AS/NZS IEC 60601.2.17:2015
IEC 60601-2-17, Ed.3.0 (2013)

AS/NZS IEC 60601.2.17:2015

Australian/New Zealand Standard™

# Medical electrical equipment

# Part 2.17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment



STANDARDS Australia

STANDARDS® NEW ZEALAND PAEREWA AOTEAROA

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 12 October 2015 and on behalf of the Council of Standards New Zealand on 2 October 2015.
This Standard was published on 16 November 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
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
Therapeutic Goods Administration
Wairarapa District Health Board
Waitemata District Health Board

---

**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 Standards may also be withdrawn.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 website 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.

---

*This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.17:2015.*

Australian/New Zealand Standard™

# Medical electrical equipment

# Part 2.17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment

Originally as AS/NZS 3200.2.17:1994.
Jointly revised and redesignated as AS/NZS IEC 60601.2.17:2015.



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.

ISBN 978 1 76035 301 8

# PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.17:1994, *Approval and test specifications—Medical electrical equipment*, Part 2.17: *Particular requirements for safety—Remote-controlled automatically-driven gamma-ray afterloading equipment*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for automatically-controlled brachytherapy afterloading ME equipment. 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 an identical adoption of IEC 60601-1, Ed.3.1 (2012) and is referred to in the source text as 'the general standard'.

This Standard is identical with, and has been reproduced from IEC 60601-2-17, Ed.3.0 (2013), *Medical electrical equipment*, Part 2-17: *Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*.

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 Standard* | | *Australian/New Zealand Standard* | |
|---|---|---|---|
| IEC | | AS/NZS IEC | |
| 60601 | Medical electrical equipment | 60601 | Medical electrical equipment |
| 60601-1 | Part 1: General requirements for basic safety and essential performance | 60601.1 | Part 1: General requirements for basic safety and essential performance |
| 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 |
| 60601-2-8 | Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV | 60601.2.8 | Part 2.8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV |

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

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

# CONTENTS

# 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 201.7 includes subclauses 201.7.1, 201.7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "clause" followed by the clause number. References to subclauses within this collateral 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

The delivery of RADIOTHERAPY over short distances is called BRACHYTHERAPY. BRACHYTHERAPY is delivered by positioning RADIATION SOURCES within or adjacent to the tissue to be treated. Historically, RADIOACTIVE SOURCES were handled manually, resulting in IRRADIATION of the OPERATOR'S hands. AFTERLOADING generally refers to the technique of placing an applicator into or adjacent to the tissue to be treated, and introducing one or more RADIATION SOURCE(S) only after the applicator position has been confirmed. This procedure minimizes the time during which the operator is exposed to the RADIATION SOURCE(S). Manual AFTERLOADING techniques were developed in the 1950s and are used routinely today for permanent implants, but less frequently for temporary implants.

Temporary implants require the use of higher dose rates, to ensure that the treatment can be completed in a length of time easily tolerated by the PATIENT. In the 1980s, automatic remote AFTERLOADING techniques were developed, that could move a RADIOACTIVE SOURCE or SOURCES through connecting tubes from a shielded safe to the applicators implanted in the patient. Because the SOURCE(S) could be moved remotely, the risk of exposure to personnel could be eliminated.

In 2007 an automatic remote afterloader was introduced that replaced the conventional RADIOACTIVE SOURCE(S) with an X-ray source. This device otherwise performed similarly to AFTERLOADERS containing RADIOACTIVE SOURCES. However, the X-ray source could be disabled when not in use, removing any risk of IRRADIATION. BRACHYTHERAPY devices that employ X-ray source(s) are subject to the requirements of IEC 60601-2-8, in addition to those of this standard.

The use of AFTERLOADING ME EQUIPMENT for BRACHYTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose to the PATIENT, or if the ME EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the RADIOACTIVE SOURCE(S) adequately within the STORAGE CONTAINER(S), if the X-RAY TUBE is energized inappropriately, or if there are inadequacies in the design of the TREATMENT ROOM.

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of AFTERLOADING ME EQUIPMENT for use in temporary BRACHYTHERAPY procedures, it does not attempt to define their 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 ME EQUIPMENT. It places limits on the degradation of ME EQUIPMENT performance beyond which it can be presumed that a fault condition exists and at which an INTERLOCK then operates to disable the X-RAY TUBE(S) or return the RADIOACTIVE SOURCE(S) to the STORAGE CONTAINER(S) and afterwards to prevent continued operation of the ME EQUIPMENT.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

# Medical electrical equipment

## Part 2.17:
## Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment

### 201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

#### 201.1.1 Scope

*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT, hereafter referred to as ME EQUIPMENT.

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.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This standard applies to automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT used for treatment or alleviation of disease.

This standard specifies requirements

a) for automatically-controlled AFTERLOADING ME EQUIPMENT

   1) which contains and uses only beta, gamma, or NEUTRON-emitting SEALED RADIOACTIVE SOURCES, or BRACHYTHERAPY X-RAY SOURCES designed and constructed for use with automatically-controlled AFTERLOADING ME EQUIPMENT,

   2) which automatically drives the RADIATION SOURCE(S) from a STORAGE CONTAINER or, in the case of BRACHYTHERAPY X-RAY SOURCES, a reference location outside the PATIENT, to a treatment position inside the SOURCE APPLICATOR(S) and returns the RADIATION SOURCE(S) to the STORAGE CONTAINER or the BRACHYTHERAPY X-RAY SOURCE(S) to the reference location,

   3) which is designed for connection to a PATIENT, and

   4) with which movements of the RADIATION SOURCE(S) are carried out automatically by the ME EQUIPMENT according to a prescribed programme using a powered mechanism whose changes are controlled by the CONTROLLING TIMER(S) and TIMING DEVICES that are either PROGRAMMABLE ELECTRONIC SUB-SYSTEMS (PESS) (computer or microprocessors) or non-programmable systems and

b) for ME EQUIPMENT intended to be

[1] The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*