

SUMMARY OF SUBMISSIONS AND RESPONSES
DRAFT CODE OF PRACTICE FOR RADIATION PROTECTION IN THE MEDICAL APPLICATIONS OF IONIZING RADIATION
Public Consultation Draft - August 2007

SUBMITTER	COMMENT	RESPONSE
<p>06 Marianne Rinks Locum Chief Radiation Therapist Radiation Oncology Northern Sydney Cancer Centre Royal North Shore Hospital St Leonards NSW 2065 Australia</p>	<p>The following comments are sent on behalf of Brian Porter, Deputy Chief Radiation Therapist, Radiation Oncology Royal North Shore Hospital and myself.</p> <p>1.. Terminology in title and throughout document: Replace the term "Radiotherapy" with "Radiation Therapy".</p> <p>2.. Re: Use of term "written" (Context examples line 148 & line 502) - This term may imply that protocols, records of treatment, etc must be written and in paper-based format when in practice these could be in electronic format. Written documentation is somewhat obsolete in this day of electronic records.... Recommend that this ambiguity be clarified in the Glossary. Overall, the document is very comprehensive.</p>	<p>Disagreed. The term is defined in the Glossary. "Radiation Therapy" could be too broad.</p> <p>"written" changed to "hard-copy" in the footnote.</p>
<p>07 Kirsten Merrall Senior Nuclear Medicine Technologist Department of Nuclear Medicine NT Medical Imaging</p>	<p>After reading the ARPANSA submission to Public Comment Draft dated the 24th August 2007, the following concerns have been raised:</p> <ul style="list-style-type: none"> - the diversity of roles often required of a Nuclear Medicine Technologists seems to be underestimated. In most departments, especially in smaller rural centres, Nuclear Medicine Technologists perform a large portion of duties/roles which are outlined under the roles of Nuclear Medicine Physicists and Radiopharmacist. - In reference to p.17 of the Code of Practise for Radiation Protection in the Medical Applications of Ionising Radiation there is reference to "ensure any person who is not required to be in attendance during the radiation exposure or the administration of a radioactive source to the patient leave the imaging, administration or treatment area before the procedure commences". Often having an adult family member in attendance when giving an injection is hugely beneficial is comforting the patient and can also assist in helping nervous patients understand and remember what was said during the procedure. As family members are often sitting a few metres away from the patient concerned and the small increase in radiation dose to family members seems to be outweighed by the benefit of having them present. 	<p>Noted.</p> <p>Wording amended to permit such circumstances.</p>
<p>09 Dr Guy</p>	<p>Please find attached my response to ARPANSA's Draft Code of Practice in the Medical Applications of Ionizing Radiation, and my concerns regarding the unacceptable and</p>	

<p>O'Connell Southern Radiology, NSW</p>	<p>unnecessary radiation risk of Nuclear Physicians obtaining CT license without qualified training.</p> <p>Nuclear Physicians obtaining CT license without qualified training is an unacceptable and unnecessary radiation risk</p> <p>I have serious concerns regarding the ARPANSA Draft Code of Practice in the Medical Applications of Ionizing Radiation which inadvertently and indirectly permits Nuclear Physicians to obtain a license to supervise CT imaging as the designated “Medical Practitioner”, without requiring them to obtain any qualified training in the utilization of this ionizing radiation apparatus.</p> <p>As a dual qualified Radiologist and Nuclear Medicine specialist, I wish to advise ARPANSA that the current generation of practicing Nuclear Physicians and training registrars do not receive any qualified theoretical or practical training in the utilization of CT imaging, in order to optimize the parameters of the examination for the best diagnostic results whilst minimizing radiation dose.</p> <p>The ARPANSA draft acknowledges that CT imaging is as capable of delivering the highest and fastest dose of potential harmful radiation. To allow any group the opportunity to supervise CT examinations without appropriate training will lead to an inevitable increased burden of radiation to patients and society, which I believe is an unacceptable and unnecessary level of risk.</p> <p>I refer to the draft Diagnostic and Interventional Radiology, Clause 11.1 “Radiation Health Professionals” which states operators and practitioners, who perform or direct exposures using ionizing radiation, need to have appropriate training. It would be anticipated the radiation professionals should have such knowledge by virtue of undertaking a course leading to their professional qualifications. And clause 3.5 “The Medical Practitioner” which states that the ultimate decision to perform or reject a radiological procedure is based on the practitioner’s knowledge of the hazard associated with the radiological exposure and clinical information.” I also refer to the draft “Radiation Protection in the Medical Application of Ionizing Radiation” clause 2.2 “Medical Practitioner: Justification of a medical radiation procedure” which states the practitioner must determine the net benefit and risks of an individual medical radiation procedure. It was be a gross oversite and error of ARPANSA to assume nuclear physicians currently receive any qualified training in CT.</p> <p>Clause 3.2.1 states the medical practitioner (radiation) who approves the procedure involving the exposure of a patient to ionizing radiation must: (a) be appropriately authorised by the relevant regulatory authority. The Department of Environment and</p>	<p>Training and qualifications for a licence will be covered in the NDRP.</p>
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	<p>Climate Change is the relevant body in NSW, it is my understanding that this authority has no specific requirement for the Nuclear Physicians to receive recognised training in CT in order to adequately act as a qualified professional capable of complying with the above clauses 11.1, 3.5 or 2.2. I suspect this is a similar situation across all states and territories in Australia.</p> <p>As a member of the Nuclear Medicine Reference Group within the Royal Australian and New Zealand College of Radiology (RANZCR), I am aware of moves being made to ensure appropriate training is available to Nuclear Physicians in both the theoretical and practical training of CT imaging. Such a training programme is required of Radiologists and the same standards should be applied to Nuclear Physicians to ensure safe and appropriate utilization of this potentially harmful ionizing radiation medical imaging apparatus.</p> <p>As the central governing body, I respectfully recommend ARPANSA accept responsibility to ensure Nuclear Physicians receive an appropriate level of theoretical and practical level of training in CT imaging, before allowing them to obtain CT licenses as the Medical Practitioner. I suggest ARPANSA include clause(s) within the draft Codes of Practice in the Medical Applications of Ionizing Radiation requiring the state and territory regulatory authorities to ensure Nuclear Physicians receive formal CT training by qualified specialists before obtaining this license.</p> <p>I look forward to your response.</p>	
<p>10 Paul Marks Senior Scientist Radiation Safety Section Environmental Health Unit Public Health Branch Department of Human Services, Vic</p>	<p>CODE: Victorian Legislation does not entertain the wording "responsible person". This term would have to be translated to "Management Licence Holder" in this jurisdiction.</p> <p>Areas of the code should be highlighted that are actually "stream" specific to avoid confusion.</p> <p>Chiropractic medicine should be covered by the code and relevant sections of the diagnostic radiology SG. The equipment and procedures carried out by chiropractors are in most parts very similar to that performed in general radiology.</p> <p>The term Medical practitioner (radiation) should be reviewed and if possible a new term used.</p> <p>Line 791 of the code indicates that a medical practitioner (radiation) will be authorised by the relevant regulatory authority. However in accordance with the NDRP sect 2.7 (b) this authorisation/licensing is based on actual use of a radiation source for a particular purposes. A medical practitioner (radiation) who may oversee a practice but not actually use a</p>	<p>Noted.</p> <p>Noted.</p> <p>Noted, but it was a decision of the RHC to not include chiropractors in this Code. There are other issues relating to Chiropractic X-ray procedures that need to be looked at separately. Changed to "radiation medical practitioner".</p> <p>"authorised by the relevant regulatory authority and" removed from glossary definition. Unlicensed personnel will be picked up under the Radiation Management Plan.</p>

