

**SUMMARY OF SUBMISSIONS AND RESPONSES**  
**DRAFT CODE OF PRACTICE FOR RADIATION PROTECTION IN THE MEDICAL APPLICATIONS OF IONIZING RADIATION –**  
**Regulatory Impact Statement**

<b>SUBMITTER</b>	<b>COMMENT</b>	<b>RESPONSE</b>
<p><b>10</b>  Paul Marks  Senior Scientist  Radiation Safety  Section  Environmental  Health Unit  Public Health  Branch  Department of  Human Services,  Vic</p>	<p>RIS:  Makes reference to the old Health Act 1958 and Radiation Safety Regulations 1994.  As of the 1 Sept 2007 there is a new Radiation Act 2005 and Radiation Regulations 2007.</p> <p>Victorian will not be assessing individual radiation management plans.</p>	<p>Amended.</p> <p>Noted.</p>
<p><b>14</b>  Don Swinbourne  Chief Executive  Officer  RANZCR  (Lisa Penlington)</p>	<p>The College queries the rationale of this process in consideration of how such documents may be used by various groups in the future.</p> <p>A major issue is that despite input from the professions these documents in their current drafts appear to have been written in isolation from existing professional standards of practice for radiology services. That may be because this process was commenced five years ago and there have been more recent developments. The College draws ARPANSA's attention to the Commonwealth Government's implementation of accreditation of Radiology services whereby services will be assessed against a set of standards drawn from the RANZCR's Standards of Practice for Diagnostic and Interventional Radiology. The College considers that the ARPANSA document exceeds its brief by prescribing the professional clinical practice of the various medical radiation specialties. Similarly, the Australian Commission on Safety and Quality in Health Care is looking at standards and accreditation activity across the health sector in Australia.</p> <p>Accordingly there are areas of overlap between existing standards and the ARPANSA documents, and while many of the aims are probably similar, some items as they are written in the ARPANSA documents are simply not yet implementable. Instead, there appears to be an overemphasis on bureaucracy and regulation of medical radiation where a more intuitive approach would be more</p>	

	<p>successful.</p> <p>Several of the documents are written in a prescriptive often dogmatic style which can make them difficult for workers to relate to.</p> <p><b>Regulatory impact statement</b></p> <p>The regulatory impact statement emphasises the regulatory impact of the Code. The College accepts that medical radiation needs to be regulated, like all forms of ionizing radiation; however the costs indicated seem very large and will entail a significant burden for practices and hence to society at large. There already is regulation by the radiation regulators of medical departments so the College questions why such additional costs appear to be so high.</p> <p>The College has addressed the regulatory impact statement by considering items summarised on page 21.</p> <p>1. Uniformity: The College supports the suggestion that uniformity in regulation is desirable and notes that ARPANSA also considers it provides efficiencies and leads to reduced administrative costs in the long term. This is an important consideration as the practice of Teleradiology increases and crosses jurisdiction boundaries. However, the College is concerned at ARPANSA's claim of a benefit of reduced administrative costs which is inconsistent with the rest of the proposed regulatory impact where it is clearly stated that there will be large increased administrative costs, in the order of \$5.4 million and ongoing recurrent annual costs of \$1.1 million.</p> <p>2. International standing and consistency: agree, this is desirable</p> <p>3. Health and safety benefits: Improved radiation awareness - The College agrees awareness of radiation effects and radiation safety is desirable and should be promoted. However the College does not agree that increased regulation will promote awareness. Awareness which effects changed behaviour is mainly achieved by education of radiation workers, referring doctors and the general public and the College considers this is a better means of improving radiation safety than increased regulation. The document mentions workplace deaths cost between \$1.6 and \$2.5 million, inferring that those costs apply to radiation induced deaths, although this link is tenuous. With the current radiation occupational limits, the risk of radiation induced death is extremely low and the benefit to occupational workers in monetary terms is</p>	<p>The administrative benefits described in the RIS are referring to those incurred by the regulators (see para. 109). The costs cited in this comment relate to the preparation and review of radiation management plans by the licensees but these are offset by the benefits gained in a lower risk to the public.</p> <p>Noted.</p> <p>The point about the risk of radiation death being extremely low is taken however, the cost here has not been included in the final cost comparison anyway. It is simply an observation within the RIS to indicate that if workplace deaths were prevented by more stringent requirements that would, in turn, prevent incidents, there would be an added benefit of that sort of magnitude.</p>
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overestimated.

