



RADIATION SAFETY ACT 1975

DIAGNOSTIC X-RAY EQUIPMENT COMPLIANCE TESTING

PROGRAM REQUIREMENTS

2000

Radiological Council
Locked Bag 2006 P O
NEDLANDS WA 6009

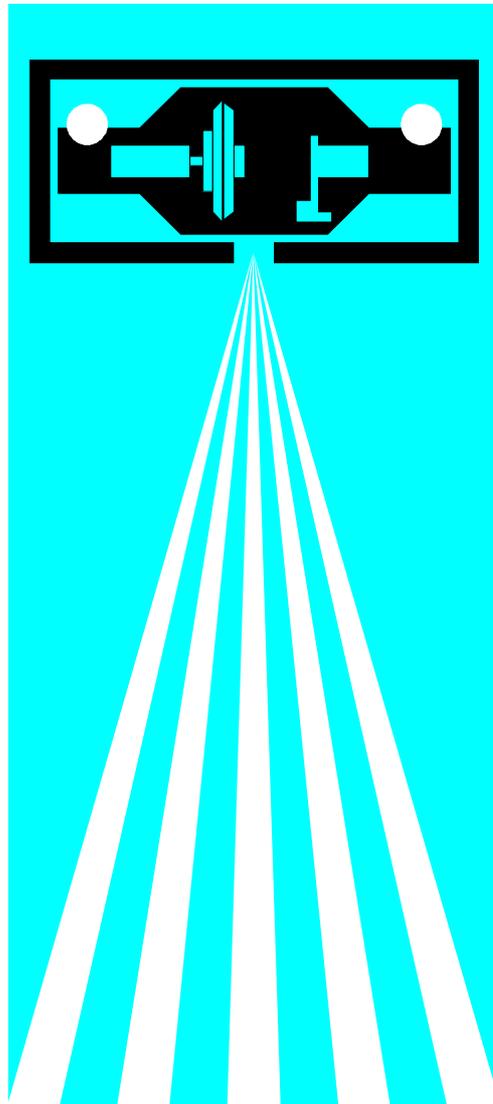
Telephone: (08) 9346 2260
Facsimile: (08) 9381 1423
e mail: radiation.health@health.wa.gov.au

© Health Department of Western Australia

DIAGNOSTIC X-RAY EQUIPMENT COMPLIANCE TESTING

PROGRAM REQUIREMENTS

2000



CONTENTS

1.	PROGRAM OVERVIEW	7
1.1	INTRODUCTION	7
1.2	EQUIPMENT SUBJECT TO TESTING	7
1.3	FREQUENCY OF TESTING	7
1.4	RESPONSIBILITY FOR TESTING	8
1.5	TEST PROTOCOLS	9
1.6	TEST PERSONNEL	10
2.	DOCUMENTATION, CERTIFICATION AND AUDITING OF COMPLIANCE TESTS	11
2.1	TEST REPORTS	11
2.2	CERTIFICATION AND AUDITING	11
2.3	CERTIFICATE OF COMPLIANCE	12
2.4	CERTIFICATE OF CONDITIONAL COMPLIANCE	13
2.5	COMPLIANCE LABELS	14
2.6	NON-COMPLYING EQUIPMENT	16
2.7	EXEMPTIONS	16
2.8	COMPLIANCE TESTING BY SERVICE PERSONNEL	17
2.9	CALIBRATION OF RADIATION MEASURING INSTRUMENTS	17
3.	REQUIREMENTS FOR QUALIFIED EXPERTS	19
3.1	FUNCTIONS	19
3.2	ROLE AND RESPONSIBILITIES	19
3.3	QUALIFICATIONS	20
3.4	ASSESSMENTS	20
3.5	EQUIVALENT ACCREDITATIONS	20
3.6	LICENSING	20
4.	REQUIREMENTS FOR COMPLIANCE TESTERS	23

4.1	FUNCTIONS	23
4.2	QUALIFICATIONS	23
4.3	ASSESSMENTS	23
4.4	TRAINING	24
4.5	LICENSING	24
5.	REQUIRED COMPLIANCE TESTS	25
5.1	MOBILE RADIOGRAPHIC EQUIPMENT	25
5.2	MAMMOGRAPHIC EQUIPMENT	25
5.3	MAJOR (FIXED) RADIOGRAPHIC EQUIPMENT	26
5.4	FLUOROSCOPIC EQUIPMENT	26
5.5	DENTAL RADIOGRAPHIC EQUIPMENT	27
5.6	COMPUTED TOMOGRAPHIC EQUIPMENT	28
	PUBLICATIONS	29
	APPENDIX 1 - COMPLIANCE TESTING PROCESS FLOW CHART	31
	APPENDIX 2 - REGISTRATION CONDITIONS	35
	APPENDIX 3 - COMPLIANCE AND CONDITIONAL COMPLIANCE CERTIFICATES	41
	APPENDIX 4 - COMPLIANCE LABELS	45
	APPENDIX 5 - NOTICE OF NON-COMPLIANCE	49
	APPENDIX 6 - QUALIFIED EXPERT SYLLABUS	53
	APPENDIX 7 - LICENCE CONDITIONS FOR COMPLIANCE TESTERS	63
	APPENDIX 8 - COMPLIANCE TESTER SYLLABUS	69
	APPENDIX 9 - DEFINITIONS	75

1. PROGRAM OVERVIEW

1.1 INTRODUCTION

Commencing 1 January 1997, the Radiological Council of Western Australia introduced a program which requires the periodic testing of diagnostic X-ray equipment for compliance with the State's Radiation Safety (General) Regulations and any additional Council requirements.

