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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Good refurbishment practices for medical imaging equipment

Bonnes pratiques de reconditionnement pour les appareils d'imagerie médicale

IEC 63077:2019-11(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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GOOD REFURBISHMENT PRACTICES FOR MEDICAL IMAGING EQUIPMENT

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 63077 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This first edition cancels and replaces the second edition of IEC PAS 63077 published in 2016. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to IEC PAS 63077:2016:

a) the scope was delineated more clearly;
b) an informative cross reference list of IEC 63077 vs ISO 13485 (Annex A) was added;
c) smaller corrections were performed.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62B/1149/FDIS	62B/1155/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

– requirements and definitions: roman type;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3: SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This document specifies requirements for a quality management system that can be used by organizations involved in REFURBISHMENT of MEDICAL IMAGING EQUIPMENT.

The requirements defined in this document can be used by MANUFACTURERS or organizations providing REFURBISHMENT. Organizations providing REFURBISHMENT can voluntarily choose to conform to the requirements of this document or can be required by contract with the MANUFACTURER of the MEDICAL IMAGING EQUIPMENT to conform.

Several jurisdictions have regulatory requirements regarding refurbished MEDICAL IMAGING EQUIPMENT e.g. regarding the import and making refurbished MEDICAL IMAGING EQUIPMENT available. These regulatory requirements differ from nation to nation and region to region. The organizations involved in REFURBISHMENT of MEDICAL IMAGING EQUIPMENT should understand how the regulatory requirements in the several jurisdictions will be interpreted and may be met by applying this document.

In some jurisdictions a definition of the term remanufacturer is available. This document does not cover the topic of how organizations are acting in the role of a remanufacturer.

This document can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet requirements applicable for the REFURBISHMENT of MEDICAL IMAGING EQUIPMENT.

It is emphasized that the requirements specified in this document are complementary to other International Standards such as on quality management system and on RISK management.

There is a wide variety of medical equipment with different requirements on REFURBISHMENT. Therefore, this document only applies to named groups of MEDICAL IMAGING EQUIPMENT. These groups are defined in Clause 1 Scope.

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 performance comparable to that of new MEDICAL IMAGING EQUIPMENT i.e. MEDICAL IMAGING EQUIPMENT that was not in use. 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 are performed, and the manner consistent, with relevant 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.

The MEDICAL IMAGING EQUIPMENT and systems covered by this document include:

– X-RAY EQUIPMENT;
– X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES;
– X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY;
– MAGNETIC RESONANCE EQUIPMENT;
– ULTRASONIC DIAGNOSTIC EQUIPMENT;
– GAMMA CAMERAS;
– PLANAR WHOLEBODY IMAGING EQUIPMENT;
– equipment for SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT);
– SPECT/CT hybrid systems, combining a GAMMA CAMERA with X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY (CT);
– POSITRON EMISSION TOMOGRAPHS (PET);
– PET/CT hybrid systems combining a POSITRON EMISSION TOMOGRAPH with X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY (CT);
– PET/MRI hybrid systems combining a POSITRON EMISSION TOMOGRAPH with MAGNETIC RESONANCE EQUIPMENT; and
– other combinations of the MEDICAL IMAGING EQUIPMENT or systems listed above.

This document does not apply to endoscopic equipment, funduscopic equipment, radiation therapy equipment, nor associated systems.

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: Adapting includes making substantial modifications to MEDICAL IMAGING EQUIPMENT already in use.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.55, modified – The term MEDICAL IMAGING EQUIPMENT is replacing ME EQUIPMENT or ME SYSTEM in the definition and in the Note to entry, and three Notes to entry have been deleted.]

3.4
MEDICAL IMAGING EQUIPMENT
medical electrical equipment that provides images for clinical applications

Note 1 to entry: See IEC 60601-1:2005, 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, 3.73, modified – "Equipment" was replaced by "medical imaging equipment".]

3.7
REFURBISHER
natural or legal person who conducts REFURBISHMENT of MEDICAL IMAGING EQUIPMENT

Note 1 to entry: In some jurisdictions, the responsible REFURBISHER can be considered as MANUFACTURER when involved in the activities described.

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
PRODUCT
result of PROCESS

[SOURCE: ISO 13485:2016, 3.15]

3.11
REFURBISHMENT
PROCESS or combination of PROCESSES applied during the EXPECTED SERVICE LIFE to restore USED MEDICAL IMAGING EQUIPMENT to a condition of safety and performance according to the specification of the MANUFACTURER.

Note 1 to entry: REFURBISHMENT can include activities such as REPAIR, REWORK, replacement of worn parts, and update of software/hardware but does not include activities that result in the need of a new certification of the MEDICAL IMAGING EQUIPMENT and a legal MANUFACTURER status of the REFURBISHER.

Note 2 to entry: REFURBISHMENT does not include restoration after the EXPECTED SERVICE LIFE.

Note 3 to entry: In some jurisdictions a definition of the term remanufacturer is available. REFURBISHMENT differs from actions related to REFURBISHER acting in the role of a remanufacturer.

Note 4 to entry: In some jurisdictions a definition of the term reprocessing is available. In those jurisdictions the term reprocessing is typically related to reusable medical devices such as single-use medical devices and is related to processes such as sterilization. REFURBISHMENT is different from reprocessing.

Note 5 to entry: REFURBISHMENT may result in a higher level of safety because e.g. safety updates released by the MANUFACTURER for the relevant MEDICAL IMAGING EQUIPMENT are applied within REFURBISHMENT.

3.12
REPAIR
means for restoring to a safe, functional, normal condition

[SOURCE: IEC 62353:2014, 3.39]

3.13
REWORK
action taken on a nonconforming PRODUCT so that it will fulfill the specified Device Master Record requirements before it is released for distribution

3.14
RISK
combination of the probability of occurrence of harm and the severity of that harm

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

3.15
USED MEDICAL IMAGING EQUIPMENT
MEDICAL IMAGING EQUIPMENT that has been put into service

4 General requirements for REFURBISHMENT of USED MEDICAL IMAGING EQUIPMENT

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 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;
– instructions, procedures, files, records, or documents to perform the REFURBISHMENT; and
– an environment for REFURBISHMENT that is in compliance with the applicable environmental, occupational health and safety 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 MEDICAL IMAGING 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 REFURBISHER 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 nonconforming 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 nonconforming 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 caused by the refurbished MEDICAL IMAGING EQUIPMENT. 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 its 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 performance.

NOTE To term installed base: All refurbished MEDICAL IMAGING EQUIPMENT provided by the REFURBISHER and installed, which meets all acceptance criteria for verification of installation.

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 document procedures to ensure that purchased components, service parts and other materials such as packaging material, services as needed for REFURBISHMENT conforms to purchasing information as specified by the MANUFACTURER of the MEDICAL IMAGING EQUIPMENT. The REFURBISHER shall establish dedicated supplier management capabilities when components, services, or other materials such as packaging materials, 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 performance requirements of the MEDICAL IMAGING EQUIPMENT are not changed from its original or applicable valid registration. All changes, including parts, shall be evaluated to determine if the MEDICAL IMAGING EQUIPMENT needs new certification and the REFURBISHER needs registration, as it may become the legal MANUFACTURER.

NOTE Control of design and design changes are not applicable to a REFURBISHER because this can result in the need of a new certification of the MEDICAL IMAGING EQUIPMENT and a legal MANUFACTURER status of the REFURBISHER.

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.