

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Amendment No. 1
to
AS/NZS 3200.2.8:1994
Approval and test specification—Medical electrical equipment
Part 2.8: Particular requirements for safety—
Therapeutic X-ray generators

REVISED TEXT

The 1994 edition of AS/NZS 3200.2.8 is amended as follows; the amendment(s) should be inserted in the appropriate place.

SUMMARY: This Amendment is in two parts. Part A applies to the title and Preface. Part B is technically equivalent to and reproduced from IEC 60601-2-8 Amendment 1:1997.

Published on 5 September 1999.

Approved for publication in New Zealand on behalf of the Standards Council of New Zealand on 23 August 1999.

PART A

AMDT
No. 1
SEP.
1999

Title

Delete the existing title of the Standard wherever it appears and *replace* with the following:

Medical electrical equipment, Part 2.8: Particular requirements for safety—Therapeutic X-ray generators.

AMDT
No. 1
SEP.
1999

Page ii Preface

Add the following new item:

- (c) In Subclause 29.101.4(d), SITE TEST grade B, as amended by Amendment 1:1977 to IEC 60601-2-8:1987 in the third line *replace* 'calibrated stopwatch' with 'calibrated device'.

Rationale: The use of a stopwatch to check the accuracy of a dose monitor is inappropriate.

AMDT
No. 1
SEP.
1999

PART B

Replace existing text as specified below.

CONTENTS

Add, after PREFACE, the following title:

INTRODUCTION

Add the titles of the following new subclauses:

1.3.103 IEC 61217

1.5 Collateral Standards

6.3 Marking of controls and instruments

Replace the title of SECTION TWO by the following:

SECTION TWO – ENVIRONMENTAL CONDITIONS

Replace the title of clause 18 by the following:

18 Protective earthing, functional earthing and potential equalization

Add the titles of the following new subclauses:

29.103 Indication of X-RADIATION output

29.104 Agreement between indicated values and effective values

29.105 General test conditions

29.106 Settings for measurements

29.107 Number of measurements

29.108 Measurements and evaluation

Replace the title of SECTION SIX by the following:

**SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION
OF FLAMMABLE ANAESTHETIC MIXTURES**

Replace the title of SECTION SEVEN by the following:

**SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES
AND OTHER SAFETY HAZARDS**

Delete the title of clause 48 and replace it by “Biocompatibility”.

Replace the title of SECTION EIGHT by the following:

**SECTION EIGHT – ACCURACY OF OPERATING DATA AND
PROTECTION AGAINST HAZARDOUS OUTPUT**

Delete the titles of subclauses 50.1 to 50.104.

Delete the title of clause 59.4.

Replace “APPENDIX AA” by “ANNEX AA”.

Add, after ANNEX AA, the following new ANNEX BB:

ANNEX BB – List of standards mentioned in this Particular Standard

In this Particular Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions, in roman type;
- explanations, advice, general statements and exceptions: in small roman type;
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN LISTED IN ANNEX AA AND DEFINED IN CLAUSE 2, OR IN THE GENERAL STANDARD 60601-1 AND ITS COLLATERAL STANDARDS OR IN IEC 60788: SMALL CAPITALS.

Replace, throughout the Standard, the term "X-RAY GENERATOR" by "X-RAY EQUIPMENT".

Add, after the foreword, the following new introduction:

INTRODUCTION

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. Clause 29 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition.

Clause 29 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, a 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.

Replace the title of SECTION EIGHT by the following:

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data

Delete the first line of this clause and delete subclauses 50.1 to 50.104.3.

NOTE – See table 104 for equivalent clause reference numbers.

51 Protection against hazardous output

Replace the text of the addition by the following:

Protection against hazardous output is considered to exist by compliance with clause 29.

NOTE – See table 104 for equivalent clause reference numbers.

Replace the title of SECTION NINE by the following:

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS, ENVIRONMENTAL TESTS

52 Fault conditions causing overheating and/or mechanical damage

Replace this title by the following:

52 Abnormal operation and fault conditions

52.1 Replacement:

a) EQUIPMENT shall be so designed and manufactured that, even in S.F.C., no SAFETY HAZARD exists (see 3.1 and clause 13).

NOTE – It is assumed that EQUIPMENT is operated according to the conditions of NORMAL USE, unless specified otherwise in the following tests.

Compliance is fulfilled if:

The introduction of any of the S.F.C.s described in 52.5, one at a time, does not lead directly to any of the SAFETY HAZARDS described in 52.4.

b) The safety of EQUIPMENT incorporating P.E.Ss shall be assessed against the requirements of IEC 60601-1-4 (see annex BB).

