General Criteria for Accreditation
New Zealand Code of Radiology Management Practice

Second Edition July 2020

The NZ mark of competence
Tohu Matatau Aotearoa

This page is intentionally blank

General Criteria for Accreditation

New Zealand Code of Radiology Management Practice

Radiology Services – Particular requirements for quality and competence

Developed from ISO 15189:2007

NZCRMP

Second Edition July 2020

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
Email: info@ianz.govt.nz
Internet: www.ianz.govt.nz

Edition Statement

Edition	Amendment	Date of Issue	ISBN No.
	New Zealand Code of Radiological Management Practice published	2006	--------
1	Replaces the 2006 Code above (see Foreword)	April 2011	978-0-908611-97-3
2	Rebranded & reformatted; Foreword edited; other minor edits (no technical change)	July 2020	978-1-877531-79-8

Contents

Foreword

The *New Zealand Code of Radiological Management Practice*: 2006 was originally developed from a draft version of ISO/IEC 17025:1995. This *New Zealand Code of Radiology Management Practice*, initially published in 2011, developed from ISO 15189:2007, replaced the *New Zealand Code of Radiological Management Practice*: 2006 for all IANZ accredited medical imaging services (herein after referred to as 'radiology services' in this document).

In 2020, the 2011 publication was rebranded and reformatted, with minimal editorial changes only and republished. There are no material changes to the requirements for accreditation as a result.

Introduction

This Code, developed from ISO 15189:2007, provides requirements for competence and quality that are particular to radiology services. It is acknowledged that there may be specific regulations or other requirements that are applicable to some or all professional personnel, and their associated activities and responsibilities in this domain.

Radiology services are essential to patient care and therefore have to be available to meet the needs of these patients and the clinical personnel responsible for their care. Such services include arrangements for referrer and patient identification, preparation, and examination; for the subsequent interpretation, reporting and advice given to clinical personnel and/or patients; and for the additional considerations of safety and ethics in radiology.

Each radiology service should also provide suitable educational and clinical opportunities for professional staff working within it.

This Code is intended for use throughout the currently recognized modalities of radiology services. The Code is complemented by Specific or Supplementary Criteria applicable to particular modalities. IANZ will use this Code and the Specific or Supplementary Criteria as the basis for their activities in the recognition of the competence of radiology services.

Demonstrated conformity to this Code does not imply conformity of the radiology service's management system with all the requirements of ISO 9001.

Additional requirements for accreditation are contained in the following IANZ publications:

a) *Procedures and Conditions for Accreditation* (AS 1)

b) *Specific (or Supplementary) Criteria for Accreditation* (as applicable to particular modalities).

Radiology services — Particular requirements for quality and competence

1 Scope

1.1 This Code specifies requirements for quality and competence particular to radiology services.

1.2 This Code is for use by radiology services in developing their management systems and assessing their own competence, and for use by International Accreditation New Zealand in confirming or recognising the competence of radiology services.

2 Normative references

This Code was developed from the medical testing standard NZS/ISO 15189:2007 *Medical Laboratories — Particular requirements for quality and competence*. However the standard is not a normative reference, indispensable for the application of the Code. Any future revisions to NZS/ISO 15189 will be incorporated into the Code where relevant.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accreditation
third party attestation related to a conformity assessment body (radiology service) conveying formal demonstration of its competence to carry out specific conformity assessment (radiological) tasks

3.2
examination procedures
activities following the pre-examination process including the management of patients within the radiology service during examination, completion of the examination and preparation of images in readiness for post-examination processes

3.3
management system
management system used to direct and control an organisation with regard to quality of both management and technical competence

3.4
patient
patient is used as an encompassing term to include hospital and private patients as well as asymptomatic persons involved in screening

3.5
post-examination procedures
processes following the examination including systematic review, formatting, reporting and interpretation, authorisation and transmission of the reports, and storage of images from the examinations

3.6
pre-examination procedures
steps starting, in chronological order, from the clinician's request, and including requisition, management of the patient to and within the radiology service prior to examination, preparation of the patient, and ending when the examination procedure begins

3.7
radiology service
service, department or practice providing diagnostic imaging and interventional radiology for diagnosis and/or treatment of human beings, and which may provide a consultant advisory service covering all aspects of radiological investigation including the interpretation of results and advice on further appropriate examinations. Diagnostic imaging modalities include bone densitometry, computed tomography (CT)

scanning, DSA (including angiography), general radiography (including fluoroscopy), magnetic resonance (MR) imaging, mammography, nuclear medicine and ultrasound (US).

3.8
radiology service capability

physical, environmental and information resources, personnel, skills and expertise available for the examinations in question

3.9
radiology service director

competent person(s) with responsibility for, and authority over, a radiology service

NOTE 1: For the purposes of this Code, the person or persons referred to are designated collectively as "radiology service director".

3.10
radiology service management

person(s) who manage the activities of a radiology service headed by a radiology service director

3.11
subcontractor radiology service

external radiology service to which a patient or image is submitted for an examination procedure or second opinion

4 Management requirements

4.1 Organisation and management

4.1.1 The radiology service or the organisation of which the radiology service is a part shall be legally identifiable.

4.1.2 Radiology services, including appropriate interpretation and advisory services, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care.

4.1.3 The radiology service shall meet the relevant requirements of this Code when carrying out work in its permanent facilities, and/or at sites outside the permanent facilities for which it is responsible.

4.1.4 The responsibilities of personnel in the radiology service with an involvement or influence on the examination of patients shall be defined in order to identify conflicts of interest. Financial or political considerations (e.g. inducements) should not influence examinations.

4.1.5 Radiology service management shall have responsibility for the design, implementation, maintenance and improvement of the management system. This shall include the following:

a) management support of all radiology service personnel by providing them with the appropriate authority and resources to carry out their duties;

b) arrangements to ensure that management and personnel are free from any undue internal and external commercial, financial or other pressures and influences that may adversely affect the quality of their work;

c) policies and procedures for ensuring the protection of confidential information (see Annex C);

d) policies and procedures for avoiding involvement in any activities that would diminish confidence in the radiology service's competence, impartiality, judgement or operational integrity;

e) the organisational and management structure of the radiology service and its relationship to any other organisation with which it may be associated;

f) specified responsibilities, authority and interrelationships of all personnel;

g) adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons conversant with the purpose, procedures and assessment of results of the relevant examination procedures;

h) technical management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of radiology procedures;

i) appointment of a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the management system, who shall report directly to the level of radiology service management at which decisions are made on radiology service policy and resources;

j) appointment of deputies for all key functions, while recognising that in radiology services individuals can have more than one function and that it could be impractical to appoint deputies for every function.

4.1.6 Radiology service management shall ensure that appropriate communication processes are established within the radiology service and that communication takes place regarding the effectiveness of the management system.

4.2 Management system

4.2.1 Policies, processes, programmes, procedures and instructions shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.

4.2.2 The management system shall include, but not be limited to, internal quality control and, where available, participation in external comparisons such as quality assessment schemes and clinical audits where available and appropriate.

4.2.3 Policies and objectives of the management system shall be defined in a quality policy statement under the authority of the radiology service director and documented in a management system policy document. This policy shall be readily available to appropriate personnel, shall be concise and shall include the following:

a) the scope of services the radiology service intends to provide;

b) the radiology service management's statement of the standard of service;

c) the objectives of the management system;

d) a requirement that all personnel concerned with examination activities familiarize themselves with the management system documentation and implement the policies and procedures at all times;

e) the radiology service's commitment to good professional practice, the quality of its examinations, and compliance with the management system;

f) the radiology service management's commitment to compliance with this Code.

