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Department of Health

## **RADIATION SAFETY ACT 1975**

# **DIAGNOSTIC X-RAY EQUIPMENT COMPLIANCE TESTING**

## **PROGRAM REQUIREMENTS**

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# 1. PROGRAM OVERVIEW

## 1.1 INTRODUCTION

Commencing 1 January 1997, the Radiological Council<sup>1</sup> introduced a program requiring the periodic testing of diagnostic x-ray equipment for compliance with the State's Radiation Safety (General) Regulations and any additional criteria that the Council may apply to the equipment under test.

The need for a program of this type was indicated by —

- studies in Australia and elsewhere demonstrating that poor x-ray equipment performance is a significant contributor to unnecessary patient radiation exposure;
- a trend towards mandatory quality assurance (QA) programs for medical radiology;
- evidence of significant non-compliance documented in inspections conducted by Council's officers.

The tests required are those primarily concerned with radiation safety. However, as patient radiation dose ultimately depends on the total imaging process, these tests should be supplemented by additional radiographic, sensitometric and image quality tests as part of a complete QA program.

The processes involved in the compliance testing program are outlined in Appendix 1. An explanation of the terms used in this document is given in Appendix 7.

## 1.2 EQUIPMENT SUBJECT TO TESTING

The program applies to all diagnostic x-ray equipment used on live humans for medical radiography and fluoroscopy, chiropractic and dental radiography and computed tomography.

## 1.3 FREQUENCY OF TESTING

The program initially required annual testing of medical and chiropractic x-ray equipment and triennial testing of dental intra-oral and panoramic equipment. However, following consideration of the first three years test results and consultation with representatives of equipment owners, users and others, the Council amended the test frequencies to those shown below.

Mammography	12 months
C-arm or U-arm fluoroscopy (fixed or mobile)	12 months
Cone Beam CT	24 months
Other fluoroscopy	24 months

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<sup>1</sup> The Radiological Council is an independent statutory body established under the Radiation Safety Act for the purpose of regulating radiation safety in Western Australia. It reports directly to the Minister for Health.

Radiography	24 months
CT	24 months
Dental (intraoral, panoramic tomography, and equipment with combined panoramic tomography and cephalometry)	36 months

The Council will continue to keep test frequencies under review and may adjust them further should the need arise.

All x-ray equipment used on humans within the scope of the program must be tested and issued with a Compliance Certificate or a Conditional Compliance Certificate before it may be used on patients, unless otherwise exempted by the Radiological Council.

## 1.4 TEST ANNIVERSARY DATE

The continued use of x-ray equipment subject to the compliance testing program after the expiry date of its current compliance certification is an offence. The Radiological Council also may issue a formal direction to cease use of the equipment.

If the new certification expiry date is calculated from the test date, those who have their equipment tested before the current expiry date do not enjoy the full extent of their current compliance period. A fixed anniversary date has thus been adopted, according to which expiry dates are calculated as follows:

Equipment test date	New expiry date
Equipment tested not more than three months before the current expiry date	The current expiry date plus one test period
Equipment tested more than three months before the current expiry date	The test date plus one test period
Equipment tested not more than six months after the current expiry date	The current expiry date plus one test period
Equipment tested more than six months after the current expiry date	The test date plus one test period

As an example of the application of the above, take the current compliance certification expiry date of a dental x-ray machine as 1 September 2005. The owner has the machine tested on 1 June 2005. As the equipment was tested not more three months before the expiry date, the new expiry date is 1 September 2005 plus 36 months, which is 1 September 2008.

Regarding Notices of Non-Compliance, the new Compliance Certificate shall be given an expiry date derived from that of the previous Compliance Certificate expiry date plus the prescribed test frequency or, for a first test, from the date the test commenced plus the prescribed test frequency.

## 1.5 RESPONSIBILITY FOR TESTING

Under Section 28 of the Act, the 'owner' of x-ray equipment, or the person having possession, must apply for its registration. Through conditions imposed on the registration under Section 36 of the Act, the registrant is legally responsible for satisfying the requirements of the compliance testing program.

Registrants must ensure that their x-ray equipment is tested by a licensed compliance tester at the prescribed frequency. Tests need to be scheduled in a timely manner to ensure that new certificates can be issued before earlier certificates expire.

A list of licensed compliance testers is available from the Radiological Council.

The conditions, restrictions and limitations imposed on registrations under Section 36 of the Radiation Safety Act make it an offence to operate or use x-ray equipment for human diagnostic radiography or fluoroscopy unless it has —

- (a) a current **Certificate of Compliance** (see section 2.3); or
- (b) a current **Certificate of Conditional Compliance** (see section 2.4);
- (c) a current **Certificate of Provisional Compliance** (see section 2.5);

'Current' means that the certificate was issued within the previous 12, 24 or 36 months (depending on the prescribed test frequency stated in section 1.3).

Examples of compliance and conditional compliance certificates are given in Appendix 2.

## 1.6 TEST PROTOCOLS

The prescribed tests assess compliance with the Radiation Safety (General) Regulations and with any other Council requirements that may apply to the equipment under test.

A series of workbooks developed by a working group of the Council describe the tests to be undertaken for each category of equipment as well as the approved test protocols. These workbooks are kept under review and updated from time to time.



Currently available are:

Computed Tomography Equipment Workbook 2019  
Dental X-ray Equipment Workbook 2023  
Digital Flat Panel Fluoroscopic Equipment Workbook 2018  
Digital Image Intensifier Fluoroscopic Equipment Workbook 2018  
Digital Mammographic Equipment Workbook 2020  
Major Radiographic Equipment Workbook 2015

In addition to the following workbooks currently under review:

Workbook 1 – Mobile Radiographic Equipment  
Workbook 7 – Mobile Digital Radiographic Equipment

Workbooks can be obtained from the Radiological Council.

Variations to the recommended test protocols may be used provided they are approved by the Radiological Council. Documentation supporting alternative test protocols must be provided to the Council.

Details of the required tests are given in section **Error! Reference source not found..**

## 1.7 TEST PERSONNEL

Compliance testing may only be undertaken by a person who holds a licence under the Radiation Safety Act for that purpose or by a person acting under the direction and immediate personal supervision<sup>1</sup> of a compliance testing licensee.

