



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

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

**Nuclear Medicine Practice  
Accreditation**

**Information, Application Form  
and Checklist**

**November 2000**

## BACKGROUND

As part of its arrangement with the Department of Health and Aged Care (DHAC) the ANZ Association of Physicians in Nuclear Medicine (the Association) has agreed to institute and run a program of practice accreditation. The program will be based on the document '*Standards for Accreditation of Nuclear Medicine Practices*' produced by the Quality Practice and Accreditation Committee (QPAC) that has been circulated to all members of the Association and to the Royal Australian and New Zealand College of Radiologists (RANZCR) for comment.

The standards detailed in the document have been agreed to by both the Association and the RANZCR as being the single set of standards that will apply to all nuclear medicine practices, where services are provided by Fellows of both the Royal Australasian College of Physicians (RACP) and RANZCR, and by members of neither College who are members of the Association.

It has been agreed that both the Association and the RANZCR will run accreditation programs using identical standards. It has also been agreed that an audit program will be implemented by a joint committee of both the RACP and RANZCR over the first two years of the program to ensure similar application of the standards.

*The Association's accreditation process will:*

- be overseen by the Accreditation Implementation Committee (AIC)
- be unambiguous and auditable, and have wide support, including from the DHAC
- have an agreed implementation timetable
- be subject to review by the AIC at regular intervals
- be the subject of regular reports to the DHAC
- cover practices that provide nuclear medicine services and receive Medicare benefits and that are run or staffed by Association members who are generally Fellows of the RACP.

*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 associated with the location.

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

## **TIMETABLE FOR IMPLEMENTATION**

The following are the timelines:

### ***1 May 2001***

The deadline for application by 'existing' practices (providing services prior to 1 April 2000) and 'new' practices (commencing operation between 1 April 2000 and 1 October 2000). The cutoff date for practices to be considered as 'existing' rather than 'new' is 1 April 2000.

### ***1 January 2001 - 1 November 2004***

Any new practice will be required to complete an application form within three months of commencing operation and undergo an accreditation visit within six months.

During this period all practices that were in operation prior to 1 January 2001 will be required to undergo an accreditation visit. Practices will be randomly allocated a date for the visit.

Accreditation will apply for a period of four years. Each year every practice will be required to complete a document indicating any changes that have occurred in the practice during the intervening period that might affect its accreditation status.

### ***1 November 2004***

The 'sunset' clause that permits exemption from the requirements for personal supervision will expire.

## **PROCEDURAL ASPECTS OF ACCREDITATION**

### **Management of Accreditation**

The Accreditation Implementation Committee will have control of the process of accreditation.

### **Accreditation Assessors**

Certified accreditation assessors will perform all site accreditation visits. The acceptance and validity of the process is entirely dependent upon the acceptance and integrity of the assessors.

Any recognised specialist in nuclear medicine is able to apply to become a certified accreditation assessor. Each will attend a training program and participate as an observer on one inspection visit before commencing activity in their own right.

For any accreditation visit, the accreditation assessor will verify that he/she has no conflict of interest, and the practice to be visited shall have the right to ask for an alternative assessor if the initial choice is unsuitable.

## **Accreditation Review Panel**

For each site visit, an Accreditation Review Panel comprising up to four members of the current assessor pool and one member of the Accreditation Implementation Committee (as Chair) is chosen. The Review Panel considers the report from the site assessor and votes on accreditation status.

## **Components of the Inspection**

These comprise:

- Application
- Pre-inspection activity
- The inspection itself
- Final report.

### ***Application***

Each practice that wishes to apply must complete the attached application form and check list that follows the format of the document '*Standards for Accreditation of Nuclear Medicine Practices*'. The form shall be completed by the senior or primary specialist in nuclear medicine at the practice. The completed application form and fee are returned. A contact person (preferably the specialist in nuclear medicine who completed the application form) is nominated for contact purposes.

