

# Mandatory requirements for Approved Testers

## *Radiation Act 2005*

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## Introduction

The Victorian *Radiation Act 2005* (Act) has the objective of protecting the health and safety of persons and the environment from the harmful effects of radiation. The Department of Health and Human Services (Department) administers this legislation.

The Act seeks to fulfil this objective by establishing a licensing framework to regulate the conduct of radiation practices and the use of radiation sources. Part 5 of the Act prescribes testing requirements for prescribed radiation sources in accordance with a set of safety standards.

The following types of X-ray equipment, when used for human diagnostic imaging purposes, have been prescribed by the Radiation Regulations 2017 (Regulations) and therefore require periodic testing against the applicable Radiation Safety Standards which have been specified by the Secretary of the Department (Secretary):

- Plain Film Radiographic X-ray Equipment
- Fluoroscopic X-ray Equipment
- Computed Tomography Scanners
- Mammography X-ray Equipment.

The Radiation Safety Standards that have to be met by the prescribed radiation sources are published by the Department on the Victorian Government website: [www.health.vic.gov.au/radiation](http://www.health.vic.gov.au/radiation).

Under Section 36 of the Act it is an offence for a person in possession of a prescribed radiation source to require, direct, allow or permit a person to use a prescribed radiation source unless there is a certificate of compliance in respect of that source that has not expired. The maximum penalty for a body corporate for this offence is in excess of \$951,420.

The certificate of compliance expiry date prescribed by the Regulations for:

- Plain Film Radiographic X-ray equipment is 2 years after the issue of the certificate.
- Fluoroscopic X-ray equipment is 2 years after the issue of the certificate.
- Computed Tomography scanners is 12 months after the issue of the certificate.
- Mammography X-ray equipment is 12 months after the issue of the certificate.

A certificate of compliance can only be issued by a person who holds an appropriate Tester's Approval issued under the Radiation Act 2005 by the Secretary. The Department publishes, with consent, the names of the approved testers on the abovementioned website. Testers are approved to test one or more types of the prescribed radiation sources.

The Department publishes, on the same website, the prerequisites for obtaining an approval as an approved tester.

## Scope

This publication is intended for approved testers. A Tester's Approval specifies the type of prescribed radiation sources for which the approved tester has been authorised to conduct tests and issue certificates of compliance. The authority is subject to the limitations and conditions specified in this document.

Approved testers may wish to vary the types of prescribed radiation sources for which they are authorised to issue certificates of compliance. In these cases the authority holder must apply to the Department for a variation to the Tester's Approval. The application to vary the authority must be approved by the Department before the authority holder can commence issuing certificates of compliance with respect to the particular radiation source.

## The role of an Approved Tester

The role of the approved tester as defined by Section 25 of the Act is to:

- conduct tests on prescribed radiation sources to determine whether the prescribed radiation sources meet the relevant radiation safety standards; and
- issue certificates of compliance in respect of prescribed radiation sources if the prescribed radiation sources meet the relevant radiation safety standards.

## Auditing of Approved Testers

An auditing program will assess the work of approved testers. It will seek to ensure that testers are meeting their conditions of approval and complying with the provisions of the Act.

The program will include:

- reviewing and analysing test reports; and
- re-testing equipment against selected criteria from the radiation safety standards.

## Enforcement action

Enforcement action will be taken against an approved tester when the approved tester fails to comply with the conditions of the Tester's Approval specified in this document and/or the provisions of the Act.

## Conditions of Tester's Approval

### Condition 1: Assessment report

The approved tester must complete an assessment report following the testing of a prescribed radiation source. The report must include the following information:

1. name of the approved tester;
2. tester's approval number as issued by the Department;
3. date that the report was issued;
4. date that the prescribed radiation source was tested;
5. the X-ray tube serial number of the prescribed radiation source;
6. the manufacture's name and model number or name of the prescribed radiation source;
7. the management licence number that authorised the possession of the prescribed radiation source at the time of testing by the approved tester;
8. authorisation number pertaining to the prescribed radiation source as found in Schedule 2 of the management licence that authorises the possession of the prescribed radiation source at the time of testing by the approved tester;

9. the source reference number of the prescribed radiation source as found in Schedule 2 of the management licence that authorises the possession of the prescribed radiation source at the time of testing by the approved tester. The approved tester may issue an assessment report without a source reference number when the prescribed radiation source is newly acquired and a source reference number has not been issued in respect of the prescribed radiation source;
10. the test measurements and results for each item contained in the applicable radiation safety standard; and
11. details of all non-compliant items identified during the test. All items of non-compliance must be reported including those that are corrected at the time of testing.

