SUMMARY OF SUBMISSIONS AND RESPONSES
DRAFT SAFETY GUIDE FOR RADIATION PROTECTION IN NUCLEAR MEDICINE

	COMMENT	RESPONSE
1.2 Background		
	Submission No. 14 *Line 6* **Safety Guides** Two of the safety guides contain the same background statement. "This Safety Guide has been prepared as a supplement to the Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation. It provides advice and guidance on measures that can be employed to assist in meeting the requirements of the Code." In the Radiotherapy Safety Guide the wording is slightly different; "The information …. is intended to provide practice specific guidance in radiotherapy on achieving the requirements of the Code". In all there is the implication that the emphasis is on meeting regulatory requirements, rather than just the simple statement of providing advice on good practice.	Agreed. Background statement amended to read "It provides advice and guidance on good radiation practice and on meeting the requirements of the Code". The forward to the Code states "three separate safety Guides for radiation protection in radiotherapy, diagnostic and interventional radiology and nuclear medicine inform best practice in each of these medical applications of ionizing radiation and provide useful radiation protection information to the medical community"
1.4 Scope		
	Submission No. 19 *Line 33* Additional scope: the exposure of members of the general public.	Agreed – additional point added to scope
1.6 Radiation Management Plan		
	Submission from Vic Soc of Nuc Med Technologists **Page 8, section 1,6 line 53** We recommend changing the sentence to read "The plan should consider the views of all stakeholders and should be signed and dated by the…."	Disagree. Paragraph remains unchanged specifying the Radiation Management Plan should be signed and dated by the Responsible Person and the RSO

	Page 8, line 58 Insert 'The plan should be reviewed within a designated timeframe (every 2-3 years?) to ensure it reflects current best practice.'	Agreed in part. Paragraph amended to reflect that the plan should be reviewed no longer than every 5 years.
	Page 8, line 62 Comment: Where relevant, key components of the Radiation Management Plan should be integrated into institutional protocol manuals such as the nursing and clinical manuals. This will ensure support for the plan from the highest levels of the organisation.	Noted
	Page 8, line 67 A statement such as the following should be inserted "All new staff should be introduced to the Radiation Management Plan as part of their orientation program."	Agreed. New paragraph inserted "The relevant sections of the Radiation Management Plan should form part of an orientation program for new staff."
2 Justification		
	Submission No. 15	
	Point 2, Line 80: The word "usually" must be deleted so that ***Line 80*** reads, "in nuclear medicine, this person will be a ***nuclear medicine specialist"***. This is the role of the nuclear medicine specialist. We are unaware of any circumstance whereby the medical practitioner responsible for the overall conduct of the procedure would not be a specialist in nuclear medicine. Certain procedures such as radiation synovectomy and intro-arterial administration of radiolabelled products are performed within a multidisciplinary environment, but nevertheless feature a specialist in nuclear medicine.	Noted.
	Line 89 refers to "*the only*" possible detriment in regard to diagnostic nuclear medicine as being the risk of cancer. In fact, maladministrations can cause adverse clinical effects (see Yenson *et al., Nucl Med Communic* 2005;**26**:1037-41); accordingly, we suggest that the word "*a*" be used rather than "*the only*" in ***line 89*** in order that this statement is accurate.	Agreed. "only" deleted.
	Line 119 in reference to mass screening. In fact, there are several mass screening programs which are of significant public health benefit (e.g. ultrasound in patients with chronic hepatitis, cervical smears for cancer detection). The authors should specify that programs employing ionizing radiation are the subject of debate. Even the phrase "*rarely justified*" may not be true with the advent of CT in lung cancer.	Agreed. Amendment made.

	We strongly recommend that this sentence be amended as follows: "*Mass screening (non-referral) of targeted population groups using ionizing radiation should be justified by clinical evidence*." **Submission from Vic Soc of Nuc Med Technologists** **Page 9, line 89** Comment: Diagnostic nuclear medicine procedures are generally accepted as low risk however in the light of recent changes to the requirements for 'informed consent' the ANZAPNM should be asked to look at this issue.	Noted.
3.1 Responsible Person		
	Submission No. 14 *Line 125* The style of the guide particularly in the initial sections emphasises bureaucracy and persons rather than processes. The Responsible Person is a legal entity; it need not be an individual. It is a concept radiation regulators like, because it emphasises the regulatory aspects, but it not one that workers in a nuclear medicine department would readily understand and relate to. It is appropriate and helpful to emphasise that in the Code but it may be confusing in the Safety Guide. The College considers it would be better if there were less emphasis on the regulatory aspects in the Safety Guide, and more on the processes for good practice. Line 172 Issuing of personal radiation monitors is listed under the Responsible Person: Issuing of personal radiation monitors is also listed in section 9.6 line 1371 under occupational exposure in section 9. The College recommends that it would be better if it was only in that latter section. **Submission No.15** The draft code of practice and safety guide refers to the "responsible person". Notwithstanding that this may reflect administrative structures in large public hospitals or private corporations, the duties and responsibilities of this person suggest highly specialised knowledge and skills and are therefore anomalous with the non-medical personnel that	Agreed. Amended to include an introductory paragraph on roles, duties and responsibilities. 1st sentence reference to Responsible Persons unchanged, but the remainder of the paragraph has been moved to section on Personal Monitoring. Agreed – see response above.

	usually occupy such positions. As an illustration, the "responsible person" is said to be responsible for the explanation of risks of ionizing radiation to patients, carers and guardians (***Safety Guide, 3.1, lines 156-157***); must demonstrate that effective doses to carers do not exceed 5mSv (***Safety Guide, 3.1, lines 146-741***); has documented working protocols for therapeutic procedures (***Safety Guide, 3.1, lines 158-159***); understands the complexity of research programs (***Safety Guide, 3.1 line 164***) and accidents (***Safety Guide, 3.1 line 165***). Whilst the draft document refers to the delegation of tasks (e.g., to an RSO, ***Safety Guide, line 127***), the ANZAPNM strongly recommends that specialists in nuclear medicine be integrated into the duties and responsibilities schedule. We suggest that lines ***126-129*** of the ***Safety Guide*** be amended to read: "*The major responsibility for adherence to the Code lies with the responsible person, in consultation with the nuclear medicine specialist and the RSO*". The responsibility ultimately rests with these three persons. The nuclear medicine specialist fulfils the role of the medical practitioner (radiation) specified in the Code, and is responsible for the justification and optimisation of the procedures. The RSO has an important role in ensuring safe work practices. This role of an RSO is often fulfilled by a physicist. All other experts provide an advisory service, and are not accountable directly. Further, the radiation management plan (***Safety Guide, line 130***) is normally developed by a specialist in nuclear medicine in conjunction with an RSO or other qualified expert. One cannot expect the RSO to develop protocols for treatment (***Safety Guide, lines 958-163***) and to explain to patients and carers the consequences of ionizing radiation (***Safety Guide, lines 156-157***). It would be highly inappropriate for an RSO to undertake such duties without the direction of the specialist in nuclear medicine, and such a proposition should not be included in any Safety Guide. If such a reference is to be retained, then it must be qualified by amending ***line 158*** to reflect that "such protocols may only be developed by an RSO under the direction of, and in consultation with, the specialist in nuclear medicine". The same comments apply with respect to ***lines 156/157*** although it should be noted that this is more appropriately undertaken by the specialist in nuclear medicine. **Section 3.1, Responsible Person, Lines 154 -155**: The concern lies more with irradiation to the breast-fed child. The potential radiation dose to the breast of women from any radiation procedure should be considered regardless of whether she is breast-feeding. This bullet point should be reworded to: "*the breast-feeding status of a female patient if there is the potential for a significant radiation dose to the breast-fed child*".	See Response to submission 14. Agreed. Inserted "Whilst some tasks may be delegated to the nuclear medicine specialist or to the RSO, the ultimate responsibility lies with the Responsible Person." See previous response Agreed. text Agreed – reference moved to Clause 3.2 – Nuclear Medicine

	Lines 191- 194: The "responsible person" is given responsibility for "*ensuring that all relevant images, or duplicates of the images, are provided to the new practice*" on transfer of a patient to another institution or facility. It is unrealistic to expect that the responsible person would even be aware of the numerous transfers made on a daily basis, let alone understand what imaging tests have been done for every individual, and then to notify all the relevant parties. Rather, the responsibility for the care of these transferred patients rests with the treating physicians, to ensure that all relevant information has been sent and also has been sought. We recommend that ***lines 191-194*** be deleted, or else amended to read, "*With regard to patient doses, and following the ALARA principle, when a patient is transferred to a different institution or practice, the Responsible Person should ensure that the department makes available all relevant images, or duplicates of images to the new practice*."	Specialist Agreed.
	Submission No. 19	
	Line 152 This definition of 'carer' is different from ARPANSA RPS#4: "Adult family members or persons who care for the patient are not necessarily subject to the 1 mSv dose limit for members of the public. The effective dose to an appropriately informed carer who knowingly and willingly provides comfort and support to the patient should not exceed a dose constraint of 5 mSv per treatment episode." This earlier definition makes it clear that it does not apply to all adults – an adult must be informed of the risk and participate 'knowingly and willingly' in order to make use of the relaxed (higher) dose constraint. Also, RPS#4 states that the dose "should not exceed" the dose constraint. This is better, and more restrictive, wording than "is unlikely to exceed".	Agreed. Paragraph 4.4.7 amended to state "effective dose received by the carer is unlikely to exceed 5 mSv per treatment episode and the dose to children and members of the public is unlikely to exceed 1 mSv per annum"
	Submission No. 21	
	With regard to the recently released draft "RPS? - Radiation Protection in Nuclear Medicine", I wish to make a number of comments about this document. 1. On Page 11, Sec. 3.1, it is stated that: 140 The Responsible Person needs to be able to demonstrate that the effective dose 141 received by the carer is unlikely to exceed 5 mSv per year.	See response to submission 19 above.

	This is different to RPS4, Sec 2.1, page 2, which states that: "The effective dose to an appropriately informed carer who knowingly and willingly provides comfort and support to the patient should not exceed a dose constraint of 5 mSv ***per treatment episode***." For the past several years we have been conducting at Fremantle Hospital, with the permission of the Radiological Council of WA, high-activity I-131 Rituximab out-patient therapy. Typical activities administered to patients have been 1.5 – 3.5 GBq. Qualifying patients are first given a non-radioactive Mabthera (Rituximab) infusion and then are administered an infusion of I-131 Rituximab and allowed to go home where they are under 'house arrest' until they have reached the normal release limit of 600 MBq which typically takes 7 days. Consenting carers and any other household members are provided with radiation dosimetry badges in order to monitor their exposure. Typical exposures (extrapolated to infinity) of carers and other household members have been between 0.5 and 3.5 mSv per treatment episode. While it is very unlikely that the carer of a patient would exceed 5 mSv per treatment episode and it is also unlikely that a patient would be given more than one course of therapy per year, it may be possible for the carer to be exposed in excess of 5 mSv per year. Consequently I suggest that the Draft RPS be changed so that it is in accordance with RPS4, or that the Draft RPS limit be increased slightly, perhaps to 7.5 or 10 mSv per year.	
	Submission from Vic Soc of Nuc Med Technologists **Page 11, clause 3.1** Comment: The society believes the term "responsible person" introduces a concept that does not maximise the value of the guide. While the code of practice may require this type of accountability, the guide should focus on promoting best practice. Best practice in nuclear medicine has always been achieved cooperatively by a team of highly qualified professionals working under the direction of the nuclear medicine specialist. This approach is in keeping with one of the founding principles of modern quality practice "when the talents of all staff are enlisted in the pursuit of better ways, the potential for improvement is boundless". *Berwick, D. "Continuous Improvement as an Ideal in Healthcare". NEJM 1989:1; 53-56.* Assigning rigid responsibility to an individual does not strengthen this culture and is at odds	Noted. The use of the term Responsible Person reflects the definition as defined in the Code of Practice. Amendments have been made to more clearly demonstrate the role of the responsible person.

