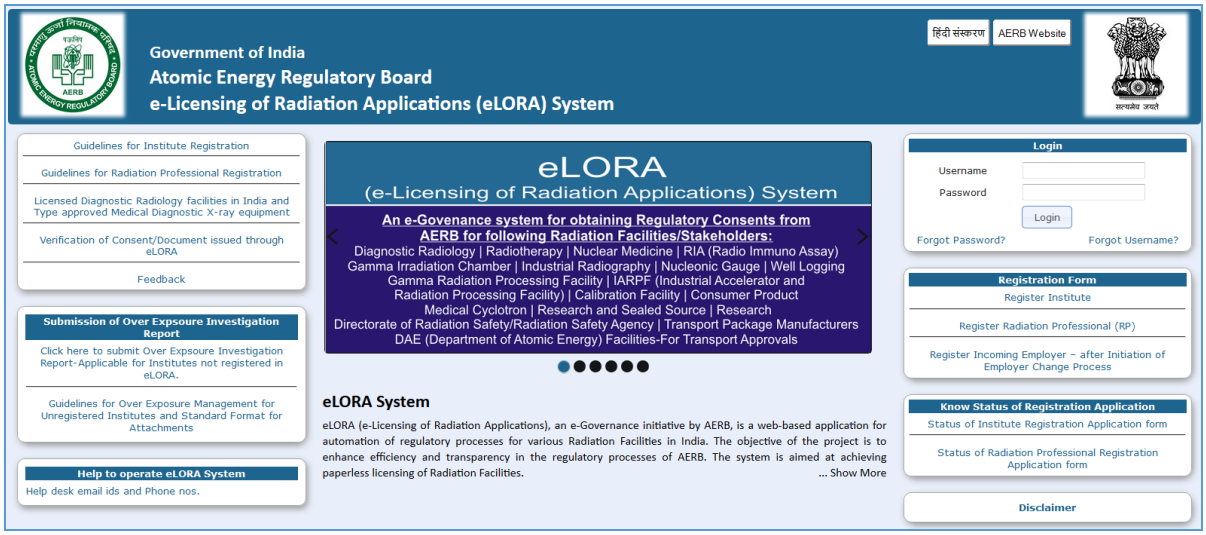
Regulatory Requirements and Guidelines for new Nuclear Medicine Facility

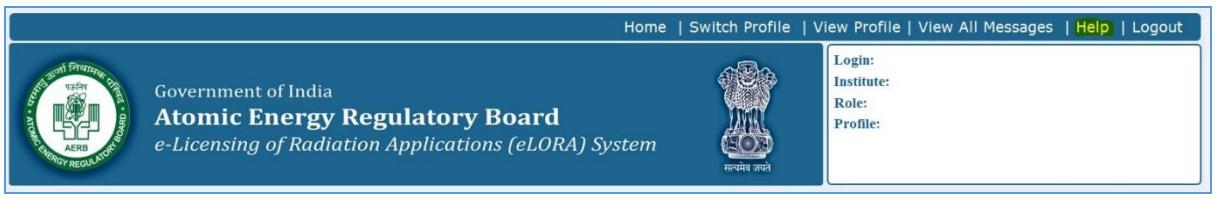
1. Introduction

To establish a Nuclear Medicine Facility (NMF), the user institute should go through the Regulatory requirements as mentioned in the Atomic Energy (Radiation Protection) Rules, 2004 and AERB Safety Code for Nuclear Medicine Facilities, AERB/RF-SC/MED-2(Rev.2), 2011 and shall obtain requisite regulatory consent from AERB as per AERB Safety Guide for Consenting Process for Radiation Facilities (AERB/RF-SG/G-3).

For obtaining requisite regulatory clearance as per the above regulatory documents, user should 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'.

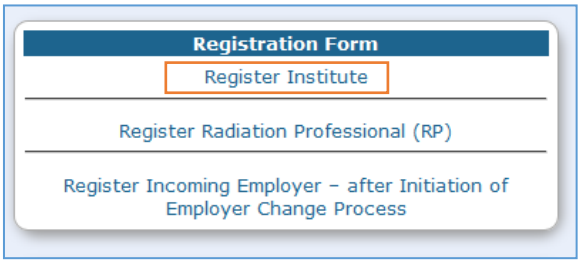


Please refer 'User Manual for Nuclear Medicine' available in 'Help' menu of eLORA for detailed information on forms to be used for obtaining requisite regulatory clearance from AERB through eLORA system.



