

SUMMARY OF SECOND ROUND SUBMISSIONS AND RESPONSES
CODE OF PRACTICE FOR THE EXPOSURE OF HUMAN SUBJECTS TO IONIZING RADIATION FOR MEDICAL RESEARCH
PURPOSES – DECEMBER 2004

SUBMITTER	COMMENT	RESPONSE
<p>01 Jill Hambling – St Vincent’s Health</p>	<p>The Human Research Ethics Committees (HRECs) at St Vincent’s Health have noted the model warning statements in Annex 2 of the revised Code, and support the inclusion of the model statements suggested for participant information and consent forms.</p>	<p>Noted</p>
<p>02 Kerry Breen – Australian Health Ethics Committee - NHMRC</p>	<p>Thank you for the opportunity to comment on the draft Code of Practice, Exposure of Humans to Ionizing Radiation for Research Purposes.</p> <p>I am pleased that many of the suggestions made in my submission, on behalf of the Australian Health Ethics Committee, proved useful to you and the drafting group the current document is significantly improved.</p> <p>There is one issue on which I wish to comment. there is a phrase in the glossary relating to a Human Research Ethics Committee which I suggest be deleted, i.e “is established by...”. I understand that the language you have chosen is the language used in the current National Statement on Ethical Conduct in Research Involving Humans but it is narrower than the National Statement actually requires when read in its entirety and narrower than the reality of how many HRECs are currently established. This language will not be used in the revised version of the National Statement.</p> <p>I look forward to the publication of the final document which will be referred to in the revised National Statement and will serve as a guide to the development of the web based National Application Form for HRECs.</p>	<p>Agreed. Wording modified</p>
<p>03 S J Critchley Director QLD Radiation</p>	<p>General Comments</p> <p>1. Throughout the document the following terms are used to describe the</p>	

SUBMITTER	COMMENT	RESPONSE
<p>Health</p>	<p>same thing:</p> <p>“medical and biomedical research” – last line of the Foreword</p> <p>“clinical research” – lines 23 and 25</p> <p>“medical research” – lines 38, 181, 352, 477, 566 and 607.</p> <p>I think the term used should be consistent throughout the document and I suggest there is no need for a descriptor because the whole context of the document is that we are speaking about research involving humans. I suggest the above references be changed to merely “research”.</p> <p>2. I think the members of the Working Group, as mentioned in the document, need to be rearranged so that Richard and his current team is at the top of the list (similar to the NDRP Code) in recognition of the large amount of work they have put in to developing this document.</p> <p>Specific Comments</p> <p>Lines 25 – 26</p> <p>The document states “including Phase I, II and III clinical trials”. Phase I, II or III of what? Should there be a reference to the source of this term or explanatory notes for this term? I suggest there should be and that it take the form of a footer reference to the source document e.g. a TGA text.</p> <p>Lines 37 – 38</p> <p>The dot point containing the words “the responsible person for the radioactive</p>	<p>Agreed</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed. Definition added to glossary.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>material, radiation apparatus facility or premises” has been removed from the document endorsed by the RHC. I suggest this omission is a substantive one because one of the bases for allowing the removal of the relevant regulatory authority from the decision making processes in relation to research was that it be made clear that the overall regulatory control of the use of the radiation sources remains with the relevant regulatory authority through the established mechanism of having a responsible person who holds a licence etc. Although the removal of this dot point does not alter the meaning of the Code, it certainly alters what appears to be the operating context of the Code and therefore it must be replaced. I advise that I am not happy about the removal of this dot point and I strongly suggest that it be re-instated.</p> <p>Line 60</p> <p>Remove the double space between “the” and “following”.</p> <p>Lines 88 – 89</p> <p>In clause 2.1.3 we refer correctly to “written information”. I think that this should be emphasized in lines 88 - 89 by changing “...sufficient information...” to “...sufficient written information...”. This does not prevent the researcher from providing other information, but it does ensure that the person making the decision on behalf of the research participant is provided with the minimum information decided as being acceptable by the Human Research Ethics Committee.</p> <p>Line 96</p> <p>Change “(a)” to “(b)”.</p> <p>Line 110</p>	<p>Agreed. Sentence re-instated.</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed</p>

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	<p>Change "...clause 2.1.6" to "...clause 2.1.6;". That is, insert a semi-colon after "2.1.6".</p> <p>Line 111</p> <p>Remove the double space between "that" and "the".</p> <p>Lines 111 – 114</p> <p>Although I cannot think of a suitable change to the text already in the document for sub-clause 2.1.7(c), I do feel a little uncomfortable about giving the RANZCR or the ANZAPNM ownership of quality assurance programs. Why can't a medical physicist come up with a quality assurance program that is better than anything devised by the RANZCR or the ANZAPNM? Does it matter, particularly in the context of this document? These QA matters are actually the domain of other Codes of practice so why do we need to be specific here?</p> <p>Line 114</p> <p>Change "...in Nuclear Medicine" to "...in Nuclear Medicine;". That is, insert a semi-colon after "Medicine".</p> <p>Line 116</p> <p>Again, in clause 2.1.3 we refer correctly to "written information". I think that this should be emphasized in lines 116 by changing "...the information..." to "...the written information...". This does not prevent the researcher from providing other information to the research participant but it will ensure that the Human Research Ethics Committee is provided with a definitive minimum set of information which has been assessed and commented on by a medical physicist.</p>	<p>Agreed</p> <p>Agreed</p> <p>Added 'such as' so that the QA programs listed are examples.</p> <p>Agreed</p> <p>Agreed</p>

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	<p>Line 148</p> <p>To ensure rigour in the assessment process and to ensure the Human Research Ethics Committee is provided with appropriate comments about the information the researcher intends to provide to research participants, the medical physicist must, in his or her report to the Committee, include his or her views on the accuracy and worth of the information. Consequently, the text in sub-clause 2.2.3(d) should be changed from “the proposed text...” to “an assessment of the proposed text...”.</p> <p>Lines 160 – 161</p> <p>Following on from the two comments above, and to ensure the thread is continued through the text of the document, I suggest that the Human Research Ethics Committee should concern itself to ensure that the information that will be provided to the research participants has been assessed by a medical physicist as being accurate and worthwhile. This can only be assured if the Code has an instruction reminding the Human Research Ethics Committee to look at this issue. I therefore suggest that sub-clause 2.1.7(c) be amended to “the written information about the radiation doses and risks to be provided to the research participants and the opinions of a medical physicist on the accuracy and worth of the written information;”.</p> <p>Line 167</p> <p>The section, Section 4, detailing the roles and responsibilities of the responsible person in the Code has been removed from the document endorsed by the RHC. As mentioned earlier, I suggest this omission is a substantive one because one of the bases for allowing the removal of the relevant regulatory authority from the decision making processes in relation to research was that it be made clear that the overall regulatory control of the use of the radiation sources remains with the</p>	<p>Proposed text is specified in Annex 2. The HREC decides on compliance or appropriateness.</p> <p>Clauses 2.3.2 b) and c) adequately covers this process.</p> <p>Agreed. Responsible person clause re-instated.</p>