	radiation source, eg a radiologist, would not require any authorisation in Victoria and as such would not be bound by the relevant sections of the code.	
<p>11 Michael Izard MBBS FRANZCR MMedicalHum Clinical Lecturer University of Sydney; Radiation Oncology Associates</p>	<p>August 07 CODE OF PRACTICE - Radiation Protection in the Medical Applications of Ionizing Radiation</p> <p>1: Why not change “medical practitioner (radiation)” to “radiation practitioner” and stating in the definitions that ‘radiation practitioner’ is the medical practitioner licensed to use the radiation equipment in question? This might later allow chiropractors and dentists to be drawn into the code.</p> <p>2: Section 3.1.9 a)a and b (line 171 and 174): In radiotherapy the personnel who wear radiation protection may not be considered likely to be exposed to 1mSv per year if they are following the appropriate methods of practice. The wording of this section as it stands suggests that the wearing of such protection may not be necessary. I suggest a change to:</p> <p>172 provided to each occupationally exposed person who might be 173 exposed to ionizing radiation in excess of 1 mSv in any one year;</p> <p>3: 3.1.20 (i) (line 266-7): the acquisition, movement, replacement or disposal of each radiation-producing equipment or sealed radioactive source: Is this to include the 100’s of iodine-125 seeds ordered for prostate brachytherapy? Line 272 mentions generic approvals by the relevant authority.</p> <p>4: 3.1.33c,d,e (lines 373-379) This is just not practical or enforceable if the patient dies some time after or some distance away from the radiotherapy department after a permanent LDR iodine seed implantation. For instance, if the patient is 1 or 2 years after implantation but 300km away, then the odds are that the relatives will not contact the RT department routinely at the time of death and it is likely that the individual will have been cremated or buried before a response has been initiated. For a second instance, with the wording, someone who had an implantation 5 or 10 years earlier that is to all intents and purposes inert would still have to be reported to the department.</p> <p>5: 3.2.13 (lines 469-475): This is sound medical advice, but it does not need to be included in the Code. In particular the use of the word “might” (line 470) negates the “must” in line 471. Also, who is the “expert” here? How do you estimate the dose, does a pacemaker technician qualify as an expert or the ROMP?</p> <p>6: Schedule A line 604: I suggest either changing: “(f) arrangements for isolation of hospital in-patients undergoing treatment with sealed or</p>	<p>Changed to “radiation medical practitioner”.</p> <p>This is based on ICRP wording and does not exclude persons who are unlikely to receive a dose in excess of 1 mSv in a year.</p> <p>3.1.20(a)(i) changed to “all” and source made plural to allow for multiple sources.</p> <p>“above the relevant activity exemption level” added to clause.</p> <p>It is felt that this is sufficiently important to leave in the Code. “might” changed to “could”. The “qualified expert” is defined in the Code.</p> <p>“appropriate” added.</p>

	<p>unsealed radioactive sources” to: (f) arrangements for isolation of hospital in-patients undergoing treatment with sealed or unsealed radioactive sources when appropriate.</p> <p>Or, alternatively, removing this to the SG.</p> <p>7: Line 620 seems to have lost its way in terms of subheadings.</p>	<p>Noted. This relates to the QA program. Changed to “quality control procedures”.</p>
<p>14 Don Swinbourne Chief Executive Officer RANZCR (Lisa Penlington)</p>	<p>The College queries the rationale of this process in consideration of how such documents may be used by various groups in the future.</p> <p>A major issue is that despite input from the professions these documents in their current drafts appear to have been written in isolation from existing professional standards of practice for radiology services. That may be because this process was commenced five years ago and there have been more recent developments. The College draws ARPANSA’s attention to the Commonwealth Government’s implementation of accreditation of Radiology services whereby services will be assessed against a set of standards drawn from the RANZCR’s Standards of Practice for Diagnostic and Interventional Radiology. The College considers that the ARPANSA document exceeds its brief by prescribing the professional clinical practice of the various medical radiation specialties. Similarly, the Australian Commission on Safety and Quality in Health Care is looking at standards and accreditation activity across the health sector in Australia.</p> <p>Accordingly there are areas of overlap between existing standards and the ARPANSA documents, and while many of the aims are probably similar, some items as they are written in the ARPANSA documents are simply not yet implementable. Instead, there appears to be an overemphasis on bureaucracy and regulation of medical radiation where a more intuitive approach would be more successful.</p> <p>Several of the documents are written in a prescriptive often dogmatic style which can make them difficult for workers to relate to.</p> <p>Revised draft Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation</p> <p>Overall there has been welcome modification of the previous draft Code which has addressed several of the College’s previously expressed concerns.</p> <p>‘The purpose of the Code is to establish the regulatory requirements for the use of ionizing radiation in medical practice that will, in the context of good practice, ensure that the risks</p>	<p>Noted.</p> <p>Noted.</p> <p>Noted.</p>

