Queensland Government

Radiation Safety Act 1999

RADIATION SAFETY STANDARD

Standard for ionising radiation apparatus–medical imaging (2021)

Standard for ionising radiation apparatus–medical imaging (2021)

Preface

This radiation safety standard sets out the minimum performance expectations for an ionising radiation apparatus used for medical imaging.

Persons who hold an appropriate Accreditation Certificate, issued under the *Radiation Safety Act 1999*, must be engaged from time to time to assess whether or not an apparatus complies, or does not comply, with this radiation safety standard. Compliance with all of the tests in the standard means that the apparatus may continue to be used. Failure of any test in the standard means that the apparatus must not be used.

Notwithstanding the above, a possession licensee has an on-going obligation to take reasonable steps to ensure that the radiation apparatus continues to comply with the radiation safety standard at all times whenever it is used to carry out a practice.

These requirements are made to ensure that ionising radiation apparatus used for medical imaging in Queensland continue to meet a minimum standard of radiation safety.

I, Yvette D'Ath MP, Minister for Health and Ambulance Services and Leader of the House, pursuant to section 16(1) of the *Radiation Safety Act 1999*, hereby make the radiation safety standard *Standard for ionising radiation apparatus–medical imaging (2021)*, for the purposes of the Act.

Yvette D'Ath MP
Minister for Health and Ambulance Services
and Leader of the House

13 / 08 / 2021

Section 1 – General

1.1 Scope

This radiation safety standard sets out the minimum performance expectations for ionising radiation apparatus used for medical imaging, including veterinary medical imaging.

For clarity, this standard includes radiation therapy treatment planning systems, but excludes radiation therapy treatment delivery systems.

1.2 Expiry

This radiation safety standard expires on 31 August 2031.

1.3 Definitions

For the purpose of these tests, the following definitions apply:

'*ACR*' means American College of Radiology.

'*baseline value*' means the reference value provided by the manufacturer. In the absence of manufacturer specifications, the value measured at acceptance testing or, if this is absent, the value derived at the first compliance test, may be used.

'*computed tomography*' means a tomographic method of imaging an object by which –

(i) the relative densities of elements of the object and their spatial distribution are calculated using the attenuation coefficients of radiation incident on the object, measured at an array of locations with the incident radiation at corresponding different positions; and

(ii) mathematical algorithms are used to construct an image of the object.

Further, computed tomography means X-ray computed tomography of any type, including, for example, cone beam computed tomography.

'*coefficient of variation*' means the standard deviation divided by the mean of a set of numbers, that is:
coefficient of variation = (standard deviation / mean)

'*CTDI*' means the computed tomography dose index.

'*CT number*' (computed tomography number) means the number used to represent the mean X-ray attenuation associated with each elemental area of the computed tomography image. The CT number is normally expressed in Hounsfield units.

'*durable*', '*durably*', when describing the acceptability of a label or a marking, means made of a material and marked in a way that can withstand the long-term effects of exposure to the environment in which the radiation apparatus is used.

'*focal spot to image receptor distance*' means the distance from the focal spot to the point at which the reference axis intersects with the image receptor plane.

'*gantry*', as it relates to a computed tomography radiation apparatus, means the protective cover usually in the shape of a toroid which encloses the X-ray source(s) and imaging detector(s).

'*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 reception area*' means the active surface of the image receptor at the time an X-ray pattern is received.

'*image receptor plane*' means the plane containing the greatest dimensions of the image reception area.

'*indicated values*' means values displayed by the X-ray system following an X-ray exposure.

'*intra-oral dental imaging*' means imaging of the dento-maxillofacial region with radiation apparatus (including hand-held dental diagnostic radiation apparatus) intended for use with intra-oral image receptors.

'*irradiation time*' means the duration of irradiation:

(i) for single phase units, the irradiation time is determined by counting the total number of pulses in the radiation waveform and multiplying by a factor of 0.02 if half wave rectified, or a factor of 0.01 if full wave rectified.

(ii) for other units, the irradiation time is determined from the time that the kilovoltage has risen the first time to a value above 65%, but not higher than 85% of the peak kilovoltage value, until the time at which it finally drops below that same value.

'*kVp*' (X-ray tube voltage) means the potential difference, applied to an X-ray tube between the anode and the cathode, which is expressed by its peak value in kilovolts (kVp).

'*loading*' means the act of supplying electrical energy to the anode of an X-ray tube.

'*mammography*' means imaging of the breast, including breast tomosynthesis and other imaging methods.

'*mA*' (X-ray tube current) means the electric current applied to the filament producing the electron beam incident on the target of an X-ray tube, which is expressed by its mean value in milliamperes (mA).

'*mAs*' (current time product) means the amount of X-ray tube current applied over a particular time, which is expressed by multiplying the mean X-ray tube current value by the seconds (mAs).