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	<p>relevant regulatory authority through the established mechanism of having a responsible person who holds a licence etc. Although the removal of Section 4 does not alter the meaning of the Code, it certainly alters what appears to be the operating context of the Code and therefore it must be replaced. I advise that I am not happy about the removal of Section 4 and I strongly suggest that it be reinstated.</p> <p>Line 171</p> <p>Remove the double space between “physicist” and “and”.</p> <p>Line 184</p> <p>Insert a space between “constraints” and “apply”.</p> <p>Lines 215 – 216</p> <p>I am not happy at all about the continued inclusion of the sentence “It should also be noted that in the case of terminally ill patients, long-term risks of radiation are negligible.”</p> <p>Firstly, I think “...of radiation...” should be changed to “...from radiation exposure...”. Secondly, we have a situation in Australia where for example Dr John Holt (a radiation oncologist in W.A.) is, at least, raising the possibility that “terminally ill” patients might not actually die when expected and that, in fact, they might live for many years if treatment protocols are changed. Thirdly, any researcher being advised by a competent medical physicist should thoroughly understand this concept without having it written down. Finally, I simply find it absolutely distasteful that such a statement be made in a document we are responsible for producing. This statement adds nothing to the document and nor should it influence in any way a decision by a properly informed Human Research</p>	<p>Agreed.</p> <p>Agreed</p> <p>Sentence has been qualified.</p>

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	<p>Ethics Committee as to whether a research project should proceed. I would like this sentence removed.</p> <p>Line 246</p> <p>Change “...represents an low...” to “...represents a low...”. That is, remove the bolding of the word “represents” and change “an” to “a”.</p> <p>Line 259</p> <p>Change “medical radiation physicist” to “medical physicist”.</p> <p>Line 283</p> <p>When we are talking about “an increased risk of cancer” are we, in fact, talking about an increased risk of cancer incidence or are we talking about an increased risk of mortality due to induced cancer? I think we need to be clearer. Morbidity is one thing, mortality is another.</p> <p>Lines 288 – 289</p> <p>Now I am really confused because we are now talking about “the incidence of cancer mortality”. We really need to be clearer about the intent here. Also, I think the average person would prefer to use terms which are clearer such as “death” or “disease”.</p> <p>Line 290</p> <p>I suggest a change from “...various diagnostic medical x-ray...” to “...several computed tomography x-ray...”.</p>	<p>Agreed</p> <p>Agreed</p> <p>Modified to clarify</p> <p>Modified to clarify</p> <p>Choice of appropriate comparator has been left to those producing the information statement.</p>

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	<p>Line 311</p> <p>Change "...second physicist..." to "...second medical physicist...".</p> <p>Line 312</p> <p>Change "...institution than the researcher." to "...institution from that of the researcher.".</p> <p>Line 325</p> <p>Change "The risks of the radiation needs to be..." to "The risk associated with radiation exposure needs to be...".</p> <p>Line 339</p> <p>Change "HREC" to "Human Research Ethics Committee".</p> <p>Line 343</p> <p>What is a "licensee"? Instead, do we really mean the "responsible person"? Not all jurisdictions have "licensees".</p> <p>Line 347</p> <p>This line says that the researcher needs to liaise with the "Head of the Radiology and/or Nuclear Medicine Departments". What if the research is in the area of radiation oncology? What if the research is in, say, a cardiac department? I do not think we should give ownership of processes to particular groups. In this instance, ownership might be being given to a totally inappropriate group by this statement. I think this statement should be changed to "...researcher to liaise with the Head of</p>	<p>Agreed</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed</p> <p>Yes. Responsible person added</p> <p>Agreed. Departments used as examples.</p>

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	<p>the relevant department.”. This would then be consistent with the text in line 343.</p> <p>Line 350</p> <p>Change ...compared to that...” to “...compared with that...”.</p> <p>Line 541</p> <p>The item “Relevant Regulatory Authority” is out of place.</p> <p>Line 553</p> <p>Remove (DRL) as it is superfluous.</p> <p>Lines 560 – 570</p> <p>Correct punctuation and grammatical errors in this definition.</p> <p>Line 582</p> <p>Change “...should avoid...” to “...should help in avoiding...”.</p> <p>Line 583</p> <p>Remove (HREC) as it is superfluous.</p> <p>Line 587</p> <p>Insert a space between “Human” and “(1999)”. Also, change “in force” to “as amended”.</p>	<p>Agreed</p> <p>Agreed. Moved to correct order</p> <p>Disagree</p> <p>Definition is as per RPS 1</p> <p>Agreed</p> <p>Disagree</p> <p>Agreed</p>

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	<p>Line 600</p> <p>Change “...issued to an...” to “...issued by the relevant regulatory authority to an...”.</p> <p>Line 613</p> <p>Change “A suitable person must be accredited...” to “The medical physicist must be appropriately accredited...”.</p> <p>Line 649</p> <p>Change “...manifest...” to “...is manifested...”.</p>	<p>Agreed</p> <p>Agreed</p> <p>Agreed</p>
<p>04 B.M.Walker Principal Physicist Nuclear Medicine Department Prince of Wales Hospital</p>	<p>The format and slant of the revised document is a great improvement on the earlier draft and I have only a few comments to make.</p> <ul style="list-style-type: none"> • 2.1 Researcher. <ul style="list-style-type: none"> i) It is possible that a Researcher may only read this Section. It would therefore be beneficial to reiterate the words in Scope line 22-23 – “procedures which are in addition to those received as part of the research participant’s normal clinical management “. This is included in the Medical Physicist section (2.2.2(a)) An appropriate place could be 2.1.6 (a) ii) 2.1.5 (b) – wrongly entered as (a) • Annex 1 and Annex 2 <ul style="list-style-type: none"> i) It would be preferable if the dose ranges in these Annexes matched. Although Table 3 is adapted from ICRP91, the ranges in Annex 2 are more clinically applicable. 	<p>Agreed</p> <p>Agreed</p>

