Guidelines on regulatory requirements for establishing Proton Therapy Facility

1. Introduction

1.1 Proton therapy system

1.2 Facility Description

1.3 Patient treatment

2. Regulatory Requirements for Proton Therapy facility

2.1 No Objection Certificate for Import and Supply

2.2 Layout approval

- 2.2.1 Radiation shielding evaluation

2.3 Procurement permission

- 2.3.1 Staff Requirements
- 2.3.2 Personnel Monitoring Services
- 2.3.3 Measuring and Monitoring Instruments
- 2.3.4 Quality Assurance tools
- 2.3.5 Decommissioning Plan

2.4 Equipment Receipt Intimation

2.5 Commissioning

2.6 Radiological Protection Survey

2.7 License for Operation

- 2.7.1 Radiological Safety Officer
- 2.7.2 Requirements of Staff
- 2.7.3 Measuring & Monitoring Instruments and QA tools
- 2.7.4 Quality Assurance

2.8 Decommissioning

3. Regulatory forms

1. Introduction

1.1 Proton therapy system:

Proton therapy uses proton beams of energy range 70 MeV–250 MeV for the treatment purpose in radiotherapy. Protons show a slow increase in energy deposition with depth leading to a point of maximum energy deposition near the end of range of the proton beam known as 'Bragg Peak'. After the Bragg Peak, the energy deposition falls rapidly. This unique property of proton beam brings various advantages of proton therapy such as significantly decreased dose to normal tissues and practically no dose to healthy tissue beyond the tumour, potential to decrease side effects and complications to normal tissue; ability to treat tumors close to critical normal organs etc. Bragg peak of a mono-energetic proton beam is too narrow and it cannot cover the tumour completely. Therefore, to provide tumour coverage, the Bragg peak can be spread out by superposition of several beams of different energies. These beams are called the Spread-Out Bragg Peak (SOBP) beams. Due to sharp dose fall off after SOBP, the healthy tissues get very low dose and hence spared.

1.2 Facility Description

A typical proton beam therapy facility comprises of Accelerator (Cyclotron), Energy Selection System (ESS), Beam Transport System (BTS) and nozzle and Treatment rooms. The treatment room can be fixed-beam treatment room or gantry treatment rooms or both.