### ***Pre-Inspection Activity***

A practice accreditation assessor is designated for the facility. A copy of the completed questionnaire and checklist is sent to the assessor for study prior to the inspection date. The ANZAPNM Secretariat communicates with the facility contact person listed on the application and arranges a mutually convenient date for the inspection. The ANZAPNM Secretariat will ask the facility contact person to arrange meetings with the medical staff, the technologists and, if appropriate, others who interact regularly with the nuclear medicine practice.

### ***Inspection***

On arrival at the facility, the assessor will discuss the day's activities with the contact person. It is expected that the inspection will last half a day.

The inspection format will follow the outline on the checklist. Patient files will be reviewed to verify documentation. General safety procedures will be evaluated in addition to the radiation safety section on the checklist and there will be a review of a random selection of studies that have been interpreted by the various medical staff who are actively involved in the practice.

The assessor should, if possible, be accompanied by the relevant staff member (e.g. medical staff, technologist) at each stage of the inspection so that questions can be answered and additional data provided if necessary. After all parts of the inspection are complete, the assessor will hold a brief summary conference with the staff to discuss the preliminary findings and to obtain, if necessary, any clarification regarding the facility's answers to the checklist or interpretation of the guidelines.

## ***Final Report***

Within two weeks of the inspection date, the assessor will provide a report on the inspection procedure that will be sent to all Accreditation Review Panel members for a decision via a ballot vote.

The medical director of the practice will be sent a letter which comments on the evaluation and gives notification of the Panel's accreditation decision.

## **The Need for Corrective Action**

If the Panel determines there is a need for corrective action before granting accreditation, the letter will indicate the necessary corrections. The medical director of the practice shall respond within two months, documenting the corrective actions that have taken place. Following receipt of reply, the Panel shall make a decision to accredit or deny accreditation and the medical director will be notified of the decision.

## **Appeals Process**

The appeals process that will be followed is that which has been developed by the RACP. The steps involved comprise reconsideration, review, and finally, formal appeal.

If reconsideration is requested, the applicant will be asked to provide further supporting information and advise the applicant accordingly. If further review is requested, a separate panel will be constituted to consider the matter. Finally, if the applicant wishes to appeal further on the grounds that due procedure has not been followed, the appeal will be considered by an independently constituted Appeals Committee.

## **Review of the Standards**

The Standards will be reviewed after four years. There is provision for review of the Standards from time to time during the intervening period if necessary.

## **INTERIM SITE ACCREDITATION**

Site accreditation will be necessary from 1 May 2001. Therefore all sites requiring accreditation will be required to fill out the attached checklist and return it to the ANZAPNM Secretariat prior to that date. Following receipt of the completed checklist the AIC will assess each application and make a decision concerning interim accreditation. Decisions will be made by a simple majority of the Committee.

The possible decisions will be:

- Interim accreditation granted until site accreditation visit;
- Provisional interim accreditation granted pending written confirmation of corrective action on deficiencies noted; or
- Accreditation refused until deficiencies corrected and a formal site visit has been undertaken.

The Chairman will have the deciding vote in the case of split decisions.

If a decision is appealed, the process that will be followed is that which is described in detail on the preceding page.

## INSTRUCTIONS FOR COMPLETING THE APPLICATION AND CHECKLIST

- The principal or senior partner in the practice must complete all sections and sign the application.
- **All questions marked with ‘!’ must be answered in the affirmative to allow accreditation.**
- Other questions can be answered in the negative and accreditation can still be granted although it is expected that corrective action will be taken before the formal site visit occurs. However if a large number of questions are answered in the negative accreditation may be refused pending corrective action.
- Not all questions can be answered with Yes or No. In these instances please feel free to add explanatory comments, either in the answer column or on the ‘Comments Page’.
- **Practices that seek either temporary accreditation on the grounds of not satisfying fully the requirement for a specialist in nuclear medicine to be involved in all parts of each procedure, accreditation as a rural solo or remote practitioner, or accreditation that includes nuclear medicine therapy are required to complete the relevant sections in Appendix 1, 2 or 3 respectively.**

*Please send the completed application and checklist to:*

Accreditation Coordinator  
ANZAPNM  
PO Box 73  
Balmain NSW 2041

## APPLICATION FOR ACCREDITATION

<b>Practice Details:</b>	
Practice Name	
Postal Address	
Postcode	
Phone	
Fax	
Specialists in Nuclear Medicine	
Other Specialists in Diagnostic Imaging (if appropriate)	