4.2.4 A quality manual, or however named, shall describe the management system and the structure of the documentation used in the management system. The quality manual shall include or make reference to the supporting procedures including general and modality-specific procedures. The roles and responsibilities of clinical and technical management and the quality manager, including their responsibility for ensuring conformity with this Code, shall be defined in the quality manual.

All personnel shall be instructed on the use and application of the quality manual and all referenced documents, and of the requirements for their implementation. The quality manual shall be kept up to date under the authority and responsibility of an individual appointed to be responsible for the maintenance of the management system by the radiology service management [see 4.1.5 i)].

The contents of a quality manual for a radiology service might be as follows:

a) Introduction;

b) Description of the radiology service, its legal identity, resources and main duties;

c) Quality policy;

d) Staff education and training;

e) External quality assurance participation (as relevant);

f) Document control;

g) Records, maintenance and archiving;

h) Accommodation and environment;

i) Radiology equipment and/or relevant consumables management;

j) Safety and radiation protection;

k) Environmental aspects [e.g., consumables and waste disposal, in addition to, and different from, h) and i)];

l) Research and development (if appropriate);

m) List of modalities and examinations;

n) Request protocols and management of patients;

o) Quality control and quality assurance of radiology equipment;

p) Radiology information system (see Annex B);

q) Reporting of examinations;

r) Remedial actions and handling of complaints;

s) Communications and other interactions with patients, health professionals, subcontractor radiology services and suppliers;

t) Internal audits;

u) Ethics (see Annex C).

4.2.5 Radiology service management shall establish and implement a programme that regularly monitors and demonstrates proper calibration and function of imaging systems and ancillary equipment. It shall also have a documented and recorded programme of preventive maintenance and calibration (see 5.3.2), which, at a minimum, follows manufacturer's recommendations.

4.3 Document control

4.3.1 The radiology service shall define, document and maintain procedures to control all documents and information (from internal and external sources) that form its management system documentation. A copy of each of these controlled documents shall be archived for later reference and the radiology service director shall define the retention period. These controlled documents may be maintained on any appropriate medium. National and local regulations and requirements concerning document retention could apply.

NOTE: In this context, "document" is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, charts, posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards or examination procedures.

4.3.2 Procedures shall be adopted to ensure that:

a) all documents issued to radiology service personnel as part of the management system are reviewed and approved by authorised personnel prior to issue;

b) a list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained;

c) only currently authorised versions of appropriate documents are available for active use at relevant locations;

d) documents are periodically reviewed, revised when necessary, and approved by authorised personnel;

e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use;

f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use;

g) if the radiology service's document control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments are defined, while amendments are clearly marked, initialled and dated, and a revised document is formally re-issued as soon as practicable;

h) procedures are established to describe how changes to documents maintained in computerized systems are to be made and controlled.

4.3.3 All documents relevant to the management system shall be uniquely identified, to include:

a) title;

b) edition or current revision date, or revision number, or all these;

c) number of pages (where applicable);

d) authority for issue;

e) source identification.

4.4 Review of contracts

4.4.1 Where a radiology service enters into a contract to provide radiology services, it shall establish and maintain procedures for review of contracts. The policies and procedures for these reviews leading to a change in the arrangements for examinations or contracts shall ensure that:

a) requirements, including the examination procedures to be used, are adequately defined, documented and understood (see 5.5);

b) the radiology service has the capability and resources to meet the requirements;

c) appropriate procedures selected are able to meet the contract requirements and clinical needs (see 5.5).

In reference to b), the review of capability should establish that the radiology service possesses the necessary physical, personnel and information resources, and that the radiology service's personnel have the skills and expertise necessary for the performance of the examinations in question. The review may also encompass results of external quality assurance schemes using phantoms/images of known value/findings as well as external audits and assessments by second and third parties.

4.4.2 Records of reviews, including any significant changes and pertinent discussions, shall be maintained (see 4.13.3).

4.4.3 The review shall also cover any work subcontracted by the radiology service (see 4.5).

4.4.4 Clients (e.g. patients, clinicians, health care bodies, health insurance companies, pharmaceutical companies) shall be informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected parties.

4.5 Examination by subcontractor radiology services

4.5.1 The radiology service shall have an effective documented procedure for evaluating and selecting subcontractor radiology services as well as consultants who are to provide second opinions. Radiology service management, with the advice of users of radiology services where appropriate, shall be responsible for selecting and monitoring the quality of subcontractor radiology services and consultants and shall ensure that the subcontractor radiology service or consultant is competent to perform the requested work.

The subcontracting radiology service shall ensure that radiologists reporting examinations for the subcontractor radiology service have recognized medical qualifications and registration for the medical jurisdiction of the subcontracting radiology service.

4.5.2 Arrangements with subcontractor radiology services shall be reviewed periodically to ensure that:

a) requirements, including the pre-examination and post-examination procedures, are adequately defined, documented, and understood;

b) the subcontractor radiology service is able to meet the requirements and that there are no conflicts of interest;

c) selection of examination procedures is appropriate for the intended use;

d) respective responsibilities for the interpretation of examination findings are clearly defined.

Records of such reviews shall be maintained in accordance with national, regional or local requirements.

4.5.3 The radiology service shall maintain a register of all subcontractor radiology services that it uses. A register shall be kept of all patients and images that have been subcontracted to another radiology service. The name and address of the radiology service responsible for the examination and report shall be provided to the user of the radiology service. A duplicate of the radiology service report shall be retained in both the patient record and in the permanent file of the radiology service.

4.5.4 The subcontracting radiology service and not the subcontractor radiology service shall be responsible for ensuring that subcontractor radiology service examination findings are provided to the person making the request. If the subcontracting radiology service prepares the report, it shall include all essential elements of the findings reported by the subcontractor radiology service, without alterations that could affect clinical interpretation.

However, this does not require that the subcontracting radiology service report include every word and have the exact format of the subcontractor radiology service report, unless local contractual arrangements require it. The subcontracting radiology service director may elect to provide additional interpretative remarks to those, if any, of the subcontractor radiology service, in the context of the patient and the local medical environment. The author of such added remarks should be clearly identified.

4.6 External services and supplies

4.6.1 Radiology service management shall define and document its policies and procedures for the selection and use of purchased external services, equipment and consumable supplies that affect the quality of its service. Purchased items shall consistently meet the radiology service's quality requirements. Records of purchase of imaging equipment and critical consumable items shall be retained. There shall be procedures and criteria for inspection, acceptance/rejection and storage of consumable materials.

4.6.2 Purchased equipment and consumable supplies that affect the quality of the services provided shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. Documentation of the supplier's conformity with its management system may also be used for verification.

4.6.3 There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies and purchased products shall be established and maintained for a period of time, as defined in the management system. This system shall include the recording of lot numbers of all relevant materials, the date of receipt in the radiology service and the date the material is placed in service. All of these quality records shall be available for radiology service management review.

4.6.4 The radiology service shall evaluate suppliers of relevant materials, supplies and services that affect the quality of examinations and shall maintain records of these evaluations and list those approved.

4.7 Advisory services

Appropriate radiology service professional staff shall provide advice on choice of examinations and use of the services, including radiation protection issues and required management of patients. Where appropriate, further interpretation of the results of examinations shall be provided.

