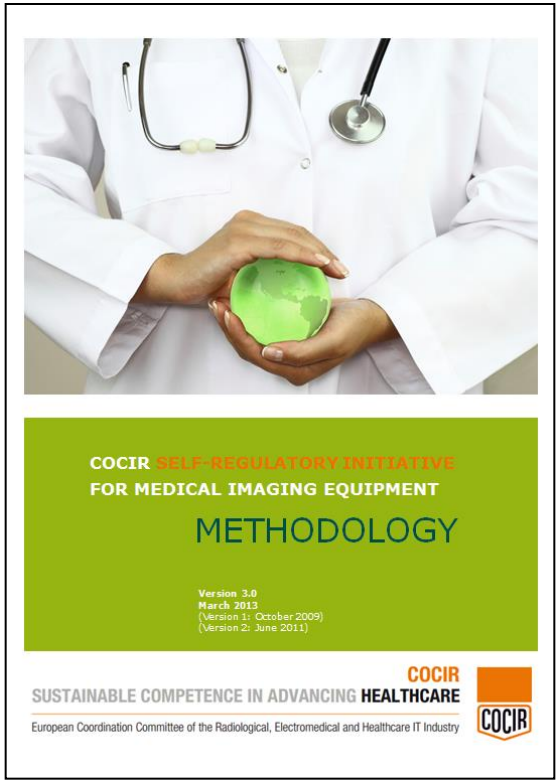
Sustainable Competence in Advancing Healthcare