<b>The practice is:</b>	<input type="checkbox"/>	Public hospital-based
	<input type="checkbox"/>	Private hospital-based
	<input type="checkbox"/>	Stand-alone private practice
	<input type="checkbox"/>	Private practice as part of a multi-modality practice
	<input type="checkbox"/>	Provincial practice
	<input type="checkbox"/>	Remote practice

**This application has been completed by:**

<b>Name:</b>
<b>Date:</b>
<b>Signature:</b>

<b>Staff (FTE)</b>	
Specialists in Nuclear Medicine	
Specialists in Diagnostic Imaging	
Technologists	
Physicists	
Radiopharmacists	
Administrative Staff	

<b>Patients Examined Per Year (approx.) (optional)</b>	
Total	

<b>Equipment</b>	
SPECT-capable gamma cameras (list type and age, and associated computer system)	
Other gamma cameras (list type and age, and associated computer system)	
Other or stand-alone computer systems (list type and age)	
Film copy systems (list type and age)	
Stress testing facilities	
Lung ventilation machines	
Dose calibrators	
Laminar flow hoods	
DEXA machines	

## **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**

**Please tick**

Each specialist in nuclear medicine is 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.		<b>Yes!</b>		No
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Recognition as a specialist in nuclear medicine by the relevant state SRAC for each specialist who provides services in the practice has been obtained for each specialist.		<b>Yes!</b>		No
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#### **2. Licence to Use Radioactive Substances**

Each recognised specialist in nuclear medicine holds a current licence from the appropriate radiation licensing body to prescribe and administer radioactive substances to humans.		<b>Yes!</b>		No
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#### **3. Personal Supervision**

Each responsible specialist in nuclear medicine is physically present at the practice location in order to fulfil the components of a nuclear medicine service: <ul style="list-style-type: none"> <li>• personal attendance upon the patient</li> <li>• determining the appropriateness of and monitoring the quality of the procedure</li> <li>• assessing and influencing the outcome of the procedure</li> <li>• providing a final consultation report.</li> </ul>		<b>Yes!</b>		No
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*Those who wish to apply for exemption to this requirement in the context of:*

- *current practice without the full-time presence of a specialist in nuclear medicine;*
- *provincial practice; or*
- *remote practice*

*must complete the relevant checklist in Appendix 1, 2A or 2B respectively at the end of the document.*

#### 4. Nuclear Medicine Therapy

Please tick

<p>Does the specialist in nuclear medicine plan to undertake therapy with unsealed sources? If so, the following issues must be addressed:</p> <ul style="list-style-type: none"> <li>• qualifications and experience of the practitioner</li> <li>• current licence for unsealed source therapy</li> <li>• the facilities and procedures for treatment</li> <li>• the availability of a radiation safety officer.</li> </ul>		Yes		No		N/A
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*If the specialist wishes to undertake such therapy the checklist at the end of the document in Appendix 3 must be completed.*

#### 5. Responsibilities of the Specialist

<p>Each specialist in nuclear medicine is responsible for the quality and safety of all procedures performed by nuclear medicine personnel at the facility during his or her attendance.</p>		Yes!		No
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#### 6. Continuing Education Activities

<p>Each specialist in nuclear medicine maintains a record describing in detail the continuing education activities that are undertaken. These may include either participation in the Maintenance of Professional Standards program of the RACP or the RANZCR Continuing Medical Education Program.</p>		Yes!		No
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#### 7. Education of Other Practitioners

<p>Each specialist in nuclear medicine participates in educational activities that inform other practitioners and health professionals about the clinical application of nuclear medicine procedures.</p>		Yes		No
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#### 8. Quality Assurance

<p>Each specialist in nuclear medicine is responsible for ensuring that appropriate departmental procedures are carried out.</p>		Yes!		No
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## **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**