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	<p>ii) Line 259. Medical <i>radiation</i> physicist. <i>radiation</i> should be deleted</p> <p>iii) Line 269 'Negligible' should be changed to 'minimal' or alternatively Table 3 should be changed</p> <ul style="list-style-type: none"> • Annex 4 Line 393 refers to the DDREF of 2 which is in fact incorporated into the values in Table 2. To be strictly correct 'Deaths' title in Table 2 on Page 9 should indicate this as given in the original Table. • Definition of Medical Physicist. (Line 609 – 615) At present it would be very difficult to achieve this as so few physicists are accredited especially in Radiology. For example in this hospital, we have accredited physicists in Radiotherapy and Nuclear Medicine only. There is not a Radiology physicist employed. This would be the situation in most hospitals and will be unlikely to change. Therefore there may need to be some other means of granting approval for physicists to do CT dose assessments. 	<p>Agreed</p> <p>Agreed</p> <p>Footnote added indicating that the risks in Table 2 include a DDREF of 2</p> <p>The definition used allows for the discretion of the regulatory authority in determining suitably trained persons to undertake the role.</p>
<p>05 Associate Professor David Ball MB BS, MD, FRANZCR TROG President</p>	<p>In terms of therapeutic use of ionizing radiation, radiotherapy clinical trials are specifically covered in Annex 3 of the revised draft Code of Practice. This section provides recommendations for implementation of the code and states that in radiotherapy studies it is not possible to apply the (mSv) dose constraints and risk level categories as per Table 1 and Annex 1.</p> <p>The mandatory requirements for researchers are stated in Section 2.1. However, not all of these requirements are applicable to research involving therapeutic use of ionising radiation. Investigators and research staff may therefore encounter difficulties when preparing</p>	<p>Not accepted. Radiotherapy trials are not exempt. Clause 2.1.5 applies as does 2.1.6 (a) organ doses and (c).</p>

SUBMITTER	COMMENT	RESPONSE
	<p>ethics submissions for TROG trials. It would be preferable if section 2.1 clearly indicated which of the requirements radiotherapy clinical trials are exempt from.</p> <p>We would recommend that the following caveat "Radiotherapy Trials Exempted - refer Annex 3" is included in the sub-sections that ARPANSA defines as not directly applicable to the therapeutic use of ionising radiation (eg. sections 2.1.5, 2.1.6 and 2.1.7).</p>	<p>A footnote has been added in 2.1.6 (a) to clarify the application to radiation therapy Appendix 3 has been amended accordingly.</p>
<p>06 Dr R S Budd Chairman, Radiation Protection Interest Group Australasian College of Physical Scientists & Engineers in Medicine</p>	<p>2.1.2(b)(ii) The intent of this clause is fine. However, the reference to Annex 1 to clarify what is meant by minimal leads to confusion since the relevant table 2 specifies the level of risk for adults. If it is intended that the fetal dose be restricted to <0.1 mSv then perhaps it should be stated explicitly at this point.</p> <p>2.1.6(a) There is confusion concerning the meaning of the term "Total Cumulative Effective Dose" (TCED) which is used in lines 32, 100, 126, 128 and 142. It is not defined in either the Glossary or in a footnote and we have been unable to find any other references to it. Similarly, the term "Cumulative Effective Dose" is used in Table 1. This term is also used in RPS-1 (r-10, r-12 & r-46) and its meaning becomes apparent within the text of RPS-1 where it discusses dose constraints and the need to estimate a cumulative dose over a period which may be many years. There are no apparent references in RPS-1 to the term Total Cumulative Effective Dose. We can suggest various meanings for the term Total Cumulative Effective</p>	<p>Covered in Table 1</p> <p>Agreed. Definition amended.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Dose. The most likely is that it has the same meaning as Cumulative Effective Dose.</p> <p>The meaning of these terms is crucial to us as medical physicists because the code of practice requires us to estimate this quantity and supply it to the Researcher and to the Ethics Committee.</p> <p>Definitions of these terms should be included in the Glossary or in Footnotes.</p> <p>Table 1</p> <p>The dose constraint (200 mSv) for the skin needs a qualifier stating that this value is averaged over any 1 cm² if the intent is truly to avoid deterministic effects to the skin. The present unqualified constraint provides no protection whatsoever.</p> <p>Whilst admirable as an aim we cannot see how the 5 mSv cumulative effective dose and the 100 mSv cumulative equivalent dose constraint for children will work given that, of necessity, it will require an individual and/or multiple organizations to keep and/or share records for up to 18 years.</p> <p>Annex 3, line 324</p> <p>You can't prevent long term effects in an absolute sense. Suggest modifying text thus: <i>...to prevent tissue effects and minimize the probability of long term effects....</i></p> <p>Annex 2, line 268</p> <p>Remove 'to 3'</p> <p>Annex 2, line 269 - 270</p>	<p>Agreed</p> <p>Advise to be given to the participant has been added to clause 2.1.8</p> <p>Agreed</p> <p>Agreed</p>

