

supplementary criteria for accreditation

Radiology

Mammography

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Edition Statement			
Edition	Amendment	Date of Issue	ISBN No.
1	First issue	Feb 2002	0908611 76 5
2	Updated	Dec 2004	0908611 76 5
3	Revised and reformatted. Changed title from "Radiology" to "Medical Imaging". (Not printed, electronic only)	Oct 2007	978-0-908611-19-5
4	Changed title from "Medical Imaging" to "Radiology". (Printed)	May 2008	978-0-908611-34-8

Published by:

International Accreditation New Zealand

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Contents		Page
1	Introduction	5
2	Definitions and acronyms	5
3	Scope of accreditation	6
4	Accommodation	6
5	Safety	7
6	Equipment management	7
7	Staff	8
8	Imaging procedures	9
9	Patient management	9
10	Reports and records	10
11	Quality control	11
12	Bibliography and references	11

1 Introduction

International Accreditation New Zealand Supplementary Criteria amplify or particularise the general accreditation criteria for specific fields of technology or for specific types of business activity.

A list of all criteria documents published to date is available on www.ianz.govt.nz/publications or from IANZ on request. This Supplementary Criteria 10.3 defines specific technical requirements for the accreditation of radiology services performing mammography.

This publication must be read in conjunction with the following IANZ publications:

- (a) *The New Zealand Code of Radiological Management Practice* (NZCRMP)
- (b) *Procedures and Conditions of Accreditation* (PCA).

The latter document describing the organisation and operation of the IANZ Accreditation Programmes, also applies in general to the accreditation of radiology services, although the procedures for accreditation described in the document may vary according to the type of service assessed.

Note: The New Zealand Code of Radiological Management Practice is developed from draft seven of the document NZS ISO/IEC 17025.

The IANZ Radiology Service Accreditation Programme offers accreditation in eight separate imaging modalities. They are as follows:

- (a) Bone Mineral Densitometry
- (b) CT Scanning
- (c) DSA
- (d) General Radiography
- (e) MR Imaging
- (f) Mammography
- (g) Nuclear Medicine
- (h) Ultrasound.

Radiology services, including those offering mammography, are assessed fully every four years. Surveillance assessments are carried out each intervening year. Advice and technical review is provided by the IANZ Radiology Professional Advisory Committee (RADPAC) and the IANZ Accreditation Advisory Committee (AAC).

This Supplementary Criteria provides information on scope of accreditation, staff, accommodation, equipment and other aspects of good radiology service management considered to be a minimum standard for radiology services offering mammography.

2 Definitions and acronyms

AAC	Accreditation Advisory Committee
ACR	American College of Radiology
AEC	Automatic Exposure Control
BSA	Breast Screen Aotearoa
CME	Continuing Medical Education
CT	Computerised Tomography
FRANZCR	Fellow of the Royal Australian and New Zealand College of radiologists
HVL	Half Value Layer
IANZ	International Accreditation New Zealand
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
kV	Kilovolts
MRI	Magnetic Resonance Imaging
MRT	Medical Radiation Technologist

MRTB	Medical Radiation Technologists Board
NRL	National Radiation Laboratory
NZCRMP	New Zealand Code of Radiological Management Practice
NZIMRT	New Zealand Institute of Medical Radiation Technologists
PCA	Procedures and Conditions of Accreditation
QC	Quality Control
QHP	Qualified Health Physicist
RADPAC	Radiology Professional Advisory Committee
RANZCR	Royal Australian and New Zealand College of Radiologists

3 Scope of accreditation

IANZ accreditation applies to specific imaging procedures or types of examination and does not constitute a blanket cover of all the diagnostic imaging activities of a radiology service. Under the IANZ radiology programme, the range of examinations performed by a radiology service in a particular imaging modality is not described in great detail. A broad description of the imaging modalities in which a radiology service has demonstrated competence is provided in the terms of accreditation of the radiology service. Further detail of the imaging capability of an accredited radiology service is retained by IANZ but is not generally published.

Accreditation is granted only for imaging modalities for which the radiology service is properly equipped and has demonstrated its capability. Specific examinations must be carried out at intervals sufficient to ensure that competence is maintained. Several factors, including the complexity of the examination, the clinical significance of the procedure, and the experience of the staff performing the examination, will be considered in defining the minimum number of examinations necessary to maintain competency.