There should be regular documented meetings of professional staff with referring clinical staff regarding the use of the radiology service and for the purpose of consultation on clinical matters. Where possible, the professional staff should participate in clinical-radiological meetings, enabling advice on effectiveness in general as well as in individual cases.

4.8 Resolution of complaints

The radiology service shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients or other parties. Records of complaints and of investigations and corrective actions taken by the radiology service shall be maintained, as required [see 4.13.3 g)].

NOTE: Radiology services are encouraged to obtain both positive and negative feedback from the users of their services, preferably in a systematic way (e.g. surveys).

4.9 Identification and control of nonconformities

4.9.1 Radiology service management shall have a policy and procedure to be implemented when it detects that any aspect of the radiology service's examinations does not conform with its own procedures or the agreed upon requirements of its management system or the requesting clinician. These shall ensure that:

a) personnel responsible for problem resolution are designated;

b) the actions to be taken are defined;

c) the medical significance of the nonconforming examinations is considered and, where appropriate, the requesting clinician informed;

d) examinations are halted and reports withheld as necessary;

e) corrective action is taken immediately;

f) the reports of nonconforming examinations already released are recalled or appropriately identified, if necessary;

g) the responsibility for authorisation of the resumption of examinations is defined;

h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals by radiology service management to detect trends and initiate preventive action.

NOTE: Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, quality control indications, equipment calibrations, checking of consumable materials, staff comments, examinations, reporting, radiology service management reviews, internal and external audits, and external assessments.

4.9.2 If it is determined that nonconforming examinations could recur or that there is doubt about the radiology service's compliance with its own policies or procedures as given in the quality manual, procedures to identify, document and eliminate the root cause(s) shall be promptly implemented (see 4.10).

4.9.3 The radiology service shall define and implement procedures for the release of reports in the case of nonconformities, including the review of such reports. Procedures for adding and distributing corrections and addenda to reports shall be defined and implemented. These events shall be recorded.

4.10 Corrective action

4.10.1 Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem. These shall, where appropriate, lead to preventive actions. Corrective action shall be appropriate to the magnitude of the problem and commensurate with possible risks.

4.10.2 Radiology service management shall document and implement any changes required to its operational procedures resulting from corrective action investigations.

4.10.3 Radiology service management shall monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems.

4.10.4 When the identification of nonconformity or the corrective action investigation casts doubt on compliance with policies and procedures or the management system, radiology service management shall ensure that appropriate areas of activity are audited in accordance with 4.14. The results of corrective action shall be submitted for radiology service management review.

4.11 Preventive action

4.11.1 Needed improvements and potential sources of nonconformities, either clinical, technical or concerning the management system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such potential nonconformities and to take advantage of the opportunities for improvement.

4.11.2 Procedures for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective.

NOTE 1: Apart from the review of the operational procedures, preventive action might involve analysis of quality control and other data, including trend- and risk-analyses.

NOTE 2: Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.

4.12 Continual improvement

4.12.1 All operational procedures shall be systematically reviewed by radiology service management at regular intervals, as defined in the management system, in order to identify any potential sources of nonconformity or other opportunities for improvement in the management system or clinical and technical practices. Action plans for improvement shall be developed, documented and implemented, as appropriate.

4.12.2 After action has been taken resulting from the review, radiology service management shall evaluate the effectiveness of the action through a focused review or audit of the area concerned.

4.12.3 The results of action following the review shall be submitted to radiology service management for review and implementation of any needed changes to the management system.

4.12.4 Radiology service management shall implement quality indicators for systematically monitoring and evaluating the radiology service's contribution to patient care. When this programme identifies opportunities for improvement, radiology service management shall address them regardless of where they occur. Radiology service management shall ensure that the radiology service participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

4.12.5 Radiology service management shall provide access to suitable educational and training opportunities for all radiology service personnel and relevant users of radiology services.

4.13 Quality and technical records

4.13.1 The radiology service shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records.

4.13.2 All records shall be legible and stored such that they are readily retrievable. Records may be stored on any appropriate medium subject to national, local and contractual requirements (see Note 4.3.1). Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.

4.13.3 The radiology service shall have a policy that defines the length of time various records pertaining to the management system and examination results are to be retained. Retention time shall be defined by the nature of the examination or specifically for each record.

NOTE: National and local regulations and requirements may apply.

These records may include but are not limited to the following:

a) request forms (including electronic versions);

b) examination results and reports;

c) examination procedures;

d) radiology service work-sheets;

e) patient accession records;

f) quality control/assurance records;

g) complaints and action taken;

h) records of internal and external audits, and external assessments;

i) quality improvement records;

j) radiology equipment maintenance records, including service and calibration records;

k) acceptance and on-going surveys by a qualified health physicist;

l) lot documentation, certificates of supplies, package inserts;

m) incident/accident records and action taken;

n) staff training and competency records.

4.14 Internal audits

4.14.1 In order to verify that operations continue to comply with the requirements of the management system, internal audits of all elements of the system, both managerial and technical, shall be conducted at intervals defined by the system itself. The internal audit shall progressively address these elements and emphasize areas critically important to patient care.

4.14.2 Audits shall be formally planned, organized and carried out by the quality manager or designated qualified personnel. Personnel shall not audit their own activities. There may be exceptions to this in terms of radiologists or MRT personnel or sonographers auditing their results or the outcome of clinical meetings as relevant.

The procedures for internal audits shall be defined and documented and include the types of audit, frequencies, methodologies and required documentation. When deficiencies or opportunities for improvement are noted, the radiology service shall undertake appropriate corrective or preventive actions, which shall be documented and carried out within an agreed upon time.

The main elements of the management system should normally be subject to internal audit once every twelve months.

4.14.3 The results of internal audits shall be submitted to radiology service management for review.

4.15 Management review

4.15.1 In order to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements, radiology management shall review the radiology service's management system and all of its radiology services, including examination and advisory activities. The results of the review shall be incorporated into a plan that includes goals, objectives and action plans. A typical period for conducting a management review is once every twelve months.

4.15.2 Management review shall take account of, but not be limited to:

a) follow-up of previous management reviews;

b) status of corrective actions taken and required preventive action;

c) reports from managerial and supervisory personnel;

d) the outcome of recent internal audits;

e) the outcome of assessment by external bodies;

f) the outcome of any other external quality assessment and other forms of inter-service comparison (where relevant);

g) any changes in the volume and type of work undertaken;

h) feedback, including complaints and other relevant factors, from clinicians, patients and other parties;

i) quality indicators for monitoring the radiology service's contribution to patient care;

j) nonconformities;

k) monitoring of turnaround time;

l) results of continuous improvement processes;

m) evaluation of suppliers.

Shorter intervals between reviews should be adopted when a management system is being established or restructured. This will allow early action to be taken in response to those areas identified as requiring amendment of the management system or other practices.

4.15.3 The quality and appropriateness of the radiology service's contribution to patient care shall, to the extent possible, be monitored and evaluated objectively.

NOTE: Data available will differ according to radiology service type or location (e.g. hospital, clinic, private or subcontractor radiology service).

4.15.4 Findings and the actions that arise from management reviews shall be recorded, and radiology service staff shall be informed of these findings and the decisions made as a result of the review. Radiology service management shall ensure that arising actions are discharged within an appropriate and agreed-upon time.

5 Technical requirements

5.1 Personnel

5.1.1 Radiology service management shall have an organisational plan, personnel policies and job descriptions that define qualifications and duties for all personnel.

