Technical Guide

Guide to the Application of the New Zealand Code of Radiology Management Practice

Second Edition July 2020

The NZ mark of competence
Tohu Matatau Aotearoa

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Contents

1 Introduction

This International Accreditation New Zealand (IANZ) guidance document is an elaboration of the requirements of the *New Zealand Code of Radiology Management Practice: 2011* (NZCRMP). It addresses items that are essential or most important for the provision of an accredited medical imaging service.

This document must be read in conjunction with current editions of the NZCRMP and the IANZ publication "*Procedures and Conditions for Accreditation*", the latter document describing the organisation and operation of the IANZ Accreditation Programmes including that for Medical Imaging Services.

The NZCRMP is a general criteria document designed to apply to all types of medical imaging services. This guidance document, on the other hand, provides information and interpretation on staff, accommodation, equipment and other aspects of good practice which are considered to be minimum standards for medical imaging services being accredited against the NZCRMP. The extent to which a medical imaging service will need to have documented policies and procedures will vary, as appropriate to the scope of service and examinations provided, and as required to maintain consistent outputs.

2 Organisation and management (NZCRMP Clause 4.1)

The overall purpose of Clause 4.1 is to ensure that the service is appropriately organised to meet the needs of patients and clinicians, and that the organisational arrangements are clearly defined. Responsibility for this is unambiguously placed with the medical imaging service management and requires that such management responsibility is also clearly defined.

To meet the requirements of this clause the service needs to ensure that all staff are aware of and understand what their role within the organisation is.

The service will need to identify and define pertinent management responsibilities, including those for the appointment of a quality manager, technical management and deputies (where appropriate) for key functions.

Responsibilities and authorities for all personnel need to be defined. These could be documented in a quality manual or it may be set out in other documents such as job descriptions and / or in operational procedures, for example. However specified, these documents will be reviewed as part of the IANZ assessment process and therefore be readily available to an assessor / assessment team.

Training programmes and supervision of staff (including locums and non-radiographic staff) will need to be appropriate to their level of expertise. Also see modality-specific *Medical Imaging Services Supplementary Criteria for Accreditation* for further details on training and supervision requirements for radiologists, specialists, sonographers and radiographers which will need to be demonstrably met, i.e. through a review of training programmes and records.

3 Management system (NZCRMP Clause 4.2)

Clause 4.2.1 succinctly sets out the desired outcomes of the management system requirements. The objective of an effective management system is to ensure that the delivery of services meets the needs of patients and clinicians to an acceptable level of quality and consistency. Such services are invariably the collective output of many integrated processes and resources within a medical imaging service. The management system needs to be designed, defined and implemented to ensure the specific outputs of each of the processes. The generally accepted means of achieving this for each process or resource is through documentation (in whatever form), thereby being available to educate, guide and instruct medical imaging service staff working with the process or resource and defining what constitutes a consistent and valid output.

The extent to which the management system is documented will depend on the size and complexity of the service and the examinations on offer. Where policies are required, these will invariably need to be documented to ensure appropriate definition and availability. The level of (detail in) documentation of procedures is always a balance between the complexity of the task being undertaken and the training and competence of the individual carrying out the task. For some aspects of the management system, detailed documented procedures and policies are required to ensure valid outputs; for others it may be sufficient that all appropriately trained staff are aware of what is required (policy) and documented procedures are not necessary. Whatever the appropriate balance is considered to be in a particular medical imaging service, the service will need to be able to demonstrate to IANZ assessment teams that the key outputs from any process or resource make a consistent and valid contribution to the overall services provided.

A quality manual (in whatever form) which describes the management system and structure of the documentation making up the management system needs to be readily available to all staff. Staff will need to have been trained in the use of the quality manual and referenced documentation.

4 Document control (NZCRMP Clause 4.3)

Clause 4.3 relates to the control of documented procedures and should not be confused with controlling records.

The purpose of document control is to ensure that valid (appropriately authorised) and up-to-date policies and instructions are readily available to all staff, as and when they are needed. They may be hard copy or electronic. The service will need to establish which documents need to be controlled. As a guide, any documented procedure that provides instructions to staff or which in some way has a direct bearing on the outcome of an examination, needs to be controlled. The process that is developed to control documents needs to include the control of internally and externally generated documents.

Documented procedures that include technical instructions, such as performing an examination, need to be reviewed and authorised by a staff member who is technically competent to do so. It may be that there is more than one individual within an organisation who is responsible for the authorisation of new / revised documents.

