International Journal of Multidisciplinary Research and Growth Evaluation.

Ensuring Radiation Safety and Compliance: Key Steps in Setting Up a Nuclear Medicine Facility in India

Priya Jacob
Independent Researcher, USA

* Corresponding Author: **Priya Jacob**

Article Info
ISSN (online): 2582-7138
Volume: 03
Issue: 06
November- December 2022
Received: 17-11-2022
Accepted: 15-12-2022
Page No: 733-737

Abstract
Establishing a Nuclear Medicine Facility (NMF) in India involves navigating a complex regulatory landscape, primarily governed by the Atomic Energy Regulatory Board (AERB). This paper provides a detailed roadmap for setting up an NMF, covering critical aspects such as site plan approval, staffing requirements, procurement of equipment and radioactive sources, pre-commissioning inspections, and operational licensing. Emphasis is placed on adherence to safety standards, regulatory compliance, and the importance of periodic quality assurance and annual safety reporting. By following this structured approach, stakeholders can ensure the safe and efficient operation of nuclear medicine facilities, contributing to advancements in diagnostic and therapeutic healthcare in India.

DOI: https://doi.org/10.54660/.IJMRGE.2022.3.6.733-737

Keywords: Nuclear Medicine Facility (NMF), Atomic Energy Regulatory Board (AERB), Radiation Safety, Quality Assurance (QA), Radiopharmaceuticals, Pre-commissioning Inspection, Operational Licensing, Radiation Protection, eLORA System

Introduction

Nuclear medicine has emerged as a cornerstone of modern healthcare, offering unparalleled diagnostic and therapeutic capabilities through the use of radioactive materials. In India, the establishment of Nuclear Medicine Facilities (NMFs) is governed by stringent regulatory frameworks, primarily overseen by the Atomic Energy Regulatory Board (AERB) [1, 2]. These regulations ensure the safe handling of radioactive substances, protecting both patients and healthcare professionals from potential radiation hazards. However, the process of setting up an NMF is intricate, requiring meticulous planning, adherence to safety protocols, and compliance with legal requirements. This paper aims to demystify the process, providing a comprehensive guide for stakeholders embarking on this journey. By addressing key aspects such as site approval, staffing, equipment procurement, and regulatory compliance, this study serves as a valuable resource for healthcare institutions, policymakers, and researchers aiming to enhance nuclear medicine infrastructure in India.

Discussion:

1. Site plan approval

The foundation for setting up a Nuclear Medicine Facility lies in understanding the essential regulatory guidelines. These include the Atomic Energy (Radiation Protection) Rules, 2004, the AERB Safety Code for Nuclear Medicine Facilities (AERB/RF-SC/MED-2(Rev.2), 2011) [1], and the AERB Guidelines for preparation of nuclear medicine facility site and layout drawings 2017. These documents serve as the primary roadmap for compliance and safety.

The initial step is registering your institution on AERB's online platform, eLORA. This is akin to creating your profile before applying for a service. The "Institute Registration" form, found on the eLORA homepage (figure1), is straightforward, and the provided guidelines will assist you. Once registered, you'll have an account to proceed with the next phase.

