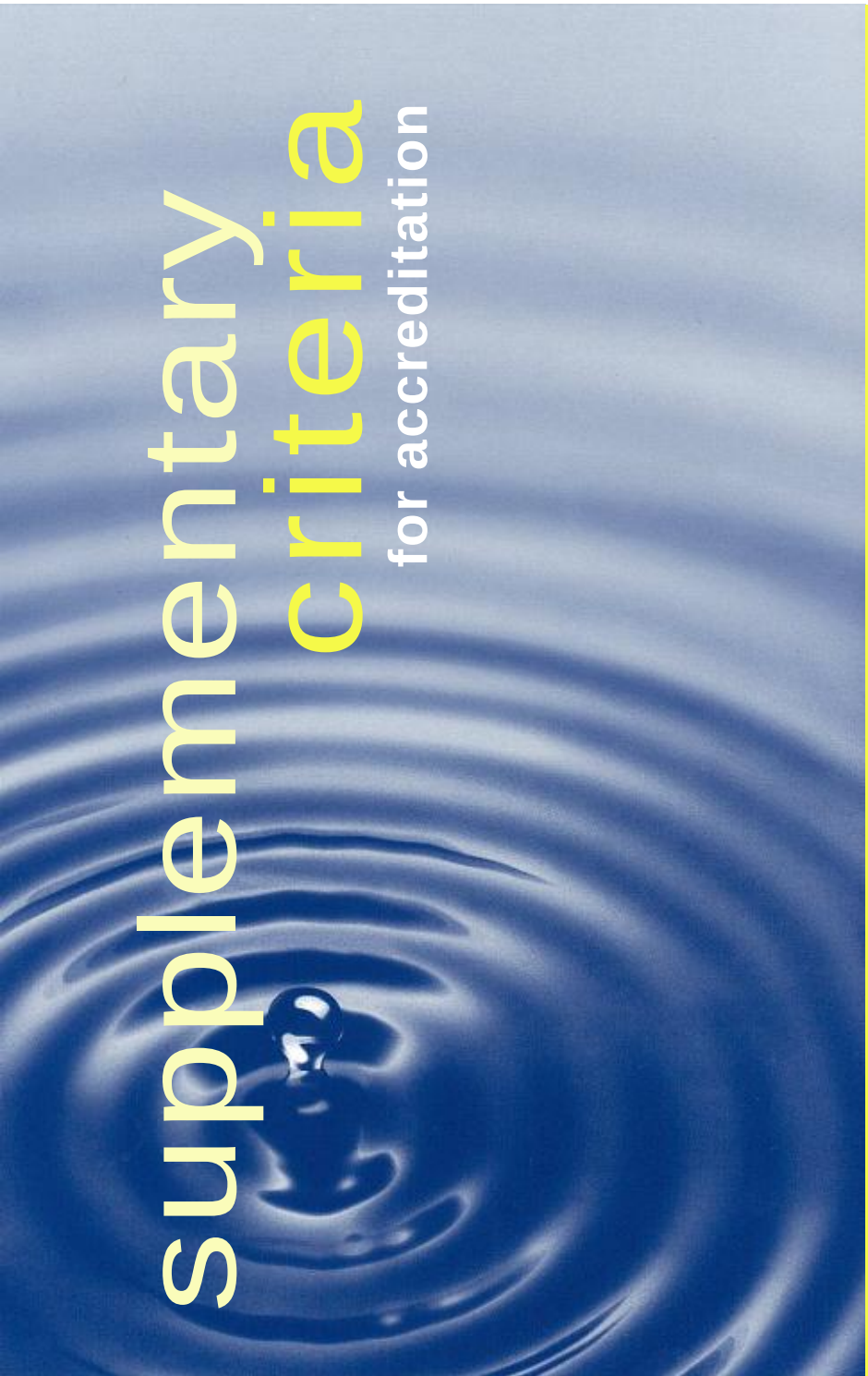
IANZ



supplementary criteria for accreditation

Radiology:

Nuclear Medicine

supplementary criteria for accreditation

Radiology

Nuclear Medicine

Fourth edition May 2008

supplementary criteria for accreditation

Radiology

Nuclear Medicine

AS RAD C 10.6

Edition Statement			
Edition	**Amendment**	**Date of Issue**	**ISBN No.**
1	First issue	Feb 2002	0908611 78 1
2	Updated	May 2005	0908611 78 1
3	Revised and reformatted. Changed document name from "Scintigraphy" to "Nuclear Medicine". 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	978-0-908611-36-2

Published by:
International Accreditation New Zealand
626 Great South Road, Ellerslie, Auckland 1051
Private Bag 28908, Remuera, Auckland 1541, New Zealand
Telephone 64 9 525 6655
Facsimile 64 9 525 2266
Email: info@ianz.govt.nz
Internet: www.ianz.govt.nz

Contents **Page**

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 10.6 defines specific technical requirements for the accreditation of radiology services performing nuclear medicine 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 nuclear medicine 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 nuclear medicine facilities.