'*mean optical density*' means the average of the film optical densities for phototimed images of 2, 4 and 6 centimetres of Polymethylmethacrylate (thickness) using clinically relevant kVp and target/filter combinations.

'*medical imaging*' means a practice in which images of parts of a body or internal organs are produced, whether by direct or computer assisted means, to assist with the clinical diagnosis or treatment of a disease or condition, including radiotherapy treatment planning, or for research purposes.

'*optical density*' means the common logarithm of the ratio of the amount of light striking one side of the film compared with the amount of light that passes through the film.

'*radiation leakage*' means ionising radiation which has passed through the protective shielding around a radiation generator as well as that which, for some types of X-ray generators, has passed through the radiation aperture before and after loading.

'*radioscopy*' means the technique for obtaining, continuously or periodically, a sequence of X-ray patterns and presenting them simultaneously and continuously as visible images.

'*SDNR*' means signal difference to noise ratio.

'$SDNR_{accept}$' means manufacturer specific values of signal difference to noise ratio for mammography radiation apparatus as approved from time to time by the chief executive.

'*set values*' means settings selected by the system operator prior to an X-ray exposure.

'*standard bite-wing settings*' means the most common settings used to obtain bite-wing images when using the radiation apparatus.

'*total permanent filtration*' means inherent filtration and other filtration not removable without the use of tools.

'*uniform test device*' means the manufacturer specified phantom used to compare measured performance values (e.g. water phantom).

Section 2 – Requirements

The following table sets out the minimum performance expectations for all ionising radiation apparatus the subject of this standard.

Note 1: This section contains a single suite of tests which apply to all radiation apparatus. Additional tests as they relate to specific modalities are also provided.

Note 2: The compliance tests are to be performed using clinically relevant mode parameters (i.e. the fields which are intended to be used by an operator).

Note 3: If a radiation apparatus is capable of multiple modalities (e.g. plain diagnostic imaging and computed tomography), the prescribed period within which an assessment of the radiation apparatus must be made is the lesser of the prescribed periods.

Note 4: If a radiation apparatus is capable of multiple modalities, the tests should be applied to the relevant modality, where applicable.

Test	Compliance test	Criteria for passing the test
TESTS FOR ALL RADIATION APPARATUS, UNLESS OTHERWISE SPECIFIED		
1	Reproducibility	The coefficient of variation of 5 consecutive radiation output measurements, at clinically relevant loading factors, must not exceed 0.05. This test does not apply to radiation apparatus designed to perform mammography.
2	Linearity	The following conditions must be met using a kVp value of clinically appropriate kVp and, if the equipment provides for such adjustments to be made, at least 4 pairs of mA (or mAs) stations including the lowest and the highest available. If clinically selectable, the test must be performed for each focal spot size. $\frac{\left\lvert \frac{K_1}{Q_1} - \frac{K_2}{Q_2} \right\rvert}{\frac{K_1}{Q_1} + \frac{K_2}{Q_2}} \leq 0.1$ for values of Q_1 and Q_2 where $0.5 \leq \frac{Q_2}{Q_1} \leq 2$ and/or $\frac{\left\lvert \frac{K_1}{I_1 t_1} - \frac{K_2}{I_2 t_2} \right\rvert}{\frac{K_1}{I_1 t_1} + \frac{K_2}{I_2 t_2}} \leq 0.1$ for values of $I_1 t_1$ and $I_2 t_2$ where $0.5 \leq \frac{I_2 t_2}{I_1 t_1} \leq 2$ Where: K_1 and K_2 are the measured values of air kerma Q_1 and Q_2 are the indicated current time products I_1 and I_2 are the indicated X-ray tube currents t_1 and t_2 and are the indicated irradiation times [note 3] Note 1: This test does not apply to capacitor discharge units. Note 2: This test only applies to apparatus with clinically accessible manual imaging modes.

<table>
<tr><th>Test</th><th>Compliance test</th><th>Criteria for passing the test</th></tr>
<tr><td></td><td></td><td>Note 3: In cases where the actual set values or the nominal values of mAs or irradiation time are not available, exposures must vary in a manner consistent with the markings on the control panel.</td></tr>
<tr><td>3</td><td>kVp accuracy</td><td>The measured kVp must be within ± 8% of the indicated value.

This test does not apply to radiation apparatus used to carry out computed tomography, mammography or intra-oral dental imaging.

Note 1: The increment or decrement of the X-ray tube voltage between any two indicated settings must be within 50% and 150% of the indicated change.
Note 2: The test must be performed for each focal spot size starting at 50 kVp and increasing in 10 kVp steps to 120 kVp or 10 kVp below the maximum selectable value whichever is the lesser.
Note 3: Values above 120 kVp must be tested where these values are used clinically.
Note 4: Where the equipment is designated for a specific clinical application an alternative range of kVp settings consistent with the clinical application may be used for testing. In this case, the kVp range tested must be noted in the Assessment Report.
Note 5: This test only applies to apparatus with clinically accessible manual imaging modes.</td></tr>
<tr><td>4</td><td>Timer accuracy</td><td>The measured irradiation time must be within:
(a) ± 10% of the indicated value for irradiation times 100 milliseconds or greater; and
(b) ± 20% of the indicated value for irradiation times less than 100 milliseconds.

