Licensing and Credentialing requirements

To set up new diagnostic and therapeutic Nuclear Medicine (NM) facility, prior approval of regulatory body is mandatory requirement. The approving authority in India is Atomic Energy Regulatory Board (AERB), Niyamak Bhavan, Anushaktinagar Mumbai-400 094, India.

The places to start nuclear medicine facility should not be located in the residential building and shall comply with all the regulatory requirements as specified in the AERB safety code for Nuclear Medicine Facilities AERB/RF-MED/SC-2 (Rev. 2) released in March 2011 & AERB Safety Guide for Radioisotope Handling Facilities AERB/RF-RS/SG-2 released in August 2015. There are other safety codes are also applicable to Nuclear Medicine and relevant to follow.

All the application forms pertaining to Nuclear Medicine Facility, required to be submitted during various stages for its approval. These applications are to be submitted though e-Licensing of Radiation Applications (eLORA) System only.

The various stages of approval for Nuclear Medicine Facility is as follows:

1. Approval of Site and Layout

2. Intimation of Available Equipment

3. Application for Source Procurement

4. Source Procurement Intimation

5. Application for License

6. QA/QC Report & Radiation Survey Report

7. Application for Decommissioning / Disposal

8. Application for Decommissioning Intimation

1. Site and Layout Plan Approval

The first step to establish a Nuclear Medicine Facility (NMF) is to submit the site and layout plan of the installation through eLORA and get it approved from AERB. It may be noted that AERB approves the layout plans from radiation safety standpoint only and therefore, all other statutory permissions must be obtained by the user institution from the respective municipal/Govt. agencies. While preparing the layout plans of the facility, it is advisable to take inputs from the Management, Nuclear Medicine Physicists, Suppliers of NM equipment and Architecture. Typical layout plan issued by AERB is placed at Appendix 'A'.

The drawings in PDF file are required to be prepared and submitted for the site and layout approval application form in eLORA. While preparing the drawings it should be kept in mind that one should able to gather three dimensional understanding of the NMF and occupancy around the installation.

Site and layout plan drawings:

1.1 Site plan drawing
1.2 Main drawing showing NMF
1.3 Cross sectional drawings
1.4 Starting construction work

1.1 Site plan drawing

- Prepare the site layout plan drawing for the NMF. Recommended scale 1:200.
- Name of institute and address of institute ('Permanent Address' of institute as seen in your eLORA account) should be mentioned on the site layout plan drawing.
- Indicate NMF(s) in the site plan.
- The location of the NMF should be so chosen that it is away from general facilities and is close to the related facilities such as general patient and reception area, UPS room, Change room, etc. All such related facilities should be shown in the site layout plan.

- Indicate all the facilities around the NMF. Do not write 'Full Occupancy', 'Partial Occupancy' etc., rather write 'Ward', 'Toilet', 'Corridor', 'Accounts Office', 'Open Land open to sky' etc.
- Indicate distance between external walls of NMF and institute's plot boundary. If the boundary is at far off distance and cannot be shown in the drawing, mention the distance at which boundary exists.
- If the NMF is located near the plot boundary, maintain a minimum distance 3 meter between external walls of NMF and plot boundary for any contingency in future.
- Since the site layout plan provides the information about facilities at the ground level, for NMFs at the basement, the room location can be shown as shaded area.

1.2 Main drawing showing Nuclear Medicine Facility (NMF)

- Prepare the floor layout plan drawing for the proposed NMF.
- Name of institute and address of institute ('Permanent Address' of institute as seen in your eLORA account) should be mentioned on the drawing.
- Indicate 'Floor' of installation (e.g. Lower Basement, Ground Floor, etc.) in the drawing. It is desirable to attach Floor plans above or below the installation, if any.
- Show appropriate legend and density for each construction material (e.g. concrete, column, hematite concrete, brick, etc.) indicated in the drawing. 1.2.5 Indicate nature of occupancy around the NMF clearly. Do not write 'Full Occupancy', 'Partial Occupancy' etc., rather write 'Ward', 'Toilet', 'Corridor', 'Accounts Office' etc.
- Ensure to indicate the following in the layout plans:
    - Plumbing lines in case of High dose therapy facility (HDTF) and their connection to the delay tanks.
    - Delay tanks – their location – over ground/underground, occupancy around, construction material and its thickness

- Show cross sectional lines (e.g. X-X', Y-Y', etc.) along the length and breadth on the installation drawing and submit cross sectional drawings accordingly.

