

## STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Amendment No. 1  
to  
AS/NZS 3200.2.17:1994  
**Approval and test specification—Medical electrical equipment**  
**Part 2.17: Particular requirements for safety—Remote-controlled**  
**automatically driven gamma-ray afterloading equipment**

## REVISED TEXT

The 1994 edition of AS/NZS 3200.2.17 is amended as follows; the amendments should be inserted in the appropriate place.

**SUMMARY:** This Amendment applies to Contents, Introduction, Clauses 1.3, 1.4, 1.5, 1.5.101, 1.5.102, 1.5.103, 1.5.104, 3, 4, 4.1, 5.2, 5.5, 5.7, 6.1, 6.8.2 d), 6.8.2 e), Section Two, Clauses 9, 10, 10.2.1, 11, 12, 36, Sections 6, 7, 8, Clauses 50, 50.1.4, 50.2.2, 51, Section 9, Clauses 52, 53, Appendix AA, and Clauses AA2 and AA2.14.

The text of this Amendment is reproduced from and is identical to IEC 601-2-17 Amendment 1:1996.

Published on 5 April 1977.

Approved for publication in New Zealand on behalf of the Standards Council of New Zealand on 7 February 1997.

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*Add the title of the following new subclause:*

1.5 Collateral Standards

*Replace the title of SECTION TWO by the following:*

**SECTION TWO – ENVIRONMENTAL CONDITIONS**

*Replace the title of clause 10 by the following:*

10 Environmental conditions

*Delete the titles of clauses 11 and 12.*

*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**

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*Replace the title of SECTION EIGHT by the following:*

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

*Replace the title of clause 51 by the following:*

51 Protection against hazardous output

*Replace the title of SECTION NINE by the following:*

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS;  
ENVIRONMENTAL TESTS

FOREWORD

*Delete item 4).*

PREFACE

*Replace the list of publications by the following:*

Publication Nos. 601-1 (1988): Medical electrical equipment – Part 1: General requirements for safety.  
Amendment 1 (1991).  
Amendment 2 (1995).

601-1-2 (1993): Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral  
standard: Electromagnetic compatibility – Requirements and tests.

788 (1984): Medical radiology – Terminology.

*Other publication quoted:*

ISO 361 (1975): Basic ionizing radiation symbol.

INTRODUCTION

*Replace the text in brackets by the following:*

IEC 601-1, second edition (1988) with amendments 1 (1991) and 2 (1995).

*Delete the footnote.*

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### 3 General requirements

*Replace the text of this clause by the following:*

This clause of the General Standard applies.

### 4 General requirements for tests

*Delete the replacement.*

#### 4.1 Tests

*Addition:*

- aa) Appropriate care should be taken to carry out compliance tests safely, for example by using a dummy source wherever possible. The type tests described in this Particular Standard may also be used by the manufacturer or by the installer as routine tests.

#### Subclause 5.2

*Replace the text of this subclause by the following:*

According to the degree of protection against electric shock:

APPLIED PART within the scope of this Standard shall be TYPE B APPLIED PART.

#### Subclause 5.5

*Replace the text of this subclause by the following:*

According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE:

EQUIPMENT within the scope of this Standard shall be EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE.

#### Subclause 5.7

*Delete this subclause.*

#### 6.1 Marking on the outside of EQUIPMENT

*Replace the title of this subclause by the following:*

*Marking on the outside of EQUIPMENT or EQUIPMENT parts*

*Insert the following before "Additional items":*

- z) *Removable protective means.*

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### 1.3 *Particular Standards*

*Replace the existing text by the following:*

This Particular Standard refers to IEC 601-1 (1988): Medical electrical equipment – Part 1: General requirements for safety, and amendments 1 (1991) and 2 (1995). They are referred to in this Particular Standard as the General Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes priority over the requirements of the General Standard.

### 1.4 *Environmental conditions*

*Delete the title and text of this subclause.*

*Add, before clause 2, the following new subclause:*

### 1.5 *Collateral Standards*

*Additional subclauses:*

#### 1.5.101 *IEC 601-1-1*

This Collateral Standard does not apply.

#### 1.5.102 *IEC 601-1-2*

IEC 601-1-2 shall apply to AFTERLOADING EQUIPMENT but, at this date, it has not been possible to determine whether any amendments, additions, or replacements will be required to its requirements or tests (see clause 36).