This test does not apply to radiation apparatus used to carry out computed tomography, mammography, or intra-oral dental imaging.

Note 1: Measurements should be performed at approximately 70 kVp and 100 mA using at least 5 irradiation time settings.
Note 2: For medium or high frequency units, the time settings must include 10 milliseconds (if available) and for all other units, 50 milliseconds (if available).
Note 3: This test only applies to apparatus with clinically accessible manual imaging modes.</td></tr>
<tr><td>5</td><td>Beam quality – half value layer</td><td>For apparatus used for plain diagnostic imaging or for radioscopy, the total permanent filtration must be such that the measured first half-value layer (HVL) is not less than the value shown in the following table:
<table>
<tr><th>X-ray tube voltage (kVp)</th><th>Minimum permissible 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></td></tr>
</table>

Test	Compliance test	Criteria for passing the test
		Note 1: Where operator-selectable additional filters are used, determination of the HVL must be carried out using minimum filtration. Note 2: Only one kVp setting needs to be tested. Note 3: This test does not apply to radiation apparatus designed to perform only intra-oral dental imaging or mammography.
6	Radiation leakage	The radiation leakage, measured at a distance of 1 metre from the focal spot, must not exceed 1 mGy in one hour with the X-ray tube operating at the maximum rated voltage and the maximum rated continuous current. Note: This test does not apply to radiation apparatus designed to perform only intra-oral dental imaging, computed tomography or mammography.
7	Focus-to-skin distance	Means must be provided to ensure that the minimum focus to skin distance is not able to be less than: (a) 150 mm for radiation apparatus capable of dental panoramic tomography; or (b) 200 mm for all other apparatus, excluding those used to carry out radioscopy or computed tomography. Note: Separation may be achieved by physical restriction or through system design and positioning of the patient in accordance with instructions for use.
8	X-ray tube housing stability	Unless it is intended to move, the X-ray tube housing must remain stationary during loading. Specifically: (a) drift or oscillation must stop within 1 second after the release of the tube head; and (b) any drift must be no greater than 5 cm. For hand-held dental radiation apparatus, this test is to be carried out when the apparatus is affixed to the tripod accessory or any other means used clinically to achieve stability when in clinical use.
9	Exposure switch	The exposure switch must be arranged so that the radiation apparatus can be operated from either: (a) a distance of at least 2 metres from the X-ray tube; or (b) from behind a protective barrier. Note 1: This test does not apply to radiation apparatus capable of radioscopy if it can be shown that the air kerma rate will not exceed 10 μGy/min at the operator's hand/foot position. Note 2: The backscatter shield attached to a hand-held dental radiation apparatus may be considered to be the protective barrier.
10	Power supply indication	The power supply indicator on the control panel must be visible and must clearly indicate when the main switch is in the 'on' position and the control panel is energised. Note: The supply indicator and the load indicator must be clearly labelled or otherwise easily distinguishable from each other.
11	Loading indication	Each loading must: (a) be initiated and maintained by means of a control requiring continuous actuation by the operator; and (b) be indicated by a visible and audible signal; and

Test	Compliance test	Criteria for passing the test
		(c) be able to be terminated by the operator at any time before its intended completion, except during serial radiography or for single loadings with a loading time of 0.5 seconds or less. The audible signal may indicate either the duration or the instant of termination of loading. Note: This test does not apply to radiation apparatus designed to perform only computed tomography.
12	Indication if more than one X-ray tube	If there is more than one X-ray tube incorporated in the apparatus, the selected tube must be clearly indicated.
13	Focal spot marking	The position of the focal spot must be clearly and visibly indicated. Note: This test does not apply to radiation apparatus designed to perform only computed tomography.
14	Light field intensity	If a light beam diaphragm is fitted to the radiation apparatus, the illuminance of the light field indicator must not be less than 100 lux at 1 metre from the focal spot of the X-ray tube. Note: For radiation apparatus designed to perform mammography, the illuminance of the light beam indicator is to be measured at the level of the breast support at the maximum achievable distance.
15	X-ray / light field alignment	If a light beam diaphragm is fitted to the radiation apparatus: (a) the centre of the illuminated area must be indicated; and (b) the extent of misalignment between any edge of the light field with the respective edge of the irradiated field must not exceed 1% of the focus to image receptor distance. Note: This test does not apply to radiation apparatus designed to perform only mammography.
16	X-ray field / image receptor	For systems with fixed or automatic alignment of the X-ray tube assembly and the image receptor assembly, in modes of operation where a light field indicator is not fitted or can not be used: (a) the X-ray beam must not exceed the image receptor dimensions by more than 1% of the focal spot to image receptor distance; and (b) for spot-film imaging, the boundaries of adjacent segmental images must not overlap. Note 1: A representative sample of the clinically used combinations of focal spot to image receptor distance and image receptors must be tested. Note 2: This test does not apply to radiation apparatus designed to perform only radioscopy or computed tomography.
17	Radiation warning label	A durable radiation warning label containing the following information must be clearly visible and conspicuous at the control panel: • radiation warning symbol (trefoil) • the words to the effect of 'Warning - X-rays produced when energised' The symbol and lettering must be black on a yellow background. The word 'caution' is acceptable in place of the word 'warning'.

