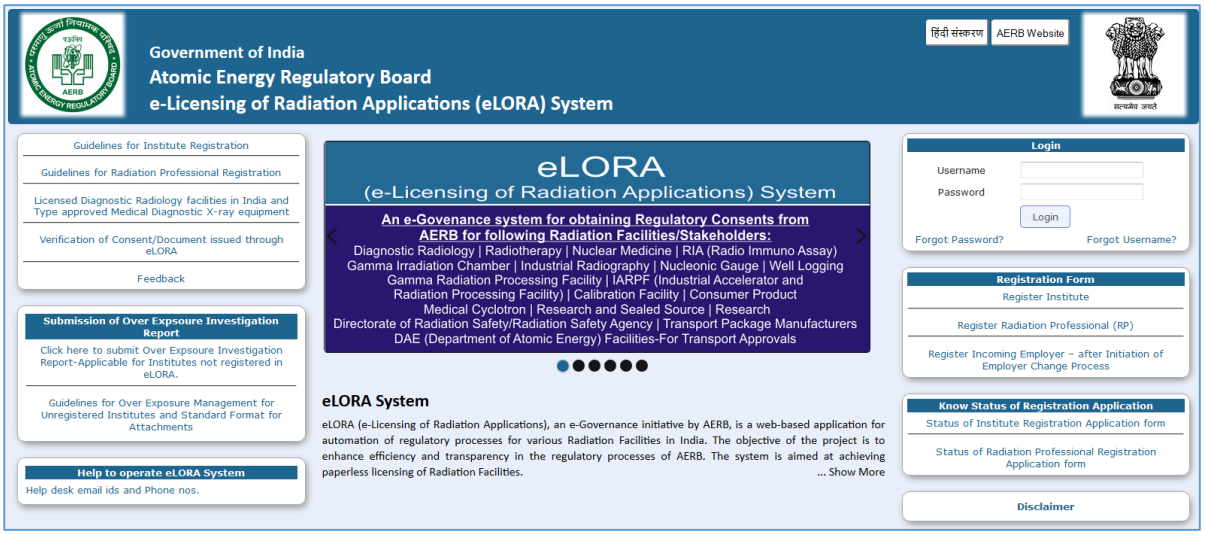
Regulatory Requirements and Guidelines for establishing new Radiotherapy Facility

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/RF/SG/G-3). No regulatory clearance is issued for establishing the radiotherapy facility by AERB, unless the user complies with the regulatory requirements.

For obtaining requisite regulatory clearance, user need to submit relevant application through AERB's e-Governance application - eLORA (e-Licensing of Radiation Applications) System after institute registration with AERB.



2. Registration of Institute in eLORA

To access eLORA system, employer need to register his/her institute for obtaining login credentials (user Id & Password). The details can be referred by visiting AERB website www.aerb.gov.in and click on 'eLORA'. **Please refer 'User Manual for Radiotherapy' available in 'Help' menu of eLORA for detailed information for obtaining requisite regulatory clearance from AERB through eLORA system**.

3. Selection of Radiotherapy equipment

Verify from the supplier that the radiotherapy equipment (which is either radiation generating equipment such as Medical Accelerator / Simulator or houses sealed radioactive material such as Telecobalt /Gamma Knife / Brachytherapy unit) is either type approved or NOC is issued by AERB to the local supplier. For this, copy of type approval certificate or NOC issued by AERB may be demanded from the local supplier. *It may be noted that, Licence to operate equipment procured based on NOC will not be issued by AERB till local supplier demonstrates its compliance with AERB requirements and user fulfills all the regulatory requirements*.

4. Radiotherapy Staff

Appoint adequate number qualified staff such as Radiation Oncologist(s), Medical Physicist(s) and Radiation Therapy Technologists as per the qualification and experience stipulated in AERB Safety Code AERB/RF-SC/MED-1(Rev.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).

5. Personnel Monitors Services

Personnel Monitoring services such as TLD badges shall be obtained from the AERB recognized agency for all the radiation workers.

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

6. 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.). Also procure appropriate monitoring instruments for area monitoring (Survey Meters, Contamination Monitors, Gamma Zone Monitors etc.), Security systems 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.

7. 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.

8. Site & Layout Plan approval for Radiotherapy Installation

It is advisable to prepare site & room layout drawings in consultation with Medical Physicist/Radiation Safety expert, Radiation Oncologists, Architects and the Supplier of the equipment. 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 application along with 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.

9. Nomination and Approval of Radiological Safety Officer (RSO)

Nominate the Medical Physicist (if eligible), to work as 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.

10. 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.

11. 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).

12. 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 authroised 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.

13. 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.

14. Commissioning of Radiotherapy Equipment

Before energising 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

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