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Australian/New Zealand Standard

Evaluation and routine testing in
medical imaging departments

Part 1: General aspects



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Australian College of Physical Scientists and Engineers in Medicine
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1 The Crescent,
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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, and issued 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 1223-1:1993, *Evaluation and routine testing in medical imaging departments*, Part 1: *General aspects*.

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<i>Reference to International Standard or other publication</i>		<i>Joint Australian/New Zealand Standard</i>	
IEC		AS	
601	Medical electrical equipment	3200	Approval and test specification— Medical electrical equipment
601-1	Part 1: General requirements for safety Amendment No. 1, 1991	3200.1	General requirements for safety (NZS 6150.1) Amdt 1 December 1992
788	Medical radiology—Terminology	—	
		AS/NZS	
1223	Evaluation and routine testing in medical imaging departments	4184	Evaluation and routine testing in medical imaging departments
1223-2-1	Part 2-1: Constancy tests—Film processors	4184.2.1	Part 2.1: Constancy tests—Film processors
ISO			
8402	Quality—Vocabulary	—	

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CONTENTS

Clause	Page
1 Scope and object	1
1.1 Scope	1
1.2 Object	1
2 References to other publications	1
3 Terminology	2
3.1 Use of terms	2
3.2 Definitions	2
4 QUALITY ASSURANCE: QUALITY CONTROL and quality administration	3
4.1 General aspects	3
4.2 Cost-benefit aspects	3
4.3 Technical aspects	4
4.4 Administrative aspects	4
4.5 Types of performance tests	7
5 Action to be taken	8
6 Assessing the effectiveness of the QUALITY ASSURANCE PROGRAMME	9
7 Subjects for CONSTANCY TESTS	10
Table 1 – Types of performance tests	11
Figure 1 – Schema for checking the performance of a diagnostic X-RAY INSTALLATION	12
Annexes	
A Terminology – Index of terms	13
B Bibliography	15

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Evaluation and routine testing in medical imaging departments**

Part 1: General aspects

1 Scope and object**1.1 Scope**

This technical report applies to equipment and subassemblies forming those constituent components of diagnostic X-RAY INSTALLATIONS that generate, influence the propagation of, and detect the X-RADIATION, and process, present and store the radiological information.

1.2 Object

This technical report presents the concept of QUALITY ASSURANCE in diagnostic X-ray departments, and introduces a series of test methods to be carried out under the responsibility of the USER.

The test methods introduced in this technical report are solely concerned with monitoring the constancy of functional performance of equipment and ASSOCIATED EQUIPMENT by means of test instrumentation and TEST DEVICES that are simple to use.

The test methods are not intended to deal with aspects of safety, such as mechanical and electrical safety, except where the intended function of the equipment or devices is to provide safety.

The individual test methods for QUALITY CONTROL are described in, and published as, separate Particular IEC Publications.

The individual tests carried out in a diagnostic X-ray department shall be linked to those aspects of a QUALITY ASSURANCE PROGRAMME, which are described in this technical report.

This technical report is not intended to cover matters of clinical judgement in the management of the patient.

2 References to other publications

The following IEC/ISO publications are quoted in this technical report:

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*

Amendment No. 1, 1991

IEC 788: 1984, *Medical radiology – Terminology*

IEC 1223-2-1: 1993, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

ISO 8402: 1986, *Quality – Vocabulary*

3 Terminology

3.1 Use of terms

In this technical report, terms printed in small capital letters are used as defined:

- in IEC 788;
- in IEC 1223-2-1;
- and in 3.2 of this part 1.

(See annex A, Terminology – Index of terms)

3.2 Definitions

3.2.1 QUALITY ASSURANCE: Planned and systematic actions necessary to provide adequate confidence by ensuring that a product or service will satisfy given requirements for quality.

3.2.2 QUALITY ASSURANCE PROGRAMME: Detailed instruction for carrying out actions of QUALITY ASSURANCE for individual items of equipment, systems of equipment or facilities, including quality administrative elements and QUALITY CONTROL techniques.

3.2.3 QUALITY CONTROL: Operational techniques and activities that are used to fulfil requirements for quality.

3.2.4 ACCEPTANCE TEST: Test carried out after new equipment has been installed, or major modifications have been made to, existing equipment, in order to verify compliance with contractual specifications (see table 1).

3.2.5 STATUS TEST: Test carried out to establish the functional status of equipment at a given time (see table 1).

3.2.6 CONSTANCY TEST: Each of a series of tests, carried out:

- to ensure that the functional performance of equipment meets ESTABLISHED CRITERIA; or
- to enable the early recognition of changes in the properties of components of the equipment (see table 1).

3.2.7 BASELINE VALUE: Reference value of functional parameter:

- either the value obtained for this parameter in the initial CONSTANCY TEST immediately following a STATUS TEST; or
- where described in a corresponding Particular Standard, the mean value of values obtained in a series of initial CONSTANCY TESTS, immediately following a STATUS TEST.

3.2.8 ESTABLISHED CRITERIA: In a QUALITY ASSURANCE PROGRAMME, acceptable variations in results of a CONSTANCY TEST which signal satisfactory functional performance of the equipment tested.