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. Approval of Layout Plan of Nuclear Medicine Facility (NMF)

Prepare room layout drawings and the site layout drawing in consultation with expert Radiological Safety Officers, Architects and the Supplier of the nuclear medicine equipment (SPECT, SPECT-CT, PET-CT, PET-MRI, etc.) unit. Once the plan is finalized by the institute, 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 will be reviewed by AERB and approval is issued from radiation safety stand point on satisfactory compliance with all the relevant requirements for the particular stage. 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 nuclear medicine site and layout drawing", available in 'Help' menu of eLORA.

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

Construct the nuclear medicine 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.

4. Appointment of Staff for the Nuclear Medicine Facility (NMF)

Appoint adequate staff as per the qualification and experience stipulated in AERB Safety Code [AERB/RF-SC/MED-2(Rev.2)]. It may be noted that, only 'Radiation Professional' (RP) registered NM staff can be declared for your institute in eLORA. These Radiation Professionals are the radiation workers whose qualifications comply with the Codal requirement. Obtain RP registration id and date of birth of appointed staff for declaring them in your institute's eLORA account.

5. 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 during his work.

Following are the Accredited Laboratories providing TLD services in the respective states:

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. Nomination and Approval of Radiological Safety Officer

Employer of the NMF should nominate staff with qualifications as mentioned in the AERB/RF-SC/MED-2(Rev.2) as Radiological Safety Officer (RSO) by submitting application form in eLORA.

7. Measuring and Monitoring Instruments

Procure appropriate measuring instruments for measurement of activity to be administered to the patients (Dose calibrator/isotope calibrator), appropriate radiation monitoring instruments (Survey Meters, Contamination Monitors, Gamma Zone Monitors etc.) and QA tools. The requisite instruments should be declared in eLORA system and their calibration details must be updated as and when instruments are being calibrated.

8. Other Associated Handling Accessories

The other associated handling accessories such localized shields in form of lead bricks, L-bench, tongs, syringe carriers/shields, tongs, etc should be made available.

9. Equipment and Source Procurement Permission

Obtain permission from AERB for procurement of equipment (such as PETCT, SPECT CT) and radioactive sources to be used for QA/Radiological Survey.

10. Equipment Receipt Intimation

Provide intimation of receipt of the equipment through eLORA within 15 days of its receipt.

11. Quality Assurance (QA) tests and Radiological Survey Report

After installing the NM equipment, QA should be undertaken and its report should be submitted through eLORA. Radiation survey is required to be carried out and its report is required to be submitted to AERB through eLORA.

12. Precommissioning inspection

When the NMF is constructed as per the approved plan and ready for commissioning, a pre-commissioning inspection of the facility may be arranged. Any modifications/suggestions made at the time of pre-commissioning inspection by this Division shall be complied with.

13. Licence for Operation

After completion of all related QA tests, submit application for obtaining Licence for operation. A report on the action taken on the recommendations during the precommissioning inspection shall also be submitted alongwith the application for licence.

14. Permission for procurement of sources for clinical use

On receipt of the licence for operation, permission for procurement of source for clinical use should be submitted. While submitting the application for procurement of source, appropriate installation (PETCT/SPECT/LDT/HDT/NIT/Beta Therapy, etc) should be chosen depending on the intended use of the source

15. Source Procurement Intimation

The NMF shall place its source requirement to a specific source supplier through eLORA and the supplier shall in turn shall acknowledge the request and supply the quantity which shall be within the AERB authorised limit.

16. Annual Report on Status of Radiation Safety for NMF

It is mandatory for all NMFs 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.

17. Periodic Quality Assurance (QA)

Periodic QA should be undertaken as per the NEMA protocol for all the nuclear medicine equipment and the report for same should be uploaded on eLORA during the renewal of license for all imaging equipment.

18. Disposal and Transport of Disused Radioactive Source(s)

Any disused/decayed sealed source shall be returned to its original manufacturer/supplier by obtaining the requisite permission through eLORA portal. Disposal of all radioactive waste arising from the use of unsealed radioisotopes should be managed as per the requirements of the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987.

19. Decommissioning of NMF

A prior consent for decommissioning of NMF shall be obtained from AERB. On receipt of the permission from AERB, decommissioning shall be undertaken under the guidance of RSO and its report shall be submitted through eLORA while submission of the Intimation on Decommissioning.

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