	<p>associated with the exposure to the patient are optimised and those to staff are kept as low as readily achievable.’ The College agrees with this and submits that it is mainly the good practice that achieves the desired outcome, not enforcement by the radiation regulator.</p> <p>Section 1 Line 37: 1.3 “Chiropractic use of x-rays is excluded from this document”. The College considers that this is absolutely untenable. Chiropractic provides a significant radiation dose to the thyroid, breast and pelvis, to a significant size of the patient population, sometimes for indications that may not be <u>clinically</u> appropriate. If radiation protection is to be taken seriously, this can not be excluded. See 2.1 the justification for this code. It is inexcusable to exclude Chiropractic x-rays from the requirements, particularly when ARPANSA’s stated rationale for this is that it has been too difficult to arrive at appropriate terminology for the role of a Chiropractor. The College would be happy to provide advice to ARPANSA in this regard.</p> <p>Section 3 Section 3.1.7 (b) DRLs are guidelines to assist radiologists in ensuring that the radiation dose to patients is within acceptable parameters. Their use assumes the radiation doses are measurable and that nationally accepted DRLs have been established. The College agrees that the ability to record exposure parameters is practicable, but that measurement of individual radiation doses in diagnostic radiology is not currently achievable.</p> <p>There are no nationally accepted DRLs in Australia. Internationally the principle of DRLs as guidelines is used to promote good practice, but they require considerable development before they are in a situation that can be accepted into radiological practice.</p> <p>ICRP now recommends the use of DRLs and states “These levels are in the form of an investigation level, and apply to an easily measured quantity. They will be intended for use as a simple test for identifying situations where the level of patient dose is unusually high. Diagnostic reference levels are supplements to professional judgement and do not provide a dividing line between good and bad medicine. They contribute to good radiological practice. The numerical values are advisory in nature.”</p> <p>While the College is aware that ARPANSA considers the reference to DRLs in the draft Code to be a means of enabling measurement against national Australian DRLs once they are established, it considers this to be an impractical validation which lacks credibility with the professions. The College considers that a more suitable and evidence-based approach would be to first conduct the necessary surveys, establish DRLs and based on these figures establish programs of activity to assist services in reducing dose. Suitable reference to DRLs can then be made in the appropriate regulatory document. The College does not</p>	<p>Noted, but it was a decision of the RHC to not include chiropractors in this Code. There are other issues relating to Chiropractic X-ray procedures that need to be looked at separately.</p> <p>Noted.</p> <p>Noted.</p> <p>Noted.</p> <p>It is recognised that DRLs for Australia are still in the development stage and have not as yet been established. Clause 3.1.7 will take effect until that time.</p> <p>RHC believes that DRLs are an important tool for dose optimisation and would be willing to meet with</p>
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<p>support inclusion of an ‘enabling clause’ in the Code.</p> <p>In addition, as was stated by a number of delegates at the recent ARPANSA consultation forum on 3 October, there are substantial practical obstacles to measurement by the wide range of radiology service structures which include a lack of radiology medical physicist resources to support this process, and the fact that there is not yet a systematic means of educating and supporting practices that wish/need to lower their doses.</p> <p>The College draws to ARPANSA’s attention work being undertaken by its Quality Use of Diagnostic Imaging Program on Paediatric CT Dose which in establishing local DRLs across a range of tertiary paediatric sites, is also establishing dose optimisation education processes so that the DRLs can be used to good effect. The College considers this to be a project that can provide proof of concept for an modality-wide approach to establishing meaningful DRL measurement infrastructures and education resources so that DRLs have credibility and practical application within the Australian health sector. The College is eager to discuss this activity with ARPANSA.</p> <p>The College acknowledges and supports the development of local DRLs and recommends that the best way of addressing this issue in the documents would be to delete the item dealing with DRLs from the Code and instead include it in the Safety Guide.</p> <p>Section 3 3.1.8 ii) “sufficient information of the procedure that would allow the radiation dose to the patient to be estimated”. The College recommends that such a requirement should only apply to high dose diagnostic procedures such as CT or prolonged fluoroscopy. For simple procedures in general radiography generic figures or reference to protocols would suffice. Recording parameters is currently impractical to perform in a busy practice as time spent documenting tube-patient-plate distance, exposure, time, kV etc would reduce throughput and patient care.</p> <p>ARPANSA must be aware that some of the currently installed equipment in Australia (eg general radiography, CT, fluoroscopy) does not display adequate dose information. The College supports the recording of dose information where the equipment provides this information and supports the need for radiology equipment vendors to provide such display information on new equipment. It is not currently feasible for radiographers in CT to detail the scan exposure parameters for every CT examination if the equipment does not provide dose information.</p> <p>3.1.24 seems to require every practice to have a survey meter The College queries whether this is the intention of this clause and questions the need for</p>	<p>the RANZCR to discuss their concerns.</p> <p>It is agreed that for simple procedures in general radiography, generic figures or reference to protocols would be sufficient. The Safety Guide could elaborate on this.</p> <p>Clause removed to Safety Guide or the NDRP.</p>
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	<p>this requirement.</p> <p>3.1.29 requires a radiation survey whenever the shielding of radiation equipment is breached and then restored (e.g. for service). The College considers that this is overzealous for routine service of diagnostic equipment by qualified personnel.</p> <p>3.1.31 Faults in equipment. These should ONLY be reported if they could potentially cause patient harm or excess radiation exposure. E.g. current CT machines are very complex, and often have minor faults that do not impact on safe functioning of the equipment. Some modern machines will even automatically contact the manufacturer regarding minor faults via internet connection and have the faults fixed without the operator even knowing there was one. It seems unreasonable to have to report a fault every time an auxiliary cooling fan heat sensor needs servicing!</p> <p>3.2.3 "... must not undertake a procedure unless a written request is obtained". This clause is of significant concern to the diagnostic imaging sector, the issue being considered in some detail with respect to the College's standards and the development of standards for the Commonwealth's radiology accreditation scheme.</p> <p>Any such rule MUST allow for the emergency situation (e.g. surgeon in car driving into hospital, patient in car accident needs urgent CT scan; Patient will die because there is no written request and scan can not be performed). Another situation is where the radiologist has changed the requested examination to a more appropriate one, i.e. a more clinically appropriate, safer, lower radiation examination etc. This must be allowed for.</p> <p>3.2.3.b states a request must include a 'specific clinical question'. This is somewhat naïve and not based on clinical practice guidelines. The College requests that ARPANSA remove the word 'specific'. The clinical question or question is often not specific. The request may be more useful if it asks a general question, rather than the referrer being forced to ask a specific one (e.g. a chest x-ray, where the request says "shortness of breath'. This is a very reasonable examination, and Australian-trained radiologists have excellent training that allows them to assess the study for the relevant potential causes of this presentation without any need for a specific clinical question or condition. It is important to remember imaging has extremely important roles far beyond answering specific questions: e.g. in exclusion of pathologies, and in categorisation of abnormalities (rather than specific diagnosis). The role of radiology is not just looking at specifics. It is inappropriate to restrict the use of imaging as such.</p> <p>3.2.7 Pregnant patients. Again, the Code needs to allow for an emergency situation, where the patient may be adversely affected if there is a delay in imaging while the pregnancy</p>	<p>Disagreed. If the integrity of the radiation shielding could be altered, it should be checked. A routine service is unlikely to do this but if it does, then it should be checked by a qualified expert.</p> <p>This clause initiates reporting of generic faults in equipment where those faults could compromise patient safety.</p> <p>Wording of 3.2.3 and 3.2.4 have been amended.</p> <p>It is believed that this is covered by 3.2.4(c)(i).</p> <p>Specific removed.</p> <p>The use of the "reasonable" allows for judgement.</p>
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	<p>status is worked out and radiation dose calculated etc.</p> <p>3.2.13 implanted electronic device This item is only relevant to radiotherapy and it would be better if it were included in the radiotherapy safety guide rather than the Code. The issue of radiation dose to an implantable device is analogous to other ‘organs at risk’ near the radiotherapy Planning Target Volume where the dose to that critical organ needs to be estimated and a decision made about whether the dose is acceptable. It would be necessary to know what an acceptable tolerance dose to the implanted device may be, and that information may be obtained from the manufacturer. Then a decision should be made about whether the dose should be modified, which in modern radiotherapy is often by modifying direction and weighting of beams rather than additional shielding. This paragraph uses the term ‘qualified expert’ but a radiation medical physicist would not be expected to know what dose constraint is needed to make a decision about shielding. The College recommends that it is the process that should be outlined and there is no need to specifically mention the “qualified expert” medical physicist. In addition the College recommends it would be better in the safety guide. It is not necessary for it to be under the heading of medical practitioner. Thus the College recommends modification to:</p> <p>“Obtain information about what is an acceptable radiation dose to the device. Estimate the radiation dose to the device.</p> <p>Using this information, devise an acceptable radiotherapy plan and treatment technique. Obtain information about what monitoring of the device is needed.”</p> <p>The College requests that ARPANSA delete this item from the Code and insert it in the Radiotherapy Safety Guide</p> <p>Summary Overall the College is disappointed with the documents and with the process conducted by ARPANSA where the input of the professions which are required to implement this Code appears to be considered less relevant than the control of the radiation regulators. There seems to be an undue emphasis on regulation and the College notes that this process has illustrated the gap between the radiation regulators and the medical groups, something which the medical groups are keen to address.</p> <p>The potential for increased bureaucracy through implementation of the Code is of concern. In the radiotherapy document the strong emphasis on particular groups of people could lead to friction in the future. The College argues that it would have been preferable for</p>	<p>Agreed. Remove to Radiotherapy Safety Guide.</p> <p>Noted, however, it needs to be stated the a Code of Practice IS a regulatory document that is under the control of Australian Regulators and used for enforcement of the given practice by those Regulators. The Safety Guides on the other hand describe Best Practice.</p> <p>Involvement of professional groups in the original 3 codes identified the areas where regulation/enforcement was considered necessary or</p>
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	<p>ARPANSA to have achieved more emphasis on the appropriate radiation safety procedures rather than emphasising who must be doing what, which is a matter for the relevant professional bodies who train, qualify and support practitioners in their practice of medical radiation specialties. The technology is rapidly changing and it is preferable also to be careful not to be too dogmatic about detail that could change.</p> <p>As far as the safety guides are concerned the College queries the role of ARPANSA in providing current advice and guidelines rather than emphasising regulation in consideration of the omission of consideration of or reference to recent authoritative publications by the IAEA.</p> <p>The College however genuinely looks forward to working with ARPANSA to improve communications between the regulator and professional bodies and to achieve the necessary amendments to ensure that the Code and Safety Guides are practical, implementable and credible to all affected parties.</p>	<p>desirable. The combined Code is a sub-set of the original requirements i.e. reduces the extent of regulation. The aim is to enforce procedures/processes that are already in place in well-run practices so that all practices achieve these standards. The WG recognises that accreditation standards also have this aim but are broader in coverage that the Code (which concentrates on radiation protection aspects).</p>
<p>15 Joseph Wong FRACP President Australian and New Zealand Assoc of Physicians in Nuclear Medicine</p>	<p>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.</p> <p>This submission also includes as an attachment the following article:</p> <p>Hesse B et al., <i>European Journal of Nuclear Medicine and Molecular Imaging</i>, 2005, 32: 855-897</p> <p>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.</p> <p style="text-align: center;">ANZAPNM SUBMISSION ON THE ARPANSA DRAFT CODE OF PRACTICE RADIATION PROTECTION IN THE MEDICAL APPLICATIONS OF IONIZING RADIATION AND SAFETY GUIDE, RADIATION PROTECTION IN NUCLEAR MEDICINE</p> <p>1. CODE OF PRACTICE: <i>Radiation Protection in the Medical Applications of Ionizing Radiation</i></p> <p>Section 2, Radiation Protection Principles</p>	