**Please tick**

The nuclear medicine technologist shall be qualified by experience and training to perform nuclear medicine procedures. The Accreditation Board of the ANZ Society of Nuclear Medicine has provided certification concerning experience and training for all technologists who work in the practice.		<b>Yes!</b>		No
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#### **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.		<b>Yes!</b>		No
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## **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**

**Please tick**

The practice provides a reasonable standard of patient privacy and dignity, including patient examination areas and convenient toilet facilities.		<b>Yes!</b>		No
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#### **2. Compliance with Statutory Radiation Safety Requirements**

The nuclear medicine practice is subject to applicable radiation safety regulations. State radiation regulations, as well as the radiation safety practices outlined in the applicable radioactive materials licence, are retained in the practice for assistance in compliance.		<b>Yes!</b>		No
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**Please tick**

Copies of reports of any inspecting agency are retained in the practice with reports of the response to any deficits noted.		<b>Yes!</b>		No
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Radiation safety policies and procedures are maintained.		<b>Yes!</b>		No
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### 3. Radiation Protection Procedures

Procedures to ensure patient and personnel radiation protection are 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.		Yes		No
B. The activity of radioactive material to be dispensed for administration to patients must be calculated according to an established protocol.		<b>Yes!</b>		No
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.		Yes		No
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 should be available, particularly for therapeutic procedures involving larger potential exposures.		Yes		No
E. Appropriate precautions regarding pregnant and breast-feeding patients are observed. This includes warning signs, verbal inquiry and the issue of special instructions to the patient where required.		<b>Yes!</b>		No
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.		Yes		No
G. Appropriate procedures are maintained for identification of radiation areas and the receipt, storage, and disposal of radioactive substances (analogous procedures should be in place for non-radioactive drugs and bio-hazardous materials in general).		<b>Yes!</b>		No
H. Appropriate procedures and resources are in place for handling accidents involving radioactive materials and subsequent decontamination.		Yes		No
I. Appropriate radiation monitoring equipment is readily available for the detection of contamination and radiation exposure levels.		Yes		No
J. Personnel are trained in radiation safety techniques and have periodic in-service reviews.		Yes		No
K. Personnel are monitored by TLD badges and/or other dosimeters. The records are retained and retrievable.		<b>Yes!</b>		No

**Please tick**

L. There is an appropriately qualified radiation safety officer to be responsible for radiation safety within the practice.		<b>Yes!</b>		No
M. A radiation safety manual is available for use within the practice.		<b>Yes!</b>		No

#### 4. Handling of Hazardous Materials

Materials presenting biological or other hazards are carefully handled to minimize risks to personnel. Eating and drinking are prohibited in patient care and laboratory areas of the practice.		<b>Yes!</b>		No
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#### 5. Airborne Materials

Noxious, toxic or volatile materials presenting a hazard of airborne transport (e.g. Xe and I) are handled in hoods providing adequate and safe venting to the atmosphere.		Yes		No		N/A
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#### 6. Eyewash Facilities

Provisions for emergency eyewash are available and clearly identified near areas where eye injuries are most likely to occur.		Yes		No
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#### 7. Physical Facilities in General

The premises are adequately ventilated. Utilities should be adequate. These include: temperature control, water taps, sinks and drains, lighting, electrical outlets and communications (telephone/intercoms) particularly for emergency situations.		Yes		No
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#### 8. Fire Precautions

Instructions for protecting patients and staff against fire must be presented periodically and posted prominently. 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.		<b>Yes!</b>		No
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#### 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.		Yes		No
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**10. Handling of Biological Materials**

Please tick

Glassware contaminated with toxic or biological materials is made safe as soon as practicable after use. Bench tops and area surfaces subject to substantial contamination risk are covered with disposable protective materials when feasible; these covers are to be discarded in a safe manner when contaminated.		Yes		No		N/A
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Procedures assure that adequate care is exercised in handling sera and other materials, especially those from jaundiced patients.		Yes		No
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**11. Staff Infection Control**

Personnel afflicted with potentially communicable diseases are restricted from patient contact.		Yes!		No
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**12. Disposal of Contaminated Objects**

Discarded needles and other sharp items are stored in specially designated containers to minimize the risk of injury or contamination.		Yes!		No
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**13. Consultation and Procedure Areas**