5.1.2 Radiology service management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. This information shall be readily available to relevant personnel, and may include, but not be limited to:

a) qualifications, registrations and licenses as relevant;

b) references from previous employment;

c) job descriptions;

d) records of continuing education and achievements;

e) competency evaluations;

f) provision for untoward incident or accident reports.

In a large department or hospital some of these records may be held by human resource departments.

Other records available to authorized persons relating to personnel health may include records of exposure to occupational hazards and records of immunisation status.

5.1.3 The radiology service shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided.

5.1.4 The responsibilities of the radiology service director or designees shall include professional, scientific, technical, consultative or advisory, organisational, administrative and educational matters. These shall be relevant to the services offered by the radiology service.

The radiology service director or designees for each task, as defined in the management system documentation, should have the appropriate training and background to be able to discharge the following responsibilities:

a) provide advice to those requesting information about the choice of examinations, the use of the radiology service and the interpretation of examination results;

b) serve as an active member(s) of the medical staff for those facilities served, if applicable and appropriate;

c) relate and function effectively (including contractual arrangements, if necessary), with

   1) applicable accrediting and regulatory agencies,

   2) appropriate administrative officials,

   3) the healthcare community,

   4) the patient population served;

d) define, implement and monitor standards of performance and quality improvement of the radiology service or services;

e) implement the management system (the radiology service director and professional radiology service personnel should participate as members of the various quality improvement committees of the institution, if applicable);

f) monitor all work performed in the radiology service to determine that reliable information is being generated;

g) ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the radiology service;

h) plan, set goals, develop and allocate resources appropriate to the medical environment;

i) provide effective and efficient administration of the radiology service, including in accordance with institutional assignment of such responsibilities, budget planning and control with responsible financial management, as relevant, if applicable;

j) provide educational programmes for the radiology service staff and participate in educational programmes of the institution, if applicable;

k) plan and direct research and development appropriate to the radiology service;

l) select and monitor all subcontractor radiology services for quality of service;

m) implement a safe radiology service environment in compliance with good practice and applicable regulations;

n) address any complaint, request or suggestion from users of the radiology service;

o) ensure good staff morale.

The radiology service director need not perform all responsibilities personally. However, it is the radiology service director who remains responsible for the overall operation and administration of the radiology service, for ensuring that quality services are provided for patients.

5.1.5 There shall be staff resources adequate to the undertaking of the work required and the carrying out of other functions of the management system.

5.1.6 Personnel shall have training specific to quality assurance and quality management for services offered.

5.1.7 Radiology service management shall authorize personnel to perform particular tasks such as management of patients, examination and operation of particular types of equipment, including use of computers and the radiology information system (see Annex B).

5.1.8 Policies shall be established that define who may use the radiology information system, who may access patient data and who is authorized to enter and change examination reports, or modify computer and radiology system programs (see Annex B).

5.1.9 There shall be a continuing education programme available to staff at all levels.

5.1.10 Employees shall be trained to prevent or contain the effects of adverse incidents.

5.1.11 The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary.

5.1.12 The personnel making professional judgements with reference to examinations shall have the applicable training and recent experience. Professional judgements can be expressed as reports, comments, opinions, interpretations, predictions.

Personnel shall take part in continuing professional development or other professional liaison.

5.1.13 Confidentiality of information regarding patients shall be maintained by all personnel.

5.2 Accommodation and environmental conditions

5.2.1 The radiology service shall have space allocated so that its workload can be performed without compromising the quality of work, equipment management, quality control procedures, safety of personnel or patient care. The radiology service director shall determine the adequacy of this space. Radiology service resources shall be of a degree necessary to support the activities of the radiology service. Radiology service resources shall be maintained in a functional and reliable condition. Similar provisions should be made for patient management and examinations at sites other than the permanent radiology service.

5.2.2 The radiology service shall be designed for the efficiency of its operation, to optimize the comfort of its occupants and to minimize the risk of injury and occupational illness. Patients, employees and visitors shall be protected from recognized hazards.

5.2.3 Consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimisation of patient preparation.

5.2.4 Design and environment of the radiology service shall be suitable for the tasks carried out therein. The environment in which the patient preparation or examinations or both are undertaken shall not invalidate the results, or adversely affect the required quality, of any examination. These include, but are not limited to, radiation protection, energy sources, lighting, ventilation, waste and refuse disposal, and environmental conditions. The radiology service should have procedures for checking that the environment does not adversely affect patient management and the performance of equipment.

5.2.5 The radiology service shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the examination findings. Attention should be paid to, but not be limited to, sterility, dust, electromagnetic interference, radiation, magnetic field, humidity, electrical supply, temperature and sound and vibration levels, as appropriate to the activities concerned.

5.2.6 There shall be effective separation between adjacent radiology service sections in which there are incompatible activities.

5.2.7 Access to, and use of, radiation and strong magnetic field areas shall be controlled. Appropriate measures shall be taken to safeguard patients and resources from unauthorized access. These measures should be approved by an appropriately qualified medical physicist.

5.2.8 Communication systems within the radiology service shall be appropriate to the size and complexity of the service and the efficient transfer of messages.

5.2.9 Relevant storage space and conditions shall be provided to ensure the continuing integrity of reference phantoms, documents, files, manuals, equipment, supplies, records, images and reports.

5.2.10 Work areas shall be clean and well maintained. Storage and disposal of hazardous materials shall be those specified by relevant regulations.

Measures shall be taken to ensure good housekeeping in the radiology service. Special procedures and training for personnel could be necessary to that end.

5.3 Radiology equipment

NOTE: For the purpose of this Code, ancillary equipment including that used for injection, sedation, monitoring and anaesthesia, reference phantoms, consumables, materials, imaging equipment, computers, monitors and workstations are included as radiology equipment, as applicable.

5.3.1 The radiology service shall be furnished with all items of equipment required for the provision of services (including patient management before, during and after examination). In those cases where the radiology service needs to use equipment outside its permanent control, radiology service management shall ensure that the requirements of this Code are met.

When selecting equipment, account should be taken of the use of energy and future disposal (care of the environment).

5.3.2 Equipment shall be shown (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.

Radiology service management shall establish a programme that regularly monitors and demonstrates proper calibration and function of ancillary equipment, phantoms and imaging equipment. It shall also have a documented and recorded programme of preventive maintenance (see 4.2.5), which, at a minimum, follows the manufacturer's recommendations.

When manufacturers' instructions, operators' manuals or other documentation are available, they may be used to establish requirements for compliance with relevant standards or to specify requirements for periodic calibration, as appropriate, to fulfil part or all of this requirement.

5.3.3 Each item of equipment shall be uniquely labelled, marked or otherwise identified.

5.3.4 Records shall be maintained for each item of equipment contributing to the performance of examinations. These records shall include at least the following:

a) identity of the equipment;

b) manufacturer's name, model/type identification and serial number or other unique identification;

c) manufacturer's contact person and telephone number, as appropriate;

d) date of receiving and date of putting into service;

e) current location, where appropriate;

f) condition when received (e.g. new, used or reconditioned);

g) manufacturer's instructions, if available, or reference to their retention;

h) equipment performance records that confirm the equipment's suitability for use;

i) maintenance carried out and that planned for the future;

j) damage to, or malfunction, modification or repair, of the equipment;

k) predicted replacement date.