In mammography for example, the criteria for maintaining competence in advanced hook wire localisation procedures may be expected to be more demanding than those required for the routine screening of asymptomatic patients.

This Supplementary Criteria defines the requirements for accreditation for a radiology service active in mammography. Some radiology services carry out mammography as part of the New Zealand breast screening programme, Breast Screen Aotearoa (BSA). BSA prescribes its own criteria for mammography facilities and some of the BSA criteria may vary from those detailed in this Supplementary Criteria. In the event the IANZ accreditation process identifies any aspect of a mammography facility which fulfils the requirements of accreditation but is at variance to the BSA criteria, such aspects are likely to be reported by IANZ as recommendations rather than as mandatory corrective action requests.

4 Accommodation

General requirements for radiology service accommodation are documented in section 3.2 of the *New Zealand Code of Radiological Management Practice*.

Accommodation requirements for mammography are less complex than those required for some other diagnostic imaging modalities such as CT Scanning or MR Imaging.

In general terms, all radiology services providing a mammography service should be expected to adequately provide for at least the following items relevant to accommodation:

- (a) Patient waiting area
- (b) Patient interview and preparation area
- (c) Patient change cubicles
- (d) Facilities for the secure storage of patient belongings
- (e) Signage in relation to restricted areas
- (f) Facilities for the performance of administrative duties
- (g) Film viewing and reporting area

- (h) Temperature and humidity control for patient comfort
- (i) Areas for the storage of equipment accessories and consumables
- (j) Facilities for the extraction of processing fumes and vapours
- (k) Provision for the safe emergency egress from the site.

IANZ does not define the exact accommodation criteria necessary for the provision of a mammography service. However, international standards and other industry specifications developed specifically by either the National Radiation Laboratory (NRL) or the Royal Australian and New Zealand College of Radiologists (RANZCR) pertaining specifically to mammography have been published and provide useful guidance for the design and construction of a radiology service active in mammography.

Note: Where patients and/or patient records are kept in a relatively public area of the radiology service, provision for the privacy of the patient and the confidentiality of patient information will be assessed as part of the on-site review of the radiology service accommodation.

5 Safety

In accordance with the *New Zealand Code of Radiological Management Practice*, NZS ISO/IEC 17025 and other related international standards, the assessment of safety within a radiology service falls outside the scope of accreditation. Any items pertaining to unsafe practice within a radiology service providing a mammography facility are likely to be raised by IANZ only as recommendations, rather than as mandatory corrective action requests.

6 Equipment Management

General requirements for the management and calibration of radiographic equipment are documented in section 3.4 of the *New Zealand Code of Radiological Management Practice*.

Mammography examinations do not involve the use of high doses of potentially harmful radiation and, thus, do not carry a high element of risk to the patient. However, the correct management and calibration of the mammography equipment and associated image processing equipment is essential to the provision of a quality imaging service.

The management of mammography equipment shall include a formal preventive maintenance and service programme provided by a qualified service engineer.

In addition, the development and implementation of a formal schedule of routine checks, tests and calibrations of the mammography and image processing equipment is necessary. While some of the more basic checks and tests may be competently carried out by staff of the mammography facility, others of a more complex nature or requiring sophisticated reference equipment will need to be carried out by a qualified service engineer or a Qualified Health Physicist (QHP) contracted to the radiology service.

Those items in need of regular checking or calibration include at least the following:

- (a) Collimation alignment check
- (b) Focal spot size measurement
- (c) kVp accuracy and reproducibility measurement
- (d) Beam quality half layer value (HLV) assessment
- (e) Automatic exposure control (AEC) check
- (f) Screen speed uniformity check
- (g) Breast entrance exposure measurement
- (h) Average glandular dose measurement
- (i) Check of phantom image quality
- (j) Artifact evaluation
- (k) Darkroom cleanliness check
- (l) Processor quality control checks

- (m) Screen cleanliness check
- (n) Darkroom fog check
- (o) Screen film contact test
- (p) Compression force measurement
- (q) Fixer retention rate analysis
- (r) Check of light output of film viewing boxes
- (s) Check of ambient light level in the film viewing room.

