



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

TECHNICAL GUIDE:

NEMA Standards Publication NEMA/MITA 1

Good Refurbishment Practices for Medical Imaging Equipment

Prepared by DITTA – the global voice of diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers – www.globalditta.org

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Foreword

In many 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 Technical Guide 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.

General information about COCIR, JIRA and MITA

This technical guide prepared with expertise from the global medical imaging industry

DITTA is the global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers to better communicate, coordinate and collaborate on matters of common interest between participating associations and member companies. DITTA enables participating associations and their member companies to work more effectively with international policymakers, organizations, professional associations and stakeholders.

DITTA was originally organized in 2003 as an unincorporated entity for national and regional trade organizations representing the medical imaging industry to address global issues and incorporated in 2012 as a non-profit trade association in the United States. DITTA's membership is currently comprised of COCIR (Europe), JIRA (Japan), ITAC (Canada), MEDEC (Canada), MITA (United States), THAIMED (Thailand), IMEDA (Russia), CAMDI (China), ABIMED (Brazil) and KMDICA (Korea). Over the past year, these associations have renewed their commitment to work together, bringing their expertise to engage with governments and other

stakeholders around the globe to promote innovation, improve market access and enhance global competitiveness in the medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical industries.

DITTA's focus is to improve the global regulatory environment for manufacturers to ensure that they remain at the forefront of technological innovation and are successful in the global marketplace as they continue to develop more advanced, life-saving products that improve quality, safety and patient access around the globe while also promoting cost efficiency.

Through DITTA, the associations are committed to working together more closely in order to promote international harmonization of medical device regulations and adoption of international standards with the goal of improving access to safe, effective, and high-quality medical technology.



Introduction

This Technical Guide is the 3rd edition of a document published by the industry associations COCIR, JIRA and MITA in 2009, based on principles first published by COCIR in 2007. With the 3rd edition we have aligned with the introduction of the NEMA Standards Publication NEMA/MITA 1 Good Refurbishment Practices for Medical Imaging Equipment.

This Technical Guide on Good Refurbishment Practice (GRP) is based on the experience of companies with global refurbishment operations. It is endorsed by DITTA and describes the process by which the Global Medical Imaging Industry refurbishes the equipment it manufactures originally. Refurbishment is hereby defined as: **“process or combination of processes applied during the expected service life to restore used medical imaging equipment to a condition of safety and effectiveness comparable to when new”.**

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 imaging 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 imaging 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.

Safety and effectiveness are the most important aspects to be considered with medical imaging equipment and this is no different when reutilizing used medical imaging 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 Technical Guide 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 Technical Guide on Good Refurbishment Practice (GRP) from used equipment when making a purchase decision
- Regulators of medical devices
- Patients to get easier access to safe and effective diagnostic procedures and therapies
- Industry to ensure the safety and effectiveness of used medical imaging equipment with a clearly defined quality process
- All stakeholders with information about good refurbishment practice for healthcare

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 imaging 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 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.



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.

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.

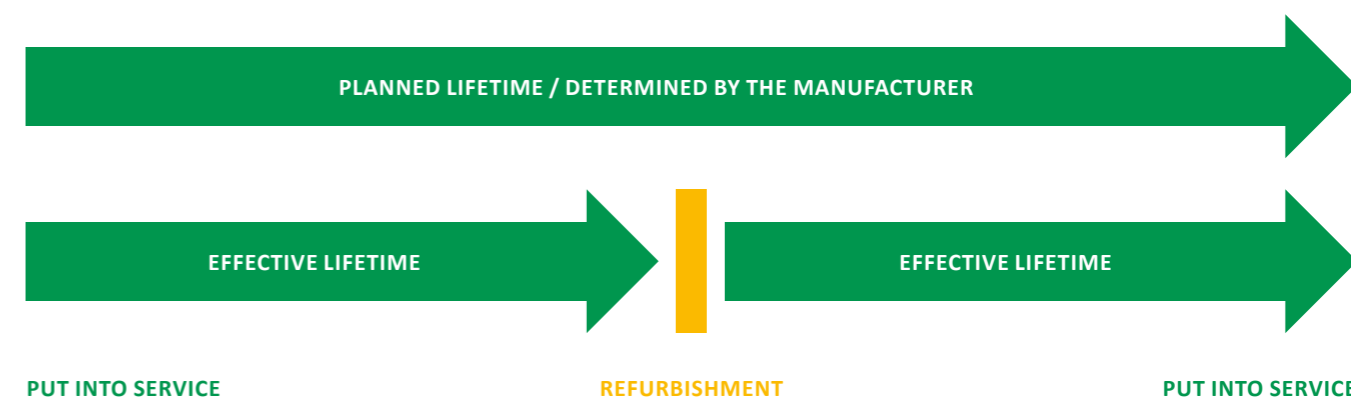
The lifetime of medical equipment and serviceability aspects are also key requirements to determine qualification for refurbishment. Medical equipment is designed and manufactured to be used for a planned lifetime. When the healthcare service provider puts the product into service, maintenance procedures 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.



