. The layout plan of Simulator Installation also requires site and layout approval from AERB as mentioned above and need authorisation prior to its procurement.

The other associated equipment/accessories includes Treatment Planning System (TPS), Last Man Out Switch (LMOS), beam modifiers, patient immobilisation devices such as moulds, quality assurance test tools, etc.

## 11. Equipment and Source Procurement Permission

Obtain authorisation from AERB for procurement of equipment (e.g. Teletherapy equipment, Brachytherapy equipment, Simulator, CT-Simulator and kV imaging system) and radioactive sources to be used in Radiotherapy equipment. For each re-procurement of radioactive source, authorisation is required to be obtained from AERB.

## 12. Equipment/Source Receipt Intimation

Provide intimation of receipt of the equipment/source within 15 days of its receipt. Install the teletherapy/brachytherapy unit as per the approved plan and carryout the mechanical and electrical tests thoroughly prior to source loading or switching on the Radiation beam in case of Radiation Generating Equipment (e.g. Medical Accelerator, Simulator).

## 13. Loading of the Source (Obtain Source Supervision Authorisation)

In case of Telecobalt source, the source shall be loaded (as well as unloaded) by the certified service engineer under supervision of the Medical Physicist/RSO, who has been authorised by AERB for the supervising the source transfer operation. Source supervision authorization is also required to obtain for first source loading in Remote Afterloading Brachytherapy unit.

## 14. Source Transfer Report

It is necessary to submit source transfer report after source transfer operation of Telecobalt source and first source loading in Remote Afterloading Brachytherapy unit.

## 15. Commissioning of Radiotherapy Equipment

Before energizing equipment for radiation, a Commissioning must be obtained from AERB. It is necessary to have adequate number of radiotherapy staff (availed with TLD badges) and requisite measuring, monitoring and QA tools in place for obtaining Commissioning approval.

## 16. Survey Report

After obtaining commissioning approval, a radiation survey is required to be carried out and survey report is required to be submitted to AERB. Only after approval to survey report, radiation related QA tests should be carried out thoroughly.

## 17. Licence for Operation

After completion of all mechanical, electrical and radiation related QA tests, submit application for Licence. Patient treatment can be started only after obtaining Licence for operation. The Licence shall be renewed before expiry of Licence.

## 18. Annual Report on Status of Radiation Safety in Radiotherapy Department

It is mandatory for all Radiotherapy facilities to submit safety status report by the end of calendar year but not later than 31st January of the next year. Non submission of annual safety status report is considered as non-compliance.

## 19. Quality Assurance/Dose Reports

Perform periodic QA test of the teletherapy/brachytherapy unit and the report of the same must be kept in the institute records. The personnel monitoring dose reports must also be maintained by the institute. These reports are to be produced while inspection of Radiotherapy Department of your institution by AERB personnel.

## 20. Disposal and Transport of Disused Radioactive Source

After end of useful life of radioactive source used in radiotherapy, the source should be disposed safely with the disposal agency. A consent must be obtained from AERB for disposal and transport of disused radioactive source to disposal agency. It may be noted that any radiotherapy source not in used for more than 1 year is deemed to be called as disused source and institute has to take immediate action for disposal of such disused source.

## 21. Decommissioning of Radiotherapy Equipment

After end of useful life of radiotherapy equipment used in radiotherapy, the equipment should be decommissioned through recognized agency. A consent for decommissioning of radiotherapy equipment must be obtained from AERB. It may be noted that any radiotherapy equipment not in used for more than 1 year is deemed to be called as disused equipment and institute has to take immediate action for decommissioning of such disused equipment.

=O=O=O=O=O=