

59. APPENDIX K: MAMMOGRAPHIC QUALITY ASSURANCE (MQA) PROGRAMME

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While each screening and/or assessment site will have its own MQA programme with the required personnel, the oversight of the MQA programme for all sites covered by the Lead Provider contract is the ultimate responsibility of the Lead radiologist.

K:1 MQA PROGRAMME

The professions involved have agreed to adopt the protocols and standards of the RANZCR Mammography Accreditation Programme as the basis of the MQA programme used in the BreastScreen Aotearoa Programme. The quality control (QC) tests will be as per the RANZCR manuals (RANZCR (2002)⁶⁹ or subsequent versions) with modifications to meet regulatory requirements or New Zealand conditions, implying additional tests without loss of acceptability to the RANZCR accreditation scheme. (While BreastScreen Aotearoa have agreed on the Standard, it is by no means the intention that all screening units must be accredited to the RANZCR scheme). Where the requirements of the regulations and the RANZCR are different, this will be explained.

K:2 MQA COMMITTEE

There must be a site MQA committee, where the designated MQA radiologist, MQC MRT and Medical Physicist co-ordinate the QC tests and their frequencies, review the results and the MQA programme generally. This committee will convene initially a minimum of every three months, or more frequently until consistency has been achieved, thereafter twice a year.

There must also be a lead MQA committee where the Lead radiologist, Lead MRT and Medical Physicist for the Lead Provider ensure that all MQA requirements are met through the Lead Provider region six monthly. The local and regional MQA Committee meetings may be combined.

K:3 MRT QC CHECKS AND TESTS

The MRT performing the role of QC MRT must have completed a mammography course endorsed by NZIMRT.

It is desirable that the Charge MRT be the QC MRT, as the maintenance of the comprehensive MQA programme will be one of their major management tasks. The QC MRT need not be the individual who performs every test but they must ensure that tests are performed, and collate the results and analyse them in consultation with the Charge MRT and the Medical Physicist. The Charge MRT must also monitor equipment maintenance, which must be recorded in the QC log and advise, in consultation with the Medical Physicist, when these interventions require the review of QC tests, intervention levels, repeat tests and related practices.

It is particularly important that the MRTs and Medical Physicists act co-operatively in their QC tests to ensure appropriate coverage of all aspects of the task. The RANZCR scheme gives an appropriate allocation of duties, the MRT contribution to which is summarised below, with the additions necessary for regulatory compliance. This is recognised as a minimum requirement and inevitably local additions, either to tests or to frequencies, will be required to deal with particular circumstances. These must be agreed with the Medical Physicist⁷⁰. The QC MRT must supervise the performance of the tests in accordance with the RANZCR Manual.

There must be an appropriate allocation of staff time to perform these tests.⁷¹

A record must be kept of the test measurements as well as any faults, breakdowns or maintenance of equipment. This should include, for example, any fault messages from on-board computers, even if they resolve themselves.

69 RANZCR. 2002. *Mammography Quality Control Manual*. Sydney: Royal Australian and New Zealand College of radiologists.

70 NRL 1994. Code of Safe Practice for the Use of X-rays in Medical Diagnosis. Report NRL-C5. Christchurch: National Radiation Laboratory.

71 RANZCR 2002 or subsequent versions.

Individual screening units must recognise that these are minimum standards and that often increased frequency (specifically items such as screen cleaning) or additional tests may be necessary to ensure quality. This will vary from site to site and time to time:

1. All tests must be fully documented using the RANZCR 2002 protocol, but a daily check of the AEC is required by the regulatory authority and documented using Template under K:4.
2. All tests must be fully documented using the appropriate protocol.
3. Test results must be made available for inter-comparison and the collation of national statistics.

If any QC test fails, the problem must be identified and corrective action taken. In some cases, when the test result falls outside action limits, this corrective action must be done before any further examinations are made. Other test failures must be corrected within 30 days of the test date.

TABLE K:1 MRT QC CHECKS AND TESTS

	RANZCR ⁷²	Corrective Action ⁷³
DAILY:		
Darkroom cleanliness	RANZCR protocol	
Processor quality control	RANZCR protocol	Immediately
Mobile Unit QC	RANZCR protocol	Immediately
Automatic exposure control (AEC)	RANZCR protocol	Immediately
Processor cleaning (crossover rollers)	Follow manufacturer’s protocols and recommendations	
WEEKLY:		
Clean screens (dry and wet)	RANZCR protocol (may require far more frequent attention)	Immediately (whenever an artefact is identified by an MRT or radiologist)
View boxes and viewing conditions	RANZCR protocol	As per RANZCR 2002
Phantom images	RANZCR protocol	Immediately
Processor: clean racks and rollers	Follow manufacturer’s recommendations and protocols	

Continued

72 RANZCR (2002) or subsequent versions

73 The failure of any critical test would require immediate suspension from use, for non-critical tests, at the radiologist’s discretion, from 30 days of test date.

