Regulating Medical and Research Activities using Ion Technology

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In the presentation…

- Applications of Ion Beam Technology in Medicine and Research
- Ion Beam Technology in India
- Configuration and Classification of Accelerators
- Regulation of Ion Beam Technology in India
- Conclusion

Applications of Ion Beam Technology in Medicine

- Proton and Heavy Ions for treatment of Cancer
  - First patient treatment: Proton Therapy (1954), Heavy Ion Therapy (1977)
  - Advantageous due to higher Radiobiological Effectiveness and reduced integral dose to normal tissues
  - Mostly used Proton up to 250 MeV and Carbon Ion up to 430 MeV/u

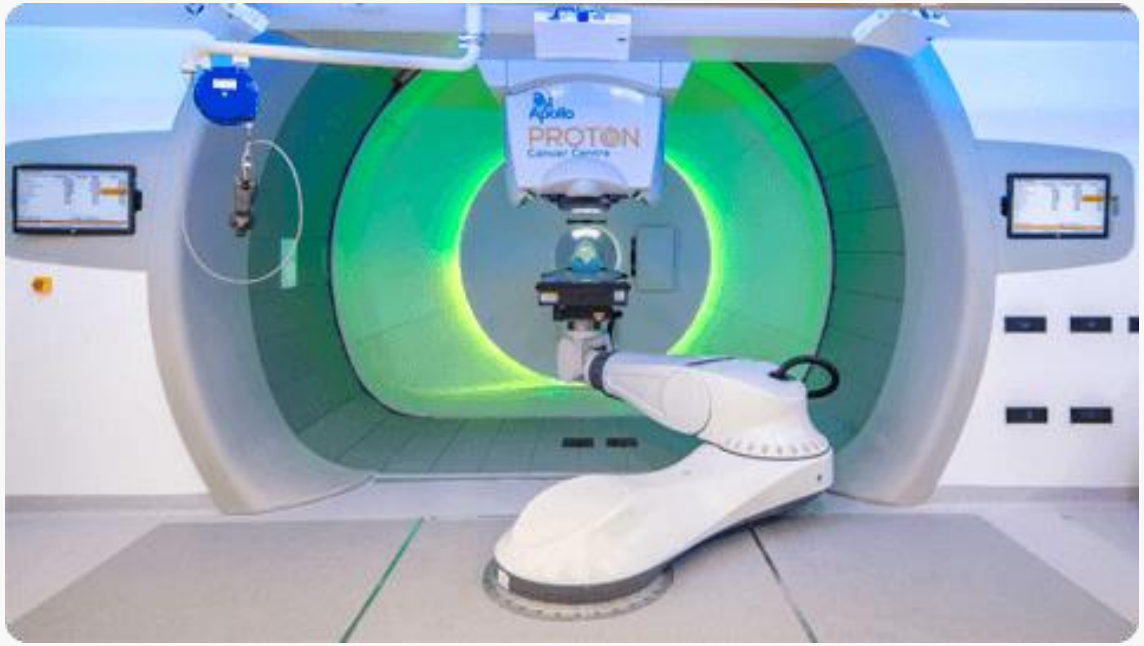
- Medical Cyclotron for production of radiopharmaceuticals
  - Cyclotron of 9 MeV to 30 MeV
  - Radioisotope mostly produced is ^{18}F (for FDG) used in PET apart from ^{11}C, ^{13}N and ^{15}O
  - Other isotopes include ^{64}Cu, ^{67}Ga, ^{86}Y, ^{103}Pd, ^{123}I, ^{124}I and ^{201}Tl

Applications of Ion Beam Technology in Research

- Ion Beam Accelerators for Research
  - HV DC type-using electrostatic fields, Radio-frequency acceleration in circular machines, Radio-frequency linear acceleration and Laser based accelerators
  - Particles accelerated: Light ions such as H^+, H^- Deuteron, He^{++} ; Medium and Heavy Ions such as C, O, Si, Ni, U
  - Research area include Material Science, Atomic Physics, Nuclear Physics, Particle Physics, Biology, Environmental Science etc.

Ion Beam Facilities for Medicine in India (1/2)

- One proton therapy facility with two gantries (operational), one fixed beam (under commissioning)
- Two more proton therapy facilities (under construction)
- One Carbon therapy and one Proton therapy (under planning stage)