The system outlining how documents are controlled will need to be documented. The rule of thumb that defines an effective document control system is that when a user consults a procedure or document they should be able to easily establish that it is the most up-to-date authorised version and it is complete.

5 Review of contracts (NZCRMP Clause 4.4)

In the context of Clause 4.4, a contract is considered to be any agreement to provide a medical imaging service. It can be verbal or written and of any size from a single patient request to a formal written contract to provide a range of services.

The purpose for review of contracts is to firstly ensure that the service clearly understands what it is the client needs, recognising that what they want may not always be what they need. Secondly, the review should establish that the service can provide the requested examinations / reporting services. Such reviews may thus range from the simple and routine to more complex variations on legal contracts for services. For the former, review of routine provision of services is often closely aligned with Clause 5.4 Pre-examination procedures. Records of the review process need to be maintained however it may not be necessary to have documented procedures in all cases.

6 Examination by sub-contractor radiology services (NZCRMP Clause 4.5)

The intent of Clause 4.5 is to ensure that where a medical imaging service sub-contracts any diagnostic service it is unable to provide, that the service to the patients and clinicians is transparent and seamless, as though the medical imaging service was performing it themselves. This requires formal management of the sub-contractors to ensure the pre-determined quality standards of the sub-contracting services are met on an on-going basis.

The service needs to ensure that the selected sub-contractors, be it consultants or other medical imaging services, are competent to perform the tasks for which they have been selected. Where the sub-contractor service is accredited, competency may be readily established by reviewing their Schedule to Certificate of Accreditation. Where a sub-contractor is not accredited, for example tele-radiology, the service being assessed will need to be able to demonstrate how competency of their chosen sub-contractor was established and what criteria they met.

Where sub-contracted services have been carried out by another service, the examination report will need to clearly show this.

7 External services and supplies (NZCRMP Clause 4.6)

Clause 4.6 is intended to ensure there are no quality failures in a medical imaging service due to the use of inappropriate equipment or consumables. Management of approved suppliers, purchasing orders, and equipment and consumable receipt and acceptance should be treated as a technical function as well as

administrative function to ensure what is purchased, accepted and used by the medical imaging service is as required by the examinations.

The service needs to have documented procedures to ensure that what is purchased (service, consumables, equipment or expertise) meets their needs. Where the quality of equipment and consumables could affect the quality of the examinations, these purchases need to be confirmed, prior to use, as meeting the desired quality.

8 Advisory services (NZCRMP Clause 4.7)

Advisory services are often provided when establishing what services the client needs, what these are and how the accredited service can provide them. This is part of or linked to the contract review provisions in Section 5 of this document. This clause takes a broader view of the service rather than individual referrals. The on-going service needs of the patients and clinicians should be examined and established, thereby ensuring the service continues to provide an appropriate (fit-for-purpose) service.

9 Resolution of complaints (NZCRMP Clause 4.8)

This section is deemed to be self-explanatory and no further clarification is required. Valid complaints are often considered as specific examples of non-conformity (Clause 4.9) and managed under the same administrative system.

10 Identification and control of non-conformities (NZCRMP Clause 4.9)

11 Corrective action (NZCRMP Clause 4.10)

When incidences of non-conformity with a medical imaging services' own requirements occur, it is important that:

- these are identified and recorded (Clause 4.9);
- the extent of the incident is investigated and the disposition of any affected past or present examinations are appropriately managed (Clause 4.9), and;
- action is taken to prevent a re-occurrence of the incident in future (Clause 4.10).

In its simplest form, once an incident has occurred, Clause 4.9 considers the past and present and the effect on work already completed; Clause 4.10 considers the future. Collectively, the ideal output from these actions is that a medical imaging service will not make the same mistake twice.

While most services have readily established processes for capturing and recording non-conforming work and implementing corrective actions e.g. the Fix-It Form, it should be noted that there are two aspects that could be improved upon.

a) Identification of the 'root cause' i.e. why did it go wrong? Without identifying the root cause it can be difficult to implement effective corrective action.

b) Maintenance of records to support the corrective action taken, for example, a service engineer report clearly stating what has been reviewed and repaired, may be appropriate as evidence of action taken to address a Qualified Health Physicist (QHP) raised non-conforming issue. Records to support the action taken need to be held with, or their location referenced on the Fix-It Form.

