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 radioscopic systems (IEC 61223-3-1:1999, MOD)

Standards Australia

STANDARDS NEW ZEALAND Paerewa Aotearoa

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.
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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 radioscopic 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.

Reference to International Standard		*Australian/New Zealand Standard*	
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 60471-1	Graphical symbols for use on equipment Part 1: Overview and application	—	
60522	Inherent filtration of an X-ray tube assembly	—	
60580	Area exposure product meter	—	
60601 60601-1	Medical electrical equipment Part 1: General requirements for safety	3200 3200.1.0	Medical electrical equipment 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	—	

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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 radioscopic 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 radioscopic 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 radioscopic 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.