

AS/NZS 3200.2.15:1994

IEC 601-2-15:1988

Australian/New Zealand Standard

Approval and test specification— Medical electrical equipment

Part 2.15: Particular requirements for safety—Capacitor discharge X-ray generators

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

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AS/NZS 3200.2.15:1994

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 Australian and New Zealand Society of Nuclear Medicine
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Approval and test specification— Medical electrical equipment

Part 2.15: Particular requirements for safety—Capacitor discharge 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 601-2-15:1988, *Medical electrical equipment Part 2: Particular requirements for safety—Capacitor discharge 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 601-2-15 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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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 words '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 2.15:
Particular requirements for safety—Capacitor discharge 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 CAPACITOR DISCHARGE X-RAY GENERATORS operating in INTERMITTENT MODE for medical RADIOGRAPHY, in which the electrical energy for LOADING of the X-RAY TUBE is completely or mainly capacitively stored at, and switched in, the high-voltage circuit.

This Particular Standard is confined to those devices which are MEDICAL ELECTRICAL EQUIPMENT and in which

- the storage capacitor is in the high-voltage circuit and has a specified capacitance not exceeding 2 μF ,
- the INITIAL X-RAY TUBE VOLTAGE is between 40 kV and 150 kV,
- an overcurrent protection, if provided, would not require a rating exceeding that which corresponds to an apparent power of 3 kVA,
- LOADING of the X-RAY TUBE is controlled in the high-voltage circuit.

This Particular Standard does not exclude CAPACITOR DISCHARGE X-RAY GENERATORS that are capable of operation in CONTINUOUS MODE for DIRECT RADIOLOGY or INDIRECT RADIOLOGY. However, for this mode of operation the device will have to comply with the relevant requirements for diagnostic HIGH-VOLTAGE GENERATORS and diagnostic X-RAY EQUIPMENT (see Sub-clause 1.3.102).

1.2 Object*Replacement:*

The object of this Particular Standard is to establish particular requirements to ensure safety and to specify methods for demonstrating compliance with those requirements.

Requirements for reproducibility and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

Rationale. — Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of CAPACITOR DISCHARGE X-RAY GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but are chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

Notes 1. — The safety philosophy on which this Particular Standard is based is described in the Introduction to the General Standard (see Sub-clause 1.3.101).

- 2.* — With respect to protection against IONIZING RADIATION, this Particular Standard deals with indirect aspects of safety, namely those that depend upon the supply and control of electric energy from the CAPACITOR DISCHARGE HIGH-VOLTAGE GENERATOR.

Direct requirements for protection against IONIZING RADIATION are given in the Collateral Standard referenced in Sub-clause 1.3.102.

- 3.* — Concerning RADIOLOGICAL PROTECTION, it has been assumed in the preparation of this Particular Standard that USERS of medical diagnostic X-RAY EQUIPMENT will accept the basic recommendations of the International Commission on Radiological Protection (ICRP), as stated in ICRP Publication 26, 1977, paragraph 12, namely:

“a) no practice shall be adopted unless its introduction produces a positive net benefit;

b) all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; and

c) the dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission.”

It is recognized that many of the judgements necessary to follow these recommendations have to be made by the USER and not by the manufacturer of the equipment.

1.3 Particular Standards

Additional sub-clauses:

1.3.101 *Relation to the General Standard*

This Particular Standard refers to IEC Publication 601-1 (First edition, 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.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied to CAPACITOR DISCHARGE X-RAY GENERATORS, a statement to that effect is given in this Particular Standard.

1.3.102 *Related international standards*

This Particular Standard requires CAPACITOR DISCHARGE X-RAY GENERATORS, or sub-assemblies thereof, to comply with the applicable requirements of the Collateral Standard: General requirements for protection against ionizing radiation (under consideration) and of the Particular Standard: IEC Publication 601-2-7 (1986): Medical electrical equipment Part 2: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators (see also the Scope, Sub-clause 1.1).

Attention is also drawn to the IEC publications listed in the Preface.

* The second edition has been published in 1988.

1.3.103 *Superseded IEC Standards*

This Standard deals with some aspects of X-RAY EQUIPMENT, particularly of CAPACITOR DISCHARGE X-RAY GENERATORS and sub-assemblies thereof, that were covered by IEC Publications 407 and 407A.

Within its scope, this Particular Standard supersedes the corresponding requirements of IEC Publications 407 and 407A.

1.4 *Environmental conditions*

a) Transport and storage

Item 2) a)

Replacement:

an ambient temperature between -20°C and $+70^{\circ}\text{C}$.

2. Terminology and definitions

This clause of the General Standard applies, except as follows:

Addition:

In this Particular Standard, terms printed in capital letters are used as defined in IEC Publications 601-1 and 788 and Sub-clause 2.12.