Patient interview and examination areas and areas where samples of blood or other materials are taken are comfortable and clean and means of screening from general view are available.		Yes		No
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**14. Facilities for Cardiac Stress Testing**

If cardiac stress testing is performed as part of myocardial imaging, the appropriate facilities are 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 (see Appendix 4 of the Accreditation Standards).		Yes		No		N/A
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**15. Procedure for Venesection and Injection**

Aseptic technique is used in entering the skin; personnel securing blood and other samples are provided with convenient means for washing their hands after removing their gloves.		Yes!		No
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**16. Procedures for Ill and Uncooperative Patients**

Please tick

Staff are instructed in procedures for handling seriously ill or uncooperative patients and patients presenting a risk of transmitting infectious disease.		Yes!		No
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**17. Procedures and Facilities for Cardiopulmonary Resuscitation and Basic Life Support**

All staff are trained in cardio-respiratory resuscitation procedures. Appropriate facilities are available, depending on the level of cardiac stress testing performed.		Yes!		No
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**Principle 4**

*For nuclear medicine imaging, procedures ensuring control and recording of the components of the medicine 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 provides information relating to the performance of the scan (as detailed in Principle 6.2).		Yes!		No
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**2. A.L.A.R.A. Principle**

Patients shall receive no more radiation exposure than is necessary in the judgement of the responsible nuclear medicine specialist for satisfactory completion of a study.		Yes!		No
The radioactivity of materials prepared for administration to each patient is verified by measurement in a suitably calibrated instrument.		Yes!		No
The quantity and identity of radionuclides administered is reported on the patient record.		Yes!		No

**3. Data Obtained or Recorded from Patient Studies**

All important technical data and images obtained during each patient procedure are preserved to assist in comparison with other studies performed.		Yes!		No
The images and relevant data are given to the patient or their nominated representative.		Yes!		No

**Please tick**

<p>The practice maintains an acceptable patient record for imaging studies on all patients, including all the information listed in Principle 7, Standard 1, 'Patient Records'. The following are added, if appropriate:</p> <ul style="list-style-type: none"> <li>A. Description of any unusual features prior to, during or following the study.</li> <li>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 variations.</li> <li>C. Any comments regarding quality of the study.</li> <li>D. Notation of important deviations from standardized procedure as described in the procedure manual.</li> <li>E. For Anger-type gamma cameras, the following information should be recorded in technical records, unless standardized in the procedure manual:</li> <li>F. camera identification</li> <li>G. collimator type</li> <li>H. window settings for each radionuclide imaged</li> <li>I. view obtained, including orientation of detector, if relevant and head I.D. for multi-head cameras</li> <li>J. patient orientation, i.e. supine, sitting, etc.</li> <li>K. total image counts</li> <li>L. time required to record image.</li> <li>M. For SPECT, details of acquisition and processing should be given. Full details are given in Appendix 5 of the Accreditation Standards.</li> <li>N. When other instruments, such as multi-crystal cameras, thyroid uptake probes etc., are used for patient study, appropriate data analogous to those described for single-crystal gamma cameras should be recorded in patient records, unless standardized in the procedure manual.</li> </ul>		<b>Yes!</b>		No
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#### 4. Daily Patient Log

<p>A daily log or equivalent recording of the names of all patients upon whom studies were performed, is recoverable for the appropriate statutory period.</p>		<b>Yes!</b>		No
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#### 5. Equipment Service Record

<p>Instrument service records describing in detail the reason for service and actions taken, including preventive maintenance, is completed by service personnel and retained in the practice.</p>		<b>Yes!</b>		No
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## 6. Equipment Quality Control

Please tick

<p>General equipment performance tests are specified and performed routinely, and the results documented. The schedule complies with that specified in the document titled 'Minimum Quality Control Procedures for Nuclear Medicine Equipment' produced by the Technical Standards Committee of the ANZSNM. (An example protocol for [non-SPECT] quality control on gamma cameras is given in Appendix 6 of the Accreditation Standards and the document itself is given in Appendix 7.)</p>		<p><b>Yes!</b></p>		<p>No</p>
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### **Principle 5**

