Queensland Government

Radiation Safety Act 1999

RADIATION SAFETY STANDARD HR001:2010

Standard for radiation apparatus used to carry out plain film diagnostic radiography

Preface

This radiation safety standard, HR001:2010 *Standard for radiation apparatus used to carry out plain film diagnostic radiography* is made under section 16 of the *Radiation Safety Act 1999*, and establishes the minimum safety criteria for radiation apparatus used to carry out plain film diagnostic radiography involving the irradiation of humans. Compliance with this standard will assist possession licensees in ensuring that health and safety of persons are not adversely affected by exposure to radiation during plain film diagnostic radiography procedures.

This radiation safety standard, which is based on information derived from reputable sources such as Standards Australia and the Australasian College of Physical Scientists and Engineers in Medicine, was prepared after extensive consultation with industry and licensees.

By ensuring compliance with this radiation safety standard, radiation safety in plain film diagnostic radiography practices across Queensland will be enhanced. Queensland Health will also ensure that the standard is reviewed periodically to assure its currency and its appropriateness for plain film diagnostic radiation apparatus.

I, Paul Lucas, Deputy Premier and Minister for Health, pursuant to section 16(1) of the *Radiation Safety Act 1999*, make the radiation safety standard HR001:2010 *Standard for radiation apparatus used to carry out plain film diagnostic radiography*, for the purposes of the Act, and repeal the previous standard HR001:2004 *Standard for radiation apparatus used to carry out plain film diagnostic radiography*

SIGNED

PAUL LUCAS MP
Deputy Premier
Minister for Health

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Standard for radiation apparatus used to carry out plain film diagnostic radiography

Section 1 – General

1.1 Scope

This radiation safety standard sets out the minimum requirements for ionising radiation apparatus that is used for plain film diagnostic radiography involving the irradiation of humans, excluding:

(a) computed tomography;
(b) mammography;
(c) radioscopy (includes fluoroscopy);
(d) intra-oral dental diagnostic radiography; and
(e) bone mineral densitometry.

1.2 Expiry

This radiation safety standard expires on 1 September 2020.

1.3 Definitions

In this standard –

"coefficient of variation" means the ratio of the sample standard deviation to the mean value of a series of measurements.

"effective focal spot size" means the size of the perpendicular projection of the actual focal spot on the reference plane.

"equivalent dimensions" means dimensions as determined by the star pattern measurement method according to:

$$F = N/57.3 \times D/(M - 1)$$

where M is the magnification (diameter of the image of the star pattern divided by the diameter of the star phantom)
D is the diameter of blur region
N is the angle of pattern lines in degrees

"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.

"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.

“irradiation time” means the duration of an irradiation determined by:

(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 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 percent, but not higher than 85 percent of the peak kilovoltage value, until the time at which it finally drops below the 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).

“leakage air kerma” means air kerma produced by ionising radiation which has passed through the protective shielding of a radiation source as well as that which, for some types of X-ray generators, has passed through the radiation aperture before and after loading (for example one containing a grid controlled X-ray tube). Leakage air kerma is usually expressed in milligray (mGy) or microgray (μGy).

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

“mA” (X-ray tube current) means the electric current of 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 electric charge resulting from the loading of an X-ray tube, expressed in milliampere seconds (mAs), as the product of the mean X-ray tube current in milliamperes and the duration of the loading in seconds.

“optical density” means the common logarithm of the ratio of the amount of light striking one side of the film with the amount of light that passes through the film.

“radiography” means the production of an image of an object on film, or other kind of image receptor, by means of X-radiation, the contrast between different areas of the image being the result of differential interaction of the radiation in the object.

“radioscopy” 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, radioscopy excludes image acquisition. Radioscopy includes fluoroscopy.

“total permanent filtration” means inherent filtration and other filtration not removable without the use of tools.

Section 2 - Standard – Plain Film Diagnostic Radiation Apparatus

Test	Compliance Test	Criteria for Passing the Test
Accuracy and reproducibility		
1	Reproducibility	The coefficient of variation of 5 consecutive radiation output measurements, at loading factors of approximately 70 kVp, 200 mA and 50 milliseconds, must not exceed 0.05.
2	Linearity	The following conditions must be met using a kVp value of approximately 70 kVp and, if the X-ray equipment provides for such adjustments to be made, at least 4 pairs of mA (or mAs) stations including the lowest and the highest available. 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 are the indicated irradiation times Note: This test does not apply to capacitor discharge units.