	with how nuclear medicine is practiced in most facilities. This culture is particularly important when developing and implementing the Radiation Management Plan. In addition, wider institutional responsibilities such as occupational health and safety, infection control etc may impact on the application of the guide and yet be beyond the control of any designated 'responsible person.'	
	Page 11, section 3.1 line 134 Rather than 'protection' change to "minimise the radiation exposure of employees…" our use of the term protection may not be understood by people outside nuclear medicine.	Disagree.
	Page 11, line 135 Replace protection as above	Disagree
	Page 11, line 138 Replace protection as above	Disagree
	Comment: Underpinning these dot points, there should be some guide addressing how the radiation exposure to these groups ought to be monitored.	
	Page 11, line 146 Comment: We would recommend the guide contain an attempt to address the issue of ensuring correct patient information is on the request before it is sent to nuclear medicine. In discussions about the common causes of error and near misses, our group has identified this as an increasing source of concern. This could perhaps be addressed in undergraduate education for staff by the nuclear medicine specialist; this is especially relevant to the training of junior medical staff in teaching institutions.	Noted. A new section has been added at 4.3 *Patient Identification and Procedure confirmation.*
	Page 11, line 163 Comment: We would suggest the insertion of a statement recommending each protocol be reviewed at regular intervals.	Dot point relating to protocols has been deleted.
	Page 12, line 169 Comment: This statement could be interpreted as accepting a sub standard examination. The decision about any piece of equipment being fit for purpose would be the responsibility of the nuclear medicine specialist.	Agreed. Paragraph deleted.
	Page 12, line 181 We would recommend changing the wording to "it would be desirable to issue extremity	Addressed in section 9.7 Personal Monitoring

	monitors…." **Page 12, line 195** This paragraph is gratuitous. The nuclear medicine specialist is fully aware of their responsibilities and would consult members of the nuclear medicine team as required. To require a physicist be consulted is unnecessary and unrealistic in most workplaces, and ignores the core skills of nuclear medicine technologists.	Agree. Text amended to read "a qualified expert is available, either as an employee or retained as a consultant…"
3.2 Nuclear Medicine Specialist (Medical Practitioner (Radiation))		
	Submission No. 15 The decision to perform a nuclear medicine procedure is based on three factors: (a) possible hazard associated with the procedure; (b) potential benefits from unique diagnostic information made available by the test, and (c) clinical information supplied by the referring clinician. Thus, we recommend insertion of the words: "*the potential benefits from information provided by the nuclear medicine procedure*" in ***line 212*** after "*...nuclear medicine exposure*". Furthermore, there is a fourth factor that should be included in this sentence, namely, the nuclear medicine specialist's consultation with the patient. Thus, ***line 212*** should be amended additionally to include, after "*the clinical information supplied by the referrer*", insertion of the words, "*and the nuclear medicine specialist's consultation with the patient*." The statement at ***lines 219-222*** beginning, "*The implications of delaying a ...",* is redundant and should be deleted. The central role of the nuclear medicine specialist is not specified and this is a serious omission. The ANZAPNM strongly endorses the notion that the specialist in nuclear medicine be on-site in order to assess each patient and to be able to tailor the conduct of the examination according to information being sought and potential risks. We recommend that the following words be inserted ***into either line 212 or line 219***: "*in order to integrate clinical information, with the appropriateness and potential risk of the requested procedure, the specialist in Nuclear Medicine must be on-site so that he/she can modify the conduct of each examination according to different needs*."	Agreed – paragraph amended Agreed – sentence deleted. Noted.

	Likewise, ***lines 230-232*** should be amended to read "*... undertake a consultation with the patient, including counselling the patient (or guardian)...*" (see also comments for ***line 212*** above).	Agreed.
	Submission from Vic Soc of Nuc Med Technologists	
	Page 13, section 3.2 line 219 This sentence is unnecessary and is restating the first paragraph in this clause.	Agreed. Sentence deleted
3.3 Referrer		
	Submission from Vic Soc of Nuc Med Technologists	
	Page 13, section 3.3 Comment: This clause has been discussed regularly at technologists' meetings. We would welcome some guidance on how non compliance with this section ought be addressed. This is an area of some concern for technologists, particularly those working in smaller practices.	Noted
	Page 14, line 251 Comment: We would recommend this sentence be removed. This type of information is notoriously unreliable on request forms and could, in the worst case scenario, deter staff from questioning the patient personally. With regard to identifying pregnant patients, we would recommend a statement addressing how to raise this issue in certain ethnic groups. It can be difficult obtaining this information when young girls are accompanied by male family members. This could be a matter for discussion lead by the medical specialists.	Noted. Sentence amended to: "The referral should also alert the nuclear medicine specialist when the referrer is aware that a female patient is pregnant or is breast-feeding."
3.4 Administering Person		
	Submission No. 15	
	Section 3.4 Administering Person, Line 257. Any two forms of identification are considered satisfactory. Thus, ***line 257*** should be amended to read as follows. "*Identification should be established by any two of name, date of birth, address and any unique patient number...*"	Noted. Amended to suggest identification be established by name, gender, and at least one of the following: date of birth, address or unique patient number.

	Lines 258-260: Further, the administering person (usually a nuclear medicine technologist) may or may not have sufficient expertise to assess the relevance of a procedure and, in any event, will not necessarily have the relevant clinical information and expertise to make such an assessment. As such, the assessment process should be conducted by the specialist in nuclear medicine, thus, ***lines 258-260*** *should be deleted*.	Disagree. Sentence retained.
	Line 272: It is stated that only "essential staff" should be present when performing administrations. Trainee medical radiation scientists, registrars and fellows could be captured inadvertently by this phrase, yet it is essential that they be trained in injections under supervision; we recommend that the phrase be amended as follows: "*ensure that only staff pertinent to the procedure be present when performing administrations*."	Agree in part. Modified to "ensure that only persons necessary to the procedure are present when performing administrations"
	Submission No. 31	
	Line 257 Administering Person provides a procedure for identifying the patient. It is felt that identifying the sex of patient should be included as an additional check. (this may also be relevant to other Safety Guides)	Address in response to submission 15 above.
	Submission from Vic Soc of Nuc Med Technologists	
	Page 14, section 3.4 line 254 This sentence is unnecessary. This is a part of professional practice for any technologist or medical specialist.	Additional introductory sentence included at the beginning of 3.4 Administering person. Reference to the responsible person has been deleted.
	Page 14, line 258 This sentence is unnecessary as this matter would be addressed by clause 3.2.	Disagee.
	Comment: We would recommend the guide contain a statement regarding the protocol for identifying patients who are unconscious. While most technologists comply with institutional policies, a statement in this type of document would be helpful where such policies do not exist. We would recommend that identification of, and consent for, examinations on non-english speaking patients be addressed. When for instance should interpreters be called for?	This is not considered necessary to be included in the safety guide as this issue would form part of standard protocol for all hospital procedures.

	Page 14, line 263 Comment: Extravasation of the radiopharmaceutical needs to be specifically addressed. We would recommend a statement in this section requiring technologists performing the injection to take whatever steps necessary to ensure the injection is intravenous We would also strongly recommend that if any uncertainty exists, the line used for the injection be flushed with normal saline to ensure it is correctly sited. Only then should the radiopharmaceutical be injected. We would also propose the nuclear medicine specialists develop a policy to address extravasation in the unlikely event it does occur. As mentioned elsewhere in the guide, extravasation of certain radionuclides can cause significant damage to tissue.	Noted.
3.5 Nuclear Medicine Technologist		
	Submission No. 3 1. With particular reference to the 'Radiation Protection in Nuclear Medicine' safety guide, there needs to be significant acknowledgement of the role Nuclear Medicine Technologists / Scientists undertake. I am in fact unaware of any Nuclear Medicine Department in Australia for which the basic description would actually apply. There must be acknowledgement of the roles and expertise provided from the smallest sole operator sites to thee large tertiary institutions. Reflecting this, the role of a Nuclear Medicine Technologist overlaps heavily with that described for the RadioChemist / Radiopharmacist and Nuclear Medicine Physicist. In many institutions these tasks are performed wholly by the Nuclear Medicine Technologist and in many others there is much overlapping of these roles. This does not take away from the importance of these other two professional groups, however the reality is that there are a number of possible task requirements which vary site to site. I would like to see the document reflect the true role and importance of Nuclear Medicine Technologists within these documents. I would suggest that the ANZSNM Technologists Special Interest Group should be specifically invited to aid in drafting this description. **Submission No. 5**	Section 3.5 has been substantially rewritten to expand on the roles and responsibilities of the nuclear medicine technologist. This section was redrafted taking into consideration submissions from the Victorian Society of Nuclear Medicine Technologists, and other nuclear medicine technologists.

	My main issue lies with section 3.5. Role of the Nuclear Medicine Technologist. Many departments such as my own employ Nuclear Medicine Technologist's to perform a wide range of duties that encompass the roles of Nuclear Medicine Technologist/Scientist, Nuclear Medicine Physicist, Radiopharmacist, and Nuclear Medicine Nurse. The main reason for this practice is due to many private practices having single camera clinics in multiple locations, making it impractical and financially difficult to employ the full range of experts at each site. However, these extended technical roles are not limited only to such practices and commonly exist in the public hospital environment so that NMT's have the opportunity to extend their roles rather than stagnate as a glorified ' button-presser'. Nuclear Medicine Technologists are trained to operate a Radiopharmacy, consult with patients, administer radiopharmaceuticals intraveneously and orally, perform imaging with Gamma cameras, hybrid SPECT/CT and PET/CT cameras, process patient data and images, monitor patients vital signs, blood pressure, blood glucose levels, and ECG changes, perform CPR and manual handling techniques. They must also be able to perform QC of gamma cameras and related equipment,dose calibration apparatus, film proccessors, and carry out radiopharmacy testing. Nuclear Medicine Technologists take charge of the training of PDY graduates of Nuclear Medicine Technology and tend to be the main mentors of most other students rotating through their department. NMT's also become involved in research and the production of educational material. Many of the Radiation Safety Officer positions throughout Australia are also taken by NMT's. I am one such person, and have written manuals for Radiation Proctection and Local Safety rules, as well has the Patient Protocol/Procedure manuals (all without the input of a Physicist). I am also responsible in my practice for providing Nuclear Medicine education to GP's and specialist's in the Perth region My final point concerns Continuing Education. In order for NMT's to gain and keep their accreditation status with the ANZSNM, they must be involved in further education and extended roles.	See response to submission 3.
	Submission No. 7 After reading the ARPANSA submission to Public Comment Draft dated the 24th August 2007, the following concerns have been raised: - the diversity of roles often required of a Nuclear Medicine Technologists seems to be	See response to submission 3.

	underestimated. In most departments, especially in smaller rural centres, Nuclear Medicine Tecnologists perform a large portion of duties/roles which are outlined under the roles of Nuclear Medicine Physicists and Radiopharmacist. **Submission No. 8** We fully endorse and support the position taken by Travis Pearson at The Royal Brisbane and Women's Hospital, in regard to the inexplicable lack of detail of the role and responsibilities of a Nuclear Medicine Technologist/Scientist in comparison with that attributed to the other professionals working within some, but not all, departments. (p14 3.5). We know of no departments where the division of duties actually corresponds to that outlined within the Draft. Nuclear Medicine Technologists are qualified for, capable of, and generally are performing the vast majority of tasks that have been attributed *only* to other staff. Whilst we hope this fact is understood within ARPANSA, it certainly is not apparent from the documentation, and we do not accept this misleading section as being suitable for publication as it stands. We certainly do not intend to detract in any way from the importance of other staff - we appreciate and respect the expertise of all the professionals with whom we work. Specific points: *Administering person* (p14 3.4) : in the vast majority of departments the Technologist is this person, performing these duties as stated. *Radiation Safety Officer* (p14 3.6) : the RSO is frequently a Technologist, and even if not, the Technologist still routinely performs many of these duties in a large department and virtually all of them in a smaller one. *Radiopharmacist / Radiochemist* (p16 3.7) : Departments employing such a person certainly have the opportunity to perform research and development, whilst those without do not. However even in large departments Technologists are involved on a daily basis with pharmaceutical manufacture and quality assurance. Most departments have no Radiopharmacist and the full running of the Hot Lab area, from ordering right through to waste disposal, is the responsibility of the Technologist staff.	See response to submission 3.