Test	Compliance test	Criteria for passing the test
18	Informative label	The radiation apparatus must be durably labelled with the following information: *X-ray generator or system label:* • the name or trademark of the manufacturer • the model name or number • the serial number
ADDITIONAL TESTS FOR APPARATUS WITH AUTOMATIC EXPOSURE CONTROL DEVICES		
19	Reproducibility	For systems with automatic exposure control devices: (a) using the centre detector, the air kerma from 5 consecutive loadings at 80 kVp with a patient equivalent phantom must be within ± 10% of the mean; and (b) the air kerma from irradiations to the lateral detectors must be within ± 10% of each other. This test does not apply to radiation apparatus designed to perform mammography. Note: For this test, a phantom constructed of 2 mm of copper or 15 cm of polymethylmethacrylate (thickness) is a suitable substitute for a patient equivalent phantom.
20	kVp compensation	For systems using a film-screen image receptor, the optical density of the images of a patient equivalent phantom using 60, 80, 100 and 120 kVp must not differ by more than 0.20 from the mean optical density. The mean optical density must be in the range 0.5 to 2.0. This test does not apply to radiation apparatus designed to perform mammography. Note 1: Where the equipment is designated for a specific clinical application an alternative range of kVp settings consistent with the clinical application must be used for testing. Note 2: This test does not apply to systems exclusively utilising a digital image receptor.
21	Thickness compensation	For systems using a film-screen image receptor, the optical density of four pairs of exposures made at the following parameters must not differ by more than 0.2 from the other value in the pair: (a) 60 kVp with 10 and 15 cm thick polymethylmethacrylate phantoms; and (b) 80 kVp with 15 and 20 cm thick polymethylmethacrylate phantoms; and (c) 100 kVp with 15 and 20 cm thick polymethylmethacrylate phantoms; and (d) 120 kVp with 10 and 15 cm thick polymethylmethacrylate phantoms. Note 1: This test does not apply to radiation apparatus designed to perform mammography. Note 2: This test does not apply to systems exclusively utilising a digital image receptor.
22	Minimum response time	For automatic exposure control systems, the minimum response time to radiation exposure must not exceed 10 milliseconds, except for single phase systems where it must not exceed 20 milliseconds.
23	Selection indication	There must be a visible indication on the control panel when the automatic exposure control function is selected.

<table>
<tr><th>Test</th><th>Compliance test</th><th>Criteria for passing the test</th></tr>
<tr><td>24</td><td>Indication of detector selected</td><td>There must be a visible indication of:
(a) the image receptor selected; and
(b) the automatic exposure control detector that is active.

The automatic exposure control must only be able to be operated if the image receptor selected is equipped with an automatic exposure control detector.</td></tr>
<tr><td>25</td><td>Backup timer / security cut-out operation</td><td>For apparatus other than apparatus designed to perform mammography, an exposure must terminate via a fail-safe timer:
(a) when any loading is more than 60 kJ; or
(b) after no more than 600 mAs.

For apparatus designed to perform mammography, an exposure must terminate:
(a) by a security cut-out mechanism within 50 ms or within 10 mAs; or
(b) by a back-up timer at ≤ 500 mAs.</td></tr>
<tr><td>26</td><td>Backup timer / security cut-out indication</td><td>A visible indication at the control panel must be provided to indicate whenever a loading has been terminated by a timer or security cut-out mechanism.</td></tr>
<tr><td>27</td><td>Backup timer / security cut-out manual reset</td><td>When an exposure has been stopped by a timer/security cut-out mechanism it must not be possible to initiate another exposure without first operating a manual reset.</td></tr>
<tr><td>28</td><td>Preset exposure limit indication</td><td>A visible or audible signal must be provided to indicate whenever a loading has been terminated by a preset exposure limit.</td></tr>
<tr><td colspan="3">ADDITIONAL TESTS FOR APPARATUS CAPABLE OF RADIOSCOPY</td></tr>
<tr><td>29</td><td>Incident air kerma rate</td><td>The maximum incident air kerma rate must not exceed the following values when measured in scatter-free conditions using the detector position specified in the table below.