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 Council is an independent statutory body established under the Radiation Safety Act.

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 9.

1.2 EQUIPMENT SUBJECT TO TESTING

The program applies to all diagnostic X-ray equipment used for medical, chiropractic and dental radiography.

The program does not yet apply to X-ray equipment used for veterinary radiography.

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. These frequencies took effect from 12 October 2000.

Mammographic	12 months
C-arm or U-arm fluoroscopy (fixed or mobile)	12 months
Other fluoroscopy	24 months
Radiographic	24 months
CT	24 months
Dental	36 months

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

Whether purchased new or second-hand or simply taken out of storage, all x-ray equipment within the scope of the program must be tested and issued with either a compliance certificate, a conditional compliance certificate or an exemption from compliance before it may be used on patients (see section 2).

1.4 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. The registrant is responsible for satisfying the requirements of the compliance testing program. A copy of typical registration conditions (in this case for medical radiology) is given in Appendix 2.

Registrants must ensure that their X-ray equipment is tested by a licensed compliance tester at the prescribed frequency. A list of licensed compliance testers is available from the Radiological Council.

Under conditions, restrictions and limitations applied to all registrations under section 36 of the Radiation Safety Act, the

operation or use of X-ray equipment for human diagnostic radiography or fluoroscopy is an offence 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); or
- (c) an **exemption from compliance** granted by the Council (see Sections 2.6 and 2.7).

“Current” means that the certificate was issued within the previous 12, 24 or 36 months (depending on the equipment category and prescribed test frequency stated in Section 1.3).

Examples of compliance and conditional compliance certificates are given in Appendix 3.

1.5 TEST PROTOCOLS

The prescribed tests assess compliance with the regulations under the Western Australian Radiation Safety Act and with other Council requirements that may apply to the class of 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 —

- Workbook 1 - Mobile Radiographic
- Workbook 2 - Mammographic
- Workbook 3 - Major Radiographic
- Workbook 4 - Fluoroscopic
- Workbook 5 - Dental
- Workbook 6 - Computed Tomographic

The workbooks can be obtained on a cost-recovery basis from the Council through the Radiation Health Section of the

Health Department of Western Australia.

This particular publication, the *Program Requirements*, is available free of charge.

Variations to the recommended test protocols may be used provided they are first approved by a qualified expert (see Section 3.2). Documentation of alternative test protocols must be provided to the Council.

Details of the required tests are given in Section 4.

1.6 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 supervision¹ of a licensee.

All tests must be assessed by a qualified expert. The licensed compliance tester must ensure that the completed test report is signed by a qualified expert.

A qualified expert is eligible for a compliance testing licence and may both carry out and certify a test.

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 2.8.*

¹ "Immediate personal supervision" requires the licensee to be physically present and to directly observe persons working under their direction and supervision.

2. DOCUMENTATION, CERTIFICATION AND AUDITING OF COMPLIANCE TESTS

2.1 TEST REPORTS

At the prescribed test frequencies, a licensed compliance tester will carry out all the tests required by the Council using the protocols described in the relevant workbook or those approved by a qualified expert (see Section 1.5).

- To standardise reporting, test report forms are provided in each workbook. These may be reproduced as necessary. *Test reports submitted to qualified experts at the Radiation Health Section for assessment must use these forms.*
- The compliance tester must provide the qualified expert with all the test results, including relevant X-ray films, waveforms and computer printouts.
- A compliance tester who is also a qualified expert need only provide to the Council test data that is necessary to support any conclusion that the x-ray equipment does not comply.
- All X-ray equipment faults 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 are to 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 2.8.

2.2 CERTIFICATION AND AUDITING

All compliance tests must be signed by a qualified expert.

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.

Note: *A signed test report only indicates that the compliance test has been conducted in accordance with the approved test protocol. It does not necessarily indicate that the equipment complies with the Radiological Council's requirements.*

Copies of the signed test report and the compliance certificate (if issued by an external qualified expert) must be forwarded promptly to —

The Secretary
Radiological Council
Locked Bag 2006 P O
NEDLANDS WA 6009

Copies should also be retained by the registrant, the compliance tester and the qualified expert.

Council officers audit the test reports and use the data to monitor the performance of the program. The audit process may include the re-testing of equipment, either at random or if an individual test report indicates this is necessary.