The report must be provided to the management licence holder (or the person who requested the test) within 60 days from the date of the test and a copy retained by the approved tester for audit purposes.

## **Condition 2: Certificate of Compliance**

If, following the testing of a prescribed radiation source, the source meets the requirements of every criteria of the applicable radiation safety standard, then the approved tester must issue a certificate of compliance in respect of that source within 60 days from the date of the test.

The certificate of compliance must include the following information:

1. certificate expiry date;
2. the management licence number that authorised the possession of the prescribed radiation source at the time of testing by the approved tester;
3. authorisation number pertaining to the prescribed radiation source as found in Schedule 2 of the management licence that authorises the possession of the prescribed radiation source at the time of testing by the approved tester;
4. the source reference number of the prescribed radiation source as found in Schedule 2 of the management licence that authorises the possession of the prescribed radiation source at the time of testing by the approved tester. The approved tester may issue a certificate of compliance without a source reference number when the prescribed radiation source is newly acquired and a source reference number has not been issued in respect of the prescribed radiation source;
5. the manufacture's name and model number or name of the prescribed radiation source;
6. the X-ray tube serial number of the prescribed radiation source;
7. date that the prescribed radiation source was tested;
8. name of the approved tester;
9. tester's approval number as issued by the Department;
10. approved tester's signature; and
11. date the certificate was issued;

## **Condition 3: Certificate of compliance must not be issued unless the prescribed radiation source is licensed**

The approved tester must not issue a certificate of compliance in respect of a prescribed radiation source unless there is a management licence that is in force and allows the possession of the prescribed radiation source.

## **Condition 4: Re-test requirements**

If a prescribed radiation source does not meet one of the required criteria of the applicable radiation safety standard, then the approved tester must advise the person who requested the test that the prescribed radiation source will have to be repaired to meet the applicable radiation safety standard.

If the prescribed radiation source is re-tested within 60 days of the initial test, then the approved tester is only required to test the item in the radiation safety standard that failed during the initial test.

When a prescribed radiation source has been re-tested, the approved tester must include, in addition to the requirements under Condition 1, the following information in the assessment report:

1. the date of the initial test;
2. the date of the re-test;
3. test measurements and results of the items that have failed during the initial test.

If the prescribed radiation source is re-tested more than 60 days after the initial test, then the approved tester must test of the prescribed radiation source against every item of the applicable radiation safety standard.

### **Condition 5: Approved testers must provide certificate information to the Department**

Under Section 34 of the Act an approved tester must provide to the Secretary the information contained in a certificate of compliance - (a) in writing; and (b) within 7 days of issuing the certificate. In relation to this requirement, the information contained in a certificate of compliance must be provided to the Department in an approved compliance notification spreadsheet. A copy of the spreadsheet can be obtained from the Department via request. The spreadsheet must contain the following information:

1. tester's approval number as issued by the Department;
2. the management licence number that authorised the possession of the prescribed radiation source at the time of testing;
3. the source reference number of the prescribed radiation source as found in Schedule 2 of the management licence that authorised the possession of the prescribed radiation source at the time of testing. The approved tester may submit a notification without a source reference number when the prescribed radiation source is newly acquired and a source reference number has not been issued in respect of the prescribed radiation source. When submitting a notification without a source reference number the approved tester must provide the following:
  - a. the X-ray tube serial number of the prescribed radiation source;
  - b. the manufacture's name and model number or name of the prescribed radiation source; and
  - c. authorisation number pertaining to the prescribed radiation source as found in Schedule 2 of the management licence that authorised the possession of the prescribed radiation source at the time of testing;
4. expiry date of the certificate; and
5. notes (if any).

