GOOD REFURBISHMENT PRACTICE
FOR MEDICAL IMAGING EQUIPMENT

GLOBAL MEDICAL IMAGING INDUSTRY / REPRESENTED BY:

COCIR

JIRA

MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

CONTENT

FOREWORD

In some countries of the world, used medical equipment is safely and reliably returned to active service, continuing to provide the "medical miracles" of advanced diagnostics and treatment it was originally designed to deliver to thousands of people.

We also know that beyond these important social benefits, the business that can develop around refurbishing used medical equipment creates a robust and sustainable economy in those countries where there is a generally accepted framework for processing such advanced equipment. Examples of these processes include validating the quality of the work, providing appropriate documentation and training for the use of the refurbished machines.

The reason why our industry decided to design a new concept called "Good Refurbishment Practice" is to provide guidelines based on best practices from our Medical Imaging Industry to ensure that refurbished equipment is as safe and effective as when new.

This Green Paper suggests an organizational framework to advance the movement toward commonly accepted, harmonized international standards. I hope that you will add your voice to this discussion and support the efforts of the Medical Imaging Industry to bring "medical miracles" to people throughout the world with equipment that is as safe and effective as when it was first put on the market.

HEINRICH VON WULFEN
COCIR PRESIDENT

GENERAL INFORMATION ON THE GLOBAL MEDICAL IMAGING INDUSTRY

COCIR

COCIR, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry, was founded as a non-profit trade association in 1959. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide. COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens.

COCIR also works with various organizations promoting harmonized international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users. We encourage the use of advanced technology to support healthcare delivery worldwide. COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European healthcare sector.

www.cocir.org

JIRA

JIRA, Japan Industries Association of Radiological Systems, is an international trade association representing all major global manufacturers of diagnostic imaging and radiation therapy devices in Japan. Collectively JIRA organizations represent more than 95% of the Japanese sales of this equipment.

www.jira-net.or.jp

MITA

MITA, Medical Imaging & Technology Alliance is a United States based trade group, serving as the collective voice of medical imaging and therapy equipment manufacturers, innovators, and product developers. MITA is a Division of NEMA (The National Electrical Manufacturers Association.)

www.medicalimaging.org

INTRODUCTION

This Green Paper on **Good Refurbishment Practice (GRP)** is based on the experience of companies with global refurbishment operations. This new edition takes into account feedback received on the 1st version that was launched in October 2007. It is endorsed by COCIR, JIRA and MITA and describes the process by which the Global Medical Imaging Industry refurbishes the equipment it manufactures originally. Refurbishment is hereby defined as: **"a systematic process that ensures safety and effectiveness of the medical equipment without significantly changing the equipment's or system's performance, safety specifications and/or changing intended use as in its original registration"**. Any upgrades processed during GRP refurbishment shall be performed in a manner consistent with the original product specifications and service procedures defined by the manufacturer for that equipment or system. Besides these important principles the reader should note that the issuing of this Green Paper on Good Refurbishment Practice (GRP) fills a need in the current healthcare market for safe and effective refurbished medcal devices.

Conserving assets is a fundamental principle of ecological thinking in a recycling economy. The replacement of medical equipment with high residual value generates a cascade of trade – which means that after refurbishment, the replaced equipment provides additional value to a new user. Several medical equipment companies have already set up refurbishment processes and have delivered refurbished equipment across the healthcare sector for many years. Refurbishment addresses the high demand for affordable and reliable products. Customers of refurbished systems are not only small hospitals with limited budgets but also leading medical institutes. Refurbishment is a well-established element of the global healthcare economy.

If used medical equipment is not maintained according to requirements defined by the original manufacturer, it may result in an additional risk for patients and operators. Consequently, to protect public health and healthcare provider interests, some countries have imposed bans on the import of used medical equipment. These bans usually fail to distinguish between high-quality refurbishment to the original manufacturer's specifications and second-hand equipment of undefined quality, with the effect that patients may be denied access to the safe and economical medical equipment they need. Furthermore, the International Atomic Energy Agency (IAEA) developed a draft document covering similar topics with a very specific focus on the risk of unnecessary radiation exposure to patients due to poorly managed or maintained second-hand equipment that is donated to developing countries. This is yet another example that the need for a well defined process around safety and effectiveness of refurbished medical equipment is relevant.

Safety and effectiveness are the most important aspects to be considered with medical equipment and this is no different when reutilizing used medical equipment. In theory, refurbishment is the method to ensure the continued safety and effectiveness of used equipment as it moves from one medical facility to another. In practice, there is a wide variety of interpretation of refurbishment.

Considering this, it will be useful to all interested parties to define and describe Good Refurbishment Practice (GRP). This Green paper describes the understanding of the Global Medical Imaging Industry regarding GRP and is based on the experiences of companies with global refurbishment operations.