All tests must be assessed and certified by a qualified expert. The licensed compliance tester must ensure that the completed test report is submitted to a qualified expert within 1 month.

A qualified expert is eligible for a compliance testing licence and may both carry out and certify tests without independent certification of the test results.

The requirements for approval as a qualified expert and the prerequisites for applicants applying for compliance testing licences are given in sections 3 and 4 respectively.

**Note:** *Persons who undertake compliance testing concurrently with the service or maintenance of x-ray equipment should take particular note of section 2.9.*

## 1.8 ACCURACY SPECIFICATION

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<sup>1</sup> 'Immediate personal supervision' requires the licensee to be physically present and to observe directly persons working under their direction and supervision.

Whilst the purchase of measuring equipment such as non-invasive x-ray beam analysing instruments, ion chambers etc is a matter of choice for the tester, it is a requirement that the accuracy of such equipment for the relevant parameter is  $\pm 3\%$  or better.

## 2. DOCUMENTATION, CERTIFICATION AND ASSESSMENT OF COMPLIANCE TESTS

The Radiological Council, at its discretion, may at any time reject and invalidate any compliance test or part thereof, and may require the withdrawal of any certificates, labels or notices prescribed by this program which it finds has or may have been issued on the basis of unapproved test methods, invalid, incomplete or inaccurate test data, or other information which cannot be substantiated.

### 2.1 TEST REPORTS

In keeping with the prescribed test frequencies and when requested by the registrant (owner), a licensed compliance tester will carry out all the tests required by the Council using the protocols described in the relevant workbook or protocols otherwise approved by the Council (see section 1.6).

To standardise reporting, test report forms are provided in each workbook. These may be reproduced as necessary. Testers may style forms to suit their own needs and record keeping systems. However, copies of test reports provided to the Council must be on the standard form<sup>1</sup> included in the relevant workbook, or on any updated versions subsequently approved by the Council.

The compliance tester must provide the qualified expert with all the test results including copies of relevant x-ray films or images, waveforms and computer printouts.

All x-ray equipment faults determined during testing must be reported even if such faults are corrected before testing is completed. Where an item of non-compliance is corrected during the test, both the pre- and post-correction test data must be included in the report.

Compliance tests that cannot be completed because of faults with the x-ray equipment must also be reported. See also section 2.9.

### 2.2 CERTIFICATION AND ASSESSING

All compliance test reports must be signed initially by the tester. The test report must also be signed by the qualified expert after assessing the report.

The signed test report will be used by the qualified expert as the basis for issuing, or not issuing (as the case may be), a Compliance Certificate for the equipment tested.

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<sup>1</sup> The 'standard form' for any report can be supplied to the tester by email. The term 'standard form' comprises the individual items of the report sheets, and the order in which they are listed, as shown in the workbooks, but excludes the detailed formats of the items. For example, the tester may replace ☒ with [✓], fonts or spacing may be changed etc, but additions, deletions or rearrangements of the order of identifying codes, version numbers, questions, results or other items will not be accepted. Council approval of any changes made by the tester is required prior to use of the form.

**Note:** A test report bearing only a tester's signature indicates that the compliance test has been conducted in accordance with the approved test protocol, that the identifying information stated is correct and that the measurements obtained are accurate within the accepted errors inherent in the measuring equipment. It does not necessarily indicate that the equipment complies with the Radiological Council's requirements.

A copy of the assessed and signed test report, together with a copy of the Compliance Certificate, must be emailed within 2 months of the date the test commenced to the Council.

The registrant, compliance tester and qualified expert should also retain copies.

Council officers may review the test reports and use the data to monitor the performance of the program. The review process may include re-testing of equipment by Council officers either on a random basis or to provide clarification of matters arising from a specific report.

## 2.3 CERTIFICATE OF COMPLIANCE

A Certificate of Compliance will be issued by a qualified expert when they are satisfied that the x-ray equipment fully satisfies the assessment criteria of the compliance test.

The certificate is valid for a period of 1, 2 or 3 years from the commencement date of the full test depending on the test frequency established for the particular equipment category (See section 1.3).

The Radiological Council's Certificate of Compliance is the only form of approval that may be issued. Each certificate is individually numbered and must not be duplicated (by any means) until it has been completed and signed by a qualified expert. The certificate number is derived as follows: sequential certificate number (for the QE for that calendar year)/year/QE initials.

A copy of the completed certificate must be forwarded to the Council together with a copy of the signed test report. The registrant should be given the original compliance certificate with copies retained by both the qualified expert and the compliance tester.

Registrants must retain a copy of the compliance documentation for all equipment in their possession. In the case of equipment that is sold or transferred to another owner all current compliance documents, including the certificate, must be handed to the new owner. This does not apply when the equipment is transferred to another site or practice belonging to the same registrant. However, in all cases when disassembly and reassembly of equipment that might affect its compliance status is involved, tests must be undertaken to ensure that compliance is not adversely affected during this process. The registrant is responsible for ensuring the equipment remains compliant.

A sample Certificate of Compliance is shown in Appendix 2.

## 2.4 CERTIFICATE OF CONDITIONAL COMPLIANCE

Conditional Compliance may be issued for x-ray equipment which does not comply fully with all program requirements but for which, in respect of the non-complying item(s), the Council is satisfied that there is no significant radiation risk to either patients or users.

Conditional Compliance may be applicable for:

- x-ray equipment that was first registered before the introduction of the compliance testing program (1 January 1997) and where its design and/or performance could not be modified, adjusted or repaired to comply fully with the program requirements; and
- x-ray equipment that was issued with a full Compliance Certificate prior to the current compliance test but which, due to 'wear and tear' or the unavailability of parts or components, no longer fully complies and can no longer be modified, adjusted or repaired to meet the compliance requirements.

