

**Industry Consultation Submissions on Draft Code of Practice in the Medical Applications of Ionizing Radiation
18 May – 2 July 07**

SUBMITTER	COMMENT	RESPONSE
<p>01 Professor Peter Johnston Discipline Head, Physics School of Applied Sciences RMIT</p>	<p>I asked the ACPSEM to put a notice about the Industry Consultation out to members and I got 40-50 e-mail yesterday in reply. I think they all include 0.3 mSv in the text.</p> <p>My comments as discussed are:</p> <p>2.2.1 implies a more limited scope than 1.3 (c) suggests.</p> <p>3.1.7 (a) A ‘personal radiation monitoring device’ must be fit for purpose and that may not always be the case. The may be exposures for which such a device is unsuitable.</p> <p>Glossary: ‘personal radiation monitoring device’, dose such a generalised device exist?</p>	<p>Noted.</p> <p>Noted.</p> <p>No change effected</p>
<p>02 Vicki Hyatt Practice Manager Chiropractic on Collins Hobart</p>	<p>We are writing in regards to the wording of the "draft code".</p> <p>The draft code defines four persons who must be involved in a medical Application of ionizing radiation.</p> <p>It refers to "the Medical Practitioner" - as Chiropractors are not Medical Practitioners, is it possible for this to be worded as :-</p> <p>Medical Practitioner or Health Professional.</p> <p>We are concerned otherwise that it will not allow our Chiropractors to take and process their own x-rays.</p>	<p>The Radiation Health Committee has decided that the Code will only apply to medical practices and does not apply to the chiropractic use of radiation. A separate Code may be developed in the future for Chiropractic X-ray procedures.</p>
<p>03 Giovanni Bibbo, PhD Radiation Safety Officer/Principal Medical Scientist (Physics) Division of Medical Imaging Women’s and Children’s Hospital</p>	<p>p. 5 - 3.1.3(b), Lines 116 – 120 Puts responsibility on the radiologist, and I would think the Head of Radiology for every radiographic/radiological procedures. That person needs to approve each procedure, directly or through written guidelines. How is this going to improve radiation safety for the patients? It will only increase the workload of the radiologists.</p> <p>p. 5 - 3.1.3(c), Lines 121 – 124 Female patients. Need to establish pregnancy status if dose to embryo/foetus ></p>	<p>The new sub-clause relating to generic justification by an accredited body could solve that problem.</p> <p>3.1.3(c) amended</p>

SUBMITTER	COMMENT	RESPONSE
<p>72 King William Road North Adelaide</p>	<p>0.3 mSv. Does it mean that every women of child bearing age need to be seen by a radiologist? How would a radiologist know that the dose is going to be > 0.3 mSv for the different stage of gestation, particularly, for fluoroscopy?</p> <p><i>The latest draft of ICRP 2005 Recommendations does not make any reference to 0.3 mSv to the embryo/foetus. For x-ray procedures it is very difficult to calculate dose to embryo/foetus because there are no dosimetry models for calculating dose to embryo/foetus at different stages of pregnancy. All the models calculate dose to the un-pregnant uterus and not pregnant one. For Nuclear Medicine, the Olinda program can be used to calculate doses to embryo/foetus at 3, 6 and 9 months of gestation – but then this program must be approved by ARPANSA/Statutory Authority to be used if this document becomes incorporated into legislation.</i></p> <p>A dose limit does not apply to medical use of radiation!!! - and it should not apply to embryo/foetus as the unborn child still gets a benefit from an x-ray procedure – even though indirectly through the mother– since if the mother is well, the unborn child has a better chance of survive than if she was not well.</p> <p>p. 6 - 3.1.5, Lines 135 – 141 Optimisation of protection and limitation of radiation doses Does it mean that a dose needs to be calculated for every patient? Also, it is not clear whether it is absorbed skin dose, effective or dose area product (DAP). Calculation of effective dose for fluoroscopy is going to be difficult because you do not know which organs/tissues are being irradiated unless the images are examined. Also, need to record exposure factors for general radiography and DLP values from CT for every patient. Need a number of physicists to do all the dose calculations, particularly for paediatric patients since the dosimetry data is scarce and what is available, is old.</p> <p>This would also require an increase in radiographic staff level in order to record all this dose relevant data.</p> <p>p. 6 - 3.1.7(a), Lines 147 – 151. Occupational radiation exposures If this clause on personal monitoring is accepted, there is no need to monitor radiographers, nurses and radiologists as they all get less than 1 mSv/y.</p> <p>p. 7 - 3.1.12, Lines 186 – 188</p>	<p>Only sufficient information needs to be kept to allow the radiation dose to be estimated if the dose administered has not been recorded.</p> <p>This could be considered as part of the cost-benefit analysis.</p> <p>“Could” changed to “is likely to”.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Inadvertent irradiation of an embryo or foetus Why 0.3 mSv? How do you know when the embryo/foetus has received 0.3 mSv? If the dose needs to be calculated to determine if the embryo/foetus receives more or less than 0.3 mSv, it means it will need to be done for every pregnant female patient. But, please note that according to ICRP (report 84 and later one) there are no lethal, malformation or mental retardation effects of radiation on the unborn child for doses below about 100 mSv. The only possible effect is the induction of cancer and the risk is the same as if the dose was received once born.</p> <p>p. 11 - 3.2.3(e), Lines 347 – 348. Justification of a medical radiation procedure Pregnancy status of female patients and the 0.3 mSv limit. As per 3.1.3(c) and 3.1.12 above.</p> <p>p. 12 - 3.2.7(a), Lines 384 – 387. Optimisation of protection and limitation of radiation doses Medical practitioner must maintain patient radiation doses or exposure factors for the doses to be estimated.</p> <p>As per 3.1.5 above. This will have the effect of increasing the paper workload for the department – but will it improve radiation safety for the patient?</p> <p>p. 13 - 3.2.12, Lines 414 – 422 Procedures for potentially pregnant or pregnant patients Limit of 0.3 mSv and 1 mSv appear for diagnostic & therapeutic procedures. <i>Why the difference. There should be no limit. For every child bearing age female, steps should be taken to establish pregnancy status of female patient. Just imagine a court case where the medical practitioner did not ascertain the status of pregnancy of patient because he/she thought the radiation to the embryo/foetus would be less than 0.3 mSv or less than 1 mSv and the child is born with malformations.</i></p> <p>p. 15 - 3.3.6, Lines 499 – 503 Limit of 0.3 mSv related to embryo/foetus appears again.</p> <p>p. 17 - A1.1(b), Lines 560 – 564 Schedule A: Radiation Management Plan The dose constraint of 0.3 mSv for members of public for the shielding of</p>	<p>Changed to 1 mSv and now only requires that protocols are in place to address the situation.</p> <p>The pregnancy status of the patient now needs to be taken into account regardless of the potential dose.</p> <p>Now a responsibility of the Responsible Person to make sure systems are in place to ensure it happens.</p> <p>Now a responsibility of the Responsible Person to make sure systems are in place to ensure it happens. This could be considered as part of the cost-benefit analysis.</p> <p>Both are now 1 mSv. This is not a limit, it is a “trigger” level below which no action needs to be taken e.g. if it is an X-ray of the hand, this clause could be ignored.</p> <p>Again, this is simply a “trigger” level above which the action needs to be taken. Also, the level has been changed to 1 mSv.</p> <p>These levels have now been removed.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>medical practices will become a limit once the document is incorporated in legislation. It is too small to be a limit. The walls of x-ray, nuclear medicine and radiotherapy rooms will be filled with lead and concrete at great expense – but how many lives are going to be saved by reducing the limit from 1 mSv/y to 0.3 mSv/y.</p> <p>p. 19 - B1 and B2, Lines 624 – 654 Schedule B: Protection of an Embryo or Foetus The 0.3 mSv dose limit for embryo/foetus appears again.</p> <p>General Comments</p> <p>The dose of 0.3 mSv is going to become a default dose limit for general public since the intention of this document is to establish regulatory requirements for the use of ionising radiation in medicine for the purpose of being adopted by State, Territory and Commonwealth Regulatory Authorities as part of their radiation protection legislation. This document will also be used by accrediting agents for accreditation of medical imaging practices in Australia. Thus, it is very important that it becomes a good and practical radiation safety working document for medical imaging practices.</p> <p>The dose of 0.3 mSv is too low to be a limit. This dose is on average what individual get from ingestion which the majority of the dose being internal to our bodies from K-40 (UNSCEAR 2000).</p> <p>The dose limit of 0.3 mSv for the embryo/foetus is going to be a big problem because there are no dosimetry models for the different stage of pregnancy for x-rays that permit with reasonable accuracy to estimate the dose to the embryo/foetus. The dose needs to be determined reasonably accurate if the 0.3 mSv becomes a legal limit (potential court cases). All the dosimetry models are for non pregnant females. Only in Nuclear medicine there is the Olinda program that incorporates pregnant phantoms of 3, 6 and 9 months gestation. For the 0.3 mSv limit to be applicable in radiology, in the guidelines, the examinations that the pregnancy status of female patients must be ascertained must be stated and doses for the different stage of pregnancy provided. My view is that female patient should be treated as per ICRP latest draft 2005 Recommendations.</p> <p>Even for shielding the dose of 0.3 mSv is too low. It should be left to 1 mSv.</p>	<p>All 0.3s have been changed to 1 mSv. These levels are also “trigger” levels, not limits.</p> <p>All 0.3 mSv in the document have either been removed or changed to 1 mSv.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>The extra cost of shielding rooms unnecessarily could be used for patient care.</p> <p>I really think that there is a need to conduct an ALARA impact study on this document taking into account the economical and social factors in consideration. This document seems to have forgotten about the economical and social factors incorporated in the definition of ALARA and radiation safety seems to be moving to the extreme of zero risk – and yet we do not know if ionising radiation causes any detrimental effects below about 100 mSv (even ICRP has recognised this). Radiation protection needs to be realistic corresponding to a realistic radiation risk and not just to increase the paper mountain of our modern society. A risk analysis related to the implication of this document must be done comparing the number of lives saved to the cost required to comply with the document.</p> <p>In addition, the Safety Guides mentioned in lines 37 – 39, p. 3, must be made available with this document for interested stakeholders to have an appreciation of the implication of this document on the workflow and associated costs of their medical imaging practices. The release of this document for comments without the Safety Guides is a repetition of what happened when ICRP released its 2005 Recommendation for comments without the associated guidelines/explanatory documents.</p>	<p>This could be addressed in the cost-benefit analysis.</p> <p>Noted. The revised safety guides will be released with the next draft of the Code for public comment.</p>
<p>04 Jim Cramb Director, Physical Sciences Peter MacCallum Cancer Centre</p>	<p>Page 3 - Line 35-39 It would be much better if the 3 safety guides were available for review at the same time as the code of practice. It's hard to comment on the code without knowing what's in the safety guides.</p> <p>Page 3 - Line 41 Not everything in the code is or should be a regulatory requirement. Some things would be more appropriate in a guide.</p> <p>Page 5 - Line 121-129 Clause (c) implies that it is sufficient to merely establish whether the patient is pregnant or breast-feeding to justify a procedure. Together with 3.2.3, it sort of makes sense, but since 3.2.11-3.2.16 specifically covers this, maybe there is no need to refer to it at all here, i.e. (c) could be deleted.</p> <p>Page 7 - Line 183-184 Isn't this the same as 3.1.9 (c)? Maybe not – perhaps the loss of a source</p>	<p>Noted.</p> <p>The Code, by definition, contains regulatory requirements. Some items have been removed to the safety guide though.</p> <p>Sub-clause (c) has been modified but needs to remain here and read in conjunction with the requirements for the medical practitioner.</p> <p>Duplicate clause deleted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>doesn't in itself constitute a radiation incident.</p> <p>Page 10 - Line 284-285 There are many international and national protocols, and while they are similar, frequencies of testing do vary and are often widely debated. Which protocols take precedence? Particular protocols should be specified.</p> <p>Page 10 - Line 307-308 In most cases, the repair or maintenance won't affect beam output characteristics, so it's unreasonable to require a "calibration" every time. The wording needs to be qualified to reflect this e.g. "(b) all..... if there is a possibility that radiation beam characteristics may have changed as a result of the repair or maintenance".</p> <p>Page 11 - Line 347-353 Since these same points are specifically covered in 3.2.11-3.2.16, there is no need to also cover them here. 3.2.3 need only cover the general case.</p> <p>Page 14 - Line 445-454 The qualified expert referred to clearly needs to be expert in radiation dosimetry. But advice from an expert in the various types of electronic devices and their possible responses to single and accumulated doses also is required. Often, these will be two different people.</p> <p>Page 2 (sorry, out of sequence) - Line 15-17 Who is the "Responsible Person" in a hospital?. After several enquiries on my part, it seems it's definitely not the RSO, or the director of a dept. Maybe it's the CEO? After several enquiries, the best answer I have received (from Noel Cleave, DHS) is that for an organization, the "Responsible Person" is not any one individual, but the hospital as a legal entity is "responsible". Whatever the correct interpretation, it would certainly help if the definition made it quite clear.</p> <p>Page 16 - Line 545 The medical practitioner certainly does not want to or need to know about every breakdown, only those that have caused, or possibly may lead to, an incorrect radiation exposure.</p> <p>Page 17 - Line 561-564</p>	<p>The protocols to be given in the Safety Guide.</p> <p>Done (see 3.1.31)</p> <p>Clause amended to be more generalised.</p> <p>Amended in new 3.2.15.</p> <p>The definition of a Responsible Person has been amended to explain what a "legal person" is. This should clarify the issue.</p> <p>Sub-clause amended.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>These clauses have generated enormous discussion, with most arguing against specification of such dose constraints, in particular the 0.3 mSv per annum for the public. I certainly question the arbitrariness, the logic and the practicality of such a low value. A design constraint of 5 mSv for an occupationally exposed person is quite reasonable, however I would argue that any dose levels lower than required by ICRP 60 should be included in the safety guides, not in the code. Putting a dose constraint in the code blurs the distinction between a level and a constraint.</p> <p>Page 18 - Line 610 However, 0.3 mSv seems quite reasonable for exposure due to radioactive waste, which should be stored well away from anybody.</p> <p>Page 19 - Line 626-629 Perhaps just (a) is sufficient. A formal risk assessment as described is not a trivial matter, and the outcome will still be very subjective, because the risk associated with such a low level of exposure is not known.</p> <p>Page 19 - Line 644-645, together with footnote 13 There seems to be a big contradiction here. On the one hand, termination of the pregnancy is not justified for anything up to 100 mSv, but on the other hand, there are all sorts of hoops to jump through for anything over 0.3 mSv.</p> <p>Page 21 - Line 698-700 “acceptable tolerances” – acceptable to who?</p> <p>Page 21 - Line 701-702 “within tolerances of published or measured data” – what tolerances and what data? Either state the tolerances or refer to specific publications.</p>	<p>Clause deleted.</p> <p>0.3 mSv changed to 1 mSv (the public limit).</p> <p>Noted, no change, but threshold dose now 1 mSv.</p> <p>0.3 mSv changed to 1 mSv. Contradiction noted however.</p> <p>Schedule D has been moved to the Safety Guide.</p> <p>Schedule D has been moved to the Safety Guide.</p>
<p>05 Dr Michael Izard MBBS FRANZCR MMedicalHum Clinical Lecturer University of Sydney; Radiation Oncology Associates</p>	<p>Attached are my comments on the code as it stands. I am still concerned about the decision to amalgamate all three groups into this one code, with significant SGs that we are unable to view. As a stand-alone document it is essentially meaningless, and very difficult to judge as to how useful it will be.</p> <p>To try to enforce many of the features would be very difficult without knowing how the SGs impact upon them.</p> <p>3.1.5 (b) line 138: If not specifying a period, this is very difficult to enforce. Might this be better in the SG?</p>	<p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>3.1.9, line 167: What is a “radiation incident”? The definition (line 856, in glossary) makes no comment about how far outside the range “normally accepted” is appropriate. 1mSv? 1%? >5mSv? >5%? Different regulatory authorities have different criteria for this. As this stands, all unexpected exposures should be reported – eg if a person has 2 CXRs because the film was over exposed, or off centre etc.</p> <p>3.1.9 (b) Impossible time constraints. I suggest inform the regulatory authority within 7 days, but submit the finalised report within (eg) 21 days.</p> <p>.1.24 (a) line 276: What if certain components of the linac’s function are not calibrated at the time of installation, but calibrated at a later date? That particular function would not be use-able until it was calibrated, but does not need to be calibrated until a later time to enhance the functionality of the machine. Eg: calibrating the 10MV photon beam or the 18MeV electron beam after the machine is clinical for the 6MV photon beam. As it stands, this could delay the clinical use of a linac for several months if EVERYTHING has to be calibrated at the time of installation. This would carry a significant economic implication.</p> <p>3.1.31 (c) (line 322): Not technically possible if the patient has moved away from the department, eg interstate or overseas</p> <p>3.2.5(b) (i) and (ii) lines 378-9: These sound as if it is the same medical practitioner for these two entirely separate tasks. It is much more likely that these two tasks will be performed by two separate doctors, one of whom (ii) has nothing to do with the radiation plan. When do radiologists write a prescription for a procedure?</p> <p>3.2.6 line 381: How do you enforce/legislate this?</p> <p>3.2.17 lines 445-454: Radiation physicists are not experts on implanted electronic devices. Advice from the appropriate expert should also be obtained. Why put this into the Code, why not into the SG?</p> <p>3.2.18 line 458: What is meant by the “duration of the treatment”? The time</p>	<p>The radiotherapy safety guide will have what “outside the range of that normally expected for a particular practice” means.</p> <p>7 days has been agreed by the regulators. It is assumed that leniency could be granted in the case of a complex investigation. “complete” removed to allow for a preliminary written report.</p> <p>Clause amended.</p> <p>This relates to a deceased patient and consideration would need to be given to such a circumstance.</p> <p>This is an “or” requirement. Protocols can be generic.</p> <p>Clause has been deleted.</p> <p>It is expected that the qualified expert will obtain the information and this is an important issue for the health of the patient.</p> <p>The latter is the intended requirement. Wording of clause</p>

SUBMITTER	COMMENT	RESPONSE
	<p>that the catheters are in place (which can be for a week or more) or just whilst the radioactive implant is out of its shielding and in use? Clarification required here if this is to become enforceable.</p> <p>3.3.11 line 540: No time limits given (consistency with previous statements required)</p> <p>D2 line 695: Suggest you title this External beam treatment planning to be consistent with D1</p>	<p>changed.</p> <p>“immediately” has been used.</p> <p>Schedule D has been moved to the Safety Guide.</p>
<p>06 Mr Jason Lemon (Chiro) President of the Chiropractors Association of Australia (Tas)</p>	<p>We have input from members, who are registered to use plain film radiography in their private practices, that the new Code of Practice may affect them.</p> <p>The concern that most report is the paragraph:</p> <p><i>"in particular, the draft Code defines four persons who must be involved in a medical application of ionizing radiation and specifies their responsibilities. These are:</i></p> <ul style="list-style-type: none"> • <i>The Responsible Person;</i> • <i>The medical Practitioner,</i> • <i>The Operator; and</i> • <i>A qualified Expert."</i> <p>Our members have concern relating to the specification only of a Medical Practitioner. If Chiropractors are able to be registered to use ionizing radiation in their practices, then perhaps it needs to be changed to "health practitioner", or specify practitioners (Chiropractors, Dentists, Medical Practitioners).</p>	<p>This Code does not apply to the chiropractic use of radiation.</p>
<p>07 Trevor Hoddy Registrar Medical Radiation Technologists Registration Board of WA</p>	<p>On the whole the Board felt the document was good and a step in the right direction.</p> <p>The Board had the following comments:</p> <p>1. The Board is concerned with the use of the term "exposure" . For Medical Imaging Technologist, this term refers to the technical factors that are used when taking a radiograph or prescribing a treatment, ie 85KVP and 350mAs.</p> <p>In the document it really means the radiographic procedure or radiation treatment (reference 1.3, 3.1.3 (b), (ii)).</p> <p>Item 3.3.4 (a) (i) refers to "the exposure has been approved by a medical practitioner", this seems to suggest that the medical practitioner must approve</p>	<p>Noted, but exposure to remain.</p> <p>This clause has been amended.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>the exposure or technical factors given by the operator for the procedure.</p> <p>The Board would suggest that the term "exposure" should in these circumstances be replaced by "radiographic procedure" or "radiation treatment".</p> <p>2. Item 3.1.27 requires the Responsible Person to obtain and keep a written record detailing the work carried out. The Board felt it should require the Responsible Person to "ensure that" records are kept and not actually do it themselves'.</p> <p>3. Item 3.2 should be expanded to allow Nurse Practitioners to authorise medical radiation procedures, in accordance with legislation.</p> <p>4. Item 3.3.8 there is no requirement on the operator to require a person other than the patient in the room to wear personal protective equipment or personal monitoring device.</p>	<p>“ensure that” now included.</p> <p>Disagreed.</p> <p>Noted. This may be required by new 3.1.10.</p>
<p>08 Paul Edwards X-ray Hobart</p>	<p>I am a diagnostic radiographer of 36 years standing. I opened my first radiographic practice in 1983 and have been running my present practice since 1999. I know there are in the order of 20 to 30 other independent radiographers who own and run their own practices in various parts of Australia. I am sure they will have the same concerns that I have in regard to this code of practice and how it will impact on our business. If this code is imposed on the industry with legislative backing, and without consideration of its impact on us, than the legislators will have to plan to compensate us for effectively putting us out of business, or putting us in breach of the trade practices act.</p> <p>My practice is located in Hobart with two satellite practices, one in New Norfolk, 25kms north of Hobart, and the other in Sorell, 25kms east of Hobart. These practices do diagnostic general work on general practitioner and chiropractor referrals. A large part of the work done in Hobart is on dental referrals, where I provide comprehensive dental practice offering OPG, PA & lat cephalometric, axial occlusal, linear tomography of any individual tooth, but particularly of impacted wisdom teeth, and most recently 3D cone beam volumetric studies for dental implants and for localisation of the mandibular canal. I transmit my images to a Radiologist in Brisbane, who has absolutely no involvement in either the ownership nor the running of the practice. He merely provides the radiological services for the practice. He has no input nor</p>	<p>Noted.</p> <p>This could be considered as part of the cost-benefit analysis.</p> <p>Addressed by new 3.3.4.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>control over the running of the practice. Obviously, if I failed to provide adequate films for him to make a diagnosis, then he would refuse to report that examination and no fee would be raised against that patient until adequate films were provided. This is the only influence he has over the conduct of my business.</p> <p>From this short description of my business structure, I hope you can see how one of the basic premise of this code is in appropriate and unworkable, i.e. the premise that “the medical practitioner” is “responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation”. The main problem is that he is physically located in Brisbane, some 2,500km from Hobart.</p> <p>Below I have listed some of the clauses that should be looked at more carefully;</p> <p>3.1.3 (b) obviously it is not practical for the radiologist to approve each and every exposure, nor is it practical for him to foresee each and every circumstance. Surely, if there is a referral from a suitable qualified and recognised health care practitioner then that person’s professional standing gives him the authority to request an xray exposure to be conducted by me or any radiographer in my employment.</p> <p>3.2.1 If I am responding to a request, from a recognised practitioner, for a radiographic examination, then I must take full responsibility for the conduct of that exam.</p> <p>3.2.3 The responsibility for any of these points that relate to my diagnostic practice must be shared between me and the referring practitioner.</p> <p>3.2.5 (b) (i) I have written the protocols for my practice, in every Hospital that I have worked, the chief radiographer, or the specialist radiographer, as the case may be, has prepared the protocols for that department. (ii) I am unsure of what is meant by “written prescription” for the procedure, what ever it is, it is not applicable in my circumstance.</p> <p>3.2.7 In My situation, the medical practitioner is not the person to keep these records, if any one should keep them, the operator should record them, probably on the request form, and the responsible person would be responsible</p>	<p>Noted.</p> <p>Addressed in new 3.1.3(b).</p> <p>Clause amended.</p> <p>Clause amended.</p> <p>Clause amended.</p> <p>This now only applies to diagnostic nuclear medicine procedures.</p> <p>Clause deleted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>for storing them. Bare in mind, request forms are only kept for 18 months. However, I do not accept that there is any useful advantage to be gained by imposing this requirement on every diagnostic radiographer in every establishment in the country. It is a very tiresome duty that has no useful purpose and the information is never likely to be retrieved or used. Most radiographers will just ignore it or make a half hearted token effort when they think of it.</p> <p>3.2.14 I believe the referring practitioner should be the one to determine the pregnancy status and advise accordingly. Apart from having pregnancy signs displayed in all change cubicles, I have great difficulty with asking EVERY female from the age of 12 to 50yrs of age regarding their pregnancy status. Most parents get very offended by asking such questions of their adolescent daughters, and older women often take the view that I should mind my own business; after all I am a complete stranger to them and have no roll in their ongoing health care. It really is up to their doctor with whom they have a more meaningful relationship, to ascertain this status and advise accordingly. I feel this is akin to asking a patient to reveal to me their HIV status.</p> <p>3.3.4 (a) (i) Surely, if a medical practitioner has requested a radiographic examination, then it goes without saying that it has been approved by that medical practitioner.</p> <p>3.3.6 (a) Again, this responsibility rests with the referring practitioner.</p> <p>3.3.6 (b) DITTO</p> <p>3.3.8 (c) In my situation, this would be reported to me, the responsible person, and I in turn would report it to the relevant authority in my state, i.e. Health Physics Branch. The radiologist in Brisbane would not be involved.</p> <p>3.3.11 (b) Again this would be reported to me and I would determine whether or not it should be reported to the Health Physics Branch.</p> <p>I hope you will find my comments useful and will help your committee to view these issues from a different perspective.</p>	<p>Clause amended (now 3.2.12).</p> <p>Clause amended.</p> <p>Clause amended.</p> <p>Noted.</p> <p>Proposed action consistent with that for the responsible person.</p> <p>Noted.</p>
<p>09 Pauline Portier Principal Coordinator</p>	<p>The Chiropractors Board of Queensland has the following comment in relation to the Draft Code of Practice in the Medical Applications of Ionising Radiation.</p>	<p>This Code does not apply to the chiropractic use of radiation.</p>