The performance records referred to in h) should include copies of reports/certificates of all calibrations and/or verifications including dates, time and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, together with the frequency of checks carried out between maintenance/calibration, as appropriate, to fulfil part or all of this requirement. Manufacturer's instructions may be used to establish acceptance criteria, procedures and frequency of verification for maintenance or calibration or both, as appropriate, to fulfil part or all of this requirement.

These records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by national regulations.

5.3.5 Equipment shall be operated by authorized personnel only. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) shall be readily available to radiology service personnel.

5.3.6 Equipment shall be maintained in a safe working condition. This shall include examination of electrical safety, emergency stop devices and the safe handling and disposal of biological and other hazardous materials by authorized persons. Manufacturers' specifications or instructions or both shall be used, as appropriate.

5.3.7 Whenever equipment is found to be defective, it shall be taken out of service, clearly labelled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria. The radiology service shall examine the effect of this defect on previous examinations and institute the procedure given in 4.9. The radiology service shall take reasonable measures to decontaminate equipment, if relevant, and reduce any hazard prior to service, repair or decommissioning.

5.3.8 A list of the measures taken to reduce contamination and hazard shall be provided to the person working on the equipment. The radiology service shall provide suitable space for repairs and appropriate personal protective equipment.

5.3.9 Whenever practicable, equipment under the control of the radiology service, which requires calibration or verification shall be labelled or otherwise coded to indicate the status of calibration or verification and the date when recalibration or re-verification is due.

5.3.10 When equipment is removed from the direct control of the radiology service or is repaired or serviced, the radiology service shall ensure that it is checked and shown to be functioning satisfactorily before being returned to use.

5.3.11 When computers, including the radiology information systems, are used for the collection, processing, recording, reporting, storage or retrieval of examination information, the radiology service shall ensure that:

a) computer software, including that built into equipment, is documented and suitably validated as adequate for use in the service;

b) procedures are established and implemented for protecting the integrity of information and data at all times;

c) computers are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of information and data;

d) computer programs and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons.

See also Annex B.

5.3.12 The radiology service shall have procedures for safe handling, transport, storage and use of equipment, to prevent its contamination or deterioration.

5.3.13 Where testing, maintenance, or recalibration give rise to a change of exposure or technical parameters, the radiology service shall have procedures for ensuring that exposure charts or technical parameters are correctly updated.

5.3.14 Equipment, including hardware, software, phantoms and consumables shall be safeguarded from adjustments or tampering that might invalidate examination results.

5.4 Pre-examination procedures

5.4.1 The request form shall contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical data.

The request form or an electronic equivalent should allow space for the inclusion of, but not be limited to, the following:

a) unique identification of the patient;

b) name or other unique identifier of physician or other person legally authorized to request examinations or use medical information together with the destination for the report; the requesting clinician's address and contact phone number should be provided as part of the request form information;

c) patient condition and the anatomic area of concern, where relevant;

d) examinations requested;

e) clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes;

f) date and time of patient referral by requester;

g) date and time of presentation of the patient to the radiology service.

The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the radiology service should be determined in discussion with the users of radiology services.

5.4.2 Specific instructions for the proper pre-examination management of patients shall be documented and implemented by radiology service management and made available to those responsible for pre-examination management of patients. These instructions shall be contained in appropriate procedure or modality-specific manuals.

The procedure or modality-specific manuals shall include the following:

a) copies of or references to

1) lists of available imaging modalities and medical imaging examinations offered,

2) information for users of radiology services on medical indications and appropriate selection of available examination procedures,

3) consent forms, when applicable,

4) information and instructions provided to patients in relation to their own pre-examination preparation or preparation by a care-giver, including medicines management, dietary preparation and preparatory medications, if indicated;

b) procedures and/or instructions for

1) completion of request form or electronic request,

2) any special transport requirements and supervision between time of collection of the patient and time patient is received by the radiology service as relevant,

3) identification of the patient,

4) reception of patients into the radiology service,

5) pre-examination management of patients including coagulation testing, renal function and preparatory medications, if indicated,

6) screening of patients for allergies, asthma, diabetes, renal disease, cardiac disease, multiple myeloma or other risk factors as relevant for intravenous contrast media and/or sedation.

5.4.3 All examinations shall be traceable, normally by request form, to an identified individual and requester.

Where there is uncertainty in the identification of the patient but their clinical condition indicates that examination should not be delayed, the radiology service may choose initially to examine the patient but not release the results until the requesting physician or person responsible for the patient takes responsibility for identifying the patient. In such an instance, the identity of that person taking responsibility for the patient should be traceable to the request form. If this requirement is not met for any reason, the person responsible should be identified in the report.

5.4.4 Where relevant, the radiology service shall monitor the transportation of patients to the radiology service such that they are transported:

a) within a time frame appropriate to the nature of the requested examinations and the modality concerned;

b) in a condition and suitable state of preparation that allows the examination to be achieved;

c) in a safe manner.

5.4.5 Details of all patients received shall be recorded. The date and time of the examination, as well as the identity of the person completing the examination, shall be recorded.

5.4.6 Criteria shall be developed and documented for acceptance or rejection of patients and requested examinations. If an examination is felt to be inappropriate for the patient, (e.g. inappropriate examination for the clinical condition, or excess radiation for the seriousness of the condition, the age, gender or pregnancy status of the patient) then the person responsible for the examination should stop the examination and notify the referring clinician and/or the director of radiology services.

If an examination is compromised by a patient's actions, such as movement or inability or refusal to cooperate, the final report shall indicate the nature of the problem, and if applicable, that caution is required when interpreting the report.

5.4.7 The radiology service shall periodically review its examination acceptance and rejection criteria to ensure that neither insufficient nor excessive imaging occurs.

5.4.8 Authorized personnel shall systematically review requests and patient details and decide which examinations are to be performed and the procedures to be used in performing them.

5.4.9 The radiology service shall, if relevant, have a documented procedure for the management, examination and reporting for those patients considered in need of urgent examination. The procedure shall include details of any special labelling of the request form and identification of the patient, the mechanism of transfer of the patient to the examination area of the radiology service, any particular procedure to be followed and any special reporting criteria to be utilized.

5.4.10 Any emergency examinations completed shall also be traceable to the patient.

5.4.11 The radiology service shall have a written policy concerning verbal requests for examinations.

5.5 Examination procedures

5.5.1 The radiology service shall use examination procedures which meet the needs of the users of the radiology service and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international or national guidelines. If in-house procedures are used, they shall be appropriately validated for their intended use and fully documented.

5.5.2 From time to time, the director of radiology services shall review the modalities and examinations provided by the service and ensure that they are appropriate for the imaging equipment and training of radiology service personnel, and also appropriate to the needs/requirements of the patients referred to that service. Such a review is normally carried out annually.

The director of radiology services, or designated person, shall ensure that any new imaging procedures/examinations offered are validated in the medical literature, and the radiology service has appropriate equipment and appropriately trained personnel. If equipment is unsatisfactory, or staff training inadequate, a new imaging procedure/examination should not be introduced until the prerequisites have been met. Some services will be introducing new procedures which are still under investigation. If so, these should be covered by the appropriate ethics committee or similar approval processes.

5.5.3 All examination procedures shall be documented. Documented procedures and necessary instructions shall be available in a style and language commonly understood by the staff in the radiology service.

Out-takes, exposure charts or similar systems that summarize key information are acceptable for use as a quick reference, provided that a complete manual is available for reference. The abbreviated systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.