Compliance testers may submit test reports directly to Council officers who are also approved qualified experts. While there is no charge for this service at present, this policy may be subject to change at any time.

2.3 CERTIFICATE OF COMPLIANCE

A Certificate of Compliance will be issued by a qualified expert when the X-ray equipment satisfies all the assessment criteria of the compliance test.

The certificate is valid for a period of 1, 2 or 3 years 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 signed by a qualified expert.

When a completed certificate is issued by an external qualified expert, a copy of the completed certificate must be forwarded

to the Council together with 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. The licensed service engineer re-installing X-ray equipment must ensure that compliance is not adversely affected during this process. Further measurements may be required to confirm the equipment's status. However, such measurements are typically part of normal service requirements and, except where a compliance test is scheduled (and performed by a licensed compliance tester), do not constitute a compliance test.

A sample Certificate of Compliance is shown in Appendix 3.

2.4 CERTIFICATE OF CONDITIONAL COMPLIANCE

Not all X-ray equipment registered before the compliance testing program was introduced will be able to satisfy the most recent assessment criteria specified in the workbooks. However, except where significant radiation safety concerns exist, it may not be appropriate to direct that the equipment must be taken out of service.

The program deals with this situation through the granting of conditional compliance certificates.

Conditional compliance may be granted to non-complying equipment provided the equipment is registered and was manufactured before the relevant regulations or standards came into effect. However, Council officers will need to be satisfied that the item(s) of non-compliance —

- cannot reasonably be rectified; and
- do not unacceptably increase radiation dose.

Conditional compliance is issued at the discretion of Council's authorised officers. However, such decisions may be appealed

to the Council.

Conditional compliance is issued for a limited period only. In principle, it is issued so that equipment no longer meeting present standards (but which remains essentially safe and serviceable) can continue to be used for a period during which for the registrant or owner can plan for its retirement or replacement. The maximum period is nominally 5 years but this may be varied on a case-by-case basis by the Council or its authorised officers. However, within that period, regular compliance testing nevertheless continues at the prescribed frequency.

Certificates of Conditional Compliance cannot be transferred. The certificates are valid only while the equipment remains at the original premises and subject to registration by the person who was the owner or registrant when conditional compliance was first granted.

However, in some circumstances, low powered mobile or portable X-ray equipment subject to conditional compliance may be re-located, providing the registrant remains unchanged.

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 signed by a qualified expert.

Conditional compliance may only be authorised by Council officers and therefore will only be issued to external qualified experts 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 3.

2.5 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 test date, the certificate number and the name of the tester and qualified expert are issued with the compliance certificate.

For conditional compliance, pink self adhesive labels are issued identifying the registrant, their registration number, the compliance test date and the certificate number.

The label for the specified X-ray equipment must be fixed in a conspicuous position on the control panel.

Sample labels are shown in Appendix 4.

2.6 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 faults².

Depending on the circumstances, the qualified expert may direct the registrant to immediately cease use of the equipment until the identified item(s) of non-compliance are corrected.

If the need for correction is not urgent, the qualified expert may direct that the identified item(s) of non-compliance are to be corrected within 3 months of the compliance test or within 3 months following the expiry of the current compliance certificate for the equipment, unless an alternative time period is granted 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 direction identifying the items requiring correction, together with the date by which those actions must be taken, will provide the owner with a period of *temporary exemption* from compliance.

Written directions in respect of non-complying equipment must be issued forthwith to the registrant by the qualified expert with a copy to the Radiological Council.

An example of the Notice of Non-Compliance form is provided in Appendix 5.

New X-ray equipment with items of non-compliance that cannot be corrected may be refused registration.

2.7 EXEMPTIONS

A registrant who possesses X-ray equipment that cannot meet

² If the registrant believes that there are extenuating circumstances, they may apply to the Radiological Council for an exemption (see Section 2.7).

either full or conditional compliance but which the registrant believes serves an ongoing clinical need, may make application to the Radiological Council for an exemption.

2.8 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 must precede any routine service and maintenance procedures.

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.

2.9 CALIBRATION OF RADIATION MEASURING INSTRUMENTS

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

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 must ensure that —

- all radiation measuring instruments used for the tests are suitably calibrated;
- compliance tests are performed by a licensed tester according to the relevant workbook or by following other approved protocols;
- copies of all test reports are submitted to the Radiological Council forthwith;
- any directions for corrective actions are issued in writing to the registrant forthwith with a copy to the Council;
- required corrective actions are completed and, if necessary, re-tested before a compliance certificate is issued;
- a signed compliance certificate is issued to the registrant and a copy of this certificate is provided to the Radiological Council forthwith;
- a compliance label is provided for display on the X-ray control panel following certification of compliance.

3.2 ROLE AND RESPONSIBILITIES

The qualified expert —

- is responsible for the accuracy of any certified compliance test and accountable for any failure or inadequacy of the test;
- must either perform the tests him or herself;

or

- must be able to demonstrate an adequate level of control over other persons performing tests 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 6.