Conditional Compliance will **not** be issued if a fault directly or indirectly relates to:

- x-ray beam quality (half value layer);
- radiographic x-ray / light beam congruency or x-ray beam dimensions;
- maximum permitted fluoroscopic dose rates;
- radiation leakage from the x-ray tube assembly (including the collimator);
- x-ray exposure warning devices (including the fluoroscopic timer);
- interlocks which are intended to prevent x-ray exposures when prescribed safe operating conditions are not met;
- patient dose / dose-rate limits or constraints that are prescribed by regulations or registration conditions;
- exposure reproducibility;
- any other matter that in particular circumstances the Council considers significant.

Conditional compliance is not transferable should the x-ray equipment be sold (as defined in the Act) and may be void if the x-ray equipment is relocated.

Depending on the nature of the non-compliant item(s), Council may stipulate a 'use by' date beyond which Conditional Compliance will not be extended. In such circumstances, the Council may give the registrant up to 6 years to plan for the equipment's replacement or its withdrawal from service. This period may be varied on a case-by-case basis on application by the registrant. The expiry date of this period will be stated on the certificate, together with the item(s) of non-compliance.

Regular compliance testing at the prescribed frequency will still be required for the class of equipment.

The Radiological Council's Certificate of Conditional Compliance is the only form of approval that may be issued. Each certificate is individually numbered and must not be duplicated (by any means) until it has been completed and signed. The certificate may be withdrawn or varied at any time by the Council.

Conditional Compliance is authorised by the Council and therefore will only be issued on application and on a case-by-case basis.

Registrants must retain a copy of the compliance documentation for all equipment in their possession.

A sample Certificate of Conditional Compliance is shown in Appendix 2.

## **2.5 CERTIFICATE OF PROVISIONAL COMPLIANCE**

Provisional Compliance may be issued for new modalities of x-ray equipment not previously covered in the program requirements, and for which Council has determined the compliance program should apply, for the interim period until specific tests for the modality are approved by the Council.

The Radiological Council's Certificate of Provisional Compliance is the only form of approval that may be issued. Each certificate is individually numbered and must not be duplicated (by any means) until it has been completed and signed. The certificate may be withdrawn or varied at any time by the Council.

Provisional Compliance is authorised by the Council and therefore will only be issued on application and on a case-by-case basis.

Registrants must retain a copy of the compliance documentation for all equipment in their possession.

## **2.6 COMPLIANCE LABELS**

X-ray equipment that has been tested and certified to comply must be labelled. Only the labels approved by the Radiological Council may be used.

For full compliance, yellow self-adhesive labels identifying the compliance certificate expiry date, the certificate number and the name of the tester and qualified expert are issued with the compliance certificate.

For conditional compliance, magenta self-adhesive labels are issued identifying the registrant, their registration number, the compliance certificate expiry date and the certificate number.

The label for the specified x-ray equipment must be fixed in a conspicuous position on the equipment or control panel. Sample labels are shown in Appendix 3.

## 2.7 NON-COMPLYING EQUIPMENT

Section 2.4 deals with non-complying equipment that may be eligible for a Certificate of Conditional Compliance. However, non-complying equipment that is ineligible for conditional compliance must be repaired or modified to correct the identified faults (see also 2.8).

### ***Immediate response to avoid unacceptable radiation exposure***

Should a qualified expert believe that continued use of the x-ray equipment may place patients, the public or users at risk of significant and unnecessary radiation exposure, he or she should promptly inform the Council and provide acceptable supporting evidence for their belief. Council's officers will review the evidence and give prompt consideration to issuing an immediate direction to the registrant to cease use of the equipment until the identified item(s) of non-compliance are corrected.

Notices to Cease Use (4) may only be issued by an authorised person e.g. the Secretary to the Radiological Council.

### ***Response for non-urgent matters***

If the need for correction is not urgent, the qualified expert will issue a Notice of Non-Compliance to the registrant listing items that must be corrected within a 3 month period in order for a compliance certificate to be issued (unless an alternative time period is stipulated by the Council).

In these situations, a certificate will not be issued for the equipment until the items of non-compliance have been corrected. However, the qualified expert's written Notice of Non-Compliance identifying the items requiring correction, together with the date by which those actions must be taken, will entitle the registrant to a period of temporary exemption from compliance.

**Note:** *Irrespective of the expiry date of the Notice of Non-Compliance, the new Compliance Certificate shall be given an expiry date derived from that of the previous Compliance Certificate expiry date plus the prescribed test frequency or, for a first test, from the date the test commenced plus the prescribed test frequency (section 1.4).*

Corrective actions are the responsibility of the registrant. However, the qualified expert and the compliance tester should liaise with the registrant to ensure that non-complying items are corrected in a timely manner and, if necessary, re-tested before a compliance certificate is issued.

Notices of Non-Compliance must be provided to the registrant by the qualified expert within 1 month of receipt of the test report, with a copy to the Radiological Council. An example of the Notice of Non-Compliance is provided in Appendix 4.

### ***New x-ray equipment which does not comply***

New x-ray equipment with items of non-compliance that cannot be corrected

may either receive an exemption for that item from the Council, or be refused registration.

It is an offence for x-ray equipment to be sold unless it complies with the regulations or other criteria specified by the Radiological Council, or unless prior written approval has been given by the Council to the seller and purchaser. Sellers may be prosecuted for breaching the Act and registration of the equipment may be refused.

However, the Council recognises that changes in technology may supersede regulatory requirements. Provided such changes can be justified in the clinical or practical context and do not give rise to unacceptable radiation exposure, Council may consider an exemption under Section 6 of the Act in respect of the non-complying item(s) and approve sale of the equipment without further modification. If approval is given, the particular equipment would be exempted from the specific regulation or criterion (although additional design and/or performance criteria may be imposed in respect of the exempted feature) and normal compliance testing procedures will apply.

X-ray equipment for which an exemption has been granted and which otherwise complies fully with the program requirements will be issued with a Compliance Certificate.

Where an exemption has general application, the Council will consider amending both the program requirements and the Regulations to reflect Council's decision.

## **2.8 EXEMPTIONS**

A registrant who possesses x-ray equipment that cannot meet either full or conditional compliance requirements but which the registrant believes serves an ongoing clinical need, may make application to the Radiological Council for an exemption.



