Australian Government

Australian Radiation Protection and Nuclear Safety Agency

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Standard for Radiation Safety and Performance Testing of Diagnostic Imaging Apparatus

Radiation Protection Series S-2

Radiation Protection Series

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August 2024

This publication was prepared jointly with the *Radiation Health Committee*. The *Radiation Health and Safety Advisory Council* advised the CEO to adopt the Guide.

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The mission of ARPANSA is to protect people and the environment from the harmful effects of radiation.

Published by the Chief Executive Officer of ARPANSA in August 2024.

Acknowledgement of Country

ARPANSA proudly acknowledges Australia's Aboriginal and Torres Strait Islander community and their rich culture and pays respect to their Elders past and present. We acknowledge Aboriginal and Torres Strait Islander people as Australia's first peoples and as the Traditional Owners and custodians of the land and water on which we rely.

We recognise and value the ongoing contribution of Aboriginal and Torres Strait Islander people and communities to Australian life and how this enriches us. We embrace the spirit of reconciliation, working towards the equality of outcomes and ensuring an equal voice.

Foreword

This Standard for Radiation Safety and Performance Testing of Diagnostic Imaging Apparatus (hereafter referred to as 'the Standard' sets requirements for the testing of and functionality of specified diagnostic imaging apparatus. The specified apparatus covered by this standard are Computed Tomography Scanners, Mammographic X-ray equipment, Fluoroscopic X-ray equipment, and Plain Radiographic X-ray equipment. For these, the Standard sets forth:

- the **Entry Level Requirements** that must be met to demonstrate compliance with national and international standards relevant to the radiation apparatus at the time of sale
- the **Acceptance Testing and Quality Assurance Requirements** that ensure that the apparatus functions as intended, meets clinical needs, and operates within acceptable parameters
- the **Compliance Testing Requirements** that ensure the regular and ongoing testing and certification of the apparatus throughout its working life.

The Standard draws its requirements from a wide range of domestic and international guidelines and standard documentation, including but not limited to those of the Royal Australian and New Zealand College of Radiologists (RANZCR), the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), the International Electrotechnical Commission (IEC), the European Commission (EC), the American Association of Physicists in Medicine (AAPM), and the Institute of Physics and Engineering in Medicine (IPEM). This document therefore reflects the guidance from the peak bodies in the safe operation of diagnostic imaging apparatus.

Research is continuing in many countries into the health effects of ionising radiation. In recognition of this, the Radiation Health Committee will continue to monitor the results of this research and, where necessary, issue amendments to this document.

It is recognised that the Standard does not operate in isolation from the legal framework within Australia. Relevant Australian occupational, health, safety, and environmental laws provide obligations on employers, and the designers, manufacturers and suppliers of plant or equipment, to ensure that their activities, or their plant and equipment, do not represent a risk to the health and safety of their employees or third parties who may be affected by them. In effect, such laws require relevant parties to continually assess and improve the safety and health impact of their activities.

This Standard is intended to complement the requirements of the relevant Work Health and Safety legislation in each jurisdiction. The relevant regulatory authority should be contacted should any conflict of interpretation arise. A listing of such authorities is provided at https://www.arpansa.gov.au/regulation-and-licensing/regulation/state-territory-regulators.

Gillian Hirth AO
CEO of ARPANSA

12 August 2024

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1. Introduction

1.1 Citation

This publication may be cited as the *Standard for Radiation Safety and Performance Testing of Diagnostic Imaging Apparatus (2024)*.

1.2 Purpose

This document describes the testing requirements for specified radiation apparatus used in Australian jurisdictions, to ensure that it is fit for purpose and the radiological risk from the intended use of the radiation apparatus is within acceptable levels.

The requirements specified in this document are the result of a review of current overseas and local requirements. It is anticipated that this document will evolve and be amended as:

a. national agreement is reached on acceptable testing requirements for the different radiation apparatus

b. professional societies, such as the ACPSEM, publish national position papers on acceptance testing and quality assurance

c. national and international standards are updated.

1.3 Scope

The testing requirements in this document apply to the following radiation apparatus when used on humans:

1. Computed Tomography Scanners
2. Mammographic X-ray equipment
3. Fluoroscopic X-ray equipment
4. Plain Radiographic X-ray equipment

The requirements cover the entire working life of the radiation apparatus and are divided into three parts:

Part A: Entry Level Requirements

Part B: Acceptance Testing and Quality Assurance Requirements

Part C: Compliance Certification against Radiation Safety Standards

1.4 Overview of Testing Requirements

1.4.1 Entry Level Requirements

The purpose of **Entry Level Requirements** is to ensure that a particular make and model of a given type of radiation apparatus that enters an Australian jurisdiction meets applicable national and international standards. These requirements apply at the time of sale, prior to the radiation apparatus being registered and/or used in a particular jurisdiction. The responsibility for compliance with these requirements lies with the entity supplying the apparatus.

1.4.2 Acceptance Testing and Quality Assurance

The purpose of **Acceptance Testing and Quality Assurance Requirements** is to ensure that the apparatus will meet clinical needs and undergoes routine quality assurance testing to ensure that it operates within acceptable parameters. The responsibility for compliance with these requirements lies with the entity authorised to possess the apparatus. The testing must be performed by an appropriately qualified person.

1.4.3 Compliance Testing against this Radiation Safety Standard

The purpose of compliance testing against the Radiation Safety Standard is to ensure that the apparatus is tested and certified at regular intervals by an approved person. The overarching requirements underpinning these testing requirements are as follows:

1. The radiation apparatus must not be used on living humans without a valid certificate of compliance issued by a person approved by the relevant regulatory authority or the relevant regulatory authority itself, if applicable.
2. A certificate of compliance is valid for a specified amount of time depending on the type of apparatus.
3. A certificate of compliance may only be issued by an approved person if the apparatus meets the relevant radiation safety standard.
4. The certificate of compliance, once issued, must be provided to the Responsible Person and the relevant regulatory authority, and must include the date upon which the radiation apparatus was tested, and information which uniquely identifies the radiation apparatus tested, such as the serial number information for the X-ray tube, tube housing and generator, and the system number where appropriate.
5. The compliance tester must complete an assessment report following the testing of the radiation apparatus. The report must include the following information where applicable in the jurisdiction:
    a. name and authorisation number (as issued by the relevant regulatory authority) of the compliance tester and the person issuing the certificate of compliance or notice of non-compliance
    b. date that the report was issued
    c. date that the radiation apparatus was tested
    d. information which uniquely identifies the radiation apparatus tested, such as the manufacturer, model and serial number of the generator, tube and tube housing of the radiation apparatus, and the system number where appropriate
    e. the name and authorisation number on the management licence/possession licence/facility registration authorising the possession of the radiation apparatus at the time of testing
    f. the apparatus reference number issued by the relevant regulatory authority. The compliance tester may issue an assessment report without an apparatus reference number when the radiation apparatus is newly acquired, and an apparatus reference number has not yet been issued
    g. details of the test equipment used, including the calibration date
    h. the test measurements and results for each item contained in the applicable radiation safety standard, including any baseline values

i. details of all non-compliant items identified during the test, including those that are corrected at the time of testing

j. justification for the tester having determined any test to be not applicable, or not verifiable, due to the hardware or software functionality of the apparatus.

6. The Responsible Person is responsible for ensuring rectification of any non-compliances and providing evidence to the compliance tester such that retesting of the equipment by a compliance tester may occur, where applicable, and a certificate of compliance issued.

7. The compliance certification (or notice of non-compliance if applicable) and assessment report must be provided to the Responsible Person (or the person who requested the test) and the relevant regulatory authority, as soon as practicable following the date of the test, and a copy retained by the compliance tester for audit purposes, along with evidence of rectification of any non-compliance.

8. Following major repair or replacement[1] which has the potential to adversely affect patient or operator radiation dose, relevant tests must be conducted to confirm that the apparatus continues to meet its compliance status. If compliance cannot be confirmed then the certificate of compliance is invalidated and the full suite of radiation safety and performance tests must be conducted, and a certificate of compliance issued, prior to the equipment being returned to clinical use, unless approved otherwise by the relevant regulatory authority. For example, the relevant regulatory authority may accept the service engineer's certification in the short term, in order to return the radiation apparatus to clinical use while awaiting full compliance testing.

9. The compliance tester must meet prerequisites specified by the relevant regulatory authority and be licensed to perform compliance testing of the radiation apparatus.

10. A compliance test may be undertaken up to 60 days prior to the expiry date of the current certificate of compliance without changing the anniversary date of the testing cycle, where permitted by the relevant regulatory authority. This is to allow flexibility for tester availability and to enable radiation apparatus owners to be proactive to ensure continuity of service provision. However, if radiation apparatus is tested outside of this timeframe, this will change the anniversary date for future compliance testing cycles. If the apparatus **meets** the specified requirements the certificate of compliance and test report must be issued within 60 days of the test being performed. However, if the radiation apparatus **does not meet** one or more of the relevant safety and performance tests then section 12 or section 13 of this part applies, and this should be reflected in the commencement date of the Certificate of Compliance. Following repairs or service adjustments, if the radiation apparatus is retested and meets the requirements of the relevant part(s) of the standard within the validity period of the existing Certificate of Compliance, then the anniversary date may be retained on the new Certificate of Compliance.

11. The compliance tester is required to ensure that the testing equipment used is calibrated to a recognised standard at regular intervals not exceeding:

    a. the calibration interval recommended by the manufacturer or 2 years, whichever is lower; or

    b. 12 months, if the manufacturer has not specified a recommended calibration interval.

[1] For the purposes of this document, '***major repair or replacement***' means a repair that could affect radiation safety (e.g. tube change, detector change, major software upgrade).

12. If, during testing of a radiation apparatus, the apparatus **fails to meet the limit specified** in the Radiation Safety Standard for any one or more of the tests, a person authorised to issue certificates of compliance must issue a notice of non-compliance to the Responsible Person or the Radiation Safety Officer, and a copy of the notice of non-compliance to the relevant regulatory authority within 7 days. The notice of non-compliance must provide a timeframe for rectification of the compliance issue and re-testing within 30 days unless a longer time period is permitted by the relevant regulatory authority. Individual consideration of circumstances on a case-by-case basis should be discussed with the relevant regulatory authority and decisions should be made using a graded approach commensurate with the risk.
13. If, during testing of a radiation apparatus, the apparatus **fails to meet the critical failure limit** specified in the Radiation Safety Standard for any one or more of the tests, a person authorised to issue certificates of compliance must immediately report the critical failure to the Responsible Person or the Radiation Safety Officer, and the relevant regulatory authority, and **use of the apparatus must cease**. Individual consideration of circumstances on a case-by-case basis should be discussed with the relevant regulatory authority and decisions should be made using a graded approach commensurate with the risk.

2. Entry Level Requirements

Each new type, or model, of radiation apparatus is required to meet an entry-level set of requirements the first time the model enters an Australian jurisdiction. Such equipment must be manufactured to conform to a current and relevant national or international standard, as specified below.

For clarity, this assessment does not apply to each specific X-ray unit – merely the first time that the model enters into any Australian jurisdiction.

2.1.1 Requirement

The following table specifies the relevant national and/or international standards and other minimum requirements that each new type or model of X-ray equipment must meet.

Note: If intended for use on humans for a diagnostic or therapeutic purpose, the requirements of the Commonwealth's Therapeutic Goods Administration, Department of Health must also be complied with, including the requirement to be registered on the Australian Register of Therapeutic Goods.

Table 1 - Entry level Requirements for Radiation Apparatus

Equipment	Requirements
Computed Tomography Scanners	Evidence of: 1. compliance with the current version of: IEC 60601-2-44 *Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*; IEC 60601-1-3: *Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*; or 2. EC declaration of conformity[2] or TUV certificate of conformity; or 3. 510(k) clearance with the United States Food and Drug Administration. **Unacceptable Computed Tomography Equipment** • Equipment without automatic dose modulation • Equipment without an indication of patient absorbed dose (e.g. weighted CT dose index or volume CT dose index)

[2] When a device has EC declaration of conformity, it can be 'CE marked'. This essentially means that the equipment complies with the standards issued by the International Electrotechnical Commission (IEC) and/or the European Committee for Electrotechnical Standardization (CENELEC).

