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PUBLICLY AVAILABLE SPECIFICATION

PRE-STANDARD

Good refurbishment practices for medical imaging equipment

IEC PAS 63077:2016-11(en)

International Electrotechnical Commission

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FOREWORD

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IEC PAS 63077 has been processed by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this PAS is based on the following document:	This PAS was approved for publication by the P-members of the committee concerned as indicated in the following document
Draft PAS	**Report on voting**
62B/1022/PAS	62B/1030/RVC

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INTRODUCTION

Keeping up with the latest innovations in medical technology often involves replacing equipment in medical practice before it reaches the end of its expected service life. This is because innovation cycles for medical technology are much shorter than the functional lifecycle of capital equipment. As a result, a sustainable resource management model is required: early replacement of installed medical imaging equipment by newer technology is more economically feasible if the residual value of the existing medical imaging equipment is utilized.

Conserving assets is a fundamental principle of ecological thinking in a recycling economy. Several medical imaging equipment companies have already set up quality management systems to refurbish used medical imaging equipment and have delivered this refurbished equipment across the healthcare sector for many years. Refurbishment addresses the high demand for affordable and reliable products. Customers of this used equipment are not only small hospitals with limited budgets but also leading medical institutes. The EU and the US represent by far the two largest markets for refurbished medical equipment. Refurbishment of used medical imaging equipment is a well-established element of the healthcare economy.

If used medical imaging equipment is not accurately maintained according to requirements defined by the manufacturer, it may result in additional risk for patients and operators. Consequently, some countries have imposed bans on the importation of used medical imaging equipment to protect public health. These bans fail to distinguish between quality-assured refurbished medical imaging equipment and second-hand medical imaging equipment of undefined quality, with the effect that patients may be denied access to the safe and economical medical imaging equipment they need.

Safety and effectiveness are the most important aspects to consider with medical imaging equipment, including used equipment. To ensure safety and effectiveness, used medical imaging equipment has to be refurbished in a highly specialized and quality-assured way.

GOOD REFURBISHMENT PRACTICES FOR MEDICAL IMAGING EQUIPMENT

1 Scope

This document describes and defines the process of refurbishment of used medical imaging equipment and applies to the restoring of used medical imaging equipment to a condition of safety and effectiveness comparable to that of new equipment. This restoration includes actions such as repair, rework, software/hardware updates, and the replacement of worn parts with original parts. This document enumerates the actions that must be performed and the manner consistent with product specifications and service procedures required to ensure that the refurbishment of medical imaging equipment is done without changing the finished medical imaging equipment's performance, safety specifications, or intended use according to its original or applicable valid registration.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
expected service life
time period specified by the manufacturer during which the medical electrical equipment or medical electrical system is expected to remain safe for use (i.e. maintain basic safety and essential performance)

Note 1 to entry: Maintenance can be necessary during the expected service life.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.28]

3.2
intended use
intended purpose
use for which a product, process, or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: Intended use should not be confused with normal use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.44]

3.3
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, labelling, assembling, or adapting medical imaging equipment, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: ISO 13485:2016 defines “labelling” as “written, printed or graphic matter as:

a) affixed to a medical device or any of its containers or wrappers, or

b) accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this document, that material is described as markings and accompanying document.

Note 2 to entry: Adapting includes making substantial modifications to medical imaging equipment already in use.

Note 3 to entry: In some jurisdictions, the responsible refurbisher can be considered a manufacturer when involved in the activities described.

Note 4 to entry: Adapted from ISO 14971:2007, 2.8.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.55, modified – The definition and Note 2 have been reworded.]

3.4
medical imaging equipment
medical electrical equipment that provides images for clinical applications

Note 1 to entry: See IEC 60601-1:2005/AMD1:2012, 3.63 for a definition of medical electrical equipment.

3.5
normal use
operation, including routine inspection and adjustments by any operator, and stand-by, according to the instructions for use

Note 1 to entry: Normal use should not be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.71]

3.6
operator
person handling the medical imaging equipment

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.73, modified – The definition has been reworded.]

3.7
refurbisher
natural or legal person who conducts refurbishment of medical imaging equipment

3.8
patient
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A patient can be an operator.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.76]

3.9
process
set of inter-related or interacting activities which transforms inputs into outputs

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.89]

3.10
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 1 to entry: 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.

3.11
repair
means for restoring to a safe, functional, normal condition

[SOURCE: IEC 62353:2014, 3.39]

3.12
rework
action taken on a nonconforming product so that it will fulfill the specified Device Master Record requirements before it is released for distribution

[SOURCE: 21 CFR 820, 3 (x)]

3.13
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.102]

3.14
used medical imaging equipment
medical imaging equipment that has been put into service

4 General requirements for refurbishment of used medical devices

4.1 Quality management system

Refurbishment of used medical imaging equipment shall be conducted under a quality management system (QMS) of the refurbisher in compliance with ISO 13485:2016. In addition to ISO 13485:2016, the provisions in paragraphs 4.2 to 4.11 shall be applied.

4.2 Resource management

The refurbisher shall determine, and provide adequate resources, including trained and qualified personal, maintained and calibrated equipment, and instructions, procedures, files, records, or documents to perform the refurbishment, as well as an environment for refurbishment that is in complete compliance with the applicable environmental, occupational health and safety, and pest control requirements.

4.3 Corrective and preventive action

The refurbisher shall implement a comprehensive corrective action and preventive action (CAPA) process, addressing the specific aspects of the refurbishment of used medical imaging equipment.