Test	Compliance Test	Criteria for Passing the Test
3	kVp accuracy	The measured kVp: (a) should be within ± (5 percent + 1 kVp) of the indicated value; and (b) must be within ±10 percent of the indicated value. Note 1. The increment or decrement of the X-ray tube voltage between any two indicated settings must be within 50 percent and 150 percent 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. Further values above 120 kVp must be tested where these values are used clinically. 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 on the Assessment Report. Note 3. If the equipment does not meet the requirements of part (a) but does satisfy the requirements of part (b), a comment to this effect must be made on the Assessment Report.
4	Timer accuracy	The measured irradiation time must be within: (a) ±10 percent of the indicated value for irradiation times 100 milliseconds or greater; and (b) ±20 percent of the indicated value for irradiation times less than 100 milliseconds. Note: Measurements should be performed at approximately 70 kVp and 100 mA using at least 5 irradiation time settings. For medium or high frequency units, the time settings must range from 10 milliseconds to 500 milliseconds. For all other units, the time settings must range from 50 milliseconds to 500 milliseconds.
Output controls and limits		
5	Beam quality – half value layer	The total permanent filtration must be such that the measured first half-value layer is not less than 2.3 millimetres of aluminium at an indicated value of 80 kVp.

Test	Compliance Test	Criteria for Passing the Test
6	X-ray source assembly leakage	The leakage air kerma averaged over any area of 100 square centimetres at one 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.
7	Minimum focus to skin distance	The minimum focus to skin distance must not be able to be less than 200 millimetres except for dental panoramic tomography, where it must not be able to be less than 150 millimetres.
8	Capacitor discharge units leakage – discharge mode	The leakage air kerma from capacitor discharge units in the charge or preparation mode averaged over any area of 100 square centimetres at one metre from the focal spot must not exceed 1 mGy in one hour. Note: This test is to be performed under conditions of normal use that are most unfavourable for compliance with this requirement (e.g. maximum clinically used kVp and maximum discharges per hour during clinical use).
9	Capacitor discharge units - maximum mAs	The maximum selectable mAs for capacitor discharge units must not exceed 30 mAs for a single loading.
10	Capacitor discharge units leakage – charge mode	The leakage air kerma from capacitor discharge units, when in the charge mode, averaged over an area of 10 square centimetres, must not exceed 20 μGy in one hour at 5 centimetres from any accessible surface. Note: This test is to be performed under conditions of normal use that are most unfavourable for compliance with this requirement (e.g. maximum clinically used kVp and maximum discharges per hour during clinical use).

Test	Compliance Test	Criteria for Passing the Test
Image quality determinants		
11	Image quality	The equivalent dimensions of focal spot sizes: (a) should not exceed the relevant values specified in Appendix A for the nominal focal spot size; and (b) must not exceed equivalent dimensions of 2.6 millimetres width and 3.7 millimetres length. Note: If the equipment does not meet the requirements of part (a), but does satisfy the requirements of part (b), a comment to this effect must be made on the Assessment Report. Alternatively, another image quality test, approved by the Chief Executive, may be used.
12	Image uniformity	An image of grids in-situ within their image receptor must be spatially uniform and free from clinically significant artifacts. The image must be obtained using a clinically representative air kerma at the image receptor and loading factors of approximately 70 kVp and at least 100 milliseconds using a focus to image receptor distance within the focal range of the grid.
13	X-ray tube housing stability	The X-ray tube housing must remain stationary during loading unless it is intended to move.
Operator controls and indicators		
14	Irradiation switch on mobile radiation apparatus	There must be an irradiation switch fitted to a mobile radiation apparatus which will allow the operator to be positioned at least 2 metres from the X-ray tube.
15	Supply indication	When the apparatus is energised, this status must be clearly indicated. The supply indicator and the load indicator must be clearly labelled or otherwise easily distinguishable from each other.
16	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.

Test	Compliance Test	Criteria for Passing the Test
17	Initiation and termination of loading	Each loading must be initiated and maintained by means of a control requiring continuous actuation by the operator. Means shall be provided for the operator to terminate each loading at any time before its intended completion, except for single loadings with a loading time of 0.5 seconds or less.
18	Loading indication	Loading must be indicated by a visible signal. Additionally, an audible signal must be provided which indicates either the duration or the instant of termination of loading.
19	Focal spot marking	The position of the focal spot must be clearly and visibly indicated.
Field indication, limitation and alignment		
20	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.
21	X-ray/light field alignment	If a light beam diaphragm is fitted to the radiation apparatus: (a) the extent of misalignment between any boundary of the light field and the equivalent boundary of the X-ray field in the plane of the image receptor must not exceed 1 percent of the focus to image receptor distance; and (b) the central axis of the X-ray beam must coincide with the central axis of the light field to within $\pm$1.4 degrees (e.g. for a 20 centimetre high field alignment test tool, the top test object must be within 5 millimetres of the bottom test object).
22	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 at the image receptor plane; and (b) the minimum focal spot to image receptor distance must not be less than 1500 millimetres.