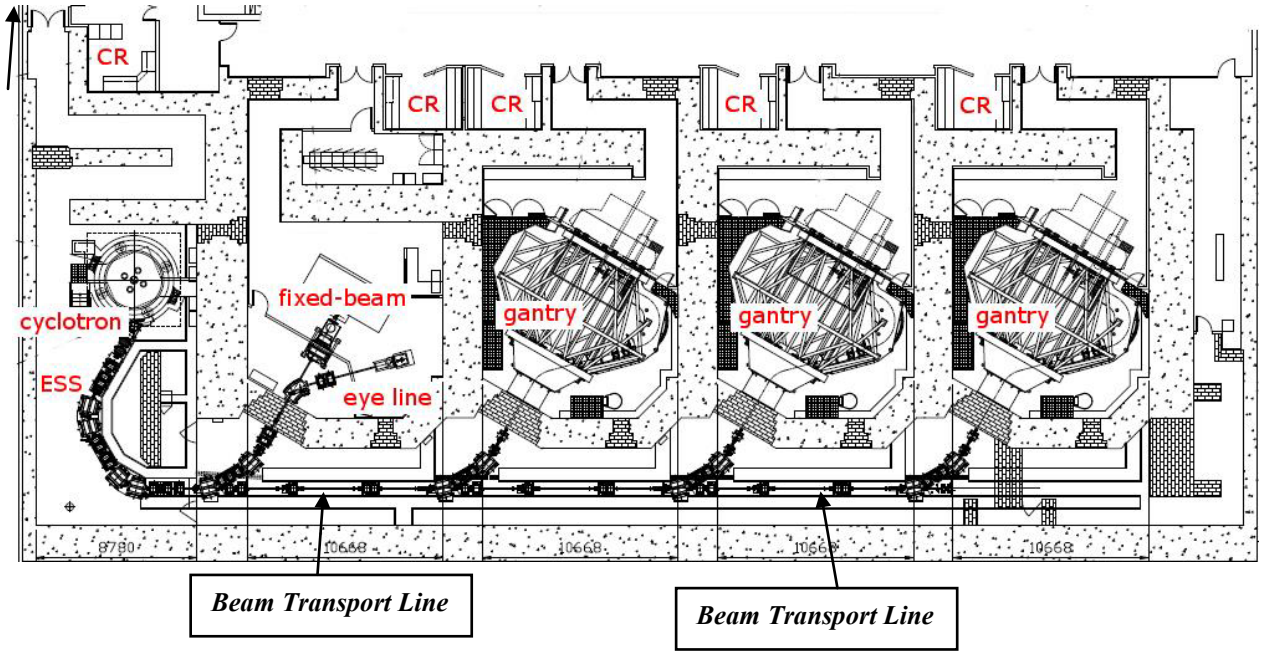

Fig 1: *Typical diagram showing description of the proton therapy facility*

1.3 Patient Treatment

The total prescribed radiation dose is delivered in fractions typically in the range of 2-3 Gy per fraction with total 20–30 fractions. As per the treatment depth, the energy of the proton beam are decided. Intensity Modulated Proton Therapy (IMPT) is one of the technique mostly used for the above purpose.

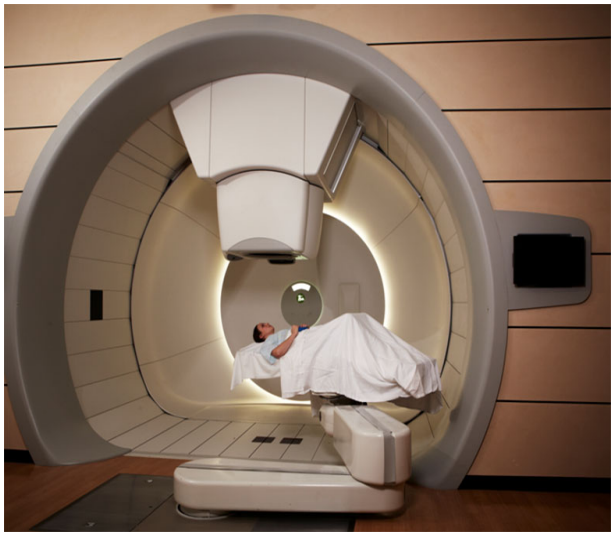

Fig 2: *The treatment of patient using proton therapy*

2. Regulatory Requirements for Proton Therapy Facility

The regulatory requirements for radiological safety are applicable to the supplier of the equipment and the user institutions. These apply to the design & construction, commissioning, operation, and decommissioning stages of the radiotherapy facility. Stages of regulatory requirements for establishing and operating proton therapy facility are elaborated in this document which is given below:

2.1 No Objection Certificate for import and supply

For import & supply of any new model of the radiotherapy equipment, the supplier needs to obtain No Objection Certificate (NOC) from AERB. User institute should verify that supplier/vendor has obtained NOC for import & supply of the equipment from AERB. It may be noted that, License to operate equipment by user institution will not be issued by AERB till supplier demonstrates that the equipment and the facility both comply with AERB requirements.

For obtaining NOC from AERB, local supplier (i.e. Indian supplier) needs to submit application form along with following details w.r.t. radiological safety and performance characteristics for the Proton Therapy Facility:

(i) Manufacturer's design specifications

(ii) Technical details and safety features of proton therapy accelerator

(iii) Design detail including drawing and functional description of the proton therapy system

(iv) A typical layout plan of the proton therapy installation and associated facilities indicating safety systems & interlocks

(v) Built-in safety features/interlocks/operational procedures

(vi) Potential hazards and preventive safety measures to be taken during installation, commissioning, operation & decommissioning

(vii) Radiological safety aspects such as radiation levels due to induced activity, induced gaseous airborne activity and soil activation, induced activity in cooling water, analysis of potential radiation exposure scenarios

(viii) Dose mapping in the accelerator room, occupied areas, and patient treatment rooms during operation, standby and beam delivery, shutdown stages.

(ix) National/international standards to which the equipment conforms

(x) Certificate from the competent authority of the country of origin

(xi) Envisaged Emergency & preparedness plan

(xii) Technical manual

(xiii) Details regarding decommissioning of the facility after its useful life of various equipment.

(xiv) Details of storage facility for activated components and procedures for their disposal

(xv) Repair and maintenance procedure, training program for users etc.

(xvi) Manufacturer's commitment for providing training to the servicing personnel for installation, commission, servicing and maintenance and decommissioning of proton therapy facility and support on spare parts.

2.2 Layout approval

During nuclear interactions of high energy protons with matter, secondary neutrons are produced in addition to gamma radiation. This secondary neutron radiation is predominant in proton therapy facility. Therefore, the objective of layout planning of the proton therapy facility is to protect the radiation workers as well the members of public from neutron dose and photon dose to be considered. There is also production of activated components due to neutron interactions with various parts of the proton accelerator.