## **2.9 COMPLIANCE TESTING BY SERVICE PERSONNEL**

Where compliance tests are performed by persons who are also licensed to service x-ray equipment, the compliance test report must show the performance of the equipment *before* any service is undertaken (unless a particular fault renders further testing invalid) i.e. compliance testing, if due, must precede any routine service and maintenance procedure.

Faults found during testing must be detailed on the report form even if they are corrected before completion of testing. Some faults may be common to the particular model of x-ray equipment and failure to report them may put other users and patients at risk.

## **2.10 CALIBRATION OF RADIATION MEASURING INSTRUMENTS**

Compliance tests involving the use of radiation measuring instruments are valid only if suitable instruments are used and they have been calibrated not more than two years before the compliance test by an organisation recognised by the Radiological Council.

### 3. REQUIREMENTS FOR QUALIFIED EXPERTS

#### 3.1 FUNCTIONS

Persons approved as qualified experts by the Radiological Council must have proven competencies in compliance testing and quality assurance procedures relevant to diagnostic medical imaging. A qualified expert who also intends carrying out compliance testing must hold a licence for the purpose.

The qualified expert shall —

- verify that all radiation measuring instruments used for the tests are suitable for the purpose and have been calibrated within the 2 years preceding the compliance test;
- verify that the compliance tests have been performed by a licensed tester according to the relevant workbook or by following other protocols approved by the Council;
- issue, as appropriate, either a signed Compliance Certificate and compliance label for display on the x-ray control panel, or a Notice of Non-Compliance, within 1 month of receiving the test report from the compliance tester;
- where relevant, provide copies of the assessed and signed test report and a copy of the compliance certificate to the Council within 1 month of the date of receipt of the report. (The Council may, at any time, request the provision of the full compliance test data.);
- where relevant, ensure that Notices of Non-Compliance are issued promptly to the registrant, and a copy forwarded to the Council within 1 month of the date of receipt of the report;

**Note:** *Corrective actions are the responsibility of the registrant. However, the qualified expert and the compliance tester should liaise with the registrant to ensure that non-complying items are corrected in a timely manner and, if necessary, re-tested before a compliance certificate is issue.*

#### 3.2 ROLE AND RESPONSIBILITIES

The qualified expert —

- by signing a compliance test report is responsible for determining the compliance or otherwise of the equipment on the basis of the test data provided by the licensed compliance tester.
- must either personally perform the tests

or

- must liaise appropriately with the compliance tester and exercise a sufficient level of control to ensure that the protocols are followed and that the test results are reliable.

### 3.3 QUALIFICATIONS

A university degree in physics, engineering or a related science.

In exceptional circumstances a lesser qualification may be acceptable if in combination with demonstrated expertise in a health specific radiation discipline.

### 3.4 ASSESSMENTS

Passes will be required in —

- a written examination which tests knowledge of the physics of radiology, imaging technology and radiation protection; and
- a practical examination in compliance testing.

A syllabus for the written examination is given in Appendix [5](#).

Applications for approval as a qualified expert should be addressed to the Secretary of the Radiological Council enclosing a statement of the applicant's qualifications and experience.

### 3.5 EQUIVALENT ACCREDITATIONS

The Radiological Council will accept as qualified experts persons who have gained certification in Radiology Medical Physics from the Australasian College of Physical Scientists and Engineers in Medicine.

Persons holding accreditations with other authorities should apply to the Council for consideration of those accreditations.

### 3.6 LICENSING

Persons who are approved as qualified experts are also eligible to apply for a compliance testing licence.

Qualified experts who are also licensed compliance testers may sign and forward their own reports to the Radiological Council. Certification by an independent qualified expert is not required.

## 4. REQUIREMENTS FOR COMPLIANCE TESTERS

### 4.1 FUNCTIONS

Persons carrying out compliance tests to satisfy the requirements of the Radiological Council must be licensed for this purpose or be acting under the direction and immediate personal supervision<sup>1</sup> of a licensed compliance tester. All test reports must be assessed and certified by a qualified expert.

Licensees must —

- have a working knowledge of the x-ray equipment;
- conduct the tests according to the protocols in the relevant workbook or use other protocols approved by the Radiological Council;
- ensure that the reported test results are accurate within the accepted error of the test equipment and that all data reported, including equipment and owner identification, is a true record pertaining to the equipment under test;
- submit the test report to a qualified expert for assessment within 1 month of the commencement date of the test.

**Note:** *Corrective actions deemed necessary by a qualified expert are the responsibility of the registrant. However, the qualified expert and the compliance tester may wish to liaise with the registrant to ensure that non-complying items are corrected in a timely manner and, if necessary, re-tested before a compliance certificate is issued.*

### 4.2 QUALIFICATIONS

A relevant technical qualification acceptable to Council, or equivalent experience in a medical radiation field.

### 4.3 ASSESSMENTS

The assessment syllabus for compliance testers is given in Appendix 6.

Applicants must pass —

- a multiple choice core examination in the fundamentals of radiation safety; and
- a written examination which tests knowledge of compliance testing, including physical principles and methods; and

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<sup>1</sup> *'Immediate personal supervision' requires the licensee to be physically present and to directly observe persons working under their direction and supervision.*

- a practical compliance testing examination for each modality to be tested, supervised by an independent<sup>1</sup> qualified expert licensed to conduct compliance tests.

Applicants who hold a licence for the service of diagnostic x-ray equipment may be exempted from the core examination.

A licence for compliance testing of dental x-ray equipment only is also available.

## 4.4 TRAINING

Applicants who require additional theoretical training prior to the written and practical examination may find it useful to attend relevant parts of a suitable Radiological Council recognised course. Instruction might also be obtained from a qualified expert. Applicants should contact the Council for further advice on suitable courses.

To comply with Sections 25 and 36 of the Radiation Safety Act, practical experience in compliance testing can only be gained under the direction and immediate personal supervision of a licensed compliance tester i.e. the licensee must be present whenever the trainee initiates an exposure. A minimum of one machine of the type in question must be tested before considering eligibility for the practical examination.

When undertaking the practical compliance testing examination both a licensed compliance tester and the qualified expert must be present. This may be the same person if the qualified expert also holds a licence for compliance testing.

