

Good Refurbishment for Good Healthcare

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For budget-conscious healthcare providers, preowned medical imaging and treatment devices may be an alternative to new systems. However, some refrain from buying used systems – they have heard too many tales of poor quality and unsafe or inefficient equipment. Based on the recently published *Green Paper on Good Refurbishment Practice*, reluctant procurement managers may reconsider their opinions.

By Doris Pischitz, MA



Safety and effectiveness are the most important requirements for any medical equipment, no matter if it is new or preowned. But not every used medical electrical system sold today fulfills these ethical and economic criteria. The *Green Paper on Good Refurbishment Practice* (GRP) published by COCIR (European Coordination Committee of the European Radiological, Electromedical and Healthcare IT Industry) aims at solving this issue by providing stakeholders with a comprehensive set of requirements for medical devices, an organizational framework, and guidelines for the refurbishing process itself, in order to make refurbished equipment as safe and effective as when it was first put into service.

Restricted Access

The growing demand for affordable equipment leads to a need for used medical imaging and treatment devices, which conserve both financial as well as environmental resources. Today, the market for preowned systems is estimated at €1.3 billion, quite a substantial segment of the total imaging and treatment systems market, with the USA accounting for about 40 percent of it. However, since processes and staff qualifications vary from one refurbisher to the next, the

At Siemens, medical electrical equipment has been refurbished for several years according to the recently published *Green Paper*.

quality of refurbished systems also varies greatly. These differences may result in unsafe and inefficient equipment. Thus, some government and regulatory agencies set up import restrictions to protect their patients and users from unsafe and ineffective used equipment. In turn, these restrictions prohibit healthcare providers and patients from accessing the latest detection and treatment technology at an affordable price.

Safety and Quality

“If we want to promote the idea of refurbishment, we need to show we are acting responsibly when it comes to safety, performance, and quality issues,” says Nicole Denjoy, Secretary General of COCIR, explaining the driving force behind the *Green Paper*. To meet these criteria, the COCIR outlines are based on many years of experience from its member companies – Siemens with its Proven Excellence program prominently among them – in refurbishing medical imaging and treatment systems.

The basic organizational framework for a good refurbishment process, according to the *Green Paper*, is the same for all medical electrical equipment production. Refurbishers have to evaluate market access requirements and comply with national legal and regulatory requirements. They must have an adequate quality management system, which also means that the refurbishment instructions must be validated and follow document control requirements. When purchasing components or services, refurbishers must establish supplier management and quality control capabilities. Refurbished equipment must be labeled as such in order to prevent fraud and to easily identify the responsible refurbishing company. A postmarket surveillance process, a process for reporting adverse events and customer complaints, a product risk management process as well as a process for corrective and preventive action in order to work towards product safety must be in place – in addition to the manufacturer’s existing processes. All of the above processes and demands also have to be audited and certified.



“Our industry members and their experience helped a lot in defining the exact requirements for good refurbishment practice.”

Nicole Denjoy, Secretary General, COCIR, Brussels, Belgium

For the refurbishment process itself, the *Green Paper* defines five steps, all of which have to be performed by experts trained according to the manufacturer’s specifications, with tools, test equipment, and other resources defined by the manufacturer, and in environments that meet the manufacturer’s specifications, for example, with regard to temperature or humidity.

Five Steps to a Like-new System

Interestingly enough, the processes defined in the *Green Paper* have been in use for several years now at Siemens refurbishing plants in Forchheim, Germany, and Hoffmann Estates, IL, USA. “Our industry members and their experience helped a lot in defining the exact requirements for good refurbishment practice,” says Denjoy.

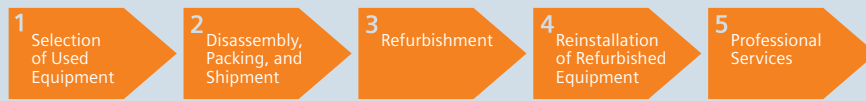
Good refurbishment starts with the selection of equipment to be refurbished. In addition to type, age, configuration and condition of the system, upgradeability and spare-part availability also play key roles in evaluating whether a system is suitable for refurbishing. “Some institutions, like university hospitals, always want the latest equipment. With the short innovation cycles in medical imaging and treatment technology, they buy new systems long before their current system comes anywhere near the end of its life-cycle,” Denjoy says, clarifying why many used systems are far from old. The system is then checked, cleaned, and disassembled at the customer site, carefully packed according to the requirements of the manufacturer, and shipped to the refurbishment facility.