	RANZCR	Corrective Action
MONTHLY:		
Visual checklist	RANZCR protocol	Immediately
QUARTERLY:		
Repeat analysis	RANZCR protocol	Within 30 days of test date.
Analysis of fixer retention in film	RANZCR protocol	Within 30 days of test date.
AEC Compensation (test to 6cm)	RANZCR protocol	*as per attached protocol
SIX-MONTHLY:		
Darkroom fog	RANZCR protocol	Immediately
Screen film contact	RANZCR protocol	Immediately
Compression	RANZCR protocol	Immediately

Mobile Mammography

The Lead Provider must verify that each mobile mammography unit meets the mammography QC standards as stated above. In addition, on arrival at each location the facility must verify satisfactory performance by performing a phantom test and noting parameters recorded on the machine. If parameters are within acceptable limits, screening can commence. Once the phantom has been processed, if it is found to be outside acceptable limits then screening should cease immediately.

It is expected that once a unit is established at a site Approach B⁷⁴ would be sufficient to ensure quality.

K:4 MRT AEC COMPENSATION TEST PROTOCOL

The MRT AEC Compensation test protocol. Testing should be done at perspex thicknesses of 2cm, 4cm and 6cm, using only one size film (18x24) and a large focal spot.

AEC Tests are to be undertaken every three months and a record is to be kept of the KV, mAs, anode and filter (even if tested in an automatic manner).

74 RANZCR. 2002. Mammography Quality Control Manual. Sydney: Royal Australian and New Zealand College of Radiologists.

K4. Procedure: Automatic Exposure Control (AEC) Compensation Assessment

BreastScreen Aotearoa: This is a version of the AEC test which will give uniformity within BSA. Technique factors should be agreed with your Medical Physicist.

OBJECTIVE

To assess the ability of the automatic exposure control system to correct for changes in kVp and breast thickness.

FREQUENCY

This test must be carried out quarterly.

REQUIRED TEST

Mammographic X-ray unit

EQUIPMENT

Perspex slabs of 2, 4 and 6 cm thicknesses

Densitometer

Test cassette

Test record sheet

TEST PROCEDURE STEPS

1. Position a 2 cm perspex slab on the breast table, centred laterally, and place loaded cassette in the Bucky.
2. Ensure that the automatic exposure control detector is in the chest wall position and bring the compression paddle into gentle contact with the phantom.
3. Select a phototimed imaging mode that allows manual selection of kVp. Use the kVp that would be used clinically for a breast with radiographic properties equivalent to the perspex thickness being used.
4. Repeat steps 1 – 4 for 4 cm and 6 cm of perspex.
5. If alternative target/filter combinations are available (eg. Mo/Rh, Rh/ Rh, W/Rh), obtain images for 6 cm of perspex using the combination used clinically at the appropriate kVp. Reach an agreement on technique with your medical physicist.
6. Calculate the mean optical density for the above group of films and the maximum variation in optical density from this mean.

PRECAUTIONS AND CAVEATS

The cassette used should be designated for this test and be in routine clinical use. Normal clinical film should be used. See Appendix 1, Section 3.4.14

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The optical density of any film must be within +/- 0.15 of the mean optical density. The mean optical density must be within 0.20 of the baseline and greater than 1.40.

AEC CALIBRATION TEST

BreastScreen Aotearoa

AEC Calibration test

Room:	Film:	Cassette #	Month:	Yr
Small Cassette ID:			Large Cassette ID:	

THICKNESS TRACKING

Image receptor (Small / large)	Grid (yes / no)				Focal Spot (small / large)	
AEC sensor position:	Density Control				mA	
Phantom thickness	Image #	AEC Mode	kVp	Anode & Filter	mAs	OD
2cm						
4cm						
6cm						
6cm (optional)						
6cm (optional)						
8cm (optional)						
Overall AEC Performance Contact Mode						
Site baseline OD (1.6 to 1.8)	Mean OD (2-6 cm)		OD Range		Allowed OD Range	

Action Limit: If the OD range exceeds ± 0.15 of mean OD, when thickness is varied from 2 to 6 cm and the kVp is varied over those values clinically relevant, then contact your medical physicist for complete assessment.

Artefact present?	
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K:5 MEDICAL PHYSICIST’S CHECKS AND TESTS

All tests must be recorded on the approved forms and in the manner described in the RANZCR Manual.

Prompt reporting is important. A preliminary report, (Refer: RANZCR 2002⁷⁵ for the format), should be given to the facility on the day that testing is completed. If any equipment fails a critical examination (MGD or Image Quality), then every effort must be made to advise the Licensee, the designated MQA radiologist, and the Charge MRT immediately. A written preliminary report shall be retained by the facility documenting the failure. A final report for all tests shall be sent to the designated Charge MRT and National Physics Co-ordinator within 20 working days.

The base frequency of testing recommended by RANZCR⁷⁶ is annual, although many authorities suggest some checks be done more frequently. The minimum testing frequency for the Critical Examinations and the AEC tests, is six monthly. The qualified Medical Physicist may decide to increase the frequency of certain tests, perhaps only for a limited period of time, based upon the machine performance. These tests must be performed within 30 days of their due date.

Existing equipment belonging to a provider new to BSA, must be tested in the six months prior to use within the programme. All film/screen mammography machines must have dual beam filters, one being molybdenum and the other rhodium.