It is not the responsibility of IANZ to define the frequency at which each of the above calibrations and checks should be carried out. In general, the frequency of checks should be such as to assure the radiology service of the on-going satisfactory performance of the mammography and image processing equipment, and may be influenced by a number of factors including:

- (a) Equipment manufacturer's recommendations
- (b) Regulatory or legislative requirements (Breast Screen Aotearoa criteria)
- (c) The make, model, age, and workload of the equipment
- (d) Established performance history
- (e) Competence and skills level of the equipment operators.

Under no circumstances shall the completion of necessary equipment servicing or calibration be delayed or cancelled in order to accommodate further patient examinations.

Detailed records shall be kept of all service work, calibrations, quality control checks and other tests carried out to confirm on-going compliance of the mammography and processing equipment with performance specifications.

Where calibrations or checks give rise to numerical data, the data shall be plotted graphically and the resultant graphs shall be carefully monitored in order to detect time related performance trends.

Where performance parameters measured are required to fall within pre-determined maximum and minimum specifications, these maxima and minima control limits shall be clearly identified. In the event the pre-determined control limits are exceeded, there shall be a detailed record kept of all actions and corrective measures taken to address any such non-compliance. In circumstances of major non-compliance with performance specifications, one such action may be the cessation of all patient imaging activity until such time as the non-compliance is corrected.

Note: Staff of the radiology service shall be responsible for the collection, collation, review and retention of all records pertaining to the management of mammography and processing equipment, irrespective of the persons responsible for carrying out the service or calibration work.

7 Staff

General requirements for radiology service staffing are documented in section 3.1 of the *New Zealand Code of Radiological Management Practice* and other relevant references are included in sections 2.2 and 2.13.

In addition to these general requirements for staff management, a radiology service providing a mammography facility shall be expected to demonstrate the following:

- (a) The registered supervising radiologist in charge of the mammography facility shall be clearly identified
- (b) The supervising radiologist and/or the radiologists interpreting mammograms shall hold FRANZCR or an equivalent qualification recognised by the RANZCR
- (c) All radiologists who interpret mammograms shall hold current (not greater than three years old) optometrists reports, and shall wear any prescribed optical aids while reporting
- (d) All mammography MRTs shall have completed a training programme approved by the supervising radiologist and acceptable for registration by the Medical Radiation Technologists Board (MRTB)
- (e) All mammography MRTs shall participate in at least 15 hours of continuing medical education relevant and appropriate to mammography in every three year period

- (f) All radiology services providing a mammography facility shall hold or have direct access to a comprehensive range of current specialist textbooks scientific journals and other reference literature appropriate and relevant to the scope of activities of the facility
- (g) The supervising radiologist and/or the radiologists interpreting mammograms shall also fulfill the following additional requirements:
 - (i) View a minimum of 480 mammograms per year
 - (ii) If qualified in radiology prior to January 1987, have documented at least 40 points (hours) continuing medical education (CME) in mammography and 15 points (hours) of CME in mammography in the past three years
 - (iii) If qualified in radiology after January 1987, have documented at least 15 points (hours) of CME in mammography in the last three years
 - (iv) Have documented at least 15 points (hours) CME in mammography during every three year period.

8 Imaging procedures

General requirements for imaging procedures are documented in section 3.3 of the *New Zealand Code of Radiological Management Practice*.

In addition to these general requirements, there are a number of activities specific to a radiology service providing a mammography facility for which formally documented procedures are necessary. These additional activities include the following:

- (a) Access to controlled or restricted areas
- (b) Screening of patients regarding pregnancy
- (c) Counselling of patients with regard to the examination
- (d) Emergency evacuation of the facility
- (e) Examination of patients with breast implants or prostheses.

To an extent, the amount of instructional detail documented in imaging procedures for mammography will depend on the experience and ability of staff members and on the user-friendliness of the mammography equipment. Generally, sufficient instructional detail should be documented to ensure the consistent operation of the equipment by all staff members who may at any time be asked to participate in the examination of patients.

All imaging procedures shall be reviewed at least annually and, where necessary, revised to ensure that they remain appropriate and relevant to the activities of the mammography facility. The review process should take into consideration the results of research relevant to mammography and industry trends specific to mammography. Records of such reviews shall be maintained.

9 Patient management

General requirements for the management of patients undergoing a radiology examination are documented in section 3.6 of the *New Zealand Code of Radiological Management Practice*.