*Procedures ensuring the quality of radiopharmaceuticals shall be followed.*

#### **Standards**

##### **1. Medical Supervision**

<p>The nuclear medicine specialist is responsible for the safety and effectiveness of any drugs used under his/her supervision. The specialist may designate individuals to prepare or administer radiopharmaceuticals. The training and experience of such personnel shall be appropriate to the particular procedure delegated, as judged by the responsible specialist.</p>		<p><b>Yes!</b></p>		<p>No</p>
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##### **2. Radiopharmaceutical Preparation**

<p>If radiopharmaceuticals are prepared on site, the procedures below are followed:</p> <ul style="list-style-type: none"> <li>A. The volume and quantity of radioactivity eluted from the generator are measured and recorded, taking suitable precautions to minimize personnel exposure during such measurements.</li> <li>B. Generator eluates are checked for breakthrough of parent nuclide at each elution.</li> <li>C. Radiopharmaceuticals are prepared according to product labelling or written procedures established in-house.</li> <li>D. Aseptic procedures are used in handling all components and preparations for potential parenteral or ophthalmic administration.</li> <li>E. Radiochemical purity of prepared radiopharmaceuticals is routinely verified as per written policies and procedures.</li> <li>F. Reagent kits and prepared radiopharmaceuticals are stored according to established criteria (e.g. product labelling).</li> </ul>		<p><b>Yes!</b></p>		<p>No</p>		<p>N/A</p>
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If radiopharmaceuticals are provided by external suppliers, the procedures below are followed:

**Please tick**

<p>A. The suppliers are appropriately licensed.</p> <p>B. Radiopharmaceutical identification is verified by checking the label.</p> <p>C. The quantity of radioactivity to be administered to each patient is 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 is deferred until the problem is resolved.</p> <p>D. Prior to administration, patient identification is verified.</p>		<b>Yes!</b>		No		N/A
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### 3. Radiopharmaceutical Records

Appropriate records shall be maintained of:

A. radiopharmaceutical receipt		<b>Yes!</b>		No
B. radiopharmaceutical preparation		<b>Yes!</b>		No
C. radiopharmaceutical disposition		<b>Yes!</b>		No
D. adverse reactions to radiopharmaceuticals		<b>Yes!</b>		No
E. misadministration and other recordable events		<b>Yes!</b>		No
F. actions taken in response to any problems identified in the above areas.		<b>Yes!</b>		No

### 4. Labelling of Blood or Blood Products

<p>A. A licensed nuclear medicine specialist is 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 supervises the administration of the final product. The training and experience of such personnel are appropriate to the particular procedure.</p>		<b>Yes!</b>		No
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Please tick

<p>B. If labelling of blood or blood products is performed in-house, the procedures below are followed:</p> <ul style="list-style-type: none"> <li>a. it is important that only one patient's blood is processed for labelling at any one time</li> <li>b. handling of multiple specimens is avoided due to the hazards associated with blood handling and the risk of swapping samples</li> <li>c. 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</li> <li>d. labelling procedures are standardised in-house and the established written procedure shall be followed</li> <li>e. labelling efficiency and the other quality control criteria including stability are standardised and established in-house. The labelled products satisfy the required standard before being administered to patients, unless otherwise determined by the supervising specialist.</li> </ul>		Yes		No		N/A
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<p>C. If labelled blood or blood product is supplied from an external source, the procedures below are followed:</p> <ul style="list-style-type: none"> <li>a. product label is verified for patient identification</li> <li>b. the radioactivity supplied is verified. Any discrepancy more than 10% from the stated activity shall be clarified with appropriate personnel before administration</li> <li>c. prior to administration, patient identification shall be verified.</li> </ul>		Yes!		No		N/A
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<p>D. Record keeping is performed so that:</p> <ul style="list-style-type: none"> <li>a. appropriate records of labelling of patient blood and blood products are maintained</li> <li>b. appropriate records of adverse reactions to labelled products are maintained</li> <li>c. appropriate records of misadministration and incidence are recorded</li> <li>d. appropriate records of salvage actions in relation to problems are maintained.</li> </ul>		Yes!		No
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## 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