Equipment	Requirements
	• Equipment without an ability to communicate and manage medical imaging information via a structured dose reporting system
Mammographic X-ray equipment	Evidence of: 1. compliance with the current version of: IEC 60601-2-45 *Medical electrical equipment Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices*; IEC 60601-1-3: *Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*; or 2. EC declaration of conformity[2] or TUV certificate of conformity; or 3. 510(k) clearance with the United States Food and Drug Administration. **Unacceptable Mammography Equipment** • Equipment with film as the image receptor. • Equipment without AEC. • Non digital equipment without a grid. • Equipment with the focus-to-image receptor distance less than 60 cm. • Equipment with a field of view less than 18 cm x 24 cm (excluding stereotactic devices). • Equipment without a foot pedal operated motorised compression plate and readout of compression thickness and force.
Fluoroscopic X-ray equipment	Evidence of: 1. compliance with the current version of: IEC 60601-2-43 *Medical electrical equipment Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures*; IEC 60601-1-3: Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment; or 2. EC declaration of conformity[2] or TUV certificate of conformity; or

Equipment	Requirements
	3. 510(k) clearance with the United States Food and Drug Administration. **Unacceptable Fluoroscopy Equipment** • Equipment without a device (where practicable) to show the quantity of radiation. • Equipment without a functioning audible 5 minute timer. • Equipment without devices to control the dose rate in the absence of special justification. • Systems intended to include paediatric use, without the option to remove the grid. • Equipment without beam collimation facilities. • Equipment using direct fluoroscopy.
Diagnostic Radiography equipment (fixed, mobile and capacitor discharge)	Evidence of: 1. compliance with the current version of: IEC 60601-2-28 *Medical electrical equipment Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*; IEC 60601-1-3 *Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*; or 2. EC declaration of conformity[2] or TUV certificate of conformity; or 3. 510(k) clearance with the United States Food and Drug Administration. **Unacceptable X-Ray generators and equipment for general radiology** • Equipment without the ability to collimate the beam. • Systems intended to include paediatric use, without the option to remove the grid.

Note: This table will be expanded for other modalities as national requirements are developed.

3. Acceptance Testing And Quality Assurance

3.1 Acceptance Testing

Acceptance testing, which includes establishing baseline values and the development and optimisation of patient protocols, verifies that the delivered system meets:

- performance expectations
- clinical requirements
- manufacturer's technical specifications.

3.1.1 Requirement

When first installed, as part of the commissioning process, all radiation apparatus used for diagnostic or radiation therapy planning purposes on humans must undergo acceptance testing by suitably qualified persons prior to clinical use (e.g. a medical physicist[3] tests the radiation apparatus and associated equipment, a diagnostic radiographer/diagnostic radiologist assesses clinical requirements). Such persons should be independent from the equipment supplier and/or manufacturer.

3.1.2 Guidance

The following table refers to various national and international documents that provide guidance to establish a suitable acceptance testing program for each modality of radiation apparatus. Other alternative, equivalent documents from relevant professional bodies, such as the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), the Royal Australian and New Zealand College of Radiologists (RANZCR), and the Australian Society of Medical Imaging and Radiation Therapy (ASMIRT), may also be accepted by the relevant regulatory authority.

Table 2 - Reference National and International Standards for acceptance testing

Equipment	Guidance Material
Computed Tomography Scanners	1. IEC 61223-3-5:2019 *Evaluation and Routine Testing in Medical Imaging Departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-Ray equipment* 2. European Commission, Radiation Protection No. 162, *Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology*, Nuclear Medicine and Radiotherapy, 2012 3. American Association of Physicists in Medicine *Performance evaluation of computed tomography systems*, The report of AAPM Task Group 233, AAPM Rep. 233, New York, 2019

[3] For the purposes of this document, 'medical physicist' defined in the current *Code for Radiation Protection in Medical Exposure (RPS C-5)*, published by ARPANSA.

Equipment	Guidance Material
	4. *Quality Assurance Programme for Computed Tomography: Diagnostic and Therapy Applications*, IAEA Human Health Series 19 (Vienna, 2012)
Mammographic X-ray equipment	1. IEC 61223-3-2:2007 *Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment* 2. IEC 61223-3-6:2020 *Evaluation and routine testing in medical imaging departments - Part 3-6: Acceptance and constancy tests - Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation* 3. ACPSEM Position Paper, *Recommendations for a digital mammography quality assurance program* V4.0.
Fluoroscopic X-ray equipment	1. AAPM - Task Group No. 272 - *Comprehensive Acceptance Testing and Evaluation of Fluoroscopy Imaging Systems* (TG272) (To be published). 2. IEC 60601-2-54:2018 - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy 3. IEC 61910-1:2014 - Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy 4. ACPSEM Position Paper *Recommendations for a technical quality control program for diagnostic X-ray equipment* (2005)
Plain Radiographic X-ray equipment	1. European Commission, Radiation Protection No. 162, Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, 2012 2. AAPM TG 150 Acceptance Testing and Quality Control of Digital Radiographic Imaging Systems 3. IEC 60601-2-54:2018 - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy 4. IEC 61910-1:2014 - Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy 5. ACPSEM Position Paper *Recommendations for a technical quality control program for diagnostic X-ray equipment* (2005)

Note: This table will be expanded for other modalities as national requirements are developed and may be updated following publication of further guidance material.

The Responsible Person must detail their acceptance testing strategy for each type of apparatus in their Radiation Management Plan.

3.2 Quality Assurance Tests

Quality assurance and preventative maintenance tests must be performed to ensure the radiation apparatus remains in good working order and to readily identify, and correct, any deficiencies.

3.2.1 Requirement

At regular intervals throughout its working life, all radiation apparatus must undergo quality assurance/preventative maintenance tests by an appropriately trained person as identified in the Responsible Person's Radiation Management Plan. Prompt and appropriate remedial action must be undertaken to correct deficiencies.

If a change to a radiation apparatus is made remotely (e.g. a supplier updating software on an apparatus), the person responsible for this change (typically the supplier or manufacturer) must notify the Responsible Person. This notification must include details of the change.

The Responsible Person must ensure that appropriate quality assurance testing is carried out, immediately following the remote access, to ensure the equipment continues to be suitable for clinical use.

3.2.2 Guidance

The following table refers to various national and international documents that provide guidance in establishing an acceptable quality control/preventative maintenance program for each modality of radiation apparatus. Other alternative, equivalent documents may also be accepted by the relevant regulatory authority.

Table 3 - Reference National and International Standards for Quality Assurance

Equipment	Guidance Material
Computed Tomography Scanners	1. *Quality Assurance Programme for Computed Tomography: Diagnostic and Therapy Applications*, IAEA Human Health Series No 19 (Vienna, 2012) 2. The current RANZCR Standards of Practice for Clinical Radiology 3. Manufacturer's recommended quality assurance and maintenance program 4. American Association of Physicists in Medicine *Performance evaluation of computed tomography systems*, The report of AAPM Task Group 233, AAPM Rep. 233, New York, 2019 5. IEC 61223-3-5:2019 Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment

Equipment	Guidance Material
Mammographic X-ray equipment	1. The current ACPSEM Radiology Position Paper *Recommendations for a Digital Mammography Quality Assurance Program* 2. The current RANZCR Standards of Practice for Clinical Radiology 3. RANZCR *Mammography Quality Control Manual (2002)* 4. The current RANZCR *Guidelines for Quality Control Testing for Digital (CR and DR) Mammography*
Fluoroscopic X-ray equipment	1. Manufacturer's recommended quality assurance and maintenance program 2. The current RANZCR Standards of Practice for Clinical Radiology 3. *Recommendations for a technical quality control program for diagnostic X-ray equipment* (ACPSEM, 2005) 4. *Quality Control in Diagnostic Radiology* (AAPM, Report 74, 2002) 5. AAPM - Task Group No. 272 - *Comprehensive Acceptance Testing and Evaluation of Fluoroscopy Imaging Systems* (TG272) 6. IPEM Topical Report: An evidence and risk assessment based analysis of the efficacy of quality assurance tests on fluoroscopy units-part I; dosimetry and safety (Mark Worrall *et al* 2019 *Phys. Med. Biol.* **64** 195011) 7. IPEM Topical Report: An evidence and risk assessment based analysis of the efficacy of quality assurance tests on fluoroscopy units-part II; image quality (Dan Shaw *et al* 2020 *Phys. Med. Biol.* **65** 225037)
Plain Radiographic X-ray equipment	1. American Association of Physicists in Medicine, Ongoing Quality Control in Digital Radiography, The Report of AAPM Imaging Physics Committee Task Group 151 (2015) 2. The current RANZCR Standards of Practice for Clinical Radiology 3. The Royal Australian and New Zealand College of Radiologists, General X-ray QA and QC Guideline, Version 1 (2013) 4. ACPSEM Position Paper, Recommendations for a technical quality control program for diagnostic X-ray equipment (2005). 5. Manufacturer's recommended quality assurance and maintenance program 6. IPEM Topical Report: an evidence and risk assessment based analysis of the efficacy of tube and generator quality assurance tests on general x-ray units (Ian Honey *et al* 2018 *Phys. Med. Biol.* **63** 245011)

Note: This table will be expanded for other modalities as national requirements are developed.

The Responsible Person must detail their quality assurance/preventative maintenance strategy for each type of equipment in their Radiation Management Plan.

4. Radiation Safety Standards

4.1 Radiation Safety Requirements – General

4.2 Frequency of Tests

The following table specifies the period within which radiation safety and performance tests must be conducted for each specified modality of radiation apparatus.

Table 4. Interval/frequency for compliance testing

Equipment	Frequency		
	Before clinical use	Interval thereafter	After Major Repair[4]
Computed Tomography Scanners	✓	2 years	✓
Mammographic X-ray equipment	✓	1 year	✓
Fluoroscopic X-ray equipment	✓	2 years	✓
Plain Radiographic X-ray equipment	✓	2 years	✓

Note: This table will be expanded for other modalities as national requirements are developed. Relevant regulatory authorities may apply more or less frequent testing than indicated above.

4.3 Test Criteria

Appendix 1: Outlines the radiation safety standard for Computed Tomography Scanners.

Appendix 2: Outlines the radiation safety standard for Mammographic X-ray equipment.

Appendix 3: Outlines the radiation safety standard for Fluoroscopic X-ray equipment.

Appendix 4: Outlines the radiation safety standard for Plain Radiographic X-ray equipment.

[4] For the purposes of this document, '***major repair or replacement***' means a repair that could affect radiation safety (e.g. tube change, detector change, major software upgrade).

Appendix 1: Computed Tomography Scanners

This appendix lists the minimum radiation safety requirements for computed tomography (CT) scanners that are intended to be used on living humans for:

- diagnostic imaging
- radiation therapy planning
- diagnostic nuclear medicine imaging

It specifically excludes the following equipment, which will be covered by alternative testing requirements:

- peripheral quantitative CT scanners
- equipment capable of tomosynthesis, e.g. breast tomosynthesis equipment
- on-board imaging systems of linear accelerators
- the following cone beam radiation apparatus:
    - dental cone beam computed tomography (CBCT) equipment
    - 3D Volumetric intraoperative fluoroscopic units

Computed Tomography Scanners used clinically on humans must comply with all of the following tests listed in Table 5.

Table 5 - Required radiation safety and performance tests for Computed Tomography Scanners

Test	Requirement – Computed Tomography (CT)
1. Markings on X-ray generators and tube assemblies	**1.1** ***Markings on X-ray generators and tube assemblies*** X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available by means of labels on the radiation apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. In the absence of such labelling on the gantry, confirmation of serial numbers may be obtained from the control panel. **1.2** ***X-ray generator markings*** X-ray generator markings must bear: • the name or trademark of the manufacturer • model name or number • the serial number. **1.3** ***X-ray tube assembly markings*** X-ray tube assemblies must bear:

Test	Requirement – Computed Tomography (CT)
	• the name or trademark of the manufacturer of the X-ray tube housing and insert • the type or model number and serial number of the X-ray tube housing and insert.
2. Baseline values	**2.1** ***Baseline values*** For the purpose of tests specified in this standard which make reference to baseline values for noise, mean CT number, uniformity, reconstructed slice thickness, high contrast resolution and CT dose index the baseline values must: a. be established in accordance with IEC 61223-3-5:2019 (or in accordance with IEC 61223-2-6:2006 for systems placed on the market prior to 2019) or be provided by the manufacturer b. be established at the first compliance test when equipment is first brought into use c. be within the manufacturer's acceptable range d. not be re-established unless the Responsible Person has provided evidence of a risk assessment conducted by the Responsible Person, in collaboration with a person authorised to issue certificates of compliance and the manufacturer, showing that the change in the baseline has been clinically justified. Note: 1. The compliance tester must obtain the previously established baseline values, including test parameters, from the Responsible Person prior to the compliance test. 2. The requirements comparing measured values with baseline values do not apply for first compliance test when equipment is first brought into use or when baseline values are re-established. This must be noted in the assessment report. 3. It is not considered justified to change a baseline value if the cause of a deviation from the baseline value is found to be due to a technical fault. 4. Baseline values may be changed following major maintenance, upgrade or repair such as in the case of replacement of the X-ray tube. However, the requirements of Item 2.1 (d) must still be met in these cases. **2.2** ***Records associated with baseline values*** The assessment report must include: a. the baseline values that were used for the purposes of tests which make reference to baseline values, including all relevant information pertaining to the baseline values used such as the test

