

Australian/New Zealand Standard™

**Evaluation and routine testing in
medical imaging departments**

**Part 3.1: Acceptance tests—Imaging
performance of X-ray equipment for
radiographic and radiosopic systems
(IEC 61223-3-1:1999, MOD)**

AS/NZS 4184.3.1:2002

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-008, Diagnostic Ionizing Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 18 March 2002 and on behalf of the Council of Standards New Zealand on 27 February 2002. It was published on 20 May 2002.

The following interests are represented on Committee HE-008:

Australasian College of Physical Scientists and Engineers in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian and New Zealand Society of Nuclear Medicine
Department of Defence (Australia)
Department of Health, W.A.
Department of Human Services, Vic.
Diagnostic Imaging Association of Australasia
Medical Industry Association of Australia
Ministry of Economic Development, New Zealand
New South Wales Department of Public Works and Services
National Radiation Laboratory, New Zealand
Queensland Health
Royal Australian and New Zealand College of Radiologists
United Dental Hospital of Sydney
University of Sydney – Faculty of Dentistry

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 Standards may also be withdrawn.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 Australia web site at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. 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 International or Standards New Zealand at the address shown on the back cover.

Australian/New Zealand Standard™

Evaluation and routine testing in medical imaging departments

Part 3.1: Acceptance tests—Imaging performance of X-ray equipment for radiographic and radioscopy systems (IEC 61223-3-1:1999, MOD)

First published as AS/NZS 4184.3.1:2002.

COPYRIGHT

© Standards Australia/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.

Jointly published by Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 4493 1

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-008, Diagnostic Ionizing Imaging Equipment. It is one of an ever-expanding series of acceptance and performance assessment Standards for use within health care facilities.

This Standard has been reproduced, with national modifications, from IEC 61223-3-1:1999, *Evaluation and routine testing in medical imaging departments, Part 3-1: Acceptance imaging performance of X-ray equipment for radiographic and radiosopic systems.*

Appendix ZZ lists the variations between this Standard and IEC 61223-3-1. These changes are indicated by a rule in the margin against each Clause affected.

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

- (a) Requirements, compliance with which can be tested and definitions
.....in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references
.....in smaller roman type
- (c) Headings of sub-clauses and text specifications
.....in italic type
- (d) Terms used throughout the Standard, which have been defined in Clause 3 or the Index of Defined Terms (see Annex A)
.....IN SMALL CAPITALS

As this publication has been reproduced from an International Standard, the following modifications apply:

- (i) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (ii) In the source text ‘this part of IEC 61223’ should read ‘this Australian/New Zealand Standard’.
- (iii) A full point substitutes for a comma when referring to a decimal marker.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex or appendix to which they apply. A ‘normative’ annex or appendix is an integral part of a Standard, whereas an ‘informative’ annex or appendix is only for information and guidance.

The references to international Standards should be replaced by references to the following Australian/New Zealand Standards.

<i>Reference to International Standard</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS/NZS	
60336	X-ray tube assemblies for medical diagnosis – Characteristics of focal spots	4274	X-ray tube assemblies for medical diagnosis – Characteristics of focal spots
60471	Graphical symbols for use on equipment	—	
60471-1	Part 1: Overview and application		
60522	Inherent filtration of an X-ray tube assembly	—	
60580	Area exposure product meter	—	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety – Parent Standard

IEC		AS/NZS	
60601-1-3	Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	3200.1.3	Part 1.3: General requirements for safety Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment
60601-2-7	Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	3200.2.7	Part 2.7: Particular requirements for safety – High voltage generators of diagnostic X-ray generators
60601-2-28	Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	3200.2.28	Part 2.28: Particular requirements for safety—X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators
60788	Medical radiology – Terminology		—
60878	Graphical symbols for electrical equipment in medical practice	4334	Graphic symbols for use on medical electrical equipment
61223	Evaluation and routine testing in medical imaging departments	4184	Evaluation and routine testing in medical imaging departments
61223-1	Part 1: General aspects	4184.1	Part 1: General aspects
61267	Medical diagnostic X-ray equipment— Radiation conditions for use in the determination of characteristics	4358	Medical diagnostic X-ray equipment Radiation conditions for use in the determination of characteristics
ISO			
2092	Light metals and their alloys—Code of designation based on chemical symbols		—