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 Accreditation in Radiological Physics and Quality Assurance 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. Compliance testing licences are subject to the conditions given in Appendix 7.

Qualified experts who are also licensed compliance testers may sign and forward their own reports to the Radiological Council. Certification by a second person 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 supervision³ of a licensee. All test reports must be reviewed 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 a qualified expert;
- submit the test report to a qualified expert for certification.

4.2 QUALIFICATIONS

A relevant technical qualification at the certificate or advanced certificate level, or equivalent experience in a medical radiation field.

4.3 ASSESSMENTS

The assessment syllabus for compliance testers is given in Appendix 8.

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
- a practical compliance testing examination supervised by

³ "Immediate personal supervision" requires the licensee to be physically present and to directly observe persons working under their direction and supervision.

a 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 the compliance testing of dental X-ray equipment only is also available.

4.4 TRAINING

Applicants for compliance testing licences may undergo the assessments described in Section 4.3 without necessarily undertaking a formal training course in compliance testing.

Applicants who require some theoretical instruction before assessment may be able to attend a Radiological Council approved TAFE course. However, this course is not always available. Applicants may therefore need to seek this instruction from a qualified expert.

Practical experience in compliance testing must be gained under the immediate personal supervision³ of an existing licensee.

The practical competencies of the applicant must be directly assessed by a qualified expert.

4.5 LICENSING

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

Licences are subject to the conditions given in Appendix 7.

See also Section 2 for the requirements for a valid compliance test.

5. REQUIRED COMPLIANCE TESTS

Testing assesses the compliance of diagnostic X-ray equipment with the regulations to the West Australian Radiation Safety Act and with any additional requirements of the Radiological Council. The complete test protocols together with the assessment criteria are provided in the workbook for each class of equipment.

Variations to the test protocols may be used provided they are first approved by a qualified expert.

The following tests are required —

5.1 MOBILE RADIOGRAPHIC EQUIPMENT

Light beam collimator

- accuracy of collimation
- illuminance test
- leakage test and measurement

Generator and X-ray tube

- tube voltage accuracy
- timer accuracy
- radiation output
- reproducibility
- half value layer
- tube housing leakage

See *Workbook 1, Sections 2 and 3.*

5.2 MAMMOGRAPHIC EQUIPMENT

Light beam collimator

- accuracy of collimation
- illuminance test

Generator and X-ray tube

- tube voltage accuracy
- timer accuracy

- radiation output
- reproducibility
- half value layer
- tube housing leakage
- automatic exposure control

Mean glandular dose

See *Workbook 2, Sections 2, 3 and 4.*

5.3 MAJOR (FIXED) RADIOGRAPHIC EQUIPMENT

Light beam collimator

- accuracy of collimation
- illuminance test
- leakage test and measurement

Generator and X-ray tube

- tube voltage accuracy
- timer accuracy
- radiation output
- reproducibility
- half value layer
- tube housing leakage

Automatic exposure devices

- standard test
- kilovoltage tracking
- phantom thickness tracking
- minimum response time

See *Workbook 3, Sections 2, 3 and 4.*

5.4 FLUOROSCOPIC EQUIPMENT

Beam collimation

- collimation accuracy for fluoroscopy
- collimation accuracy for radiography

Generator and X-ray tube

- apparatus configuration
- tube voltage accuracy (fluoroscopic and radiographic)
- timer accuracy (radiographic)
- radiation output (fluoroscopic and radiographic)
- reproducibility (radiographic)
- half value layer
- tube housing and collimator leakage

Automatic exposure devices

- standard density test
- kilovoltage tracking
- phantom thickness tracking
- minimum response time

Image intensifier and imaging system

- congruency of X-ray beam and image
- image intensifier input dose rate
- image quality

Patient dose information

- fluoroscopic timer
- maximum dose rate
- dose rates with patient equivalent phantom

See Workbook 4, Sections 2, 3, 4, 5 and 6.

5.5 DENTAL RADIOGRAPHIC EQUIPMENT

Light beam collimation

- accuracy of collimation
- illuminance test
- leakage radiation test and measurement

X-ray beam size, beam alignment and focal spot to skin distance

Control and X-ray tube

- tube voltage accuracy
- timer accuracy
- radiation output
- reproducibility

- half value layer
- tube housing leakage

See Workbook 5, Sections 2, 3 and 4.