Please tick

The preparation and maintenance of the procedure manual are supervised directly by the nuclear medicine specialist.		Yes!		No
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#### 2. Contents of the Manual

The technical procedure manual includes 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.		Yes		No
B. A description of instruments used and the control settings, and the technical and analytic steps followed in performing the procedure, including: <ul style="list-style-type: none"> <li>a. study identification</li> <li>b. radiopharmaceuticals and non-radioactive drugs used</li> <li>c. patient dosage and route of administration</li> <li>d. patient preparation required</li> <li>e. routine patient position for the study</li> <li>f. collimation</li> <li>g. required views</li> <li>h. preset counts or time, typical count rate for each view or information density, as applicable</li> <li>i. list of special views frequently needed</li> <li>j. typical indications for performing the study.</li> </ul>		Yes		No
C. Reagents or other materials used in the test, including a listing of any special precautions for the use of such substances and restrictions on the source of supply.		Yes		No
D. Type of nuclear medicine procedure performed as identified in the practice procedure manual. Any special modifications of the procedure shall be noted and explained.		Yes		No
E. Medical literature citations when appropriate for a more thorough understanding of the procedure.		Yes		No

Please tick

<p>F. A description of:</p> <ul style="list-style-type: none"> <li>a. any special quality assurance measures specific to the particular procedure</li> <li>b. a definition of quality control limits if appropriate</li> <li>c. instructions on any preliminary actions to be taken in case of deviation from acceptable limits before referring the problem to the nuclear medicine specialist</li> <li>d. examples of typical indications for performing procedure</li> <li>e. details of required quality control procedures.</li> </ul>		Yes		No
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### 3. Review and Revisions

The procedure manual reflects current practices followed in the practice and shows evidence of at least annual review by the nuclear medicine specialist.		Yes!		No
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Revisions in the manual are approved by the specialist and are clearly identified; superseded methods with inclusive dates used are recoverable as long as the reports of the procedures performed by the superseded methods are preserved.		Yes!		No
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The procedure manual or practice policies contains provisions for correction of clerical errors, significant analytical errors or unusual results.		Yes!		No
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### 4. Modification to Procedures

Such modification is noted in the patient records of the nuclear medicine practice or in the consultation report as judged appropriate by the reporting nuclear medicine specialist.		Yes		No
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## 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 identify:

Please tick

A. Name of patient and identification number or other satisfactory identification of the patient.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No
B. Name of practitioner initiating the request.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No
C. Date of the request.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No
D. A record of type, activity, route and injection site of any radioactive or non-radioactive substances administered to the patient.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No
E. The nuclear medicine technologist performing the procedure.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No
F. Date and description of findings of any procedures performed.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No
G. 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.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No
H. Identification and signature of the responsible nuclear medicine specialist.	<input type="checkbox"/>	<b>Yes!</b>	<input type="checkbox"/>	No

#### 2. Patient Reports

These include the following items from the patient record:

A. Name of patient.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
B. Name of practitioner initiating the request.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
C. Type of nuclear medicine procedure performed as identified in the practice procedure manual. Any special modifications of the procedure are noted and explained.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
D. Date and description of findings of any procedures performed.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
E. 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.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
F. Identification and signature of the responsible nuclear medicine specialist.	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

### 3. Timeliness of Reports

Please tick

In general, the report is sent to the referring practitioner within 24 hours of completion of the study.		Yes		No
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If there are urgent or unexpected findings, the specialist uses reasonable endeavours to communicate directly to the referrer or an appropriate representative who will be providing clinical follow-up.		Yes		No
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### 4. Confidentiality

Except in circumstances of a medical emergency, during the course of professional communication and as required by law, medical records are not, without the patient's express written consent, released to persons other than the patient. Where appropriate the patient's legally appointed guardian or attorney may be sufficient.		Yes!		No
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### 5. Retention of Results

Request forms, records, films, photos and/or electronic media with imaging studies are retained for an appropriate time or as long as required by Federal rules/regulations for retention.		Yes!		No
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### 6. Directions for Referring Practitioners

There are directions for requesting nuclear medicine studies available to referring practitioners responsible for initiating requests.		Yes		No
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## **COMMENTS**

It may not be possible to answer some questions with a simple 'Yes' or 'No'. Some explanation may be required. Furthermore the person completing the form may wish to make additional comments or provide extra information. The space below is provided for these purposes.