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<sup>1</sup> *Independent – having no familial, matrimonial, business etc relationships.*

## **4.5 LICENSING**

Persons who satisfy the qualifications and assessment criteria are eligible to apply for a compliance testing licence.

See also section 2 of this workbook for the requirements for a valid compliance test.

## PUBLICATIONS

1. **Radiation Safety Act 1975 (and Amendments)**  
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3. **Radiation Doses to Patients from Dental Radiography in New Zealand.**  
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4. **Variability of Medical Diagnostic X-ray Machine Parameters as determined from a National Survey.**  
National Radiation Laboratory, Christchurch, New Zealand  
Le Heron J, Report NRL 1989/1
5. **Assurance of Quality in the Diagnostic X-ray Department.**  
British Institute of Radiology 1988
6. **Quality Control in Diagnostic Imaging**  
Gray J E, Winkler N T, Stears J and Frank E D.  
University Park Press 1983
7. **Radiation Doses to Patients in Medical Diagnostic X-ray Examinations in New Zealand: a 1983-84 Survey.**  
National Radiation Laboratory, Christchurch, New Zealand  
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Report NRL 1993/1
8. **Quality Assurance for Diagnostic Imaging Equipment.**  
National Council on Radiation Protection and Measurements  
NCRP Report No 99
9. **2007 Recommendations of the International Commission on Radiological Protection.**  
ICRP Publication 103, 2007
10. **Recommendations for limiting exposure to ionizing radiation (1995)**  
National Health and Medical Research Council

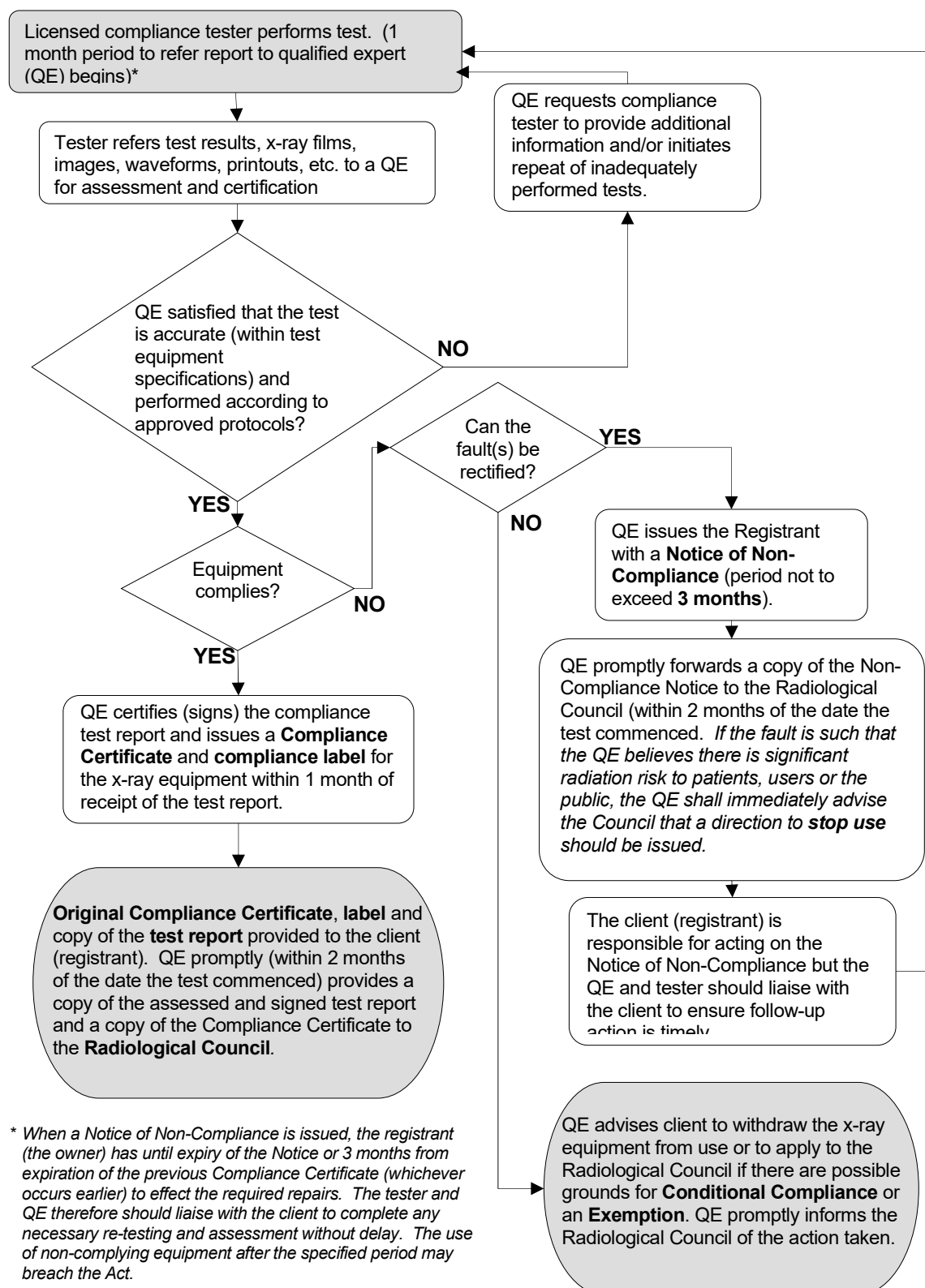




# **APPENDIX 1**

## **COMPLIANCE TESTING PROCESS FLOW CHART**





### Overview of the Processes in Compliance Testing



## **APPENDIX 2**

### **COMPLIANCE CERTIFICATES**



# **RADIATION SAFETY ACT (WA)**

## **CERTIFICATE of COMPLIANCE**

*for the following x-ray equipment:*

**Manufacturer**

**Model**

**Serial Number**

**Equipment Use**

**Registrant**

**Premises Location**

**Location on Premises**

**Tested by**

**Licence No.**

**Test Date**

*I certify that, at the date of test, the equipment satisfied the compliance assessment criteria stipulated by the Radiological Council in the Workbook applicable to this class of equipment.*

**Qualified Expert<sup>1</sup>**

**Signature**

**Certificate Number**

**Expiry Date**

---

<sup>1</sup> A 'qualified expert' means an expert whose qualifications are approved by the Radiological Council.

