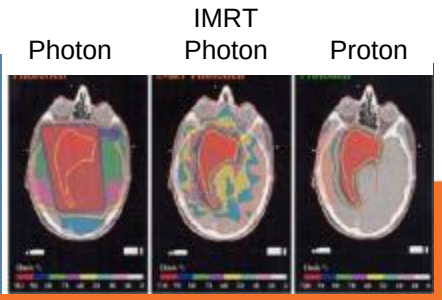
COCIR

Sustainable Competence in Advancing Healthcare



International Atomic Energy Agency – IAEA

International Conference on Occupational Radiation Protection

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How to cope with Basic Safety Regulation for which the IAEA Guidelines do not exist ?

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The case of Proton Therapy- Current difficulties in field of international standardization

1. **IAEA Safety Standards for protecting people and the environment - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards: General Safety Requirements Part 3**
   - As of Today, no International *Criteria for Acceptability of Medical Radiological Equipment are published*

2. **As currently, Radiation protection standards are maintained by the already existing International Scientists Committees and Users Experts**

- What is the process for defining new standards for Novelty equipment such as Particle Therapy ?
  - e.g., in EU, the *"RADIATION PROTECTION N° 162 - Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy",* does not include criteria for Particle therapy
  - e.g., in India, to get the *"Authorisation from RSD/AERB before producing beam with the accelerator is planned to be based on the specifications from our authorization letter",* but no specifications are defined yet!

Current state: Regulatory framework

- Member states and international organizations are implementing these into the Regulations and standards as for example:
  - EU COUNCIL DIRECTIVE 2013/59/EURATOM (BSS)
  - US NRC (10 CFR) and US DOT (49 CFR)
  - India Atomic Energy Act 1962 , India Environmental Protection Act, 1986. AERB….
  - Radiological Equipment is making a broad usage of ICRP (1950 and 1928 for IXRPC the forerunner of ICRP) & ICRU (1925) standards and other guidelines (EU-RP, AAPM…)

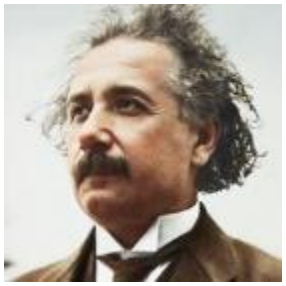
ADDITIONALLY

- Free-market economies set rules for the placing on the market and the post-market vigilance, as for example the:
  - EU Council Directive 93/42/EEC, US FDA regulation (21 CFR), Brazil Good Manufacturing Practice as found in RDC 16/2013, …
  - ISO and IEC standards through regional/national representative to ISO/IEC

Manufacturers' Perspective

- Medical devices for radiology or radiation therapy have long development and innovation cycle which ranges between 5 and 7 years (up to 11 for particle therapy)
- Manufacturers need a legislative and regulatory framework and transitional periods stable and flexible enough to allow for nimble development processes as large and complex equipment need lithe processes to be compatible with such long duration of cycles.
- The actual situation impacts companies:
  - Increasing costs and burden by lack of harmonization in the acceptance criteria
  - Increasing the time to market by multiplication and variance in acceptance reviews country/region per country/region
- The consequences of the actual situation are:
  - Reduced access to healthcare and critical diagnosis or treatment for patients
  - Reduced ability to innovate due to reduced available resources
  - Increased time to bring on the market new innovative technologies and their benefits for patients.