The compliance notification spreadsheet must be submitted via email to:

[approvedtesters.notifications@dhhs.vic.gov.au](mailto:approvedtesters.notifications@dhhs.vic.gov.au)

### **Condition 6: Copies of documents to be retained by Approved Tester**

A copy of the assessment report, the certificate of compliance, and the compliance test notification submitted to the Department must be retained by the approved tester for each prescribed radiation source tested by the approved tester for at least 5 years. The documents must be made available when requested by an Authorised Officer under the Act.

### **Condition 7: Equipment calibration**

The approved tester must use radiation testing equipment that is:

1. appropriate for the radiation being measured; and
2. calibrated to a recognised standard at regular intervals not exceeding:
  - a. the calibration interval recommended by the manufacturer or 3 years, whichever is lower; or
  - b. 12 months, if the manufacturer has not specified a recommended calibration interval.

## Condition 8: Critical failures

If, during testing of a prescribed radiation source, the source exceeds the critical failure limit specified in Attachment 1 for any one or more of the tests, the approved tester must immediately:

1. notify the management licence holder (or the person who requested the test) of the findings and recommend to them that the source not be used until it has been repaired. The approved tester does not have the authority to take a prescribed radiation source out of service; and
2. report the failure to the Department initially by telephone and then via email within 24 hours of the test.

## Condition 9: Personal radiation monitoring

The approved tester must wear an approved personal radiation monitoring device at all times while testing prescribed radiation sources.

## Condition 10: Radiation safety equipment

The approved tester must ensure that all radiation safety equipment is replaced on the ionising radiation apparatus and that the apparatus is left in a safe condition following testing.

# Frequently Asked Questions

### **1. Is the previous compliance certificate (if it has not yet expired) still valid during/after the current compliance test?**

Yes. A certificate of compliance is valid up to the date of expiry on that certificate. However, if a prescribed source fails any of the criteria in the radiation safety standard, and the Department deems that the source poses a radiation safety risk, the Department may request that the source is taken out of service until it is repaired and re-tested. Any test that meets the criteria of a critical failure is deemed to pose a radiation safety risk.

### **2. For a multi-tube device where each tube is powered by the one generator, is it necessary to test each tube separately against the relevant radiation safety standard?**

Yes. E.g. where the radiation apparatus consists of an over-table plain radiography X-ray tube head and an under-table fluoroscopy tube, both X-ray tubes must be tested against the relevant safety standard even if a single generator powers both devices.

### **3. Is a certificate of compliance required if the prescribed radiation source is in storage or is otherwise not being used?**

No. A certificate of compliance is not required where a management licence holder possesses a prescribed radiation source but the source is not in use (e.g. if it has been decommissioned or is in storage). The Act requires a prescribed radiation source to have a current certificate of compliance before it can be used.

### **4. Will updated versions of the Radiation Safety Standards be issued in the future?**

It is likely that minor changes will be made to the safety standards in due course. Updated versions will be notified via the Government Gazette and published on the Department's website. All approved testers will receive notification of such changes via email.

# Attachment 1: Critical Failures

## Plain Film Radiographic X-ray Equipment

Item	Test	Critical failure	
3.1	Half Value Layer	X-ray Tube Voltage (kVp)	Minimum HVL (mm Al)
		50	1.5
		60	1.8
		70	2.1
		80	2.3
		90	2.5
		100	2.7
		110	3.0
		120	3.2
		130	3.5
		140	3.8
		150	4.1
4.2	Timer Accuracy	$\pm 50\% \pm 2$ pulses of the indicated value	
5.1	kVp Accuracy	kVp accuracy $\geq \pm 10\%$	
6.1	Radiation output reproducibility	Coefficient of variation $\geq 0.1$	
6.2	Radiation output linearity	$\frac{ X_1 - X_2 }{X_1 + X_2} \geq 0.2$	
7.2	Automatic termination of exposure	The exposure must terminate after 6 sec or after an exposure of no more than 600mAs.	
7.3	Reproducibility	$\geq \pm 20\%$ of the mean $\geq \pm 20\%$ of each other	
8.1	Minimum focus to skin distance	Focus to skin distance $< 200$ mm	
9.1	Alignment	Misalignment $> 5\%$	
9.2	Illuminance	Average illumination $< 50$ lux	
11	Tube house leakage	Tube house leakage $> 1$ mGy in 1 hour	
12.1	Leakage radiation with shutter open	Leakage radiation from X-ray tube assembly $> 0.4$ mGy in 1 hour.	

