



A.N.Z.A.P.N.M

Australian and New Zealand Association of Physicians in Nuclear Medicine (Inc)

NUCLEAR MEDICINE PRACTICE
ACCREDITATION PROGRAM

Standards
for
Accreditation
of
Nuclear Medicine Practices

Second Edition

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A.N.Z.A.P.N.M

Australian and New Zealand Association of Physicians in Nuclear Medicine (Inc)

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BACKGROUND

As part of its Memorandum of Understanding (1999-2003) with the Department of Health and Ageing (DHA) the Australian and New Zealand Association of Physicians in Nuclear Medicine (the Association) agreed to develop and run a program of accreditation for nuclear medicine practices throughout Australia. This Nuclear Medicine Practice Accreditation Program (the Program) is based on this document *Standards for Accreditation of Nuclear Medicine Practices* produced by the Association's Quality Practice and Accreditation Committee (QPAC) and developed in consultation with the Royal Australian and New Zealand College of Radiologists (RANZCR) over several years. This set of Standards was adopted by both organisations as the Standards that will apply to nuclear medicine practice accreditation across Australia, thus ensuring uniformity of accreditation for all nuclear medicine practices. It was agreed that an audit program would be implemented by a joint committee of the Royal Australasian College of Physicians (RACP) and the RANZCR over the first two years of the Program to ensure similar application of the Standards.

Reciprocal Recognition

It was also agreed that while the Association and the RANZCR would run separate practice accreditation programs, they would have reciprocal recognition for their respective Nuclear Medicine Practice Accreditation Programs. Thus, any nuclear medicine practice that has achieved accreditation through either the Association or the RANZCR will be considered to have fulfilled the professional, technical and administrative accreditation requirements of the other organisation.

For purposes of accreditation the following definition of a practice will apply:

A 'practice' comprises the physical facilities and staff necessary to provide all components of nuclear medicine services at a specific geographic location. At least one appropriate state radiation licence and one Health Insurance Commission provider number of a recognised specialist in nuclear medicine will be linked to the location.

The accreditation document is formulated as a number of principles (professional, technical, administrative), each of which is expanded as a series of specific standards. The standards describe the minimum requirements for accreditation.

This document is to be read in association with the document titled *Nuclear Medicine Practice Accreditation—Information, Application Form and Checklist— January 2005*.

Interpretation and Application of the Standards

A *Handbook on Interpretation and Application of the "Standards for Accreditation of Nuclear Medicine Practices – November 2000"*, dated June 2003 was circulated to all Members of the ANZAPNM in 2003, in accordance with a resolution passed at the ANZAPNM Annual General Meeting in May 2001.

This *Handbook* sets out the Accreditation Implementation Committee's (AIC's) interpretation and application of each Standard, and can be consulted for clarification of any interpretative

issues in the first instance. Copies of the *Handbook* are available from the ANZAPNM Secretariat, contactable by phone on 02 9818 4824 or by email at: secretariat@anzapnm.org.au.

Queries about accreditation matters in general, or the Standards in particular, may be directed to the AIC at any time, via the ANZAPNM Secretariat.

Application for Accreditation

Nuclear medicine practices may make an initial application for accreditation at any time. The application form and checklist can be obtained from the ANZAPNM Secretariat, phone 02 9818 4824, or email: secretariat@anzapnm.org.au.

Credentiailling of Nuclear Medicine Specialists

In addition to practice accreditation, all specialists providing nuclear medicine services are required to be credentiailled by the Joint Nuclear Medicine Credentiailling and Accreditation Committee (JNMCAC) of the RACP and RANZCR, in order for their patients to be eligible to receive Medicare benefits for nuclear medicine services. A register of credentiailled specialists is provided to the Health Insurance Commission (HIC).

Enquiries about credentiailling may be directed to the JNMCAC Secretariat, c/o the ANZAPNM, P O Box 73, Balmain, NSW 2041; phone 02 9818 4824; email: secretariat@anzapnm.org.au.

PRINCIPLES

PROFESSIONAL

Principle 1

Each nuclear medicine service shall be provided by a qualified specialist in nuclear medicine who is responsible for performing procedures in the best interest of the patient.

Principle 2

Performance of the nuclear medicine procedures shall be undertaken by a qualified nuclear medicine technologist under the supervision of the specialist in nuclear medicine.

TECHNICAL

Principle 3

The physical facilities and practices in the nuclear medicine practice shall be sufficient to maintain the dignity and safety both of patients and of practice personnel.

Principle 4

For nuclear medicine imaging, procedures ensuring control and recording of the components of the imaging process shall be followed to ensure that data are of optimum quality, allowing reliable diagnoses to be made, and that the radiation dose to patients and staff is kept to a minimum.

Principle 5

Procedures ensuring the quality of radiopharmaceuticals shall be followed.

Principle 6

All nuclear medicine procedures shall be identified and described in the technical procedure manual.