	<p>2.1 Justification, Lines 61- 65: As no harm has been clearly documented with radiation from diagnostic imaging, and the linear, no-threshold model is used to be conservative in its estimates for radiation protection, we strongly recommend that the wording in 2.1, line 65, be changed <u>from</u> “to offset the detriment caused by radiation” <u>to</u> “to offset any potential detriment caused by radiation”.</p> <p>Section 3, Responsibilities</p> <p>3.1.7, Lines 145-147: Delete reference to diagnostic reference levels (DRLs). The ANZAPNM vigorously opposes the promulgation of DRLs, and these lines should be deleted as they lack professional endorsement (see also comments on <i>Safety Guide, Section 3.8, lines 425-428</i>, and <i>Section 7.8, lines 1160-1197</i>).</p> <p>3.1.25 Expert advice, Lines 297-305: This would be better worded as “The Responsible Person <u>should</u> ensure that: (a) a qualified expert is “<i>available for consultation</i>” ... rather than “<i>is involved</i>”. Line 299 (a) (i) should be amended to: “<i>for advice on patient dosimetry and quality assurance</i>”. For Line 303 (b), the wording should be “<i>for radiotherapy</i>” rather than “<i>for therapeutic uses of radiation</i>”, as treatment with unsealed sources does not require a “qualified expert” to conduct or supervise the procedure.</p> <p>Indeed, in Section 1.2, PURPOSE, lines 18-21, the Code correctly refers to: “<u><i>the medical practitioner (radiation) being the person responsible for the justification and optimisation of the procedure involving the exposure of the patient to ionizing radiation, either for each individual patient or by way of protocols specific for the procedure;</i></u>”</p> <p>and Section 3.2.5., Optimisation of Protection, lines 429-430, also correctly states that: “<u><i>The medical practitioner (radiation) must ensure that the radiation dose arising from a diagnostic procedure is optimised.</i></u>”</p> <p>Accordingly, these amendments will ensure consistency between the different sections of the Code; the current wording in part 3.1.25 is inconsistent.</p> <p>3.1.29, Equipment repair and maintenance, Lines 348-351: Line 351(b), should be amended to: “<i>...by a qualified expert, including a service engineer</i>”. The radiation survey must be able to be completed by the service engineer of the camera company. It is important that a service engineer be able to perform as a “qualified expert” (see also comments at Glossary - Qualified expert, lines 815-821 below).</p> <p>3.2.8, Potentially pregnant or pregnant patients, Lines 449-453: We recommend that these lines be deleted, as this principle is already contained in item 3.2.7 for both diagnostic and</p>	<p>Changed to the direct quote from ICRP 60 (paragraph 112), as referenced in ICRP 73 (1996), paragraph 33.</p> <p>DRLS are only to be used when and if they are available. It is expected that they will be agreed by the relevant professions.</p> <p>“must” needs to remain for Code purposes. “involved” changed to “available”. “optimisation” remains but “including has been deleted. “therapeutic uses of radiation” changed to “radiotherapy”. Sub-clause (a)(i) will cover unsealed sources. Noted.</p> <p>Noted.</p> <p>Change effected.</p> <p>Qualified expert can include service engineer for some circumstances under “relevant to the person’s area of expertise” in Part (b) of the definition.</p> <p>“the embryo ...” changed to “an embryo ...”.</p>
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	<p>therapeutic nuclear medicine procedures, and provides the flexibility to manage the care of the patient according to her clinical circumstances, taking into consideration the age of the patient and the type of procedure. For example, it is unnecessary to perform a pregnancy test on a 50 year-old pre-menopausal woman who is not sexually active prior to I-131 treatment for thyrotoxicosis.</p> <p>For consistency, the sentence beginning, “<i>The Code requires...</i>” at lines 931-933 of the <i>Safety Guide</i> will also need to be deleted.</p> <p>We agree that the most important consideration is the clinical assessment of the individual patient, which is covered by lines 930-931 and 935-936 of the <i>Safety Guide</i>.</p> <p>3.3.8 (b), Control of exposure to persons other than the patient, Lines 544-545: Maintaining visual surveillance “throughout an imaging procedure” is impractical for nuclear medicine procedures, which can take up to an hour. Unlike CT and radiotherapy, the visual surveillance in nuclear medicine is concerned more with patient safety and image quality than control of the radiation dose received.</p> <p>We recommend that lines 544-545 be amended to: <i>(b) ensure that visual surveillance of the imaging room is maintained to facilitate patient safety</i>”:</p> <p>Glossary</p> <p>Qualified expert, Lines 815-821: There is significant concern shared by the diagnostic imaging, nuclear medicine and radiotherapy sectors - and which was expressed at the recent forum - that there are insufficient numbers of qualified experts to perform the duties listed in this Code. A recent estimate of medical physicists accredited for nuclear medicine was <u>less than 10 for the whole of Australia</u>. Furthermore, concern has been expressed to the ANZAPNM on a number of occasions that the process of qualifying under the Training, Education and Accreditation Program (TEAP) of ACPSEM is not currently facilitating an increase in the overall numbers; in fact there remains concern that numbers are not keeping pace with retirements. There is also the unresolved matter of the “competency requirements” (see below). Accordingly, the ANZAPNM supports the use of service engineers from camera companies to perform equipment quality control checks (see also comments on item 3.1.29 above).</p> <p>The ANZAPNM does not support remote consultancy work by “qualified experts”.</p> <p>As the competency requirements are still to be established, the ANZAPNM seeks input into the requirements, as these may have significant impact on the performance of nuclear</p>	<p>The wording of 3.2.7 and 3.2.8 has been amended.</p> <p>Clause changed to: “The operator must ensure that no person is in the imaging, administration or treatment area during a radiation exposure or the administration of a radioactive source to a patient unless that person is required to be in attendance.”</p> <p>Sub-clause has been removed in revised clause.</p> <p>Noted, and passed on to ARPANSA for future consideration.</p> <p>Noted.</p> <p>Noted.</p>
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	<p>medicine facilities, and thus on the provision of nuclear medicine services to the Australian community.</p>	
<p>17 Emile M Badawy Executive Officer Australian Institute of Radiography</p>	<p>The Australian Institute of Radiography (AIR) appreciates the opportunity to comment on the Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA) draft Code of Practice for '<i>Radiation Protection in the Medical Applications of Ionizing Radiation</i>' and the accompanying Safety Guides for Radiation Protection in Diagnostic and Interventional Radiology, Radiotherapy (<i>should read Radiation Therapy</i>) and Nuclear Medicine.</p> <p>AIR representatives were in attendance at the recent ARPANSA National Conference on Radiation Protection in Medicine held in Melbourne on the 3rd October 2007. In keeping with ARPANSA's request for public comment on the current draft documents as part of the consultation process, the following recommendations are submitted by the AIR.</p> <p>The AIR commends ARPANSA on the development of the single Code of Practice with separate Safety Guides for each discipline. We believe that this format is very logical and simplifies the application within the individual disciplines. In keeping with this format the AIR has provided comments separately (attached) for the Code of Practice and the Safety Guides for Diagnostic Imaging and Radiation Therapy.</p> <p>Thank you for considering this submission and we look forward to further correspondence once the public consultation period has been completed.</p> <p><u>General Comments</u></p> <p>Although not strictly in the Code of Practice, the AIR is concerned with the interpretation that ARPANSA places on radiation incident and that they do not fully appreciate the distinction between a 'radiation incident' as outlined in legislation and the numerous other types of incidents that are associated with the delivery of radiation for therapeutic or diagnostic purposes, which may or may not also involve radiation. Not all 'incidents' within a department are reportable under legislation but are still dealt with in a timely manner including 'near misses'.</p> <p>Of further concern is that ARPANSA considers their organization as the most appropriate body to manage/monitor any Radiation Oncology Incident Monitoring agency that may be established in the future. It is felt that ARPANSA's approach is too pure, too idealistic and too remote from the clinical environment to fully appreciate the complexity of the issues that may arise. Such incidents require proactive and rapid action to alert the appropriate service providers and authorities of a potential problem.</p> <p>Radiation safety (occupational, medical and public) is the responsibility of everyone. Health</p>	<p>Noted.</p> <p>Noted.</p> <p>Noted.</p>