12 Preventive action (NZCRMP Clause 4.11)

Medical Imaging services should note that preventive action refers to a proactive process of identification of potential sources of non-conformity and the correction of them before problems develop, rather than a reaction to the identification of problems. Often the same administrative system as that used for the management of non-conformities and corrective action is used for preventive action.

13 Continual improvement (NZCRMP Clause 4.12)

Clause 4.12 requires medical imaging services to demonstrate that they are active in implementing improvement initiatives across their management system; that the system is not simply put in place and forgotten. Much of the evidence to demonstrate this will arise from the effective implementation of other

clauses of the NZCRMP, but there is also a requirement to put in place quality indicators to monitor and evaluate the service's contribution to patient care (Clause 4.12.4).

14 Quality and technical records (NZCRMP Clause 4.13)

The requirements for controlling quality records and technical records are succinctly defined in the NZCRMP. In essence, the medical imaging service needs to be organised, irrespective of the format in which the records are maintained, so the service can demonstrate unequivocally that it carried out what was stated.

Where there are no medico-legal requirements for record retention, the service should consider retaining records for at least the time-frame of an IANZ assessment cycle e.g. four years. Records relating to equipment need to be retained for at least the life-time of the equipment (see NZCRMP Clause 5.3.4).

15 Internal audits (NZCRMP Clause 4.14)

The primary purpose of internal audits is to provide objective and factual information, generally to management, on whether and how well the management system is being implemented, and its effectiveness. In order for management to make informed decisions, the internal audit outputs need to be of good quality and thus require internal audit systems to be quite formal.

The internal audit programme needs to cover all aspects of the NZCRMP, both quality and technical. Where the scope of the service covers more than one site and / or modality, the internal audit records need to clearly show that all sites and modalities were reviewed. The records resulting from the internal audit also need to reflect the actions taken for any non-conformities identified.

Internal audits may be carried out at one time, or scheduled to be carried out over several days / weeks / months as best suits the service's arrangements.

16 Management review (NZCRMP Clause 4.15)

Review of the management systems by medical imaging service management is a mechanism for them to be informed about the operation of the service and how well it is performing. It is designed to be a strategic overview and not operational in nature, hence the recommended time-frame of once every twelve months. The aspects to be covered in the management review process are set out in the NZCRMP and this could be considered as the review agenda. They essentially specify the type of information and metrics that medical imaging service management should gather together and review in order to set direction for future requirements of the management system so that it continues to meet service needs and objectives.

Part of the management review is for the service to consider quality indicators for monitoring the contribution to patient care, such as aiming for a percentage of examination reports to be reported within a pre-defined timeframe.

17 Personnel (NZCRMP Clause 5.1)

This is one of the more critical clauses of the NZCRMP. Its purpose is to ensure that the service is, and will continue to be, staffed by competent personnel that are knowledgeable in their areas of expertise, who are all aware of their role and responsibilities and will effectively implement the management system on an on-going basis. While this fundamental requirement is the same for any accredited medical imaging service, the systems in place to manage the human resources and demonstrate the same will be commensurate with the size of the service and the scope of accreditation.

Where key responsibilities of the medical imaging service director are delegated, there should be a register of delegations that is maintained.

Authorisations for personnel to perform functions such as patient management, use of equipment and use of RIS / PACS will need to be supported by records. These could be current training records, including competencies and authorisations, to carry out specific tasks.

Competencies to perform tasks needs to be assessed after the provision of training and periodically thereafter. Also see the modality-specific *Supplementary Criteria for Accreditation* which sets out specific training and continuing professional development requirements as stipulated by the MCNZ, MRTB, RANZCR and other relevant governance bodies.

There is an expectation that review of competencies will be carried out annually.

It is also important that there are policies in place to define authorisations within the RIS / PACS with regard to patient data, amending reports and modification of the RIS / PACS. This may be controlled by password access in which case it is important that passwords are not shared.

18 Accommodation and environmental conditions (NZCRMP Clause 5.2)

Accommodation for medical imaging services will vary but it will be appropriate for the type of examinations carried out and will meet the needs of both the patients and employees. Please also see the Ministry of Health Codes of Safe Practice (CSP3 and CSP5) and the medical imaging *Supplementary Criteria for Accreditation* for modality-specific requirements.

Additionally, it should be noted that for new MRI units and accommodation, an initial review should be carried out by the QHP, a decision which has been ratified by the IANZ Medical Imaging Services Professional Advisory Committee (MISPAC) in 2008.

19 Radiology equipment (NZCRMP Clause 5.3)

Services need to be able to demonstrate that equipment is appropriate for the examinations carried out and is operating accordingly.