GRP AIMS TO SUPPORT:

- **Healthcare Service Providers** to enable them to distinguish refurbished medical equipment processed according to this Green Paper on Good Refurbishment Practice (GRP) from used equipment when making a purchase decision;
- **Patients** to get easier access to safe and effective diagnostic procedures and therapies;
- **All stakeholders** with information about good refurbishment practice for healthcare;
- **Industry** to ensure the safety and effectiveness of used medical equipment with a clearly defined quality process.

1. PURPOSE OF GOOD REFURBISHMENT PRACTICE

Medical equipment placed on the market and put into service must meet the requirements for safe and effective use of the equipment as defined by the manufacturer. There is no difference whether the equipment is brand new or used.

Refurbished medical equipment is specially processed used equipment. Compared to new equipment, used equipment may bear additional risks (e.g. contamination, worn parts and misalignment) for the patient, user, third parties and the environment if not adequately maintained. The target of the refurbishment process is to restore such used equipment to its original condition (as good as when it was new).

GRP follows standard operating procedures and dedicated quality requirements that ensure that refurbished medical equipment is as safe and effective as when it was new.

It is important to understand that refurbishment is different from maintenance or repair as well as from fully-refurbishing or remanufacturing. The scope of this document is focused specifically on the process of refurbishing used equipment based on experience gathered from original manufacturers of medical imaging equipment.

2. MEDICAL EQUIPMENT FOR REFURBISHMENT

Not every medical device is appropriate for refurbishment, but if it is intended for refurbishment, it must fulfill certain elementary requirements regarding the following factors to be qualified and eligible:

- **Intended use and product specifications**
- **Standards for Medical Equipment at time of first placement**
- **Lifetime and serviceability**

The first key factor for refurbishment qualification is the **intended use** as determined by the manufacturer including its product specifications. Devices intended for single use or designed as not eligible for refurbishment should not be refurbished.

The second key factor for refurbishment qualification is that it is good practice to refurbish only equipment that still meets the **original standards at time of first placement**. That means used medical equipment that does not meet, or cannot be refurbished to meet, these original standards should neither be refurbished nor utilized any more.

The **lifetime** of medical equipment and serviceability aspects are also key requirements to determine qualification for refurbishment. Medical equipment is designed and manufactured to be used for a planned lifetime. When the healthcare service provider puts the product into service, maintenance procedures defined by the original manufacturer ensure that the intended levels of safety and performance are preserved. The end of planned lifetime is generally reached when original manufacturer service, spare parts and components are no longer available for the product.

The effective lifetime of equipment usually differs from the planned lifetime and can be limited by different reasons:

A **Functional reasons** can impair the use of the equipment because it may no longer be safe and effective. Such cases can mainly be traced back to poor maintenance or a lack of maintenance, which usually means that the manufacturer's specifications for servicing and maintenance were not fulfilled.

B **Economic reasons** can restrict the effective lifetime of the equipment for a particular user because they may want to take the equipment out of service and replace it with a new product. Elevating the medical equipment to newer technology through replacement is a need in healthcare that releases existing and economically valuable assets for new investments. These replaced systems are the input to the GRP Process.

The figure below gives an overview about the context of 'Planned Lifetime', 'Effective Lifetime' and refurbishment. Refurbishment maximizes the functional and economic life.