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	<p>Remove 'no harmful effects of radiation have been demonstrated and' replace with 'the risk level is too low to measure. It is believed that'...</p> <p>Annex 2, line 273 Remove 'very'</p> <p>Annex 2, line 275 Remove 'to 3'</p> <p>Annex 2, line 276-277 Remove 'no harmful effects of radiation have been demonstrated and' add 'being approximately equivalent to.....' after 'the risk is low' and add a footnote stating 'the risk of contracting fatal cancer should be given in a manner that will be understood by the research participant. An example is that the risk is approximately equivalent to (dose in mSv x 5)* % of the average chance of being killed on Australian roads in a period of 10 years.' And another footnote providing an explanation of the approximate dose as being 'based on a risk of 5×10^{-2} per Sv. For studies in children or for persons over the age of 50, the risk of radiogenic cancer should be calculated using age- and sex-specific risk factors given in Table 2 of Annex 1.'</p> <p>Annex 2, line 282 Remove 'to 3'</p> <p>Annex 2, line 282 Insert 'fatal' before 'cancer'</p> <p>Annex 2, line 285-286 Remove 'about 1 in.....(calculate using....risk factors given in Table 2 in Annex 1)' and replace with 'approximately equivalent to.....' and add a</p>	<p>Statement modified</p> <p>Accepted</p> <p>Accepted</p> <p>Agreed to include comparator. References provided for appropriate comparators of risk.</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed to include comparator. References provided.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>footnote stating ‘the risk of contracting fatal cancer should be given in a manner that will be understood by the research participant. An example is that the risk is approximately equivalent to (dose in mSv x 5)* % of the average chance of being killed on Australian roads in a period of 10 years.’</p> <p>Annex 2, line 291-292 Delete sentence</p>	
<p>07 Don Swinburne RANZCR</p>	<p>Thank you for the opportunity to comment on the Revised Code of Practice.</p> <p>The College supports the approach taken in the revised ARPANSA draft where the emphasis is on providing the institutional research ethics committee with accurate information about the radiation dose to the research participants and the risks involved. It would seem that the institutional ethics committee is in the best position to evaluate all the risks involved for the individual participants, preserving their rights and interests and to decide whether it is appropriate for the project to proceed. The change in emphasis away from the Radiological Advisory Council or radiation regulator to the medical physicist as the authority on accurate information about radiation for the institutional research ethics committee and for the research participant is also supported.</p> <p><i>Our main concerns are about the dose constraints listed in Table 1</i> With respect to the actual limits, it is submitted that for adults, a dose constraint of 5 mSv is too low a limit to be practicable for research. While the dose constraint of 5 mSv is much greater than the limit for the general public of 1 mSv, it is still much lower than many radiological procedures that may be the subject of research. Many radiological and nuclear medicine procedures entail use of doses that are much greater than an effective dose of 5 mSv. For</p>	<p>Noted</p> <p>Based on data collected for the Regulatory Impact Statement, a change to a 10 mSv constraint would impact on very few projects (1 in Victoria during 2002). Application of the lower constraint contributes to optimization of doses. Issue was also referred to Radiation Health Committee in March 2005 and the Committee agreed that the 5 mSv dose constraint be maintained</p>

SUBMITTER	COMMENT	RESPONSE
	<p>in adults, a more liberal limit could apply to those with medical conditions where the radiation research relates to something about that medical condition. The Code states that the dose constraints are only applicable to that radiation which is in addition to normal medical practice, but defining what normal medical practice is, and what is research can be difficult. It may be preferable to have different dose constraints applicable for these different categories.</p> <p>There would seem to be limited guidance from overseas organisations as to what are reasonable radiation dose constraints for participants in research involving radiation. Does ARPANSA have information from other regulatory authorities and radiation protection agencies apart from the ICRP and EU guidelines, as to what dose limits are reasonable in research? The ICRP and EU documents are clearly guidelines with no strict limit recommended. Rather, they suggest a limit can be applied according to the situation of the category of the research participants and the risk that one wishes to accept.</p> <p>The limits in the ARPANSA Code are more restrictive than the ICRP and EU guidelines. The ICRP uses a dose of 10 mSv as a point of division between the various categories. The EU guidelines also use 10 mSv as the division point and emphasise risk. The limit of 10 mSv is more realistic than the 5 mSv limit in the Code as it does permit the use of modern radiological procedures.</p> <p>In annex 2, the ARPANSA draft code discusses risk where the division between categories is 20 mSv. Presumably, those categories are from a different source so perhaps some other groups regard 20 mSv as acceptable in some cases.</p> <p>The EU document states that "For each of the risk categories the dose figures could be increased by a factor of 5 to 10 for people aged 50 years or over." Accepting their division between categories at 10 mSv with that modification</p>	<p>The Code already provides for a higher dose constraint in patients with a limited life expectancy.</p> <p>The draft 2005 ICRP Recommendations refer to dose constraints of "a few millisieverts"</p> <p>The risk statements in Annex 2 came from the NSW HURSOG guidelines, not from a regulatory publication. The value of 20 mSv was not used by HURSOG as a dose constraint, but as an aid to categorizing the risk statements.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>factor, would mean that a dose of 50 mSv would be reasonable for those over 50 years. In comparison the draft ARPANSA Code suggests 50 mSv only for those who have a life expectancy of less than 5 years and 12 mSv for those over 70 years. One could infer that the EU guidelines would suggest 100 mSv is reasonable in the subgroup with a life expectancy of less than 5 years, and perhaps also 100 mSv in the older age group such as 70 years.</p> <p>As to what the dose constraint level should be is debatable. Why there should be different levels of dose listed in table 1, Annex 1 and Annex 2 is not clear. It would be better having consistency between the tables. There seems little justification in a lower limit in table 1 than in the risk categories in Annex 1.</p> <p>We submit that the levels should be such that modern radiological procedures are able to be used in research. A level of 10 mSv is the lowest level that would allow that, but even that is lower than the 20 mSv categories mentioned in the communication section in Annex 2.</p> <p>In terms of what limits should apply we suggest that the following limits are reasonable in adults and are the lowest practicable level for research that involves modern radiological imaging:</p> <ul style="list-style-type: none"> • Adults - healthy volunteers -10 mSv in 5 years (no annual limit), with a note that if the effective dose is greater than 5 mSv, research participants should be over 40 years old. • Adults - research participants with a medical condition - 20 mSv in any one year, with a note that if the effective dose is greater than 10 mSv, research participants should be over 40 years old. • Adults with a life expectancy of less than 5 years - 50 mSv in any one 	<p>Corrected in the final Code</p> <p>Disagree</p>

SUBMITTER	COMMENT	RESPONSE
	<p>year.</p> <ul style="list-style-type: none"> Children and fetuses - doses as listed in the post-consultation draft <p>The limit of 20 mSv is still within what is regarded as reasonable for occupational exposure, even though occupation exposure may be as small amounts over a long time. As examples, if a scan involved a dose of 10 mSv, the above levels would permit a single scan for healthy volunteers every five years, and two scans per year for those with a medical condition.</p> <p>The above suggestion about liberalising the dose constraints in table 1 only applies for adults. The restrictions listed in the draft ARPANSA Code for children are supported.</p> <p>As mentioned previously it would seem that the main references are the ICRP and EU guidelines. If only guidelines exist, then perhaps the ARPANSA document could be drafted as a "Safety Guide" rather than a "Code". There would seem little in it that the regulatory authority would reference as a condition of licence.</p> <p><i>Annex 2 communication</i></p> <p>We suggest an additional paragraph to the effect:</p> <p>"The amount of information about radiation that should be communicated to the research participant depends upon the circumstances of the research study. Where the principal element of the research involves radiation, for instance a new type of nuclear medicine scan, considerable detail needs to be given about the radiation and its risks. However when the main question being addressed by the research involves some other factor such as a drug, and the radiation is</p>	<p>Noted</p> <p>Disagree. It is essential that the document is published as a Code and will therefore be added to the National Directory of Radiation Protection. The regulators must therefore adopt the Code and can include it as a condition of licence for the responsible person. It can then be audited by the regulator.</p> <p>Disagree. Although the risks from a drug may be higher than the risk from the radiation that does not diminish the radiation risk (and could potentially</p>