Reducing unnecessary exposure, justification - the College agrees that unnecessary medical radiation exposure should be reduced, and strongly agrees with the principle of justification which is internationally accepted. Justification is the principle where before any activity (of radiation) is to take place, the consequential benefit should outweigh the harm. Thus it is a principle where the benefits and risks are evaluated. In medical practice, the persons who are qualified to do this are both the referring doctor and the radiation medical practitioner who are each required to exercise their professional judgement which will be influenced by new evidence of benefits and harm. Professional medical judgement is a principle underpinning medical practice and ultimately it is not feasible nor clinically appropriate for a radiation regulator to 'police' this; in the College's view it is best achieved and promoted by education. It should be noted that referring medical practitioners are not regulated in relation to radiation safety and that there are other regulatory impediments to Radiologist practice that limit the role of the radiologist in reducing unnecessary exposure. To claim that increased 'regulation' of the justification principle by radiation regulators will 'save' \$13 million is questionable.

Formalisation of training - Training is very important but the College is not aware that ARPANSA or the state radiation regulators are involved in training. Training is a matter for the professional groups. Training of nurses who are occupationally exposed to radiation is usually done within hospitals or departments. The College seeks advice on how the figure of \$5600 in the summary section was arrived at. In the detail of the document initial costs are listed at \$407000 and ongoing costs are \$31,050 per year.

Tightening occupational dose limits - The College is not aware that this Code tightens occupation dose limits, as those national limits were designated in Radiation Protection Standard 1, ARPANSA, 1995. It would seem that not all State radiation regulatory bodies have adopted that national standard. The College is surprised to find in this document the statement that some States such as Western Australia have not included the internationally, and nationally accepted limits in their radiation protection legislation. It is also surprising that the Northern Territory still uses the outmoded term 'rem' in legislation which was not in RPS1. ICRU report 33 (1980) recommended SI international units be used for all radiation matters including replacing the rem. The national commitment to uniformity in radiation matters appears somewhat inconsistent when some Australian regulators appear to be 20-30 years out of date; document. Improved uniformity of

While it is agreed that education is the basis of reducing the risk in any human activity, it is still often necessary to have a regulatory backup.

The figure of \$13 million benefit derives from reducing the number of CT scans undertaken by 1% as a result of the justification principle. Paragraph 99 of the RIS explains how the figure was derived and goes on to give benefits if the reduction was 5% and 10%. In the final analysis, only the 1% value was used.

The benefit of \$5600 is given in para 102 and footnote 37 describes how the figure was derived. That is, actual exposure to nurses, no of nurses exposed, cost per person sievert and an assumed reduction of dose of 1% due to increased radiation safety awareness through training.

The costs and benefits of training have been revised in the final version of the RIS.

As the Code, once approved, will be included in the *National Directory*. This will provide a level of uniformity for radiation protection in the medical use of ionizing radiation across Australia, including dose limitation.