Test	Compliance Test	Criteria for Passing the Test
23	X-ray/image receptor alignment - panoramic mode	For dental panoramic tomography radiation apparatus in the panoramic mode: (a) the X-ray field from the primary collimator (at the X-ray tube) must fall no greater than 2 millimetres outside of the top and bottom borders of the secondary collimator (at the image receptor plane) and no greater than 2 millimetres outside of the top and bottom borders of the image receptor; and (b) the vertical edges of the X-ray field must not fall outside the secondary collimation.
Automatic exposure control systems		
24	Reproducibility	(a) Using the centre detector, the air kerma from 5 consecutive loadings at 80 kVp with a patient equivalent phantom, must be within ±10 percent of the mean; and (b) the air kerma from irradiations to the lateral detectors must be within 10 percent of each other. Note: For this test, phantoms constructed of 2 millimetres of copper or 15 centimetres of acrylic are suitable substitutes for a patient equivalent phantom.
25	kVp compensation	For systems utilising a film-screen image receptor system, the mean 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. 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. For systems exclusively utilising a digital image receptor the variation in radiation dose absorbed by the receptor (e.g. as indicated by the exposure index) should not exceed that implied by the optical density variation allowed for film-screen image receptor systems. Note 3. For this test, a phantom constructed of 15 centimetres of acrylic is a preferable patient equivalent phantom.

Test	Compliance Test	Criteria for Passing the Test
26	Thickness compensation	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) 60kVp with 10 and 15 centimetre acrylic phantoms; and (b) 80kVp with 15 and 20 centimetre acrylic phantoms; and (c) 100kVp with 15 and 20 centimetre acrylic phantoms; and (d) 120kVp with 10 and 15 centimetre acrylic phantoms.
27	Minimum response time	The minimum response time of the automatic exposure control to radiation must not exceed 10 milliseconds, except for single phase systems where it must not exceed 20 milliseconds.
28	Indication of automatic exposure control	There must be a visible indication when the automatic exposure control function is selected.
29	Indication of detector(s) selected	There must be a visible indication of the image receptor selected and the automatic exposure control detector(s) active. For clarification, the automatic exposure control must only be able to be operated if the image receptor selected is equipped with an automatic exposure control detector.
30	Failsafe timer – 600 mAs operation	A failsafe timer must be provided and must limit any loading to not more than 60 kilojoules or the current time product to no more than 600 mAs.
31	Failsafe timer – 600 mAs indication	A visible indication must be provided whenever a loading has been terminated by the failsafe timer.
32	Failsafe timer – 600 mAs reset	When a loading has been terminated by the failsafe timer it must not be possible to initiate another loading without first operating a manual reset.
33	Preset exposure limit indication	A visible or audible signal must be provided whenever a loading has been terminated by a preset exposure limit.
34	Density control	Where the operator can alter the sensitivity of the detectors, this adjustment must cause a change in air kerma consistent with manufacturer's instructions for use.

Test	Compliance Test	Criteria for Passing the Test
Tomographic performance		
35	Irradiation uniformity and pattern	The density of the image of the hole in the lead sheet of a phantom must be nearly uniform or must vary in uniformity according to the pattern expected. The image must reveal no unexpected overlaps, inconsistencies of irradiation or asymmetry in motion.
36	Resolution	The system must resolve a 40 mesh (1.6 holes/millimetre) screen pattern or better. Note: This test does not apply to dental panoramic tomography radiation apparatus.
37	Section thickness	The section thickness must comply with manufacturer's specifications or instructions for use. Note: This test does not apply to dental panoramic tomography radiation apparatus.
38	Section levels	Agreement between the indicated and measured section levels must be within ±5 millimetres. Note: This test does not apply to dental panoramic tomography radiation apparatus.
Radiation warning sign		
39	Radiation warning sign	The radiation apparatus must be marked on or adjacent to the control panel with a 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.

Appendix A

Permissible values of focal spot dimensions for nominal focal spot values

Nominal focal spot value	Permissible values in mm	
F	Width	Length
0.1	0.10 … 0.15	0.10 … 0.15
0.15	0.15 … 0.23	0.15 … 0.23
0.2	0.20 … 0.30	0.20 … 0.30
0.25	0.25 … 0.38	0.25 … 0.38
0.3	0.30 … 0.45	0.45 … 0.65
0.4	0.40 … 0.60	0.60 … 0.85
0.5	0.50 … 0.75	0.70 … 1.10
0.6	0.60 … 0.90	0.90 … 1.30
0.7	0.70 … 1.10	1.00 … 1.50
0.8	0.80 … 1.20	1.10 … 1.60
0.9	0.90 … 1.30	1.30 … 1.80
1.0	1.00 … 1.40	1.40 … 2.00
1.1	1.10 … 1.50	1.60 … 2.20
1.2	1.20 … 1.70	1.70 … 2.40
1.3	1.30 … 1.80	1.90 … 2.60
1.4	1.40 … 1.90	2.00 … 2.80
1.5	1.50 … 2.00	2.10 … 3.00
1.6	1.60 … 2.10	2.30 … 3.10
1.7	1.70 … 2.20	2.40 … 3.20
1.8	1.80 … 2.30	2.60 … 3.30
1.9	1.90 … 2.40	2.70 … 3.50
2.0	2.00 … 2.60	2.90 … 3.70

Extract from Australian/New Zealand Standard AS/NZS 4274:1995 *X-ray tube assemblies for medical diagnosis – characteristics of focal spots*