3. Organizational Framework for Refurbishment

Listed below are the detailed processes which are expected for refurbishment and must be established.

- 3.1 Quality Management System
- 3.2 Resource Management
- 3.3 Corrective and Preventive Action
- 3.4 Customer Complaints
- 3.5 Production and Service Provision
- 3.6 Control of Non-Conforming Product
- 3.7 Post Market Surveillance Process
- 3.8 Document Control
- 3.9 Purchasing
- 3.10 Control of Design and Design Changes
- 3.11 Risk Management Process

3.1 Quality Management System

Refurbishment of medical imaging 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 according to ISO 13485. When returning refurbished medical imaging 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.

3.2 Resource Management

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.

3.3 Corrective and Preventive Action

The refurbished medical imaging 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. In addition, in the event the refurbisher identifies through its CAPA system safety related issues, which are the responsibility of the original manufacturer and are not related to the refurbishment, it shall inform the manufacturer.

3.4 Customer Complaints

The refurbisher shall have in place a system for managing complaints. As with the CAPA system, if the refurbisher becomes aware of a complaint that is not related to the refurbishment, the information shall be communicated to the original manufacturer.



3.5 Production and Service Provision

The refurbisher shall have documented procedures in place for refurbishment and servicing including process validation, disinfection, identification, traceability and packaging. The organization that performs refurbishment must make provisions to have the knowledge and the ability for installing and servicing medical equipment in those markets where the medical equipment is placed. Proper servicing is essential for medical equipment to continue to perform safely and effectively.

3.6 Control of Non-Conforming Product

It shall be ensured that a product that does not conform to its requirements is identified during the refurbishment process and is controlled to prevent its unintended use or delivery. If the non-conforming product is corrected during refurbishment, it shall be subject to a documented verification process to demonstrate conformity with the requirements of the original manufacturer.

3.7 Post Market Surveillance 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. This feedback should be used by the refurbisher to determine if adverse events related to the refurbishment need to be reported to the regulatory authorities and/or communicated to the original manufacturer. In addition, the refurbisher should monitor its installed base to allow for any necessary updates for safety and effectiveness.

3.8 Document Control

The refurbisher shall control all work instructions and procedures used to refurbish medical imaging equipment.

3.9 Purchasing

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.

3.10 Control of Design and Design Changes

The refurbisher shall review, verify, and validate any potential design changes to ensure the safety and effectiveness of the medical imaging equipment is not changed per the original or applicable valid device registrations. All changes, including parts, need to be evaluated to determine if a new registration will be needed for the device making the refurbisher the new legal manufacturer of the device.

3.11 Risk Management Process

A risk management process shall be established by the refurbisher to cover any risk introduced through the refurbishment process. This includes changes that would affect parts.



4. Refurbishing Process

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.

4.1 General Quality 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.



4.2 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. Accordingly the principles outlined in section 2, the following criteria are relevant:

- Intended use and normal use of the medical imaging equipment
- Expected Service Life
- Applicable standards
- Service/Maintenance history for the medical imaging equipment

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. Used medical imaging equipment that are at the end of their Expected Service Life, or which cannot be restored to at least their original safety and performance levels including mandatory safety updates shall not be refurbished.

4.3 Evaluating Market Access Requirements

To ensure regulatory compliance, the refurbisher shall have a process in place to evaluate market access requirements such as valid registrations and licenses and/or restrictions, and to provide for user manuals/instructions for use in the appropriate languages, safety information, warnings and labels.

Refurbished Medical Imaging Equipment for which the registrations and/or licenses of the original or refurbished Medical Imaging Equipment have been discontinued or where there is no original license may require the refurbisher to obtain a valid registration prior to commercialization.

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.

4.4 Preparation for Refurbishment, Disassembly, Packing and Shipment

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. 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.

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):
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

4.5 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.

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.

4.6 Installation of Safety Updates (Hardware/Software)

All relevant safety updates since the equipment was originally placed on the market shall be installed. 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.



4.7 Performance and Safety Test

Tests specified for the original medical imaging equipment shall be conducted to verify the original performance and safety specifications are met.