2 Definitions and acronyms

AAC	Accreditation Advisory Committee
ANZAPNM	Australian and New Zealand Association of Physicians in Nuclear Medicine Inc
CME	Continuing Medical Education
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
MLAC	Medical Licensing Advisory Committee
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
SPECT	Single Photon Emission Computed Tomography

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 nuclear medicine for example, the criteria for maintaining competence in advanced myocardial perfusion studies may be expected to be more demanding than those required for routine whole body bone scans.

Note: Some radiology services perform nuclear medicine 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 nuclear medicine 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 and the radioisotopes are critical to the adequacy of the nuclear medicine service provided.

In general terms, all radiology services providing a nuclear medicine 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) Radiopharmaceutical administration area
(e) Patient toilet facilities specific to nuclear medicine
(f) Patient recovery area
(g) Facilities for the secure storage of patient belongings
(h) Signage in relation to restricted areas
(i) Equipment console and operating areas
(j) Facilities for the performance of administrative duties
(k) Film viewing and reporting area
(l) Temperature and humidity control for patient comfort
(m) Areas for the storage of equipment accessories and consumables
(n) Provision for the safe emergency egress from the site.

In addition to the above general accommodation requirements, a nuclear medicine facility may be expected to adequately provide for at least the following specialist items relevant to the accommodation of the gamma camera or radioisotopes:

(a) Radioisotope preparation and storage ("hot-room") facilities
(b) Personnel decontamination facilities
(c) Radioactive waste disposal facilities
(d) Controlled access to the imaging room and appropriate signage
(e) Temperature and humidity control for computing equipment
(f) Communication with the patient being examined
(g) Sedation and general anaesthesia facilities.

In addition to the careful management of the above accommodation requirements specific to nuclear medicine facilities by the staff of the radiology service, it may be necessary for local body and emergency authorities to be made aware of many of these items, thereby avoiding the consequences of unauthorised or inappropriate access to radiation hazards in the event of an emergency.

IANZ does not define the exact accommodation criteria necessary for the provision of a nuclear medicine service. However, international standards and other industry specifications developed specifically by the National Radiation Laboratory (NRL), the Royal Australian and New Zealand College of Radiologists (RANZCR), and the Australian and New Zealand Association of Physicians in Nuclear Medicine Inc (ANZAPNM) pertaining specifically to nuclear medicine facilities, have been published and provide useful guidance for the design and construction of a nuclear medicine 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 nuclear medicine 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*.

Although the gamma camera and associated nuclear medicine equipment does not in itself present a significant risk to patients or staff, there is a significant element of risk arising from the radioisotopes used in nuclear medicine procedures. The correct management and calibration of the gamma camera, dose measuring equipment and associated image processing equipment is essential to the provision of a quality imaging service.

The management of nuclear medicine 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 gamma camera and image processing equipment is necessary. While some of the more basic checks and tests may be competently carried out by staff of the nuclear medicine 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) Dose calibration and constancy checks
(b) Reproducibility and linearity checks of the dose calibrator

(c) Geometric correction factor checks
(d) Calibration of energy window settings
(e) Check of signal uniformity, linearity, sensitivity and resolution
(f) Check of geometric distortion and spatial resolution
(g) Check of collimator absolute and relative sensitivity
(h) Centre of rotation checks
(i) Pixel calibration
(j) SPECT phantom reconstruction checks
(k) Crystal energy resolution checks
(l) Molybdenum break-through checks
(m) Ambient radiation dose measurements
(n) Check of phantom image quality
(o) Radiopharmaceutical sterility checks
(p) Film processor checks
(q) Check of light output of film viewing boxes
(r) 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 gamma camera, accessories and image processing equipment, and may be influenced by a number of factors including:
(a) Equipment manufacturer's recommendations
(b) Regulatory or legislative requirements including NRL C3
(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 gamma camera and radioisotopes 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 nuclear medicine 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 nuclear medicine facility shall be expected to demonstrate the following:

(a) A supervising nuclear medicine specialist or radiologist in charge of the nuclear medicine facility shall be clearly identified
(b) All radiologists practicing nuclear medicine shall meet the guidelines of the Medical Licensing Advisory Committee (MLAC) for "grandfathering" in nuclear medicine and shall be able to demonstrate competence in nuclear medicine procedures by the following:
    (i) Hold vocational registration in radiology
    (ii) Full-time or part-time practice in nuclear medicine for at least three consecutive years
    (iii) Demonstrated clinical experience in supervision and interpretation of at least 1000 scans with a minimum of 200 scans in any one year.
(c) New applications (after 31/12/2001) from radiologists for nuclear medicine diagnosis shall meet the guidelines of the MLAC as follows:
    (i) Have completed the two year programme of the Joint Specialist Advisory Committee in Nuclear Medicine

    or shall:

    (ii) Hold vocational registration in radiology and have completed six months full-time in an accredited nuclear medicine department and have reported at least 500 scans under supervision.
(d) New applications (after 31/12/2001) from physicians for general nuclear medicine shall meet the guidelines of the MLAC as follows:
    (i) Hold vocational registration in a branch of internal medicine; and
    (ii) Completed the two year programme of the Joint Specialist Advisory Committee in Nuclear Medicine or another programme recognised as at least equivalent by the MLAC.
(e) All nuclear medicine specialists or radiologists who interpret nuclear medicine images shall hold current (not greater than three years old) optometrists reports and shall wear any prescribed optical aids while reporting
(f) All nuclear medicine MRTs shall hold current registration in nuclear medicine with the Medical Radiation Technologists Board (MRTB) or shall have an exemption to practice from the MRTB
(g) All nuclear medicine MRTs shall actively participate in continuing medical education relevant and appropriate to nuclear medicine
(h) All radiology services providing a nuclear medicine 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 nuclear medicine facility for which formally documented procedures are necessary. These additional activities include the following:

(a) Access to controlled or restricted areas including the gamma camera and the "hot-room"
(b) Counselling of patients with regard to the examination procedure
(c) Administration of radiopharmaceuticals
(d) Administration of sedatives
(e) Administration of local or general anaesthetic
(f) Emergency evacuation of the facility.

To an extent, the amount of instructional detail documented in imaging procedures for nuclear medicine will depend on the experience and ability of staff members and on the user-friendliness of the gamma

camera 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 nuclear medicine facility. The review process should take into consideration the results of research relevant to nuclear medicine and industry trends specific to nuclear medicine. 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 nuclear medicine facility which need to be carefully managed to ensure the quality of the nuclear medicine 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 surgery, employment or other history that may complicate the examination or influence post examination management of the patient
(d) Obtaining information from the patient in relation to any medication or medical condition which may complicate the examination
(e) Questioning the patient in relation to pregnancy
(f) Physically exercising the patient prior to cardiac studies
(g) Advising the patient of the outcome of the examination, where appropriate
(h) Provision for post-examination care of the patient, where necessary
(i) 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 nuclear medicine 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 nuclear medicine facility shall maintain formal records of at least the following items relevant to the examination of a patient:
(a) Details of the radiopharmaceuticals administered, including the type and dose of isotope, the time and means of administration, and the identity of the person or persons responsible for the administration
(b) Adverse reaction to the radiopharmaceuticals administered
(c) Incidental observations or findings not specifically related to the examination requested
(d) 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 nuclear medicine examination of a patient.

Radiology services providing a nuclear medicine 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 nuclear medicine facility
(f) Name and signature of the reporting specialist or 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 a nuclear medicine facility will need to develop 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 imaging 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 a nuclear medicine facility shall place particular emphasis on the following aspects of quality control:
(a) Acceptance testing of newly installed gamma cameras and ancillary 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 nuclear medicine diagnoses with surgical and other patient outcomes, where possible
(d) Participation in a phantom image review programme
(e) Quality control and validation of data processing software, especially those used to produce quantitative results
(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 nuclear medicine images by a second specialist or radiologist competent in nuclear medicine 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 nuclear medicine 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

International Accreditation New Zealand, *New Zealand Code of Radiological Management Practice*: AS RAD C.

International Accreditation New Zealand: *Procedures and Conditions of Accreditation*: AS 1.

NZS/ISO 15189 *Medical Laboratories – Particular requirements for quality and competence.*

NZS ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories.*

Medical Licensing Advisory Committee: *Criteria for Recommending "Special Knowledge" in Nuclear Medicine.*

Ministry of Health National Radiation Laboratory: *Code of Safe Practice for the use of X-Rays in Medical Diagnosis.* NRL C5 1995.

Ministry of Health National Radiation Laboratory: *Code of Safe Practice for the use of Unsealed Radioactive Materials in Medical Diagnosis, Therapy and Research.* NRL C3 1994.

Ministry of Health National Radiation Laboratory: *Guidelines for Quality Assurance in Radiation Protection for Diagnostic X-Ray Facilities: Large X-Ray Facilities*. NRL 1995/1.

Royal Australian and New Zealand College of Radiologists: *Accreditation standards for diagnostic and interventional radiology*. Version 3.0 November 1999.