	Nuclear Medicine Physicist (p17 3.8) : As above, many departments operate without a Physicist. Whilst some tasks will then be outsourced, the Technologist is qualified to develop new protocols, manage computer systems, manage the equipment …….. once again there is a major overlapping of roles which is not acknowledged in the way this document describes the Technologists role. The implication as it stands is that the Technologists sole function is to produce patient data, and even this (somewhat vital !) complex task is virtually brushed aside. We think it essential that the description be amended and expanded to a level that is both accurate and comparable with that provided for the other professions : the current number of lines describing each position is - Admin.person: 20 RSO : 51 R/chemist 28 NM physicist: 39 NM tech: 3 ! This could be achieved by having the description written by the ANZSNM Technologists Special Interest Group, and we recommend their participation before the final draft is written.	
	Submission No. 13 I fully endorse the comments made by Travis Pearson and the Technologists from Princess Alexandra Hospital in Brisbane about the lack of description of the Nuclear Medicine Technologist's role. I also agree with their suggestions for change.	See response to submission 3.
	Submission No. 16 The Nuclear Medicine Technology staff of this department would like to submit the following comments regarding this Public Draft. We fully endorse and support the position taken by Travis Pearson at The Royal Brisbane and Women's Hospital, in regard to the inexplicable lack of detail of the role and responsibilities of a Nuclear Medicine Technologist/Scientist in comparison with that attributed to the other professionals working within some, but not all, departments. (p14 3.5). We know of no departments where the division of duties actually corresponds to that outlined	See response to submission 3.

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	NM physicist: 39 NM tech: 3 ! This could be achieved by having the description written by the ANZSNM Technologists Special Interest Group, and we recommend their participation before the final draft is written. **Submission No. 25** On behalf of the staff at the Townsville Hospital Nuclear Medicine Department I would like to submit the following comments in regard to the above document. Townsville is a regional centre in Nth Queensland. Myself and staff presently are operating a remote Nuclear Medicine service. I felt that the above draft did little to recognise the functions and responsibility of Nuclear Medicine Technologists working in this region and is misleading in its representation of our roles as professionals. Staff at this site perform all tasks relating to the overall management and running of this department. Nuclear Medicine Technologists at this site and many others perform all the tasks you have ascribed to the radio chemist as well as many of the tasks ascribed to medical physicist. Including reconstitution and administration of all radio pharmaceuticals and performing all quality assurance necessary, both in the Hot Lab and for the gamma cameras. I as a qualified Nuclear Medicine Technologist am the Radiation Safety Officer for this department. I am aware of many other departments that are managed in a similar capacity as described. It is unfortunate that as it stands the ARPANSA draft does not acknowledge the fundamental role of Nuclear Medicine Technologists. Possible referral to the ANZSNM Technologists Special Interest Group for a more accurate descriptor of our profession may be appropriate prior to the final draft. **Submission No. 29** The Nuclear Medicine Technologist staff of The Royal Brisbane and Women's Hospital Department of Nuclear Medicine and QLD PET Service, would like to submit their	See response to submission 3. See response to submission 3.

	endorsement of the letter submitted by Princess Alexandra Hospital with respect to the following comments regarding this Public Draft. "We fully endorse and support the position taken by Travis Pearson at The Royal Brisbane and Women's Hospital, in regard to the inexplicable lack of detail of the role and responsibilities of a Nuclear Medicine Technologist/Scientist in comparison with that attributed to the other professionals working within some, but not all, departments. (p14 3.5). We know of no departments where the division of duties actually corresponds to that outlined within the Draft. Nuclear Medicine Technologists are qualified for, capable of, and generally are performing the vast majority of tasks that have been attributed *only* to other staff. Whilst we hope this fact is understood within ARPANSA, it certainly is not apparent from the documentation, and we do not accept this misleading section as being suitable for publication as it stands. We certainly do not intend to detract in any way from the importance of other staff - we appreciate and respect the expertise of all the professionals with whom we work. Specific points: *Administering person* (p14 3.4) : in the vast majority of departments the Technologist is this person, performing these duties as stated. *Radiation Safety Officer* (p14 3.6) : the RSO is frequently a Technologist, and even if not, the Technologist still routinely performs many of these duties in a large department and virtually all of them in a smaller one. *Radiopharmacist / Radiochemist* (p16 3.7) : Departments employing such a person certainly have the opportunity to perform research and development, whilst those without do not. However even in large departments Technologists are involved on a daily basis with pharmaceutical manufacture and quality assurance. Most departments have no Radiopharmacist and the full running of the Hot Lab area, from ordering right through to waste disposal, is the responsibility of the Technologist staff. *Nuclear Medicine Physicist* (p17 3.8) : As above, many departments operate without a Physicist. Whilst some tasks will then be outsourced, the Technologist is qualified to develop	

	new protocols, manage computer systems, manage the equipment …….. once again there is a major overlapping of roles which is not acknowledged in the way this document describes the Technologists role. The implication as it stands is that the Technologists sole function is to produce patient data, and even this (somewhat vital !) complex task is virtually brushed aside. We think it essential that the description be amended and expanded to a level that is both accurate and comparable with that provided for the other professions : the current number of lines describing each position is – Admin.person: 20 RSO : 51 R/chemist 28 NM physicist: 39 NM tech: 3 ! This could be achieved by having the description written by the ANZSNM Technologists Special Interest Group, and we recommend their participation before the final draft is written." Find attached the names of the Nuclear Medicine Technologists who are in support of the above mentioned letter. Louise Campbell Sarah Stephenson Nikki-Louise Scott Antonio Lou James Hunter Peter Garcia Stephen Rumble Margaret Birnbaum Rowena Reichel Shonika Scortechini Melissa Vartzoks Sarah Frecker Jacob Bolwell Troy Hanley	
	Submission from Vic Soc of Nuc Med Technologists **Page 14, section 3.5** We recommend the following: The Nuclear Medicine Technologist is a person who has completed tertiary level studies in Medical Radiations, specialising in Nuclear Medicine. Upon completion of one of the many courses available in Australia, and a full year of	See response to submission 3. The statement regarding in-depth knowledge of Nuclear Medicine

	supervised clinical practice, they are considered to have the following skills and professional capabilities: An accredited nuclear medicine technologist would have in-depth knowledge of the following: • The scientific concepts and principles underpinning nuclear medicine imaging and non-imaging equipment. • The principles of radiation dosimetry. • The risks and benefits related to the use of radiopharmaceuticals. • Physiology, gross and sectional anatomy, pathophysiology and radiopharmaceutical biodistribution. • Radiation safety and occupational health and safety. • The role of professional standards of conduct; • Requirements of appropriate legal and ethical frameworks. • The biological effects of ionizing radiation on cells & tissues and mechanisms repairing sustained biological damage. • The principles of radiation protection and possible risks associated with irradiation during diagnostic and therapeutic procedures. • The preparation and administration of radiopharmaceuticals. • The skills to receive, dispense, store and properly dispose of radiopharmaceuticals and radionuclides. The nuclear medicine technologist would be expected to: • Safely prepare, administer and dispose of radiopharmaceuticals. • Perform diagnostic, therapeutic and laboratory based nuclear medicine procedures. • Analyse clinical data and prepare studies for reporting by the nuclear medicine specialist • Perform cell labelling procedures. • Administer therapeutic radionuclides under the direction of the nuclear medicine specialist. • Work in a multidisciplinary team using both leadership and collaboration skills. • Implement and monitor quality assurance programs. • Participate in the clinical education programs of undergraduate technologists. • Access and evaluate research information. • Identify relevant research issues and design and implement an ethically sound research project.	Technologists hasn't been included, as this knowledge is already expected as part of their accreditation. Section 3.5 Nuclear Medicine Technologist has been expanded to include a list of duties, including: imaging; preparation, dispensing and administering radiopharmaceuticals; and quality assurance procedures. It has also been expanded to list other possible responsibilities such as administering person, radiation safety officer, person preparing radiopharmaceuticals and the nuclear medicine physicist.
3.6 Radiation Safety Officer (RSO)		

	Submission No. 19	
	Line 332 The advice should refer to the general public as well (eg travel restrictions if necessary).	Information included in Section 4 – Optimisation of Protection for Medical exposures. New table included (Table 6) advising recommended travel times on public transport.
	Submission No. 31	
	Generally it is felt that the Code and safety guides adequately cover the relevant area of medical radiation practice. There however appears to be inconsistencies in the way various sections are addressed. An example of this is the treatment of radiation safety officers. In most safety guides it appears in the body of the document where as in the Diagnostic and Interventional Safety Guide it is an annex. Generic wording for common practice could be used within the safety guides.	Noted.
	Submission from Vic Soc of Nuc Med Technologists	
	Page 14, section 3.6 Comment: The role of Radiation Safety Officer is very difficult to precisely define given nuclear medicine is practiced in a variety of different settings across Australia. A simple overview of the role could be given with examples of the core duties, rather than the detail contained in the guide. We would agree that the role requires sufficient professional and/or technical training and there are requirements to keep appropriate records and documentation common to all jurisdictions. We feel the guideline would be better served emphasizing a team approach that is relevant to the specific nuclear medicine practice. The RSO should be approachable and capable of assisting staff to achieve best practice as a group. As we have commented earlier, a consultative rather than punitive attitude is desirable and consistence with modern quality practices.	Section relating the Radiation Safety Officer has been redrafted to provide more of an overview of the role of the RSO. Specific duties have been removed. Annex B lists typical RSO duties in the Radiation Management Plan.
	Page 15, section 3.6 line 292 This examples our earlier comments. Rather than "ensure the responsible person is kept informed" we would prefer "the radiation status of the practice was discussed with all staff."	Noted.

	Page 15, line 295 Replace "added as extra levels of duties for a medical physicist or other qualified expert" with "added as extra levels of duties for a medical physicist or nuclear medicine technologist". We are happy for technologists to be mentioned by name, given we perform this role throughout Australia.	Added "the RSO should liaise with the relevant nuclear medicine staff".
	Page 15, line 301 Again, any institutional radiation safety manual should be developed in consultation with the staff in nuclear medicine. It has long been recognised in the quality movement that staff involvement in policy development affords significant benefits in both the quality of the document and compliance.	Noted.
	Page 15, line 303 Comment: We think technologists are being referred to in this sentence although we are not specifically identified. Given our previous comments, this sentence can be deleted.	Noted.
	Page 15, line 309 This sentence is unnecessary. The majority of practices in Australia would have no access to a physicist. In these practices the role of RSO is performed by nuclear medicine technologists. We are unaware of any evidence to suggest practices with technologists as RSO's have different outcomes from those with physicists as RSO's. In reality, they undertake the role under the direction of the responsible person.	Agreed. Sentence deleted.
	Page 15, line 316 Change to "to maintain and regularly review the Radiation Management Plan".	Agreed. Section 3.1.1 also updated. The two last sentences of 2nd paragraph state "The Radiation Management Plan should be reviewed within a designated timeframe of no longer than every 5 years. Revisions should be signed and dated by the Responsible Person and the RSO."
	Page 15, line 321 Delete: This is not a duty of the RSO. This is the responsibility of the nuclear medicine technologist.	Deleted.
	Page 16, line 330 This line is unnecessary, nuclear medicine technologists do not need to be provided with radiation safety training. We have it provided in our undergraduate training and professional	Disagree. Relates to all staff, not just nuclear medicine technologists

	development year. It is a core skill of a nuclear medicine technologist. Other staff would not handle radionuclides	
	Page 16, line 331 Delete, this is core skill of a both nuclear medicine specialists and nuclear medicine technologist.	Disagree. As above
	Page 16, line 332 Comment: This would seem to us to be the role of the nuclear medicine specialist.	Amended to read: "to provide advice, as required, to the nuclear medicine specialist on the radiation safety of individual patients undergoing diagnostic or therapeutic nuclear medicine procedures, including discharge planning and advice to ensure any exposure to patient's relatives friends and carers is minimised"
	Page 16, lines 344 – 336 Delete, physician role.	Noted
	Page 16, line 338 Delete, core skill of a nuclear medicine technologist.	Noted
	Page 16, line 340 Comment: We support this statement. Provision of a safe working environment is a critical issue for technologists. We would prefer this guide to be more detailed in what it recommends in this area.	Noted
	Page 16, line 348 Comment: We support this statement however this role should be integrated within the overall quality plan of the facility.	Noted
	Page 16, line 350 Again, we support this role but it needs to be performed within the overall risk management framework of the facility. Confusion about reporting of incidents needs to be avoided.	Noted
	Page 16, line 354 Comment: We are not sure what "local approval" means in this context. This needs to be more clearly defined.	Agree. Statement deleted.