In addition to these general requirements, there are a number of patient issues specific to radiology services providing a mammography facility which need to be documented and carefully managed to ensure the quality of the mammograms and the comfort and well-being of the patient.

These additional issues include the following:

- (a) Provision of useful information to the patient in relation to the examination procedure
- (b) Advising the patient of the risks and the limitations of the examination procedure
- (c) Obtaining information from the patient in relation to surgery, family history of breast disease, or other items that may influence or prevent the mammography examination
- (d) Advising the patient of the need for further views or for further examination using alternative imaging procedures (ultrasound)
- (e) Advising the patient of the outcome of the examination, where appropriate
- (f) Provision for the post-examination care of the patient, where necessary

- (g) Seeking feedback from the patient in relation to the quality of service provided.

In accordance with the need to review imaging procedures, patient management procedures shall also be subject to annual review and revision where necessary.

10 Reports and records

General requirements for reporting and recording are documented in sections 3.8 and 3.9 of the *New Zealand Code of Radiological Management Practice*.

Requirements for recording defined in this section of this Supplementary Criteria apply to those records arising from the mammographic examination of a patient, which may not normally be included in the diagnostic report of the examination ultimately despatched to the referring clinician.

Radiology services providing a mammography facility shall maintain formal records of at least the following items relevant to the examination of a patient:

- (a) The number and orientation of views taken, including details of any non-standard views
- (b) Details of the exposure, kV, and compression settings used
- (c) Details of any additional views taken and of any examinations by alternative imaging procedures (ultrasound)
- (d) Identity of the MRT who carried out the examination
- (e) Any incidental observations or findings not specifically related to the examination requested
- (f) Notification of preliminary results by telephone to the referring clinician prior to the issue of the final diagnostic report.

Requirements for reporting defined in this section apply to formal diagnostic reports arising from the mammographic examination of a patient.

Radiology services providing a mammography facility shall issue a formal report pertaining to each patient examination which shall include at least the following:

- (a) Patient identification
- (b) Name of the referring clinician
- (c) Date of the examination
- (d) Date of issue of the report
- (e) Address and contact details of the mammography facility
- (f) Name and signature of the reporting radiologist
- (g) Reference to the radiologist responsible for double-reading
- (h) Reference to the findings of any additional examinations (ultrasound)
- (i) Diagnosis and other relevant clinical findings.

In addition to the above requirements for records and reports, there are a number of related issues for which the radiology service providing a mammography facility will need to develop formal protocol and procedures. These issues include the following:

- (a) Mechanism and authority for the release of urgent or clinically significant results
- (b) Seeking second opinions or double-reading of mammograms
- (c) Reference to any earlier mammograms considered during reporting
- (d) Provision of advice in relation to follow-up studies or additional examinations
- (e) Release of results by telephone, fax or other electronic means
- (f) Release of results to patients
- (g) Confidentiality of results and other patient records
- (h) Retention, storage and retrieval of films, records and reports.

11 Quality Control

General requirements for quality control are documented in section 3.7 of the *New Zealand Code of Radiological Management Practice*.

In addition to these general requirements, radiology services providing a mammography facility shall place particular emphasis on the following aspects of quality control:

- (a) Acceptance testing of newly installed mammography equipment by a qualified service engineer and/or a Qualified Health Physicist (QHP)
- (b) Checks, calibrations and tests in accordance with the requirements defined in section 6 of this Supplementary Criteria
- (c) Analysis of reject films
- (d) Regular correlation of radiology interpretations with pathology, surgical and other patient outcomes
- (e) Participation in the RANZCR clinical image review programme or an alternative programme recognised by the RANZCR
- (f) Participation in a phantom image review programme
- (g) Regular and systematic checks for errors in transcription and other reporting errors
- (h) Implementation of a programme for the blind double-reading of mammograms by a second radiologist competent in mammography
- (i) Maintenance of a library of reference images and case studies for comparison and teaching purposes.

Detailed records shall be kept of all quality control activities, and these records shall be closely monitored to ensure that the mammography equipment and the imaging and reporting procedures continue to conform to pre-determined performance standards. Where anomalies in performance are detected, these shall be effectively investigated and resolved through the corrective and preventive action procedures of the radiology service.

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