



**Queensland
Government**

Radiation Safety Act 1999

RADIATION SAFETY STANDARD

HR004:2020

Standard for radiation apparatus used to carry out film-screen mammography

Preface

Under section 17 of the *Radiation Safety Act 1999*, a possession licensee who, under a licence, possesses an ionising radiation apparatus to carry out a radiation practice, must ensure that the apparatus is not used for this purpose, unless the radiation apparatus complies with the relevant standard.

This radiation safety standard HR004:2020 *Standard for radiation apparatus used to carry out film-screen mammography* is made under section 16 of the *Radiation Safety Act 1999*.

This standard sets the minimum safety criteria for radiation apparatus used to carry out film-screen mammography. Compliance with this standard will assist in ensuring that public and occupational exposure to radiation is minimised.

Queensland Health has prepared this standard based on information derived from reputable sources such as Standards Australia and Standards New Zealand.

The standard will be reviewed periodically to re-evaluate its currency and its appropriateness as the standard for radiation apparatus used for film-screen mammography.

By ensuring compliance with this radiation safety standard, the standard of radiation apparatus used for film-screen mammography in Queensland will be significantly enhanced.

I, Steven Miles, Deputy Premier and Minister for Health and Minister for Ambulance Services, pursuant to section 16(1) of the *Radiation Safety Act 1999*, make the radiation safety standard HR004:2020 *Standard for radiation apparatus used to carry out film-screen mammography*, for the purposes of the Act, and repeal the previous standard HR004:2010 *Standard for radiation apparatus used to carry out film-screen mammography*.

STEVEN MILES MP
Deputy Premier and
Minister for Health and
Minister for Ambulance Services

25 May 2020

Contents

Section 1 – General

- 1.1 Scope
- 1.2 Expiry
- 1.3 Documents
- 1.4 Definitions

Section 2 – Standard - Film-screen mammography

Appendix

- A Documents

Standard for radiation apparatus used to carry out film-screen mammography

Section 1 – General

1.1 Scope

This radiation safety standard sets out the minimum requirements for ionising radiation apparatus that is used for film-screen mammography.

To remove doubt, this standard also applies to radiation apparatus that is used to carry out research involving film-screen mammography on humans.

1.2 Expiry

This radiation safety standard expires on 1 September 2021.

1.3 Documents

Documents which may provide some useful information are listed in Appendix A.

1.4 Definitions

In this standard -

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

"kVp" 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 radiation" means 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).

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

"mammography" means radiographic examination of the breast.

"mAs" means the electric current of the electron beam incident on the target of an X-ray tube over a particular time, which is expressed by multiplying the mean value in milliamperes 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 perspex using clinically relevant kVps and target/filter combinations.

"optical density" means the common logarithm of the ratio of the amount of light striking one side of the film compared to the amount of light that passes through the film.

"radiation level" means the air kerma radiation dose during a specified time.

Section 2 – Standard – Film-screen mammography

| Test | Compliance Test | Criteria for Passing the Test |
|-------------------------|-------------------------------|--|
| Radiation output | | |
| 1 | Reproducibility of output | The coefficient of variation of 5 consecutive radiation dose measurements at a commonly used (manual) exposure setting, taken within a time period of 10 minutes, must not exceed 0.02. |
| 2 | kVp accuracy | The kVp accuracy, starting at the lowest kVp used clinically and increasing in 1kVp steps until the maximum kVp used clinically is reached, must not be within ± 5 percent of the indicated value. |
| Radiation level | | |
| 3 | Radiation level | The system must be capable of: <ul style="list-style-type: none"> (a) producing a minimum radiation level of 7mGy in one second when operating at 28kVp in the standard mammography (Mo/Mo) mode at any focus to film distance at which the system is designed to operate and when measured by a detector with its centre located 4.5 centimetres above the breast support surface with the compression paddle in place between the source and the detector; and (b) maintaining the 7mGy in one second output, averaged over a 3 second period. |
| 4 | X-ray source assembly | The leakage radiation level must not be able to exceed 1mGy per hour at 1 metre from the housing. |
| Radiation dose | | |
| 5 | Mean glandular radiation dose | The mean glandular radiation dose must not exceed: <ul style="list-style-type: none"> (a) 3mGy for a 5 centimetre breast phantom of 50 percent adipose tissue, 50 percent glandular tissue; or (b) 2mGy for an American College of Radiology accreditation phantom. |
| Control panel | | |
| 6 | Exposure switch | Each loading must be initiated and maintained by means of a control requiring continuous actuation by the operator. |

