AS/NZS IEC 60601.1.3:2015
IEC 60601-1-3:2008+AMD1:2013+AMD2:
2021 CSV
(Incorporating Amendment No. 1)

Australian/New Zealand Standard™

Medical electrical equipment

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

AS/NZS IEC 60601.1.3:2015

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 19 August 2015 and on behalf of the Council of Standards New Zealand on 21 August 2015.

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The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
Medical Technology Association of Australia
Ministry of Business, Innovation and Employment, New Zealand
New Zealand Institute of Healthcare Engineering
Testing Interests, Australia
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Originated as AS/NZS 3200.1.3:1996.
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Preface

This Standard was prepared by the joint Standards Australia/Standards New Zealand Committee, HE-003 Medical Electrical Equipment, to supersede AS/NZS 3200.1.3:1996, *Approval and test specification—Medical electrical equipment, Part 1.3: General requirements for safety—Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment*.

〈A1〉*Amendment No. 1 (June 2022) to this Standard was prepared by the joint Standards Australia/Standards New Zealand Committee HE-033, Medical Electrical Equipment.*〈A1〉

The objective of this Standard is to specify general requirements for protection against X-radiation in X-ray equipment, in order that the irradiation of the human patient, the operator, staff, and members of the public can be kept low as reasonably achievable, without jeopardizing the benefit of the radiological procedure. It considers radiation protection aspects related to X-radiation only. The particular requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015.

〈A1〉This document is identical with, and has been reproduced from IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 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 Amendments 1 and 2 is indicated in the source document by marginal bars, redline and strikeout.〈A1〉

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian/New Zealand Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standards	*Australian/New Zealand Standards*
IEC 60601.1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	AS/NZS IEC 60601.1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the annex to which they apply. A 'normative' annex is an integral part of a Standard, whereas an 'informative' annex is only for information and guidance.

NOTES