

REQUIREMENTS AND GUIDELINES TO START A RADIATION THERAPY FACILITY

The requirements and guidelines listed below includes procurement of any of the Radiation Sources to be used in Radiation Therapy i.e. Source for Telecobalt unit, Medical Accelerator, Sources for Gamma Knife unit, Source(s) for Remote Afterloading Brachytherapy unit, Sources for Manual Afterloading Brachytherapy, Simulator, Check source or any other new modality involving ionizing radiation for therapeutic purposes.

Clearance of the unit by AERB

1. Verify from the supplier that the unit (which is either radiation generating equipment such as Medical Accelerator / Simulator or houses sealed radioactive material such as Telecobalt / Gamma Knife / Brachytherapy unit) to be installed is either **type approved** by Atomic Energy Regulatory Board (AERB) or a **NOC** is issued by AERB to the local supplier of the unit. The copy of type approval certificate or NOC issued by AERB will be furnished by the local supplier on demand. (*Type Approval/NOC: No radiotherapy unit is allowed to be sold in the country without a valid certificate from AERB. When a new model is to be imported to the country for the first time, AERB issues NOC to the local supplier to import only ONE unit based on the evaluation of specifications of the unit, the documents related to the design standards the unit meet and approval from the competent authorities of other countries. Once the first unit is imported, AERB representatives witness the performance of the unit and check whether the unit meets the required standards. Based on the physical evaluation of the unit, the type approval certificate is issued to the local supplier to market the same type of unit with certain terms and conditions*)

Approval of Room Layout Plan of Radiation Therapy Installation

2. Prepare room layout drawings (to scale 1: 50) and the site layout drawing (to scale 1: 500) in consultation with Medical Physicists, Radiation Oncologists, Architects and the supplier of the unit and submit two copies of the drawings along with the application [AERB/RSD/RT/PLAN](#) to the Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai – 400 094 for approval from radiation safety stand point. The plans not submitted in proper format or insufficient information may cause delay in obtaining the approval. **It is recommended to commence the construction of the Radiation Therapy facility only on receipt of the approved plan from AERB.**

The location of the teletherapy installation should be so chosen that it is away from unconnected facilities and is close to the associated facilities. The associated facilities include Simulator room, Minor Operation Theatre (for Brachytherapy), Mould room, Treatment Planning System room, Physicist(s) room, Radiation Oncologist(s) room, Patient waiting area etc.

3. Construct teletherapy/brachytherapy facility as per the plan the approved by AERB at the location shown in the approved plan. In case any modification is required to be carried out in the approved layout plan, concurrence must be obtained from RSD, AERB prior to modification.

Appointment of Radiation Therapy Staff

4. Appoint **adequate number** (must also be considered for additional facility in existing setup) of full time Radiation Oncologists, Medical Physicists and Radiation Therapy Technologists as per the qualification and experience stipulated in AERB Safety Code SC/MED- 1 and 3. 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). *(Those who have passed Diploma in Radiological Physics from University of Mumbai are eligible to work as level-III RSO in Medical, Industrial and Research Centres. However, those who have passed M.Sc.(Medical Physics) or equivalent from other universities are eligible to work as level-III RSO in Medical Institutions only if they possess a certificate of successfully passing the RSO examination from BARC.)*

Nomination and Approval of Radiological Safety Officer

5. Nominate the Medical Physicist (if eligible), to work as Radiological Safety Officer (RSO) in your institution by sending the filled in form [AERB/441/RSOM-II/III-FORM](#)

Procurement of Personnel Monitors

6. Procure Personnel Monitoring Badges from the agency recognised by AERB for all the radiation workers so that they are available during installation of the unit. Pocket dosimeters for the radiation workers may also be procured, which are meant for measuring radiation dose received by the radiation worker on the spot.

Measuring and Monitoring Instruments

7. Procure appropriate measuring instruments for measurement of output and other dosimetric parameters (Thimble Ionisation Chamber, Parallel Plate Ionisation Chamber, Well type Ionization Chamber, Electrometer, Radiation Field Analyser etc.) and appropriate monitoring instruments for area monitoring (Survey Meters, Contamination Monitors, Gamma Zone Monitors etc.). *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.*

Other Associated equipment/Accessories

8. 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 approval from this Division as mentioned above and need authorisation prior to its procurement.
9. The other associated equipments/accessories includes Treatment Planning System (TPS), beam modifiers, patient immobilisation devices such as moulds, quality assurance test tools etc.