<u>Mode</u>
Normal 100 mGy.min^{-1}
High Level (boost) 176 mGy.min^{-1}

Note: Any mode in which the maximum incident air kerma rate can exceed the values application to normal mode is classified as high level (boost) mode.

<u>Conditions for measurement of incident air kerma rate</u>
<table>
<tr><th>Condition</th><th>Detector position</th></tr>
<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-arm 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 (source to image distance ≤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>At the patient entrance reference point (as defined by the manufacturer)</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Test</th><th>Compliance test</th><th>Criteria for passing the test</th></tr>
<tr><td>30</td><td>Typical air kerma rates</td><td>For radioscopy systems capable of operation in automatic dose control mode, the air kerma rate, other than in high level or boost mode, must not exceed 50 $mGy.min^{-1}$ when measured under the test conditions specified in the table below.

Conditions for measurement of typical air kerma rate
<table><tr><th>System Configuration</th><th>Dosemeter and System Positions</th></tr><tr><td>Under-table X-ray tube
When a patient support is permanently between the X-ray tube assembly and the position of the patient</td><td>Dosemeter:
10 mm from the patient support on the patient side of the support

System:
Image receptor 300 mm above patient support</td></tr><tr><td>Over-table X-ray tube
When a patient support is permanently between the X-ray tube assembly and the position of the patient</td><td>Dosemeter:
300 mm above the patient support on the X-ray tube side of the support

System:
Focus to image receptor distance as near as possible to 1000 mm</td></tr><tr><td>C-arm or U-arm systems
Where the X-ray tube and the image receptor are mechanically linked and where a patient support may or may not be permanently in the radiation beam</td><td>Dosemeter:
300 mm from the image receptor plane

System:
Focus to image receptor distance as near as possible to 1000 mm</td></tr><tr><td>Other fluoroscopic systems
No permanent patient support</td><td>At the patient entrance reference point (as defined by the manufacturer)</td></tr></table>
Note 1: For each of the above configurations, 20 cm thick of polymethylmethacrylate or equivalent must be placed between the dosemeter and image receptor. Each non-boost automatic dose control mode must comply with the stated limits. Dose measurements are to be obtained free-in-air (i.e. no backscatter). The selected image reception area's largest dimension (field size) must be as near as possible to 23 cm.

Note 2: If the automatic dose control requires the selection of either kVp or mA, then the system must be adjusted such that approximately 80 kVp is the value used.</td></tr>
<tr><td>31</td><td>Focus-to-skin distance</td><td>Means must be provided to ensure that the distance between X-ray tube focus and the patient entrance surface is:

(a) not less than 300 mm; or

(b) in the case of special surgical applications requiring shorter distances, not less than 200 mm.

Note 1: Separation may be achieved by physical restriction or through system design and positioning of patient in accordance with instructions for use.

Note 2: This test does not apply to C-arm systems designed specifically for extremity use.</td></tr>
<tr><td>32</td><td>Spatial resolution</td><td>Using a Westmead test object, or similar, attached to the face of the image receptor, the high contrast resolution as displayed on a clinical reference monitor must be greater than or equal to:

<table><tr><th>Field size
(millimetre)</th><th>Line pairs
(per millimetre)</th></tr><tr><td>< 140</td><td>1.6</td></tr><tr><td>140 to < 230</td><td>1.2</td></tr><tr><td>≥ 230</td><td>0.8</td></tr></table></td></tr>
</table>

Test	Compliance test	Criteria for passing the test
		Note: This test must be performed using an optimised combination of imaging mode, acquisition and processing parameters.
33	Low contrast detectability	The low contrast resolution as displayed on a clinical reference monitor must be greater than or equal to 5% for 10 millimetre diameter detail. Note 1: If a Westmead test object is used, at least 9 of the 10 millimetre diameter circles must be detectable. Note 2: This test must be performed: • using a test object attached to the face of the image receptor, and 2 mm of copper (thickness) in the beam positioned as close as practicable to the collimator; and • using an optimised combination of imaging mode, acquisition and processing parameters. Note 3: The test must be performed using an (non-boost) automatic dose control mode, where available. For systems that do not have a fully automatic dose control mode of operation, select a technique factor such that approximately 70kVp is obtained. Note 4: For systems with manual dose control only, the test must be performed using values not exceeding the following image receptor input air kerma rates: Field size (millimetre) / Air kerma rates ($\mu Gy.min^{-1}$) < 140 — 120 140 to < 230 — 80 ≥ 230 — 60
34	Loading indication	There must be a specific and conspicuous audible signal indicating loading in the high level or boost mode. This signal must be readily distinguishable from that used for normal fluoroscopy.
35	Indication of radioscopy time	The system must have a radioscopy timer, and the timer must provide an audible signal at intervals not exceeding 5 minutes.
36	Loading indication – image acquisition	Loading in an image acquisition mode must be indicated by a visible signal, and an audible signal must be provided which indicates either the duration or the instant of termination of loading.
37	Loading indication – radioscopy mode	Loading in radioscopy mode must be indicated by a specific visible signal.
38	Indicators of operation	Loading factors must be continuously displayed. Note: Loading factors include the X-ray tube voltage and either: (a) average current; or (b) current-time product and pulse rate.
39	X-ray field / image receptor	It must not be possible to initiate radioscopy loading without an image receptor in place to intercept the X-ray beam. The X-ray beam must not fall outside the image receptor (including its associated housing) under any circumstances. If the X-ray beam is rectangular, and the image receptor is circular, the length and width of the X-ray beam must fall within the image receptor area. In all other circumstances, the discrepancy between any edge of the X-ray beam and the corresponding visible edge of the image on the monitor must not exceed 1.5% of the focal spot to image receptor distance.