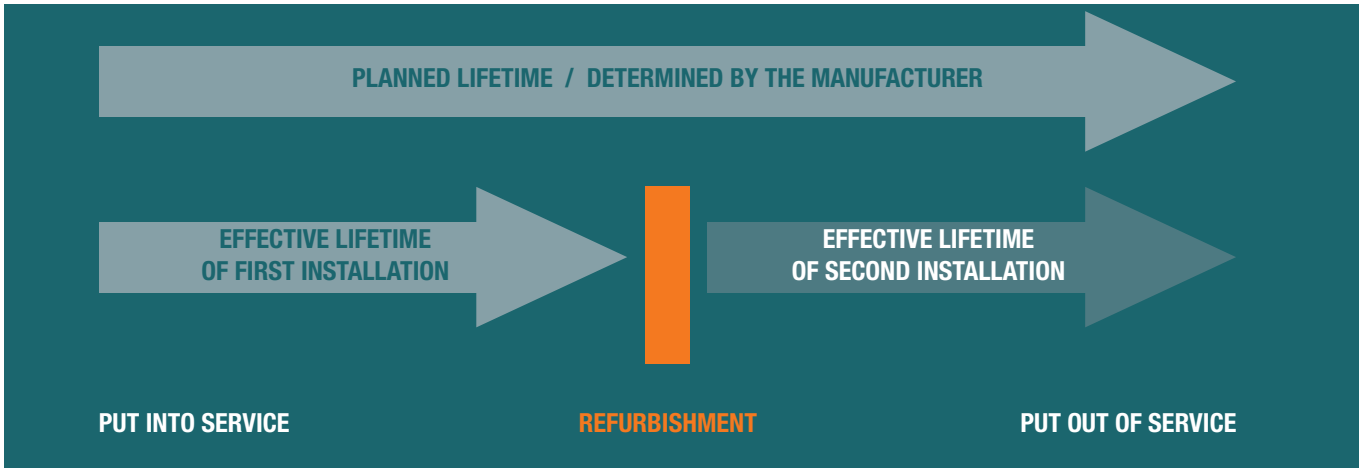


Figure 1 *Context of 'Planned Lifetime', 'Effective Lifetime' and refurbishment*

Refurbishment can prolong the effective lifetime of specific equipment. At the end of its effective lifetime, medical equipment is usually taken out of service, dismantled and/or recycled. This phase is not in the scope of refurbishment.

3. ORGANISATIONAL FRAMEWORK FOR REFURBISHMENT

Any organization that refurbishes medical equipment must meet the specific requirements for market access. Listed below are the detailed processes which are specific to refurbishment and must be established.

QUALITY MANAGEMENT SYSTEM
RESOURCE MANAGEMENT
CORRECTIVE AND PREVENTIVE ACTIONS
CUSTOMER FEEDBACK
PRODUCTION AND SERVICE PROVISIONS
CONTROL OF NONCONFORMING PRODUCT
REFURBISHMENT LABELING
POST MARKET SURVEILLANCE PROCESS
PROCESS OF INSTRUCTIONS FOR VALIDATION AND DOCUMENTATION
SUPPLIER MANAGEMENT PROCESS

Table 1 *Process to follow by the organization that performs refurbishment*

Refurbishment of medical equipment encompasses processes that require a dedicated organizational framework. An organization that performs refurbishment must embed the medical device-specific refurbishment processes in an adequate Quality Management System (e.g. according to ISO 13485:2003). When returning refurbished medical equipment into the market, the seller must comply with general legal and regulatory requirements. These include the ability to assume the responsibility for contractual or liability claims resulting from product failures, data privacy breaches, etc., due to refurbishment activities.

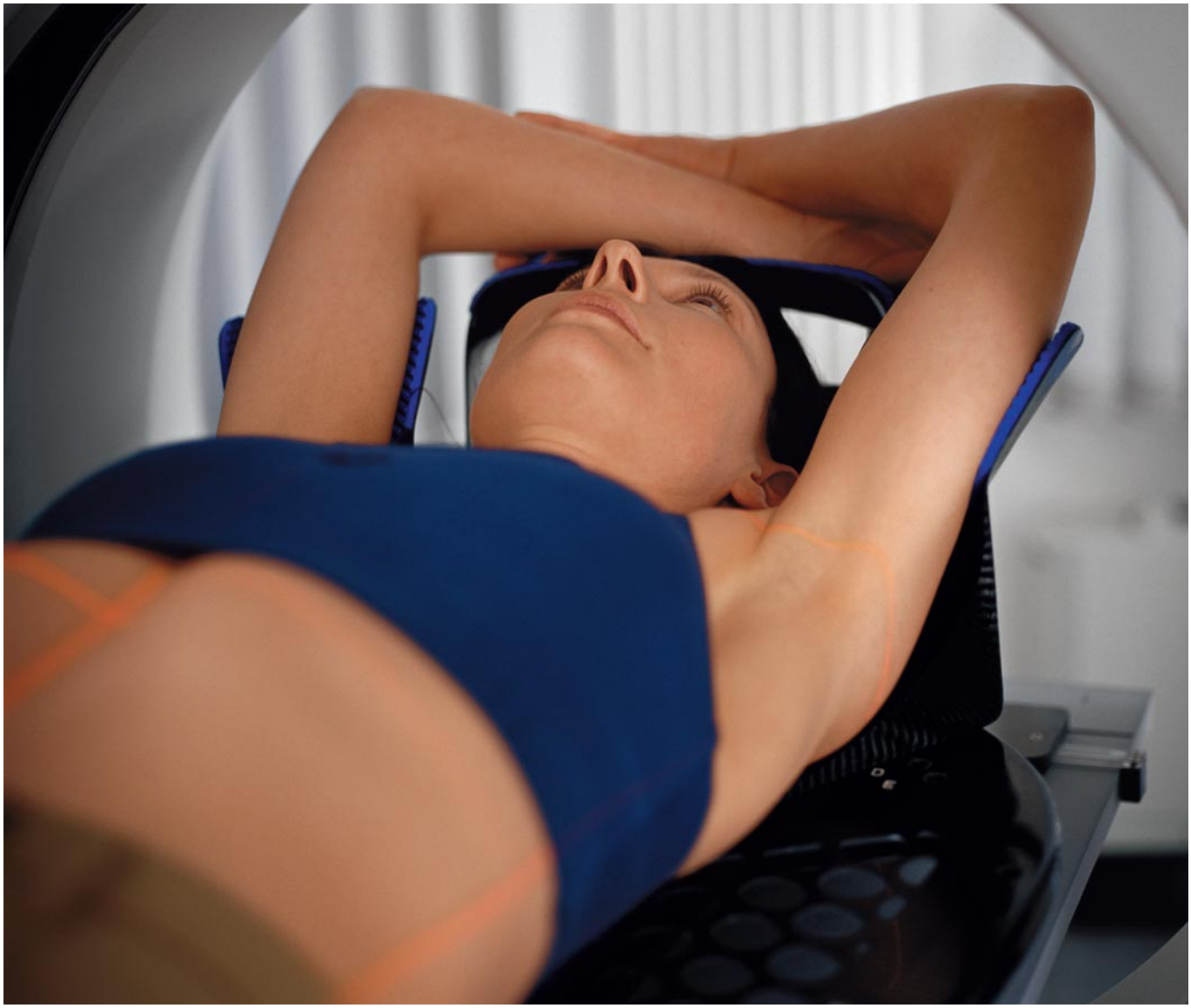
The organization that performs refurbishment is required to determine and provide adequate Resource Management including trained and qualified people, maintained and calibrated production equipment as well as instructions, procedures, files, records or documents, and an environment for refurbishment that is in complete compliance with the applicable environmental and work safety requirements.