SUBMITTER	COMMENT	RESPONSE
(Board Support & Advisory Program) Office of Health Practitioner Registration Boards	3.2 Medical Practitioner. This definition should not be exclusive to medical practitioners. Health Practitioner may be appropriate as it includes other practitioners such as medical radiation therapists.	
10 CONFIDENTIAL SUBMISSION		
11 Jill Fitch PSM	<p>It is difficult to comment on the draft Code without knowledge of the content of the 3 Safety Guides which are to supplement it. Nevertheless, the following comments are offered for consideration:</p> <p>Section 1.2 Purpose</p> <p>Will this Code establish the regulatory requirements for the use of ionizing radiation by chiropractors and any other health professionals who may be responsible for conduct of procedures? There is no mention of such persons in the Code.</p> <p>Section 1.5 Interpretation</p> <p>The Glossary defines many terms which are not used in this Code. In addition, the Code uses a variety of terms which are similar, eg</p> <p>Line 16 'radiation source, apparatus' Line 33 'medical radiation equipment and radioactive sources' Line 193 'radiation producing equipment or source of radiation' Line 200 'radiation producing equipment or radioactive source' Line 235 'radiation producing apparatus, radioactive sources' Line 240 'radiation apparatus or radioactive source' Line 242 'radiation producing apparatus or sealed radioactive source'</p> <p>Etc</p> <p>The terminology needs to be consistent throughout, and with the Glossary definitions.</p> <p>Section 2.3 Dose Limits</p>	<p>Noted.</p> <p>This Code does not apply to the chiropractic use of radiation.</p> <p>Noted. Consistent use of terms to be used throughout the document.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>This Section appears to deal with only 3 of the 8 types of exposure listed in Section 1.3 Scope; Section 2.3.1 appears to apply to 1.3(e) and 1.3(h), while Section 2.3.2 appears to relate to 1.3(a). This raises the question, what dose limits apply in the case of 1.3 (b), (c), (d), (f) and (g)?</p> <p>Section 3.1 The Responsible Person</p> <p>Line 107 The phrase 'all applicable dealings involving medical radiation' seems too vague for a regulatory document. 'Medical radiation' should be replaced by 'radioactive material'.</p> <p>Line 172 The loss or theft of any radiation source (including radiation apparatus) should be reported to the regulatory authority.</p> <p>Line 178 The reference should be to 3.1.9(a)</p> <p>Line 193 Suggest 'radiation source and ancillary equipment' to replace 'radiation producing equipment or source of radiation'. It is important for the training to cover ancillary equipment.</p> <p>Line 200 It is important that any shielding modifications made subsequent to commissioning are also documented.</p> <p>Line 236 It may be useful to add 'and updated as appropriate'. There may be instances other than following repair and maintenance (which is dealt with in 3.1.27-3.1.30) where additional relevant information is acquired, eg from the manufacturer.</p> <p>Line 255 The phrase 'in a way that enables easy access and understanding' seems unsuited to a regulatory document. It raises the question 'by whom?'</p> <p>Line 306 Replace 'or' by 'and' so it reads 'the radiation safety of patients, staff and the public'</p> <p>Section 3.2 Medical Practitioner</p> <p>Line 341 Suggest 'the characteristics of the individual patient'</p> <p>Line 380 Replace 'limitation' with 'recording'</p>	<p>Clause 2.3.2 will need to be amended.</p> <p>The wording of the clause has been changed.</p> <p>Agreed.</p> <p>Done.</p> <p>Done.</p> <p>Done.</p> <p>Done.</p> <p>Phrase removed.</p> <p>Sub-clause removed.</p> <p>Done.</p> <p>Heading changed to reflect change of paragraphs.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Line 382 This is a misuse of ALARA. Replace 'ALARA' with 'as low as reasonably practical'. Compare Line 79.</p> <p>Section 3.3 Operator</p> <p>In 3.3.11, the steps to be taken in the event of equipment malfunction or error are detailed. Should there also be a requirement to cease use of the equipment until the matter is resolved?</p> <p>Schedule A Radiation Management Plan</p> <p>The use and choice of dose constraints for occupationally exposed persons and members of the public will require regulatory impact assessment.</p> <p>In the case of radioactive waste, the requirement that no member of the public receive an effective dose greater than 0.3mSv per annum as a consequence of storage is impractical as a regulatory requirement. The use of a dose constraint of 0.3mSv for the critical group may have been intended. If so, this also should be subject to regulatory impact assessment.</p> <p>In line 618, it is not clear what transport is meant, and whether this includes transport within and outside the institution or practice. There is no mention of spillage of radioactive material elsewhere. If this is not to be explicit in the Code, it should certainly be covered in the relevant Safety Guide.</p>	<p>Clause amended.</p> <p>Done.</p> <p>Dose constraints have been removed from the Code.</p> <p>0.3 mSv changed to 1 mSv.</p> <p>This is meant to be all encompassing.</p>
<p>12 Harry Hanson Norwood, Tasmania</p>	<p><u>PERSONAL BACKGROUND.</u></p> <p>I am an experienced diagnostic radiographer, who has had 30 years experience in the field of diagnostic radiography, in both the public and private sectors. I have served on professional bodies at a state and national level, and believe I have a good understanding of how the application of ionising radiation to medical procedures occurs. From this perspective, I believe I am able to make an informed submission</p> <p><u>OVERVIEW.</u></p> <p>The overall approach of the code is to spell out specific roles, and physical procedures to be adopted in order to ensure that anyone coming into contact with medical radiation is protected, and exposed to the minimum possible dose.</p>	<p>Noted.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>The approach and physical systems proposed seem quite appropriate in general, however, the proposed systems for persons involved in medical radiation are I believe flawed.</p> <p><u>SPECIFIC RESPONSES</u></p> <p>My responses are in relation to the perspective of a diagnostic radiographer. There seems to be a general misunderstanding in the document regarding the actual process of radiation delivery. It should be made very clear that the specialist medical practitioner’s primary role in a radiology department is to provide an expert diagnostic report, and in that context prescribe standard views they require to arrive at a diagnosis. They are not responsible for the <u>conduct</u> of most procedures, nor would they physically or temporally be able to. Most would have little idea of exposure factors to employ or how to manipulate the patient to the required position.</p> <p>They do conduct and are directly responsible for interventional procedures. The term medical practitioner in this document, should be changed to specialist medical practitioner (SMP), since the title of medical practitioner does not endow the holder with specific radiation knowledge.</p> <p>The term of “operator” as proposed is completely at odds with the role of this person. I propose this term be replaced with the term “radiation professional” (RP), as it is they who prescribe the actual dose.</p> <p>I suggest Lines 18 & 19 read : “The specialist medical practitioner in conjunction with the radiation professional, are responsible for the conduct and overall procedure involving the exposure of the patient to ionizing radiation: and”</p> <p>The RP is the gatekeeper for radiation exposure, and has a major role in any efforts to reduce radiation dose. I and others have seen many times an inappropriate request from a referrer being queried, only to be told by the specialist medical practitioner to proceed, a more appropriate exam will be done later. In this situation the RP either discusses it with the referrer, or does a limited series.</p> <p>The role of the radiation professional needs to be tightened, and given more authority, not less, as they are the ones who directly influence the conduct of the examination. If a referral is received that is ambiguous,</p>	<p>New 3.1.3(a)(ii) allows for generic justification by an accredited body.</p> <p>Title changed to medical practitioner (radiation).</p> <p>Disagreed. Operator is defined in the glossary. Further, many different people will be delivering radiation doses, and term “opereator” it definitely does not diminish the key radiation protection role that this person has Disagreed.</p> <p>There is nothing in the Code to prevent discussion between the operator and the medical practitioner (radiation). This would be seen to be part of the optimisation obligations on both of these individuals anyway.</p> <p>Agreed, as per previous response.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>then of course it will be discussed with a SMP, and the required views obtained.</p> <p>In a public hospital situation, the RP, makes a professional decision on what extra views may or may not be helpful in achieving a diagnosis for the casualty staff. The increasing use of nurse practitioners (NP) also increases the need for the role of the RP to be expanded, and be in a position to offer advice the NP, whose radiation knowledge may well be very limited.</p> <p>Radiation professionals are well qualified and trained to conduct examinations. They also are the only person who sees and talks to the patient, and thus can glean extra information from them. The RP also has the management of the examination, in their hands, by positioning the patient, and making decisions on how to get the best and most diagnostic views, whilst always keeping in mind to minimize the dose. This point is especially important, as we encounter some very difficult patients, who require the adaptation of standard views to get the best results.</p> <p>The term operator suggests that is all they do, operate a console. This is far from a realistic idea of what a RP does. Dealing with and interacting with the patient is an essential part of the job. This person is a professional and must be treated as such.</p> <p>Remote operators and remote GP's who have a license, do need to be supervised, and perhaps another category needs to be created, so it can be ensured they are closely supervised. I have seen many times poor quality undiagnostic work coming from license holders, that has to be repeated, and thus is a radiation concern.</p> <p>The other area of concern that is not identified in this document, is that of self referrers. This category includes Chiropractors and remote GP's. Chiropractors irradiate the whole spine without specific problems in all areas. They do this on nearly all patients, and are totally unregulated. I have seen uneducated GP's request inappropriate exams on very young children, for insignificant histories. The RP queries this and minimizes the exam to the barest minimum.</p> <p>I suggest Line 20 reads “ The radiation professional who performs the examination, and exposes the patient to ionizing radiation.”.</p>	<p>Noted.</p> <p>Noted.</p> <p>Noted.</p> <p>Noted.</p> <p>Noted. Also, chiropractors are regulated but are excluded from this Code.</p> <p>Disagreed.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>This would require a change throughout the document.</p> <p>In relation to justification of a medical radiation procedure, 3.1.3, the referrer will have all the patients history, and is making a value as well as medico legal judgment, on what is required, so it is not possible for the SMP or the RP to totally evaluate the reasons for an examination. If there is a mistake made, or irregularities identified, these can and are checked with the referrer before proceeding. Further in 3.2.1, again the SMP is not responsible for the conduct of the examination, but does take responsibility for the procedure, by way of examining the final images and issuing a report on them.</p> <p>So 3.2.2 should read “the specialist medical practitioner and the radiation professional must comply with the relevant provisions of the radiation management plan.” This then increases the supervision of an examination onto two parties.</p> <p>In 3.2.3 the same applies and radiation professional must be added, along with a limit put on to what extent a history has to be pursued. As previously stated, the referrer is the one with the full medical picture, and all that knowledge can not always be at hand. A summary should be, and this is what happens on request form in the clinical notes section, as per 3.2.4.</p> <p>In 3.2.5 (b), the protocol will be prescribed as per a handbook of the workplace that is incorporated into the radiation management plan. The prescription for radiography will be made by the RP.</p> <p>In 3.3 again this should be Radiation Professional, with an extra section for non qualified personnel.</p> <p>In 3.3.3 should have a note added specifying that the RP should have evidence of participation in continuing education.</p> <p>In 3.3.4, the terminology is confusing, as at first glance this looks like it means approval from a referrer, but I believe it means the SMP. This once again reduces the important role of the RP who is the expert in positioning the patient, determining exposures and liaising with the SMP for specific advice and special views.</p> <p>I would therefore propose that this section read:</p>	<p>Addressed in amended clauses.</p> <p>3.3.2 already requires the operator to comply with the RMP.</p> <p>Clause amended.</p> <p>This is relevant for the safety guide.</p> <p>Clause amended.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>460 3.3 Radiation Professional</p> <p>461 Authorisation for a medical procedure</p> <p>462 3.3.1 Only a person who is appropriately authorised by the relevant regulatory authority to administer ionizing radiation to a patient for radiology, nuclear medicine or radiotherapy may administer ionizing radiation to a patient.</p> <p>465 General requirements for a Radiation professional</p> <p>466 3.3.2 The radiation professional must comply with the relevant provisions of the Radiation Management Plan including evidence of continuing education.</p> <p>468 3.3.3 The radiation professional must:</p> <p>469 (a) wear all personal protective equipment provided by the Responsible Person where applicable to the procedure as detailed in the Radiation Management Plan; and</p> <p>472 (b) wear a personal radiation monitoring device where provided by the Responsible Person.</p> <p>474 Specific requirements for a medical radiation procedure</p> <p>475 3.3.4 The radiation professional must:</p> <p>476 (a) not expose a person to ionizing radiation unless:</p> <p>477 (i) the exposure has been approved by a specialist medical practitioner; or</p> <p><u>478 (ii) the radiation professional does so in accordance with the referrers request using 479 established protocols, and if required liaison with 480 the specialist medical practitioner,</u></p> <p>481 (b) follow the established protocol for the procedure;</p>	<p>All noted. The revised version of the Code addresses these points.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>482 (c) ensure that the protection of the patient is optimised within the scope of 483 the parameters under the control of the operator;</p> <p>484 (d) ensure that the radiation exposure of persons other than the patient is 485 minimised; and</p> <p>486 (e) in the case of radiotherapy, ensure that:</p> <p>487 (i) the radiation treatment plan has been endorsed by the medical 488 practitioner as being consistent with the prescription for the 489 patient's treatment; and</p> <p>490 (ii) the radiation dose to the patient is delivered in accordance with 491 the medical practitioner's prescription.</p> <p><u>SUMMARY</u></p> <p>In this submission I have tried to put forward a view that a significant area of good practice in order to reduce radiation dose to the general population, is to recognise the important role of the radiation professional and build on it.</p> <ul style="list-style-type: none"> • The prescription of dose is their role (diagnostic). • They are also the gatekeepers for delivering radiation. • In many situations the radiation professional works without the presence of a SMP, and is qualified and capable of making decisions as to the conduct of an examination. • The role of the specialist medical practitioner is in diagnosis and as a point of reference for complicated matters. • The role of legal issues has not been addressed, as a large factor in referrals. • The issue of self referral from chiropractors and remote GP's, or others, has not been addressed. 	

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> • <u>The importance of ensuring competence and continuing education for RP's, as a tool to reduce radiation dose, needs to be incorporated into the regulations.</u> • Identify correctly that the title medical practitioner does not automatically mean that person has expert radiation knowledge. • The term suggested is specialist medical practitioner • Clearly differentiate the referrer in the document. 	
<p>13 Kim Firth Assistant Registrar Medical Radiation Technologists Registration Board of Western Australia</p>	<ul style="list-style-type: none"> • While it is appropriate and beneficial to reinforce, by way of a Code of Practice, the general principles justification of procedure, dose minimization and optimisation and so on, some terminology and requirements presented in the draft differ from state legislation. To avoid confusion and in the interest of uniformity, these differences should be considered. • The main confusion with regard to terminology is the use of the word “exposure” and this is mentioned below. The term ‘exposure’ has a scientific definition in relation to the ionization of air by x and γ radiations. ‘Exposure’ also has common usage amongst Technologist in relation to the technical parameter used as part of the examination so that there are two reasons why it should not be used to describe the procedure as is the case in 3.3.4 (a) (i) and (ii). The word ‘exposure’ in this case clearly refers to the procedure and therefore needs to be replaced. • There is much emphasis placed on the term the ‘responsible person’. The WA legislation uses a system of licensing (the user) and registration (equipment and premises) as the principle mechanism to administer radiation safety. Further responsibility is given to an appropriately qualified ‘Radiation Safety Officer’ who is nominated as part of the registration process. While the basic concept appears to be similar in that there is a nominated responsible person for each procedure, the terminologies used are different. This is perhaps unavoidable and may not be a problem so long as there is not a doubling up of roles. • There is definitely inconsistency with the requirements given in 3.2 and 	<p>Noted.</p> <p>Agreed.</p> <p>A change to the definition of RP might solve this problem.</p> <p>A person can refer a patient for an X-ray procedure but the</p>

SUBMITTER	COMMENT	RESPONSE
	<p>those given in the registration conditions under the RSA. Patients under state legislation can be referred for imaging procedures by medical practitioners, chiropractors, physiotherapists, podiatrists, osteopaths, dentists and nurse practitioners. It is inappropriate therefore to restrict the approval to medical practitioner only. It may be more appropriate to replace ‘medical practitioner’ with ‘the approved referrer’ in this instance.</p> <ul style="list-style-type: none"> Section 3.3.8 seems OK. The patient is the only person involved in the procedure who does not have a specified dose limit, either public or occupational. Naturally the ALARA principle and other dose minimization and optimisation principles apply. 	<p>Code requires that a medical practitioner (radiation) takes responsibility for that procedure.</p> <p>Noted.</p>
<p>14 Hakan Bilal Chiropractor Director GHEKO Holdings Pty Ltd</p>	<ul style="list-style-type: none"> I am a registered and practicing Chiropractor of some 10 years. I am also Director of a dedicated chiropractic radiology reporting service and find that your Draft Code impacts on all of my businesses. Whilst I support a national code of practice (certainly the varied or non-existent legislation and standards across States is a barrier to the conduct of my clinical chiropractic business and to the reporting business), it is important that the code is not restrictive in its application against other health professionals legitimately using ionising radiation to manage patient well being, when this application of radiation is within the training of the health professional and within normal clinical management practice. Chiropractors are trained in radiation hygiene, are trained in image interpretation and are trained in clinical evaluation of the need for x-ray examination. Chiropractors using x-ray facilities are under licencing and registration controls in each State or Territory and within the specialised range of examinations conducted, they are often producing x-rays of superior clinical value than those produced by the average radiographer. This is one reason that many chiropractors choose to perform their own examination, others include the lack of local radiology resources and the restricted access to local radiology resources where the extended hours of service provided by Chiropractors is not matched and this can lead to delayed treatment of the patient. Your Draft Code imposes many restrictions that arise from the false assumption that the radiologist is the sole person who can be assumed capable of accepting responsibility for the conduct of an x-ray examination. Your assumption is that by putting the responsibility for the 	<p>The Radiation Health Committee has decided that the Code will only apply to medical practices. A separate Code may be developed in the future for Chiropractic X-ray procedures.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>prescription into the hands of the radiologist that overall does from ionising radiation will be minimised and certainly this is the opposite of the reality within the Chiropractic profession. Chiropractors as the initiator of the examination have struggled to get radiology clinics to only perform the requested AP and Lateral projections for the indicated body regions. Radiologists on the large continue for example to have oblique and functional views performed within the cervical spine series, despite chiropractors specifying fewer views. I need not remind you of the radio-sensitivity of the thyroid and salivary glands. Similarly the patient posture at the time of exposure will greatly influence Chiropractic postural interpretation and therefore clinical management and often radiological needs are at odds with chiropractic needs resulting in additional views within radiology (eg the obsession with disc height demonstration), or the need to request the examination be repeated with due attention to posture.</p> <ul style="list-style-type: none"> • From the perspective of the dedicated Chiropractic Radiology reporting business that I operate, my clients enjoy the support of specialist radiological opinion of the films that have been produced. I do not deny that the specialist pathology based opinion provided by radiologists is highly valued by Chiropractors and the growth of this service is strong testament to the desirability of that report. Our company has specialist personnel to manage the quality activities of the operation, the safety of patients, their carers and operators, the exposure of patients, their carers and operators. All aspects of the service are managed along the model of a general radiology service, but our emphasis is on the chiropractic needs. Within this model the radiologists do not determine the views performed, the techniques for acquiring those views, nor the exposure parameters applied. The specifics of view and techniques are determined in consultation with client Chiropractor to ensure that the special needs of the model or discipline of chiropractic practice prescribed to by the chiropractor are met. There is no single model of chiropractic practice. Exposure selection is also left to the training and skills of the individual chiropractor with due consideration to patient age, the region being examined, the use of compensation filters, patient frailty and much more. My company also conducts regular seminars where issues of quality are uppermost, including exposure selection, equipment maintenance and radiation safety. 	

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> The service provided by my company is tele-radiology based with radiologists widespread across Australia. The management of the operation is centralised and is the responsibility of the Chief Operations Officer (C.O.O.). The responsibility of risk management and minimisation of exposure are the responsibility of the C.O.O. and all policies for the prescription of ionising radiation are managed at this level, just as “Chief Radiographers” across the country manage this function. This function is not independent of radiologists, but in consultation with radiologists. Indeed the radiologists have significant power with ultimate decision to decline to report on any images of undiagnostic value and any such events are flagged for immediate remedial action. Due to time restraints (unfortunately my attention has only recently been brought to the existence of this Draft Code), I have not provided detailed response to the document. I assure you that when general public response is requested that a detailed submission will be made. As you see the major concerns I have arise from Section 3 of the document. The basic premise of this code that the medical practitioner [as defined] is “responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation” is appropriate, is out of touch with the widespread dispensing practices (of ionising radiation) and unworkable within the field of Chiropractic, Dental/Orthodontic, radiographer run Radiology practice or alike. 	
<p>15 Leo J Klein. MIR. Director Newcastle Xray</p>	<ul style="list-style-type: none"> I write with concern on the level of understanding of the Radiation Health Committee, or their consultants, in their interpretation of the delivery of General Diagnostic Radiology in day to day private practice. I write to you as a Diagnostic Radiographer, who has for the past twelve years owned and operated a Radiology Practice in Newcastle. I qualified in 1970 in Victoria and have worked in major teaching Hospitals in Victoria, Queensland and New South Wales. I have held senior positions in Private Radiology Practices and since 1992 owned and operated Newcastle Xray. The practice has 15 employees and works with four Consultant Radiologists. Medical Applications of Ionizing Radiation in the “practical world” does not only come under the direction of a medical practitioner. 	<p>Noted All points to be considered in the cost-benefit analysis.</p> <p>Noted</p> <p>Noted</p>

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> • Do you really think that the doctor at a Radiology practice, [if there is one present,] checks the request forms, speaks to the patient, justifies the request, sets the exposure to the ALARA principles ?. • If this is what your consultants think happens, then you really need to get new consultants. • There are chiropractors, dental nurses, remote nurses, but close to 90% of diagnostic examinations would be performed by Radiographers who have University, Bachelor of Science Degrees in Medical Radiation. To call us “Operators” that can only work under the direction of a “Medical Practitioner”, is a professional insult and a severe restriction to our ability to trade. The ACCC has very clear guidelines on such matters. • Over the past 10 years both the Institute of Radiography and the Universities and developed programs and courses that create greater role development and career structures for Radiographers. The ever increasing lists of Imaging modalities and equipment, that Radiographers now are required to study and master, has created the need to specialize in selected modalities. General Radiography, CT Scanning, MRI Scanning, Mammography or Breast Imaging, Medical Radiation Therapy, Dental Cone-Beam Imaging, PET Imaging, and the many specialties of Ultrasound are well outside the scope of your definition of an “Operator”. • There are over 30 Diagnostic Radiology practices around Australia that are owned and operated by Radiographers. They are well operated by qualified professional experienced Radiographers, the patients are referred to them by qualified practitioners and the films are reported by qualified Radiologists. • In your “code of practice” you infer that a “medical practitioner” would be available at each centre that was using ionizing radiation, and that only they could be responsible for the examination. In many practices, the Radiologist reporting the films could be hundreds of kilometers away, or even interstate. There are more Radiology Practices in Australia than Radiologists, so the responsibility of the day to day operations of such practices is in the hands of the Radiographers. They do not need a 	<p>Comment noted. The revised version of the Code permits the operator to work in accordance with written guidelines.</p> <p>Noted.</p> <p>Noted. Many different people will be delivering radiation doses under this Code, and the term “operator” definitely does not diminish the key radiation protection role that this person has. The radiographer is not working under the direction of a medical practitioner, but that approval of a radiation procedure requires justification and optimisation, which require medical review of the benefits. The Code allows this to be in the form of standard protocols in addition to individual scripts issued by a medical practitioner.</p> <p>Noted. “Operator” covers the administering of radiation to a patient and does not necessarily exclude the other modalities listed.</p> <p>The revised version of the Code addresses the remaining points.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Radiologists to supervise their every move or decision.</p> <ul style="list-style-type: none"> The role of the Radiographer in the management, application and delivery of Ionizing Radiation in small private practices includes all of the points noted in your “Code of Practice”. To believe that only “medical practitioners “have the qualifications and ability to run a Diagnostic General X-ray Practice is not only false, but demeaning and breaks down the working relationship between the Radiologists and Radiographers. Radiologists cannot work without the support of the Radiographers and Radiographers cannot work without the support of the Radiologists. Together they provide a Medical Imaging Service. 	
<p>16 Trevor Jones A/Manager Hazardous Materials and Radiation for Radiation Advisory Council – NSW</p>	<ul style="list-style-type: none"> The RAC feels that the release of the draft code has been premature. Better evaluation could have taken place had the safety guides for each area of speciality been also available. Clause 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. Clause 2.1.1: The word "patient" should be changed to “individual" as it encompasses a wider range of activities. Not all people having procedures are patients. Eg research. 3.1, page 26 (Glossary): There is no mention of delegation by the Responsible Person of any responsibilities within Clause 3. Is this inherent in the definition? This needs to be clarified. 3.1.2 (a) There is a need for the term "dealings" to be defined in the glossary 3.1.3 (c) Query of the term “all reasonable attempts". The term needs further clarification. 3.1.3 (c)(i), 3.1.12, A2.1 (d), B2.1: The radiation dose of 0.3 mSv is queried. This is thought to be too low. Should be 1 mSv. 	<p>Noted.</p> <p>This is a quote and therefore needs to remain.</p> <p>Done.</p> <p>It is entirely up to the RP whether they want to delegate a task. The RP must maintain the legal responsibility.</p> <p>“dealings” has been deleted.</p> <p>Deleted.</p> <p>0.3 mSv has either been changed to 1 mSv or deleted</p>

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> • 3.1.3 (c)(ii)(b): Why has breast dose from nuclear medicine procedures during breast feeding been singled out? Surely breast dose during chest CT is equally important, but is not referred to in the Code. This issue would be better addressed in the Safety Guides. There is also no definition as to what is a " significant dose". • 3.1.5(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 to regulate without a specific process in place. • 3.1.5: The term "to a patient for diagnostic purposes is" should be replaced with "t o patients for diagnostic purposes are: " Presumably this will be compared for a group of patients, not for a single patient. • 3.1.8: This dose limit is endorsed and its use is recommended elsewhere in the Code for embryo dose limit. • 3.1.9(b): This sub clause is inconsistent with NSW Regulation. Including "or as required by the local regulatory authority" would give greater consistency. • 3.1.10(b): The investigation being referred in this clause needs to be clarified i.e. 3.1.9(a) • 3.1.14: It is suggested that the term "adequate" be expanded to specify that a shielding plan that meets the requirements of the radiation management plan is to be prepared by a suitably qualified person. • 3.1.15(c): This requirement should also be for fluoroscopy and computed tomography. • 3.1.18(b): The correct word to use is "inform" and not "advise" • 3.1.22: The code should set the minimum calibration frequency. This could be either annually or according to manufacturer's advice. 	<p>altogether. This is to raise awareness for the possibility of high doses to the breast due to the production of milk that could contain the radiopharmaceutical.</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>Noted but disagreed.</p> <p>Noted.</p> <p>Noted. RHC has previously agreed not to include such discretionary statements in Codes.</p> <p>Done.</p> <p>Noted. The RP will decide who will do that.</p> <p>Done.</p> <p>Noted.</p> <p>The calibration will only hold for as long as defined.</p>