COCIR SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING EQUIPMENT

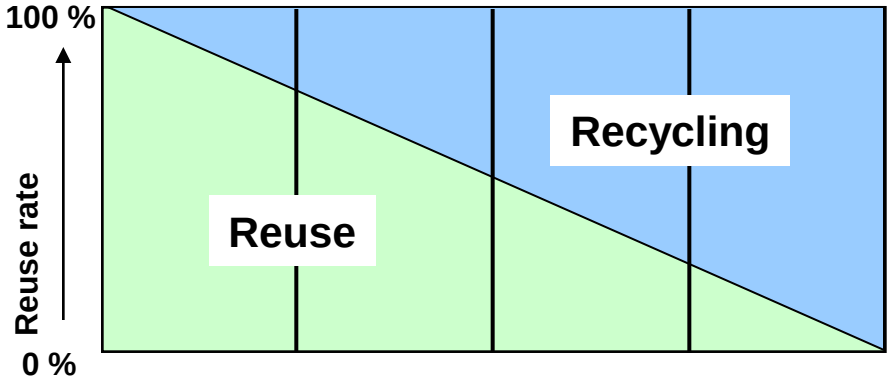
RESOURCE EFFICIENCY AND COCIR SRI

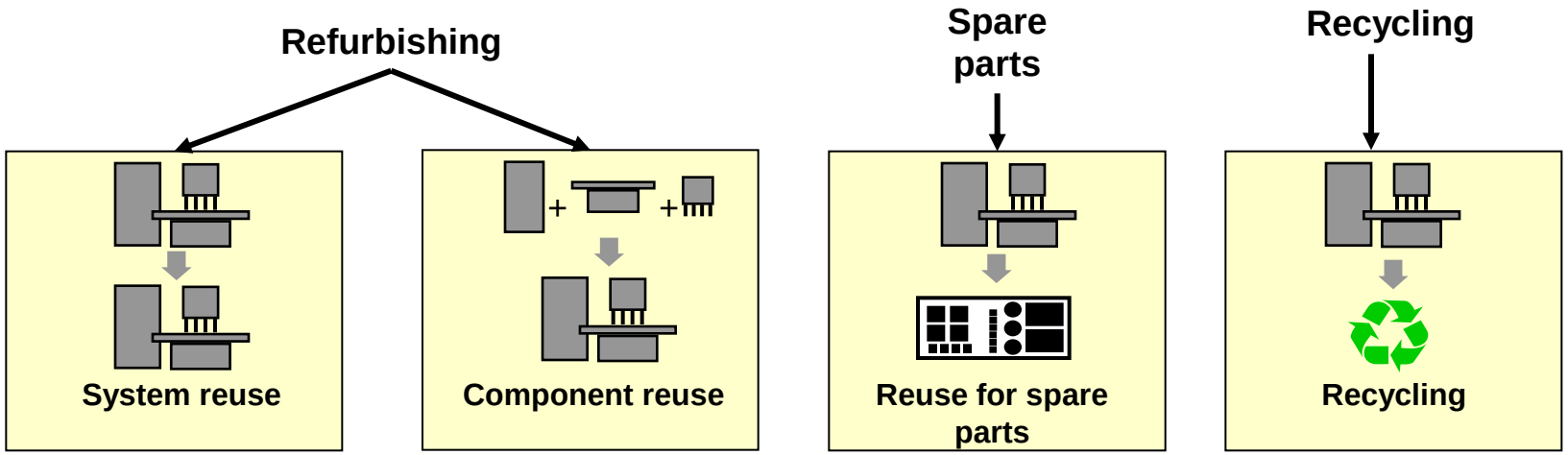


RESOURCE EFFICIENCY

- Resource efficiency means using the Earth's limited resources in a sustainable manner.
- Many initiative now undergoing in EU:
  - Development of indicators
  - Development of methodologies (Environmental footprint)
  - Development of resource efficiency parameteres (reusability/recyclability/recoverability-RRR, use of relevant resources, recycled content, use of hazardous substances, durability)
  - Integration of RE and waste management
- COCIR supports advanced activities in the field of resource efficiency.

End of Life Strategy

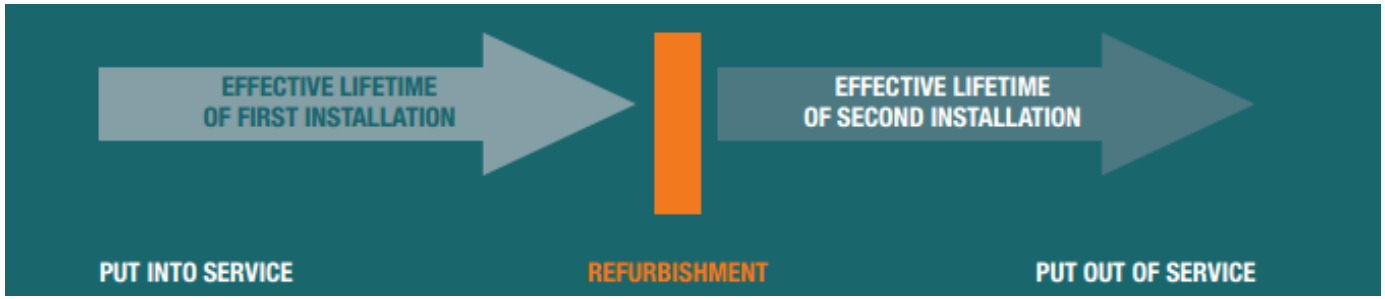




WHAT DOES GRP STAND FOR?