The refurbished medical equipment data from product market surveillance needs to be collected and evaluated systematically through a comprehensive Corrective Action and Preventive Action (CAPA) process addressing the specific aspects of the refurbishment process.

Manufacturers are obligated by regulators to perform post market surveillance and to use customer feedback as input to continuously ensure safety and improve performance of the products placed on the market. Therefore all customer feedback that is related to the refurbishing process as well as related to safety and performance of the equipment has to be used as input to continuously ensure safety and to improve performance of the products placed on the market.

The organization that performs refurbishment makes provisions to have the knowledge and the ability for installing and servicing medical equipment in those markets he places medical equipment. Proper servicing is essential for medical equipment to continue to perform safely and effectively.

A medical device shall not be released for shipment to a customer site if it becomes apparent, during refurbishment, that this medical equipment does not conform to the specifications of the product registration as when the product was first placed on the market.



The organization that performs refurbishment must be easily identifiable by the responsible organization, operator, inspector, or regulating authority. This is documented with a special Refurbishment Label. This is important in order to identify the last organization that processed the equipment, which is the organization that takes responsibility for the quality of the product.

The organization that performs refurbishment is required to establish its own Post Market Surveillance Process, to monitor whether the additional risks resulting from refurbishment have been mitigated adequately. This organization is also required to report to the appropriate authorities in case of adverse events.

The detailed Refurbishment Instructions must be validated and, as with all other medical equipment manufacturing processes, follow Document Control requirements as required by the relevant regulators. This includes the creation, maintenance and archiving of relevant technical documentation.

When components or services are purchased, the entity responsible for refurbishing the equipment must also establish dedicated supplier management capabilities to control the quality of supplied parts and services.

4. REFURBISHING PROCESS

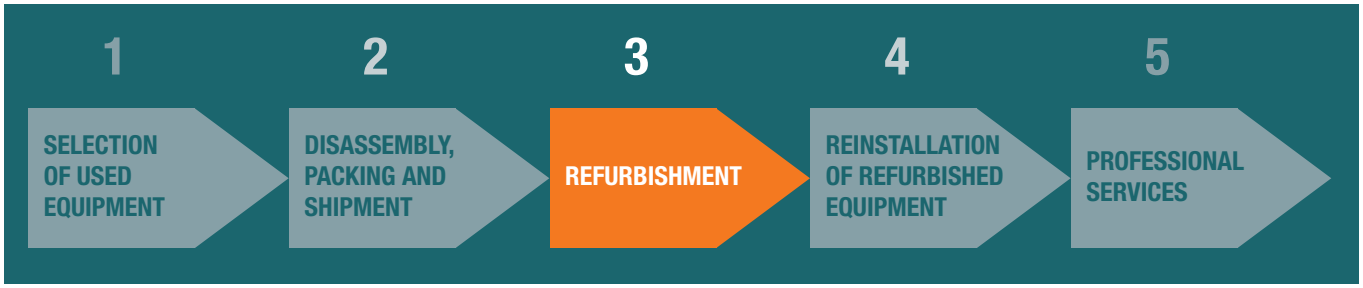
INTRODUCTION

As previously indicated, the most important aspects to be considered in reutilizing used medical equipment are quality, performance, safety and intended use. Following ethical principles, it must be ensured that there are no compromises on quality or safety on any level. Therefore, the purpose of any of the process steps described below is to make sure that any system that will be refurbished according to GRP will have the same quality, performance, safety, and intended use - including full warranty and service - as when it was new.