5.6 COMPUTED TOMOGRAPHIC EQUIPMENT

Tube voltage accuracy

Radiation output and X-ray beam quality

CT dose index

Image quality

- mean CT number/uniformity/noise
- beam alignment for CT phantom
- linearity
- table indexing
- alignment light and image slice congruence
- slice thickness
- high contrast resolution

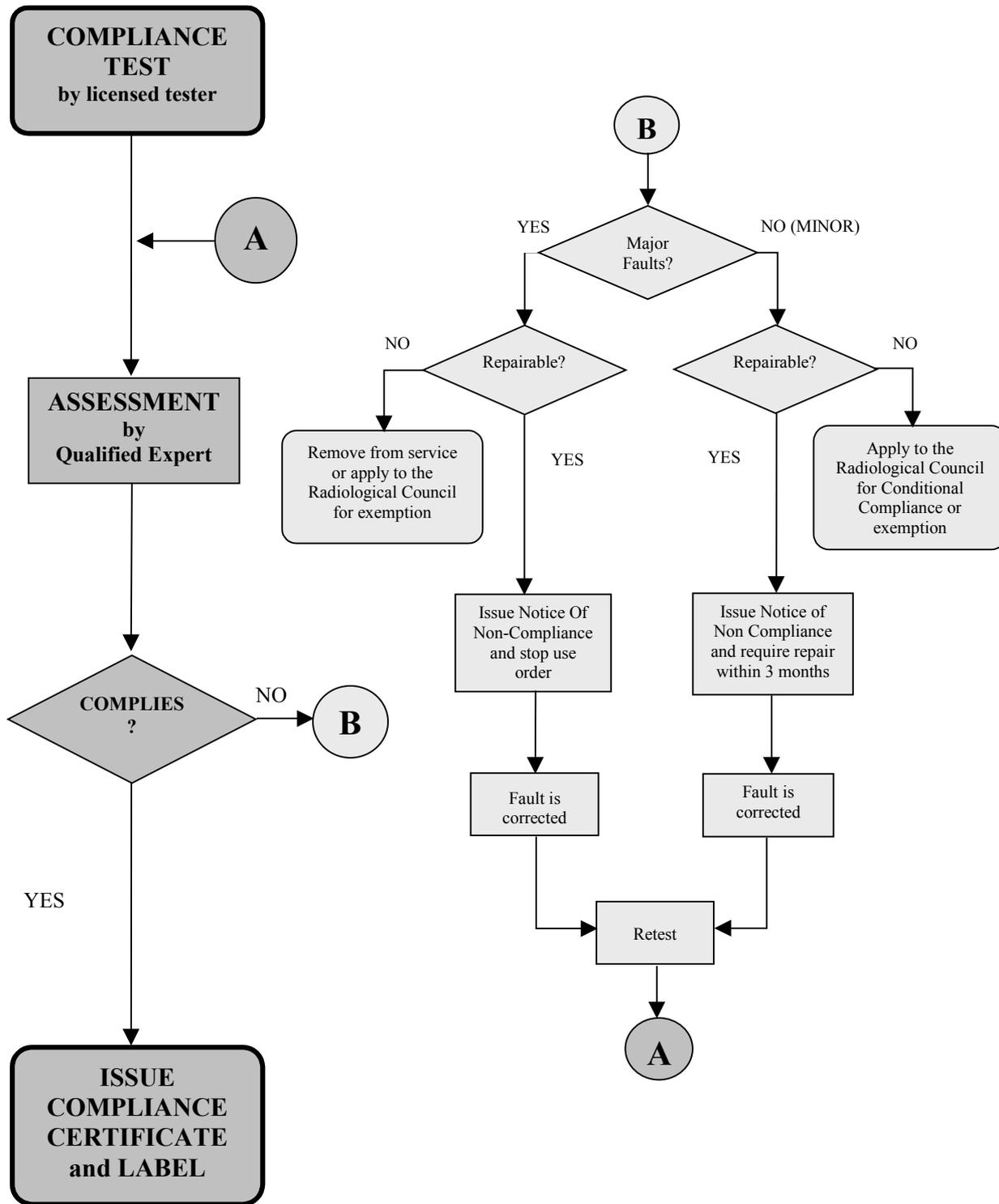
See Workbook 6, Sections 2, 3 and 4.

PUBLICATIONS

1. **Radiation Safety Act 1975** (and amendments)
Schedule IX , Radiation Safety (General) Regulations 1983 (and amendments)
State Law Publisher
2. **Patient Dose Reduction in Diagnostic Radiology.**
Report by the Royal College of Radiologists and the National Radiological Protection Board (UK)
Documents of the NRPB, Vol 1 No 3 1990.
3. **Radiation Doses to Patients from Dental Radiography in New Zealand.**
National Radiation Laboratory, Christchurch, New Zealand
Williamson B D P, Report NRL 1990/6
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
Williamson B D P, Poletti J L, Cartwright P H and Le Heron J C
Report NRL 1993/1
8. **Quality Assurance for Diagnostic Imaging Equipment.**
National Council on Radiation Protection and Measurements
NCRP Report No 99
9. **1990 Recommendations of the International Commission on Radiological Protection.**
ICRP Publication 60
10. **Recommendations for limiting exposure to ionizing radiation (1995)**
National Health and Medical Research Council