	<p>workers involved in the therapeutic use of radiation have a responsibility to maintain and promote radiation safety because of their knowledge and training. It therefore concerns the AIR that professional groups such as physicists are defined in this document as having a greater control and responsibility than other trained and qualified radiation workers.</p> <p><u>Code of Practice.</u></p> <p>The AIR does not agree with the use of the term ‘operator in the Code of Practice. The use of such a term degrades the Degree level education and technical knowledge of Radiographers, Radiation Therapists and Nuclear Medicine Technologists. Whilst we are aware that a generic term has been selected for use to incorporate those persons working as licensed operators in remote and rural areas of Australia, the AIR recommends that the definition in the glossary be changed to read as follows:</p> <p><i>Radiographer/Radiation Therapist/Operator</i></p> <p><i>Any natural person who is authorised by the relevant regulatory authority to administer radiation to a patient for radiology, radiation therapy or nuclear medicine. The administration of radiation is performed by a qualified Radiographer, Radiation Therapist, or Nuclear Medicine Technologist who holds a degree level or equivalent qualification in Medical Radiation Science and/or is accredited by the appropriate professional body. Where access to such practitioners is not possible (remote and/or rural practice) the examination must be performed by a person who holds an appropriate licence issued by the relevant regulatory authority.</i></p> <p>3.1.19</p> <p>The AIR feels that the statement regarding the requirement for specialist procedures to be performed using equipment designed for that purpose is limiting and should state that <i>‘The Responsible Person must ensure that all diagnostic and therapeutic procedures are performed using equipment that has been designed for the intended purpose.</i></p> <p><i>Line 456 to 458 - 3.2.10</i></p> <p>The role of identification of a patients current pregnancy status in most cases is only determined through questioning by the Radiographer (or Operator) in preparation for an examination. This information is then conveyed to Referrer and a discussion regarding the urgency and importance of the examination ensues. If it is determined by the referrer, understanding the risks associated with radiation exposure to the fetus in-utero, that the requested examination or a modified version of the examination is still required, the responsibility of informing the patient of the risks associated with radiation exposure to the</p>	<p>“operator” is a generic term designed to cover any person who will administer radiation to a patient, including radiologists, medical specialists, GPs etc.</p> <p>The point is taken but a superior short name that covers all persons administering radiation to a patient has not been identified at this time.</p> <p>The more generic “The Responsible Person must ensure that all diagnostic and therapeutic procedures are performed using equipment that has been designed for the intended purpose” replaces the previous clause.</p> <p>Noted, however there are also obligations on the operator to ascertain pregnancy status (clause 3.3.6).</p>
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	<p>fetus in-utero commonly falls on the Radiographer. This scenario not only takes place in emergency, out of hours and rural and remote situations, it commonly occurs in all Radiology practices.</p> <p>In emergency, out of hours and rural and remote situations where a Medical Practitioner (Radiation) is not present or available, the responsibility for discussing the potential risks of radiation exposure to the fetus and the requirement or the benefits of the examination should be shared equally between the Radiographer (or Operator) and the Referrer.</p>																									
<p>19 Howell Round President, Australasian College of Physical Scientists and Engineers in Medicine Suite 3.13 Aero 247 247 Coward Street Mascot</p>	<p>Code of Practice – Specific comments and feedback</p> <table border="1" data-bbox="421 467 1384 1273"> <thead> <tr> <th>Pg No</th> <th>Clause & Line(s)</th> <th>Comment</th> </tr> </thead> <tbody> <tr> <td>7</td> <td>3.1.20 251</td> <td>Why is it necessary to provide a means by which a trend in dosimetry equipment performance can be monitored? Surely accuracy is enough considering this applies to all equipment.</td> </tr> <tr> <td>7</td> <td>3.1.23 265</td> <td>Physicist involvement seems to be under the guise of a “qualified expert” however this is not fully defined as yet. This may be dangerous in the future. This is probably not something to change just to be wary of.</td> </tr> <tr> <td>9</td> <td>3.1.24 276, 278</td> <td>Currently there is no requirement on who can calibrate a linac.</td> </tr> <tr> <td>10</td> <td>3.1.26 293</td> <td>Why do we need detailed brachy planning procedures and not external beam? Should be both or neither</td> </tr> <tr> <td>14</td> <td>3.2.18 456</td> <td>Why is intracavity brachy left out? While vaginal applicators may be removable by other staff, intrauterine and possible other applicators may need a doctor. I may be off the mark with this comment.</td> </tr> <tr> <td>18</td> <td>Section 3.3.10 lines 561 – 563</td> <td>My interpretation of this section is that it refers to radiation therapeutic equipment and, therefore, should refer to radiation therapeutic equipment. Diagnostic equipment does not have interlocks.</td> </tr> <tr> <td>21</td> <td>D1.1 689</td> <td>I think section D2 covers this if it is written in a general form. The brachy verification is too specific compared to the external beam verification. If detail is required refer to international and national recommendations.</td> </tr> </tbody> </table>	Pg No	Clause & Line(s)	Comment	7	3.1.20 251	Why is it necessary to provide a means by which a trend in dosimetry equipment performance can be monitored? Surely accuracy is enough considering this applies to all equipment.	7	3.1.23 265	Physicist involvement seems to be under the guise of a “qualified expert” however this is not fully defined as yet. This may be dangerous in the future. This is probably not something to change just to be wary of.	9	3.1.24 276, 278	Currently there is no requirement on who can calibrate a linac.	10	3.1.26 293	Why do we need detailed brachy planning procedures and not external beam? Should be both or neither	14	3.2.18 456	Why is intracavity brachy left out? While vaginal applicators may be removable by other staff, intrauterine and possible other applicators may need a doctor. I may be off the mark with this comment.	18	Section 3.3.10 lines 561 – 563	My interpretation of this section is that it refers to radiation therapeutic equipment and, therefore, should refer to radiation therapeutic equipment. Diagnostic equipment does not have interlocks.	21	D1.1 689	I think section D2 covers this if it is written in a general form. The brachy verification is too specific compared to the external beam verification. If detail is required refer to international and national recommendations.	<p>“provide a means by which trends in the performance of each such instrument can be monitored” to Safety Guide.</p> <p>Noted.</p> <p>Covered in 3.1.26(a).</p> <p>“brachytherapy” removed.</p> <p>Clause amended.</p> <p>This refers to all radiation-producing equipment because some future diagnostic equipment might have interlocks. The word “any” has been inserted before “safety interlock devices”.</p> <p>The Schedule has been deleted from the Code (removed to the Safety Code).</p>
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<p>20 Tracy Fleming Manager - Medical Imaging, National Assoc</p>	<p>Feedback on Draft code of Practice in the Medical Applications of Medical Imaging, Safety Guide Diagnostic and Interventional Radiology and Safety Guide Radiation Protection in Nuclear Medicine</p> <p>NATA’s feedback, detailed below, raises issues from an accreditation point of view. The</p>																									