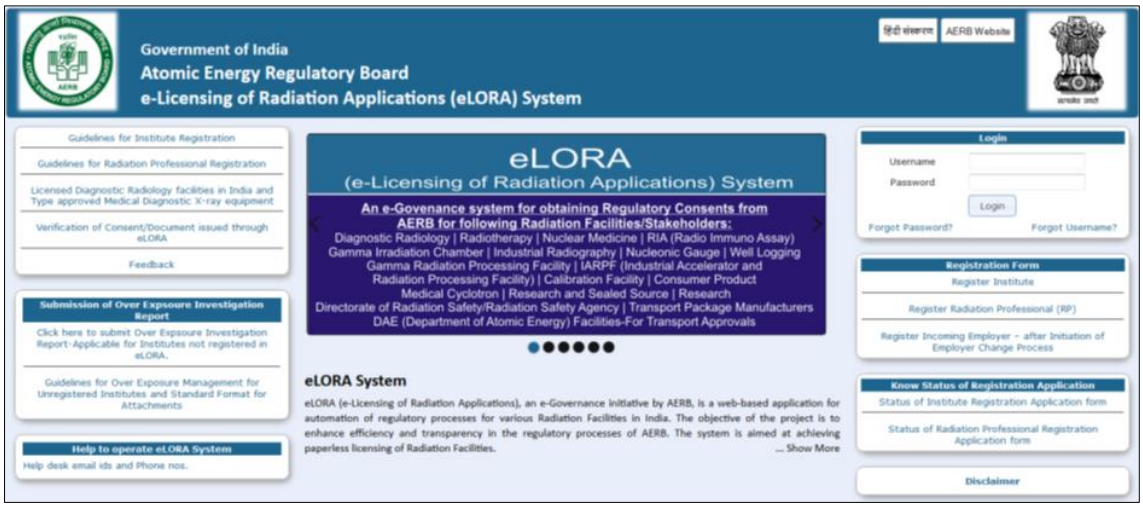
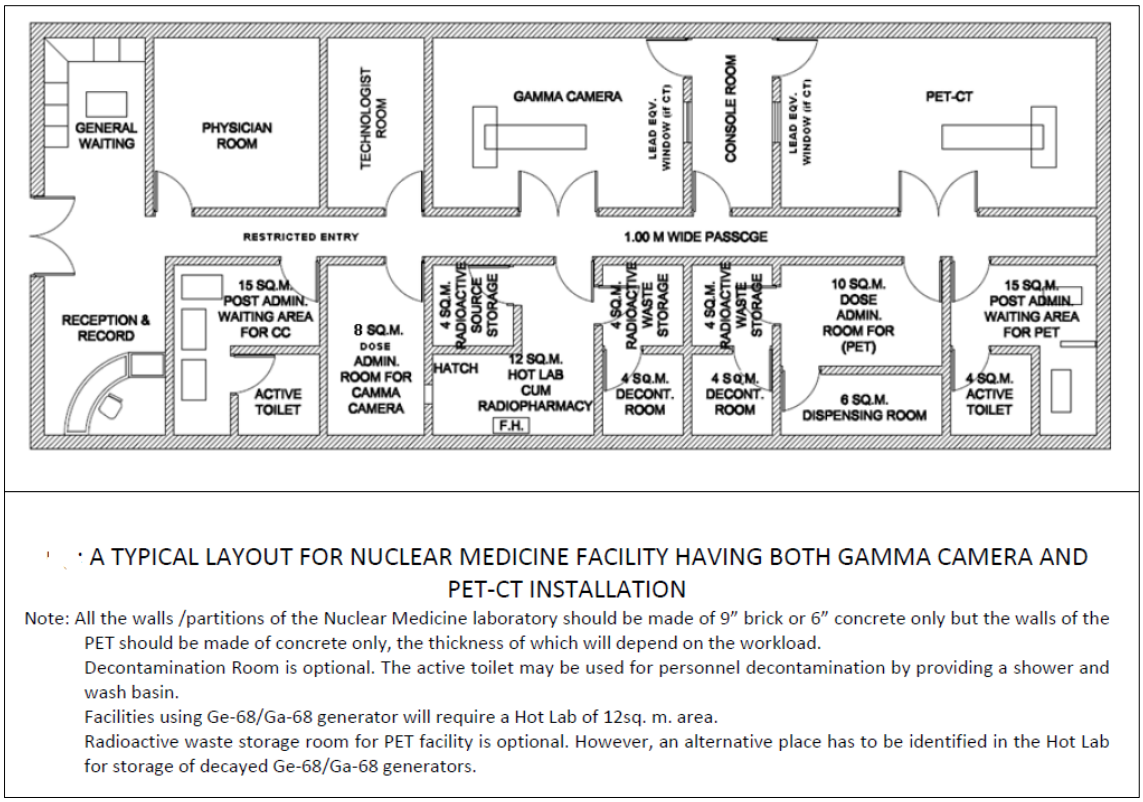


Fig 1: AERB eLORA website

Site and Layout Approval involves submitting detailed plans of your NMF, ensuring it meets radiation safety standards. Imagine these plans as a blueprint for your facility, meticulously drawn to demonstrate how radiation will be contained and managed. You'll need to collaborate with experts: Radiological Safety Officers, architects, and the suppliers of your nuclear medicine equipment (like SPECT, PET-CT, etc.). They'll help you create accurate and compliant drawings.