Test	Requirement – Computed Tomography (CT)
	parameters and equipment used in obtaining the baseline values; and b. if baseline values have been re-established, the risk assessment as described in section 2.1(d) above.
3. Radiation warning signage	**3.1** ***Radiation warning signage*** The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words "caution" or "warning" • words to the general form of "X-rays produced when energised". The symbol and lettering must be black on a yellow background. A radiation warning sign, displaying the words 'Caution X-rays in use – authorised entry only' (or equivalent) must be displayed at each entry point to the room. **3.2** ***Illuminated warning signage*** An illuminated radiation warning sign, displaying the words 'ionising radiation – do not enter' (or equivalent), must be positioned directly adjacent to any entry point of the room. This sign must illuminate as the apparatus is placed in preparation mode and continue to illuminate for the duration of the exposure.
4. Termination of exposure	**4.1** ***Termination*** Readily identifiable and accessible means must be provided to terminate the exposure at any time during a scan.
	4.2 ***Pre-set time*** A device must be incorporated in the X-ray equipment to terminate the exposure after the conclusion of the programmed exposure. For clarity, test 4.2 does not apply to CT fluoroscopy equipment.
5. Indicators of operation	**5.1** ***Mains indicator*** A mains indicator must be clearly identified. 'ON' and 'OFF' positions must be marked with suitable symbols or adjacent indicator light or other unambiguous means. A visible signal must be displayed at the control panel and on the gantry to indicate when the X-ray tube is in preparation mode.
	5.2 ***Beam 'on' status indicator*** When and only when radiation is produced, visible and readily identifiable indication of the beam 'on' status must be provided: a. on the control panel

Test	Requirement – Computed Tomography (CT)
	b. on or near the gantry.
	5.3 ***Exposure factors*** When X-ray tube potential, current and scan duration are capable of being independently varied, the values must be indicated on the control panel. If any are not capable of being independently varied, the fixed values must be indicated at the control panel.
6. Mechanical accuracy	**6.1** ***Light localisation*** Scan plane lights (or lasers) must be provided for marking the tomographic section (i.e. for axial positioning of the patient). The external scan plane lights, if external scan plane lights are available, must coincide with the internal scan plane lights and the scan plane to within: a. ± 2mm for equipment used for diagnostic imaging, or b. ± 1 mm for equipment used for radiation therapy planning **Critical failure:** if the above requirements are not met for radiation therapy planning. Note: For clarity, internal scan plane lights are those that are used to identify the tomographic plane. External scan plane lights are those that are used to identify the transaxial plane set at a fixed distance from the tomographic plane.
	6.2 ***Preview image localisation*** A preview image must be provided on which the operator may set up the tomographic sections to be taken and the reference lines indicating the start and finish of the preview image must not differ from the true positions by more than 2 mm. **Critical failure:** if the above requirements are not met.
	6.3 ***Coronal and sagittal plane lights*** The coronal and sagittal plane lights must intercept at the x = 0, y = 0 on the corresponding axial image and any difference must not exceed: a. ± 2 mm for equipment used for diagnostic imaging, or b. ± 1 mm for equipment used for radiation therapy planning **Critical failure:** if >± 1mm for radiation therapy planning.
	6.4 ***Couch movement position accuracy*** Positioning accuracy of the patient support includes both longitudinal positioning and backlash, as defined in Clause 5.1 of IEC 61223-3-5:2019. The accuracy of the patient support (couch) positioning is evaluated by moving the couch a defined distance (longitudinal measurement) and subsequently moving it back to the start position (backlash measurement), preferably with a patient-equivalent load on the couch. Position accuracy

Test	Requirement – Computed Tomography (CT)
	measurements must be made in both forward and backward directions from a central position. a. Longitudinal positioning of the patient support: must not deviate by more than ± 2mm from the fixed indicated distances. b. Backlash of the patient support: must not be greater than ± 2mm.
7. Image quality	**7.1** ***Noise*** The measured value of noise must: a. be within manufacturer-specified tolerances, where provided, and b. not be more than 10% above the baseline value or 0.2HU above the baseline, whichever is larger. **Critical failure:** if measured value of noise is > 15 % above baseline values. Test parameters Unless otherwise specified by the manufacturer, measurements of noise must be performed by determining the standard deviation of the CT number for a region of interest placed in the centre of the displayed image of a uniform test device. For the purpose of this test, 'region of interest' means a circular region of interest of approximately 40% of the diameter of the uniform test device. Two CT conditions of operation must be tested, one representing a typical axial head scan and one representing a typical axial body scan.
	7.2 ***Mean CT Number*** The mean CT number: a. must be within manufacturer-specified tolerances, where provided, and b. of the central region of interest must not deviate by more than ±4 Hounsfield units (HU) from the baseline value. **Critical failure:** if mean CT number deviates by > ±10 HU from the baseline value for water up to 30cm diameter. Test parameters Unless otherwise specified by the manufacturer, mean CT numbers are determined from a region of interest placed in the centre of the displayed image of a uniform test device. For the purpose of this test, 'region of interest' means the circular region of interest of approximately 10% of the diameter of the uniform test device. Two CT conditions of operation must be tested, one representing a typical axial head scan and one representing a typical axial body scan.

Test	Requirement – Computed Tomography (CT)
	7.3 ***Uniformity*** Uniformity must: a. be within manufacturer-specified tolerances, where provided, and, b. not vary by more than ±2 Hounsfield units (HU) from the baseline value. **Critical failure:** if deviation of mean CT number from specified value >10 HU for water phantom up to 20 cm diameter, or > 20 HU for water phantom above 20cm diameter. Test parameters Unless otherwise specified by the manufacturer, uniformity must be evaluated by calculating the absolute values of the difference between the mean CT number of the region of interest in the central position and those in each of the 3, 6, 9, and 12 o'clock positions in the image of a uniform test device. For the purpose of this test, 'region of interest' means a circular region of interest of approximately 10% of the diameter of the uniform test device. Two CT conditions of operation must be tested with appropriately sized phantoms, one representing a typical axial head scan and one representing a typical axial body scan.
	7.4 ***Reconstructed Slice Thickness*** The reconstructed image slice thickness must: a. be within manufacturer-specified tolerances, where provided, and b. not deviate from the specified nominal values by more than: i. 1.0 mm for slice thicknesses > 2 mm ii. 50% for slice thicknesses 1 mm to 2 mm iii. 0.5 mm for slice thicknesses < 1 mm. **Critical failure:** if the reconstructed image slice thickness does not comply with above requirements. Test parameters The measurements must be performed for all reconstructed slice thicknesses used clinically that are accessible in axial mode. A representative number of tomographic sections must be acquired for each reconstructed slice thickness. The evaluation must be performed for at least both outer tomographic sections and one representative inner tomographic section (in the axial plane).
	7.5 ***Low contrast resolution*** The low contrast resolution must be within manufacturer-specified tolerances.

Test	Requirement – Computed Tomography (CT)
	Note: This test is only required for equipment used for radiation therapy planning.
8. Radiation dosimetry	**8.1** ***CT Dose Index (CTDI) in air*** The dose values must: a. be within manufacturer-specified tolerances, where provided, and b. all be within ±10% of the baseline value. **Critical failure:** if deviation of CTDI free-in-air from manufacturer's specifications or baseline values > 20%. Test parameters The following dose measurements must be performed for a range of clinical protocols, including: ○ $CTDI_{free\ air}$ at the typical body conditions of operation ○ $CTDI_{free\ air}$ at no less than 5 nominal beam collimations (all other independent conditions of operation must be maintained at the typical body conditions of operation)
	8.2 ***Volume CT Dose Index and Dose Length Product*** The volume CT dose index ($CTDI_{vol}$) and the Dose Length Product (DLP) must be available to the operator and recorded with CT images. The displayed value of $CTDI_{vol}$ and DLP must be within ±20% of the measured value. Test parameters The following dose measurements must be performed for a range of clinical protocols, including: ○ $CTDI_{vol}$ at the typical head and body conditions of operation ○ $CTDI_{vol}$ at all kVp settings clinically used (all other independent conditions of operation must be maintained at the typical head and body conditions of operation)

Appendix 2: Mammographic X-ray Equipment

This appendix lists the radiation safety standard for mammographic X-ray equipment that is intended to be used on humans for:

- diagnostic imaging
- screening
- research

It specifically includes the following mammographic X-ray equipment:

- mammography units using digital radiography technology (DR mammography units)
- mammography units using computed radiography technology (CR mammography units)
- tomosynthesis mammography units
- breast biopsy mammography units (includes 'integrated' units where the same detector is used for mammography and biopsy, 'separate image receptor' where a different image receptor is used, and 'stand-alone' biopsy units)

Mammographic X-ray equipment used clinically on humans must satisfy one of the following options:

OPTION 1

Evidence has been provided that the mammographic X-ray equipment meets the following requirement:

Requirement
Accreditation program Within the last 12 months, there is evidence demonstrating that the radiation apparatus has been assessed by an ACPSEM certified mammography equipment assessor as complying with: a. the systems tests, as outlined in the BreastScreen Australia National Accreditation Standards (NAS) accreditation program; or b. the system tests, as outlined in the current 'RANZCR Guidelines for Quality Control Testing for Digital (CR and DR) Mammography'.

or

OPTION 2

The mammographic X-ray equipment complies with all of the requirements in Table 6 below. The test protocols and methodology as described in the current ACPSEM Radiology Position Paper '*Recommendations for a Digital Mammography Quality Assurance Program*' should be used, unless otherwise specified in this document.

Notes: The tests apply to all mammography units, unless otherwise specified.

For the purposes of this option, assume that film-based and computed radiography (CR) technology are not used for biopsy procedures.

Table 6 - Required radiation safety and performance tests for mammographic X-ray equipment

Test	Requirement - Mammography
1. Markings on X-ray generators and tube assemblies	**1.1** ***Markings on X-ray generators and tube assemblies*** X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available on labels on the radiation apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. **1.2** ***X-ray generator markings*** X-ray generator markings must bear: a. the name or trademark of the manufacturer b. the model name or number c. the serial number. **1.3** ***X-ray tube assembly markings*** X-ray tube assemblies must bear: **a.** the name or trademark of the manufacturer of the X-ray tube housing and insert b. the type or model number and serial number of the X-ray tube housing and insert **c.** the position of the focal spot.
2. Radiation warning signage	**2.1** ***Radiation warning signage*** The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words “caution” or “warning” • words to the general form of “X-rays produced when energised” The symbol and lettering must be black on a yellow background. A radiation warning sign, displaying the words ‘Caution X-rays in use’ (or equivalent) must be displayed at each entry point to the room.
3. Indicators	**3.1** ***Mains indicator*** A mains indicator must be clearly identified. ‘ON’ and ‘OFF’ positions must be indicated by a suitable light or other unambiguous means.
	3.2 ***Visual indicator*** A visible signal must indicate when the X-ray tube is energised. The signal must be displayed at the control panel or, for remotely controlled apparatus, at the operator’s position.

Test	Requirement - Mammography
	3.3 ***Audible signal*** A signalling device audible at the location from which the apparatus is operated must indicate the duration or termination of the exposure.
	3.4 ***Automatic mode*** For radiation apparatus operating with automatic exposure control, the preselected mode of operation must be indicated on the control panel.
	3.5 ***Exposure factors*** When X-ray tube potential, current and current-time product (mAs) are capable of being independently varied, the values must be indicated on the control panel. If any are not capable of being independently varied, the fixed values must be indicated at the control panel.
4. Exposure switch	**4.1** ***Position of exposure switch*** Control of the X-ray unit must be from behind a protective screen or from a distance of not less than 2 metres from the focal spot. Note: This test does **not** apply to breast biopsy mammography units.
	4.2 ***Dead man type switch*** Each exposure must be initiated and maintained by means of a control requiring continuous activation by the operator and the exposure must be able to be interrupted at any time.
	4.3 ***Security of exposure switch*** The exposure switch must: a. be such that it is not possible to initiate another exposure without releasing the switch; and b. be designed so that it is protected against accidental operation.
5. X-ray beam collimation and alignment	**5.1** ***X-ray field/image receptor alignment*** The X-ray field must: a. fully irradiate the image receptor b. not extend beyond the breast support on the chest wall edge of the image receptor by more than 2 mm. **Critical failure:** if the above requirements are not met. <u>Test parameters</u> This test must be performed for clinically relevant X-ray tube targets and geometry combinations. Note: This test does **not** apply to image receptors which are only for biopsy use. Note: 5.1 (a) does not apply to Mag mode.