3.7 Radiopharmacist/Radiochemist

	Submission from Vic Soc of Nuc Med Technologists	
	Page 16, section 3.7 Comment: It needs to be recognised that the vast majority of nuclear medicine practices in Australia do not employ radiopharmacists.	Section on Radiopharmacist/radiochemist has been rewritten. Relabelled "Person Preparing Radiopharmaceticals".
	Page 16, line 365 Delete, core skill of a nuclear medicine technologist.	
	Page 16, line 366 Delete, core skill of a nuclear medicine technologist.	
	Page 16, line 368 Comment: We are not sure why this statement is included in a document like this. The leadership role would surely be taken by the nuclear medicine specialist with all staff, radiopharmacists, nuclear medicine technologists, and physicists contributing to decisions where appropriate.	Sentence on leadership role has been deleted.
	Page 17, line 370 Comment: This is a core skill of the nuclear medicine technologist. While in some bigger institutions a radiopharmacist can perform this role, it is almost universally the responsibility of the nuclear medicine technologist. We are unaware of any physicist involvement in this activity.	Relabelled section heading to "Person Preparing radiopharmaceuticals"
	Page 17, line 375 Comment: This needs to be modified. As already stated it is a core skill of a nuclear medicine technologist to prepare radiopharmaceuticals. We are unaware of the role of radiopharmacists in teaching medical and scientific staff in routine nuclear medicine practice.	Noted.
	Page 17, line 377 Comment: The monitoring of adverse drug reactions etc would be the responsibility of the nuclear medicine specialist.	Sentence deleted.
	Page 17, line 380 Comment: This role would be performed by the nuclear medicine specialist with support of the nuclear medicine technologist in most Australian facilities.	Agree. Deleted

	Page 17, para 382 Comment: Again, this role is fulfilled by the nuclear medicine team with the technologist playing a primary role in most practices throughout Australia.	Paragraph amended.
3.8	Nuclear Medicine Physicist (Qualified Expert)	
	Submission No. 15	
	Lines 390-428: The Responsible Person must consult the nuclear medicine specialist who is responsible to the patient and for the justification and optimisation of the procedure, not the medical physicist. If required, the nuclear medicine specialist would seek advice from the qualified medical physicist specifically on issues such as dosimetry.	Reference to Response Person deleted from Section 3.8 Nuclear Medicine Physicist.
	Lines 390-428 must be deleted for the reasons below, and replaced with: "*The Code requires that the Responsible Person utilise a qualified expert to advise on matters relating to radiation protection if required*."	Amended to read "a qualified expert is available for consultation"
	Line 391: The nuclear medicine specialist is the person responsible for optimisation and can consult a qualified expert if required.	Agreed.
	Line 392: Routine treatment with unsealed sources is different from radiotherapy and does not require a "qualified expert" to perform any calibration, dosimetry or quality assurance.	Agreed.
	Lines 395-402: Medical physicists do not have the skills, knowledge or expertise to assess the accuracy of nuclear medicine diagnosis; their expertise lies with matters such as dose calculations and equipment quality control. Unless novel radiopharmaceuticals are used, there is no need for a formal medical physicist input to the Human Research Ethics Committees, as radiation dose estimations and risk assessment can be readily obtained from established tables.	Noted
	There is no specific requirement for a medical physicist to "manage the clinical computer systems and undertake software design and development'. Unless these systems are developed in-house by the physicist, the computer and software systems purchased can and should be supported by the manufacturer through service agreements. Any involvement by the medical physicist is at the discretion of the Responsible Person and the nuclear medicine specialist. To routinely require involvement by a medical physicist in these systems is not	

	appropriate and, in the case of the existence of service agreements, may void such agreements.	
	Lines 403-417: These are <u>not</u> key roles for a medical physicist. These roles belong solely to the nuclear medicine specialist. Any strategic management decisions, planning patient procedures, design and implementation of new diagnostic procedures and treatments, leadership in research, procurement of nuclear medicine equipment and training of staff are the responsibilities of the nuclear medicine specialist. Certainly, advice may be sought as required from medical physicists on the areas above and, as with the roles of the 'Responsible Person', tasks may be delegated appropriately, but the responsibility is ultimately that of the nuclear medicine specialist.	Noted
	Lines 425-428: For the reasons we have previously given, including comments in relation to DRLs, these lines should be deleted (see also comments on ***Section 7.8, lines 1160-1197*** below, and ***Code of Practice, Section 3.1.7, lines 145-147***, above).	Noted
	Submission No. 19	
	Line 394 Assessing diagnoses is probably beyond the remit of the physicist. Perhaps the first point could be reworded as: "Enable high-quality delivery of diagnostic and therapeutic procedures through dose calculations and ongoing quality control of equipment;"	Section on Nuclear Medicine Physicist (Qualified Expert) has been substantially rewritten, to take into accounts comments received.
	Line 401 Additional point: "supervise the radiation protection issues associated with therapeutic procedures, including the administration of high activities, and the discharge of patients who potentially pose a significant radiation hazard."	
	Submission No. 21	
	3. The Draft RPS only very briefly mentions patient dosimetry and does not mention prospective dosimetry at all. For example, Section 3.8 mentions: 390 The Code requires that the Responsible Person utilise a Qualified Expert for	See response to Submission 19 above. Amendment to read "a Qualified Expert is available for consultation on optimisation of medical exposures, including clinical dosimetry and quality assurance, and to give advice on matters relating to

	391 consultation on optimisation, to advise on matters relating to radiation protection 392 and, for therapeutic uses, calibration, dosimetry and quality assurance. In a nuclear 393 medicine department, this person will normally be a nuclear medicine physicist who 394 will have the following duties: 395 • assess the accuracy of nuclear medicine diagnosis to ensure the accurate 396 delivery of prescribed treatment through dose calculation procedures and 397 ongoing quality control of equipment; However this (and elsewhere) is very vague and does not provide very much guidance on the very important topic of patient dosimetry and the requirements necessary in order to achieve a good therapeutic outcome while at the same time allowing the 'ALARA' principle to be applied to radionuclide therapy. If you have any queries with regard to this submission, I would be happy to discuss them with you.	radiation protection "
	Submission from Vic Soc of Nuc Med Technologists **Page 17, section 3.8 line 389** "(Qualified Expert)"". We are unsure why this term is specifically stated. All staff in nuclear medicine are qualified experts in their field. We see no reason to have the nuclear medicine physicist referred to in this way. delete	Disagree. Refer to the Code of Practice. Section on Nuclear Medicine Physicist (Qualified Expert) has been redrafted.
	page 17, line 395 Delete "assess the accuracy of nuclear medicine diagnosis". This is surely the responsibility of the nuclear medicine specialist. The "ongoing quality control of equipment" is routinely performed by nuclear medicine technologists. A nuclear medicine physicist would perform this role in only a very small percentage of Australian nuclear medicine facilities.	Section written.
	Page 17, line 401 Comment: It is routinely the role of the nuclear medicine technologist to manage the clinical computer systems in most Australian facilities. A small number of physicists and technologists do undertake software design and development.	Section written
	Page 17, line 404 Comment: This could equally be said for technologists depending on the facility. In any case, we are unsure of the relevance of this comment to this guide.	See above

	Page 17, line 408 "new and innovative" replace with new. **Page 18, line 410** Comment: Remove the word leadership. The leadership of research and development could be provided by any member of the nuclear medicine team and would depend on the specific subject being investigated. This statement needs to again reflect the earlier comments regarding a team approach to all aspects of nuclear medicine practice. **Page 18, line 412** Modify: This statement needs to be reworded to specify who this advice is being provided to. We presume it is not to nuclear medicine technologists, as this is one of their core skills. **Page 18, line 414** Comment: The term "management" needs to be defined in this context. We are unsure how this would be interpreted in the general nuclear medicine community. A physicist would participate in this role in only a small number of facilities. In the majority of Australian practices this role is performed by the nuclear medicine team. We would support acceptance testing of new equipment, but are unsure how this would be achieved Australia wide. **Page 18, section 3.8** General Comment: We recognise the crucial role physicists play within departments and the greater nuclear medicine community. They are however few in number and primarily confined to the larger tertiary centres. We think the guide needs to promote their role as consultants more widely so they can be accessed by a wider group of nuclear medicine providers.	See above See above See above See above See above Nuclear Medicine Physicists role as consultants has been specifically highlighted.
4.1 General Considerations		
	Submission No. 14 Line 450 DRLs: As indicated above in comments about the Code the College argues that the use of DRLs must not be a requirement of the radiation regulator, but a method of guidance. It is suggested line 450 read: "It is recommended that DRLs be implemented as a practical tool to aid in dose optimisation."	Reference to Diagnostic Reference Levels removed.

	Submission No. 15 The fact that patient surveys indicate a wide variation in the prescribed activity for similar examinations in no way implies that there is "*significant scope for the implementation and optimisation of patient protection*" (***lines 447-450***). With respect to Smart and Towson, no such case has been made; rather, variations exist in order to tailor examinations according to information sought, potential risk and individual factors such as a patient's clinical condition and body habitus. The data of Smart and Towson are merely a survey and do not provide evidence for the existence of any problem. The matter of guidance in protocols on prescribed activity is the domain of the nuclear medicine specialist alone and no compelling case has been presented on the need for its inclusion within the code. ***4.1, General Considerations, Therapy with unsealed radioactive substances, Lines 479-480***: In diagnostic nuclear medicine, no clear harm has been documented. The sentence beginning, "*In diagnostic nuclear medicine..."* should be rephrased to, "*In diagnostic nuclear medicine the radiation doses are very low, with a very low theoretical possibility of any harmful effects*."	Noted. Noted
4.3 Hot Laboratory Procedures		
	Submission No. 15 ***Dispensing, Lines 539, 545-546, 561-563 & 590-591***: The need for a laboratory coat (***line 539***), double gloving and the use of shoulder-length sleeve guards (***lines 590-591***) is not compelling, particularly since I-131 capsules are used nowadays rather than the liquid formulation. Furthermore, only surfaces where radiopharmaceuticals are handled need to be covered, not all surfaces as stated at ***lines 545-546***. At ***line 563***, we suggest the word "*manipulated*" be changed to "*handled*". **Submission No. 32** *Page: 20 – comment inserted at Line 510 –* **Daily Schedule** **Receipt of radioactive substances**	Agreed

	Deliveries of packages containing radioactive substances must be taken to the nominated receiving areas. Packages containing radioactive substances must not be left unattended in an unlocked room. The following procedure must be used for opening packages containing radioactive substances. Use disposable gloves when opening the package. Check the activity of the radioactive substances against the consignment note. Record the receipt of the radioactive substance and store it in its designated storage location Survey the packing materials for radioactive contamination. If contaminated treat the packing materials as radioactive waste. If not contaminated, dispose of as general waste ensuring that all radioactive labels have been removed or defaced as appropriate. **Storage of radioactive substances** When not in use, radioactive substances must be stored in their nominated storage areas. Vials of radioactive substances are to be stored in appropriate shielded areas. Tc-99m generators must be stored within a lead garage of sufficient thickness to ensure radiation levels are within appropriate limits. # Thickness of the lead garage for Tc-99m generators is 4cm Volatile or gaseous radioactive substances must be stored in nominated storage areas with appropriate ventilation or air extraction systems. Of particular note: Vials containing therapy doses of I 131, liquid or capsules are to be opened in fume cupboards Any radiopharmaceutical preparation that requires boiling must be done in a fume cupboard Storage areas or lockable storage containers must be secured to ensure access is limited to authorised persons. Only persons authorised by the possession licensee have access to the store. The movement of radioactive substances in and out of the radioactive materials store is to be recorded in the Hot Lab record keeping system. **Dispatch of Radioactive Substances** Dispatch of packages containing radioactive substances must be from the Hot Laboratory during working hours. Packages containing radioactive substances must not be left unattended in an unlocked room. Only persons permitted to do so by the possession licensee may dispatch packages containing radioactive substances. A Courier licensed to transport radioactive materials must be used. The package must be appropriately signed in accordance with radiation transport regulations A appropriately filled out dangerous goods form must accompany the package. *Page: 21 - comment inserted at Line 539* - **DISPENSING**	Noted. Section 4.2 Radiopharmaceuticals has been substantially rewritten, taking into consideration comments. Noted