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	<p>used to monitor the effects of the drug perhaps with a CT scan, a different emphasis is appropriate. In the latter example, the risks from the drug may be much higher than the risks from the radiation. More information about the risks of radiation needs to be provided to children (or their carer) and young adults than to the elderly or those with a limited life expectancy."</p> <p>Clearly it is important that the research participant needs to be provided with sufficient information about the risks from the radiation to make an informed decision about participating in the study.</p> <p>The other minor point concerns the use of a second medical physicist. They are professionals and experts at estimating doses. It is submitted that a second medical physicist should only be necessary where there is some doubt about dosage, not based upon whether the dose is above some arbitrary value.</p> <p><i>References (from Code)</i></p> <p><i>European Commission, Radiation Protection 99 - Guidance on Medical Exposures in Medical and Biomedical Research 1999.</i></p> <p><i>ICRP publication 62, 1999. Radiological Protection in Biomedical Research.</i></p>	<p>enhance the risk if the radiation effects and the drug acted together).</p> <p>Purpose is to provide research participants with the protection of a second opinion on the proposed dose, to ensure the accuracy of the calculation of such doses and that participants and HRECs are correctly informed.</p>
<p>08 Mary Aerts Health Physicist Radiation Health Branch</p>	<p>Role of Regulatory Authority:</p> <p>The role of the regulatory authority in relation to assessment of these projects differs between States with some States mandatorily requiring approval of the research project by the regulatory authority (in addition</p>	

SUBMITTER	COMMENT	RESPONSE
	<p>to the approval of the institution’s Ethics Committee) where the radiation received by participants is above certain dose constraints.</p> <p>This needs to be addressed in a way with allows for the differing approaches of the States.</p> <p>It is suggested that the following is inserted, perhaps at the end of the 1st paragraph in Section 3:</p> <p>“Some States may require approval by the radiation regulatory authority for research projects involving diagnostic investigations with radiation doses above the dose constraints.”</p> <p>Suggested amendment to wording in Section 3:</p> <p>The second sentence is inappropriate, as the very nature of some research projects will involve diagnostic doses greater than the dose constraints of Table 1, and one of the functions of this Code is to ensure that when this is the case, there will be particular consideration given to the grounds for justification before approval is granted. The (presumed) intention of this section (and avoidance of some of the objections from some researchers who tend to mis-interpret the intention of dose constraints as limits), would be met if the 2nd and 3rd sentences both have “should” replaced by “must” and are amended slightly to read:</p> <p>“Wherever possible, the cumulative effective doses and organ doses to adults and children must conform with the dose constraints as tabulated below. If these dose constraints will necessarily be exceeded, the Human Ethics Committee must give particular attention to the</p>	<p>The aim of the Code is to set out a standard for the exposure of humans to ionizing radiation for research purposes. It is then up to jurisdictions to adopt the requirements as appropriate in their jurisdictions.</p> <p>The current wording was discussed at the July 2004 meeting of the Radiation Health Committee and supported. Implementation of the Code will still be according to the needs of the regulator.</p> <p>Agree to use ‘whenever possible’. The HREC is given guidance. The HREC are subject to the requirements of the National Statement.</p>

SUBMITTER	COMMENT	RESPONSE
	<p>justification for the radiation exposure, and if necessary, seek further independent authoritative advice before approving the proposal.”</p> <p>Then on to the suggested sentence (see above): “Some States may require . . .”</p> <p>“Must” versus “should”</p> <p>There are still a few cases of “should” that should be “must” in line with the requirements for a Code of Practice. Examples are:</p> <ul style="list-style-type: none"> • Section 2: 2.3.1 • Section 2: 2.3.2 • Section 2: 2.1.2(b) (v) (The “should” in 2.1.2(a)(i) is OK as it is a “where practicable” contained in the “must” statement of 2.1.2) • Section 3: 2nd & 3rd sentences. (But the 2nd sentence is inappropriately worded – see above.) <p>Annex 2: Communication of the Risk to the Research Participant</p> <p>The amendments recently proposed for Annex 2 by Dr Richard Fox and the ACPSEM submission are supported.</p> <p>However it is also strongly recommended that a quantitative statement of the risk estimation must be stated, at least for doses above 2mSv. This is the bottom line for factual information (in terms of best current knowledge) that should be given to volunteer participants. Those members of the public who may not understand this or who do not find</p>	<p>The aim of the Code is to set out the standard for the exposure of humans to ionizing radiation for research purposes. It is then up to jurisdictions to adopt the requirements as appropriate in their jurisdictions.</p> <p>The HREC are subject to the requirements of the National Statement</p> <p>Use of risk comparator has been added</p>

SUBMITTER	COMMENT	RESPONSE
	<p>it helpful can simply ignore it.</p> <p>(In Western Australia, for projects delivering more than 5mSv from diagnostic investigations, the Radiological requires a statement of the estimated dose of any radiation additional to normal clinical management, a statement of the associated quantitative risk estimate for fatal cancer, and a comparison of this risk probability to some relatively easily understood risk. Comparison with road accident risks and with the annual natural radiation background dose are suggested in the Council's application form as useful ones.)</p>	
<p>09 Radiological Council of WA</p>	<p>Revised Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes</p> <p>The above Code has been considered by members of the Radiological Council and the following comments are provided.</p> <p>Role of the Regulatory Authority</p> <p>Council members believe that replacing the role of the Regulatory Authority by an independent physicist in cases where the dose constraint is exceeded is unacceptable.</p> <p>Codes of Practice are defined as being "<i>prescriptive in style and may be referenced by regulations or conditions of licence. They contain practice-specific requirements that must be satisfied to ensure an acceptable level of safety in dealings involving exposure to radiation.</i>"</p> <p>Prescriptive controls that "must be satisfied" and "may be referenced in regulations" imply an ongoing role for the regulatory authority. It is Council's</p>	<p>The working group considered the contribution of the regulator and its interaction with the HREC in regulating research projects</p> <p>Not accepted. The Code will be incorporated into the National Directory for Radiation Protection and</p>