ADMINISTRATIVE

Principle 7

Patient records of the nuclear medicine department shall be accurate and complete and the responsibility for each significant component of the patient consultation report traceable. Reports shall be completed and sent to the referring practitioner in a timely fashion.

PROFESSIONAL STANDARDS

Principle 1

Each nuclear medicine service shall be provided by a qualified specialist in nuclear medicine who is responsible for performing procedures in the best interest of the patient

Standards

1. Training in Nuclear Medicine

The specialist in nuclear medicine shall be qualified by experience and training to assess the proper role of nuclear medicine procedures in patient management, and to direct the performance and evaluate the quality of such procedures.

Training in nuclear medicine is currently supervised and assessed by the Joint Specialist Advisory Committee in Nuclear Medicine of the Royal Australasian College of Physicians and the Royal Australian and New Zealand College of Radiologists.

Recognition as a specialist in nuclear medicine by the relevant state Specialist Recognition Advisory Committee (SRAC) of the Health Insurance Commission (HIC) is required.

2. Licence to use Radioactive Substances

The specialist in nuclear medicine shall hold a current licence from the appropriate radiation licensing body to prescribe and administer radioactive substances to humans. Where State or Territory regulations permit multi-user licences, the specialist shall operate under an appropriate radiation licence that shall be held in the practice.

3. Personal Supervision

The physical presence of the responsible specialist in nuclear medicine at the practice location is mandatory, in order to fulfill the components of a nuclear medicine service:

- § Personal attendance upon the patient;
- § Determining the appropriateness of and monitoring the quality of the procedure;
- § Assessing and influencing the outcome of the procedure;
- § Providing a final consultation report.

Explanation and Guidelines in Relation to Personal Supervision

Personal supervision is a core principle to ensure the quality practice of nuclear medicine. The components of the nuclear medicine service that require personal supervision, are specified in these Standards, and have been agreed to by both the Association and the RANZCR.

Nuclear medicine services differ from other imaging procedures in that the length of the procedure (defined as the time from the first patient contact to the completion of the report) can vary from less than half an hour to almost a week, although the average length is at least several hours. Although each component of the nuclear medicine service requires personal

supervision this does not imply direct physical attendance by the specialist during the entirety of each component.

For every patient the specialist must complete the report on site, and there must be consultation with the patient. The specialist must also take responsibility for ensuring that each of the other components is completed satisfactorily. Mostly this will require the physical presence of the specialist at some time during each component, although this will vary from patient to patient, and from study to study. The attending specialist will be required to take these matters into consideration and take responsibility for whatever decision he or she takes in a particular case.

The rationale for each component of the nuclear medicine service, exemptions with respect to the involvement of other imaging specialists, and the timetable for future modifications to these requirements are enumerated in Appendix 1. Exemptions to this requirement in the contexts of provincial and remote practice are given in Appendix 2.

4. Nuclear Medicine Therapy

If the specialist in nuclear medicine plans to undertake therapy with unsealed sources, the following issues must be addressed:

- § Qualifications and experience of the practitioner.
- § Current licence for unsealed source therapy.
- § The facilities and procedures for treatment.
- § The availability of a radiation safety officer.

The requirements are given in detail in Appendix 3.

5. Responsibilities of the Specialist

The specialist in nuclear medicine shall be responsible for the quality and safety of all procedures performed by nuclear medicine personnel at the practice. This responsibility includes ensuring that staff are properly trained, qualified and competent to perform each procedure in which they are directed to participate. Only the responsible specialist in nuclear medicine should delegate responsibility to other persons to perform patient care tasks.

6. Continuing Education Activities

The specialist in nuclear medicine should maintain a record describing in detail the continuing education activities (specifically including those relating to nuclear medicine) that are undertaken. These may include participation in either the Maintenance of Professional Standards program of the RACP or the RANZCR Continuing Medical Education program.

7. Education of Other Practitioners

The specialist in nuclear medicine should participate in educational activities that inform other practitioners and health professionals about the clinical application of nuclear medicine procedures.

8. Quality Assurance

The specialist in nuclear medicine shall be responsible for ensuring that appropriate practice procedures are carried out. This includes quality control of instruments, procedures and radiopharmaceuticals as stipulated in other parts of these Standards.

Principle 2

Performance of the nuclear medicine procedures shall be undertaken by a qualified nuclear medicine technologist under the supervision of the specialist in nuclear medicine.

Standards

1. Training in Nuclear Medicine

The nuclear medicine technologist shall be qualified by experience and training to perform nuclear medicine procedures. The Accreditation Board of the Australian and New Zealand Society of Nuclear Medicine certifies experience and training.

2. Performance of Duty

The nuclear medicine technologist will be available to perform appropriate aspects of the procedure, including radiopharmaceutical preparation and administration, imaging and data processing, and the full range of nuclear medicine procedures under the supervision of the specialist in nuclear medicine.

TECHNICAL STANDARDS

Principle 3

The physical facilities and practices in the nuclear medicine practice shall be sufficient to maintain the dignity and safety both of patients and of practice personnel.