	Additional Stand behind the protective screen to withdraw the required activity of the radionuclide and reconstitute the radiopharmaceutical. The dispensing operator should check the displayed background activity is insignificant prior to the use of the activity measuring device Volatile or gaseous radioactive substances must be used in the fume cupboard with appropriate ventilation or air extraction systems on required settings. Perform quality assurance tests as required. *Page: 21 - comment inserted at Line 543* - **DISPENSING** Additional. Use tongs to handle vials when measuring the activity. Check to make sure the isotope you are measuring has been selected on the dose calibrator.	Noted
	Submission from Vic Soc of Nuc Med Technologists	
	Page 20, section 4.3 General Comment: We think the guide needs to recognise the variation in how practices acquire, dispense, and dispose of radionuclides/radiopharmaceuticals. The guide, in its present format, does not address most of the real life situations occurring throughout Australia. The guide needs to be applicable to those practices that are supplied by commercial radiopharmacies. As an example, in many practices, radiopharmaceuticals are supplied in syringes as single patient doses. We believe more consultation needs to take place on this very important section of the guide. We, as a group, cannot offer more definitive comments until we consult more widely.	Agree. Paragraph amended. See 4.2.1 and 4.2.2, 9.11.1 and 9.11.2.
	The guide needs to address the specific radiation protection issues inherent in labelling blood cells with radiopharmaceuticals. This seems to be missing from the guide, as is non-imaging laboratory studies performed in nuclear medicine facilities.	Agree. New paragraph at 9.11.5
	We would also recommend that the teaching of nuclear medicine technologists reflect best practice and this should be incorporated into the guide. Students and interns need to be exposed to 'real' hot laboratory situations yet patients and staff need to be protected.	Noted
	Page 20, section 4.3 line 506 We are unsure whether this comment is recommending a wipe test for all containers, or containers that show signs of damage. A wipe test on all containers would be excessive. We would strongly support the comment "any problems with containers or vials should be reported immediately to the supplier." Is this also something the relevant state authorities	Agreed. Paragraph amended to " if damage is suspected, a wipe test should be performed"

	should be told about? We would recommend that the activity of all vials be measured on arrival in the laboratory and that this be reconciled against the delivery documentation. **Page 20, line 511** We recommend that this sentence be changed to "The nuclear medicine technologist should review …." This reflects both routine practice throughout most of Australia and the core skills of technologists. **Page 20, line 516** Comment: There has been a question raised by specialists in infection control in relation to the use of plastic backed absorbent paper. Could specialist advice be sought on this matter **Page 21, line 522** Comment: This sentence needs to be rewritten after we have a complete picture of the different ways radionuclides/radiopharmaceuticals are supplied. P**age 21, line 525** Again this reflects one form of practice. Some facilities are supplied with bulk sodium pertechnetate and reconstitute 'cold kits' from this solution. In most private practices radiopharmaceuticals are supplied in cold kits prepared by radiopharmacies. We are again of the view that more information needs to be collected about current practices before any guide can be written in this area. **Page 21, line 537** Radiopharmacy needs to be defined in the glossary. **Page 21, line 539** We would not recommend the wearing of laboratory coats. Gowns are preferred and should be worn at the discretion of the person dispensing the radiopharmaceutical. **Page 21, line 558** We would also recommend including a comment recommending that people are not to be interrupted while performing these tasks. We have anecdotal evidence that being called away to answer phone calls or other requests can increase the possibility of error. **Page 22, line 567** Rather than this type of comment, the guide should focus its recommendations on ensuring all	This section has been deleted. Noted. Disagree Noted. Addressed in section 4.2.2 and 7.6 Agreed. Definition added to glossary Agree Agree. New point added at 9.11.3 Noted

	facilities are properly equipped with monitors etc and that staff be encouraged to use them. **Page 22, section 4.3** General Comment: As stated earlier, the guide does not address the labelling of blood components with radionuclides/radiopharmaceuticals. This is a significant omission that should be corrected. This guide also does not address the use of radionuclides/radiopharmaceuticals in non imaging applications. We would be happy to assist the working group if it wished to address these omissions.	Acknowledged. (9.11.5) Noted
4.4 Prevention of Erroneous Administration of Radiopharmaceuticals to Patients		
	Submission No. 13 *Line 614* In addition - Section 4.4 - line 614 refers to requiring to state quantity in Becquerel. Surely this should be to state it in SI units so that we can continue to use MBq and GBq?	Noted
	Submission No. 14 Line 596 "maladministrations of radiopharmaceuticals": The College does not agree with the use of the term "maladministration". It seems to be referring to an error in administration of radiopharmaceuticals and perhaps the simpler word error would be easier to understand. There are then several different types of errors of administration, and listing them would be helpful. Although the word maladministration is in the English dictionary, that is usually in the context of bad or dishonest administration as management or governance, rather than in the context of incorrect administration of a medication. If there is a simple word like error, that is preferable to a longer word, particularly if it introduces new jargon.	Noted. Section moved to 8.2 with heading "Misadministration of Radiopharmaceuticals"
	Submission No. 32 *Page: 22 - comment inserted at Line 593 –* **4.4 Prevention of Erroneous Administration of Radiopharmaceuticals to Patients**	Noted.

	A shielded trolley is normally used to transport the lead or tungsten transport pot containing radioiodine. *Page: 22 - comment inserted at Line 594–* **4.4 Prevention of Erroneous Administration of Radiopharmaceuticals to Patients** Misadministration more widely adopted term. *Page: 22 - comment inserted at Line 597 –* t**he request for the procedure is misread or misinterpreted;** Additional A total extravasation of a dose, which was intended to be intravenous. **Submission from Vic Soc of Nuc Med Technologists** **Page 22, section 4.4** We would again stress the importance of obtaining correct patient information at the time the request is written. Putting the wrong patient ID label on requests means checks in the department do not always uncover the mistake This error may be discovered by the nuclear medicine staff if there is an obvious discrepancy, for example a request describing a 63 year old patient when the ID label states the patient is 36. We would recommend this issue be highlighted in the guide by the addition of the dot point after line 596 • The request information does not match the intended patient **Page 22, line 603** We would also recommend encouraging the use of interpreters where possible. **Page 23, line 604** This comment reflects a very old fashioned view of how to improve quality. The concept of seeking to hold individuals personably accountable and expecting performance to improve does not take into account the complex nature of why errors occur. "Inattention to detail" is a cover all statement that may mask inadequacies of equipment, the work environment, the process of preparing and injecting etc. As W Edwards Deming emphasised "improving quality is concerned with improving systems not blaming people". Promoting good practice, as this guide intends, should incorporate an understanding of systems as an adjunct to reducing error and improving performance.	Agreed Noted. Addressed in Section 8.3 Agree. Additional line to be inserted in SG at 4.3 Patient Identification Agree. Additional comment added at 4.3 Disagree – attention to detail is critical. See statement at 8.3 Misadministraton "Inattention to detail at key times during the dispensing or administration of the radiopharmaceutical is a common cause of error (Yenson et al 2005)."

4.5 Radionuclide Therapy Procedures		
	Submission No. 14	
	Lines 620 **confirmation of absence of pregnancy** "It is preferable to also determine the B-HCG result on a separate occasion in the week prior to treatment.": The College does not understand why this is stated, surely one test is sufficient, immediately prior to administration of the therapeutic radionuclide.	Noted. Deleted sentence stating "it is preferable to also determine the β-HCG result on a separate occasion in the week prior to the treatment".
	Line 624 **avoidance of conception**: Would "avoidance of pregnancy" be clearer?	Noted. Leaving unchanged
	Line 681 **Design of treatment areas and wards** The College notes the statement that "in most cases excreta may be disposed of directly via the sewer system": It agrees that the biological hazard from storage of excreta creates a far greater risk to staff and the environment than disposal into the sewage system. The College suggests deleting the last clause "although the regulatory authority might require the use of delay tanks in special circumstances". It is always the case that the regulatory authority as part of licensing for therapeutic radionuclides needs disposal of waste to be addressed, and in certain circumstances will require special provisions.	Noted.
	Line 812 **Administration of therapeutic radioactive substances** - Wrist bands: The College queries why an additional wrist band needs to be placed on a patient. If the patient is isolated in a single room the wrist band is unnecessary.	A wrist band is useful to identify deceased patients.
	Submission No. 15	
	Prior to radiopharmaceutical administration: Yenson *et al*. (see above) have shown that incidents with therapeutic doses of radiopharmaceuticals can have serious adverse consequences. One such incident was related to the non-attendance of the specialist in nuclear medicine on the patient.	Noted
	Accordingly, it is essential that this section commence with: "*It is imperative that the*	Inserted information as new heading at 4.4.2 "medical supervision"

	specialist in Nuclear Medicine attend the patient and that he/she provides immediate supervision, so that clinical issues, possible side-effects of the radiopharmaceutical administration and checking of the activity to be administered are reviewed. The following should be discussed..." ***Administered activity, Lines 799-792***: In practical terms, this permissible range should be broadened to 20%. There is greater potential for increasing radiation dose to staff with diminishing benefit while attempting to adjust and readjust to within 10%. This can be very difficult with low activities. ***Procedures in wards used by patients receiving radionuclide therapy, Lines 831-832***: Gloves are usually sufficient. For example, routine nursing check of pulse and blood pressure, which involves patient contact, does not require gowning. A gown may be required when handling very ill or incontinent patients. ***Lines 846-847***: The "attending physician" would not be cognizant of the issues involved or, if this wording refers to the nuclear medicine specialist, then this should be specified. This sentence should therefore state, "*... without the approval of the nuclear medicine specialist or the RSO*." **Submission No. 19** *Line 615* Additional point: "Therapeutic procedures should be performed under the general supervision of a Nuclear Medicine Physicist, who ensures an adequate level of training and supervision for staff who administer therapeutic activities, and provide radiation protection advice." *Line 753* Typo. Space between "to" and "5". *Line 766* Table 2 The title "Sleeping with non-pregnant partner", should be "Close contact with partners/carers" as it should apply to all time in close proximity, not just time while sleeping. The periods of precautions for partners/carers are quoted correctly from Woodings (2004),	Unchanged. Any activity above 15% becomes a reportable incident under the NDRP. Agree. Text amended Agree Noted. Supervision must be under a physician in case of any clinical complications. Noted Amended to "minimise close contact with" with an explanation of what minimise close contact means before the table (now table 3). Additional table added relating to periods for avoiding pregnancy after radionuclide therapy (new table 2).

	however they were calculated for a dose constraint of 3 mSv. ARPANSA specify a dose constraint of 5 mSv for this group. Applying the method of Woodings (2004) with a 5 mSv dose constraint gives precautions of 5 days (for 600 MBq) and 1 day (for 400 MBq). In addition, recent results from Cappelen et al. (2006 Eur J Nucl Med Mol Imaging 33:81-86) demonstrate that 3 days is sufficient for partners limiting time in close proximity with patients administered 600 MBq or less. Barrington et al. (1999, Eur J Nucl Med 26:686-692) demonstrate that infants have a greater likelihood of exceeding their dose constraints. They propose that this is due to patients being unable to minimise time in close proximity because of the imperative to provide care. For this reason Barrington et al. expressly recommend that infants should be cared for in separate accommodation. The Table 2 footnote does not meet this recommendation. Various clinical and laboratory studies have established that the specific dose constant for thyrotoxicosis patients is 0.06 $\mu Sv\ m^2\ MBq^{-1}\ h^{-1}$, including the effects of attenuation (Woodings, 2004). Thus the conversion between administered activity and dose rate at 1 m would equate 600 MBq to 36 $\mu Sv\ h^{-1}$ etc. Not 30 $\mu Sv\ h^{-1}$ as presented in the safety guide. *Line 771* Table 3 The precautions for "Child care/nursery worker" are conservative. They were obtained from ACPSEM WA guidelines where the calculations for "care providers" were given as the extreme conservative example. The ACPSEM WA guidelines recommend that child care workers are more consistent with the "close worker" category. The authors of the safety guide may wish to consider whether the final column of Table 3 should be included at all. *Line 773* Table 4 Suggest title change to specify that the patients are receiving therapy for "thyroid cancer after surgical thyroidectomy". Partner/Carer comments for thyrotoxicosis patients (above) apply here as well. The precautions for a 600 MBq patient should be 1 day rather than 2, for a 5 mSv constraint. The footnote regarding separate accommodation for infants is far less important for thyroid cancer patients. The ACPSEM WA guidelines suggest 1 day of separate accommodation. *Line 780*	Table Review – Child care/nursery worker now 1 hour at 0.3 metres and 4 hours at 1 metre. Agree – table reviewed and amended. New table inserted (Table 6) – No of hours of public transport allowed sitting next to the same person. Includes 1.5 hours for a