	<p>occupational limits in radiation safety does not require this medical radiation document.</p> <p>Overall, the Regulatory Impact Statement emphasises increased regulation by the radiation regulators, and includes claims of expenses and benefits. The large monetary savings which are claimed from this increased regulation do not appear to be well-founded and therefore lack credibility. The indicated costs of the increased regulation are alarming and will create a burden for medical practice and to society as a whole. When any Code is developed it should be done so in a manner whereby the stakeholder group which is required to implement the Code is consulted with closely to ensure that the requirements of the Code are practical and implementable, and where the compliance costs are kept as low as possible.</p> <p>It is the College's view that the role of the radiation regulator is licensing of radiation workers who can prescribe and administer radiation, licensing of radiation premises, and ensuring that appropriate procedures for radiation safety are in place.</p> <p>For an individual patient, the control of medical radiation is achieved by applying the principles of justification and optimisation. That is a matter for the individual departments/services and medical radiation personnel. There should be guidelines about appropriate management and procedures, and it should be noted and recognised that technology is rapidly changing. There is regulation about who can administer radiation to patients but there is no regulatory limit to the amount of radiation a patient can receive as part of their medical management. It is inappropriate for the radiation regulator to intrude into matters of individual patient management.</p> <p>The College believes that the Code goes beyond the role of a radiation safety regulatory document to that of instructing how clinical practice must be carried out. The College recommends that ARPANSA consult with the College and Faculty and the ANZAPNM in relation to the respective professional bodies Standards of Practice which are considered to be more appropriate documents guiding and supporting the practice of medical radiation specialities. It would be preferable for the Code and Safety Guides to work in concert with the professions' standards rather than compete with them.</p>	<p>It is felt that the RIS outlines the costs and the benefits of the proposed Code and the benefits significantly outweigh the costs of introducing the Code.</p> <p>Members of all three disciplines participated on the original working groups that were instrumental in formulating the draft Code. Further, the Code was subjected to two comment periods during 2007 and a conference was held on 3 October 2007 during which, industry representatives were able to raise any queries. Agreed.</p> <p>Guidelines about appropriate management and procedures will be incorporated into the relevant Safety Guides.</p> <p>The Code has not attempted to place "limits" on the amount of radiation a patient can receive as part of their care.</p> <p>The Code does not instruct how a clinical practice is to be carried out. It requires that the radiation protection principles of justification, optimisation and limitation (for occupational exposure) be employed for all medical procedures.</p>
<p><b>15</b> Joseph Wong FRACP</p>	<p>Please find attached a submission from the Australian and New Zealand Association of Physicians in Nuclear Medicine on the ARPANSA Draft Code of Practice, Radiation Protection in the Medical Applications of Ionizing Radiation, and the</p>	