For layout approval purposes, an application needs to be submitted to AERB along with the following details:

(i) make/model of equipment,

(ii) maximum deliverable Proton energies and its energy range,

(iii) workload including the treatment, QA & maintenance of the unit,

(iv) the material and density of concrete used for shielding

(v) total number of gantry and fix beam treatment rooms etc.

(vi) Radiation dose estimation to public from likely release of liquid and gaseous activation products from the facility

The layout of facility including detailed room design of the treatments rooms, cyclotron/synchrotron room, beam transport line, storage of activated components, etc., needs to be submitted. Apart from the floor layout plan, all the relevant cross sections and the site layout plan showing the occupancy all around the installation also needs be submitted. The entrance door to the treatment room as well as the door to the cyclotron/synchrotron room should have interlocks. The location of the entrance door should be such that the operator can supervise it to avoid unauthorized entry during the operation.

2.2.1 Radiation shielding evaluation

The basic method of evaluation of the shielding requirements of Proton therapy facility are generally by hybrid mode i.e. analytical and Monte Carlo methods.

The analytical methods are easy to use and have the advantage of rapidly providing an estimate of the dose rates behind the shield. On the other hand, many aspects of the neutron transport physics are simplified and the models are limited to simple planar geometries.

For geometries as complex as a proton therapy room, these limitations often result in large errors on the calculated doses outside the room. Therefore, Monte Carlo technique is used for shielding evaluation which is helpful in computing the neutrons generated from high energy proton beam, estimating dose due to high energies neutrons at a depth in concrete.

From radiation protection view point as a conservative approach neutron produced for the lowest extracted proton energy is considered for shielding evaluation at the degrader point and maximum available proton energy is considered for the shielding evaluation of treatment rooms. Along the beam transport line the neutron production varies depending upon the reduction in the proton current.

The most preferred shielding material used is concrete as it contains hydrogen. Hydrogen is a very effective neutron moderator because of (i) its high elastic scattering cross-section and (ii) its small mass as a target nucleus which allows for large energy transfers during an elastic collision.

Concrete also has advantages e.g. (i) it effectively attenuates photons, (ii) it has sufficient structural strength to support a building, (iii) it can be poured in almost any configuration, and (iv) it is relatively inexpensive.

2.3 Procurement permission

User institute needs to submit the required application form to obtain authorization for procurement of Proton therapy accelerator along with following details:

2.3.1 Staff Requirement

Provision for appointment of adequate number of qualified staff such as Radiation Oncologists, Medical Physicists and Radiation Therapy Technologists should be made available. At least one Radiation Oncologist, one Medical Physicist and two Radiation Therapy Technologists per gantry room per shift will be considered to be adequate. Further, the qualification of the staff shall meet the requirement as stipulated in AERB Safety Code AERB/RF-MED/SC-1(Rev.1). 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). In case the above said staffs are not trained for Proton therapy facility, then details of the action plan for their training in Proton therapy facility need to be provided.

2.3.2 Personnel Monitoring Services

Provision to avail appropriate personnel radiation monitoring badges for estimation of neutron and photon dose should be made from the recognized agency for all the radiation workers.

2.3.3 Measuring and Monitoring Instruments

Provision for procurement of appropriate measuring and monitoring instruments (in case not available) should be included in the application to establish the facility. Appropriate measuring instruments required for proton therapy facility are explained in subsequent section. Monitoring instruments includes area monitors survey meter etc. for photon and neutron radiation level in and around proton therapy facility. The user needs to ensure that the neutron survey meter are calibrated and sensitive to the neutron energy ranges likely in the proton therapy facility.

2.3.4 Quality Assurance(QA) tools

Provision should be made for procurement of appropriate quality assurance tools for carrying out measurement to ensure the performance of the equipment. To determine appropriateness of the above QA tools, facility may consult with the supplier/Medical Physicist.

2.3.5 Decommissioning plan

The term decommissioning refers to set of actions at the end of the useful life of a particular facility, or when a facility ceases to be utilized for its intended purpose. Such facility should be duly decommissioned before the site and building premises are made available for other uses. Decommissioning needs to be carried out in a systematic manner to ensure safety of the workers, environment and public. Decommissioning plan for the Proton Therapy system should be prepared and submitted. Decommissioning plan includes activities such as planning, physical and radiological characterization of facility, site decontamination, dismantling, materials management, final radiation survey and release of the facility for unrestricted use with due approval from AERB. It is advisable to make plans for decommissioning at the time of procurement of Proton therapy facility including financial provisions for decommissioning.

2.4 Equipment receipt intimation

Intimation of receipt of the Proton therapy system at the facility premises should be submitting using required application form under list of forms in section 3.