The procedure for use of equipment shall be based on the instructions for use written by the manufacturer, provided that they are in accordance with 5.5.1 and 5.5.2 and that they describe the procedure, as it is performed in the radiology service. Any deviation shall be reviewed and documented. Additional information that could be required to perform the examination shall also be documented. Any procedural changes shall be dated and authorized as for other procedures.

In addition to document control identifiers, documentation should include, when applicable, the following:

a) purpose of the examination;

b) performance specifications (e.g. positioning, technique, images as relevant);

c) patient management procedures;

d) ancillary equipment;

e) required imaging equipment and materials;

f) calibration procedures, if required;

g) procedural steps;

h) quality control procedures;

i) influencing factors (e.g. body habitus, implants);

j) records to be maintained;

k) safety precautions, including safe disposal of materials used in the examination procedures.

5.5.4 Specific instructions for the proper management of patients during examination shall be documented and implemented by radiology service management. These instructions shall be contained in appropriate procedure or modality-specific manuals.

The procedure or modality-specific manuals shall include procedures and/or instructions for the following:

a) receipt of patients into the modality as relevant;

b) management of patients during examination, including any special requirements and sedation as relevant;

c) type and amount of the contrast medium, whether intravenous, oral or other, required for imaging, if applicable;

d) special timing of contrast medium required for imaging, if applicable;

e) unique labelling of images traceable to an individual patient;

f) recording the identity of the person examining the patient;

g) repetition of an examination due to unsatisfactory imaging.

5.5.5 Electronic manuals are acceptable provided that the above-specified information is included. The same requirements for document control should also apply to electronic manuals.

The radiology service director shall be responsible for ensuring that the contents of examination procedures are complete, current and have been thoroughly reviewed.

5.5.6 If the radiology service intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the radiology services in writing, prior to the introduction of the change.

5.6 Assuring quality of examination procedures

5.6.1 The radiology service shall design internal quality control systems that verify the attainment of the intended quality of reports. It is important that the control systems provide staff members with clear and easily understood information on which to base decisions. Special attention should be paid to the elimination of mistakes in the process of managing patients, requests, examinations and reports.

5.6.2 A programme for calibration of equipment and verification of consistency shall be designed and performed (see 5.3.2).

5.6.3 The radiology service shall participate in external quality assessment inter-service comparisons and clinical audits, where available and appropriate. Radiology service management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when criteria are not fulfilled.

5.6.4 Whenever a formal inter-service comparison programme is not available or appropriate, the radiology service shall endeavour to develop a mechanism, such as internal and external clinical audits, for determining the acceptability of procedures not otherwise evaluated.

5.7 Post-examination procedures

5.7.1 Specific instructions for the proper management of patients during the post-examination phase shall be documented and implemented by radiology service management. These instructions shall be contained in appropriate procedure or modality-specific manuals.

The procedure or modality-specific manuals shall include procedures and/or instructions for the following:

a) management of patients after examination including any special requirements for post-examination recovery, on-site and off-site, and any other particular post-examination cautionary measures;

b) determining whether any further examinations of the patient are required.

5.7.2 Safe disposal of materials no longer required for examination shall be carried out in accordance with national and local regulations or recommendations for waste management.

5.7.3 Qualified radiologists or physicians as relevant shall systematically review the images arising from examinations, evaluate them in conformity with the clinical information available regarding the patient, produce and authorize the release of the report.

5.7.4 Images shall be stored for a specified time, under suitable conditions, to enable further review of the examination.

5.8 Reporting of examinations

5.8.1 Radiology service management shall be responsible for formatting and producing reports. The format of the report (i.e. electronic or paper), and the manner in which it is to be communicated from the radiology service, should be determined in discussion with the users of radiology services.

5.8.2 Radiology service management shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval.

5.8.3 Reports shall be legible, without mistakes in transcription and reported to persons authorized to receive and use medical information. The report shall also include, but not be limited to, the following:

a) clear, unambiguous identification of the examination;

b) the identification of the radiology service that issued the report;

c) name or other unique identifier of the requester and the requester's address;

d) unique identification and location of the patient, where possible, and destination of the report;

e) details of the patient and indications for examination;

f) identification of the modality and equipment used as relevant;

g) date and time of performance of the examination of the patient by the radiology service;

h) a summary of any contrast media doses or other relevant medication used during the taking of the images reported upon;

i) findings of the examination;

j) prior examination findings where relevant;

k) interpretation of results, where appropriate;

l) other comments (e.g. condition of the patient which may have compromised the result, findings/interpretations from subcontractor radiology services);

m) date and time of release of report, which, if not on the report, shall be readily accessible when needed;

n) identification of the person authorizing the release of the report;

o) signature or authorization of the person checking or releasing the report, where possible.

5.8.4 As appropriate, the description of examinations performed, their results and reports should follow the vocabulary, syntax and nomenclature recommended by recognized bodies or authoritative texts, which must be referenced in procedural documentation.

5.8.5 The report shall indicate if the condition of the patient received was unsuitable for examination or could have compromised the result.

5.8.6 Copies or files of reported examinations shall be retained by the radiology service such that prompt retrieval of the information is possible. The length of time that reported information is retained may vary; however, the reports shall be retrievable for as long as medically relevant or as required by national or local requirements.

5.8.7 The radiology service shall have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results fulfil established 'alert' or 'critical' parameters. This includes results received on patients sent to a subcontractor radiology service for examination.

5.8.8 In order that local clinical needs can be served, the radiology service shall determine their 'alert/critical' criteria, in agreement with the clinicians using the radiology service.

5.8.9 Records of actions taken in response to reports that fulfil 'alert/critical' criteria shall be maintained. These shall include date, time, responsible radiology service staff member, person notified. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.

5.8.10 For results transmitted as an interim report, the final report shall always be forwarded to the requester.

5.8.11 Radiology service management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs.

There shall be a policy for notifying the requester when an examination is delayed. Turnaround times as well as any feedback from clinicians in relation to them shall be monitored, recorded and reviewed by radiology service management. Corrective action shall be taken to address any problems so identified.

This does not mean that the clinical personnel are to be notified of all delays in examination, but only in those situations where the delay could compromise patient care. This procedure should be developed in collaboration between clinical and radiology service personnel.

5.8.12 When examination results are transmitted to another site of the service or to a subcontracted radiology service for reporting, the integrity of the images shall be assured. All applicable requirements of reporting shall be met.

5.8.13 When examination results from a subcontracted radiology service need to be transcribed by the referring radiology service, procedures for verifying the correctness of all transcriptions shall be in place.

5.8.14 The radiology service shall have clearly documented procedures for the release of examination reports, including details of who may release reports and to whom. The procedures shall also include guidelines for the release of findings and reports directly to patients and third parties.

5.8.15 The radiology service shall establish policies and practices for ensuring that reports distributed by telephone or other electronic means reach only authorized receivers. Reports provided verbally shall be followed by a properly recorded report.

5.8.16 The radiology service shall have written policies and procedures regarding the alteration of reports. When altered, the record must show the time, date and name of the person responsible for the change. Original entries shall remain legible when alterations are made.

Original electronic records shall be retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.

5.8.17 Information that has been available for clinical decision-making and revised shall be retained in subsequent reports and be clearly identified as having been revised. If the reporting system cannot capture amendments, changes or alterations, an audit log shall be used.