## Fluoroscopic X-ray equipment

Item	Test	Critical failure	
3.1	Half Value Layer	X-ray Tube Voltage (kVp)	Minimum HVL (mm Al)
		50	1.5
		60	1.8
		70	2.1
		80	2.3
		90	2.5
		100	2.7
		110	3.0
		120	3.2
		130	3.5
		140	3.8
		150	4.1
4.3	Radiographic Timer Accuracy	$\pm 50\% \pm 2$ pulses of the indicated value	
5.1	Fluoroscopic Tube kVp Accuracy	kVp accuracy $\geq \pm 10\%$	
5.2	Radiographic kVp Accuracy	kVp accuracy $\geq \pm 10\%$	
6.1	Radiographic Radiation Output Reproducibility	Coefficient of variation $\geq 0.1$	
6.2	Radiographic Radiation Output Linearity	$\frac{ X_1 - X_2 }{X_1 + X_2} \geq 0.2$	
7.2	Automatic Termination of Exposure	The exposure must terminate after 6 sec or after an exposure of no more than 600mAs.	
7.4	Reproducibility	$\pm 20\%$ of the mean	
		$\geq \pm 20\%$ of each other	
8.1	Minimum Focus to Skin Distance	Focus to skin distance $< 200$ mm	
11	Collimation Accuracy for Radiography on Mobile Fluoroscopic Apparatus	Misalignment $> \pm 5\%$	
12	Radiation Exposure Limits	Dose Rate Mode	Max Absorbed dose rate in air
		Manual	$> 100$ mGy/min
		Automatic	$> 150$ mGy/min
		High level (boost)	$> 225$ mGy/min
14	Absorbed Dose Rate in Air at Input Surface of Image Intensifier	$> 20\%$	

## Computed Tomography Scanners

Item	Test	Critical failure	
2.1	Agreement Between Internal and External Scan Plane Lights	$> \pm 5$ mm	
2.2	Co-incidence of Internal Scan Plane Lights and Scan Plane	$> \pm 5$ mm	
2.3	Coronal and Sagittal Plane Lights	$> \pm 5$ mm	
2.4	Axial Scan Incrementation Accuracy	$> \pm 2$ mm	
2.5	Positioning of the Patient Support.	$> \pm 5$ mm	
3.2	Noise, Mean CT number, Uniformity	Parameter	Deviation
		Noise	$\pm 20\%$
		Mean CT number	$\pm 8$ HU
		Uniformity	$\pm 4$ HU
3.3	Reconstructed Slice Thickness	$\pm 1.0$ mm for thicknesses above 2 mm	
		0.25 mm $\pm 50\%$ for thicknesses of 2 mm or less	
4.1	Computed Tomography Dose Index in Air (CTDI)	The CTDI must be within $\pm 10\%$ of the baseline value.	

## Mammography Equipment

Item	Test	Critical failure
2.1	Light field / X-ray Field Alignment	$> 2\%$
2.2	X-ray field/film/breast-support alignment	(iii) Extends $> 4\%$ of the SID beyond any edge of the film
4.1	kVp Accuracy	$\geq 10\%$
4.2	kVp Reproducibility	$COV \geq 0.04$
7.2	Reproducibility	$COV \geq 0.1$
10	MEAN GLANDULAR DOSE	$> 3$ mGy



## More information?

If you require clarification or require more information about this document, please contact the Department's Radiation Team on:

telephone: 1300 767 469  
e-mail: [radiation.safety@dhhs.vic.gov.au](mailto:radiation.safety@dhhs.vic.gov.au)  
website: [www2.health.vic.gov.au/public-health/radiation](http://www2.health.vic.gov.au/public-health/radiation)

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