Test	Requirement - Mammography
	5.2 ***Compression paddle/image receptor alignment*** The chest wall edge of the compression paddle must: a. be aligned just beyond the chest wall edge of the image receptor such that the chest wall compression paddle does not appear in the image b. not extend beyond the chest wall edge of the image receptor by more than 1% of the source-to-image receptor distance (SID). <u>Test parameters</u> This test must be performed for clinically relevant X-ray tube targets, bucky, field sizes and paddle geometry combinations. Note: This test does **not** apply to image receptors which are only for biopsy use.
	5.3 ***Missing tissue at chest wall*** The amount of tissue not imaged between the edge of the breast support and the imaged area must be ≤ 5 mm in contact mode and ≤ 7mm in Mag mode. **Critical failure:** if the above requirement is not met. Notes: This test does **not** apply to image receptors which are only for biopsy use.
6. Generator performance	**6.1** ***kVp Accuracy*** The measured kVp must be within ±5% of the indicated kVp setting over the clinically relevant range in, at most, 2 kVp increments. **Critical failure:** if the above requirement is not met. <u>Test parameters</u> The kVp need only be verified for one target/filter combination. However, the kVp meter must be calibrated for that particular target/filter combination.
	6.2 ***kVp Reproducibility*** The **coefficient of variation** for a minimum of five exposures at a typical clinical kVp value must not be greater than 0.02. **Critical failure:** if the above requirement is not met. Where: '*coefficient of variation*' means the standard deviation divided by the mean of a set of numbers. <u>Test parameters</u> The kVp reproducibility need only be verified for one target/filter combination in routine clinical use.

Test	Requirement - Mammography
7. Exposure time	**7.1** ***Exposure time*** For all clinically relevant source-image-distance settings, the maximum exposure time when irradiating a 6 cm PMMA phantom must be: a. less than 3.5 seconds for fine focus b. less than 2 seconds for broad focus. **Critical failure:** if the above requirements are not met. <u>Test parameters</u> 1. This test must: ○ assess both contact and magnification modes ○ use clinically relevant technique factors for the PMMA thickness consistent with SDNR and MGD measurements. 2. Record the mAs and infer the exposure time from tube rating, or measure directly using a manual exposure matched to mAs needed for AEC initiated exposure.
8. Beam quality	**8.1** ***Half Value Layer (HVL)*** With the compression device in place, the HVL for all X-ray tube target and filter combinations must be such that: [(kVp/100) + 0.03] mm Al ≤ HVL < [(kVp/100 + C)] mm Al where C = 0.12 for Mo/Mo = 0.19 for Mo/Rh = 0.22 for Rh/Rh = 0.23 for Rh/Ag = 0.30 for W/Rh = 0.32 for W/Ag = 0.31 for W/Al (for tomosynthesis mode) = 0.25 for W/Al (for all other modes) **Critical failure:** if the above requirements are not met. Note: This test should include a measure of the HVL required for mean glandular dose calculations.
9. Automatic exposure control (AEC) performance	**9.1** ***Reproducibility*** The coefficient of variation for both mean pixel value and mAs for at least five AEC controlled exposures of a test object must be less than or equal to 0.05 at clinically relevant kVp and target/filter selections. <u>Test parameters</u> A 4 cm PMMA phantom, or equivalent must be used for this test.

Test	Requirement - Mammography
	9.2 ***Back-up timer and security cut-out*** **DR and tomosynthesis mammography units** A cut-off mechanism must be present and terminate the exposure within 50 ms or within 5 mAs of the exposure being initiated when the current-time product (mAs) required to sufficiently expose the detector to form an acceptable image would be greater than 500 mAs. **CR mammography units** The current-time product (mAs) must be limited to no more than 500 mAs. **Critical failure:** if the cut-off mechanism does not terminate the exposure < 800 mAs.
	9.3 ***Backup timer/security cut-out indication*** A visible indication at the control panel must be provided whenever an exposure has been terminated by the backup timer or security cut-out mechanisms.
	9.4 ***Backup timer/security cut-out manual reset*** When the exposure has been stopped by the backup timer/security cut-out mechanism it must not be possible to initiate another exposure without first operating a manual reset.
	9.5 ***Density control (DR and CR only)*** If density control is available, it must be capable of changing the mAs from the value used normally by -25% to +50%.
	9.6 ***Thickness compensation and SDNR System Performance (DR and CR only)*** The Signal Difference to Noise Ratio (SDNR) when measured in contact mode and in Mag mode under the conditions specified below for 2, 4 and 6 cm PMMA thicknesses must be: ○ SDNR for 2 cm PMMA > 1.1 × $SDNR_{accept}$ ○ SDNR for 4 cm PMMA > $SDNR_{accept}$ ○ SDNR for 6 cm PMMA > 0.9 × $SDNR_{accept}$ (does not apply to CR Mag mode) ○ SDNR for 6 cm PMMA > 0.65 × $SDNR_{accept}$ (CR Mag mode only) **Critical failure:** if the above requirements are not met. Where: 1. $SDNR_{accept}$ is the minimum acceptable SDNR value for 0.2 mm Al on 4 cm PMMA test object. 2. The $SDNR_{accept}$ values to be used are those DR and CR manufacturer specific values detailed in the current ACPSEM Recommendations for a Digital Mammography Quality Assurance Program* (ACPSEM Program)

Test	Requirement - Mammography
	* *Table 2 at time of publication* 3. Where an $SDNR_{accept}$ value is not specified in the ACPSEM Program, an equivalent international body may be used. $$SDNR = \frac{MPV_b - MPV_{Al}}{\sqrt{(SD_b^2 + SD_{Al}^2)/2}}$$ 4. MPV_b and SD_b are defined to be the mean pixel value and standard deviation respectively for a ROI located in a uniform part of the PMMA phantom. 5. MPV_{Al} and SD_{Al} are defined to be the mean pixel value and standard deviation respectively for a ROI located in a uniform part of the PMMA phantom with 0.2 mm thickness of Al foil added. <u>Test parameters</u> 1. Al test object should be 1 cm x 1 cm 2. ROIs used in the analysis should be approximately 0.25 cm^2 3. Both ROIs should be centred on a line parallel to and 6 cm from (3 cm for magnification images) the chest wall to minimise the impact of the heel effect and ideally the image pixel values should be linearised with respect to dose before the SDNR as defined above is calculated. Note: For those DR mammography units with a separate image receptor, and for stand-alone biopsy systems: a. typical exposure conditions used for biopsy operation should be used b. a minimum PMMA thickness of 2cm is to be used c. for those units with a field of view of less than 100 mm square, the ROIs defining where the SDNR is to be calculated should be placed parallel to the chest wall and centrally in the image along the anode-cathode axis.
	9.7 ***AEC Thickness compensation (Tomosynthesis mode only)*** The AEC must maintain the mAs for 2, 4 and 6 cm PMMA thicknesses to within ±10% of the mean mAs value for that thickness of PMMA , when using clinically relevant kVp and target/filter selections. <u>Test parameters</u> 1. Mean mAs value is defined as the mean of mAs values used by the AEC for 2, 4 and 6 cm of PMMA thicknesses. 2. The PMMA must completely cover the detector. Note: This test does **not** apply to breast biopsy mammography units.

Test	Requirement - Mammography
10. Compression device	**10.1** ***Compression force*** The radiation apparatus must incorporate a compression device which meets the following requirements. a. For manual compression devices (including manual override) the compression device must not be able to apply a force > 300N. b. For power driven compression devices, the compression device must be able to apply a force of at least 150N, and it must be unable to apply a force > 200N. c. For power driven compression, the available operating force must be adjustable down to 70N or less. d. If the value of applied force is displayed, the indication must be given in units of force and must be accurate to within ±20N (or equivalent). e. The compression force must not decrease by more than 20N during a time interval of 30 seconds or an interval of time that would be typical of clinical compressions. f. For mammographic X-ray equipment with a moving anti-scatter grid, the application of the maximum force attainable for the compression device must not impede the motion of the anti-scatter grid. **Critical failure:** if the above requirements are not met. Note: This test does **not** apply to 'stand-alone' biopsy units.
	10.2 ***Compressed breast thickness indicator*** The indicated compressed breast thickness must be accurate to ±5 mm and reproducible to ±2 mm across 5 different readings using the manufacturer's specified compression force and specified paddle.
11. Monitor and Print	**11.1** ***Interpretation* and acquisition monitors*** The TG18-QC test pattern image displayed at a scale of 1:1 must be such that: a. borders are visible b. lines are straight c. squares appear square d. the ramp bars appear continuous without any contour lines e. there is no smearing or bleeding at black-white transitions f. all corner patches are visible g. squares of different shades from black to white are distinct h. all high contrast resolution patterns and two low contrast patterns are visible in all four corners and in the centre i. the 5% and 95% pixel value squares are clearly visible

Test	Requirement - Mammography
	j. the pattern is centred in the active area and no disturbing artefacts are visible k. the number of letters visible in the phrase “Quality Control” for the dark, mid-grey and light renditions is at least eleven l. Luminance for interpretation monitor > 450 cd/m^2 m. Luminance for acquisition monitor > 250 cd/m^2. * Note: A physical test of the interpretation monitor should be performed if the monitor is attached to the workstation. If the interpretation monitor is remote, it is acceptable to sight a certification that the monitor has been tested to a recognised standard, provided that the certification has been conducted within the last 12 months.
	11.2 ***Printer (if applicable and only if printed images are used for diagnosis)*** Printed TG18-QC test pattern must be such that: a. all borders are visible b. lines are straight c. all corner patches are visible d. squares of different shades from black to white are distinct e. all high contrast resolution patterns are visible in all four corners and the centre f. the 5% and 95% pixel value squares are clearly visible g. no disturbing artefacts are visible h. the number of letters visible in the phrase “Quality Control” for the dark, mid-grey and light renditions is at least eleven i. the mid density (MD) and density difference (DD) must be within ±0.15 OD of their baseline values j. Base + Fog (B+F) must be within ±0.03 OD of the baseline value, and B+F must also be ≤0.25 OD k. D_{max} must be within ±0.10 OD of the baseline value, and D_{max} must also be ≥3.4 OD l. optical density = baseline ±20% and the OD must be in the range of 1.60 to 2.0.
12. Image quality	**12.1** ***Image quality evaluation*** **DR and CR image receptors** At least the following must be visible in contact mode:

Test	Requirement - Mammography
	a. 5 fibres, 3.5 speck groups and 4 masses in an image of an ACR accreditation phantom; or b. 4 fibres, 3 speck groups and 3 masses in an image of an ACR DM phantom. **Critical failure:** if the above requirements are not met. **DR image receptors in Digital Breast Tomosynthesis mode** At least the following must be visible in contact mode: a. 4 fibres, 3 speck groups and 3 masses in an image of an ACR accreditation phantom; or b. 2 fibres, 1 speck group and 2 masses in an image of an ACR DM phantom. **Biopsy operation: for separate image receptor or stand-alone biopsy systems** At least the following must be visible: a. 3 fibres, 3 speck groups and 2.5 masses in an image of an ACR 'mini' digital stereotactic phantom; or b. 3 fibres, 2 speck groups and 1.5 masses in an image of an RMI 156S phantom. Test parameters Slice used for scoring should be 37±2 mm (ACR accreditation phantom) or 34±2 mm (ACR DM phantom) above breast support and must not change by more than ±1 mm from previous measurement. Notes: 1. It may be necessary to evaluate image quality using a diagnostic image workstation. 2. Image quality requirements outlined in this section for DR and biopsy units must be achieved with a mean glandular dose of ≤2.0 mGy.
13. System linearity	**13.1** ***Image Receptor Linearity (DR only)*** The relationship between entrance surface air kerma (ESAK) and mean pixel value (MPV) must be linear, with the square of the correlation coefficient (R-squared value from the RANZCR Equipment Assessor Report Templates) greater than 0.99. **Critical failure:** if this requirement is not met. Test parameters 1. Use standard test block (4 cm PMMA) at a clinically relevant kVp and target/filter combination (i.e. those selected under AEC for 4 cm PMMA). 2. Measure the ESAK at 6 cm from chest wall.

<table>
<tr><th>Test</th><th>Requirement - Mammography</th></tr>
<tr><td></td><td>
3. Measure the MPV and standard deviation in region of interest placed 6 cm from chest wall.
4. Correct MPV for any pixel offset as specified by the manufacturer.
5. The range of mAs values selected should cover the clinically useful range (e.g. 5 to 300 mAs) so that the MPV increases to a value corresponding to about a factor of three above the value obtained using an AEC initiated exposure. A minimum of seven mAs values should be used.
</td></tr>
<tr><td></td><td>
13.2 Image Receptor Linearity (CR only)

The relationship between ESAK and exposure indicator listed in the table below must be linear, with the square of the correlation coefficient (R-squared value) greater than 0.99.