FIVE STEP REFURBISHING PROCESS

Hereinafter is described which activities a refurbishing process comprises to meet the necessary requirements. Each refurbishing process step incorporates certain dedicated activities and certain necessary resources. These resources could be qualified people, tools, instructions, files/records/documents, test equipment, parts, packing material, etc.

- As with the manufacturing process of new equipment, the refurbishing process must meet critical specifications (e.g. environmental conditions such as facility temperature and humidity) as defined by the original manufacturer. Special training may also be required, for example general instructions on ESD (Electro Static Discharge) and the handling of medical equipment.
- All the steps and activities described below must be performed by experts, trained using original manufacturer's specifications, and all refurbishment activities must be validated to ensure that these activities are effective.



4.1 REFURBISHING PROCESS **STEP 1** SELECTION OF EQUIPMENT FOR REFURBISHMENT

- Not every used system is suitable for refurbishment. Generally, the selection of used equipment is based on the principle that the used system can be refurbished to a system that has the same quality, performance, safety and intended use as when it was new. According to this principle and the principles outlined in section 2, the following criteria are relevant.
- Type, configuration and condition of a used system are criteria for GRP-refurbishment, as well as age, upgradeability and the phase in the life cycle. The phase in the lifetime of a system is generally defined by spare part availability. Since lack of spare part availability limits the ability to service a system, it is an important selection criterion for refurbishment.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
Evaluate type, age and configuration of the system	Product service history, data of the Installed Systems Data Base
Evaluating system condition	Service records of the relevant equipment; site and incoming check instructions; service instructions by the manufacturer; equipment condition requirements that have to meet the refurbishment criteria
Evaluating upgradeability of software and hardware status	Device upgradeability documentation of the original manufacturer
Evaluating availability of original spare parts and service	Original manufacturer spare parts and service availability

4.2 REFURBISHING PROCESS **STEP 2** DISASSEMBLY, PACKING AND SHIPMENT

4.2.1 DISASSEMBLY

- During the disassembly it has to be ensured that the system will not be damaged. To avoid any additional risk, the organization that performs refurbishment has to make sure any system that is to be disassembled will afterwards be in the same condition as before.
- Where the equipment has been used in a special environment (e.g. emergency room, operating room) it might be necessary to perform a first disinfection at the place of the disassembly, so that the people (for example at the incoming inspection) are protected and not exposed to pathogens.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
System check at customer's site	Instructions of the manufacturer for system check, tools needed for system check as specified by the original manufacturer
Preliminary Decontamination/Disinfection	Preliminary Decontamination Instructions
Professional Disassembly	Original manufacturer instructions for system disassembly, appropriate tools needed for system disassembly as specified by the original manufacturer, appropriate tools for transportation lock, trained personnel performing the disassembly

4.2.2 PACKING & SHIPMENT

- The organization that performs refurbishment is responsible for developing instructions to make sure that systems will not be damaged during packing or shipment. Therefore, the purpose of this process step is to make sure that any system that is destined for refurbishment will be packed and shipped in such a way that it prevents damage in shipment. All instructions have to be validated.

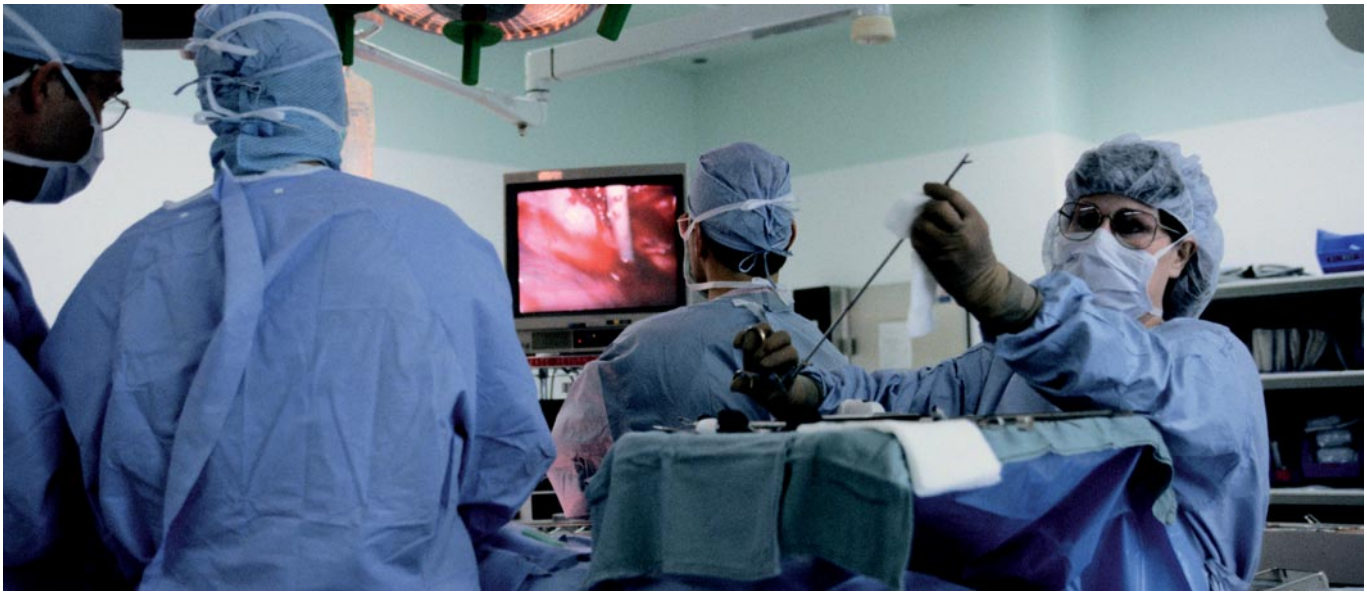
ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
Packing of the used system	Original manufacturer product instructions for packing, incl. specified tools, packing material e.g. frames, etc.
Transportation to the refurbishment facility	Original manufacturer product instructions for transportation, incl. specified tools for monitoring transportation e.g. shock indicators
Incoming inspection	Validated incoming inspection instructions, specified tools

