



**COCIR**

**SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE**

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

# ECODESIGN – STANDARDIZATION IN THE MEDICAL IMAGING SECTOR

COCIR 6<sup>th</sup> ANNUAL FORUM

ON THE SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING DEVICES

# ECODESIGN STANDARDS IN THE MEDICAL SECTOR

- **IEC 60601-1-9:2007** Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
- The objective of this collateral standard is to improve the environmental impact for the entire range of medical electrical equipment, taking into account all stages of the product life cycle:
  - product specification;
  - design;
  - manufacturing;
  - sales, logistics, installation;
  - use;
  - end of life management.
- The criteria needed to reach this goal must be integrated into all stages of the medical electrical equipment life cycle from the specification stage to end of life management.
- **The acceptability of medical electrical equipment's environmental impacts are balanced against other factors**, such as the product's intended function, performance, safety, cost, marketability, quality, legal and regulatory requirements. A manufacturer of medical electrical equipment might have to justify, as a result of risk management, that a medical benefit outweighs the associated adverse environmental impacts.

# SUCCESSOR TO 60601-1-9

- A new standard, not included in the 60601 series was deemed a better solution than trying to update the “-9”.
- A new proposal has been developed in 2016, with the aim to publish a successor by 2019
- Withdraw 60601-1-9 and use the new standard IEC 6XXXX around 2024.
- The NP was approved by 78% of the voting SC62A members on February 2017, more than needed.
- Only 2 NCs nominated experts, namely IT and CH. For approval 5 NCs that have voted positive are needed that delegate an expert to the project.
- If not enough experts are nominated we will be required to start the project from scratch and we will see a delay of approx. one year.

# SUCCESSOR TO 60601-1-9 ELEMENTS TO BE CONSIDERED

- **DESIGN FOR CIRCULAR ECONOMY**

- Design for durability, reusability, reparability (reference docs: EC studies and mandates for standards on material efficiency)
- Reuse of parts for repair, refurbishment, maintenance, new devices
- Chemicals management in reuse:
- Closed loop B2B take back system:

- **ENERGY EFFICIENCY**

- **Energy efficiency:** the findings of the COCIR SRI can be used as a basis to integrate the already existing sections in IEC60601-1-9

# SUCCESSOR TO 60601-1-9 ELEMENTS TO BE CONSIDERED

- **MANAGEMENT OF HAZARDOUS CHEMICAL**
  - REACH flow of information
  - IEC63000
  - Use of recycled materials
  - Substitution process

# SUCCESSOR TO 60601-1-9 ELEMENTS TO BE CONSIDERED

## GREEN PUBLIC PROCUREMENT

- **Evidence to be provided for tenders:** *the standard should specify which information are sufficient to be provided in the context of a public procurement to satisfy the information requests:*
  - *Energy efficiency or energy consumption*
  - *Existence of a refurbishment/closed loop take back system*
  - *Proper hazardous chemical management system*
  - *Social responsibility (?)*
  - *Conflict mineral due-diligence system*