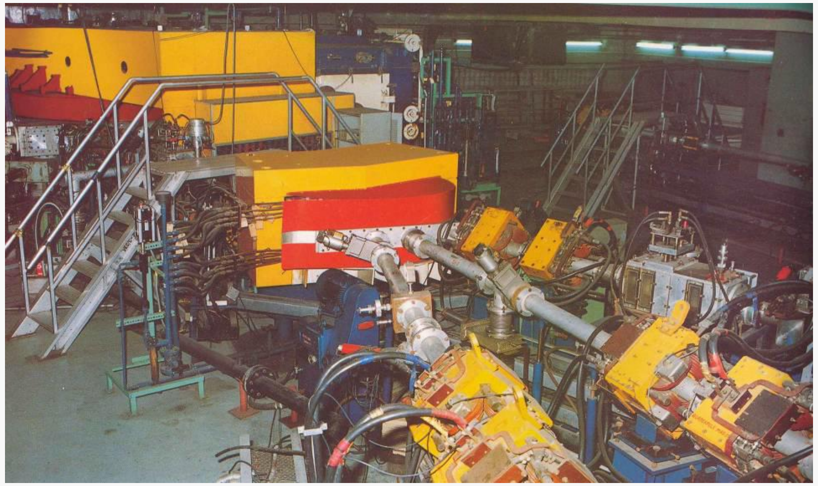
Ion Beam Facilities for Medicine in India (2/2)

- 21 Medical Cyclotron facilities with energy up to 18 MeV are operational, which supply F-18 based radiopharmaceuticals to Nuclear Medicine Centres in the country

- One 30 MeV Medical Cyclotron with 5 beam lines are under commissioning

Ion Beam Facilities for Research in India (1/2)

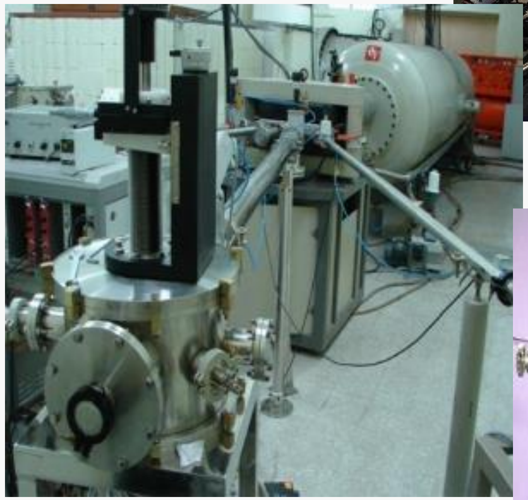
- Variable Energy Cyclotron with Proton energy (6-60MeV), Deuteron energy (12-65MeV) Alpha energy (25-130MeV)



- Super-conducting Cyclotron to accelerate light heavy ion up to 80 MeV/u and medium heavy ions up to 10 MeV/u (under commissioning)

Ion Beam Facilities for Research in India (2/2)

- Two 1.7 MV Tandetron Accelerators
- Two 3 MV Tandetron Accelerators (1 u/construction)
- Three (12 MV, 14 MV and 15 MV) Tandem Pelletron Accelerators
- Two (14UD and 15 UD) Pelletron Accelerators
- Two 14 MeV Neutron Generator through acceleration of H^+ or D^+ ion (1 under construction)
- Folded Tandem Ion Accelerator
- Low Energy Ion Beam facility
- Low Energy High Intensity Proton Accelerator of 20 MeV (under commissioning)
- Radioactive Ion Beam Facility (under construction)



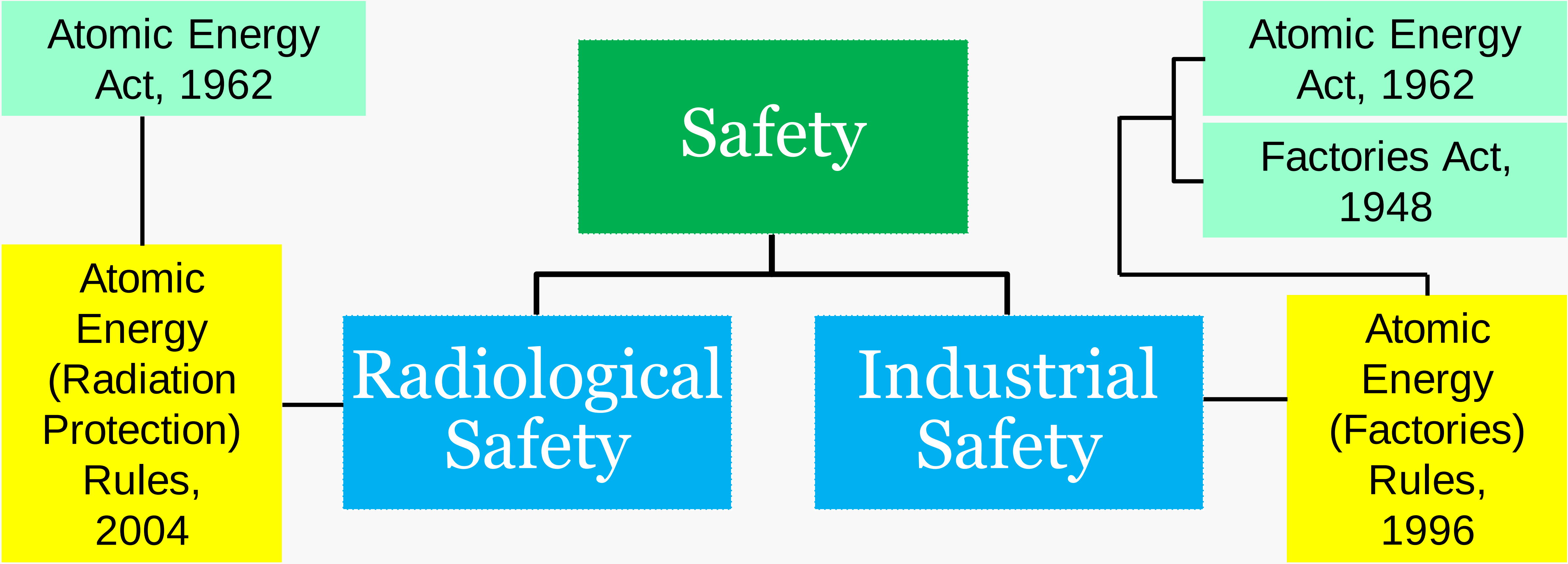
Generic Configuration of Accelerators : Sub-systems