Conclusions



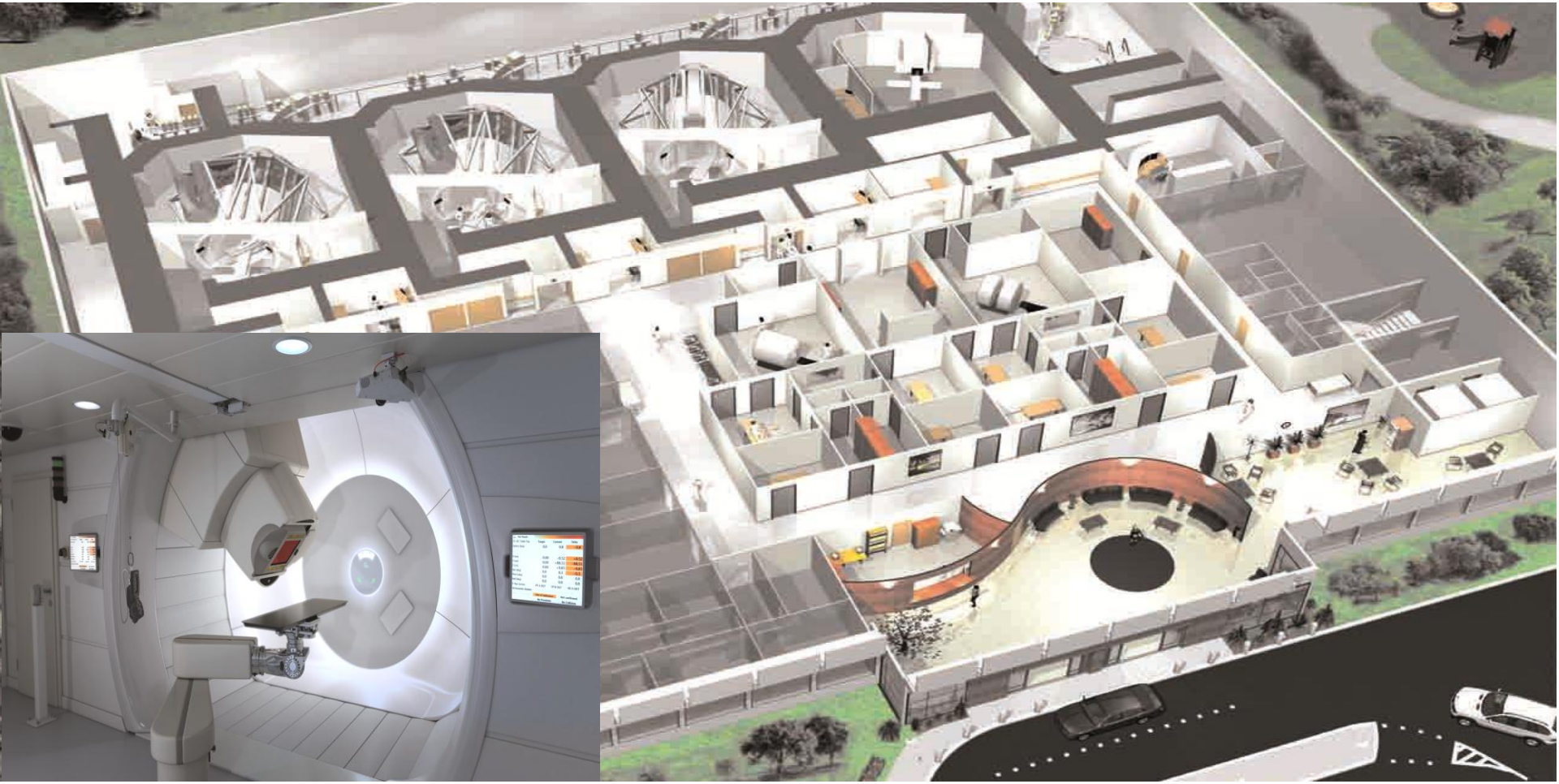
"You can never solve a problem with the same kind of thinking that created the problem in the first place." Albert Einstein

- With innovation and the rapid advancement of technologies, medical devices are currently one of the fastest growing industries. A new framework needs to be introduced :
  - International integration of RP safety and performance standards
  - International co-operation organisation for Accreditation of QPs in RP and CLs in RP

- Due to continued globalization of the free-market economies and the integration of the emerging economies, Governments are encouraged to follow the growing movement towards harmonized regulatory systems. The new global framework will protect Users and Governments for allowing them to place emphasis and initial resources on areas such as vendor and device registration, training, and surveillance and information exchange systems on the assessment of medical devices in use.

