Radiation Protection Test Protocol

Test Protocol for Mammography X-ray Apparatus 2016

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This protocol provides the mandatory requirements for an accredited tester compliance testing mammography X-ray apparatus.

It should be read in conjunction with the Radiation Protection and Control Act 1982 (the Act) and the Radiation Protection and Control (Ionising Radiation) Regulations 2015 (the regulations).

Citation

This protocol may be cited as the Test Protocol for Mammography X-ray Apparatus 2016.

Part 1—Interpretation

In this protocol, unless the contrary intention appears—

accredited tester means a person performing compliance testing who is a holder of an accreditation as a third party service provider under section 33B of the Act;

aperture means a gap in the protective material of a tube housing through which ionising radiation from an X-ray tube within the tube housing may pass with little or no attenuation;

apparatus means ionising radiation apparatus;

fixed, in relation to apparatus, means any apparatus that is neither a mobile apparatus nor a portable apparatus;

general objective means the requirements under section 23 of the Act. Applicable sections are indicated by the symbol †;

mammography means imaging of breast tissue;

mobile, in relation to apparatus, means apparatus that is designed and constructed so as to be moveable from place to place for use as required but does not include a portable apparatus;

portable, in relation to apparatus, means any apparatus that is designed to be carried manually from place to place for use as required;

tube housing, in relation to an apparatus, means a container in which an X-ray tube is mounted for normal use, providing protection against electric shock and against ionising radiation except for an aperture for the useful beam;

X-ray tube, in relation to an apparatus, means an evacuated glass envelope in which electrons are accelerated for the purposes of the production of ionising radiation.
Part 2—General requirements

1—Application of protocol

This protocol applies to fixed X-ray apparatus capable of mammography.

2—Exemptions applicable to this protocol

The exemption notice pursuant to section 44 of the Act in the Government Gazette - 28 March 2013, page 906—that exempts, subject to conditions, owners of apparatus used for mammography and soft tissue radiography from the requirements of regulation 99(1), 99(2), 99(3), 99(4), 99(5), 99(6)(b), 99(7), 99(8), 99(10), 99(12), 99(13), 99(14), and 99(15) of the Radiation Protection and Control (Ionising Radiation) Regulations 2000—has been applied to the test method of section 16.1.

3—Complying with this protocol

The accredited tester must—

(a) perform compliance testing in accordance with the test methods specified in Part 3; and

(b) provide in a report—

(i) the details as specified in sections 4 to 7; and

(ii) the test parameters used and results obtained for the compliance tests performed under Part 3; and

(c) complete the approved Certificate of Compliance for Mammography X-ray Apparatus document.

4—Owner details

Record, where known, the details of the owner of the apparatus including at least—

(a) the name of the owner; and

(b) the address of the owner; and

(c) the telephone number of the owner.

5—Apparatus details

Record the details of the apparatus including at least—

(a) the make and model of the apparatus; and

(b) the serial number—

(i) of the generator, where it is practical to do so; and

(ii) the serial number of the X-ray tube, where it is practical to do so; and

(iii) the serial number of the tube housing, where it is practical to do so; and

(c) the location of the apparatus (e.g. surgery 1, room 1).

6—Accredited tester details

Record the details of the accredited tester including at least—

(a) the name of the accredited tester; and

(b) the accreditation number of the accredited tester; and

(c) the date on which the accredited tester performed the compliance tests.
7—Test instrument details

Record for each test instrument used, at least—

(a) the make and model; and
(b) the serial number; and
(c) the date of the next calibration or the date of the last calibration.

Part 3—Construction and installation requirements of mammography apparatus

8—Apparatus to be in good working order

8.1 Test method

Verify that there is no abnormality, fault, or condition, that is not subject to another section of this protocol, that prevents the apparatus from functioning or performing in a manner for which it has been designed.

8.2 Legislative reference

Regulation 8(2) of the regulations.

9—Labelling of apparatus

9.1 Test method

Verify that the apparatus has a label—

(a) that complies with the requirements of AS 1319–1994 Safety Signs for the Occupational Environment applying to warning signs; and
(b) bears the words “RADIATION PRODUCED WHEN ENERGISED” or words to that effect; and
(c) bears the radiation symbol as specified in Schedule 1; and
(d) is clearly legible at a distance of 2 metres.

9.2 Legislative reference

Regulation 63 of the regulations.

10—Radiation area sign

10.1 Test method

(1) Verify that a sign is clearly displayed, at each entrance, walkway or access route to the room or area in which the apparatus is located—other than an entrance to the room from a place or another room which can only be entered from the room.

(2) Verify that the sign—

(a) complies with the requirements of AS 1319–1994 Safety Signs for the Occupational Environment applying to warning signs; and
(b) if it does bear words, the words are "RADIATION AREA" or "X-RAYS" sign or words of similar effect; and
(c) has a total surface area of not less than 4500 square millimetres; and
(d) bears the radiation symbol as specified in Schedule 1; and
(e) is clearly legible at a distance of 2 metres.

10.2 Legislative reference

Regulation 64 of the regulations.
11—Exposure switch – closed circuit contact

11.1 Test method
Verify that—
(a) continuous pressure must be maintained on the exposure switch in order to maintain radiation exposure; and
(b) after a radiation exposure has terminated, another exposure is not possible without releasing the exposure switch; and
(c) in the case of programmed exposures, verify that there is a means of interrupting the programme.

11.2 Legislative reference
(1) Regulation 98(6)(a) of the regulations.
(2) Exemption referred to in section 2 is applicable (i.e. regulation 99(6)(b) of the old regulations).

12—Exposure switch – foot operated†

12.1 Test method
In the case of a exposure switch designed to be operated with the foot, verify that the switch has a cover designed to prevent accidental activation.

12.2 Legislative reference
The general objective is applicable.

13—Warning device

13.1 Test method
Verify that when the X-ray tube is energised there is a warning device that consists of—
(a) a red or amber light that is clearly distinguishable from the operator position; and
(b) an audible signal that is audible from that operator position and indicates either the duration or termination of the exposure.

13.2 Legislative reference
Regulation 98(9) of the regulations.

14—Mains switch

14.1 Test method
Verify that the apparatus has a mains switch—
(a) that controls the supply of mains power to the apparatus; and
(b) a mains indicator light to indicate when the control panel is energised and the mains switch is in the "ON" position.

14.2 Legislative reference
Regulation 98(11) of the regulations.

15—Focal spot

15.1 Test method
Verify that the position of the focal spot is clearly indicated on the tube housing.

15.2 Legislative reference
Regulation 98(16) of the regulations.
16—Mammography Quality Assurance Program

16.1 Test method
   Verify that the apparatus complies with the requirements of the Medical Physicist’s Quality Control Tests of the Mammography Quality Assurance Program of the Royal Australian and New Zealand College of Radiologists, as amended from time to time.

16.2 Legislative reference
   The exemption referred to in section 2 has been applied to the test method of section 16.1.
Part 4—Schedules

Schedule 1—Radiation symbol

(1) The radiation symbol consists of the conventional three blade design shown below.

(2) The symbol and background colours must comply with the requirements of AS 1319–1994 Safety Signs for the Occupational Environment.