Standards

1. Physical Facilities for Patients

The practice should provide a reasonable standard of patient privacy and dignity. Patient examination areas should provide adequate privacy. Convenient toilet facilities for ambulatory patients should be provided.

2. Compliance with Statutory Radiation Safety Requirements

The nuclear medicine practice shall comply with applicable radiation safety regulations. State radiation regulations, and the radiation safety practices outlined in the applicable radioactive materials licence, shall be retained in the practice to assist compliance. Copies of any inspecting agency reports, including responses to any deficits noted, will be retained in the practice. Radiation safety policies and procedures shall be maintained.

3. Radiation Protection Procedures

Procedures to ensure patient and personnel radiation protection shall be maintained:

- a.* Patient waiting areas should be located, and shielded if necessary, so that radiation exposure from radiation sources in the nuclear medicine area is as low as possible.
- b.* The activity of radioactive material to be dispensed for administration to patients must be calculated according to an established protocol.
- c.* The activity of radioactive material to be administered to each patient must be measured prior to administration. Where necessary, the radioactive purity of this material must also be checked.
- d.* All persons who may be exposed to radiation as a result of a nuclear medicine procedure must be advised of precautions they can take to minimise their radiation dose. Written instructions must be available, particularly for therapeutic procedures involving larger potential exposures.
- e.* Appropriate precautions regarding pregnant and breast-feeding patients should be observed. These include warning signs, verbal inquiry and the issuing of special instructions to the patient where required.
- f.* The standard activity of radioactive material to be administered for each procedure should be established and recorded in the procedure manual, along with an estimate of the corresponding effective dose.
- g.* Appropriate procedures should be maintained for identification of radiation areas and the receipt, storage, and disposal of radioactive substances (similar procedures should be in place for non-radioactive drugs and any bio-hazardous materials).

- h.* Appropriate procedures and resources should be in place for handling accidents involving radioactive materials and subsequent decontamination.
 - i.* Appropriate radiation monitoring equipment shall be readily available for the detection of contamination and radiation exposure levels.
 - j.* Personnel should be trained in radiation safety techniques and should have periodic in-service reviews.
 - k.* Personnel should be monitored by TLD badges and/or other dosimeters. The records should be retained and retrievable.
 - l.* The practice should appoint an appropriately qualified radiation safety officer to be responsible for radiation safety within the practice.
 - m.* A radiation safety manual should be available for use within the practice.
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4. Handling of Hazardous Materials

Materials presenting biological or other hazards should be carefully handled to minimize risks to personnel. Eating and drinking shall be prohibited in patient care and laboratory areas of the practice.

5. Airborne Materials

Noxious, toxic or volatile materials presenting a hazard of airborne transport (e.g. Xe and I) shall be handled in hoods providing adequate and safe venting to the atmosphere.

6. Eyewash Facilities

Provisions for emergency eyewash shall be made and clearly identified near areas where eye injuries are most likely to occur.

7. Physical Facilities in General

The premises must be adequately ventilated. Floors, work surfaces and other areas shall be kept clean and neat. Utilities should be adequate. These include: temperature control, water taps, sinks and drains, lighting, electrical outlets and communications (telephones/intercoms) particularly for emergency situations.

8. Fire Precautions

Instructions for protecting patients and staff against fire must be posted prominently and reviewed periodically in accordance with relevant local fire safety regulations. Sufficient and appropriate fire extinguishers and fire exits shall be provided. Smoking shall be prohibited in all patient care and laboratory areas of the practice.

9. Precautions for Toxic Substances

All toxic, irritant or caustic chemicals must be appropriately labelled, and personnel shall be trained in the safe use of such materials. Suitable eye protection devices, impervious aprons and means for flushing materials from the skin rapidly in the event of accidental splashing must be available in the practice.

10. Handling of Biological Materials

Glassware contaminated with toxic or biologic materials shall be made safe as soon as practicable after use. Bench tops and area surfaces subject to substantial contamination risk should be covered with disposable protective materials when feasible; these covers should be discarded in a safe manner when contaminated.

Adequate care shall be exercised in handling sera and other materials. Routine procedures must ensure that sufficient care is taken to avoid uncontrolled release of any potentially infectious material; thus, special marking of samples from infectious patients will be optional. Typical precautions should include: wearing gloves and gown while preparing undiluted specimens for analysis, decontamination of work surfaces and special attention to prevention of volatilization of samples during preparation.

11. Staff Infection Control

Personnel afflicted with potentially serious communicable diseases should be restricted from patient contact.

12. Disposal of Contaminated Objects

Discarded needles and other sharp items must be stored in specially designated containers to minimize the risk of injury or contamination.

13. Consultation and Procedure Areas

Patient interview and examination areas, and areas where samples of blood or other materials are taken, should be comfortable and clean and means of screening from general view shall be available.