Critical failure: if this requirement is not met.

<table>
<tr><th>Manufacturer</th><th>ESAK and exposure indicator relationship</th></tr>
<tr><td>Fuji, Philips & Konica</td><td>S# versus reciprocal of ESAK</td></tr>
<tr><td>Kodak (Carestream)</td><td>EI versus log (ESAK)</td></tr>
<tr><td>Agfa</td><td>SAL versus SQRT(ESAK) or SAL log versus log(ESAK) or PVI log 16 versus log(ESAK), dependent on software version and plate type</td></tr>
</table>
Where:
1. The ESAK and EI relationship to be used for a particular manufacturer is as detailed in the current ACPSEM Recommendations for a Digital Mammography Quality Assurance Program* (ACPSEM Program).
*Appendix 6 at time of publication
2. Where a relationship is not specified in the ACPSEM Program an equivalent international body may be used.

<u>Test parameters</u>
1. Use standard test block (4 cm PMMA) at a clinically relevant kVp and target/filter combination (i.e. those selected under AEC for 4 cm PMMA).
2. Measure the ESAK at 6 cm from chest wall.
3. Measure the EI and standard deviation in region of interest placed 6 cm from chest wall.
4. The range of mAs values selected should cover the clinically useful range (e.g. 5 to 300 mAs) so that the EI increases to a value corresponding to about a factor of three above the value obtained using an AEC initiated exposure. A minimum of seven mAs values should be used.

Note: This test does not apply to breast biopsy mammography units.
</td></tr>
</table>

Test	Requirement - Mammography
14. System resolution	**14.1** ***System resolution (DR and CR only)*** Using a line pair phantom 4 cm above the breast support, or using the MTF tool, the measured system resolution must not be below the baseline resolution value by more than 10%. Note: This requirement applies to both contact and magnification modes. **Critical failure:** if < 5 line pairs per mm. Test parameters Measurements parallel and perpendicular to the chest wall must be made.
15. Artefact evaluation	**15.1** ***Artefact Evaluation*** An image of a 4 cm PMMA phantom using clinically relevant technique factors must not have evidence of any clinically significant artefacts, e.g. a. blotches or regions of altered noise appearance b. grid lines or breast support structures c. bright or dark pixels d. dust artefacts mimicking calcifications e. stitching or registration artefacts f. any processing artefacts (if applicable). Test parameters 1. The assessment should be performed on both the processed and unprocessed image. 2. View the image on the acquisition monitor using zoom and roam to check for possible detector faults. 3. Print the image if interpretation is performed using a hard copy. 4. Artefacts must be assessed for conventional, tomographic and magnification mode and for all clinically relevant target/filter combinations.
16. Distance calliper accuracy	**16.1** ***Distance calliper accuracy*** **DR and CR image receptors** (test only applicable following image receptor system change or significant software upgrades) Distance callipers must agree to within ± 2% of the true distance values when allowance has been made for manufacturer's calibration plane. **DR image receptors in Digital Breast Tomosynthesis mode** Measured dimensions of an object within the reconstructed image plane should be within 2% of the true dimensions. **Critical failure:** if this requirement is not met.

Test	Requirement - Mammography
	Test parameters For DR image receptors in digital breast tomosynthesis mode, the accuracy of the distance calliper must be confirmed in at least three reconstructed slices spread across the full height of the breast. Callipers must be assessed in both contact and magnification modes and in the PACS environment.
17. Image receptor homogeneity	**17.1** ***Image uniformity*** **DR and CR image receptors in 2D mode** The maximum deviation of mean pixel value must be less than ± 10% of the mean pixel value from the central region of interest (ROI). **Critical failure:** if this requirement is not met. **Digital Breast Tomosynthesis mode** For systems only used in DBT mode, the above 2D mode tests apply. Test parameters 1. This test is to be carried out using a 4 cm PMMA phantom. 2. For DR image receptors – Use five ROIs each of ~100 mm^2, one central, with the other 4 at the corners approximately 20 mm from any edge. For biopsy operation, those DR mammography units with a separate image receptor, and for stand-alone biopsy systems, the ROIs in the corners of the image are to be approximately 10 mm from any edge. 3. For CR image receptors – Use three ROIs each of ~100 mm^2, one central, with the other 2 at approximately 20 mm from the edges placed on a line parallel to and approximately 20 mm from chest wall edge. 4. Exclude phantom non-uniformity by rotating block 180^o and repeating. Note: This requirement applies to both contact and magnification modes.
18. Image receptor ghosting (DR and CR only)	**18.1** ***Image Receptor Ghosting (DR and CR only)*** The Ghost Image Factor as defined below must be less than 2, when measured under the conditions specified below, and is reliant on having passed the uniformity test above. $$\text{Ghost Image Factor} = |(MPV1 - MPV2)|/SD_2$$ where: MPV_1 = Mean Pixel Value in ROI 1

Test	Requirement - Mammography
	MPV_2 = Mean Pixel Value in ROI 2 SD_2 = Standard deviation of pixel values in ROI 2 Note: This test is not applicable to scanning systems as their design means ghosting is not possible. Test parameters Firstly, an exposure must be made using clinical exposure factors under manual control (e.g. 28 kVp, 50 mAs) of a 4 cm thick PMMA block positioned such that half the image receptor is covered. Secondly, a second exposure must be taken at the same clinical settings but with the PMMA block completely covering the image receptor, either as soon as the X-ray system allows (in the case of DR), or as soon as CR plate has been reprocessed (in the case of CR). The ROI 1 and ROI 2 are placed equidistant from the boundary defining where the PMMA and no PMMA regions existed in the initial image, with ROI 2 located in PMMA region.
19. Uniformity of cassette / image plate response	**19.1** ***Uniformity of cassette / image plate response (CR only)*** When imaging a 4 cm thick PMMA block completely covering the CR plate using AEC controlled exposure: a. the mAs values used for all plates of the same size should be within ±5% of the mean of the mAs values for plates of that size b. for any two different plate sizes, the difference between the mean of the mAs values used for plates of the largest of the two sizes and that used for plates of the smallest of the two sizes must be no more than 20% of the lower value. **Critical failure: if these requirements are not met.** Note: This test does **not** apply to breast biopsy mammography units.
20. Exposure indicator calibration and image fading	**20.1** ***Exposure indicator calibration and image fading (CR only)*** The accuracy and fading of the exposure indicator must be within the manufacturer's specifications. Note: This test does **not** apply to breast biopsy mammography units.
21. Mean glandular dose	**21.1** ***Mean glandular dose*** The calculated mean glandular dose, when assessed using AEC controlled exposure, must be: a. ≤ 2.0 mGy for a 4.2 cm 50% adipose, 50% glandular breast (i.e. ACR accreditation phantom or ACR DM phantom) for contact and tomosynthesis modes

Test	Requirement - Mammography
	b. < 1 mGy for 2.0 cm PMMA (2.3 cm 50% adipose, 50% glandular breast) for contact mode or < 1.2 mGy for tomosynthesis mode c. < 4.5 mGy for 6.0 cm PMMA, (6.5 cm 50% adipose, 50% glandular breast) for contact and tomosynthesis modes. **Critical failure:** if the above requirements are not met. Additionally, the displayed mean glandular dose value must be within 25% of the calculated value. Note: Integrated units, DR mammography units with a separate image receptor and stand-alone biopsy systems are not required to comply with these requirements when in operation for biopsy purposes.
22. Mechanical stability	**22.1** ***Stability of X-ray tube and image receptor assembly*** Once positioned, the X-ray tube and the image receptor assembly must remain mechanically stable. Additionally, when in biopsy operation, integrated units, DR mammography units with a separate image receptor, and stand-alone biopsy systems, must meet the following requirements: a. the column rotation, vertical drives, locks and indicators function correctly. b. there are no miscellaneous safety related issues (e.g. jam risk, system stability, loose cabling). c. the X-ray tube angular locations are positively locked, image receptor and compression plate/biopsy window free of wobble, Vernier drive and needle guide rigid and wobble free, localisation system zeros and biopsy device properly immobilised.
23. X-ray tube housing leakage (Only applicable before first use and following tube change)	**23.1** ***X-ray tube housing leakage at 1 m*** The kerma rate in air at a distance of 1 m from the focal spot of the X-ray tube must not exceed 1.0 mGy per hour.
	23.2 ***X-ray tube housing leakage at 30 cm*** The kerma in air at a distance of 30 cm from the focal spot of the X-ray tube must not exceed 0.01 mGy per 100 mAs at 30kVp.
24. Stereotactic accuracy (Only applicable to breast biopsy mammography units)	**24.1** ***Localisation accuracy*** The indicated needle tip coordinates must be within ± 1 mm of the actual pre-set needle position in each direction (horizontal, vertical and depth). **Critical failure**: if the above requirements are not met. <u>Test parameters</u> The test may be performed by:

Test	Requirement - Mammography
	a. using air or a suitable localisation phantom; or b. following the manufacturer's recommended procedure.

Appendix 3: Fluoroscopic X-ray Equipment

This appendix lists the radiation safety standard for fluoroscopic X-ray equipment that is intended to be used on humans for:

- diagnostic imaging
- interventional, cardiology and orthopaedic procedures
- research

The standard covers the following types of fluoroscopy apparatus:

- Fixed and mobile fluoroscopy units
- Mini C-arm
- Fluoroscopy units with multiple X-ray tubes
- Fluoroscopy systems used for 3D imaging including 3D Volumetric intraoperative fluoroscopic units, e.g. O-arm

Table 7 - Required radiation safety and performance tests for fluoroscopic X-ray equipment

Test	Requirement - Fluoroscopy
1. Markings on X-ray generators and tube assemblies	**1.1** ***Markings on X-ray generators and tube assemblies*** X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available by means of labels on the radiation apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. **1.2** ***X-ray generator markings*** X-ray generator markings must bear: • the name or trademark of the manufacturer • model name or number • the serial number. **1.3** ***X-ray tube assembly markings*** X-ray tube assemblies must bear: • the name or trademark of the manufacturer of the X-ray tube housing and insert; and • the type or model number and serial number of the X-ray tube housing and insert.

Test	Requirement - Fluoroscopy
2. Radiation warning signage	**2.1** ***Radiation warning signage – apparatus*** The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words “caution” or “warning” • words to the general form of “X-rays produced when energised”. The symbol and lettering must be black on a yellow background. **2.2** ***Radiation warning signage – room entry point*** A radiation warning sign, displaying the words ‘Caution X-rays in use – authorised entry only’ (or equivalent) must be displayed at each entry point to the room, including at locations where mobile fluoroscopy equipment is used. **2.3** ***Illuminated warning sign*** For fixed apparatus, an illuminated radiation warning sign, displaying the words ‘ionising radiation – do not enter’ (or equivalent), must be positioned directly adjacent to any entry point of the room. This sign must illuminate immediately upon exposure and continue to illuminate during the exposure.
3. Mains indicator	**3.1** ***Mains indicator*** A mains indicator must be clearly identified. ‘ON’ and ‘OFF’ positions must be indicated by a suitable light or other unambiguous means.
4. Energised X-ray Tube	**4.1** ***Energised X-ray tube*** There must be an obvious visual and/or audible indicator when radiation is being emitted.
5. Automatic Mode	**5.1** ***Automatic mode*** For X-ray apparatus operating with automatic control systems the preselected mode of operation must be indicated on the control panel.
6. Indicators of operation	**6.1** ***Indicators of operation*** The tube voltage, exposure time, tube current and, where appropriate, magnification setting, current-time product, frame rate, pulse rate, and beam filtration must be displayed by a suitable indicator, even if these factors are under automatic control. For permanently fixed exposure factors, the value must be indicated on the control panel.
7. Audible signal - radiographic mode only	**7.1** ***Audible signal - radiographic mode only*** A signalling device audible at the location from which the equipment is operated must indicate the duration or termination of the exposure.