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> • 3.1.23(a): It is suggested that the word "involved" be replaced with the word "available" to provide certainty to their role. • 3.1.28: The wording in this clause should indicate that the survey be carried out by a qualified person and that the results of the survey confirm that the integrity of the shielding is intact and that the safety of patients, staff and public is maintained. • 3.2.1: It may not always be a medical practitioner who has responsibility for a procedure involving radiation. Eg Chiropractic procedures. • 3.2.3(c): It is noted that the weighing up of net benefits of the medical radiation procedure with benefits to society generally would usually arise for activities for research purposes. It is suggested that this be clarified in the code b a separate point. • 3.2.4: Medical practitioners do not always approve an exposure. A procedure may be preformed prior to the medical practitioner seeing the request. Eg. radiographers do not seek approval prior to performing a general x-ray. • 3.2.10: NSW Health policy is to require written consent. It is felt that this should also be include in this clause • 3.2.11: What are all reasonable steps to determine if patient is pregnant? • 3.2.12: It seems inconsistent to use the dose of 0.3 mSv at 3.2.11, but 1 mSv for therapeutic nuclear medicine treatment at 3.2.12. It is suggested that a period of 10 day abstinence prior to biochemical testing for pregnancy be used for therapeutic nuclear medicine procedures. • 3.3.4: Medical practitioners may not always issue formal directions e.g. a request by a physiotherapist. Approval of an exposure may not take place as radiographers do not seek approval prior to performing a general x-ray. • 3.3.5(a): There is a need to clarify what is meant by the term "all reasonable" in relation to the steps that must be taken in correctly identifying a patient. 	<p>Noted. No change considered necessary.</p> <p>“a radiation survey is carried out by a qualified expert” has been added to the clause.</p> <p>It is under this Code.</p> <p>Noted.</p> <p>The medical practitioner (radiation) will need to approve a procedure, either directly or generically.</p> <p>Noted, but not included.</p> <p>This will depend on the magnitude of the exposure.</p> <p>Both are now 1 mSv.</p> <p>Noted.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> • 3.3.8(b): This part could be clarified for nuclear medicine procedures which are much longer in duration. Visual surveillance throughout a procedure is impractical. Although a technologist will be present throughout the procedure he/she will often be processing other studies while the scan is in progress and not directly observing the patient. • Al. 1(b)(ii): Dose constraint for public is too low. A value of 1 mSv per annum is recommended. • Al. 1(e): The term "observation" may place too heavy an onus on operator. The RAC suggests that the term "monitoring" might be more appropriate. • Al.1(f): Add " licensing and registration " to this sub clause • A2.1(f): It is suggested that the term " authority" be replaced with the plural "authorities" as this will often involve additional authorities such as water utilities or environment agencies. • C1.3: It is questioned why only gallium-67 has been singled out. For example, an I-131 diagnostic scan will also require the patient to cease breast-feeding. It is suggested that the term "gallium-67" be removed and instead just leave the term "diagnostic radiopharmaceutical " • C2.2: The length of time a patient can hold a child will depend on the dose limit set for the child. It is suggested that this dose limit be set at 1 mSv. • Glossary: The definition of "radiology" should be expanded. • Glossary: Responsible Person: In NSW sources, apparatus and premises are registered in a company name not in the name of a "legal person", whereas parts (a) and (b) would equate to a legal person". It is not clear from the definition whether a legal person equates to a natural person or also encompasses other entities such as a company. If it is a natural person then this is not sufficient to have the responsibilities specified in (a), (b) and (c). 	<p>Changed to "ensure that visual surveillance of the imaging or treatment room is maintained throughout an imaging or radiotherapy procedure."</p> <p>Removed.</p> <p>This is a component of the RMP and will be as involved as necessary contingent on the procedures carried out.</p> <p>Licensing is covered within the body of the Code.</p> <p>This Code is to be applied only by an rra. Other authorities could have their own requirements.</p> <p>Gone to Safety Guide.</p> <p>Gone to Safety Guide.</p> <p>Agreed.</p> <p>Clarifying footnote added.</p>
<p>17 Dr Howell Round</p>	<p>Collated Comments and Suggestions from the Specialty Groups and Members of the Australasian College of Physical Scientists in Medicine</p>	

SUBMITTER	COMMENT	RESPONSE
<p>President ACPSEM</p>	<p><u>General Comments</u></p> <ul style="list-style-type: none"> • The current medical paradigm is moving swiftly towards an evidence based approach rather than handed down knowledge and supposition. It would seem appropriate that we follow a similar approach with ionising radiations. In this light, the suggested 0.3 mSv constraints would appear to be tenuous at best and unsupportable from an evidence based position. • We are concerned that this draft code has been released for comment without the associated safety guides. It is difficult to provide comprehensive comment without the corresponding guides and both should have been released simultaneously. • Dose constraints should not be specified in the code. Otherwise it is likely that they will become de facto limits. Further it is likely that they will become retrospectively applied given that some states (eg. Qld) work with performance based radiation safety standards (rather than design based) and that these do not discriminate between existing and new facilities. There is significant concern regarding the cost impact of these (effectively) lower dose constraints. A rational justification for the 0.3mSv dose constraint has not been provided. We consider that it will increase facility costs without any measurable gain in safety. Australia should not be going down this path without a thorough economic impact assessment and would be wise to follow the lead of NCRP (refer NCRP Report No. 147, 2004) in this regard, which considered the introduction of a 0.3mSv constraint (which will inevitably become a limit) as unjustifiable. A1.1 (b) should be amended back to the 1mSv level for members of the public. • Imaging equipment can be employed by clinicians other than radiologists for purposes other than diagnosis. Although allusions are made in the glossary to Medical Practitioners being clinicians other than radiologists, in most of these instances the operationally guided nature of the way they operate does not neatly fit with the descriptions of the way the code describes their relationship. For example, it is not uncommon for both a radiographer (digital acquisition) and cardiologist (fluoroscopy) to be involved in the direct administration of radiation to a patient during procedures. 	<p>All 0.3 mSv references have either been changed to 1 mSv or deleted.</p> <p>Noted.</p> <p>Agreed, these have been removed to the Safety Guides.</p> <p>Noted. The imaging equipment in interventional radiology is actually a diagnostic tool and not the actual therapeutic agent. The definition of “interventional radiology” in the Code has been clarified.</p>

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> The use of dose constraints should be used in the Safety Guides. Only ICRP MPE' should be referred to in the CoP as limits. Otherwise dose constraints will become de-facto limits. The 1 mSv dose constraint for members of the public and non-occupationally exposed staff (note, also, that there is a difference between the two groups) should be adhered to. The use of 0.3 mSv is a suggestion for taking into account exposures from multiple sources where this is necessary, <u>but was never intended to be applied as a global dose constraint</u>. The ICRP, in the latest version of its new draft recommendations, states: <i>Dose constraints in public exposure</i> (216) <i>In planned situations, the Commission continues to recommend that public exposure be controlled by the procedures of optimisation below the source-related dose constraint and by the use of dose limits. In general, especially for public exposure, each source will cause a distribution of doses over many individuals, so the concept of a representative individual should be used to represent the most highly exposed individuals. This concept replaces the critical group concept previously used by the Commission (see Section 5.4.3). The dose constraint should be applied to the dose to the representative individual from the source for which the protection is being optimised. Occasionally, the representative individual will receive doses from other sources subject to regulatory control. If the relevant exposures to the representative individual are likely to approach the dose limit for public exposure (see Section 5.9), the constraints applied to each source must be selected to account for any significant contribution from other relevant sources to the exposure of the representative individual. The constraints for members of the public in planned situations should be smaller than the public dose limit.</i> Undoubtedly, in some situations, exposure from multiple sources will have to be taken into consideration. A clause may have to be inserted in the CoP to cover this; for example: <i>If the relevant exposures to the representative individual are likely to approach the dose limit for public exposure, the constraints applied to each source must be selected to account for any significant contribution from other relevant sources to the exposure of the representative individual.</i> The application of this, where it is necessary, can be dealt with in the relevant Safety Guide. 	<p>Dose constraints now in the Safety Guides.</p>

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> The dose of 0.3 mSv is going to become a default dose limit for general public since the intention of this document is to establish regulatory requirements for the use of ionising radiation in medicine for the purpose of being adopted by State, Territory and Commonwealth Regulatory Authorities as part of their radiation protection legislation. This document will also be used by accreditation agents for accreditation of medical imaging practices in Australia. Thus, it is very important that it becomes a good and practical radiation safety working document for medical imaging practices. <p>The dose of 0.3 mSv is too low to be a limit. This dose is on average what individuals get from ingestion with the majority of the dose being internal to our bodies from K-40 (UNSCEAR 2000).</p> <p>The dose limit of 0.3 mSv for the embryo/foetus is going to be a big problem because there are no dosimetry models for the different stage of pregnancy for x-rays that permit with reasonable accuracy to estimate the dose to the embryo/foetus. All the dosimetry models are for non pregnant females. Only in Nuclear medicine there is the Olinda program that incorporates pregnant phantoms of 3, 6 and 9 months gestation. For these limits to be applicable in radiology, in the guidelines, the examinations that the pregnancy status of female patients must be ascertained must be stated and doses for the different stage of pregnancy provided. Female patient should be treated as per ICRP latest draft 2005 Recommendations.</p> <p>Even for shielding the dose of 0.3 mSv is too low. It should be left to 1 mSv. The extra cost of shielding rooms unnecessarily could be used for patient care.</p> <p>There is a need to conduct an ALARA impact study on this document taking into account the economical and social factors in consideration. This document seems to have forgotten about the economical and social factors incorporated in the definition of ALARA. Radiation protection needs to be realistic corresponding to a realistic radiation risk and not just to increase the paper mountain of our modern society.</p> <p>In addition, the Safety Guides mentioned in lines 37 – 39, p. 3, must be made available with this document for interested stakeholders to have an appreciation of the implication of this document on the workflow and associated costs of their medical imaging practices. The release of this document for comments without the Safety Guides is a repetition of what happened when ICRP released its 2005 Recommendation for comments without the associated guidelines/explanatory documents.</p>	<p>3 mSv now changed to 1 mSv or deleted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Document seems to be a copy of the ICRP revised 2005 recommendations of application of medical radiation except that this document has more stringent conditions. Does this document include radiography conducted by chiropractors and dentists?</p> <p>There are two major concerns about this document. First, the 0.3 mSv limit to embryo/foetus and the methods to determine this dose. No information is given on what dosimetric model and data set is to be used for this calculation. Second, patient doses need to be estimated. Again, what dosimetric model and data set are to be used. For CT, different CT dose calculation programs give different results. For children dosimetric data is very limited, particularly for CT. Will this information be given in the Safety Guide documents. For nuclear medicine the data set to use must also be specified. This need to be done as the aim of this document is to be incorporated in radiation protection legislations. Depending which data set or program is used, you get different result.</p> <p>For shielding, has anyone done calculation of what is the risk reduction going from 1 mSv/y to 0.3 mSv/y for the general public versus the cost of the extra shielding that in the end the community has to pay. Has anyone done a cost benefit analysis on the implications of this document. In the application of ALARA need to take in consideration the economical and social factors too not just the reduction of dose. Eventually, the community will have to pay for any dose reduction from the present radiation protection standards.</p> <ul style="list-style-type: none"> • If draft dose constraints are used in CoP will they become retrospective? If that is not envisaged how can they ensure that they will not be so in the future? <p>As a general comment (and this will probably go down like a lead balloon), should we perhaps be considering the expectation value for the dose, as well as the maximum, when it comes to a dose constraint for stochastic effects? In real life, there will often be a fair degree of uncertainty with regard to the dose. For example, if we may know that the dose to a person or group from a given procedure or operation will be (say) between 1 ± 0.8 (SD) mSv. The actual radiation risk is a statistical parameter which will be related to the <u>mean or expectation value of the dose</u>, and not the maximum. If we <u>have</u> to use a maximum, what should it be:</p> <ul style="list-style-type: none"> -the 95th percentile value (about 2.6 mSv in this example)? -the maximum ever measured for this procedure or operation? -something else? 	<p>A cost-benefit analysis will be performed on the whole Code.</p> <p>Dose constraints moved to Safety Guides.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Although this may seem pedantic, there are cases where there is a substantial difference between the mean and maximum dose (e.g in the calculated dose from therapy patients with unsealed radionuclides “on board”) and the choice of which should be used can have a substantial impact (for example, on the time for which restrictions on close contact need to be applied).</p> <p>Avoid the use of phrases such as: “construction and shielding of the medical practice so that: i) a dose constraint of not more than 5 mSv per annum is applied for occupationally exposed persons;” The use of “per annum”, as this implies a dose rate rather than the integrated dose over one year. Dose <u>rates</u> in medical imaging can be of the order of tens of Sieverts per annum over short periods of time. Substitute “distance” for “dose”, “km” for “mSv” and “hour” for “annum” above and you’ll see how ridiculous it sounds! Suggest that such phrases are replaced with something like: “construction and shielding of the medical practice so that: ii) occupationally exposed persons do not accrue an effective dose of more than 5 mSv in any 2000 hour period from occupational exposure;” The nexus between the responsible person and the qualified expert needs to be clearly established. My reading of the situation is that the responsible person will be the managerial figurehead with whom “the buck stops”, and who may know bugger all about the mechanics of radiation safety and medical radiation physics. The qualified expert or experts will do all of the actual work and administration related to radiation safety and quality control.</p> <ul style="list-style-type: none"> • It is necessary that the code better specify and define what is meant by “Medical practitioner” – especially within radiology. In some circumstances it is not clear whether the code is referring to one Medical Practitioner (which one?), or all Medical Practitioners within a department (for example 3.3.11 (b) (i) line 545), or whether the term could include referring doctors (for example 3.2.4 line 362). For interventional procedures it should be made clear that the Medical Practitioner is the person undertaking the procedure. For routine radiology there should be a specified medical practitioner (i.e. radiologist) charged with the responsibility for each area of investigation. It is not practical to assume that all radiologists in a radiology practice take this responsibility since many will simply read films, possibly at a site remote from the 	<p>Correct interpretation.</p> <p>Definition of medical practitioner changed to medical practitioner (radiation).</p>

SUBMITTER	COMMENT	RESPONSE
	<p>practice. In addition, the definition may not be sufficiently precise to unambiguously identify the appropriate person, should legal action be required.</p> <p><u>Specific Comments</u></p> <p>Page 2, Clause 1.2, Lines 15-17</p> <p>Who is the “Responsible Person” in a hospital?. After several enquiries on my part, it seems it’s definitely not the RSO, or the director of a dept. Maybe it’s the CEO? After several enquiries, the best answer I have received (from Noel Cleave, DHS) is that for an organization, the “Responsible Person” is not any one individual, but the hospital as a legal entity is “responsible”. Whatever the correct interpretation, it would certainly help if the definition made it quite clear.</p> <p>Page 3, Clause 1.3, Lines 35-39</p> <p>It would be much better if the 3 safety guides were available for review at the same time as the code of practice. It’s hard to comment on the code without knowing what’s in the safety guides.</p> <p>Page 3, Clause 1.4, Line 41</p> <p>Not everything in the code is or should be a regulatory requirement. Some things would be more appropriate in a guide.</p> <p>Page 4, Clause 2.2.2</p> <p>The terms diagnostic and therapeutic as used in this clause (and throughout the document) seem to ignore that some procedures undertaken using imaging equipment do not use the imaging process for diagnosis but as a tool for a therapeutic intervention. Examples include PTCA, PTA, EP ablation procedures and cardiac device implants (PPM, ICD, etc).</p> <p>Page 4, Clause 2.2.3</p> <p>It would be helpful to have an overt statement in the Code to deal with circumstances where a procedure involving ionising radiation is required to deal with a potentially life threatening situation with the mother. Such circumstances may arise where cardiac EP or device implant procedures are</p>	<p>The definition of a Responsible Person has been amended to explain what a “legal person” is. This should clarify the issue.</p> <p>Noted.</p> <p>Noted. Regulatory requirements will be in the Code, other material in the Safety Guide.</p> <p>Noted. The imaging equipment in therapeutic intervention is actually a diagnostic tool and not the actual therapeutic agent.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>required to deal with life threatening arrhythmias in pregnant women. This is dealt with under schedule B but not referenced in this clause.</p> <p>Page 5, Clause 3.1.1</p> <p>With reference to (e.g.) a situation where a nuclear medicine service is an independently operated resident of hospital or clinic and delivers service to patients that may be inpatients of the facility: The responsible person may not be linked to the facility by anything other than a lease agreement for space. Under whose responsibility does it lie for dealing with situations relating to ‘hot’ patients while they are under the care of the hospital? The issue here is that the responsible person for the nuclear medicine practice may not have any legitimate authority outside the nuclear medicine department (to deal with spills or waste). This has implications for 3.1.9 and 3.1.10 as well. The question here is which responsible person has responsibility (the host facility or the imaging practice). For 3.1.10 (b) to be effective the responsible person may need to have authority to implement change in the host facility. Under 3.1.13, with a resident imaging service, does this imply that they run education programs for the host facility?</p> <p>Page 5, Clause 3.1.2</p> <p>The waste management plan should be a component of the radiation management plan.</p> <p>Page 5, Clause 3.1.2(a), Line 107</p> <p>“Dealings” should be defined in the Glossary. It is a term that is used in the ARPANSA regulations but is not a term in common use.</p> <p>Page 5, Clause 3.1.3</p> <p>Here and elsewhere there are references to the Responsible Person “ensuring” safe practice. Perhaps these should read “take reasonable steps to ensure that ...” As another example section 3.1.9 requires the responsible person to investigate radiation incidents – which of course they would not personally, do, particularly in a large organization.</p> <p>Page 5, Clause 3.1.3(b), Lines 116-120</p>	<p>The Responsible Person for the nuclear medicine facility.</p> <p>Change effected.</p> <p>Dealings has been deleted.</p> <p>Change effected.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Puts responsibility on the radiologist, and probably the Head of Radiology for every radiographic/radiological procedure. That person needs to approve each procedure, directly or through written guidelines. How is this going to improve radiation safety for the patients? It will only increase the workload of the radiologists.</p> <p>Page 5, Clause 3.1.3(c) (i)</p> <p>The use of a 0.3mSv action level is introduced for the dose to the unborn child. It asks for “all reasonable attempts” to be made to establish whether such a dose is possible for a female patient. It is difficult to accurately determine doses to the unborn child due to a lack of published data. This is especially true at the 0.3mSv level. The proposal under Schedule B 1.3 and B2.2 which requires patient counselling if the 0.3mSv level, should be amended to 1mSv. The lower threshold would cause considerable unnecessary anxiety amongst parents when there is no demonstrably greater risk than at the 1mSv level.</p> <p>Page 5, Clause 3.1.3(c), Lines 121-124</p> <p>Female patients. Need to establish pregnancy status if dose to embryo/foetus > 0.3 mSv. Does it mean that every women of child bearing age need to be seen by a radiologist? How would a radiologist know that the dose is going to be > 0.3 mSv for the different stage of gestation, particularly, for fluoroscopy?</p> <p><i>The latest draft ICRP Recommendations does not make any reference to 0.3 mSv to the embryo/foetus. For x-ray procedures it is very difficult to calculate dose to embryo/foetus because there are no dosimetry models for calculating dose to embryo/foetus at different stages of pregnancy. All the models calculate dose to the un-pregnant uterus and not pregnant one. For Nuclear Medicine, the Olinda program can be used to calculate doses to embryo/foetus at 3, 6 and 9 months of gestation.</i></p> <p>A dose limit does not apply to medical use of radiation!!! - and it should not apply to embryo/foetus as the unborn child still gets a benefit from an x-ray procedure – even though indirectly through the mother– since if the mother is well, the unborn child has a better chance of survive than if she was not well.</p> <p>Page 5, Clause 3.1.3, Lines 121-129</p> <p>Clause (c) implies that it is sufficient to merely establish whether the patient is</p>	<p>Change made to this clause allowing generic approvals.</p> <p>0.3 mSv has been removed.</p> <p>0.3 mSv has been removed.</p> <p>This is now part of a “protocol” that the RP needs top</p>

SUBMITTER	COMMENT	RESPONSE
	<p>pregnant or breast-feeding to justify a procedure. Together with 3.2.3, it sort of makes sense, but since 3.2.11-3.2.16 specifically covers this, maybe there is no need to refer to it at all here, i.e. (c) could be deleted.</p> <p>Page 5, Line 124</p> <p>There should be no dose limit if it is a medical procedure for the mother. However, advice must be available for the medical practitioner, radiographer, etc. to explain possible radiation risk (as it is done now at the Alfred), and without having the medical physicist calculate each and every dose to the foetus. ICRP does not specify dose limit to foetus for medical exposure of mother. To my knowledge there is no evidence for increased untoward effects for foetal doses up to 100 mSv.</p> <p>Page 5, Clause 3.1.3(c) (ii), Lines 128-129</p> <p>Use of the word significant in the phrase “significant radiation dose to breast glandular tissue” seems a little vague. The dose considered significant will undoubtedly differ between people. Could a specific absorbed dose threshold be specified instead?</p> <p>Page 5, Clause 3.1.3(c)</p> <p>Some redundancy here – this would be (and is currently) established for <u>ALL</u> female patients. Change to</p> <p>(c) in the case of a female patient, all reasonable attempts have been made to establish; (i) the pregnancy status of the patient; and (ii) where a radiopharmaceutical is to be administered, the breast feeding status and the radiation dose to the breast glandular tissue of the patient.</p> <p>Page 5, Clause 3.1.3(c) (i), Line 124 and other references [Clause 3.1.12 Line 186, Clause 3.2.3 (e) Line 347, Clause 3.2.11 Line 414, Clause 3.3.6 (a) Line 500, Schedule B]</p> <p>Determining the potential dose to the location of a potential foetus could be very difficult. It may be suitable for nuclear medicine and radiotherapy, but it may not be suitable for radiology. For radiology, an alternative condition could be whether the primary beam is within a defined distance from the uterus.</p>	<p>establish.</p> <p>The dose levels have been removed.</p> <p>Clause has been removed.</p> <p>Clause amended.</p> <p>Clause amended.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 6, Clause 3.1.5</p> <p>It seems here that under (a) the onus for recording the radiation dose information lies with the medical practitioner and that the responsible person has the role of ensuring compliance with this requirement. This seems inconsistent as the information recorded may not be readily accessible by the responsible person which may hinder their ability to perform (b) or (c). It would be much more practical to make the responsible person responsible for recording the information and controlling the process of audit and review. Attention is drawn to the American College of Radiology standard for diagnostic medical physics performance monitoring of radiographic and fluoroscopic equipment which stipulates that: “Patient radiation doses shall be evaluated for radiographic and fluoroscopic equipment¹ at least annually. Tables of patient radiation exposure for representative examinations shall be prepared and supplied to the facility. These tables shall be prepared using measured radiation output data and imaging techniques provided by the facility”. It is also suggested that guidance be provided on what constitutes sufficient recording of radiation information. Reference is made to the work by Miller et al² where definite guidelines are provided.</p> <p>¹ American College of Radiology. ACR standard for diagnostic medical physics performance monitoring of radiographic and fluoroscopic equipment. In: Standards. Reston, VA: American College of Radiology, 1999 :167–169</p> <p>² Miller DL, Balter S, Wagner LK, Cardella J, Clark TW, Neithamer CD Jr, et al; SIR Standards of Practice Committee. Quality improvement guidelines for recording patient radiation dose in the medical record. J Vasc Interv Radiol. 2004 May;15(5):423-9.</p> <p>Page 6, Clause 3.1.5, Lines 135-141</p> <p>Does it mean that a dose needs to be calculated for every patient? Also, it is not clear whether it is absorbed skin dose, effective or dose area product (DAP). Calculation of effective dose for fluoroscopy is going to be difficult because you do not know which organs/tissues are being irradiated unless the images are examined. Also, need to record exposure factors for general radiography and DLP values in CT for every patient. Need a number of physicists to do all the dose calculations, particularly for paediatric patients</p>	<p>Clause has been changed to cover diagnostic procedures for which DRLs have been established in Australia.</p> <p>Clause has been changed to cover diagnostic procedures for which DRLs have been established in Australia.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>since the data the dosimetric data is scarce and what is available is old.</p> <p>This would also require an increase in radiographic staff level in order to record all this dose data.</p> <p>Page 6, Clause 3.1.5(a), Line 137</p> <p>This regulation will be a significant burden for radiology. Many additional parameters will need to be recorded by the operator.</p> <p>Page 6, Line 138</p> <p>No reference for the DRL's. Will these be given in the Radiation Safety Guide?</p> <p>Page 6, Clause 3.1.5</p> <p>Financial cost of implementation?</p> <p>Page 6, Clause 3.1.5(c), Line 141</p> <p>Clarify to mean 'consistently exceeded' because DRLs can be exceeded on a case by case basis.</p> <p>Page 6, Clause 3.1.7</p> <p>There is general concern and opposition to the specification of trigger points/constraints etc that may be adopted as de facto limits.</p> <p>Page 6, Clause 3.1.7(a), Lines 147-151</p> <p>If this clause on personal monitoring is accepted, there is no need to monitor radiographers, nurses and radiologists as they all get less than 1 mSv/y.</p> <p>Page 6, Clause 3.1.7(a), Line 150</p> <p>Change the word "could" to "is likely to" to bring into line with the ICRP 75 para (209) recommendation on who is required to be monitored.</p> <p>Page 6, Clause 3.1.7(b), Line 152</p> <p>The meanings of "internal radiation dose assessments" and "biological monitoring" may not be clear, and may not be referred to in the National</p>	<p>Clause amended to put the onus on the RP to ensure that appropriate records are kept.</p> <p>The DRLs will be given in another document.</p> <p>Noted.</p> <p>Change effected.</p> <p>Noted.</p> <p>Change made to "is likely to". They will now be covered.</p> <p>Change effected.</p> <p>Noted. These will be in future editions of the NDRP.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Directory for Radiation Protection.</p> <p>Page 6, Lines 152-154</p> <p>The detailed method of internal radiation dose assessments and biological monitoring does not appear to be in the <i>National Directory for Radiation Protection</i>.</p> <p>Page 6, Clause 3.1.7(d) (ii)</p> <p>And? Recorded? – how, actioned? – how? Does 5 mSv become a de-facto limit?</p> <p>Page 6, Clause 3.1.8, Lines 162-165</p> <p>There is a degree of uncertainty in this statement as the duration of a pregnancy is not the same as the dose limit period specified in RPS1. A statement in line with ICRP 75 3.3.6 para (124) is recommended. This states that the working conditions once the pregnancy has been declared and notified to the employer should make it unlikely that the additional equivalent dose to the conceptus will exceed about 1mSv during the remainder of the pregnancy. To confuse matters further, ICRP84 in its summary Recommendations para (164) states that Pregnant medical radiation workers may work in a radiation environment as long as there is a reasonable assurance that the fetal dose can be kept below 1 mGy during the course of the pregnancy.</p> <p>Page 7, Line 169</p> <p>A dose limit of 1 mSv should be used for reporting notifiable radiation incidents to regulatory authority.</p> <p>Page 7, Clause 3.1.9(b), Line 171</p> <p>The specified period of 7 days may be incompatible with State legislation. In NSW, a radiation accident must be notified to the DECC within 2 days, with a final report within 10 days.</p> <p>Page 7, Clause 3.1.10(b), Line 178</p> <p>Is the investigation being referred to the one in 3.1.9(a), so “in (a)” should be “in 3.1.9(a)”?</p>	<p>Noted. These will be in future editions of the NDRP.</p> <p>Recording will be done by internal administrative methods. 5 mSv action level removed.</p> <p>Noted.</p> <p>Noted. A reportable radiation incident is defined in the glossary and, in turn, the NDRP.</p> <p>Noted.</p> <p>Change effected.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 7, Clause 3.1.11, Lines 183-184</p> <p>Isn't this the same as 3.1.9 (c)? Maybe not – perhaps the loss of a source doesn't in itself constitute a radiation incident.</p> <p>Page 7, Clause 3.1.12, Lines 186-188</p> <p>Why 0.3 mSv? How do you know when the embryo/foetus has received 0.3 mSv. If the dose needs to be calculated for the embryo/foetus, it may as well be for any exposure.</p> <p>Please note that according to ICRP (report 84 and later one) there are no lethal, malformation or mental retardation effects of radiation on the unborn child for doses below about 100 mSv. The only possible effect is the induction of cancer and the risk is the same as if the dose was received once born.</p> <p>Page 7, Clause 3.1.12</p> <p>How will we know? Who can do a dose calculation to an accuracy of 0.3 mSv – ridiculous requirement? Just change to: Where an embryo or fetus inadvertently receives a radiation dose, the Responsible Person must ensure that the requirements of section B2 of Schedule B are met and modify B2 appropriately (<i>ut infra</i>).</p> <p>Page 7, Clause 3.1.13</p> <p>Training of “all” occupationally exposed persons is not practical. As an example, a wards person who occasionally visits radiology or even ICU (mobile X-rays) will be occupationally exposed (a few microsieverts perhaps) but all such persons cannot practically be trained. This needs to be clarified. Perhaps it is just those persons who are users of radiation sources or who could reasonably be exposed to an effective dose in excess of 1 mSv per year that need to be trained.</p> <p>Page 7, Line 187</p> <p>There should be no dose limit if it is a medical procedure for the mother. However, advice must be available for the medical practitioner, radiographer,</p>	<p>Change effected.</p> <p>0.3 mSv references has been changed to 1 mSv.</p> <p>0.3 mSv references has been changed to 1 mSv. Section in Schedule B has been removed to the Safety Guide.</p> <p>The level of training is expected to be commensurate with the nature of the persons work.</p> <p>0.3 mSv changed to 1 mSv.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>etc. to explain possible radiation risk (as it is done now at the Alfred), and without having the medical physicist calculate each and every dose to the foetus. ICRP does not specify dose limit to foetus for medical exposure of mother. To my knowledge there is no evidence for increased untoward effects for foetal doses up to 100 mSv.</p> <p>Page 7, Clause 3.1.12, Line 188</p> <p>B2.1 of Schedule B uses the term “may be more than 0.3 mSv” – the same criteria should apply to 3.1.12.</p> <p>Page 7, Clause 3.1.14, Line 198</p> <p>The requirements for shielding are collected into one word adequate. Would it not be better to specify that a radiation shielding plan be prepared by a suitable qualified person that meets the requirements of the radiation management plan? Having just participated in the exercise of a developing a Shielding Guideline for NSW I do not believe the word adequate quite fits the bill.</p> <p>Page 8, Clause 3.1.15(b)</p> <p>What is a “general” access point? Further explanation or a definition is required.</p> <p>Page 8, Clause 3.1.15(c) (i) a., Line 220</p> <p>Add “fluoroscopy and computed tomography” after “radiotherapy”.</p> <p>Page 8, Clause 3.1.15(c)</p> <p>This section needs to be re-worded. The requirement for signage or otherwise outside CT and fluoroscopy facilities is not well explicated.</p> <p>Page 8, Clause 3.1.16</p> <p>The use of the term “dedicated” is ambiguous and could lead to a situation where a general x-ray system is “dedicated” to use exclusively for mammography (for example).</p> <p>Does this include cardiology (interventional and diagnostic) and electrophysiology? What about the situation where a “dedicated” system fails in the middle of an interventional procedure? Under these circumstances, the</p>	<p>Section B2 of Schedule has been removed to Safety Guide.</p> <p>Noted.</p> <p>“general” removed.</p> <p>Done.</p> <p>Done.</p> <p>Changed to “designed”.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>patient could be at extreme risk should attempts be made to move them or withdraw from the procedure without image guidance. The only viable option may be to use a mobile II to enable a safe withdrawal, however, the wording here implies that this would be a breach.</p> <p>Page 8, Clause 3.1.17, Lines 233-236</p> <ul style="list-style-type: none"> • <i>Performance Specifications:</i> There may be virtually no documentation on the oldest equipment (e.g. for legacy ²²⁶Ra sources the only thing known may be the activity). Technical reference manuals are more likely to be available than performance specifications for most equipment. • <i>Maintenance instructions:</i> The intended scope of this clause is not clearly defined. <ul style="list-style-type: none"> ○ If the intention is to ensure that routine daily maintenance is documented: e.g. the coolant level is checked/ topped up on the accelerator, the machine appropriately run up and machine parameter values logged each day then the I have no issues with the clause. ○ However if the intention is to ensure that comprehensive maintenance texts including troubleshooting trees are completely defined in writing, on site then I'm not as comfortable. Our equipment is partially supported by service contracts. Suppliers are typically only prepared to provide partial maintenance information to customers. Maintenance information available to us is therefore limited in scope and we escalate problems to the supplier where we don't have the resources (or the information) to resolve an issue in-house. <p>Page 8, Lines 241-242</p> <p>The draft code states: 3.1.18 The Responsible Person must: (b) advise the relevant regulatory authority of the receipt of each new radiation producing apparatus or sealed radioactive source.</p> <p>We need more clarity on this statement. For example I-125 seeds are sealed radioactive sources. If we are mandated to advice the regulatory authority whenever we receive sealed radioactive source that will create unnecessary paperwork.</p> <p>Page 8, Clause 3.1.18(a), Lines 241-242</p> <p>The onus placed on the Responsible Person to advise the relevant regulatory</p>	<p>This clause has been removed to the Safety Guides.</p> <p>Noted, the authorisation issued by the rra will outline the reporting requirements for such sources.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>authority of the receipt of each new radiation producing apparatus or sealed radioactive source may be interpreted in such as way that each individual radiation producing apparatus or sealed radioactive source must be reported where it is more practical to report batches of sealed radioactive sources, particularly when sealed radioactive source are used for permanent implants.</p> <p>Page 8, Clause 3.1.18(b), Line 242</p> <p>As written, this would require hospitals to notify regulatory bodies whenever a pot of iodine-125 seeds is delivered. The regulation is probably intended to refer to new types/categories of sealed sources, or something similar.</p> <p>Page 9, Clause 3.1.22, Line 257</p> <p>The Code should state the minimum calibration frequency (e.g. annually).</p> <p>Page 9, Clause 3.1.23(a), Line 270</p> <p>A qualified expert must also be involved in determining the methods and interpretation of radiation surveys undertaken.</p> <p>Page 9, Clause 3.1.23</p> <p>Especially in a larger institution, there may be more than one expert involved. Suggest changing “a qualified expert is involved” to “a qualified expert or experts are involved”.</p> <p>Need to make clear that each expert <u>must be provided</u> with the human and other resources they require to perform their function.</p> <p>In larger institutions the qualified expert may have to be appointed as a member of staff given the level of consultation and functions that will need to be performed (maybe this is something for the Safety Guide)</p> <p>This clause refers to the qualified expert (QE), however it does not mandate under ANY circumstances the requirement to access the qualified expert. This needs to be rectified by role definition expansion and reference to the QE in subsequent clauses as detailed below:</p> <p>The role of the qualified expert should be expanded to:</p> <ul style="list-style-type: none"> • <i>to carry out the physical measurements related to evaluation of the dose delivered to the patient and to take responsibility for dosimetry.</i> 	<p>Noted, the authorisation issued by the rra will outline the reporting requirements for such sources.</p> <p>Noted, the authorisation issued by the rra will outline the reporting requirements for such sources.</p> <p>Calibration frequency will be determined by expiry date of the calibration certificate.</p> <p>Noted.</p> <p>Noted. “a” can mean more than one.</p> <p>Resourcing is part of the RMP.</p>