In addition, in the event that the refurbisher identifies, through its CAPA system, safety-related issues that are the responsibility of the original manufacturer and not related to the refurbishment, it shall inform the original manufacturer accordingly.

4.4 Customer complaints

The refurbisher shall have in place a system for managing complaints.

In addition, the refurbisher shall communicate to the original manufacturer all customer complaints that are not related to the refurbishment of the equipment.

4.5 Production and service provision

The refurbisher shall have documented procedures for refurbishment and service including but not limited to process validation, disinfection processes, identification, traceability and packaging. In addition the organization shall make provisions to have the knowledge and the ability for installing and servicing medical imaging equipment, or to ensure that servicing can be made available in those markets where the refurbisher makes refurbished medical imaging equipment available on the market.

4.6 Control of non-conforming product

The refurbisher shall ensure that a product that does not conform to product requirements is identified during refurbishment and controlled to prevent its unintended use or delivery. When a non-conforming product is corrected during refurbishment, it shall be subject to re-verification to demonstrate conformity to the requirements of the original manufacturer.

4.7 Post-market surveillance process

The refurbisher shall collect feedback from customers and establish documented procedures to notify regulatory authorities of adverse events. The process shall also determine if the adverse event is related to the refurbishment of the used medical imaging equipment or needs to be reported to the original manufacturer.

The refurbisher shall also establish his or her own post-market surveillance process to monitor whether the additional risks resulting from refurbishment have been adequately mitigated.

The refurbisher shall enable monitoring of its installed base of refurbished medical imaging equipment to allow for update management for safety and effectiveness.

4.8 Document control

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

4.9 Purchasing

The refurbisher shall establish dedicated supplier management capabilities when components or services are purchased.

4.10 Control of design and design changes

The refurbisher shall review, verify, and validate potential design changes to ensure that the safety and effectiveness requirements of the equipment are not changed from its original or applicable valid registration. All changes, including parts, shall be evaluated to determine if the refurbisher needs registration, as he or she may become the legal manufacturer.

4.11 Risk management process

The refurbisher shall also establish a risk management process that includes any risk introduced by the refurbishment of used medical imaging equipment. This includes changes that would affect parts.

5 Specific requirements for good refurbishment practice

5.1 General

The refurbisher shall establish a specific process for the refurbishment of used medical imaging equipment that, in addition to the general requirements described in Clause 4 includes the following specific requirements.

5.2 Selection of medical imaging equipment for refurbishment

The refurbisher shall determine the criteria that used medical imaging equipment need to meet in order to qualify for refurbishment, based on an assessment of the risk (in accordance with ISO 14971:2007) associated with refurbishment, for any type of medical imaging equipment it wishes to process.

This determination shall consider the following items:

a) intended use and normal use of the equipment;

b) expected service life;

c) applicable standards;

d) service/maintenance history for the equipment;

e) existing procedures for the refurbishment of medical imaging equipment, such as service, repair, production, and maintenance.

Used medical imaging equipment that is at the end of expected service life or that cannot be restored to at least the original safety and performance levels, including all mandatory safety updates, shall not be refurbished.

5.3 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 or restrictions, and to provide instructions for use in the appropriate languages, safety information, warnings, and labels.

Refurbished medical imaging equipment for which the registrations 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.

5.4 Preparation for refurbishment, disassembly, packing, and shipment

The refurbisher shall have procedures in place to ensure that the medical imaging equipment has been suitably cleaned and disinfected to avoid harming any person involved in the disassembly, packing, and shipment. The medical imaging equipment shall be adequately

disassembled (if necessary) and packed to prevent damage during shipment. Appropriate procedures shall be in place to avoid violation of privacy rules concerning patient data possibly stored on the relevant equipment.

5.5 Planning

A refurbishment plan shall be developed and followed to restore the medical imaging equipment to a condition of safety and effectiveness comparable to when new.

5.6 Installation of safety updates (hardware/software)

The refurbisher shall install all safety updates released by the manufacturer for the relevant medical imaging equipment since it was placed on the market.

5.7 Performance and safety test

Tests specified for the original medical imaging equipment shall be conducted to verify that original performance and safety specifications are met, including all mandatory safety updates.

5.8 Packing, shipment, and installation of refurbished medical imaging equipment

Packing and shipment shall be adequate to prevent damage during transit and load/unload operations. Installation, inspection, and any required testing shall be performed according to documented procedures of the manufacturer.

5.9 Record of refurbishment

The record shall reflect for the relevant medical imaging equipment that all operations and processes described in the refurbishment plan have been accomplished. In addition, the record of refurbishment is specifically required to contain, or refer to the location of, the following information:

a) date of refurbishment;

b) any medical imaging equipment identification and control numbers used;

c) the primary identification label and labelling used for each refurbished unit;

d) the acceptance records that demonstrate that the equipment has been refurbished in accordance with the refurbishment plan;

e) list of replaced parts and their identification information.

The record shall authenticate any refurbished medical imaging equipment through means that allow inspection by authorities and verification by customers as requested.

5.10 Refurbishment label

The refurbisher shall label all refurbished medical imaging equipment in proximity to the original label identifying that the medical imaging equipment has been refurbished by the refurbisher and the date of refurbishment.

Bibliography

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 62353:2014, *Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment*

US FDA 21 CFR Part 820 Quality System Regulation, *Title 21 – Food and drugs – Chapter I – Food and drug administration department of health and human services – Subchapter H – Medical devices – Part 820: Quality system regulation*

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