

supplementary criteria for accreditation

Radiology

Ultrasound

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Edition Statement			
Edition	Amendment	Date of Issue	ISBN No.
1	First issue	Feb 2002	0908611 75 7
2	Updated	Dec 2004	0908611 75 7
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	978-0-908611-33-1

Published by:

International Accreditation New Zealand

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1 Introduction

International Accreditation New Zealand's 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 10.2 defines specific technical requirements for the accreditation of radiology services performing ultrasound procedures.

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 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 ultrasound facilities, 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 ultrasound facilities.

2 Definitions and acronyms

AAC	Accreditation Advisory Committee
ASUM	Australasian Society for Ultrasound in Medicine
CME	Continuing Medical Education
CT	Computerised Tomography
FRANZCR	Fellow of the Royal Australian and New Zealand College of Radiologists
IANZ	International Accreditation New Zealand
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
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 Technology

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
SMPTE	Society of Motion Picture Technology and Engineering

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 staff performing the examination, will be considered in defining the minimum number of examinations necessary to maintain competency.

In ultrasound for example, the criteria for maintaining competence in advanced foetal echocardiography or nuchal translucency procedures may be expected to be more demanding than those required for routine obstetric or gall bladder examinations.

Note: Some radiology services perform ultrasound examinations on veterinary animals or carry out examinations on human patients and other subjects for research purposes. These examinations are not covered by the IANZ radiology accreditation programme.

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 ultrasound facilities are less complex than those required for CT Scanning or MR Imaging facilities, where the accommodation requirements are to an extent dictated by the special needs of the imaging equipment itself. Accreditation may be granted to a facility with portable ultrasound equipment operated at relatively remote sites where only basic accommodation is provided.

In general terms, all radiology services providing an ultrasound facility 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) Private examination rooms providing proper privacy for patients under-going "sensitive" examinations
- (f) Signage in relation to restricted areas
- (g) Facilities for the performance of administrative duties
- (h) Film viewing and reporting area
- (i) Temperature and humidity control for patient comfort
- (j) Areas for the storage of equipment accessories and consumables
- (k) Provision for the safe emergency egress from the site.

IANZ does not define the exact accommodation criteria necessary for the provision of an ultrasound service. However, international standards and other industry specifications developed specifically by either the Australasian Society for Ultrasound in Medicine (ASUM) or the Royal Australian and New Zealand College of Radiologists (RANZCR) pertaining specifically to ultrasound facilities, have been published and provide useful guidance for the design and construction of a radiology service providing an ultrasound facility.

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*, 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 an ultrasound facility are likely to be raised by IANZ only as recommendations, rather than as mandatory corrective action requests.

Radiology services offering an ultrasound facility may also need to take into consideration industry specific guidelines in relation to patient safety defined by ASUM, with particular reference to scan exposure times.

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*.

Ultrasound examinations do not involve the use of potentially harmful radiation and do not carry a high element of risk to the patient or to staff of the radiology service. However, the correct management and calibration of the ultrasound and associated image processing equipment is essential to the provision of a quality imaging service.

The management of ultrasound 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 ultrasound and image processing equipment is necessary. While some of the more basic checks and tests may be competently carried out by staff of the ultrasound 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) Calibration of power output
- (b) Calibration of signal to noise ratio
- (c) Calibration of calipers
- (d) Check of signal uniformity
- (e) Check of geometric distortion
- (f) Check of phantom image quality
- (g) Check of signal optimisation using SMPTE patterns or equivalent
- (h) Check of light output of film viewing boxes
- (i) 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 ultrasound and image processing equipment, and may be influenced by a number of factors including:

- (a) Equipment manufacturer's recommendations
- (b) Regulatory or legislative requirements
- (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 ultrasound 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 ultrasound 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 an ultrasound facility shall be expected to demonstrate the following:

- (a) The registered supervising radiologist in charge of the ultrasound facility shall be clearly identified
- (b) The supervising radiologist shall hold FRANZCR or an equivalent qualification recognised by the RANZCR
- (c) The supervising radiologist shall be able to demonstrate competence in ultrasound procedures by one of the following:
 - (i) Obtained FRANZCR and have completed a radiology training programme which included a specific curriculum in ultrasound.
 - (ii) Completed at least six months ultrasound fellowship training.
 - (iii) Demonstrated clinical experience in supervision and interpretation of ultrasound images.
- (d) All radiologists who review clinical indications, specify use of any contrast agents and assure the quality of both images and the interpretations, shall hold FRANZCR or an equivalent qualification recognised by the RANZCR
- (e) All radiologists who interpret ultrasound images shall hold current (not greater than three years old) optometrists reports and shall wear any prescribed optical aids while reporting
- (f) All sonographers shall hold current registration with the Medical Radiation Technologists Board (MRTB)
- (g) All sonographers shall have completed a training programme approved by the supervising radiologist and acceptable for registration by the MRTB

- (h) All trainee sonographers must hold an exemption to practice ultrasound from the MRTB and shall be supervised by a fully qualified sonographer
- (i) All sonographers shall actively participate in continuing medical education relevant and appropriate to ultrasound
- (j) All radiology services providing an ultrasound 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.

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 other activities specific to a radiology service providing an ultrasound facility for which formally documented procedures are necessary. These additional activities include the following:

- (a) Access to examination rooms
- (b) Counselling of patients
- (c) Administration of contrast agents
- (d) Administration of sedatives
- (e) Administration of local anaesthetic
- (f) Emergency evacuation of the facility.

To an extent, the amount of instructional detail documented in imaging procedures for ultrasound will depend on the experience and ability of staff members and on the user-friendliness of the ultrasound 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 ultrasound facility. The review process should take into consideration the results of research relevant to ultrasound and industry trends specific to ultrasound and other diagnostic imaging modalities. 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 an ultrasound facility which need to be carefully managed to ensure the quality of the ultrasound images 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 associated with the examination procedure and the obtaining of the patient's consent where necessary
- (c) Obtaining information from the patient in relation to any medication or medical condition which may complicate the examination
- (d) Advising the patient of the outcome of the examination, where appropriate
- (e) Provision for the post-examination care of the patient, where necessary
- (f) 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 ultrasound 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 an ultrasound facility shall maintain formal records of at least the following items relevant to the examination of a patient:

- (a) Name of sonographer or radiologist who performed the examination
- (b) Name of any other persons present during the examination
- (c) Drugs or contrast agents administered, including details of the volumes and strengths used and the identity of the person or persons responsible for the administration
- (d) Any adverse reaction to drugs or contrast agents
- (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 ultrasound examination of a patient.

Radiology services providing an ultrasound 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 and time of the examination
- (d) Date of issue of the report
- (e) Address and contact details of the ultrasound facility
- (f) Name and signature of the reporting radiologist
- (g) 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 an ultrasound facility will need to develop and document formal protocol and procedures. These issues include the following:

- (a) Mechanism and authority for the release of urgent results
- (b) Seeking second opinions for difficult to interpret or ambiguous images or for images arising from highly specialised examination procedures
- (c) Provision of advice in relation to follow-up studies or additional examinations
- (d) Release of results by telephone, fax, or other electronic means
- (e) Release of results to patients
- (f) Confidentiality of results and other patient records
- (g) The retention, storage and retrieval of 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 an ultrasound facility shall place particular emphasis on the following aspects of quality control:

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

Detailed records shall be kept of all quality control activities and these records shall be closely monitored to ensure that the ultrasound 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.

12 Bibliography and references

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