Practical case: Particle Therapy

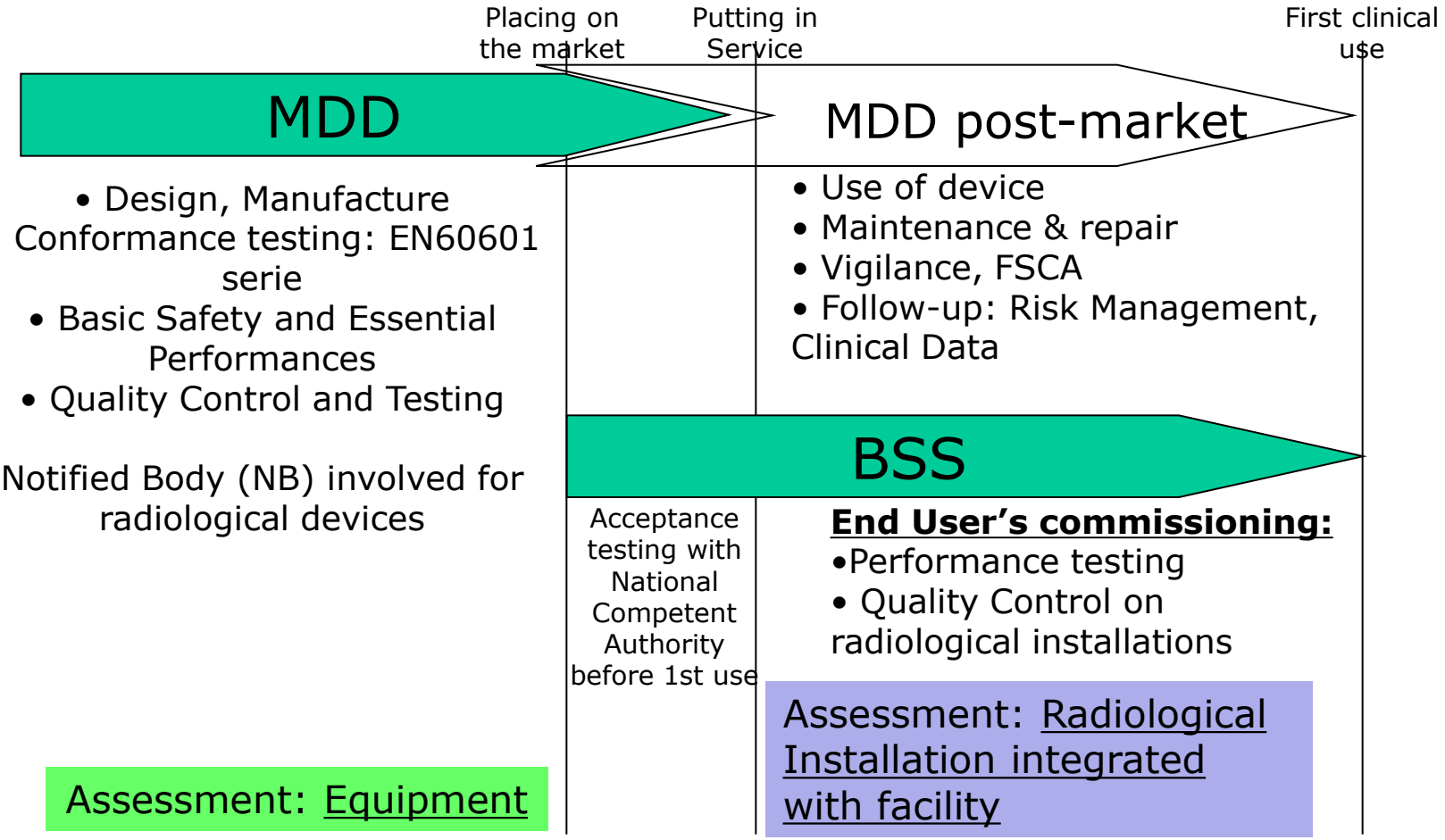
Particle Therapy Center



Annexes

Implementation in Radiotherapy in the EU

European Commission ensuring Commissions Directorates for the Council Directive 93/42/EEC on Medical Devices (MDD) and for Euratom Basic Safety Standards (BSS) - COM(2011) 593 final 2011/0254 (NLE) are cooperating as to keep consistency in the implementation of these two directives that concern the **External-beam Radiotherapy devices** is illustrated below:



Current difficulties in field of international standardization

3. Acceptance criteria are subject to adjustments from each Qualified Person (QP) in RP, or an Accredited Competent Laboratory (CL) in RP to is involved in each different country
   - This is going against all the current trend of internationalization and harmonization of best practices in Radiation Protection

Avenues for improvement

for conformity assessment of the new Medical Devices using Ionizing Radiation

- Government Authorities or third party Notified Bodies responsible for the marketing clearance or the pre-market assessment should involve a Qualified Person (QP) in RP, or an Accredited Competent Laboratory (CL) in RP in the kind of Device under assessment
- The Qualified Person should confirm that all the safety and performance requirements of the IAEA BSS and the RP standards specific to the specific type of Device are implemented
- An International co-operation organisation for Accreditation of QPs in RP and CLs in RP (e.g., under IAEA authority) should be installed as a network of nationally recognised accreditation bodies to:
  - Maintain a system of mutual recognition between accreditation schemes and reciprocal acceptance of accredited conformity assessment services and results
  - managing a peer evaluation system consistent with the international practices