Medical electrical equipment
Part 1.3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment

Amendment No. 1

Revised text amendment

Publishing and Approval Dates

Council of Standards Australia Approval: 15 May 2022

New Zealand Standards Approval Board Approval: 4 May 2022

Published: 3 June 2022

Summary

This Amendment applies to the following elements:

- Front cover
- Preface
- Amendment 2

Amendment Details

AS/NZS IEC 60601.1.3:2015 is amended as follows. The amendments should be inserted in the locations as instructed.

Element		Instruction / New text
Front cover		Top right-hand corner, *replace* "IEC 60601-1-3 Ed.2.1 (2013)" with the following: IEC 60601-1-3:2008+AMD1:2013 CSV IEC 60601-1-3:2008/AMD 2:2021 (Incorporating Amendment No. 1)
Preface	1	After the first paragraph, *add* the following: Amendment No. 1 to this Standard was prepared by the joint Standards Australia/ Standards New Zealand Committee HE-003, Medical Electrical Equipment.
	2	*Delete* the third paragraph and *replace* with the following: This document is identical with, and has been reproduced from IEC 60601-1-3:2008+AMD1:2013 CSV, *Medical electrical equipment, Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment*. The text affected by Amendment 1 is indicated in the source document by marginal bars, redline and strikeout. Amendment No. 2 (2021) has been added at the end of the source text.
Amd 2 (new)		After "Index of defined terms used in this collateral standard", *add* the following Amendment No. 2 (2021):

© Standards Australia Ltd/the Crown in right of New Zealand, administered by the New Zealand Standards Executive 2022

ISBN 978 1 76113 798 3

Full document details: AS NZS IEC 60601.1.3-2015 amd1-2022

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

PART 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment

AMENDMENT 2

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

Amendment 2 to IEC 60601-1-3:2008 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

Draft	Report on voting
62B/1176/CDV	62B/1227/RVC

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

Documents
Document Sharing Hub

Full document details: AS NZS IEC 60601.1.3-2015 amd1-2022