14. Facilities for Cardiac Stress Testing

If cardiac stress testing is performed as part of myocardial imaging, the appropriate facilities shall be available. The facilities required and the procedures to be followed are given in detail in the *Cardiac Society of Australia and New Zealand (CSANZ) Standards for Exercise Testing* and the joint CSANZ/ANZAPNM Standards for Pharmacological Stress Testing (available at: www.csanz.edu.au).

15. Procedure for Venesection and Injection

Aseptic technique shall be used when penetrating the skin; personnel obtaining blood and other samples should be provided with convenient means for washing their hands after removing their gloves.

16. Procedures for Ill and Uncooperative Patients

Staff shall be instructed in procedures for handling seriously ill or uncooperative patients and patients presenting a risk of transmitting infectious disease.

17. Procedures and facilities for Cardiopulmonary Resuscitation and Basic Life Support

All staff involved in patient care should be trained in cardiopulmonary resuscitation procedures. The level of resuscitation facilities available shall be appropriate to the level of services offered by the practice (e.g. cardiac stress testing).

Principle 4

For nuclear medicine imaging, procedures ensuring control and recording of the components of the imaging process shall be followed to ensure that data are of optimum quality, allowing reliable diagnoses to be made, and that the radiation dose to patients and staff is kept to a minimum.

Standards

1. Procedure Manual

The procedure manual should provide information relating to the performance of the examination (the suggested content is given in detail in Principle 6, Standard 2, 'Contents of the Manual').

2. A.L.A.R.A. (As Low As Reasonably Achievable) Principle

Patients shall receive the minimum radiation exposure necessary for satisfactory completion of the study according to the judgement of the responsible nuclear medicine specialist. The radioactivity of materials prepared for administration to each patient shall be verified by measurement in a suitably calibrated instrument. The quantity and identity of radionuclides administered shall be recorded on the patient record.

3. Data Obtained or Recorded from Patient Studies

All important technical data and images obtained during each patient procedure shall be preserved to assist in comparison with other studies performed. The images and relevant data shall be given to the patient or his/her nominated representative (who may include the referring doctor). The nuclear medicine practice shall, at its discretion, archive images and associated data.

An acceptable patient record for imaging studies includes all the information listed in Principle 7, Standard 1, 'Patient Records'. The following should be added if appropriate:

- a.* Description of any unusual features prior to, during, or following the study.
- b.* Supplementary information, e.g., evidence of previous surgery, to include sketch and use of radioactive markers, when the interpretation of the study may be influenced by the results of surgery or anatomical variation.
- c.* Any comments regarding quality of the study.
- d.* Notation of important deviations from standardized procedure as described in the procedure manual.

For Anger-type gamma cameras, the following information should be recorded in technical records, unless standardized in the procedure manual:

- e.* Camera identification.
- f.* Collimator type.
- g.* Window settings for each radionuclide imaged.
- h.* View obtained, including orientation of detector, if relevant, and head I.D. for multi-head cameras.

- i.* Patient orientation, i.e., supine, sitting, etc.
- j.* Total image counts.
- k.* Time required to record image.
- l.* For SPECT, details of acquisition and processing should be given. Full details are given in Appendix 5.
- m.* When other instruments, such as multi-crystal cameras, thyroid uptake probes, etc., are used for patient study, appropriate data similar to those described for single-crystal gamma cameras should be recorded in patient records, unless standardized in the procedure manual.

The patient record may not be a unique document and the information may be kept in a number of places in the practice or department.

4. Daily Patient Log

A daily log or equivalent recording of the names of all patients upon whom studies were performed, shall be retained for the appropriate statutory period.

5. Equipment Service Record

Instrument service records describing in detail the reason for service and actions taken, including preventive maintenance, shall be completed by service personnel and retained in the practice.

6. Equipment Quality Control

General equipment performance tests should be specified and performed routinely, and the results documented. The schedule should comply with that specified by the equipment manufacturer or the ANZSNM's Technical Standards Committee in the document *Minimum Quality Control Procedures for Nuclear Medicine Equipment* (available at: www.anzsnm.org.au/ftp/standard/minQC.pdf). An example protocol for (non-SPECT) quality control on gamma cameras is given in Appendix 5.

Principle 5

Procedures ensuring the quality of radiopharmaceuticals shall be followed.

Standards

1. Medical Supervision

The nuclear medicine specialist is responsible for the safe and effective use of any drugs used under his/her supervision. The specialist may delegate the preparation and administration of radiopharmaceuticals to appropriately qualified and experienced individuals in the practice.