SUBMITTER	COMMENT	RESPONSE
	<ul style="list-style-type: none"> • <i>to improve any conditions that will lead to a reduction in patient dose</i> • <i>to lay down tests in the field of quality assurance of the equipment.</i> • <i>to assure the surveillance of the installations with regard to radiological protection.</i> • <i>to choose equipment required to perform radiation protection measurements and to give advice on medical equipment.</i> • <i>to take part in the training of medical practitioners and other staff in relevant aspects of radiation protection.</i> <p>These arrangements should generally apply to all medical departments using ionising radiation on patients, i.e. diagnostic radiology, nuclear medicine and radiotherapy.</p> <p>While supporting expanded requirements for QE involvement there may be scope for exemptions applied to radiology practices without CT or interventional fluoroscopy. Where CT or interventional procedures are undertaken there must be a strong link with regular consultation and involvement of the QE. This argument is supported by clauses such as 3.2.10 where a lack of interaction between medical practitioner and expert would lead to inappropriate decision making.</p> <p>There is concern regarding the lack of definition of “qualified expert” and how regulatory authorities will assess persons wishing to be considered to be qualified experts.</p> <p>Line 283</p> <p>Like to see the Code endorse patient-specific independent calculations of monitor unit or treatment time, not just routine checks at intervals. Many radiation incidents have been caused by lack of independent testing of treatment times incorrectly calculated by treatment planning software.</p> <p>Pages 9-10, Clauses 3.1.24-31</p> <p>These clauses should mandate the involvement of the qualified expert rather than simply requiring the responsible person ensuring that the respective outcomes are achieved.</p> <p>Page 10, Clause 3.1.24, Lines 284-285</p> <p>There are many international and national protocols, and while they are similar,</p>	<p>Noted.</p> <p>Noted.</p> <p>The protocols to be given in the Safety Guide.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>frequencies of testing do vary and are often widely debated. Which protocols take precedence? Particular protocols should be specified.</p> <p>Page 10, Line 286</p> <p>A calibration currency period of 12 months should be included.</p> <p>It's probably implicit, but calibration of thermometers and barometers is just as important as calibration of ionisation chambers for calibration of radiotherapy equipment.</p> <p>Page 10, Line 288</p> <p>There should be a reference to the need for independent checks of treatment plans before treatment commences, i.e. checks by a qualified person (not the original planner) on the treatment plan's geometric and dosimetric accuracy and its compliance with the medical practitioner's prescription.</p> <p>Page 10, Clause 3.1.28, Line 301</p> <p>Is it intended that the radiation survey is carried out by a qualified person, or that it should have any objectives? The statement seems to leave any action open to interpretation. It is recommended that wording indicate that the survey be carried out by a suitable qualified person and that the results of the survey confirm that the integrity of the shielding is intact and that the safety of patients, staff or the public is maintained.</p> <p>Page 10, Clause 3.1.29(b), Lines 307-308</p> <p><i>The responsible person must ensure that, following repair or maintenance ... (b) all radiation producing therapy equipment is calibrated before it is returned to clinical use.</i></p> <ul style="list-style-type: none"> • There are many repairs and maintenance that do not necessitate machine recalibration e.g. replacement of a cable or hose. • The checks/ recalibration that are done need to be appropriate for the repair undertaken. Replacement of a field light globe implies the need for a check film confirming congruence of X-ray and optical fields. It may imply a need to check on the integrity of the head shielding if this has had to be disturbed to change the globe. 	<p>Calibration frequencies will be determined by the calibration expiry date.</p> <p>Noted.</p> <p>Clause changed. QE is now required to do the survey.</p> <p>Clause change.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 10, Clause 3.1.29, Lines 307-308</p> <p>In most cases, the repair or maintenance won't affect beam output characteristics, so it's unreasonable to require a "calibration" every time. The wording needs to be qualified to reflect this e.g. "(b) all..... if there is a possibility that radiation beam characteristics may have changed as a result of the repair or maintenance".</p> <p>Page 10, Lines 307-308</p> <p>It will create unnecessary work if it is mandated to calibrate before it is returned to clinical use following repair or maintenance. Several minor repairs on the machine do not have any affect on accuracy of dose delivery. I believe this task should be left at the discretion of qualified expert. The wording should, perhaps, be changed to: QA checks relevant to the repair should be performed.</p> <p>Page 10, Clause 3.1.29</p> <p>It is not necessary to calibrate after each repair, which might be something simple and mechanical, e.g. repairing a couch panel. Suggest (b) reads</p> <p>307 (b) all radiation producing therapy equipment is calibrated before it is</p> <p>308 returned to clinical use, if the repair or maintenance could have affected the beam output.</p> <p>Alternatively (a) could be changed to read</p> <p>305 (a) the operation of any radiation emitting equipment is re-assessed, and calibrated if necessary, so that</p> <p>306 the radiation safety of patients, staff or the public is maintained;</p> <p>Clause (b) could then be deleted. It's also not clear to me whether "calibration" refers just to beam output or to other calibration, e.g. gantry angle readouts. The re-worded clause (a) above would cover all situations and is therefore preferable.</p> <p>Page 11, Clause 3.2</p> <p>There are concerns regarding possible conflicts between this code of practice and licensed operators' responsibility to not administer services that are excessive, unnecessary, or not reasonably required. e.g. medical practitioner</p>	<p>Clause changed.</p> <p>Clause changed.</p> <p>Clause changed.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>requests for inappropriate examinations, particularly CT, and also particularly in practices where there is no radiologist presence. There is also a need for clarification regarding the current QLD allowance for nurse practitioner and specifically trained RN x-ray requests.</p> <p>Page 11, Clause 3.2.1, Lines 332-334</p> <p>There may be some licensed remote operators as well as others taking responsibility for the overall conduct of a procedure who are not medical practitioners. The medical practitioner definition in the glossary would need to be expanded to cover chiropractors, remote operators who may be nurse practitioners etc, as well as diagnostic radiographers who work at sites where there is no medical practitioner (as currently defined) present. This will flow on to the other sections where medical practitioners are mentioned.</p> <p>Page 11, Clause 3.2.3</p> <p>Suggested alterations: <i>In determining the net clinical benefit from a medical radiation procedure, the medical practitioner must take into account:</i></p> <ul style="list-style-type: none"> <i>(a) the specific objectives of the procedure;</i> <i>(b) the characteristics of the individual involved;</i> <i>(c) the total potential diagnostic or therapeutic clinical benefits, including the direct health benefits to the patient and the benefits to society in general;</i> <i>(d) the individual (radiation and non-radiation) detriment to the patient that may result from the procedure;</i> <i>(e) the pregnancy status of a female patient if there is the potential for a radiation dose to the embryo or fetus of more than 0.3 mSv;</i> <i>(f) the breast-feeding status of the female patient to be administered a radiopharmaceutical if there is the potential for a:</i> <ul style="list-style-type: none"> <i>(i) radiation dose of more than 1 mSv to a breast-fed child; or</i> <i>(ii) significant radiation dose to the breast glandular tissue of the patient,</i> <i>(g) the efficacy, benefits and risk of available alternative techniques having the same objectives, either with less exposure to ionizing radiation or in combination with the medical radiation procedure; and</i> <i>(h) any medical data (such as previous diagnostic information or medical records) relevant to the medical exposure.</i> <p>Item (g) is somewhat controversial in light of the current debate regarding</p>	<p>This Code does not apply to the chiropractic use of radiation.</p> <p>Clause has been amended.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>cardiac CTA. This is a procedure that has been demonstrated to deliver higher radiation exposures than conventional angiography (arguably with poorer performance) but may have some credibility if the non-radiation related risks are taken into consideration (as it is believed that these are lower for CTA). If radiation risk alone is the determinant then CTA should never be justified. Please note that the “trigger levels” for foetal dose investigation are ignored above but are dealt with elsewhere in this document.</p> <p>Page 11, Clause 3.2.3(b), Line 341</p> <p>It seems to be very unclear what the “characteristics of the individual” is meant to mean.</p> <p>Page 11, Clause 3.2.3, Lines 347-353</p> <p>Since these same points are specifically covered in 3.2.11-3.2.16, there is no need to also cover them here. 3.2.3 need only cover the general case.</p> <p>Page 11, Clause 3.2.3(e), Lines 347-348</p> <p>As per 3.1.3(c) above: Female patients.....</p> <p>Page 11, Clause 3.2.3(e), Line 348</p> <p>There should be no dose limit if it is a medical procedure for the mother. However, advice must be available for the medical practitioner, radiographer, etc. to explain possible radiation risk (as it is done now at the Alfred), and without having the medical physicist calculate each and every dose to the foetus. ICRP does not specify dose limit to foetus for medical exposure of mother. To my knowledge there is no evidence for increased untoward effects for foetal doses up to 100 mSv.</p> <p>Page 11, Clause 3.2.3(g), Line 354</p> <p>It is not reasonable to expect the Nuclear Medicine specialist to consider “the efficacy, benefit and risk of available techniques having the same objectives”. The specialist will offer guidance about the available techniques in their area of expertise, but not outside it. Thus, they may recommend MIBI instead of Thallium for a cardiac scan. But it is not up to them to send the patient for an ultrasound, instead.</p>	<p>Noted.</p> <p>Noted.</p> <p>Noted.</p> <p>0.3 mSv has been removed.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 12, Clause 3.2.5 Therapeutic and diagnostic procedures must be clearly defined. Where do interventional radiology/cardiology procedures fit in?</p> <p>Page 12, Clause 3.2.5(a), Lines 375-376 It is not clear from the wording of Clause 3.2.5(a) that the medical practitioner must comply with all of 3.2.5(a)(i), 3.2.5(a)(ii) and 3.2.5(a)(iii) before the first treatment delivery. As it is written it could be interpreted that the medical practitioner must comply with only 3.2.5(a)(iii) before the first treatment delivery.</p> <p>Page 12, Clause 3.2.7 It is unclear how the medical practitioner could be routinely and practically involved in the recording of radiation dose (see also comments on 3.1.5).</p> <p>Page 12, Clause 3.2.7(a), Lines 384-387 As per 3.1.5 (Does it mean that a dose) above. This will have the effect of increasing the paper work for the department – but will it improve radiation safety for the patient?</p> <p>Page 12, Clause 3.2.7(a), Line 385 This regulation will be a significant burden for radiology. Many additional parameters will need to be recorded by the operator.</p> <p>Page 12, Clause 3.2.7(b), Line 389, footnote 8 Footnote 8. Starting from “... for a therapeutic procedure, ...” suggest alternate wording: “a system be established whereby a second such person verifies the measurement of the dispensed activity”. A second trained person should not be required to witness every measurement.</p> <p>Page 12, Clause 3.2.7(b), Lines 388-389 +, footnote 8 The requirement in footnote 8, which mandates that for therapeutic nuclear medicine procedures “... for a therapeutic procedure, a second such person witnesses and verifies the measurement of the dispensed activity” seems unduly prescriptive. Many (?all?) modern dose calibrators allow for a printout</p>	<p>The use of ionizing radiation in interventional procedures is considered as “diagnostic” as the radiation is not the therapeutic agent.</p> <p>The wording of this clause has been amended.</p> <p>Clause deleted.</p> <p>Clause deleted.</p> <p>Clause deleted.</p> <p>Clause deleted.</p> <p>Clause and footnote deleted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>of measured activity, isotope setting, date and time of measurement, surely the checking of this information by someone would be sufficient to verify the correct activity has been prepared, without the need to witness the measurement. Suggest alternate wording “for a therapeutic procedures a system must be established whereby a second such person verifies the measurement of the dispensed activity”.</p> <p>Line 289 The word “physics” looks out of place, perhaps “dosimetry” instead.</p> <p>Page 12, Clause 3.2.8, Line 392 Part (b) is often delegated to physicists. In order to allow delegation, perhaps the initial text could read “... the medical practitioner must ensure that the patient, carer, or patient’s legal guardian is provided with written instructions that ...”.</p> <p>Page 12, Clause 3.2.7(a) Do they mean technique charts???</p> <p>Page 13, Clause 3.2.8, Line 399 Ideally this written information should be provided prior to the day of treatment. It could be too late if it is only provided on the day of treatment, or after treatment.</p> <p>Page 13, Clause 3.2.11 Some redundancy here – this would be (and is currently) established for <u>ALL</u> female patients. Change to: Immediately before the commencement of a radiation procedure that is likely to result in a radiation dose to the embryo or fetus, the medical practitioner must take all reasonable steps to establish whether a female patient is pregnant.</p> <p>Page 13, Clause 3.2.12 What is the justification for this specifically applying to therapeutic nuclear medicine (why not the same rule for other modalities given that a limit is set)? Also, the 1mSv trigger point is inconsistent with the 0.3mSv trigger point</p>	<p>Change effected.</p> <p>Change effected.</p> <p>Clause deleted.</p> <p>Noted.</p> <p>0.3 mSv changed to 1 mSv. This is a trigger level below which there is no need to determine the pregnancy status of the patient e.g. for a finger X-ray.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>specified elsewhere. Further note that the 0.3mSv trigger point is not supported (see other comments – 3.1.3(c)).</p> <p>Page 13, Clause 3.2.12, Lines 414-422</p> <p>Procedures for potentially pregnant or pregnant patients Lines 414 – 422, p. 13, 3.2.11 -. Limit of 0.3 mSv and 1 mSv appear for diagnostic & therapeutic procedures.</p> <p>Why the difference. There should be no limit. For every child bearing age female, steps should be taken to establish pregnancy status of female patient. Just imagine a court case where the medical practitioner did not ascertain the status of pregnancy of patient because he/she thought the radiation to the embryo/foetus would be less than 0.3 mSv or less than 1 mSv and the child is born with malformations.</p> <p>Page 13, Clause 3.2.11, Line 415</p> <p>There should be no dose limit if it is a medical procedure for the mother. However, advice must be available for the medical practitioner, radiographer, etc. to explain possible radiation risk (as it is done now at the Alfred), and without having the medical physicist calculate each and every dose to the foetus. ICRP does not specify dose limit to foetus for medical exposure of mother. To my knowledge there is no evidence for increased untoward effects for foetal doses up to 100 mSv.</p> <p>Page 13, Clause 3.2.12, Line 420</p> <p>If a dose constraint of 0.3 mSv to the embryo or fetus is used for radiation procedures as in Line 415, the same value should be used for nuclear medicine procedures.</p> <p>C1.2 provides for a limit of 1 mSv for breastfed children following nuclear medicine procedures ,so we seem to have adopted different standards.</p> <p>In regard to what is the appropriate level to adopt, ICRP84 gives some pointers. Para(85) notes the Commission’s recommendation that following administration of radionuclides a woman not become pregnant unless the fetal dose from remaining radionuclides is less than 1 mSv.</p> <p>In para (50) ICRP 84 states that the level and degree of disclosure should be related to the risk and notes that for low dose procedures the only information that may be needed is a verbal assurance that the risk is judged to be extremely low. And also that when foetal doses are above 1 mGy, usually more detailed</p>	<p>0.3 mSv changed to 1 mSv. These are not limits, they are trigger levels below which nothing needs to be done.</p> <p>Noted. This is a trigger level below which nothing needs to be done.</p> <p>0.3 mSv changed to 1 mSv.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>explanation is given. These would tend to support a 1 mSv threshold for requiring dosimetry and risk assessment, at which level the natural incidence of cancer risk (there being no evidence to support detectable malformation risk or CNS damage at this level) in the 0-15 year old age group would increase from 2 to 3 per thousand by an additional 0.06 per thousand – i.e. risk is raised from 0.2%-0.3% by 0.006%. (Using data from ICRP84 Section 3.3)</p> <p>Page 13, Clause 3.2.12, Line 422</p> <p>Pregnancy test should be performed in the 24 hours prior to the commencement of treatment.</p> <p>Page 14, Clause 3.2.17, Lines 445-454</p> <p>The qualified expert referred to clearly needs to be expert in radiation dosimetry. But advice from an expert in the various types of electronic devices and their possible responses to single and accumulated doses also is required. Often, these will be two different people.</p> <p>Page 14, Clause 3.3.1</p> <p><i>“Only a person who is appropriately authorised by the relevant regulatory authority to administer ionizing radiation to a patient for radiology, nuclear medicine or radiotherapy may administer ionizing radiation to a patient.”</i></p> <p>What about cardiac, vascular, orthopaedic applications? Procedures or applications included in “Radiology” should be clarified.</p> <p>Page 15, Clause 3.3.4, Lines 476-480</p> <p>In some sites there will not be approval by a medical practitioner for a procedure or formal directions issued to the operator based on the current definition of medical practitioner e.g. where a remote site is staffed by a nurse practitioner. This will also flow onto the other requirements of the section 3.3 Operator.</p> <p>Pages 15 & 19, Clauses 3.3.6 and B2</p> <p>We support the introduction of guidance on radiation applied to pregnant patients but have two problems with the specified requirements: a) 0.3mSv is too low – it implies a risk of childhood cancer (best estimate)</p>	<p>“before” added.</p> <p>Noted.</p> <p>Definition of “radiology” changed.</p> <p>Generic approval under written protocols of an accredited body now permitted.</p> <p>0.3 mSv changed to 1 mSv.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>around 1:50000, which is very small cf. incidence from other causes. The requirements for follow-up will require unnecessary additional concern to the patient.</p> <p>b) it may be difficult to establish which procedures result in a dose in excess of the specified value – it is not clear how the operator would establish whether or not the specified dose level is likely to be exceeded.</p> <p>Page 15, Clause 3.3.6(a) “of more than 0.3 mSv” is redundant.</p> <p>Page 15, Clause 3.3.6, Lines 499-503 Limit of 0.3 mSv related to embryo/foetus appears again.</p> <p>Page 15, Clause 3.3.6(a), Line 501 There should be no dose limit if it is a medical procedure for the mother. However, advice must be available for the medical practitioner, radiographer, etc. to explain possible radiation risk (as it is done now at the Alfred), and without having the medical physicist calculate each and every dose to the foetus. ICRP does not specify dose limit to foetus for medical exposure of mother. To my knowledge there is no evidence for increased untoward effects for foetal doses up to 100 mSv.</p> <p>Page 15, Clause 3.3.6(a), Line 501 (and refer to Clause 3.2.4, Line 360) Query whether operator should check with medical practitioner? Or patient? Or whether this should be in the safety guide as the medical practitioner should bear legal responsibility. Also query whether referring medical practitioner should have responsibility of establishing whether or not the patient is pregnant. (3.2.4 page 11).</p> <p>Page 16, Clause 3.3.8(b) The Code requires “visual surveillance of the patient throughout an imaging.. procedure”. This needs to be clarified for nuclear medicine: the “imaging procedure” must be clearly stated to correspond only to the time the patient is being scanned (as opposed to the time from injection to the end of the last scan). In addition, the requirement should be for “reasonable visual surveillance”: if the scan duration is 30 or 45 minutes, it is not reasonable to</p>	<p>0.3 mSv changed to 1 mSv.</p> <p>0.3 mSv changed to 1 mSv.</p> <p>0.3 mSv changed to 1 mSv. These are not limits, they are trigger levels below which nothing needs to be done.</p> <p>Noted.</p> <p>Clause changed to the “imaging or treatment room”.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>expect that the technologist will maintain close attention on the patient for all that time.</p> <p>Page 16, Clause 3.3.9</p> <p>There are concerns over the lack of definition of operating parameters (which should be displayed) and whether or not these can be <u>continuously</u> monitored during treatment.</p> <p>Page 16, Clause 3.3.9, Line 521</p> <p>Should this regulation refer to all radiotherapy? If not, why does it refer to external beam and intra-operative but not HDR brachytherapy?</p> <p>Page 16, Clause 3.3.11, Line 545</p> <p>The medical practitioner certainly does not want to or need to know about every breakdown, only those that have caused, or possibly may lead to, an incorrect radiation exposure.</p> <p>Page 16, Clause 3.3.11(b), Line 544</p> <p>In many circumstances it would be an over-reaction to report a simple machine fault (potentially on one of many available machines) to all medical practitioners and the Responsible Person.</p> <p>If this regulation is intended to be “malfunction or error which affects the safety of the patient” then it should be clarified as such.</p> <p>Page 16, Clause 3.3.11(b) (i) & (ii), Lines 545-546</p> <p>If this requirement is followed to the letter the “Responsible Person” is going to be contacted every time a computer workstation hangs or a linac interlock occurs. In practice these issues are currently handled by physics and engineering staff. Our practice is that the medical practitioner and Responsible Person are notified only if there has been, or may have been, a radiation incident or there will be a significant delay to treatment or the associated radiotherapy procedures. There should be scope to delegate this type of problem to a qualified expert (but see definition below) if patient throughput is not to suffer.</p>	<p>Sub-clause deleted.</p> <p>HDR brachytherapy now included.</p> <p>Sub-clause modified.</p> <p>Sub-clause modified.</p> <p>Sub-clause modified.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 17, Clause A1.1</p> <p>The emphasis on shielding is inappropriate for the RMP. The emphasis should be on the outcome ie. Occupational and public exposures.</p> <p>Page 17, Clause A1.1 b (i) & (ii), Lines 560-564</p> <p>MPD for an occupationally exposed persons is currently 20 mSv per year and a mandatory requirement that ¼ of this be achieved is inappropriate. Rather, 5 mSv should be recommended as a 'local investigation trigger' under an institution's management plan. Otherwise we will have a de facto (but enforceable) MPD of 5 mSv and require a 'trigger' of 1.25 mSv, and so on in endless regression.</p> <p>MPD for a member of the public is currently 1 mSv per year. I contend the 0.3 mSv limit suggested is misguided – it is based on the notion that a person can receive radiation from more than one source sequentially, which will occur with low frequency in the population, and is a misunderstanding of the nature of stochastic risk. The aim of the dose limit is to protect the population as an aggregate, not as individuals, and it is meaningless to base the MPD for stochastic effects on the rare case of maximum exposure, which is not of the 'representative person'.</p> <p>The question of multiple exposure should be dealt with by making a conservative estimate of the proportion of the population that might receive such exposure, for example (and conservatively) 5%. Then the aggregate risk is maintained if a dose limit of $0.95 \times 1 = 0.95$ mSv is applied, which of course would be rounded to 1 mSv.</p> <p>Unfortunately, if this figure is adopted, there will be a perception that only 0.3 mSv is 'safe', and we will go through the same process again, in another endless regression. The implications for costs in developing countries are alarming.</p> <p>The current dose limits of 20 and 1 mSv/year are the result of long and careful scientific appraisal. They must be supported.</p> <p>Page 17, Clause A1.1 (b), Lines 560-564</p> <p>The dose constraint of 0.3 mSv for members of public for the shielding of medical practices will become a limit once the document is incorporated in legislation. It is too small to be a limit. The walls of x-ray, nuclear medicine</p>	<p>Clause amended.</p> <p>Dose constraints removed to Safety Guides.</p> <p>Dose constraints removed to Safety Guides.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>and radiotherapy rooms will be filled with lead and concrete at great expense – but how many lives are going to be saved by reducing the limit from 1 mSv/y to 0.3 mSv/y.</p> <p>Page 17, Clause A1.1, Lines 561-564</p> <p>These clauses have generated enormous discussion, with most arguing against specification of such dose constraints, in particular the 0.3 mSv per annum for the public. The arbitrariness, the logic and the practicality of such a low value is certainly questionable. A design constraint of 5 mSv for an occupationally exposed person is quite reasonable, however some would argue that any dose levels lower than required by ICRP 60 should be included in the safety guides, not in the code. Putting a dose constraint in the code blurs the distinction between a level and a constraint.</p> <p>Page 17, Lines 561-564</p> <p>The dose constraint should incorporate Use factor, Occupancy factor and Workload factor and the dose constraint for occupationally exposed persons and for members of the public should be 10 mSv and 1 mSv per annum respectively. The suggested dose constraints for occupationally exposed and general public will have detrimental effect on application of radiation for useful purposes as it would cost more money to provide additional shielding with no proven benefit. This goes against ALARA principle stated in the draft code which says: <i>Radiation doses received by the public and occupationally exposed persons arising from medical radiation exposures must be kept as low as reasonably achievable, economic and social factors being taken into account (ALARA)</i>. By deciding arbitrary dose constraint we don't take into account economic and social factors in designing radiation shields.</p> <p>Page 17, Clause A1.1(b)</p> <p>See General Comments (The use of dose constraints...).</p> <p>Change to:</p> <ul style="list-style-type: none"> b) construction and shielding of the medical practice so that: <ul style="list-style-type: none"> i) occupationally exposed persons do not accrue an effective dose of more than 5 mSv in any 2000 hour period from occupational exposure; ii) members of the public and non-occupationally exposed staff do 	<p>Dose constraints removed to Safety Guides.</p> <p>Dose constraints removed to Safety Guides.</p> <p>Dose constraints removed to Safety Guides.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>not accrue an effective dose of more than 1 mSv in any one year period; and</p> <p>iii) compliance with the above dose constraints takes into account, where necessary, the probability of concurrent or sequential exposures to multiple sources of radiation,</p> <p>The 5 mSv dose constraint is for occupationally exposed persons working a “normal” 40 hour week (about 2000 hours in any one year period). This will also cover persons working normal hours divided between multiple practices. Persons working in excess of these hours may receive a higher dose and be at higher risk, but this is no different from occupational risk in any other professions.</p> <p>Prescriptive information on how to deal with concurrent or sequential exposures can be dealt with in the Safety Guide(s). Some information on suggested occupancy factors also needs to be laid down in the guide so that everybody is singing from the same song sheet.</p> <p>Page 17, Clause A1.1 (b) (ii), Lines 563-564</p> <p>The dose constraint for members of the public of 0.3mSv per annum stated in this clause is well below the internationally accepted public dose constraint of 1mSv per annum. There are no grounds given in the document for reducing the public dose constraint from 1mSv per annum. This decrease in public dose constraint may increase the risk to the population as a whole, particularly given the increase in lead exposure to workers who will be required to manufacture and install lead shielding to make existing installations comply with the proposed public dose constraint. In conclusion, the dose constraint for shielding for members of the public should be 1mSv per annum (ref Dixon et al Rad Prot Dosim 2005, 115:16-22).</p> <p>Page 17, Clause A1.1 (b) (ii), Line 563</p> <p>As discussed on the list server recently, the dose constraint for shielding for members of the public should be 1 mSv per annum (ref Dixon et al Rad Prot Dosim 2005, 115:16-22).</p> <p>Page 17, Clause A1.1 (b) (ii)</p> <p>We are concerned that a dose constraint of 0.3 mSv may not be justified within Australia where there exist very few (if any) radioactive installations that</p>	<p>Dose constraints removed to Safety Guides.</p> <p>Dose constraints removed to Safety Guides.</p> <p>Dose constraints removed to Safety Guides.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>irradiate very large numbers of the general public. If it must be implemented, the regulation could also specify that this constraint should be used with realistic dose, shielding and occupancy factors.</p> <p>It was also queried whether this regulation would apply to existing structures. If not, there would need to be a statement to this effect.</p> <p>Page 17, Clause A1.1, Lines 561-564</p> <p>Is there any justification for the dose constraints in this clause? Since most facilities were designed for limits of 20 mSv to staff and 1 mSv for public, it seems inappropriate to introduce new limits which will add a lot of cost for no proven benefit.</p> <p>Similar comments apply to Schedule B, protection of an embryo.</p> <p>Page 17, Clause A1.1 (e)</p> <p>The Code requires “visual surveillance of the patient throughout an imaging.. procedure”. This needs to be clarified for nuclear medicine: the “imaging procedure” must be clearly stated to correspond only to the time the patient is being scanned (as opposed to the time from injection to the end of the last scan). In addition, the requirement should be for “reasonable visual surveillance”: if the scan duration is 30 or 45 minutes, it is not reasonable to expect that the technologist will maintain close attention on the patient for all that time.</p> <p>Page 18, Clause A2.1 (d)</p> <p>As in comments for page 17 A1.1.b “See General Comments (The use of dose constraints...).</p> <p>Change to:” etc.</p> <p>Use 1 mSv dose constraint.</p> <p>Page 18, Clause A2.1 (d), Lines 607-610</p> <p>The public dose constraint of 0.3mSv per annum stated in this clause will need to be consistent with the value used in Clause A1.1(b)(ii).</p> <p>Page 18, Clause A2.1 (d), Line 607</p>	<p>Dose constraints removed to Safety Guides.</p> <p>0.3 mSv changed to 1 mSv in Schedule B.</p> <p>Clause modified.</p> <p>Now requires the limits in RPS1 to be observed.</p> <p>Now requires the limits in RPS1 to be observed.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>This is changing a constraint to a dose limit by setting a value of 0.3 mSv – it would be more appropriate to use a constraint of 0.3 for this. Part of the difference is that constraints are prospective and thus do not necessarily apply to existing facilities, whereas setting a limit could cause existing facilities to be closed even though dose limits may not be exceeded.</p> <p>Page 18, Line 610</p> <p>As discussed on the list server recently, the dose constraint for shielding for members of the public should be 1 mSv per annum (ref Dixon et al Rad Prot Dosim 2005, 115:16-22).</p> <p>Page 18, Clause A2.1, Line 610</p> <p>However, 0.3 mSv seems quite reasonable for exposure due to radioactive waste, which should be stored well away from anybody.</p> <p>Page 18, Clause A2.1 (e), Line 611</p> <p>Does the Code intend to address the issue of discharges to the environment from all patients who have been administered radionuclides or just those via the sewage system of the premises where administered? Whilst most are short lived radionuclides, there are still a large number of patients who have been administered radionuclides such as 131-I and will discharge into the sewer system outside of a medical facility, or in some instances use recycling sewage systems that can discharge into gardens.</p> <p>Page 19, Clause B1.1</p> <p>Use 1 mSv.</p> <p>Page 19, Clauses B1 and B2, Lines 624-654</p> <p>The 0.3 mSv dose limit for embryo/foetus appears again.</p> <p>Page 19, Line 625</p> <p>As discussed on the ACPSEM list server recently, the dose constraint for shielding for members of the public should be 1 mSv per annum (ref Dixon et al Rad Prot Dosim 2005, 115:16-22).</p>	<p>Now requires the limits in RPS1 to be observed.</p> <p>Now requires the limits in RPS1 to be observed.</p> <p>Now requires the limits in RPS1 to be observed.</p> <p>Noted. NDRP limits stand.</p> <p>Done.</p> <p>0.3 mSv changed to 1 mSv.</p> <p>0.3 mSv changed to 1 mSv.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 19, Line 634 As discussed on the ACPSEM list server recently, the dose constraint for shielding for members of the public should be 1 mSv per annum (ref Dixon et al Rad Prot Dosim 2005, 115:16-22).</p> <p>Page 19, Clause B1.1, Lines 626-629 Perhaps just (a) is sufficient. A formal risk assessment as described is not a trivial matter, and the outcome will still be very subjective, because the risk associated with such a low level of exposure is not known.</p> <p>Page 19, Clause B1.4 Should also apply to diagnostic procedures.</p> <p>Page 19, Clause B2.1, Lines 644-645, together with footnote 13 There seems to be a big contradiction here. On the one hand, termination of the pregnancy is not justified for anything up to 100 mSv, but on the other hand, there are all sorts of hoops to jump through for anything over 0.3 mSv.</p> <p>Page 19, Clauses B2.1 & B2.2, Lines 644-647 The value of 0.3mSv seems a very low value for the process of dose assessment and risk assessment for exposure of the pregnant patient to commence. The probability of a child not developing cancer in the age group 0 to 19 is 99.7% at 0 mGy above background and 99.7% at 5 mGy dropping to 99.6% at 10 mGy – Table 4 of ICRP 84. What judgments are we expecting practitioners to make? Is it realistic to set the threshold for assessing individual exposure risks at a level of 1 in 50,000, which is what the additional childhood cancer risk of a 0.3mGy exposure represents to the conceptus? In practical terms conceptus doses below 1 mGy will represents cancer risks below 1 in 20,000 and below 10 mGy risks below 1 in 2000. Determining more accurate risk estimates given the uncertainties in the calculations would seem meaningless in any real life situation where a decision to carry out a procedure will depend on the results of such an assessment.</p> <p>Page 19, Clause B2.1 As with 3.1.12 (How will we know.....).</p>	<p>0.3 mSv changed to 1 mSv.</p> <p>Noted.</p> <p>Clause deleted.</p> <p>Section B2 and footnote transferred to the Safety Guide.</p> <p>Section B2 transferred to the Safety Guide.</p> <p>Section B2 transferred to the Safety Guide.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 19, Clause B1.3 Use 1 mSv.</p> <p>Page 19, Clause B2.2 Use 1 mSv.</p> <p>Pages 20-21, Schedules C and D Schedules C & D should be removed as they delve into a level of practice detail which should not be in a general document of principal such as this. Better to be placed in the relevant Safety Guide.</p> <p>Page 20, Clause C2.2, Lines 679-684 There is no dose limit (or constraint) provided here – for children RPS4 refers to the 1 mSv limit for children excluding medical and background sources. Should this not give the same requirements as RPS4 or refer to that Code?</p> <p>Page 21, Clause D1.1 The code should not specify exactly what basic data is included and verified as the required data can change over time. For example (c) ‘source wall information’ is no longer required within the TG43 methodology.</p> <p>Page 21, Clause D2.1, Lines 696-702 In clause (a) the phrase “acceptable tolerances” is too vague; this clause should refer to the ACPSEM as the local authority. Failing that, the phrase should be re-written as “..... are within acceptable 700 tolerances specified in international and national protocols; as per clause 3.1.24 (pages 9 and 10), which reads: 282 (c) each of the treatment beams or sources for all radiation producing 283 therapy equipment (both planning and treatment delivery) is checked 284 and recalibrated at intervals specified in international and national 285 protocols; In (b) there is no mention of what tolerances are to be used, so this should be</p>	<p>0.3 mSv changed to 1 mSv.</p> <p>Section B2 transferred to the Safety Guide.</p> <p>Section C and D transferred to the Safety Guide.</p> <p>Section C transferred to the Safety Guide.</p> <p>Section D transferred to the Safety Guide.</p> <p>Section D transferred to the Safety Guide.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>similarly re-worded.</p> <p>Page 21, Clause D2.1, Lines 698-700</p> <ul style="list-style-type: none"> • I think the term here should really be “all radiotherapy treatment modalities” not “all ..external radiotherapy beams”. To check every beam exhaustively the planning system would never go into clinical service. In practice a finite number of measured beams profiles, depth doses, output factors etc are compared with computed profiles. • A limited number of measurements will be carried out under heterogeneities or in missing tissue situations and the results compared with calculated results. The potential permutations are endless if “all radiotherapy beams” are to be tested. <p>Page 21, Clause D2.1, Lines 698-700</p> <p>“acceptable tolerances” – acceptable to who?</p> <p>Line 699</p> <p>“are within acceptable tolerances” seems rather vague. Perhaps a reference to international standards could be added.</p> <p>Page 21, Clause D2.1, Lines 701-702</p> <p>“within tolerances of published or measured data” – what tolerances and what data? Either state the tolerances or refer to specific publications.</p> <p>Page 22, Line 737</p> <p>Add RPS8 to the Bibliography, referred to in footnote 2, page 2.</p> <p>Page 23, Line 754</p> <p>Add “or individual” after “organisation”, otherwise this does not cover radiation licenses issued to radiologists, radiographers, etc.</p> <p>Page 23, Line 776</p> <p>The words effective dose should also be in bold font for uniformity.</p>	<p>Section C and D transferred to the Safety Guide.</p> <p>Section D transferred to the Safety Guide.</p> <p>Section D transferred to the Safety Guide.</p> <p>Section D transferred to the Safety Guide.</p> <p>Done.</p> <p>“for an operating organisation” has been deleted.</p> <p>Disagreed. Not the first use of effective dose in the Code.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 24, Lines 787 & 796 Incorrect definition of effective dose and equivalent dose (swapped).</p> <p>Page 25, Line 826 Replace “...general practitioner” with “...in some cases a general practitioner”. This makes it clear that it is not normal that a general practitioner would be the “medical practitioner” referred to in the Code.</p> <p>Page 25, Lines 746-752 <i>Qualified expert- A person who: (a) is qualified in the application of the physics of therapeutic or diagnostic uses of ionizing radiation; and (b) has been recognised by the relevant regulatory authority as being able to perform the dosimetric calculations, measurements and monitoring relevant to the person’s area of expertise.</i></p> <ul style="list-style-type: none"> • A key safety factor is the clause <i>recognised by the relevant regulatory authority</i>. However, I can foresee the potential for radiation therapists to argue that they are “qualified experts” in terms of the code, given: <ul style="list-style-type: none"> ○ They have qualifications that are built on <i>the application of the physics of therapeutic or diagnostic uses of ionizing radiation</i>. ○ The loose use of the terms: “<i>dosimetry/ dosimetric calculations</i>” to mean “radiotherapy treatment planning”; ○ “<i>Measurements</i>” to mean measurement in general (e.g. measuring the distance of an anatomical landmark from some point using a ruler). • Perhaps the clause should read “<i>being able to perform the dosimetric calculations, radiation measurements and monitoring relevant to the person’s area of expertise</i>”. <p>Page 25, Line 846 How will the qualifications of a qualified expert be assessed in order to ensure that adequate scientific support is provided, especially within small centres?</p> <p>Page 25, Line 852 The requirements for a qualified expert should be developed in tandem with the code so that the requirements in the code can be matched to the skills of the experts expected to meet them. There will obviously be different criteria for the different roles they will be asked to perform and these need to be established.</p>	<p>Disagreed. This is not correct.</p> <p>“for limited procedures” added.</p> <p>Agreed.</p> <p>The recognition of the rra will determine this.</p> <p>The recognition of the rra will determine this.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 26, Line 867</p> <p>Most definitions of radiology include the use of ultrasound, MRI and even conventional nuclear medicine imaging and PET, as well as the use of x-rays. If the definition is intended just to include the use of x-rays in imaging, it may need to be expanded to include CT usage in nuclear medicine and radiotherapy which is for attenuation and anatomical localization purposes.</p> <p>Page 26, Responsible Person</p> <p>In the legal sense, can this be a body corporate (e.g, the Board of Management”. Who has to pay the fines and go to jail? It should be made clear (maybe this is for the Guidelines) that a practice can’t appoint (say) a Chief Radiographer as the “Responsible Person” and expect him/her to take the rap for anything that goes wrong.</p>	<p>Definition modified.</p> <p>Footnote describing what a “legal person” added for clarification.</p>
<p>18 Dr Graeme Dickie Chairperson Radiation Advisory Council – Qld</p>	<p>As the Radiation Advisory Council is advisory to the Minister and to Radiation Health in Queensland, we will confine our comments about how the Code might impact on the radiation regulator.</p> <p>The draft Code seems to contain a mixture of regulatory issues and also advice and guidelines. In medicine, the medical practitioner is regulated by the Medical Board. Radiographers are regulated by their Radiographer Registration Board. In radiation there is also regulation by the radiation regulator. As far as patients are concerned there is no limit or restriction to the amount of radiation they can receive as part of their medical condition and thus for a specific patient there should not be any intervention by the radiation regulator (apart from reporting radiation accidents).</p> <p>As far as implementation of the Code, it is important for the medical radiation practice and for the regulator to be able to identify what parts of the draft Code are applicable to the radiation regulator to enforce, and what parts are not. All parts of the Code may be relevant to the radiation practice including the parts as guidelines for best practice, but not all parts may be relevant to the radiation regulator. There needs to be proper licensing of individuals, licensing of equipment and facility, a proper radiation management plan and clear lines of responsibility and a mechanism to report accidents. The practice needs to have guidelines following the important radiation safety principles of justification</p>	<p>Submission noted. Many changes already effected arising from above comments.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>and optimisation. The regulator should be concerned that the radiation safety principles are being applied, not with the detail for individual patients. If such a framework is established there should be little reason for the radiation regulator to intervene. The details of management of an individual patient which includes radiation is not relevant for the radiation regulator (unless there is an error or accident involving radiation).</p> <p>For instance, in many parts of the Code radiation and pregnancy or possible pregnancy are mentioned with the constraint of 0.3 mSv. The matter of whether radiation is used for a diagnostic test in a person who is pregnant or potentially pregnant depends upon the particular medical problem affecting the patient. The dose that can be given is not a matter that should be regulated by the radiation regulator. It is appropriate that there be guidelines that take into consideration the radiation dose involved and hence the risks for the fetus. Thus this section about pregnancy should be regarded as guidelines and advice, and it needs to be clear to the radiation regulator.</p> <p>Similarly in the justification section about use of radiation in a patient, there is a statement that the medical practitioner must take into account several factors which are listed. That provides very sound advice and is likely to be helpful to clinicians, but is not something the radiation regulator can mandate or regulate. It should be viewed as advice or a guideline as it relates to the use or management. The regulator should be satisfied there is a framework that includes justification (and optimisation); it is inappropriate for the regulator to get into detail.</p> <p>Similarly Schedule C contains very sound and important advice about protection of children but it is not clear how much detail should be checked, implemented or enforced by a regulator. In our opinion it should be viewed as advice.</p> <p>The above are just examples which illustrate that within the Code there are several sections that provide guidance for the radiology practice and are not things that the radiation regulator needs to regulate or enforce. It needs to be clear to a radiation regulator what parts and how much detail they are to enforce or implement, and which sections are meant for guidance. Some of the items discussed in the Code are similar to the ICRP publications about radiation in medicine, and in those documents the emphasis is advisory in</p>	