#### 1.5.103 *IEC 601-1-3*

This Collateral Standard does not apply.

#### 1.5.104 *IEC 601-1-4*

IEC 601-1-4\* shall apply to AFTERLOADING EQUIPMENT but, at this date, it has not been possible to determine whether any amendments, additions, or replacements to its requirements or tests will be required (see 52.1).

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*Replacement:*

EQUIPMENT shall be declared as unsuitable for alternative applications which require the removal of a protective means to utilize a particular function.

*Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*

**6.8.2 d) Parts in contact with the PATIENT**

*Replace the title of this item by the following:*

*Cleaning, disinfection and sterilisation of parts in contact with the PATIENT*

**6.8.2 e) MAINS OPERATED EQUIPMENT with additional power source**

*Replace "MAINS OPERATED" in the title by the following:*

*Mains operated*

*Addition:*

NOTE – "Mains operated" is no longer a defined term.

*Replace the title of SECTION TWO by the following:*

**SECTION TWO – ENVIRONMENTAL CONDITIONS**

**9 Removable protective means**

*Replace the existing text by the following:*

This clause of the General Standard applies.

**10 Special environmental conditions**

*Replace the title and the text of this clause by:*

**Environmental conditions**

This clause of the General Standard applies except as follows:

**10.2.1 Replacement:**

- a) ambient temperature between +15 °C and +35 °C;
- b) relative humidity between 30 % and 75 %;
- c) atmospheric pressure between 70 kPa and 110 kPa,  
unless otherwise specified by the manufacturer.



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## **11 Special measures with respect to safety**

*Delete the title and text of this clause.*

## **12 SINGLE FAULT CONDITION**

*Delete the title and text of this clause.*

## **36 Electromagnetic compatibility**

*Add the following:*

NOTE – See 1.5.102.

*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**

*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**

### **50.1.4 Information required for limiting the IRRADIATION during transit of the RADIOACTIVE SOURCES**

*Add, at the end of the first paragraph, the following sentence:*

The other is to limit the IRRADIATION of other parts of the PATIENT's body.

### **50.2.2 CONTROLLING TIMERS**

*Replace twice "PER CENT AVERAGE ERROR" by the following:*

per cent average error.

*Addition:*

NOTE – "Per cent average error" is no longer a defined term.

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## 51 Protection against incorrect output

*Replace the title of this clause by the following:*

## Protection against hazardous output

*Replace the title and text of SECTION NINE by the following:*

### SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

*Clauses 52 and 53 of the General Standard apply except as follows:*

52.1 Amendment 2 to IEC 601-1 does not apply.

NOTE – See 1.5.104.

## APPENDIX AA

### TERMINOLOGY

*Delete the following terms:*

MAINS OPERATED A2.7

PER CENT AVERAGE ERROR A2.10

*Replace TYPE B EQUIPMENT by the following:*

TYPE B APPLIED PART

### AA2 Definitions

*Delete definitions A2.7 and A2.10.*

*Replace A2.14 TYPE B EQUIPMENT (601-1) 2.2.24 by the following:*

A2.14 TYPE B APPLIED PART (601-1) 2.1.24

AS/NZS 3200.2.17:1994  
IEC 601-2-17:1989

Australian/New Zealand Standard

Approval and test specifications—  
Medical electrical equipment

Part 2.17: Particular requirements  
for safety—Remote-controlled  
automatically-driven gamma-ray  
afterloading equipment

[IEC title: Medical electrical equipment, Part 2: Particular  
requirements for the safety of remote-controlled automatically-driven  
gamma-ray afterloading equipment]



**AS/NZS 3200.2.17:1994**

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 30 May 1994 and on behalf of the Council of Standards New Zealand on 27 June 1994. It was published on 22 August 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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## Australian/New Zealand Standard

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### **Approval and test specifications— Medical electrical equipment**

### **Part 2.17: Particular requirements for safety—Remote-controlled automatically-driven gamma-ray afterloading equipment**

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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 601-2-17:1989, *Medical electrical equipment, Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment*.

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 601-2-17 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

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

Both the Appendices to this Standard, AA1 and AA2, are for information and guidance only.

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