Test	Requirement - Fluoroscopy
8. Control of multiple X-ray tubes	**8.1** ***Control of multiple X-ray tubes*** Except for apparatus specifically designed for two-tube techniques (e.g. bi-plane angiography rooms), means must be taken to ensure that it is not possible to energise more than one X-ray tube at any one time. Safety measures must be provided to ensure against accidental activation of the wrong X-ray tube. In the case of two-tube techniques, there must be a clear indication on the control panel that two tubes are energised. **8.2** ***Indicator of which X-ray tube is energised*** Where more than one X-ray tube can be operated from a control panel, there must be a clear indication on the control panel to signify which tube is energised. In the case of an under-table tube and associated over-table tubes used in fluoroscopic apparatus, there should be a visual indicator at or near the fluoroscopy controls to signify which tube is selected.
9. Exposure switch	**9.1** ***Exposure switch*** The exposure switch must have a circuit closing contact such that continuous pressure must be applied to maintain the exposure and that it must be possible to interrupt the exposure at any time. **9.2** ***Prevention from accidental operation*** The exposure switch must be designed so that it cannot be accidentally operated. In the case of a foot exposure switch, this may be achieved by shrouding the foot switch or by the provision of an isolation switch at the operator's console. **9.3** ***Radiographic exposure*** It must not be possible to initiate another radiographic exposure without first releasing the switch. **9.4** ***Mobile apparatus exposure*** For mobile apparatus, control of the X-ray unit must be possible from a distance of not less than 2 metres from the focal spot or X-ray beam.
10. Protection of the Operator at the table side	**10.1** ***Protection of the operator at the table side*** For fluoroscopic apparatus with a fixed under-table X-ray tube and adjacent operator controls, an adjustable drape must be provided, and must meet the requirements below: a. have a lead equivalence of not less than 0.5 mm b. have a minimum width of 450 mm c. be designed to attach to the lower edge of the image receptor carriage d. consist of overlapping sheets, or equivalent

Test	Requirement - Fluoroscopy
	e. attach to the image receptor carriage in such a way that there is no gap between the drape and the image receptor carriage f. reach the table-top when the image receptor carriage is in its maximum vertical position g. be adjustable to protect the operator when the table is in the tilted position. Note: Apparatus used in a sterile environment may not necessarily comply with above requirements. In such instances, alternative means of operator protection, such as a ceiling-suspended shield (at least 0.5 mm lead equivalence) must be provided. **10.2** ***Shielded bucky slot cover*** For a fluoroscopic table also designed for radiography, a shielded bucky slot cover must be provided. Bucky slot cover should provide the equivalent protection of at least 0.5 mm of lead at 100 kVp.
11. Fluoroscopy units with an over-table X-ray tube	**11.1** ***Fluoroscopy units with an over-table X-ray tube*** In the case of fluoroscopic apparatus with a fixed over-table X-ray tube: a. the collimator must contain a light beam device. b. for equipment where the direct radiography mode is not disabled, the alignment of the area illuminated by the light beam collimator and the X-ray field must be coincident to within ±1% of the distance from the focus to the image receptor. c. an exposure switch for radiographic exposures must be located at the control panel. d. additional radiographic exposure switches must not be provided at the table unless shielding is provided for use by the operator.
12. Stability of X-ray tube assembly	**12.1** ***Stability of the X-ray tube assembly*** The X-ray tube assembly must remain stationary when placed in position and remain stationary during exposure unless it is intended to be moved.
13. Stability of mobile apparatus	**13.1** ***Stability of mobile apparatus*** Means must be provided on mobile apparatus to prevent movement once positioned for exposure, e.g. lockable wheels. **13.2** ***C-arm position lock*** Mobile apparatus must be effectively balanced or positively locked to remain stable when the C-arm is in any position.
14. kVp Accuracy	**14.1** ***kVp accuracy***

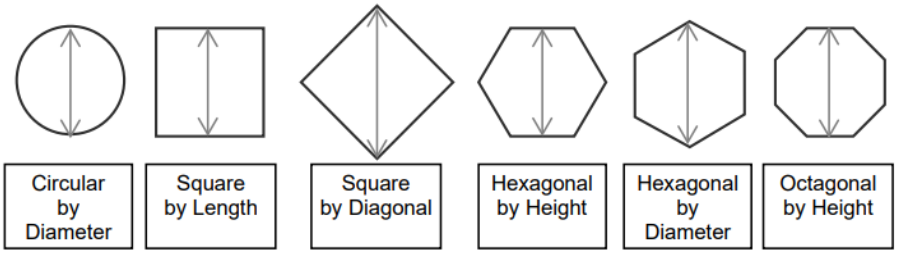
Test	Requirement - Fluoroscopy
	Whether the tube voltage (kVp) is manually selectable or automatically controlled, the measured kVp must be within ±5% or 5kV (whichever is greater) of the indicated (selected) value. For equipment with multiple X-ray tubes, the kVp accuracy must comply for all X-ray tubes across the range of available kVp settings. **Critical failure**: if ≥ ±10% or ≥ ±10 kV whichever is the greater.
15. Radiographic Timer Accuracy	**15.1** ***Radiographic timer accuracy*** The exposure timer accuracy for radiographic timer settings across a clinical range must be within: • ±10% of the indicated value for exposure times greater than or equal to 100ms • ±20% ± 1 pulse of the indicated value for exposure times less than 100 ms. **Critical failure:** ≥20 % (for times ≥ 100 ms) or ≥30 % (for times < 100 ms).
16. Radiographic Radiation Output Reproducibility and Linearity	**16.1** ***Radiographic radiation output reproducibility and linearity*** The coefficient of variation of the X-ray output of a series of 5 consecutive radiographic exposures, using the same exposure factors and taken within a time period of approximately 10 minutes, should not be greater than 0.05 for any combination of exposure factors across the clinical range. **Critical failure:** if coefficient of variation ≥ 0.1 **16.2** ***Variable mA*** Where there is a choice of mA settings, the linearity of the output of the X-ray unit with nominal X-ray tube current should comply with the following relationship between any pair of current settings taken over a range of clinically used settings for each focal spot size: $$\frac{|\ X1 - X2\ |}{X1 + X2} \leq 0.1$$ • Where *X1* is the X-ray output expressed in terms of dose to air per mAs at mA setting 1. • *X2* is the X-ray output expressed in terms of dose to air per mAs at mA setting 2. **16.3** ***Variable mAs*** Where there is a choice of mAs settings the linearity of the output of the X-ray unit should comply with the following relationship between any two mAs settings taken over a range of clinically used settings for each focal spot size: $$\frac{|\ X1 - X2\ |}{X1 + X2} \leq 0.1$$

Test	Requirement - Fluoroscopy
	Note: Above tests are not applicable for Capacitor discharge units. • Where *X1* is the X-ray output expressed in terms of dose to air per mAs at mAs setting 1. • *X2* is the X-ray output expressed in terms of dose to air per mAs at mAs setting 2. **Critical failure**: if > 0.1
17. Fluoroscopy Radiation Output Reproducibility and Linearity	**17.1** ***Fluoroscopy radiation output reproducibility and linearity*** The air kerma rate from 5 consecutive measurements at approximately 80 kVp must be within ±10% of the mean. **Critical failure:** if ≥ ±20% **17.2** ***Variable mA*** Where the mA can be varied independently of the kVp, the linearity of the output of the X-ray unit should comply with the following relationship between any two mA settings taken over a range of clinically used settings for each focal spot size: $$\frac{\mid X1 - X2 \mid}{X1 + X2} \leq 0.1$$ • Where *X1* is the X-ray output expressed in terms of dose to air per mAs at mA setting 1. • *X2* is the X-ray output expressed in terms of dose to air per mAs at mA setting 2. **Critical failure**: if > 0.1
18. Accuracy of output air kerma area product	**18.1** ***Accuracy of output air kerma area product*** Displayed air Kerma Area Product (KAP) **must** be within ±20% of the measured value. **Critical failure:** if ≥ ±35% Notes: • Measurements must be taken at a minimum of 3 clinically relevant exposure settings, involving various kVp settings, dose rates and irradiated field areas, using a patient equivalent phantom or PMMA blocks of suitable size placed on the patient table or couch. • Automatic Exposure Control (AEC) may also be used in conjunction with lead or another suitable attenuator covering the image receptor to drive up the kV and mA. • Direct reading Dose area product meter or suitable dosimeter (such as ionisation chamber) may be used to carry out measurement. Field size

<table>
<tr><th>Test</th><th>Requirement - Fluoroscopy</th></tr>
<tr><td></td><td>and backscattering factor must be taken into account where appropriate.</td></tr>
<tr><td>19. Fluoroscopic timing device</td><td>19.1 Fluoroscopic timing device
A cumulative timing device must be activated by the fluoroscopic control circuit when it is energised and must give an indication of the total screening time.
19.2 Audible signal at pre-set time
After the integrated time has reached a pre-set time not exceeding 5 minutes, a continuous audible signal must be given to enable resetting of the integrating device.</td></tr>
<tr><td>20. Radiation Beam Quality</td><td>20.1 Radiation beam quality
The permanent filtration must be such that the measured half value layers are greater than or equal to the values specified in the table below.
<table>
<tr><th>X-ray Tube Voltage (kVp)</th><th>Minimum HVL (mm Al)</th></tr>
<tr><td>50</td><td>1.8</td></tr>
<tr><td>60</td><td>2.2</td></tr>
<tr><td>70</td><td>2.5</td></tr>
<tr><td>80</td><td>2.9</td></tr>
<tr><td>90</td><td>3.2</td></tr>
<tr><td>100</td><td>3.6</td></tr>
<tr><td>110</td><td>3.9</td></tr>
<tr><td>120</td><td>4.3</td></tr>
<tr><td>130</td><td>4.7</td></tr>
<tr><td>140</td><td>5.0</td></tr>
<tr><td>150</td><td>5.4</td></tr>
</table>
Critical failure: if the filtration does not meet the above requirements.</td></tr>
<tr><td>21. Last-image-hold</td><td>21.1 Last-image-hold</td></tr>
</table>

Test	Requirement - Fluoroscopy
	Fluoroscopic apparatus must be capable of retaining the last image on the viewing monitor ('last-image-hold').
22. Focus-to-skin distance (FSD)	**22.1** ***Focus-to-skin distance (FSD)*** Fluoroscopic apparatus must be designed and constructed such that: • Fixed apparatus— if the apparatus has a patient support permanently between the X-ray tube and the patient, FSD is not less than 400 mm; and in the case of any other fixed apparatus FSD is not less than 300 mm; and in the case of special surgical applications FSD is not less than 200mm. • Mobile apparatus – FSD is not less than 200 mm. Note: Above requirement is not applicable for mini C-arm apparatus, that has a maximum X-ray tube current not exceeding 200 microamperes.
23. Beam alignment and collimation	**23.1** ***Beam alignment and collimation*** It must not be possible to operate the X-ray tube without the image receptor being properly aligned relative to the primary beam. **23.2** ***Beam centred*** The primary beam must be centred to the input surface of the image receptor and must appear as the centre of the image on the monitor. **23.3** ***Primary beam within image receptor*** The primary beam must not fall outside the image receptor (including its associated housing) under any circumstances. **23.4** ***Beam-limiting operation*** It must not be possible to manually override the beam-limiting operation to give a larger field. **23.5** ***Maximum ratio of radiation field area to imaged field area*** The beam limiting device must limit the area of the primary beam so that the maximum ratio of the radiation field area to the imaged field area is ≤ 1.15. **23.6** ***Beam collimation*** Beam-limiting devices must allow the collimation of the primary beam to the clinical area of interest. **23.7** ***Nominal field size*** The selected nominal field size must not differ from the imaged field size by more than ± 10%. Note that for some flat-panel image receptors, the selected field size refers to the diagonal measurement. **Critical failure:** if radiation area > 1.25 × image area.

Test	Requirement - Fluoroscopy
	Test method: **Exposure factors** • Automatic Exposure Rate Control (AERC) or set low kVp. **Method** Note: This example uses a CR cassette. **Other means to measure the radiation field area may be substituted.** • Set maximum SID. • Ensure collimators are fully open. • Place CR cassette as close as possible to image receptor surface. • Expose cassette under AERC for 1–2 seconds. • Record the radiation field shape and measure the dimensions (see below). Note: A magnification correction is required for the distance between the image receptor and the CR cassette. • Calculate the radiation field area (see below). • Remove the CR cassette and place a test object of known physical dimensions (ideally with markings at known spacings) as close as possible to the image receptor surface. • Expose under AERC for 1–2 seconds. • Record the shape of the imaged field. • Record the dimensions of both the image and the test object on TV monitor. Use the ratio of the nominal test object length and measured test object length from the display image and calculate the imaged field dimensions. Note: A magnification correction is required for the distance between the image receptor and the test object. • Calculate the imaged field area (see below). • Repeat measurements for a selection of nominal field sizes, including the maximum and minimum. • Repeat all the above at minimum SID. • Compare the radiation field area to the imaged field area for all selected field sizes. • Compare the imaged field dimensions to the nominal field dimensions. • Confirm that the radiation field lies within the image receptor (including its associated housing).