Here, refurbishment itself starts with a thorough cleaning and disinfection. Then, the specific process for that very system is planned based on the system configuration ordered by the new owner. Of course, this final configuration must be within the scope of the product registration. The technical documentation of the manufacturer serves as a basis for mandatory hard- and software updates, cosmetic, mechanical and electrical repairs and replacements, system configuration, testing, packaging and shipment.

During the whole process, the existing technical documentation of the specific system must be continuously updated. Once all steps have been completed, the refurbisher releases the system with a self-declared statement of compliance to GRP standards. Denjoy could also imagine future barcoding that states compliance to GRP processes and refurbishment on the basis of the product specifications.

After the installation of the system at the new customer’s site, it is checked again. Together with the system, the customer also receives the required user documentation and the GRP declaration. Depending on the contract, the customer’s employees may also undergo application training. But refurbishment doesn’t stop here: Financing, warranty, spare parts availability, maintenance contracts, up-

Five steps of the Refurbishing Process



date management and other services fall just as well into the realm of a refurbisher as they do fall into the realm of a manufacturer. Despite the strict guidance, GRP can be adopted by any refurbishing company, according to Denjoy, be it for international or local markets.

To Whose Benefit?

Healthcare systems, healthcare providers, and the public all benefit from reliable, safe, and efficient preowned medical imaging and treatment devices. Costs for healthcare infrastructure – both for the healthcare system as well as the single healthcare provider – decrease through the purchase of refurbished devices, while quality increases through better access to the latest technology at the same time. “Affordable prevention and earlier detection are also beneficial to the public, and may in the long run even lead to less treatment costs,” Denjoy states. Last but not least, the environment benefits as well, with fewer resources used and less carbon dioxide emitted – thus nicely

rounding up COCIR’s sustainable competence in advancing healthcare.

International Standard

The first version of the *Green Paper*, published in November 2007, has been very well received with COCIR’s members, other industry associations (for example for in vitro diagnostic equipment), as well as government and regulatory agencies in the European Union (EU) and beyond. Positive signs have also come from NEMA (National Electrical Manufacturers Association, USA), JIRA (Japan Industries Association of Radiological Systems), MIISC (Medical Imaging & Information Systems Council, Canada), the US Department of Commerce, and the Chinese Hospital Association. Currently, COCIR is collecting the feedback of all stakeholders in order to draft a second version, which is then to become the basis for a future international standard. “We want to define what is internationally state-of-the-art,” Denjoy says, referring to COCIR’s goals.

Summary

Challenge:

- Growing market for refurbished medical imaging and treatment devices
- Quality discrepancies in refurbished medical electrical equipment
- Import restrictions in some countries, based on bad experiences and adverse events

Solution:

- Publication of COCIR’s *Green Paper on Good Refurbishment Practice*
- Future wide-spread adoption of the *Green Paper*

Result:

- Refurbished equipment as effective and safe as when it was first put into service
- Access to newest technology at lower price for both healthcare providers and patients
- Environmental benefits

Further Information

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Prior to becoming Chief Editor of Medical Solutions, **Doris Pischitz** was responsible for Siemens computed tomography magazine SOMATOM Sessions.

COCIR

COCIR, the non-profit trade association founded in 1959, is the voice of the European Radiological, Electromedical and Healthcare IT Industry. COCIR’s members play a driving role in developing the future of healthcare in Europe and the world. COCIR supports its members and communicates with its partners in Europe and beyond on issues which affect the medical technology sector and the health of citizens of the European Union (EU).

As well as communicating with EU policymakers on economic, regulatory and technical issues related to healthcare, COCIR works with various organizations promoting harmonized standards and fair regulatory control across the world. COCIR encourages the use of advanced technology in deliv-

ering cost-efficient and state-of-the-art healthcare worldwide. Its key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European industry. COCIR represents the interests and activities of its members and acts as a communication channel between its members and the European institutions and other regulatory bodies. It also cooperates with other organizations on issues of common interest.

COCIR seeks to promote the development of harmonized international standards and regulatory control, which respect the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users.

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