	ACPSEM WA guidelines suggest that travel on public transport for as little as 1.5 h (for a patient with 600 MBq) can deliver appreciable dose to a fellow traveller.	600 MBq ^{131}I.
	Submission No. 21	
	2. While the Draft RPS does make reference to 'Procedures in wards used by patients receiving radionuclide therapy' and does make a few comments on the use of I-131-labelled antibodies, it does not address the issues of *out-patient* therapy using I-131-labelled antibodies or other similar day- or out-patient therapies such as Lu-177-Octreotate. There are a number of issues that relate to these types of therapies that need to be addressed in the draft RPS and for which an Australian-wide standard or guidance would be preferable, rather than an ad-hoc state by state ruling. These issues include:	Noted.
	• Frequency of staff visits to the patient's residence. In Western Australia, the Radiological Council previously required that a Nuclear Medicine physicist visit the patient at their residence (or place where the patient was to reside whilst under 'house arrest') prior to the therapy. Another visit by the physicist to the patient's residence was required immediately after the therapy had been administered and the patient had arrived home. The Council also required that the physicist visit the patient every two days after that (including week-ends) until the patient's whole body activity had fallen to below 600 MBq, on which the patient was to be officially 'released' from house-arrest. As the number of out-patient therapies is frequently 2 per week and is rapidly rising, this amount of travel was very onerous on staff and was limiting the number of patient therapies that could be carried out, it was eventually accepted by the Council that the number of visits could be reduced to three visits (pre-therapy, immediate post-therapy, final release visit after 7 days). However even this may often be excessive and it is suggested for future guidance, that the RPS recommend that only the pre-therapy visit and the release visit be necessary.	Addressee by ensuring the dose to the carer does not exceed 5 mSv per treatment episode.
	• Of particular concern to us is that the guidance in the Draft RPS on the topic of the disposal of contaminated urine of out-patients is rather sparse. It states that: 679 Radioactive excreta should not be stored in containers as this is likely to result in 680 unnecessary exposure of staff and would also create a biological hazard. In most 681 cases, excreta may be disposed of directly via the sewer system (ICRP 2004),	Noted
	The ICRP 2004 (pp1) states that:	Noted

	"Storing patients's urine after therapy appears to have minimal benefit." and "With the exception of contact with a patient's urine, several studies have shown that the risk of contamination with radioiodine is generally low although not negligible. This report shows that with appropriate regulations and even without storage of urine, sewer disposal of excreta from radiotherapy patients is well within both occupational and public radiation dose limits. Storing the urine of patients treated with radioiodine appears to have minimal benefit. Radionuclides released into modern sewage systems are likely to result in doses to sewer workers or the public that are well below public dose limits." (ICRP 94, pp.2) However the condition from the Radiological Council of WA is in direct contradiction with this and requires that contaminated urine from out-patients be collected and returned to the Hospital for disposal. Monitoring of the exposure to the physicist who is currently required to package and return the contaminated urine from the patient's house to the Hospital for subsequent disposal shows that the exposure to the physicist is typically between 30 and 75 µSv per patient, with most of this due to the packaging and handling of the contaminated urine for transport back to the hospital. As the number of therapies is currently about two per week and is expected top rise to three or four per week, this is resulting in exposures to the NM physicist of 3000 – 4000 µSv/year, on top of exposure at the hospital undertaking other physics duties, and may increase to perhaps double this. It is suggested that the Draft RPS address this issue more thoroughly and provide some more guidance, based upon the ICRP recommendations, for the various state and bodies. **Submission No. 32** *Page: 23 - comment inserted at Line 615* – **4.5 Radionuclide Therapy Procedures** Additional If a misadministration occurs: (1) Notify the RSO who will then notify the responsible person. The patient must be notified of the error. (2)The RSO must calculate the anticipated absorbed dose as soon as possible. The RSO must coordinate efforts to reduce the potential absorbed dose to the patient.	Noted Noted Not appropriate for SG. Should be addressed in local rules. Section 8 on Radiation Incidents discussed misadministration and investigation and reporting requirements.

	(3)A radiation incident report must be completed to determine the cause of the misadministration, the estimated dose delivered, the likely harmful effects and the action required to prevent a recurrence. *Page: 23 - comment inserted at Line 616* – **4.5 Radionuclide Therapy Procedures - Pregnancy and Avoidance of Conception** The patient must be questioned as to the possibility of pregnancy, and any known allergies, or previous adverse reaction to a radiopharmaceutical, or a compound to which there may be cross-reaction with a radiopharmaceutical to minimise probability of complications. *Page: 26 - comment inserted at Line 733* – **the manner and place of administration** Where possible a cannula should be used to ensure the injection lies in the vein when radiopharmaceuticals containing Thallium-201, Gallium-67, and Indium-111 or therapy doses are to be administered. This method helps prevent extravasation of an injected substance. Tl-201, Ga-67 and In-111 emit low energy electrons that can give rise to very high local radiation dose if deposited in tissue. *Page: 26 - comment inserted at Line 746* – **additional dot point** **Oral administration – liquid:** Receptacle with radioactive substance (e.g. I 131) product should be placed in a spill tray. A straw or tube must be used to transfer liquid to the patient's mouth. The patient must not be permitted to handle the receptacle, or drink directly from the receptacle. If vomiting is likely – the medical specialist may require the use of an anti-emetic drug prior to administration. If vomiting occurs use decontamination procedures outlined in this plan. Ensure patient clothing is protected with a non-absorbent gown or apron **For oral administration – capsule:** Capsules must not be handled directly by the patient or use licensee because of possible high exposure and surface contamination. A cup or other appropriate receptacle must be used to administer the capsule. If vomiting is likely – the medical specialist may require the use of an anti-emetic drug prior to administration. If vomiting occurs use decontamination procedures outlined in this plan. *Page: 30 - comment inserted at Line 827* – **Procedures in wards used by patients receiving radionuclide therapy** Pregnant nursing staff should not be rostered to iodine therapy rooms. Patients are admitted to the ward before the I131 dose is ad ministered, to allow nursing staff	Should be addressed in local rules. Should be addressed in local rules. Should be addressed in local rules. Should be addressed in local rules.

	to make their own assessment of the level of nursing care required. Potential problems should be identified and discussed before the dose is given. Bladder catheterisation may be required for patients who are confined to bed, or require lengthy assistance for toileting, or who may be incontinent. The use of bedpans is not recommended because of the spill risk. Patients with chest congestion or tracheostomy should be advised about precautions including the use of tissues and disposable cups etc. If possible, avoid taking blood samples during the first 48 hours following the dose. Urine samples shall not be collected unless absolutely essential, and only after discussion with the RSO. When it has fallen to an acceptable level, the patient may be discharged or transferred to another ward. Thyroid cancer patients will have a post-therapy whole body scan in the Department of Nuclear Medicine, usually on the day of discharge. These patients should be showered, with hair washed, and wear clean cloth *Page: 30 - comment inserted at Line 827* – **Procedures in wards used by patients receiving radionuclide therapy** Due to the high dose given to therapy patients additional precautions should be taken prior to the dose being given. The patients identity must be checked with the prescription and confirmed by a second person prior to the dose being administered. The patients must have been read and signed the information sheet detailing the restrictions placed on them and the additional requirements imposed during their stay. The information sheet must cover any additional recommendations or precaution that are required after the patients discharge.	Addressed in 4.3 – Patient identification and procedure confirmation..
	Submission from Vic Soc of Nuc Med Technologists **Page 25, line 679** We agree and strongly support this statement.	Noted
	Page 29, line 784 The nuclear medicine specialist is the appropriate person to provide this advice. Delete physicist and RSO.	Added reference to nuclear medicine specialist
	Page 29, line 790	

	We agree with the comments in this paragraph. The activity to be administered needs to be calibrated and the amount reported to the nuclear medicine specialist. The physician will then decide if that activity is to be administered. We would strongly agree that radioiodine capsules should not be broken up in an attempt to reduce the activity and this should be stated in the guide. This is a particularly dangerous manoeuvre and should not occur. **Page 30, line 850** Comment: We would recommend the inclusion of a statement on reducing the chance of nausea in patients where this is likely to be an issue. Perhaps the physicians could look at this.	Noted Additional statement added under "4.4.9 administration…" heading
4.6 Medical emergencies involving patients undergoing radionuclide therapy		
	Submission from Vic Soc of Nuc Med Technologists **Page 31, line 877** Comment: The RSO is not the person to consult. We would recommend that only a nuclear medicine specialist provide advice in this situation. They are the only group that will have an intimate appreciation of the surgical procedure and its consequences. **Page 31, line 890** Comment: This sentence advises the surgeon to undertake "personal decontamination procedures". Would most surgeons know what these procedures are? We would recommend inserting "the surgeons consult the nuclear medicine specialist before commencing the procedure." This approach would prepare the surgeon before he/she commences the procedure.	Amended draft to include the medical specialist Noted.
4.7 PET/CT and SPECT/CT examinations		
	Submission No. 19 *Line 909* Additional point: Where it is known in advance that a PET, SPECT or other tomographic scan is to be used to assist with radiation oncology treatment planning, the scan should be acquired with the patient in the intended treatment position. This may require a flat couch (or couch insert),	Not relevant in Safety Guide. Should be address in local rules.

	treatment immobilisation devices and attachments, and accurately aligned external lasers. Where possible, scans should also be acquired with fiducial markers (ball bearings, radionuclide spheres etc) to facilitate co-registration of image sets. **Submission No. 31** As the Diagnostic and Interventional Safety Guide does not cover CT attached to a PET or SPECT scanner it is suggested a further paragraph be added to this section. The paragraph should recommend that compliance testing of the CT should be performed using the same criteria as a diagnostic CT scanner.	Agreed. Additional paragraph added
5 Protection of the Embryo/Fetus		
	Submission No. 15 ***Section 5, Protection of the Embryo/Fetus, Line 930***: Urinary β-HCG is as accurate as serum results and these are available more readily. Thus, ***line 930*** should be amended to read, "*...serum or urinary β-HCG testing before ....*". ***Lines 934-935***: The statement "*It is also preferable to determine the β-HCG result on a separate occasion in the week prior to treatment*" should be deleted. There is no reason to test the patient one week prior to treatment, as the patient may become pregnant after this test. The pregnancy test within 24 hours prior to treatment is the most important test, as it is closer in time to the treatment and more likely to detect elevated β-HCG levels. Despite a recent publicised case, the addition of a pregnancy test one week before treatment cannot increase the chances of detection of pregnancy. **Submission from Vic Soc of Nuc Med Technologists** **Page 33, line 918** As mentioned earlier the guide should have a comment about how sensitive this questioning may be in certain cultural groups. We would advocate the use of multi-lingual signs in	Agreed. Sentence amended to read "If the β-HCG test is equivocal it may be advisable to defer the nuclear medicine procedure for a few days and repeat the test. Section 5 on Protection of the Embry/Fetus has been significantly rewritten and expanded and includes Table 7, Radiation dose to the uterus and embryo/fetus… Additional sentence added "When language barriers exist it may be useful to seek the service of an interpreter. History alone may

	waiting areas.	not be reliable because a woman may not be aware of pregnancy."
6 Protection of an Infant		
	Submission No. 15 ***Lines 961-965 (a) and (b):*** There are other diagnostic nuclear medicine scans where cessation of breast-feeding is required besides Ga-67, as presented in Table 6 (pages 35 and 36). Therefore, replace (a) and (b) with, "*...commencing radiopharmaceutical therapy or diagnostic scan for radiopharmaceuticals listed in Table 6*." ***Table 6 components, pages 35 and 36***: There is inconsistency between the ^{99m}Tc myocardial perfusion agents, MIBI (sestamibi) and tetrofosmin, which have similar elimination pathways. The data for MIBI and tetrofosmin in this table have come from different sources, which explains the inconsistency. The EANM/ESC Procedural Guidelines Imaging in Nuclear Cardiology states, under "Lactation": "*According to the European Commission Guidelines, interruption of breast-feeding is not essential for 201 TI chloride up to 80 MBq and not at all for ^{99m}Tc-labelled radionuclides*." (see p. 862, *European Journal of Nuclear Medicine and Molecular Imaging*, *2005, **32**: 855-897 - copy attached*). **Submission from Vic Soc of Nuc Med Technologists** **Page 34, line 955** Comment: We recommend that the guide specifies this advice should be given by the physician not the technologist. **Page 34, line 976** Comment: The issue of breast feeding before radioiodine therapy raises 2 questions. One is the problem of radioiodine in the breast milk which this guide addresses. The other is the high concentration of radioiodine in breast tissue when the patient has been breast feeding. Could a specific time be nominated to cease breast feeding before administering radioiodine to minimise breast tissue concentration to acceptable levels.	Noted. Section 6 – Protection of an Infant has been rewritten. Agreed. Table amended Noted Noted.
7.1 General		

	Submission No. 19 *Line 1023* "...should endeavour to..." is a very loose statement. Ideally this would be rewritten as "The Responsible person *must* seek the advice of a nuclear medicine physicist...". At the very least it should be "...should seek the advice...".	Agree
	Submission No. 32 *Page: 38 – comments inserted at Line 1034 –* **7.1 Quality Assurance General** Other benefits of a quality assurance program are: (1) continued production of images with optimal diagnostic quality (2) ability to identify problems before they impact on clinical procedures (3) ability to evaluate the performance and extended life of equipment	Agreed. Text inserted
	Submission from Vic Soc of Nuc Med Technologists **Page 38, section 7.1** Comment: The quality assurance program of the practice should reflect the activity and resources of the practice as the guide points out. The QA program should be developed as part of the overall quality program of the facility. All staff should be involved and contribute to the program. The comments regarding seeking the advice of a physicist is impossible for most practices that operate without physics support, and unnecessary in most cases The ANZSNM provides guidelines on many aspects of QA which can be easily accessed.	Agree. Text amended
7.2 Acceptance Testing of Nuclear Medicine Equipment		
	Submission No. 3 *Line 1039* 2. With particular reference to the 'Radiation Protection in Nuclear Medicine' safety guide, consideration should be given to including CT specific detail in the section 7.2 for	Noted.