CONTENTS

INTRODUCTION	vi
--------------------	----

Clause

1	Scope and object	1
1.1	Scope	1
1.2	Object.....	1
2	Normative references	2
3	Terminology	3
3.1	Degree of requirements.....	3
3.2	Use of terms	3
3.3	Defined terms	3
4	General aspects of ACCEPTANCE TESTS	4
4.1	General conditions to be considered in test procedures	4
4.2	Documents and data for the tests	4
4.3	Test conditions.....	4
4.4	Test parameters.....	5
4.5	Test equipment including PHANTOMS (ATTENUATION devices) and TEST DEVICES	6
4.6	Evaluating the test results	7
5	Test methods for RADIOGRAPHY EQUIPMENT	8
5.1	Visual and functional tests.....	8
5.2	*X-RAY TUBE VOLTAGE.....	8
5.3	*TOTAL FILTRATION	9
5.4	*FOCAL SPOT of the X-RAY TUBE.....	9
5.5	*Limitation and indication of the extent of the X-RAY BEAM.....	10
5.6	*Linearity and reproducibility of TRANSMISSION KERMA or RADIATION OUTPUT.....	12
5.7	*ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR.....	13
5.8	*AUTOMATIC EXPOSURE CONTROL (AEC).....	13
5.9	LINE PAIR RESOLUTION for DIRECT RADIOGRAPHY.....	15
5.10	* AIR KERMA area product indicator	15
6	Test methods for RADIOSCOPY EQUIPMENT	15
6.1	Visual and functional tests.....	15
6.2	X-RAY TUBE VOLTAGE.....	16
6.3	TOTAL FILTRATION	16
6.4	FOCAL SPOT of the X-RAY TUBE	16
6.5	Functioning of the AUTOMATIC EXPOSURE RATE CONTROL (AERC).....	16
6.6	Limitation of the extent of the X-RAY BEAM	17

Clause		
6.7	ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR.....	18
6.8	*AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for RADIOSCOPY	18
6.9	*Entrance AIR KERMA RATE for RADIOSCOPY with X-RAY IMAGE INTENSIFIER.....	19
6.10	AIR KERMA at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)	20
6.11	Entrance AIR KERMA for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)	20
6.12	*LINE PAIR RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)	21
6.13	*LOW CONTRAST RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)	22
6.14	AIR KERMA area product indicator	23
7	Additional tests required for TOMOGRAPHY EQUIPMENT.....	23
7.1	*Requirements	23
7.2	Test method	24
8	Test report and statement of compliance	24
Annex A (normative)	Terminology – Index of defined terms	31
Annex B (informative)	Test parameters, symbols and units	34
Annex C (informative)	Examples of low contrast TEST DEVICES.....	35
Annex D (informative)	Examples of requirements (accuracy, tolerances, discrepancies) according to actual IEC standards or state of the art.....	37
Annex E (informative)	Bibliography	41
Tables		
B.1	Test parameters, symbols and units.....	34
D.1	Typical values of FOCAL SPOT dimensions for NOMINAL FOCAL SPOT VALUES	37
D.2	Values for the discrepancy parameters X, Y and Z according to IEC 60601-1-3	38
D.3	Typical values for the TRANSMISSION KERMA index.....	38
D.4	Typical values for the ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR	39
Figures		
1	Measuring arrangement for RADIOGRAPHY and RADIOSCOPY EQUIPMENT for AIR KERMA measurements.....	26
2	Measuring arrangement for RADIOGRAPHY and RADIOSCOPY EQUIPMENT to test geometry and resolutions.....	27
3	LINE PAIR RESOLUTION TEST DEVICE	28
4	TOMOGRAPHY LINE PAIR RESOLUTION TEST DEVICE.....	29
5	Discrepancies in visual indication of the X-RAY FIELD	30
6	Discrepancies in covering the IMAGE RECEPTION AREA	30
Appendix ZZ	Variations to IEC 61223-3-1:1999 for application in Australia and New Zealand	43

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for subsystems and systems (for example diagnostic X-RAY EQUIPMENT), including film processing, used in medical imaging departments.

Some provisions or statements in this standard require additional information. Such information is presented in annex D. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

AUSTRALIAN/NEW ZEALAND STANDARD

Evaluation and routine testing in medical imaging departments

Part 3.1:

Acceptance tests—Imaging performance of X-ray equipment for radiographic and radioscopy systems (IEC 61223-3-1:1999, MOD)

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which influence the image quality and PATIENT dose of diagnostic X-ray systems using radiographic and radioscopy imaging systems.

This standard applies to the performance of X-RAY EQUIPMENT in the ACCEPTANCE TEST on the following medical diagnostic X-RAY EQUIPMENT and ASSOCIATED EQUIPMENT:

- radiography equipment, for example:
 - stationary radiography EQUIPMENT;
 - mobile radiography EQUIPMENT;
 - skull radiography EQUIPMENT;
 - lung radiography EQUIPMENT;
 - TOMOGRAPHY EQUIPMENT – excluding COMPUTED TOMOGRAPHY;
 - radiography devices (SPOTFILM DEVICES) in RADIOSCOPY EQUIPMENT;
 - angiography EQUIPMENT (excluding DSA function);
 - CINERADIOGRAPHY equipment;
- RADIOSCOPY EQUIPMENT, including:
 - combined radiographic and radioscopy EQUIPMENT.

This standard applies to the generation of X-RADIATION and ACCESSORIES of digital systems. It does not apply to any digital image acquisition or image processing parts of the above mentioned diagnostic X-RAY EQUIPMENT.

NOTE – Since the characterization of digital detectors and image processing is still under development, this will be included in a later edition of this standard.

This standard does not apply to mammographic X-RAY EQUIPMENT, RADIOTHERAPY simulators, nor to dental X-RAY EQUIPMENT.

1.2 Object

This standard defines:

- a) the parameters which describe the performance of X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;
- b) methods of testing whether measured quantities related to those parameters comply with the specified tolerances.