# RADIATION SAFETY ACT (WA)

## CERTIFICATE of CONDITIONAL<sup>1</sup> COMPLIANCE

*for the following x-ray equipment:*

Manufacturer

Model

Serial Number

Equipment Use

Registrant

Registration No.

Premises Location

Location on Premises

Tested by

Test Date

*At the date of test, the equipment satisfied the compliance assessment criteria stipulated by the Radiological Council in the Workbook applicable to this class of equipment, **except in respect of the following item(s):***

Radiological Council Authorised Person:

Certificate Number

Expiry Date<sup>2</sup>

---

<sup>1</sup> This certificate is not transferable and is valid only for the current compliance period. Compliance has been issued on the grounds that faults identified are unlikely to impact on patient or occupational doses and inherent design features of the unit make corrective modification infeasible.

<sup>2</sup> The Radiological Council has stipulated that Conditional Compliance applies for a maximum period of 6 years. Routine compliance testing at the specified frequency for this class of equipment must continue during this period.  
Conditional Compliance certificates will not be issued for this machine after .....




## **APPENDIX 3**

### **SAMPLE COMPLIANCE LABELS**



	<b>RADIATION SAFETY ACT 1975 WESTERN AUSTRALIA</b>	
This x-ray unit has been tested and found to comply with the Radiation Safety (General) Regulations and additional requirements imposed under Section 36 of the Act.		
Tested by	<input type="text"/>	Expiry Date <input type="text"/>
Certified by	<input type="text"/>	Certificate # <input type="text"/>

Compliance label - yellow

	<b>RADIATION SAFETY ACT 1975 WESTERN AUSTRALIA</b>	
This x-ray equipment has been tested for compliance with the Radiation Safety (General) Regulations and additional requirements imposed under Section 36 of the Act. Certification of compliance is conditional and is restricted to the current registrant.		
Registrant	<input type="text"/>	Expiry Date <input type="text"/>
Registration #	<input type="text"/>	Certificate # <input type="text"/>

Conditional compliance label - magenta

*Shown larger than actual size*



## **APPENDIX 4**

### **NOTICES OF NON-COMPLIANCE AND CEASE USE**



**RADIATION SAFETY ACT 1975****NOTICE OF NON-COMPLIANCE**

*for the following x-ray equipment:*

<b>Manufacturer</b>	<b>Model</b>
<b>Serial No.</b>	<b>Location</b>
<b>Equipment Use</b>	<b>Test Date</b>
<b>Tested by</b>	<b>Lic No.</b>
<b>Registrant</b>	

The following corrective actions must be undertaken by<sup>1</sup>:

- 1.
- 2.

**Signature** \_\_\_\_\_ **Date** \_\_\_\_\_  
**Qualified Expert<sup>2</sup>**

Copies of this document must be provided forthwith to the Registrant and the Radiological Council

<sup>1</sup> The Radiological Council has stipulated that Conditional Compliance applies for a maximum period of 6 years. Routine compliance testing at the specified frequency for this class of equipment must continue during this period.  
this period.

Conditional Compliance certificates will not be issued for this machine after .....

<sup>2</sup> Qualified Expert' means an expert whose qualifications are approved by the Radiological Council.

## RADIATION SAFETY ACT 1975

# NOTICE UNDER SECTION 46

*to CEASE USE of the following x-ray equipment:*

<b>Manufacturer</b>	<b>Model</b>
<b>Serial No.</b>	<b>Location</b>
<b>Equipment Use</b>	<b>Test Date</b>
<b>Tested by</b>	<b>Lic No.</b>
<b>Registrant</b>	

**TO:**

I, ....., being a duly appointed 'authorised officer' for the purposes of the Radiation Safety Act 1975 (the Act), and being of the opinion that the irradiating equipment specified above may affect the safety or health of any person if the equipment is permitted to continue to be used without a current certificate of compliance (as required as part of the conditions of registration), hereby direct you –

- (a) to stop using the equipment immediately, and
- (b) to not resume using the equipment until –
  - (i) the following non-compliant items have been corrected:
  - (ii) the equipment has been retested for compliance
  - (iii) a certificate of compliance has been issued in respect of the equipment
  - (iv) notice of completion of the requirements set out at (i), (ii) and (iii) has been given to the Radiological Council
  - (v) notice has been received that this direction has been withdrawn.

<b>Signature</b> _____	<b>Date</b> _____
<b>Authorised Officer</b>	

***Note** that in accordance with provisions of Section 12 of the Act, you have a right to apply to the State Administrative Tribunal for a review of this decision within 28 days from the day on which the decision was made.*



## **APPENDIX 5**

### **QUALIFIED EXPERT SYLLABUS**



## WRITTEN ASSESSMENT

### 1. Interactions between x-rays and matter

- 1.1 Nature of x-radiation
- 1.2 Interaction processes:
  - photoelectric effect
  - characteristic radiation
  - Compton scattering
  - bremsstrahlung
  - x-ray spectrum
- 1.3 Attenuation:
  - monoenergetic attenuation
  - linear attenuation coefficient
  - half-value layer
  - factors affecting attenuation
- 1.4 Scattered radiation:
  - effect of kV, field size, thickness

### 2. Production of x-rays

- 2.1 X-ray spectrum:
  - general radiation
  - characteristic radiation
- 2.2 Effect of variation of:
  - kV
  - mA
  - filtration
  - voltage waveform
- 2.3 X-ray tubes:
  - principal types and construction
  - line focus principle
  - heel effect
  - causes of failure
  - HT cables
  - tube ratings
  - tube housing leakage
- 2.4 Types of generators:
  - rectification
  - 3-phase, 6- and 12 pulse
  - medium frequency
  - capacitor discharge
  - battery powered
- 2.5 Exposure timers.
- 2.6 Automatic exposure control.