Test	Compliance test	Criteria for passing the test
		Note: A representative sample of the clinically used combinations of focal spot to image receptor distance and image receptors must be tested.
40	Exposure switch	The exposure switch must be designed so that it cannot accidentally be operated. Note: For example, this could be achieved by shrouding the foot switch or by the provision of an isolation switch at the operator's console.
41	Air kerma-area product meter	If an air kerma area product (KAP) meter is provided, the accuracy of the displayed KAP must be within ± 20% of the measured value.
ADDITIONAL TESTS FOR APPARATUS CAPABLE OF EXTRA-ORAL DENTAL DIAGNOSTIC IMAGING		
42	X-ray/image receptor alignment – cephalometric mode	For dental panoramic tomography radiation apparatus in the cephalometric mode: (a) the X-ray field must not exceed the size of the image receptor area; and (b) for digital imaging systems where there is no slot in the secondary collimator adjacent to the image receptor, the primary beam must not exceed the receptor dimensions by more than 10 mm or 10% (whichever is the greater); and (c) there must be a means to ensure correct alignment of the image receptor and the primary beam.
43	X-ray/image receptor alignment – panoramic mode	For dental panoramic tomography radiation apparatus in the panoramic mode: (a) the dimensions of the primary beam must be larger than the size of the slot in the secondary collimator immediately adjacent to the image receptor. (b) for digital imaging systems where there is no slot in the secondary collimator adjacent to the image receptor, the primary beam must be within the dimensions of the image receptor.
ADDITIONAL TESTS FOR APPARATUS CAPABLE OF INTRA-ORAL DIAGNOSTIC IMAGING		
44	Irradiation time	The irradiation time for standard bite-wing settings must not exceed 1.0 second.
45	Entrance skin air kerma	For standard bite-wing settings, the air kerma at the open end of the beam applicator must not exceed 3.5 mGy.
46	Beam quality – half value layer	The total filtration must be such that the measured half-value layer: (a) is not less than 1.5 mm of aluminium (thickness) for each of the available kVp options on the radiation apparatus; and (b) increases with increases in kVp.
47	Radiation leakage	The radiation leakage measured at a distance of 1 metre from the focal spot must not exceed 0.25 mGy in one hour with the X-ray tube operating at the maximum rated voltage and the maximum rated continuous current.
48	Maximum dimension of X-ray field	The maximum dimension of the X-ray field at the patient end of the beam applicator must not exceed 60 millimetres.
49	Alignment – X-ray field	The central axis of the X-ray beam must lie within 3 millimetres of the central axis of the applicator measured at the patient end of the applicator.
ADDITIONAL TESTS FOR APPARATUS CAPABLE OF COMPUTED TOMOGRAPHY Note: Some tests relate only to axial computed tomography devices and are not applicable to non-traversing devices.		
50	X-ray/image receptor alignment – dental cone beam computed tomography	For dental cone beam computed tomography radiation apparatus, the X-ray beam must not exceed the image receptor dimensions by more than 1% of the focal spot to image receptor distance.