Activity:	Information and resources needed (examples):
<ul style="list-style-type: none"> Performing a system check Thorough checking of components and subsystems 	<ul style="list-style-type: none"> Instructions per original manufacturer test specifications Test equipment and system check procedure
<ul style="list-style-type: none"> Updating the DHR to show evidence that the equipment was refurbished according to the specification of the equipment 	<ul style="list-style-type: none"> Device History Record of the relevant equipment regarding refurbishment

4.8 Packing, Shipment, and Installation of Refurbished Medical Imaging Equipment

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. Packing and shipment shall be adequate to prevent damage during transit and load/unload operations.

Activity:	Information and resources needed (examples):
<ul style="list-style-type: none"> Packing of the refurbished system 	<ul style="list-style-type: none"> 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

Activity:	Information and resources needed (examples):
<ul style="list-style-type: none"> Transportation to customer's site 	<ul style="list-style-type: none"> Original manufacturer instructions for transportation Original manufacturer specified tools for monitoring transportation, e.g. shock and temperature indicators

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):
<ul style="list-style-type: none"> Professional installation 	<ul style="list-style-type: none"> All involved employees must be trained according to original manufacturer requirements
<ul style="list-style-type: none"> Start-up and repeated check-up of the system's performance 	<ul style="list-style-type: none"> All involved employees must be trained according to original manufacturer requirements
<ul style="list-style-type: none"> Application training as contracted between customer and the organization that performs refurbishment/manufacturer 	<ul style="list-style-type: none"> All involved employees must be trained according to original manufacturer requirements
<ul style="list-style-type: none"> Hand-over of required user documentation and GRP Declaration 	<ul style="list-style-type: none"> User documentation and GRP Declaration
<ul style="list-style-type: none"> Updating the DHR to show evidence that the equipment was refurbished according to the original manufacturer 	<ul style="list-style-type: none"> Device History Record of the relevant equipment regarding refurbishment

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:
<ul style="list-style-type: none"> 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 Refurbishment

Process or combination of processes applied during the expected service life to restore used medical imaging equipment to a condition of safety and effectiveness comparable to when new. Note: Refurbishment can include activities such as repair, rework, replacement of worn parts and update of software/hardware, but shall not include activities that result in regulatory submissions.

5.2 Repair

Means for restoring to a safe, functional, normal condition.

5.3 Used Medical Imaging Equipment

Medical imaging equipment that has been put into service.

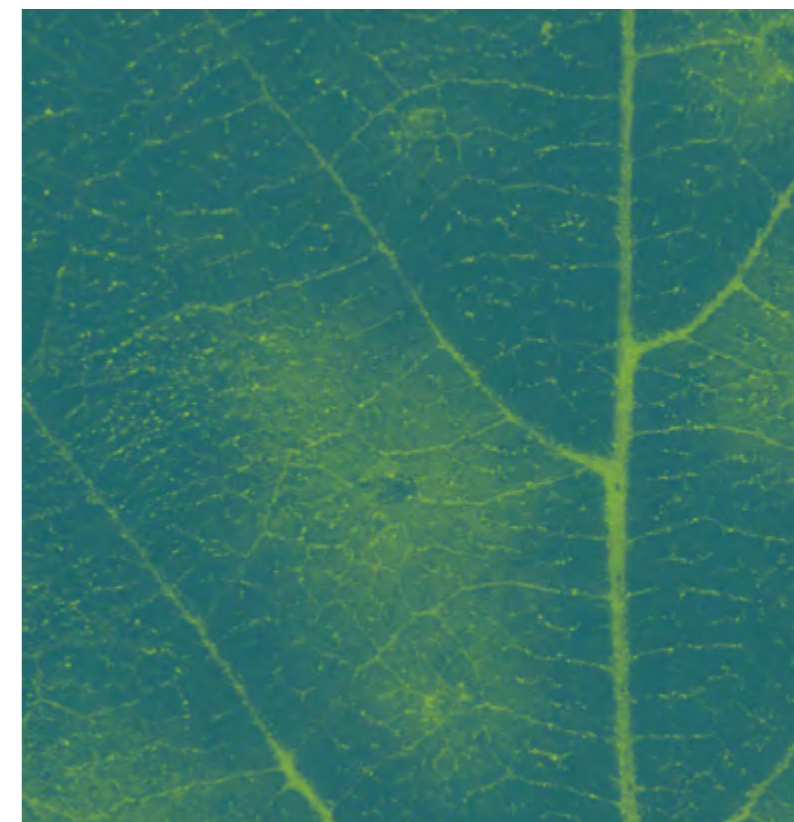
Conclusion

The knowledge about the requirements for refurbishment of used medical imaging equipment or systems described in this Technical Guide 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 health-care service providers to distinguish used medical equipment or systems from those that have been refurbished according to this Technical Guide. 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-Technical Guide should also help the industry to improve the safety and effectiveness of used medical imaging equipment and systems by establishing common quality process standards.

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About DITTA

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