For these terms and for the adjectives "specific" and "specified", the alphabetical index refers to the standards mentioned; see Appendix AA.

2.12 *Miscellaneous*

Additional definition:

2.12.101 *Specified range of compliance*

For RADIOLOGICAL EQUIPMENT for which information on the behaviour of functional parameters is required in a standard, range or set of ranges over which the reproducibility, linearity, constancy or accuracy of such parameters is within limits described in the standard.

3. General requirements

This clause of the General Standard applies, except as follows:

Additional sub-clauses:

3.101 *Conventional meanings of electrical quantities*

In this Particular Standard, unless otherwise indicated,

- values of X-RAY TUBE VOLTAGE refer to the maximum value at the initial stage of the LOADING of the X-RAY TUBE;
- values of electric current in the high-voltage circuit refer to the maximum value of the X-RAY TUBE CURRENT during the initial stage of the LOADING of the X-RAY TUBE.

3.102 *RADIATION quantities*

In accordance with a policy of avoiding the use of the quantity EXPOSURE with its unit the coulomb per kilogram ($C.kg^{-1}$) and its earlier unit the röntgen (R), the quantity AIR KERMA is used in this Particular Standard with its unit the gray (Gy). 1 Gy corresponds approximately to 1 $J.kg^{-1}$.

For X-RADIATION generated by high voltages up to 150 kV, covered by this Particular Standard, an AIR KERMA of 1 Gy corresponds to an EXPOSURE $X = 29.7 mC.kg^{-1}$ or $X = 115 R$.

All values of AIR KERMA given in this Particular Standard are followed by an indication of the corresponding approximate value of EXPOSURE in röntgen, reading: ($X = \dots R$).

4. General requirements for tests

This clause of the General Standard applies, except as follows:

Addition:

Safety tests to be carried out after installation of a CAPACITOR DISCHARGE X-RAY GENERATOR, or after putting it into use, are under consideration.

4.1 *Type tests and routine tests**a) Type tests**Addition:*

The tests described in this Particular Standard are type tests, to be carried out under controlled conditions, usually prevailing only in test laboratories.

4.10 *Moisture pre-conditioning treatment**Addition (see Sub-clause 1.3.101):*

This test shall be applied only to those parts of CAPACITOR DISCHARGE X-RAY GENERATORS likely to be influenced by the climatic conditions that are simulated by the test.

Where it is not practicable to treat a CAPACITOR DISCHARGE X-RAY GENERATOR as a whole, the treatment may be given sequentially to separate parts.

Also, where testing cannot be carried out without dismantling or reassembling, a period longer than that required in the General Standard may elapse between treatment and testing.

5. Classification

This clause of the General Standard applies, except as follows:

5.1 *Replacement:*

CAPACITOR DISCHARGE X-RAY GENERATORS energized from an external power source shall be classified as CLASS I EQUIPMENT.

5.2 *Replacement:*

Unless otherwise specified to a higher degree of protection against electric shock, CAPACITOR DISCHARGE X-RAY GENERATORS shall be classified as TYPE B EQUIPMENT.

5.3 Replacement:

Unless otherwise specified, CAPACITOR DISCHARGE X-RAY GENERATORS are ordinary MEDICAL ELECTRICAL EQUIPMENT (enclosed equipment without protection against the ingress of liquids).

5.6 Replacement:

Unless otherwise specified, CAPACITOR DISCHARGE X-RAY GENERATORS shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS in INTERMITTENT MODE (see also Sub-clause 6.8.5).

6. Identification, marking and documents

This clause of the General Standard applies, except as follows:

6.1 Marking on the outside of equipment or equipment parts

Addition at the beginning of the sub-clause:

CAPACITOR DISCHARGE X-RAY GENERATORS and their constituent sub-assemblies and components shall be appropriately marked if their correlation to one another influences safety (see also Sub-clause 6.8.1).

g) Connection to the supply

Addition at the end:

- For CAPACITOR DISCHARGE X-RAY GENERATORS that are specified to be permanently installed, the information required in Item *g)* of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

h) Supply frequency (in hertz)

Addition at the end:

- For CAPACITOR DISCHARGE X-RAY GENERATORS that are specified to be permanently installed, the information required in Item *h)* of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

j) Power input

Addition at the end:

- For CAPACITOR DISCHARGE X-RAY GENERATORS that are specified to be permanently installed, the information required in Item *j)* of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

p) Output

Replacement:

For CAPACITOR DISCHARGE X-RAY GENERATORS, instead of the marking required in Item *p)* of Sub-clause 6.1 of the General Standard, the output characteristics according to Item *a)* of Sub-clause 6.8.2 shall be stated in the ACCOMPANYING DOCUMENTS.