SUBMITTER	COMMENT	RESPONSE
	<p>nature. If the radiation regulator were to encroach on medical management other than in an advisory way that could create difficulties.</p> <p>The above comments are not critical of the content of those sections. For instance, radiation in pregnancy is a very important issue and steps need to be taken to protect the fetus. In our opinion such steps are best viewed as guidelines. Our concern with the document is that it needs to be clear how it is to be implemented by both the medical radiation practice as well as the radiation regulator.</p>	
<p>19 Paula Veevers Acting Assistant Director Radiation Health Unit – Qld</p>	<p><u>General Comments</u></p> <ol style="list-style-type: none"> 1. The terminology used throughout the draft Code is inconsistent. For example, the terms ‘medical radiation equipment’, ‘radiation producing apparatus’ and ‘radiation emitting equipment’ are used interchangeably throughout the document. This equipment should simply be referenced as ‘radiation apparatus’. For specific types of equipment, the term should be, for example, ‘therapy radiation apparatus’. 2. The spelling of foetus throughout the draft Code is ‘fetus’. This spelling is inconsistent with RPS1 and with Australian spelling protocols. It is therefore suggested that the Code be updated to the correct spelling of the term (i.e. foetus). 3. The Scope of the draft Code refers to ‘patients’ and ‘individuals’. It would appear that the term ‘individual’ is used if the person is not being exposed to radiation as part of their medical diagnosis or treatment. However, throughout the document, some sections are only referring to patients – which implies that the requirements of that section does not relate to all other medical applications. We have attempted to highlight this discrepancy in our specific comments (table attached). 4. It is not clear from the scope, or from the definition of ‘medical practitioner’ found in the glossary, whether certain clinical applications of ionising radiation (e.g. chiropractic radiography) are bound by this Code. This should be made very clear in the next draft of the Code. 5. The draft Code does not detail the responsibilities for persons supplying, installing and servicing the radiation sources used in medical applications. Such responsibilities should be included in the next draft of the Code. 6. Consideration should be given to including a statement similar to that 	<p>Consistency of terminology addressed.</p> <p>“fetus” now the accepted spelling for Codes. This spelling is included in the Macquarie Dictionary and therefore valid.</p> <p>Noted.</p> <p>Noted. This Code does not apply to the chiropractic use of radiation.</p> <p>Disagreed. The onus is on the RP to have appropriate equipment.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>found in clause 2.5 <i>Compliance Testing of X-ray Equipment</i> of the Dental Code. This statement describes the requirements relating to compliance testing of equipment, as required by the regulatory authority.</p> <p>7. The use of ‘medical practitioner’ throughout the Code is confusing. There appears to be several types, for example, a referring medical practitioner, an authorised medical practitioner, and a medical practitioner with clinical responsibility. How the term is used in the Code is confusing, and it is not clear which practitioner the Code is referring to. This should be addressed in the next draft of the Code.</p> <p>8. In certain sections of the draft Code, there are clauses that only relate to specific types of equipment (e.g. therapy radiation apparatus) or relate to certain types of practices. While the majority of the requirements relate to all practices, where there is an additional element, it is suggested that a separate clause (e.g. <i>Additional requirements for</i>) be included at the end of the section. This would be similar to that found in the Security Code for the additional requirements for security enhanced sources.</p> <p><u>Specific Comments</u></p> <p>Lines 22-39, Section 1.3 Scope</p> <ul style="list-style-type: none"> ○ For clarity, it is suggested that a separate statement be included in the Scope which clearly states that the Code does not apply to dental applications of ionising radiation. <p>While footer 1 does imply this circumstance, it is not a definitive statement.</p> <ul style="list-style-type: none"> ○ Part (f) if the Scope refers to the ‘exposure of health professionals other than those with training in the medical applications of ionizing radiation’. <p>It is not clear what the intention of this statement is, and how it differs from part (e) (<i>the occupational exposure of individuals</i>) and (h) (<i>the exposure of members of the public....</i>).</p> <p>It is assumed that it refers to persons such as physiotherapists or social workers who may be required to work with a person who has been injected, for example, with a radiopharmaceutical. It would be expected that such a group would be considered to be a member of the public.</p> <p>It is therefore suggested that part (f) could simply read ‘exposure of health professionals other than those occupationally exposed’.</p>	<p>Compliance testing will be included in the appropriate Safety Guides.</p> <p>Definition changed to “medical practitioner (radiation)”.</p> <p>Noted.</p> <p>Scope has been amended.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Lines 57-64, Section 2.1 Justification</p> <ul style="list-style-type: none"> ○ The justification principle as stated in the draft Code is very general, and uses differing terminology to the Code as it references only individuals. This is confusing as the scope implies that the terms ‘patient’ and ‘individual’ differ. This may need to be re-written. ○ Clause 2.1.1 refers to patients. As individuals are also mentioned in the scope, another clause should be included in this section to include the justification requirements for individuals. <p>Line 87, Section 2.3 Dose Limits</p> <p>Clause 2.3.2 states that ‘dose limits do not apply to the exposure of patients as part of their diagnosis or treatment’.</p> <p>For clarity, it is suggested that a footer be included which clarifies the requirements in relation to the exposure of the embryo or foetus of a pregnant patient.</p> <p>Lines 91-109, Section 3.1 The Responsible Person – Radiation Management Plan</p> <p>Clauses 3.1.1 and 3.1.2 details the requirements in relation to radiation management plans and radioactive waste management plans.</p> <p>It is suggested that such plans be required to be approved by the relevant radiation regulatory authority.</p> <p><i>Radiation management plans</i></p> <ul style="list-style-type: none"> ○ In relation to 3.1.1(a), it is suggested that this be amended to read ‘.....<i>implemented and regularly reviewed to ensure safety in all applicable dealings involving medical radiation.</i>’ ○ Section 3.1.1(b) is considered unnecessarily prescriptive, and should therefore be deleted. <p><i>Radioactive waste management plans</i></p> <p>It is not clear why a separate plan to cover the management of radioactive waste should be required. As waste production is a day to day result of using certain radioactive substances, it is suggested that the maintenance of such</p>	<p>Changes made to relevant sections of the text.</p> <p>“patient” changed to “individual” in 2.1.1.</p> <p>Noted.</p> <p>Some jurisdictions do not require this approval process.</p> <p>Disagreed</p> <p>Disagreed.</p> <p>Change effected.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>waste would simply be part of the radiation management plan.</p> <p>It is therefore suggested that section 3.1.2 be deleted from the draft Code</p> <p>Lines 110-129, Section 3.1 The Responsible Person – Justification of a medical radiation practice</p> <ul style="list-style-type: none"> ○ Line 120 (3.1.3(b)(ii)) refers to ‘written guidelines established by the medical practitioner’ while line 480 refers to such guidelines as ‘formal directions issued by the medical practitioner’. The draft Code needs to be amended to ensure that these terms are consistent. It is suggested that ‘formal directions issued by the medical practitioner’ is the most appropriate term to use. ○ 3.1.3(b) implies that the responsible person must ensure that a radiation procedure is not carried out unless it has been approved for each individual. Should this requirement also cover patients? The scope implies that the terms ‘patient’ and ‘individual’ differ. ○ The section on ‘Justification of a medical radiation procedure’ is unnecessarily prescriptive. It is suggested that section 3.1.3(c) be simplified to the following: <i>‘in the case of a female patient, all reasonable attempts have been made to establish:</i> <ul style="list-style-type: none"> <i>(i) the pregnancy status of the patient; and</i> <i>(ii) where a radiopharmaceutical is to be administered, the breast-feeding status of the patient’</i> <p>There are several reasons for this simplification. These include that:</p> <ul style="list-style-type: none"> • 3.1.3(c)(ii)b references a ‘significant radiation dose’ – what does this mean? The meaning of such a term differs between individuals. • It is not clear why the 0.3 mSv and 1 mSv dose qualifications have been chosen. It is believed that such quantities are better placed in the Safety Guide (and ultimately the Radiation Management Plan), and an Annex be included in the Guide which provides for the derivation of such dose levels. • The Responsible Person should require all relevant patients to be asked about their pregnancy/breast feeding status, regardless of the potential radiation dose. 	<p>Clause has been modified.</p> <p>Not necessarily a patient here.</p> <p>Sub-clause (c) has been modified.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Lines 130-144, Section 3.1 The Responsible Person – Optimisation of protection and limitation of radiation doses</p> <ul style="list-style-type: none"> ○ 3.1.5 implies that the responsible person must establish a program about radiation doses administered to patients for diagnostic purposes. Should this requirement also cover individuals? It is expected that this requirement should also apply, for example, to the exposure of individuals as part of a health screening program. ○ It is suggested that the wording in line 135 be changed to <i>‘The Responsible Person must establish a program to ensure that radiation doses administered to patients for diagnostic purposes are:...’</i> <p>Lines 145-165, Section 3.1 The Responsible Person – Occupational radiation exposures</p> <ul style="list-style-type: none"> ○ In 3.1.7(d), it should also be a requirement for the results of the investigation to be recorded. ○ Line 160 (i.e. 3.1.7(d)(ii)), change to <i>‘.....extremities and lens of the eye as specified in RPS1.’</i> <p>Lines 166-178, Section 3.1 The Responsible Person –Radiation incident</p> <ul style="list-style-type: none"> ○ Line 172 details the requirements in relation to a lost or stolen radioactive sources. The regulatory authority should also be contacted if radiation apparatus is lost or stolen. It is also important that the regulatory authority be contacted even if the radiation source appears to be, or is expected of being, lost or stolen. <p>Consequently, line 172 should be changed to: <i>‘immediately report to the relevant regulatory authority in the event that a radioactive source or radiation apparatus is, or appears to be, lost or stolen.’</i></p> <ul style="list-style-type: none"> ○ Line 175 – delete the words ‘the institution’s’. The line should read: <i>‘.....kept in a radiation incident report register...’.</i> <p>Lines 189-195, Section 3.1 The Responsible Person –Training</p> <p>This section mentions training of individuals who may be occupationally exposed to ionising radiation and relates to specific competency requirements that are established in the National Directory.</p>	<p>This is for patients.</p> <p>Noted.</p> <p>Sub-clause deleted.</p> <p>“or may be” added.</p> <p>Done.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>The competency requirements in the National Directory relate to the criteria for granting a licence – it is believed that, as the training mentioned in this section differs to the training for licensing, it is inappropriate to reference the National Directory in this section.</p> <p>Lines 196-201, Section 3.1 The Responsible Person –Radiation shielding</p> <p>Referring to the Radiation Management Plan for radiation shielding requirements is inappropriate. The requirements should clearly be stated in the Code.</p> <p>Additionally, it would be more appropriate to require that the Responsible Person must ensure that a person cannot be exposed to greater than a certain radiation dose level as a result of working at the practice (an outcome based statement). The Safety Guide could say that a way to achieve this would be to install shielding which meets certain parameters.</p> <p>Lines 202-228, Section 3.1 The Responsible Person –Warning notices</p> <ul style="list-style-type: none"> ○ This section is very prescriptive, and it is suggested that the section could be simplified, and the information included in a Safety Guide. ○ Line 204 refers to ‘illustrated notices’. What does this mean? <p>Lines 229-242, Section 3.1 The Responsible Person – RA and RS - General</p> <ul style="list-style-type: none"> ○ Line 235 includes the term ‘written form’. In certain circumstances it may be appropriate for the information to be available in electronic form in a central database maintained by the Responsible Person. ○ It is assumed that part 3.1.18 relates to the requirements for the tracking of radiation sources. The regulatory authority should also be notified by the Responsible Person when each source is disposed of, relocated, or is no longer in possession of the radiation source. ○ Part 3.1.18 also refers to the receipt of new radiation apparatus. As not all radiation apparatus is new when it is acquired, the word ‘new’ should be deleted. ○ It is also suggested that, in part 3.1.18, the regulatory authority should be notified if a new type of unsealed source is acquired. 	<p>The RMP now includes requirements that acceptable dose constraints are exceeded. Further, dose limits are a general requirement that the RP must meet.</p> <p>Noted. This will stay in the Code.</p> <p>Dictionary definition of “illustrated” holds.</p> <p>Clause removed to Safety Guide.</p> <p>Done.</p> <p>Done.</p> <p>This will be part of the authorisation process.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Lines 243-255, Section 3.1 The Responsible Person – Quality Assurance Program</p> <ul style="list-style-type: none"> ○ Line 248 – change ‘all’ to ‘any’ ○ Line 251 – change ‘piece of equipment’ to ‘instrument’ ○ Line 254 – change ‘documented’ to ‘recorded’ ○ It is suggested that clause 3.1.20 be simplified to read: ‘<i>The Responsible Person must implement and regularly review the Quality Assurance program.</i>’. ○ It is suggested that clause 3.1.21 be simplified to read: ‘<i>The Responsible Person must ensure that the results of the Quality Assurance program and its outcomes are recorded.</i>’. <p>Lines 256-263, Section 3.1 The Responsible Person – Calibration of a survey meter</p> <ul style="list-style-type: none"> ○ Before detailing the technical requirements for radiation survey meters, the Code must clearly and definitively state which radiation practices are actually required to even use such a device (e.g. Responsible Persons should be required to provide survey meters for their nuclear medicine practices and radiotherapy practices). <p>The Safety Guide and the Radiation Management Plan should then go into greater detail on the requirements for radiation survey meters.</p> <ul style="list-style-type: none"> ○ The Code should specifically state that traceability is only required when quantitative measurements are required. Qualitative measurements will not require calibration. ○ It is also suggested that line 257 be changed to: ‘<i>.....radiation survey meter for the radiation sources used at the practice is maintained and traceable to.....</i>’. <p>Lines 274-287, Section 3.1 The Responsible Person – Equipment - Radiotherapy</p> <ul style="list-style-type: none"> ○ Line 282 describes the requirement for the checking and recalibration of treatment beams or sources for therapy radiation apparatus at intervals specified in international and national protocols. 	<p>Noted. Done. Noted</p> <p>Helps describe what the QA program covers. Can be left.</p> <p>Clause modified.</p> <p>Noted.</p> <p>Agreed.</p> <p>Disagreed.</p> <p>Noted. This only applies to air kerma, therefore X- and gamma radiation.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>The Code should merely require that such checks be conducted. However, the details (e.g. interval period, what protocols to follow) should be outlined in the Safety Code and, ultimately, the Radiation Management Plan.</p> <ul style="list-style-type: none"> ○ Line 286: ‘field measuring equipment’ should be changed to ‘radiation measuring equipment’ <p>Lines 288-290, Section 3.1 The Responsible Person – Radiotherapy treatment planning</p> <ul style="list-style-type: none"> ○ Line 289 refers to ‘physics data’. What is this? The term needs to be defined. The data that is required to be kept should be clearly described. ○ Line 295 should read: ‘the testing of treatment planning equipment...’ (i.e. delete the word ‘a’). ○ The following additional requirement should be included in this section of the Code, as it is considered to be a fundamental record keeping requirement: <i>‘The Responsible Person must ensure a radiation treatment summary is kept for every patient’.</i> <p>Lines 297-315, Section 3.1 The Responsible Person – Equipment maintenance and repair</p> <ul style="list-style-type: none"> ○ Clause 3.1.27 refers to work performed on a radiation apparatus or a radioactive source. Do you mean sealed source apparatus (e.g. HDR units) rather than the actual radioactive source itself? ○ Clause 3.1.29 should be simplified to: <i>‘The Responsible Person must ensure that, following repair or maintenance:</i> <i>(a) the operation of any radiation apparatus is assessed; and</i> <i>(b) therapy radiation apparatus is calibrated before it is returned to clinical use.’.</i> <p>Additionally, it is not clear from the Code who is to assess the operation, or calibrate, the apparatus, or who has responsibility to ensure it is done. This needs to be clearly stated in the Code.</p>	<p>This will most likely happen.</p> <p>Done.</p> <p>Changed to “dosimetry”.</p> <p>Clause changed.</p> <p>Clause 3.1.25 covers this.</p> <p>“or source” has been removed from the end of the clause.</p> <p>This clause has been modified.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Lines 316-329, Section 3.1 The Responsible Person – Death of a patient</p> <p>Line 328: change ‘.....who handles a deceased patient with a radioactive source in situ.’, to ‘.....<i>who handles the deceased patient.</i>’.</p> <p>Lines 330-335, Section 3.2 Medical Practitioner – Authorisation for a medical radiation procedure</p> <p>What is meant by the terms ‘authorised’ and ‘authorisation of a medical procedure’ as used in this section? It would appear to be at odds with the definition of ‘authorisation’ found in the Glossary. Does the medical practitioner really need to be authorised by the regulatory authority?</p> <p>Lines 337-358, Section 3.2 Medical Practitioner – Justification for a medical radiation procedure</p> <p>The sections on ‘Justification for a medical radiation procedure’ and ‘Approval of a medical radiation procedure’ (lines 359 – 379) should be combined, or at least cross-referenced. A medical radiation procedure should not be granted approval unless the justification process has been followed.</p> <p>Additionally, the details on what should be considered during the justification process should be provided in the Safety Guide (or alternatively a Schedule).</p> <p>Lines 380-389, Section 3.2 Medical Practitioner – Optimisation of protection and limitation of rad doses</p> <p>Clause 3.2.7 should be the first clause under this section (i.e. come before clause 3.2.6).</p> <p>Lines 413-431, Section 3.2 Medical Practitioner – Procedures for potentially pregnant or pregnant patients</p> <ul style="list-style-type: none"> ○ A therapy radiation procedure may consist of set exposures over a long period of time (e.g. once/month). It is important that the pregnancy status of a pregnant woman is established prior to each exposure. This requirement is not clear. ○ As the requirements of this part are already detailed in Schedule B, it is suggested that the content be deleted. Simply referring to schedule B is all that is necessary. 	<p>Done.</p> <p>The medical practitioner (radiation) will need to be authorised by the rra.</p> <p>Noted.</p> <p>Clause transferred to a duty of the RP.</p> <p>Noted.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Lines 444-454, Section 3.2 Medical Practitioner – Procedure for a patient with an implanted electronic device</p> <ul style="list-style-type: none"> ○ Whether or not a patient has an implanted electronic device, and determining the requirements in relation to this, should be part of the justification/approval process for the medical procedure. Consequently, there should be no need to specifically reference section 3.2.17 in the Code. Specific requirements which may relate to this should be included in the Safety Guide. ○ Line 451 refers to ‘qualified expert’. A qualified expert, as defined in the draft Code, may not necessarily be the most appropriate person to determine if the electronic device will be affected by radiation. This could be a clinical engineer, rather than a radiation physicist. <p>Line 459, Section 3.3 Operator – Authorisation for a medical procedure</p> <ul style="list-style-type: none"> ○ Clause 3.3.1 refers to patients. Should this requirement also cover individuals? The scope implies that the terms ‘patient’ and ‘individual’ differ. <p>Lines 465-473, Section 3.3 Operator – General requirements for an operator</p> <ul style="list-style-type: none"> ○ Clause 3.3.3 specifies that the operator must wear personal protective equipment and personal radiation monitoring device provided by the Responsible Person. These requirements are required to be detailed in the Radiation Management Plan. <p>Is there a reason why these specific requirements are detailed in the Code, and not some of the other requirements? As the Code already states that the operator must comply with the relevant provisions of the Radiation Management Plan, it is considered repetitive to include clause 3.3.3.</p> <p>Lines 474-491, Section 3.3 Operator – Specific requirements for a medical radiation procedure</p> <ul style="list-style-type: none"> ○ Line 487 (Clause 3.3.4(e)(i)) should be changed to simply read: <i>‘the radiation treatment plan has been approved by the medical practitioner; and’</i> 	<p>Noted.</p> <p>Noted.</p> <p>Change effected.</p> <p>Change effected.</p> <p>Change effected.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>This is considered necessary as the plan needs to be approved, rather than be endorsed. The prescribing medical practitioner should also sign off of the actual plan – the actual prescription may differ to the final plan.</p> <ul style="list-style-type: none"> ○ Line 490 – the radiation dose to the patient should be delivered in accordance with the radiation treatment plan, not the medical practitioner’s prescription. <p>Lines 498-510, Section 3.3 Operator – Operator – Procedures for potentially pregnant or pregnant patients</p> <ul style="list-style-type: none"> ○ Clause 3.3.6 refers to patients. Should this requirement also cover individuals? The scope implies that the terms ‘patient’ and ‘individual’ differ. ○ A therapy radiation procedure may consist of set exposures over a long period of time (e.g. once/month). It is important that the pregnancy status of a pregnant woman is established prior to each exposure. This requirement is not clear. ○ Clause 3.3.7 states that the operator must take into account ‘relevant’ requirements of Schedule B. What are the ‘relevant’ requirements? Who determines the relevancy? <p>Lines 511-534, Section 3.3 Operator – Control of exposure to persons other than the patient</p> <ul style="list-style-type: none"> ○ Line 516 should be simplified to read: ‘ensure that visual surveillance of the patient is maintained throughout a procedure; and....’ ○ Clause 3.3.9 refers to intra-operative radiotherapy. Does this procedure still occur, or do you mean brachytherapy? This section appears to be overly prescriptive, and it is suggested that it be moved to the Safety Guide. <p>Lines 560-564, Schedule A Radiation Management Plan</p> <ul style="list-style-type: none"> ○ Section A1.1(b) refers to the construction and shielding requirements of the medical practice. This requirement has no place in a Radiation Management Plan. <p>The plan should be a document which details how the Responsible Person is going to maintain radiation safety at the practice and the obligations on</p>	<p>Change effected.</p> <p>This can be left as patient.</p> <p>Noted.</p> <p>“relevant” removed.</p> <p>Changed to “imaging or treatment room”.</p> <p>Added “HDR brachytherapy” but left IOR.</p> <p>It was agreed to leave this in.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>the various personnel at the practice. The document should not include information about an engineered safeguard that should be established before a practice is even built.</p> <ul style="list-style-type: none"> ○ The Radiation Management Plan should also address the safety devices to be worn by persons involved in the use of radiation. ○ Footer 11 – change to: ‘<i>Observation may be by indirect means....</i>’. ○ Section A1.1(n) seems to incorporate two requirements – one regarding the provision of expert advice, and the other in relation to the requirements to review the plan. It is suggested that the two requirements be separated. ○ Line 593 – change ‘utilised’ to ‘used’. ○ As stated previously, it is not clear why a separate plan to cover the management of radioactive waste should be required. As waste production is a day to day result of using certain radioactive substances, it is suggested that the maintenance of such waste would simply be part of the radiation management plan. It is therefore suggested that A2 be deleted from the draft Code. <p>This is particularly relevant in the light of the fact that a document on the pre-disposal management of radioactive waste is being produced by ARPANSA at present.</p> <ul style="list-style-type: none"> ○ Line 615 – change ‘provision of advice’ to ‘notification’. <p>Lines 660-673, Schedule C Protection of a child</p> <ul style="list-style-type: none"> ○ Line 663 – change ‘administering person’ to ‘operator’ ○ Line 669 – change ‘to the both the’ to ‘to both the’ ○ Line 672 – this line refers to the need to advise a patient who is breast-feeding about the risks if diagnostic gallium-67 is being administered. While this is sound advice, it is likely that other radiopharmaceuticals will be used which may have similar risks. Consequently, it is suggested that this requirement be more generic in its application. <p>Lines 686-716, Schedule D</p> <ul style="list-style-type: none"> ○ The Schedule does not have a title. Suggest ‘Treatment Planning’. ○ Line 687 refers to ‘basic data’. Is this the same as ‘physics data’ referred 	<p>(g) and (h) appear to do this.</p> <p>Done.</p> <p>Done.</p> <p>Done.</p> <p>Change effected.</p> <p>Done.</p> <p>Section C transferred to the Safety Guide.</p> <p>Section D transferred to the Safety Guide.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>to in line 289?</p> <ul style="list-style-type: none"> ○ It is suggested that the information found in Schedule D should be included in the Safety Guide, rather than the Code. <p>Lines 752-755, Glossary – Authorisation</p> <p>The definition of authorisation is confusing, and is inconsistent with the term used in Code which refers to the ‘authorisation for a medical radiation procedure’. This needs to be re-considered.</p> <p>Lines 768-774, Glossary – Diagnostic reference level</p> <p>This definition refers to ‘medical radiodiagnostic practices’. This is clumsy, and it is suggested that the definition be simplified.</p> <p>Lines 778-786, Glossary – Dose constraint</p> <p>This definition is confusing, and should be simplified.</p> <p>Lines 813-816, Glossary – Ionizing radiation</p> <p>This definition should be changed to that found in the National Directory.</p> <p>Lines 827-830, Glossary – Nuclear medicine</p> <ul style="list-style-type: none"> ○ Change ‘utilises’ to ‘uses’. ○ Change ‘and or’ to ‘and/or’. <p>Lines 831-833, Glossary – Occupational exposure</p> <p>The wording in footer 14 should be included as part of the definition for occupational exposure.</p> <p>Lines 840-842, Glossary – Practice</p> <ul style="list-style-type: none"> ○ This word is not bolded the first time it appears in the draft Code. ○ Change ‘may’ to ‘will’ or ‘results’. <p>Lines 868-870, Glossary – Radiotherapy</p> <p>Change to: <i>‘the use of radiation apparatus and sealed radioactive sources to</i></p>	<p>Definition changed.</p> <p>Noted.</p> <p>Taken from RPS1.</p> <p>Taken from RPS1.</p> <p>Disagreed.</p> <p>“and” removed.</p> <p>Noted.</p> <p>First appearance now bolded.</p> <p>RPS1 definition.</p> <p>Change effected.</p>