· A TYPICAL LAYOUT FOR NUCLEAR MEDICINE FACILITY HAVING BOTH GAMMA CAMERA AND PET-CT INSTALLATION

Note: All the walls /partitions of the Nuclear Medicine laboratory should be made of 9" brick or 6" concrete only but the walls of the PET should be made of concrete only, the thickness of which will depend on the workload.
Decontamination Room is optional. The active toilet may be used for personnel decontamination by providing a shower and wash basin.
Facilities using Ge-68/Ga-68 generator will require a Hot Lab of 12sq. m. area.
Radioactive waste storage room for PET facility is optional. However, an alternative place has to be identified in the Hot Lab for storage of decayed Ge-68/Ga-68 generators.

Fig 2: Layout for Nuclear Medicine Facility

Your submission through eLORA must include PDF files of these drawings. AERB will review them, and approvals are granted only if all safety requirements are met. Common reasons for rejection include poorly formatted plans, incomplete information, or plans deemed unsafe.

The site plan should give a bird's-eye view of your facility within the institute's grounds, showing surrounding areas and distances from plot boundaries. The floor layout plan details the internal structure, including construction materials and the arrangement of rooms. Cross-sectional drawings provide a detailed view of the walls and internal structures. It is important to label the surrounding areas with their exact function, such as "Patient Ward" or "Accounts Office" instead of vague terms like "occupied area."

Crucially, no construction work whatsoever can begin until AERB has granted its formal approval for the specific layout of your installation. Once approved, construction must strictly adhere to the approved plan. Any deviation from the

approved plan, must be promptly brought to the attention of AERB for their review and approval.

It is very important to understand that the AERB only approves the layout plan from a radiation safety point of view. You will still need to obtain all required approvals from your local municipal and other government agencies. Think of this process as a collaborative effort involving various experts and regulatory bodies, all working to ensure the safe and effective operation of your Nuclear Medicine Facility.

2. Appointment of staff for the Nuclear Medicine Facility (NMF)

The AERB Safety Code underscores critical importance of adequate and qualified staffing in ensuring radiation safety within a Nuclear Medicine Facility. It mandates that staff appointments must strictly adhere to the qualifications and experience criteria outlined in the AERB Safety Code [AERB/RF-SC/MED-2(Rev.2)] [1]. A key regulatory requirement is that only 'Radiation Professional' (RP) registered Nuclear Medicine staff can be declared for an institute in the eLORA system. This ensures that these radiation workers possess qualifications fully compliant with the Code's requirements, establishing a baseline of competence for handling radioactive materials and procedures.

The employer are obligated to employ an adequate number of staff, including Nuclear Medicine Physicians, Nuclear Medicine Technologists, and Radiological Safety Officers (RSOs), on a continual basis. This highlights the necessity of maintaining a stable and sufficient workforce to uphold safety protocols and operational efficiency. The employer must promptly report to the competent authority if any of these qualified staff members leave the institution and must detail the alternate arrangements made to ensure continued safety and compliance.

The Code meticulously defines the qualifications and responsibilities for each staff category within the Nuclear Medicine Facility, as cited in sections 107, 3.3, 3.4, and 3.5. This includes specific requirements for Nuclear Medicine Physicians, Nuclear Medicine Technologists, and Radiological Safety Officers (RSOs), outlining the necessary education, training, and expertise for each role. The employer is also responsible for providing necessary resources and ensuring the implementation of safety measures. This includes providing appropriate equipment and tools for the safe handling of radioactive material, assigning responsibilities according to the Code, providing personnel monitoring devices to radiation workers, and ensuring that all provisions of the Code are implemented by all staff members.

The AERB Safety Code assigns a critical role to the Radiological Safety Officer (RSO) in upholding radiation safety within a Nuclear Medicine Facility. The process of appointing an RSO begins with the employer nominating a staff member for this position. This nomination is strictly conditional upon the candidate fulfilling the qualifications detailed in the AERB/RF-SC/MED-2(Rev.2) [1] document. The Code specifies distinct qualification levels for RSOs, which vary according to the facility's nature. For most nuclear medicine facilities, the RSO should possess a post-graduate degree or diploma in Nuclear Medicine, recognized by the Medical Council of India or the National Board of Examination, or a degree, post-graduate degree, or post-graduate diploma in Nuclear Medicine Technology. In contrast, facilities equipped with radioisotope-producing accelerators, such as medical cyclotrons, necessitate an RSO level III with a Post M.Sc. diploma or post-graduate degree in radiological physics, medical physics, or an equivalent qualification.