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

Replace the first line of SECTION TEN by the following:

Clauses 54 to 59 of the General Standard apply.

APPENDIX AA

Replace "APPENDIX AA" by "ANNEX AA" and amend as indicated below:

AA2 ALPHABETIC INDEX OF ENGLISH TERMS

FRENCH TERMS

Delete the following terms:

ADDITIONAL PROTECTIVE EARTH CONDUCTOR	NG.06.01	CONDUCTEUR SUPPLÉMENTAIRE DE PROTECTION
COEFFICIENT OF VARIATION, SEE rm-73-02	NG.12.01	COEFFICIENT DE VARIATION, VOIR rm-73-02
PROTECTIVE EARTH TERMINAL	NG.06.08	BORNE DE TERRE DE PROTECTION
PROTECTIVE IMPEDANCE	NG.03.06	IMPÉDANCE DE PROTECTION
TYPE B EQUIPMENT	NG.02.25	APPAREIL DE TYPE B

Add the following terms:

Publication IEC 60601-2-11 (1997)	2.....	Publication CEI 60601-2-11 (1997)
Publication IEC 60601-2-1 Ed. 2 (to be published)	2.1.....	Publication CEI 60601-2-1 Ed. 2 (à paraître)
Publication IEC 60601-1-2 (1993)	2.203....	Publication CEI 60601-1-2 (1993)
CONTROLLING TIMER (abbr.: TIMER)	2.1.101	MINUTERIE
DISPLAY	rm-84-01	AFFICHER/AFFICHAGE
DOSE MONITORING SYSTEM	rm-33-01	SYSTÈME DE SURVEILLANCE DE DOSE
ELECTROMAGNETIC COMPATIBILITY (EMC)	2.203.4	COMPATIBILITÉ ÉLECTROMAGNÉTIQUE (CEM)
FLAMMABLE ANAESTHETIC MIXTURE WITH AIR	NG.12.15	MÉLANGE ANESTHÉSIQUE INFLAMMABLE AVEC DE L'AIR
FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	NG.12.16	MÉLANGE ANESTHÉSIQUE INFLAMMABLE AVEC OXYGÈNE OU PROTOXYDE D'AZOTE
INTERLOCK (TO INTERLOCK)	rm-83-05	VERROUILLAGE (VERROUILLER)
INTERRUPTION OF RADIATION / TO INTERRUPT IRRADIATION	2.1.106	INTERROMPRE L'IRRADIATION / INTERRUPTION DE L'IRRADIATION
IONIZING RADIATION	rm-11-02	RAYONNEMENT IONISANT
MANUFACTURER	rm-85-03	CONSTRUCTEUR
MOVING BEAM RADIOTHERAPY	rm-42-41	RADIOTHÉRAPIE CINÉTIQUE
NORMAL TREATMENT DISTANCE	2.1.109	DISTANCE NORMALE DE TRAITEMENT
PRIMARY/SECONDARY (TIMER) COMBINATION	2.109	COMBINAISON PRIMAIRE/SECONDAIRE DE MINUTERIES
PRIMARY/SECONDARY DOSE MONITORING COMBINATION	2.1.112	COMBINAISON SYSTÈME PRIMAIRE/SYSTÈME SECONDAIRE DE SURVEILLANCE DE DOSE
RADIATION SOURCE TO SKIN DISTANCE	rm-37-14	DISTANCE SOURCE DE RAYONNEMENT – PEAU
REDUNDANT (TIMER) COMBINATION	2.113	COMBINAISON REDONDANTE DE MINUTERIES
REDUNDANT DOSE MONITORING COMBINATION	2.1.115	COMBINAISON REDONDANTE DE SYSTÈMES DE MESURE DE DOSE
SITE TEST	2.1.117	ESSAI SUR LE SITE
TERMINATION OF IRRADIATION / TO TERMINATE IRRADIATION	2.1.118	FIN DE L'IRRADIATION / FINIR L'IRRADIATION
TIMER (abbr. FOR CONTROLLING TIMER, see IEC 601-2-11 Ed.2)	2.1.101	MINUTERIE
TYPE B APPLIED PART	NG.2.24	PARTIE APPLIQUÉE DE TYPE B
TYPE TEST	2.1.120	ESSAI DE TYPE

Annex BB (normative)

List of standards mentioned in this Particular Standard

This Particular Standard incorporates references to other publications. These normative references are cited at the appropriate places in the text and listed below.