Authorisation to procure Radiation Sources

10. Obtain authorisation from RSD, AERB by sending the filled in form [AERB/RSD/RT/ATH](#) along with all the necessary documents mentioned therein for **procurement of sources** to be used in Radiotherapy *(which includes sealed radioactive sources, depleted uranium and radiation generating equipments such as Medical Accelerator and Simulator)*. The form must be filled in properly to avoid undue delay.

11. Procure radioactive sources, radiation generating equipment (Accelerator or Simulator) as per the specifications mentioned in the authorisation letter.

Road Transport Approval

12. Obtain road transport permission from RSD, AERB for transporting the radioactive source from the airport/port to the institution (not required in case of Accelerator and Simulator)

Receipt of Sources

13. Intimate regarding the receipt of the source (includes Accelerator and Simulator) to RSD, AERB by filling in the form [AERB/RSD/RT/SRI](#) within 15 days of its receipt

Installation of the Unit

14. 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 incase of Radiation Generating Equipment.

Loading of the source/Switching on Radiation in case of Radiation Generating Equipment

15. Incase of Telecobalt source, the source shall be loaded 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. To obtain the authorisation for supervising the source loading operation the Medical Physicist/RSO should submit the duly filled in form [AERB/RSD/RT/SSA](#) prior to 15 days of actual date of source transfer. Incase the Medical Physicist is not having prior experience in source transfer operation of Telecobalt unit, the institution may seek assistance of Medical Physicist from any other Radiotherapy Centre under intimation to his/her employer. In such a case a consent letter from the Medical Physicist with endorsement from his/her employer must be attached along with the filled in form [AERB/RSD/RT/SSA](#). The telecobalt source shall not be loaded if the authorised Medical Physicist(s) are not present. After loading the telecobalt source, the source transfer report is to be submitted by the Medical Physicist/RSO in the prescribed format [AERB/RSD/RT/ST-REPORT](#).
16. Before Loading of the source/Switching on Radiation in case of Radiation Generating Equipment ensure that all the persons involved in the source loading, operation and testing of the unit have personnel monitoring badges.
17. After loading the source or switching the beam on, it is the responsibility of the RSO and the service engineer to carryout radiation protection survey of the installation prior to any other radiation tests. Incase the radiation levels around the installation are not within the limit, all other tests must be suspended and AERB shall be intimated promptly with the recorded survey data.

Quality Assurance/Acceptance test

18. Perform thorough Quality Assurance/Acceptance test of the teletherapy/brachytherapy unit and the report of the same must be kept in the hospital records, which are to be produced while inspection of Radiotherapy Department of your institution by AERB personnel.

Commissioning Approval for Patient Treatment

19. Obtain commissioning approval for using the unit for patient treatment from RSD, AERB (i) submit undertaking regarding the performance of the unit in the prescribed format [AERB/RSD/RT/UT-COM](#) and (ii) intimate regarding the availability personnel, associated

equipments etc. by sending the filled in form [AERB/RSD/RT/COM](#). Commissioning permission shall not be granted unless adequate number of full-time staff in Radiotherapy Department as mentioned in clause 4, personnel monitoring badges for all the radiation workers and all the required associated instruments/accessories are available. **Please note that no patient treatment should be started without obtaining the commissioning approval from RSD, AERB**

Periodic Performance/ Quality Assurance test

20. Carryout performance tests of the unit, integrity check of the sources in case of brachytherapy and survey of the radiation installation periodically and maintain all the records, which are to be produced while inspection of Radiotherapy Department of your institution by AERB personnel.

Annual Status Report

21. Send Annual Report on Status of Radiation Safety in Radiotherapy Department in the prescribed format [AERB/RSD/RT/ASR/2K1](#) to RSD, AERB so that it reaches by the end of each calendar year. **Please note that it is a mandatory requirement to submit the report every year.**

All regulatory forms are available at our website www.aerb.gov.in

For Radiotherapy forms the link is as given below

Link: www.aerb.gov.in/t/forms/regforms/radiotherapy/Radiotherapy_forms.html