Test	Compliance test	Criteria for passing the test
51	Examination can be interrupted by operator	Readily identifiable and accessible means must be provided for interruption of a scan to terminate loading.
52	Loading indication	When, and only when, radiation is produced, visible indication must be provided: (a) on the control panel; and (b) on or near the gantry.
53	Light localisation	A light field must be provided for marking the tomographic section (i.e. for axial positioning of the patient). The width of the light field must not exceed 3 mm measured in the centre of the gantry opening. The centre of the tomographic section must be within ± 2 mm of the centre of the light field.
54	Preview image localisation	A preview image must be able to be provided on which the operator may define the tomographic sections to be taken. The reference lines indicating these sections must not differ from the true positions by more than 2 mm.
55	Slice thickness	The slice thickness must either: (a) be within manufacturer specified tolerances; or (b) if manufacturer specified tolerances are not provided, the measured tomographic section thickness values must not deviate from the specified nominal values by more than the values listed below: (i) 1.0 mm for thicknesses above 2 mm (ii) 50% for thicknesses of 1 mm to 2 mm (iii) 0.5 mm for thickness less than 1 mm The measurements must be performed for all collimator settings that are accessible in axial mode. The maximum number of tomographic sections must be acquired for each collimator setting. The evaluation must be performed for, at least, both the outer tomographic sections and one representative inner tomographic section.
56	Image noise	The value of noise must either: (a) be within manufacturer specified tolerances; or (b) if manufacturer specified tolerances are not provided, the value of noise must not be more than 15% above the baseline value. Unless otherwise specified by the manufacturer, measurements of noise must be performed by determining the CT number standard deviation 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 a circular region of interest of approximately 40% of the diameter of the uniform test device. Two conditions of operation must be tested, one representing a typical axial head scan and one representing a typical axial body scan. The noise must be evaluated for each image acquired simultaneously in a single tube rotation.
57	Uniformity	Uniformity must either: (a) be within manufacturer specified tolerances; or

Test	Compliance test	Criteria for passing the test
		(b) if manufacturer specified tolerances are not provided, the uniformity must not be greater than 4 Hounsfield units. Unless otherwise specified by the manufacturer, uniformity must be evaluated from the mean CT numbers from regions of interest placed at different positions (central and 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, one representing a typical axial head scan and one representing a typical axial body scan. The uniformity must be evaluated for each image acquired simultaneously in a single tube rotation. 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 edge positions.
58	Mean CT Number	The mean CT number must either: (a) be within manufacturer specified tolerances; or (b) if manufacturer specified tolerances are not provided, the mean CT number of the central region of interest must not deviate by more than ± 4 Hounsfield units from the baseline value. 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. The mean CT number must be evaluated for each image acquired simultaneously in a single tube rotation.
59	Spatial resolution	The spatial resolution must either: (a) be within manufacturer specified tolerances; or (b) if manufacturer specified tolerances are not provided, the measurement of the 50% point and the 10% point of the modulation transfer function curve must be not more than 0.5 line pairs per centimetre or 10% below the baseline value, whichever is the greater. Unless otherwise specified by the manufacturer, spatial resolution is best described by the modulation transfer function curve obtained from the fourier transform of the point-spread function. Alternative (validated) methods may be used. CT conditions of operation including a typical head and body scan, and a scan having maximum spatial resolution must be tested.
60	Radiation dose	The dose value must either: (a) be within manufacturer specified tolerances; or (b) if manufacturer specified tolerances are not provided, all dose values must be within ± 20% of the baseline value. The following dose measurements must be performed: • $CTDI_{free\ air}$ at all nominal beam collimations (all other independent conditions of operation must be maintained at the typical body conditions of operation)

Test	Compliance test	Criteria for passing the test
		• $CTDI_{free\ air}$ at all kVp settings (all other independent conditions of operation must be maintained at the typical body conditions of operation) • $CTDI_{free\ air}$ at the typical head condition of operation
61	CTDI and DLP – available	After an exposure, the volume CTDI and the dose length product of the exposure must be available to the operator.
ADDITIONAL TESTS FOR APPARATUS DESIGNED TO PERFORM MAMMOGRAPHY		
62	kVp accuracy	The kVp accuracy, starting at the lowest kVp used clinically and increasing in 2 kVp steps until the maximum kVp used clinically is reached, must be within ± 5% of the indicated value.
63	Exposure time	For all clinically relevant source-image-distance settings, the maximum exposure time when irradiating a 6 cm thick polymethylmethacrylate phantom must be: (a) less than 3.5 seconds for fine focus; and (b) less than 2 seconds for broad focus. This test does not apply to digital breast tomosynthesis mode or scanning mammography systems.
64	Radiation leakage	The radiation leakage at 30 cm from the focal spot must not exceed 0.01 mGy per 100 mAs with the X-ray tube operating at 30 kVp.
65	Mean glandular radiation dose	The mean glandular radiation dose must not exceed: (a) 1 mGy for 2.0 cm thick polymethylmethacrylate phantom (2.3 cm 50% adipose, 50% glandular breast), and <1.2 mGy for digital breast tomosynthesis mode; or (b) 2.0 mGy for a ACR Mammography Accreditation Phantom or ACR Digital Mammography Phantom (i.e. 4.2 cm 50% adipose, 50% glandular breast); or (c) 4.5 mGy for 6.0 cm thick polymethylmethacrylate phantom (6.5 cm 50% adipose, 50% glandular breast). When mean glandular dose values are displayed, the values must be within: (a) manufacturer specified tolerances; or (b) if manufacturer specified tolerances are not available, be within ± 20%. Note: This test also applies to digital breast tomosynthesis mode.
66	X-ray field/image receptor alignment	The X-ray field must: (a) fully irradiate the image receptor; and (b) not extend beyond the breast support on the chest wall edge of the image receptor by more than 2 mm or 5 mm for stereotactic biopsy units; and (c) be contained within the breast support on the left, right and nipple sides.
67	Reproducibility	The coefficient of variation for both mean pixel value (MPV) and mAs for at least three automatic exposure control exposures of a test object, taken within a time period of 10 minutes, must be less than or equal to 0.05. The coefficient of variation for MPV is not required for film-screen systems.
68	kVp compensation, thickness compensation	**Film-screen image receptors:** The film optical density must be within ± 0.15 of the mean optical density for automatic exposure control images of 2, 4 and 6 cm thick polymethylmethacrylate phantoms using clinically relevant kVp and target/filter combinations (for both contact and magnification imaging).