Test	Requirement - Fluoroscopy
	Calculating area • The dimension of the radiation field and imaged field should be measured as per the diagrams below:  • the radiation and imaged field areas should be calculated for the specific field shape using the formula below: • dimension^2 x shape-specific constant (see table below) **Field shape** / **Constant** Circular (by diameter): 0.785 Square (by length): 1.000 Square (by diagonal): 0.500 Hexagonal (by height): 0.866 Hexagonal (by diameter): 0.650 Octagonal (by height): 0.828
24. Exposure limit during fluoroscopy	**24.1** ***Exposure limit during fluoroscopy*** The incident air kerma rate during fluoroscopy must not exceed the values listed below: Mode / Maximum permissible incident air kerma rate during fluoroscopy (mGy/min) / **Critical failure:** maximum air kerma rate during fluoroscopy (mGy/min) Normal / 100 / ≥150 High Level (boost) / 150 / ≥225 Note: Refer to section 25 for further requirements which must be satisfied when in high level (boost) mode. Measurements must be made for a combination of X-ray tube potential and current settings which achieves the maximum air kerma rate, and in scatter-free conditions using the detector position as mentioned in the table below: Measurement condition / Detector position

<table>
<tr><th>Test</th><th>Requirement - Fluoroscopy</th></tr>
<tr><td></td><td>
<table>
<tr><td>Under table X-ray tube
X-ray tube permanently under the table</td><td>On the table</td></tr>
<tr><td>Over-table X-ray tube
Image receptor permanently under the table</td><td>300 mm above the table</td></tr>
<tr><td>C- or U-arm systems
X-ray tube and image receptor mechanically linked, with or without permanent patient support</td><td>300 mm from image receptor plane but not less than 400 mm from the focal spot</td></tr>
<tr><td>C-arm systems specifically for extremity use (FSD ≤ 450 mm)
X-ray tube and image receptor mechanically linked</td><td>At the minimum focus-to-skin distance</td></tr>
<tr><td>Other fluoroscopic systems
No permanent patient support</td><td>400 mm from focal spot</td></tr>
</table>
Note: Above requirement is not applicable for O-arm apparatus.
</td></tr>
<tr><td>25. High Level (Boost) during fluoroscopy (excludes DSA)</td><td>
25. High Level (Boost) during fluoroscopy (excludes DSA)
Any mode in which the maximum incident air kerma rate can exceed the values applicable to normal mode, is classified as high level (boost) mode.
25.1 Where a high level (boost) mode is activated, the control must:
a. require continuous activation by the operator for its operation
b. maintain a continuous audible signal that is readily distinguishable from that used for normal fluoroscopy, to indicate that the high level control is in use
c. only be accessed through the automatic mode of operation.
25.2 Where a high level (boost) mode is selected (other than by a “dead man” type switch), it must automatically return to the lower dose rate setting if not used within a pre-determined time after ceasing X-ray production or if power to the radiation apparatus is disconnected whilst boost mode is selected.
</td></tr>
<tr><td>26. Entrance air kerma rate at surface of image receptor</td><td>
26.1 Entrance air kerma rate at surface of image receptor during fluoroscopy
The entrance air kerma rate at the input surface of the image receptor (other than high level or boost mode) must not exceed the values indicated in the table below:
</td></tr>
</table>

<table>
<tr><th>Test</th><th>Requirement - Fluoroscopy</th></tr>
<tr><td>during fluoroscopy</td><td>
<table>
<tr><th>Field size (cm)</th><th>Entrance air kerma rate (µGy/min) under AERC</th><th>Critical failure if entrance air kerma rate (µGy/min) under AERC</th></tr>
<tr><td>11–14</td><td>≤120</td><td>>120</td></tr>
<tr><td>>14–23</td><td>≤80</td><td>>80</td></tr>
<tr><td>>23</td><td>≤60</td><td>>60</td></tr>
</table>
Measurement conditions:

The measurement conditions should be such that sufficient copper or aluminium filtration is added to the X-ray beam to obtain, on automatic brightness/dose rate systems, an X-ray tube voltage between 70kVp and 80kVp. Some systems may require use of a contrast phantom to carry out this test.
For manual systems, the radiation levels should not be exceeded for the normal clinical settings when used with average patients.
The measurements should be obtained without the grid or alternatively, by applying a traceable grid correction factor for the energy of the radiation beam being used.

</td></tr>
<tr><td>27. High-contrast resolution of the live image</td><td>
27.1 High-contrast resolution of the live image
The high-contrast resolution of the live image must not be less than the values specified in the table below.
<table>
<tr><th>Apparatus</th><th>Field Size(cm)</th><th>Resolution (lp/mm)</th></tr>
<tr><td rowspan="5">Equipment manufactured from 2015 onwards</td><td><18</td><td>1.8</td></tr>
<tr><td>18 to <26</td><td>1.6</td></tr>
<tr><td>26 to <30</td><td>1.4</td></tr>
<tr><td>30 to 36</td><td>1.2</td></tr>
<tr><td>>36</td><td>1.0</td></tr>
<tr><td rowspan="2">Equipment manufactured before 2015</td><td>≤ 25</td><td>1.2</td></tr>
<tr><td>>25</td><td>1.0</td></tr>
</table>
Critical failure: if < 0.8 lp/mm for field sizes > 25 cm
</td></tr>
</table>

<table>
<tr><th>Test</th><th>Requirement - Fluoroscopy</th></tr>
<tr><td></td><td>if < 1.0 lp/mm for field sizes ≤ 25 cm

Note:

• Measurements should be made with clinically relevant AEC exposure settings.
• Source-to-image receptor distance (SID) should be minimum.
• High contrast resolution test object (e.g. line pair phantom) must be placed directly onto the centre of the image receptor.
• The manufacturer's instructions should be followed while using the test object.
• Exposure should be made at clinically relevant AEC exposure settings.
• The number of line pairs visible on the live image on the clinical reference monitor should be evaluated.</td></tr>
<tr><td>28. Low-contrast resolution and low-contrast threshold of the live image</td><td>28.1 Low-contrast resolution of the live image

Low-contrast resolution of the live image, as displayed on a clinical reference monitor, must not be less than the values indicated in the table below.

Low-contrast resolution

<table><tr><td>Mode</td><td>Minimum resolution</td></tr><tr><td>Normal</td><td>1.5 mm (e.g. 6 circles on Westmead test object)</td></tr><tr><td>High dose rate (boost)</td><td>1.0 mm (e.g. 7 circles on Westmead test object)</td></tr></table>
28.2 Low-contrast threshold of the live image

The low contrast threshold of the live image must not exceed 4% (e.g. minimum 10 large circles on Westmead test object).

Critical failure: if low contrast threshold >4%

28.3 Artefacts or distortion

Any clinically significant artefacts or distortion must be noted on the compliance inspection report.

Note:

• Measurements should be made using an appropriate image quality test object (e.g. Westmead test object or equivalent) and following the test object manufacturer's instructions.
• The source-to-image receptor distance (SID) should be set at normal operating distance or at 100 cm.</td></tr>
</table>

Test	Requirement - Fluoroscopy
	• The test object must be placed directly onto centre of image receptor. • The exposure should be made at clinically relevant AEC exposure settings, and the live image on the clinical reference monitor should be evaluated.
29. Radiation leakage	**29.1** ***Radiation leakage*** The X-ray tube must be enclosed in a housing in such a manner that the air kerma from leakage radiation must not exceed 1.0 mGy in any 1 hour period at a distance of 1 m from the focal spot, averaged over an area of 100cm^2. **Critical failure:** if the above requirements are not met. Note: • Collimator must be completely covered with lead of sufficient thickness to ensure that the primary beam contribution to the measurements is negligible. • Automatic Exposure Control (AEC) or set maximum kVp and maximum mA, ensuring that tube rating is not exceeded. • Position the detector at an appropriate distance from focal spot (e.g. 10–30 cm). Make a series of exposures at positions including cathode, anode and front of tube assembly. • Use inverse square law correction to calculate exposure rates at 1 m from focal spot. • Calculate time averaged leakage using manufacturer recommended continuous mA rating at the kVp used for the measurement or using tube cooling curve data.

Appendix 4: Plain Radiographic X-ray equipment

This appendix lists the radiation safety standard for Plain Radiographic X-ray equipment that is used for medical diagnostic imaging of humans, including chiropractic, and for research purposes.

This appendix is applicable to Fixed, Mobile and Capacitor discharge X-ray units used for human diagnostic imaging.

Diagnostic X-ray apparatus must comply with all of the following tests listed in Table 8.

Table 8 – Required radiation safety and performance tests for Diagnostic X-ray equipment

Test	Requirements – Plain X-ray
1. Markings on X-ray generators and tube assemblies	**1.1** ***Markings on X-ray generators and tube assemblies*** X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available by means of labels on the radiation apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. **1.2** ***X-ray generator markings*** X-ray generators must bear: • the name or trademark of the manufacturer • the model name or number • the serial number. **1.3** ***X-ray tube assembly markings*** X-ray tube assemblies must bear: • the name or trademark of the manufacturer of the X-ray tube housing and insert • the type or model number and serial number of the X-ray tube housing and insert • the position of the focal spot(s) • the relative position of the anode and cathode. Note: For dual focus X-ray tubes, a single indication of mean focal spot position is permissible.
2. Radiation warning signage	**2.1** ***Radiation warning signage*** The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words “caution” or “warning”

Test	Requirements – Plain X-ray
	• words to the general form of "X-rays produced when energised" The symbol and lettering must be black on a yellow background. A radiation warning sign, displaying the words 'Caution X-rays in use – authorised entry only' (or equivalent) must be displayed at each entry point to the room.
3. Stability of X-ray tube assembly	**3.1** ***Stability of X-ray tube assembly*** The X-ray tube assembly must be supported and remain stationary when placed in position for radiography.
4. Stability of mobile apparatus	**4.1** ***Stability of mobile apparatus*** Means must be provided on mobile apparatus to prevent movement once positioned for radiography.
5. Control of multiple X-ray tubes	**5.1** ***Control of multiple X-ray tubes*** Where more than one X-ray tube can be operated from a control panel, there must be a clear indication on the control panel to indicate which tube is selected. **5.2** It must not be possible to energise more than one X-ray tube at the same time, except for two-tube techniques.
6. Mains Indicator	**6.1** ***Mains indicator*** A mains indicator must be clearly identified. "ON" and "OFF" positions must be marked by a suitable indicator light or other unambiguous means.
7. Indicators of operation	**7.1** ***Indicators of operation*** The tube voltage, tube current and exposure time, or current-time product, must be displayed by an analogue or digital indicator, even if these factors are under automatic control. Should one factor be permanently fixed, its value must be indicated on the control panel. **7.2** There must be an obvious visual and audible indicator when radiation is being emitted.
8. Exposure Switch	**8.1** ***Exposure switch*** The exposure switch must have a circuit closing contact such that: • continuous pressure must be applied to maintain the exposure • it must not be possible to make repeat exposures without first releasing the switch • it must be possible to interrupt the exposure at any stage and, in the case of programmed exposures, at any stage of the programme.