4.3 REFURBISHING PROCESS **STEP 3 REFURBISHMENT**

4.3.1 CLEANING & DISINFECTION

- Used medical equipment can sometimes become contaminated by its use in a clinical environment. The purpose of this process step is to make sure that any system that will be refurbished will bear no risks regarding infection of any person during or after the refurbishment process.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
Cleaning and disinfection	Requirements for cleaning and disinfection as part of a validated refurbishing process, dedicated tools needed for cleaning and disinfection validated for refurbishment, agents for cleaning and disinfection validated for refurbishment



4.3.2 REFURBISHMENT PLANNING

- This process step depends on the specific equipment/system to be refurbished. The system configuration must be defined either by the organization that performs refurbishment itself or according to a customer order. The final configuration of the refurbished system must be within the scope of the original product registration from the manufacturer when the system was originally produced and put on the market for the first time.

- In some countries a dedicated registration or licensing process might be required; therefore, the organization that performs refurbishment must have qualified knowledge on regulatory requirements in the target market. In any case, the system must keep its original identity (e.g. labeling). Linked to this issue are language requirements for manuals/instructions for use, safety information and warnings, labels, etc.

- The refurbishment planning process is a critical phase for refurbishment because all necessary actions must be thoroughly assessed and determined. Throughout the refurbishing process, the Device History Record (DHR) must be continuously updated. The people planning the necessary refurbishment actions must be skilled to ensure that the required actions do not represent a modification that might impair the original identity and approved configuration, meaning that regulatory implications might arise. Due to the criticality of the refurbishment planning process, the organization that performs refurbishment must have reliable controls for this process step and have it defined in detail in its quality management system.

- Refurbished equipment that does not comply with the original intended use, specifications, and registration has to be treated like unapproved, unregistered medical equipment. In some countries such significant changes through refurbishment are defined as "fully refurbishing" or "remanufacturing". Such altered equipment without proper controls and registrations may be considered "adulterated" by regulatory authorities and the sale or use of such products can bring serious legal consequences and penalties for the organization that performs refurbishment and user, as well as significant safety and quality risks.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
• Check for relevant technical documentation for detailed planning to ensure that the equipment will be refurbished according to original manufacturer product specifications	• Original manufacturer product specifications • Technical documentation for the planning of the refurbishment
• Check for necessary field updates regarding safety, reliability, performance etc. • Planning appropriate updates	• Original manufacturer product specifications • The results of product surveillance of the relevant equipment
• Planning cosmetic, mechanical and electrical refurbishment as well as system configuration	• Original manufacturer product specifications and documentation; e.g. system configuration documentation
• Planning system testing	• Original manufacturer product specifications and documentation
• Preparing of GRP declaration	• Technical documentation for the respective equipment
• Planning packing & shipment	• Original manufacturer product specifications and documentation
• Planning reinstallation and start-up check on customer site	• Original manufacturer product specifications and documentation

4.3.3 COSMETIC REFURBISHMENT

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
• Surface treatment, painting as needed	• Instructions according to the refurbishment plan • Original paint tested and approved by the original manufacturer regarding biocompatibility

4.3.4 MECHANICAL AND ELECTRICAL REFURBISHMENT AND SYSTEM CONFIGURATION

- The organization that performs refurbishment is also required to take appropriate actions to avoid violation of privacy rules concerning patient data stored on the relevant medical equipment.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
• Replacing worn parts	• Instructions according to the refurbishment plan • Original manufacturer spare parts
• Performing the planned applicable updates • Customizing through options and accessories within the scope of product registration • Adding new and complete original manufacturer user documentation in the required language	• Instructions according to the refurbishment plan • Original manufacturer parts, components and accessories, original manufacturer user documentation in the required language or verified translation
• Updating the DHR to show evidence that the equipment was refurbished according to the specification of the equipment	• DHR of the relevant equipment regarding refurbishment
• Appropriate actions to avoid violation of privacy rules concerning patient data stored on the relevant medical equipment	• Dedicated tool and validated process