2. Radiopharmaceutical Preparation:

If radiopharmaceuticals are prepared on site:

- a.* The volume and quantity of radioactivity eluted from the generator shall be measured and recorded, taking suitable precautions to minimize personnel exposure during such measurements.
 - b.* Generator eluates shall be checked for breakthrough of parent nuclide at each elution.
 - c.* Radiopharmaceuticals shall be prepared according to product labelling or written procedures established in-house.
 - d.* Aseptic procedures shall be used in handling all components and preparations for potential parenteral or ophthalmic administration.
 - e.* Radiochemical purity of prepared radiopharmaceuticals shall be routinely verified as per written policies and procedures.
 - f.* Reagent kits and prepared radiopharmaceuticals shall be stored according to established criteria (e.g. product labelling).
 - g.* External suppliers of radiopharmaceuticals shall be appropriately licensed. The following procedures shall be followed:
 - h.* Radiopharmaceutical identification shall be verified by checking the label.
 - i.* The quantity of radioactivity to be administered to each patient shall be verified by measurement and recorded. If there is significant discrepancy (e.g. greater than 10%) between measured radioactivity and label data or prescribed dosage, or if a question arises for any other reason, administration to patients should be deferred until the problem is resolved.
 - j.* Prior to administration, patient identification shall be verified.
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3. Radiopharmaceutical records:

Appropriate records shall be maintained of:

- a.* radiopharmaceutical receipt;
- b.* radiopharmaceutical preparation;
- c.* ultimate fate of radiopharmaceutical (e.g. by administration to patient, storage for decay, return of spent generators etc.);
- d.* adverse reactions to radiopharmaceuticals;

- e. misadministration and other recordable events; and
 - f. actions taken in response to any problems identified in the above areas.
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4. Labelling of Blood or Blood Products

- A. A licensed nuclear medicine specialist shall be responsible for the quality and safety of the labelled blood or blood product before it is administered to a patient. The specialist may delegate the responsibility of the standardising and labelling procedures to a radiochemist or technologist but the specialist shall supervise the administration of the final product. The training and experience of such personnel shall be appropriate to the particular procedure performed.
- B. If labelling of blood or blood products is performed in-house:
 - § Procedures shall be established to ensure the correct readministration of the blood products to the correct patient. Handling of multiple specimens should be avoided due to the risks associated with blood handling and the potential for readministration errors.
 - § It is an absolute requirement that blood is processed in aseptic conditions (using preferably a Class III enclosed system but at least using a Class II system). Lesser systems are undesirable.
 - § Labelling procedures shall be standardized in-house and the established written procedure shall be followed.
 - § Labelling efficiency and the other quality control criteria including stability shall be standardized and established in-house. The labelled products shall satisfy the required standard before being administered to patients, unless otherwise determined by the supervising specialist.
- C. If labelled blood or blood product is supplied from an external source:
 - § Product label should be verified for patient identification.
 - § The radioactivity supplied shall be verified. Any discrepancy more than 10% from the stated activity shall be clarified with appropriate personnel before administration.
 - § Prior to administration, patient identification shall be verified.
- D. Record keeping will be performed so that:
 - § Appropriate records of labelling of patient blood and blood products shall be maintained.
 - § Appropriate records of adverse reactions to labelled products shall be maintained.
 - § Appropriate records of misadministration and incidence shall be recorded.
 - § Appropriate records of salvage actions in relation to problems shall be maintained.

Principle 6

All nuclear medicine procedures shall be identified and described in the technical procedure manual.

Standards

1. Preparation and Maintenance of Technical Procedure Manual

The preparation and maintenance of the procedure manual shall be supervised directly by the nuclear medicine specialist.

2. Contents of the Manual

The technical procedure manual shall include for each procedure performed:

- A. A summary of patient conditions that may affect the physician's interpretation of the nuclear medicine procedure. Examples of such conditions include: posture, time and content of previous drug dosage, diet, time of day and other factors.
- B. A description of instruments used and the control settings, and the technical and analytic steps followed in performing the procedure, including:
 - § Study identification.
 - § Radiopharmaceuticals and non-radioactive drugs used.
 - § Patient dosage and route of administration.
 - § Patient preparation required.
 - § Routine patient position for the study.
 - § Collimation.
 - § Required views.
 - § Preset counts or time, typical count rate for each view or information density, as applicable.
 - § List of special views frequently needed.
 - § Typical indications for performing the study.
- C. Reagents or other materials used in the test, including a listing of any special precautions for the use of such substances and any restrictions on the source of supply.
- D. Medical literature citations when appropriate for a more thorough understanding of the procedure.
- E. A description of:
 - § Any special quality assurance measures specific to the particular procedure.
 - § A definition of quality control limits if appropriate.
 - § Instructions on any preliminary actions to be taken in case of deviation from acceptable limits before referring the problem to the nuclear medicine specialist.
 - § Examples of typical indications for performing procedure.
 - § Details of required quality control procedures.

Components applicable to a number of procedures may be described elsewhere in the manual, if suitably referenced, and need not be reprinted with each method.

3. Review and Revisions

The procedure manual shall reflect current procedures followed in the practice and show evidence of at least annual review by the nuclear medicine specialist. Revisions to the manual must be approved by the specialist and should be clearly identified. Superseded methods with inclusive dates used should be recoverable for the same period as the reports of procedures performed by the superseded methods are preserved. The procedure manual or practice policies should contain provisions for correction of clerical errors, significant analytical errors or unusual results. The system should provide for timely correction and written documentation.