APPENDIX 1

COMPLIANCE TESTING PROCESS FLOW CHART



APPENDIX 2

REGISTRATION CONDITIONS

RADIATION SAFETY ACT**CONDITIONS, RESTRICTIONS AND LIMITATIONS (SECTION 36)****MEDICAL RADIOLOGY**

1. This registration provides for the possession and use of the specified x-ray apparatus for the purpose of human diagnostic radiography and fluoroscopy, performed under the direction and supervision of a licensed medical practitioner. *Self referred screening x-ray examinations are excluded unless the registration has been otherwise endorsed.*
2. Subject to the restrictions and limitations that may be imposed by these conditions and provided that all x-ray examinations are performed on x-ray equipment designed for the purpose, the range of x-ray examinations permitted is unrestricted.
3. The registrant is directed to ensure that —

3.1 x-ray apparatus on the premises is not operated or used for human diagnostic radiography or fluoroscopy unless it has —

- (a) a current^a Certificate of Compliance^b; or
- (b) a current Certificate of Conditional Compliance^c; or
- (c) an exemption from compliance granted by the Council.

Any x-ray apparatus which has been tested but which requires service before a Certificate of Compliance can be issued, can continue to be used for a period of 3 months after expiry of the current certificate provided —

- *a qualified expert is satisfied that the fault(s) do not pose a significant radiation risk to users and/or patients; and*
- *the qualified expert has issued a written order (Notice of Non-Compliance) to the registrant for correction of the fault(s).*

3.2 fluoroscopic x-ray apparatus is used only by —

3.2.1 licensed radiologists^d;

3.2.2 medical practitioners training for qualifications in diagnostic radiology and working under the direction and general supervision of a licensed radiologist;

3.2.3 medical practitioners with specialist qualifications (other than a licensed radiologist) who hold a licence or an exemption from licence and who are using the apparatus -

- (i) for a purpose relevant to those qualifications; and
- (ii) in the presence of a radiographer^e who has responsibility for positioning and manipulating the apparatus, minimising patient and personnel radiation exposure and maintaining the records required by the conditions of the registration;

-
- 3.2.4 medical practitioners training for specialist qualifications (other than a person to whom paragraph 3.2.2 applies) who -
- (i) has attended an approved course of training and has passed an examination in radiation safety;
 - (ii) is using the apparatus under the direction and general supervision of a medical practitioner who holds a licence or an exemption from licence; and
 - (iii) is using the apparatus for a purpose relevant to those qualifications in the presence of a radiographer^e who has responsibility for positioning and manipulating the apparatus, minimising patient and personnel radiation exposure and maintaining the records required by the conditions of the registration;
- 3.2.5 radiographers^e using the apparatus as part of a procedure —
- (i) while working under the direction and personal supervision of a licensed radiologist who is responsible for that procedure; or
 - (ii) where -
 - (a) conventional radiography is inadequate; and
 - (b) the licensed radiologist responsible for that procedure has given permission for such use.
- 3.3 radiographic x-ray apparatus is used only by —
- 3.3.1 radiographers^e, and
- 3.3.2 approved x-ray operators^f for chest and extremity radiography using low powered^g x-ray equipment only.
- 3.4 radiographic x-ray examinations are performed only on receipt of a written request authorised^h by a medical practitioner, or for examinations of the teeth and jaws, on receipt of a written request signed by a dentist.
- Note: In exceptional circumstances, a verbal request from the practitioner directly to the person expected to perform the examination will suffice but full authorisation must be provided at the earliest opportunity.*
- 3.5 unless exempted by the regulations or by Council, each person on the premises who is occupationally exposed to radiation, is individually issued with and wears an approved radiation monitoring device to record their cumulative radiation dose and that —
- 3.5.1 each device is used only by the person to whom it was issued;
 - 3.5.2 the device(s) are returned for assessment at the intervals directed by the Council;
 - 3.5.3 continuing records are maintained of all personal monitoring, and
 - 3.5.4 the results of this monitoring are made available forthwith to the individuals concerned.
-

Note: An exemption from monitoring applies to persons who must necessarily be present during the use of mobile fluoroscopic x-ray apparatus, provided —

- *they stand no closer than 3 metres to the patient and x-ray tube during exposures, and*
- *they wear a 0.25 mm (minimum) lead equivalent apron or are standing behind an equivalent approved barrier.*

3.6 these conditions are brought to the attention of all personnel authorised to use the x-ray apparatus and are a copy displayed or kept available within the x-ray room, department or practice to which such personnel have access¹.

NOTES:

a “current” means that the certificate is valid for the following periods from the date of issue—

*12 months for mammographic and C-arm or U-arm fluoroscopic apparatus (fixed or mobile);
24 months for other fluoroscopic, general radiographic and CT apparatus; and
36 months for dental x-ray apparatus*

Note: These periods apply from the date that the most recent certificate was issued

b “compliance” means compliance with the Radiation Safety (General) Regulations 1983, with any subsequent amendments to those regulations, and with any additional requirements of the Council applicable to that class of x-ray apparatus

c “conditional compliance” may be granted to non-complying equipment if the equipment has an existing registration and was manufactured before the particular regulations or standards applying to the non-compliance came into effect, and if the non-compliance, as assessed by Council officers —