1.3 Cross sectional drawings

- Prepare the cross sectional drawings along the length and breadth of the rooms wherein radioactivity will be handled eg. Imaging room, post injection rooms for patients, isolation wards, etc.
- Indicate Cross Section No. (e.g. X-X', Y-Y', etc.) in the drawing.
- Ensure consistency of wall thickness, materials and occupancy around in cross sectional drawing in line with main drawing.

1.4 Starting construction work

No construction work should be undertaken by the institution unless prior approval of AERB for the specific layout of the installation has duly been obtained by the institution. The construction must be in accordance with the plan approved by AERB. In case of any deviation, the same must be promptly brought to the notice of AERB for necessary approval.

2. Intimation of available equipments/installations

After due regularization of layout, every institution needs to register/intimate the details of the equipment (e.g. PET-CT, SPECT etc) and installations (High dose therapy, Low Dose Therapy, Beta-Therapy etc). Give all the details as sought and SUBMIT. The system will automatically record the details as provided. The path and URL is as follows:

Login>>Regulatory Forms>>Nuclear Medicine>>Intimation of available equipments/installations

https://elora.aerb.gov.in/ELORA/intimationAvailableEquipments.htm

3. Application for Source Procurement

On successful intimation of available equipments, eLORA takes note of availability of the equipments/installations with the facility. The next step is to Apply for procurement of source. During installation stage, this application for source procurement is for QA (quality assurance) source. Later on same URL and path can be used to get NOC for procurement of routine sources. The path and URL is as follows:

Login>> Regulatory Forms>> Nuclear Medicine>> Application for Source Procurement

https://elora.aerb.gov.in/ELORA/NMSourceProcAction.htm

4. Source Procurement Intimation

Once QA source is received, this needs to be intimated through eLORA. The path and URL is as follows:

Login>>Regulatory Forms>>Nuclear Medicine>>Source Procurement Intimation

https://elora.aerb.gov.in/ELORA/NMSourceProcInformation.htm

5. Application for License:

Now apply for License of the installation. Follow the path or URL:

Login>>Regulatory Forms>>Nuclear Medicine>>Application for License

https://elora.aerb.gov.in/ELORA/NMLicenseAction.htm

6. QA/QC Report & Radiation Survey Report

The QA/QC is performed for the installed equipments. QA/QC is performed based on the criteria set by NEMA (National Electrical Manufacturers Association) as well as parameters set by Atomic Energy Regulatory Board (AERB). A step by step Guide for NEMA and AERB QA/QC of SPECT, SPECT-CT, PET and PET-CT is prepared to help Nuclear Medicine Physicists/Bio-Medical Engineers.

Once QA/QC is done, follow the following path and upload it on eLORA.

Login>>Regulatory Forms>>Nuclear Medicine>>QA/QC Report

On ensuring the compliance of requirement as specified in AERB safety Code AERB/RF-MED/SC-2 (Rev. 2), 2011 for the safe handling of radioactive material in the approved nuclear medicine facility, the authorization for the procurement of radioactive material will be issued for the stipulated time period. Periodically, the Annual Status Report AERB/NM/Radiation Safety/02 has to be submitted to AERB for renewal of the authorization. This report, in any case, should reach to AERB on or before 31st December every year.

7. Application for Decommissioning/ Disposal

In case you wish to decommission an installation or dispose of a sealed source, follow the mentioned path for application:

Login>>Regulatory Forms>>Nuclear Medicine>>Application for Decommissioning / Disposal

8. Application for Decommissioning Intimation

On actual decommission /disposal of an installation or source AERB should be intimated about the same by this application. Follow the path;

Login>>Regulatory Forms>>Nuclear Medicine>>Application for Decommissioning Intimation