- Accelerating system with electrical input power, high voltage DC/RF power
- Magnets for guiding or analysing the beam
- High vacuum systems to enable transport with minimum loss and maximum KE
- Steering and focusing electric & magnetic field in beam transport systems
- Radiation shielding for radiation produced through interaction in the pathways
- Beam diagnostics and control systems
- Gases like SF6 for high voltage insulation
- Ventilation system to bring down the conc. of toxic gases, chemicals and airborne activity
- Cooling systems using water/air for magnets, accelerating cavities, targets and beam dumps
- Cryogenic systems involving superconducting devices like cavities and magnets
- Appropriate interlocks and access control systems
- Facilities for radioactive material handling, storage, waste storage and disposal etc.

Classification of Accelerators : Graded Approach

- Class I Accelerators: Incapable of producing accidental dose >1 mSv
  - Low beam power, particle energy within elastic scattering range, inherently safe
- Class II Accelerators: Potential to produce accidental dose up to 3 times of annual dose limit
  - Low beam energy up to 6 MeV/nucleon except deuteron
- Class III Accelerators: Potential to produce accidental dose more than 3 times of annual dose limit but unlikely to produce lethal dose
  - exclude possibility of whole body exposure, mostly self-shielded accelerators
- Class IV Accelerators: Potential to produce accidental dose more than 3 times of annual dose limit to whole body and may be lethal
  - Effective dose rate 1 mSv/h at 30 cm, capable of producing airborne activity, ex. spallation or photonuclear neutron source facility and radioactive ion beam (RIB) facility

Legal Frame Work for Safety Regulation



Regulatory Stages for Ion Beam Accelerators

- Consent for Siting
  - Only if, facility can cause impact on the surroundings
- Consent for Design and Construction
  - Based on review of Preliminary Safety Analysis Report
- Consent for Commissioning and Trial Operation
  - Based on satisfactory construction as per approved design
- Licence for Routine Operation
  - Based on review of Final Safety Assessment Report
- Consent for Decommissioning
  - With due management of residual activity

Safety Review during Licensing (1/2)

- Radiation Shielding (Passive Protection)
  - Sources of Radiation (Source Term); Shielding Design of Accelerator
- Engineered Protection System (Active Protection)
  - Safety Interlocks; Access Control System (Zoning); Search and Secure Procedure; Emergency Manual Shut-down; Alert and Caution System; Administrative Controls and Work Permit System
- Radiological Protection
  - Staffing/Safety Personnel; Personnel Dose Monitoring; Area Radiation Monitoring; Monitoring of Visitors

Safety Review during Licensing (2/2)

- Residual Activity
  - Possibility of activation of component and airborne activity; Handling Storage and Disposal of Radioactive Materials; Degradation due to Radiation Damage
- Non-radiological Safety
  - Industrial Safety and Occupational Health; Fire Safety; Non-ionizing Radiations and Fields; Electrical Safety; Ventilation; Cryogenic Safety
- Other Documents reviewed
  - Maintenance Programme; Training of Personnel; Quality Assurance Manual; Emergency Preparedness; Decommissioning Plan

During Operation of the Facility

- Review of Periodic Safety Report submitted by the facility
  - Radiological Safety Officer (RSO) submits periodically Safety report through Licensee to demonstrate compliance to safety requirements during useful life
- Inspection and Enforcement
  - To verify compliance to safety requirements and initiate enforcement action, if required

Conclusion

- In India, we have a robust regulatory framework to regulate Ion Beam Technology
- Regulation of Ion beam applications is challenging due to
  - non-routine nature of the work in research, non-standard design of the facility, selection of appropriate measuring instruments, involved quality assurance measures and limited operational feedback.
- Though we have specific regulation for particle accelerators, regulation for use of ion beam for therapy is under progress

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