SUBMITTER	COMMENT	RESPONSE
	<p>view that without the involvement of the regulatory authority the Code would seem to be just another largely unenforceable self-regulatory document.</p> <p>Annexe 2 Council members have reviewed the suggested statements for insertion in the “Information Statement for Participants” that is included as Annexe 2.</p> <p>Members strongly believe that the currently proposed wording does not provide research participants with a clear understanding of the risk that they are taking and that if patients are going to make an informed choice they need to be provided with information in a form that enables them to clearly understand what the risks are and their magnitude.</p> <p>A suggested rewording of Annexe 2 is enclosed that addresses the concern of Council members.</p> <p>Annex 2, line 268 Remove ‘to 3’</p> <p>Annex 2, line 269 - 270 Remove ‘no harmful effects of radiation have been demonstrated and’ replace with ‘the risk level is too low to measure. It is believed that’...</p> <p>Annex 2, line 273 Remove ‘very’</p> <p>Annex 2, line 275 Remove ‘to 3’</p> <p>Annex 2, line 276-277</p>	<p>become part of the regulatory framework in each jurisdiction.</p> <p>Reference to risk comparators have been added.</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed</p>

SUBMITTER	COMMENT	RESPONSE
	<p>Remove ‘no harmful effects of radiation have been demonstrated and’ add ‘being approximately equivalent to.....’ after ‘the risk is low’ and add a footnote stating ‘the risk of contracting fatal cancer should be given in a manner that will be understood by the research participant. An example is that the risk is approximately equivalent to (dose in mSv x 5)* % of the average chance of being killed on Australian roads in a period of 10 years.’ And another footnote providing an explanation of the approximate dose as being ‘based on a risk of 5×10^{-2} per Sv. For studies in children or for persons over the age of 50, the risk of radiogenic cancer should be calculated using age- and sex-specific risk factors given in Table 2 of Annex 1.’</p> <p>Annex 2, line 282 Remove ‘to 3’ Annex 2, line 282 Insert ‘fatal’ before ‘cancer’</p> <p>Annex 2, line 285-286 Remove ‘about 1 in.....(calculate using...risk factors given in Table 2 in Annex 1)’ and replace with ‘approximately equivalent to.....’ and add a footnote stating ‘the risk of contracting fatal cancer should be given in a manner that will be understood by the research participant. An example is that the risk is approximately equivalent to (dose in mSv x 5)* % of the average chance of being killed on Australian roads in a period of 10 years.’</p> <p>Annex 2, line 291-292 Delete sentence</p>	<p>Agreed to include comparator. References provided for appropriate comparators of risk.</p> <p>Agreed</p> <p>Agreed</p> <p>Agreed to include comparator. References provided.</p> <p>Agreed</p>
<p>10 Jocelyn Towson RSO Royal Prince Alfred Hospital</p>	<p>Thank you for the invitation of 1 December 2004 to comment on the revised CoP for the Exposure of Humans to Ionizing Radiation for Research Purposes. I have a few more comments to make.</p>	

SUBMITTER	COMMENT	RESPONSE
	<p>L93-95 The exclusion "whenever possible" of healthy volunteers who have previously been exposed to radiation from research projects is too restrictive as it ignores the time factor of dose constraints. For example, adults could be excluded from a longitudinal study of bone mineral density even though the last exposure occurred more than 5 years ago. Suggest alternative wording "... select persons who have not previously, or are not currently exposed to radiation from research unless it can be demonstrated that the dose constraints in this Code will be met when those previous or current exposures are taken into account."</p> <p>L121 Only applies to adult participants. Suggest "The researcher must advise the research participant or guardian to retain the information about the procedure including the radiation dose for at least 5 years (in the case of an adult) or to age 18 (in the case of a child), so that it can be provided to researchers in any future research project involving exposure to ionizing radiation."</p> <p>L133-134 Insert an additional responsibility of the Medical Physicist: "(d) verify the radiation dose received by the participant from other research exposures, if any, in the previous 5 years (in the case of an adult) or to the present (in the case of a child)."</p> <p>L136-138 This is a key statement which should clarify what exposures in a clinical trial are to be considered as part of the research, with no consideration of whether the participant is expected to benefit from either the research or the exposure. The phrase "normal clinical management" is still ambiguous (at least for this medical physicist) -</p>	<p>Agreed</p> <p>Agreed</p> <p>This is covered in the responsibilities of the researcher in selection of participants.</p> <p>Clause 2.2.2(a) modified</p>

SUBMITTER	COMMENT	RESPONSE
	<p>maybe it should be "usual clinical management if not in the trial". For example, if a novel therapeutic agent or procedure has a real risk of causing cardiac side effects, gated heart pool scans might be clinically indicated to monitor safety and efficacy and it would be up to the HREC to judge how many. Could you please confirm whether the intention of the statement is simply "assess only those radiological procedures which are performed specifically for the research protocol".</p> <p>L175-176 The words that the HREC should "... if necessary, seek further independent authoritative advice before approving the proposal" is as close as the CoP comes to defining a role for the regulatory authority. In NSW the Radiation Control Regulation 2003 requires research to be conducted according the 1995 Code Administration of Ionizing Radiation to Human Subjects in Medical Research, "as in force from time to time". I take that to mean that the new CoP will apply instead, without any amendment to the Regulation. But given its opposition to relinquishing the role, I am not sure whether the DEC will be able to require proposals exceeding the dose constraints to be referred to it - I guess we will have to wait and see.</p> <p>L179 Table 1 I note that the requirement to assess cumulative ED over 5 year does not apply to any adult with a life expectancy of less than five years, or to any proposal involving only adults aged 60 or more. My understanding is that the constraints on equivalent dose to skin or any other organ or tissue over 1 year still apply in all cases.</p> <p>L180 Footnote I does not appear in the text - missing from L178?</p> <p>L185 Change "radiotherapy" to "radiation therapy" to include</p>	<p>Noted</p> <p>Adult participant categories have been re-ordered to signify that skin and other organ/tissue does apply in all cases</p> <p>Corrected</p>