<p>of Testing Authorities (NATA)</p>	<p>Code and associated safety guidelines compliment the radiation safety aspects of the current RANZCR/NATA accreditation standards.</p> <p>The following issues are raised for consideration:</p> <p><u>Draft code of Practice in the Medical Applications of Medical Imaging</u></p> <p>97-99 “regularly reviewed” should be defined e.g. at least yearly.</p> <p>117 & 122 The term “accredited body” should be defined.</p> <p>123-124 It is noted that the term “child bearing age” has not been defined. It is suggested that each practice/medical imaging facility document their definition of “child bearing age”, so that consistency is obtained in each medical imaging facility.</p> <p>143-147 “periodically compared” should be defined.</p> <p>246-248 Clarification required – warning lights to “any entry door”. Does this just relate to entrances where there is a physical door, or does it include any entry point? Does this still apply to doors where there is a one way lock fitted (e.g. from change rooms)?</p> <p>445-448 Suggest include “medical practitioner, or delegate”</p> <p>We trust that the above comments provide some useful points for consideration.</p>	<p>A1.1(r) requires review mechanism to be placed in the Radiation Management Plan. “Accredited body” will generally be a professional body acceptable to the radiation regulatory authority. Determination of child bearing age is a medical issue and not within the scope of this Code.</p> <p>There is no “period” to define at this stage.</p> <p>Changed to “entry point”.</p> <p>Delegation is implied.</p>												
<p>22 Daniel Schick Principal Medical Physicist Biomedical Technology Services Princess Alexandra Hospital</p>	<p>Comments on: Code of Practice; Radiation Protection in the Medical Applications of Ionizing Radiation (draft 24th August 2007)</p> <table border="1" data-bbox="360 1114 1346 1457"> <thead> <tr> <th>Page</th> <th>Clause and Line</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>1.3(f)</td> <td>It is unclear to me why this line exists. Aren't this category of people “occupationally exposed”? What is special about this group?</td> </tr> <tr> <td>2</td> <td>1.3 (c)&(d)</td> <td>Have the application of all parts of the Code (eg. justification and approval by the medical practitioner) been considered in the context of research participants and medico-legal cases? (see comment re: line 805)</td> </tr> <tr> <td>3</td> <td>Line 37</td> <td>I do not support the exclusion of chiropractors from the Code. Surely there is sufficient commonality between general</td> </tr> </tbody> </table>	Page	Clause and Line	Comments	2	1.3(f)	It is unclear to me why this line exists. Aren't this category of people “occupationally exposed”? What is special about this group?	2	1.3 (c)&(d)	Have the application of all parts of the Code (eg. justification and approval by the medical practitioner) been considered in the context of research participants and medico-legal cases? (see comment re: line 805)	3	Line 37	I do not support the exclusion of chiropractors from the Code. Surely there is sufficient commonality between general	<p>Agreed. (f) removed.</p> <p>The Scope defines what is covered.</p> <p>RHC decision not to include.</p>
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		radiology and chiropractic X-ray practice for inclusion ie. The effort to produce a separate (and substantially different) Code does not seem warranted.	
6	117 and 122	Who are these accredited bodies (accredited by whom?) Perhaps this should be defined or at least examples given.	“Accredited body” will generally be a professional body acceptable to the radiation regulatory authority.
6	3.1.3(c)	Must pregnancy status be ascertained for exposures remote from the uterus (<1mSv)? Is so there is a conflict with 3.2.7 which implies otherwise. For consistency with ICRP 84 it would be preferable to remove the reference to 1mSv in 3.2.7. ie. Pregnancy status always ascertained for females of childbearing age, albeit with limited action required (eg. patient assurance/counselling only) if uterus is not in the primary beam.	Clause changed to “where a medical procedure may result in a radiation dose of more than 1 mSv to an embryo or fetus, a radiation medical practitioner has determined the pregnancy status of the patient.”
9	3.1.14	Insert full-stop after “1mSv”.	Clause amended
10	Line 248	The room in question may not have a door. Suggest replace “door of any” with “to a”.	Changed to “entry point”. Applies to all radiation-producing equipment.
12	3.1.29	Is this intended to apply to imaging?	Change to paragraph effected.
12	3.1.31	This should be limited to faults that have compromised patient safety consistent with 3.3.11(c) – otherwise the Responsible Person will not be informed of the fault and thus can’t report it – pls also note my comments on 3.3.11	Done.
12	3.1.31(b)	Suggest “ensure that a record of such faults and the necessary corrective maintenance performed is maintained”.	“in combination with the medical radiation procedure” removed.
14	404	Perhaps I’ve missed something – What does “in combination with the medical radiation procedure” mean?	Handled above.
15	3.2.7	See 3.1.3(c) comment above.	Agreed. Clause amended.
15	3.2.10	In many cases it would not be typical or required for the medical practitioner (radiation) to be directly involved in this advice. ie. The radiographer could inform the patient of the negligible risks for an extremity exposure. Suggest a change to “reasonable steps to ensure that the pregnant patient is advised of the potential risks...”	
16	3.3.1	Check that “radiology” should be highlighted here.	Highlight removed.
17	3.3.6 and 3.3.7	See 3.1.3(c) comments ie. Pregnancy status should be established for all procedures (even if this means putting the patient in the “probably pregnant” category and treating them as if pregnant). Furthermore, if the trigger point for special consideration is to be quantitative (ie. 1mSv) then there is no reason to refer to “abdominal and pelvic regions” in 3.3.7. ie. The medical practitioner or operator establishes whether or not the 1mSv threshold may be exceeded then enacts the requirements of Schedule B	Wording of 3.3.7 has been incorporated into 3.3.6 and changed accordingly.
18	3.3.11(c)	This implies that many forms of equipment failure or malfunction that can and are presently handled within the	Wording of 3.1.31 amended to tie this in.