**Appendix 1 - Application for Accreditation under the Clause Allowing Exemption from the Requirement for Personal Supervision by a Specialist in Nuclear Medicine**

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. In order that practices that currently operate without the services of a specialist in nuclear medicine full-time not be disadvantaged, it is permissible for:

**Please tick**

<ul style="list-style-type: none"> <li>• A specialist in diagnostic imaging to consult with the patient, monitor and influence the conduct of the study and the quality of the diagnostic output before the patient leaves the practice</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>• This specialist will be located on site throughout the procedure.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>• A specialist in nuclear medicine who has access to other investigations including diagnostic imaging films will report all procedures on site.</li> </ul>		Yes		No		N/A

**Appendix 2A - Nuclear Medicine Practice in Provincial Sites**

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

**Please tick**

<ul style="list-style-type: none"> <li>• Direct patient consultation by the specialist in nuclear medicine has occurred.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>• 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.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>• The specialist in nuclear medicine provides the final report on the study on site.</li> </ul>		Yes		No		N/A

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:*

<ul style="list-style-type: none"> <li>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.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>During the remainder of the time the practice can function remotely, under the operating conditions set out below for remote nuclear medicine practices.</li> </ul>		Yes		No		N/A

**Absence from the practice during professional and recreational leave**

<ul style="list-style-type: none"> <li>For a provincial solo nuclear medicine practice to continue to operate while the specialist is on leave, such absence shall not exceed ten weeks in any one year.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>During the course of such absence, this practice shall operate as the remote practice of another cooperating fully staffed nuclear medicine practice, under the operating conditions set out below for remote nuclear medicine practices.</li> </ul>		Yes		No		N/A

## Appendix 2B - Nuclear Medicine Practice in Remote Sites

### Operating conditions for a remote nuclear medicine practice

These shall accord with the following conditions:

Please tick

<ul style="list-style-type: none"> <li>The establishment and conduct of a remote practice complies fully with all relevant Commonwealth and State laws and regulations.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>The remote practice is associated with a host department, which is capable of providing a full range of nuclear medicine services as indicated above.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>A radiologist or appropriately qualified specialist is in attendance during the conduct of all procedures at the remote practice.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>The range of services offered at the remote practice is confined to those appropriate to the expertise of the specialist attending the remote site.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>Secure lines of communication exist between the remote and host practices, which permit:               <ol style="list-style-type: none"> <li>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;</li> <li>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.</li> </ol> </li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>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.</li> </ul>		Yes		No		N/A
<ul style="list-style-type: none"> <li>The facilities of the host department are available for further evaluation of the patient from the remote practice if required.</li> </ul>		Yes		No		N/A

### **Appendix 3 - Nuclear Medicine 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 specialist in nuclear medicine undertaking nuclear medicine therapy procedures in his/her practice must have:

**Please tick**

<ul style="list-style-type: none"> <li>recognised specialist qualifications in nuclear medicine, and have adequate prior training and practical experience</li> </ul>	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A
<ul style="list-style-type: none"> <li>a current licence for the therapy to give unsealed sources</li> </ul>	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A
<ul style="list-style-type: none"> <li>actively practised the use of unsealed source therapy</li> </ul>	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A

**If specialists at the practice in addition to the specialist who completes this form are involved in the administration of radionuclide therapy, the names of each for whom all answers are 'Yes' must be given below:**

**Please tick**

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.		Yes		No		N/A
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.		Yes		No		N/A
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.		Yes		No		N/A

***Please send this completed application form and checklist to:***

Accreditation Coordinator  
 ANZAPNM  
 P O Box 73  
 Balmain NSW 2041

### **Confidentiality**

All information provided in this application and checklist is confidential and will not be released to anyone other than members of the Accreditation Implementation Committee who have a valid interest in the accreditation process of the particular site.