	'Acceptance testing for Nuclear Medicine Equipment.' This detail should be consistent with the 'Diagnostic and Interventional Radiology' safety guide. **Submission No. 19** *Line 1032* Again, the word "preferably" should be removed *Line 1044* This recommendation should be strengthened. The equipment tolerances are chosen because they are significant. If equipment is outside tolerance it should not be used until either (i) the equipment is repaired and re-calibrated such that it is within tolerance or (ii) the equipment is replaced. **Submission No. 32** *Page: 38 – comments inserted at Line 1051 –* **7.2 Acceptance Testing of nuclear medicine equipment** **Recommended for gamma camera the following be carried out** **Daily checks** Visual inspection Photopeak check and adjustment Uniformity check [Bone Mineral Densitometer standard phantom scan with automatic assessment] **Weekly checks** High count flood uniformity check **Twelve monthly checks or following service or repair** Spatial resolution Deadtime Multiple window spatial reolution Whole body resolution	Disagree. Agree. Paragraph amended Recommended constancy tests for gamma cameras and PET scanners are referenced in section 7.2.
7.4 Dose Calibrators		

	Submission No. 32 *Page: 39 – comment inserted at line 1066* – **7.4 Dose calibrations** **Radiation monitoring device** A calibration check of the radiation survey meter and a contamination meter will be performed once every twelve months and following suspected damage or repair. The survey meter is to be calibrated if the calibration check yields erroneous results. *Page: 39 – comment inserted at line 1077* – **7.4 Dose calibrations** **Daily checks** Long term drift on the 99mTc, 67Ga, 131I, 123I and 201Tl settings Background and zero adjustment **Three monthly** Cross comparison of dose calibrators using different nuclides, typically 99mTc, 67Ga, 131I and 201Tl. Tolerance less than or equal to ± 2 per cent in the relative activity readings. **Annual checks** Linearity and reproducibility tests **Bi-annual checks** Accuracy Following adjustment or repair Accuracy, linearity, reproducibility and geometry	Addressed at Annex F New table of testing frequency inserted (table 9).
7.5 Film Processing		
	Submission No. 32 *Page: 40 - comment inserted at line 1109* – **7.5 Film Processing** **Sealed radioactive substances used for quality control or marker sources** **General** All sealed radioactive substances will be visually checked on a monthly basis for damage and to ensure encapsulation integrity. Any loss or damage of sealed sources is to be reported immediately to the RSO. **Marker sources** Marker sources are to be stored in appropriately shielded containers. Marker sources are checked daily for loss or damage.	Addressed in section 10.4 “Storage and Safe Handling of Sealed Radionuclide Sources” and section 8.1 “Types of Radiation incidents”

	Marker sources are stored in a designated radioactive substances store. **Sealed radioactive substances for quality control** Sealed radioactive substances are to be stored in an appropriately shielded container and kept in the designated radioactive substances store. **Submission from Vic Soc of Nuc Med Technologists** **Page 40, section 7.5** Does this need to be in a guide on radiation protection?	No. Section removed
7.6 Radiopharmaceutical Quality Testing		
	Submission No. 32 *Page: 40 - comment inserted at line 1129 –* **dose calibrator setting where the isotope is manually dialled** Add dot point - Sterility test **Submission from Vic Soc of Nuc Med Technologists** **Page 40, section 7.6 line 1122** Comment: We endorse this statement. Practices need to be conscious of this requirement irrespective of where they source their radiopharmaceuticals. **Page 41, line 1144** Comment: We endorse this statement and as such recommend the guide should particularly address the practice of fractionation. We regard this practice as a potential source of risk to patients.	Disagree Noted Noted
7.7 Record Keeping		
	Submission No. 32 *Page: 41 - comment inserted at line 1149 –***7.7 Record keeping**	

	The following records are to be maintained by the responsible person or on behalf by the RSO: Responsible person's and use licences issued under by radiation safety regulatory agency The approved radiation management plan Reports by the RSO Approvals to acquire the radioactive substances and the X-ray equipment. Approvals to dispose of radioactive substances. Personal monitoring records and explanations of unusual dose readings. Assessment reports of premises. Equipment log books. Results of quality control checks. Register of examinations performed. Inventory and location of radioactive substances. Calibration check certificates for the radiation monitoring devices. Radiation store log (movement of radionuclides to and from the hot laboratory) Radiation safety audit reports. Incident reports, misadministrations and spills.	Can be components of the Radiation Management Plan.
7.8 Patient activity surveys and diagnostic reference levels (DRLs)		
	Submission No. 14	
	Line 1160 DRLs The College supports the use of DRLs and encourages their use and so much, but not all of this section is supported.	Noted
	Line 1164 "To encourage institutions to perform activity surveys it is recommended that accrediting bodies such as the ANZAPNM and the ACHS consider including compliance with DRLs for a core set of examinations as one element in achieving accreditation.":	Agreed. Section written.
	The College does not does not agree that Radiation regulators should give advice on what professional accrediting bodies should do about accreditation in a document such as this.	
	Line 1189 The College argues that DRLs should not be regulated by the radiation regulator.	Noted.
	Submission No. 15	

	Section 7.8 Patient Activity Surveys and Diagnostic Reference Levels (DRLs), Lines 1160-1197: should be deleted (see also comments on ***Section 3.8, lines 425-428***, and ***Code of Practice, Section 3.1.7., lines 145-147*** above). DRLs have not been endorsed by the nuclear medicine profession, and as noted, Towson and Smart's data are simply a survey and provide no evidence for there being any problem. Furthermore, statements such as those in ***lines 1167-7768***, that "*..compliance with DRLs for a core set of examinations as one element in achieving accreditation*.." are inconsistent with the purpose of DRLs. <u>As has been stated from the outset by ARPANSA</u>, any DRLs should serve only as a guide and not be intended for prescriptive application now or in the future. This would be contrary to the intention of the ICRP that the purpose of DRLs is <u>advisory</u>, and that DRLS are not to be used for regulatory purposes, are not a dose constraint, and are not linked to limits or constraints. **Submission No. 32** *Page: 41 - comment inserted at line 1161 –***7.8 Patient Activity Surveys and DRLS** Include Annex with tabulated DRLs with references cited. **Submission from Vic Soc of Nuc Med Technologists** **Page 41, section 7.8** We agree with the comments made by the ANZAPNM on this matter.	Noted. DRLs for common nuclear medicine procedures are available on the ANZSNM website. Safety Guide states that "DRLs are advisory, allowing for flexible application to individual patients…" Noted. Not able to be cited as DRL's are a transient document Noted
8.1 Investigative and Reporting Requirements		
	Submission from Vic Soc of Nuc Med Technologists **Page 43, section 8.1** Comment: The reporting of radiation incidents is encouraged by our group. We support a culture that constantly strives to improve. To this end we do not wish to re-enforce an attitude that seeks to focus on finding a culprit and punishing them. As stated earlier, we support a process that identifies all the factors that contributed to an incident. As such, the facts pertinent to any incident should be clearly established. This should include exploring factors such as the availability of equipment, the practicality of protocols, the work	Noted.

	environment such as size of rooms, lighting etc, and the workload. Discussions with all relevant staff should occur to ensure all input is considered. And finally any changes made should be accompanied by an education program for staff. Wherever possible auditing of compliance with any changes should be introduced.	
9.2 Pregnant or Breast-feeding Staff		
	Submission No. 32 *Page: 44 - comment inserted at line 1243 –***…. with a personal dose monitor if they do not already have one.** Passive personal dosemeters do not allow real time dose assessment required for the protection of the embryo or foetus in a nuclear medicine environment where doses can readily exceed 1mSv per annum. Electronic personal dosemeters are readily available, reliable, low cost and display dose, dose rate and integrated dose alarm, features that can immediately confirm that the embryo or foetus is being appropriately protected. Therefore, where pregnancy is declared a passive personal dosemeter used for legal dose measurement should be supplemented with an active electronic dosemeter.	Agreed. Sentence inserted.
9.3 Exposure from Radioactive Patients		
	Submission No. 15 ***9.3, Exposure From Radioactive Patients, Lines 1273-1276:*** This section has potential to create false alarm. The problem we have found with promulgation of advice to delay x-ray or ultrasound after a nuclear medicine procedure is that this would be seen by non-radiation workers, including reception staff, nurses, blood collectors, ward assistants, physiotherapists, occupational therapists, ECG technicians, social workers etc. as "proof" that nuclear medicine patients are radioactive and therefore represent a health hazard, These staff would have the impression that, if radiation workers such as radiographers deem it necessary to avoid close contact with nuclear medicine patients, then so should they. The consequence of this perception would be such that even non-close contact with such patients would subsequently be avoided, to the detriment of patient care and treatment. As a general statement, it is proper practice to schedule procedures so as to minimise the radiation burden to staff such as sonographers. However, it should suffice, particularly since	Noted. Section amended.

	Table 6 (pages 35 and 36) lists the necessary restrictions on close contact with children, that patients who have nuclear medicine procedures that do not require any restrictions whatsoever should therefore have no restrictions on having other procedures such as ultrasound or x-ray. ***Lines 1270-1276*** restate the principle in ***lines 1255-1258***, and could be deleted. In addition, multiple tests are often referred by the patient's doctor to various facilities and may not be picked up by one facility's "institutional protocol". **Submission No. 19** *Line 1281* Additional point. The nuclear medicine department should have a proactive system of education sessions for general hospital staff to encourage best practice of patient care and sensible (rather than phobic) radiation protection precautions are observed. **Submission from Vic Soc of Nuc Med Technologists** **Page 45, Section 9.3 line 1279** Comment: The recommendation is commendable however it depends entirely on hospital staff having an understanding of what each nuclear medicine procedure entails. Many large teaching hospitals could rely on senior nursing and medical staff understanding what precautions need to be taken. However in many nuclear medicine practices, the majority of other hospital staff will not know what is required when nursing these patients. Placing a prominent radiation sticker in the patients notes is counterproductive if staff do not know what to do. We would recommend that this guide specifically promote the dissemination of this basic information as part of the role of the RSO.	Agree. Section deleted. Addressed in section 11.2 Training Other Health Professionals Noted
9.4 Designation of areas		
	Submission from Vic Soc of Nuc Med Technologists **Page 46, 1322** We would recommend the facilities' waiting area warrant specific local rules. This should be explained as part of an education program for reception and nursing staff. These sessions should contain all relevant information and allow time for staff to question the RSO.	Covered sufficiently in sections 9.5 and 11.2