4. Modification to Procedures

The existence of written procedures should not preclude modification of procedures in the best interests of the patient. Such modification shall be noted in the patient records of the nuclear medicine practice, or in the consultation report, as judged appropriate by the reporting nuclear medicine specialist.

ADMINISTRATIVE STANDARD

Principle 7

The patient records of the nuclear medicine practice shall be accurate and complete, and the responsibility for each significant component of the patient consultation report traceable. Reports shall be completed and sent to the referring practitioner in a timely fashion.

Standards

1. Patient Records

Patient records shall identify, when pertinent:

- § Name of patient and identification number or other satisfactory identification of the patient.
- § Name of practitioner initiating the request.
- § Date of the request.
- § Type of nuclear medicine procedure performed as identified in the practice procedure manual. Any special modifications of the procedure shall be noted and explained.
- § A record of type, activity, route and injection site of any radioactive or non-radioactive substances administered to the patient.
- § The nuclear medicine technologist performing the procedure
- § Date and description of findings of any procedures performed
- § Interpretive information, including, if appropriate, background on the predictive value of the procedure or expected values on a reference population, to assist referring practitioners in understanding the results of a procedure.
- § Identification and signature of the responsible nuclear medicine specialist.

It is permissible that the information not be available in one unique record, but in a number of places in the practice or department. For example, in a copy of the patient results, in the daily log and in the radiopharmacy log.

Special Calculations and Technical Data

Special calculations, instrumentation and control data of a technical nature need not be included as a part of the patient consultation report, but should be accessible in the practice records. Information considered in performing the consultation may be included in the patient consultation report if the responsible nuclear medicine specialist considers this information relevant.

Technical data that may be applicable to a group of patient studies during a defined time span need not be included with each individual record, but the record should include sufficient information to allow retrieval of such data from other records maintained in the practice. Examples of such data might include: imaging quality control studies and values found or measurements performed on reference materials.

2. Patient Reports

These should include the following items from the patient record:

- § Name of patient.
 - § Name of practitioner initiating the request.
 - § Type of nuclear medicine procedure performed as identified in the practice procedure manual. Any special modifications of the procedure shall be noted and explained.
 - § Date and description of findings of any procedures performed.
 - § Interpretive information, including, if appropriate, background on the predictive value of the procedure or expected values on a reference population, to assist the referring practitioner in understanding the results of a procedure.
 - § Identification and signature of the responsible nuclear medicine specialist.
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3. Timeliness of Reports

The timeliness of reporting will vary with the nature and urgency of the clinical problem. In general, the report should be sent to the referring practitioner within 24 hours of completion of the study. If there are urgent or unexpected findings, the specialist should use reasonable endeavours to communicate directly to the referrer or an appropriate representative who will be providing clinical follow-up.

4. Confidentiality

Handling of patient records shall comply with all statutory privacy requirements. Except in circumstances of a medical emergency, during the course of professional communication and as required by law, medical records should not, without the patient's express written consent, be released to persons other than the patient. Where appropriate the patient's legally appointed guardian or attorney may be sufficient.

5. Retention of results

Request forms, records, films, photos and/or electronic media with imaging studies should be retained in accordance with statutory requirements.

6. Directions for Referring Practitioners

Directions for requesting nuclear medicine studies should be available to referring practitioners.

APPENDICES

Appendix 1 — Components of the Nuclear Medicine Service and Their Rationale, Exemptions to Requirements for Personal Supervision and a Timetable for Removal of Exemptions

1. Components of the Nuclear Medicine Service and Their Rationale

These components and their rationale are:

- (i) *Personal attendance upon the patient:*
 - § to evaluate the patient's history, physical and ancillary laboratory findings, and other diagnostic imaging results
 - § to determine the presence of medical conditions or medications which may modify or contraindicate the procedure
 - § to communicate to the patient the nature, and the potential benefits and risks, of the procedure to be undertaken, including the radiation safety aspects
- (ii) *Determining the appropriateness of and monitoring the quality of the procedure:*
 - § to establish the appropriateness of the requested procedure
 - § to modify or otherwise intervene in the procedure in the light of the above and in the context of the clinical question to be answered
- (iii) *Assessing and influencing the outcome of the procedure:*
 - § to evaluate the clinical significance of unforeseen findings, including (when appropriate) obtaining additional history from the patient and/or arranging additional investigations
 - § to ensure that the procedure is fully completed and to determine that the quality of the results is satisfactory before the patient leaves the practice
- (iv) *Providing a final consultation report:*
 - § to communicate the findings to the referring practitioner, including a written report, and ensure the appropriate disposition of the patient

2. Specialists Permitted to Provide Nuclear Medicine Services

In quality nuclear medicine practice, the specialist in nuclear medicine who prepares the report will also have direct responsibility for all components of the service. Therefore the following will apply:

- § In any new practice (either in a new geographic location or as part of an existing diagnostic imaging facility) commencing operation after 1 April 2000 a specialist in nuclear medicine will be responsible for all components of each nuclear medicine service.
- § In order that practices that were established prior to 1 April 2000 that currently operate without the services of a specialist in nuclear medicine full-time not be disadvantaged, it is permissible for the components as set out in (i – iii) above to be performed by a specialist in diagnostic imaging. This specialist will be located on site throughout the procedure. A specialist in nuclear medicine who has access to other investigations including diagnostic imaging films will report all procedures on site.