SUBMITTER	COMMENT	RESPONSE
	<p>radionuclide therapies.</p> <p>L238 Change "normal jobs" to "employment".</p> <p>L239 Change "totality of sources" to "totality of naturally occurring sources"</p> <p>Annex 2 I find it a little confusing that the risk categories in Annex 1 and the risk statements in Annex 2 are not aligned. After much thought, I would like to suggest an alternative categorization to cover both purposes - see below.</p> <p>L283-285 Change "In this particular study, ..." to "At these dose levels, ..." . I know I previously recommended that risk assessments should be specific to the subject cohort, but as per Health Physics Association guidelines, I would prefer that risk statements for doses less than 50mSv don't appear to be too specific to the individual participant reading the statement.</p> <p>L300 Delete "cumulative"</p> <p>L314 Delete "multicentre". I don't see why the onus to obtain an authoritative dose estimate shouldn't be on the sponsor every time.</p> <p>L317-328 Why only radiotherapy, not "radiation therapy"? And add "or nuclear medicine physician" after "radiation oncologist".</p> <p>L325-327 Broaden the sentence to "The risk of the radiation exposure, whether for treatment or to monitor treatment, needs to be outlined to</p>	<p>Agreed</p> <p>Agreed</p> <p>Agreed</p> <p>Disagree</p> <p>Agreed</p> <p>Agreed</p> <p>Text modified</p>

SUBMITTER	COMMENT	RESPONSE																				
	<p>the research participant. In oncology trials it is not meaningful to assign a risk level category as per Annex 1 to radiation treatments. Nor is it necessary to include an estimate of cancer risk from radiological procedures used to monitor treatment, including chemotherapy, in the Information Statement as per Annex 2."</p> <p>L346-347 Radiology and Nuclear Medicine may not be the only departments. For example, BMD studies in Rheumatology or Endocrinology. Suggest "... liaise with the Head of Radiology, Nuclear Medicine or other department as appropriate."</p> <p>p13, second footnote, change "essentially" to "numerically".</p> <p>Suggested alignment dose and risk categories in Annex 1 and Annex 2</p> <p>Annex 1 Table 3</p> <table border="1" data-bbox="412 868 1388 1283"> <thead> <tr> <th>Risk level</th> <th>Risk Category</th> <th>Effective Dose range (adults) (mSv)</th> <th>Level of societal benefit</th> </tr> </thead> <tbody> <tr> <td>Negligible to minimal</td> <td>Category Ia ~10⁻⁶ to 10⁻⁵</td> <td>< 0.2</td> <td>Minor</td> </tr> <tr> <td>Very low</td> <td>Category Ib ~10⁻⁵ to 10⁻⁴</td> <td>0.2 to 2</td> <td>Intermediate</td> </tr> <tr> <td>Low</td> <td>Category II ~10⁻⁴ to 10⁻³</td> <td>2 to 20</td> <td>Moderate</td> </tr> <tr> <td>moderate</td> <td>Category III ~10⁻³ or more</td> <td>> 20</td> <td>Substantial</td> </tr> </tbody> </table>	Risk level	Risk Category	Effective Dose range (adults) (mSv)	Level of societal benefit	Negligible to minimal	Category Ia ~10 ⁻⁶ to 10 ⁻⁵	< 0.2	Minor	Very low	Category Ib ~10 ⁻⁵ to 10 ⁻⁴	0.2 to 2	Intermediate	Low	Category II ~10 ⁻⁴ to 10 ⁻³	2 to 20	Moderate	moderate	Category III ~10 ⁻³ or more	> 20	Substantial	<p>Departments have been listed as examples</p> <p>Agreed</p> <p>The effective dose range has been aligned to those in Annex 2. The numbers are in accordance with the ICRP risk of fatal cancers of 5% per Sv.</p>
Risk level	Risk Category	Effective Dose range (adults) (mSv)	Level of societal benefit																			
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SUBMITTER	COMMENT	RESPONSE
	<p>Category I The dose range for this project category is up to 2mSv, comparable to the dose delivered by natural background radiation in up to a year.</p> <p>Category Ia (risk of the order of 1 in 100,000 or less) represents a negligible to minimal level of risk. The dose range of up to 0.2mSv is considerably less than the differences in annual dose from natural background to persons living in different locations. The level of benefit to justify research with doses in this subcategory will be minor and include those investigations expected only to increase knowledge.</p> <p>Category Ib (risk of the order of 1 in 10,000 or less) represents a very low level of risk. The dose range of 0.2 to 2mSv covers the allowable annual dose to the public from controlled sources. To justify risks in this category, the research should be related to increases in knowledge leading to health benefits.</p> <p>Category II (risk of the order of 1 in 10,000 to 1 in 1,000) represents a low level of risk. The dose range of 2 to 20 mSv covers the annual doses received by essentially all radiation workers in the course of their employment, and most diagnostic radiological procedures. To justify risks in this category a moderate benefit will be required. The benefit will be more directly aimed at the diagnosis, cure or prevention of disease.</p> <p>Category III (risk of the order of 1 in 1,000 or greater) The dose range for this project category is tens of mSv which may be greater than the annual dose limit of 20mSv for occupational exposure, and comparable to some CT procedures. To justify research involving doses or risks in this category, the benefit will have to be substantial and</p>	

SUBMITTER	COMMENT	RESPONSE
	<p>usually directly related to the saving of life or the prevention or mitigation of serious disease.</p> <p>Annex 2 Sample risk statements:</p> <p>Category I Effective dose less than 2 mSv "At this dose level, ... the risk is negligible (if dose < 0.02mSv) / minimal (if dose < 0.2 mSv) / very low (if dose is between 0.2 and 2 mSv)."</p> <p>Category II Effective dose between 2 and 20 mSv "At this dose level, ... the risk is low."</p> <p>Category III Effective dose more than 20 mSv "At this dose level, the risk is moderate and the calculated risk of harm is about ..."</p>	
<p>11 George Larcos, FRACP President, Australian and New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM)</p>	<p>I am grateful for the opportunity to comment on the above draft Radiation Health Committee document.</p> <p>The Australian and New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM) is recognised as the peak professional body of nuclear medicine specialists in this country.</p> <p>I would like to offer the following comments in regard to the draft code.</p> <p>In general, the ANZAPNM supports the introduction of a revised code in this field.</p> <p>In <u>2.1.6</u>, the code suggests that researchers obtain “assessment or verification by a medical physicist”, however the ANZAPNM believes that the latter category is too broad; certainly, there are medical physicists with</p>	<p>Not accepted. Current definition is specific enough to ensure physicists with appropriate expertise undertake assessments and verification</p>