Annex A: Correlation between ISO 15189: 2007 and the New Zealand Code of Radiology Management Practice: 2011

(Informative)

NZS/ISO 15189:2007		NZ Code of Radiology Management Practice:2011	
1	Scope	1	Scope
2	Normative references	2	Normative references
3	Terms and definitions	3	Terms and definitions
4	Management requirements	4	Management requirements
4.1	Organization and management	4.1	Organization and management
4.2	Quality management system	4.2	Management system
4.3	Document control	4.3	Document control
4.4	Review of contracts	4.4	Review of contracts
4.5	Examination by referral laboratories	4.5	Examination by subcontractor radiology services
4.6	External services and supplies	4.6	External services and supplies
4.7	Advisory services	4.7	Advisory services
4.8	Resolution of complaints	4.8	Resolution of complaints
4.9	Identification and control of non-conformities	4.9	Identification and control of non-conformities
4.10	Corrective action	4.10	Corrective action
4.11	Preventive action	4.11	Preventive action
4.12	Continual improvement	4.12	Continual improvement
4.13	Quality and technical records	4.13	Quality and technical records
4.14	Internal audits	4.14	Internal audits
4.15	Management review	4.15	Management review
5	Technical requirements	5	Technical requirements
5.1	Personnel	5.1	Personnel
5.2	Accommodation and environmental conditions	5.2	Accommodation and environmental conditions
5.3	Laboratory equipment	5.3	Radiology equipment
5.4	Pre-examination procedures	5.4	Pre-examination procedures
5.5	Examination procedures	5.5	Examination procedures
5.6	Assuring the quality of examination procedures	5.6	Assuring quality of examination procedures
5.7	Post-examination procedures	5.7	Post-examination procedures
5.8	Reporting of results	5.8	Reporting of examinations

Annex B: Recommendations for protection of radiology information systems

(Informative)

Recommendations include, in their entirety, the Radiology Information System (RIS), Hospital Information System (HIS) and Picture Archiving and Communications System (PACS)

B.1 General

B.1.1 Images and reports are the products of the radiology service. Because radiology information systems can be damaged or subverted in a variety of ways, it is important to establish policies that protect patients from harm caused by loss or change of data.

The recommendations given in this annex ought to result in a high level of data/information integrity for radiology information systems. In a large organisation, many of the tasks in this annex may be delegated to an Information Services (IS) department, but will need approval by the radiology service director or designee.

B.2 Environment

B.2.1 The radiology information system facilities and equipment should be clean, well maintained and in a location and environment that comply with vendor specifications.

B.2.2 The radiology information system components and storage areas should be readily accessible to appropriate fire-fighting equipment.

B.2.3 Wires or cables should be protected if located in traffic areas.

B.2.4 There should be provision for an uninterruptible power supply (UPS) where relevant.

B.2.5 The radiology information system facilities should be protected from unauthorized access.

B.3 Procedure manual

B.3.1 A complete radiology information system procedure manual, which may be electronic, should be readily available to all authorized computer users.

B.3.2 The radiology information system procedure manual should be reviewed and approved at defined intervals by the radiology service director or a person designated for this task.

B.3.3 There should be written procedures for actions necessary to protect the data or radiology information system equipment or both in case of fire or hardware/software failure.

B.4 System security

B.4.1 Radiology information system programs should be adequately protected to prevent alteration or destruction by casual or unauthorized users.

B.4.2 Strict policies should be established for authorizing use of the radiology information system. Policies should define those authorized to access patient information and those authorized to enter patient and examination information, change examination information or alter radiology information system programs.

B.4.3 If data in other information systems can be accessed through the radiology information system (e.g. pharmacy, laboratory or medical records), there should be appropriate computer security measures to prevent unauthorized access to these data through the radiology information system. The radiology information system should not be allowed to jeopardise the data security of other systems.

B.5 Data entry and reports

B.5.1 Reports and images in the radiology information system should be compared with original input in order to ensure the integrity of data transfer at defined intervals by detecting errors in data transmission, storage or processing.

B.5.2 Whenever multiple copies of tables are maintained within a radiology information system, (e.g. referrer databases), they should be periodically compared in order to ensure consistency among all copies in use. Appropriate replication or comparison procedures should be in place.

B.5.3 The radiology information system output to the medical record constitutes direct patient-care data. Accordingly, the radiology service director should approve and review the content and format of the radiology service reports in order to ensure that they effectively communicate radiology service information and meet the needs of the clinical staff.

B.5.4 There should be an audit mechanism allowing the radiology service to identify all individuals who have entered or modified patient data, control files or radiology information system programs.

B.6 Data retrieval and storage

B.6.1 Stored patient details and archival information should be easily and readily retrievable within a time frame consistent with patient-care needs.

B.6.2 The radiology information system should be able to completely reproduce archived examination images and reports, originally given for an examination and any flags, footnotes or interpretative comments attached to the report.

B.6.3 Patient and radiology service information should be retrievable “on-line” for a designated period of time, depending on the needs of the individual organization.

B.6.4 Data-storage media should be properly labelled, stored and protected from damage or unauthorized use.

B.6.5 Efficient back-up should be in place to prevent loss of data in case of hardware or software failure.

B.6.6 Radiology information system alarm systems (usually the main computer console that monitors hardware and software performance) should be monitored and tested regularly to ensure their proper functioning.

B.7 Hardware and software

B.7.1 A written procedure and a complete record of all preventive maintenance for all radiology information system hardware should be readily available.

B.7.2 The radiology information system should be checked after each back-up or restoration of data files in order to ensure that no inadvertent alterations have occurred.

B.7.3 Mistakes detected during system backup should be documented, along with corrective action taken, and reported to the responsible person in the radiology service.

B.7.4 Any alterations to the radiology information system hardware or software should be verified, validated and completely documented in order to confirm that changes are acceptable and appropriate.

B.7.5 The radiology service director or person designated for the task is responsible for the accurate and effective delivery of examination findings to the requesting clinician and should approve all changes in the radiology information system that may affect patient care.

B.7.6 Programs should be checked for proper performance when first installed and after changes or modifications have been made.

B.7.7 The purpose of a program, the manner of its functioning and its interaction with other programs should be clearly stated. The degree of detail should be adequate to support any troubleshooting, system modification or programming as applicable, done by the computer operators.

B.7.8 Those interacting with the radiology information system should be taught how to use a new system or modifications of the old system.

B.7.9 The radiology service should have designated a responsible person to whom all significant radiology information system malfunctions are to be promptly reported.

B.8 System maintenance

B.8.1 “Downtime” for maintenance should be scheduled to minimize interruption of patient-care services.

B.8.2 There should be documented procedures for handling the shutdown and restarting of all or part of the radiology information system in order to ensure integrity of the data, uninterrupted delivery of radiology services and proper functioning of the system after restarting.

B.8.3 There should be written procedures for handling downtime on each part of the radiology information system (RIS, HIS, PACS), to ensure the integrity of patient data. Procedures for verifying recovery of the affected system and the replacement or updating of data files should be available.

B.8.4 All unscheduled radiology information system downtime, periods of system degradation (response time) and other radiology system problems should be documented, including the reasons for failure and the corrective action taken.

B.8.5 Written contingency plans should be developed to handle services in the event of a radiology information system failure such that patients' results are reported in a prompt and useful fashion.

B.8.6 Records should be maintained that document regular maintenance and allow operators to trace any work done on the radiology information system.

Annex C: Ethics in radiology

(Informative)

C.1 General

The professional personnel of a radiology service are bound by the ethical codes of their respective profession. Different professions can have particular rules or requirements for some or all professional personnel which have to be observed.

Personnel responsible for the management of radiology services should accept that, as with other health professionals, they could have responsibilities over and above the minimum required by law.