Test	Requirements – Plain X-ray
	8.2 In the case of a foot exposure switch, the exposure switch must be designed so that it cannot be accidentally operated. This may be achieved by shrouding the foot switch or by the provision of an isolation switch at the operator's console. **8.3** For mobile apparatus, control of the X-ray unit must be possible from a distance of not less than 2 metres from the focal spot or X-ray beam.
9. Accuracy of kilovoltage controls	**9.1** ***Accuracy of kilovoltage controls*** The measured kVp across the clinical range must be within ± 5kV or ± 5% of the indicated value, whichever is greater. **Critical failure:** if the measured value differs from the set value by ≥±10%. **9.2** The coefficient of variation of at least five consecutive measurements at the same kVp setting must not exceed 0.02.
10. Type of timer	**10.1** ***Type of timer*** The timer must be electronic. **10.2** It must not be possible to make exposures when the timer is set to the zero setting.
11. Timer Accuracy	**11.1** **Timer accuracy** The exposure timer accuracy for timer settings across the clinical range must be within: i. ±10% of the indicated value for exposure times greater than or equal to 0.1 seconds* ii. ±20% or ± 1 pulse of the indicated value for exposure times less than 0.1 seconds* *Any measuring equipment error must be taken into account in determining whether compliance criteria are satisfied. **Critical failure:** if the measured value differs from the indicated value by ≥±20% of the indicated value for indicated values ≥100ms or ≥±30% for indicated values <100ms. **11.2** The coefficient of variation of at least 5 consecutive measurements at the same timer setting must not exceed 0.05.
12. Radiation output (air kerma) reproducibility	**12.1** ***Radiation output (air kerma) reproducibility*** The apparatus must produce a consistent radiation output (air kerma), so that the coefficient of variation of at least 5 consecutive measurements, taken at the same control settings, does not exceed 0.05. **Critical failure:** if the coefficient of variation ≥0.1

Test	Requirements – Plain X-ray
13. Radiation output (air kerma) linearity	**13.1** ***Radiation output (air kerma) linearity*** **Variable mA** Where there is a choice of mA settings, the linearity of the output of the X-ray unit with nominal X-ray tube current should comply with the following relationship between any pair of current settings taken over a range of clinically used settings for each focal spot size: $$\frac{|\ X1 - X2\ |}{X1 + X2} \leq 0.1$$ • Where *X1* is the X-ray output expressed in terms of dose to air per mAs at mA setting 1. • *X2* is the X-ray output expressed in terms of dose to air per mAs at mA setting 2. **13.2** **Variable mAs** Where there is a choice of mAs settings the linearity of the output of the X-ray unit should comply with the following relationship between any two mAs settings taken over a range of clinically used settings for each focal spot size: $$\frac{|\ X1 - X2\ |}{X1 + X2} \leq 0.1$$ *Note: Above tests are not applicable for Capacitor discharge units.* • Where *X1* is the X-ray output expressed in terms of dose to air per mAs at mAs setting 1. • *X2* is the X-ray output expressed in terms of dose to air per mAs at mAs setting 2. **Critical failure**: if > 0.1
14. Automatic exposure control	**14.1** ***Automatic exposure control*** There must be a visual indication on the control panel when the automatic exposure control (AEC) is selected, and which chambers are selected. **14.2** ***Backup timer*** Backup timer: when the AEC is utilised, the exposure must terminate after no more than 6 seconds or 600 mAs, whichever occurs first. **Critical failure:** if this requirement is not met. **14.3** ***Manual reset*** In the case of an exposure that terminates under AEC backup timer there must be a visible or audible signal which indicates that termination has occurred; and manual resetting of the AEC must be required before further AEC exposures can be made.

<table>
<tr><th>Test</th><th>Requirements – Plain X-ray</th></tr>
<tr><td></td><td>
14.4 Exposure Index (EI)

The AEC device must control exposures such that the displayed exposure index (EI) does not vary by more than 20% from the mean measured EI when kVp and patient thickness are varied as indicated below. The Mean Pixel Value (MPV) may be used instead of Exposure Index for this test.

Note: If the detector has a non-linear relationship between detector air kerma (DAK) and EI (or MPV), the EI (or MPV) must be linearised with DAK.

<table>
<tr><th>Tube kVp[a]</th><th>Perspex phantom thickness, cm</th></tr>
<tr><td>60</td><td>10 and 15</td></tr>
<tr><td>80</td><td>15 and 20</td></tr>
<tr><td>100</td><td>15 and 20</td></tr>
<tr><td>120</td><td>15 and 25</td></tr>
<tr><td>120 [b]</td><td>10 and 15</td></tr>
<tr><td colspan="2">[a] If any of these values are not available use the nearest selectable value.

[b] For tests on dedicated chest units. Not applicable to other radiographic units.</td></tr>
</table>
14.5 Reproducibility

• Using each AEC detector (chamber) separately, the air kerma from 5 consecutive exposures at 80 kVp with a patient-equivalent phantom, must be within ±10% of the mean for each AEC detector; and

• the air kerma from irradiations to the lateral detectors must be within ±5% of the mean for the lateral chambers.

Note: For this test, phantoms constructed of 2 mm of copper or 15 cm of acrylic are suitable substitutes for a patient equivalent phantom.
</td></tr>
<tr><td>15. Minimum Focus to skin distance</td><td>
15.1 Minimum focus to skin distance (FSD)

The minimum distance between the focal spot and skin must not be less than 200mm, and means must be provided to prevent irradiation using focal spot to skin distances of less than 200 mm.
</td></tr>
<tr><td>16. Collimator /Light beam alignment</td><td>
16.1 Collimator

The X-ray tube must be fitted with a collimator that is continuously adjustable, has a light beam, has the centre of the illuminated area indicated, and can be rotated around the centre of the X-ray beam.

16.2 Light beam alignment

The area illuminated by the light beam collimator must be effectively coincident with the irradiated area. The total misalignment of any edge
</td></tr>
</table>

<table>
<tr><th>Test</th><th>Requirements – Plain X-ray</th></tr>
<tr><td></td><td>of the light field with the respective edge of the irradiated field must not exceed 1% of the source-to-image distance (SID).

Critical failure: if misalignment >3% of the SID.

16.3 Illuminance

The illuminance of the light beam must be not less than 100 lux above ambient at a distance of 1 metre from the focal spot.

Critical failure: if <50 lux above ambient.</td></tr>
<tr><td>17. Tube housing leakage</td><td>17.1 Tube housing leakage

The air kerma from leakage radiation from a tube assembly must not exceed 1.0 mGy in 1 hour at a distance of 1 m from the focal spot, averaged over an area of not more than 100 cm^2.

Critical failure: if this requirement is not met.</td></tr>
<tr><td>18. Capacitor discharge apparatus</td><td>18.1 Capacitor discharge apparatus

Leakage radiation from the X-ray tube assembly when the exposure device is not activated must not exceed 0.2 mGy in one hour at 50 mm from any accessible surface of the X-ray tube assembly with the collimator fully open and with the maximum voltage on the capacitors.

18.2 Capacitor discharge apparatus must be fitted with electrically interlocked shutters to limit emission of radiation before the exposure, after the termination of the exposure and during discharging of the capacitors when patient exposure is not required.

18.3 Means must be provided to prevent the initiation of exposure during the charging of the capacitors.

18.4 Capacitor discharge apparatus must be provided with an automatic top-up facility that operates when the kilovoltage drops below the pre-set value by more than 3%.

18.5 A control switch must be provided to allow manual discharge of the capacitors when the apparatus is connected to the mains supply and when patient exposure is not required.

18.6 Capacitor discharge apparatus must be limited to a maximum of 30 mAs. The lowest indicated terminating voltage must not be less than 45 kV.</td></tr>
<tr><td>19. Beam Quality Filtration</td><td>19.1 Beam quality filtration

The permanent filtration must be such that the measured half value layers are greater than or equal to the values specified in the table below for a particular kVp:

<table><tr><td>X-ray tube voltage (kVp)</td><td>Minimum HVL (mm of Al)</td></tr></table></td></tr>
</table>

Test	Requirements – Plain X-ray	
	50	1.8
	60	2.2
	70	2.5
	80	2.9
	90	3.2
	100	3.6
	110	3.9
	120	4.3
	130	4.7
	140	5.0
	150	5.4
	Critical failure: if equipment does not meet the above requirements.	
20. Digital detectors	**20.1** ***Digital detectors*** Exposure Index: The digital detector must provide a consistent Exposure Index (EI) such that the coefficient of variation of at least 5 consecutive measurements, taken at the same control settings, does not exceed 0.05.	

Glossary

AEC means automatic exposure control. This is also known as the Automatic Brightness Control (ABC) for image intensifiers.

AERC means automatic exposure rate control. This is also known as the Automatic Brightness Control (ABC) for image intensifiers.

Coefficient of Variation (CoV) means the ratio of the sample standard deviation to the mean value.

Critical failure means non-compliance with a requirement which has been identified as critical for the safety and/or performance of the radiation apparatus and which may have an unacceptable impact on radiation dose to the patient, operator or others in the vicinity, including the potential for non-diagnostic quality imaging.

DSA means Digital Subtraction Angiography.

Fluoroscopic apparatus means radiation apparatus that emits ionising radiation used for the purpose of fluoroscopy or radioscopy.

Fluoroscopy means the technique for obtaining, continuously or periodically, a sequence of X-ray patterns and presenting them simultaneously and continuously as visible images. For the purpose of tests related to air kerma or image quality assessment, fluoroscopy excludes image acquisition.

Focal spot means the area of the target from which X-rays are emitted.

Half-value layer (HVL) means the thickness of a specified material that reduces the air kerma of a given X-ray beam to half its original value.

High dose rate fluoroscopic apparatus includes apparatus used for cardiac catheterisation, angiography and interventional radiology.

High level or boost mode means a mode where the air kerma entrance rate may exceed 100 mGy in one minute.

Image acquisition means the acquisition of intermittent image sequences where the image presentation is not primarily intended for simultaneous and immediate observation and the acquired images are automatically captured and stored for later clinical or diagnostic reference.

Image receptor means an image intensifier or flat panel digital detector.

KAP means air kerma-area product i.e. air kerma multiplied by radiation area. The KAP value may be displayed on the operator's console, or on a separate kerma-area product meter. The units of KAP are typically $Gy.cm^2$, or similar e.g. $mGy.cm^2$, $cGy.cm^2$, $\mu Gy.cm^2$. It is important to make a note of the unit when conducting a patient dosimetry audit.

KERMA means kinetic energy released per unit mass; it is a measure of the sum of the initial kinetic energies of all charged particles liberated by uncharged radiation, such as photons and neutrons, per unit mass of material. Unit: J/kg or gray (Gy).

Loading means the act of supplying electrical energy to the anode of an X-ray tube.

Permanent filtration means inherent filtration and other filtration not removable without the use of tools.

Preparation mode means that electrical current is induced across the filament in the cathode and that a further activation of the switch will cause X-rays to be emitted. Also known as the "Ready State".

Radiation leakage means ionising radiation transmitted through the protective shielding of a radiation source other than the primary beam, usually expressed in milligray (mGy) or microgray (µGy).

Radiation quality refers to the penetrating ability of a beam of X-rays. The quality of an X-ray beam is described by the HVL of the beam and is measured in terms of mm of aluminium in the diagnostic range.

Responsible Person means[5], in relation to any radiation source, prescribed radiation facility or premises on which radiation sources are stored or used means the legal person:

(a) having overall management responsibility including responsibility for the security and maintenance of the radiation source, facility or premises

(b) having overall control over who may use the radiation source, facility or premises

(c) in whose name the radiation source, facility or premises would be registered if this is required.

SID means source-to-image receptor distance.

[5] Responsible Person as defined in the ARPANSA *Code for Radiation Protection in Planned Exposure Situations* (RPS C-1)

References

ACPSEM Position Paper, Recommendations for a digital mammography quality assurance program V4.0.

ACPSEM, Recommendations for a technical quality control program for diagnostic X-ray equipment (2005).

American Association of Physicists in Medicine, Performance evaluation of computed tomography systems, The report of AAPM Task Group 233, AAPM Rep. 233, New York, 2019.

American Association of Physicists in Medicine Report 74, Quality Control in Diagnostic Radiology (2002).

Australian Radiation Protection and Nuclear Safety Agency, Code for Radiation Protection in Medical Exposure (RPS C-5, 2019).

Australian Radiation Protection and Nuclear Safety Agency, Safety Guide Radiation Protection in Diagnostic and Interventional Radiology (RPS 14.1, 2008).

Department of Health and Human Services, Tasmania. 2011. CERTIFICATE OF COMPLIANCE: Standard for Radiation Apparatus - X-ray Medical Diagnostic (Fixed Radioscopy).

Department of Health and Human Services, Tasmania. 2013. CERTIFICATE OF COMPLIANCE: Standard for Radiation Apparatus- X-ray Medical Diagnostic (Mobile Radioscopy).

Department of Health, Victoria. 2007. Radiation Safety Standard: Fluoroscopic X-ray equipment.

Environment Protection Authority, NSW. 2020. Radiation Standard 6 - Compliance requirements for ionising radiation apparatus used in diagnostic imaging—Fluoroscopy.

Environment Protection Authority of South Australia. 2016. Test Protocol for Medical and Veterinary Fluoroscopy X-ray Apparatus 2016.

European Commission, Radiation Protection No. 162, Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, 2012.

IAEA Human Health Series 19, Quality Assurance Programme for Computed Tomography: Diagnostic and Therapy Applications, (2012).

IEC 60601-2-44 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography.

IEC 60601-2-43 Medical electrical equipment Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures.

IEC 60601-2-45 Medical electrical equipment Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices.

IEC 61223-3-2:2007 Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment.

IEC 61223-3-5:2019 Evaluation and Routine Testing in Medical Imaging Departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-Ray equipment.

Ministry of Health, New Zealand. 2018. Code of Practice for Diagnostic and Interventional Radiology: ORS C1. Wellington: Ministry of Health.

QLD Government. Radiation safety standard. Standard for ionising radiation apparatus—medical imaging (2021).

Radiological Council of Western Australia. 2018. Diagnostic X-ray equipment compliance testing - Digital Flat Panel Fluoroscopic Equipment.

The Royal Australian and New Zealand College of Radiologists, Guidelines for Quality Control Testing for Digital (CR & DR) Mammography (2017).

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