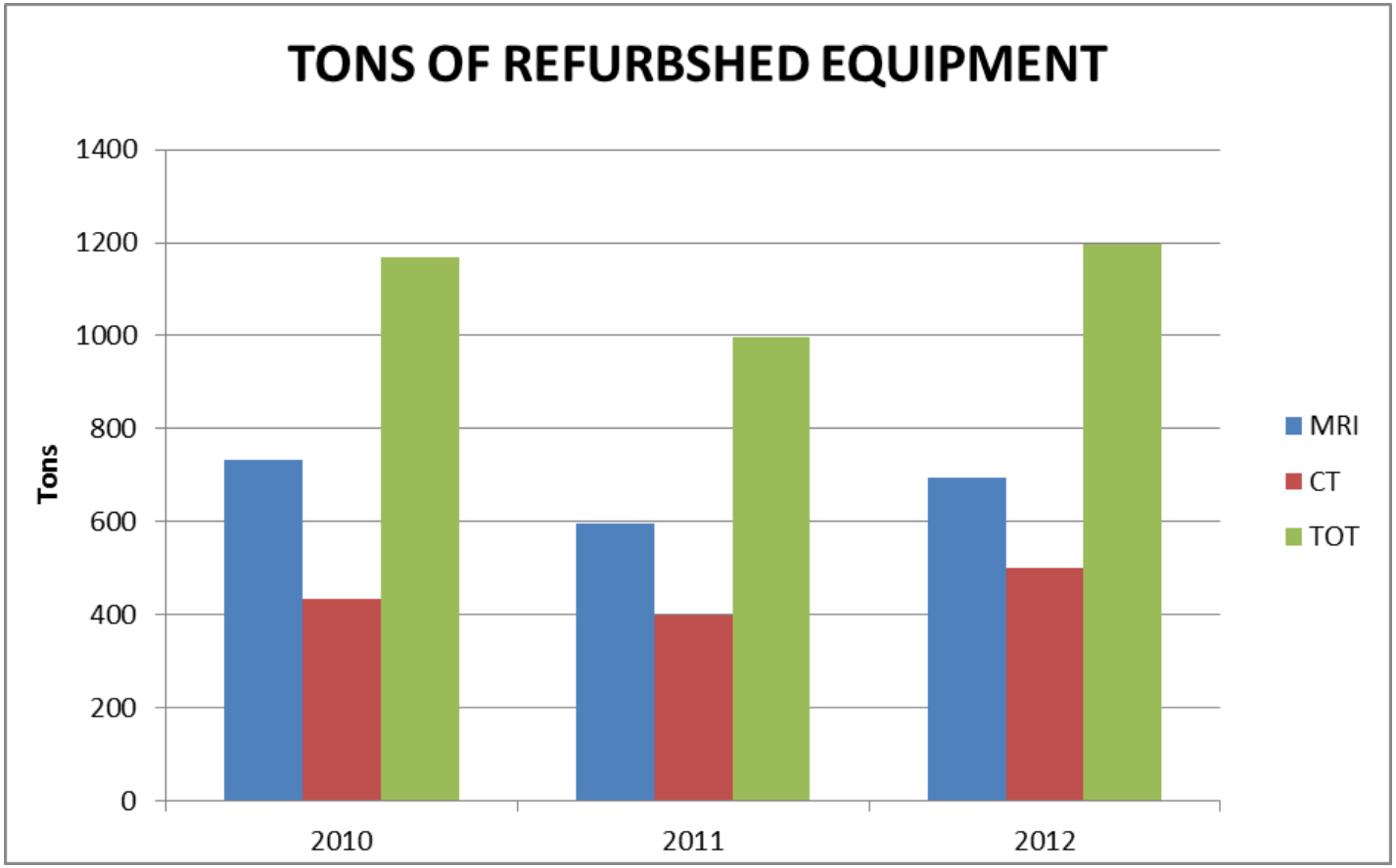
- GRP = Good Refurbishment Practice
- GRP is currently a synonym for 'manufacturer refurbishment'.
- Used medical devices re shipped to the manufacturer and processed to restore safety and performancesas when new (including all relevant updates)
- GRP is not touching the regulatory scope for medical imaging devices
- In 2009 the GRPv2 paper was released together with an Industry Standard.
- GRP is a globally perceived approach which is supported by COCIR, MITA and JIRA.

REFURBISHMENT



- Refurbishment is a form of re-use of whole equipment. It extend the lifetime of the medical equipment, ensuring at the same time that safety and performances when the equipment was new are maintained (or even improved).
- Refurbishment prevents equipment to be wasted

TONS OF REFURBISHED CT/MRI



REGULATORY LANDSCAPE AFFECTING REFURBISHMENT

- **WEEE II Directive:**
  - Limits shipments of used equipment for refurbishment (and repair) from EU to non-OECD Countries
- **RoHS II Directive:**
  - Limits the possibility to made available on the market refurbished after 2019.
  - Limits the possibility to import in EU equipment for refurbishment (or already refurbished)
- **Basel Convention TG on e-waste:**
  - Limits shipments of used equipment for refurbishment (and repair) from EU to non-OECD and EXTRA-EU Countries.
- **Lack of clear definitions harmonized at global level**
- **Extra-EU markets wit restrictions to imports of refurbished equipment**

The refurbishment and reuse of medical devices is hampered by EU and International legislation which disregard the environmental and social benefits of refurbishment.

Any future commitment of COCIR to promote and increase refurbishment (and resource efficiency) has to be supported by EU Legislation.