<p>President Australian and New Zealand Assoc of Physicians in Nuclear Medicine</p>	<p>Safety Guide, Nuclear Medicine.</p> <p>This submission also includes as an attachment the following article:</p> <p>Hesse B et al., <i>European Journal of Nuclear Medicine and Molecular Imaging</i>, 2005, 32: 855-897 [attachment removed]</p> <p>As noted in our submission, the ANZAPNM strongly supports a review of all submissions on the above documents by the Working Group for the Safety Guide, Radiation Protection in Nuclear Medicine, as such review is considered essential to ensure that due consideration is given to the wide range of feedback on the draft documents.</p> <p style="text-align: center;"><b>ANZAPNM SUBMISSION ON THE ARPANSA DRAFT CODE OF PRACTICE</b></p> <p><b>4. Regulatory Impact Statement Consultation Draft</b></p> <p>It is clear from the Code that the “Responsible Person” will need to have ultimate responsibility over medical radiation. ARPANSA assumes that this non-medical person (CEO/general manager/director of medical services) will be the person “<i>to ensure justification principles are adhered to</i>” for each individual patient, and that this person needs only four hours of medical training to become familiar with the justification principles.</p> <p>In practice, it is the medical practitioner who makes these decisions many times a day for each patient. Hence, the costing analysis seems somewhat irrelevant. Apart from the Responsible Person, surely all medical practitioners and radiation safety officers (at a minimum) will need to be familiar with the Code, hence a much higher “training cost”. Our understanding from the Code is that justification for each medical radiation procedure must be assessed and approved by the medical practitioner before radiation is administered. If this is the case, this would mean significant changes in work practices in most radiology and some nuclear medicine practices (assuming documentation such as “protocols” must be in place), and castings for this are not mentioned anywhere in the RIS.</p> <p>Regarding the need for “radiation management plans”, the ANZAPNM assumes all hospital-based departments would have these in place for accreditation purposes. However, smaller, non-hospital-based practices may not. Hence, estimates of 8-hour preparation time for large centres and four hours for small centres may in fact be the</p>	<p>It is entirely possible that the Responsible Person will have no formal medical training. That person is required to have protocols in place that <i>ensure that justification principles are carried out at the institution</i>. He or she will not be required to perform these functions, only ensure that they are done.</p> <p>Provision is made within the Code for generic justification of certain procedures, therefore reducing the costs.</p> <p>If large hospitals already have such plans in place, the cost of preparation will indeed be minimal. It is</p>
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	<p>wrong way around, leading to a possible cost under-estimation.</p> <p>Finally, training of extra physicists to cope with the increased workload relating to all of the formal regulations and documentation is not mentioned in the RIS. This is likely to be the greatest cost and potential stumbling-block to implementation of the Code as it is currently worded.</p>	<p>assumed however, that four hours preparation time for small centres is appropriate.</p> <p>It is not perceived that there would need to be “training of extra physicists” for the purposes of the Code.</p>						
<p><b>19</b> Howell Round President, Australasian College of Physical Scientists and Engineers in Medicine Suite 3.13 Aero 247 247 Coward Street Mascot</p>	<p><b>ARPANSA Regulatory Impact Statement - -Specific feedback and comments:</b></p> <table border="1" data-bbox="416 440 1400 1182"> <thead> <tr> <th data-bbox="416 440 517 504">Page No</th> <th data-bbox="517 440 667 504">Clause &amp; Line(s)</th> <th data-bbox="667 440 1400 504">Comment</th> </tr> </thead> <tbody> <tr> <td data-bbox="416 504 517 1182">2 to 5</td> <td data-bbox="517 504 667 1182">1.3 Statement of problem</td> <td data-bbox="667 504 1400 1182">A sample regulation in the Radiation Protection and Control (Ionising Radiation) Regulations 2000 under the Radiation Protection and Control Act of 1982 in South Australia highlights how these outdated regulations would result in higher costs being transferred to those business who are the operators of radiation producing facilities, and then ultimately to the community. Regulation 105 under the S.A Radiation Protection and Control Act stipulates a maximum dose equivalent per hour limit when radiation survey measurements are carried out when the radiation producing apparatus is operated at the maximum potential and one half of the maximum radiation output available at that potential. The equivalent workload dictated by this regulation result in a very high attenuation factor leading to considerably over estimated shielding requirements. Regulation 105 requires the use of 6,000 Gy per week workload. However, a typical radiotherapy department treats 40 patients per day and 2 Gy/patient dose. This is equivalent to weekly linac workload of 500 Gy. Therefore, the workload stipulated in regulation 105 is a gross overestimation and results in wasted resources without achieving any safety gains. The shielding calculations should be based on ALARA principles incorporating concepts of workload, use factor and occupancy factors.</td> </tr> </tbody> </table>	Page No	Clause & Line(s)	Comment	2 to 5	1.3 Statement of problem	A sample regulation in the Radiation Protection and Control (Ionising Radiation) Regulations 2000 under the Radiation Protection and Control Act of 1982 in South Australia highlights how these outdated regulations would result in higher costs being transferred to those business who are the operators of radiation producing facilities, and then ultimately to the community. Regulation 105 under the S.A Radiation Protection and Control Act stipulates a maximum dose equivalent per hour limit when radiation survey measurements are carried out when the radiation producing apparatus is operated at the maximum potential and one half of the maximum radiation output available at that potential. The equivalent workload dictated by this regulation result in a very high attenuation factor leading to considerably over estimated shielding requirements. Regulation 105 requires the use of 6,000 Gy per week workload. However, a typical radiotherapy department treats 40 patients per day and 2 Gy/patient dose. This is equivalent to weekly linac workload of 500 Gy. Therefore, the workload stipulated in regulation 105 is a gross overestimation and results in wasted resources without achieving any safety gains. The shielding calculations should be based on ALARA principles incorporating concepts of workload, use factor and occupancy factors.	<p>Noted.</p>
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<p><b>28</b> Robert Fitchew Principal Physicist Cancer Care Services</p>	<p>Some comments for your consideration on the draft Code of Practice "Radiation Protection in the Medical Applications of Ionizing Radiation" dated 24.8.07 are set out below. I apologise for having missed Friday's deadline for the submission.</p> <p>line 700: Paragraph 46 of the Regulatory Impact Statement Consultation Draft says that the NHMRC has rescinded all of its health based codes that are over 10 years</p>							