			clinical department must be reported to the likes of a hospital CEO (note that the current statement says “could” rather than “has” compromised patient safety etc.). Almost any malfunction has the potential to compromise safety, diagnosis or treatment but surely the responsible person does not need to be told of all malfunctions. I would suggest that the malfunction should have to constitute a “radiation incident” before informing the responsible person who, in turn, would advise the regulatory authority.		
	18	3.3.12	In many cases the operator is going to need to seek the advice of an expert as to whether or not an event is classified as a “radiation incident”, and to further characterise the event (ie. Arrange dosimetry assessment etc.). In practical terms, this clause places a legal obligation on a radiographer to (almost immediately) inform a hospital CEO of this event. This is an unnecessary and impractical requirement. At the very least this time frame should be relaxed for reportable incidents and no time frame stated for other incidents. Non-reportable incidents could then simply be tabled (as done presently where I work) at a radiation committee meeting that involves the responsible person.		Both “radiation incident” and “reportable radiation incident” are defined in the Glossary. The mechanics of how they are dealt with in the organisation will be covered in the Radiation Management Plan
	21	667 and 675-677	These statements imply that a qualified expert must be available for fetal dosimetry (including prospectively). Perhaps 3.1.25 (a)(i) should add “fetal” dosimetry. Unfortunately, this requirement for (individual) fetal dosimetry seems to be contradicted by aspects of the radiology safety guide (see Annex B) which provides approximate fetal doses for a range of procedures and implies that the tabulated data can be used for clinical decision making.		Removed “patient” from 3.1.25(a)(i). Now means any dosimetry.
	24	760 and 770	Who defines W_T ? Is it as specified by ICRP and updated from time to time?? Similar issue for W_R		Yes, it is as specified by ICRP.
	25	805	“radiology” is not defined. Does this include imaging for research purposes or medico-legal procedures?		Both “diagnostic” and “interventional” radiology are defined separately.
26 Dr Graeme Dickie Chairperson Radiation Advisory Council Qld			We note that a further draft of the ARPANSA <i>Code of practice on Radiation Protection in the Medical Applications of Ionizing Radiation (2007)</i> has been released for public comment. The Radiation Advisory Council has discussed one item in the revised draft which is the clause line 37: “This code does not apply to the chiropractic use of radiation.”		Noted, but it was a decision of the RHC to not include chiropractors in this Code. There are other issues relating to Chiropractic X-ray procedures that need to