IEC 60529: 1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1: 1992, *Medical electrical equipment – Part 1: General requirements for safety – 1: Collateral standard: safety requirements for medical electrical systems*
Amendment 1 (1995)

IEC 60601-1-2: 1993, *Medical electrical equipment – Part 1: General requirements for safety – 2: Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3: 1994, *Medical electrical equipment – Part 1: General requirements for safety – 3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60601-1-4: 1996, *Medical electrical equipment – Part 1: General requirements for safety – 4: Collateral standard: Programmable electrical medical systems*

IEC 60788: 1984, *Medical radiology – Terminology*

IEC 61217: 1996, *Radiotherapy equipment – Coordinates, movements and scales*

AS/NZS 3200.2.8:1994
IEC 601-2-8:1987

Australian/New Zealand Standard

Approval and test specification— Medical electrical equipment

Part 2.8: Particular requirements for safety—Therapeutic X-ray generators

[IEC title: Medical electrical equipment, Part 2: Particular requirements for the safety of therapeutic X-ray generators]

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AS/NZS 3200.2.8:1994

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/23, Medical Diagnostic Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 29 June 1994 and on behalf of the Council of Standards New Zealand on 27 June 1994. It was published on 17 October 1994.

The following interests are represented on Committee HT/23:

Australian Academy of Dento-Maxillo-Facial Radiologists
 Australian and New Zealand Society of Nuclear Medicine
 Australian Chamber of Commerce and Industry
 Australian College of Physical Scientists and Engineers in Medicine
 Australian Dental Association
 Australian Institute of Radiography
 Australian Radiation Laboratory
 Department of Defence, Australia
 Environment Protection Authority, N.S.W.
 Health Department, W.A.
 Ministry of Commerce, New Zealand
 Public Works Department, N.S.W.
 Queensland Health
 Radiation Health Standing Committee
 Royal Australasian College of Radiologists
 South Australian Health Commission
 United Dental Hospital, Sydney
 University of Sydney
 University of Waikato, New Zealand

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Suggestions for improvements to Joint Standards, addressed to the head office of either Standards Australia or Standards New Zealand, are welcomed. Notification of any inaccuracy or ambiguity found in a Joint Australian/New Zealand Standard should be made without delay in order that the matter may be investigated and appropriate action taken.



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AS/NZS 3200.2.8:1994

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Approval and test specification— Medical electrical equipment

Part 2.8: Particular requirements for safety—Therapeutic X-ray generators

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/23 on Medical Diagnostic Imaging Equipment as a Joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

This Standard is identical with and has been reproduced from IEC 601-2-8:1987, *Medical electrical equipment, Part 2: Particular requirements for the safety of therapeutic X-ray generators*.

This Standard is one of a series of Approval and Test Specifications issued by Standards Australia and Standards New Zealand for various categories of medical equipment. It is supplementary to AS/NZS 3200.1:1990, *Approval and test specification—Medical electrical equipment, Part 1, General requirements for safety*.

The international Standard IEC 601-2-8 modifies and supplements the corresponding Clauses of IEC 601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS/NZS 3200.1 hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

In the text of this Standard, the following print types are used:

- (i) Requirements, compliance with which can be tested and definitions in large roman type
- (ii) Explanations, advice, introductions, general statements, exceptions and references in smaller roman type
- (iii) Headings of sub-clauses and text specifications in italic type
- (iv) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS

The Appendices of this Standard, AA and BB form an integral part of the Standard; Appendix CC is for information purposes only.

Under arrangements made between Standards Australia/Standards New Zealand and ISO/IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover and title page.

For the purpose of this Standard, the IEC text should be modified as follows:

- (a) *Terminology* The words 'this Australian/New Zealand Standard' should replace the word 'this International Standard' wherever they appear.
- (b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.

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AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification—Medical electrical equipment**Part 2.8:****Particular requirements for safety—Therapeutic X-ray generators**

SECTION ONE — GENERAL

1. Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope*Addition:*

This Particular Standard applies to therapeutic X-RAY GENERATORS that operate with NOMINAL X-RAY TUBE VOLTAGES from 10 kV to 400 kV inclusive when connected to alternating current SUPPLY MAINS.

1.2 Object*Replacement:*

The object of this Particular Standard is to establish the particular requirements for safety including 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.

An object of this Particular Standard is to present the general functional requirements of the demand for safety, rather than any particular technological means of implementation.

1.3 Particular Standards*Additional sub-clauses:***1.3.101 Relation to the General Standard**

This Particular Standard refers to, and is to be read in conjunction with IEC Publication 601-1 (1977): Safety of Medical Electrical Equipment, Part 1: General Requirements and its Amendment No. 1 (1984).

For brevity Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over the corresponding General Requirement(s).

Where there is no corresponding clause or sub-clause in this Particular Standard, the clause or sub-clause of the General Standard applies without modification.

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