Guidelines to Set up a Nuclear Medicine Facility

In Nuclear Medicine (NM), the diagnostic and therapeutic procedures using unsealed radioisotopes shall be carried out only in a facility approved by the Atomic Energy Regulatory Board (AERB). The approved 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 on nuclear medicine facilities AERB/RF-MED/SC-2 (Rev. 2), 2011. All the application forms pertaining to nuclear medicine facility which are required to be submitted during various stages for its approval are available at www.aerb.gov.in.

The various stages of approval of nuclear medicine facility by AERB are given as follows:

1. Site and Layout Plan Approval
2. Application for Authorization for Commissioning of the Facility
3. Pre-commissioning Inspection.
4. Approval for Commissioning / Routine Operation.
5. Decommissioning.

1. Site and Layout Plan Approval:

Two copies each of the proposed layout plan, site plan and elevation drawing of the facility indicating the floor, nature of occupancy around, above and below, if any, has to be submitted in "B3" size paper (353 x 500 mm^2) along with the application form no. AERB/RSD/NMF/SLA. The dimension of all the rooms in the proposed layout plan of the nuclear medicine department should be indicated clearly alongwith the thickness and material of all the walls pertaining to the facility. The typical layout plans may be referred to design the nuclear medicine facility with respect to the arrangement / allocation of rooms and area requirement. The above documents have to be submitted to Head, Radiological Safety Division (RSD), AERB. On scrutinizing the above submitted plans, necessary approval for the construction of facility may be granted.

2. Application for Authorization for Commissioning of the facility:

After due completion of the construction of the facility as per the approved layout plan, the facility may start installing the diagnostic equipment, if any, in the approved location. Details of the completion of the construction work as per the approved plan, installation of equipments, procurement of radiological protection accessories, enrolment of radiation workers in Personal Monitoring Services (PMS) and availability of qualified staff as per AERB Safety Code AERB/RF-MED/SC-2 (Rev. 2), 2011, shall be intimated to Head, RSD, AERB by submitting the 'Application for Authorisation for Commissioning & Operation of Nuclear Medicine Facility' [Form No. AERB/RSD/NMF/ACO], so that a pre-commissioning inspection may be planned. The report for the QA tests of the diagnostic equipments as prescribed by AERB [tests & prescribed format] shall be submitted with the aforesaid form. The Radiological Safety Officer (RSO) has to be nominated by the employer

for the nuclear medicine facility by submitting the application form no. AERB/RSD/RSO/APP.

3. Pre-Commissioning Inspection:

The pre-commissioning inspection will be carried out by AERB to ensure whether the construction of nuclear medicine facility is as per the approved plan and to verify the information provided in stage '2' and whether all the facilities for operation of NM lab are available. The facility may be required to perform the QA tests as per the NEMA protocol in front of the AERB Inspector during inspection. The facility may apply for permission for procurement of radioisotopes by using the form AERB/RSD/NM/PROC, after satisfactory compliance to the inspection report issued by RSD, AERB.

4. Approval for Commissioning / Routine Operation:

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.

5. Work Practice:

All the labels on the containers having contaminated radioactive material should be removed / defaced prior to disposal. In NM facility, the radiopharmaceutical formulation should be prepared, handled, administered to the patients and disposed off in a safe manner taking into account adequate radiation protection measures. Radioisotopes should be stored, used and transported safely and securely all the time. Any unusual event which has resulted or has potential to result in over exposure to the workers or public should be reported to AERB. Annual Safety Status report of the facility should reach to AERB in the prescribed format in the first week of January each calendar year. Any change in the qualified person or design of the facility shall be reported to AERB. All cooperation should be extended to the authorized inspectors from AERB during inspection of the facility. Failure of compliance to radiation safety procedures may attract enforcement action by AERB.

6. Decommissioning:

When the nuclear medicine facility is no longer to be used, the permission for decommissioning should be obtained from AERB. The facility may use the application form AERB/RSD/NM/DECOM for the same. The RSO should attach a report on decontamination of the facility with the application.