

supplementary criteria for accreditation

Radiology

CT Scanning

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1 Introduction

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

A list of all Schedules published to date is available on www.ianz.govt.nz/publications or from IANZ on request. This Supplementary Criteria 10.4 defines specific technical requirements for the accreditation of radiology services performing computed tomography (CT scanning) 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 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 CT scanning 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 CT scanning facilities.

2 Definitions and acronyms

AAC	Accreditation Advisory Committee
CME	Continuing Medical Education
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
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
kV	Kilovolts
mA	Milliamperes
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.

Note: Some radiology services perform CT scanning 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 CT scanning facilities are more complex than those required for some other diagnostic imaging modalities. In addition to the need to accommodate the patient and members of the radiology service staff, specific accommodation needs of the equipment itself are critical to the adequacy of the CT scanning service provided.

In general terms, all radiology services providing a CT scanning 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) Signage in relation to restricted areas
- (f) Equipment console and operating 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.

In addition to the above general accommodation requirements, a CT scanning facility may be expected to adequately provide for at least the following specialist items relevant to the accommodation of the CT scanner:

- (a) Controlled access to the imaging room and appropriate signage
- (b) Temperature and humidity control for computing equipment
- (c) Communication with the patient during examination
- (d) Radiation protection facilities for the patient and radiology staff.

IANZ does not define the exact accommodation criteria necessary for the provision of a CT scanning 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 to CT scanning facilities have been published and provide useful guidance for the design and construction of a radiology service providing a CT scanning 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*, 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 CT scanning 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*.

CT scanning examinations involve the use of potentially harmful radiation and may carry a high element of risk to the patient and to staff of the radiology service. The correct management and calibration of the CT scanner and associated image processing equipment is essential to the provision of a quality imaging service.

The management of the CT scanner 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 CT scanner and image processing equipment is necessary. While some of the more basic checks and tests may be competently carried out by staff of the CT scanning 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 mA
- (b) Calibration of kV
- (c) Calculation of dose index (CTDI)
- (d) Calibration of signal to noise ratio
- (e) Check of signal uniformity
- (f) Check of geometric distortion
- (g) Check of slice thickness and positioning accuracy
- (h) Check of phantom image quality

- (i) Check of signal optimisation using SMPTE patterns or equivalent
- (j) Check of light output of film viewing boxes
- (k) 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 CT scanner 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 CT scanner 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 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 the CT scanner, 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 CT facility shall be expected to demonstrate the following:

- (a) The registered supervising radiologist in charge of the CT 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 CT scanning procedures by one of the following:
 - (i) Obtained FRANZCR after 1 January 1985 and have completed a radiology training programme which included a specific curriculum in CT scanning
 - (ii) Completed at least six months CT scanning fellowship training
 - (iii) Demonstrated clinical experience in supervision and interpretation of CT scanning images of relevant anatomic regions
 - (iv) Attended recognised courses in CT scanning (four weeks or 125 hours).

Note: The requirements for the supervising radiologist may be expected to vary according to the type and complexity of examinations carried out, with the requirements within a major teaching facility being more rigorous than those in a small private radiology service

- (d) The supervising radiologist shall actively participate in continuing medical education relevant and appropriate to CT scanning
- (e) All radiologists who review clinical indications, specify use of contrast agents, specify examination sequences and assure the quality of both images and interpretations, shall hold FRANZCR or an equivalent qualification recognised by the RANZCR
- (f) All radiologists who interpret CT images should hold current (not greater than three years old) optometrists reports and shall wear any prescribed optical aids while reporting
- (g) All CT scanning MRTs shall have completed a training programme approved by the supervising radiologist and acceptable for registration by the Medical Radiation Technologists Board (MRTB)
- (h) All CT scanning MRTs shall actively participate in continuing medical education relevant and appropriate to CT
- (i) All radiology services providing a CT scanning 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 a CT scanning facility for which formally documented procedures are necessary. These additional activities include the following:

- (a) Access to controlled or restricted areas in close proximity to the CT scanner
- (b) Counselling of patients with regard to claustrophobia
- (c) Administration of contrast agents
- (d) Administration of sedatives
- (e) Administration of local or general anaesthetic
- (f) Sterilisation of interventional instruments and equipment
- (g) Operation and maintenance of power injector equipment
- (h) Operation and maintenance of patient monitoring and resuscitation equipment
- (i) Emergency evacuation of the facility
- (j) Management of reactions to contrast agents.

To an extent, the amount of instructional detail documented in imaging procedures for CT will depend on the experience and ability of staff members and on the user-friendliness of the CT scanner and its control console. 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 CT scanning facility. The review process should take into consideration the results of research relevant to CT scanning and industry trends specific to CT. 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 CT scanning facility which need to be carefully managed to ensure the quality of the CT scanning 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
- (c) Obtaining information from the patient in relation to any medication or medical condition which may complicate the examination
- (d) Questioning the patient in relation to claustrophobia and advising the patient of available options to reduce complications
- (e) Nursing procedures, especially for interventional examinations
- (f) Special procedures for paediatric patients, especially when multi-slice CT scanners are used
- (g) Special procedures for patients with allergies or renal impairment, etc.
- (h) Advising the patient of the outcome of the examination, where appropriate
- (i) Provision for the post-examination care of the patient, where necessary
- (j) 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 CT scanning 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 CT scanning facility shall maintain formal records of at least the following items relevant to the examination of a patient:

- (a) 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
- (b) Advice given to the patient in relation to the risks associated with the examination and of iodinated contrast agents and, where necessary, obtaining of the patient's consent to proceed with the examination
- (c) Adverse reaction to drugs or contrast agents
- (d) Incidental observations or findings not specifically related to the examination requested
- (e) 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 CT scanning examination of a patient.

Radiology services providing a CT scanning 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 CT scanning facility
- (f) Methodology details e.g. slice thickness, pitch, axial/helical, etc.
- (g) Name and signature of the reporting radiologist
- (h) 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 CT scanning 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) 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 a CT scanning facility shall place particular emphasis on the following aspects of quality control:

- (a) Acceptance testing of a newly installed CT scanner 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, where possible
- (d) Participation in a phantom image review programme
- (e) Regular and systematic checks for errors in transcription and other reporting errors
- (f) Implementation of a programme for the blind double-reading of a percentage of CT scanning images by a second radiologist competent in CT scanning procedures
- (g) 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 CT scanner and the imaging and reporting procedures continue to conform to pre-determined performance standards. Where anomalies in performance are detected, these shall be an effectively investigated and resolved through the corrective and preventive action procedures of the radiology service.

12 Bibliography and references

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