2.5 Commissioning

Prior to applying for regulatory consent/authorization for commissioning approval, user institute should ensure that construction is completed as per layout plan approved by AERB. It is necessary that adequate numbers of qualified & trained radiotherapy staff, neutron and photon personnel dose monitoring badges for staff, requisite measuring, monitoring & QA tools are available for obtaining commissioning approval. Commissioning approval may be issued by AERB in multiple phases. These phases are beam generation in cyclotron/synchrotron, beam extraction up to degrader, beam extraction till subsequent gantry rooms to carryout radiological protection survey and carrying out acceptance test & Quality Assurance (QA) of the equipment.

The user should approach AERB after completion of each phase for obtaining requisite commissioning approval for next phase along with details of staff with training certificate in proton therapy facility, details of personnel monitoring, details of measuring, monitoring and QA tools and emergency preparedness plan as per the prescribed format.

2.6 Radiological Protection Survey

After obtaining commissioning approval for each phase, a radiation protection survey is required to be carried out and survey report needs to be submitted to AERB as mentioned in the commissioning consent. Radiation protection survey should include energy, beam current, duty cycle etc. of proton beam; neat sketch of approved layout indicating complete dose map at the adjacent locations, nature of occupancy, cardinal gantry angles, maximum dose rate at which survey carried out, details of instrument used for survey etc. After approval of radiation protection survey report, performance tests should be carried out as per AERB acceptance test criteria and customer acceptance protocol.

2.7 License for operation

User institute needs to submit required application form to obtain License for operation of Proton therapy facility. The following are the requirements for issuance of the license for operation.

2.7.1 Radiological Safety Officer

Radiological Safety Officer having appropriate qualification and training in proton therapy should be available.

2.7.2 Requirements of staff

Adequate number of Radiation Oncologists, Medical Physicists and Radiotherapy Technologists having appropriate qualifications and training in proton therapy should be available considering number of treatment rooms and working shifts**.** All the radiation professionals working in Proton therapy facility should be provided with personnel monitoring services for neutron and photon dose estimation.

2.7.3 Measuring & Monitoring Instruments and QA tools

Parallel plate chamber (PPC) for output measurements, Radiation Field Analyser for beam data generation, large volume PPC for Integrated Depth Dose (IDD) measurements, phantoms for patient specific QA and other instruments required for dosimetry tests should be available in the facility. Appropriate neutron & photon survey meter as well as photon & neutron area monitors should be provided at appropriate places such as accelerator (cyclotron/synchrotron) vault, control console, energy degrader, beam transport line, treatment room console etc. Appropriate QA tools for carrying out measurement to ensure the performance of the equipment should be available in the facility.

2.7.4 Quality Assurance (QA)

Quality assurance test for performance of the equipment should be provided as per required format and also as per manufacturer's Customer Acceptance Protocol including the details of the tools used to carry out each tests.

2.8 Decommissioning

User institute needs to obtain consent from AERB for decommissioning of Proton beam therapy facility along with following details:

i. Consent from supplier for decommissioning and transportation of radiation contaminated material, if any, to the concerned agencies for safe management after obtaining approval from AERB
ii. Availability of RSO
iii. Availability of requisite monitoring instruments
iv. Action plan for removal of activated parts of equipment & room walls/flooring/ceiling and their disposal

After decommissioning the facility, permission from AERB needs to be obtained for release of site/premises from regulatory control.

3. Regulatory forms

For obtaining various regulatory permissions, regulatory forms as mentioned in section 2 are listed below:

3.1 Application for issuance of No Objection Certificate (NOC) for import and supply of Hadron Therapy Accelerator (AERB/RSD/Hadron/NOC)

3.2 Application for Layout Plan approval of Hadron Therapy Facility(AERB/RSD/Hadron/Layout)

3.3 Application for Issuance of Authorisation for procurement of Hadron Therapy Accelerator (AERB/RSD/Hadron/ATH)

3.4 Intimation regarding receipt of Hadron Therapy Accelerator (AERB/RSD/Hadron/SRI)

3.5 Application for Issuance of Commissioning Permission for Hadron Therapy Accelerator (AERB/RSD/Hadron/COM)

3.6 Performance test report for Hadron therapy accelerator: AERB/RSD/RT/ATR/ HADRON ACC

3.7 Application for Issuance of License for Hadron Therapy Accelerator (AERB/RSD/Hadron/LIC)

3.8 Application for Issuance of Decommissioning of Hadron Therapy Accelerator (AERB/RSD/Hadron/DECOM)