SUBMITTER	COMMENT	RESPONSE
	<p><i>treat disease.'</i></p> <p>Lines 875-879, Glossary – Relevant regulatory authority</p> <ul style="list-style-type: none"> ○ The regulatory authority deals with all applications for ionising and certain non-ionising radiation sources. The definition in the draft Code is limiting. It is therefore suggested that the preceding words to the definition be '<i>for the purposes of this Code....</i>'. ○ Additionally, the last sentence should read '<i>A list of relevant regulatory authorities in Australia is included.....</i>' <p>Lines 895-900, Glossary – Sealed radioactive source</p> <p>The word 'substance' in line 896 should be changed to 'material'.</p> <p>Lines 901-903, Glossary – Transport Code, the</p> <p>The title of the Transport Code should be in italics.</p> <p>Lines 906-914, Annex 1 – Regulatory authorities</p> <ul style="list-style-type: none"> ○ For Queensland, the unit should be changed from 'Radiation Health' to 'Radiation Health Unit'. ○ It is suggested that Queensland's website address could also be included in the contact list – that is, www.health.qld.gov.au/radiationhealth. 	<p>This is an agreed definition.</p> <p>Agreed.</p> <p>“substance” is considered acceptable.</p> <p>Done.</p> <p>This will all be done and finalised at publishing.</p>
<p>20 Dr David Causer RSO Royal Perth Hospital, WA</p>	<p>As a member of the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) I subscribe to the comments which will be forwarded from this body, but would also like to make the following personal observations regarding the practical application of the draft COP "Radiation Protection in the Medical Applications of Ionizing Radiation".</p> <p>* Schedule A A1.1(b) (ii) A dose constraint of 0.3 mSv per annum is lower than that of 0.5 mSv per annum which has hitherto been used in designing x-ray and nuclear medicine facilities in WA. If the new constraint is to be applied retrospectively a large number of rooms will need to be subjected to area monitoring surveys and some may need to be provided with increased shielding. The position needs to be clarified.</p> <p>* Schedule B B2.2 (c) Inadvertent CT scanning of the pregnant abdomen may give an effective dose to the foetus of 20-40 mSv. A mandatory</p>	<p>Dose constraints removed to the Safety Guide.</p> <p>Section B2 of Schedule B has been removed to the Safety Guide.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>requirement to inform the patient of this dose will mean that they are given a figure which is meaningless to them unless they are also informed that the acceptable dose limit is 0.3 mSv ie. about a hundred times lower. It will then be necessary to inform them that unless the foetus has received more than 100 mSv there is very little risk of radiation induced abnormalities. I suggest that this may both alarming and confusing.</p> <p>* Responsibilities 3.1.5(b) I applaud the intent to introduce a mandatory requirement to control patient doses by the use of Diagnostic Reference Levels.</p>	Noted.
<p>21 Graeme Palmer Executive Officer, Radiation Protection Committee, EPA, SA</p>	<p>General: Safety Guides</p> <p>Informed review and comment has been difficult in the absence of the Safety Guides.</p> <p>There may be further comment once the Safety Guides are available.</p> <p>3.1.1-2: Responsible Person (and RSOs)</p> <p>The rationale for not placing Code responsibilities on the RSO is understood. In many situations, the Responsible Person delegates the implementation of the RMP to the RSO. Given the key nature of this relationship, this section should clearly state that the Responsible Person retains the accountability and is responsible for bringing in such expert advice as is required to discharge the RMP.</p> <p>It is vital that the Responsible Person provides adequate resource to the implementation of the plan. It would be a good opportunity to explicitly specify this rather than wrap it up in 3.1.1(a).</p> <p>3.1.23 & Glossary: Qualified Expert</p> <p>Does this mean only a medical physicist, or does it include nuclear medicine specialists with experience in therapy?</p> <p>There are a number of examples in current clinical practice where medical physicists are not routinely involved in nuclear medicine therapy, especially in private practice with I-131 for hyperthyroidism and Y-90 Spheres.</p> <p>They need to be available if required for consultation, and in practice have often prepared generic guidance that can be adapted by the nuclear medicine specialist for individual patient use.</p> <p>3.1.12, 3.2.11, 3.3.6 & B1: Dose constraints (foetus/embryo)</p> <p>It is presumed that the 0.3mSv trigger/constraint for the foetus/embryo is to</p>	<p>Noted</p> <p>Noted.</p> <p>“resourced” is included as part of 3.1.1(a).</p> <p>Definition will cover this through recognition by the rra.</p> <p>0.3 mSv has been changed to 1 mSv or removed where</p>

SUBMITTER	COMMENT	RESPONSE
	<p>account for multiple procedures with reference to a 1mSv limit. However, it would be preferable for the medical practitioner to query the mother as to prior medical exposures during the pregnancy so that these can be taken into account during justification/optimisation.</p> <p>It is noted that there is no evidence of effects below 100mSv that justify termination, and that the foetus/embryo receives indirectly the benefits from the procedure performed on the mother.</p> <p>It is noted also that once it becomes a person, the baby toddler is most unlikely to receive any dose as a member of the public, so even if regarded as an in utero member of the public for limitation purposes, there is the option of 5 year averaging over the gestation period.</p> <p>Calculation of inadvertent doses to the foetus/embryo may be very difficult, and to an accuracy of 0.3mSv might not be possible.</p> <p>A1.1(b)(ii) & A2.1(d): Dose constraints (member of the public)</p> <p>There should be no reference to dose constraints in relation to construction and shielding. In particular, dose constraints below the 1mSv dose limit are of concern.</p> <p>Dose constraints are not well understood amongst many radiation professionals, let alone medical staff. They are liable to be misused and become de facto limits.</p> <p>There is a danger that existing guidance for shielding such as conservative occupancy factors will be used and unnecessary additional shielding installed.</p> <p>It is highly unlikely that with a single source constraint of 1mSv, the 95th percentile representative individual member of the public would receive multiple exposures such that they exceeded 1mSv in any year. Constraints lower than 1mSv should be reserved for the rare situation where particular circumstances indicate that it is possible. (This would be for the Safety Guide rather than the Code.)</p> <p>B1.3: Doses to foetus/embryo</p> <p>The Code pays significant attention to foetal/embryonic doses. Given its importance, should there be a mandated central register of planned and accidental doses exceeding a set value (say 1mSv)?</p> <p>3.1.3(c), 3.2.11: Establishing pregnancy status</p>	<p>appropriate.</p> <p>Dose constraints moved to Safety Guides.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>What does ‘reasonable’ mean in relation to establishing pregnancy status? The Radiation Protection Committee considers that further professional consultation on requirements and wording for establishing pregnancy status are required.</p> <p>3.2.14: Counselling</p> <p>Counselling of radiation risks needs to include the risks of not performing the procedure. There is the general question of whether counselling of patients should fall under the remit of the radiation regulator.</p> <p>General: Referrers</p> <p>The relationship between referring practitioner, medical practitioner and operator are key to Code compliance, and to achieving its requirements for justification and optimisation. There are significant potential issues such as lack of awareness by the referrer, and ‘scan shopping’ if a medical practitioner rejects or changes a referred request for a procedure. This will need to be addressed in the Safety Guides.</p> <p>General: Chiropractors, nurse practitioners and dentists</p> <p>The Committee recommends that the Code applies to chiropractors, nurse practitioners and anyone else who exposes humans in the medical use of ionising radiation.</p>	<p>“reasonable” will depend on the magnitude of the exposure.</p> <p>Noted.</p> <p>Noted.</p> <p>Noted.</p> <p>This Code does not apply to the chiropractic use of radiation.</p>
<p>22 Kevina Choma Honorary Secretary Qld Branch Australian Institute of Radiography</p>	<p>Thank you for the opportunity to attend a workshop held at Radiation Health 18 June 07, and comment on the code of Practice – Radiation Protection in the Medical Applications of Ionizing Radiation.</p> <p>In broad terms, the intent of the document seems reasonable in that it provide a national uniform approach to acceptable standards.</p> <p>It was difficult to comment on the suitability of the Code of Practice without the accompanying Safety Guides. Their inclusion may have given relevance to the Code of Practice.</p> <p>From the document and the information session attended, the following points are made:-</p> <p><u>Comments</u> <i>Section 3.1</i></p>	

