Sustainable Competence
in Advancing Healthcare

IAEA International Conference on Radiation Protection in Medicine

IAEA Headquarters Vienna, Tuesday 12 December 2017

Breakout Session

30 years of regulating medical exposures: progress so far, challenges and opportunities

Manufacturers' Perspective

Nicole Denjoy

COCIR Secretary General & DITTA Vice-Chair

THE BSS DIRECTIVE

- The medical technology sector in Europe represented by COCIR is highly technological and innovative, with around **28 billion € total turnover and 7 to 8% of annual revenues invested in research and development**.
- COCIR Companies welcome the new BSS Directive and are ready to be compliant by February 2018.
- COCIR is happy about the collaboration established with DG ENERGY, other involved DGs (DG SANTE, DG GROW) and HERCA on the practical implementation of this important legislation.

COCIR CONCERNS

COCIR has a few concerns on the lack of harmonization and practical implementation of the Directive:

1. **Justification**: The lack of **mutual recognition** in Europe may delay adoption of innovative technologies, affecting benefits to patients.
2. **Acceptability criteria and constancy testing:** there will continue to be differences at national and local level with little or no recognition given to state of the art international standards.
3. **Documentation**: Manufacturers provide to undertakings documentation according to **CE marking** containing **all the information required for safe use.** The additional requirements on information, e.g. article 78, may end up in local interpretations requiring a **duplication of documentation** adding a **significant burden** on manufacturers with no benefits for undertakings.

Sustainable Competence
in Advancing Healthcare

BACKUP SLIDES
Additional information on COCIR concerns

ARTICLE 60.1.D)

(d) acceptance testing is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any maintenance procedure liable to affect the performance

- CE marked medical devices are compliant with harmonized IEC standards
- Type-testing, review of technical documentation by notified body is enforced for CE-marking
- Unique approach for acceptance testing is already existing based on standardized manufacturer protocols demonstrating compliance with applicable standards, performance according to product specifications and safety
- Country specific acceptance criteria / acceptance test procedures for equipment providers do constitute an unnecessary burden

COCIR wishes that **competent authorities promote acceptability criteria and methods based on internationally recognized standards** and common technical content (metrics, test objects, etc.)

ARTICLE 60.3.B)

(b) equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters. Equipment installed prior to 6 February 2018 may be exempted from this requirement

- Devices from COCIR Members have been equipped with such devices for many years based on international standards requirements
- According to the standards applicable to each technology, a set of well defined "key treatment parameters" are displayed and controlled, to ensure that the ongoing treatment is fully under control. An example of some of such parameters is:
  - Radiation Type / Energy
  - Dose output
  - Geometrical Parameters (Field Size/Gantry/Collimator/MLC/Table)
  - Patient Identification
- **The definition of such parameters should be as harmonized as possible to avoid the introduction of technical barriers among different Member States.**

ARTICLE 78.2 AND 78.1

1. Member States shall ensure that any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided with adequate information about its potential radiological hazards and its proper use, testing and maintenance, and with a demonstration that the design permits to restrict exposures to a level which is as low as reasonably achievable.
2. Member States shall ensure that any undertaking acquiring medical radiological equipment is provided with adequate information on the risk assessment for patients, and on the available elements of the clinical evaluation.

- CE-marked equipment complies with EN 60601 and in particular 60601-1-3 for diagnostic imaging, which requires already to provide to responsible organization (undertakings) in **accompanying documents, any information helping to understand, justify, control, and optimize the irradiation consecutive to procedures.**