Good refurbishment practices for medical imaging equipment

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 63077:2019 sisaldab Euroopa standardi EN IEC 63077:2019 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 63077:2019 consists of the English text of the European standard EN IEC 63077:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.12.2019.	Date of Availability of the European standard is 20.12.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.55

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 63077

December 2019

ICS 11.040.55

English Version

Good refurbishment practices for medical imaging equipment (IEC 63077:2019)

Bonnes pratiques de reconditionnement pour les appareils d'imagerie médicale (IEC 63077:2019)

Sachgemäße Verfahren zur Aufarbeitung von medizinischen bildgebenden Geräten (IEC 63077:2019)

This European Standard was approved by CENELEC on 2019-12-18. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 63077:2019 E

European foreword

The text of document 62B/1149/FDIS, future edition 1 of IEC 63077, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 63077:2019.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-09-18
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-12-18

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 63077:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1:2005	NOTE	Harmonized as EN 60601-1:2006 (not modified)
IEC 62353:2014	NOTE	Harmonized as EN 62353:2014 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
ISO 13485	-	Medical devices -- Quality management systems -- Requirements for regulatory purposes	EN ISO 13485	2016
-	-		+ AC	2018
ISO 14971	2007	Medical devices - Application of risk management to medical devices	-	-

CONTENTS

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.