IEC 63077

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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

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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*