TABLE K:2 MEDICAL PHYSICIST’S CHECKS AND TESTS

Test Frequency	Corrective Action
1. Mammographic unit assembly evaluation Six-monthly	Within 30 days of test date
2. Collimation assessment	Within 30 days of test date
3. Evaluation of focal spot performance	Within 30 days of test
4. kVp accuracy and reproducibility Six-monthly abbreviated test Annually, full test	Within 30 days of test date
5. Beam quality assessment (half-value layer)	Within 30 days of test date
6. Automatic exposure control (AEC) system performance assessment Six-monthly (Density control function annually)	Within 30 days of test date
Note: Care must be taken to test this control over the range of breast thicknesses encountered amongst the screened population. In particular it may be necessary to go down to 1 cm and up to 8 cm (for example, the Waikato pilot programme has found 10% of their women to have >8 cm compressed breast thickness).	
7. Uniformity of screen speed	Within 30 days of test date

75 RANZCR. 2002. *Mammography Quality Control Manual*. Sydney: Royal Australian and New Zealand College of Radiologists.

76 RANZCR. 2002. *Mammography Quality Control Manual*. Sydney: Royal Australian and New Zealand College of Radiologists

Test Frequency	Corrective Action
8. Breast entrance exposure, average glandular dose, and AEC reproducibility Six-monthly	Immediately if >3mGy; * Within 30 days if >2mGy
9. Image quality evaluation Six-monthly	Immediately
10. Artefact evaluation**	Within 30 days of test
11. Assessment of site's QC programme Six-monthly	Within 30 days of test date
12. Measurement of view box luminance and illuminance	Within 30 days of test date
13. Output linearity	Within 30 days of test date

* It is unusual for the MGD to the MAP to exceed 2 mGy. If this occurs then technique and equipment parameters shall be reviewed to bring it below 2 mGy. If the MGD exceeds 3 mGy then the system shall be suspended from use until MGD is brought under control.

** This test may have to be modified by the Medical Physicist to accommodate daylight loading film processors.

K:6 ACCEPTANCE TESTING OF MAMMOGRAPHIC X-RAY UNITS

These tests, performed by the Medical Physicist, provide baseline values for the Physicist's tests, ensure compliance with NRL-C5⁷⁷ and ensure that equipment performance meets the contract specifications. The tests must be performed prior to the use of the equipment for breast cancer screening.⁷⁸ To facilitate this, ample notice of the installation data must be supplied to the Medical Physicist. A comprehensive description of acceptance tests is given in the UK NHSBSP document.⁷⁹

Acceptance testing should be done against the following Standards. The first two apply to all equipment used in the Programme, the third and fourth to new equipment, and the remainder are valuable guidance, but allowance must be made for the New Zealand regulations and the purchase conditions.

1. Tests as per Approach B of the document, i.e. modified RANZCR (2002)⁸⁰.
2. For stereotactic breast biopsy units, the ACR Mammography Quality Manual⁸¹ for stereotactic units should be followed.
3. Code of Safe Practice for the use of x-rays in Medical Diagnosis, NRL-C520.⁸²
4. The purchase contract.
5. The manufacturer's specifications.

Resource Materials

1. A list documenting the specific tests that are required to be met for Medical Physicists acceptance testing.
2. Commissioning and Routine Testing of Mammographic X-ray Systems.⁸³ This provides very detailed tests. Some allowance must be made for New Zealand regulations. Compliance with some of the tests here would need to be specified at purchase.
3. Acceptance testing prone stereotactic breast biopsy units.⁸⁴
4. Recommended Specifications for New Mammography Equipment: Report of the ACR-DCD Focus Group on mammography Equipment.⁸⁵

Electrical Safety

Under the Electricity Regulations 1993, responsibility for electrical safety lies principally with the owners and operators of medical equipment. Electrical safety will be checked initially by the suppliers at installation, but further checks will normally be made by engineers employed by the Lead Providers or the subcontracted parties. The responsibility for electrical safety checks (both at installation and afterwards) should be clearly laid down, e.g. in the purchase or maintenance contract. QA Medical Physicists normally have no training or experience in this field.

It should be noted that stereotactic localisation equipment, where the normal electrical resistance of the skin is broken by the penetration of the needle, will require 'body protected' status.

77 NRL 1994.

78 NRL 1994.

79 IPSM Report 59 (2nd Edition) (IPSM 1994).

80 RANZCR. 2002. *Mammography Quality Control Manual*. Sydney: Royal Australian and New Zealand College of Radiologists.

81 ACR 1999. *Mammography Quality Control Manual*. Reston, Virginia: American College of Radiology. ISBN 1- 55903-142-5.

82 NRL 1994.

83 IPSM Report 59 (2nd Edition) (IPSM 1994).

84 Kimme-Sith C Solberg T. 1994. Acceptance testing prone stereotactic breast biopsy units. *Med Phys* 21(7):1197-201.

85 Yaffe et al. 1995. Recommended Specifications for New Mammography Equipment: Report of the ACR-DCD Focus Group on mammography Equipment. *Radiology* 197:19-26.