<p>Royal Brisbane and Women's Hospital</p>	<p>old. This should be noted if it is necessary to quote this Code in the Bibliography.</p>							
<p><b>31</b> ALAN RITCHIE A/Manager Hazardous Materials and Radiation Department of Environment &amp; Climate Change, NSW</p>	<p>Generally it is felt that the Code and safety guides adequately cover the relevant area of medical radiation practice. There however appears to be inconsistencies in the way various sections are addressed.</p> <p>An example of this is the treatment of radiation safety officers. In most safety guides it appears in the body of the document where as in the Diagnostic and Interventional Safety Guide it is an annex. Generic wording for common practice could be used within the safety guides.</p> <p>Thank you for the opportunity for DECC to provide input into these documents.</p> <p style="text-align: center;"><b><u>Department of Environment and Climate Change (NSW) Comments on ARPANSA's Comments provided by DECC on the Code of Practice: <i>Radiation Protection in the Medical Applications of Ionizing Radiation</i></u></b></p> <p style="text-align: right;"><b>Attachment 5</b></p> <p><b><u>Comments on Regulatory Impact Statement Code of Practice for Radiation Protection in Medical Applications</u></b></p> <p><b><u>General Comment</u></b></p> <p>The RIS is unrealistic in its projected savings from improved safety benefits, reducing unnecessary exposure and uniformity. The increased costs of regulating the new requirements have not been included.</p> <p>Below are specific comments on the public consultation draft:</p> <table border="1" data-bbox="416 1197 1400 1436"> <thead> <tr> <th data-bbox="416 1197 515 1292">Page No</th> <th data-bbox="515 1197 779 1292">Clause</th> <th data-bbox="779 1197 1400 1292">Comment</th> </tr> </thead> <tbody> <tr> <td data-bbox="416 1292 515 1436">4</td> <td data-bbox="515 1292 779 1436">2.1 (Lack of uniformity)</td> <td data-bbox="779 1292 1400 1436">A lack of consistent regulations is not the only hindrance to cross jurisdiction activities. State Medical Board Registration is also an issue. Anecdotal evidence would suggest there is currently very little</td> </tr> </tbody> </table>	Page No	Clause	Comment	4	2.1 (Lack of uniformity)	A lack of consistent regulations is not the only hindrance to cross jurisdiction activities. State Medical Board Registration is also an issue. Anecdotal evidence would suggest there is currently very little	<p>This Code has no jurisdiction over Medical Registration Boards.</p>
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4	2.1 (Lack of uniformity)	A lack of consistent regulations is not the only hindrance to cross jurisdiction activities. State Medical Board Registration is also an issue. Anecdotal evidence would suggest there is currently very little						

		cross jurisdiction activity.	
5	2.1 (Different skill sets)	It is not understood how the code will address the examples of different jurisdiction requirements for licensing. The Code does not set any training standards. It will still be up to each jurisdiction to set these.	<p>This Code can have no jurisdiction over the mechanics of licensing in each State or Territory as these are covered under the respective Acts of those States or Territories.</p> <p>The Code is expected to be an instrument that provides uniform requirements for the medical field in each State or Territory. At the time of writing, ARPANSA has very little stakeholding in the medical field and is therefore not in the position to administer the Code, other than for a few isolated instances (eg medical equipment used in the military). The States and Territories are expected to administer the Code.</p> <p>The figures used in the RIS are illustrative only and have not been incorporated into the overall calculated benefit.</p> <p>The justification provisions of the Code are expected to reduce the number of CT scans currently performed in Australia.</p> <p>Education is a basic tenet in allaying fear across a wide range of hazards, radiation included. Training is therefore an important requirement for those involved with the use of ionizing radiation in order that the work can be done with minimal risk to the nurse or others.</p>
5	2.1 (absence of a specialist regulator)	How will the Code address this issue? It is up to each jurisdiction on how the mixes of health or environmental agencies administer the regulation of the medical field. Regulation of the medical use of radiation is controlled through licensing and registration requirements as well as Acts and Regulations. Is it being suggested that ARPANSA be the national specialist organization to regulate all jurisdictions?	
14	4.2 (Improving radiation protection awareness)	It is not believed that the Code will markedly reduce the number of radiation incidents in NSW. The health benefits are over stated. The vast majority of radiation incidents have no detrimental affect on those involved. The reference to savings on deaths seems irrelevant as there are no deaths attributed to radiation incidents.	
15	4.2 (Reducing unnecessary exposure)	Justification of diagnostic procedures is taken by the referring medical practitioner. A nuclear medicine physician or radiologist is not in a position to refuse an examination or change the type of diagnostic procedure requested. There is very little chance that the code will reduce the number of CT examinations being performed.	
16	4.2 (Formalisation of training)	Nurses currently have an unrealistic fear of radiation due to lack of education (as does the public) and avoid radiation as much as possible. Education will have no effect on doses received.	