9.5 Equipment and Clothing		
	Submission No. 32 *Page: 47 - comment inserted at line 1348* – **Protective clothing is to be used ….** Additional dot points - (1) Lead bricks for localised temporary radiation shielding (2) Fume cabinet for storage and preparation of volatile or gaseous radioactive substances (e.g. I 131) (3) Lead lined waste bins for used syringes and vials (designed to fit standard sharp bins) (4) Movable lead screens for protection of technologists during the imaging of patients. (5) Radiation contamination wall monitors	Additional dot points added at 9.6 – "Fume cupboards"; and "biohazard cabinets". Also added "face masks where there is a risk of airborne droplets"
	Submission from Vic Soc of Nuc Med Technologists **Page 47, line 1347** We recommend including a statement that "spillage packs" be pre-prepared and available in the facility.	Inserted in section 10.3.3 – Contents of a spill kit
9.6 Personal monitoring		
	Submission No. 32 *Page: 48 - comment inserted at line 1377* – **9.6 Personal monitoring** Users of radioactive substances and those persons involved in procedures where radioactive substances are used (particularly for therapy doses of radioactive substances) may need to be provided with electronic monitoring services. Electronic monitoring devices maybe given to staff when: (1) They request the use of a personal monitoring alarm (2) A staff member declares herself to be pregnant (3) A staff member is administering a large therapeutic dose to a patient (4) Temporary staff who will not be in the department long enough to wear a usual radiation monitoring device (5) Staff who have had consistently high readings from the usual radiation monitoring device	Section 9.7 on Personal Monitoring redrafted. "When a single personal radiation monitoring device is utilised it should be worn on the anterior trunk, between the waist and the chest, and under any protective garments. It may be appropriate in some circumstances for an individual to be issued with two personal monitoring devices. For example, an electronic dosemeter may be used to measure any exposure during a particular task in addition to the integrating dosemeter which would be routinely worn"

	Page: 48 - comment inserted at line 1386 – **9.6 Personal monitoring** If a protective apron is worn, the personal monitoring device must be worn underneath the apron **Submission from Vic Soc of Nuc Med Technologists** **Page 48, 1389** We would strongly recommend the use of TLD rings.	Noted
9.7 Dosimetry Investigation		
	Submission No. 14 Line 1394. Section 9.7 The College recommends that "responsible person" not be used as it is the process of determining an investigation level that is important, not regulatory jargon for policing.	Agreed – amended to RSO
9.8 General procedures to reduce occupational exposure		
	Submission No. 14 Line 1403 "to prevent the occurrence of spillage": The College recommends "to prevent spills" would be better. **Submission No. 15** ***9.8 General Procedures to Reduce Occupational Exposure*** The ***lines 1403-9406***, "*...and/or nuclear medicine physicist*" need to be deleted. Advice from the RSO is sufficient, as this is, after all, one of the roles of the RSO and it is often the physicist who occupies this role. If the RSO and/or nuclear medicine specialist deems it necessary, further consultation with a medical physicist, radiochemist or other suitable professional may be obtained. **Submission No. 32**	Agreed Noted.

	Page: 48 - comment inserted at line 1407 – **9.8 General procedures to reduce occupational exposure** Radioactive materials shall be received, handled, and stored at the specifically designated controlled location. Vessels containing radioactive materials shall be labelled as to the radionuclide, chemical form, activity, and date and time of calibration, and shall be properly shielded while in use and in storage.	Agreed – text inserted.
	Page: 49 - comment inserted at line 1420 – **9.8 General procedures to reduce occupational exposure** e.g.remote handling devices shall be used when practicable	Disagree
	Page: 49 - comment inserted at line 1427 – **9.8 General procedures to reduce occupational exposure** Radiopharmaceutical preparation shall be performed behind protective lead barriers. All lead glass face shield shall be used when appropriate. Lead syringe holders shall be used to transport syringes containing radioactive materials. Syringe shields shall be provided for ready use during radiopharmaceutical preparation and administration whenever practicable.	Agreed. Paragraph inserted
	Submission from Vic Soc of Nuc Med Technologists	
	Page 48, line 1403 Delete this paragraph. We are not aware of any evidence that this is justified. Indeed, nuclear medicine technologists are experts in handling radionuclides and are very capable of introducing new procedures. The advice of the RSO and/or physicist would not normally be required.	Disagree. Covered in existing statement
	Page 49, line 1433 Comment: This statement is very proscriptive; we would recommend a statement suggesting technologists use their professional judgement as to what supervision is required.	Paragraph reworded
	Page 49, line 1439 We would recommend including a statement advocating the regular monitoring of technegas units.	Paragraph at 9.9 amended
10.1	Radiation Shielding and Signs	

	Submission No. 32 *Page: 51 - comment inserted at line 1470* – **10.1 Radiation shielding and signs** **Radioactive waste management** All radioactive waste or suspected radioactive waste material must remain segregated from non-radioactive waste. Whenever possible radioactive waste generation must be kept to a minimum. All radioactive waste must be segregated into short half-life and long half-life radioactive waste decay bins and retained until the activity concentration is not more than that prescribed. They can then be disposed of as normal clinical waste or as appropriate. This includes unused radiopharmaceuticals and contaminated syringes, swabs, needles, disposable pipettes etc. Contaminated aerosol equipment, disposable gloves, absorbent material and protective covers must be packed into plastic bags, labeled with the current date and retained until the activity concentration is not more than that prescribed. They can then be disposed of as normal clinical waste or as appropriate. Where it is difficult or impracticable to estimate the exact concentration of solid radioactive waste it is recommended that storage for 10 half-lives be used as a guide.	Agreed. Added a new section 10.1 Radioactive Waste.
10.2	Decontamination Procedures	
	Submission No. 32 *Page: 52 - comment inserted at line 1495* – **Decontamination of persons** For major spills, an incident report should be written and kept on file and from this report recommendations may need to be given to help prevent another spill occurring. In many circumstances it may be preferable to isolate items contaminated with short lived radionuclides (eg 99mTc) than attempt decontamination due to unnecessary staff dose and difficulty achieving a worthwhile level of decontamination.	Agreed
	Submission from Vic Soc of Nuc Med Technologists **Page 52, line 1519** We would recommend the use of thyroid blocking agents be considered. This would need the input of the nuclear medicine specialist regarding dosage etc.	Agree. Addressed in section 10.3.1 Decontamination of persons

11.1 Radiation Health Professionals		
	Submission from Vic Soc of Nuc Med Technologists	
	Page 54, section 11.1 Comment: Nuclear medicine technologists have completed an applied science degree with a curriculum focused specifically on the knowledge and skills required to operate as nuclear medicine technologists. In addition, they have completed a full-time professional development year to further enhance their skills.	New para added
	Only then can they be accredited to practice. As such, the responsible person need only ensure they employ accredited technologists. Technologists are aware of their responsibilities regarding continuing professional development. Senior technologists would provide any training required. We would therefore recommend this section need only the first sentence.	Disagree. All staff may need additional training for continuing professional development
11.2 Other Health Professional groups		
	Submission No. 32	
	Page: 54 - comment inserted at line 1567 – **11.2 Other health professional groups** The emphasis here is on practical knowledge, such as the location of sources, the use of shielding and spill kits.	Noted
	Annual refreshers All staff are given annual refresher courses. Again the emphasis is on practical knowledge. The course will generally consist of a mock situation, such as a spill, with staff required to show competence in dealing with the particular circumstances.	Noted
	On-going review Incidents which arise from time to time are used as training for the whole staff: i.e. incidents of mis administration, radioactive spills or high staff doses are discussed with the staff to minimise repeat occurrences.	Noted
11.3 Staff involved in radionuclide therapy		
	Submission No. 19	

	Line 1585 Additional point. Training should include decontamination of items and decontamination of the treatment suite.	Agree. Additional dot point added
Annex A		
	Submission No. 19 *Line 1602* Additional point. The radiation management plan should also indicate appropriate staffing numbers and training to provide safe and effective services. It should also indicate a program of education and CPD to ensure adequate ongoing staff training.	Should be covered in local rules.
Annex B		
	Submission No. 19 Line 1712 The "additional week" of protection for children is not necessary given the precautions recommended in the body of the safety guide (it is a legacy from the European Union guidelines). It could potentially be confusing for patients – do precautions need to be followed or not? Are they 'safe' or not?	(Comment now refers to Annex C). Agree. Dot point No. 3 has been amended to the specified restriction period.
References		
	Submission No. 14 It is disappointing that ARPANSA in the references has ignored the recent IAEA publication: *IAEA safety report series 40, 2006. Applying radiation safety standards in nuclear medicine.*	Agree – reference inserted.
General		
	Submission No. 14	

	Safety Guide for Radiation Protection in Nuclear Medicine Overall the Safety Guide in nuclear medicine seems to have been written in a prescriptive rather than a discussion style and there seems to be a lack of explanation for some statements. On many occasions, long cumbersome adjectives are used that make the document rather difficult to follow. In several places the document makes reference to the Code; for instance: Line 172 "The Code requires" Line 234 "although it is not mandated in the Code" Line 390 "The Code requires" Line 450 "the Code requires" Line 604 "the Code provides detailed responsibilities" Line 915 "required by the Code" Line 931 "the Code requires" Line 946 "required by the Code" Line 1028 "the Code requires" All this does is emphasise policing of nuclear medicine practice. It gives the impression that the reason for such a practice is to highlight the power or the radiation regulator, not because of the merit of a particular practice. It is also very irritating for anyone reading this document to have to frequently refer to a different document (the Code) only to find bureaucratic jargon. In most cases such statements do not contribute to the guide; they emphasise bureaucracy, particularly the potential for intrusion by the radiation regulator. Such statements should be deleted.	Noted.
	Tables 1-6 are very helpful and the College supports inclusion of such authoritative and practical advice. The College has not had opportunity to confirm the accuracy of the tables, but suggests that it is important to check the detail to ensure no errors have occurred.	Agree
	Submission No. 15	
	Please find attached a submission from the Australian and New Zealand Association of Physicians in Nuclear Medicine on the ARPANSA Draft Code of Practice, Radiation Protection in the Medical Applications of Ionizing Radiation, and the Safety Guide, Nuclear Medicine.	Noted

	This submission also includes as an attachment the following article: Hesse B et al., *European Journal of Nuclear Medicine and Molecular Imaging, 2005,* ***32****: 855-897* [SEE PDF DOCUMENT 15b - Joseph Wong - ANZAPNM (article).pdf] As noted in our submission, the ANZAPNM strongly supports a review of all submissions on the above documents by the Working Group for the Safety Guide, Radiation Protection in Nuclear Medicine, as such review is considered essential to ensure that due consideration is given to the wide range of feedback on the draft documents. **Submission No. 15** **3. General Comments on both the *Code of Practice* and *Safety Guide, Nuclear Medicine*** ***3.1*** The ANZAPNM strongly supports a review of all submissions by the **Working Group** for the ***Safety Guide, Radiation Protection in Nuclear Medicine*** in order that due consideration can be given to the wide range of feedback. ***3.2*** Lack of qualified medical physicists. Given the continuing lack of qualified medical physicists (a shortage unlikely to be rectified in the near future), requirements for review of DRLs, conduct of dose surveys etc. are considered unrealistic. ***3.3*** Other providers of diagnostic imaging services. The ANZAPNM notes that other providers of diagnostic imaging services are not captured by these draft Codes of Practice and Safety Guides. Such providers include chiropractors, podiatrists and nurse practitioners, among others, some of whom have themselves noted their exclusion from these Codes. The ANZAPNM does not consider it appropriate that such providers be excluded from the proposed Codes of Practice, with a resultant double-standard of care in diagnostic imaging. The Codes of Practice and Safety Guides must therefore ensure that <u>all</u> providers of DI services are covered by these arrangements in order to avoid inadvertent promotion of a lesser standard of DI service among some provider groups. **Submission No. 20** NATA's feedback, detailed below, raises issues from an accreditation point of view. The	Agree. Done Noted Noted. The Code states that a separate Code of Practice applying to the use of ionizing radioing by chiropractors is being planned. Noted.

	Code and associated safety guidelines compliment the radiation safety aspects of the current RANZCR/NATA accreditation standards. The following issues are raised for consideration: **Safety Guide Radiation Protection in Nuclear Medicine** No comments raised. We trust that the above comments provide some useful points for consideration **Submission No. 31** ***General Comment*** The Safety Guide covers all areas of radiation safety in radiation nuclear medicine. The overall guide appears to be a reasonable document. **Submission from Vic Soc of Nuc Med Technologists** The guide seems to reinforce practices in nuclear medicine that only occur in large tertiary centres. We received feedback critical of the guide in that it lacked an appreciation of the diversity of nuclear medicine practice. The guide reflects an ignorance of the training, expertise and role of nuclear medicine technologists. The technologist community is concerned about the lack of direct representation on the working group. The guide appears to be based on the assumption that physicists and radiopharmacists are employed in most nuclear medicine practices. The reality is that most practices operate without these people on staff.	Noted. Noted