There is an expectation that the servicing of equipment will be at least annual where this is critical to the functioning of the service. QHP and / or manufacturer guidelines need to be followed for establishing the frequency of services and quality control checks. QHP testing should be carried out at least annually and in some instances more frequently. If equipment is subject to high use, or is an aging unit, then more frequent checks may be required to confirm the equipment continues to operate in accordance with expectations.

As part of the installation process of new equipment, QHP checks need to be carried out. This should also apply to MRI units (see Section 18 of this document).

Equipment records (see Clause 5.3.4 of NZCRMP) need to be retained for at least the life-time of the equipment.

20 Pre-examination procedures (NZCRMP Clause 5.4)

Documented pre-examination procedures need to be available to ensure that the correct examination is performed on the appropriately prepared and correct patient.

The review of pre-examination procedures needs to include review of the documented acceptance / rejection criteria of patients and requested examinations.

21 Examination procedures (NZCRMP Clause 5.5)

Accreditation is granted for internationally or nationally accepted standard examination procedures or in-house procedures that have been validated as fit-for-purpose.

Documented examination procedures need to be available, as appropriate, to the range of examinations carried out by the service. The procedures need to include examination-specific instructions and instructions for management of patients during examination. The documented procedures need to be regularly reviewed (at least annually is recommended) by the medical imaging service director or designee.

Examination procedures may be held in either hard copy or electronic format, bearing in mind that electronically held documentation needs to be subject to the same level of document control as hard copies.

22 Assuring quality of examination procedures (NZCRMP Clause 5.6)

A quality assurance programme is designed to reduce the potential for errors to occur, whether it is with equipment function, patient management, examination or reports.

There are a variety of internal quality control systems that may be implemented, such as:

- Image comparisons,
- Reject analysis,
- Equipment calibration and verification (see Clause 5.3.2 of NZCRMP),

- Clinical audits. Where these are carried out, they should start from the beginning of the process i.e. the referral process and include imaging and reporting.

Consideration also needs to be given to situations where personnel are working in isolation and how / what aspects of an effective quality control programme may be implemented.

It is expected that the internal quality control programme is documented in the management system procedures.

23 Post-examination procedures (NZCRMP Clause 5.7)

The requirements are set out in Clause 5.7 of NZCRMP and no further clarification is required here.

24 Reporting of examinations (NZCRMP Clause 5.8)

Examination reports need to include the information as set out in Clause 5.8.3 of NZCRMP. Where the information is not included in the written report it must be readily available to the user on request. Any deviations to the reporting requirements need to be justified and in written agreement with the end user of the reports. The onus will be on the service to justify the report content where it is not in alignment with the requirements of the NZCRMP.

It is recognised that offsite reporting organisations provide an important service to the medical imaging community. As such, IANZ has developed an information guide pertaining to offsite reporting, which is available on the IANZ website.

The NZCRMP Clause 5.8.3 h) states the report shall include a summary of any contrast media doses or other relevant medication used during the taking of images reported on. It has been decided, and ratified by the MISPAC at the July 2013 meeting, that the intent of the requirement is for the information regarding doses of both the medication and contrast media administered must be available and readily accessible to those who are entitled to it and who need or wish to know. This means it needs to be recorded, but does not necessarily mean it needs to be included in the written examination report, and it is up to each accredited medical imaging service to determine how it is to be recorded and retrieved at a later time and on request. For a medical imaging that chooses not to include this information in the written examination report they will need to be able to demonstrate to an assessment team how this is achieved.

When an examination report is issued under the service's accreditation the report needs to be on letterhead or clearly identifying the organisation (name and address) issuing the report, including which site the report was issued from. This needs to be very clear for services that include multiple sites in their scope of accredited modalities. The inclusion of name and address was a requirement of the superseded NZCRMP which had been inadvertently removed from the 2011 edition. This requirement will be reinstated in the next version.

Where the site of the examination is different to that where the report was issued, it is expected that this be recorded in the examination report. Without this information the implication of accreditation may be misleading to the recipients of the report.

Where interim reports are issued by the service, these need to be very clearly identified as such.

Once a report has been issued the service needs to ensure that any amendments to the report are authorised and dated. The amended reports should include the original information as well as the altered details. The system to be followed for amending reports needs to be documented.

24.1 Use of IANZ accreditation symbol on endorsed reports

The rules of the use of the IANZ accreditation symbol are set in the document *"Procedures and Conditions for Accreditation"*.