These standards are not to be regarded as superseding state radiation licensing regulations. Where a more stringent level of attendance or supervision is required by state regulation, such regulatory requirements shall always take precedence over the corresponding component in these Standards.

2A — Nuclear Medicine Practice in Provincial Sites

Currently nuclear medicine practice takes in provincial sites takes two forms:

- § provincial solo nuclear medicine practice in which the specialist resides permanently in the region
- § provincial group nuclear medicine practice in which the specialists live elsewhere and provide the service on a 'fly in, fly out' basis

In the former the specialist in nuclear medicine is more likely than his/her metropolitan counterpart to engage in medical specialties other than nuclear medicine. This may result in the absence of the specialist from the practice during part of the procedure.

In the latter a specialist in nuclear medicine may not be present in the practice during the entirety of each working week.

Therefore the following exemptions are permissible:

Absence from practice during conduct of the nuclear medicine procedure

In a provincial solo practice, necessary absences of such sole specialist for the conduct of associated duties, and for the purpose of professional and recreational leave, is acknowledged. However such an acknowledgment is not intended to accept, promote or otherwise condone a lower standard of practice than has been set out in these Standards.

Therefore the specialist in nuclear medicine may be absent from the practice during part of the procedure if:

- § direct patient consultation by the specialist in nuclear medicine has occurred
- § secure and efficient lines of communication have been established between the practice and the specialist during the specialist's absence, so that the specialist can monitor and influence the conduct and outcome of the procedure
- § the specialist in nuclear medicine provides the final report on the study on site.

It is important that the form of provincial practice in which a specialist is absent during part of the week is differentiated from and functions at a higher level than the remote practice in which the specialist in nuclear medicine is not present for any part of the study and provides all reports remotely.

Therefore in this form of provincial practice:

- § a specialist in nuclear medicine shall be present in the practice at least half-time during any working week and shall provide all final reports on site
- § during the remainder of the time the practice can function remotely, under the operating conditions set out below for remote nuclear medicine practices.

Absence from the practice during professional and recreational leave

- § For a provincial solo nuclear medicine practice to continue to operate while the specialist is on leave, such absence for professional or recreational leave shall not exceed ten weeks in any one year.
- § If the practice is to operate during the period of absence of the nuclear medicine specialist, it shall do so as the remote practice of another cooperating fully staffed nuclear medicine practice, under the operating conditions set out below for remote nuclear medicine practices.

2B — Nuclear Medicine Practice in Remote Sites

This shall accord with the document *ANZAPNM Working Party On Remote Practices - Final Recommendations (1992)*. This document, with minor modification to reflect the current situation, is reprinted below:

'In metropolitan areas of Australia, it is expected that all nuclear medicine practices should offer a wide range of diagnostic and therapeutic services under the direct supervision of a fully trained specialist in nuclear medicine. It is possible that the exigencies of geography, population density and the medical workforce may dictate the application of a slightly different policy with respect to the initial establishment of practices in remote rural areas.

It is suggested that isolated rural centres may be serviced remotely ("remote practices") provided that:

- § *the establishment and conduct of a remote practice complies fully with all relevant Commonwealth and State laws and regulations*
- § *"remoteness" is clearly defined. A practical and reasonable definition is that: "No practice staffed by a trained specialist in nuclear medicine exists within 200 km of the proposed remote practice"*
- § *the remote practice is associated with a host department, which is capable of providing a full range of nuclear medicine services as indicated above*
- § *a qualified radiologist or appropriately trained specialist is in attendance during the conduct of all procedures at the remote practice*
- § *the range of services offered at the remote practice is confined to those appropriate to the expertise of the specialist attending the remote site*
- § *secure lines of communication exist between the remote and host practices, which permit:*
 - Ø *a trained specialist in nuclear medicine at the host practice to review the request, obtain additional information as necessary, authorise the study and prescribe the radiopharmaceutical*
 - Ø *data of high and consistent diagnostic quality to be viewed by the nuclear medicine specialist at the host practice before the patient leaves the remote practice site*
- § *supervision of each procedure at the remote practice shall be by an accredited nuclear medicine technologist; supervision of radiopharmaceutical administration shall be by an appropriately licensed person in attendance at the remote site*
- § *the facilities of the host department are available for further evaluation of the patient from the remote practice if required*
- § *such arrangements for the initial establishment of a remote practice must be considered interim arrangements, existing until such time as the remote practice can feasibly be attended by a fully trained specialist in nuclear medicine.'*

Other Procedures Performed in the Practice Location

The preceding sections refer only to nuclear medicine procedures and the requirements are not meant to apply to other procedures. For example, cardiac stress testing performed prior to myocardial perfusion scintigraphy should be performed in accordance with the standards set out by the Cardiac Society of Australia and New Zealand, (provided on the CSANZ website at www.csanz.edu.au), and not in the absence of the appropriately qualified medical practitioner.