Test	Compliance test	Criteria for passing the test
		Digital radiography (DR) and computed radiography (CR) image receptors in 2D mode: The following requirements must be satisfied when SDNR values are compared with baseline for a 4 cm thick polymethylmethacrylate phantom ($SDNR_{accept}$): • SDNR 2 cm > 1.1 x $SDNR_{accept}$ • SDNR 4 cm > $SDNR_{accept}$ • SDNR 6 cm > 0.9 x $SDNR_{accept}$ For CR image receptors in magnification mode, this last requirement is relaxed to: • SDNR 6 cm > 0.65 x $SDNR_{accept}$ Only in circumstances where an $SDNR_{accept}$ value is not available, the SDNR must be equal to baseline ± 10% for polymethylmethacrylate phantom thicknesses of 2 cm, 4 cm and 6 cm. This test must be performed with the most commonly used automatic exposure control modes for contact and magnification imaging. **Digital breast tomosynthesis mode:** For systems only used in digital breast tomosynthesis mode, the above 2D mode tests must still be conducted.
69	Compression	(a) The compression device must not be able to apply a force exceeding 300 N; and (b) for power driven compression, the compression device must be able to apply a force of at least 150 N, and must be unable to apply a force exceeding 200 N; and (c) the chest wall edge of the compression paddle must be aligned just beyond the chest wall edge of the image receptor such that it does not appear in the image. In addition, the compression paddle must not extend beyond the chest wall edge of the image by more than 1% of the source to image-receptor distance.
70	Image uniformity & artefact evaluation	This test is to be carried out using a 4 cm thick polymethylmethacrylate phantom. **Digital radiography (DR) and computed radiography (CR) image receptors in 2D mode:** The maximum deviation of mean pixel value must be less than ± 10% of mean pixel value from the central region of interest (ROI). This requirement applies to both contact and magnification modes. Note 1: For DR image receptors; use five ROIs each of ~100 mm^2, one central, with the other 4 at the corners approximately 20 mm (10 mm for biopsy units) from any edge. Note 2: 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. **Digital breast tomosynthesis mode:** For systems only used in digital breast tomosynthesis mode, the above 2D mode tests, or another image uniformity test approved by the chief executive, must be conducted. **Artefact evaluation:** There must be no evidence of clinically significant artefacts.

Test	Compliance test	Criteria for passing the test
71	System resolution	**Film-screen image receptors:** Using a resolution phantom 4.5 centimetres above the breast support: (a) measurements made parallel to the anode-cathode axis must resolve at least 13 line pairs per millimetre; and (b) measurements made perpendicular to the anode-cathode axis must resolve at least 11 line pairs per millimetre. This requirement applies to both contact and magnification modes. **Digital radiography (DR) and computed radiography (CR) image receptors:** Using a resolution phantom 4.5 centimetres above the breast support, measurements made parallel and perpendicular to the anode-cathode axis must not be less than 10% of baseline resolution values. This requirement applies to both contact and magnification modes.
72	Image quality evaluation	**Film-screen image receptors:** At least 4 fibres, 3 speck groups and 3 masses in an image of an ACR Mammography Accreditation Phantom in contact mode must be visible. **Digital radiography (DR) and computed radiography (CR) image receptors:** At least the following must be visible in contact mode: (a) 5 fibres, 3.5 speck groups and 4 masses in an image of an ACR Mammography Accreditation Phantom; or (b) 4 fibres, 3 speck groups and 3 masses in an image of an ACR Digital Mammography Phantom. **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 Mammography Accreditation Phantom; or (b) 2 fibres, 1 speck groups and 2 masses in an image of the ACR Digital Mammography Phantom. The slice used for scoring should be 37 ± 2 mm (ACR Mammography Accreditation Phantom) or 34 ± 2 mm (ACR Digital Mammography Phantom) above breast support and must not change by more than ± 1 mm from the previous measurement.
73	Film-screen mammography	Film-screen for mammography must not be used after 31 March 2022.