### 3. Filters, collimators, grids

- 3.1 Filtration:
  - inherent
  - added
  - K-edge (erbium, hafnium)
- 3.2 Types of collimators:
  - radiography
  - fluoroscopy
- 3.3 Scatter reduction
  - collimation

techniques:

- compression
- grids (grid ratio)
- air gaps

## **4. Radiographic films, screens and processing**

### **4.1 Film:**

- structure of x-ray film
- latent image formed by light or x-rays
- photographic density
- characteristic curve and film contrast, latitude
- speed
- spectral sensitivity

### **4.2 Luminescent screens:**

- general principles
- intensification factor
- speed
- types of phosphor
- emission spectrum
- resolution
- response to kV

### **4.3 Film processing:**

- darkroom safelights
- manual processing
- automatic processors

## **5. Radiographic image**

### **5.1 Contrast:**

- subject contrast
- film contrast
- fog

### **5.2 Image quality:**

- quantum mottle - noise
- sharpness
- limiting resolution
- line spread function
- modulation transfer function
- Weiner power spectrum

### **5.3 Geometrical considerations:**

- effect of magnification
- effect of focal spot size
- distortion

## **6. Image intensification and TV chain**

### **6.1 Principles of system.**

### **6.2 Design and operation.**

### **6.3 Performance characteristics:**

- contrast, resolution, Gx
- distortion
- veiling glare
- MTF

### **6.4 Automatic brightness control.**

## 7. Digital radiographic systems

- 7.1 Modalities:
  - computed radiography, principle of photostimulable plate
  - charge coupled devices, principle of CCD chip, CMOS and uses in fluoroscopy, mammography and dental radiography
  - indirect flat panel, principle of thin film transistor array
  - direct flat panel, principle
- 7.2 Image production and processing:
  - general principles of laser read out in computed radiography and display in other modalities
  - image processing techniques available
- 7.3 System performance:
  - correlation of 'exposure index' and incident plate dose for various manufacturers, e.g. Agfa 'IgM', Fuji 'S', etc
  - relationship between incident dose and dynamic range of image
  - calibration of dynamic range
  - other aspects of system performance including: erasure cycle efficiency, sensitivity index consistency/sensitivity, uniformity, blurring, limiting resolution, threshold contrast detail detectability

## 8. Types of x-ray machines

- 8.1 Familiarity with:
  - dental, mobile radiographic, fluoroscopic, CD units
  - chest and general x-ray units
  - fluoroscopic tables, C-arms and special units
  - mammography units
  - CT scanners

## 9. Instrumentation

- 9.1 Ionisation chambers:
  - principles of ionisation chambers
  - types of ionisation chambers
  - calibration of chambers
  - maintenance of chamber
- 9.2 Non-invasive testers e.g. NERO:
  - principles of the test device
  - familiarity with and ability to use test device and associated software for kV, mA, timer, reproducibility checks, HVL measurement etc
- 9.3 Image quality test objects e.g. Leeds test object:
  - principles of the device
  - familiarity with and ability to use the test object correctly according to the manufacturer's instructions regarding test factors

## 10. Compliance tests

- 10.1 Workbook tests:
- knowledge of the physical basis of the tests
  - assessment of alternative methods of performance of the tests
  - ability to perform the tests

## 11. Physical concepts

- 11.1 Radiation units:
- exposure (air kerma)
  - absorbed dose

## 12. Radiation protection concepts

- 12.1 ICRP 60:
- principles of justification
  - optimisation
  - dose limits
  - dose constraints
  - occupational exposure
  - medical exposure
  - population exposure
  - radiation weighting factor
  - equivalent dose
  - tissue weighting factor
  - effective dose
- 12.2 Protection of the patient:
- summary of principles given in ICRP 62 (in Summary)

## 13. Practical radiation protection

- 13.1 Inverse square law and distance.
- 13.2 Shielding:
- control area barriers
  - personal aprons, lead effectiveness etc
- 13.3 Personal monitoring:
- basic understanding of personal radiation monitoring dosimetry

## 14. Regulations

- 14.1 ICRP 57:
- familiarity with section on requirements for diagnostic imaging equipment
- 14.2 State Regulations:
- familiarity with sections dealing with diagnostic imaging equipment

## PRACTICAL ASSESSMENT

- A pass in the written paper is normally required before candidates without compliance testing experience may attempt the practical assessment.
- The assessment involves the candidate performing a compliance test under the direct supervision of a qualified expert who holds a licence for compliance testing.
- The documented test and the qualified expert's report on the candidate's performance are then submitted to the Council for consideration.

- If, by mutual agreement with a qualified expert, a candidate has taken and passed a practical assessment before applying to sit the written examination, no additional practical assessment will be required.
- Candidates who require tuition before the practical assessment must be under the immediate personal supervision of a person who holds a licence for compliance testing. This person does not have to be a qualified expert.

## References

### **Applied imaging technology: Lecture notes for the DRACR examination.**

#### **Part 1: Radiodiagnosis.**

Heggie, J. C. P., Liddell, N. A., Mather, K. P.  
St. Vincent's Hospital, Melbourne, 1993.

#### **The Physics of Radiology.**

Johns, H. E., Cunningham, J. R.  
Charles C. Thomas, Springfield, 1983.

### **1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60**

Pergamon Press 1990.

### **Radiological Protection of the Worker in Medicine and Dentistry.**

#### **ICRP Publication 57**

Pergamon Press, 1990

### **Radiological Protection in Biomedical Research (includes Summary of the Current ICRP Principles for Protection of the Patient in Diagnostic Radiology)**

#### **ICRP Publication 62**

Pergamon Press, 1993

### **Diagnostic X-Ray Equipment Compliance Testing Workbooks**

Radiological Council of Western Australia 2005

### **Radiation Safety (General) Regulations 1983 (and amendments)**

### **Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems**

Report of Task Group #10, American Association of Physicists in Medicine, 1998

### **Protocol for the QA of Computed Radiography Systems: Routine QA Tests**

Kings Centre for the Assessment of Radiological Equipment (KCARE), London, 2004.

### **Specification, acceptance testing and quality control of diagnostic X-ray imaging equipment.**

Seibert J A, Barnes G T and R G Gould

AAPM Medical Physics Monograph No 20, 1994, American Institute of Physics.