The nominated individual must receive approval from AERB to officially serve as the RSO. To secure this approval, the employer must submit an application form through the eLORA system. This includes comprehensive details of the nominee's qualifications, experience, and other pertinent information, which AERB will use to evaluate the individual's suitability for the RSO role.

3. Measuring and Monitoring instruments [3, 4, 5]

To ensure the safety and well-being of all personnel within a Nuclear Medicine Facility, the procurement and proper utilization of measuring and monitoring instruments is of paramount importance. This necessitates obtaining personnel monitoring badges, such as TLD badges, for every radiation worker, sourced from an agency accredited by the AERB. In addition to these, pocket dosimeters may also be acquired, serving the purpose of providing an immediate measurement of the radiation dose a worker receives during their work.

Furthermore, the facility must secure appropriate measuring instruments designed for determining the activity of radiopharmaceuticals before their administration to patients, a function typically fulfilled by a dose calibrator or isotope calibrator. It is equally vital to have suitable radiation monitoring instruments, including survey meters, contamination monitors, gamma zone monitors, and other necessary tools for effectively monitoring radiation levels and contamination within the facility premises.

Beyond these fundamental monitoring tools, the facility should also procure QA tools, essential for upholding the quality and accuracy of both procedures and equipment. To facilitate the safe handling of radioactive materials, the availability of associated handling accessories is crucial. These include localized shielding, such as lead bricks, L-benches for conducting procedures, tongs for manipulating radioactive sources, and syringe carriers or shields, designed to minimize exposure during the preparation and administration of radiopharmaceuticals.

It is mandatory that all the necessary instruments be declared within the eLORA system. Moreover, it is imperative to maintain current records of their calibration details, with the eLORA system updated whenever the instruments undergo calibration.

4. Equipment and source procurement permission

The AERB Safety Code plays a vital role in regulating the use of radioactive materials and radiation-generating equipment within nuclear medicine practices. A fundamental aspect of this regulatory oversight is the mandatory requirement to obtain explicit permission from the Atomic Energy Regulatory Board (AERB) before the procurement of specific equipment and radioactive sources. This prerequisite for permission applies to the acquisition of significant equipment essential to nuclear medicine procedures, notably advanced imaging systems such as PET-CT and SPECT-CT scanners. Nuclear Medicine Facilities must actively seek and secure authorization from the AERB prior to proceeding with the procurement of such equipment.

In a similar vein, obtaining permission from the AERB is a mandatory condition for the procurement of radioactive sources. This stipulation includes radioactive sources

intended for utilization in quality assurance (QA) [6] procedures and radiological surveys. These procedures and surveys are indispensable for upholding the accuracy, safety, and overall integrity of nuclear medicine practices.

Following the granting of the necessary permission and the subsequent receipt of the equipment or radioactive sources by the Nuclear Medicine Facility, then required to provide formal intimation of the receipt of the equipment through the eLORA system within 15 days from the date of receipt. The AERB Safety Code enforces a system of regulatory control over the acquisition of significant equipment and radioactive materials employed in nuclear medicine.

5. Pre-commissioning inspection

According to the AERB Safety Code, once the Nuclear Medicine Facility has been constructed in accordance with the approved plan and is ready for commissioning, a pre-commissioning inspection of the facility may be arranged. During this inspection, the facility will be assessed to ensure it meets the required safety standards and is suitable for its intended purpose. It is important to note that any modifications or suggestions that are made by the inspecting division at the time of the pre-commissioning inspection must be complied with. This process ensures that the facility adheres to all necessary safety regulations before it begins operation.

6. Licence for Operation

After completing all necessary Quality Assurance (QA) tests, the next critical step in establishing a nuclear medicine facility is to submit an application for obtaining a license for operation. This step marks a significant milestone in the journey toward operational readiness, as it signifies that the facility has met the stringent safety, technical, and regulatory standards set forth by the Atomic Energy Regulatory Board (AERB). A key requirement during this phase is the submission of a detailed report outlining the actions taken in response to the recommendations made during the pre-commissioning inspection. This report serves as a critical document that underscores the facility's proactive approach to addressing any identified gaps or areas for improvement. The report must be thorough, transparent, and well-documented, providing clear evidence of how each recommendation has been addressed and resolved.