| Test | Compliance Test | Criteria for Passing the Test |
|--|--------------------------------------|---|
| 7 | Loading indication | Loading must be indicated by an amber light and an audible signal. |
| <i>Beam limiting device</i> | | |
| 8 | Light field intensity | The illuminance of the light beam indicator measured at the level of the breast support (maximum achievable distance) must be greater than or equal to 100 lux. |
| 9 | X-ray field/light beam alignment | The extent of misalignment between any boundary of the light beam and the equivalent boundary of the X-ray beam in the plane of the image receptor must not exceed 1 percent of the focus to film distance. |
| 10 | X-ray field/image receptor alignment | The X-ray field must: <ul style="list-style-type: none"> (a) extend to the edge of the patient support that is designed to be adjacent to the chest wall of the patient and must not extend beyond this edge by more than 5 millimetres; and (b) not extend, by more than 2 percent of the perpendicular distance from the image receptor plane to the position of the focal spot, beyond all edges of the image receptor area. |
| <i>Automatic exposure control</i> | | |
| 11 | Selection indication | There must be an indication on the control panel that the automatic exposure control function has been selected. |
| 12 | Backup timer operation | The backup timer must limit the mAs to no more than 600mAs per irradiation. A preset exposure of less than 600mAs also constitutes a backup timer. |
| 13 | Backup timer indication | A visible indication at the control panel must be provided whenever a loading has been terminated by the backup timer. |
| 14 | Backup timer manual reset | When the exposure has been stopped by the backup timer it must not be possible to initiate another exposure without first operating a manual reset. |
| 15 | Reproducibility | The coefficient of variation of the radiation dose from 5 consecutive, phototimed exposures of an acrylic phantom, or similar, taken within a time period of 10 minutes, must be less than or equal to 0.05. |

| Test | Compliance Test | Criteria for Passing the Test |
|-----------------------------|--|---|
| 16 | kVp compensation, thickness compensation | For phototimed images of 2, 4 and 6 centimetres of perspex using clinically relevant kVps and target/filter combinations (for both contact and magnification imaging), the film optical density must be within ± 0.15 of the mean optical density. |
| Compression | | |
| 17 | Compression | <p>(a) The compression device must not be able to apply a force exceeding 300 newtons; and</p> <p>(b) for power driven compression, the compression device must be able to apply a force of at least 150 newtons, and must be unable to apply a force exceeding 200 newtons; and</p> <p>(c) the inner lip of the chest wall side of the compression device must be aligned just beyond the chest wall edge of the image receptor by a distance not exceeding 1 percent of the focus to film distance.</p> |
| Mean optical density | | |
| 18 | Mean optical density | The mean optical density must be greater than or equal to 1.2 of the optical density. |
| Image quality | | |
| 19 | System resolution | <p>Using a line pair phantom 4.5 centimetres above the breast support:</p> <p>(a) measurements made with the bars parallel to the anode-cathode axis must resolve at least 13 line pairs per millimetre; and</p> <p>(b) measurements with the bars perpendicular to the anode-cathode axis must resolve at least 11 line pairs per millimetre.</p> <p>These limits apply for both contact and magnification modes.</p> |
| 20 | Object visualisation | <p>Using an American College of Radiology accreditation phantom in contact mode, it must be possible to visualise: 4 of 6 fibres, 3 of 5 specks and 3 of 5 masses.</p> <p>The optical density difference due to the 4 millimetre thick acrylic disc must be greater than or equal to 0.40.</p> |

| Test | Compliance Test | Criteria for Passing the Test |
|---------------------------------|-------------------|---|
| <i>Protective screen</i> | | |
| 21 | Protective screen | <p>The protective screen:</p> <ul style="list-style-type: none"> (a) must not prevent the operator from observing the patient during mammography; and (b) must extend from not more than 15 centimetres above the floor to a height of not less than 185 centimetres; and (c) must not be narrower than 60 centimetres; and (d) must be able to attenuate 35kVp radiation to an extent greater than or equal to 0.08 millimetres of lead. |

Appendix A

Documents

Australian/New Zealand Standard. *Approval and test specification - Medical electrical equipment - Part 1.3: General requirements for safety - Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment.* AS/NZS 3200.1.3:1996.

Australian/New Zealand Standard. *Evaluation and routine testing in medical imaging departments Part 3.2: Acceptance tests - Imaging performance of mammographic X-ray equipment.* AS/ANZ 4184.3.2:1998.

Australian/New Zealand Standard. *Medical electrical equipment Part 2.45: Particular requirements for safety – Mammographic X-ray equipment and mammographic stereotactic devices.* AS/ANZ 3200.2.45:1999.

Australian/New Zealand Standard. *Medical electrical equipment, Part 2.7: Particular requirements for safety - High-voltage generators of diagnostic X-ray generators.* AS/ANZ 3200.2.7:1999.

Department of Health and Human Services. *Mammography Quality Standards; Final Rule.* Food and Drug Administration, Federal Register. October 28 1997; 68 (208); 55852-55994.