

Australian/New Zealand Standard™

Medical electrical equipment

**Part 2.8: Particular requirements for the
basic safety and essential performance
of therapeutic X-ray equipment
operating in the range 10 kV to 1 MV**



AS/NZS IEC 60601.2.8:2015

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 23 November 2015 and on behalf of the Council of Standards New Zealand on 4 November 2015.

This Standard was published on 18 December 2015.

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, New Zealand
College of Biomedical Engineering, Engineers Australia
Department of Defence, Australia
Engineers Australia
Medical Technology Association of Australia
New Zealand Institute of Healthcare Engineering
Testing Interests, Australia
Therapeutic Goods Administration, Australia
Wairarapa District Health Board, New Zealand
Waitemata District Health Board, New Zealand
WorkSafe New Zealand

Keeping standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.saiglobal.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

Australian/New Zealand Standard™

Medical electrical equipment

**Part 2.8: Particular requirements for the
basic safety and essential performance
of therapeutic X-ray equipment
operating in the range 10 kV to 1 MV**

Originally as AS/NZS 3200.2.8:1994.
Jointly revised and redesignated as AS/NZS IEC 60601.2.8:2015.

COPYRIGHT

© Standards Australia Limited/Standards New Zealand

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Australia) or the Copyright Act 1994 (New Zealand).

Jointly published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001 and by Standards New Zealand, Private Bag 2439, Wellington 6140.

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.8:1994, *Medical electrical equipment, Part 2.8: Particular requirements for safety—Therapeutic X-ray generators*.

The objective of this Standard is to establish requirements for the safety of therapeutic X-ray equipment, including the accuracy and reproducibility of performance to the extent that these are related to radiation quality and the quantity of ionizing radiation produced.

The 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, which is referred to in the source text as ‘the general standard’.

This Standard is identical with, and has been reproduced from IEC 60601-2-8, Ed.2.0 (2014), *Medical electrical equipment, Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*.

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:

<i>Reference to International Standard</i>	<i>Australian/New Zealand Standard</i>
IEC	AS/NZS IEC
60601 Medical electrical equipment	60601 Medical electrical equipment
60601-2-1 Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	60601.2.1 Part 2.1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

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

CONTENTS

201.1	Scope, object and related standards	6
201.2	Normative references	7
201.3	Terms and definitions	8
201.4	General requirements	8
201.5	General requirements for testing of ME EQUIPMENT	9
201.6	Classification of ME EQUIPMENT and ME SYSTEMS	11
201.7	ME EQUIPMENT identification, marking and documents	11
201.8	Protection against electrical HAZARDS from ME EQUIPMENT	4
201.9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	15
201.10	Protection against unwanted and excessive radiation HAZARDS	15
201.11	Protection against excessive temperatures and other HAZARDS	30
201.12	Accuracy of controls and instruments and protection against hazardous outputs	30
201.13	HAZARDOUS SITUATIONS and fault conditions	30
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	31
201.15	Construction of ME EQUIPMENT	31
201.16	ME SYSTEMS	31
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	31
	Bibliography	32
	Index of defined terms used in this particular standard	33
	Table 201.101 – Data required in the technical description to support Clause 201.10 SITE and TYPE TEST compliance	10
	Table 201.102 – Permissible LEAKAGE RADIATION	16
	Table 201.103 – Permissible LEAKAGE RADIATION from X-RAY TUBE ASSEMBLIES with BEAM LIMITING DEVICES	18
	Table 201.104 – Overview of measurements	29

IEC FOREWORD

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic 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 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

INTRODUCTION

X-RAY EQUIPMENT for RADIOTHERAPY purposes is used for TELETHERAPY, where the RADIATION SOURCE is far from the tissues to be treated (usually more than 50 cm), and also for BRACHYTHERAPY, where the RADIATION SOURCE is positioned within or adjacent to the tissue to be treated. This particular standard covers X-RAY EQUIPMENT for both TELETHERAPY and BRACHYTHERAPY.

The use of X-RAY EQUIPMENT for RADIOTHERAPY purposes may expose the PATIENT to danger if the equipment fails to deliver the required dose to the PATIENT, or if the equipment design does not satisfy standards of electrical and mechanical safety. The equipment may also cause danger to persons in the vicinity if the equipment itself fails to contain the radiation adequately and/or if there are inadequacies in the design of the TREATMENT ROOM.

This particular standard establishes requirements to be complied with by the MANUFACTURERS in the design and construction of therapeutic X-RAY EQUIPMENT. Subclause 201.10.1 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition.

Subclause 201.10.1 does not attempt to define optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such equipment. It places limits on the degradation of equipment performance beyond which it can be presumed that a fault condition exists, e.g. a component failure, and where an INTERLOCK then operates to prevent continued operation of the equipment.

It should be understood that, before installation, the MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS: data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the equipment at installation.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.8:

Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Replacement:

This international standard applies to the basic safety and essential performance of therapeutic X-RAY EQUIPMENT with NOMINAL X-RAY TUBE VOLTAGES in the range 10 kV to 1 MV when connected to alternating current SUPPLY MAINS, hereafter referred to as ME EQUIPMENT.

NOTE This standard covers TELETHERAPY and BRACHYTHERAPY.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular basic safety and essential performance requirements for therapeutic X-RAY EQUIPMENT. It includes the requirements for accuracy and reproducibility of performance to the extent that these are related to radiation quality and the quantity of ionizing radiation produced and thus must be considered as aspects of safety.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3 and IEC 60601-1-10²⁾ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

2) IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*