SUBMITTER	COMMENT	RESPONSE
	<p>Item 3.1.15 speaks about warning notices for fixed equipment but no mention is made of warning procedures or safety protocols for mobile x-ray equipment.</p> <p>Section 3.2 Medical Practitioner – definition v expected role In a Medical Imaging environment, “Medical Practitioner” responsibilities seem to match closely with the role of a Radiologist. However, any medical practitioner could read this document and infer, as it will be law, that they are the responsible authority and make requests while not having the required specialist skills. Additionally this document does not seem to make allowances for the fact that medical practitioners are not the only professional group which may request medical imaging procedures.</p> <p>Item 3.2.4 details items which must be noted in an imaging request but does not indicate that a request should be complete before an operator (ie radiographer or licensed operator) can action the request.</p> <p>Item 3.2.8 re advice to patients and carers – is it necessary to include this item as part of legislation. The information supplied may vary depending on source type, procedure, patient and department so it may create problems in determining if adequate information has been supplied. These issues may be better addressed in the Safety Guides. Similarly item 3.2.17 should be addressed in the Safety Guides rather than as part of legislation.</p> <p>Section 3.3 Item 3.3.11 Equipment malfunction or error – it is not necessary to report this to the medical practitioner unless it results in lack of safety or incorrect treatment to the patient. In general, the implementation expectations of the regulators and how this code of practice will be embraced in modern clinical practice will determine its effectiveness on protecting the public. Once again thank you for the opportunity to comment on this document and we look forward to further involvement in the process.</p>	<p>Noted.</p> <p>Definition and classification changed. This should clarify the roles.</p> <p>Obligation within operator requirements.</p> <p>Noted</p> <p>Clause changed.</p>
<p>23 Hazel Upton Secretary Radiological Council, WA</p>	<p>The draft of the above report was considered by Council members out of session and the following comments have been provided.</p> <p>General Comment</p>	

SUBMITTER	COMMENT	RESPONSE
	<p>The Draft Code sets out material that “<i>will be adopted by State, Territory and Commonwealth Regulatory Authorities as part of their regulatory controls...</i>” i.e. the Code has to be in a form which can be tested in the courts. This may be achievable in relation to the responsibilities of the <i>Responsible Person</i> who, by definition, is a designated “legal person”. It also may be achievable in relation to individual medical practitioners who can be unambiguously identified as being responsible for a specific examination or procedure. i.e. an examination or procedure which they themselves undertake under a licence issued by the relevant regulatory authority and that licence requires compliance with the Code.</p> <p>However, the majority of examinations and procedures, particularly in diagnostic radiology, are not linked to an individual medical practitioner who is “<i>responsible for the overall conduct</i>” of the examination or procedure. This lack of certainty about which individual may be responsible in a given situation will create significant problems in attempting to enforce these aspects of the Code.</p> <p>Specific Comments</p> <p>1.2 Purpose 1.2(c) notes that the Code will establish the specific roles and responsibilities of the <i>Responsible Person</i>, the <i>medical practitioner</i> and the <i>operator</i>. The possible legal implications of being unable to identify an individual medical practitioner with responsibility for the overall conduct of an examination or procedure are mentioned in the General Comment above.</p> <p>There are a number of obligations imposed generally on medical practitioners under the Code which would be difficult to enforce. e.g. consider a large radiology practice or hospital department with many medical practitioners involved in the use of ionising radiation. Under 3.2.11, which <i>medical practitioner</i> is responsible if an operator undertakes, say, a CT examination of the abdomen and pelvis resulting in a fetal dose > 0.3 mSv? Is it the radiologist who just happens to be on duty and who reports on the particular images? Perhaps it is some other practitioner, a senior partner perhaps, who might have failed to establish (and enforce) protocols for such examinations?</p> <p>If there is an equipment malfunction or error, the operator is required to report the matter to the <i>medical practitioner</i> and the <i>Responsible Person</i> (3.3.11).</p>	<p>Noted.</p> <p>This could be considered as part of the cost-benefit analysis.</p> <p>Noted.</p> <p>This clause has been changed, which should clarify the situation.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>The Responsible Person is an identifiable person but to which <i>medical practitioner</i> should the report be made? A medical practitioner who happens to be nearby, or perhaps, in diagnostic radiology, the radiologist who just happens to be on duty at the time?</p> <p>Recommendation While individual medical practitioners licensed to use ionising radiation have responsibilities (and certain parts of the Code should be applied as individual licence conditions) the general responsibilities for “overall conduct” should be assigned to one licensed practitioner in each hospital or practice (one from each of the specialties of radiology, nuclear medicine and therapy) who should be nominated by the Responsible Person in the organisation’s Radiation Management Plan.</p> <p>While this practitioner would be assigned responsibility for developing relevant protocols, working practices, etc. which apply to the practice or institution as a whole, neither they nor the <i>Responsible Person</i> should be liable for the actions of colleagues or other workers who might contravene those protocols or working practices, provided the Responsible Person maintains records to demonstrate that those individuals have been properly instructed in, and directed to comply with, the protocols and working practices in the RMP.</p> <p>1.3(a) Scope Footnote 1 excludes dentistry but it should be stated that “medical diagnosis” in the Code also excludes chiropractic radiography. It is assumed that a separate Code would need to be developed for chiropractic in collaboration with that profession.</p> <p>2.1 (and 3.1.3) Justification of a medical radiation procedure The Code requires the Responsible Person to ensure that radiation procedures are justified. While appropriately qualified medical practitioners (radiologists, nuclear medicine physicians, radiation oncologists, cardiologists, etc) will undertake that role for procedures or examinations which they (individually) carry out or direct, most examinations and procedures will be performed by operators on the basis of written or oral protocols which might address the question of “generic justification”.</p> <p>However, the Code appears to direct full responsibility for justification at the <i>Responsible Person</i> and the <i>medical practitioner</i> and does not discuss the role</p>	<p>This could be done administratively by the RP if they choose to do so.</p> <p>Done.</p> <p>Generic justification now included.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>of the <i>Referrer</i>. Section 2.1 also should mention the referrer’s responsibility to consider which examination or procedure is appropriate to the patient’s clinical condition and, indeed, if an examination or procedure involving ionising radiation is appropriate. The pregnancy status of the patient at referral also should be addressed. See also 3.2.4(b).</p> <p>While this is not a matter that can be enforced by the Code it is important background information and could recommend that <i>referrers</i> take note of referral guidelines prepared by the professional Colleges.</p> <p>2.2 Optimisation 2.2.1 applies the ALARA principle to radiation doses received by the public and occupationally exposed persons but should include patients (although partly addressed in 2.2.2) as noted in <i>Radiation Protection in the Medical Applications of Ionizing Radiation Regulatory Requirements and Good Practice</i>. ARPANSA May 2007, p3.</p> <p>3.1.1(c) 3.1.1 (c) would be impractical for a regulator to enforce. The Responsible Person cannot <i>ensure</i> that all persons follow and comply with the Radiation Management Plan. At best, he should be required to ensure that workers are instructed in and directed to comply with the Plan with that instruction documented. Each worker might be required to sign a statement that they have read and understand the contents. In some circumstances, enforcement for a worker breach of the Code might then be a possibility.</p> <p>3.1.2(b) has the same concerns as 3.1.1(c).</p> <p>3.1.3 Similar enforcement difficulties. “The Responsible Person must ensure that <i>systems are in place and protocols developed</i> to ensure that no radiation procedure is carried out unless...”</p> <p>3.1.3(b)(ii) Delete “, <i>where it is not practicable for the medical practitioner to approve a diagnostic exposure,</i>”. The Code requires a medical practitioner to have responsibility for the overall conduct of a procedure so it seems inappropriate to have a loophole. In practice, most diagnostic radiology examinations and</p>	<p>Noted.</p> <p>Disagree. Similar to other OHS obligations.</p> <p>Disagree. Similar to other OHS obligations.</p> <p>Noted.</p> <p>Done.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>some nuclear medicine procedures, will not be individually approved by a medical practitioner and the operator will (or should) be acting in accordance with written guidelines established by a medical practitioner</p> <p>3.1.3(c) presupposes that medical practitioners and operators will know which examinations or procedures might give rise to a fetal dose > 0.3 mSv or > 1 mSv to a breast-fed child. This rarely will be the case in practice and the Responsible Person will need to direct a medical practitioner and/or qualified expert to establish protocols which identify the types of examinations or procedures which, in defined circumstances, might give rise to such a dose.</p> <p>However, apart from determining the pregnancy status of the patient and the possible fetal dose, no actions are outlined to modify or defer the examination or procedure. Schedule B simply requires individual justification and, in some circumstances, an explanation to the patient of the risk. This might be dealt with in a Safety Guide but the Code also needs to indicate what actions should follow</p> <p>3.1.4 “The Responsible Person must <i>establish a program</i> to ensure that radiation doses...”</p> <p>3.1.5c "exceeded" should be replaced by "consistently exceeded" since DRLs are not limits that should never be exceeded.</p> <p>3.1.7(b) applies “where relevant”.</p> <p>3.1.13 Amend (c) to “potential radiation hazards associated with the practice <i>and means of protection and the minimisation of radiation dose.</i>”</p> <p>3.1.14 Add new item (c) requiring the Responsible Person to ensure that the effectiveness of such shielding is reviewed at intervals and using methods defined in the Radiation Management Plan.</p>	<p>Clause modified. The dose levels have been removed.</p> <p>Noted.</p> <p>Noted.</p> <p>Done.</p> <p>Clause amended.</p> <p>Done.</p> <p>Disagreed. It will be in the RMP anyway.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>3.1.15(c) states that it applies to radiotherapy, fluoroscopy and computed tomography yet sub-item (i) only refers to radiotherapy. However, the first part of 3.1.15(c)(i) requiring the sign to be “positioned directly adjacent to the entry doors of any room housing...” equally should be applicable to fluoroscopy and computed tomography.</p> <p>3.1.18(b) “advise the relevant regulatory authority of the receipt of each new <i>any additional radiation producing apparatus or sealed radioactive source and of the intended disposal of any radiation producing apparatus or sealed radioactive sources</i>”.</p> <p>3.1.20 It is unlikely that the Responsible Person would have the knowledge to review the QA Program. Change to “The Responsible Person must <i>ensure that a Quality Assurance Program for all dosimetry and associated measuring instruments is implemented and regularly reviewed to:...</i>”</p> <p>3.1.21 As noted in 3.1.20. This item also only requires the results of a QA program to be documented. An item should be added (or 3.1.20 amended) to require some prescribed action to be taken should the QA program detect undesirable changes</p> <p>3.1.22 “<i>The Responsible Person must ensure that verifiable systems are in place for the maintenance and calibration of any radiation survey meters used to ensure compliance with the Radiation Management Plan, with the calibration traceable to...</i>”</p> <p>3.1.24(c) “...recalibrated at intervals specified in international and national protocols <i>or by the relevant regulatory authority</i>; and..”</p> <p>3.1.27 “The Responsible Person must <i>ensure that a written record is maintained which details the work performed...</i>”.</p>	<p>Clause amended.</p> <p>Done.</p> <p>Done.</p> <p>Noted.</p> <p>Noted.</p> <p>Disagreed. The RHC has recommended that such statements are not included in Codes.</p> <p>Done.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>The term “radiation emitting equipment” is another variation of different terms used throughout the Code. cf radiation producing apparatus (3.1.18(b)); Radiation Apparatus (line 229); Ionizing Radiation Apparatus (line 857); medical radiation equipment (line 33); radiation producing equipment (line 193); etc. Can a single, consistent term be used?</p> <p>3.1.28 Similar comment to 3.1.27 on the term used</p> <p>3.1.29 Similar comment to 3.1.27 on the term used</p> <p>3.1.30 Similar comment to 3.1.27 on the term used</p> <p>3.1.30(a) “<i>immediately</i> report details of the fault...”</p> <p>3.2 The definition of medical practitioner needs to make it clear that this is a named specialist who takes responsibility for the procedure or the facility. In cases where the specialist is actually undertaking the procedure it is clear who the responsible medical practitioner will be. However for the majority of x-ray examinations, CT etc unless someone is specifically allocated as taking responsibility then no-one will be doing so. For example, it is not practical to define all radiologists reading CT scans as being responsible for the procedures. A single, named radiologist must take this responsibility.</p> <p>3.2.2 may be legally unenforceable except where individual medical practitioners are licensed and those licences are conditional on compliance with the Radiation Management Plan.</p> <p>3.2.3(c) “...direct health benefits to the patient and, <i>where relevant</i>, the benefits to society...”</p> <p>3.2.3(e) “...the pregnancy status of a female patient <i>of child-bearing age</i> if there is the</p>	<p>Consistency of terminology to be amended.</p> <p>Noted.</p> <p>Classification of this person has been changed to medical practitioner (radiation) which should clarify the situation.</p> <p>Noted.</p> <p>Done.</p> <p>Done.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>potential...” This term is also used in 3.2.12 and Schedule C.</p> <p>3.2.3(f) As for 3.2.3(e).</p> <p>3.2.4 “...the medical practitioner must not undertake or approve a procedure involving exposure to ionising radiation unless a written request, <i>authorised and signed by the referrer</i> is provided that ...” The intention is to reduce the incidence of referrers pre-signing blank referral forms for other personnel to complete as they see fit.</p> <p>Responsibility for the matters in 3.2.4 (and 3.2.5) might more properly be assigned to the Responsible Person in the same manner as 3.1.3.</p> <p>3.2.4(b) should include a requirement for the referrer to state if female patients of child-bearing age are pregnant or not. The referrer has the initial responsibility to consider this question and to consider if a particular examination or procedure is appropriate to the patient’s clinical circumstances. (See comments on 2.1).</p> <p>3.2.7 There does not seem to be any individual or public health benefit in applying this requirement to all examinations or procedures. It might be applied to higher dose examinations or procedures but would be logistically difficult to apply, for example, to fluoroscopic procedures unless all equipment was fitted with dose-area product meters.</p> <p>3.2.8 “...the medical practitioner must <i>ensure that</i> the patient, carer or the patient’s legal guardian <i>is provided with</i> written...” Such matters might be undertaken by medical physicists.</p> <p>3.2.8(a) preferably should say “<i>the precautions to be taken by carers and other person to minimise the risks associated with ionising radiation exposure.</i>”</p> <p>3.2.11</p>	<p>Disagreed. She does not have to be of child-bearing age.</p> <p>Noted.</p> <p>Considered under the justification clause.</p> <p>Clause removed to Safety Guides.</p> <p>Done.</p> <p>Done.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>“... must take <i>ensure</i> that all reasonable steps <i>are taken</i> to establish whether a female patient <i>of child-bearing age</i> is pregnant.” This term is also used in 3.2.12 and Schedule C.</p> <p>3.2.14 “The medical practitioner must <i>ensure that</i> all reasonable steps <i>are taken</i> to advise a pregnant patient...” In practice, this advice is more likely to be given (if at all) by the operator rather than the medical practitioner. It also should state that it only applies if the potential fetal radiation dose is likely to exceed 0.3 mSv otherwise the advice is required even for inconsequential exposures.</p> <p>3.3.3(b) “wear a personal radiation monitoring device <i>if required by regulation, directed by the relevant regulatory authority or</i> provided by the Responsible Person.” The wording otherwise provides a defence for a person who is not “provided” with a device by the Responsible Person.</p> <p>3.3.5(b) delete “to be”.</p> <p>3.3.6(b) It is not clear what the operator should do if they are conducting an examination or procedure in accordance with 3.3.4(a)(ii) and the patient is found to be pregnant. Item 3.3.7 requires the operator to take Schedule B into account but B1.1 to B1.3, matters which should be the responsibility of a medical practitioner, cannot be acted on if, according to 3.3.4(a)(ii), the medical practitioner is not able (available?) to approve the exposure in the first place.</p> <p>3.3.8(a) should include a reference to situations where persons are required to be present in the room (cf 3.3.9(a)(i) and (ii)).</p> <p>3.3.11 requires equipment and malfunction errors to be reported “immediately”. However, 3.3.8(c) requires radiation incidents to be reported within 24 hours. The definition of “radiation incident” includes equipment failure and therefore the reporting time frame should be consistent.</p>	<p>“ensure that” done.</p> <p>The obligation is still on the mp(r).</p> <p>Disagreed. The RHC has recommended that such statements are not included in Codes.</p> <p>No, this is a future occurrence.</p> <p>Noted.</p> <p>Noted.</p> <p>Clause 3.3.8(c) has been removed.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>A1.1 should require the RMP to identify matters that must be reported to the relevant regulatory authority.</p> <p>A1.1(a) The list of important matters for inclusion in the RMP should include ensuring that referrals are only acted on if they have been received from persons authorised to do so by the relevant regulatory authority.</p> <p>A1.1(b) Some regulatory authorities prescribe lower dose constraints for construction and shielding. A footnote should be added referring to possible lower dose constraints in some jurisdictions.</p> <p>A1.1(f) also should address the need for certain personnel to be authorised by the relevant regulatory authority.</p> <p>A1.1(j) “emergency procedures to cover <i>in response to</i> radiation incidents”</p> <p>A1.1(l) should add “..and for radioactive waste disposal (See A2).”</p> <p>A2.1(f) “provision of advice to the relevant regulatory authority of any radiation incident which has, <i>or may have</i>, resulted in:...”</p> <p>B2.1 The radiation dose should be calculated by a Qualified Expert or by the medical practitioner in accordance with protocols prepared by a Qualified Expert.</p> <p>GLOSSARY Diagnostic Reference level (DRL) for medical exposure Some regulatory authorities already prescribe DRLs for some examinations. Amend the definition to provide for DRLs also to be set by the relevant regulatory authority.</p>	<p>Noted.</p> <p>Noted.</p> <p>Dose constraints removed to Safety Guides.</p> <p>Noted.</p> <p>Done.</p> <p>Noted.</p> <p>Done.</p> <p>Noted.</p> <p>Done.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Interventional radiology Interventional procedures also may be performed using CT</p> <p>Medical Practitioner The definition of medical practitioner needs to make it clear that this is a named specialist who takes responsibility for the procedure or the facility. In cases where the specialist is actually undertaking the procedure it is clear who the responsible medical practitioner will be. However for the majority of x-ray examinations, CT etc unless someone is specifically allocated as taking responsibility then no-one will be doing so. For example, it is not practical to define all radiologists reading CT scans as being responsible for the procedures. A single, named medical practitioner must take this responsibility.</p> <p>Nuclear Medicine Simplify to “<i>the use of unsealed radioactive sources for diagnostic imaging, physiological testing and therapy.</i>”</p> <p>Occupational Exposure Although implicit by reference to the person’s work, footnote 14 should include “medical exposure” as excluded exposure.</p> <p>Radiation Incident Delete reference to “non-ionizing radiation” (for this Code).</p> <p>Referrer It is not completely clear that the clause starting "who will be responsible ..." does not relate to the referrer. The clause needs to be reworded to leave no doubt about what is intended.</p> <p>Responsible Person Refers to the “legal person”. This term also should be defined.</p>	<p>Medical practitioner (radiation) now used.</p> <p>Done.</p> <p>Noted.</p> <p>Standard definition. It can stay.</p> <p>Change to the definition, medical practitioner (radiation), could resolve this issue.</p> <p>The footnote clarifies this.</p>
<p>24 Radiation Safety Reference Group RANZCR</p>	<p>It is noted that ARPANSA is proposing to produce a Code of Practice on medical radiation that will be adopted by reference into the National Directory for Radiation Protection, and from there will be referenced in Commonwealth/State /Territory regulations and thus form part of the regulatory requirements for radiation protection.</p> <p>It is noted that only a draft Code has been produced and distributed for</p>	