## **APPENDIX 6**

### **COMPLIANCE TESTER SYLLABUS**



## WRITTEN ASSESSMENT

The written assessment comprises two sections:

- **Core Paper**  
*Closed book, one-hour paper covering general radiation safety*
- **Main Paper**  
*Open book, two-hour paper covering compliance testing*

The main paper is based on material contained in the Radiological Council's workbooks for the following equipment categories —

- Mobile Radiographic
- Mammographic
- Major Radiographic
- Fluoroscopic
- Dental Radiographic
- Computed Tomography

Two main papers are available depending on the applicant's needs. One deals with dental x-ray equipment (*with reference to the dental workbook only*) and the other with all medical and dental categories (*with reference to all workbooks*).

### 1. Core Paper –

- 1.1 Legislation: ➤ Radiation Safety Act and Regulations
- 1.2 Dose limits: ➤ workers and members of the public
- 1.3 Radiation types & properties.
- 1.4 Background radiation.
- 1.5 Quantities and units of measurement.
- 1.6 Biological effects.
- 1.7 Radiation risk.
- 1.8 Basic radiation safety calculations.
- 1.9 Inverse square law.
- 1.10 Pro rata dose calculations.
- 1.11 Personal radiation monitoring.
- 1.12 Principles of protection: ➤ time, distance and shielding

### 2. Main Paper –

- 2.1 Half value layer
- 2.2 Leakage: ➤ tube housing  
➤ light beam diaphragm

- |      |   |   |
|------|---|---|
| 2.3  | Light beam diaphragm:                         | ➤ alignment<br>➤ congruency<br>➤ illuminance  |
| 2.4  | CD leakage requirements.                      |   |
| 2.5  | Tube voltage accuracy.                        |   |
| 2.6  | Exposure time accuracy.                       |   |
| 2.7  | Radiation dose measurement.                   |   |
| 2.8  | Radiation output linearity with tube current. |   |
| 2.9  | Reproducibility of outputs:                   | ➤ coefficient of variation  |
| 2.10 | AEC tests:                                    | ➤ standard<br>➤ thickness and tube voltage tracking<br>➤ minimum response time                                |
| 2.11 | Fluoroscopic doserates:                       | ➤ maximum, typical and high doserate  |
| 2.12 | Mammography:                                  | ➤ dose measurements<br>➤ mean glandular dose calculation<br>➤ QA measurements (focal spot size, sensitometry) |
| 2.13 | CT:   | ➤ CT dose index<br>➤ noise<br>➤ mean CT number<br>➤ uniformity<br>➤ resolution<br>➤ slice thickness           |

## PRACTICAL ASSESSMENT

- A pass in the written paper is normally required before candidates without compliance testing experience may attempt the practical assessment.
- The assessment involves the candidate performing a compliance test under the direct supervision of an independent<sup>1</sup> qualified expert who holds a compliance testing licence.
- The documented test and the qualified expert's report on the candidate's performance are then submitted to the Council for consideration.
- If, by mutual agreement with an independent qualified expert, a candidate has taken and passed a practical assessment before applying to sit the written examination, no additional practical assessment will be required.

Candidates who require practical tuition before the assessment must work under the immediate personal supervision of a person who holds a licence for compliance testing. This person does not have to be a qualified expert.

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<sup>1</sup> *Independent: having no familial, matrimonial, business etc relationships*

## **APPENDIX 7**

### **DEFINITIONS**



## DEFINITIONS

The following terms and definitions have been extracted from the Radiation Safety Act, the regulations and relevant registration conditions. They may assist in interpreting the requirements of the compliance testing program.

Term or Definition	Meaning
'approved'	approved in writing by the Radiological Council
'authorised officer'	a person who is appointed in writing by the Executive Director (of Public Health), either generally or in a particular case, to perform duties under the Radiation Safety Act 1975 and is thereby authorised to exercise the powers conferred by or under the Act, and also includes any member of the Council
'compliance'	means compliance with the Radiation Safety (General) Regulations, with any subsequent amendments to those regulations, and with any additional requirements of the Council applicable to that class of x-ray apparatus
'compliance tester'	a person licensed under the State's Radiation Safety Act for that purpose
'condition'	conditions, restrictions and limitations imposed under Section 36 of the Radiation Safety Act
'conditional compliance'	non-transferable compliance which may be granted to non-complying equipment if the equipment has an existing registration and if the non-compliance, as assessed by Council officers cannot reasonably be rectified; and does not cause an unacceptable increase in radiation dose.
'Council'	the Radiological Council established pursuant to Section 13 of the Radiation Safety Act
'current'	in relation to a compliance certificate means that the certificate was issued within the past 12, 24 or 36 months, depending on the test frequency established by the Radiological Council for that class of x-ray equipment
'exemption'	exemption referred to in Section 6 of the Radiation Safety Act 1975
'fluoroscopy'	the use of a continuous or pulsed x-ray beam to produce a dynamic real time image, the duration of which is not predetermined before the exposure is initiated;
'general supervision'	the exercise of control over radiation safety without the person exercising such control necessarily being present at the registered premises or field site
'image receptor'	x-ray film, fluorescent screen, image intensifier input phosphor or electronic device in or from which an image is created following exposure to x-rays
'immediate personal'	the exercise of control over radiation safety by the person exercising such control being in the company of and

<b>Term or Definition</b>	<b>Meaning</b>
supervision'	directly observing the person under supervision.
'irradiating apparatus'	any apparatus capable of producing ionising radiation of any prescribed type, or capable of accelerating atomic particles under any prescribed conditions
'licence'	licence granted under the Act
'licensed'	in relation to a person, means that the person is the holder of a relevant licence under the Act
'licensee'	holder of a licence
'owner'	used in relation to any substance, apparatus, product, article or premises, means the person to whom it belongs or the hirer, lessee, borrower, bailee, or mortgagee in possession, thereof, and includes any attorney, agent, manager, foreman, supervisor or other person in charge or having control of management thereof
'qualified expert'	expert whose qualifications are approved
'registered'	registered under the Act
'registrant'	person in whose name premises are registered