Appendix 3 — Nuclear Medicine Therapy

The specialist in nuclear medicine undertaking nuclear medicine therapy procedures in his/her practice must have recognised specialist qualifications in nuclear medicine, and have adequate prior training, practical experience and a current licence to administer unsealed sources for therapy and also actively practise the use of unsealed source therapy.

The therapeutic use of unsealed sources requires substantial training and experience by the treating specialist in nuclear medicine in order for standards of practice to be maintained. There is a marked difference between the therapeutic use of unsealed sources compared to the diagnostic use of radioisotopes, both in terms of experience and training, the radiation safety approaches to this treatment, and the facilities available within the practice or inpatient facility for this treatment.

The administration of unsealed sources for therapy (i.e. hyperthyroidism, thyroid carcinoma, treatment of metastatic bone pain, polycythaemia vera, synovectomy, etc) is a complex procedure which must take into account all relevant details concerning the patient's medical condition and management as well as radiation safety and radionuclide administration issues. A formal assessment of the patient prior to administration of unsealed sources for therapy is essential, and must take into account the overall patient medical history and management. The choice of radionuclide for therapy and the activity to be administered must be selected for each individual patient, based on the consultation and assessment of the patient, and the patient's medical history.

Practices and nuclear medicine departments that administer unsealed sources for therapy must provide written protocols for administration that take into account all appropriate radiation safety issues for the patient, staff and regulatory requirements. Information to patients must be available and provided, and radiation safety protocols documented.

Where unsealed sources are used for therapy for inpatients, protocols for these procedures must be available, and appropriately qualified radiation safety officers present on site. Facilities used for inpatient unsealed source therapy must conform to appropriate regulatory requirements for radiation protection of staff and other patients, procedures for handling contamination and patient waste. Regulatory requirements with regard to disposal of waste from patients treated with unsealed sources must be documented and observed.

Appendix 4 — Details of SPECT Studies

A SPECT clinical protocol should contain the following information:

1. Radiopharmaceutical, activity and route of administration.
2. Time interval between administration and imaging.
3. Acquisition parameters such as:
 - § Collimator.
 - § PHA window width and position.
 - § Matrix size.
 - § Zoom (magnification).
 - § Type of rotation, i.e. continuous or step and shoot, circular or non-circular.
 - § Number of projection images and total angle sampled, 180 or 360 degrees.
 - § Acquisition time per projection.
4. Pre-reconstruction process parameters:
 - § Type of filter.
 - § Normalization scale (older cameras).
 - § Need for attenuation correction.
 - § Need for uniformity correction.
5. Reconstruction process parameters:
 - § Type of reconstruction used.
 - § Baseline filter characteristics (to be modified if required).
 - § Need for attenuation correction.
 - § Need for correction for errors in the axis of rotation.
 - § For multi-detector systems, alignment of all detectors.
 - § Slice thickness.
6. Post-reconstruction process parameters:
 - § Type of filter.
 - § Attenuation correction.
 - § Reorientation of matrices.
 - § Thickness of reorientation slices.
7. Image display information.

Appendix 5 — Example Of Protocol For Quality Control On Gamma Cameras

The following are adaptable to most equipment and are given as examples, subject to appropriate modifications for individual instruments. Results of these checks should be recorded in a permanent log and the results on a given day compared with previous results. Any important changes should be evaluated and the probable cause recorded. The frequency of these checks may be modified on the basis of experience recorded in the individual practice (except that 1 and 2 should be performed daily), but a regular schedule must be specified and followed.

For all gamma cameras:

1. Adjust peak energy window for each radionuclide to be used; record instrument settings.
2. Record flood field image to assess uniformity of response, ensuring that the non-uniformity of the source is much smaller than other non-uniformities inherent in the system.
3. Check linearity, spatial resolution, distortion and field of view by means of suitable test pattern images.
4. Observe background count rate and distribution on monitor or persistence scope to reveal any significant asymmetry reflecting instrument or room contamination.
5. Examine each collimator for physical damage or damage to locking mechanisms. Image a high count flood source at a distance sufficient for it to serve as a quasi-point source annually to detect internal collimator damage. Proper operation of collimator lock alarms, if present, should be verified.
6. Measure the count rate of a known source under controlled conditions. This may be from the flood field image acquisition.
7. Observe the mechanical operation of the equipment, noticing any excessive vibration, slippage or other changes.
8. Check accessory equipment. Phantom images obtained on various accessory imaging format equipment should be compared to assess relative performance.

Emergency stop and other safety systems should be checked regularly.