- *cannot reasonably be rectified; and*
- *does not cause an unacceptable increase in radiation dose.*

d “radiologist” means a medical practitioner with qualifications in diagnostic radiology that are recognised by the Royal Australian and New Zealand College of Radiologists

e “radiographer” means a person with qualifications in diagnostic radiography who is eligible for ordinary membership of the Australian Institute of Radiography

f “x-ray operator” means a person who has attended an approved course of training and has passed an examination in radiation safety and radiographic techniques for plain radiography of the chest and extremities

g “low powered irradiating apparatus” means irradiating apparatus registered for the purpose of medical radiography (other than mammography or dental radiography) that has a maximum rating of 100 kV(peak) at 100 mA or 100 kV(peak) and 1 microfarad

h “authorised” means by personal signature or by any other method approved by the Council.

i Regulations 18 and 19 of the Radiation Safety (General) Regulations 1983 require the Registrant and Radiation Safety Officer to ensure that training and instruction is given to all persons working with x-ray equipment on the premises.

“approved” means approved in writing by the Council

“plain radiography” means an x-ray examination during the course of which the x-ray tube and film remain stationary and no contrast medium is introduced into the patient

CONDITION NO: 2

CERTIFICATE NO: RX

EXPIRES ON:

February 2000\

APPENDIX 3

COMPLIANCE AND CONDITIONAL COMPLIANCE CERTIFICATES

WESTERN AUSTRALIA RADIATION SAFETY ACT Certificate of Compliance

The following X-ray equipment has been assessed and is certified to be in compliance with the Radiation Safety (General) Regulations 1983, with any subsequent amendments to those regulations, and with any additional requirements of the Radiological Council applicable to this class of X-ray equipment as of the date the assessment was performed.

Manufacturer

Model

Serial Number

Equipment Use

Registrant

Location on Premises

Tested by

Test Date

Licence Number of Tester

Qualified Expert¹

Signature _____ **Date** _____

¹ *Radiation Safety (General) Regulations 1983, sections (5) and (6) of regulation 23. A "qualified expert" means an expert whose qualifications are approved by the Radiological Council.*

Certificate Number

Certificate issued

WESTERN AUSTRALIA RADIATION SAFETY ACT

Certificate Of Conditional Compliance

The following X-ray equipment has been assessed for compliance with the Radiation Safety (General) Regulations 1983, with any subsequent amendments to those regulations, and with any additional requirements of the Radiological Council applicable to this class of X-ray equipment. Conditional¹ compliance only has been issued.

Manufacturer

Model

Conditions Apply

Serial Number

Equipment Use

Registrant

Location on Premises

Areas of Non Compliance²

Tested by

Test Date

Qualified Expert³

Signature _____ **Date** _____

¹ *This certificate is not transferable and is valid only for the current compliance period. Compliance has been issued on the grounds that the equipment predates applicable regulations, the fault is not likely to impact on patient or occupational doses and inherent design features of the unit make corrective modification infeasible.*

² *Full details of non compliance are contained in the compliance report.*

³ *Radiation Safety (General) Regulations 1983, sections (5) and (6) of regulation 23. A "qualified expert" means an expert whose qualifications are approved by the Radiological Council.*

Certificate Number

Certificate issued

APPENDIX 4
SAMPLE COMPLIANCE LABELS

Compliance Label

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

Conditional Compliance Label

	RADIATION SAFETY ACT 1975 WESTERN AUSTRALIA		
<p>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.</p>			
Registrant	<input type="text"/>	Date Tested	<input type="text"/>
Registration #	<input type="text"/>	Certificate #	<input type="text"/>

Samples shown are larger than actual size

APPENDIX 5

NOTICE OF NON-COMPLIANCE

WESTERN AUSTRALIA RADIATION SAFETY ACT

NOTICE OF NON-COMPLIANCE

The following x-ray equipment has been assessed and found not to comply with the Radiation Safety (General) Regulations 1983.

Manufacturer	Model
Serial No.	Location
Equipment Use	Test Date
Tested by	Lic No.
Registrant	Reg No.

Use of this equipment for human radiography must cease forthwith until the following corrective actions are taken —

Use of this equipment without a current compliance certificate is permitted, provided the following corrective actions are taken by

Qualified Expert¹

Signature _____ **Date**

¹ *Radiation Safety (General) Regulations 1983, sections (5) and (6) of regulation 23. A "qualified expert" means an expert whose qualifications are approved by the Radiological Council.*

APPENDIX 6

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 techniques

- collimation
- 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 Types of X-ray machines

7.1 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

8 Instrumentation

8.1 Ionization chambers

- principles of ionization chambers
- types of ionization chambers
- calibration of chambers
- maintenance of chamber

8.2 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

8.3 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

9 Compliance tests

9.1 Workbook tests

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

10 Physical concepts

10.1 Radiation units

- exposure (air kerma)
- absorbed dose

11 Radiation protection concepts

11.1 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

11.2 Protection of the patient

- summary of principles given in ICRP 57

12 Practical radiation protection

12.1 Inverse square law and distance

12.2 Shielding

- control area barriers
- personal aprons, lead effectiveness etc

12.3 Personal monitoring

- basic understanding of personal radiation monitoring dosimetry

13 Regulations

13.1 ICRP 57

- familiarity with section on requirements for diagnostic imaging equipment.