Acceptable practice may vary in different situations. A radiology service will need to determine what is appropriate for its own situation and incorporate the details in their quality manual.

Radiology services shall not engage in practices restricted by law and should uphold the reputation of their profession.

C.2 General principles

C.2.1 The general principle of healthcare ethics is that the patient's welfare is paramount. However, the relationship between the radiology service and the patient is complicated by the fact that there could also be a contractual relationship between the requester and the radiology service. Although this relationship (which may be commercial) can frequently be seen as the more important, the radiology service's obligation should be to ensure that the patient's welfare and interest are always the first consideration and take precedence.

C.2.2 The radiology service should treat all patients fairly and without discrimination.

C.3 Collection of information

C.3.1 Radiology services should collect adequate information for the proper identification of the patient, which enables the requested examinations and other radiology service procedures to be carried out, but should not collect unnecessary personal information.

The patient should be aware of the information collected and the purpose for which it is collected.

C.3.2 Safety of staff and other patients are legitimate concerns when communicable diseases are possible and information may be collected for these purposes. Billing purposes, financial audit, resource management and utilisation reviews are also legitimate management concerns for which information may be collected.

C.4 Patient management

C.4.1 All procedures carried out on a patient require the informed consent of the patient. For most routine radiology service procedures, consent can be inferred when the patient presents him or herself at a radiology service with a request form and willingly submits to the usual procedure. A patient in a hospital bed should normally be given the opportunity to refuse.

Special procedures, including the more invasive procedures, will require a more detailed explanation and, in some cases, written consent. This is desirable when there is a likelihood of complications following the procedure.

In emergency situations, consent might not be possible and under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

C.4.2 Some examinations may require special counselling. This would normally be carried out by the clinical staff or requesting physician, but the radiology service should endeavour to ensure that findings with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

C.4.3 Adequate privacy during reception and preparation of the patient should be available and appropriate to the type of examination and information being requested.

C.4.4 If a patient arrives at the radiology service in a condition that is unsuitable for the requested examination, they should normally be refused and the referring physician notified.

C.5 Performance of examination

C.5.1 All radiology service examinations should be carried out according to appropriate standards and with the level of skill and competence expected of the profession.

Any fabrication of results is completely unacceptable.

In situations where the radiologist or the radiology service can determine the amount of work involved with a requested examination the selection should be appropriate for the particular clinical situation.

C.5.2 When examinations require use of ionising radiation, the principles of radiation protection must be followed:

a) justification (no process shall be introduced unless its introduction produces a positive net benefit to exposed individuals or society);

b) limitation (of individual dose and risk);

c) ALARA (as low as reasonably achievable).

This applies to the patient, persons accompanying the patient and staff.

NOTE All radiology services must meet nationally legislated radiation protection requirements.

C.6 Reporting of examinations

C.6.1 Results of radiology service examinations, which can be attributed to a specific patient, are confidential unless disclosure is authorized. Results will normally be reported to the requesting clinician and may be reported to other parties with the patient's consent or as required by law. Results of radiology service examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

C.6.2 Decisions concerning implied consent for the reporting of results to other parties (e.g. consultant practitioners to whom the patient has been referred) should be made cautiously, taking local customs into account. Radiology services should have written procedures detailing how various requests are handled and this information should be made available to patients on request.

Policies and procedures must take into account and comply with relevant privacy legislation.

C.6.3 In addition to the accurate reporting of examinations, the radiology service has an additional responsibility to ensure that, as far as possible, the examinations are correctly interpreted and applied in the patient's best interest. Specialist advice with regard to the selection and interpretation of examinations is part of the service provided.

C.7 Storage and retention of medical records

C.7.1 The radiology service should ensure that the information is stored such that there are reasonable safeguards against loss, unauthorized access or tampering and other misuse.

C.7.2 The retention of medical records is defined by various statutory requirements and these requirements will need to be considered together with any guidelines issued by relevant professional bodies.

Local customs, particularly the reliance of clinicians on radiology service records as opposed to their own records, also need to be taken into account.

C.7.3 Concerns regarding legal liability for certain types of procedure may require the retention of certain records for much longer periods than for other records.

C.7.4 Radiology services should develop their own protocols for the retention of records, indicating the time various examination results are to be retained. The system should provide ready access, when required, by authorized individuals.

C.8 Access to radiology service records

C.8.1 Access to radiology service records varies somewhat according to different situations. Patient access will normally be through the requesting physician. In many situations access will normally be available to:

a) the person requesting the examination;

b) radiology service staff, if required for the performance of their duties;

c) other authorized individuals.

The rights of children and mentally impaired individuals need to be recognized. Health information can sometimes be withheld from individuals who would normally be expected to be authorized to receive it. This could be for reasons of maintenance of law or individual safety and when access would involve unwarranted disclosure of the affairs of another individual.

C.8.2 The radiology service should develop protocols addressing the handling of different requests in accordance with national regulations and local policies.

C.9 Use of images for purposes other than those requested

The use of images for purposes other than those requested without prior consent should occur only if the images are rendered anonymous. Radiology services/institutions should have documented policies for handling identifiable images for purposes other than those requested, taking into account the legal implications. Relevant national and local regulatory and ethical committee requirements should be observed.

C.10 Financial arrangements

C.10.1 Radiology services should not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an inducement for the referral of examinations or patients, or interfere with the physician's independent assessment of what is best for the patient.

C.10.2 Where possible, rooms used for examinations should be completely independent and separate from referring practitioners' rooms, but where this is not possible, financial arrangements are to follow normal commercial practice.

C.10.3 Radiology services should try to avoid situations that give rise to a conflict of interest. Where this is not possible, the interests should be declared and steps taken to minimize the impact.

Bibliography

ISO 15189:2007 Medical Laboratories - Particular requirements for quality and competence

Procedures and Conditions for Accreditation (AS 1), IANZ

Radiology Supplementary Criteria for Accreditation – Ultrasound (AS RAD C10.2), May 2008, IANZ

Radiology Supplementary Criteria for Accreditation – Mammography (AS RAD C10.3), May 2008, IANZ

Radiology Supplementary Criteria for Accreditation – CT Scanning (AS RAD C10.4), May 2008, IANZ

Radiology Supplementary Criteria for Accreditation – Nuclear Medicine (AS RAD C10.6), May 2008, IANZ

Radiology Supplementary Criteria for Accreditation – MR Imaging (AS RAD C10.7), May 2008, IANZ

Radiology Accreditation Offsite Reporting (AS IG 8), December 2008, IANZ

Standards of Practice for Diagnostic and Interventional Radiology - Version 9.0, 2008, RANZCR

NRL C3 Code of safe practice for the use of unsealed radioactive materials in medical diagnosis, therapy and research, January 1994, Revised June 2010, National Radiation Laboratory, Ministry of Health

NRL C5 Code of safe practice for the use of x-rays in medical diagnosis, January 1994, Revised June 2010, National Radiation Laboratory, Ministry of Health

Guidelines for quality assurance in radiation protection for diagnostic x-Ray facilities: large x-ray facilities. NRL 1995/1, National Radiation Laboratory, Ministry of Health

Guidelines for quality assurance in radiation protection for diagnostic x-ray facilities: limited x-ray facilities. NRL 1996/6, National Radiation Laboratory, Ministry of Health

Guidelines for quality assurance in radiation protection for diagnostic x-ray facilities: small x-ray facilities. NRL 1996/7, National Radiation Laboratory, Ministry of Health