7. Permission for procurement of sources

Following the receipt of the license for operation, the Nuclear Medicine Facility must formally seek permission for the procurement of radioactive sources intended for clinical use. When submitting the application for the procurement of sources, it is imperative that the appropriate installation type is chosen. The selection of the installation, such as PET-CT, SPECT-CT, LDT (Low Dose Therapy), HDT (High Dose Therapy), NIT (Nuclear Imaging Therapy), or Beta Therapy, must accurately reflect the intended use of the radioactive source. This categorization is essential for regulatory purposes, ensuring that the sources are procured and utilized in a manner consistent with the facility's approved activities and safety protocols.

The Nuclear Medicine Facility is required to place its source requirement to a specific source supplier through the eLORA system. This electronic system facilitates the communication of the facility's needs to the supplier in a structured and traceable manner. The source supplier, in turn, has a responsibility to acknowledge the request received through eLORA. Furthermore, the supplier is obligated to ensure that the quantity of radioactive material supplied to the Nuclear Medicine Facility remains within the limits authorized by the AERB. This mechanism provides a check to prevent the procurement of quantities exceeding the facility's approved limits, thereby reinforcing regulatory control and safety.

8. Periodic quality assurance and annual report on status of radiation safety [7, 8]

To maintain the accuracy, reliability, and safety of nuclear medicine procedures, periodic Quality Assurance (QA) [9] is essential. The AERB Safety Code mandates that this periodic QA be undertaken according to the NEMA (National Electrical Manufacturers Association) protocol, providing standardized procedures for testing and evaluating the performance of medical imaging equipment.

Following these standardized protocols ensures that the equipment functions within acceptable parameters, delivering accurate diagnostic information and ensuring patient safety. This report must be uploaded on the eLORA system. Specifically, this upload is required during the renewal of the license for all imaging equipment within the Nuclear Medicine Facility. This process integrates QA reporting with the licensing process, ensuring that the regulatory body has access to up-to-date information on the performance of the facility's equipment.

It is mandatory for all Nuclear Medicine Facilities to submit a safety status report. This report provides a comprehensive overview of the facility's radiation safety practices and performance throughout the year. The deadline for submission is no later than the 31st of January of the next year. The AERB Safety Code emphasizes non-submission of the annual safety status report is considered as non-compliance.

Conclusion

The establishment of a Nuclear Medicine Facility in India is a multifaceted endeavor that demands a thorough understanding of regulatory requirements, a commitment to safety, and a collaborative approach involving various stakeholders. From obtaining site plan approval to ensuring periodic quality assurance and annual safety reporting, each step plays a pivotal role in the successful operation of an NMF. Adherence to AERB guidelines not only ensures regulatory compliance but also fosters a culture of safety and excellence in nuclear medicine practices. As India continues to advance in healthcare innovation, the establishment of well-regulated and efficiently managed NMFs will be instrumental in addressing the growing demand for advanced diagnostic and therapeutic services.

References

1. Atomic Energy Regulatory Board (AERB). Safety Code for Nuclear Medicine Facilities (AERB/RF-SC/MED-2(Rev.2)). 2011. [Online]. Available: http://www.aerb.gov.in.
2. Atomic Energy Regulatory Board (AERB). Guidelines for Preparation of Nuclear Medicine Facility Site and Layout Drawings. 2017. [Online]. Available: https://www.aerb.gov.in/english/guidelines-for-preparation-of-nuclear-medicine-facility-site-and-layout-drawings.

3. International Atomic Energy Agency (IAEA). Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. IAEA Safety Standards Series No. GSR Part 3. Vienna: IAEA; 2014.
4. Cherry SR, Sorenson JA, Phelps ME. Physics in Nuclear Medicine. 4th ed. Philadelphia, PA, USA: Elsevier Saunders; 2012.
5. Khalil MM. Basic Sciences of Nuclear Medicine. 2nd ed. Berlin, Germany: Springer; 2011.
6. National Electrical Manufacturers Association (NEMA). Performance Measurements of Gamma Cameras. NEMA Standards Publication NU 1-2018; 2018.
7. World Health Organization (WHO). Radiation Protection in Medicine: Setting the Scene for the Next Decade. Geneva, Switzerland: WHO; 2017.
8. Kenge RP, Sharma SK. Regulatory framework for nuclear medicine in India: Challenges and opportunities. Journal of Medical Physics. 2020;45(3):123–130.
9. Singh AK, Kumar P. Quality assurance in nuclear medicine: A review of protocols and best practices. Indian Journal of Nuclear Medicine. 2019;34(2):89–95.