4.3.5 SYSTEM TESTING

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
• Performing a system check • Thorough checking of components and subsystems	• Instructions per original manufacturer test specifications • Test equipment and system check procedure
• Updating the DHR to show evidence that the equipment was refurbished according to the specification of the equipment	• Device History Record of the relevant equipment regarding refurbishment

4.3.6 GRP DECLARATION (RELEASE)

- When all necessary actions for refurbishment have been successfully completed, the organization that performs refurbishment releases the equipment, self declares compliance to GRP (GRP-Declaration) and labels the product accordingly (name & place of the organization and date of refurbishment). The GRP-Declaration is handed over to the final customer as a proof for GRP-compliance.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
• Labeling – adding date of refurbishment and GRP-Label to the genuine labeling	• GRP Labeling tool for controlled labeling
• Updating the DHR to show evidence that the equipment was refurbished according to the specification of the equipment	• Installed System Data Base for tracking the system and ensuring optimized maintenance
• Preparing the GRP Declaration	• GRP Declaration
• Updating the DHR to show evidence that the equipment was refurbished according to the specification of the equipment	• Device History Record of the relevant equipment regarding refurbishment

4.3.7 PACKING & SHIPMENT

- The overall objective of refurbishment is to provide the new user of the refurbished system the advantage of a system that has the same quality, performance, safety and intended use as at the time of its first shipment. Following this objective the process steps after refurbishment itself such as packing and shipment must be identical or equivalent to the process steps for new systems.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
• Packing of the refurbished system	• Original manufacturer instructions for packing • Original manufacturer specified tools needed for packing • Original packing material of the manufacturer e.g. frames • Country specific regulation regarding packing material
• Transportation to customer's site	• Original manufacturer instructions for transportation • Original manufacturer specified tools for monitoring transportation, e.g. shock and temperature indicators

4.4 REFURBISHING PROCESS **STEP 4** REINSTALLATION OF REFURBISHED EQUIPMENT

- Equipment processed according to GRP is intended to meet original quality, performance and safety standards, hence it is essential to follow original manufacturer installation procedures including site planning and preparation works.

ACTIVITY	INFORMATION AND RESOURCES NEEDED EXAMPLES
• Professional installation	• All involved employees must be trained according to original manufacturer requirements
• Start-up and repeated check-up of the system's performance	• All involved employees must be trained according to original manufacturer requirements
• Application training as contracted between customer and the organization that performs refurbishment / manufacturer	• All involved employees must be trained according to original manufacturer requirements
• Hand-over of required user documentation and GRP Declaration	• User documentation and GRP Declaration
• Updating the DHR to show evidence that the equipment was refurbished according to the original manufacturer product specifications	• Device History Record of the relevant equipment regarding refurbishment

4.5 REFURBISHING PROCESS **STEP 5** PROFESSIONAL SERVICES

- A buyer or user of GRP-processed equipment can expect after-sale services and support, identical to what is provided for new systems. Therefore, the organization that performs refurbishment will ensure that professional services and support are provided in the same way as for a new system. It is, thus, ensured that the buyer of a GRP-processed system will have the full necessary support over the planned lifetime of the equipment.

ACTIVITY
• Warranty equivalent to a new system
• Original spare parts availability
• Maintenance contracts
• Manufacturer update management
• Application training
• Financing solutions and service contracts
• Qualified contact partners for product support when needed

5. DEFINITIONS

5.1 DEVICE HISTORY RECORD

History records for refurbished equipment representing individual devices or lots of devices for all finished devices that were processed. The history record for refurbished equipment should reflect that all operations, processes, etc., described in the validated refurbishment plan have been accomplished.

5.2 REFURBISHMENT

To restore used equipment or systems into a condition of safety and effectiveness comparable to when new including actions such as repair, rework, update and replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service procedures defined by the manufacturer for that equipment or system without significantly changing the equipment's or system's performance, safety specifications and/or changing intended use as in its original registration.

5.3 SECOND HAND EQUIPMENT

Equipment that has been in service and is put into service again, usually at another location without any processing.

5.4 REPAIR AND MAINTENANCE

The restoration of an equipment or system by a service provider to its original function, in response to the failure of the equipment or system. The repair process may also include servicing, reconditioning, modification and refurbishment.

5.5 FULLY REFURBISHING

Fully refurbishing of medical devices is regulated in the European Economic Area because in this case the Medical Device Directive (93/42/EEC) applies. A Notified Body Recommendation NB-MED/2.1/Rec 5 - "Placing on the market of fully refurbished Medical Devices" is available and describes criterias indicating whether a device is considered "Fully Refurbished".