SUBMITTER	COMMENT	RESPONSE
	<p>insufficient knowledge of radiation dosimetry and safety. Thus, it would be more appropriate to specify that the medical physicist has expertise in this field or is an active member of the Hospital and University Radiation Safety Officers' Group or the Australian Radiation Protection Society.</p> <p>In <u>2.1.7 (c)</u>, there is a statement that the research be conducted in a facility which "is actively involved in a relevant quality assurance program...". The ANZAPNM notes this suggestion but recommends that the requirement for involvement in quality assurance be more strongly stated and, in this regard, it is our view that it is preferable for the code to require that the facility be accredited according to the joint practice accreditation standards of the ANZAPNM and Royal Australian and New Zealand College of Radiologists (RANZCR) ("Standards for Accreditation of Nuclear Medicine Practices"). A facility accredited under these Standards would be involved in a well-defined quality assurance program relevant to both the facility and its processes and procedures. A copy of the relevant documentation can be provided if required.</p> <p>It is also important that nuclear medicine specialists participating in any proposed research are credentialled as such by the Joint Nuclear Medicine Specialist Credentialling Committee of the ANZAPNM and RANZCR; this ensures that specialists involved in research are working according to professional standards agreed by the relevant bodies. The ANZAPNM supports the dose constraints of 5mSv/annum in adults and believes that 8mSv for adults >60yo is also sensible.</p> <p>We have serious reservations in regard to <u>Table 3 of Annex 1</u>.</p> <p>We strenuously reject the attempt to link the radiation dose with expected</p>	<p>Programs have now been included as examples</p>

SUBMITTER	COMMENT	RESPONSE
	<p>benefit. Medical research in humans is conducted for a wide variety of objectives; as long as the proposed work is ethical and volunteers and subjects are informed of the potential risks associated with ionising radiation, there should be no additional requirement that the research “<i>increase knowledge</i>” (Category I), “<i>increase knowledge leading to health benefit</i>” (category IIa), “<i>directly aimed at diagnosis, cure or prevention of disease</i>” (Category IIb) or “<i>have substantial benefit leading to... saving of life or the prevention or mitigation of serious disease</i>” (category III). The ANZAPNM strongly believes that these terms should be deleted from the draft code. Research using ionising radiation in this country would be seriously stifled if the draft code were unaltered at these points.</p> <p>In Annex 2, the language employed in the various sections (A, B, C etc) is based on the linear no-threshold (LNT) hypothesis. Since this theory is unproven, it is reasonable to talk to patients only in terms of a <i>theoretic</i> rather than <i>calculated</i> increase in cancer risk.</p> <p>In Annex 4, there is further reference to the LNT hypothesis. It is uncertain why this has been given prominence in this section. Accordingly, the ANZAPNM recommends that lines 384-8 and 397 be deleted.</p> <p>I welcome the opportunity of meeting with you or members of the RHC, especially in regard to Table 3 (Annex 1), to discuss our concerns about these aspects of the proposed code.</p>	<p>Link maintained. Annexes are supplementary guidance and do not form part of the mandatory component of the Code. The table is based on internationally accepted advice from the ICRP.</p> <p>Agreed</p> <p>Agreed – risk statement now refer to a theoretical risk of</p> <p>Disagree. The LNT hypothesis remains the basis for the ICRP’s estimates of risk from radiation exposure, and therefore needs to be discussed here, even though the ICRP recognises the limitations at low doses.</p>
12 Mark Carey	The NSW Department of Environment and Conservation (DEC) has revised	

SUBMITTER	COMMENT	RESPONSE
<p>A/Manager Radiation Policy NSW Dept Environment and Conservation</p>	<p>the Code of Practice, Exposure of Humans to Ionizing Radiation for Research Purposes dated 30 November 2004. The DEC has only one further comment:</p> <p>It would be useful to mention towards the beginning of the Code the general role of regulatory authorities. Readers of the Code could then be referred to Annex 5 for their regulatory authority's contact details so they may check they have the appropriate radiation licences and registrations.</p>	<p>Role of responsible person added who is responsible for the radiation licences and registrations within the institution.</p>
<p>13 Martin Caon</p>	<p>My enquiry relates to section 2.3.2 (e) It requires the HREC to pay particular attention to: "the measures to be taken during the project to assess the radiation doses actually received where these may differ from the expected radiation doses and the arrangements for the retention of records of these doses."</p> <p>The HREC would probably not be aware of the situations where "these may differ from the expected radiation doses".</p> <p>Does this section refer specifically to doses received due to novel uses of radiation, as stated in section 2.1.7 (f), or to all doses ?</p> <p>On page 12, annex 2, Part C, "effective dose greater than 20mSv". I would like the Committee to consider stating a range for the effective dose, eg 20 - 50 mSv.</p> <p>Clearly 200 mSv is an effective dose greater than 20 mSv, but many people would argue that the exposure is not a "small amount of radiation"</p> <p>My question is "Who decides that the radiation exposure is in excess of that</p>	<p>Novel uses only. Clause 2.3.2(e) is with regard to 2.1.7(f) and has been clarified to indicate as such.</p> <p>Agreed. Further passage added</p> <p>It would not normally be necessary to get</p>

SUBMITTER	COMMENT	RESPONSE
	<p>required for normal clinical management" ? I serve on an ethics committee that considers protocols for chemotherapy trials on cancer patients. The CT assessment of their tumors may deliver then 200 mSv per annum.</p> <p>Now we could</p> <ol style="list-style-type: none"> 1. accept at face value that the frequency of CT scanning required by the protocol is indistinguishable from Australian best practice medical care and therefore that whatever is in the Draft code does not apply to this research. In my opinion this would be a dangerous (and indefensible) position to take as sponsors (& researchers) have an interest in keeping ethical compliance requirements as simple as possible and the ethics committee would be avoiding their obligation to safeguard the research participants. <p>or</p> <ol style="list-style-type: none"> 2. seek an expert opinion about the frequency of imaging procedures for patients of this nature. <p>If the expert opinion says the frequency is higher than would be applied to patients who are not involved in a research study, then the Draft code applies. I would be happy for the research to proceed as the controlled exposure of such patients (with their consent) is justifiable given the benefits that would be obtained by society.</p> <p>If the expert opinion says the frequency is what is expected, then the draft code does not apply.</p>	<p>external expert opinion. The way this would normally work is as follows:</p> <ol style="list-style-type: none"> 1. the protocol specifies all the radiological procedures to be undertaken 2. the researcher specifies to the medical physicist, on the hospital application form, which studies (and at what frequency) would be part of his usual management for this type of patient 3. the medical physicist includes the information in point 2 in their report to the HREC and allow the members of the HREC to question the researcher on this issue. <p>Believe that this is adequate and sufficient. We must accept that for many types of treatment there are no "standard" protocols, and that what is "normal clinical management" may well differ between different hospitals and even between different specialists within the one hospital.</p>