	<p>It was the feeling of the members of the Council that the same standards and radiation safety issues should apply for chiropractic x-rays as for other clinical x-rays. The members of the Council could not understand why such a clause excluding chiropractors, should be inserted in the revised draft.</p> <p>We suggest the issue of excluding chiropractic x-rays from this Code should be reconsidered.</p>	<p>be looked at separately.</p>
<p>28 Robert Fitchew Principal Physicist Cancer Care Services Royal Brisbane and Women's Hospital</p>	<p>Some comments for your consideration on the draft Code of Practice "Radiation Protection in the Medical Applications of Ionizing Radiation" dated 24.8.07 are set out below. I apologise for having missed Friday's deadline for the submission.</p> <p>line 51: To avoid giving the impression that the Code may also contain requirements which are not compulsory, this sentence could be replaced by "All the requirements of the Code are mandatory. This is indicated by use of the word 'must'".</p> <p>line 96: Whether or not the word "ensure" has an accepted legal definition, it should be defined in the document, either in the glossary or as a footnote, since some of the outcomes the R.P. is required to ensure (i.e. "make certain" in the dictionary definition) are beyond the R.P.'s power. Examples are 3.1.1 (c) and 3.1.4 (a), where individuals could, even inadvertently, negate the measures taken by the R.P. If there is no legal definition, something like "make certain to the extent that it is within his/her ability" would be appropriate.</p> <p>line 117: "accredited body" should be defined.</p> <p>line 290: "X-ray" should be "X-rays".</p> <p>line 299: Does (i) intentionally imply that the consultation with the qualified expert about patient dosimetry and Q.A. is only in the context of optimisation? If not, delete "including".</p> <p>line 307: The terminology in 3.1.26 is unconventional. "Calibration" usually refers to equipment, as in (a) and (b), or to beams, as in (e); not to techniques, as in (c) and (d). "Technique" is usually taken to refer to the method of application of the (calibrated) beams; the technique as such is not calibrated, though it may be verified, e.g. by phantom measurements. Wording such as "techniques of radiation-producing therapy equipment" and "these techniques are calibrated" in (d) are therefore confusing.</p> <p>line 330: "and national" should be replaced by "or national (Australian if available)".</p> <p>line 343: "unit" should be "units".</p>	<p>Current wording considered acceptable.</p> <p>Disagreed. It is felt that "ensure" conveys the appropriate legal attitude.</p> <p>"Accredited body" will generally be a professional body acceptable to the radiation regulatory authority. Changed, although this clause might be removed.</p> <p>Clause changed, "including" deleted.</p> <p>(c) amended to say that the equipment must be calibrated. (d) deleted as there is no timeframe specified in (c) and would therefore cover before and during.</p> <p>Change to order of wording.</p> <p>Done.</p>

	<p>line 451: The first "the" should be replaced by "an".</p> <p>line 474: (b) is an unusual requirement, since additional shielding may be only one of the available options, and the need for it could depend on a number of factors and require input from others such as the cardiologist.</p> <p>line 502: Need to define "accredited body".</p> <p>line 594: The Glossary defines "practice" as an activity, whereas "construction" and to a lesser extent "shielding" apply more appropriately to the building within which the practice occurs and the radiation-producing equipment used.</p> <p>line 596: "or" should be "and".</p> <p>line 661: Does this schedule need an exemption for emergency cases where all of the listed requirements may not be possible?</p> <p>line 700: Paragraph 46 of the Regulatory Impact Statement Consultation Draft says that the NHMRC has rescinded all of its health based codes that are over 10 years old. This should be noted if it is necessary to quote this Code in the Bibliography.</p> <p>line 753: "Critical group" should be defined in the Glossary.</p> <p>line 784: "gamma rays and" should be deleted from this line and inserted before "neutrons" in the following line. (See e.g. the ARL "Glossary of Terms Recommended for Use in Radiation Control Legislation and Associated Codes of Practice". The initial ionization event is ignored in the classification. The incorrect classification of gamma rays as directly ionizing radiation also occurs in a number of previous NHMRC/ARPANSA documents.)</p>	<p>Done.</p> <p>Noted, but this clause could be removed to the Safety Guide anyway.</p> <p>“Accredited body” will generally be a professional body acceptable to the radiation regulatory authority. Changed to “facility or premises”.</p> <p>Done.</p> <p>No. Even a general idea of the dose to be received by an embryo or fetus should be known for most common diagnostic procedures. The 1986 Code is still in use in some jurisdictions. The NHMRC has rescinded these Codes but they can and are still incorporated into legislation.</p> <p>Bibliography section removed.</p> <p>Examples removed.</p>
<p>31 ALAN RITCHIE A/Manager Hazardous Materials and Radiation Department of Environment & Climate</p>	<p>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.</p> <p>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.</p> <p>Thank you for the opportunity for DECC to provide input into these documents.</p>	

Change, NSW	<p><u>Department of Environment and Climate Change (NSW) Comments on ARPANSA's</u> <u>Comments provided by DECC on the Code of Practice: <i>Radiation Protection in the</i></u> <u><i>Medical Applications of Ionizing Radiation</i></u></p> <p><u><i>[SEE ATTACHMENT 1]</i></u></p>	
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Department of Environment and Climate Change (NSW) Comments on ARPANSA's Comments provided by DECC on the Code of Practice: Radiation Protection in the Medical Applications of Ionizing Radiation

Original Comment on the Industry Draft (All relevant clauses now relate to the August 2007 draft)	ARPANSA Comment	DECC Comment on ARPANSA Comment	ARPANSA Response
<ul style="list-style-type: none"> • 2.1: The word "should" in the definition of the justification principle is capable of giving too much scope on whether the principle referred to is to be conformed with. The suggestion is changing this to a more definite term. • 3.1.3 (c) Query of the term "all reasonable attempts". The term needs further clarification. • 3.1.7(b): The term "periodically compared" needs to be clarified. How often should this comparison happen? There is also concern about the term "commonly". How would this process be enforced? This would be very hard 	<p>This is a quote and therefore needs to remain.</p> <p>Deleted.</p> <p>The establishment of a program of comparison with DRLs is the important issue here. The period will be determined as part of that program.</p>	<p>The quote can remain, but must be put within "inverted commas", not in <i>italics</i>.</p> <p>New wording of this clause, "has been addressed", is unacceptable and less clear than previous wording.</p> <p>This has still not been addressed. The phrase "periodically compared" is left open to discretion. A period should be stated to avoid confusion. The phrase "in accordance with" recommendations needs to be referenced, if possible.</p>	<p>The Australian Style Manual permits italics for cited phrases.</p> <p>Sub-clause changed to "where a medical procedure may result in a radiation dose of more than 1 mSv to an embryo or fetus, a radiation medical practitioner has determined the pregnancy status of the patient"</p> <p>The previous comment/response stands.</p>

<p>to regulate without a specific process in place.</p> <ul style="list-style-type: none"> 3.2.7: What are all reasonable steps to determine if patient is pregnant? 	<p>This will depend on the magnitude of the exposure.</p>	<p>The changed wording in the new draft is not acceptable as it is not in the interest of the patient. The overall statement is weakened with the removal of "all".</p>	<p>Other submitters have commented that "all" needed to be removed as it was not possible to specify what "all" reasonable steps are.</p>
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Additional Comments		Response
3.1.8 CIII	<p>The word "confirmed" requires a #4 to link it to the foot note</p>	<p>Already referenced in the lead in paragraph.</p>
3.1.14	<p>The wording does not read correctly. The statement that the responsible person must ensure protocols are in place is stated twice in the one sentence.</p>	<p>The wording of this clause has been amended..</p>