5.6 REMANUFACTURING

Actions taken, such as processing, conditioning, renovating, repackaging, etc. on a used equipment or system, that significantly changes the equipment's or system's performance, safety specifications, or intended use. Remanufactured equipment is not covered by this GRP.

5.7 VALIDATION

Confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled.

CONCLUSION

The knowledge about the requirements for refurbishment of used medical imaging equipment or systems described in this Green Paper should help governments, **governmental organizations, non-governmental organizations or other parties** for their regulation work or healthcare framework setting.

The Good Refurbishment Practice (GRP) should enable **healthcare service providers** to distinguish used medical equipment or systems from those that have been refurbished according to this Green Paper. It should raise their expectations for quality equipment when making a purchasing decision and should support that patients get improved access to safe, effective, and affordable diagnostic procedures and therapies. The GRP-Green Paper should also help the **industry** to improve the safety and effectiveness of used medical imaging equipment and sytems by establishing common quality process standards.

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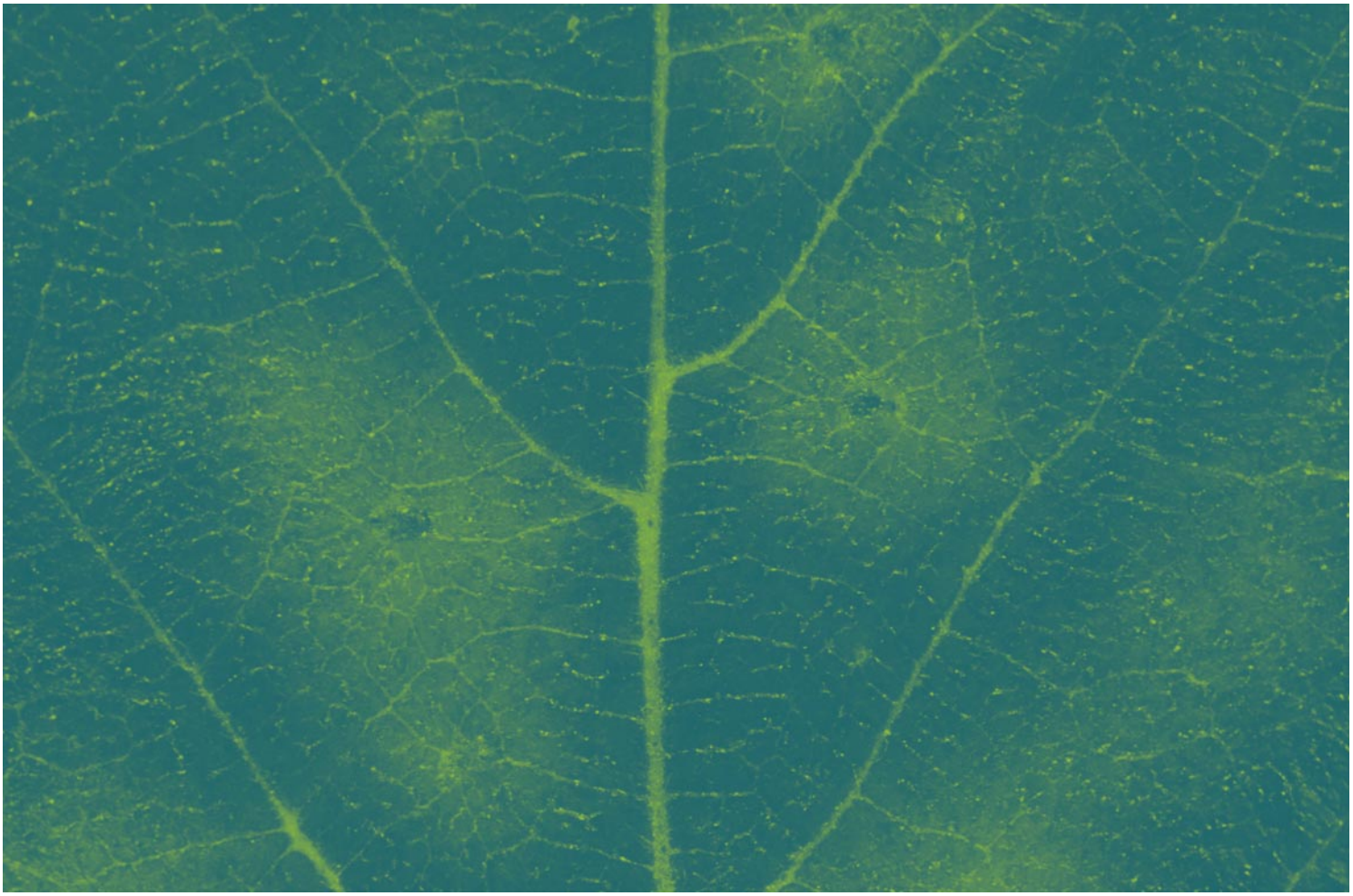

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