SUBMITTER	COMMENT	RESPONSE
	<p>comment, and ARPANSA intends to produce Safety Guides with the Code which are intended to be guidelines of best practice for radiation protection.</p> <p>It is difficult to provide a comprehensive response to the ARPANSA document when industry has only been asked to comment on part of the overall documentation. As to what items are best in a Code and thus part of the regulatory framework, and what should be in a Safety Guide can be a matter of debate, and what balance is achieved between the two documents can only be commented on when all documentation is available.</p> <p>There is a covering paper dated May 2007 which provides helpful explanation about the background of and rationale for the Code. That paper contains explanation and gives a rationale about the Code and Safety Guide, whereas the Code itself is written in a didactic style of jargon which is difficult to understand with no explanation. In that covering document, ARPANSA states that the basis for radiation protection is ICRP 60 published in 1991. We find it surprising that ARPANSA has not included ICRP publications as references in the Code. In fact there are no references apart from ARPANSA documents in the bibliography. This makes us wonder whether ARPANSA developed the Code without considering international guidelines.</p> <p>ICRP has recently produced several publications relating to medical radiation which seem to have been ignored by ARPANSA. Those ICRP documents are written in a different style to previous ICRP publications, and contain much more discussion about the pros and cons about medical radiation safety issues. ICRP clearly recognizes that in medical radiation the emphasis should be on promoting best practice.</p> <p>Issue of one Code or three Codes</p> <p>ARPANSA is proposing a single unified Code to cover the three areas of medical radiation; diagnostic radiology, nuclear medicine and radiotherapy with three separate Safety Guides. Another option is three separate Codes, one for each medical area with an attached Safety Guide, which would enable a user in a particular branch of medicine to readily identify the documents relevant to their field. It is puzzling why the proposed Radiation Safety Guides were not distributed for comment at the same time as the Code.</p> <p>Within our College, several of our members have contributed a lot of time and effort into producing the drafts. At a very late stage in development of the drafts the whole process was put into disarray, and that has caused a great deal of ill feeling and loss of good will towards this whole project. It is not just</p>	<p>Noted.</p> <p>Noted</p> <p>Noted.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>medical persons who feel alienated by such an arbitrary decision; others have also expressed their dismay at the process. The way ARPANSA has handled this issue does not inspire confidence. There seems no compelling reason to have a single Code and thus we respectfully request ARPANSA reconsiders this issue. For instance the section on requirements for testing radiotherapy computers and equipment only applies to radiotherapy so there is no benefit including such statement in a diagnostic radiology code. The Codes should be written so they are relevant to each area. If separate Codes are developed, they should be, as much as possible, similarly formatted and any sections common to all areas should be identical.</p> <p>While it may sound reasonable for ARPANSA to produce Codes and Safety Guides about various topics the difference is not clear cut and there may be considerable overlap. ARPANSA states that the Code will be regulatory and the Safety Guide describes best practice. Thus the distinction between a Code and a Safety Guide is what is regulatory and what is not. In some ways the regulatory requirements are minimum standards that must be done and the Guide is best practice for radiation safety. They are not mutually exclusive. Another option is a single document with any regulatory items within the document clearly identified as regulatory requirements. To have two documents where one has to continually go back and forward from one document to another is cumbersome and difficult to manage.</p> <p>The following statements are based upon the premise that the Code will be a regulatory document used by the radiation Regulatory Authorities.</p> <p>In our view, in medical practice, regulation of medical radiation by the radiation regulators should be kept to a minimum. The degree of regulation should be consistent with the degree of regulation of other methods of medical practice. There should be regulation of qualifications; thus who can obtain a radiation license to use the radiation, and there should be regulation by licensing of operators of equipment and accredited inspectors. There should be regulation of the facility and equipment to ensure safety of operators and staff. However there should not be any regulation of the radiation delivered to a particular patient. The appropriate amount of radiation for a particular procedure depends upon the circumstances of the case, that is the clinical problem and the potential benefits and risk from the procedure. That is a matter of what constitutes best practice and it is a matter for guidelines from the College's and professional bodies. ICRP and ARPANSA do not recommend or set any limits for radiation for medical radiation, rather the control of radiation</p>	<p>Noted.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>is by an emphasis on justification and optimisation. Efforts should be made to encourage and develop best practice in radiation safety issues in the medical area rather than increasing radiation regulatory requirements. It is appropriate that ARPANSA as the national radiation safety body also produces radiation safety guidance documents, and we look forward to the Safety Guides.</p> <p>Overall, in our opinion, the document is written in bureaucratic jargon of regulators, with little explanation, which will make it difficult for medical radiation departments to follow. It is strange that many of the headings throughout the document are not numbered but individual paragraphs are, which makes it difficult follow or to go from one section to another.</p> <p>The following comments refer to specific sections of the draft Code:</p> <p>Section 3.1.3 (c)(i) “Female patients and pregnancy or possible pregnancy”</p> <p>The issue of radiation dose and pregnancy is discussed many times in this document. This outlines steps to confirm or exclude pregnancy. In our opinion the issue of pregnancy and steps to exclude pregnancy are important but depend upon the particular circumstances of the clinical situation. The Code emphasizes steps to confirm or exclude pregnancy but gives no guidance on how that information is to be handled, and how a decision is made as to whether a procedure should be undertaken or not.</p> <p>It is our recommendation that all sections relevant to pregnancy or potential pregnancy should be in the Safety Guide and not in the Code. As indicated it is important to have guidelines in place but they should be guidelines and not regulations.</p> <p>Irrespective of where it is placed, we suggest the phrase in section 3.1.3(c) “all reasonable attempts’ be replaced by “reasonable attempts”. Attempts are either reasonable or not reasonable and depend upon the circumstances of the case; otherwise it is semantics as to what comprises “all”.</p> <p>We draw ARPANSA’s attention to the RANZCR guidelines on pregnancy and radiation, which are available on our website.</p> <p>Similarly section 3.1.3(c)(ii) about breast feeding should be in the Safety Guide and not the Code.</p> <p>Section 3.1.5b Compare doses from diagnostic procedures with DRLs</p> <p>Suggest delete this section from the Code and place it in the Safety Guide.</p>	<p>Noted.</p> <p>Noted.</p> <p>Most material relating to pregnancy has been removed to the Safety Guides.</p> <p>This clause has been modified and this phrase has been removed.</p> <p>Done.</p> <p>Disagreed.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>It sounds reasonable from a radiation safety point of view to compare doses from diagnostic procedures to DRLs. However, while ICRP and IAEA have published lists of common doses from radiological procedures as guidelines, as far as we are aware no such Australian list exists and ARPANSA have not produced any lists. It is unreasonable for a radiation regulator to impose such a condition of regulation for radiation licensing that it is mandatory to compare radiation doses with non-existent data. How could the radiologist comply with this and how could a regulator implement this? In other countries DRLs are used as guidelines for diagnostic imaging to promote radiation safety best practice. The issue of DRLs is important as they are a tool to guide best practice. It is our opinion that use of DRLs should not be in the Code, rather they should be as guidelines in the Safety Guide.</p> <p>3.1.7 (a) “ a radiation monitoring device is provided for each occupationally exposed person who could be exposed to ionizing radiation in excess of 1 mSv in any one year”</p> <p>It would be helpful to provide additional guidance as to how such a requirement is to be implemented. There are many occupational workers such as radiographers, working in medical radiation facilities that have appropriate radiation safety systems, where the chance of them being exposed to radiation a dose over 1 mSv is extremely unlikely. Does an extremely unlikely occurrence constitute “could be exposed”? This mentions the National Directory but it is not clear which part of the National Directory is referenced, nor indeed whether there are criteria about this listed in the National Directory.</p> <p>3.1.7(b)</p> <p>This section does not make clear when internal dose assessments and biological monitoring are to be carried out. Clearly such monitoring would be uncommonly required. The National Directory lists exemptions for internal activity.</p> <p>3.1.12 inadvertent irradiation of the fetus.</p> <p>We suggest this should be in the Safety Guide. It is a very important issue but it is a particular issue for that particular patient. It should not a matter for the regulator. There should be clear guidelines as how to handle such incidents and being in the Safety Guide does not diminish the importance of this problem.</p>	<p>Changed to “is likely to”.</p> <p>Noted.</p> <p>Wording of clause amended so that protocols are in place.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>3.1.24 Radiotherapy equipment</p> <p>The issue of accurate calibration of radiotherapy equipment before clinical use is of sufficient importance that it should be a matter of regulation and so it is appropriate that it be in the Code. Some of the major accidents in radiotherapy where many patients have been affected have been through errors in calibration of equipment.</p> <p>3.1.25</p> <p>Agree, similar comments to 3.1.24.</p> <p>3.1.26</p> <p>In our opinion this item and all of Schedule D would more appropriately be included in the Safety Guide rather than in the Code. The regulator should not be concerned with the detail of the testing. It is extremely important that testing and quality assurance procedures are in place. Placing such detail of such procedures and protocols in the Safety Guide does not diminish their importance. The issue for the regulator is to ensure that appropriate systems and checks are in place, not to rigidly define minute detail. While we have not seen the Nuclear Medicine Safety Guide, (or any other Safety Guide) we would expect and hope that it would contain detail of protocols and procedures. In addition as the technology changes and other international guidelines for procedures are developed, the detail of what is the appropriate method of testing might change. Having such detail in the Safety Guide makes it easier to change as it is then not a regulatory item.</p> <p>3.1.31 Death of a patient</p> <p>In our opinion this is a matter about a particular patient and this section would more appropriately be included in the Safety Guide. It is important that guidelines and systems are in place to provide advice and ensure the safety of all who could handle the body including crematorium workers. We would hope that there will be more detailed information that this in the Safety Guide. In our opinion is should not be a matter for the Code.</p> <p>3.2.3 Justification of a medical radiation procedure</p> <p>The issue of justification of any medical procedure including any radiation procedure is very important. The detail and items outlined in this section are</p>	<p>Wording of this clause has been amended.</p> <p>“physics” has been changed to “dosimetry”.</p> <p>Schedule D has been removed to the Safety Guide and references to it removed.</p> <p>Disagreed, this has been left in the Code.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>important. However, what this section is saying is that the doctor must consider a number of issues when making a management decision. It does not give advice as to how one deals with information obtained. As it is just considering issues about a particular patient, we recommend that it is appropriate for such detail to be included in the Safety Guide. The Code should cover the principle of justification not the detail. It would also be very difficult for the regulator to determine whether a medical practitioner “has considered” a range of items.</p> <p>3.2.5 (a)(iii)</p> <p>We are not convinced that this clause is necessary in the Code and recommend it be deleted. It is prefaced by the statement “where relevant” and it also uses the term “assess” so it is recognized that it is not always applicable. In our opinion section 3.2.5(a)(iii) is already covered by 3.2.5(a)(ii). In approving a plan for radiotherapy the radiation oncologist is approving all aspects of the treatment plan for the particular patient.</p> <p>3.2.5 (b) Diagnostic procedures.</p> <p>It is important to know how the words in this section are to be interpreted.</p> <p>In diagnostic radiology and nuclear medicine it is the licensed medical practitioner (usually the radiologist) who is responsible for the procedure including the exposure of the patient even though the radiographer performs the exposure. The referring doctor provides a request for the test. The radiologist authorizes the radiographer to proceed with the test by either:</p> <ul style="list-style-type: none"> • signing or initialling the specific referral form, or giving verbal approval, indicating their authorisation that the procedure on that specific patient is to proceed, • indicating the type or types of tests where the radiographer has authorisation to proceed, (and this is the most common method of authorization), or • provides a written prescription (this is very uncommon). <p>The wording of this section needs to be clear that “specify the protocol for the procedure” refers to authorisation for the radiographer to proceed. “Protocol” does not mean the actual technical details such as exposure parameters for the procedure, such detail is a matter for guidelines.</p> <p>Perhaps the section could read:</p>	<p>Done.</p> <p>Clause changed to “specify the radiological procedure to be performed”.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>section should be in the Safety Guide.</p> <p>3.2.15 to 3.2.16 breast feeding</p> <p>In our opinion it is inappropriate to include such detail in the Code; all this section should be in the Safety Guide.</p> <p>3.2.17 radiotherapy and implantable electronic device</p> <p>In our opinion it is inappropriate to include such detail in the Code which is a matter for Regulation, all this section should be in the Safety Guide.</p> <p>3.2.18</p> <p>Agree</p> <p>3.3.4 (a) (i)</p> <p>Suggest “the exposure has been approved or prescribed by a medical practitioner who holds a relevant radiation license”</p> <p>3.3.4 (a) (ii)</p> <p>We are not sure if this section is necessary. The Medical practitioner may give approval or authorisation for particular classes of groups of diagnostic procedures, for the radiographer to proceed, and that is also covered in 3.3.4(a)(i). However if it is felt desirable to reinforce that the medical approval can be for classes of diagnostic procedures, then we suggest this could be altered to “the approval for a diagnostic x-ray exposure or diagnostic nuclear medicine procedure by a radiation-licensed medical practitioner may be by way of formal directions by the licensed medical practitioner for specified groups or classes of tests, rather than by individual approval”</p> <p>(a)(iii) (new sub clause)</p> <p>“Also in the uncommon situation of rural and remote hospitals, there may be only a radiographer and no medical staff, and then I suppose it is the Responsible Person from the hospital administration who gives authority to the operator to take diagnostic x-rays.”</p> <p>3.3.6 to 3.3.7</p>	<p>Clause modified and Schedule C removed to Safety Guides.</p> <p>Sub-clause on cardiac monitoring removed but the rest remains.</p> <p>Noted.</p> <p>Wording has been changed to allow specific written protocols to be followed.</p> <p>The wording has been modified.</p> <p>Disagreed.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>In our opinion it is inappropriate to include such detail in the Code; all this section should be in the Safety Guide.</p> <p>3.3.8 (b) “ensure that visual surveillance of the patient is maintained throughout an imaging or radiotherapy procedure”</p> <p>While we agree that this is appropriate and desirable for the majority of procedures to have direct surveillance, there are uncommon situations where this is not practicable. For instance in brachytherapy treatment using low-dose-rate isotopes such as LDR or PDR iridium or LDR caesium the patient is not kept under visual surveillance throughout the procedure. In I-125 brachytherapy for prostate cancer the radiation treatment is delivered over several weeks after the patient has gone home. Similarly in I-131 therapeutic nuclear medicine the patient is not kept under surveillance. There may be some brief low dose diagnostic imaging procedures where the radiographer stands behind a protective shield for a few seconds and during that time the patient is not under direct visual surveillance. Perhaps this section needs to be reworded so it is not too rigid, and only applicable to relevant situations.</p> <p>Schedule B protection of an Embryo or Fetus</p> <p>In our opinion it is inappropriate to include such detail in the Code; all this section should be in the Safety Guide.</p> <p>Schedule C Protection of a child</p> <p>In our opinion it is inappropriate to include such detail in the Code; all this section should be in the Safety Guide.</p> <p>Schedule D</p> <p>In our opinion it is inappropriate to include such detail in the Code; all this section should be in the Safety Guide.</p> <p>Dose constraints to Carers</p> <p>In our opinion it may be reasonable to include a section on radiation exposure to carers who voluntarily accept some radiation exposure, to care for a relative. The limit applicable to the general public of 1 mSv should not apply. It is reasonable that a dose constraint of 5 mSv applies, (note it is a dose constraint not a limit).</p>	<p>Some amendments made to the wording of this clause otherwise it remains.</p> <p>Wording changed to the “imaging or treatment room”.</p> <p>Schedule B2 has been removed to the Safety Guides.</p> <p>Schedule C has been removed to the Safety Guides.</p> <p>Schedule D has been removed to the Safety Guides.</p> <p>It is felt that sufficient requirements are included in the Code for the protection of carers.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Construction of Facility</p> <p>Optimal design and construction of a medical radiation facility is a very important issue, but the only mention of construction of a medical radiation facility is in Schedule A, Radiation Management Plan, and even there only in section A1.1(b). To put such an important matter in the small text of a schedule seems strange as that is one of the major regulatory issues. This issue should be addressed as a topic with its own heading within the body of the Code. For construction and shielding of a medical practice the draft Code specifies a dose constraint of 5 mSv per annum for occupational exposure and a dose constraint of 0.3 mSv per annum for the public. Although the word constraint is used, in the context of shielding design it is a limit that will be rigidly applied by the Regulatory Authority. This, and the fact that it will not be applied retrospectively should be made clear in the document.</p> <p>It would seem that the radiation regulators are continually imposing lower and lower arbitrary limits, for the design requirements for medical radiation premises. There is no explanation how such arbitrary limits are determined. Some ICRP publications mention a dose constraint for public exposure of 0.3 mSv/yr but that is in the context of exposure to radioactive sources including radioactive waste. The dose constraint of 0.3 mSv/yr mentioned is ICRP is intended to apply to any one radioactive source, as potentially there may be other radioactive materials. There is no evidence that ICRP intended that the dose constraint of 0.3 mSv/yr be applied in the context of shielding design for radiological practices. There are no specific design limits recommended by ICRP or IAEA. Both ICRP and IAEA make general recommendations that the radiation facility should be designed to give annual radiation doses lower than the limits of 20 mSv and 1 mSv respectively, so as not to be near the limit. If there are multiple x-ray rooms close to each other, the exposure from all rooms should be considered, and in our opinion, for the sum of all exposures the limits of 20 mSv and 1 mSv should apply. We agree with ICRP that there should be a conservative approach to the design limits so that exposure of occupational persons and the public is not near the limits of 20 mSv and 1 mSv respectively. However, to arbitrarily choose a design limit of one quarter of the limit for occupational exposure and 0.3 of the limit for the public, when the design calculations contain a lot of conservative elements in the estimation, is unreasonable. Applying those design limits seems to ignore the limits of 20 mSv and 1 mSv recommended by the ICRP and in ARPANSA RPS1, and imposes much stricter limits arbitrarily.</p>	<p>The numerical dose constraints have been removed to the Safety Guides. Wording changed to "...dose constraints acceptable to the relevant regulatory authority are applied ..."</p>

SUBMITTER	COMMENT	RESPONSE
	<p>While it is important to reduce exposure to radiation and hence reduce the risks to an individual, at extremely low doses near background radiation the additional benefits may be slight and additional shielding does add significantly to costs. The level of exposure of 0.3 mSv is well below background radiation and hence very difficult to measure.</p> <p>We draw ARPANSA's attention to IAEA Safety Report Series 39, 2006 page 19 which states</p> <p style="padding-left: 40px;">“However, when using constraints for shielding calculations, consideration should be given to the remark made in ICRP Publication 33, that the actual dose values to individuals are 1/10 (for equivalent dose) to 1/30 of dose values of effective dose used as shielding design parameters (ICRP33 para 256). This is due to a number of conservative assumptions made in the calculation.”</p> <p>We would like to know how ARPANSA arrived at the proposed design limit level and the justification for such a severe imposition.</p> <p>The imposition of stricter radiation design limits will add substantially to the costs of construction of new medical radiation facilities. If the radiation regulator also imposes these very strict radiation design criteria upon established facilities when radiation apparatus is replaced there will also be substantial costs to those practices.</p> <p><i>IAEA Safety Report Series 39, 2006. Applying radiation safety standards in diagnostic radiology and interventional procedures using x rays. IAEA Vienna International Commission on Radiological Protection, Protection against ionizing radiation from external sources used in medicine. Publication 33, Annals of the ICRP Pergamon Press, Oxford (1981).</i></p> <p>In addition to the above comments we are surprised and dismayed that on 26 June 2007 the “Consultation Draft Safety Guide for Radiation Protection in Nuclear Medicine” appeared on the ARPANSA website, with the statement that submissions should be forwarded to ARPANSA by 2 July 2007. To expect an industry to provide comment on that 94 page document within four working days is completely unreasonable, and it is impossible for us to comment within that time frame. It makes us wonder how seriously ARPANSA views the whole consultation process.</p>	
25	Chiropractors practicing here in Tasmania would like to draw your attention to	This Code does not apply to the chiropractic use of radiation.

SUBMITTER	COMMENT	RESPONSE
<p>Vicki Hyatt, Chiropractic on Collins, Hobart AND several Tasmanian Chiropractors</p>	<p>their concerns in regards to the Code of Practice Draft, which you have issued for discussion.</p> <p>Chiropractors utilise plain film radiography in their private practices for diagnostic purposes. Reading the Draft Code suggests that it includes:</p> <ul style="list-style-type: none"> (a) Chiropractors who are licenced to perform radiographic procedures (b) Chiropractors or other entities who provide radiographic facilities and perform radiographic procedures for the use of Chiropractors or, under the instruction of the Chiropractor. <p>If Chiropractors, (or other entities), that are legislatively endorsed to provide services are to be included into the new Code, then there is no clear evidence of this inclusion. Please confirm whether this Code, as it is written, is to include Chiropractors?</p> <p>Your draft Code defines four persons who must be involved in a MEDICAL application of ionizing radiation and their responsibilities. The following terms are not acceptable to Chiropractors, if the Code is to include them (There are some 200-500 Chiropractors involved around Australia).</p> <ul style="list-style-type: none"> • Medical Application • Medical Practitioner • Medical Radiation • Medical Radiation Procedure •Medicine <p>Acceptable options are:</p> <ul style="list-style-type: none"> • Medical Application suggest Health Application • Medical Practitioner suggest Medical Practitioner or Chiropractor • Medical Practitioner suggest Health Practitioner • Medical Radiation suggest Radiation • Medical Radiation Procedure suggest Radiation Procedure •Medicine suggest Health Care <p>Any possible direct, or indirect, inference that Registered Chiropractors are Medical Practitioners, or are providing Medical Services (ie. Medical Radiation Procedures) must be removed.</p>	

SUBMITTER	COMMENT	RESPONSE
	<p>The Chiropractors as identified are registered by Statutory Authorities in each State and Territory but are not Registered Medical Practitioners.</p> <p>We appreciate the opportunity to respond to the Draft Code of Practice.</p>	
<p>26 Francesca Holloway Professional Advisor Medical Radiation Technologists Board Queensland</p>	<p>The Medical Radiation Technologists Board of Queensland welcomes the opportunity to comment on the Code of Practice – Radiation Protection in the Medical Applications of Ionizing Radiation, version for Industry Consultation.</p> <p>The Board took the opportunity to consult with the Regulatory Authority in Queensland on the draft code.</p> <p>The Board recognises the importance of the document for the future of radiation protection and wishes to have the opportunity to review the Safety Guides, Regulatory Impact Statement and Cost Benefit Analysis in draft form. The Board also seeks the opportunity to consider the draft Code developed after the initial consultation process.</p> <p>The Safety Guidelines which underpin the Code are of particular interest to the Board, as they will affect the daily practice of the three professions regulated by the Board.</p> <p>The Board raised a number of issues at the local consultative meeting, and whilst some of the issues were explained and resolved, the Board still has reservation regarding the following:</p> <p>1.2 c the operator</p> <p>The Board is sensitive to the fact that this term in most jurisdictions in Australia is used for a licensed operator rather than a medical imaging practitioner.</p> <p>2.2.2, 2.3.2, 3.1.5 Dose to the patient</p> <p>No dose limit is set for patients in regard to diagnosis or treatment.</p> <p>2.1, 3.1.3 (a) Justification</p> <p>This clause appears to assume there are currently or will be, written protocols established by the medical practitioners. This is not the case industry wide.</p>	<p>Noted.</p> <p>Agreed.</p> <p>Noted.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>There is no ability for the operator to use professional discretion as to the appropriateness of examination.</p> <p>The Board has concern with the use of the term 'or generically.</p>	<p>Noted.</p> <p>Noted.</p>
<p>27 Emile Badawy Executive Officer Australian Institute of Radiography</p>	<p>The Australian Institute of Radiography (AIR) would like to thank you for the opportunity to comment on the 'Code of Practice - Radiation Protection in the Medical Applications of Ionizing Radiation'.</p> <p>In broad terms, the intent of the document seems appropriate in that it provides a national uniform approach to defining acceptable standards for radiation protection in the medical applications of ionizing radiation. It was difficult to provide comprehensive comment on the suitability of the Code of Practice without being able to review the corresponding safety guides. Their inclusion may have given relevance to the Code of Practice.</p> <p>However from review of the document and the information session attended by our members, the following points are made:-</p> <p><u>Section 2.2</u></p> <p><u>Item 2.2.2</u>, the use of the terms diagnostic and therapeutic purposes, does not appear to address that in procedures for example; Percutaneous Coronary Intervention (PCI), CT guided steroid injection, CT guided ablation procedures and imaging for the implants of cardiac devices (PPM and ICD's), require the use of imaging procedures is as a tool for therapeutic intervention.</p> <p><u>Section 3.1</u></p> <p><u>Item 3.1.13</u> refers to the 'training of all individuals who may be occupationally exposed to ionizing radiation', this would not be a practical undertaking as a hospital staff member who only occasionally (1-2 times per year) visits the radiology department to escort a patient may be occupationally exposed to radiation, or a staff member on a ward where mobile x-ray examinations are performed on rare occasions may only be exposed to a few micro Sieverts). Training all these hospital staff that may be exposed would be a mammoth task, perhaps just those persons who are regularly in situations where they may be exposed to ionizing radiation (such as theatre staff, ICU and CCU staff, staff in wards where Brachytherapy patients are nursed), perhaps an effective dose</p>	<p>For the purposes of the Code, interventional radiology will be come under diagnostic procedures as per the definition in the <i>Health Insurance (Diagnostic Imaging Services Table) Regulations 2004</i> (Statutory Rules 2004 No. 307) as amended made under the Health Insurance Act 1973. Advice to this effect added to the Scope (1.3).</p> <p>It is expected that the level of training provided will be commensurate with the likelihood that the employee will be exposed. For example, an administrative person may be advised not to proceed past emergency signs or lights and to report apparent "mishaps" at induction of work and at annual refresher courses.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>in excess of 1 mSv per year, should undertake training.</p> <p><u>Item 3.1.15</u> refers to warning notices for fixed equipment but no mention is made of warning procedures or safety protocols for the use of mobile x-ray equipment or image intensifiers. Item 3.1.15 (c) (i) a., the words ‘fluoroscopy and computer tomography’ should be added after ‘external beam radiotherapy’</p> <p><u>Item 3.1.16</u>, what would happen in a situation where the dedicated equipment fails in the middle of performing an interventional procedure and it would be dangerous for the patient if the procedure was terminated. For medical reasons the procedure needs to be completed and the use of a mobile image intensifier (II) unit is required. Would this be considered to be in breach of the code of practice?</p> <p><u>Section 3.2</u></p> <p>This section discusses the ‘Medical Practitioner’; their role is defined in relation to the authorisation, justification and approval of the request for medical radiation procedures.</p> <p>In a Medical Imaging environment, "Medical Practitioner" responsibilities seem to match closely with the role of a Radiologist. However, any medical practitioner could read this document and infer, as it will be law, that they are the responsible authority and make requests while not having the required specialist skills. Perhaps the document should define and refer to Radiologists and Radiation Oncologists as ‘Specialist Medical Practitioners’.</p> <p>There seems to be a general misunderstanding regarding the process of radiation delivery, it should be made clear that in the use of ionising radiation for diagnostic imaging the Radiologist, or specialists Medical Practitioner, has a primary role of providing an expert diagnostic report and in that context prescribe standard views required to arrive at a diagnosis. They are not the person responsible for the conduct of the majority of diagnostic imaging procedures, nor do they have the training and skills to do so. They do conduct and are directly responsible for interventional radiological procedures.</p> <p>Additionally this document does not seem to make allowances for the fact that medical practitioners are not the only professional group which may request</p>	<p>Clause amended.</p> <p>It is unknown how a jurisdiction would respond in such a circumstance.</p> <p>Terminology has been changed to clarify who and what is the medical practitioner (radiation).</p>

SUBMITTER	COMMENT	RESPONSE
	<p>medical imaging procedures.</p> <p><u>Item 3.2.4</u> details items which must be noted in an imaging request, but does not indicate that a request must be completed and signed before an operator (defined as a radiographer or licensed operator) can action the request.</p> <p><u>Item 3.2.5</u>, see notes above for item 2.2.2.</p> <p><u>Item 3.2.7 (a)</u> states that ‘<i>the medical practitioner must maintain a record of the radiation dose administered to the patient, or sufficient information on the exposure of radiation or administration parameters that would allow the radiation dose to the patient to be estimated</i>’, it is unclear how a medical practitioner would be able to determine this dose and how and where it would be practically recorded.</p> <p>For example, how would a General Practitioner, who is a medical practitioner, determine the dose that their patient who was referred for a chest x-ray and where this dose would be recorded. We do not feel that there would be a problem with this in Radiation Therapy as the dose received by the patient is prescribe and closely monitored.</p> <p><u>Item 3.2.8</u>, regarding the provision of advice to patients and carers, is it necessary to include this item as part of legislation. The information supplied may vary depending on the person or the source of the information, the requested medical radiation procedure, the patient and the department in which the examination will be performed. This may create problems in the determination of what would/should be considered adequate information to be supplied to patients and carers. These issues may be better addressed in the Safety Guides.</p> <p>Similarly item 3.2.17, procedure for a patient with an implanted electronic device, would perhaps be better addressed in the Safety Guides rather than as part of legislation.</p> <p><u>Section 3.3</u></p> <p>The use of the term ‘Operator in relation to the person with the minimum education, training and skills to perform radiological and nuclear medicine procedures and deliver radiation therapy treatments, is at odds with the role of</p>	<p>Noted.</p> <p>See above response.</p> <p>Clause removed to Safety Guide.</p> <p>The requirement remains in the Code. The detail can be placed in the Safety Guide.</p> <p>Clause amended although the requirement remains in the Code. The detail can be placed in the Safety Guide.</p> <p>Noted. Many different people will be delivering radiation doses under this Code, and the term “operator” definitely does not diminish the key radiation protection role that this</p>

SUBMITTER	COMMENT	RESPONSE
	<p>this person. We recommend that throughout the document the term ‘operator be replaced with the term ‘radiation professional’ (RP) as they are the person responsible for determining and administering the radiation dose.</p> <p>A section should be included to encompass those persons who hold a limited remote operators licence.</p> <p>We suggest that <u>lines 18 and 19</u> of this document are changed to read ‘<i>The specialist medical practitioner in conjunction with the radiation professional, are responsible for the conduct and overall procedure involving the exposure of the patient to ionizing radiation</i>’. We suggest that <u>line 20</u> of this document is changed to read ‘<i>The radiation professional who performs the examination and exposes the patient to ionizing radiation</i>’.</p> <p><u>Item 3.3.1</u> states that ‘<i>Only a person who is appropriately authorised by the relevant regulating authority to administer ionizing radiation to a patient for radiology, nuclear medicine or radiotherapy may administer ionizing radiation to a patient</i>’. The term radiology needs to be further defined if it is to include cardiac and vascular applications.</p> <p><u>Item 3.3.4 (a) (ii)</u>, the terminology in this item is confusing; we believe that it would be beneficial for this item to be reworded to ensure that it is made clear where a medical practitioner is being referred to and where a specialist medical practitioner is being referred to.</p> <p><u>Item 3.3.9</u> refers to the delivery of external beam radiotherapy or intraoperative radiation therapy, HDR Brachytherapy has not been included in this list.</p> <p><u>Item 3.3.11</u> Equipment malfunction or error - it is not necessary to report this to the medical practitioner unless it results in a lack of safety, the incorrect treatment to the patient or an unplanned exposure to ionising radiation.</p> <p>In general, the implementation expectations of the regulators and how this code of practice will be embraced in modern clinical practice will determine its effectiveness in protecting the public.</p> <p>Once again thank you for the opportunity to comment on this document and we look forward to further involvement in the process.</p>	<p>person has.</p> <p>Noted.</p> <p>Noted, but no change made.</p> <p>Change effected.</p> <p>Clause amended.</p> <p>Clause amended.</p> <p>Clause amended.</p>
28	Page 5, Clause 3.1.3 (c) and other areas where this topic is mentioned	

SUBMITTER	COMMENT	RESPONSE
<p>Peter Collins Radiation Safety Officer (RAH/IMVS) & Principal Medical Scientist Dept of Nuclear Medicine Royal Adelaide Hospital</p>	<p>The dose constraint should be 1 mSv - to be consistent with the 1 mSv to breast fed child. It is unlikely that there would be more than one procedure on a patient, unless the patient's (and therefore the child's) life was at risk, so the general public limit of 1 mSv should apply.</p> <p>Page 5, Lines 128-129, Clause 3.2.15 (b)</p> <p>Is this is to limit external radiation dose to infant? If so, (b) can be removed as the 1 mSv dose in (a) would cover the dose from both ingested radioactive milk and the external dose from close proximity to the breast.</p> <p>Page 6, Clause 3.1.7 (c)</p> <p>This is not possible if the person is not given a badge using above 1 mSv criteria (a). Suggest remove (c) and add comment to (a) to also record doses.</p> <p>Page 6, Clause 3.1.7 (d)</p> <p>The action thresholds should be pro-rata for the wearing period (eg. 3 mth.)</p> <p>Page 7, Lines 174-178 and 856-862</p> <p>The definition of an incident is very vague and would be difficult to interpret – so record keeping could be very onerous. It is important that a suitable definition is found. There needs to be a meaningful lower threshold (based on effective dose, significant spill etc.) below which no recording/reporting is necessary.</p> <p>Page 8, Clause 3.1.18 (a)</p> <p>It is not workable to expect to keep a detailed register for unsealed Nuclear Medicine radionuclides. This information is often kept in different places (eg. purchase records, dose given to patient) and the amount that decays away is usually only grossly estimated.</p> <p>Page 11, Clause 3.2.3 (b)</p> <p>What does “characteristics” of the individual mean?</p> <p>Page 11, Clause 3.2.4</p> <p>Should also say “, or individuals involved in approved research projects, “</p>	<p>0.3 mSv changed to 1 mSv.</p> <p>Sub-clause removed.</p> <p>Noted.</p> <p>Clause amended.</p> <p>Noted.</p> <p>Noted.</p> <p>Characteristics that would affect the radiation procedure.</p> <p>Changed.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Page 12, Line 395</p> <p>The information given will give ways to reduce exposure (to below dose constraint levels) – it should not be stating risks (ie. of getting cancer) as these estimates are only hypothetical.</p> <p>Page 17, Lines 563-564</p> <p>The dose constraint of 0.3 mSv is too low and will add considerable cost to new (and possibly existing) installations. It should be 1 mSv. The argument for using the lower value is that individuals may be exposed at different locations. However, the occupancy factor takes this into account. If, for the “average” length of time someone is in a corridor, the factor is say 0.01 then it would “average” 0.005 for 2 locations etc.</p> <p>Page 19, Section B1</p> <p>It should state that the estimated embryo/fetus dose must be recorded if the study is performed.</p>	<p>Changed to “the precautions”.</p> <p>Dose constraints have been removed.</p> <p>Noted.</p>