13.2 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.

Diagnostic X-ray equipment compliance testing.

Workbooks 1 to 6.
Radiological Council of Western Australia 2000

Radiation Safety (General) Regulations 1983 (and amendments)

State Law Publisher

APPENDIX 7

LICENCE CONDITIONS FOR COMPLIANCE TESTERS

RADIATION SAFETY ACT

CONDITIONS, LIMITATIONS AND RESTRICTIONS (SECTION 36)

COMPLIANCE TESTING OF DIAGNOSTIC X-RAY EQUIPMENT

1. This licence permits the holder, and persons acting under the direction and immediate personal supervision^a of the licensee, to operate diagnostic x-ray equipment for testing purposes and, in particular, for compliance testing^b.
2. The licensee is directed —
 - 2.1 to ensure that no person is exposed to the direct x-ray beam for any purpose during test procedures;
 - 2.2 to use protective barriers and/or lead equivalent drapes and aprons to minimise the radiation dose to themselves and any persons in the vicinity (except in the case of intra-oral and panoramic tomographic x-ray equipment when distance from the x-ray source and appropriate beam orientation will provide adequate protection); and
 - 2.3 to wear a radiation monitoring film or other approved personal monitoring device, issued to the licensee for his or her exclusive use, whenever x-ray equipment is used.
3. For compliance testing of x-ray equipment which has been imposed as a statutory requirement by the Radiological Council, the licensee is directed to —
 - 3.1 test the equipment according to the protocols in the workbook approved by the Council relevant to the class of equipment under test, or by following other approved test procedures, and using appropriately calibrated instruments;
 - 3.2 ensure that any faults found, or found and corrected, during testing are detailed in the test report;
 - 3.3 ensure that the test result for each item of x-ray equipment is certified by a qualified expert^c; and to
 - 3.4 forthwith provide a copy of the certified test report to the Radiological Council.

^a *'Immediate personal supervision'* means maintaining direct visual supervision of the person concerned.

^b *'Compliance testing'* means testing X-ray equipment for compliance with the regulations under the Act and with other standards that may have been adopted by the Radiological Council for that class of equipment.

^c *'Qualified expert'* means an expert whose qualifications are approved by the Radiological Council

NOTES:***For compliance testing imposed as a statutory requirement —***

- *The qualified expert must sign a compliance certificate and provide it to the registrant (the 'owner' of the equipment) for each item of X-ray equipment tested and found to be in compliance.*
- *Equipment certified to be in compliance with the regulations and other Council requirements must bear an approved label showing the test date, the certificate number and the name of the tester and qualified expert.*

Workbooks, compliance certificates and equipment labels are available from the Radiological Council.

*Radiological Council
18 Verdun Street
NEDLANDS W A 6009*

*Locked Bag 2006 P O NEDLANDS W A 6009
Telephone (08) 9346 2260 Fax (08) 9381 1423*

CONDITION NO: 119

LICENCE NO: LX

EXPIRES ON:

June 1995

APPENDIX 8

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*

1. Core Paper

1.1 Legislation

- Radiation Safety Act 1975
- Radiation Safety (General) Regulations 1983

1.2 Dose limits

- workers
- members of the public

1.3 Radiation types & properties

1.4 Background radiation

1.5 Quantities & 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
- Shielding

2. Main Paper

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

1. Mobile Radiographic
2. Mammographic
3. Major Radiographic
4. Fluoroscopic
5. Dental
6. Computed Tomography

Two papers are available depending on the applicant's needs. One deals with dental X-ray equipment (*with reference to workbook 5 only*) and the other with all medical and dental categories (*with reference to workbooks 1-6*).

The syllabus includes —

- 2.1. Half value layer
- 2.2. Leakage
 - tube housing
 - light beam diaphragm
- 2.3. Light beam diaphragm
 - alignment
 - congruency
 - 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
 - subject thickness tracking
 - tube voltage tracking

- minimum response time

2.11. Fluoroscopic doserates

- maximum
- typical
- high dose rate restrictions

2.12. Mammography

- dose measurements
- mean glandular dose calculation
- QA measurements (focal spot size, sensitometry)

2.13. CT

- CT dose index
- noise
- mean CT number
- uniformity
- resolution
- 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 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 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.

APPENDIX 9

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
"authorized 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 Act
"conditional compliance"	non transferable compliance issued to a specified item of equipment under an existing registration when the equipment was manufactured before the applied standard was introduced, subject to satisfying additional criteria
"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

Term or Definition	Meaning
	phosphor or electronic device in or from which an image is created following exposure to X-rays
"immediate personal supervision"	the exercise of control over radiation safety by the person exercising such control being in the company of and 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
